Department of Graduate Medical Education

2023 Graduate Physicians Manual

From the Director of GME and Chair of the Education Institute

Dear Colleague-in-Training,

Welcome to the Cleveland Clinic! You are an integral part of one of the largest and best medical facilities in the country. Adjusting to life as a resident or fellow has its challenges and its rewards, and an institution of the size of the Cleveland Clinic can make it seem overwhelming. We recognize the complexities you may face and have structured this Graduate Physicians manual to help answer some of your questions.

All policies and procedures concerning Graduate Medical Education are developed, approved and implemented by the Graduate Medical Education Council (GMEC). The majority are identical to those that apply to your attendings, the full-time medical staff. While every effort was made to ensure the accuracy of the information presented in this manual, it is possible that changes will be made to some of the policies after its publication. Cleveland Clinic Institutional and GMEC policies will take precedence over those in this publication in matters of arbitration. To keep you current, any changes to policies and/or revisions will be communicated on the intranet site, GME|com, as they are implemented. Cleveland Clinic Institutional policies can be found in the Policy and Procedure Manager (PPM). Please note that these are both intranet sites, only accessible when on the Cleveland Clinic network.

Cleveland Clinic celebrates “systemness” in education, with the goal of providing uniformly excellent educational opportunities to all trainees in the Cleveland Clinic Health System. By shifting oversight of several of our regional teaching hospitals to a single sponsoring institution, many of our educational approaches and processes are now as uniform as possible. At the same time, each of our regional teaching hospitals has its own employment criteria and rules because prior to their integration with Cleveland Clinic, they were separate hospitals. Thus, certain aspects of employment, including employee benefits, may vary across hospitals. We provide you with hospital-specific employee benefits, which are similar in aggregate, despite differences in specific details.

Your well-being is extremely important to us and the Cleveland Clinic offers many opportunities for support and help for those who need them. The Cleveland Clinic strongly promotes team work and inter-professional education and collaboration and you will be an indispensable

member and sometimes leader of many teams during your training.

We very much look forward to your extended stay with us.

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Any reference in this manual to “clinical trainee” includes residents and fellows. Any reference to “trainee”, “caregiver”, “employee” or “house staff” includes residents, fellows, and research fellows.

Contact Information for Cleveland Clinic Trainee Sites

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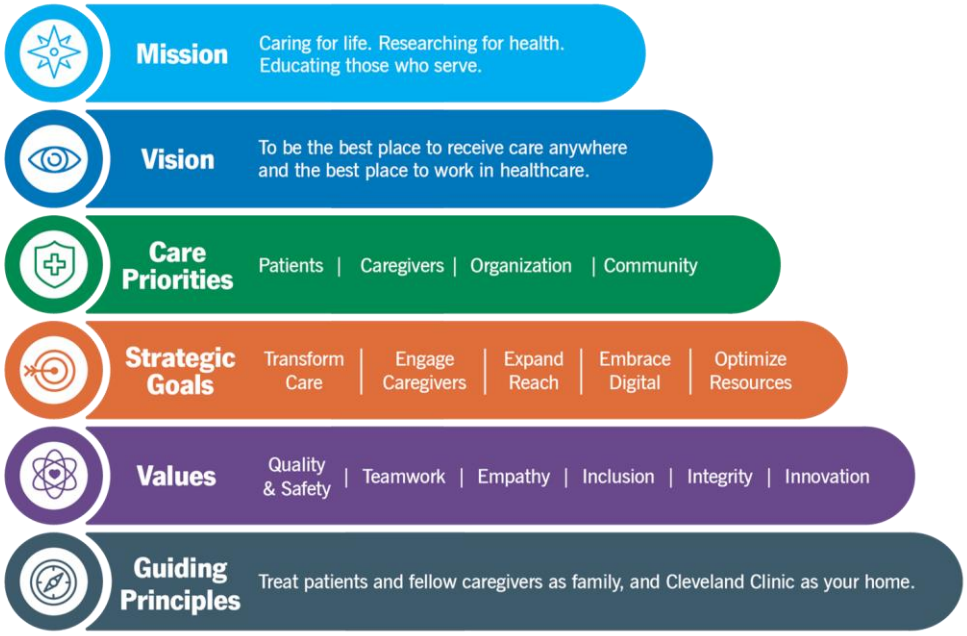
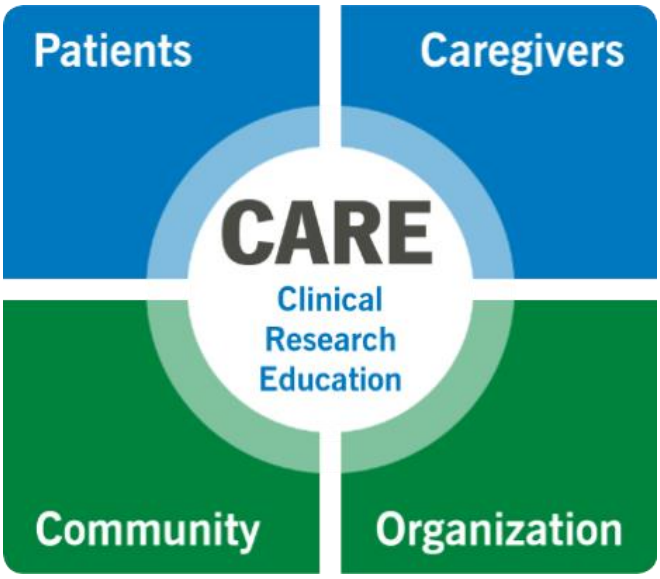
The Cleveland Clinic's goal is to be the best place to receive care anywhere and be the best place to work in healthcare. Though it all, we work as a team of teams, guided by our values and Care Priorities, everywhere there is a Cleveland Clinic.



Care Priorities Inform the Work We Do



Patients: We provide each patient a lifetime of high quality, seamless care enabled by technology.
Caregivers: We create an inclusive and supportive culture that empowers caregivers to thrive.
Organization: We steward our resources, enabling us to grow responsibly and serve as many patients as possible.
Community: We serve our communities by tailoring care to meet their unique needs and ensure better health.

Culture Defines Who We Are

Our Cleveland Clinic Values define who we are. There're essential to our culture. By living our Values every day, in every interaction, we ensure the best possible care and service for all.

Quality & Safety: We ensure the highest standards and excellent outcomes through effective interactions, decision-making, and actions.
Empathy: We imagine what another person is going through, work to alleviate suffering, and create joy whenever possible.
Teamwork: We work together to ensure the best possible care, safety, and well-being of our patients and fellow caregivers.
Integrity: We adhere to high moral principles and professional standards by a commitment to honesty, confidentiality, trust, respect, and transparency.
Inclusion: We intentionally create an environment of compassionate belonging where all are valued and respected.
Innovation: We drive small and large changes to transform healthcare everywhere.

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Cleveland Clinic History

Cleveland Clinic was conceived during World War I by Cleveland surgeons serving in military hospitals. Three of the founders, Frank E. Bunts, MD, George W. Crile, MD, and William Lower, MD, served in the same Army unit. They were impressed by the efficiency of the military hospital, where physicians from different specialties collaborated on patient care. As the war was coming to a conclusion, Dr. Crile and his colleagues discussed creating a new type of medical center when they returned to Cleveland. It would be a not-for-profit group practice, where patient care was enhanced by research and education. The mission of the practice would be "better care of the sick, investigation into their problems and further education of those who serve."

Their dream became reality in 1921 when the fourth founder, John Phillips, MD, the only internist, joined them. Cleveland Clinic opened its doors in a four-story building at the corner of East 93rd Street and Euclid Avenue. Fourteen physicians welcomed 42 patients that first day.

Their vision was to "act as a unit." The bold concept was for each of them to draw a salary, to return all revenue back to the institution to support the continuing health of the clinic, and to support research and education. This basic formula continues today. Millions of patients later, Cleveland Clinic continues to honor the vision of its founders, who believed that "the patient is the most important person in the institution."

Cleveland Clinic physicians and researchers have made significant breakthroughs that have changed the course of medical care in multiple areas. These innovations include the discovery of cine coronary arteriography; the first published coronary artery bypass; the first successful larynx transplant; the discovery of a "heart attack" gene; the identification of and first test for carpal tunnel syndrome; new techniques in kidney, cardiac and colorectal surgery; the isolation and naming of serotonin; the first endovascular valve repair; and the first subtotal face transplant. The original Cleveland Clinic building still stands at the corner of East 93rd and Euclid. Much has changed around it, but Cleveland Clinic's core values remain the same.

Institutional Commitment to Graduate Medical Education

Graduate Medical Education has been an integral component of the Cleveland Clinic's mission since its inception in 1921. Cleveland Clinic recognizes the importance and value of Graduate Medical Education (GME) programs, throughout our health system, which provide the skills physicians need to administer to their patients. Our focus is and always has been to train physicians to deliver the highest quality medical care, to teach future generations of health care professionals and to pursue research into the causes and treatments of disease.

The commitment by Cleveland Clinic to GME is exhibited by its leadership, organizational structure and resources. These assets enable the institution to achieve or exceed substantial compliance with national accreditation requirements and institutional standards. This includes providing an environment focused on ethics, attention to diversity in all programs, professionalism and academia. Competency-based curricular requirements as well as applicable requirements for scholarly activity are met under the careful guidance and graded supervision of the Clinic's teaching faculty. Cleveland Clinic is also committed to ensuring compliance with

work hour requirements as set forth by the ACGME for the purpose of improved resident well-being and patient safety.

Cleveland Clinic holds all GME programs to high academic and professional standards through ongoing formal internal quality assessment of educational programs, resident performance and the use of outcomes-based assessment for program improvement. Cleveland Clinic is committed to ensuring safe and compassionate care of patients, the success of resident physicians in their training and maintaining an appropriate balance between education and service needs.

Cleveland Clinic recognizes the necessity for adequate resources and optimal conditions to enable GME programs to sustain academic excellence; these include adequate funding, support personnel, equipment, facilities and dedicated faculty teaching time. Cleveland Clinic also acknowledges the importance of dedicated faculty teaching time as essential to the success of every program under our institutional sponsorship, and the need for periodic review of the adequacy of these resources.

Equal Opportunity Employment Statement

Cleveland Clinic is committed to diversity and inclusion. We provide equal opportunity across all employment practices including recruitment, selection, training, promotion, transfer and compensation, without regard to age, gender, race, national origin, religion, creed, color, citizenship status, physical or mental disability, pregnancy, sexual orientation, gender identity or expression, marital status, genetic information, ethnicity, ancestry, veteran status, or any other characteristic protected by federal, state or local law ("protected categories"). In addition, Cleveland Clinic administers all personnel actions without regard to disability, and provides reasonable accommodations for otherwise qualified disabled individuals.

Discrimination or harassment based on any of the protected categories will not be tolerated and is cause for disciplinary action up to and including termination of employment. To maintain our culture of integrity, we also encourage the reporting of concerns without fear of retaliation. Cleveland Clinic will not retaliate against any caregiver who in good faith has made a complaint based on a reasonable belief that the law or a Cleveland Clinic policy has been violated, or for assisting with or participating in an investigation or exercising any employment right protected by law. Any caregiver who believes he or she has been discriminated or retaliated against should report it to his or her manager, to any member of Cleveland Clinic's management, or to his or her Human Resources or Professional Staff Affairs representative. Cleveland Clinic will investigate these complaints and take appropriate corrective actions.

Patients' Rights and Responsibilities

All members of Cleveland Clinic's professional staff need to be aware of the Statement of Patients' Rights and Responsibilities that is endorsed by Cleveland Clinic and shared with patients. This statement may be found in the Patient Rights-Responsibilities Brochure.

Corporate Social Responsibility Policy

Cleveland Clinic is a not-for-profit, multispecialty academic medical center providing state-of-the-art medical care, education, research and technology. As a major healthcare institution, Cleveland Clinic has a leadership role in the communities it serves. Executive policy and procedural decisions are attuned to the current civic, social, economic and political environment. It is the policy of the institution to aid those community efforts that bear upon its mission.

This social commitment takes the form of monetary and non-monetary resources allocated in accordance with existing policy. The following guidelines describe the scope of Cleveland Clinic's corporate social responsibility, permitting the clinic to: assist the public and private sectors in initiatives that improve the health and vitality of its communities; serve as a resource and catalyst for educational institutions to promote workforce development and training in medicine, research and allied health professions; foster positive relations with community leaders to identify community needs, and to assess programs and projects of mutual concern; and provide appropriate participation in selected community functions or activities.

These guidelines are reviewed periodically and modified according to changing conditions within the community and within Cleveland Clinic. The Executive Management Team and the Chair of the Division of Community Relations and Diversity assist the Chair of the Board of Governors/Medical Executive Committee in making the decisions to request the allocation of resources under this policy.

Institutional Education Committees

In keeping with the mission to offer a complete and comprehensive graduate medical education experience and in accordance with the ACGME Institutional Requirements, Cleveland Clinic clinical trainees participate in numerous committees and councils at various levels throughout the enterprise.

In clinical departments, it is anticipated that there will be clinical trainee membership on at least the following committees: Education Committee, Quality and Patient Safety Committee, Resource Utilization (when in existence) or other appropriate departmental committees.

Duties and Responsibilities of Clinical Trainees

A clinical trainee shall perform in a competent manner as determined by the Program Director and the supervisory staff in all areas of the general competencies as defined by the ACGME and, all other related tasks and duties assigned to him or her by the Program Director, including but not limited to:

Educational Responsibilities:

- Execute all duties assigned under the on-call schedule as may be established and amended by the Program Director and all duties as may be assigned to be performed at such other teaching hospitals and medical facilities as may be designated by the Program Director.
- Participate in safe, effective and compassionate patient care under supervision, commensurate with the clinical trainees level of advancement and responsibility at sites specifically approved by the Program and under circumstances and at locations covered by the Hospital's Professional Liability Insurance maintained for the clinical trainee.
- Participate fully and perform satisfactorily in the educational and scholarly activities of the Program, including the performance of scholarly and research activities as assigned by the Program Director and/or as necessary for the completion of applicable graduation requirements.
- Assume responsibility for participation in the teaching of more junior trainees and medical students.
- Attend all educational conferences as required and participate in educational programs, activities and required courses. Participate in applicable departmental and institutional committees, especially those relating to patient care review activities.

Responsibilities to the Institution:

- Subsequent to the first day of training, submit to a health screening which include tests for drug & tobacco use. Supplementary tests may be performed at any point during training as deemed necessary to the operation of Cleveland Clinic; this may include tests for drug use and alcohol abuse. In addition, the clinical trainee agrees to meet Cleveland Clinic standards for immunizations in the same manner as all Cleveland Clinic personnel.
- Apply for in a timely manner, obtain and provide Cleveland Clinic with evidence that he or she has obtained certifications, licenses, visas, test results, work permits and registrations required by state, federal or local laws and regulations to enroll and remain in graduate medical education training in the State of Ohio.
- Abide by and adhere to hospital standards including the legible and timely completion of patient medical records, charts, reports, statistical operative and procedure logs, faculty and program evaluations and any other paperwork required by the Program.
- Comply with the policies and procedures of Cleveland Clinic pertaining to all employees and those specific to clinical trainees which are contained in the Graduate Physicians Manual.
- Comply with institution and program specific requirements regarding record keeping, logging and/or reporting work hours and work hour violations.
- Comply with institution and program specific requirements regarding standards for supervision.
- Comply with institution and program specific requirements regarding timely completion of training courses; including but not limited to courses in MyLearning.
- Comply with institution and program specific requirements regarding evaluation of attending physicians, rotations and the training program.
- Apply such cost effective measures as directed or instructed by Cleveland Clinic in the provision of patient care while acting in the best interests of patients at all times.
- Upon departure from the training program, the clinical trainee must return all Cleveland Clinic property including but not limited to, books, equipment, patient data, pager, iPhone and complete all necessary records and settle all professional and financial obligations.

Personal Responsibilities:

- Develop and follow a personal program of self-study and professional growth under guidance of the Program's teaching faculty.
- Refrain from conduct that would impact adversely on the medical profession or the mission of the Cleveland Clinic or have the appearance of impropriety or which might otherwise damage the Cleveland Clinic's reputation or interfere with the Cleveland Clinic's business or the proper performance of the clinical trainee's duties.
- Develop an understanding of ethical, socioeconomic and medical/legal issues that affect the practice of medicine and graduate medical education training.

Administrative Responsibilities:

- Fully cooperate with the Program and Cleveland Clinic in coordinating and completing RC and ACGME/ADA/CPME accreditation, submissions and activities. This includes participation in any review of a clinical trainee's own training program as well as participation on Review Teams to assess other training programs.
- Abide by and adhere to Cleveland Clinic professional standards and all applicable state, federal and local laws, as well as the standards required to maintain accreditation by the

Joint Commission, ACGME/AOA/ADA/CPME and any other relevant accrediting, certifying or licensing organizations.

- Comply with all ACGME requirements including but not limited to those regarding work hours and moonlighting. Please refer to specific ACGME institutional requirements and RC program requirements at www.acgme.org.
- Comply with Cleveland Clinic reporting requirements such as completion of personal incident reports, patient incident reporting, etc.
- Attend & participate in department, institute and/or institutional meetings as required.

Education of Medical Students: Cleveland Clinic has had medical students rotating on its campus since 1974 and clinical trainees have always played a central role in their educational experience. In 2004, the first class of the Cleveland Clinic Lerner College of Medicine (CCLCM) of Case Western Reserve (CWRU) matriculated. Cleveland Clinic serves as a core training site for all medical students from CWRU, including students from CCLCM (College Program) and students from the traditional School of Medicine program (University program). Additionally, over 300 visiting students come to Cleveland Clinic each year, including from the Ohio University Heritage College of Osteopathic Medicine, Cleveland. All medical students on educational rotations fall under the purview of the CCLCM. Each medical student rotation has a Cleveland Clinic faculty who is responsible for outlining the student learning objectives and expected roles and responsibilities. Clinical trainees play a critical role in the education of medical students. In the hospital setting, the clinical trainees are the point of first contact for the student. Clinical trainees will teach a substantial amount of what the students learn. Clinical trainees need to be aware of the rotation learning objectives and student roles. The Clerkship Director/Faculty of the medical school rotation will often talk with the clinical trainees regarding what is to be expected while they are in these roles. After these discussions, there will be follow-up to clinical trainees via email, written material or direct conversation with the Clerkship Director/Faculty and/or student. If the clinical trainee has not received any communication or is not sure of the student role, they should contact the CCLCM Office (216-445-7435). In addition to the specific rotation objectives there are general principles that will help a clinical trainee be an effective teacher. For South Pointe rotations, contact the South Pointe GME Office (216-491-7460).

Clinical trainees have multiple roles, including supervisor, teacher, role model and assessor. Clinical trainees must orient students to a new service. Students depend on the clinical trainee to give them a tour of the facility, to tell them where to be and when and what to do when they get there. The clinical trainee needs to spend time with the student specifying his or her role in various areas listed below. Many of these areas will be specified as part of the rotation description/objectives: required procedures, precautionary measures such as infection control, numbers of patients to be seen per day, patient write ups, conferences to attend, frequency of call and where the on call rooms are for that service, time of rounding, use of the electronic medical record for charting, policy on placing orders with counter signature, expected times for arrival and departure, policy for absenteeism and layout of facilities.

Clinical Trainee as Role Model: Clinical trainees are role models for students. Role modeling behavior includes ethical behavior and professionalism, medical reasoning, clinical decision making and compassionate, humanistic approaches to patient care. Students should be treated with respect. Mistreatment (e.g. destructive, belittling comments) neglect and microaggressions do not enhance learning and are inappropriate.

Teaching Role of Clinical Trainees:

- Specify learning objectives. The clinical trainees should be familiar with rotation objectives as noted above. If the trainee has questions about the objectives they can reach out to the clerkship director/faculty. The medical students are also good sources of information regarding the rotation's learning objective. The students should be informed about the objectives for their rotation on their first day.
- Specify organization. The clinical trainee should describe the rotation expectations for example, how much time students should spend on different activities such as rounding and patient care responsibilities.
- Specify teaching methods. Students should have time set aside each week to meet with the attending and/or senior resident. This provides an opportunity for the student to ask questions, receive feedback and to learn for example, medical facts, ethical issues, the diagnostic process, treatment options, management plans, doctor-patient communication skills, value-based care, preventive medicine and interdisciplinary care. An essential component of good teaching is providing helpful feedback to improve performance.
- Clinical trainees should provide constructive feedback to students on an ongoing basis throughout their rotation. It should be clearly defined and should include both constructive criticisms (targeted areas for improvement) and positive feedback (areas of strength). Clinical trainees are expected to directly observe and assess the student's performance in areas such as patient care, histories and physicals, procedures, etc. Direct observation forms the foundation of feedback.
- Evaluative Role. Students who have ongoing difficulties or serious events occur during the rotation need to be identified with the expectations for the student written down and a plan agreed upon by all parties on how these problems can be solved. In general the attending and/or Clerkship Director should be included in this process.

Clinical Assessment System (CAS): CWRU uses the CAS for student assessment/feedback. This system allows students to request feedback from a faculty/resident/fellow based on observations of interactions of the student with one or more patients. Clinical trainees will receive an email from a generic mailbox (clerkshipevaluation@case.edu) initiated by the student requesting feedback on those observations/interactions. A direct link to the CAS system is provided in the email. The "?" button in CAS is available for more information on the system and examples of types of feedback that are useful.

Other methods of evaluation, electronic or paper, may be used by other medical schools. It is the responsibility of the medical student to provide information regarding the evaluation method to the Clerkship Director/Faculty at the start of the rotation.

Conditions of Employment & Requirements

Eligibility, Selection and Appointment

Recruitment: Recruitment efforts shall be directed toward and appointments offered only to those candidates who meet the eligibility requirements for appointment to residency or fellowship training.

Applicants with one of the following qualifications are eligible to be considered for training at Cleveland Clinic:

- Graduates of medical schools in the United States and Canada accredited by the Liaison Committee on Medical Education (LCME)

- Graduates of Osteopathic medicine in the United States accredited by the American Osteopathic Association (AOA)
- Graduates of medical schools outside the United States or Canada who meet one of the following:
    - Received a currently valid certificate from the Educational Commission for Foreign Medical Graduates (ECFMG)
    - Holds a full and unrestricted license to practice medicine in a United States licensing jurisdiction in his/her current ACGME specialty-/subspecialty program
- Graduates of medical schools outside the United States who have completed a Fifth Pathway program provided by an LCME-accredited school
- Fellows who meet the prerequisite training and documentation requirements to be considered for training in a non-standard (non-accredited) fellowship
- Fellows must have completed ACGME prerequisite training to be considered for training in an accredited fellowship
    - If a trainee who holds a valid ECFMG certificate does not meet the requirements listed above, he or she may be considered an "exceptional candidate" based on specific criteria outlined in the subspecialty requirements and only if the individual RC allows exceptions to the general eligibility requirements. Please refer to the Graduate Medical Education Council Eligibility Procedure located on Connect Today for details.

Selection: Programs must select from eligible applicants on the basis of residency program related criteria such as: preparedness, ability, aptitude, academic credentials, written and verbal communication skills as well as motivation and integrity. Decisions concerning employment, transfers and promotions are made upon the basis of the best qualified candidate. Cleveland Clinic is an equal opportunity and affirmative action employer and seeks to ensure that employment decisions are based only on valid job requirements and that all caregivers and applicants are provided with equal opportunity in all employment practices including: recruitment, selection, promotion, compensation and salary administration, benefits, transfers, training and education, working conditions and application of policies without regard to race, color, religion, gender, sexual orientation, gender identity, pregnancy, marital status, age, nationality, ethnicity, ancestry, disability, military status, genetic information, protected veteran status, or any other factor or characteristic protected by law. Information provided on this application may be shared with any Cleveland Clinic facility. View the Equal Employment Opportunity/Workforce Diversity and Inclusion Policy.

Residency programs recruiting first year clinical trainees are required to participate in the National Resident Matching Program (NRMP) and must adhere to the "all in" requirement. Other programs are encouraged to participate in an organized matching program where such is available. Before accepting a clinical trainee who is transferring from another institution into the same program, the Program Director must obtain written or electronic verification of the previous educational experience and a summative competency based performance evaluation of the transferring resident. These documents must be received by the Program Director prior to accepting the resident into the program.

Appointment: Initial appointments and any subsequent appointment are contingent upon meeting the requirements. Requirements are listed on the GME website, distributed to candidates when they interview and included as an addendum with the formal appointment letter. At the

recommendation of the Program Director, the formal appointment letter is generated on behalf of the Director of GME, who is also the Designated Institutional Official (DIO). The GME Department screens the application materials to assure each candidate meets the requisite academic and employment eligibility requirements to enter the respective training program. Neither Cleveland Clinic nor any of its GME programs require clinical trainees to sign a non-competition guarantee or restrictive covenant. Appointment letters for all programs sponsored by the Cleveland Clinic will be issued by the DIO.

Transfer of Clinical Trainees: Clinical trainees are encouraged to discuss their plans to seek other training opportunities with their Program Director or advisor. Clinical trainees should provide adequate notice when they decide to leave their training program in order to provide a smooth transition of patient care responsibilities.

Transfer to Cleveland Clinic: Prior to discussion with a potential candidate (committed to another training program) the Cleveland Clinic Program Director should obtain a release from the candidate's current Program Director. Before a program accepts a clinical trainee who is transferring from another program, the Program Director must obtain written or electronic verification of previous educational experiences and a summative competency based performance evaluation and the last Milestone evaluation of the transferring clinical trainee. Pursuant to the ACGME requirements on transfers, the current Program Director must provide timely verification of residency education and summative performance evaluations for clinical trainees who request to leave the program prior to completion.

Prior to Start of Training: If a clinical trainee has matched to a program (through the NRMP) and decides (before starting) he or she does not want to train in that program and/or at that institution, the clinical trainee must request a waiver from the NRMP in order to break the contract. A Program Director cannot consider a candidate who has matched to another program unless a waiver is issued to the clinical trainee in question. If a Program Director wishes to break the NRMP contract with a clinical trainee (i.e. student didn't meet criteria to complete medical school, international graduate not able to obtain visa), the Program Director must request a waiver from the NRMP in order to fill that position. No positions may be offered or accepted prior to the NRMP granting a waiver.

Requirements to Begin Training

Prior to training/working at Cleveland Clinic, clinical trainees/research fellows will be required to complete an electronic onboarding packet as well as attend a scheduled orientation session with GME. The documents will be kept as part of his or her permanent record. Salary and/or benefits will be not begin until the clinical trainee/research fellow has successfully completed all conditions of employment.

1. Complete and receive medical clearance from a pre-employment health screening performed by Cleveland Clinic Occupational Health before the orientation date.

Controlled Substances
Positive results for any illicit drugs or non-prescribed controlled substances will constitute ineligibility for employment.

Nicotine/Tobacco
The cotinine test will detect the presence of nicotine in all forms of tobacco. If a candidate tests positive for nicotine but agrees to stop using nicotine (in any form), they will be allowed to start work and re-test within 90 days. However, if the caregiver's nicotine re-test is positive, their employment will be terminated at that time. They will be eligible to re-apply after one year.

COVID-19 Vaccination Policy
To protect patients, the community, and all individuals covered by this policy from COVID-19 infection, and to comply with the rules promulgated by the Centers for Medicare and Medicaid Services (CMS), by requiring all Individuals to obtain a COVID-19 vaccine. The complete COVID-19 Vaccination Policy can be found in the PPM.

2. Complete a criminal background check as required by Cleveland Clinic Department of Protective Services.
3. Complete all tasks in Workday: the Cleveland Clinic Human Resource Management System, including: an Employment Eligibility Verification Form (I-9) as required by the U.S. Department of Homeland Security. Original documents must be presented at GME Orientation for verification.
4. Complete all required tasks, forms and uploads in MedHub: the institutional Residency Management System.
5. Provide documentation of a current Ohio permanent medical license, training certificate, or acknowledgement letter.

Licensure

The State of Ohio requires clinical trainees to have either a Permanent Ohio Medical License or a Temporary Training Certificate. Applying and renewing of licensure is the clinical trainee's responsibility. Clinical trainees will be required to maintain licensure throughout their training program. Failure to maintain licensure will result in the inability to work and may result in termination of employment.

The State Medical Board of Ohio will contact the clinical trainee directly via email. The clinical trainee must provide GME a copy before they can start their training. If the Ohio Board does not issue a training certificate before the time a clinical trainee is scheduled to start training, they will issue the clinical trainee an acknowledgment letter. This letter will permit a clinical trainee to begin their training program while their application is in process. A similar letter is available for permanent licensure applicants – please contact the State Medical Board of Ohio for this letter.

Clinical trainees are required to notify their Program Director of any communication from the State Medical Board of Ohio during the application process (for either a Training Certificate or Permanent Licensure) that will delay or prevent issuance of a Permanent License or Training Certificate. Failure to do so may result in disciplinary action, termination of employment and/or rescission of the trainee's appointment.

Permanent Licensure
To be eligible the State Medical Board of Ohio requires:

- U.S. medical school graduates to complete one year of U.S. or Canadian accredited graduate medical education
- International medical school graduates to complete two years of U.S. or Canadian accredited graduate medical education.
- In addition, all 3 steps of USMLE must have been passed within a 10-year period from the date of the first exam passed. Information on Permanent Licensure may be obtained by contacting the State Medical Board of Ohio at 614-466-3934; 30th East Broad Street, 3rd Floor, Columbus, Ohio 43215 or visiting their website http://www.med.ohio.gov.

If a clinical trainee is joining an advanced fellowship, their program may require a permanent license, please check with the Program Coordinator; the Office of Professional Staff Affairs (OPSA) handles credentialing of Limited Clinical Practitioner (LCP).

USMLE Step 3

According to the Federation of State Medical Boards (FSMB), individuals wishing to take USMLE Step 3 to be used for licensure by the State of Ohio requires the following:

- U.S. medical school graduates must have completed one year of U.S. or Canadian accredited graduate medical education.
- International medical school graduates must have completed two years of U.S. or Canadian accredited graduate medical education.

Training requirements vary by state; refer to the FSMB website for details). This requirement is the same for U.S., Canadian and International medical school graduates. The Graduate Medical Education Department does not have applications for Step 3. Please contact the FSMB at 817-868-4000 for an application. Clinical trainees may also obtain an application by submitting an email request to the FSMB at usmle@fsmb.org. Clinical trainees must include their full name, mailing address, USMLE ID number (if known) and the state for which they will be taking Step 3.

COMLEX Level 3

Clinical trainees that completed COMLEX must pass Level 3 of the National Board of Osteopathic Examiners (NBOME) in order to matriculate into their 3rd year of residency training. Trainees are encouraged to take the COMLEX Level 3 no later than by the end of their first resident training year. If you are unable to comply, he or she must notify and explain the delay to their Program Director and to the South Pointe Education Chair.

If a resident fails COMLEX Level 3 on his or her initial attempt, he or she must immediately notify the South Pointe GME department within two business days of the NBOME score release date. Failure to comply may result in corrective action. The resident may continue with the rotation that they are scheduled with, but is required to meet with the Program Director along with the Education Chair and/or designee to set up an academic plan including a board preparation program at the clinical trainee's expense. The resident cannot register for another exam until the board preparation program is approved and completed.

If the resident fails the exam for the second time, he or she must immediately notify the South Pointe GME department within two business days of the NBOME score release date. Failure to

comply may result in corrective action up to and including termination. The resident is required to meet with the Program Director and the Education Chair and/or designee to set up a new remediation/board preparation proposal, which may include repeating selected core rotations or ceasing rotations in order to study. If rotations are impacted and the resident is removed from rotations, paid time off (PTO) must be utilized. If there is no available PTO, the resident will be placed on unpaid time off (UPTO) and the time accrued while on UPTO will be added to the end of the residency.

Failure of COMLEX Level 3 for the third time will be grounds for dismissal and ultimately could lead to problems with licensure in the state of Ohio.

Graduate Medical Education must be notified within 2 business days about each attempt and receive official notification of results, regardless of outcome, pass or fall. It is the resident's responsibility to keep GME apprised of all attempts and results. Failure to comply with this request may result in corrective action up to and including termination. If the Graduate Medical Education Office has not received notification that a resident has passed COMLEX Level 3 in time to matriculate into their 3rd year, a resident appointment will not be granted.

National Provider Identifier (NPI)

All health care providers that file electronic claims are required by HIPAA law to obtain the National Provider Identifier (NPI). The NPI is a number every physician will need throughout their career. The purpose of the NPI is to utilize one identifying number per health care provider for all health plans. As a clinical trainee at Cleveland Clinic who has the ability to write prescriptions, clinical trainees are required to have a National Provider Identifier number. The NPI for each health care provider is assigned by the National Plan and Provider Enumeration System (NPPES).

The NPI application process is the means by which health care provider organizations and individuals become uniquely identified in a national database known as the National Plan and Provider Enumeration System (NPPES). Go to NPPES and apply as an individual. The website will walk a person through the online process. Clinical trainees may also complete a paper application and mail it directly to NPPES. NPI is a Cleveland Clinic requirement; please upload a copy of the NPI confirmation letter and number into the MedHub record. A Social Security Number is required to apply for the NPI; therefore, a clinical trainee can only apply for an NPI after they receive a social security number and then follow the above process.

Medicaid and Medicare Enrollment Requirements

To order, refer and prescribe to Medicaid and Medicare patients, it is essential to enroll in both systems. Prescriptions will only be accepted after enrollment has been approved. To enroll a clinical trainee will need a Social Security Number, National Provider Identifier (NPI Number) and a Permanent License or Training Certificate Number. Click here for details, including link and instructions.

Evaluations

Timely feedback is important to clinical trainees to help them recognize areas of their performance that require improvement and areas in which performance meets or exceeds expectations. Verbal feedback in real time is the most valuable for a clinical trainee to reflect on their behaviors, actions and determine what modifications need to be made. In addition, formal

assessments need to be completed on clinical trainees at the completion of each rotation by faculty that they worked with. These assessments will be available (individually and in aggregate) for the clinical trainee's review in MedHub. Faculty should be available for discussion of the clinical trainee's performance and assessment.

Clinical trainees are also expected to provide feedback to others such as peers, faculty and the program. Feedback should be constructive in nature and help in further development of the person or program being evaluated.

Formative Assessment of Clinical Trainees (Feedback)

Teaching faculty are required to provide an assessment of the performance of clinical trainees they supervise at the end of each rotation, or at least every three months for rotations longer than three months. These assessments are completed in MedHub, Cleveland Clinic's institutional residency management system.

If required by the ACGME, Milestone-based assessments must be utilized. Assessments in MedHub can be linked to both the Milestones and the six ACGME competency areas (Patient Care, Systems-Based Practice, Interpersonal & Communication Skills, Practice-Based Learning and Improvement, Medical Knowledge, and Professionalism). These assessments frequently incorporate numerical rating scales with behavioral anchors to assess progress. Teaching faculty are strongly encouraged to include specific, narrative feedback on the assessment form, as these comments can be used formatively by clinical trainees and provide important data for the Clinical Competency Committee's (CCC) semi-annual review. Programs with Osteopathic Recognition will also incorporate the Osteopathic Principles into their assessments.

***Formative Assessment*:** Frequent formative assessment (assessment designed to help clinical trainees improve their performance), is a critical feature of all competency based educational programs. While formative assessment is often verbal (e.g., feedback to clinical trainees after an observation), written formative assessment should be offered by faculty and can be collected independently to show improvement of performance over time. Formative assessment drives learning and helps our clinical trainees reach both program and individual goals. We encourage programs to increase the use of formative assessment.

The number of assessments that each faculty member is required to complete varies with their individual service assignment and/or number of clinical trainees in a program. MedHub will assign performance assessments to faculty by matching their service dates to the program's rotation schedule, or as queued by the Program Coordinator. MedHub notifies faculty via e-mail that they have assessments to complete. Upon logging into MedHub, faculty can view a list of their assigned assessments; MedHub will continue to send weekly reminders until assigned assessments have been completed. Those faculty who had limited or no teaching contact with the clinical trainee may remove the evaluation from their listing by denoting insufficient contact to evaluate. Nonetheless, faculty are encouraged to provide feedback based on their observations of single encounters.

Additional Evidence Used for Assessment Purposes

In addition to the formative assessments completed by faculty, programs are encouraged to use peer-to-peer, 360-degree, and self-assessments which contain an individual learning plan designed by the resident. 360-degree assessments are extremely helpful to the CCC (Clinical Competence Committee), due to the variety of stakeholders who have an opportunity to participate. The forms for these assessments will be developed, deployed and determined by individual programs. Additionally, patients may be asked to anonymously assess clinical trainees who participated in their care at Cleveland Clinic in the outpatient setting. The Press-Ganey survey is sent to patients treated by a clinical trainee in continuity clinics scheduled under their name, as well as being an add-on to the faculty survey for those working with faculty in their clinic. This information is available to Program Directors via the Tableau Dashboard.

***Summative Assessment*:** Summative assessments are used to evaluate resident/fellow learning, skill acquisition, and Milestone achievement at the conclusion of each six months of training. It is a reflection of progress over a period of time; what has been achieved, and what areas may be an opportunity for growth.

Many different components make up the summative assessments, not only is it a summary of the formative assessments received during that time period, but an incorporation of feedback from other sources, such as procedural accomplishments during the period, peer feedback, patient feedback, test scores and scholarly accomplishments.

Faculty also receive summative assessments of their teaching skills using anonymous resident fellow feedback. Faculty can use this feedback to further hone their teaching skills, thus creating a robust learning community which encourages continual growth.

Summative Assessments (High Stakes)

All assessment data should be considered by the program for the overall assessment of a clinical trainee's performance. Documentation must be completed by the Program Director and shared with the clinical trainee using the Summative Evaluation of Resident/Fellow Performance assessment, or the Summative Evaluation of Resident/Fellow Performance (Osteopathic Recognition) if the trainee is identified as a designated osteopathic resident. This documentation should indicate if the clinical trainee is achieving level appropriate specialty-specific competency Milestones and thereby is ready to progress to the next level of training or graduate from the program. Summative assessments are required for a clinical trainee's permanent education file at least twice per year.

For ACGME accredited programs, CCC's are tasked with synthesizing assessments data in order to advise Program Directors regarding clinical trainees' progress on competency based Milestones. Program Directors are required to review the CCC recommendations, make appropriate determinations regarding the clinical trainee's current level of competency and provide their objective assessments of progress to the ACGME at 6-month intervals.

The Program Director must also complete the Cleveland Clinic Verification of Residency/ Fellowship Training assessment, or the Cleveland Clinic Verification of Residency/Fellowship Training (Osteopathic Recognition) if the trainee is identified as a designated osteopathic resident, for each clinical trainee at the completion of the program. This final assessment must be accessible for review by the clinical trainee and will document his/her performance during the final period of training and verify that the graduating resident demonstrate the knowledge, skills, and behaviors necessary to enter autonomous practice. At the program's discretion, a summative "Dean's Letter" may also be provided to the clinical trainee.

Assessment of Teaching Faculty

Clinical trainees are required to complete anonymous assessments of their supervising teaching faculty at the end of each rotation; these assessments are administered via MedHub. MedHub will assign performance assessments to clinical trainees by matching their service dates to the programs faculty rotation schedule, or as queued by the Program Coordinator.

At the end of each rotation, MedHub notifies clinical trainees via e-mail that they have assessments to complete. Upon logging into MedHub, clinical trainees can view a list of their assigned assessments; MedHub will send weekly reminders until all assigned assessments have been completed. Clinical trainees are not be able to view their assessments until the assessments of faculty are submitted. Included in each teaching assessments are items which assess a range of teaching domains, including: the ability of a faculty member to establish a safe learning environment, provide specific, actionable feedback, and to teach effectively in a variety of settings. Clinical trainees are encouraged to provide narrative feedback highlighting areas of strength and targeted areas for improvement to aid in faculty development. Each program is required to use the standard Evaluation of Faculty Teaching (2.0) form provided by the GME Office.

In order to assure timely feedback to teaching faculty, the anonymous staff teaching assessments completed by clinical trainees will be available in an aggregate form once at least five (5) assessments are completed on a specific teaching faculty. This will not jeopardize the confidentiality of the online system in MedHub as faculty will be unable to review individual assessments completed on them. Access to the aggregate staff teaching assessments is intended to afford each staff physician the opportunity to make improvements to their methodology for teaching clinical trainees.

Evaluation of Training Program

Clinical trainees and faculty are required to complete an annual survey (the Resident/Fellow Annual Evaluation of a Clinical Training Program 2.0 and the Faculty Annual Evaluation of a Clinical Training Program 2.0); our ACGME Osteopathic Recognized Programs they will use the Resident/Fellow Annual Evaluation of a Clinical Training Program 2.0 (Osteopathic Recognition) and the Annual Faculty Evaluation of a Clinical Training Program 2.0 (Osteopathic Recognition versions) in MedHub that anonymously evaluates the strengths and targeted areas for improvement of the training program. These assessments were designed with the assistance of the House Staff Association. Trainees and Faculty members have an opportunity to answer questions about a number of factors that contribute to the overall effectiveness of their respective programs.

The confidentiality of program assessment data is strictly ensured. The results from each program are summarized by evaluator group and only provided to the Program Director and the Graduate Medical Education Council (GMEC) if 5 or more assessments were completed. Any program with less than 5 assessments submitted per year in each data set will not receive specific data for that academic year; instead, they will receive an aggregate report including as many years as necessary to reach the target of 5; under no circumstances will the results of individual assessments be linked to an individual clinical trainee or faculty member.

Information gathered from program assessments are helpful in measuring the effectiveness of the training program and are considered in future planning. The results are also used during the ACGME required Annual Program Evaluation (APE) process, which is monitored by the GMEC

Program Improvement Plan Subcommittee. Each clinical training program must undergo an APE yearly. At this meeting clinical trainees and faculty discuss the quality of the training program, a variety of assessments, graduate performance on board examinations, as well as faculty development opportunities. Upon completion of the APE the program prepares a written plan of action to document initiatives to improve performance. The action plan ought to be reviewed and approved by the teaching faculty and documented in meeting minutes, which also includes attendance by program leaders, faculty and clinical trainee representatives. During the APE meeting the following year, discussion will focus on how successful the program was in executing the action plan of the prior year.

Performance

GME Remediation and Corrective Action Policy

Purpose: The purpose of this policy is to describe the Graduate Medical Education (GME) guidelines to address any remediation and corrective actions (probation, non-promotion, non-reappointment, or dismissal). The Program Director (PD) and trainee should attempt to resolve any trainee's performance and/or behavior professionalism problems using verbal counseling and discussions prior to invoking the procedure set forth below. The procedure below is based on the Accreditation Council of Graduate Medical Education (ACGME) Institutional Requirements, however, all trainees, whether in an ACGME-accredited program or not, are held to the same standards.

Policy Statement: All trainees who are appointed through GME are required to meet the competencies and expectations (both academic and professional) of the training program in which they are enrolled and those of the Cleveland Clinic.

Definitions:

- **Remediation**: The act of remedying a trainee's academic and/or professional performance when performance is below expectations of their training program.
- **Corrective Action**: A disciplinary action taken against a trainee to communicate necessary improvement of academic and/or professional performance, without which improvement, additional actions, including dismissal may become necessary.
- **Counseling**: Advice and support meant to improve the performance of trainees and not considered disciplinary in nature. Counseling is intended to be positive and constructive in nature and not negative or derogatory. Whether verbal or written, it is considered to be an integral component of GME and should never be construed as a limitation or restriction on the trainee. Counseling is not disciplinary, probationary or investigatory in nature nor a reflection of unsatisfactory performance or academic incompetence. Counseling is not an adverse charge or action and may not be appealed by the trainee. The program has complete discretion regarding the appropriate handling and remediation of a trainee's under-performance
- **Verbal Counseling**: An informal communication between PD or designee and a trainee that is a result of his/her performing below expectations of a training program.
- **Written Counseling**: A formal documented communication between PD or designee and a trainee that is a result of his/her performing below expectations of a training program.
- **Probation**: Probation is a disciplinary corrective action in which the PD or designee notifies a trainee in writing of specific deficiencies that must be corrected in a stated period of time, otherwise the trainee will not be allowed to continue in the program or will be continued on continued probationary status. Salary and benefits remain in force

during probation.

- **Administrative Leave of Absence**: Action that removes the trainee from any programmatic duties for a specified amount of time. Reasons for administrative leave of absence may include, but are not limited to: investigation of alleged misconduct and/or unprofessional behavior (i.e. violation of patient privacy rules, conduct that is illegal/unethical, conduct that is inconsistent with CC Policy on Professional Conduct); failure to comply with conditions of probation or other corrective actions; or academic and/or professional deficiencies warranting removal of the resident from patient care. A trainee who is issued a dismissal disciplinary action will be placed on administrative leave of absence pending decision to appeal the dismissal. If the trainee decides to appeal the dismissal, administrative leave will be extended until the outcome of the appeal is rendered.
- **Non-Promotion**: Disciplinary corrective action that indicates that the trainee will not be promoted to the subsequent PGY-year at the completion of the current year of training and that training will be extended.
- **Non-Reappointment**: Disciplinary corrective action in which a program decides not to offer a contract to the trainee for the next academic year or training period.
- **Dismissal**: Disciplinary corrective action that removes a trainee from a training program prior to completion of the contract due to failure to successfully meet expectations after probation or as a result of trainee actions of an egregious nature necessitating immediate termination.
- **Trainee**: An individual who is appointed through GME; including residents, fellows, clinical fellows, postdoctoral psychology fellows, special fellows or research fellows.
- **Program Director (PD)**: Individual who is appointed as the director of a training program. For the purpose of this policy, this also include Primary Investigators and Research Supervisors of research fellows.
- **Designee**: In the event the PD is unavailable because of extenuating circumstances, the PD can designate an APD or Chair as their proxy to execute the disciplinary actions.
- **Reportable**: Information or disciplinary actions that must be reported to credentialing or licensing bodies.

Policy Implementation: This policy applies to all trainees who are appointed to a GME program. Remediation is commonly accomplished in a progressive fashion and the purpose of remediation is for the trainee to overcome any difficulties or shortcomings in his/her attaining expected competencies and professional conduct. The steps in the remediation process include in increasing order of complexity and seriousness, verbal counseling, written counseling, and probation, which if not successful, can lead to non-promotion to the next level of training or to termination. Steps may be skipped depending on the severity and seriousness of the trainee's deficiencies or unacceptable actions and behaviors.

<u>Verbal Counseling</u>

When a trainee's academic and/or professional performance is below expectations of a training program, the PD engages in verbal counseling with the trainee. Verbal counseling about a specific area(s) of deficiency(ies) in competence may occur at any time, and as many times as necessary during a trainee's educational program. Notes regarding the counseling should be kept in the trainee's program/department file (not GME office) for future consultation/documentation, if needed.

Written Counseling

If under-performance continues despite verbal counseling and without the desired improvement, or if other action/behavior of resident/fellow necessitates intervention, the PD then provides the trainee with formal written counseling. Written counseling involves the delivery of a written memo *(GME Counseling & Remediation Form)* to the trainee that specifies the reasons for the written counseling and specific remediation steps that are aimed to improve the trainee's performance, as well as expectations and timeline thereof. The written counseling form is kept in the program/department's file, not the trainee's formal GME file. The written counseling memo must be signed by the PD and trainee. While the GME Department encourages the trainee to address and resolve issues related to verbal and written counseling with their PD, officials in the GME Department are available to answer any questions and assist the trainee in resolving such issues.

Corrective Action: Probation – This should only be delivered to the trainee after consultation and review by the GME office.

In the event that at the end of the timeline specified in the written counseling, the trainee's performance has not improved to the extent deemed acceptable by the program, or if the offense committed by the trainee is egregious enough in nature to necessitate skipping verbal and written counseling, the trainee may be placed on probation. The program invokes probation status to the trainee by written notification and using the GME Counseling & Remediation Form. This formal written notification advises the trainee that his/her performance is not satisfactory and includes a clear statement that the trainee is on probation. This notice to the trainee shall include a detailed description of the unsatisfactory performance, the expectations for performance improvement and time parameters in which performance is to improve and may include resources to facilitate improvement. The PD and trainee shall sign for the delivery and receipt of the notice. As a result of probation, and depending on the circumstances, some trainee clinical duties and other activities may be restricted or otherwise modified by the PD. Likewise, research fellow's duties and activities may be restricted or modified by the PD. Probation is considered a disciplinary corrective action and is reportable to credentialing agencies and state medical boards. This action is also considered adverse and as such is appealable by the trainee. In the event the probation occurs toward the end of the academic year, the trainee's current contract may be extended until the end of the probation period to allow time to meet competencies required for progression to the next level of training.

Probation status is issued for a predetermined period of time (e.g., three months), as determined by the PD and on the recommendation of the Clinical Competence Committee (CCC). The PD also has the discretion to extend the duration of probation status. A trainee who has been placed on probation shall have his/her progress toward performance improvement reviewed by the PD or designee on a regular basis. At the end of the probationary period, the PD meets again with the trainee. Depending on the trainee's performance, he/she may be: (1) removed from probation, (2) given an additional period of probation, or (3) be subject to immediate termination or non-promotion upon the completion of the current contract. If probation is extended, an extension of training at the current post graduate level may be required to assure the trainee meets competencies required for the next level of training. After the meeting, the PD shall provide the trainee with written confirmation that: 1. the probation has been lifted and that all requirements of the probation have been satisfied and no further corrective action is required; 2. the period over which probation will be continued and expectations for remediation; or 3. date of termination.

A copy of the signed probation notice will be forwarded to the Director of GME. The Director of GME or designee will meet with the trainee to discuss the significance of the probation and the trainee right to appeal the probation. The trainee shall inform the Director of GME of the decision to accept or appeal the probation within 10 calendar days of the meeting. If the trainee accepts the probation, it will be recorded in his/her permanent GME academic record. If the trainee chooses to appeal the corrective action, it will not be documented until an Appeal Task Force decision has been rendered. If no request for an appeal is received within the 10 calendar days from the meeting, the corrective action becomes final and no appeal will be permitted.

The trainee shall have the right to appeal the probation in the manner set forth in the GME Appeals Policy.

As a formal disciplinary corrective action, probation can be reported to state medical boards and/or credentialing agencies.

Corrective Action: Dismissal from Training

Dismissal may occur in the event the trainee does not successfully remediate after a probation. Dismissal may also occur "for cause" for:

(1) Apparent serious violations of ethical, legal or medical practice standards of conduct
(2) Significant patient safety concerns; or
(3) If found responsible after investigation for adverse incidents/issues

While dismissal may be appealed by the trainee, the appeals process does not apply in the case of certain egregious events such as: falsification of records, material omission of information on application or any official paperwork, violation of Substance Abuse Policy, conviction of a felony, or loss of medical license leading to inability to practice clinical medicine.

In the event a trainee is dismissed from a program, and is eligible for an appeal, he/she will be placed on paid administrative leave for 10 calendar days, or until they provide a decision to the Director of GME (if less than 10 days). If the trainee decides not to appeal, the dismissal will stand and the trainee will be terminated on that date. If the trainee appeals, paid administrative leave (salary and benefits) will continue until decision is rendered by the appeals committee.

Regulatory Requirement/References (taken from ACGME requirements):

The Cleveland Clinic is accredited by the ACGME (Accreditation Council for Graduate Medical Education). All trainee, whether in an accredited program, or not, are upheld to the same standards. Per the ACGME, program appointment, advancement, and completion are neither assured nor guaranteed to the trainee but are contingent on the trainee's satisfactory demonstration of progressive advancement in scholarship and continued professional growth in all ACGME-required competency areas. Programs are required to evaluate residents on their Milestones and must have documented criteria for promotion and/or renewal of a resident's/fellow's appointment. IR.IV.C.1

A program must provide a resident/fellow with a written notice of intent when that resident's/fellow's agreement will not be renewed, when that resident/fellow will not be promoted to the next level of training, or when that resident/fellow will be dismissed. IV.C.1.a)

The Sponsoring Institution must have a policy that provides residents/fellows with due process relating to the following action regardless of when the action is taken during the appointment period: suspension, non-renewal, non-promotion; or dismissal. IV.C.1.b)

Oversight and Responsibility:
The Graduate Medical Education Council (GMEC) and the Graduate Medical Education department are responsible for the review, revision, update, and operationalization of this policy to maintain compliance with regulatory or other requirements. It is the responsibility of each hospital, institute, department and discipline to implement the policy and to draft and operationalize related procedures to the policy if applicable.
Other Background Information
Originally created and approved 7/9/2021 by GMEC

Appendices/References
GME Counseling & Remediation Form Instructions
GME Counseling & Remediation Form
GME Appeal Policy
GME Promotion Policy
Standard Operating Procedure – GME Remediation and Corrective Action

GME Appeal Process Policy

Purpose: The purpose of this policy is to describe the Graduate Medical Education (GME) appeal process for trainees who are formally notified in writing of a corrective action (e.g. that they are placed on probation, non-promotion, non-reappointment, or termination/dismissal). The procedure below is based on the Accreditation Council of Graduate Medical Education (ACGME) Institutional Requirements, however, all trainees, whether in an ACGME accredited program or not, are held to the same standards and subject to the same rules and process.

Policy Statement: All trainees who are appointed through GME are required to meet the competencies and expectations (both academic and professional) of the respective training program in which they are enrolled and those of the Cleveland Clinic. In the event the trainee does not meet expectations or violate policies they may receive corrective action that they may appeal.

Definitions:

- **Remediation**: The act of remedying a trainee's academic and/or professional performance when performance is below expectations of their training program.
- **Corrective Action**: A disciplinary action taken against a trainee to communicate necessary improvement of academic and/or professional performance, without which improvement, additional actions, including dismissal may become necessary.
- **Counseling**: Advice and support meant to improve the performance of trainees and not considered disciplinary in nature. Counseling is intended to be positive and constructive in nature and not negative or derogatory. Whether verbal or written, it is considered to be an integral component of GME and should never be construed as a limitation or restriction on the trainee. Counseling is not disciplinary, probationary or investigatory in nature nor a reflection of unsatisfactory performance or academic incompetence. Counseling is not an adverse charge or action and may not be appealed by the trainee. The program has complete discretion regarding the appropriate handling and remediation of a trainee's under-performance

- **Verbal Counseling**: An informal communication between PD or designee and a trainee that is a result of his/her performing below expectations of a training program.
- **Written Counseling**: A formal documented communication between PD or designee and a trainee that is a result of his/her performing below expectations of a training program.
- **Probation**: Probation is a disciplinary corrective action in which the PD or designee notifies a trainee in writing of specific deficiencies that must be corrected in a stated period of time, otherwise the trainee will not be allowed to continue in the program or will be continued on continued probationary status. Salary and benefits remain in force during probation.
- **Administrative Leave of Absence**: Action that removes the trainee from any programmatic duties for a specified amount of time. Reasons for administrative leave of absence may include, but are not limited to: investigation of alleged misconduct and/or unprofessional behavior (i.e. violation of patient privacy rules, conduct that is illegal/unethical, conduct that is inconsistent with CC Policy on Professional Conduct); failure to comply with conditions of probation or other corrective actions; or academic and/or professional deficiencies warranting removal of the resident from patient care. A trainee who is issued a dismissal disciplinary action will be placed on administrative leave of absence pending decision to appeal the dismissal. If the trainee decides to appeal the dismissal, administrative leave will be extended until the outcome of the appeal is rendered.
- **Non-Promotion**: Disciplinary corrective action that indicates that the trainee will not be promoted to the subsequent PGY-year at the completion of the current year of training and that training will be extended.
- **Non-Reappointment**: Disciplinary corrective action in which a program decides not to offer a contract to the trainee for the next academic year or training period.
- **Dismissal**: Disciplinary corrective action that removes a trainee from a training program prior to completion of the contract due to failure to successfully meet expectations after probation or as a result of trainee actions of an egregious nature necessitating immediate termination.
- **Trainee**: An individual who is appointed through GME; including residents, fellows, clinical fellows, postdoctoral psychology fellows, special fellows or research fellows.
- **Program Director (PD)**: Individual who is appointed as the director of a training program. For the purpose of this policy, this also include Primary Investigators and Research Supervisors of research fellows.
- **Designee**: In the event the PD is unavailable because of extenuating circumstances, the PD can designate an APD or Chair as their proxy to execute the disciplinary actions.
- **Reportable**: Information or disciplinary actions that must be reported to credentialing or licensing bodies.
- **Appeal Task Force (ATF)**: A peer-review committee within the definition of the Ohio Revised Code; its members, proceedings, reports and minutes, shall be afforded the confidentiality guarantees and protections from discovery and immunities available to hospital peer review and quality management activities.
- **Appellant**: An individual trainee who is actively appealing a corrective action.

Policy Implementation: In the event a trainee has received a corrective action by their PD, the PD must send a copy of the completed GME Counseling & Remediation Form to the Director of GME. The Director of GME, or designee, will meet with the trainee to discuss the significance of the corrective action and their right to appeal the corrective action. The trainee shall inform

the Director of GME of their decision to accept or appeal the corrective action within 10 calendar days of the meeting. If the trainee accepts the corrective action, it will be recorded in their permanent GME academic record. If the trainee chooses to appeal the corrective action, it will not be documented until an Appeal Task Force (ATF) decision has been rendered. If no request for an appeal is received within the 10 calendar days from the meeting, the corrective action becomes effective and final and no appeal will be permitted.

If a trainee chooses to appeal the corrective action, the appeals process will be initiated. If the appellant engages legal counsel to assist him/her with the preparation of the appeal, such legal counsel may not represent or accompany the appellant or otherwise appear before the ATF at any time. The ATF may seek legal advice from the Cleveland Clinic Office of General Counsel as desired, but the Cleveland Clinic's attorneys should not serve in a prosecutorial role before the ATF.

Structure of the Appeals Process

1. Formation of the ATF: The Chairman of the GMEC shall guide final composition of the ATF and will not be eligible to participate. The ATF is formed as an ad hoc subcommittee of the Graduate Medical Education Council (GMEC) to investigate each appeal as it occurs. The ATF shall consist of:
    a. Five voting members who have no direct conflict of interest by way of being part of the teaching faculty in the appellants training program, department, or institute, personal involvement with the appellant or a member of the involved faculty or any other situation which might cause the member to be prejudiced and have a preexisting opinion.
        i. One member from the GMEC to serve as chairperson. This person will set a date for the meeting a maximum of 30 calendar days after the Chairman of the GMEC received written notice of the appellant's request of an appeal.
        ii. Three additional faculty members.
        iii. One House Staff Representative, such as a HSA committee officer or senior resident.
        iv. A representative from the GME Department will be present during the appeal to serve as an administrative consult to ATF regarding GME policy and procedures. This representative is a non-voting member.
2. Appeal Task Force Solicitation of Documentation
    a. The GME Committee Manager will solicit documentation and general information relevant to the corrective action under appeal from the appellant and the PD. The ATF Chair will review the documentation and make sure it is pertinent to the appeal prior to distributing to the ATF for review in advance of the meeting. Written documentation submitted to the ATF for deliberation, reports and minutes shall not be made available to either the PD or the appellant.
        i. The PD will be expected to submit documentation that justifies and explains the reason for the corrective action that has been taken and is being appealed. This documentation may include, but is not limited to, summaries of counseling sessions, department/individual evaluations and anecdotal notes regarding specific incidents, memos or letters from other individuals who have been involved in associated incidents, action minutes of departmental educational committee meetings or any other information which appears pertinent.

ii. The appellant is asked to submit any information that he/she feels may help to explain the grounds for the appeal.

b. Both the PD and the appellant will be asked to provide a list of individuals with relevant information at that time. That list may include: fellow trainees, various members of the faculty, Allied Health personnel, patients or anyone else who may be in a position to have direct knowledge and eventually have an impact on the appeal process decision. The list must include a brief two or three sentence explanation why each person is identified and what their potential input would be to the overall process. Members of the ATF may make recommendations as to whom they would like to interview for further clarification of events that lead to the corrective action.

i. The Chair of the ATF will review the list of potential individuals with relevant and decide who will or will not be invited to attend the meeting.

3. Meeting Process

a. The GME Committee Manager will set the agenda for the appeals meeting. The PD, appellant, and invited individuals with relevant information will be scheduled to meet with the ATF. The PD and the appellant will not be present before the ATF at the same time.

b. The ATF will initially meet with the PD who will be asked to summarize the events, issues and overall factors that have led to the appealed action. The ATF may or may not question the PD at that time for additional facts and information and may choose to ask him/her to return if necessary to complete the information gathering process.

c. The ATF will then meet with the appellant who will be offered an opportunity to present information in his/her defense. The ATF may or may not question the appellant at that time and may or may not ask them to return to complete the explanation of and/or questioning of the appellant.

d. The ATF will meet with individuals who have relevant information identified by the Chair based on documentation previously submitted by the PD and appellant (if applicable).

e. After scheduled meetings with all parties involved, the ATF will deliberate the need for additional interviews based on the information obtained.

i. If the ATF feels that additional information is needed to render a decision, they will then invite and interview additional individuals with relevant information from the list provided by the PD and appellant and/or other relevant individuals identified during the course of the interviews.

ii. At the discretion of the ATF, some of those on the original submitted list may not be called to give information if the reasons for their presence are either excessively redundant, seem inappropriate, or are felt to not affect the outcome of the appeal.

f.When the ATF feels that it has obtained all of the pertinent information, it will take the matter under discussion until it is prepared to make a decision. A simple majority of the voting members of the ATF present will be required to act on the appeal. That action may either be to uphold the appeal, which in effect negates the corrective action taken by the training program or reject the appeal and thereby sustain the corrective action taken by the program.

4. Appeal Task Force Decision

a. When the ATF has come to a majority decision, the information will be relayed to the Director of GME in writing within one week.

b. The Director of GME will then inform both the appellant and the PD. In the event that a dismissal of a trainee is sustained, the salary and benefits of the trainee will cease the day following notification of the ATF decision to the appellant.

Confidential meeting minutes and other materials used in the appeals process will be maintained within the Department of GME in a secure location and will be accessible only by those who need access. These materials are only available for review if subpoenaed or requested by the Cleveland Clinic Office of General Council.

Regulatory Requirement/References (taken from the ACGME requirements):
The Cleveland Clinic is accredited by the ACGME (Accreditation Council for Graduate Medical Education). All trainee, whether in an accredited program, or not, are upheld to the same standards. Per the ACGME, program appointment, advancement, and completion are neither assured nor guaranteed to the trainee but are contingent on the trainee's satisfactory demonstration of progressive advancement in scholarship and continued professional growth in all ACGME-required competency areas. Programs are required to evaluate residents on their Milestones and must have documented criteria for promotion and/or renewal of a resident's/fellow's appointment. IR.IV.C.1

A program must provide a resident/fellow with a written notice of intent when that resident's/fellow's agreement will not be renewed, when that resident/fellow will not be promoted to the next level of training, or when that resident/fellow will be dismissed. IV.C.1.a)

The Sponsoring Institution must have a policy that provides residents/fellows with due process relating to the following action regardless of when the action is taken during the appointment period: suspension, non-renewal, non-promotion; or dismissal. IV.C.1.b)

The Sponsoring Institution must have a policy that outlines the procedures for submitting and processing resident/fellow grievances at the program and institutional level and that minimizes conflicts of interest. IV.D.

Oversight and Responsibility:
The Graduate Medical Education Council (GMEC) and the Graduate Medical Education department are responsible for the review, revision, update, and operationalization of this policy to maintain compliance with regulatory or other requirements.

It is the responsibility of each hospital, institute, department and discipline to implement the policy and to draft and operationalize related procedures to the policy if applicable.

Other Background Information
Originally created and approved 7/9/2021 by GMEC

Appendices/References GME Counseling & Remediation Form Instructions
GME Counseling & Remediation Form
GME Remediation and Corrective Action Policy
GME Promotions Policy
Standard Operating Procedure – GME Remediation and Corrective Action

Board Eligibility/Training Extensions

Some specialties may have specific requirements as to allowable time away during training as specified by the designated American Board of Medical Specialties (ABMS) Member Board. Each Member Board has its own requirements for allowable time away (absence from training). When a clinical trainee requests a leave of absence, the Program Director is required to apprise the clinical trainee resident/fellow of an extension to training, if an extension is known to be required at that time. Certification requirements for each specialty may be reviewed on the ABMS website or AOA website. Please refer to the section on Leave of Absence in the Benefits and Conditions of Employment Information Booklet.

A clinical trainee may also be required to extend training to reach an acceptable level of performance to progress to the next graduate level or to successfully complete the training program. The Program Director is required to apprise the clinical trainee of an extension to training for deficient performance in accordance with the GME Promotion Policy. The Program Director must also complete the Application for an Extension of Training and submit the paperwork to the GME Office. The Program Director should advise a clinical trainee of reappointment without promotion or extension to successfully complete the training program at least four months before the end of the current appointment. If the primary cause of the non-promotion occurs within the four months prior to the end of the contract, Program Director must provide as much written notice as the circumstances reasonably allow. Specific board requirements regarding allowable time away are provided on the ABMS website for each accredited program and the AOA website for each Osteopathic program and should be provided to the clinical trainee at the beginning of the program and when a leave of absence may/will extend training.

Promotion

All appointments shall be for a period not to exceed one year and may be renewed by the Director of Graduate Medical Education in writing, upon recommendation by the Program Director. Letters of reappointment generally are generated during the second half of each academic year. Due to the fact that these offers are generated in advance of the conclusion of the academic year, each such letter of appointment is issued contingent upon the clinical trainee/research fellow satisfactory completion of the current academic year. Therefore, in the event a clinical trainee/research fellow is dismissed at any time during the academic year or if for any reason fails to satisfactorily complete the academic year, any previously issued reappointment letter shall be considered null and void. In the event a decision is made not to reappoint or not to promote to the next graduate level, the clinical trainee/research fellow should be advised of such decision in writing by the Program Director at least four months prior to the end of the appointment. If the primary reason(s) for the non-reappointment or non-promotion occur(s) within the four months prior to the end of the contract, the Program Director must provide the clinical trainee/research fellow with as much written notice of the intent not to reappoint or not to promote as the circumstances will reasonably allow, prior to the end of the current appointment. This notice shall include a description of the grounds for the decision not to renew the clinical trainee/research fellow appointment or not to promote to the next graduate level. Non-promotion includes any extension of training in the final year of the program. The clinical trainee/research fellow may appeal a non-reappointment or non-promotion by submitting a written request within two weeks of the meeting with the Director of GME or designee per our Corrective Action Policy located in this document.

Certificates of Completion of Training

Official Certificates of Completion of Training are issued to clinical trainees/research fellows who have successfully completed a Cleveland Clinic program in its entirety as determined by the program length approved by the GMEC. Research fellows who successfully complete at least six months of research in the same program are also eligible for a Certificate of Completion of Training. Clinical trainees/research fellows who do not meet the above criteria will receive, upon request, a letter verifying their actual training dates at Cleveland Clinic.

The Certificate of Completion of Training will include the legal name of the clinical trainee/research fellow, dates of training and the name of the program as listed by the accrediting body or, in the case of non-accredited programs, as named when approved by the GMEC.

Termination Procedure

When a clinical trainee/research fellow completes their training and leaves Cleveland Clinic for any reason, they are required to process out through the Graduate Medical Education Department. The processing out procedure includes meeting all training program requirements, returning Cleveland Clinic's property and obtaining the signature on the Cleveland Clinic GME Checkout Form from either the Program Director, Program Coordinator or an authorize representative. The Cleveland Clinic GME Checkout Form will be sent via email by the Graduate Medical Education Department after a termination record has been entered into MedHub for the clinical trainee/research fellow. The completed Checkout form should be returned to the Graduate Medical Education Department. All trainees who discontinue their appointment before their end date should submit a letter of resignation to Graduate Medical Education to be included in their MedHub file.

Compensation & Benefits

Graduate Medical Education at the Cleveland Clinic offers a comprehensive and competitive benefits program that recognizes the needs of a diverse workforce, as well as providing individuals and families with meaningful benefit choices.

Benefits & Conditions of Employment Information Booklet for Clinical Trainees vary by site and will provide detailed information on: Eligibility, Programs, (Qualifying Life Events, Health Care Plans, Dental Plans, Vision Plan, Flexible Spending Accounts and Life Insurance Plan), Disability Plan, Additional Valuable Cleveland Clinic Benefits (Vacation, Savings & Investment Plan, Employee Assistance Program), Benefit Contact Information and How to Get More Plan Information.

FMLA

Pursuant to the Family and Medical Leave Act (FMLA), Cleveland Clinic allows eligible employees time off from work for up to 12 work weeks in a rolling 12-month leave year for qualifying employee's and family member's serious health conditions and family care events. Except in the case of leave to care for a covered service member with a serious illness or injury (see FMLA - Military Family Leave of Absence policy), an eligible employee's entitlement is limited to a total of 12 work weeks of leave during any leave year for all qualifying FMLA leaves. FMLA leave will run concurrently with other qualifying leaves (e.g. Workers' Compensation, short-term disability leave, etc.)

Eligibility: Employees must have been employed for at least 12 months (need not be continuous) and have worked at least 1,250 hours during the 12-month period prior to the commencement of leave to be eligible for consideration for leave under the FMLA. An employment period prior to a break in employment of seven years or more will not be counted toward the 12 months of service required for eligibility unless the break in service is due to National Guard or Reserve military duty. Employees who return to work from National Guard or Reserve or active military duty will be credited with the time that they were on military leave toward the 1,250 hours of service.

Leave Year: The leave year is a rolling 12-month period measured backward from the date an employee uses any FMLA leave.

Qualifying Event
FMLA/Medical: Leave of absence due to an employee's own serious health condition.

FMLA/Family Care: Leave of absence for the birth and/or care of a newborn, for placement and/or care of an adopted or foster child, or to care for a family member with a serious health condition. Family member includes the employee's spouse, son or daughter, or parent. A son or daughter must be under age 18, or 18 or older and incapable of self-care because of mental or physical disability.

FMLA leaves for serious health conditions normally do not cover short-term illnesses such as the common cold, flu, ear infection, upset stomach, minor ulcers, and headaches (other than migraines).

It is the employee's responsibility to notify his or her supervisor of the need for FMLA leave. See full policy for how to submit a request FMLA Policy.

Professional Liability

Cleveland Clinic provides professional liability coverage for all clinical trainees while working within the confines of the Cleveland Clinic training programs. This insurance provides coverage for acts or omissions that occur during the course and scope of performing professional responsibilities as an employed clinical trainee of Cleveland Clinic. Outside rotations at participating sites that are a required component of the training program are included and covered under the professional liability coverage offered by Cleveland Clinic. Elective rotations outside of Cleveland Clinic are not covered by Cleveland Clinic professional liability coverage. Upon completion of the training program, this professional liability coverage remains in effect for any litigation that may arise from incidents that occurred while the clinical trainee was were in training. The clinical trainee does not have to purchase any "tail" coverage when they leave. For more information, refer to the Enterprise Risk & Insurance website. After the clinical trainee leaves the Clinic, verification of professional liability insurance or claims history can be obtained via written request only by emailing Tracy Brockway at brockwt@ccf.org

Trainee Salary & Benefit Policy

(View the complete Trainee Salary & Benefit Policy which is effective as of July 1, 2022)
Purpose: To develop a fair and equitable policy with regard to salary and benefits for all trainees appointed through the Center for Graduate Medical Education (GME).

Policy Statement: Cleveland Clinic is dedicated to providing a fair and equitable salary and

benefit package for all trainees. In addition, there are U.S. government regulations to which Cleveland Clinic must adhere. The following reflects our consideration of trainees' needs as well as U.S. government regulations.

Definitions

Clinical Trainee: A physician appointed to an Accreditation Council for Graduate Medical Education (ACGME) accredited residency or fellowship or a non-standard program approved by the Graduate Medical Education Council (GMEC).

Research Trainee: A physician who conducts research with no or incidental patient contact. Any patient contact must be within the context of an approved clinical research project and must be supervised by a licensed staff physician. Research trainees may not discuss diagnosis or treatment with the patient. All questions are to be referred to the staff physician.

J-1 Clinical Exchange Visitor: A foreign national physician seeking entry into U.S. programs of graduate medical education or training sponsored by the Educational Commission for Foreign Medical Graduates (ECFMG). It is a temporary nonimmigrant visa reserved for participants in the Exchange Visitor Program.

J-1 Research Exchange Visitor: A foreign national sponsored by organizations designated by Department of State (DOS) to come to the U.S. for the purpose of educational and cultural exchange. Cleveland Clinic is designated by DOS to use the research scholar category for M.D. / Ph.D. applicants who wish to pursue research in the U.S.

H-1B Temporary Worker: This nonimmigrant classification applies to positions which are considered a specialty occupation. The position offered must require: a theoretical and practical application of a body of highly specialized knowledge; and attainment of a bachelor's or higher degree in the specific specialty (or its equivalent) as a minimum for entry into the occupation in the United States. Employers must prove that the H-1B employee is not replacing a U.S. worker who has been laid off, is on strike or where work has been stopped for some reason. They must also prove that they are paying the actual or prevailing wage, whichever is higher, for the position.

Cleveland Clinic - main campus: Includes main campus, and all Family Health Centers, Physician practice sites, Nevada practice sites, Emergency Departments, Express Care Centers, Urgent Care Centers and Ambulatory Surgical Centers reporting to this facility.

Policy Implementation:

Upon approval of the GMEC all Program Directors and Program Coordinators will be notified of the change. GME personnel will review appointments and reappointment requests for adherence to the policy. Any requests which do not meet the policy requirements they will be returned to the program for revision.

Salary

Clinical Trainees: Clinical trainees (U.S. and International) appointed to ACGME Accredited programs will receive an annual salary commensurate with their post-graduate level. Clinical trainees being paid by Cleveland Clinic are to be paid at the graduate level required to enter the program; additional compensation is not provided to those who have completed training above and beyond those requirements. Salaries are determined each year and are posted on GME|com

and disseminated through various communication channels. These salaries and benefits are paid by GME. New programs or programs who have increased in complement after the GME maximum number was set will incur chargebacks to department.

Clinical trainees (U.S. and International) in non-standard programs will receive an annual salary commensurate with their post-graduate level, or in some cases, a higher salary agreed upon between the department and the trainee if the latter is acting in the capacity of LCP (limited clinical practitioner). In cases in which trainees are paid a higher salary, all trainees working in the same capacity at the same level will be paid the same salary. Departments will pay the salary and benefits for these individuals. The department will provide GME with the account to be charged at the time of appointment.

To ensure compliance with H-1B visa requirements, the wages set for clinical trainees shall take into consideration the prevailing wage as published by the Association of American Medical Colleges (AAMC). If a salary level increases after a trainee has been contracted for the year, the new wage will take precedence over the contracted rate on the effective date the post graduate level rates are increased.

Clinical trainees cannot be paid by outside funds regardless of immigration status unless (1) the funding is coming from the U.S. Military, (2) the trainee was accepted from an ACGME program at another institution which closed and per closure policy has agreed to fund the trainee(s) through completion of training, or (3) the parties enter into a suitable agreement that does not create a conflict of interest and has been vetted by the Cleveland Clinic Legal Department. Regardless of the source of funding, the wages will be comparable to wages received by clinical trainees with similar responsibilities/situations.

Research Trainees: All research trainees in clinical departments appointed by GME must receive a minimum of $47,476 in funding, or the prevailing wage, whichever is greater, preferably funded by the department. For research trainees, the prevailing wages will be obtained from the U.S. Department of Labor Office, Bureau of Labor Statistics, and Office of Employment Statistics (OES). Prevailing wages may vary from year to year. Clinical departments should check with International Physician Services for the current prevailing wages.

In the event alternative funds are used, the funding source must be vetted PRIOR to the appointment of the trainee. Funding sources may include a university, hospital or academic medical organization. Funding from family businesses will not be accepted. Funding from foreign governments will not be accepted, unless expressly approved in writing by the institute/department chair wherein the trainee will be hosted/working, the Law Department and the IM&COI Office. The funding will align with the research purpose and be comparable to wages received by similarly situated research fellows. The alternative funding must not obligate the trainee to share any intellectual property or other information related to CC's research activities. The trainees will be required to fully disclose any and all information related to the funding source and cooperate with the vetting of the outside funding source. If required, the department/institute proposing to host the trainee will need to cover the cost associated with appropriate background checks and other due diligence activities related to vetting the funding source and/or trainee. The outside funding must be disclosed on any federal grants or awards under which the trainee is performing research and any changes to the funding must be immediately reported to the IM&COI Office.

Funding requirements may vary based on visa type:

Visa Type	Funding Requirements
H1-B	Without exception: • Salary and benefits must be paid by the department and must be at or above prevailing wage as determined by the U.S. Department of Labor Office of Occupational Employment Statistics • The department is responsible for all costs (filing fees) associated with the filing of the H-1B petition. • Third party funding earmarked for a specific trainee may not be transferred to department accounts in order to meet the prevailing wage requirements • H-1B trainees may be paid out of Cleveland Clinic grants and/or funds earmarked specifically for research
J-1	• Salary may be paid by CC or an approved outside source, which may include a university hospital or academic medical organization* • Departments are responsible for obtaining verification of funds directly from the approved outside source. Funding from family businesses will not be accepted • ***Personal funds may not be used as a supplement to the main source of funding***

Part-time Employment: Research trainees may not work part-time; these are salaried positions and trainees in these positions cannot be paid an hourly wage.

*In keeping with CC technological and intellectual property security processes, outside funding sources will be vetted for possible relationships with known perpetrators of technological and intellectual property espionage. If according to CC sources the funding organization is a high-risk organization, the research trainee will not be appointed unless CC funds can be provided.

Verification of Funding Sources: If outside funding is utilized, the source must be verified in writing utilizing the GME Outside Funding for Cleveland Clinic Research Fellows Template and signed by the responsible person at the organization providing funding. The amount of funding must be given in U.S. dollars. Department or program coordinators must directly verify the funding with the source reflected on the funding verification form. This can be achieved by an email confirmation from the funding source. Annual renewal is required for reappointments and should be obtained 4 months in advance of the contract expiration. These documents must be in English or accompanied by a certified English translation.

Benefits

All research and clinical trainees will be offered medical benefits through the CCHS Health Plan for themselves and any eligible dependents, regardless of source of funding of salary. For research trainees, benefits will be paid by the appointing department. Reimbursement of benefit costs by an approved outside source is acceptable and must be arranged between the organization and the financial manager in the department. Departments cannot require research trainees to pay out of pocket for their benefits or to transfer personal funds for this purpose. Medical insurance provided by outside sources is not acceptable as it may not meet visa requirements. The accounting unit provided for salary will be utilized for benefits. If the trainee is the dependent of a Cleveland Clinic employee and they are enrolled in the CCHS Health Plan through the

primary's plan, proof of coverage must accompany the appointment request.

Regulatory Requirement/References
U.S. Department of State regulations pertaining to J-1 Exchange Visitors 22 CFR 62.15(a)(4)-(5) (4) Proof of insurance. Certification of compliance with insurance coverage requirements set forth in § 62.14; (5) Certification. The following certification: "I certify that the information in this report is complete and correct to the best of my knowledge and belief; and, that the above-named program sponsor has complied with all health and accident insurance requirements for exchange visitors and their accompanying spouses and dependents (22 CFR 62.14)." (i) For exchange visitor programs classified as "Government Programs," this certification will be signed by the Responsible Officer. (ii) For exchange visitor programs classified as P–1 or P–2 "Academic Programs" this certification will be signed by the institution's Chief Executive Officer or Responsible Officer. (iii) For exchange visitor programs classified as P–3 and P–4 "Private Sector Programs," this certification will be signed by the organization's Chief Executive Officer or Responsible Officer.

22 CFR 62.10(b) (b) Pre-arrival information. At the pre-arrival stage, sponsors must provide exchange visitors clear information and materials on, but not limited to, the following topics: Program activities, cultural goals and components of the program, employment information and terms and conditions of employment (including employer name and address, position duration, job duties, number of work hours, wages, other compensation and benefits, deductions from wages, including those taken for housing and transportation), insurance costs, and other conditions and restrictions of their exchange visitor.

The U.S. Department of Labor (DOL) Fair Labor Standards Act (FLSA) and regulations: The FLSA requires that most employees in the United States be paid at least the federal minimum wage for all hours worked and overtime pay at not less than time and one-half the regular rate of pay for all hours worked over 40 hours in a workweek. However, Section 13(a)(1) of the FLSA provides an exemption from both minimum wage and overtime pay for employees employed as bona fide executive, administrative, professional and outside sales employees. Section 13(a)(1) and Section 13(a)(17) also exempt certain computer employees. These exemptions are often called the "white-collar" or "EAP" exemptions. To qualify for exemption, employees generally must meet certain tests regarding their job duties and be paid on a salary basis. A salary basis means that the employee receives a predetermined salary regardless of the number of hours they work.

H-1B Prevailing wage and benefits regulations Payment of the higher of the prevailing and actual wage 20 CFR 655.730(d)(1) (1) The employer is offering and will offer during the period of authorized employment to H-1B nonimmigrants no less than the greater of the following wages (such offer to include benefits and eligibility for benefits provided as compensation for services, which are to be offered to the nonimmigrants on the same basis and in accordance with the same criteria as the employer offers such benefits to U.S. workers): (i) The actual wage paid to the employer's other employees at the worksite with similar experience and qualifications for the specific employment in question; or (ii) The prevailing wage level for the occupational classification in the area of intended employment.

Benefits 20 CFR 655.731(c)(3)(i) (i) For purposes of this section, the offer of benefits "on the same basis, and in accordance with the same criteria" means that the employer shall offer H-1B nonimmigrants the same benefit package as it offers to U.S. workers, and may not provide more

strict eligibility or participation requirements for the H-1B nonimmigrant(s) than for similarly employed U.S. workers(s) (e.g., full-time workers compared to full-time workers; professional staff compared to professional staff). H-1B nonimmigrants are not to be denied benefits on the basis that they are "temporary employees" by virtue of their nonimmigrant status. An employer may offer greater or additional benefits to the H-1B nonimmigrant(s) than are offered to similarly employed U.S. worker(s), provided that such differing treatment is consistent with the requirements of all applicable nondiscrimination laws (e.g., Title VII of the 1964 Civil Rights Act, 42 U.S.C. 2000e-2000e17). Offers of benefits by employers shall be made in good faith and shall result in the H-1B nonimmigrant(s)'s actual receipt of the benefits that are offered by the employer and elected by the H-1B nonimmigrant(s).

Working Conditions 20 CFR 655.730(d) (2) (2) The employer will provide working conditions for such nonimmigrants that will not adversely affect the working conditions of workers similarly employed (including benefits in the nature of working conditions, which are to be offered to the nonimmigrants on the same basis and in accordance with the same criteria as the employer offers such benefits to U.S. workers)

Oversight and Responsibility The GMEC and Director of GME will have oversight of this policy. GME personnel shall be responsible for ensuring compliance with this policy and reporting any irregularities to the GMEC and GME Director.

Other Background Information
GMEC reviewed/approved 10/8/2021

Appendix
Outside Funding For Cleveland Clinic Research Fellows Template

GME Trainee Vacation and Leave of Absence Policy

The purpose of this policy is to address all relevant requirements and procedures regarding Trainee vacation and leaves of absence as required by the Accreditation Council of Graduate Medical Education (ACGME). This policy describes vacation, leaves of absence, and salary continuation for leaves taken by Trainees during a Cleveland Clinic Graduate Medical Education (GME) Training Program ("Program"). To be eligible, the Trainee must be an active clinical or research Trainee appointed through GME. Vacation and leaves of absence benefits begin upon the Trainee's initiation of training in their GME Training Program.

Trainees at South Pointe Hospital are subject to the MEC and bylaws of their respective hospitals and should refer to the Trainee Vacation and Leave of Absence Policies for their hospitals.

Definitions:
"Clinical Trainee" includes both residents and fellows. "Trainee" includes residents, fellows, and research fellows.

Policy Implementation
Program Responsibilities:

1. Each Program must have a policy and process for submitting and approving requests for vacation and leaves of absence that is shared with Trainees annually. All time away dates must be recorded in MedHub. (*Institutional Requirement ("IR") IV.H.1.e.*)

2. Each Program must provide their Trainees with accurate information regarding the impact of leaves of absence on the criteria for satisfactory completion of the program and on a Trainee's eligibility to participate in examinations by the relevant certifying board. (*IR IV.H.1.g*) The potential need for an extension of training time must be reviewed with the Trainee at the time of a leave request.
3. The Program Coordinator will keep an accurate record of all paid and unpaid time off for each Trainee, including vacation, paid leaves of absence, and allowable holidays according to each Program's policies.

Trainee Responsibilities:

1. Trainees must request all vacation and leaves of absence in advance of the desired dates in accordance with program policy and with the approval of the Program Director. Anticipated time away must be requested as soon as the need is identified. Leaves of absence can only be approved by the Program Director.
2. It is the responsibility of the Trainee to be aware of their vacation and leave of absence time utilized.

Vacation Time: Trainees receive three weeks (15 working days) of vacation per academic year. For appointments of less than one year in length; vacation is prorated at the rate of 1.25 days per month worked and rounded to the nearest whole day. Vacation time is not cumulative and must be taken in the year earned; it does not carry over into the next academic year. Vacation must be requested per guidelines in the program specific policy. Trainees may, but are not required to, utilize available paid vacation time should they exhaust the paid leaves below, per guidelines in the program specific policy.

Paid Personal Days: Trainees are eligible for a minimum of 5 personal days per year. Personal days must be approved by the Program Director, and can be used for events such as exams, when too ill to work or as interview days. Personal days must be requested in advance whenever possible.

Types of Leave

FMLA: Pursuant to the Family and Medical Leave Act (FMLA), Cleveland Clinic allows eligible Trainees time off from work (up to 12 work weeks in a rolling 12-month period) for qualifying employee and family members' serious health conditions and family care events. Except in the case of leave to care for a covered service member with a serious illness or injury, an eligible Trainee's entitlement is limited to a total of 12 work weeks of leave during any leave year for all qualifying FMLA leaves. FMLA leave will run concurrently with other qualifying leaves (e.g. Workers' Compensation, Short-Term Disability Leave, Maternity Leave, Parental Leave, Caregiver Leave, etc.). FMLA is unpaid unless it is taken concurrent with available vacation or other applicable paid leave of absence.

Caregiver Leave: With approval of the Program Director, Trainees are eligible for a maximum of six (6) weeks of paid Caregiver Leave over the course of their time in a training program. All Trainees are eligible for this leave for the birth and care of their newborn child, for placement with the Trainee of a child for adoption or foster care; to care for an immediate family member (i.e., spouse, child, or parent) with a serious health condition. Trainees who are not otherwise eligible for paid Disability Leave may also take paid Caregiver Leave for personal medical reasons. Paid Caregiver Leave must be taken concurrently with other leaves such as Maternity,

Parental, and FMLA leaves. As reflected above, available paid vacation may be used outside of/in addition to the first 6 weeks of approved Medical, Parental or Caregiver Leave. Caregiver Leave may be taken continuously or as intermittently.

Maternity Leave: Eight (8) weeks paid leave is provided for Maternity Leave beginning with the birth of the child. Trainees must notify their Program Director of a need for Maternity Leave as soon as possible. Maternity Leave must be taken concurrent with available FMLA and Caregiver Leave. Maternity Leave must be taken continuously.

Parental Leave: Four (4) weeks paid Parental Leave is provided to Trainees for the birth and care of their newborn child or for placement with the Trainee of a child for adoption or foster care. Trainees must notify their Program Director of a need for Parental Leave as soon as possible. Parental Leave must be taken concurrently with available FMLA and Caregiver Leave. Parental Leave must be taken continuously.

Bereavement Leave: Per Cleveland Clinic Policy, Trainees are eligible for paid bereavement days for a death in the immediate family. Bereavement Leave will be paid for attending the funeral or memorial service and/or the time necessary to make arrangements or manage personal affairs related to the death of an immediate family member. Five (5) days are granted for the death of a spouse or child (step-child), three (3) days are granted for other immediate family members defined as: mother/stepmother, mother-in-law, father/stepfather, father-in-law, siblings/stepsiblings, grandmother, grandfather, and grandchild. Bereavement Leave may be taken within 30 days of the date of death of the immediate family member, except in those circumstances where the service is held beyond that time frame due to extenuating reasons. Additional unpaid time off may be granted by the Program Director. Available vacation time or paid personal days may also be used to extend the Bereavement Leave.

Medical Leave of Absence: If a Trainee is temporarily unable to work due to illness or accident as determined by their primary care physician and is unable to carry on duties and responsibilities as required in the Program, salary and benefits will continue for the lesser of (1) 90 days, (2) the duration of the illness, or (3) the remainder of the contract. For Clinical Trainees, if the illness continues and the Clinical Trainee holds a valid appointment, they will be eligible to apply for disability benefits in accordance with the terms of the Disability Plan and remain eligible to receive Cleveland Clinic benefits. Written verification is required from the primary care physician stating duration of leave required as well as medical necessity of the leave. Please refer to the Disability Benefit program for further information.

Military Leave of Absence (FMLA): Pursuant to the Family and Medical Leave Act (FMLA), Cleveland Clinic allows eligible Trainees time off from work for up to twelve (12) weeks in a rolling 12-month period as a result of a "qualifying exigency" arising out of the fact that the Trainee's spouse, son, daughter or parent is a covered military member on active duty (or has been called to active duty) in support of a contingency operation and allow eligible Trainees up to 26 weeks in a single leave year to care for a covered service member with a serious injury or illness if the Trainee is the spouse, son, daughter, parent or next of kin of the service member.

Administrative Leave of Absence: A Trainee may be placed on a paid Administrative Leave of Absence, removing the Trainee from any programmatic duties for a specified amount of time. Reasons for administrative leave of absence may include, but are not limited to: investigation of alleged misconduct and/or unprofessional behavior (i.e. violation of patient privacy rules,

conduct that is illegal/unethical, conduct that is inconsistent with CC Policy on Professional Conduct); failure to comply with conditions of probation or other corrective actions; or academic and/or professional deficiencies warranting removal of the Trainee from patient care. A Trainee who is issued a dismissal disciplinary action will be placed on administrative leave of absence pending decision to appeal the dismissal. If the Trainee decides to appeal the dismissal, administrative leave will be extended until the outcome of the appeal is rendered.

Unpaid Personal Leave: It is the policy of the Cleveland Clinic to grant Trainees an unpaid leave of absence for urgent or emergency situations that personally affect the Trainee and cannot be handled in any other way. Program Directors have the final approval for all requests for an Unpaid Personal Leave of absence.

Regulatory Requirement/References (taken from ACGME requirements)
The Cleveland Clinic is accredited by the ACGME (Accreditation Council for Graduate Medical Education). All Trainees, whether in an accredited program, or not, are held to the same standards. Per the ACGME the Sponsoring Institution must have a policy for vacation and other leaves of absence, consistent with applicable laws. (IR IV.H.1)

Oversight and Responsibility
The Graduate Medical Education Council (GMEC) and the Graduate Medical Education department are responsible for the review, revision, update, and operationalization of this policy to maintain compliance with regulatory or other requirements.
It is the responsibility of each hospital, institute, department and discipline to implement the policy and to draft and operationalize related procedures to the policy if applicable.

Other Background Information
Originally created and approved 8/26/2022 by GMEC.

Appendices
FMLA - Family Medical Leave of Absence Policy
FMLA – Military Family Leave of Absence Policy
GME Maternity Leave Policy
GME Parental Leave Policy

GME Maternity Leave Policy

The purpose of this policy is to provide information regarding eligibility for the Maternity Leave Program and to provide clear expectations regarding the request and approval process. It is the policy of Cleveland Clinic to provide income protection for a maximum of eight (8) consecutive weeks for eligible, full-time employees who are on authorized Maternity Leave. This policy describes the process for Trainees during a Cleveland Clinic Graduate Medical Education (GME) Training Program.

Definitions:
Cleveland Clinic United States locations: Includes the main campus, Avon, Euclid, Fairview, Hillcrest, Lutheran, Marymount, Medina, South Pointe, Children's Hospital for Rehabilitation, Cleveland Clinic Florida, Cleveland Clinic Hospital (Weston), Coral Springs Ambulatory Surgery Center, and all Family Health Centers, Physician practice sites, Nevada practice sites, Emergency Departments, Express Care Centers, Urgent Care Centers and Ambulatory Surgical Centers reporting to these facilities.

"Trainee" includes residents, fellows, and research fellows.

Eligibility Criteria for Maternity Leave Benefit Payments:

A. To be eligible, the employee must be an active trainee appointed through GME. Employees on Personal or Military Leave of Absence at the time of the birth of the child are not considered "active" for the purpose of Maternity Leave benefit payments.

B. Eligibility for payment of the Maternity Leave benefit (or any corresponding Family and Medical Leave Act (FMLA) Leave (see FMLA- Family and Medical Leave of Absence Policy) or Medical Leave of Absence will be determined by GME once:
   - The request was discussed with the Program Director and the potential need to make up time to meet board requirements was determined
   - The trainee submitted the request via MedHub; GME will approve and send a Report of Delivery Form to the requestor. Instructions are included on the form to send back to GME within 31 days of the baby's date of birth.

C. The Maternity Leave benefit is available for an employee's pregnancy loss at or after 24 weeks of the gestation period with the submission of appropriate documentation to GME in a timely manner.

D. Except as otherwise indicated, the Maternity Leave benefit will not be paid to any employee who attempts to secure the Maternity Leave benefit under fraudulent and/or misrepresented conditions. Under such circumstances, the employee shall be subject to corrective action.

Maternity Leave Benefit Payments:

A. The Maternity Leave benefit begins on the day of delivery or next full day following childbirth if the employee worked on the date of delivery. The Maternity Leave benefit is not available for intermittent or partial day absences and only full days of continuous absence will be counted toward the Maternity Leave benefit. The authorized Maternity Leave shall run concurrently with leave under the FMLA when FMLA eligibility criteria are met (see FMLA – Family and Medical Leave of Absence Policy).

B. The payment of the Maternity Leave benefit will be processed by GME upon the confirmation of birth reported to GME. It is the responsibility of the employee to report birth within 48 hours and to ensure completion and submission of both the Maternity Leave Request form and proof of birth to GME in a timely manner, or no later than 31 days following the birth of the child.

C. Based on a customary period of recovery from childbirth, the Maternity Leave benefit period is eight (8) consecutive weeks. The benefit will be paid for a maximum period of eight (8) consecutive weeks at 100% of the employee's base salary for either one or multiple births.

D. An employee receiving the Maternity Leave benefit may also be eligible for the Parental Leave benefit to be used immediately following the Maternity Leave benefit period (see Graduate Medical Education (GME) Parental Leave Policy section of this manual).

Maternity Leave during a Holiday

If a Cleveland Clinic designated holiday occurs during the Maternity Leave period:

1. The Maternity Leave benefit is provided for that holiday.
2. The Maternity Leave benefit will not be extended.

Maternity Leave during Bereavement Leave
If an eligible employee gives birth after completing the last scheduled work day before Bereavement Leave, the Maternity Leave benefit shall be applied in the following manner:

1. If the employee is granted an FMLA leave or Medical Leave of Absence, then the employee will use Maternity Leave benefits (not Bereavement).
2. If Bereavement days occur during the Maternity Leave period:
    a) Maternity Leave is provided in lieu of Bereavement Leave.
    b) The Maternity Leave benefit will not be extended.

Termination of Coverage
Benefit payments under this program will terminate at the first to occur of:

1. When employment ceases.
2. When the employee is no longer in an eligible job status.
3. When the Maternity Leave benefit period of eight (8) consecutive weeks is exhausted.

Regulatory Requirement/References

FMLA- Family and Medical Leave of Absence Policy
FMLA- Military Family Leave of Absence Policy
View the complete GME Maternity Leave Policy.

Oversight and Responsibility

The Graduate Medical Education Council is responsible to review, revise, update, and operationalize this policy to maintain compliance with regulatory or other requirements.
It is the responsibility of each hospital, institute, department and discipline to implement the policy and to draft and operationalize related procedures to the policy if applicable.

Other Background Information
GMEC Approval: 2/14/2020, updated 8/2022

GME Parental Leave Policy

The purpose of this policy is to provide information regarding eligibility for the Parental Leave Program and to provide clear expectations regarding the request and approval process. It is the policy of Cleveland Clinic to provide income protection for a maximum of four (4) consecutive weeks for eligible, full-time employees who are on an authorized Leave of Absence to care for and/or bond with a newborn or a newly adopted child. This policy describes the process for Trainees during a Cleveland Clinic Graduate Medical (GME) Training Program.

Definitions:
An eligible parent is an employee who:

- has given birth to a child
- is the spouse or partner of an individual who has given birth to a child;
- is the biological parent, or spouse or partner of the biological parent of the child
- has adopted a child who is 17 years old or younger.

This provision does not apply to the adoption of a stepchild by a stepparent or the placement of a foster child.

"Trainee" includes residents, fellows, and research fellows.

Cleveland Clinic United States locations: Includes the main campus, Avon, Euclid, Fairview, Hillcrest, Lutheran, Marymount, Medina, South Pointe, Children's Hospital for Rehabilitation, Cleveland Clinic Florida, Cleveland Clinic Hospital (Weston), Coral Springs Ambulatory Surgery Center, and all Family Health Centers, Physician practice sites, Nevada practice sites, Emergency Departments, Express Care Centers, Urgent Care Centers and Ambulatory Surgical Centers reporting to these facilities.

Eligibility Criteria for Parental Leave Benefit Payments:

A. To be eligible, the employee must be an active trainee appointed through GME. Employees on Personal or Military Leave of Absence at the time of the birth of the child are not considered "active" for the purpose of Parental Leave benefit payments.
B. Eligible employees must use the approved Parental Leave benefit within twelve (12) weeks of the birth or placement of the child. In the event both eligible parents are employees of Cleveland Clinic, the approved Parental Leave benefit must be used within sixteen (16) weeks of the birth or placement of the child.
C. Eligibility for payment of the Parental Leave benefit (or any corresponding Family and Medical Leave Act (FMLA) Leave (see FMLA – Family and Medical Leave of Absences Policy) or Medical Leave of Absence (see Leave of Absence – Medical Policy)) will be determined by GME once:
    - The request was discussed with the program director and the potential need to make up time to meet board requirements was determined.
    - The trainee submits the request to GME via MedHub for approval; upon preliminary approval GME will forward an informational packet with instructions for completion.
    - Once leave commences GME must receive (1) a Parental Leave Request form completed by the employee, and (2) sufficient written proof of birth or adoption that contains the employee's name, the child's name, the employee's relationship to the child, and the date of birth or adoption that is signed by a hospital or government official, or other supporting documentation as appropriate.
    - Eligible employees must use the Parental Leave benefit for the purpose of caring for and/or bonding with the newborn or newly adopted child. For surrogacy and egg or sperm donations, the Parental Leave benefit is only available to an employee who is an intended parent of and responsible for the child, whether or not there is any genetic relation between the employee and child.
    - Except as otherwise indicated, the Parental Leave benefit will not be paid to any employee who attempts to secure a Parental Leave payment under fraudulent and/or misrepresented conditions. Under such circumstances, the employee shall be subject to corrective action according to the GME Corrective Action Policy section of this manual.

Parental Leave Benefit Payments:

A. The Parental Leave benefit can be used as soon as the day of birth or placement of the eligible child, or the next full day following childbirth or adoption if the employee has worked on the day of delivery, or, if applicable, immediately following the conclusion of the employee's Maternity Leave of absence. The Parental Leave benefit is not available for intermittent or partial day absences and only full days of continuous absence will be counted toward the Parental Leave benefit. The authorized Parental Leave shall run

concurrently with leave under the FMLA when FMLA eligibility criteria are met (see FMLA – Family and Medical Leave of Absence Policy).

B. The payment of the Parental Leave benefit will be processed by GME upon the confirmation of birth or placement. It is the responsibility of the employee to ensure completion and submission of the informational packet and proof of birth or adoption to the One HR Leave Team in a timely manner, or no later than 31 days following the birth of the child or placement for adoption.
C. The Parental Leave benefit will be paid for a maximum period of four (4) consecutive weeks at 100% of the employee's base salary for either one or multiple births/adoptions. No waiting period is required prior to the Parental Leave benefit payments.
D. Following exhaustion of a Parental Leave benefit period, FMLA leave may be available for an employee to continue to care for and bond with a newborn or a newly adopted child.

Parental Leave during a Holiday

If a Cleveland Clinic designated holiday occurs during the Parental Leave period:

1. The Parental Leave benefit is provided for that holiday.
2. The Parental Leave benefit will not be extended.

Parental Leave during Bereavement Leave

If an eligible employee becomes a parent through the birth or adoption of a child after completing the last scheduled work day prior to Bereavement Leave, the Parental Leave benefit shall be applied in the following manner:

1. If the employee is granted FMLA leave, then the employee will use the Parental Leave benefit (not Bereavement).
2. If Bereavement days occur during Parental Leave period:
    a) Parental Leave is provided in lieu of Bereavement Leave.
    b) The Parental Leave benefit will not be extended.

Termination of Coverage

Benefit payments under this program will terminate at the first to occur of:

1. When employment ceases.
2. When the employee is no longer in an eligible job status.
3. When the Parental Leave benefit period of four (4) consecutive weeks is exhausted.

Regulatory Requirement/References

FMLA- Family and Medical Leave of Absence Policy
FMLA- Military Family Leave of Absence Policy
Graduate Medical Education (GME) Maternity Leave Policy

Oversight and Responsibility

The Graduate Medical Education Council is responsible to review, revise, update, and operationalize this policy to maintain compliance with regulatory or other requirements.

It is the responsibility of each hospital, institute, department and discipline to implement the policy and to draft and operationalize related procedures to the policy if applicable.

Other Background Information GMEC Approval: 2/14/2020, updated 8/2022

Complaint & Problem Resolution

This policy is intended to provide clinical trainee/research fellows with the opportunity to raise and resolve issues in their training program without fear of intimidation or retaliation. When a trainee experiences a problem such as perceived harassment, unfair treatment, concerns regarding work environment, program noncompliance with ACGME, RC or Cleveland Clinic requirements or procedural discrepancies/inequities, it is best handled within the program whenever possible. Trainees are encouraged to engage the Chief Resident, Program Director, Principle Investigator, Department Chairman, Advisor or other designated individuals in the training program in resolving issues or complaints. Occasionally, these issues are unable to be resolved at the program level, in which case the clinical trainee/research fellow is encouraged to contact Graduate Medical Education at 216-445-5690 to arrange a meeting. The trainee will be scheduled to meet with the Director of Graduate Medical Education, Administrative Directors of Graduate Medical Education, or a designee to discuss the issue or complaint. Every attempt will be made by GME leadership to investigate and resolve the reported issues/complaints.

If a workable solution is not reached by the Director and Administrator of GME, the clinical trainee/research fellow may choose to bring the matter before the Graduate Medical Education Council. Findings and action taken by the Graduate Medical Education Council are considered final and binding on all parties involved.

The GME Department created a GME Confidential Reporting form for all trainees to use to safely and anonymously report any concern about their training. This is to raise issues related to: work hours, supervision, fatigue or any other concern. Access the GME Confidential Reporting form. This feedback is sent anonymously to the GME Department. We urge trainees to be candid so that we can take action where appropriate and continue to make Cleveland Clinic a great place to learn and grow. If contact information (not required) is provided we will follow up with the trainee to discuss next steps.

- Reports of discrimination or harassment, including sexual harassment, may be made anonymously through the Office of Educational Equity's anonymous reporting portal. Reports made through the anonymous reporting portal will be sent directly to the Office of Educational Equity. The Office of Educational Equity will address the report to the extent possible with the information provided.

SERS event reporting provides information as to where processes are breaking down and targets opportunities for improvements which reduces the likelihood of recurrence. You can report by calling Ext. 6-RISK, or 216.636.7475, or by using the online SERS Reporting form.

Discrimination, Harassment and Retaliation

Trainees who have experienced or witnessed discrimination, harassment or retaliation on the basis of a protected characteristic may report the conduct to the Office of Educational Equity, EduEquity@ccf.org. A protected characteristic is a person's race, color, religion, sex, gender, sexual orientation, gender identity, pregnancy, marital status, age, nationality, ethnicity, ancestry, disability, military status, genetic information, protected veteran status, or any other characteristic protected by law. Trainees may also contact the Office of Educational Equity if they have been subject to or witnesses micro-aggressions.

The Office of Educational Equity shall maintain the confidentiality of reports of discrimination, harassment, retaliation and micro-aggressions to the extent reasonably possible consistent with Cleveland Clinic's responsibility to provide a safe educational and work environment, to provide

a prompt, fair and impartial resolution of the report and to comply with applicable laws related to reporting.

House Staff Resources

House Staff Association (HSA)

The Cleveland Clinic House Staff Association (HSA) is a peer-elected representative body of Cleveland Clinic clinical trainees. HSA's mission is to promote house staff personal well-being, professional experience and education. It accomplishes this mission statement through serving as a liaison to our Graduate Medical Education Committee (GMEC) to help inform policy that improves the clinical trainee work environment, as well as patient care. HSA sponsors opportunities for professional development, wellness, educational seminars, diversity and inclusion, community service, quality and patient safety, AMA involvement, and social events throughout the year. The HSA also promotes clinical trainee involvement on various institution committees. HSA's meetings are open to all house staff and additional information including meeting time, current officers, and more can be found on the HSA website.

House Staff Spouse Association (HSSA)

The Cleveland Clinic House Staff Spouse Association (HSSA) is a philanthropic, social and support organization for the spouses and significant others of Cleveland Clinic clinical trainees. The HSSA provides a monthly newsletter, *The Stethoscoop*, detailing its activities. Some of their events include a Welcome Party at the Cleveland Botanical Gardens, playgroups, book club and volunteer opportunities. HSSA website.

Information for International Medical Graduates

The GME|com website contains a section devoted to information for non-U.S. citizens who are in training at Cleveland Clinic, including the International Physician/Scientist handbook; quick links to important agencies (ECFMG, USCIS, etc.), and general information on living in Cleveland.

Employee Wellness Program

Employee Wellness Mission: To support and empower employees to incorporate wellness into their daily lives resulting in a more active, healthy and engaged workforce. This mission is accomplished through a variety of programs including Cleveland Clinic sponsored fitness centers, yoga, Wellness Grand Rounds, Wellness Connection, Wellness Walks and other events throughout the year. In addition, an engaged Wellness Champions program helps spread wellness initiatives and programming throughout the system in support of the Employee Wellness department.

Cleveland Clinic Caregivers and their eligible family members who are members of the Employee Health Plan (EHP) can take advantage of a free membership at all EHP approved fitness centers (Walker, Lyndhurst, Fairview, CCAC, Hillcrest, Lutheran, BOC, Medina and Wooster). Updated details on the Employee Wellness program or e-mail wellness@ccf.org.

Employee Health Plan members also have access to other wellness programs, including nutrition and weight management programs like Cleveland Clinic Eat Well program and Weight Watchers. For full information to go www.clevelandclinic.org/healthplan

Caring For Caregivers

Cleveland Clinic is committed to the wellbeing of its caregivers and understands how personal and work stresses can impact our quality of life and ability to provide skillful and compassionate care.

The Caring for Caregivers Programs help caregivers take care of themselves and maintain their ability to provide a world class patient experience. The programs offer expert, confidential and free support through the: Professional Staff Assistance Program (PSAP), Licensed Professionals Health Program (LPHP), Employee Assistance Program (EAP), and Wellbeing Resource and Referral Center. Together these programs demonstrate the importance Cleveland Clinic places on caring for our caregivers. To receive more information, please refer to the Caring for Caregivers site.

Caring for Caregivers (CFC) offers private and confidential assessment, short-term counseling and follow-up services to benefit-eligible employees and their dependent family members. Enrollment in Cleveland Clinic EHP is not required for access to Caring for Caregivers' services. Services are available at numerous locations throughout Northeast Ohio and are not part of medical or GME records. The Cleveland Clinic recognizes that clinical trainees/research fellows are an important part of our team and provides this benefit to assist them in reaching their highest potential, both at work and in their personal life. To access, please call 216-445-6970 or 1-800-989-8820.

Academic Awards Program

Each year the Education Institute sponsors a variety of award opportunities for Cleveland Clinic clinical trainees and professional staff. There are two categories: manuscript awards and nomination awards. Most submissions and nominations will be accepted beginning in November through March. Detailed information on the various award opportunities can be found on the Academic Awards Program website.

The award recipients are presented their award at the Annual Awards Dinner hosted by Jeremy Lipman, MD, MHPE, Director, Graduate Medical Education.

GME Department Functions

Providing a quality educational experience to our clinical trainees/research fellows is our number one job, which is why our Graduate Medical Education caregivers are committed to ensuring that our training programs meet or exceed national and institutional standards. The GME Department helps in the following areas:

- Administration: oversees and monitors program accreditation and all institutional policies affecting GME programs.
- Human Resources: recruit trainees, administer payroll, authorize benefits and verify employment as well as perform other HR-related functions.
- Customer Service: resource center for questions about graduate medical education.
- Notary: this service is provided free of charge.

On-Call Rooms

TT-Building On-call rooms and amenities within them are managed by the Education Institute (EI) Shared Services team. Our team is available to manage requests Monday – Friday from 8:30 a.m. to 5 p.m. Support can be requested through the TT On-Call Rooms Ticketing System.

Additional Questions can be emailed to oncallrooms@ccf.org.

Purpose:
To provide safe, secure areas in which residents, fellows, staff, nursing and others assigned to overnight call at the hospital can sleep to alleviate fatigue thus increasing their own well-being and enhancing patient care.

Procedure/Policy:
1. To gain access to a TT Building on-call room, an Access Request Ticket must be submitted. Requests will be reviewed by the On-Call Room team for approval, which can take between five to seven business days.
2. Assigned room keys are located within a secure key box on the room's corresponding floor. Steps to access assigned keys can be found on the On-Call Room website. Any access issues, including but not limited to, lost keys, technical issues, etc., should be reported through the TT On-Call Rooms Ticketing System immediately.
3. In the event of an access issue after business hours, users may contact Security at 216-444-2250 to gain access to the assigned space. Users are required to complete the on-site emergency access sheet prior to Security granting access to the space. All emergency access requests will be tracked and monitored by the On-Call Rooms Team. Multiple requests will result in further investigation.
4. Additional shared on-call spaces are available on TT5 and TT6 for assigned users to access in the event their assigned space is unavailable. Steps to access shared spaces can be found on the On-Call Room website.

5. Use of an on-call room by a person other than who it is assigned is forbidden. Rooms may only be utilized within a person's scheduled on-call shift. Misuse of rooms may lead to termination of on-call room privileges.
6. Misuse of assigned keys, including sharing lock box pin codes and ID badges, may lead to termination of on-call room privileges. Copies of keys are not permitted, and if used, the on-call room lock will be re-keyed and all fees will be charged back to the program. Rooms must be locked and secured at all times.
7. EI Shared Services and the Cleveland Clinic retain the right to conduct routine and random on-call room inspections at any time and without prior warning or approval.
8. EI Shared Services will conduct mandatory audits throughout the course of the year, including but not limited to, user access and program contacts. All audits must be completed by the program within the given deadline.
9. EI Shared Services and the Cleveland Clinic are not responsible for personal property that is lost or stolen. Personal property brought into the on-call room must be properly stored and removed after call.
10. It is each user's responsibility to keep the on-call room neat and clean at all times. EI Shared Services retains the right to charge the program for any damage or repairs resulting from misuse of the space.
11. Upon assignment and during use, users are responsible for reporting any damage or needed repairs via the TT On-Call Rooms Ticketing System.
12. Flammable materials, dangerous chemicals, explosives or weapons of any kind are strictly prohibited inside of the on-call room. Illegal or controlled substances such as drugs and alcohol are strictly prohibited inside the on-call room. Possession of prohibited items in on-call rooms may be cause for termination of on-call room privileges.

By having access to the On-Call Rooms the user agrees to abide by above On-Call Room policy/procedure.

GME Locker and Lock Agreement

Purpose: To provide a facility where GME trainees can secure their belongings. Lockers and locks will be provided to trainees as determined by the GME office based on program needs.
Procedure/Policy:

1. Lockers, locks and keys are issued by GME and considered property of the Cleveland Clinic.
2. Use of a locker by a person other than who it is assigned is forbidden. Misuse of a locker may lead to the termination of locker privileges. Personal locks are not permitted, and if used, will be removed from the locker and replaced by a GME lock.
3. GME and the Cleveland Clinic retains the right to conduct routine and random locker inspections at any time and without prior warning or approval. Misuse of these facilities may be cause for corrective action.
4. GME and the Cleveland Clinic are not responsible for personal property that is lost or stolen. All trainees are encouraged to leave valuables at home. Secure their lock and refrain from giving their key or lock code to other individuals.
5. All personal property must be stored completely within the locker or shelf. All items left outside of a locker or shelf, whether secured or not, will be removed and disposed of accordingly.
6. Flammable materials, dangerous chemicals, explosives or weapons of any kind are strictly prohibited inside of the lockers and locker rooms.
7. It is each trainee's responsibility to keep his/her locker neat and clean at all times. Perishable items (food and beverages) and illegal or controlled substances such as drugs and alcohol are strictly prohibited inside of the lockers and locker rooms.
8. If your key is lost/stolen, please contact the GME office at 216-444-5690 or meded@ccf.org to obtain a new key to access to your locker. The key replacement fee is $40. Replacements will be provided during GME hours 8:30am-5:00pm.
9. Upon assignment and during use, trainees are responsible for reporting any damage or needed repairs to the GME office by contacting 216-444-5690 or meded@ccf.org. Trainees will assume the cost of any unreported damages.

Signature below indicates the trainee agrees to abide by above Lockers and Lock policy.

Print Name:_____ Date: _____

Signature: _____ Employee ID: _____

Program: _____

Locker Location: _____ Locker #: _____

Institutional Policies

Hand Off Communication Policy

Purpose: To enhance communication when care of a patient is being transferred from one caregiver to another, in permanent and/or temporary situations. Many patients depend on those who provide care to coordinate services whether tests, consultations, or procedures to ensure that accurate and timely information reaches those who need it at the appropriate time. This

framework provides for effective communication among members of the health care team in order to ensure consistency of communications and continuity of treatment through a standardized approach to giving and receiving information across the care continuum.

Policy Statement: All caregivers, including but not limited to physicians, clinical trainees, licensed independent practitioners (LIP), Care Coordinators, nurses, therapists and transporters, will allocate sufficient time to perform and receive hand off information when patient care is transferred to another caregiver.

Policy Implementation: Hand off communication of patient care will occur in relationship to, but not limited, to the following circumstances:

- Transfer of complete responsibility for a patient such as a primary care physician, LIP or Care Coordinator
- Transfer of on-call responsibility
- Transfer of patients between units, including admissions from the Emergency Department and from ambulatory care settings
- Transfer of care in procedural areas, such as, the surgical invasive procedure care environment, including surgery, PACU, ICU Ambulatory Surgery, Cath Lab, Cardiovascular Care Unit Holding, Dialysis, and Interventional Radiology
- Transfer of care to another hospital, nursing home, home care agency or referring facility; include providing hand-off to transport services/personnel
- Transportation of patients to and/or from patient care areas to diagnostic or procedural areas
- Change-of-shift reports
- Anesthesia provider report to post-anesthesia care unit (PACU) caregivers
- Temporary assignment of responsibility of care when staff leaves a unit for a short period of time (e.g. lunch breaks, off-unit minutes, special studies, hemodialysis, endoscopy)
- Patient undergoing exam or treatment in ancillary service area requiring adjunct medication therapy or ongoing patient monitoring, including but not limited to, Physical Therapy, Occupational Therapy, Speech, Respiratory Services, Imaging, and Non-Invasive Cardiology

Cleveland Clinic's process for effective hand off communication includes the following:

- Interactive communication that allows the opportunity for questioning and responding to questions between the giver and receiver of patient information
- Up-to-date information regarding the patient's condition, care, treatment, medications, services, and any recent or anticipated change
- A method to verify the received information, including repeat-back or read-back techniques
- An opportunity for the receiver of the hand-off information to review relevant patient historical data, which may include previous care, treatment, and services

Interruptions during hand off are limited to minimize the possibility that information fails to be conveyed or is forgotten. Hand-off communication will occur prior to providing care except in the case of urgent or emergent patient needs.

View the complete Hand Off Communication Policy.

Personal Appearance Policy

Cleveland Clinic recognizes the importance of the professional appearance of its staff in maintaining an atmosphere conductive to the delivery of quality health care services. To promote such an atmosphere, clinical trainees/research fellows are expected to dress in a manner appropriate to the jobs that they perform and the professional level they represent. Although it is not necessary to recount all of the components in the employee policy, the following tenets are set forth for clinical trainees:

- Clinical trainees must present themselves in appropriate attire to reflect their position. Male trainees, when caring for patients, should be dressed in a dress shirt and slacks with appropriate footwear and lab coat. Male trainees are encouraged to wear ties unless they pose a safety hazard. Female trainees should be dressed in appropriate business attire which would include suits, dresses or appropriate top and slacks, with appropriate footwear and lab coat.
- Clothing should be neat, clean and in good condition. Clinical trainees/research fellows should be dressed in a fashion that represents their professional level. Hair should be clean and well groomed (including facial hair).
- Furnished Cleveland Clinic uniforms or other garments are expected to be kept clean, pressed and in good repair. Ceil blue scrubs must be laundered by Cleveland Clinic and are to be worn within Cleveland Clinic only (not worn to and from Cleveland Clinic). Caps, booties and masks should be removed when outside of the operating room. Misty green scrubs are the clinical trainee's responsibility to launder.
- When responding to after-hours or weekend calls, appropriate business casual attire may be worn. Business casual attire includes casual slacks, shirts without ties, polo shirts and shirts or blouses with collars.
- The employee ID Badge must be worn above the waist, in compliance with Clinic policy.

Failure to adhere to standards of dress and grooming may result in corrective action.

View the complete Personal Appearance Policy.

Scrub Personnel Responsibility Policy

The scrub personnel responsibility information listed here is to encourage hygiene, ensure OSHA compliance, promote compliance with infection control and preserve our public image.

No surgical attire (ceil blue scrubs or surgical white) can be worn outside of the hospital/facility or to and from work. Staff and employees must change into ceil blue scrubs or surgical whites once they enter their work locations and change again before leaving work. When leaving the surgical or procedure rooms, ceil blue scrubs and surgical whites must be covered with white buttoned lab coats or warm up jackets, while inside the hospital (i.e. during a lunch break in the cafeteria, running an errand outside of the surgical department). However, this attire cannot be worn when traveling to and from work). Employees must completely change out of ceil blue scrubs or surgical whites with or without a lab coat or warm up jacket before leaving the premises. Disposable hats, masks, gowns, gloves and shoe coverings, must be removed when leaving surgical departments. Discard these items prior to leaving the surgical department or procedure rooms.

Employees and Staff will be held accountable for compliance. Supervisors will be asked to enforce compliance with the policy and will issue verbal warnings, anecdotal notes and

corrective action in cases of non-compliance. Institute chairs will be notified of frequent offenders. Signs have been posted throughout surgical departments to remind employees to remove disposable caps, masks, shoe covers and gowns. Please help remind colleagues of this policy, and do your part to encourage hygiene, ensure OSHA compliance, promote compliance with infection control and preserve our public image.

View the complete Scrub Personnel Responsibility Policy.

Vendor Standard Operating Procedures

Purpose: To provide instructions on obtaining entry into the physician offices and administrative areas.

Instructions

Dear Vendor:

Due to the increasing amount of unscheduled visits by vendors and/or sales reps, we will be changing the procedures for obtaining entry into the physician office and administrative areas in the department. The following changes will take effect on October 1, 2009. Adherence to these procedures is mandatory and anyone not complying will subject themselves, and their company, to a corrective action and termination from these areas.

- In order to obtain an appointment with a surgeon, you must contact the office to schedule via email or phone call. All appointments will be scheduled based on surgeon availability and approval.
- You must report to Desk J4-1 and check in with the Patient Service Reps who will call the office to announce your arrival. You may not walk back to the offices until you have been advised by the desk that the surgeon is available to see you or the secretary comes out to greet you.
- You must have your visitor badge clearly visible and will not be permitted to enter the office area without it
- These procedures are in effect for each and every visit that you schedule.
- If you have multiple appointments on the same day in the department, you must check back in at the desk in between each appointment.
- All luncheons must take place in the J4-408 lounge and are not to be delivered to the offices.

We request your immediate attention to the procedures identified above and appreciate your compliance in advance.

Oversight and Responsibility

The Department Supervisor is responsible to review, revise, update, and operationalize this standard operating procedure to maintain compliance with regulatory or other requirements

View the complete Vendor Standard Operating Procedure.

Social Media Use Policy

Purpose: To provide all Cleveland Clinic employees and to any students, volunteers, contractors, or vendors who are obligated to comply with Cleveland Clinic policies and procedures with rules and standards for participation in social media (also known as social networking). This policy

will also apply to any students, volunteers, contractors or vendors who are obligated to comply with Cleveland Clinic policies and procedures. The intent of this policy is not to restrict the flow of useful and appropriate information, but to safeguard the interests of Cleveland Clinic, its employees and its patients. This policy is not intended to limit any employee's rights under the National Labor Relations Act (NLRA) and does not apply to communications protected by the NLRA. Although Cleveland Clinic recognizes the value of social media as a tool for communicating and gathering information, time spent posting on or viewing social media sites must not interfere with job responsibilities.

Social Media (Social Networking) – Social media and social networking include, but are not limited to the following:

- Cleveland Clinic internal intranet sites and blogs
- Cleveland Clinic publicly facing internet web sites
- Social networking sites, such as Facebook®, MySpace®, LinkedIn®, Instagram® or Parler®
- Blogs (including corporate or personal blogs and comments to blogs) and other on-line journals and diaries
- Forums and chat rooms, such as discussion boards, Yahoo! Groups® or Google® Groups
- Microblogging, such as Twitter®
- Online encyclopedias, such as Wikipedia®
- Video or image based sites such as Flickr®, YouTube®, TikTok® and similar media

In addition to posting on websites like those mentioned above, social media and social networking also include permitting or not removing postings by others where an employee can control the content of postings, such as on a personal profile or blog.

View the complete Social Media Use Policy.

Use of Electronic Devices

Cellular Phones: All workers are required to use Cleveland Clinic-approved encryption technology when confidential or restricted confidential data is stored on a mobile computing device, including but not limited to cell phones. Please review the Mobile Device Guidelines.

iPhone for Clinical Trainees: Trainees are issued an Apple iPhone to make patient care activities

Things to know about clinical trainee iPhones

1. The plan gives:
    a. 3GB monthly pooled data, with unlimited minutes and text messages
    b. Free long-distance for calls within the U.S.
2. The plan doesn't include international data and calls.
3. If the iPhone gets lost, broken or stolen, the clinical trainee is financially responsible for replacing it. The current replacement cost is $99 (subject to change). Inform the Program Coordinator and then call the HELP Desk (Ext. 44357).
4. Do not upgrade to the newest IOS until IT approves the upgrade.
5. Clinical trainees have access to key applications such as IRIS (secure access to MyPractice), Cleveland Clinic email and MedHub.

Things to know about iPhone Etiquette:

1. When using an iPhone around a patient, acknowledge the patient and inform them that a work phone is being used. Do not ignore the patient or family members while using the phone.
2. Do not send patient information via text message.
3. Do not use speaker phone in a public area if discussing patient information.

safer and more efficient. Clinical trainees will have 24/7 access to Cleveland Clinic email and can take advantage of various clinical applications including IRIS and Haiku. IRIS and Haiku offer secure access to patient data that reside in the EMR. The ability to connect to patients' medical records instantly is another step toward transforming the delivery of quality patient care.

Personal use: Using the Cleveland Clinic-issued iPhone for personal use is permitted. However, clinical trainees cannot port their personal mobile number to their Cleveland Clinic iPhone. Once a clinical trainee leaves, they will have limited functionality, retrieval and storage of personal data from the iCloud. Cleveland Clinic treats all information transmitted or stored in its computers and systems, including email and voice mail messages, as Cleveland Clinic business information. Instant messaging, social media use in a business capacity and any other business chat data related to Cleveland Clinic are considered company information. All files and other information stored on Cleveland Clinic computers and systems, even if considered personal by an employee, are business information and remain the property of Cleveland Clinic. Cleveland Clinic may review or use such business information as it deems appropriate.

Email: Employees must use their Cleveland Clinic email account and network for all Cleveland Clinic business communication. The use of personal email or cloud storage providers poses a serious risk of violating patient privacy and potential loss of Cleveland Clinic Intellectual Property (IP). Always check with the department's IT representative or Compliance Office if unsure. Employees are prohibited from auto-forwarding Cleveland Clinic email to a personal email account.

Photography: The use of electronic imaging function of cell phones (i.e., phone cameras) is prohibited on Cleveland Clinic premises except when conducting authorized or approved Cleveland Clinic business. The use of a personal cell phone or other personal recording device to record or maintain PHI is strictly prohibited unless first approved by the Cybersecurity Department.

View the complete General Information Security Policy.

Harassment, Fraud or Illegal Activity: Cleveland Clinic prohibits the use of its telephones, owned cellular phones and voicemail systems for purposes of harassment, fraud or other illegal activity.

View the complete Acceptable Use of Information Assets Policy.

Professional Conduct Policy

Purpose: This policy is to define disruptive and inappropriate behavior involving clinical trainees/research fellows and to delineate the response to be followed in all cases involving such behavior. In almost all cases the institution's response to inappropriate behavior is initially directed towards remediation rather than punishment. It is recognized that it will be beneficial to patients to keep clinical trainees at work in the practice setting. This policy has this as its objective. Unprofessional behavior compromises the ability to provide the best quality care to patients so that behavior must change. It is expected that in almost all cases it will be possible, after intervention, for the clinical trainee and those around him or her to work together to achieve the common goal of continuing to provide the best quality patient care. Depending on severity and response to intervention, disruptive behavior by clinical trainees or refusal of trainees to

cooperate with the procedures described in this policy, may result in corrective action, which shall be carried out according to the Graduate Physicians Manual.

Background: Most health care professionals entering their chosen discipline have a strong interest in caring for and helping other human beings. They try to carry out their duties in a manner consistent with this ideal, maintaining a high level of professionalism. Intimidating and disruptive behavior by physicians and others can erode this professionalism and contributes to an unhealthy and hostile work environment. Such an environment can jeopardize patient safety, contribute to poor patient outcomes, increase the cost of care, and cause clinical personnel, administrators and managers to seek new positions in more professional environments.

Policy: The stated mission of the Cleveland Clinic fosters the highest levels of professional conduct from its health care professionals in order to fulfill that mission. In doing so, Cleveland Clinic strongly desires and expects an environment free from disruptive, threatening, and violent behavior, and does not tolerate inappropriate, unprofessional or intimidating behavior within the workplace. This policy emphasizes the need for all individuals working in Cleveland Clinic to treat others with respect, courtesy, and dignity and to conduct themselves in a professional manner. Patients, visitors, healthcare professionals and all employees must be treated with courtesy, respect, and dignity. This policy is in complementary to and consistent with, the Cleveland Clinic Code of Conduct and other communications addressing appropriate conduct, such as the MyLearning Module on Disruptive Behavior and Code of Conduct initiatives by Cleveland Clinic Institutes.

Behavior by clinical trainees/research fellows that generates a complaint by any other person(s), including patients, will be responded to according to this policy and referred to the Chairman, Graduate Medical Education Council (GMEC). Behavior that indicates that the clinical trainee/research fellow suffers from a physical, mental or emotional condition will be referred to the Physician Health Committee or otherwise evaluated with the intent to assist the clinical trainee/research fellow. The Physician Health Committee can be particularly helpful in monitoring a troubled trainee, enabling the clinical trainee/research fellow to be helped while preserving the clinical trainee/research fellow's residency or fellowship training. The process of inquiry into and response to inappropriate behavior by clinical trainees/research fellows is confidential.

Disruptive behavior means any behavior that prevents or interferes with an individual's or group's clinical/academic performance or creates an unprofessional, unsafe, intimidating, hostile or offensive work environment and jeopardizes or is inconsistent with quality patient care or with the ability of others to provide quality patient care at the hospital. While there can be increasing levels of severity with respect to the type of disruptive behavior, there may be incidents that rise to a more serious level, due not to their severity but, to the repetitiveness of the action in spite of previous counseling and intervention.

Three levels of severity of disruptive behavior:

- Level I: Verbal abuse which is directed at-large, but has been reasonably perceived by a witness to be disruptive behavior as defined above
- Level II: Verbal abuse such as unwarranted yelling, swearing or cursing; threatening, humiliating, sexual or otherwise inappropriate comments directed at a person or persons or physical violence or abuse directed in anger at an inanimate object (including throwing objects in anger); discrimination or retaliation
- Level III: Physical violence or other physical abuse which is directed at people; sexual harassment involving physical contact; and persistent Level II & III behavior that is unresponsive to remediation

Active vs. Passive: Disruptive/inappropriate behavior can be overt or passive; either type can undermine the team's effectiveness or compromise the safety of patients. For purposes of this policy, examples of overt disruptive conduct include, but are not limited to the following:

- Threatening or abusive language directed at hospital personnel, patients or other physicians (e.g., belittling, berating and/or threatening another individual)
- Threats of harm or actions that can reasonably be interpreted as threatening
- Degrading or demeaning comments regarding patients, families, nurses, physicians, hospital personnel or the hospital
- Profanity or similarly offensive language while in the hospital and/or while speaking with hospital personnel
- Inappropriate physical contact with another individual that is unwelcome, threatening or intimidating
- Public derogatory comments about the quality of care being provided by other physicians, nursing personnel or the hospital
- Harassment (e.g. sexual)

Examples of passive disruptive conduct include but are not limited to the following:

- Exhibiting uncooperative attitudes during routine activities
- Reluctance or refusal to answer questions about patient care, return calls or pages
- Condescending language or voice intonation
- Inappropriate medical record entries concerning the quality of care being provided by the hospital or any other individual
- Acts of discrimination or retaliation

It is recognized that due to circumstances, it may be necessary to exercise clear and sometimes presumed forceful medical direction to focus on acute patient care. This in and of itself, does not necessarily constitute inappropriate behavior. However, even in the most acute circumstances, intimidating, belittling, offensive and/or threatening behavior or language is not appropriate and can be counterproductive to obtaining the cooperation of those involved in the emergency response.

Sexual harassment is defined as unwelcome sexual advances, requests for sexual favors or verbal or physical activity through which submission to sexual advances is made an explicit or implicit condition of employment or future employment-related decisions. It is also defined as

unwelcome conduct of a sexual nature which has the purpose or effect of unreasonably interfering with a person's work performance or which creates an offensive, intimidating or otherwise hostile work environment.

Communication & Education**:** Cleveland Clinic is committed to educate all healthcare team members, both physicians and non-physician staff, on appropriate professional behavior including the following efforts: sponsoring or supporting educational programs on disruptive behavior to be offered to clinical trainees/research fellows, professional staff members and hospital employees; educational programs emphasizing civility, respect, basic business etiquette and people skills; skills-based training and coaching are provided for leaders and managers in relationship-building and collaborative practice, including skills for giving feedback on unprofessional behavior and conflict resolution; surveying and assessing health care professionals perceptions of unprofessional behavior; disseminating this policy to all current clinical trainees/research fellows upon the adoption of the policy and to all new clinical trainees/research fellows upon joining a Cleveland Clinic training program; requiring that clinical trainees/research fellows positively affirm they have reviewed the educational material (via the MyLearning module on disruptive behavior) and agree to comply with this policy.

Direct Interactions and Reporting: Each Cleveland Clinic health professional is responsible for protecting our positive work environment. When a conduct violation occurs it may be possible for the involved team members to deal with the issue person-to-person through direct professional conversations which can precede the formal professional conduct management process.

Empowerment in Team Interactions:

- Team members are encouraged to avail themselves of the option, whenever feasible to speak directly with the other party whenever civility, respect and team function are below standard. E-mail is never appropriate for this purpose.
- It is recognized that some team members may lack the training required for such an interaction and that further such training is needed. The option to interact at the front-line level is not meant to preclude the individual's right to report inappropriate behavior as outlined below.
- Even when an incident of inappropriate behavior on the part of another team member occurs, the remainder of the team is expected to continue excellent patient care and adhere to the highest standard of interaction.
- At an appropriate time, after the incident and out of earshot of patients and others, a team member may initiate a civil, non-confrontational but crucial conversation with the other presumed offending team member. In doing so, the team member should use statements that confirm the value of the person to the team or organization (if this is the case) while asking what led to the observed behavior, why it appeared to the observer to be disruptive and whether there was unexpected occurrence that led to it and if the person understood why it was below expected standards of behavior.
- Using this approach, a resolution of the conflict (e.g. verbalized mutual understanding, apology or pursuit at a higher level) should be sought to preserve mutual respect and professionalism.

Reporting Conflict Management at the Next Level: When a team member is not able to do the above, the expectation is that he or she informs his or her Program Director, the Human

Resources Department or the Graduate Medical Education Department of the inappropriate behavior issue. Regardless of the reporting pathway, all such complaints must be communicated to the Chairman, GMEC who works with the clinical trainee/research fellow's Program Director to address the complaint. Any individuals who report policy violations are protected from retribution as are those who cooperate in the investigation of intimidating, disruptive and other unprofessional behavior. Individuals who have reason to believe that their complaints have not been dealt with should report the inappropriate conduct further up their chain of command to the Chairman GMEC or to the Chairman Education Institute. It is expected that a Program Director acts in a timely fashion to investigate and take appropriate action regarding any allegation of disruptive behavior. This includes letting the complainant know in general terms, what is being done in response. Cleveland Clinic intends that questions about whether a physician's conduct is or is not ethical, shall be determined by the definitions and guidance found in the current edition of the American Medical Association Code of Medical Ethics. The Code can be accessed via the AMA website.

Complaints about a clinical trainee/research fellows regarding alleged disruptive behavior should ideally include:

- Date(s) and time(s) of the behavior in question
- A factual description of the questionable behavior
- The name of any patient or patient's family member who was involved in the incident, including any patient or family member who witnessed the incident
- The circumstances which precipitated the incident
- The names of other witnesses to the incident
- Consequences; if any, of the inappropriate conduct as it relates to patient care, personnel or hospital operations
- Any action taken to intervene in or remedy, the incident

Violations, especially by non-physician personnel, may also be reported to the Human Resources Department. For Professional Staff, reports about inappropriate behavior should utilize the pathway identified by the Chief of Staff or Professional Conduct Committee. Refer patients and/or their families who report witnessing intimidating and/or disruptive behaviors to the Ombudsman's Office. The response should include hearing and empathizing with patients' concerns, thanking them for sharing those concerns and apologizing. Immediately report to Cleveland Clinic Police (216-444-2222) any actions which pose or appear to pose an immediate threat of physical harm to any individual in order to safeguard the health and safety of others. Immediately report all violations that appear to involve discrimination, retaliation or sexual/other harassment to the respective institute chair, Human Resources Department or Chairman, GMEC.

Role of the Graduate Medical Education Council (GMEC): Council consists of representatives of the various clinical Institute Education Committees and is chaired by the Director of Graduate Medical Education. Other Cleveland Clinic personnel involved in graduate medical education may also serve as members of this group. The Chairman, GMEC (or designee) will act on behalf of the Council in matters concerning professional conduct and as such will determine when issues need to be brought to the GMEC as a group. The purpose of this council is to oversee and monitor graduate medical education programs and trainees to assure training programs meet the high academic standards established and clinical trainees are provided with the requisite skills in a professional environment to deliver safe appropriate patient care.

The exact flow of how information regarding inappropriate trainee behavior gets to the Chairman, GMEC is not critical; normally the Chairman, GMEC will be contacted initially by the Program Director, Human Resources or Professional Staff Affairs and determine the appropriate initial course of action. The Chairman, GMEC, on receiving the complaint, shall request that the trainee's Program Director interview the complainant to begin initial discussion regarding the complaint. As necessary, any witnesses or other appropriate parties will be interviewed by the Chairman of the GMEC (or designee). This shall be done routinely, expeditiously or immediately, depending on whether the complaint is level I, II or III. The Chairman, GMEC shall then meet with the reported clinical trainee/research fellow if necessary and provide that individual the opportunity to respond in writing as well as in person. The Chairman, GMEC should, in the investigation, address potential causes and mitigating factors, such as stress, fatigue, personality disorders and incompetence on the part of the accused or the accuser.

The GMEC Chairman's action may consist of one or more of the following:

1. Determine that no action is warranted
2. Recommend the reported clinical trainee/research fellow develop an action plan to avoid future incidents
3. Require a written apology to the complainant
4. Recommend to the clinical trainee/research fellow Program Director
    a) counseling (verbal or written)
    b) referral to the Physician Health Committee
    c) implement formal remediation plan
5. Consideration of other disciplinary action pursuant to the Graduate Physicians Manual. Recommendation of further disciplinary action (beyond counseling) may result in a GMEC Task Force being formed to review the allegations, complainant response, information from witnesses and review and assessment of the severity of the incident

Responses to Inappropriate Physician Behavior
Principles:

1. It is recognized that disciplinary action has far-ranging consequences for health professionals and in particular for physicians. Therefore, every effort should be made to educate and remediate before proceeding to disciplinary steps.
2. All Cleveland Clinic team members are held accountable for modeling desirable behaviors; the code of conduct is enforced consistently and equitably among all Cleveland Clinic health professionals. All interventions are conducted within the context of the organizational commitment to the health and well-being of our clinical trainee/research fellow with resources to support individuals whose behavior is caused or influenced by physical or mental health pathologies.
3. Based on level of severity, interventions should begin with non-confrontational steps starting with informal conversations at the level of the Program Director and/or Department Chair, directly addressing the problem and moving toward action. These initial interventions should always aim to build trust, place accountability on and rehabilitate the offending trainee, while protecting patient safety.
4. If inappropriate behavior patterns persist, progressive responses are instituted. Formal counseling and other disciplinary steps are initiated in accordance with the appropriate Cleveland Clinic policies and procedures depending on the recommendations of the Program Director in collaboration with the Chairman, GMEC based on the specific facts and circumstances of the case.

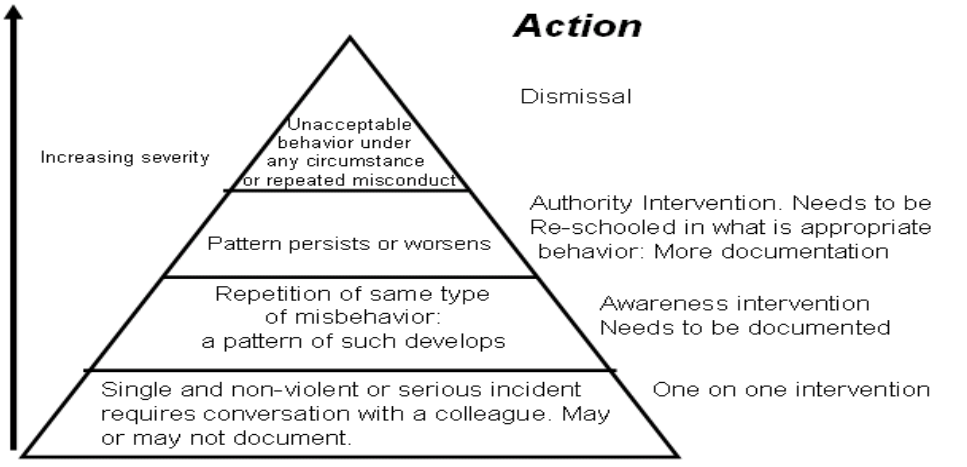
5. Level III behavior is the most severe violation of this policy. Responses will be commensurate with the nature and severity of the disruptive behavior.
6. Repeated instances of disruptive behavior will be considered cumulatively and action shall be taken accordingly. Such significant violations or a pattern of disruptive behavior may result in serious action, up to and including dismissal. If of sufficient gravity, even a single instance of disruptive behavior may be sufficient to merit disciplinary or corrective action, including dismissal. Cleveland Clinic has "zero tolerance" for intimidating and/or disruptive behaviors, especially the most egregious instances of disruptive behavior such as assault, sexual harassment and other criminal acts.

Process:

1. Responses are staged based on severity level of inappropriate conduct.
2. The Chairman, GMEC (and the GMEC in certain circumstances) investigates and acts on reports of inappropriate conduct, in collaboration with the trainee's Program Director and Department Chair.
3. The Chairman, GMEC reviews the recommendations with the Education Institute Chairman and institutes appropriate intervention in collaboration with the Program Director and Department Chair.
4. Where applicable, a follow-up report is submitted to the Chairman, GMEC and the Chairman, Education Institute by the involved Institute Chair, addressing the outcome of the intervention.

Abuse of Process: Threats or actions directed against the complainant by the subject of the complaint will not be tolerated under any circumstance. Retaliation or attempted retaliation by members against complainants will give rise to corrective action pursuant to the Major Policies of the Professional Staff. Individuals who submit a complaint or complaints which are determined to be false shall be subject to corrective action under the Professional Staff bylaws or hospital employment policies, whichever applies to the individual.

View the complete Professional Conduct Policy.



Modified from Hickson et al. 2007

Lactation Break Policy

Recognizing the well documented health advantages of breastfeeding for infants and mothers, this policy provides clear expectations for a supportive environment to enable breastfeeding employees to express their milk during work hours.

All employees who are breastfeeding a child, and who need to express milk during their scheduled work time, may express milk during normal breaks and meal times, and will also be provided other reasonable break time(s) to express milk. A reasonable break time shall be provided each time such employee has a need to express milk, up to one (1) year after the date of the birth of the employee's nursing child.

A private, sanitary space, or designated lactation room, shall be available where the nursing mother is shielded from view and free from intrusion of her co-workers and the public. Lactation rooms and private space are provided throughout the enterprise for employees to express milk during scheduled work time. If employees prefer, they may also express milk in their own private offices, or in other private locations agreed upon in consultation with the employee's supervisor. Space must be completely private to ensure no one can see inside the space and no one is able or permitted to enter the space while it is being used to express milk. The space provided cannot be a restroom.

House Staff Resource Center Lactation Room – space was reallocated to create a dedicated lactation room exclusively for residents and fellows. This space has a door activation swiping system, desk with computer, chair and clean and safe refrigeration for the storage of breast milk. To gain access trainees complete the H15 Lactation Room access request form so that the GME office can verify they are eligible and provide access.

View the complete Lactation Break Policy.

Disability Accommodation in Education

This policy confirms Cleveland Clinic's commitment to provide access to educational opportunities for qualified students and applicants with disabilities and establishes criteria for the consideration of requests for reasonable accommodation by such students and applicants. This policy reflects Cleveland Clinic's compliance with the Americans with Disabilities Act of 1990, as amended, Section 504 of the Rehabilitation Act of 1973, as amended, and all other relevant federal and state laws and regulations.

Cleveland Clinic does not discriminate against qualified individuals with disabilities in regard to their application to, or participation in, educational programs or activities. Cleveland Clinic will make, upon the request of a qualified individual with a disability and under the conditions described herein, a reasonable accommodation to permit such individual to participate in an educational program or activity.

View the complete Disability Accommodation in Education Policy.

Disability Accommodation in Education Appeals Procedure

This procedure is supports the Disability Accommodation in Education Policy (the "Policy") in order to provide an opportunity for individuals who have requested a reasonable accommodation to appeal the failure to engage in the interactive process, the denial of a request for Reasonable Accommodation, or a decision to provide an accommodation that the individual does not accept.

This procedure is intended to be flexible in order to allow Cleveland Clinic to promptly, fairly and impartially address complaints related to disability accommodations. The Section 504 Coordinator has discretion to deviate from this procedure, including by extending any deadlines, when deemed appropriate for that purpose. The Section 504 Coordinator may Disability Accommodation in Employment Appeal Procedure designate another person to fulfill their duties under these procedures. If the Section 504 Coordinator has a conflict of interest with respect to a particular appeal, the Law Department shall designate a person to fulfill the duties of the Section 504 Coordinator.

View the complete Disability Accommodation in Education Appeals Procedure.

Non-Discrimination, Harassment or Retaliation Policy

This policy affirms Cleveland Clinic's commitment to provide a work environment that is free from discrimination or harassment, defines the types of prohibited harassment and provides a process for reporting and investigating complaints of discrimination, harassment and/or retaliation.

Cleveland Clinic is committed to providing a work environment in which all individuals are treated with respect and dignity. It is the policy of Cleveland Clinic to ensure that the work environment is free from discrimination or harassment on the basis of race, color, religion, gender, sexual orientation, gender identity, gender expression, pregnancy, marital status, age, national origin, disability, military status, citizenship, genetic information or any other characteristic protected by federal, state or local law. Cleveland Clinic prohibits any such discrimination, harassment, and/or retaliation.

This policy applies to all employees/physicians/vendors/third parties/contractors or contracted employees/students/volunteers affiliated with or under contract with Cleveland Clinic. Conduct prohibited by these policies is unacceptable in the workplace or in any work-related setting outside the workplace, such as during business trips or business meetings. Those individuals who engage in acts prohibited by this policy, regardless of status, position or title, will be subject to appropriate action, including but not limited to corrective action up to and including discharge. View the complete Non-Discrimination, Harassment or Retaliation Policy.

Sexual Misconduct in Education

This policy expresses Cleveland Clinic's commitment to equal opportunity in its educational programs and activities and establishes a procedure for addressing reports of sex discrimination, sexual harassment, sexual violence and retaliation in those programs and activities. This policy reflects Cleveland Clinic's compliance with Title IX of the Education Amendments of 1972, as amended, and all other relevant laws and regulations.

In accordance with Title IX of the Education Amendments of 1972, as amended, the Violence Against Women Reauthorization Act of 2013 (VAWA) and other applicable statutes and regulations, Cleveland Clinic prohibits all forms of discrimination on the basis of sex, gender, sexual orientation, gender expression and gender identity in its educational programs and activities. Prohibited conduct under this policy includes sex discrimination, sexual harassment, sexual violence and retaliation, as those terms are defined herein.

This policy applies to all individuals participating in Cleveland Clinic educational programs and activities, including, without limitation, employees, Professional Staff, medical and other clinical trainees, researchers, interns, students enrolled in Cleveland Clinic and affiliate programs, and third parties (such as patients, vendors and visitors). This policy applies to conduct on Cleveland Clinic property and to locations, events, or circumstances where Cleveland Clinic exercises substantial control over the person alleged to have engaged in the conduct and the context in which it occurred.

View the complete Sexual Misconduct in Education Policy.

Drug Free Workplace

Substance Abuse: Cleveland Clinic is committed to maintaining a safe, healthful and efficient working environment for its employees, patients and visitors. Consistent with the spirit and intent of this commitment, Cleveland Clinic prohibits:

- The unlawful or unauthorized use, manufacture, possession, sale or transfer of illegal drugs and/or controlled substances on Cleveland Clinic premises
- Reporting to work or working impaired or under the influence of any illegal drug, controlled substance, and/or alcohol
- Consumption of alcohol (except at approved or sponsored Cleveland Clinic functions) on Cleveland Clinic premise
- Improper self-medication of over-the-counter or prescribed drugs on Cleveland Clinic premises

View the complete Substance Abuse Policy.

Physician Impairment: Impairment is defined as "inability to practice medicine in a competent, consistent and ethical manner for reasons of illness, excessive stress or substance misuse." Physical, emotional and psychiatric conditions may influence a physician's ability to practice. In addition, physicians as a group are at high risk for chemical dependency that may lead to impairment. Alcohol is the most frequent offending substance, although all categories of drugs and drug combinations have been reported in association with physician impairment. It is not known whether physicians are more at risk for substance misuse problems than other people in the general population, but the predisposing factors of high stress, fatigue, drug familiarity, and relative ease of access to substances are frequently seen with physicians. Recognizing these factors and risks, Cleveland Clinic assists its professional staff in identifying and receiving treatment for conditions which may lead to impairment, while assuring the highest degree of safety and care for the patients. Cleveland Clinic complies fully with state and federal laws regarding reporting, monitoring and compliance for all members of the professional staff. Staff members undergoing evaluation and therapy for problems leading to impairment will, like all patients, receive dignified, confidential and competent management of their impairment problems.

To insure the safety of patients and employees, and to provide the highest quality of medical care, the Cleveland Clinic is committed to providing a drug-free environment. Cleveland Clinic will not tolerate the unlawful or unauthorized use, manufacture, possession, sale or transfer of illegal or controlled substances, or the abuse of unauthorized use of alcohol, on or off clinic property. Cleveland Clinic Substance Abuse Policy *applies to non-staff employees and to*

professional staff, with certain modifications for physicians because of the greater responsibility in the care of patients. Cleveland Clinic is also bound by the Federal Drug-Free Workplace Act of 1988. All employees, including physicians, must abide by all terms of the Substance Abuse Policy as a condition of their employment. In addition, all employees must report to their supervisor or to the Office of Professional Staff Affairs within five days any conviction under a criminal drug statute for violations occurring in the workplace. Cleveland Clinic recognizes that the misuse of drugs or alcohol may indicate an illness with drug-induced effects on thinking, attitude and behavior. Cleveland Clinic encourages all employees to seek help voluntarily, and also provides education, prevention, treatment re-entry and monitoring to assist employees while insuring a drug-free environment. Help for the staff person and his or her family will include appropriate medical, psychological and chemical dependency care in conformance with the Substance Abuse Policy and the Staff Benefit Plan.

To facilitate this process, the Board of Governors/Medical Executive Committee (BOG/MEC) authorized the following:

- The Physician Health Committee: Cleveland Clinic will establish and maintain a standing committee of the Office of Professional Staff Affairs for the purpose of dealing with all matters related to physician impairment. This committee will be designated as the Physician Health Committee, and will serve as a clearinghouse for complaints, referral, evaluation, treatment, re-entry, monitoring and compliance. All matters regarding possible or suspected physician impairment may be referred to the Physician Health Committee for review, comment and recommendations. This committee will be a knowledgeable, experienced resource for the handling of such matters. The committee will serve as an ongoing resource for education, evaluation and treatment recommendations; for information about legal requirements of reporting, licensing and other matters; and as a resource for quality control of physician services. The chair of the committee will be appointed by the Chief of Staff, with input from members of the Physician Health Committee. The committee will convene regularly for the purposes of reviewing and monitoring all cases before it, and for remaining up to date on all aspects of physician impairment. All matters before the Physician Health Committee will be kept strictly confidential and will be dealt with on a need-to know basis.
- Procedure for Screening New Clinical Trainees/Research Fellows: As a condition of employment, the Graduate Medical Education Department will assure that a standardized health screening is completed by Occupational Health for each new clinical trainee/research fellow. Failure to complete the health screening will result in withdrawal of the appointment. A former or resolved drug/alcohol abuse problem will not prevent employment at Cleveland Clinic, but in the event of a prior substance misuse problem, a comprehensive evaluation under direction of Physician Health Committee will be required as part of the pre-employment process. Candidates for residency and residency candidates with a history of substance misuse will be subject to the same regulations requiring pre-employment physical examination, health questionnaires and urine analysis for unauthorized controlled substances. All results will be forwarded to the Director of Graduate Medical Education.
- Policies and Procedures for Existing Staff: As employees of the Foundation, all staff and resident physicians must comply with the Foundation's Substance Abuse Policy. In addition, Cleveland Clinic physicians must also conform to state laws and State Medical Board regulations regarding impairment, reporting, treatment and compliance. Legal requirements also extend to non-substance-involved colleagues and supervisors who become aware of a colleague's impairment. Clinical Trainees and Research Fellows are

encouraged to refer themselves through the Department of Graduate Medical Education. The Cleveland Clinic reserves the right to withdraw the offer of training if the substance abuse policy is violated.

Substance Abuse/Chemical Dependency

Physicians are at an elevated risk of developing substance abuse or chemical dependency issues. Caring for Caregivers (CFC) is available to any clinical trainee/research fellow in need. Clinical trainees/research fellows identified as having a problem with chemical dependency will be connected with treatment commensurate with clinical necessity criteria and professional licensure board requirements.

A CFC referral by the Program Director must be made for known or suspected substance abuse/dependency and/or any related issues of impairment that might impact the trainee's ability to obtain a medical license and/or safely perform their duties.

The Physician Health Committee (PHC), established in 1992, is composed of a multi-disciplinary group of professionals with expertise related to impairment. Individuals with an impairment will be reviewed by CFC with the PHC for additional oversight of evaluation, management and follow-up, including return to training status.

For further information, please visit the Caring for Caregivers intranet site.

Corporate Compliance

Corporate Compliance is the ongoing process of fulfilling the legal, ethical, and professional requirements applicable to Cleveland Clinic. In May 1996, the Board of Trustees of Cleveland Clinic adopted "The Cleveland Clinic Corporate Compliance Program" (Program), which is intended to prevent, or promptly detect, violations of applicable laws, rules, regulations, policies and standards by Cleveland Clinic employees, independent contractors, trustees, directors, officers and those conducting business for, or on behalf of Cleveland Clinic (Affiliates). Each Affiliate of Cleveland Clinic is required to implement the Program within its operations, or to adopt its own program which meets or exceeds Program requirements, to ensure compliance with applicable laws, rules, regulations, policies and standards. By acting in accordance with the Program, Cleveland Clinic is best able to fulfill its mission which is caring for life, researching for health, and educating those who serve.

The Program is administered by the Office of Corporate Compliance and Business Ethics and is comprised of seven core elements modeled after Guidance issued by the Department of Health and Human Services' Office of Inspector General. Cleveland Clinic's Corporate Compliance Committee, in consultation with a number of Compliance Committees representing the activities and operations of our Institutes, Markets and Shared Services, maintain oversight of the Program and its implementation. All Institutes, Markets and Shared Services are responsible for the implementation of Program elements across the Cleveland Clinic global enterprise. All Cleveland Clinic employees and Affiliates are to carry out their duties in full compliance with applicable laws, rules, regulations, policies and standards. In the event of an actual or suspected compliance violation, the Program provides a mechanism for reporting such concerns, including anonymous reporting options.

Although the Program can help clinical trainees/research fellows to adopt practices that promote compliance and ethical standards while performing job duties, each individual is ultimately accountable for their own conduct.

As a Cleveland Clinic employee or Affiliate, you are expected to:

- Carry out your job duties with integrity and honesty and use good judgment while performing those duties
- Fully comply with the Cleveland Clinic Code of Conduct
- Learn and understand the laws and regulations applicable to your operations and activities, and comply with those requirements
- Recognize and report actual or suspected compliance violations

Recognizing Compliance Issues: Compliance issues generally involve conduct that violates applicable laws, rules, regulations, policies, and standards, including Cleveland Clinic's Code of Conduct. Here are some examples: accessing another person's medical record when you are not involved in their care or conducting IRB-approved research; disclosing or sharing patient information with a third party without having appropriate contracts in place or prior approval; using another person's login credentials to access confidential information or document in a patient's medical record; billing for services that were not performed or were not medically necessary; falsifying medical documentation; copying confidential patient information to a personal computer or other unapproved device; accepting cash, gifts or bribes.

No one shall prevent a clinical trainee/research fellow from reporting a compliance issue. Reports can be submitted confidentially in person, in writing or verbally to: the clinical trainee/research fellow's supervisor or department administrator; the Office of Corporate Compliance at 216-444-1709; or the Law Department at 216-448-0200. Compliance issues and concerns can also be reported anonymously by phoning the Corporate Compliance Reporting Hotline 800-826-9294 or by sending an untraceable email via the Office of Corporate Compliance website and clicking on "Report a Concern" button. For those who desire complete anonymity, it is important that names, dates, times, locations and any other issue-specific facts are provided so that the report may be fully investigated. The investigation and any findings will also remain confidential but the information will be used to identify deficiencies and to take corrective action when appropriate. Regardless of which reporting mechanism a clinical trainee/research fellow prefers, all reports will be investigated. No one who submits a report in good faith will be subjected to retaliation for having made a report.

If an employee feels that issues reported related to the submission of false claims to the U.S. government have not been addressed through the formal reporting process as outlined above, the False Claims Act allows citizens with direct and independent knowledge of false claims activities to sue the organization to recover funds on behalf of the government. The False Claims Act prohibits retaliation against an employee if (1) an employee filed a claim against the institution, (2) the employer knew that the employee filed the claim and (3) the employer's actions were a result of the employee's filing of the claim. Prior to seeking resolution outside Cleveland Clinic, employees and others are strongly encouraged to first contact the Chief Integrity Officer at 216-444-6185 or the Law Department at 216-448-0200 to discuss their concerns.

Privacy and Security of Protected Health Information (PHI): PHI is individually identifiable health information (including demographic information) that relates to an individual's physical

or mental health or the provision of, or payment for, health care. PHI is not limited to the electronic medical record and includes paper, photographs, audio, video, x-rays and other types of media. State, Federal and international privacy rules provide standards to protect individuals' medical records and other forms of PHI. Although this section of the Manual discusses a few key standards of U.S. Federal privacy rules, all Cleveland Clinic employees are required to comply with all applicable standards and must complete a designated training program upon hire. According to the Health Insurance Portability & Accountability Act of 1996 (HIPAA), The Health Information Technology for Economic and Clinical Health Act (HITECH) and the HIPAA Omnibus Rule 2013, PHI may be accessed only by those individuals who, within the scope of their job responsibilities, have a legitimate need for such information for purposes of patient care, research, education, or administrative uses. Any other use or disclosure of PHI may be considered a major infraction of Cleveland Clinic policy and may subject the clinical trainee/research fellow to corrective action and criminal penalties ["Use" of PHI refers to the access, sharing, applying or analyzing of PHI within Cleveland Clinic. "Disclosure" refers to the release, transfer, provision of access to, or divulging in any other manner PHI outside of the Cleveland Clinic.]. Cleveland Clinic systems, such as the electronic medical record, are configured to log access by individual users. These systems are routinely audited for inappropriate access. Clinical trainee/research fellows who violate Cleveland Clinic's privacy policies are subject to disciplinary action up to and including termination. The employee may also be subject to civil monetary penalties and/or criminal prosecution by the Department of Health & Human Services and/or other enforcement authorities.

Breach Notification and Reporting Rules: Any unauthorized acquisition, access, use or disclosure of patient data may constitute a breach and result in serious consequences for Cleveland Clinic as well as for the responsible clinical trainee/research fellow. Breach notification and reporting rules were published by the U.S. Department of Health and Human Services (HHS) in 2009 and modified by the Omnibus Rule of 2013. These rules mandate notification to individuals, HHS and in some cases the media upon the discovery of a breach of unsecured PHI. In addition, there are mandatory state and international breach reporting laws that may apply. A breach of PHI due to lost or missing unencrypted laptops and portable media; unsecured data transmission (e.g., unencrypted e-mail, FTP); and use of unapproved cloud-based software or data sharing Apps without the appropriate contractual agreements in place, are some of the greatest compliance risks we face. Clinical trainees and research fellows are required to review and comply with the Data Classification and Protection Policy, the Encryption Standard Operating Procedure, and all other Cleveland Clinic Privacy and Information Security policies and procedures.

De-identification of PHI mitigates privacy risks to individuals and thereby supports the secondary use of data for comparative effectiveness studies, policy assessment, life sciences research and other endeavors. The HIPAA Privacy Rule allows PHI to be de-identified using only two methods: (1) Expert determinations; and (2) the Safe Harbor method. In order to be considered "de-identified" under the Safe Harbor method, ***both*** of the following criteria must be met: 18 types of identifiers* of the individual (patient) or of relatives, employers or household members of the individual, are removed and there is no actual knowledge that the remaining information could be used alone or in combination with other information to identify the individual. Detailed Guidance on both de-identification methods can be accessed from The US Department of Health and Human Services Website or requested directly from the Office of Corporate Compliance & Business Ethics at corporatecompliance@ccf.org.

*Identifiers include the following data elements of the individual (i.e. patient) or of relatives, employers or household members of the individual:

1. Names
2. All geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code and their equivalent geo codes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Phone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social Security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic or code (note: this does not mean the unique code assigned by an investigator to code data)

Additional Safeguards:

- Do not use personal laptops, mobile phones or other electronic devices to store PHI or other confidential Cleveland Clinic information.
- PHI may not be taken off-premises unless necessary for patient care and appropriately safeguarded from loss or theft. For example, PHI in paper form must be secured, such as in a sealed envelope and never left on or in an unattended vehicle.
- PHI must never be downloaded to a portable media device (e.g. flash or thumb drive) unless the device is encrypted in accordance with the Information Technology Division (ITD) Security policies and approved by your department administrator. This includes but is not limited to: CD's, DVD's, 'thumb' or flash drives, memory sticks, and portable hard drives.
- All portable media used for the storage of any PHI must be provided by the Cleveland Clinic. Encrypted flash drives may be requested through the Department or Institute Administrators.

- It is important to remember that simply deleting PHI files from mobile devices does not ensure that the information cannot be retrieved. Therefore, any media that has ever been used for PHI must be turned into the Cleveland Clinic for proper disposal. Contact your local IT Service Support desk for assistance. Contact information can be found on the Information Technology Division intranet site.
- When sending sensitive information by email, be sure to use the word, 'Confidential' in the subject line to trigger secure (encrypted) message delivery. Even when sending an encrypted email to a non-ccf.org email address, do not include patient identifiers in the subject line, as this part of the message will not be encrypted.
- Clinical trainees/research fellows may **not** use personal webmail accounts (e.g. Gmail, Yahoo, etc.) to send or receive confidential Cleveland Clinic information, such as PHI and research data. Automatic forwarding of Cleveland Clinic email to a personal webmail account is likewise strictly prohibited. In short, the email could potentially be accessed by unauthorized parties which could result in a breach of PHI or disclosure of other confidential information.
- PHI must never be included when using unapproved cloud-based document sharing Applications (e.g. Google calendars or "Drop Box") unless there are appropriate contractual agreements executed between Cleveland Clinic and the cloud-based provider. Contact your administrator or ITD to ensure you are only using CCF-approved data sharing applications. File Transfers (To/From the Internet) use only Cleveland Clinic approved Secure File Transfer Protocols (SFTP) that contain the required encryption technologies (your IT support team can manage this properly).
- Do not take or use photographs of patients without their written consent. Note: Consent is not the same as a HIPAA Authorization. Consent is needed to take the photo/video/audio recording; whereas, Authorization is needed to use or disclose the PHI in the photo/video/audio recording for purposes that are not otherwise permitted or required by HIPAA (e.g., other than treatment, payment, health care operations or as permitted or required by the applicable privacy regulations). If you plan on using a photo in a publication, or to share in a case study situation you will need to obtain the patient's written Authorization in addition to the consent. See the Cleveland Clinic Policy on Patient Recordings (Photo, Video, and Audio).

Research Compliance

The Research Compliance team within the Office of Corporate Compliance & Business Ethics oversees the administration of the Program related to all aspects of research and is a valuable resource for any employees involved in research activities. The Research Compliance team is responsible for providing information, training and support to any researcher (enterprise-wide) to promote compliance with laws, regulations and policies governing research in the most efficient and effective manner. They work closely with the Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), the Law department, the Center for Clinical Research (CCR), Research Finance and others to carry out Program activities and implementation. Whether an employee plans to conduct human subject, animal or laboratory research, we encourage contacting the Office of Corporate Compliance & Business Ethics (216-444-1709) so that compliance considerations can be identified and addressed as early on as possible. Visit the Research Compliance page on the Corporate Compliance & Business Ethics intranet site for additional information.

Code of Conduct

Cleveland Clinic has a tradition of compliance with high ethical standards in the provision of health care services as well as in the management of its business affairs which has earned the confidence of patients and the respect of the community. The Code of Conduct supports the mission, vision and values of Cleveland Clinic and applies to all of our employees and Affiliates. The Cleveland Clinic Code of Conduct is an integral part of the Program and details standards of conduct designed to protect and promote integrity and to enhance Cleveland Clinic's ability to achieve its mission and compliance goals.

There are 5 principles in the Code of Conduct: Integrity in Patient Care, Integrity in Billing and Financial Practices, Integrity in the Workplace, Legal and Regulatory Compliance and Ethical Responsibility. These principles are to be followed by all Cleveland Clinic employees and Affiliates. All activity conducted by or on behalf of the Cleveland Clinic must comply with all applicable laws, regulations and policies. Honesty and integrity are required of all who represent Cleveland Clinic. Claims and records are to accurately document and report all services and supplies that are billed. Employees and other service providers owe a duty of complete loyalty to Cleveland Clinic and should refrain from directly or indirectly performing duties, incurring obligations, or engaging in business or professional relationships where there is or would appear to be a conflict of interest. No outside activity may interfere with job performance. Cleveland Clinic employees and Affiliates are not to offer, authorize or promise to provide anything of value, directly or indirectly, to a government official or other person or entity in connection with Cleveland Clinic's cross-border transactions that does or might appear to secure an improper advantage in obtaining or retaining business. Employees and Affiliates also have a duty to preserve and protect the assets of the organization and to ensure their appropriate and efficient use. Cleveland Clinic computers, systems and computer accounts are intended for business use only. Cleveland Clinic prohibits retaliation in any form against any employee for bringing or lodging a complaint of discrimination or harassment or engaging in any other activity protected by law.

Cleveland Clinic has a policy of corrective action for those who violate the Code of Conduct, as well as for those who know or reasonably suspect that wrongdoing may be occurring and fail to report it. All those covered by the Code of Conduct are responsible for reporting any suspected or actual violation of the Code of Conduct or other policy irregularities to a supervisor, the Corporate Compliance Office or the Law Department. For those who wish to remain anonymous, the report may be submitted through the Corporate Compliance reporting line at 1-800-826-9294 or by using the secure email link on the Corporate Compliance Intranet site.

Investigation of Criminal Conduct

Any incident of employee misconduct, including theft, embezzlement, fraud or other wrongdoing, which could result in criminal prosecution should be reported immediately to the Office of General Counsel (216) 448-0200.

Investigation of Alleged Scientific or Academic Misconduct

It is the desire of the Cleveland Clinic to uphold the highest principles of scientific integrity and to protect against scientific fraud or misconduct. There are specific policies and guidelines that define the procedures to conduct preliminary inquiry and/or definitive investigation in cases of alleged scientific or academic misconduct. Misconduct is defined as fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. Misconduct

does not include honest error or honest differences in interpretation or judgments of data. Inherent in these procedures is the Clinic's recognition that all individuals will be afforded the protection of due process and the avoidance of conflict of interest. It is recognized that allegations concerning misconduct vary from the trivial to the serious and that evidence may also vary from weak to compelling. For these reasons, the exercise of discretion and good judgment by individuals concerned with this process is of paramount importance and these considerations should have a bearing on the degree to which steps herein delineated might be applied. These guidelines comply with the federal regulations issued by the Public Health Service of the U.S. Department of Health and Human Services regarding misconduct in science.

Conflicts of Commitment

Purpose: To assure professional and commercial integrity in all matters, our Organization maintains a program that identifies and addresses conflicts of commitment for the Target Group members of the Professional Staff, Clinical trainees and Employees.

Policy Statement: Our Organization recognizes that Target Group members of the Professional Staff ("Staff"), Clinical trainees and Employees periodically serve in external roles and in other activities that may or may not require the use of their professional competence*. Service in external activities can be beneficial to Target Group Staff, Clinical trainees and Employees professionally, our Organization, its patients, and the public. These activities are generally permissible (subject to compliance with institutional policy) provided that the individual's commitment to professional responsibilities at our Organization remains primary (or as defined in the conditions of employment) at all times. An overabundance of such external activities may conflict with a Target Group Staff member's, Resident's, Fellow's or Employee's responsibilities at our Organization.

View the complete Policy I - Conflicts of Commitment.

Conflict of Interest in Business Affairs in General Policy

Members of the Target Group workforce have broad access to confidential information regarding our Organization's clinical, business, research, education and other activities, including proprietary information, intellectual property, and strategic plans. No Target Group Professional Staff member ("Staff"), Resident, Fellow, Employee or Cleveland Clinic – main campus Official shall use a position with our Organization (including its wholly-owned affiliates), or confidential information acquired as a result of his or her position with our Organization, to permit a Conflict of Interest to arise between the Organization's interests and his or her personal interests.

A Conflict Of Interest may exist when a Target Group Staff member, Resident, Fellow, Employee or a member of his or her Immediate Family or an entity directed or controlled by any of them, has an interest in (including relationships with) a Non-Cleveland Clinic (CC) Entity—whether investment, compensation*, or otherwise—that could be reasonably perceived as influencing his or her activities in patient care, research, administrative decisions, education or business transactions for our Organization. To help advance our Organization's mission, Target Group Staff members must respect the confidentiality of our Organization's information, act in the best interests of the Organization, and disclose to the IM&COI Program all of their existing and potential personal interests that may result in a Conflict Of Interest. In addition, certain Target Group Employees must also comply with these requirements. These Target Group Employees include managers, clinical trainees, advanced practice providers, pharmacy, law, innovations, ventures, compliance, strategy, supply chain management, construction

management, researchers and others as identified from time to time by Human Resources and the Innovation Management and Conflict of Interest Program of the Office of Professional Staff Affairs.

- Members of the Target Group Professional Staff and identified Employee groups must disclose all potential and existing relevant personal interests (including Significant Financial Interests in research**) that may result in a Conflict of Interest. The disclosure must be made through the online Conflict of Interest Disclosure system at least annually and within 30 days in response to a material change in Financial Interests.
- Cleveland Clinic – main campus Officials, whether Members of the Professional Staff or not, must disclose Financial Interests to the IM&COI Program as described above and also must disclose any Significant Financial Interests in research.*** (In addition to these requirements, Cleveland Clinic – main campus Officials who are elected Officers must separately comply with the conflict of interest requirements of the Board of Directors.)

Interests reported in prior years must be re-disclosed annually if still applicable. The IM&COI Program will review all disclosed interests – whether they involve clinical care, education, research, or other activities - and notify the affected discloser if the circumstances warrant further review, recusal, oversight, a Conflict Management Plan, Public Health Service-Reportable Conflict Management Plan, or other action.

No Royalty Payments or other Commercialization Revenues for use at CCE of Products Commercialized by our Organization or developed by our Organization's Employees: See Policy III Conflicts of Interest in Research for restrictions on the receipt of royalty revenues from products used, sold or purchased by our Organization. There is no restriction on the receipt of royalty payments by our Organization or its Healthcare Providers for the purchase and use of products at locations other than our Organization.

Donating to Charities Part or All of Honoraria or Consulting Compensation, Royalties and Other Revenues from Commercialization Received from Non-Cleveland Clinic Entities: See Policy III Conflicts of Interest in Research and Policy VI Conflicts of Interest in the Practice of Medicine for information on donating compensation to charity.

Our Organization maintains the highest degree of integrity and fiscal responsibility and compliance with the obligations of tax-exempt Organizations, physician self-referral laws, and applicable fraud and abuse laws. This policy is enacted, in part, to comply with these laws. Questions about the information to be disclosed may be addressed to the Director of the IM&COI Program. Personal or institutional interests that may involve potential legal or compliance issues are to be referred to the Cleveland Clinic Law Department.

View the complete Conflict of Interest in Business Affairs in General Policy.

Conflicts of Interest in Clinical Practice

This policy applies to Target Group Professional Staff, advanced practice providers, pharmacists and clinical trainees who provide healthcare to our Organization's patients (Healthcare Providers) [See also the Policy III - Conflicts of Interest in Research]. A Healthcare Provider may deliver outside lectures or external activities related to their Institutional Responsibilities for which he or she receives Honoraria and/or Consulting Compensation from a Non-CC Entity, as long as the Healthcare Provider complies with applicable policies referenced herein and the provisions in the Policy Implementation section below. Under the policies, when the

compensation—which may be direct or indirect, financial or otherwise—is received by an Immediate Family Member or an entity controlled by the Healthcare Provider or Immediate Family Member, it is treated as compensation to the Healthcare Provider. Target Group Healthcare Providers may also engage in activities related to the commercialization of intellectual property, as long as the Healthcare Provider complies with this and other policies related to conflicts of interest and commercialization of intellectual property. The intent of this policy is to ensure that the Healthcare Provider's primary concern is promoting the best interests of their patients.

The Innovation Management and Conflict of Interest (IM&COI) Program will review all potential Conflicts of Interest in clinical practice and may require certain actions, such as disclosure to patients, limits on the relationship with the Non-CC Entity or adoption of a Conflict Management Plan, to ensure, to the extent possible, that the clinical activity is free from bias that may result from the Financial Interest. In its evaluation of Conflicts of Interest in Clinical Practice, the IM&COI Program will strive not to interfere with clinical practice. Any required actions will not limit the clinical activities that Target Group Healthcare Providers believe to be in the best interests of his/her patients; rather, the IM&COI Program will make efforts to manage the relationship or Financial Interest in the Non-CC Entity.

View the complete Policy VI - Conflicts of Interest in Clinical Practice.

Policy Implementation covers:

- Receipt of Gifts by Healthcare Providers from Non-Cleveland Clinic Entities
- Distribution of Non-Cleveland Clinic Entity-Derived Materials Containing Information Directed at Patients as Part of Clinical Practice or Patient Education
- Having Financial Interests in a Non-Cleveland Clinic Entity (stock, stock options, rights to royalties or other commercialization revenues, receiving consulting, speaking or other fees) While Using the Entity's Product in Treating Patients
- Donating to Charities Part or All of Honoraria or Consulting Compensation, Royalties and Other Revenues from Commercialization Received from Non-Cleveland Clinic Entities
- No Royalty Payments or other Commercialization Revenues for use at our Organization of Products Commercialized by our Organization or developed by our Organization's Employees
- Patient Referrals to a Physician, Entity or Practice with which there is a Potentially Conflicting Relationship with the Referring Healthcare Provider
- Distribution of Prescription or Over-the-Counter Samples to Patients
- Site Access to our Organization by Pharmaceutical, Diagnostic and Medical Device Non-Cleveland Clinic Entity Representatives
- Ghostwriting

Conflicts of Interest in Education Policy

The intent of the provisions in the Policy Implementation section below are ensure that Target Group Staff, Employees and Trainees adhere to the highest ethical standards when they participate in educational endeavors. This policy applies to Target Group Staff, Employees and Trainees who are responsible for educating, and to trainees and other learners who work and/or learn at our Organization as part of their career development.

View the complete Policy VII - Conflict of Interest in Education Policy.

Policy Implementation covers:

- Required Disclosure of Industry Relationships to Trainees by Faculty
- Attending Non-Cleveland Clinic Entity-Sponsored Education and Training Activities
- Receipt of Educational Funds from Non-Cleveland Clinic Entities
- Speaking and Training at Non-Cleveland Clinic Entity-Sponsored Events
- Gifts of Educational Materials from Non-Cleveland Clinic Entities
- Trainees Supervised by Faculty with Non-Cleveland Clinic Entity Relationships
- Trainee Relationships with Non-Cleveland Clinic Entities

Conflicts of Interest in Research Policy

To assure professional and commercial integrity in all matters, our Organization maintains a program that identifies and addresses conflicts of interest in research. This policy applies to Investigators, which means any Target Group member of the Professional Staff, employed physician, other Employee or Trainee participating in research and includes the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research performed under the auspices of our Organization's locations which have adopted this policy, which may include outside collaborators with, or outside consultants to our Target Group's Staff, Employees or Trainees.

If an Investigator has a Significant Financial Interest ("SFI") and that SFI is considered to be a Conflict of Interest (or a Public Health Service ("PHS")-Reportable Financial Conflict of Interest; see below), the Investigator must obtain approval from the IM&COI Program to participate in human subjects or non-human subjects research.

View the complete Policy III - Conflicts of Interest in Research

Policy Implementation covers:

- Additional Requirements for Human Subjects Research
- Disclosure
- Travel Disclosure for Investigators participating in Research Supported by the PHS
- Retrospective Review and Mitigation Reports
- Public Accessibility
- Disclosures to the Scientific Community
- Training
- No Royalty Payments or other Commercialization Revenues for use at our Organization of Products Commercialized by our Organization or developed by its Employees
- Donating to Charities Part or All of Honoraria or Consulting Compensation, Royalties and Other Revenues from Commercialization Received from Non-Cleveland Clinic Entities

Patient Blood Management (PBM) Guidelines

The Cleveland Clinic respects the right of adult patients to refuse blood/blood products. Therefore, it is important for patients to have the ability to make their choice regarding blood/blood products known to the healthcare team.

The following persons may refuse blood/blood products on behalf of certain patients, as identified below, regardless of the potential consequences to the patient, even when blood would be a life-saving treatment:

- A mentally competent adult patient 18 years or older (an “Adult”) on his or her own behalf;
- For a mentally incompetent Adult patient, the first-listed competent person(s) from the following list, in order, if such persons exist and are reasonably available:
    - Court appointed legal guardian or attorney-in-fact under a durable power of attorney for health care (if both are in place for the Adult, consent from both must be obtained)
    - Spouse
    - Majority of Adult children
    - Parent
    - Majority of Adult siblings
    - Next adult relative by blood or adoption
- A court-approved Emancipated Minor on his or her own behalf as described in the Cleveland Clinic Informed Consent Policy; and
- A Mature Minor on his or her own behalf as described in the Cleveland Clinic Informed Consent Policy.

View the complete Patient Blood Management (PBM) Guidelines for When Blood Is Not an Option (BNAO) (including Jehovah's Witnesses).

Patient Safety

At Cleveland Clinic, Patient Safety is a core value that cannot be compromised, and is the responsibility of every physician and caregiver. The Patient Safety Plan and Program are designed to support and promote the mission, vision and values of Cleveland Clinic with a systematic, coordinated approach to continuously improving patient safety and reducing risk. The Cleveland Clinic Safety Plan and Program are supported by leadership and executed through the integration and coordination of patient safety initiatives across the Enterprise. The Patient Safety Plan provides the foundation for a systematic and coordinated approach to integrating patient safety priorities into the design and redesign of all relevant organizational processes, functions and services to create an accountable Culture of Safety. The Patient Safety Program builds a framework for the delivery of safe care, perpetuates a culture of safety and improves patient outcomes through reducing variability in care processes, increasing reporting of safety events and overall reduction of preventable adverse events.

View the complete Patient Safety Plan.

The goals and objectives of the Cleveland Clinic Patient Safety Plan are:

1. Achieve Clinical Enterprise Priorities
    - Access Solutions
    - Digitization
    - Engagement
    - High Reliability
    - Populations Management
    - System Development
2. Promote High Reliability Principles
    - Design standardized data-driven systems and processes that safeguard against preventable harm.
    - Assess patient care delivery to enhance workflow and process redesign.

- Promote implementation of standard order sets, care paths, and use of the electronic medical record to enhance patient safety.
- Conduct risk assessments (e.g. Failure Mode & Effects Analysis, Critical Incident Reviews, Root Cause Analyses).
- Actively participate in a Patient Safety Organization by engaging in a formal process that allows the health system to conduct patient safety, quality and risk activities within a protected space for the purpose of improving patient care services. The PSO will expand our learning community around safety and make the Cleveland Clinic more highly reliable. Cleveland Clinic is committed to submitting safety events and also learning from expertise, data, and analytics from the PSO vendor.

3. Support a Culture of Safety
    - Support and promote a culture of safety for all caregivers.
    - Engage leadership to set and model expectations for patient safety and communicate the safety message to all stakeholders.
    - Conduct a safety culture survey assessment on a regular basis.
    - Encourage reporting of events and promote a learning environment.
    - Provide reward and recognition for quality and patient safety efforts throughout the health system.
4. Education and Training
    - Promote physicians' and caregivers' awareness of safety principles through the creation and implementation of policies, procedures, manuals and programs for orientation, training and remediation with the intent to improve safe practices.
    - Introduce and sustain a patient safety education program for all Cleveland Clinic caregivers.
    - Structure educational opportunities focused on patient safety. These programs will be highlighted during National Patient Safety Week and ongoing through established system- wide educational venues.
5. Patient Safety Measurement and Reporting
    - Data used in the assessment of organizational performance and the quality of care are collected from many sources. These sources include, but are not limited to, information systems, financial data, patient experience data, root cause analyses, internal databases, medical records and external accreditation and regulatory survey findings. Data are also collected from occurrence screening, safety and clinical risk program reviews.
    - Data relating to patient safety and quality improvement initiatives will be collected, analyzed and reported to the governing bodies as outlined in the Performance Improvement Plan.
    - Implementation strategies will be monitored through activities such as data collection, facility inspections, and safety walk rounds.

The Patient Safety Program includes monitoring compliance with The Joint Commission National Patient Safety Goals (NPSG).

Culture of Safety

The Cleveland Clinic supports a Culture of Safety. Elements of our program include:

- Teamwork; acting as a unit
- High Reliability; performing consistently, as intended, every time – reluctance to simplify, preoccupation with failure, deference to expertise, commitment to resilience, and sensitivity to our operations
- Activated Patient and family; enlisting the patient and/or family as part of the healthcare team – listening
- Accountability and Just (Culture); establishing expectations and consistent accountability for expected safety behaviors
- Expecting 'speaking up' through event reporting – understanding why errors occur
- Learning; full cycle learning from reported events

Speak Up: The Cleveland Clinic supports a safe culture by establishing expected safety behaviors which include stopping the line when something doesn't seem right and reporting actual or potential safety events. Management should support and encourage the caregiver to report and share lessons about safety events so others are able to learn.

Cleveland Clinic Enterprise Quality supports several committees, projects and resources providing opportunities for clinical trainees to become involved in patient safety. To receive additional information on Cleveland Clinic Patient Safety, National Patient Safety Goals or the Cleveland Clinic Enterprise Quality, please refer to the Cleveland Clinic Quality and Patient Safety website.

Safety Event Reporting (SERS)

Reporting a safety event when it occurs provides an opportunity to identify and learn about system failures, hazards and risks. It is critical to note that safety events are not limited to those events that cause a patient harm. Often we have the most to learn from near-miss events and no harm events. Learning about these events can help safeguard our patients from future harm events. The safety event can provide information as to where processes are breaking down and therefore reduce the likelihood of recurrence. Ultimately this review and analysis process will lead to improvements in the quality of patient care.

View the complete Safety Event Reporting (SERS) Policy.

Any Cleveland Clinic hospital or facility caregiver, who is involved in, observes or otherwise becomes aware of a safety event, is responsible for promptly reporting the event in the electronic Safety Event Reporting System (SERS). Reports may be submitted in an identifiable or anonymous manner. Events should be reported as soon as possible within 24-hours of occurrence. The information in the report or generated from the event reporting system is confidential and privileged as outlined in the Ohio Revised Code Section 2305.25(D), 2305.252, and 2305.253. If a Needlestick or Bloodborne Pathogen Exposure occurs the caregiver must call the 24/7 BBPE HOTLINE at 216-445-0742 and they will speak directly with a nursing caregiver.

Cleveland Clinic caregivers can report safety events without fear of retribution. Event reporting is a mechanism for organizational learning, not a disciplinary pathway. Our response to events is centered on being "just" with a focus on understanding the context in which errors occur.

Cleveland Clinic is committed to supporting an environment which is neither purely punitive nor blame-free. Of critical importance in determining a "just" response to an event is understanding that while all caregivers bring expected behaviors to work (avoiding reckless behavior, gross neglect or intentional acts of harm), we do work within complex and imperfect systems. Learning from these events allows us to improve the systems that all caregivers work within.

- Adverse Event: Any injury (undesirable clinical outcome) caused by the omission or commission of medical care
- Event: Any happening that is not consistent with the routine care of a patient, or an occupational injury/illness of a Cleveland Clinic healthcare system caregiver or any happening that is not consistent with the normal operations of the Cleveland Clinic health system. An event may involve a patient, Cleveland Clinic health system caregiver, visitor or the physical environment within a Cleveland Clinic health system facility and is associated with actual or potential for harm, loss or damage. An event may involve an error, but the term 'event' is not synonymous with 'error'. Safety events are classified into three categories:
    - Near Miss: Circumstances or events that result from a deviation from generally accepted performance standards (GAPS), have the capacity to cause error, and did NOT reach the patient. These events were "caught" by either change or a planned barrier.
    - Precursor Safety Event: An event resulting from a deviation from GAPS that reaches the patient but does not cause significant harm.
    - Serious Safety Event*: An event resulting from a deviation from GAPS that reaches the patient and causes moderate-to-severe harm, or death. *The Cleveland Clinic also classifies unintended retained foreign bodies, wrong side/site procedures, operative flame/spark/smoke, and falls with injury as serious safety events.
- Patient Safety Organization (PSO): A private or public entity or component thereof that is listed by the Secretary pursuant to section 924(d) of the PSQIA. Section 924(d) describes the certification and listing requirements for a PSO. The Cleveland Clinic partners with the Cleveland Clinic Alliance for Patient and Caregiver Safety PSO to comply with this rule, and the primary purpose of the PSO is to receive, analyze, and feedback data in the form of patient safety work produced to improve the safety and quality of care.
- Root Cause Analysis: A Root Cause Analysis (RCA) is a process for identifying the basic causal factors that underlie variation in performance, including the occurrence or risk of occurrence for a sentinel event. The RCA focuses primarily on systems and processes, not individual performance.
- Sentinel Event: A patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in any of the following: Death, Permanent Harm or Severe Temporary Harm. Severe Temporary Harm is critical, potentially life-threatening harm lasting for a limited time with no permanent residual, but requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition or additional major surgery, procedure or treatment to resolve the condition. The Joint Commission also outlines 14 events that will be considered sentinel regardless of harm. See the 2015 Joint Commission Sentinel Event Policy for more details. Please refer to the SERS web site page for additional information.

Restraint and/or Seclusion Use Policy

All patients have the right to be free from restraint or seclusion of any form. The decision to use restraints or seclusion is not driven by diagnosis but by a comprehensive individual patient assessment. Restraints and/or seclusion are used temporarily to prevent the risk of therapy disruption, and/or to ensure the immediate physical safety of the patient, a staff member, or others.

View the complete Restraint and/or Seclusion Use Policy.

Restraint and/or Seclusion Use Procedure for Violent/Self-Destructive Behavior (VSD)

To support the Restraint and/or Seclusion Use Policy, this procedure specifies the roles, responsibilities and accountability of those involved in the assessment, documentation, ordering, monitoring, and care of patients in restraint or seclusion for Violent/Self Destructive behavior. This procedure does not apply for use of restraints for management of the following:

- Prisoners restrained with a Law Enforcement Restraint
- Restrictive devices during anesthesia induction, surgery or immediate recovery period. These devices are applied as a standard practice to ensure patient safety.

View the complete Restraint and/or Seclusion Use Procedure for Violent/Self-Destructive Behavior (VSD).

Restraint Use Procedure for Non-Violent/Non-Self-Destructive Behavior (NVNSD)

To support the Restraint and/or Seclusion Use Policy, this procedure specifies the roles, responsibilities and accountability of those involved in the assessment, documentation, ordering, monitoring, and care of patients in restraint for Non-Violent/Non Self-Destructive behavior. This procedure does not apply for use of restraints for management of the following:

- Medical immobilization for medical, dental, diagnostic, or surgical procedure and the related immediate post procedure processes
- Prisoners restrained with a Law Enforcement Restraint
- Restrictive devices during anesthesia induction, surgery or immediate recovery period. These devices are applied as a standard practice to ensure patient safety.

View the complete Restraint Use Procedure for Non-Violent/Non-Self-Destructive Behavior (NVNSD).

HIPAA

HIPAA rules govern the privacy and security of protected health information (PHI). PHI is individually identifiable health information (including demographic information) that relates to an individual's physical or mental health or the provision of or payment for health care. PHI is not limited to the electronic medical record and includes paper, photographs, audio, video, x-rays and other types of media. All members of the Cleveland Clinic workforce are required to complete a designated training program on or around their start date. In addition, employees must review the HIPAA Policies located in the PPM. When you reach the PPM site (only accessible when on the Cleveland Clinic network), click on the + sign next to Privacy & Security on the left side of the screen. Then select the HIPAA Privacy folder and review the policies listed.

OSHA

Federal law mandates that all clinical trainees/research fellows receive annual training regarding the Blood borne Pathogen Standards. This is accomplished with an on-line course in MyLearning.

Infection Prevention

Clinical Trainees/research fellows at the Cleveland Clinic will follow all infection prevention policies and procedures available on the intranet in the Policy and Procedure Manager (PPM) and the Infection Prevention website. Hand hygiene and Standard Precautions are the cornerstones of infection prevention. Performing hand hygiene before and after patient contact is regarded as a professional responsibility. Sinks and alcohol-based hand rubs are readily available in all patient care locations. To ensure Cleveland Clinic is complying with Joint Commission National Patient Safety Goals, hand hygiene is monitored among employees.

View the complete Hand Hygiene Policy.

Standard Precautions includes the use of personal protective equipment to prevent exposure to potentially infectious material, use of cough etiquette, masking for lumbar punctures and following safe injection practices (one needle, one syringe, one time, for one patient). Transmission-based Precautions includes the use of Contact, Droplet and Airborne Precautions for certain defined conditions or pathogens. Clinicians are expected to follow the directions posted on the patient's door. In addition, clinicians will follow recommended infection prevention bundles for the prevention of central line-associated bloodstream infection (CLABSI), catheter-associated urinary tract infections (CAUTI), ventilator-associated pneumonia (VAP) and surgical site infections (SSIs). Bundles include daily assessment for need and prompt removal of indwelling devices as soon as clinically feasible.

Healthcare workers will wash hands with soap and water:

- When hands are dirty or visibly soiled
- After removing gloves if there has been any contact with blood or other potentially infectious material
- After using the restroom
- Before eating
- When caring for patients with *Clostridium difficile*, *Hepatitis A*, or *Norovirus* infections
- After suspected or proven exposure to *Bacillus anthracis*

Hand hygiene using soap and water (hand washing):

- Wet hands with water
- Apply enough soap to generate a lather
- Rub hands together, covering all surfaces of the hands and fingers, for at least 15 seconds
- Rinse hands with water
- Dry hands thoroughly with a single use towel
- Use towel to turn off faucet

Alcohol-based hand rub (ABHR) is preferred over soap and water for hand hygiene when hands are not visibly soiled. Hand hygiene with ABHR or soap and water will be performed:

- Before and after direct contact with patients and their immediate environment if hands are not visibly soiled and there has been no contact with blood or other potentially infectious material
- Before inserting indwelling catheters, peripheral vascular catheters, or other invasive devices that do not require a surgical scrub
- When going from a dirty procedure to a clean procedure on the same patient
- Before donning and after removing gloves if there has been no contact with blood or other potentially infectious material (the use of gloves does not eliminate the need to perform hand hygiene)

Influenza Vaccination

The Influenza Immunization Policy covers all Cleveland Clinic employees. The vaccination program is coordinated through Occupational Health and commences at the beginning of the influenza season. Immunizations will be offered throughout the influenza season. Occupational Health will provide influenza vaccinations to Cleveland Clinic employees. All employees must participate in the annual Cleveland Clinic Flu Vaccine Program by receiving the annual influenza vaccine, or receiving a religious or medical exemption. Cleveland Clinic employees who are vaccinated through services other than Cleveland Clinic Occupational Health (i.e. private physician office, public clinics) must provide documentation from the source of immunization as proof to Occupational Health. A final date to comply with the annual Cleveland Clinic Flu Vaccine Program will be determined annually.

Review the Influenza Immunization Policy and Standing Order: Employee Influenza Vaccination Program.

Employees must receive a flu shot from Cleveland Clinic Occupational Health or submit proof of vaccination from another source to Cleveland Clinic Occupational Health or receive a medical or religious exemption. If such employees are not in compliance with the required participation in the mandatory program by the identified date, their non-compliance will be subject to a step of corrective action.

Medication and Allergy Reconciliation Policy

Medication reconciliation is the process of comparing a patient's medication list to all of the medications that the patient has been taking and updating the medications to provide an accurate and current list at the end of this encounter. This reconciliation is done to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions. It should be done at every admission and at every transition of care in which new medications are ordered or existing orders are rewritten.

View the complete Medication and Allergy Reconciliation Policy.

The Cleveland Clinic Medication and Allergy Reconciliation Policy and Procedure outline the following allergy and medication requirements:

- Allergy information is compiled and documented with the involvement of the patient (or patient representative) upon entry into any Cleveland Clinic Health System location
- Medication list is compiled and documented with the involvement of the patient (or patient representative) upon entry into any Cleveland Clinic Health System location
- Information regarding allergies and medications is not required in circumstances that do not involve medication management or administration of medication
- A healthcare provider with prescriptive authority or pharmacist will reconcile either the comprehensive or focused list of medications and allergies
- A healthcare provider with prescriptive authority or pharmacist will reconcile the comprehensive list of allergies and medications during transition points within the healthcare delivery system
- The patient (or patient representative) will receive information regarding his or her allergies and medications
- The patient (or patient representative) will be educated when discharged from the inpatient setting, or at the end of the outpatient encounter, on the importance of managing medication information such as providing the allergy and medication list to their primary provider

Universal Protocol - Safety Checklist Policy

The Universal Protocol (UP)/Safety Checklist process applies to all surgical and nonsurgical invasive procedures in all inpatient and outpatient settings, to include bedside procedures. Universal Protocol/Safety Checklist does not apply in an emergency situation when the risk of performing the Universal Protocol/Safety Checklist outweighs the benefit.

This policy addresses: Sign-in or Pre-procedure verification/huddle; Marking of the procedure site; Time-out; Implant Verification; Pause prior to Sign-Out; Post procedure Sign-out and Documentation.

Oversight and Responsibility:

- Physicians are responsible for ensuring the safety of their patients during any procedure

that is associated with more than minimal risk by adhering to the Universal Protocol/Safety Checklist

- Members of procedure teams are responsible for active communication and participation as outlined in the Universal Protocol/Safety Checklist policy in addition to appropriate documentation
- All procedural team members are responsible for the immediate resolution of any discrepancy during any process of the Universal Protocol/Safety Checklist
- It is the responsibility of each hospital, institute, department and discipline providing direct patient care to implement the policy and to draft and operationalize related procedures to the policy if applicable
- The enterprise Patient Safety Committee (ePSC) is responsible for reviewing, revising, and updating this policy to maintain compliance with regulatory or other requirements
- The ePSC is responsible for data analysis, as indicated, at the system level to drive related performance improvement initiatives
- Each organizational Patient Safety Committee is responsible for local level data analysis, as indicated, to drive related performance improvement initiatives

For more information review the complete Universal Protocol - Safety Checklist Policy e-mail: safety@ccf.org; call x4-SAFE (47233), or view the Quality and Patient Safety website.

Verbal Orders Policy

Verbal orders should only be used to meet the care needs of the patient when it is impossible or impractical for the ordering practitioner to write the order or enter it into the EMR (electronic medical record) without delaying treatment (e.g. in perioperative and periprocedural areas). This policy outlines the information to be communicated when verbal orders are given by a Licensed Independent Practitioner (LIP) to the appropriate accepting personnel. Verbal orders are verified by a read back process.

View the complete Verbal Orders Policy.

1. Verbal orders are discouraged at Cleveland Clinic. Verbal orders must be used infrequently and must not be common practice.
2. Verbal orders for chemotherapy or biological agents shall not be given or accepted except to discontinue treatment.
3. Documentation of Verbal Orders includes the date, time and names of the individuals who gave, received and recorded the orders.
4. All verbal orders must be authenticated (signed, dated, and timed) by the LIP within 7 days. If the prescribing LIP is unavailable to authenticate the verbal order, any LIP concurrently involved in the care of that patient may authenticate the order within 7 days.
5. An APRN (Advance Practice Registered Nurse) or PA (Physician Assistant) may authenticate a physician's or other qualified licensed practitioner's verbal order only if the order is within his or her scope of practice and the patient is under his or her care.
6. The verbal order must be recorded and "read-back" to the ordering provider as outlined in Write Down/ Read-Back: Verbal Orders and Critical Test Results/Values Policy.
7. A receiver of verbal orders may refuse to accept or implement a verbal order that, in his professional judgment, is unclear or inaccurate. In this instance, the receiver must clarify the verbal order with the prescriber. If clarity is not obtained, the receiver can contact an alternate provider caring for the patient, or if necessary, the prescribers immediate supervisor.
8. Verbal orders for medication must include the patient, medication, dose, route of administration, and frequency.
9. Employees authorized to accept verbal orders include the following (refer to the matrix on page 3 of the policy for a complete listing of employees authorized to accept orders).

Confidentiality Policy

In addition to the obligation to maintain confidentiality of Protected Health Information ("PHI") (see HIPAA Permitted Uses and Disclosures Policy and other HIPAA policies), employees of Cleveland Clinic and other individuals may have access to other confidential information concerning Cleveland Clinic budgets, strategic business plans, patients, or employees. This information may be in the form of verbal, written, and/or computerized data. The protection of this confidential information is a critical responsibility of each employee or individual. Employees and other individuals are required to adhere to Privacy and Information Security policies and the Cleveland Clinic Confidentiality Agreement (attachment A in the policy). As such, the unauthorized acquisition, release, disclosure and/or discussion of any confidential information related to Cleveland Clinic business, patients, current and past employees, job applicants and computerized data is strictly prohibited by this policy and all employees and other individuals, regardless of position or title will be subject to corrective action up to and including discharge, or other appropriate action.

View the complete HR Confidentiality Policy.

Identity Theft Prevention and Mitigation Standard Operating Procedure

It is the policy of the Cleveland Clinic to protect confidential patient information in accordance with state and federal regulations and Cleveland clinic policies. If patient information is compromised through identity theft or fraud (i.e. use of someone else's name, social security number, insurance card/benefits, credit card, etc.) this policy and procedure for managing the situation and account will be adhered to consistently throughout the health system.

As a Cleveland Clinic employee, please uphold this policy by notifying your supervisor if you observe any of the following situation or "Red Flags":

- Alerts, notification or warnings from a credit agency
- Suspicious-looking documents (i.e. altered)
- Suspicious activity on an account (i.e. change of address)
- Notice from patient, victim of identity theft or fraud, law enforcement, etc.
- Medical treatment inconsistent with physical exam

View the complete Identity Theft Prevention and Mitigation Standard Operating Procedure.

Release of Information on Patients

The patient's condition, diagnosis and prognosis are to be discussed only with the patient, the patient's family and others who are involved with the patient's care under the direction of the staff doctor in charge, unless the patient objects.

- Requests for copies of patient information must be directed to Health Information Management and require authorization from the patient.
    - Links are available on the intranet and public web page for a paper or an electronic authorization.
    - Records can also be requested electronically from within MyChart for:
        - Release to MyChart
        - Release to another individual or requester
- Patients can also be directed to their MyChart account to view their information and use the above options to request any additional information needed.
- To Reporters: All inquiries from newspaper and television reporters regarding accidents, rumors, professional standing of doctors and nurses or anything that involves the Clinic shall be referred to the Director of Media Relations.
- To Lawyers: All inquiries from lawyers, adjustors and others regarding accidents and care and treatment of patients should be referred to the Office of General Counsel and the staff physician in charge. No information may be released without written authorization from the patient.
- To Police: All inquiries should be referred to the Director of Protective Services.
- To the Public: Information that can be given over the telephone regarding the condition of patients is recorded at the hospital information desk. Inquiries involving the condition of patients, which cannot be answered on the basis of such daily reports, are referred to the staff physician or surgeon. If he or she cannot be located, the inquiry should be referred to the senior resident.

Informed Consent Policy

Purpose: The purpose of the Informed Consent Policy is to provide an environment in which patients have the opportunity to accept or reject "Health Care Treatments" in an informed and voluntary manner, and to provide physicians and hospital personnel guidance in the consent process.

Policy Statement: Cleveland Clinic Health System (CCHS) recognizes that a patient with decision-making capacity has the right to provide informed consent or refuse to consent to any of the following health care treatments (referred to as "Health Care Treatments"):

- Operative or invasive procedures

- Procedures under anesthesia or moderate (conscious sedation) or deep sedation and other high-risk interventions or tests, whether diagnostic or therapeutic. “High-risk” refers to those risks that the patient reasonably would consider to be important in deciding whether or not to refuse the intervention or test.
- Percutaneous procedures traversing into an organ
- Intravascular insertion of a catheter or other device (excluding peripheral IVs)
- General anesthesia or moderate or deep sedation that is administered independently from the procedures and interventions listed above.
- Administration of blood or blood products (e.g., a transfusion) that is unrelated to the procedures and interventions listed above. (The administration of blood or blood products intra-operatively or post-operatively during a hospital stay is considered related to the procedure and does not require another informed consent unless a material change in the risks for post-op transfusion has occurred.)

The practitioner who is performing or supervising the Health Care Treatment (referred to as the “Responsible Practitioner”) has the primary responsibility for ensuring that informed consent is obtained and that the informed consent discussion is documented.

Exclusions: This policy does not apply to (1) informed consent for clinical research or other interventions that fall within the Institutional Review Board’s authority or (2) routine care such as routine diagnostic, imaging, laboratory, therapeutic, or other routine hospital tests or services.

View the complete Informed Consent Policy.

Human Subject Research

All research involving human subjects requires Institutional Review Board (IRB) approval prior to implementation. Research involving human subjects is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge or any experiment that involves a test article other than the use of a marketed product in the course of medical practice.

The Cleveland Clinic is ***engaged* in human research** when its employees obtain: (1) data about subjects through interaction for research purposes; (2) data about subjects through intervention for research purposes; (3) individually identifiable private information about subjects for research or purposes; or (4) informed consent of subjects to take part in the research. Common types of human research involve retrospective chart reviews, surveys, questionnaires, innovative surgical procedures, drug and device trials, registries and outcome research. Depending upon the type of research, it will either be reviewed by the convened IRB, under expedited review by a member of the IRB, or by a member of the IRB (or designee) to make a determination that it is exempt human subject research. Only the IRB can make a determination that research is exempt under the categories specified in IRB policy. You should contact the IRB office for assistance if you have questions whether an activity is considered human research requiring IRB approval. Some research may involve the recruitment of employees (staff, clinical trainees, students) as research volunteers and require additional safeguards. If you have any concerns regarding a request for you to participate as a research subject, please contact the IRB, the Director of Graduate Medical Education or the Chairman of the Education Institute.

Human Research Training Requirements: Investigators, Co-Investigators, Study Coordinators

and other key research support personnel involved with study design, recruitment, consenting, data collection or data analysis are required to complete the on-line CITI course (Collaborative IRB Training Initiative) at www.citiprogram.org and the HIPAA in Human Subject Research module in MyLearning. Completion of the Investigator Human Subject Research Education Course is also required for all Staff, Clinical trainees and Scientists participating as PI or Co-Investigators in human research. The course is offered on-demand in MyLearning. An on-line review course is required every 3 years after completing the live training.

Information on the IRB submission process and research resources can be found on the CCR New Investigator webpage.

Although clinical trainees and research fellows may not be immediately involved in human research, we strongly encourage all trainees to take these courses to gain special knowledge and use of reference material relating to the conduct of clinical research. The Cleveland Clinic main campus IRB is responsible for the review of all human subject research conducted in whole or in part on premises owned or operated by CCF, regardless of who is conducting the research and includes the main campus, the family health and surgery centers, physician practice sites, wholly-owned regional hospitals, and other components as listed on our Federal wide Assurance agreement. In order to ensure that there is enough time to complete a research project, it is extremely important to begin the development of the protocol and submission with your mentor as soon as possible. Volumes impact turnaround time at the IRB.

You can contact the CCF IRB at 216-444-2924 or email at IRB@ccf.org

All proposals requesting funding from private foundations, health associations, corporations, or federal, state, and local governments require input and sign-off from the Institute Research Administrator to ensure compliance with institutional policies governing the conduct of sponsored research (regulatory, legal and financial).

ClinicalTrials.gov Registration and Reporting:
ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world that is designed, in part, to promote transparency of clinical research to trial participants and the public. The responsible party (sponsor/sponsor investigator) is required to register, update, and report results for applicable clinical trials at specific time periods consistent with the regulation and outlined in Institutional policy. If the Responsible Party is leaving Cleveland Clinic, he or she must update the ClinicalTrial.gov record prior to their departure. If the study remains open, and/or results are not yet submitted, a new Owner must be identified, and accept the study.

Noncompliance can result in the labeling of the study as non-compliant on ClinicalTrials.gov, loss of grant funding if federally funded, and civil monetary penalties over $10,000/day.

Contact your Institute's ClinicalTrials.gov Administrator with questions or for assistance.

Safety & Security

The personal safety and health of each employee, patient and visitor is a primary importance to Cleveland Clinic. It is our policy to maintain a safety program conforming to all applicable local, state and federal safety and health standards, fire codes and environmental regulations. Since these regulations only define minimum requirements, it is the position of Cleveland Clinic that

every effort will be made to exceed them whenever practical. If a clinical trainee/research fellow is working late and feel the need to be escorted safely to their assigned parking location, contact the Cleveland Clinic Police at 216-444-2250 for assistance. Additionally, you can find Hotlines and Emergency Numbers for all Cleveland Clinic Locations at the Protective Services site. For all caregiver safety, "blue light emergency intercoms" blanket the Cleveland Clinic campus. The blue lights enable caregivers to easily find them. Push the button once to be connected directly to the Cleveland Clinic Police Department and it will alert them to the caregiver's location for an immediate response. Uses include reporting a crime, suspicious persons, property lost, found or stolen and car trouble such as a dead battery (there is free "jump start" assistance available) or keys locked in the caregiver's car.

Hazardous Chemical Identification and Communication Policy

Cleveland Clinic caregivers shall be informed about the hazardous chemicals used in the workplace. This shall be accomplished by means of comprehensive hazard communication programs, which include chemical lists, container labeling (and other forms of warning), safety data sheets (SDS), and employee information and training. For the safety of our caregivers, the Cleveland Clinic maintains compliance with the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29CFR 1910.1200).

View the complete Hazardous Chemical Identification and Communication Policy.

Human Immunodeficiency Virus Infection

Human immunodeficiency virus (HIV) infection is an epidemic of major proportion with serious medical, social and economic consequences. Physicians must be familiar with the clinical manifestations of symptomatic HIV infection (AIDS and AIDS-related conditions) as well as the indications for his limitations of various laboratory diagnostic tests that are currently available.

If an employee sustains a significant exposure (needle stick, sharp injury or a mucous membrane splash of patient blood or other body fluids), that employee should

1. Stop working
2. Irrigate exposed skin or mucous membrane, if applicable
3. IMMEDIATELY Call Needle Stick Line: 216-445-0742, Cleveland Clinic Occupational Health
4. File a Safety Event Reporting System (SERS) form with their supervisor

Employees with exposure to source patients who are HIV-positive will be recommended for follow-up HIV testing and will be referred to an Infectious Disease Physician for evaluation for antiviral medication as deemed necessary. Such employees should be advised to report and seek medical evaluation for any active illness that occurs during the follow-up period. For especially the first 6-12 weeks after exposure, when most exposed persons would be expected to seroconvert, the Public Health Services recommends the following measures for preventing transmission of HIV: avoiding pregnancy and breastfeeding (if possible), avoiding blood, semen or organ donation, refraining from sharing needles and abstaining from sexual intercourse or using barrier measures to prevent HIV transmission during sexual intercourse.

Confidentiality: All Cleveland Clinic employees must preserve the confidential nature of HIV testing and results. Breach of confidentiality is grounds for dismissal.

Disclosure of Information: Copies of patient records, which contain HIV-related information, may be released to specified individuals, upon receipt of a written and valid authorization. HIV-related information may be released to the following without patient authorization; a health care facility or provider that procures, processes, distributes or uses a human body part from a deceased individual which is donated for a purpose; the appropriate governmental health department; a health care provider who treats the individual; health care provider, EMS worker, or peace officer who has sustained a significant exposure to a patient. If the patient receives post-exposure testing for HIV, his or her identity may not be revealed.

View the Ohio Revised Code for Disclosing of HIV Test Results or Diagnosis.

Hepatitis B Infection

If a source patient is identified as Hepatitis B surface antigen positive it is recommended that the Caregiver have follow up testing. This should occur at the time of the exposure to establish baseline results. This is followed by testing at 6 weeks, 3 months and 6 months. If seroconversion should occur, the Caregiver will be referred immediately to Hepatology for evaluation and treatment.

Any Cleveland Clinic hospital or facility caregiver, who is involved in, observes or otherwise becomes aware of a safety event, is responsible for promptly reporting the event in the electronic Safety Event Reporting System (SERS). Reports may be submitted in an identifiable or anonymous manner. Events should be reported as soon as possible within 24-hours of occurrence. The information in the report or generated from the event reporting system is confidential and privileged as outlined in the Ohio Revised Code Section 2305.25(D), 2305.252, and 2305.253. If a Needlestick or Bloodborne Pathogen Exposure occurs the caregiver must call the 24/7 BBPE HOTLINE at 216-445-0742 and they will speak directly with a nursing caregiver.

The CDC recommends the following based on knowledge of the source patient's Hepatitis B status as well as the health care workers Hepatitis B status:

Recommended post-exposure prophylaxis for exposure to Hepatitis B Virus Treatment

Vaccination/Antibody Status of Exposed Caregivers	Source Hepatitis B Surface Antigen Positive	Source Hepatitis B Surface Antigen Negative	Source Unknown or Not Available for Testing
Unvaccinated	Hepatitis B immune globulin and vaccination series.	Hepatitis B vaccination series.	Hepatitis B vaccination series.
Previously vaccinated:			
• Known responder	No treatment	No treatment	No treatment
• Known non-responder	Hepatitis B immunoglobulin and begin re-vaccination series or repeat Hepatitis B	No treatment	If known high risk source, treat as if source were Hepatitis B surface antigen positive.

	immunoglobulin (2 doses).		
• Antibody response unknown	Test exposed person for antibody to Hepatitis B surface antigen: 1. If adequate, no treatment necessary. 2. If inadequate, Hepatitis B immune globulin, and vaccine booster.	No treatment	Test exposed person for antibody to Hepatitis B surface antigen: 1. If adequate, no treatment necessary. 2. If inadequate, administer vaccine booster and recheck titer in 1-2 months.

View the updated CDC guidelines.

Trainee DEA Registration Number Policy

Purpose: It is the policy of the Cleveland Clinic that every medical trainee who administers, prescribes, dispenses, or distributes controlled substances must be registered with the Drug Enforcement Administration (DEA).

Policy Statement: Trainees are expected to update and maintain required documentation relating to DEA registration and to continue an active registration as long as the need to administer, prescribe, dispense, or distribute controlled substances is necessary in their training role. Refer to the Licensure/Certification/Clinical Competency Policy for details.

Trainees who practice in specialty areas that do not require the administration, prescription, dispensing, or distribution of controlled substances are not required to obtain a DEA Registration Number. Consult Graduate Medical Education Department (GME) regarding details.

Trainees whose DEA registration does not include all schedules required by their training program must inform the GME and their training program of any and all limitations/exceptions/exclusions regarding their DEA registration before their training start date and/or orientation date.

Trainees who plan to move to Ohio from another state or move their place of practice within the state must request an update/modification of their DEA Registration Number to reflect the state of Ohio.

Trainees who are appointed as limited clinical practitioners or moonlighters through the Office of Professional Staff Affairs are required to obtain a Personal DEA Registration Number to practice in said capacity. Refer to the Moonlighting Policy for details.

Trainees are not permitted to apply for a Personal DEA Registration Number until they have a permanent Ohio License.

Trainees with a Personal DEA Registration Number

GME will verify status of trainees' Personal DEA Registration Numbers.

Onboarding – Trainees who enter training with a Personal DEA Registration Number must

provide GME with documentation (e.g., wallet card) of said number including issue and expiration dates. GME will verify the information using primary source verification via the U.S. Department of Justice, Drug Enforcement Agency, Diversion Control Division website and upload supporting documentation while recording the Registration Number and expiration date in the trainees' MedHub records.

Maintenance – Personal DEA Registration Numbers stored in MedHub are automatically searched weekly for registration changes, schedule changes, and expirations. GME will monitor these reports regarding said changes and update records accordingly. GME will notify trainees prior to the expiration date of their Personal DEA Registration Number and recommend appropriate steps to ensure un-interruption of DEA registration. Documentation of changes is accomplished by the GME uploading an online verification of current Personal DEA Registration Number status using data provided by the U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division data files. This website is updated weekly and is an acceptable source of verification by the Joint Commission on Accreditation of Healthcare Organizations (JC) and National Committee for Quality Assurance (NCQA).

Trainees whose instate Personal DEA Registration Numbers lapse/expire while in training have the option to renew their personal registration with the U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division, or obtain the Institutional DEA Registration Number provided that the expired personal registration was in good standing. Additionally, the trainee must provide written details that the failure to renew in a timely manner with the U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division was not due to any current or pending corrective action on the part of the U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division or the State of Ohio Board of Pharmacy. Citing adequate evidence to the above and presenting the documented reasoning regarding the failure to renew an instate Personal DEA Registration Number with the U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division, the Main Campus Pharmacy would be able to issue the Institutional DEA Registration Number.

Trainees without a Personal DEA Registration Number

A suffix to be used with the Institutional DEA Registration Number is issued to Main Campus trainees without Personal DEA Registration Numbers by the institute for the duration of a given trainee's appointment. Reference Issuing Temporary DEA Number to Authorized Physicians Policy for more information regarding this policy. Trainees at Fairview Hospital and South Pointe Hospital have Institutional DEA Registration Numbers issued and verified by those respective institutions.

It shall be the responsibility of the GME to maintain and record as part of trainees' personnel records the assigned DEA Registration Number along with the issue and expiration dates when available.

Transition from Institutional DEA Registration Number to Personal DEA Registration Number while in training

In order to be eligible to apply for a Personal DEA Registration Number, trainees must first secure permanent medical licensure with the state of Ohio. Trainees are not permitted to apply for a Personal DEA Registration Number under a training certificate. All trainees who intend to procure a Personal DEA Registration Number when they have been issued and are currently

using an Institutional DEA Registration Number are required under this policy to notify GME when applying for a Personal DEA Registration Number. Trainees who acquire a Personal DEA Registration Number must provide GME with documentation (e.g., wallet card) of said number including issue and expiration dates. GME will verify the trainee's Personal DEA Registration Number and inform trainee, training program leadership, and appropriate Pharmacy regarding the rescinding of the Institutional DEA Registration Number. Under no circumstances shall any trainee whether knowingly or unknowingly administer or prescribe controlled substances under an Institutional DEA Registration Number when assigned a Personal DEA Registration Number. Doing so violates applicable codes and laws of the State of Ohio.

Trainees Visiting from another Institution with an Institutional or Personal DEA Registration Number

Trainees visiting from an outside institution are not eligible for an Institutional DEA Registration Number from Cleveland Clinic unless a special agreement is in place. Trainees shall provide either their Institutional DEA Registration Number from their home institution or Personal DEA Registration Number during the onboarding process. This information will be stored in MedHub and made available for programs to request electronic medical record access.

View the Trainee DEA Registration Number Policy.

Clinical Trainee Life Support Certification Policy

Purpose: The purpose of this policy is to define and standardize life support training requirements for all clinical trainees in Cleveland Clinic training programs under the sponsorship of the Main Campus Graduate Medical Education department.

Policy Statement: All clinical trainees who are involved in direct patient care are required to obtain and maintain active applicable certifications throughout their training to ensure they are capable of assessing the need for and initiating cardiopulmonary resuscitation according to established standards by the American Heart Association or equivalent organizations.

All clinical trainees are either required to enter their training program already in possession of required certification or obtain it within 45 days of beginning employment with the Cleveland Clinic. Recertification must be obtained prior to the expiration date of certificates. The program is responsible to make arrangements for clinical trainees to attend new or recertification course(s).

This policy outlines the following certifications and the acceptable course curricula:

a. **ACLS** – American Heart Association-accredited course (BLS is incorporated)
b. **BLS** – American Heart Association-accredited course
c. **NRP** – American Academy of Pediatrics-accredited course
d. **PALS** – American Heart Association-accredited course (BLS is incorporated)

Individual specialties may require additional certification(s) not outlined in this policy.

Documentation – Clinical trainees are expected to obtain certification(s) based on data in the appendix (grid of programs/requirements). The GMEC will review the attached grid bi-annually to ensure that required certifications meet institutional requirements. GME will monitor certification status on an ongoing basis and notify clinical trainees of upcoming expiration. Clinical trainees are required to provide copies of acceptable forms of documentation (ex. wallet

card) for storage in MedHub.

View the Clinical Trainee Life Support Certification Policy.

ACGME Policies

Institutional Clinical Experience and Education Work Hour Policy

Purpose: Providing clinical trainees with adequate academic and clinical education requires careful planning with specific considerations of the impact of training requirements and clinical and educational work hours on patient safety and the trainees' well-being. Didactic and clinical education must have priority in the allotment of the trainees' time and energy. The training program and its sponsoring department must establish an environment that is optimal for the trainees' education and for safe patient care, while ensuring that undue stress and fatigue among trainees is avoided. The structuring of clinical and educational work hours and on-call schedules must focus on the needs of the patient, continuity of care and the educational needs of the trainee while not being excessive.

The Graduate Medical Education Committee (GMEC) is committed to ensure that clinical trainees are able to report concerns regarding workhour requirements without retribution. This may be done in the following ways:

- Through the House Staff Association representatives or officers
- A meeting with the Director, Associate Director or Administrator of Graduate Medical Education (GME)
- Anonymous link on GME|com; comments automatically forwarded to the GME Administrator for investigation

Program Specific Work Hour Policy: Each training program must have a written policy and procedure consistent with the Institutional and program-specific RC requirements for clinical trainee clinical experience and educational work hours. The policy must regularly be distributed to the trainees and faculty within their program and reviewed annually to assure accuracy.

- Each program must ensure that the goals and objectives of the program are not compromised by excessive reliance on clinical trainees to fulfill service obligations
- Clinical experience and educational work hours must reflect the fact that responsibilities for continuing patient care are not automatically discharged at specific times
- Programs must mandate that clinical trainees are provided with appropriate senior and/or faculty back-up support at all times

Averaging Clinical and Educational Work Hours: All must occur by rotation (4 week block, month or the period of the rotation if shorter than 4 weeks). When rotations are shorter than 4 weeks, averaging must be done over these shorter rotations. This avoids heavy and light assignments being combined to achieve compliance. "Rolling" averages are not permitted. Programs that use a rotation period that is greater than 4 weeks will be provided with 4 week rotation review periods (the system will overlap the last 2 weeks of a rotation with the first 2 weeks of the next rotation; the single work period and shift violations will not double count, but the system will take into consideration the 80-hour maximum and the 1 day off in 7 violations over the overlapping time period). Programs that use a rotation period that is less than 4 weeks will be provided with the Cleveland Clinic module dates review periods. If a clinical trainee takes vacation or other leave, those vacation or leave days are omitted from the numerator and

the denominator when calculating clinical and educational work hours and days off. For example, if a clinical trainee is on vacation for one week, the hours will be averaged over the remaining 3 weeks or the remainder of the rotation if shorter than 4 weeks.

Clinical Experience and Educational Work Hours Requirements

Maximum Hours of Clinical and Educational Work per Week: Clinical and educational work hours must be limited to no more than 80 hours per week, averaged over a four-week period/rotation, inclusive of all in-house clinical and educational activities, clinical work done from home, and all moonlighting.

Clinical and Educational Work Hours are defined as all clinical and academic activities related to the program. The following must be included when reporting hours:

- Patient care (both inpatient and outpatient)
- Administrative duties related to patient care
- The provision for transfer of patient care
- Time spent in-house during call activities
- In-hospital hours when on the phone
- Scheduled academic activities such as conferences
- Required research (research hours or any combination of research/patient care activities)
- Hours spent on activities that are required by the accreditation standards, such as membership on a hospital committee, or that are accepted practice in programs, such as clinical trainees' participation in interviewing program candidates
- Time spent at regional/national conferences/meetings when attendance at the meeting is required by the program, or when the clinical trainee is acting as a representative of the program (i.e. presenting a paper or poster). Only actual meeting time counts; travel and non-conference time is excluded.
- Any tasks related to performance of duties, even if performed at home, count toward the 80-hour limit

The following should not be included when reporting hours:

- Reading and study time spent away from the work site
- Academic preparation time, such as time spent preparing for presentations or journal clubs

Mandatory Time Free of Clinical Work and Education:

1. Clinical trainees should have eight hours off between scheduled clinical work and education periods
    - There may be circumstances when clinical trainees choose to stay to care for their patients or return to the hospital with fewer than eight hours free of clinical experience and education. This must occur within the context of the 80-hour and the 1 day off in 7 requirements.
2. Clinical trainees must have at least 14 hours free of clinical work and education after 24 hours of in-house call
3. Clinical trainees must be scheduled for a minimum of 1 day in 7 free of clinical work and required education (when averaged over 4 weeks/rotation).
    - One (1) day is defined as one continuous 24-hour period free from all clinical, educational, and administrative activities
    - At-home call cannot be assigned on these free days

- It is not permissible to have the day off regularly or frequently scheduled on a clinical trainee's post-call day
- Because at-home call does not require a rest period, the day after at-home call may be used as a day off, but extended or prolonged at-home call is not permitted as it would be in violation of the 1 day off in 7 requirement.

Maximum Clinical Work and Education Period Length: Clinical and educational work periods for clinical trainees must not exceed 24 hours of continuous scheduled clinical assignments. Programs must encourage clinical trainees to use alertness management strategies in the context of patient care responsibilities.

1. Clinical trainees may be allowed to remain on-site in order to accomplish transition in care or to attend educational conferences; however, this period of time must be no longer than an additional four hours. During this four-hour period, clinical trainees must not be permitted to participate in the care of new patients in any setting, must not be assigned to outpatient clinics including continuity clinics, and must not be assigned to participate in a new procedure.
2. Clinical trainees must not be assigned additional clinical responsibilities after 24 hours of continuous in-house work.
    a) Additional clinical responsibilities that clinical trainees must not be assigned to include: the care of new patients in any clinical setting; continuity or outpatient clinics; participation in new procedures including elective scheduled surgery.
3. Clinical trainees may be allowed to remain on site for patient safety or clinical trainee education; however, this period of time must be no longer than an additional four hours.
4. In unusual circumstances, clinical trainees, on their own initiative, may remain beyond their scheduled period of work to continue to provide care to a single patient. Justifications for such extensions of work are limited to reasons of required continuity for a severely ill or unstable patient, academic importance of the events transpiring, or humanistic attention to the needs of a patient or family.
    a) Under those circumstances, the clinical trainee must appropriately hand over the care of all other patients to the team responsible for their continuing care and document the reasons for remaining to care for the patient in question and submit that documentation in every circumstance in MedHub.
    b) The Program Director must review each submission of additional service, and track both individual clinical trainee and program-wide episodes of additional work.
    c) These additional hours of care or education will be counted toward the 80-hour weekly limit.

Maximum In-House On-Call Frequency: Clinical trainees must be scheduled for in-house call no more frequently than every third night (when averaged over a four-week period).

Maximum At-Home Call Frequency: The Program Director must monitor the demands of at-home call in their programs and make scheduling adjustments as necessary to mitigate excessive service demands and/or fatigue.

- Time spent on patient care activities by clinical trainees on at-home call must count toward the 80-hour maximum weekly limit. The frequency of at-home call is not subject to the every-third-night limitation, but must satisfy the requirement for one day in seven free of clinical work and education, when averaged over four weeks/rotation.

- At-home call must not be so frequent or taxing as to preclude rest or reasonable personal time for each resident
- Clinical trainees are permitted to return to the hospital while on at-home call to provide direct care for new or established patients. These hours of inpatient patient care must be included in the 80-hour maximum weekly limit

In-House Night Float: Night float must occur within the context of the 80-hour and 1 day off in 7 requirements. The maximum number of consecutive weeks of night float, and maximum number of months of night float per year may be further specified by the Review Committee.

Moonlighting: Because graduate medical education is a full-time endeavor, the Program Director must ensure that moonlighting does not interfere with the ability of the clinical trainee to achieve the goals and objectives of the educational program. The Program Director must comply with Cleveland Clinic's Moonlighting Policy, as well as ACGME requirements and/or federal regulations.

- Moonlighting is voluntary: clinical trainees must not be required to engage in moonlighting
- All clinical trainees who moonlight must be compensated for their time and hold a current permanent license issued by the State Medical Board of Ohio
- PGY 1 trainees are not permitted to moonlight
- Clinical trainees on clinical J-1 exchange visitor visas are NOT permitted to engage in independent patient care activities due to federal regulations that restrict unsupervised medical practice
- Time spent moonlighting (internal and external) must be counted toward the 80-hour weekly limit

<u>Alertness Management</u>
In accordance with the ACGME Common Program Requirements, all programs must educate their faculty and trainees in alertness management and fatigue mitigation processes, including recognizing signs of fatigue and sleep deprivation. All new clinical trainees are required to complete the online MyLearning course entitled "Sleepiness and Fatigue in Medical Professionals" within the first 90-days of training. Annually, all clinical trainees are required to complete the refresher course of "Sleepiness and Fatigue in Medical Professionals."

The Rest Ensures Safe Treatment (REST) Room, located in TT5-517, is a designated call room in the event that a clinical trainee is fatigued from post-call, coming into hospital from at-home call or for strategic napping, etc. Programs must provide a form of transportation for clinical trainees who may be too fatigued to safely return home; an acceptable method would be reimbursement or vouchers for a taxi or other means of public transportation. Each program must also have their own policies and procedures in place that ensure coverage of patient care in the event that a resident may be unable to perform their patient care responsibilities. These policies must be implemented without fear of negative consequences for the resident who is unable to provide the clinical work.

Clinical Trainee Responsibilities Relating to Recording Clinical Experience and Educational Work Hours: Clinical trainees MUST complete a weekly timesheet in MedHub, the institutional residency management system, by recording their in and out times of each day worked. They must also tag the time entered to an activity by choosing from the following: Standard Work

Period, Internal Moonlighting, External Moonlighting, Home Call (called in) or Work from Home. After completing each weekly timesheet, the trainees must select the 'Submit Completed Work Hours' button to confirm recorded hours. The trainee always has access to the current week and prior week to record their work hours. Recording of work hours in MedHub is required for all clinical trainees; 100% compliance is expected. Failure to do so is looked upon as unprofessional behavior and should be duly addressed by the Program Director; repeat offenses/non-compliance with reporting or breaking of clinical experience and educational hour rules may be result in disciplinary action.

Activity flagged by MedHub as a violation on a specific timesheet is an actual violation if the trainee violated the single work period (8-hour break, 24+4 hours max), but only a "potential violation" regarding the 80-hour rule and 1-day-off-in-7, as it is not averaged over a four-week period. Regardless if the violation is actual or potential, MedHub will ask the trainee to document a mitigating reason. This allows both the trainee and the program to identify and correct potential work hour problems before they actually occur.

Program Oversight of Clinical Trainees Clinical Experience and Educational Work Hours: Clinical experience and educational work hours (including moonlighting) must be monitored at the program level with a frequency sufficient to ensure an appropriate balance between education and service and compliance with ACGME requirements. Programs must have a process to ensure continuity of patient care in the event that a clinical trainee may be unable to perform his or her patient care duties.

At the conclusion of each rotation the Program Director will have access to the Work Hours Review Periods section in MedHub. This will provide the Program Director with any clinical experience and educational work hour's violations, details of the violation and the rationale provide by the clinical trainee when logging their mitigating reason. The Program Director is responsible for reviewing each violation, providing a comment and using that information when adjudicating/justifying their work hour violations. Every quarter, the program is responsible for providing the Institute Education Committee with the number of adjudicated and justifiable work hour violations incurred by their trainees.

Institute Education Committee Oversight of Clinical Experience and Educational Work Hours: The GMEC requires that each Institute Education Committee review the Work Hours Review Periods information and program submitted adjudicated/justifiable work hour violations for each accredited program on a quarterly basis. The Institute Education Committee will complete an Excel sheet provided by the GME department that contains the work hour violations as determined by MedHub and the program submitted adjudicated/justifiable work hour violations. Each Institute Education Committee data will be placed on a GMEC agenda for discussion.

GMEC Oversight of Clinical Experience and Educational Work Hours: The GMEC will monitor each training program's work hours on a quarterly basis through the review of the Institute Education Committee Excel sheet data and Work Hours Review Periods reports from MedHub. Based on the extent and severity of non-compliance, the GMEC will determine if any additional followed-up is required. A survey of clinical trainees may be conducted; after the survey results are compiled, the Program Director will be required to produce a written plan of action. If areas of non-compliance are still in existence, the Program Director may be invited to a GMEC meeting to discuss the non-compliance issues and program response. The GMEC will continue to follow-up until compliance with all requirements is achieved.

The GMEC will also monitor compliance of clinical experience and educational work hours through:

- Annual Cleveland Clinic Evaluation of a Training Program results
- Annual ACGME Clinical Trainee Survey results
- GME Executive Review process
- Program Improvement Plan (PIP) process
- RC Notification Letters
- Periodic monitoring of individual programs
- Random surveying of clinical trainees as determined by Council
- GMEC Special Review Process

Moonlighting Policy

The time spent in Graduate Medical Education is designed and dedicated to achieving competence in clinical care and academic excellence within the chosen specialty. Moonlighting is permitted if opportunities exist that, in the opinion of program director, does not interfere with the main objectives of training, adherence to work hour rules, or with the wellbeing of the Resident or Fellow. The Accreditation Council for Graduate Medical Education (ACGME) requires that Sponsoring Institutions have a written policy on moonlighting. The Graduate Medical Education Council (GMEC) is responsible for monitoring and advising on all aspects of training at Cleveland Clinic, including but not limited to, each program's adherence to the prudent work requirement limits set by the Review Committees (RC).

In this capacity, the GMEC has implemented the following general rules regarding moonlighting:

1. PGY1 Clinical trainees are NOT permitted to moonlight.
2. Moonlighting must occur outside training hours and not conflict with training activities. This means moonlighting may occur in the evening or on weekends based on the Resident or Fellows educational/program responsibilities.
3. Moonlighting must not interfere with the ability of the Resident or Fellow to achieve the goals and objectives of the educational program or hinder patient care in any way.
4. Clinical trainees must not be required to moonlight.
5. Each academic year Clinical trainees who would like to moonlight must submit a Moonlighting Request in MedHub with details on location, description, type (internal/external), start/end date, and number of hours per week. This will be routed to the PD for review. If approved by the PD, the request would then go to the GME Office for secondary approval. The GME Office would ensure that the resident/fellow meets all needed parameters to qualify for moonlighting and take action accordingly.
6. All moonlighting (internal and external) must be counted toward the 80 hour weekly limit on workhours and Clinical trainees must document and account for all approved internal and external moonlighting activities in MedHub.
7. As required by the Joint Commission (JC), Clinical trainees engaged in moonlighting (regardless of level of responsibility and/or supervision) must hold a current permanent license issued by the State Medical Board of Ohio.
8. As required by the DEA and Board of Pharmacy, any resident or fellow engaged in moonlighting that could involve writing a script for a scheduled drug must obtain their own personal DEA number. Once a personal DEA number is obtained it will be used for all purposes and the institutional DEA must no longer be used. Programs may appeal to the GME Office for an exemption if circumstances prevent the resident from writing a script for or providing scheduled drugs bedside. This applies in the case of pathology trainees who do not see patients, or imaging trainees providing oversight for contrast reactions at family health centers where no drugs are available to be administered.
9. Clinical trainees on J-1 visas are not eligible to moonlight under any circumstances due to federal regulations which do not permit activity and/or compensation outside of the sponsored program, or moonlighting.

Types of Moonlighting

1. External moonlighting: Voluntary, compensated, medically-related work performed outside the institution where the clinical trainee is in training and any of its related participating sites.
    - It is the responsibility of the institution hiring the Resident or Fellow to determine whether licensure and DEA number are in place, adequate liability is provided and whether the Resident or Fellow has the appropriate training and skills to carry out assigned duties during moonlighting assignments.
    - Cleveland Clinic malpractice liability coverage does not cover external moonlighting, the Resident of Fellow will need to acquire their own liability insurance.

2. Internal Moonlighting: Voluntary, compensated, medically-related work performed within the institution in which the Resident or Fellow is in training or other Cleveland Clinic sites. There are two types of internal moonlighting:

    A. Independent patient care activities at Cleveland Clinic or within the Cleveland Clinic Health System (CCHS)
        - Requires credentialing and appointment through Main Campus Professional Staff Affairs and/or Regional Hospital Medical Staff Office(s), where applicable.
        - Clinical trainees in accredited programs must have RC approval specific to independent practice
            - Clinical trainees can only be credentialed for independent practice in the area/field in which they are board certified/eligible; credentialing will not be granted in areas of practice specific to scope of current training program.

    B. Supplemental on-call or any other supplemental responsibilities that are within the scope of the Clinical trainees training and commensurate with the Clinical trainees level of experience and skill.
        - These supplemental responsibilities must be fully supervised
        - Must occur outside normal training hours

Permission to Moonlight: The decision to allow Clinical trainees in any training program to participate in moonlighting activities shall be at the discretion of the Program Director. The Program Director may decide that a Resident or Fellow may not moonlight for any of the following reasons:

1. The moonlighting activity would lead to exceeding the RC requirement that limits work hours.
2. The Resident or Fellow is unable to meet any of the requirements of the training program.
3. The Resident or Fellow's performance doesn't meet expected competency based Milestones.
4. The Program Director feels the requirements of the program are such that none of the Resident or Fellow in the training program may moonlight.
5. The Resident or Fellow exhibits signs of fatigue during training activities.

Program Directors must review and take action on all Moonlighting Requests in MedHub and assist the resident or fellow in the credentialing/appointment process, if applicable. Program Directors must monitor the performance of the Resident or Fellow to assure that factors such as fatigue are not contributing to diminished learning, substandard performance, or inadequate patient care. If a Program Director identifies any of these issues with a Resident or Fellow who is moonlighting, the Program Director would advise the Resident or Fellow to discontinue moonlighting activities. If a Resident or Fellow is found to be moonlighting without Program Director approval, the Resident or Fellow may be subject to disciplinary action.

The Program Director must also monitor that the resident or fellow is including moonlighting in their work hours submissions as required by the ACGME.

View the complete Moonlighting Policy.

Clinical Trainee Work Environment

Graduate Medical Education at Cleveland Clinic is committed to promoting a learning environment where patient safety and clinical trainee wellbeing are of paramount importance. Education of clinical trainees must occur in an environment in which they are able to raise and resolve issues without fear of intimidation or retaliation. An organizational system for clinical trainees to communicate and exchange information about their work environment and their programs will be provided in a confidential and protected manner. This may be accomplished through direct communication with the Program Director, Chief Resident, and Faculty or with the Director or the Administrative Directors of Graduate Medical Education and/or through the House Staff Association.

The following services are provided to support the environment in which clinical trainees work, and maximize the educational value of the time spent in clinical activities. Please refer to your institutions Benefit Booklet for details on to access these services.

a) Food Services: Clinical trainees on duty must have access to adequate and appropriate food services. Clinical trainees who are required to be in-house overnight call are provided with on-call meals.
b) Call Rooms: Cleveland Clinic maintains on-call rooms for clinical trainees who are on in-house overnight call. Any clinical trainee required to be in-house must have access to a call room.
c) Caring For Caregivers: Employee Assistance Programs: Cleveland Clinic and the Education Institute are committed to the wellbeing of clinical trainees and understand how personal and work stresses can impact your quality of life and ability to provide skillful and compassionate care. The Caring for Caregivers Programs offer expert, confidential and free support through various referrals and resources. To learn more, seek assistance confidentially, schedule an appointment or speak to a counselor immediately, call 216-445-6970. For additional information, refer to Caring for Caregivers.
d) Laboratory/Pathology/Radiology Services: There are laboratory, pathology, and radiology services to support timely and quality patient care in all training programs. This includes 24-hour retrievals of laboratory, pathology, and radiology information via electronic or online systems. All clinical trainees have access to this patient information through EPIC.
e) Support Services: Patient support services, such as intravenous services, phlebotomy services, and patient transportation services are provided to all clinical trainees and training programs.
f) Medical Records: Cleveland Clinic utilizes EPIC System's electronic medical record (EMR). There are several components to the Epic System software that include an outpatient electronic medical record (EpicCare) and an inpatient electronic medical record (Epic Inpatient) as well as a scheduling/registration, patient access and inpatient pharmacy. These integrated components are accessed through a single MyPractice/Epic Systems login screen. Providers use EPIC to document each patient's illness, treatment and care; the EMR is available at all times except during scheduled downtimes. The system supports quality patient care, the education of clinical trainees, quality assurance activities, and provides a resource for scholarly activity.
g) Security/Safety: Appropriate security and personal safety measures are provided to clinical trainees at all Cleveland Clinic locations including but not limited to parking facilities, on-call quarters, hospital and institutional grounds, and related clinical facilities. Cleveland Clinic has a safety and security program that conforms to all

applicable local, state and federal safety and health standards, fire codes and environmental regulations. Security is provided by the Cleveland Clinic Police Department. Personal security escorts are provided by contacting the Cleveland Clinic Police Department for trainees who are concerned about displacement on campus.

h) Transportation: Training programs offer a taxi service for clinical trainees who may be too fatigued to safely return home. The taxi services are reimbursable through each department. Clinical trainees in need of this service should contact their Chief Resident, Program Coordinator or Program Director for more information.

i) Space: Cleveland Clinic offers conference rooms with AV equipment, computers and access to library material. Programs also provide workspace areas for trainees in their programs, please contact the Program Coordinator regarding what is available in the clinical area.

j) Simulation and Advanced Skills Center: Cleveland Clinic has a 10,000-square-foot multidisciplinary Simulation and Advanced Skills Center which is open to physicians, nurses, clinical trainees and allied health professionals. Simulation-based education offers education and training for clinical trainees and other healthcare providers in a low stress, risk-free environment with the goal of promoting active, hands-on learning opportunities and delivering quality patient care. The Simulation and Advanced Skills Center has a focus on skill building in teamwork and communication. The Center offers some of the newest simulation technology, including a patient simulator that responds to drugs; a fully functional OR equipped with oxygen and gases; a difficult airway center; 4 ICU beds; debrief rooms and audio/video recording for performance evaluation in debrief rooms or via the intranet. Simulation Center staff can assist faculty in building and creating scenarios.

k) iPhones: iPhones are made available to all clinical trainees, which allow 24/7 access to key applications such as the IRIS app. This app permits patient record retrieval (including images). The impetus for this significant institutional commitment is the belief that this technology will assist clinical trainees in conducting improved transitions of care through the hand off tool in EPIC, our institutional electronic medical record system and will enhance quality and patient safety.

l) Additional Program Resources: Cleveland Clinic and each program must ensure that adequate resources (e.g., sufficient laboratory space and equipment, computer and statistical consultation services) are available to clinical trainees. In addition, necessary professional, technical and clerical personnel must be provided to support the program.

Emergent Situations or Disasters (Extreme Events) Policy

The purpose of this policy is to:

- Minimize the impact of an extreme event or disaster on clinical trainees and to protect their well-being, safety and educational experience.
- Provide general information and procedures to support Cleveland Clinic GME programs and clinical trainees in the event of a disaster or interruption in their educational experience.
- Provide guidelines for communication with Program Directors and clinical trainees regarding reconstitution or restructuring of a clinical trainees educational experience as rapidly as possible after an extreme event or determining the need for transfer or closure in the event of that normal program activity cannot be reconstituted.

For purposes of this policy an extreme event can be either:

- A disaster – defined as an event or set of events causing significant alteration to the clinical trainee experience at one or more training programs in an entire community or region. These may include, but are not limited to natural disasters (tornado, external flood, earthquake, etc.) or terrorism. The ACGME Executive Director makes the declaration of a disaster or
- An extreme emergent situation – defined as a local event (such as a hospital-declared disaster for an epidemic) that affects clinical trainee education or the work environment but does not rise to the level of an ACGME-declared disaster.

The primary source for communication regarding an extreme event and recovery plan for Program Directors, Program Coordinators and clinical trainees will be GME|com. This will likely be complemented by other communications via other CC electronic venues.

Clinical trainees are first and foremost healthcare providers, whether they are acting under normal circumstances or in extreme events as defined above. Clinical trainees must be expected to perform according to society's expectations of healthcare providers as professionals and leaders in health care delivery. Decisions regarding a clinical trainee involvement in local extreme emergent situations must take into account the following aspects of his or her multiple roles as a trainee, a physician and an institutional employee:

- The nature of the health care and the clinical work they are expected to deliver;
- Clinical trainees level of post-graduate education;
- Clinical trainees safety, considering their level of post-graduate training, associated professional judgment, capacity and the nature of the disaster at hand;
- Board certification eligibility during or after a prolonged extreme emergent situation;
- Reasonable expectations for duration of engagement in the extreme emergent situation;
- Self-limitations according to the clinical trainee's maturity to act under significant stress or even duress

Clinical trainees are students who should not be first-line responders without appropriate supervision given the clinical situation at hand and their level of training and competence. If a clinical trainee is working under a training certificate from a state licensing board, he or she must work under supervision. Clinical trainee performance during extreme events should not exceed expectations for their scope of competence as judged by Program Directors and other attending physicians. In addition, a clinical trainee must not be expected to perform in any situations outside of the scope of their individual license.

DIO/GME Office Process for an Extreme Emergent Situation: The Program Directors first point of contact for answers regarding an extreme emergent situation and the resulting impact on clinical trainee education and work environment must be the Director of GME/Designated Institutional Official (DIO) or his or her designee. The DIO will contact the Executive Director of the Institutional Review Committee (ED-IRC) via telephone only if an extreme emergent situation causes serious extended disruption to resident and fellow assignments, educational infrastructure or clinical operations that might affect the Sponsoring Institution's or any of its programs' ability to conduct resident education in substantial compliance with ACGME, Institutional, Common and Specialty-Specific Program Requirements. The DIO will provide information to the ED-IRC regarding the extreme emergent situation and the status of the educational environment for its accredited programs resulting from the extreme event. The DIO

will receive electronic confirmation of this communication with the ED-IRC which will include copies to all EDs of Review Committees (RCs).

Only upon receipt of this confirmation by the DIO, may the Program Directors contact their respective EDs-RCs if necessary, to discuss any specialty-specific concerns regarding interruptions to resident education or effect on educational environment. Program Directors are expected to update the DIO on the results of conversations with EDs-RCs, regarding any specialty-specific issues. The DIO will notify the ED-IRC when the institutional extreme emergent situation has been resolved.

DIO/GME Office Process for a Disaster: The Program Directors first point of contact for answers regarding a disaster and the resulting impact on clinical trainee education and work environment, must be the Director of GME/DIO or designee. The DIO will contact the Executive Director of the Institutional Review Committee (ED-IRC) via telephone in the case of a disaster which causes serious, extended disruption to resident and fellow assignments, educational infrastructure or clinical operations that might affect the Sponsoring Institution's and its programs' ability to conduct resident and fellow education in substantial compliance with ACGME Institutional, Common, and specialty-specific Program Requirements.

The DIO will monitor progress of both healthcare delivery and functional status of GME programs for their educational mission during and following a disaster. The DIO or designee will call or email the ED-IRC with information and/or requests for information. Similarly the Program Directors will contact the appropriate ED-RC with information and/or requests for information. Clinical trainees can call or email the appropriate ED-RC with information and/or requests for information.

The DIO or designee will work with the ACGME to determine the appropriate timing and action of the options for disaster impacted institution and/or programs:

- Maintain functionality and integrity of program(s)
- Arrange temporary transfers of clinical trainees to other programs/institutions until such time as the training program(s) can provide an adequate educational experience for each of its clinical trainees
- Assist the clinical trainees in permanent transfers to other programs/institutions, as necessitated by program or institution closure

If more than one program/institution is available for temporary or permanent transfer of a particular clinical trainee, the transfer preferences of each clinical trainee will be considered. Decisions to keep/transfer will be made expeditiously so as to maximize the likelihood that each house officer will complete the training year in a timely manner.

Within ten days after the declaration of a disaster by the ACGME, the DIO or his or her designee will contact ACGME to discuss due dates that ACGME will establish for the programs: (a) to submit program reconfigurations to ACGME and (b) to inform each program's house officers of transfer decisions. The due dates for submission shall be no later than 30 days after the disaster unless other due dates are approved by ACGME.

Every effort will be made to insure that clinical trainees continue to receive their salary and fringe benefits during disaster event response and recovery period and/or accumulate salary and benefits until such time as utility restoration allows for fund transfer. Clinical trainees should

frequently refer to GME|com to keep informed regarding the status of programs affected by the extreme event.

Residency Closure/Reduction Policy

In order to reiterate the institutional commitment of the Cleveland Clinic to graduate medical education, the following policy has been established and approved by the Graduate Medical Education Council (GMEC). The Cleveland Clinic will inform the GMEC, the Designated Institutional Office and the affected clinical trainees as soon as possible, when it decides to reduce the size of or close one or more programs or when the Cleveland Clinic intends to close. In the event Cleveland Clinic decides to reduce the number of residency or fellowship positions in any ACGME program, Cleveland Clinic will attempt to reduce the numbers over a period of time so that it will not affect the clinical trainees currently in the program. If this is not possible, Cleveland Clinic will make reasonable efforts to assist the clinical trainees in identifying and entering another ACGME program.

In the event Cleveland Clinic decides to close a residency or fellowship program, the clinical trainees in it or committed to it, will be allowed to complete their education if faculty and patient material is adequate. If either faculty or patient material is inadequate, the Cleveland Clinic will make reasonable efforts to assist the clinical trainees in identifying and entering another ACGME program. In the event that Cleveland Clinic was to close, the DIO and the GMEC would be notified as soon as possible. The DIO would work in conjunction with the ACGME, the GMEC and Cleveland Clinic Program Directors as well as local teaching hospitals to arrange permanent transfers for clinical trainees to other ACGME programs. If a reduction or closure would occur at Cleveland Clinic, the DIO and the GMEC would work with the Program Director of the affected program(s) to develop a rotation at another medical center that could offer the requisite educational experience.

Accepting Clinical Trainees from Other Programs Due to Emergent Situations, Disasters or Program Closures

There may be situations which require training programs in other academic medical centers to seek temporary or permanent positions for their clinical trainees. This policy is intended to provide guidance to Cleveland Clinic Program Directors who may be asked to provide positions for clinical trainees who are unable to continue in their current programs due to an emergent or disaster situation.

When a Cleveland Clinic Program Director is approached about accepting a displaced clinical trainee, the first point of contact should be the DIO at Cleveland Clinic to determine the feasibility of sponsoring an additional clinical trainee. The Program Director will be asked to provide assurance documentation that; 1) there is enough clinical material available for an additional clinical trainee 2) an additional clinical trainee will not negatively impact the training experience of current clinical trainees, rotators and/or medical students and 3) this request has been presented to and approved by the appropriate (institute or academic) education committee. If the DIO is satisfied that the program meets these criteria, the process will move forward.

The DIO will contact the ACGME to ascertain the status of the academic medical center/program currently sponsoring the displaced clinical trainee. If it is confirmed that clinical trainees are being relocated to other training programs and the Cleveland Clinic Program Director is interested, the DIO (or GMEC representative) will contact the current sponsoring institution regarding transfer of the FTE (for CMS GME reimbursement). If the FTE is not

transferred, the clinical department at Cleveland Clinic would need to financially sponsor the displaced clinical trainee from department operating funds.

Rotations Policy

Cleveland Clinic is committed to providing clinical trainees with an educational program that offers an experience of learning and broad education in the science and art of medicine. Recognizing that some educational experiences may need to be obtained outside of Cleveland Clinic or one of its affiliates, this policy is adopted concerning those experiences.

In compliance with ACGME Requirements; the Sponsoring Institution (Cleveland Clinic) and the training Program Director have responsibility for monitoring the quality of GME, including when clinical trainee education occurs in other institutions. There must be full consideration of the quality of the rotation, including goals, objectives and supervision, the educational necessity of the rotation, the accreditation implications and the financial implications of the rotation. It is also expected that the site will provide all ancillary services as expected by the ACGME as well as provide sufficient workspace and sleeping quarters if applicable.

Program Directors must ensure that each rotation (required or elective) complies with RC specialty specific requirements and board requirements for training. Numerous options for elective rotations in a wide variety of specialties and settings are available within Cleveland Clinic Health System (CCHS) and clinical trainees should be encouraged to schedule their elective rotations within the system. If a clinical trainee selects an elective option not available within the CCHS, the Program Director would make the decision based on educational merit. Please note: Electives outside of CCHS are not covered under Cleveland Clinic malpractice; coverage will need to be obtained through the institution which the clinical trainee is rotating or the clinical trainee may purchase an individual policy. The program is responsible for assuring this is in place prior to the rotation.

All Cleveland Clinic affiliation agreements must go through an internal review process with the GME office prior to signing. The review process will ensure accuracy, compliance, and appropriateness of the relationship with the external site. The Training Affiliation Agreement Request Form must be completed and submitted to the GMEC office 10-weeks prior to the scheduled start of the proposed rotation and/or for renewal of the rotation. The GME office will then contact the site, ensure the appropriate affiliation agreement template is filled out correctly, and route the agreement for signatures. Failure to adhere to proper procedures could result in delays in agreement processing. Please refer to the International Away Rotations Policy for information on experiences outside of the United States.

Required Rotations: Rotations are considered required rotations when all clinical trainees (at a specific graduate level or anytime during training) are scheduled for the rotation. Required rotations should be obtained within CCHS whenever possible. If an experience which is a required component of the program truly cannot be obtained within CCHS (such as trauma experience), the institution will provide malpractice insurance for the rotation.

Elective Rotations: Many programs provide elective time for their clinical trainees to gain additional experience in work environments or subspecialties of particular interest. As CCHS provides a vast diversity of experiences (tertiary care center experiences, community hospital and various ambulatory settings) it is expected that clinical trainees complete their elective experiences within the system whenever possible. When a clinical trainee is interested in an

experience outside of CCHS approval and proof of malpractice must be obtained as Cleveland Clinic does not extend malpractice coverage for clinical trainees on elective rotations outside of CCHS.

Program Director Responsibilities when clinical trainees(s) are on rotations:

1. Ensure that a current affiliation agreement exists that meets ACGME Common & RC-specific requirements and is reviewed at least annually and revised every five (5) years or sooner if significant changes such as: Program Director, Site Director, Goals & Objectives, PGY level or length of the rotation occur.
2. Ensure that there are competency-based goals and objectives and that they are distributed to the clinical trainee prior to the rotation.
3. Ensure that the patient care responsibility is appropriate for the clinical trainee's level and ability.
4. Monitor all aspects of the rotation, including:
    a) Curriculum, including conference participation at participating site(s)
    b) The on-call schedule to assure appropriate supervision and adequate back-up while on-call
    c) Work hours of clinical trainees
    d) Compliance with ACGME common program requirements, RC specialty requirements and policies, including, but not limited to: work hours, fatigue mitigation and supervision
    e) Evaluations are completed for the clinical trainees by attending faculty
    f) That clinical trainees complete evaluations for the attending faculty with whom they rotate
    g) That clinical trainees complete a rotation evaluation at the completion of the rotation. Any evaluation reflecting a significantly negative experience should result in a personal interview with that clinical trainee and follow-up with the Site Director if necessary.
5. Participate in regular and ongoing communication with the Site Director.
6. Ensure that the rotation is providing the clinical trainee with a quality educational experience (didactic conferences as well as clinical education) as described in the rotation goals and objectives.
7. Ensure that the clinical trainee is informed of and adhere to established educational and clinical practices, policies and procedures at all sites to which clinical trainees are assigned.
8. Conduct annual visits the site and meet with the Site Director of the participating site(s) to assure an optimal experience.
9. In conjunction with the Site Director; monitor the clinical trainee's work environment, which includes but is not limited to adequate food service, call rooms, patient support services, laboratory/pathology/radiology services, medical records, lactation room availability, safety/security and parking.

Procedure for Offsite Required Rotations: For Required rotations, all clinical trainees in the program at a particular PGY level must participate in the rotation, which must be a required component of the curriculum and noted on the ACGME ADS block diagram. The Training Affiliation Agreement Request Form must be completed and submitted to the GME office 10-weeks prior to the scheduled start of the proposed rotation. The GME office will then contact the site, ensure the appropriate affiliation agreement template is filled out correctly, and route the agreement for signatures.

Affiliation Agreements are required for all non-Cleveland Clinic external sites and Cleveland Clinic Regional Hospitals. The maximum term for an affiliation agreement is five years, but the term length can fluctuate depending on the specific circumstances with the site and rotation experience. The program must submit Goals and Objectives for the particular rotation they are requesting.

Executed versions of the affiliation agreement are stored in the GME office, with Cleveland Clinic legal, and uploaded in MedHub. The Cleveland Clinic program and participating site contacts will receive the executed version of the affiliation agreement. Once there is an affiliation agreement in place, the site must be listed appropriately in the ACGME ADS system under the participating sites location, on the programs academic year block diagram and in MedHub. Any time spent at the external site must be reflected on the MedHub schedule and tagged appropriately.

Procedure for Offsite Elective Rotations: For elective rotations, the clinical trainee must first seek approval from their Program Director to pursue the elective experience. By pursuing the elective, the clinical trainee will need to ensure that they have enough elective time to accommodate the experience. Elective time must be available on the block diagram in order for the clinical trainee to pursue the experience. While the clinical trainee is on an elective rotation, the PC must appropriately track their time away in MedHub. The clinical trainee must be Board eligible by the time of graduation, and the elective experience should not impede this requirement.

Clinical trainees may participate in domestic elective experiences outside of Cleveland Clinic sites, if approved by the PD, however, as the sponsoring site, Cleveland Clinic does not provide clinical trainees with malpractice insurance for elective rotations. It will be the responsibility of the clinical trainee to purchase the coverage for the rotation. Proof of purchased malpractice insurance coverage must be submitted to the participating site stored in the clinical trainee MedHub file and also included with the executed affiliation agreement. The clinical trainee will have to complete appropriate onboarding requirements, including but not limited to, fulfilling medical licensure requirements.

The Training Affiliation Agreement Request Form must be completed and submitted to the GME office 10-weeks prior to the scheduled start of the proposed rotation. The GME office will then contact the site, ensure the appropriate affiliation agreement template is filled out correctly, and route the agreement for signatures. Affiliation agreements for elective experiences should be done on the specific elective affiliation agreement template, and the term of the agreement should only cover the specific rotation dates.

Executed versions of the affiliation agreement are stored in the GME office, with Cleveland Clinic legal, and also uploaded in MedHub. The Cleveland Clinic program and participating site contacts will receive an executed version of the affiliation agreement. Any time spent at the external site must be reflected on the MedHub schedule and tagged appropriately.

Procedure for Visiting Resident/Fellow Rotations: The Visiting Resident Appointment Request Form must be submitted to the appropriate GME staff no less than 10 weeks prior to the start date of the requested rotation for new visiting clinical trainees and 4 weeks prior for returning visiting clinical trainees. If the visiting resident appointment request form is missing any

information, the form may be returned and could delay the rotation. After a completed visiting resident appointment request form is provided to GME by the Program Coordinator, the GME office will have the necessary information to initiate the affiliation agreement process with the sponsoring site. The GME office will work in conjunction with the sponsoring site and Cleveland Clinic program to ensure that the template is filled out accurately prior to signing. Cleveland Clinic will never provide the malpractice insurance for a visiting resident/fellow. The visiting resident/fellow's home institution will either have to cover the insurance, or the clinical trainee will have to purchase the insurance coverage on their own.

The agreement term should be listed for the specific rotation dates unless the Cleveland Clinic program is a required rotation and/or receives several visiting clinical trainees from the particular sponsoring site on a consistent basis. Once a fully executed agreement is in place, a copy will be stored in MedHub through the expiration date of the agreement. The following will also receive executed version of the agreement: Cleveland Clinic legal, the Cleveland Clinic program and sponsoring site program. Prior to the start of the rotation a fully executed affiliation agreement must be in place and the visiting resident/fellow must fulfill all onboarding requirements.

Procedure for Visiting Resident/Fellow Observation Experiences: Many rotations may appear to be observational in nature, however, if the visiting resident/fellow is in any way interacting with patients, even indirectly such as reviewing lab results or x-rays, they are not considered observers and must meet licensure requirements and have medical malpractice coverage for the duration of the rotation. True observation experiences, in which a visitor simply follows the faculty member and observes may be vetted and on boarded through SilkRoad by the department, and are for three days or less. The observer will have absolutely no patient care or interaction. Cleveland Clinic GME will have no record of their observation, and the observer will not be able to seek credit for this experience.

International Away Rotations Policy

Cleveland Clinic clinical trainees may participate in elective experiences outside of the United States provided appropriate approvals are obtained and the international rotation is felt to provide an experience which cannot be provided at Cleveland Clinic. An application must be completed by the resident/fellow which includes a detailed description of the rotation's goals, objectives and competency-based curriculum. Program Directors must ensure that appropriate evaluations are completed for clinical trainees on away electives in order to document credit for the time spent away. There must be a program policy on how to apply for away rotations, amount of permissible away time and if necessary, procedure for the completion of missed core educational sessions.

Funding of salary, all fringe benefits will remain as fiscally approved by Cleveland Clinic unless explicitly stated otherwise in the Affiliation Agreement. Professional liability coverage should be provided by the inviting institution, if possible. In cases in which liability coverage is not provided by the inviting institution, GME will review each case individually and may be able to extend Cleveland Clinic liability.

Graduate Medical Education is not responsible for any subsidization for travel, housing, meals, or other living expenses while on international rotations. If a resident/fellow is currently training on a visa, a consultation with the International Physician Services is required to determine any potential visa issues.

Guidelines for requesting and approving an international off-site elective rotation are:

A. Clinical Trainees must discuss with the Program Director and determine if ACGME or Board approval needs to be obtained prior to seeking institutional approval.
B. Clinical Trainee must complete the international elective request form and obtain the permission and signature of the Program Director. This paperwork must be submitted to the Education Institute a minimum of 90 days prior to the time of the requested elective. This allows time for processing and execution of an affiliation agreement. The completed application must include:
    a. A letter of acceptance from the supervising physician to your Program Director that includes:
        i. Detailed description of the rotation
            1. Dates
            2. Projected work hours
            3. Summary of clinical and/or research responsibilities
        ii. Educational goals and objectives of the rotation
        iii. Statement that appropriate supervision will be maintained
        iv. Agreement to complete an evaluation at the end of the rotation
C. Once approved, it is the responsibility of the Program Director and Coordinator to communicate with the Graduate Medical Education Office in order to create an affiliation agreement for the rotation and ensure that accreditation standards including supervision, working hours, and safety are followed.

Travel Advisory: There are inherent risks when travelling out of the United States. The State Department's Travel Advisory can change overnight, which can result in suspension of previously approved international electives at the last minute. As such, we strongly encourage Clinical trainees to purchase trip insurance when making their travel arrangements in case change or cancellation of the arrangements is unavoidable at the last minute. If the U.S. Department of State labels a country under a Level 4 Travel Advisory, than the rotation is automatically prohibited. If a country is labeled under a Level 3 Travel Advisory, special consideration will be taken to ensure the rotation is appropriate. Please note that Level 3 and Level 4 Travel Advisories will be primarily reviewed for security, crime and terrorism concerns. All Cleveland Clinic business related travel should be booked through AmEx Global Business Travel. If the participating institution makes the travel arrangements through a different travel agency, than the travel itinerary must be provided to the Cleveland Clinic Program Director and the GME office. The itinerary will be submitted to World Aware so the traveler will have access to daily travel advisories and Protective Services will be aware of the global travelers whereabouts in the event of a crisis in that part of the world.

Immunizations: Trainees are responsible for obtaining any required travel immunizations and medications. The Cleveland Clinic Health Plan does not cover immunizations required only for international travel. Please refer to the Centers for Disease Control and Prevention website (http://wwwnc.cdc.gov/travel) for up-to-date information and speak with your host site for their requirements. The cost of immunizations is completely the responsibility of the traveler. It can be several hundred dollars at a minimum.

Supervision of Clinical Trainees

Purpose:

- To maximize the clinical trainee educational experience while maintaining a focus on patient safety and quality patient care
- To provide clear communication regarding which physician faculty member has supervisory responsibility, the nature of that responsibility and contact information for anticipated circumstances
- To assure appropriate supervision is provided to clinical trainees based on program/graduate level specific policies, which indicate gradual responsibility and progression toward each clinical trainee becoming an independent practitioner in their specialty

Policy Standards:

1. In the clinical learning environment, each patient must have an identifiable, appropriately credentialed and privileged supervising physician, who is ultimately responsible for clinical services provided for each patient's care.
    - This information should be available to clinical trainees, faculty, patients and other caregivers.
    - Clinical trainees and faculty should inform patients of their respective roles.
    - The supervising physician is responsible for determining the level of supervision required for appropriate training and to assure quality of patient care.
2. The Program Director must ensure that appropriate (program and graduate level specific) supervision policies are developed, communicated and adhered to by teaching faculty, supervising physicians and clinical trainees.
3. Program Directors must set guidelines for circumstances and events which clinical trainees must communicate with appropriate supervising faculty members. Inclusive, but not limited to the transfer of a patient to an intensive care unit, request to discharge a patient against medical advice and end-of-life decisions.
4. Each clinical trainee is responsible for knowing the limits of his or her scope of authority and the circumstances under which he or she is permitted to act with conditional independence. To allow clinical trainees to accomplish this, each Training Program Director shall develop explicit written descriptions of supervisory lines of responsibility for the care of patients. Such guidelines must be communicated to all clinical trainees and members of the program’s teaching faculty.
5. Supervising physician schedules must be structured to provide clinical trainees with rapid reliable systems for communication and interaction with supervisory physicians. In addition, on-call schedules shall be established that guarantee full and comprehensive coverage of institutional patients and facilities.
6. Supervising physicians are responsible for determining when a clinical trainee is unable to function at the level required to provide safe high quality patient care to assigned patients and must have the authority to adjust assigned work hours as necessary to ensure that patients are not placed at risk by clinical trainees who are overly fatigued, stressed or otherwise impaired.

Progressive Responsibility: Supervision should be graded to provide gradually increased responsibility into the role of a judgmentally sound, technically skilled and independently credentialed provider.

- The privilege of progressive responsibility, authority and a supervisory role in patient care delegated to each clinical trainee must be assigned by the Program Director and supervising faculty.
- Faculty supervision assignments should be of sufficient duration to assess the knowledge and skills of each clinical trainee and delegate him or her the appropriate level of patient care authority and responsibility.
- The Program Director must evaluate each clinical trainee's abilities utilizing specific criteria, based on the general competencies and incorporated in various methods of assessment.
- Supervising physicians should delegate portions of care to clinical trainees, based on the needs of each patient and the respective skills of the clinical trainee.
- Senior residents or fellows can serve in a supervisory role of junior residents in recognition of their progress toward independence, based on the needs of each patient and the skills of the individual clinical trainee.
- Ultimately, the clinical responsibilities for each clinical trainee must be based on the PGY-level, clinical experience, severity and complexity of patient illness/condition, available support services and foremost; patient safety.

Levels of Supervision: The type of supervision required by clinical trainees at various levels of training must be consistent with the requirement for progressive increased responsibility, the applicable program requirements of the individual Review Committee (RC) as well as common standards for quality and safe patient care.

1. Direct Supervision
    a. The supervising physician is physically present with the resident and patient.
2. Indirect Supervision
    a. With direct supervision immediately available – the supervising physician is physically within the hospital or other site of patient care and is immediately available to provide Direct Supervision.
    b. With direct supervision available – the supervising physician is not physically present within the hospital or other site of patient care, but is immediately available by means of telephonic and/or electronic modalities and is available to provide Direct Supervision.
3. Oversight
    a. The supervising physician is available to provide review of procedures/encounters with feedback provided after care is delivered.

Program Specific Supervision Policy:

- Develop and review annually, a program specific policy regarding supervision, progressive responsibility and fatigue management.
- Include criteria for determining needed level of supervision for a given clinical trainee under a given set of circumstances.
- Provide expectations for how supervision will be documented in the medical record, as well as procedures for monitoring supervision of clinical trainees.
- Include circumstances in which clinical trainees must communicate with the supervising physician, including but not limited to, end of life decisions, discharge against medical advice and transfer to an intensive care unit.
- Assure supervising physicians and clinical trainees receive and understand the lines and levels of supervision for each graduate level and rotation (when appropriate).

- Assess that supervising physicians are providing the appropriate level of supervision based on adherence to the program specific policy as well as evaluations, surveys and other feedback submitted by clinical trainees.
- Develop options for clinical trainees who are identified (or self-identify) as too fatigued to provide quality patient care.
- Incorporate the general standards for supervision from the Graduate Medical Education Council policy.

Appendix

Substance Abuse – Signs & Symptoms in the Workplace

Signs of substance abuse with potential impact to the workplace include, but are not limited to:

- Increased mistakes and errors in judgment
- Extended breaks and absences from the work area
- Repeated last-minute call-offs
- Red or glassy eyes
- Odor of alcohol on the breath
- Slurred speech
- Unsteady gait
- Drowsiness
- Mood swings
- Difficulty getting along with others
- Problems with memory or concentration
- Frequent runny nose
- Signs of withdrawal (sweating, tremors, nausea, vomiting)

In addition, medical professionals who abuse substances are also at risk for illegal diversion. Drug diversion involves taking medications that are prescribed for a patient or intended for patients. Signs of diversion include prescribing more than clinically indicated and defensiveness when questioned about medications and associated documentation issues.

Procedure – Suspected Impairment/Reasonable Suspicion/For Cause

Policy applies to On-Duty Staff, Clinical trainees, Trainees, Nurses and Employees. Of note: because of safety issues, the individual suspected of impairment should never be left alone. If the individual refuses to cooperate with the evaluation process, he or she should be informed this will result in disciplinary action up to and including termination.

Observer	Supervisor, Staff/Senior Resident on Service/NOM	Caring for Caregivers
Identify concerning behaviors (smell of alcohol, slurred speech, stumbling, sleepiness, glassy eyes, etc.). Contact Supervisor, Staff, or Sr. Resident on service/NOM. If available, ask another supervisor to concur. Suspect Diversion without obvious signs of impairment? Contact Caring for Caregivers and leadership to plan an intervention.	Contact GME or Program Director. Contact Caring for Caregivers 24/7, 216-445-6970, or 216-444-4000pager #23411 (To use this pager, enter a 10 digit call back number followed by #. This is not an alphanumeric pager). Contact Occupational Health Suspicion Hotline 216-445-8246 to initiate "For Cause" testing (Note: Inform collector if this is an Anesthesia provider.) Collection occurs in pre-determined locations identified by Occupational Health. You	Assist as needed contacting Occupational Health Hotline. Assist as needed contacting Cleveland Clinic Police Department 216-444-2222 or Regional Security to arrange for assistance in supervision of suspected impaired caregiver. Arrive on-site as necessary. As needed meet and escort Mobile Unit collector to pre-determined collection location (typically the ED) to perform testing Initiate substance abuse intake.

Observer	Supervisor, Staff/Senior Resident on Service/NOM	Caring for Caregivers
	will be informed of location. No use of restroom in advance. If caregiver attempts to leave, call security at 216-444-2222 If immediate medical attention is needed, contact AMET or RRT for rapid response. Caregiver will be suspended pending investigation and may not return to work. Mandatory referral to Caring for Caregivers; if Caring for Caregivers determines they will not be on-site, instruct caregiver to call 445-6970 for follow up. Consult with Caring for Caregivers/Occupational Health regarding transfer home or facility for evaluation. Caregivers are not permitted to drive. Take cab home, family member, UberHealth or transfer to facility.	If needed – Arrange for transportation to treatment facility. Case manage and follow up. Notify Chair of Physician Health Committee.

Standard Operating Procedure – GME Remediation and Corrective Action

Purpose: The purpose of this Standard Operating Procedure (SOP) is to describe the Graduate Medical Education (GME) guidelines for addressing any remediation and corrective actions (probation, non-promotion, non-reappointment, or dismissal). The Program Director (PD) and trainee should attempt to resolve any trainee's performance and/or behavior professionalism problems using verbal counseling and discussions prior to invoking the procedure set forth below. The procedure below is based on the Accreditation Council of Graduate Medical Education (ACGME) Institutional Requirements, however, all trainees, whether in an ACGME-accredited program or not, are held to the same standards and thus subject to the same procedure.

Definitions:

- **Remediation**: The act of remedying a trainee's academic and/or professional performance when performance is below expectations of their training program.
- **Corrective Action**: A disciplinary action taken against a trainee to communicate necessary improvement of academic and/or professional performance, without which improvement, additional actions, including dismissal may become necessary.
- **Counseling**: Advice and support meant to improve the performance of trainees and not considered disciplinary in nature. Counseling is intended to be positive and constructive in nature and not negative or derogatory. Whether verbal or written, it is considered to be an integral component of GME and should never be construed as a limitation or restriction on the trainee. Counseling is not disciplinary, probationary or investigatory in

nature nor a reflection of unsatisfactory performance or academic incompetence. Counseling is not an adverse charge or action and may not be appealed by the trainee. The program has complete discretion regarding the appropriate handling and remediation of a trainee's under-performance

- **Verbal Counseling**: An informal communication between PD or designee and a trainee that is a result of his/her performing below expectations of a training program.
- **Written Counseling**: A formal documented communication between PD or designee and a trainee that is a result of his/her performing below expectations of a training program.
- **Probation**: Probation is a disciplinary corrective action in which the PD or designee notifies a trainee in writing of specific deficiencies that must be corrected in a stated period of time, otherwise the trainee will not be allowed to continue in the program or will be continued on continued probationary status. Salary and benefits remain in force during probation.
- **Administrative Leave of Absence**: Action that removes the trainee from any programmatic duties for a specified amount of time. Reasons for administrative leave of absence may include, but are not limited to: investigation of alleged misconduct and/or unprofessional behavior (i.e. violation of patient privacy rules, conduct that is illegal/unethical, conduct that is inconsistent with CC Policy on Professional Conduct); failure to comply with conditions of probation or other corrective actions; or academic and/or professional deficiencies warranting removal of the resident from patient care. A trainee who is issued a dismissal disciplinary action will be placed on administrative leave of absence pending decision to appeal the dismissal. If the trainee decides to appeal the dismissal, administrative leave will be extended until the outcome of the appeal is rendered.
- **Non-Promotion**: Disciplinary corrective action that indicates that the trainee will not be promoted to the subsequent PGY-year at the completion of the current year of training and that training will be extended.
- **Non-Reappointment**: Disciplinary corrective action in which a program decides not to offer a contract to the trainee for the next academic year or training period.
- **Dismissal**: Disciplinary corrective action that removes a trainee from a training program prior to completion of the contract due to failure to successfully meet expectations after probation or as a result of trainee actions of an egregious nature necessitating immediate termination.
- **Trainee**: An individual who is appointed through GME; including residents, fellows, clinical fellows, postdoctoral psychology fellows, special fellows or research fellows.
- **Program Director (PD)**: Individual who is appointed as the director of a training program. For the purpose of this policy, this also include Primary Investigators and Research Supervisors of research fellows.
- **Designee**: In the event the PD is unavailable because of extenuating circumstances, the PD can designate an APD or Chair as their proxy to execute the disciplinary actions.
- **Reportable**: Information or disciplinary actions that must be reported to credentialing or licensing bodies.

Instructions: When a trainee's academic and/or professional performance is below the expectations of their training program or if they fail to meet the professional standards of the Cleveland Clinic, the PD or designee should follow these steps for remediation and corrective action:

1. Verbal Counseling – When a trainee's academic and/or professional performance is below expectations of a training program, the PD or designee should verbally counsel a trainee about specific areas of deficiency. Verbal counseling may occur at any time, and as many times as necessary during a trainee's educational program. Notes regarding the counseling should be kept in the trainee's program/department file (not GME office) for future consultation/documentation, if needed.

2. Written Counseling – The PD engages the trainee in written counseling if under-performance continues without the desired improvement or other action/behavior of resident/fellow necessitates intervention. Written counseling involves the delivery of a written memo (*GME Counseling & Remediation Form*) to the trainee that specifies the reasons for the written counseling and specific remediation steps that are aimed to improve the trainee's performance, expectations and timeline thereof. The written counseling memo must be signed by the PD and trainee. The written counseling memo is kept in the program/department's file, not the trainee's formal GME file.

3. Probation – The PD can place a trainee on probation: (a) in the event that at the end of the timeline specified in the written counseling, the trainee's performance has not improved to the extent deemed acceptable by the program; (b) the severity of the action leading to the probation justifies skipping written counseling.

   The PD must notify the GME Office prior to discussion of the probation with the trainee.

   The program invokes probation status to the trainee by written notification and using the *GME Counseling & Remediation Form*. This formal written notification advises the trainee that his/her performance is not satisfactory and includes a clear statement that the trainee is on probation. This notice to the trainee needs to include a detailed description of the unsatisfactory performance, the expectations for performance improvement and time parameters in which performance is to improve. The PD and trainee shall sign for the receipt of the notice.

   As a result of probation, and depending on the circumstances, a program may restrict a trainee clinical duties and other activities. Likewise, research fellow's duties and activities may be restricted or modified by the PD. Probation is considered a corrective disciplinary action, reportable to any credentialing agency or state licensing boards.

   Probation status is issued for a predetermined period of time (e.g., three months), as determined by the PD and on the recommendation of the Clinical Competence Committee (CCC). The PD also has the discretion to extend any period of probation status based on progress made in targeted areas for improvement. A trainee who has been placed on probation shall have his/her progress toward performance improvement reviewed by the PD or designee on a regular basis and shall set the standard follow-up periods with the trainee at the time of probation (e.g. will meet every two weeks).

   At the end of the probationary period, the PD meets again with the trainee. Depending on the trainee's performance, he/she may be: (1) removed from probation, (2) given an additional period of probation, or (3) be subject to termination or non-promotion/extension of training.

The PD informs the trainee, in writing, when the probation has been lifted and that all requirements of the probation are satisfied and no further disciplinary action is required. At this time, the PD and trainee sign the bottom of the *GME Counseling & Remediation Form* that documented the probation.

The PD or Program Coordinator (PC) sends a copy of the probation notice to the Director of GME. The Director of GME or designee will meet with the trainee to discuss the significance of the probation and the trainee right to appeal the probation (refer to the GME Appeals Process for more information). The trainee shall inform the Director of GME of the decision to accept or appeal the probation status within 10 calendar days of the meeting. If the trainee accepts the probation, it will be recorded in his/her permanent GME academic record. If the trainee chooses to appeal the corrective action, it will not be documented until an Appeal Task Force decision has been rendered. If no request for an appeal is received within the 10 calendar days from the meeting, the corrective action becomes final and no appeal will be permitted.

4. Other Corrective Actions a PD can take that the trainee shall have the right to appeal in the manner set forth in the GME Appeals Policy:
    a. Non-promotion (extension of training) – In instances where a trainee will not be promoted to the next level of training based on the program's predetermined criteria for promotion, the PD must notify the GME Office prior to discussion with the trainee.
    b. Non-reappointment – In instances where a trainee will not be reappointed to the training program based on the program's predetermined criteria for reappointment, the PD must notify the GME Office prior to discussion with the trainee.
    c. Dismissal – The PD must notify the Designated Institutional Official (DIO) if he/she intends to dismiss a trainee. Dismissal removes a trainee from a training program even though he/she holds a current Resident/Fellow Agreement. This involves immediate removal from an educational program for failing to maintain academic and/or other CC professional standards required to progress in or complete the program.

<u>Regulatory Requirement/References:</u>
The Cleveland Clinic is accredited by the ACGME (Accreditation Council for Graduate Medical Education). All trainee, whether in an accredited program, or not, are upheld to the same standards. Per the ACGME, program appointment, advancement, and completion are neither assured nor guaranteed to the trainee but are contingent on the trainee's satisfactory demonstration of progressive advancement in scholarship and continued professional growth in all ACGME-required competency areas. Programs are required to evaluate residents on their Milestones and must have documented criteria for promotion and/or renewal of a resident's/fellow's appointment. IR.IV.C.1

A program must provide a resident/fellow with a written notice of intent when that resident's/fellow's agreement will not be renewed, when that resident/fellow will not be promoted to the next level of training, or when that resident/fellow will be dismissed. IV.C.1.a) The Sponsoring Institution must have a policy that provides residents/fellows with due process relating to the following action regardless of when the action is taken during the appointment period: suspension, non-renewal, non-promotion; or dismissal. IV.C.1.b)

Oversight and Responsibility:
The Graduate Medical Education Council (GMEC) and the Graduate Medical Education department are responsible for the review, revision, update, and operationalization of this policy to maintain compliance with regulatory or other requirements.

Appendices/References
GME Counseling & Remediation Form Instructions
GME Counseling & Remediation Form
GME Remediation and Corrective Action Policy
GME Appeals Policy
GME Promotion Policy

GME Counseling and Remediation Template Instructions

Please follow the instructions below when completing the GME Counseling & Remediation Form. Contact Krista Lombardo-Klefos, MBA, GME Administrative Director, with any questions.

The GME Counseling & Remediation Form is used to appropriately document the program's actions in response to deficiencies in competency areas as they are detected in trainees through existing supervision and assessment mechanisms. The form can be used to document all actions, including verbal and written counseling (non-disciplinary), probation, non-promotion, extension of training, non-reappointment, and dismissal. Further information regarding GME Remediation and Corrective Action and the GME Appeals Policy can be found in the Graduate Physicians Manual (GPM).

Fields in the form should be completed as much as necessary and possible, to provide a clear plan for the trainee to improve their performance. Counseling or corrective actions that follow should occur as early as possible after the clear identification and documentation of deficiencies to allow the trainee enough time to make improvements before resolution of the problems or additional corrective actions are taken.

1. Please complete: the trainee name, Program Director (PD) name, program, PGY level (if applicable) and date of start of counseling or remediation action.

2. Please choose type of action:
   - **Non-disciplinary actions:** Non-disciplinary actions are not reportable to the board or licensing agencies. These documents are maintained in the program's files and are not a part of the permanent GME record
     i. Verbal Counseling
     ii. Written Counseling
   - **Formal corrective actions**: Please contact the GME office prior to delivering any formal corrective action.
     These actions are reportable to licensing boards and are appealable in most cases (the trainee can request to have a formal inquiry into the program's action). Corrective actions that are not appealed, or whose decision is not overturned during the appeal process become part of the trainee's permanent record maintained in the GME office.

Actions that are **NOT** appealable include: falsification of records, material omission of information on application or any official paperwork, violation of substance abuse policy, conviction of a felony or loss of medical license leading to inability to practice clinical medicine.

i. Probation
ii. Non-promotion (extension of training for competency-related deficiencies)

Please note: Although formal corrective actions generally follows non-disciplinary actions in a step-wise fashion, (1. verbal counseling, 2. written counseling, 3. probation, 4. dismissal) non-disciplinary steps may be omitted depending on the seriousness and nature of the issues at hand.

3. Area(s) of Deficiency/Affected Competencies: Deficiencies should be noted by areas of competency. Multiple competencies may be checked, if necessary. If other is selected, please explain.

4. Description of Performance Issue: A thorough description of the performance issue, including specifics of behavior or knowledge deficits, as well as dates of occurrence should be provided to the trainee. Please assure you have appropriate non-anecdotal documentation to back up performance issues.

Example: (Professionalism) Dr. Smith consistently communicates with nursing staff in a condescending manner. This has been noted on several occasions by staff with whom he has worked (Dr. X on Green service 7/1/2021, Dr. Y on Red service 8/1/2021 and Dr. Z on 8/15/2021).

5. Action for Improvement: SMART goals should be developed to ensure timely results-focused remediation. The PD or CCC may set these goals should work with the trainee to develop the remediation plan, which the PD will review and approve as appropriate.

SMART goals are:

- **S**pecific: What are the expectations? What improvement is expected?
- **M**easurable: How will you determine if the goal has been met, what measurement will be used?
- **A**chievable**:** Is the goal achievable? What the resources are provided?
- **R**esults Focused: What will be accomplished if goals are met?
- **T**ime Oriented: What is the time period in which the goal should be achieved? Time period will depend on reason for counseling or remediation.

For example:

Action for Improvement (please add/delete rows as necessary)			
Targeted Area for Improvement/Reason	**Expected Improvement Outcomes**	**Measurement of Improvement**	**Time Frame**
Professionalism: Dr. Smith has been observed using inappropriate language and acting in an unprofessional manner with other caregivers. This was observed by several Faculty members and reported by the nurse manager on several occasions.	Effective immediately, Dr. Smith is expected to behave in a professional manner towards all caregivers at all times. Dr. Smith should act in a respectful manner and use appropriate language in all interactions in the workplace. If goals are accomplished Dr. Smith will be considered successfully remediated. As this performance issue was not formal in nature it will not be reported to boards or other agencies unless further issues are noted at a later date.	Feedback regarding professional behavior will be solicited from nursing personnel with whom Dr. Smith works over the next 90 days.	Immediate improvement expected and will be monitored over a 90 day period.
Medical Knowledge: Dr. Smith's medical knowledge seems to lag significantly behind that of his peers. This has been noted both in his rotation evaluations recently and his in-service exam scores last year (for which he was counseled previously). Dr. Smith's knowledge in several instances (which we have discussed) could have affected patient care outcomes if not recognized by other team members.	Dr. Smith will be provided with a mentor who can help develop a study plan to increase his knowledge and prepare him for future rotations as well as the next in-service exam. It is expected he/she will be prepared for rotations by reading recommended materials. It is also expected that he/she will discuss cases with his faculty or senior prior to making medical knowledge based decisions until he reaches an adequate level of competency for his level of training	Feedback from mentor Improved rotation evaluations in regards to medical knowledge Improved in-service exam scores next month	Dr. Smith will meet with his mentor biweekly to discuss progress and with the PD after every rotation to review evaluations over a 90-day period at which time his progress will be assessed for adequate improvement.

6. Resource(s) Recommended/Provided to help the trainee meet his or her goals: Please list any resources provided to the trainee for improvement. Examples of possible resources include books or journal article to read, mentorship, or simulation training.

   Dr. Smith should review the goals and objectives of upcoming rotations to determine appropriate reading materials to build knowledge base. Dr. Smith should also reference the following materials: 1. 2. 3.…

7. Monitoring Mechanism: Who will monitor progress? How will they do so? How often? It is the ultimate responsibility of the PD to monitor the progress of the improvement plan.

Example: *The PD will meet with Dr. Smith weekly to review progress using feedback from team members with whom Dr. Smith has worked that week.*

8. Consequences for failure to meet expected improvement in competency areas – What will happen if the trainee fails to meet SMART goals? What will occur if goals are not met in the expected time frame must be clearly delineated.

   Example: If further incidents displaying a lack of professionalism when dealing with nursing staff occur within the 90 days of this remediation plan, the next step of corrective action which is "insert here" will be taken.

9. Signature: For all corrective actions, **the form must be signed and dated by both the PD and the trainee.** Additional documentation can be attached to substantiate the need for remediation. As noted above, it is recommended that a written record of all steps in the remediation process be maintained by the program. By signing the form, the trainee does not agree with the information contained on the form, it merely indicates that they have received, read and understand the performance improvement plan. The trainee can appeal any appealable formal corrective actions.

10. Trainee Performance Comments: Although optional, the trainee may comment here.

11. Outcome of Action Plan: At the end of the counseling or remediation period the trainee and PD should meet to discuss outcomes. Outcomes of formal corrective actions and consequent steps should be discussed with GME prior to holding meeting with trainee.
    Potential outcomes are:
    - Successfully Remediated
    - Written Counseling (if verbal counseling was not successful, or new events have occurred which necessitate further remediation)
    - Probation (if written counseling was not successful or new events have occurred which necessitate further remediation)
    - Extension of Probation (extension of Probation/training - if progress was made but was not found to be adequate to discontinue remediation)
    - Non-Reappointment (allowed to complete current year of training but will not receive a contract to continue in the program)
    - Dismissal (immediate termination of contract due to inability to remediate)

Comments and signature of both PD and trainee are required as a part of outcome plan; if trainee refuses to sign, the PD should denote and date.

Completed forms should be sent to GME for permanent record if they pertain to formal corrective actions. If additional remediation is required, a new form should be completed.

GME Counseling and Remediation Template

Cleveland Clinic

GME Counseling & Remediation Form

Please reference the GME Counseling & Remediation Form Instructions (separate document) when completing the GME Counseling & Remediation Form. Contact Krista Lombardo-Klefos, MBA, GME Administrative Director, with any questions.

Trainee Name:		Program Director:
Date:	Program:	PGY:

Non-Disciplinary Actions - Counseling - (Not Reportable, Non-Appealable)	
☐ Documentation of Verbal Counseling	☐ Written Counseling
Formal Disciplinary Actions - (Reportable & Appealable) **(please seek advice from GME prior to issuing)**	
☐ Probation	☐ Non-Promotion (Extension of Training)

Area(s) of Deficiency/Affected Competencies (select one or more)		
☐ Interpersonal Skills and Communication	☐ Practice Based Learning	☐ Research
☐ Medical Knowledge	☐ Professionalism	☐ Systems Based Practice
☐ Patient Care	☐ Surgical/Procedural Skills	☐ Other (Please specify below)
If Other selected above, please explain:		

Description of Performance Issue **(additional documentation may be attached)**

Action for Improvement **(please add/delete rows as necessary)**

Please provide SMART Goals (**S**pecific, **M**easurable, **A**chievable, **R**esults Focused and **T**imely)

Targeted Area for Improvement	Expected Improvement Outcomes	Measurement of Improvement	Time Frame
1.			
2.			

3.			
Resource(s) Recommended/Provided to help the trainee meet his/her goals:			
Monitoring Mechanism: Name of responsible faculty member and responsibilities including frequency of meetings/audits, reporting, etc.			
Consequences for failure to meet expected improvement in competency areas:			

Signatures

Program Director Signature:	Date:

- My signature below does not signify that I agree with the information contained herein, it acknowledges that my PD (or his/her designee) has discussed this performance improvement plan with me and that I have read and understand the content and terms of the plan.
- If applicable, I have been advised that I will need to meet with the GME Designated Institutional Official or designee to discuss my rights to appeal this decision (remediation level only- appeals do not apply to counseling).

Trainee Signature:	Date:

Trainee Performance Comments (Optional)

Outcome of Action Plan

☐ Successfully Remediated	☐ Written Counseling	☐ Probation	☐ Extension of Probation	☐ Non-Reappointment	☐ Dismissal

Please comment (required):		
Program Director Signature:		Date:
Trainee Signature:		Date:

International Away Rotations Request Form

Must be completed 90 days in advance of planned start of requested rotation

Resident Name	Today's Date
Resident Phone	Resident Email
Program	
PGY Level	Dates of Requested Rotation
Elective Requested	
Location of Elective	
Does this program have an ACGME or Board requirement which must be met for approval? _____ Yes _____ No	If yes, what is the requirement and has it been met?
Preceptor/Supervisor	Preceptor/Supervisor's Phone #
Preceptor/Supervisor's Address	Preceptor's E-Mail:
Address where you can be reached	Phone # where you can be reached
Emergency Contact Name	Emergency Contact
Emergency Contact Phone	Emergency Contact Email
Passport Number and Expiration	
Attachment Checklist _____ Goals & Objectives _____ Rotation Details _____ License Information if required _____ Summary of Responsibilities	
I hereby request permission to complete the elective noted above. _____ _____ _____ Resident Signature Printed Name Date	

All signatures below must be obtained to indicate institutional approval of the elective noted on the previous page:

_____ Program Director Approval	_____ (Printed Name)	_____ Date
_____ GMEC Chair Approval	Jeremy Lipman, M.D.	_____ Date
_____ Education Institute Chair Approval	James K. Stoller, MD, MS	_____ Date
_____ Enterprise Risk Management Approval	Michele J. Johns, ESQ., CPHRM	_____ Date
_____ Protective Services/ Global Security Approval	Tim Riley	_____ Date

Assumption of Risk and Release Form Liability

This Assumption of Risk and Release from Liability pertains to travel to **"institution name and address"** during the time period of **"start date"** through **"end date"**.

I, **"insert name"**, wish to travel to and hereby state that:

1. Travel to **"insert institution"** is not required as part of any course or degree program in which I am enrolled or as a condition of current or future employment and that, therefore, my decision to travel to is entirely voluntary.
2. I understand that certain risks are inherent in any foreign travel experience and I fully accept those risks. These risks may include, but are not limited to, such things as war, quarantine, civil unrest, public health risks, criminal activity, terrorism, exposure to communicable diseases, ill effects of unfamiliar food and water, incidents related to ground, air or water transportation, adverse weather conditions, accident, injuries or damage to property, and other physical, mental, and emotional injury.
3. I have been advised that no one can guarantee my safety in and I have been advised to have adequate insurance before my departure, which should include medical evacuation, repatriation of remains and life insurance. I have been advised that if I am currently included on my family's insurance policy, that I should make sure that the coverage is valid overseas for the duration of my travel.
4. I fully understand the above risks involved in the proposed travel and I agree to assume the risks of this travel, including the risk of catastrophic injury or death.
5. I agree to indemnify, hold harmless, release and forever discharge Cleveland Clinic, its Trustees, employees, agents, and cooperating institutions and their offices and agents (if any) from any and all claims and expenses, including reasonable attorney's fees, for any injury, loss, or damage to personal property, including catastrophic injury or death, related to travel.

_____ _____

Resident/Fellow Signature Date

_____

Resident/Fellow Name (printed)

Anesthesiology Institute: Notice of Substance Abuse Prevention Program

The Anesthesiology Institute is fully committed to patient safety and employee well-being. As part of this commitment, a Substance Abuse Prevention Program (SAPP) has been established. Candidates in the residency and fellowship training programs in the Anesthesiology Institute and the Anesthesiology residency at South Pointe Hospital are required to participate in SAPP. As a condition of employment, all clinical trainees must agree to participate in the SAPP and to abide by the terms of the Substance Abuse Policy. Occupational Health Services or the SAPP Coordinator will perform all testing outlined in the protocol. Occupational Health Service or the SAPP Coordinator will distribute the Anesthesiology Institute Pre-Hire Consent Form and the Policy Statement during the clinical trainees initial Occupational Health Screening (pre-employment testing). An Occupational Health employee or SAPP Coordinator will be the witness to the Pre-Hire Consent Form and this form will be filed in the clinical trainees Occupational Health record. If you have any issues regarding the Policy or Consent, please speak with the Anesthesiology Institute's SAPP/Substance Abuse Prevention Program Director or Coordinator.

The policy is outlined as follows:

- Required drug screen testing (pre-hire testing, random testing, reasonable suspicion for cause testing, return to duty testing)
- Controlled substances that will be tested (pre-hire, random testing, reasonable suspicion for cause testing) will be identified for participants
- Anesthesia chain of custody drug screen collection protocol (collection procedures) will be explained

The components of the program encompass increased education on prevention, recognition and risk of substance abuse and include:

1. Screening of all new clinical trainees potential employees in anesthesia
2. Pre-hire drug screens
3. Random toxicology screens after primary hiring
4. "For cause" drug screens if indicated
5. Return to duty testing following a violation of alcohol or controlled substance use policies if indicated

Expanded Random Drug Testing Program: Cleveland Clinic retains the right to subject you to random toxicology screens after initial hiring. Cleveland Clinic is committed to patient safety and caregiver health. As part of our pledge to deliver safe, reliable care, we recognize that impairment caused by drug abuse adversely impacts caregivers and patients. Beginning January 1, 2016, Cleveland Clinic implemented an Expanded Drug Testing Program (EDT) that requires participation of all caregivers. This was an expansion of the previous random drug testing programs and our commitment to a drug-free workplace. Cleveland Clinic is committed to a testing process that is respectful, fair and non-disruptive to patient care. The intent of this program is to improve early detection and treatment of those who abuse substances and to reduce the incidence of dependency, abuse and misuse of substances that may be readily accessible to healthcare workers. Cleveland Clinic supports the Department of Health and Human Services' recommendation, advocating random drug testing of all healthcare professionals. More information on the Expanded Random Drug Testing Program.

Behavioral Health Issues

The role of Caring for Caregivers is to provide an entry point for screening of wellness issues as well as counseling and referral services. Caring for Caregivers' confidential services can be accessed through self-referral and/or referral by concerned supervisors (i.e. Program Directors). Access is available on campus and at various offices throughout Northeast Ohio. Caring for Caregivers personnel are independently licensed mental health and/or chemical dependency professionals with expertise in interpersonal stress management, substance abuse screening, mental health, work relationships, personal relationships, performance issues, and other areas of daily living. Issues of medical leaves and FMLA are considered as the clinicians provide a balance of advocacy and institutional/patient risk management.

Following the initial assessment by the clinician, a referral can be made as needed to other levels of assessment and/or treatment, including: psychiatric assessment/treatment, psychological assessment, neuropsychological testing, substance abuse assessment/treatment, stress management courses, marital/family therapy.

It is important that residency/fellowship directors and chief/supervising clinical trainees have knowledge and awareness of Caring for Caregivers services, promote these services, and make timely referrals in consultation with the program.

Caring for Caregivers offers 24/7 telephonic support for urgent situations through its on-call pager (216-444-4000 pager 23411. Enter a 10 digit call back number followed by #. This is not an alphanumeric pager).

In addition, a member of the Department of Psychiatry and Psychology is on call 24/7 and can be accessed by calling the hospital operator. The psychiatric staff on call will also facilitate appointments for psychiatric assessment as needed. This staff member is available to discuss with the referring physician (Program Director, chief resident, or colleague) a screening assessment of the psychiatric emergency and appropriate triage which may include and not limited to: emergency room assessment, urgent psychiatric inpatient admission, same day or next day psychiatric assessment, urgent chemical dependency assessment and/or inpatient chemical dependency admission.

Outside Funding For Cleveland Clinic Research Fellows Template

Please complete this form for outside funding sources; a form must be completed for each source.

Personnel Information		
Individual to be funded:		
Dates of funding:		
Purpose of funding:		
Benefits Information		
*Will the employer paid portion of Cleveland Clinic benefits be funded by outside organization?	☐ No	
	☐ Yes	☐ Partial Amount
		☐ Full Amount
If benefits to be paid, what amount (USD):		
Salary Information		
Annual salary amount to be funded (USD):		
How is funding for the salary to be paid:	☐ Cleveland Clinic	
	☐ Directly to individual	
Funding Information		
Total amount of funding provided (salary and benefits in USD):		
Funding source:		
Type of source:	☐ Academic Organization	
	☐ Government Organization	
	☐ Private Institution	
	☐ Other (Please identify):	
Funding source contact name:		
Address of funding source:		
Email of funding source:		
Phone of funding source (include country/city code):		
Additional comments:		

*Cleveland Clinic Benefits include an employer Cleveland Clinic funded portion and an employee funded portion. Outside organizations can choose to fund the Cleveland Clinic portion of benefits, or a partial portion. Please verify amount of funding needed with Cleveland Clinic Program if funding entire employer portion for exact costs. If the organization also chooses to fund the employee portion, organization must provide that funding directly to trainee. Cleveland Clinic cannot accept funding for the employee paid portion.

By signing this application, the individual acknowledges approval of the contents of the application.

Person Responsible at the Organization who is providing the Funding

Print Name:

Signature:

Date: