

GRADUATE PHYSICIAN POLICY MANUAL

2015-2016

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Institutional Commitment to Graduate Medical Education

Education has been an integral component of Cleveland Clinic's mission since its inception in 1921 and Cleveland Clinic Florida since 1989. As part of that overall commitment to education, we recognize the importance and value of graduate medical education programs, which help to train the physicians who will serve future generations through the provision of the highest quality medical care.

We hereby reaffirm the Institution's commitment to graduate medical education. The graduate medical education programs at Cleveland Clinic Florida will continue to emphasize the development of personal, clinical and professional competency under the careful guidance and supervision of the Institution's faculty. The programs will also continue to be monitored to be certain they provide safe and humane care of patients at the same time that our clinical trainees progress in responsibility as appropriate for their experience and competency.

With this commitment, we recognize the necessity for adequate funding, facilities, support personnel, and faculty teaching time to be certain that every program under our Institutional sponsorship offers the best possible training environment and opportunities.

WELCOME

To Cleveland Clinic Florida in Weston, Florida, affiliated medical facilities of The Cleveland Clinic Foundation in Cleveland, Ohio.

During your period of training, you will be an integral part of one of the largest and best medical institutions in the country. The Cleveland Clinic Foundation and its affiliated facilities are a national referral center and an international health resource dedicated to providing the finest medical care in response to public need. The integration of research and education with outpatient and hospital care in a private, not-for-profit group practice distinguishes the Cleveland Clinic in American medicine.

This Graduate Physician Manual has been prepared to help and guide you towards an easier adjustment to life as clinical trainees and a successful and productive training experience.

When you have questions ask your fellow clinical trainees and refer to the manual. If you have additional questions, please feel free to contact your GME Coordinator.

We are happy that you chose to train with us. We will do our best to insure that your experience meets or exceeds your expectations.

Eric G. Weiss, M.D., DIO Center Director, Education Center Chair, Graduate Medical Education and DIO Cleveland Clinic Florida

GRADUATE MEDICAL EDUCATION CLEVELAND CLINIC FLORIDA

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GENERAL STATEMENT

All policies and procedures concerning graduate medical education are developed, approved and implemented by the Graduate Medical Education Committee (GMEC). While every effort was made to ensure the accuracy of the information presented in this booklet, it is conceivable that there may be changes made to policies since its publication. Cleveland Clinic and Graduate Medical Education Committee (GMEC) policies will take precedence over this publication in matters of arbitration.

Changes to policies and/or revisions to them will be communicated to the Clinical Trainees/Researchers on the GME Florida intranet site as they occur.

When specific Cleveland Clinic policies are quoted in this booklet, they refer to policies found in the Cleveland Clinic's Supervisory Policy and Procedural Manual. This manual is located on Cleveland Clinic Florida intranet at http://ppmsso.ccf.org/

ELIGIBILITY & SELECTION

Recruitment

Recruitment efforts shall be directed toward, and appointments offered only to those candidates who meet the eligibility requirements for appointment to residency training. Applicants with one of the following qualifications are eligible to be considered for training at Cleveland Clinic Florida:

• 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 and Canada who have received a currently valid certificate from the Educational Commission for Foreign Medical Graduates.

• Graduates of medical schools outside the United States who have completed a Fifth Pathway program provided by an LCME-accredited school.

• Fellows must meet the prerequisite training and documentation requirements to enter accredited or non-accredited fellowships.

Selection

Programs must select from among 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 without regard to color, race, religion, national origin, age, sex, sexual orientation, marital status, ancestry, status as a disabled or Vietnam era veteran or any other characteristic protected by law. Information provided on this application may be shared with any Cleveland Clinic facility.

Residency programs recruiting first year residents are required to participate in the National Resident Matching Program (NRMP). Other programs are encouraged to participate in an organized matching program (such as the NRMP) 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 appointment and any subsequent appointment are contingent upon meeting the requirements 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 GME Department generates the formal appointment on behalf of the Designated Institutional Official (DIO). The GME Department screens the application materials to assure each candidate meets the requisite academic requirements to enter the respective training program. Neither Cleveland Clinic nor any of its ACGME accredited programs require residents or fellows to sign a non-competition guarantee or restrictive covenant.

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. Pursuant to the ACGME requirements on transfers, the current Cleveland Clinic 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.

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 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/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.

CONDITIONS OF EMPLOYMENT & REQUIREMENTS

In order to begin training/working at the Cleveland Clinic, you must first process in with Graduate Medical Education Department (GME). All clinical trainees and visiting researchers1 must attend a scheduled orientation session. You will not receive salary or benefits until you have formally processed in with the GME Department and successfully completed all conditions of employment and requirements.

- 1. Provide a copy of either a permanent **Florida Medical License** or obtain a training license from the Florida Board of Medicine for training at Cleveland Clinic Florida. Florida Board of Medicine website <u>www.doh.state.fl.us</u>.
- 2. Complete a **health screening** performed by the Cleveland Clinic Employee Health nurse before your start date, which includes completion of a health questionnaire, vital signs, urine test for substance abuse, TB skin testing, vision screening, and immunization screening. As the Cleveland Clinic is committed to providing a drug-free work environment, please be advised that positive results for any illicit drugs or non-prescribed controlled substances will constitute ineligibility for employment.
- 3. To take further steps in preserving and improving the health of all its employees and patients, Cleveland Clinic has implemented a **non-smoking hiring policy** requiring all job applicants and individuals receiving appointments to take a cotinine test during their preplacement physical exam. This is a pre-employment test only. The cotinine test will detect the presence of nicotine in all forms of tobacco. Appointments that have been offered to prospective residents and fellows who test positive will be rescinded. Those individuals testing positive who then test negative after 90 days, may be reconsidered for appointment at the discretion of the program director.
- 4. Cleveland Clinic requires a criminal background check for all employees. The Department of Security will conduct the background check and through a database search and handle fingerprinting for all new employees. Employment is conditional pending the return of the background check.
- 5. All Center of Online Medical Education and Training (COMET) modules are due to be completed 30 days after the start of your training. These courses are required to comply with federal laws on Occupational Safety & Health Administration (OSHA) blood borne pathogens and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Trainees will also be required to complete additional courses as assigned throughout the academic year.
- 6. Clinical Trainees are required to have a **National Provide Identifier (NPI)**. The NPI for each health care provider is assigned by the National Plan and Provider Enumeration

¹ Visiting Researchers must attend the scheduled orientation; however, all visiting researchers, by contract, do not receive salary nor benefits.

System (NPPES). NPI confirmation letter must be forward to GME. To apply refer to <u>https://nppes.cms.hhs.gov</u>. Internationals must have a social security number to apply for an NPI. See #9 for information regarding application for a social security card.

7. Provide the requested documents to accompany the **Employment Eligibility** Verification Form (I-9) as required by the U.S. Department of Homeland Security. Original documents are required and must be presented at GME Orientation.

In accordance with the Accreditation Council on Graduate Medical Education (ACGME) requirements, graduates of medical schools outside of the U.S., Canada and Puerto Rico must provide either a copy of a currently valid standard **ECFMG Certificate** or written documentation that the physician is eligible to receive the same.

- 8. Each clinical trainee must produce or obtain a **social security number** for payroll purposes and enrollment in the Cleveland Clinic health care plan. A copy of the actual social security card is required. If you do not have a social security number/card, information on how and where to apply can be obtained for www.ssa.gov/reach.htm or by calling 800-772-1213. Internationals: If on a J1 visa, please wait 5 days after your GME orientation before applying.
- 9. All other supporting documents required for permanent education file will be requested with the formal appointment letter.

CLINICAL FELLOWS

Many clinical departments require clinical fellows to obtain permanent licensure in the state of Florida. Please check with the program director of your cleveland clinic fellowship regarding other requirements you will be expected to meet to begin the program.

Adult Reconstructive Hip and Knee Surgery Advanced GI Minimally Invasive Surgery **Breast Medicine** Colon and Rectal Minimally Invasive Surgery Fellowship Electrodiagnostic Medicine Female Pelvic Medicine and Reconstructive Surgery Hepatobiliary Surgery Male and Fertility and Prosthetics/Male and Female Sexual Dysfunction Minimally Invasive Gynecological Surgery Movement Disorder Shoulder Reconstructive and Sports Medicine Spine Stroke Urologic Oncology Vascular Medicine Voiding Dysfunction

Documents Required for Permanent Record

1. Acceptance Letter (signed)

2. Certification of all Graduate Medical Education Training (submit a copy of certification for current and previous training)

- 3. Cleveland Clinic Personal Data Sheet
- 4. Cleveland Clinic Confidentiality of Information Form
- 5. Completed Application
- 6. Current Curriculum Vitae

7. ECFMG - Current, valid copy of certificate (for International Medical Graduates only)

8. Medical School Diploma (copy) - if in any language other than English, please upload certified translated copy as well (if graduation is pending, upload when diploma is received)

9. National Provider Identifier (NPI) - Clinical trainees are required to have an NPI. The NPI for each health care provider is assigned by the National Plan & Provider Enumeration System (NPPES). NPI confirmation letter must be forwarded to the GME department. Apply as an

individual at https://nppes.cms.hhs.gov (you can only apply once you have a social security number)

10. Letter of Recommendation (one) from a physician who has supervised you in a clinical setting

11. Social Security Card with correct name (for example, due to marriage or divorce). The name on the social security card is the name used for all Cleveland Clinic records. You cannot apply for a social security card until you are in the United States

12. Score Report (copy) or official transcript from pertinent qualifying examinations. (Test scores where applicable: USMLE, COMLEX, MCCQE, NBOME, FMGEMS, NBME or ABPS)

13. You must have filed either an application for a permanent medical license or a training license AND the GME office must receive at least an acknowledgment letter for the application from the Florida Medical Board in order for you to begin your training program. Training license application is included with appointment packet unless residency/fellowship application indicated the need for a Permanent Florida License.

LICENSURE

The State of Florida requires clinical trainees to have either a Permanent Florida Medical License or a Temporary Training License. Under no circumstance will you be permitted to begin your training program if you do not have a Permanent License or Temporary Training License issued by the Florida Board of Medicine.

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

Permanent Licensure

Clinical fellows are required to obtain a Permanent Medical License from the Florida Medical Board. Please check with your Program Director regarding your program's specific licensure requirements to begin training. If you do not have a Permanent License but intend to apply for one, please submit a written request with your application asking the Board to send a letter to the Cleveland Clinic Graduate Medical Education Department acknowledging receipt of your application. This will allow you to begin your program while the application is being processed.

Please note: for Permanent Licensure, the Florida Board of Medicine requires U.S. medical school graduates to complete one year of accredited graduate medical education and international medical school graduates to complete two years of accredited graduate medical education. In addition, all 3 steps of USMLE must have been passed within a 7-year period from the date of the first exam passed. Information on Permanent Licensure may be obtained by contacting the Florida Board of Medicine at 850-245-4131 or visiting their website at www.flboardofmedicine.gov

Reminder: renewal of licensure is the clinical trainee's responsibility.

Training License

Future clinical trainees must apply for their Training License online by visiting <u>www.flboardofmedicine.gov</u>. Trainees applying for a Training License must select the "House Physician" option. The trainee is responsible for the initial application with the Florida Board of Medicine. If additional documents are requested for further application processing, the trainee is responsible for notifying their Program Coordinator. Any trainee who currently has a Florida Training License is responsible for submitting a renewal application online at <u>www.flboardofmedicine.gov</u>. You should expect the entire process to take between two to six months from the time your application is received. All clinical trainees must renew their training certificate every two years.

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 Florida, must have completed 9 months of ACGME accredited post-graduate training (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. You may also obtain an application by submitting an email request to the FSMB at <u>usmle@fsmb.org</u>. You must include your full name, mailing address, USMLE ID number (if known) and the state for which you will be taking Step 3.

National Provider Identifier (NPI)

All heath 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 resident/fellow at Cleveland Clinic who has the ability to write prescriptions, **you 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). Clinical residents/fellows can apply on line for this NPI number at any point in time; there is no charge and it is a number they will use for their entire career.

How to Apply

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 the NPI website https://nppes.cms.hhs.gov/NPPES/Welcome.do and apply as an **individual.** The website will walk you through the online process. You may also complete a paper application (found on this website) and mail it directly to NPPES.

NPI is a Cleveland Clinic requirement. Please upload a copy of your NPI confirmation letter and number into your MedHub record.

Social Security Number

A Social Security Number is required to apply for the NPI. Therefore, you can only apply for an NPI after you receive a social security number. You will then follow the above process.

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 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

For further information, please refer to the Clinic 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 abuse." 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. 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, it is the intent of the Cleveland Clinic to assist its physicians in identifying and receiving treatment for conditions which may lead to impairment, while at the same time assuring the highest degree of safety and care to the patients.

In order to ensure the safety of patients and employees, the Cleveland Clinic provides the highest quality of medical care and is committed to providing a drug-free environment. Because of this commitment, Cleveland Clinic will not tolerate the unlawful or unauthorized use, manufacture, possession, sale or transfer of illegal or controlled substances or the abuse or unauthorized use of alcohol on or off Clinic property. The Cleveland Clinic Substance Abuse Policy applies to non-staff employees and to physicians with certain modifications because of the greater responsibility of physicians in the care of patients. Cleveland Clinic is also bound by the Federal Drug-Free Workplace Act of 1988 and thus all employees including physicians, must, as a condition of their employment, abide by all the terms of the Substance Abuse Policy. Cleveland Clinic recognizes that the misuse of drugs or alcohol may indicate an illness with drug-induced effects on thinking, attitude and behavior. All employees are encouraged to seek help voluntarily. Cleveland Clinic

also provides education, prevention, treatment, reentry and monitoring to assist employees while ensuring a drug-free environment. Help for physicians will include appropriate medical, psychological and chemical dependency care in conformance with the substance abuse policy and the benefit plan.

To facilitate this process, the Board of Governors authorizes the following:

The Physician Health Committee

Cleveland Clinic maintains a committee for the purpose of dealing with all matters related to physician health and impairment. Cleveland Clinic recognizes those medical, emotional and psychiatric conditions, as well as the misuse of drugs or alcohol may influence thinking, attitude and behavior. The Physician Health Committee (PHC) serves as a clearinghouse for complaints, referral, evaluation, treatment, re-entry, monitoring and compliance. All matters regarding possible or suspected physician impairment must be referred to the Physician Health Committee for review, comment and recommendations. All matters brought 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/Visiting researchers

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.

Policies and Procedures for Physicians

As employees of Cleveland Clinic, all staff and clinical trainees/research fellow physicians must comply with the 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 Visiting researchers 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.

SMOKE FREE POLICY

In an effort to provide a healthy environment for all employees, patients and visitors and to continue our dedication to health and wellness; Cleveland Clinic and the Cleveland Clinic Health System became a smoke free environment. Smoking bans on all Clinic and CCHS properties will be strictly enforced. To assist our employees, Cleveland Clinic offers special programs to help employees quit or reduce their tobacco use.

Nonsmoking Hiring Policy

To take further steps in preserving and improving the health of all its employees and patients; Cleveland Clinic has a **nonsmoking hiring policy** requiring all job applicants and individuals receiving appointments to take a cotinine test (nicotine metabolite) during their pre-placement physical exam (health screening). This is a pre-employment test only. The cotinine test will detect the presence of nicotine in all forms of tobacco.

Appointments that have been offered to prospective residents and fellows who test positive will be rescinded. Those individuals who test positive, then test negative after 90 days, may be reconsidered for appointment at the discretion of the training program director should the residency/fellowship position remain vacant.

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 recognizes the need for clinical trainees' involvement in multiple levels of committees and councils.

The GME Coordinators will coordinate the assignments of the committees prior to the start of each academic year. This includes contacting the Chairman of each of these councils and committees to see if the clinical trainee participants are attending the meetings and if they will remain on the committee for the following academic year. If a replacement is needed, the Chairman of the committee or council may identify another clinical trainee to participate on the committee or council. Or, they may ask for the assistance of the GME Coordinators in identifying a clinical trainee that would be interested in participating. Once the list is finalized, it should be submitted to the GMEC Coordinator for presentation to the Graduate Medical Education Committee.

Clinical Trainees who are members of Institutional Committees are required to attend scheduled meetings. If the Clinical Trainee who is a designated member of a Committee is unable to

attend a scheduled meeting, they should designate an alternate in their absence.

In addition to those committees and councils identified, the Institutes are required to involve clinical trainees in all committees, councils and task forces that are appropriate. At the minimum, clinical trainees should be involved in any institutional committees dealing with educational programs, quality assurance and other graduate medical education affairs.

Clinical Trainees are also required to attend all meetings and conferences considered mandatory by the Institution or their department.

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.

EDUCATIONAL RESPONSIBILITIES OF CLINICAL TRAINEES

The clinical trainee shall:

•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 trainee's 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

The clinical trainee shall:

•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/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 Florida.

•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 duty hours and duty 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 COMET.

•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 - and complete all necessary records and settle all professional and financial obligations.

PERSONAL RESPONSIBILITIES OF CLINICAL TRAINEES

The clinical trainee shall:

•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 OF CLINICAL TRAINEES

The clinical trainees shall:

•Fully cooperate with the Program and Cleveland Clinic in coordinating and completing RRC 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/ADA/CPME and any other relevant accrediting, certifying or licensing organizations.

•Comply with all ACGME requirements including but not limited to those regarding duty hours and moonlighting. Please refer to specific ACGME institutional requirements and RRC program requirements at <u>www.acgme.org</u>

•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 (CC) has had medical students rotating on its campus since 1974 and clinical trainees have always played a central role in their educational experience. CC serves as a core training site for medical students from various medical schools. Additionally, many visiting students come to CC each year. All medical students on educational rotations fall under the purview of the Cleveland Clinic. Each medical student rotation has a CC faculty who is responsible for outlining the student learning objectives and expected roles and responsibilities.

Residents/fellows play a critical role in the education of medical students. In the hospital setting, the residents/fellows are the point of first contact for the student. Residents/fellows will teach a substantial amount of what the students learn. Residents/fellows need to be aware of the rotation learning objectives and student roles. Ideally, the director of the medical school rotation will talk with the residents/fellows regarding what is expected of the residents/fellow in these roles. After these discussions, there will be follow-up to residents via email, written material or direct conversation with the student and/or rotation director.

In addition to the specific rotation objectives there are general principles that will help a resident/fellow be an effective teacher:

Residents/fellows have multiple roles, including supervisor, teacher, role model and assessor.
Residents/fellows must orient students to a new service. Students depend on the resident 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 resident/fellow needs to spend time with the student specifying his/her role in various areas listed below. Many of these areas will be specified as part of the rotation description/objectives:

Blood draws Precautionary measures, such as infection control Numbers of patients to be seen per day Write ups to be handed in per week Conferences to attend Frequency of call and where the on call quarters are for that service Time of rounding How to access computers for patient information Policy on placing orders with counter signature Expected times for arrival and departure Policy for absenteeism Layout of facilities

•Resident/Fellow as Role Model:

Residents/fellows 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. Destructive, belittling comments do not enhance learning and are inappropriate.

•Teaching Role of Residents/Fellows

<u>Specify learning objectives</u>: The clinical trainees should be familiar with rotation objectives as noted above. The students should be informed about the objectives for their rotation on their first

day.

<u>Specify organization</u>: 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.

<u>Specify teaching methods</u>: 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, cost-containment, preventive medicine and interdisciplinary care.

An essential component of good teaching is providing helpful feedback to improve performance.

Residents/fellows 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).

•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 rotation director should be included in this process. Residents/fellows are expected to directly observe and assess the student's performance in areas such as patient care, histories and physicals, etc. Direct observation forms the foundation of feedback.

PROFESSIONAL CONDUCT

Professional Conduct Code

The purpose of this Policy is to define disruptive and inappropriate behavior involving residents and fellows (referred to as clinical trainees) and to delineate the response to be followed in all cases involving such behavior.

In almost all cases the institutions 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. 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 at Cleveland Clinic to treat others with respect, courtesy, dignity and to conduct oneself in a professional manner. Patients, visitors, healthcare professionals and all employees must be treated with courtesy, respect and dignity. This policy is complementary to and consistent with, the Cleveland Clinic Code of Conduct and other communications addressing appropriate conduct, such as the COMET Module on Disruptive Behavior and Code of Conduct initiatives by Cleveland Clinic Institutes.

Behavior by clinical trainees that generates a complaint by another clinical trainee, an employee of the hospital, clinical or administrative staff or individuals in contact with the clinical trainee at the hospital including patients, will be responded to according to this policy and referred to the

Chairman, Graduate Medical Education Committee (GMEC).

Behavior that suggests that the trainee may suffer 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. The Physician Health Committee can be particularly helpful in monitoring a troubled trainee, enabling the trainee to be helped while preserving the trainee's residency or fellowship training. The process of inquiry into and response to inappropriate behavior by clinical trainees is confidential.

Code of Conduct

Cleveland Clinic has a tradition of ethical standards in the provision of health care services as well as in the management of its business affairs. The Code of Conduct supplements the mission, vision and values of Cleveland Clinic and applies to all who provide services under the auspices of Cleveland Clinic and its affiliates. Our Code of Conduct provides guidance to all in carrying out daily activities within appropriate ethical and legal standards. The Code of Conduct also provides standards of conduct to protect and promote integrity and to enhance Cleveland Clinic's ability to achieve its mission and compliance goals. The Code of Conduct is part of Cleveland Clinic's General Compliance Program. There are 7 principles: Legal and Regulatory Compliance Business Ethics Conflicts of Interest Appropriate Use of Resources Confidentiality Professional Conduct

Responsibility

As a CCHS employee, you 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. To review the entire Code of Conduct, go to http://intranet.ccf.org/compliance/Code%20of%20Conduct%20Feb%2008.pdf

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 Cleveland Clinic Law Department (216) 448-0200, <u>http://portals.ccf.org/lawdepartment</u>

Investigating Scientific Misconduct

It is the desire of 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.

All clinical trainees and researchers are required by the Board of Governors to take a course on the Responsible Conduct of Research and Scientific Integrity (RCR) to meet PHS and NIH education requirements. Beginning in the fall 2001, web-based instructions will be available to meet this requirement (currently done in two, one and one-half hour modules, offered in the spring and fall of each year.).

For the complete policy, refer to the Policy and Procedure Manager http://portals.ccf.org/today/Policies/tabid/14282/Default.aspx

Conflict of Interest

A Conflict Of Interest (COI) may exist when a CC 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-CC party - whether investment, compensation or otherwise - that could be reasonably perceived as influencing the Employee's actions or judgments in patient care, research, administrative decisions or business transactions for CC. For example:

Business – "A Conflict of Interest" may exist if a CC Official receives financial benefits from an entity that does business with CC.

Researcher – An employee owning stock in a pharmaceutical company that sponsors his or her research would present a "Significant Financial Interest" in research.

Institutional (Research) – An employee performing research sponsored by a company in which CC itself owns stock may constitute an "Institutional Financial Interest" in research.

To assure professional and commercial integrity in all matters, CC maintains a program that identifies and addresses conflicts of interest, conflicts of commitment and consulting. These policies provide a comprehensive system of disclosure and oversight of all Conflicts Of Interest for all employees. COI policies are available for your review at

<u>http://cc- clirb52.cc.ad.cchs.net/coi/policies.asp</u>. Any further questions should be directed to your Program Director or Department Chairman.

Conflict of Interest in the Practice of Medicine

<u>Purpose</u>

To assure professional and commercial integrity in all matters, Cleveland Clinic United States (CCUS) maintains a program that identifies and addresses conflicts of interest in the practice of medicine.

Policy

Having Relationships with Non-Cleveland Clinic (CC) Entities While Also Practicing Medicine This policy applies to CCUS Professional Staff, residents and fellows who provide healthcare to CCUS patients (Healthcare Providers) [See also the Conflicts of Interest in Research Policy]. A Healthcare Provider may deliver outside lectures or engage in consulting or other 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 CCUS policies. 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. CCUS 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.

[See also the CCF Intellectual Property and Commercialization Policy] 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 the practice of medicine. Any required actions will not limit the clinical activities that CCUS Healthcare Providers believe to be in the best interests of

their patients; rather, the IM&COI Program will make efforts to manage the relationship or Financial Interest in the Non-CC Entity.

Receipt of Gifts by Healthcare Providers from Non-CC Entities

In general, CCUS Healthcare Providers and their Immediate Family Members may not accept gifts from Non-CC Entities. Gifts include any transfer of value (financial or otherwise) provided by a Non-CC Entity to a CCUS Healthcare Provider that is not for services rendered or is not for goods received or that is in excess of fair market value and includes, but is not limited to compensation for attendance at a conference, goods, cash, gift cards, meals*, travel and event tickets. Accepting items of minimal value such as flashlights, pens and notepads is discouraged, but not prohibited.

*Exception for Meals: It is permissible to accept meals that are off-site of CCUS facilities paid

for by Non-CC Entities if these meals are modest, infrequent, from a single provider and served during or in conjunction with medical education, healthcare information exchange, biomedical research discussions or discussions of data relevant to clinical practice. [Subject to Policy VII on Conflicts of Interest in Education]

The Institution will only accept philanthropic gifts from Non-CC Entities if made through the Philanthropy Institute in accordance with its policies. [See also Policy VII Conflicts of Interest in Education for other limitations regarding gifts]

Distribution of Non-CC Entity-Derived Materials Containing Information Directed at Patients as Part of Clinical Practice or Patient Education

Educational materials directed at patients that are developed by Non-CC Entities for use in patient care may only be made available following approval by a Professional Staff physician. If the Professional Staff physician has financial interests of any kind related to the company in question, he/she may not participate in the determination. In that case, the Institute Chair in collaboration with the Department Chair in that Institute must decide whether the materials should be made available. The decision will be based on the best interests of patients and the limitation of inappropriate Non-Cleveland Clinic (CC) Entity influence. Educational items with Non-CC Entity logos are discouraged.

[See also the Pharmaceutical Representative Policy. Also, the receipt of educational materials directed at providers is subject to the requirements of Policy VII Conflicts of Interest in Education.]

Having Financial Interests in a Non-CC 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

All CCUS Healthcare Providers who have a Financial Interest in a Non-CC Entity making drugs or devices being used by or at the direction of the Healthcare Provider to diagnose or treat patients, whether the use is on-label or off-label, must receive approval from the IM&COI Program unless the total of the annual fees for services, annual royalties, and the approximate market value of the holdings over the prior 12 months are below \$20,000 from a single Non-CC Entity and the stock holdings are less than five percent of the Non-CC Entity (excluding stock held in a diversified mutual fund). The IM&COI Program may require elimination or a reduction of the Financial Interest or devise a Conflict Management Plan to ensure, to the extent possible, that clinical practice is free from bias that may result from the Financial Interest. Certain types of relationships will be publicly disclosed via CCUS webpages, brochures or other means generally accessible to CCUS patients.

[For relationships with Non-CC Entities related to the use of experimental devices and drugs, see the conflict of interest policies that pertain to research, i.e., Conflict of Interest Policies III and IV.]

Donating to Charities Part or All of Honoraria or Consulting Compensation, Royalties and Other Revenues from Commercialization Received from Non-CC Entities

The potential of a Significant Financial Interest ("SFI") to create a Conflict of Interest, or in research, either a Conflict of Interest or PHS-Reportable Financial Conflict of Interest, is not eliminated by donating Honoraria or Consulting Compensation or Royalties and Other Revenues from Commercialization received from Non-CC Entities to a charity designated by the individual with the SFI. The only exception to this provision is where the individual with the SFI donates the Honoraria or Consulting Compensation, or Royalties and Other Revenues from Commercialization to the Cleveland Clinic Innovators' Charitable Fund.

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

Patient Referrals to a Physician, Entity or Practice with which there is a Potentially Conflicting Relationship with the Referring Healthcare Provider

A conflict of interest between the recipient of a referral and the referring Healthcare Provider occurs when the referring Healthcare Provider or member of his or her Immediate Family could benefit financially from the referral. If the referring physician is personally compensated by a Non-CC Entity or the referring physician or member of their Immediate Family owns any part of a company to which he/she is referring a patient, approval must be obtained from the IM&COI Program and the Law Department. In all cases, prior to referral, approval must be obtained from the referring Healthcare Provider's Department Chair and his/her Institute Chair must be notified. He/she must also disclose the relationship to the patient being referred and any reasonable alternatives should be made clear.

The restrictions herein do not apply when a Healthcare Provider is referring a patient to a sub-unit of CCUS (e.g. a physician is referring a patient to radiology, but not to a specific radiologist and the physician's spouse works in CCUS radiology). It is emphasized that all referrals of patients be made based on the best interest of the patient.

Distribution of Prescription or Over-the-Counter Samples to Patients

CCUS has a policy containing specific restrictions regarding drug samples. [See Department of Pharmacy Policy 10-002: "Pharmaceutical Representative Guidelines"]

Site Access to CCUS by Pharmaceutical, Diagnostic and Medical Device Non-CC Entity Representatives

CCUS has a policy pertaining to site access by Pharmaceutical Representatives. This policy hereby extends the limitations contained in the Department of Pharmacy Policy to include all Non-CC Entity representatives. [See Department of Pharmacy Policy, Pharmaceutical Representative Guidelines, and the Conflict of Interest Procedure for Vendors].

The IM&COI Program may grant exceptions where the Non-CC Entity representative visit is of direct benefit to a patient currently being treated.

Ghostwriting

CCUS Staff, residents and fellows are prohibited from allowing their professional presentations, oral or written, to be ghost-written by other(s). Ghostwriting encompasses instances in which a person who qualifies for authorship is not acknowledged or listed as an author on a publication and instances in which a person who does not qualify for authorship is named as an author on a publication. All persons designated as authors should qualify for authorship. [Qualifications for authorship should be in accordance with the Guidelines for Manuscripts and Books and Commercial Publication, included in the Major Policies for the Professional Staff (Yellow Book)]

Conflict of Interest in Education

<u>Purpose</u>

To assure professional and commercial integrity in all matters, Cleveland Clinic United States (CCUS) maintains a program that identifies and addresses conflicts of interest in education.

Policy

Engaging in Activities Related to Industry While Delivering or Receiving Medical Education. The intent of this policy is to ensure that CCUS Staff and Trainees adhere to the highest ethical standards when they participate in educational endeavors. This policy applies to CCUS Staff and Trainees who are responsible for educating, and to trainees and other learners who work and/or learn at CCUS as part of their career development.

Required Disclosure of Industry Relationships to Trainees by Faculty

CCUS Staff and Trainees who teach, whether to multiple Trainees or to one Trainee, must disclose to their Trainee(s) their relevant Financial Interests in Non-Cleveland Clinic (CC) Entities, including book royalties. For example, the relationship must be disclosed if the products of the

Entities are mentioned in the course of the training. Typically, such disclosure should be made in the presentation mentioning the product and also in the syllabus, if the course has a syllabus.

Attending Non-CC Entity-Sponsored Education and Training Activities

CCUS Staff and Trainees may not accept gifts, remuneration, or other forms of compensation from Non-CC Entities solely for attending or listening to Non-CC Entity-sponsored educational events. They may not accept funds for reimbursement or defrayment of costs associated with travel to the activity unless serving as faculty at the activity. Attendees must pay their own tuition or reimburse the Non-CC Entity sponsor at fair market value for the educational activity. Certain exceptions to this provision (e.g., FDA-required training for use of a new procedure or device; certain professional society funded scholarships to attend meetings) may be permissible with approval from the IM&COI Program.

Non-CC Entities may not provide meals to CCUS Staff and Trainees during or in conjunction with an on-site educational activity unless the educational activity is ACCME accredited. It is permissible to accept modest meals paid for by Non-CC Entities and served during or in conjunction with an off-site educational activity.

Receipt of Educational Funds from Non-CC Entities

Support of scholarships, fellowships, and other educational awards (Educational Funds) for training at CCUS by Non-CC Entities must be in the form of an educational grant to the institution, not an individual. Such support includes sponsorship of travel expenses for educational meetings. The provision of these funds must be in accordance with policies and procedures of the Philanthropy Institute or the Office of Sponsored Research and Programs. For such Non-CC Entity support of Trainees, selection of the individual recipients is at the sole discretion of CCUS. There must be no quid pro quo provision of any kind for either the selected trainee or the program. Funds must be directed to the institution at the Institute level or higher, not to the Department or individual trainee. Allocation of such funds for scholarships, fellowships or educational meetings, including travel expenses to and from educational meetings, must be made by a committee designated by the Institute Chair (or the Education Institute Chair for allocation of funds to the institution). Any member of such a committee who has a Financial Interest of any kind with the Entity donating to the fund may not participate in decisions related to fund allocation. For Non-CC Entity support to attend educational meetings or programs, the Institute Chair or designee must agree to the educational merit of the program and approve the financial support.

Any exceptions to these provisions must be approved by the IM&COI Program.

Speaking and Training at Non-CC Entity-Sponsored Events

CCUS Staff and Trainees are approved to speak at educational activities supported by Non-CC Entities that are ACCME accredited.

For presentations that are not ACCME accredited and are sponsored by Non-CC Entities, CCUS Staff and Trainees should ensure that the following conditions are met:

The presenter is the developer of the content of the talk and is responsible for, and agrees with, all aspects of the content or the presentation has a high educational value and the content is totally devoid of the mention of any drug (i.e. non-branded), drug product or device and is purely scientific in nature and the speaker is in agreement with all aspects of the content.
The presenter ensures that the presentation cannot be interpreted as purely promotional of a particular product. The content should be accurate, data-driven and balanced with respect to

current views.

•The presenter should disclose all relevant Financial Interests in Non-CC Entities at the beginning of the presentation.

•The presenter may accept honoraria for presenting and reasonable travel expenses and modest meals. Honoraria should be commensurate with time and effort and meet fair market value standards.

•The presenter will appropriately credit collaborators and other sources of materials used in the presentation (e.g., slides, data, videos, etc.).

Upon request, exceptions to these guidelines may be permitted after review and approval by the Innovation Management & Conflict of Interest (IM&COI) Program, and where relevant, the Law Department. [See Policy V, Consulting]. If for example, FDA guidelines require that the

presenter use FDA-approved materials and these have been developed or provided by a Non-CC Entity, the IM&COI Program would consider such a request, provided that the presentation's content is, in the presenter's best professional judgment, accurate, data-driven and balanced with respect to current views.

Gifts of Educational Materials from Non-CC Entities

Other than philanthropic donations to the institution, which must be given in accordance with the policies and procedures of the Philanthropy Institute, gifts from Non-CC Entities are generally prohibited. [See Policy VI, Conflicts of Interest in the Practice of Medicine, Conflict of Interest Procedure for Purchasing Decision Makers and The Cleveland Clinic Foundation Center for Continuing Education Commercial Funding Policy 2008-03]

Single-use (consumable/disposable) items may be provided, but only in amounts necessary for adequate evaluation or education. Multiple-use products should only be provided for periods necessary for adequate evaluation or education. Items bearing commercial trademarks or logos are discouraged in patient care areas. Exceptions must be approved as specified in the Policies referred to above.

Trainees Supervised by Faculty with Non-CC Entity Relationships

Trainees at CCUS may not be involved in research projects in which the Staff supervisor of the research project or mentor of the Trainee has a Significant Financial Interest in the sponsor of the research or the maker of the product being evaluated, without approval from the IM&COI Program. Staff may not engage Trainees in research projects if the outcome of the research may jeopardize the Trainee's productivity or career development or if publication or communication of results is restricted. The stipend or payment received by the Trainee may not be dependent on the outcome of the research, nor may Non-CC Entity funding of the Trainee be dependent on the success of the company or its associated research endeavors. In all cases, Staff mentors must disclose to their Trainees all of their relevant Financial Interests with Industry.

Trainee Relationships with Non-CC Entities

Trainees are subject to the same policies, rules, regulations, and procedures as CCUS Staff and Employees with regard to relationships with Non-CC Entities. In addition, the Trainee may not have Financial Interests in Non-CC Entities without full disclosure to and approval by the Trainee's direct supervisor, Department Chair, educational program director for the Institute, where applicable, the Office of the Chairman of the Education Institute and the IM&COI Program.

Access to Trainees by industry representatives is permitted only with permission of the Trainee's direct supervisor. Such visits must be in accordance with accompanying IM&COI policies and the Pharmaceutical Representative Guidelines.

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 resident 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 by accessing the following link: <u>http://www.certificationmatters.org/about-board-certified-doctors/about-board-certification.aspx</u>. Please refer to the section on Leave of Absence (LOA) in the Graduate Physicians Manual (under Benefits) for types of LOA and detailed policies for authorized leave of absence.

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 resident of an extension to training for deficient performance in accordance with the GME Promotion and Renewal of Appointment Policy. 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 directors must provide as much written notice as the circumstances reasonably allow.

Specific board requirements regarding allowable time away are provided on the ABMS website <u>http://www.abms.org/About_ABMS/member_boards.aspx</u> for each accredited 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.

PERFORMANCE & EVALUATIONS

Performance

There shall be regular ongoing evaluations of clinical trainee/researchers performance during training. Regular evaluations are required in all training programs as is feedback to the individual regarding his/her performance. On each service within a training program, clinical trainees will be rated by the staff physicians with whom they have been working and evaluations may be completed by other medical personnel who are involved in the clinical trainee/researchers training. 360 degree evaluations are encouraged. The Program Director or designee will provide the clinical trainee/researchers with summative feedback, regarding his/her overall performance in the program, after periods of no longer than 6 months of the beginning of training and earlier if needed. It is anticipated that the Program Director or designee will provide this summative feedback at least twice a year.

Whenever a clinical trainee/researchers competence (with respect to any element of his/her conduct, skills, duties or responsibilities) is determined by the program to be less than satisfactory or otherwise worthy of discussion, the Program Director or designee shall meet and discuss his/her performance with the clinical trainee/researcher. Minutes shall be kept of this discussion. A clinical trainee/researchers performance as referred to in this policy, shall include, in addition

to general clinical skills and expected fund of medical knowledge at their level of training, the clinical trainee/researchers behavior and conduct as well as actions which are considered adverse or incompatible to the general philosophy of Cleveland Clinic, including but not limited to, sexual harassment, smoking, noncompliance with federal regulations and Cleveland Clinic policies, applicable to all employees and noncompliance with all state and local laws.

In the event a clinical trainee/researchers performance warrants further action the program may:

- provide verbal or written counseling
- issue a performance warning
- reappoint but not promote to the next year of training (not applicable to visiting researchers)
- not reappoint (not applicable to visiting researchers)
- dismiss the clinical trainee/researcher from the training program

The action to be taken would be determined by the nature and extent of the inadequacy of general performance or specific egregious violations.

The overall spirit of any counseling or performance warning is one of attempting to assist the trainee in improving in the areas of deficiency. It should be done in a positive fashion and with specific improvements, expectations and timelines that are clear to the trainee. Training programs are encouraged to have their Clinical Competency Committee assist the Program Director to determine appropriate courses of action and improvement plans.

Counseling - Verbal and Written

Although a program has complete discretion regarding the appropriate handling or treatment of a clinical trainee/researchers performance, the following describes an example of how the counseling status may be applied:

A first step may involve "verbal counseling". Verbal counseling may occur at any time or several times in a clinical trainee/visiting researchers training and should be duly noted in the clinical trainee/researchers department file. If performance continues without the desired improvement, the second step is "written counseling". The written counseling should involve the delivery of a written memo or other notification to the clinical trainee/research fellow that specifies the reasons for the written counseling and specific improvements, expectations and timeline thereof and be kept in the clinical trainee/researchers department file.

Counseling is intended to be positive and constructive in nature and not negative or derogatory. Counseling, when appropriate whether verbal or written, is considered to be an integral component of graduate medical education and should never be construed as a limitation or restriction on the clinical trainee/researcher or involve a special requirement to be met by the clinical trainee/researcher. Counseling is not disciplinary, probationary or investigatory in nature nor is counseling necessarily a reflection of unsatisfactory performance or academic incompetence. Counseling is not an adverse charge or action and may not be appealed by the clinical trainee/researcher. While the GME Department encourages the trainees to address and resolve issues related to verbal and written counseling with their Program Director, officials in the GME Department are available to answer any questions and assist the trainees in resolving such issues.

Performance Warning

In the event of unsatisfactory performance (depending upon the nature and/or extent of the unsatisfactory performance) or if at the end of the timeline specified in the written counseling improvement plan, the clinical trainee/researchers performance has not improved to the extent and within the period of time considered acceptable by the program, the clinical trainee/researcher may be issued a performance warning. The program invokes performance warning status by written notification to the clinical trainee/researcher that advises that his/her performance is not satisfactory and that includes a clear statement that the clinical trainee/researcher is on performance warning. This notice to the clinical trainee/researcher shall include a detailed description of the unsatisfactory performance, the expectations for performance improvement and time parameters in which performance is to improve. As a result of a performance warning, clinical trainee/researchers clinical duties and other activities may be restricted or otherwise curtailed by the Program Director.

In the event a clinical trainee/researcher is placed on performance warning, a copy of the performance warning notice shall be forwarded to the Director of Graduate Medical Education for inclusion in the clinical trainee/researcher's academic file. The Director of Graduate Medical Education or the Center Director, Education Center or his/her designee will discuss the performance warning with the parties involved.

Performance warning status may be issued for a predetermined period of time (for example, three months) or for an indefinite period, as determined by the program. The program also has the discretion to extend any period of performance warning status. A clinical trainee/researcher who has been placed on performance warning shall have this status and his/her progress towards performance improvement reviewed by the Program Director or designee on a regular basis.

The Program shall inform the trainee in writing when the performance warning has been lifted and that the program is now satisfied with the improvement and current status of their performance.

Performance warnings may be appealed to the GME Department (See Procedure for Clinical Trainee/Researcher Appeal Process) by the clinical trainee/researcher.

Dismissal from Training and Administrative Leaves of Absence

If upon the expiration of the performance warning status or in the event of an indefinite period of performance warning after at least the first periodic review by the Program Director or designee, the clinical trainee/researchers performance has not improved to the extent considered acceptable by the Program and the Director of Graduate Medical Education or Center Director, Education Center, the clinical trainee/researcher may be immediately dismissed from the program.

In addition and notwithstanding, any of the foregoing to the contrary, a clinical trainee/researcher

may be dismissed from Cleveland Clinic "for cause" or otherwise dismissed from the program or placed on an administrative leave of absence without prior counseling and/or performance warning status for: 1) apparent serious violations of ethical, legal or medical practice standards of conduct 2) patient safety concerns or 3) investigation of adverse incidents/issues involving a clinical trainee/research fellow. In the event a clinical trainee/researcher is dismissed from the program under any circumstance or placed on administrative leave of absence, the clinical trainee/researchers Program Director and the Director of Graduate Medical Education or Center Director, Education Center or his/her designee, shall advise the clinical trainee/researcher in writing of the dismissal or the administrative leave of absence and the general nature of the grounds therefore. Dismissal from training may be appealed by the clinical trainee/researcher unless, the reason for dismissal falls under the single significant events noted below*.

Right to Appeal

A clinical trainee may appeal:

- a performance warning
- reappointment but non-promotion to the next year of training
- non-reappointment (unless the reason for non-reappointment falls under the single significant events noted below*).
- dismissal (unless the reason for dismissal falls under the single significant events noted below*).

The clinical trainee may request an appeal by submitting a written request to the Director of Graduate Medical Education or the Center Director, Education Center within 2 weeks of the meeting with the Director of Graduate Medical Education or the Center Director, Education Center or his/her designee. Verbal counseling, written counseling and administrative leaves of absence may not be appealed.

A researcher may appeal:

- a performance warning
- dismissal (unless the reason for dismissal falls under the single significant events noted below*).

* Single Significant Events (Non-Appealable)

•falsification of Records**

•material omission of information on an application and/or official paperwork**

•conviction of a felony

•loss of medical licensure

**A thorough non-biased investigation shall be conducted by uninvolved parties before a determination is made that this is indeed the case of the single significant event.

Evaluation of Clinical Trainees

Formative Evaluations

Individual teaching faculty is required to complete evaluations rating the skills of the clinical trainees they supervised at the end of each rotation. Evaluations are administered via MedHub by each individual program coordinator. The number of evaluations that each faculty member is required to complete will vary depending upon their service assignment and/or number of clinical trainees. Teaching faculty are advised to complete these performance evaluations at the end of a trainee's rotation on their service. MedHub will assign performance evaluations to faculty by matching their service dates to a trainee's rotation schedule. Ultimately, faculty can remove evaluations from their assigned list based on their service experience. Thus, faculty members are not obligated to complete evaluations on trainees with whom they had only minimal contact.

Scale questions relating to clinical skill, medical knowledge, communication, professionalism, systems-based practice and practice based learning, as well as other important attributes, are included in each performance evaluation. If required to do so by the ACGME, Milestone-based evaluations should be used to assess clinical trainees' performance. Each program has the ability to create their own evaluation form. Teaching faculty is required to provide rationale for any answers of unsatisfactory or below. In addition, they have the option to supplement their answers with general comments.

Program directors must provide objective assessments of competence in patient care, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism and system based practice. If required by the ACGME, Milestones should be used for assessments. These assessments should be a culmination of the various evaluations completed on each clinical trainee as well as any other methods utilized for evaluating overall trainee performance. Clinical trainee performance assessment must be provided by multiple evaluators (i.e. faculty, peers, patients, self, etc.). Documentation should be completed and shared with the clinical trainee indicating performance appropriate to the graduate level with progressive responsibility.

Clinical trainees have the ability to review their individual evaluations and/or an aggregate view via MedHub or by contacting their Program Coordinator. Program Directors should meet periodically with clinical trainees to review the results of their performance evaluations.

Summative Evaluations

Refer to specific RRC Program Requirements for more detailed information regarding the requirement for frequency of these reviews. Composite evaluations are required for a trainee's permanent education file at least twice per year. The program director must also provide a summative evaluation for each clinical trainee at the completion of the program. This final evaluation must be assessable for review by the clinical trainee and will document the clinical trainee has demonstrated sufficient competence to enter practice without direct supervision.

Evaluation of Teaching Faculty

Clinical trainees are required to complete evaluations of their supervising teaching faculty at the end of each rotation. Evaluations are administered via MedHub; Cleveland Clinic's residency management system. The number of evaluations that each trainee is required to complete will vary depending upon their service assignment and/or number of attending staff. Each individual program coordinator is responsible for delivering all evaluations pertaining to evaluation of teaching faculty.

At the end of each rotation, MedHub will notify clinical trainees, via e-mail, that they have evaluations to complete. Upon logging into MedHub, trainees can view a list of their assigned evaluations. MedHub will continue to send weekly reminders to trainees until all of their assigned evaluations have been completed.

Included in each teaching evaluation are required Likert Scale questions relating to various teaching skills including: clinical teaching abilities, clinical knowledge, communication skills, feedback skills, supervisory skills, professionalism and commitment to the training program. Clinical trainees have the option to supplement their answers with comments about a faculty's strengths and suggestions for improvement with open comment boxes throughout the evaluation. Each program is required to use the GME created, Evaluation of Faculty Teaching form.

The confidentiality of teaching evaluation data is strictly ensured. Teaching faculty are never provided the results of individual evaluations completed by trainees. MedHub strictly protects the anonymity of clinical trainees and provides only aggregate results to the faculty if they have 5 or more completed evaluations. Under no circumstances will the results of an individual teaching evaluation be linked to an individual trainee.

Teaching evaluations completed by clinical trainees are an important part of a teaching faculty's Annual Professional Review (APR). These results are used to reward teaching excellence and identify areas where improvement is necessary.

Evaluation of Training Programs

Annually, clinical trainees are required to anonymously evaluate the strengths and weaknesses of their training programs by completing the Resident/Fellow Annual Evaluation of a Clinical Training Program evaluation via MedHub.

Using an evaluation form designed with the assistance of the House Staff Association, trainees have an opportunity to answer questions about an array of factors that contribute to their overall impression of their respective programs. For example, the survey includes specific questions about program leadership, learning resources, compliance with ACGME requirements and individual clinical trainee's future goals. The questions are Yes/No answer choices with required and optional comment boxes throughout the form.

The confidentiality of program evaluation data is strictly ensured. The results from each program's trainees are summarized and only provided to the Program Director and The Graduate Medical Education Committee (GMEC) if 5 or more evaluations were completed. Any program with less than 5 evaluations submitted per year will not receive data. For smaller programs with less than 5

trainees per year, data will be aggregated across years to ensure a report. Under no circumstances will the results of an individual evaluation be linked to an individual trainee.

Information gathered from program evaluations is helpful in measuring the effectiveness of the training program and is considered in future planning. The results will also be used during the ACGME required Annual Program Evaluation (APE) process, which is monitored by the GMEC. Each clinical training program must undergo an APE yearly, which is a meeting where the trainees and faculty discuss the quality of the training program as well as clinical trainee and graduate performance and faculty development. Upon completion of the APE the program will prepare a written plan of action to document initiatives to improve performance. The action plan should be reviewed and approved by the teaching faculty and documented in meeting minutes, which should also include attendance. At the APE the following year discussion will focus on how successful the program was in executing the action plan.

Additional Types of Evaluations

Clinical trainees and teaching faculty may also be asked to complete additional types of evaluations in MedHub, including: peer-to-peer, 360, and self-evaluations. These forms will be developed and deployed on a per program basis and will be used as the program sees fit. Additionally, patients may be asked to anonymously evaluate clinical trainees which they encountered as a result of their visit to the Cleveland Clinic.

AVAILABILITY OF STAFF TEACHING EVALUATIONS AND CLINICAL TRAINEE EVALUATIONS

Feedback and access to evaluations are such important components in graduate medical education that the GMEC has formulated the following regarding availability of evaluations:

Teaching Faculty:

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

Clinical Trainees:

Clinical Trainees need timely feedback in order to understand and correct areas of their performance that require improvement and to understand areas of performance that are adequate and exceed expectations. Feedback in real time is the most valuable as a clinical trainee is more easily able to reflect on their behaviors and actions and better understand what corrections need to be made. In addition, formal evaluations should be completed on clinical trainees at the completion of each rotation by faculty they worked with. These evaluations will be available for the clinical trainee's review in MedHub and faculty should be available for discussion of the clinical trainee's performance and evaluation.

Release of Trainee/Researchers Files

The following policy has been established for release of clinical trainee files:

- i. Clinical trainee/researcher files may be reviewed by the clinical trainee/research fellow, their program director, division/department chairman or the full-time department education coordinators (designated by the program director).
- ii. Division chairman, department chairman, program director or designated individuals (secretary or education coordinator) will be required to sign upon receipt of files and again upon their return. Files should be returned to the GME office within two (2) weeks.
- iii. Review of clinical trainee/research fellow files by other staff will require a release signed by the clinical trainee. The clinical trainee/research fellow files are permanent and original records. They must be hand delivered, not mailed back to the GME Department or given to someone else requesting the file.
- iv. Upon graduation/termination from a Cleveland Clinic training program, the program director or his/her designee will dictate a summary letter of the clinical trainee/research fellow's training for the file. If the former clinical trainee/research fellow signs a release, a copy of the summary letter only, (not the entire file) will be provided as requested.
- v. After an individual has completed training or departed the Cleveland Clinic for other reasons, they are no longer considered employees and no longer have access to their file.
- vi. Most file documents and all evaluations are available in the institutional GME database (MedHub) from July 2011 forward. Access to clinical trainee MedHub records is limited to the PD and PC; the clinical trainee is not able to access MedHub when he/she leaves Cleveland Clinic.
- vii. As of July 2013, all clinical trainees' files were converted to electronic files and can only be accessed through MedHub.

PROMOTION

All residency/fellowship 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. Neither Cleveland Clinic nor any of its ACGME accredited programs require residents or fellows to sign a non-competition guarantee or restrictive covenant. 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's satisfactory completion of the current academic year. Therefore, in the event a clinical trainee is dismissed at any time during the academic year or if for any reason a clinical trainee 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 a resident/fellow or not to promote to the next graduate level, the clinical trainee should be advised of such decision in writing by the Program

Director at least 4 months prior to the end of the appointment. If the primary reason(s) for the non- reappointment or non-promotion occur(s) within the 4 months prior to the end of the contract, the Program Director must provide the resident/fellow with as much written notice of the intent not to reappoint or not to promote the clinical trainee as the circumstances will reasonably allow, prior to the end of the current appointment (contract). This notice shall include a description of the grounds for which determination not to renew the resident/ fellow's appointment or not to promote the resident/fellow to the next graduate level. Non-promotion includes any extension of training in the final year of the program.

The clinical trainee 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 the Center Director, Education Center or the Associate Director of GME.

INSTITUTIONAL OVERSIGHT RESPONSIBILITIES

INSTITUTIONAL DUTY HOUR POLICY

Purpose

The Accreditation Council for Graduate Medical Education (ACGME) requires sponsoring institutions to have a written policy that addresses duty hours. Providing clinical trainees with adequate academic and clinical education requires careful planning with specific considerations of the impact of training requirements and duty hours on patient safety and the clinical trainees' well-being. Didactic and clinical education must have priority in the allotment of clinical trainee's time and energies. Duty hour assignments must recognize that faculty and clinical trainees collectively share responsibility for the care, safety and welfare of patients. The training program and its sponsoring department must establish an environment that is optimal for clinical trainees' education and for safe patient care, while ensuring that undue stress and fatigue among clinical trainees is avoided.

Clinical trainees' duty hours and on-call periods must not be excessive. The structuring of duty hours and on-call schedules must focus on the needs of the patient, continuity of care and the educational needs of the clinical trainee. Duty hours must be consistent with the ACGME Institutional Requirements, Common Program Requirements and Residency Review Committee (RRC) Program Requirements. More stringent duty hour requirements established by an RRC would take precedent over the duty hour requirements listed below.

• 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.

• Duty 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.

The Graduate Medical Education Committee (GMEC) is committed to ensure that clinical trainees are able to report concerns regarding duty hour 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; all comments are automatically forwarded to the Administrator of GME who will investigate concerns and report findings to the GMEC for review and action plan.

Program-Specific Duty Hour Policy

Each program must have a written policy and procedure consistent with the Institutional and program specific RRC requirements for clinical trainee duty hours and must regularly distribute those to the clinical trainees and faculty within their program. The written policy and procedure must be reviewed annually to assure accuracy and reinforce importance.

Averaging Duty Hour Periods

Averaging hours 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. The rotation with the greatest hours and frequency of call must comply with duty hour requirements.

If a clinical trainee takes vacation or other leave, those vacation or leave days are omitted from the numerator and the denominator when calculating duty hours and days off. Ex- 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.

Duty Hour Requirements

Maximum Hours of Work per Week:

Duty hours must be limited to 80 hours per week, averaged over a 4-week period or the length of the rotation, inclusive of all in-house call activities and all moonlighting. Duty hours are defined as all clinical and academic activities related to the program. The following must be included when reporting duty 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 towards duty hours; travel and nonconference 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 duty hours:

• Reading and study time spent away from the duty site

• Academic preparation time, such as time spent preparing for presentations or journal club Mandatory Time Free of Duty:

Clinical trainees must be scheduled for a minimum of 1 day free of duty every week, when averaged over four weeks.

• One day is defined as one continuous 24-hour period free from all clinical, educational, and administrative activities.

• It is not permissible to have the day off regularly or frequently scheduled on a clinical trainee's post-call day.

• At-home call cannot be assigned on these free days.

• Because at-home call does not require a rest period, the day after at-home call may be used as a day off.

• Extended or prolonged at-home call is not permitted as it would be in violation of the 1 day off in 7requirement.

• It is permissible for clinical trainees to take call for an entire weekend to allow them to have the entire next weekend off as long as the total duty hours, 1 day off in 7 and frequency of call are within the limits as specified by the requirements.

Minimum Time Off between Scheduled Duty Periods

The Cleveland Clinic GMEC has determined that clinical trainees must have 10 hours of rest between duty hour periods.

PGY-1 clinical trainees should have 10 hours free of duty between scheduled duty periods. Intermediate-level clinical trainees [as defined by the RRC] should have 10 hours free of duty between scheduled duty periods. They must have at least 14 hours free of duty after 24 hours of inhouse duty.

Clinical trainees in the final years of education [as defined by the RRC] *must* be prepared to enter the unsupervised practice of medicine and care for patients over irregular or extended periods.

• While it is desirable that clinical trainees in their final years of education have ten hours free of duty between scheduled duty periods, there may be circumstances [as defined by the RRC] when these clinical trainees must stay on duty to care for their patients or return to the hospital with fewer than ten hours free of duty.

• Circumstances of return-to-hospital activities with fewer than ten hours away from the hospital by clinical trainees in their final years of education must be monitored by the program director.

Maximum Duty Period Length

Duty periods of PGY-1 clinical trainees must not exceed 16 hours in duration.

Duty periods of PGY-2 clinical trainees and above may be scheduled to a maximum of 24 hours of continuous duty in the hospital. 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 duty.

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 duty to continue to provide care to a single patient. Justifications for such extensions of duty 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 duty.

Maximum In-House On-Call Frequency

PGY-2 clinical trainees and above must be scheduled for in-house call no more frequently than every third night (when averaged over a four-week period). Scheduled shifts (generally 8, 10 or 12 hours in length) in an ICU or night float rotations are exempt from the requirement that call be scheduled no more frequently than every third night.

Maximum At-Home Call Frequency

Time spent in the hospital by clinical trainees on at-home call must count towards the 80-hour maximum weekly hour limit. The frequency of at-home call is not subject to the every-third-night limitation, but must satisfy the requirement for 1-day-in-7 free of duty, when averaged over four weeks. At-home call must not be so frequent or taxing as to preclude rest or reasonable personal time for each clinical trainee. Clinical trainees are permitted to return to the hospital while on at-home call to care for new or established patients. Each episode of this type of care, while it must be included in the 80-hour weekly maximum, will not initiate a new "off-duty period". Therefore, the requirement of 10 hours off between shifts does not apply.

PGY-1 clinical trainees are limited to a 16-hour duty hour period and are not allowed to take at-home call.

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.

Maximum Frequency of In-House Night Float

Clinical trainees at all levels are eligible for night float, but may not be scheduled for more than six consecutive nights of night float.

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 written policy and procedure regarding moonlighting, in compliance with the ACGME Institutional Requirements. Moonlighting is voluntary: clinical trainees must not be required to engage in moonlighting. All clinical trainees who moonlight must be compensated for their time.

All moonlighting (internal and external) including compensated moonlighting at any of Cleveland Clinic's primary clinical sites must be counted toward the 80-hour weekly limit on duty hours. None of the other ACGME duty hour requirements apply to moonlighting. Refer to the Moonlighting Policy for additional information.

Alertness Management

In accordance with the ACGME Common Program Requirements, the program must educate all faculty and clinical trainees to recognize the signs of fatigue and sleep deprivation as well as fatigue mitigation processes. All new clinical trainees are required to complete the online COMET 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" in COMET.

Clinical Trainee Responsibilities Relating to Recording Duty 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, clinical trainees must hit the 'Submit Completed Duty Hours' button to confirm recorded hours. The trainee always has access to the current week and prior week to record their duty hours. Recording of duty hours in MedHub is required for all clinical trainees; 100% compliance is expected. Failure to do so is looked upon as unprofessional behavior and will be duly addressed by the program director; repeat offenses may be subject to 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 (16 hours max PGY1, 28 hours max PGY 2+) or 10 hour break between shifts, 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 clinical trainee to document a mitigating reason. This allows both the clinical trainee and the program to identify and correct potential duty hour problems before they actually occur.

Program Oversight of Clinical Trainees Duty Hours

Duty 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 the duty hour 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/her patient care duties. At the conclusion of each rotation the Program Director will have access to the Duty Hours Review Periods section in MedHub. This will provide the Program Director with the duty hour violation, 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 and commenting on each, as the ACGME expects Program Directors to review and sign-off on all duty hour violations. Once complete the Duty

Hours Review Periods information will be forwarded to their Institute Education Committee for review and approval.

Refer to the Duty Hour Review Periods Policy for additional information.

Institute Education Committee Oversight of Duty Hours

The GMEC requires that each Institute Education Committee review the Duty Hours Review Periods information for each accredited program on a quarterly basis. The Institute Education Committee will send a resolution with the action and decision to the GME office to be placed on a GMEC agenda for discussion.

GMEC Oversight of Duty Hours

The GMEC will monitor each training program's duty hours on a quarterly basis and if needed random intervals as requested by Council through the Duty Hours Review Periods reports and resolutions provided by each Institute Education Committee. 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 trainee's duty hours through the following:

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

WORK ENVIRONMENT

Graduate Medical Education at Cleveland Clinic is committed to and responsible for promoting patient safety and clinical trainee well-being in a supportive educational environment. Education of clinical trainees must occur in an environment in which they may raise and resolve issues without fear of intimidation or retaliation. An organizational system for clinical trainees to communicate and exchange information on their work environment and their programs will be provided. This may be accomplished through the House Staff Association or other forums in which to address clinical trainees' issues.

Cleveland Clinic encourages a process by which individual clinical trainees can address concerns in a confidential and protected manner. Any clinical trainee should feel comfortable and safe to discuss any concerns with their Program Director, Advisor, Chief Resident or the Director of Graduate Medical Education.

The following services are provided to minimize the work of clinical trainees that may be extraneous to their training programs and ensure that the following conditions are met:

a. <u>Food Services</u>: Clinical trainees on duty must have access to adequate and appropriate food services. Clinical trainees who are required to be on in-house call overnight, are provided with on-call meals. Clinical trainees entitled to on-call meals have their on-call meal allowance pre-loaded on their ID Badge. See the full On-Call Meal Policy for details.

b. <u>Call Rooms</u>: Cleveland Clinic maintains on-call rooms for clinical trainees who are required to be on-call in-house overnight. Any clinical trainee required to be in-house must have access to a call room. The ACGME strongly suggests strategic napping, especially after 16 hours of continuous duty and between the hours of 10:00 p.m. and 8:00 a.m. This would be available to clinical trainees during in-house call, night rotations and post-call.

c. <u>Support Services</u>: Patient support services, such as intravenous services, phlebotomy services, and patient transportation services are provided to all clinical trainees and training programs.

d. <u>Laboratory/Pathology/Radiology Services</u>: 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.

e. <u>Medical Records</u>: 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 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 and the EMR is available except during

occasional scheduled downtimes. The system is adequate to support quality patient care, the education of clinical trainees, quality assurance activities, and provides a resource for scholarly activity.

f. <u>Security/Safety</u>: Appropriate security and personal safety measures are provided to clinical trainees at all 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 Cleveland Clinic Police Department. Personal escorts are provided by contacting Security Department.

f. <u>Transportation</u>: 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.

h. <u>Additional Program Resources</u>: 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.

MOONLIGHTING

The Accreditation Council for Graduate Medical Education (ACGME) requires Sponsoring Institutions have a written policy that address professional activities outside the educational program. For the purpose of this policy, the following shall be considered moonlighting:

1. External moonlighting: Voluntary, compensated, medically-related work performed outside the institution where the clinical trainee is in training or at any of its related participating sites.

a. Clinical trainees engaged in moonlighting that involves independent patient care activities must be licensed for unsupervised medical practice by the state medical board. It is the responsibility of the institution hiring the clinical trainee to moonlight to determine whether such licensure is in place, adequate liability protection is provided and whether the resident has the appropriate training and skills to carry out assigned duties.

b. Clinical trainees on clinical J-1 exchange visitor visas are NOT permitted to engage in independent patient care activities due to federal regulations restricting unsupervised medical practice. Therefore, exchange visitors are NOT able to participate in moonlighting in category 3.

2. Internal Moonlighting: Voluntary, compensated, medically-related work (not related with training requirements) performed within the institution in which the resident is in training or at any of its related participating sites.

3. Independent patient care activities at Cleveland Clinic that require appointment through Professional Staff Affairs as a Limited Clinical Practitioner (LCP).

4. Supplemental on-call or any other supplemental responsibilities that are within the scope of the clinical trainee's training and commensurate with a clinical trainee's level of experience and skill. These supplemental responsibilities are fully supervised and occur outside normal training hours.

The Graduate Medical Education Committee (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 Residency Review Committees (RRC). In this capacity, the GMEC has implemented the following policy regarding activities outside the training program (referred to as moonlighting).

1. 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 a clinical trainees' educational/program responsibilities.

2. Moonlighting must not interfere with the ability of the clinical trainee to achieve the goals and objectives of the educational program or hinder patient care in any way.

3. Clinical trainees must not be required to moonlight.

4. Clinical trainees must submit prospective written notification to their program director indicating that they will be engaged in moonlighting activities. The program director must acknowledge the moonlighting activity with a signature on the notification form and this form will be maintained in the clinical trainees' program file.

5. All moonlighting (internal and external) that occurs must be counted toward the 80 hour weekly limit on duty hours.

6. PGY 1 clinical trainees are not permitted to moonlight.

The decision to allow clinical trainees of any training program to participate in moonlighting activities shall be at the discretion of the program director. The program director may request that a clinical trainee not moonlight for any of the following reasons:

1. The moonlighting activity would exceed the RRC requirement limiting duty hours or interfere with on-call assignments.

- 2. The clinical trainee is unable to meet any of the requirements of the training program.
- 3. The clinical trainee's performance is below the expected standard for his/her level of training.

4. The program director feels the requirements of the program are such that none of the clinical trainees in the training program may moonlight.

5. Moonlighting is not permitted during an interval of Performance Warning

Program directors should monitor the performance of the clinical trainee 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 clinical trainee who is moonlighting, the program director would advise the clinical trainee to discontinue moonlighting activities. If a clinical trainee is found to be moonlighting without program director approval, the clinical trainee may be subject to disciplinary action.

Moonlighting Notification Form

The Accreditation Council for Graduate Medical Education (ACGME) requires that clinical trainees submit prospective written notification to their program director indicating that they will be engaged in moonlighting activities. The program director must acknowledge the moonlighting activity with a signature on the notification form and this form will be maintained in the clinical trainees' program file.

The program director should assure (to the best of his/her ability) that the moonlighting experience for each clinical trainee does not compromise the following: the educational experience of the clinical trainee's training program; the clinical trainee's prescribed duty hours for that specialty (established by the Residency Review Committee); and the nature of the moonlighting work is appropriate for the clinical trainee's level of experience.

Program directors have the authority to approve or deny moonlighting opportunities for clinical trainees based on their ability to meet training program goals and objectives. Also, program directors may feel the requirements of the training program preclude clinical trainee involvement in outside activities during portions of the training program or during the entire training program. Any moonlighting (internal and external) that occurs must be counted toward the 80 hour weekly limit on duty hours.

Clinical trainees in programs that are accredited are required to complete this form and submit to their program director prospectively for approval prior to accepting and engaging in moonlighting activities.

Site of Moonlighting	Supervisor	Frequency (i.e. 1/wk for 12 hr. shift)	General Responsibilities

Attach additional sheet if necessary

PROGRAM DIRECTOR

Clinical Trainee Printed Name
Not Approved

Approved

Clinical Trainee Printed Name

Program Director Signature Date Signed

GME Institutional Manual

EMERGENT SITUATIONS OR DISASTERS (EXTREME EVENTS)

Purpose

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 trainee's 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.

Policy

The primary source for communication regarding an extreme event and recovery plan for program directors, program coordinators and clinical trainees will be the CC GME web page (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's involvement in local extreme emergent situations must take into account the following aspects of his/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 trainee's level of post-graduate education
- clinical trainee's 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/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/her designee.

The DIO will contact the Executive Director, Institutional Review Committee (ED-IRC), via telephone only if an extreme emergent situation causes serious extended disruption to resident 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 Residency Review Committees (RRCs).

Only upon receipt of this confirmation by the DIO may the program directors contact their respective EDs-RRCs 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-RRCs 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, Institutional Review Committee (ED-IRC) via telephone in the case of a disaster which causes serious, extended disruption to resident assignments, educational infrastructure or clinical operations that might affect the Sponsoring Institution's and its programs' ability to conduct resident 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-RRC with information and/or requests for information. Clinical trainees can call or email the appropriate ED-RRC 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/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 the Cleveland Clinic GME web page (GME|com) to keep informed regarding the status of programs affected by the extreme event.

HOSPITAL CLOSURE OR PROGRAM CLOSURE/REDUCTION

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 Committee (GMEC).

The Cleveland Clinic will inform the GMEC, the Designated Institutional Office and the affected residents 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 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 residents currently in the program. If this is not possible, Cleveland Clinic will make reasonable efforts to assist the residents in identifying and entering another ACGME program.

In the event Cleveland Clinic decides to close a residency program, the residents 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 residents 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 residents and fellows 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 Residents 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 (CC) program director is approached about accepting a displaced clinical trainee, the first point of contact should be the DIO at CC 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 CC 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 CC would need to financially sponsor the displaced clinical trainee from department operating funds.

ROTATION AT PARTICIPATING SITES (OUTSIDE ROTATIONS)

Cleveland Clinic is committed to providing clinical trainees with an educational program that offers a personal program 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.

Required Rotations

In order to obtain adequate experience and/or skills not available at Cleveland Clinic, program directors may arrange for rotations at participating sites. Rotations are considered required

rotations when all clinical trainees (at a specific graduate level or anytime during training) are scheduled for the rotation. For these rotations it is expected that program directors will:

1. Monitor all aspects of the curriculum including conference participation at participating site(s).

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 the on-call and rotation schedule to assure appropriate supervision and adequate back-up while on-call.

- 5. Monitor duty hours of clinical trainees.
- 6. Ensure that evaluations are completed for the clinical trainees by attending faculty.

7. Ensure that clinical trainees complete evaluations for the attending faculty with whom they rotate.

8. Ensure 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 supervisor, if necessary.

9. Conduct visits to and meets with the site supervisor of the participating site(s) (at least annually).

10. Participate in regular and ongoing communication with the site supervisor.

11. Ensure compliance with ACGME Common Program Requirements, RRC Program Requirements and Cleveland Clinic policies including but not limited to duty hours, fatigue mitigation and supervision.

12. 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.

13. Ensure that clinical trainees are informed of and adhere to established educational and clinical practices, policies and procedures at all sites to which clinical trainees are assigned.

14. Ensure that a current affiliation agreement exists that meets ACGME Common & Programspecific requirements and is reviewed at least annually and revised every five (5) years. 15. In conjunction with the site supervisor; monitor the clinical trainees' work environment which includes but is not limited to adequate food service, call rooms, patient support services, laboratory/pathology/radiology services, medical records, safety/security and parking.

Elective Rotations

Clinical trainees are allotted a specific amount of time (depending on RRC and Specialty Board requirements) for elective rotations. With numerous options for elective rotations in a wide variety of specialties, clinical trainees should be encouraged to schedule their elective rotations at Cleveland Clinic or within the Cleveland Clinic Health System. If a clinical trainee selects an elective option not available at Cleveland Clinic, the program director would make the decision based on educational merit. Cleveland Clinic does not extend malpractice coverage for clinical trainees on elective rotations. Program specific policies regarding off-site elective rotations supersede this policy.

SUPERVISION

Supervision for the care of patients by attending physicians for Cleveland Clinic Florida Training Programs. Cleveland Clinic Florida Staff is encouraged to promote among the clinical trainees a progressive degree of responsibility in the care of patients both in and out of the hospital.

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/her scope of authority and the circumstances under which he/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 duty 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/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.

Direct Supervision

The supervising physician is physically present with the resident and patient.

Indirect Supervision

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. 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.

<u>Oversigh</u>t

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 GME Institutional Manual 2015-2016 59

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
- Committee policy.

Outpatient Service

In the outpatient setting, the clinical trainee will work under the supervision of a faculty member. Typically the clinical trainee will interview and examine the patient first and then present him or her to the staff, which will also interview and examine the patient. The clinical trainee makes the assessment and plan but the final decision is the responsibility of the staff physician. However, to promote clinical trainee education there will be an active discussion between the clinical trainee and the attending regarding final management decisions.

Inpatient Service

In the inpatient setting, all patients in the hospital are under the care of a staff member. Working prerounds occur on a daily basis by the intern and the senior residents. Interns and seniors will meet to discuss each patient before the morning report. To promote clinical trainee education there will be an active discussion between the clinical trainee and the attending regarding final decisions on patient care during work rounds.

All the patients admitted to an inpatient service have to be interviewed and examined by the attending physician on-call within a 24 hour period from the admission time; the assessment and plan should be elaborated by the clinical trainee but the final decision will be the responsibility of the attending physician.

The attending on-call must be easily accessible by telephone and available to come to the hospital should the medical need arise.

The attending on-call must be available to admit patients after the clinical trainees have reached their cap of admissions as determined by ACGME regulations.

All procedures performed on patients must be done or supervised by a clinical trainee who has previously demonstrated the technical and theoretical skills required. If the clinical trainees do not meet this criterion, the procedure must be done or supervised by the attending or a clinical trainee who has demonstrated the technical and procedural skills required.

The attending on-call must always be notified of every new admission to the team and must always benotified of major changes in the condition of patients on service.GME Institutional Manual2015-201660

LINES OF RESPONSIBILITY

Lines of Responsibility on Inpatient Services

On all inpatient hospital teaching services, the ultimate responsibility for all patient care activities belongs to the attending physician-faculty member. This physician will review all diagnostic and treatment plans with the clinical trainee and assume responsibility for those plans. While assigned to the inpatient service, the supervision-attending physician will see each patient on a regular basis, and be available by pager on a continuous basis during the period of assignment. For inpatient teaching services, the lines of responsibility are as follows:

Attending Physician ↓ Subspecialty Resident (when applicable) ↓ Senior Resident (PGY3& above) ↓ Junior Resident (PGY2) ↓ Intern Resident (PGY1) ↓ Medical Student

Lines of Responsibility on Outpatient Setting

In primary care clinics, subspecialty clinic, continuity clinics, clinical trainees are supervised on site by the staff consultant to whom the resident is assigned. All patients are seen first by the clinical trainee who then reviews the assessment and management with the supervision consultant. Orders for diagnostic tests and therapeutic interventions are written by the clinical trainee under the supervision of the attending physician.

TRANSFER OF PATIENT CARE RESPONSIBILITIES

To ensure effective transfer of care responsibilities from a primary care team to an on-call care team, the following requirements have been established by the Graduate Medical Education Committee. These requirements are compliant with standards specified by The Joint Commission (TJC). These requirements are effective for all inpatients beginning January 1, 2006:

- 1. The physician primarily responsible for the patient's care must provide essential information to cross-covering residents who will assume temporary care responsibility.
- 2. A transfer of patient care responsibility cannot occur if the primary care physician is providing immediate lifesaving efforts for a patient.
- 3. The transferring physician must provide for the on-call physician a minimum of the following information which constitutes a "patient list": A complete list of patients being cared for, location and medical record number for these patients, admitting diagnosis and responsible staff physician, specific details that are directly relevant to the on-call physician for that coverage time period, and any tasks or information that must be obtained during the period of coverage.
- 4. This previously defined patient list can be generated as a legible handwritten document until that time when an electronic Epicare system is implemented.
- 5. When an Epicare system is implemented, residents will obtain and document training for this system.
- 6. The transferring physicians will insure that the on-call physician obtains the patient list and allow for dialogue between physicians to insure that medical issues are clarified and questions answered. This must occur before the transferring physician leaves the physical premises of the Cleveland Clinic Florida.
- 7. Transfer of a patient list must occur for primary care teams as well as consultative services.

INSTITUTIONAL POLICIES

Personal Appearance

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 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 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.

For the complete policy, refer to the HRConnect portal https://erc.enwisen.com/asi/page.aspx?alias=navigator&header=on

Scrub Policy

Effective June 1, 2010, a new surgical scrub policy was implemented 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.

For the complete policy, refer to the Policy and Procedure Manager http://portals.ccf.org/today/Policies/tabid/14282/Default.aspx

Vendor Policy

Subject

This policy and procedure describes how vendors will do business with Cleveland Clinic.

Definitions

Cleveland Clinic Personnel and Facilities - For the purpose of this policy, Cleveland Clinic personnel are defined as all personnel, whether employed, contracted or affiliated with Cleveland Clinic, including all physicians, health care providers and students of Cleveland Clinic. Cleveland Clinic facilities are defined as all facilities and respective campuses and regional hospitals, whether owned, leased, rented or controlled by Cleveland Clinic

Vendor For the purpose of this policy, Vendors are defined as manufacturers, suppliers, distributors, or providers of products, equipment or services, whether medical or non-medical.

Vendor Representative(s) For the purpose of this policy, Vendor Representatives are defined as any representative; that is, sales person, manager, liaison, account executive, contact, administrator, company technician, manager, medical/scientific liaison of a manufacturer or company who visits Cleveland Clinic for the purpose of soliciting, marketing or distributing information regarding the use of vendor products or services.

Policy

Vendor contact is not permitted outside the guidelines of this policy. Vendors must follow the requirements established in this policy to be allowed access to Cleveland Clinic including facilities and staff including Operating Rooms where requested by attending physician surgeons. Vendors must comply with this policy or risk losing the opportunity to become a supplier to Cleveland Clinic.

Purpose & Scope

Cleveland Clinic's mission serves to promote medical research and quality patient care in a safe environment. Cleveland Clinic recognizes that from time-to-time, non-organizational personnel, including Vendor Representatives, can play an important role in a patient's care and may be present in the Cleveland Clinic's Operating Room (OR) at the request of the attending physicians, surgeons, anesthesiologists, or appropriate hospital administrators. This policy serves to establish uniform guidelines for permitting vendor representative access to Cleveland Clinic's OR and associated areas so as to ensure reasonable control and identification of Vendor Representatives, while ensuring safe patient care.

This policy applies to all operations of Cleveland Clinic.

Procedures

Vendor Credentialing Process-The completion of the designated training and information below is required for obtaining an ID badge for any Vendor Representative who routinely (weekly or more than three days annually) visits clinical or nonclinical settings. The ID Badge is for identification purposes, safety and security and the Vendor

Representative is still required to adhere to any specific criteria outlined by the particular department

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he/she has a previously scheduled appointment. All vendors are required to register with Vendormate to do business with Cleveland Clinic. To register the vendor company and to create a Vendor Representative profile, registration is to be requested through Vendormate at the following link: https://myclevelandclinic.vendormate.com.

1. Documentation through Vendormate

The following documentation must be completed through Vendormate to utilize the sign-in/sign-out process for an ID badge:

a) Documentation of vendor's company training time and associated certificates of completing said training demonstrating proof of vendor representative's clinical competency on appropriate use of vendor's device or product. Documentation must specify in detail all equipment and products which vendor representative is competent to use.

b) Documentation of Vendor Representative's clearance for infection control, including date and results of last Tb test.

c) Documentation of Vendor Representative completing Comet Training education modules.

d) Vendor Representative must complete training on organization's policy on patient privacy and sign organization's privacy agreement.

e) Documentation of receipt of all pertaining policies and procedures including the Supplier Relationship Handbook.

Upon completion of the above validating steps, Vendor Representatives will be issued an identification badge every time they sign-in at a Cleveland Clinic facility through Vendormate. Vendor Representative information must be renewed annually. Vendor Representatives without a valid identification badge will not be permitted to access the OR and/or associated areas under any circumstances.

2. Vendor Representative Access to the OR

Upon completion of the above requirements, Vendor Representatives will be permitted access to Cleveland Clinic's OR and associated areas upon the request of the attending physician, surgeon, anesthesiologist or appropriate hospital administrator. In doing so, the following is required prior to every encounter.

a) Permission for Vendor Representative to enter a patient care area is upon the request of the Physician and/or Nurse Manager performing the procedure. All Vendor Representatives must obtain permission from the department manager or designee prior to the day of the procedure and before entering any patient care area. The departments will be responsible for notifying the vendor of the check-in policy and giving them specific direction as to where to check-in.

b) Upon signing in, Vendor Representative may then proceed directly to the appropriate OR area and/or designated waiting area until the start of the surgical procedure.

c) All staff should be observant of others around them. If a Vendor Representative is in any area without an appointment and badge (temporary or permanent), staff should politely request that the Vendor Representative leave that area. Repeated instances should be reported to Supply Chain Management and Protective Services.

d) The primary role of the Vendor Representative in a patient care area is to provide product consultation, or to answer questions deemed essential for patient care. Under no circumstances will a Vendor Representative be permitted to:

(1) Participate in hands-on delivery of patient care (e.g. scrub)

(2) Operate equipment and/or administer supplies; or

(3) Provide initial training of equipment and/or supplies during a procedure

e) Prior to the admission of any Vendor Representative into a patient care area, a clinical staff member must verify that the patient's consent concerning the Vendor Representative's presence has been obtained and verification is documented in the patient's medical records.

Clinical staff will verify that Vendor Representative's access has been approved by demonstration of the proper hospital-issued identification badge.

f) For all Vendor Representatives participating or observing in a clinical procedure at Cleveland

Clinic's Main Campus they will be required to wear orange scrubs. This scrub color is specific to Vendor Representatives and is designed to ensure Vendor Representatives are easily identifiable. When leaving the surgical or procedure rooms, Vendor Representatives must cover their scrubs with a white, buttoned lab coat while inside the hospital — for example during a lunch break in the cafeteria or running an errand outside of the surgical department. However, this attire cannot be worn when traveling to and from work. Vendor Representatives must completely change out of their scrubs with or without a lab coat before leaving the premises. Disposable hats, masks, gowns, gloves and shoe coverings must be removed when leaving the OR area. Discard these items prior to leaving OR area. If Vendor Representatives do not comply with these guidelines, they risk loss of privileges of the OR area.

g) For all other Cleveland Clinic facilities, the specific location will provide the Vendor Representative with their scrubs. The Vendor Representative must cover their scrubs with a white, buttoned lab coat while inside the hospitals. This attire cannot be worn when traveling to and from the hospital. Vendor Representatives must completely change out of their scrubs with or without a lab coat before leaving the premises. Disposable hats, masks, gowns, gloves and shoe coverings must be removed when leaving the OR area. Discard these items prior to leaving the OR area. If Vendor Representatives do not comply with these guidelines, they risk loss of privileges of the OR area.

h) To provide appropriate cleaning of clothing or uniform that became contaminated with blood or other body fluids, please refer to Cleveland Clinic's Policy No. IC-507.

i) Vendor Representatives must remain in the designated area pertaining to their visit. Specifically, Vendor Representatives are not permitted to move freely about in other areas not pertaining to their specific visit, including but not limited to staff break rooms, other operating suites or physician call rooms. Under no circumstances may a Vendor Representative wander through the halls of the hospital. Unannounced visits and soliciting of promotional activities by Vendor Representatives are strictly prohibited.

j) Vendor Representatives shall only discuss price or negotiation of price and/or contract with Supply Chain Management. Under no circumstances shall the Vendor Representative solicit product or services or contracts in hospital areas other than Supply Chain Management. Cleveland Clinic reserves the right to refuse to pay for any product or service not authorized by Supply Chain Management or the specific department.

k) Vendor Representative may not use Cleveland Clinic's phones, computers or other equipment for vendor's business or personal use.

l) Vendor Representatives may not distribute or post any type of brochure, advertisements, pens, cups or similar promotional or marketing materials in the OR and/or associated areas or to any personnel.

3. Equipment/Device/Implant Sets

a) All equipment/device/implant sets to be used by Vendor Representative must be delivered at least 24 hours before a scheduled procedure to allow for inventory, sterilization, and/or biomedical safety evaluation in accordance with Cleveland Clinic's policies.

b) All new products are subject to review by the New Products Committee. A formal process has been established for documentation of product evaluations. Supply Chain Management will provide assistance with the required documents.

(1) Vendor will not be paid for product use if prior approval is not obtained.

(2) No products should be left in any area of the Cleveland Clinic without prior approval of the New Products Committee.

(3) Vendor Representatives leaving products without permission from Supply Chain Management will be subject to discipline under compliance. Items not previously approved will not be paid for.

(4) Supply Chain Management will help make arrangements with vendors when their products will be needed for evaluation or trial.

c) All equipment/device/implant sets must contain a complete inventory checklist plus written cleaning and sterilization instructions.

d) All staff training for new equipment, instrumentation or surgical instruments must be coordinated through Cleveland Clinic's OR administrator at least one week prior to the scheduled surgical procedure.

4. Conclusion of Vendor Representative Access

a) Upon completion of the surgical procedure, a complete inventory of any equipment/device/implant sets and other products must be completed by the OR staff.

b) All instruments and related equipment used in the OR area must be properly decontaminated prior to removal from Cleveland Clinic in accordance with Cleveland Clinic's policies and procedures.

5. Compliance

a) Vendor Representatives who fail to comply with Cleveland Clinic's policies will be subject to disciplinary action up to and including losing their business privileges.

b) Repeated non-adherence to this policy by Vendor Representatives may result in suspension, a request to replace company representatives and possible loss of business privileges at Cleveland Clinic and its facilities. Violations may include, but not limited to:

(1) First Occurrence – Written confirmation of the incident and notification to the Vendor Representative's immediate supervisor will be sent and if the incident occurs again or corrective action is not remedied, visitation privileges to the Cleveland Clinic hospitals and affiliate locations may be revoked for a specified period of time determined by Supply Chain Management Leadership.

(2) Second Occurrence – A letter to the Vendor Representative's immediate superior with a copy to Senior Sales and Marketing Officers informing them that a second incident occurred violating the Cleveland Clinic Supplier Relationship Management Program and informing them that the specified individual will not be permitted to enter the Cleveland Clinic Hospitals and affiliate location requesting another representative be identified to continue the business relationship.

II. Pharmaceutical Vendor Interactions

The guidelines below were extracted from the Pharmaceutical Representative Rules of Conduct PWO 8920 Revised 10/2010, which can be found in its entirety at: http://pharmacy.ccf.org/Employees/DOCS/Pharmaceutical%20Representative/PRs%20Code%20of %20Conduct%20online.pdf

Definitions

Pharmaceutical Representative (PR): Any individual employed by a pharmaceutical company who has business to conduct at any CC facility. This includes but is not limited to personnel in sales, marketing, education and account management. Individuals employed by pharmaceutical companies whose responsibilities are restricted solely to research activities are exempt from this policy. Cleveland Clinic (CC): For the purposes of this document, CC refers to the Main Campus and all Family Health Centers (FHCs) and Ambulatory Surgery Centers (ASCs).

Policy

Cleveland Clinic is a private, not for profit institution. Facilities are for the use of employees, patients and patient visitors. Pharmaceutical Representatives (PRs) shall conduct their business activities at CC to promote safe, efficacious and cost effective drug therapy with due consideration for CC personnel time expenditure. All activities must be consistent with and promote CC's mission and formulary activities. All PRs must follow the "Pharmaceutical Representative Rules of Conduct at Cleveland Clinic" which addresses appointments, contacts, badges and registration, restricted areas, restricted activities, prohibition of samples, prohibition of food and beverages, patient educational materials, displays, presentations and rules of conduct compliance. All representatives receive this information upon registration with the Department of Pharmacy. It is the responsibility of each pharmaceutical representative to understand and comply with the rules of conduct.

Appointments

PR visits to the CC are limited to Monday–Friday by appointment only. No visits are permitted on weekends or CC designated Holidays.

a. PRs are not permitted in CC facilities without an appointment.

b. All appointments are to be scheduled through the physician's office, the Nursing office, the Center for Continuing Medical Education or through the pharmacy offices (or with individual Pharmacy personnel).

c. For visits to the Main Campus, the physician's office, nursing office or pharmacy personnel must call the Department of Pharmacy (216-444-6498) prior to a scheduled appointment to register the appointment and authorize the issuance of a vendor badge. At the FHCs and ASCs, PR's are not required to call the Department of Pharmacy and no badges will be issued. One-on-one appointments with nursing personnel at the FHCs are limited to the Clinical Nurse Manager.

d. PRs are prohibited from scheduling individual appointments at CC with house staff physicians. House staff physicians include Residents, Fellows, Medical Students and other physicians in training. PRs may meet with house staff physicians at conferences approved by CC Center for Continuing Medical Education office or Institute Chairs.

e. PRs are prohibited from scheduling individual appointments with hospital or FHC administrators.

f. Physicians (including house staff), nurses and pharmacists are not to be contacted by the paging system or at home unless requested to do so.

Registration and Identification

All PRs must obtain a photo identification badge. Photo identification badges are obtained at the JJNorth basement on Monday through Friday from 8:30 a.m. to 4:00 p.m. The PR is responsible for the cost of issuance of an identification badge. PR identification badges must be renewed annually. Arrangements for photo-identification badges are to be made through the Department of Pharmacy. All PR identification badges will list the representative's name, the company's name and the company's business relationship with CC (Pharmaceutical Representative).

Registration for appointments at the Main Campus

1. All PRs visiting CC Main Campus shall register with the Department of Pharmacy (JJ1-201) prior to visiting any area. At the Department of Pharmacy, the PR must leave a business card along with the following information: appointment date, company name, PR name, person requesting visit, product marketed, articles distributed, appointment time, time identification badge issued, time identification badge returned.

2. PRs will not be issued an identification badge for appointments that have not been registered with Pharmacy. If an appointment has not been registered with Pharmacy, the PR must call the individual they are scheduled to visit and request that they call Pharmacy (extension 46498) to confirm and register the appointment.

3. PR identification badges will be issued to the Department of Pharmacy only. The PR shall obtain his/her badge from the Department of Pharmacy (JJ1-201) for scheduled appointments. Badges will be available Monday - Friday from 8:00 a.m. to 4:30 p.m.

4. A temporary badge will be issued for all PR initial visits.

5. The identification badge may be obtained at the Department of Pharmacy (JJ1-201) thirty minutes prior to a scheduled appointment.

6. Identification badges must be worn visibly at all times and will permit the representative to visit the authorized CC areas.

7. All PR identification badges must be returned to the Department of Pharmacy (JJ1-201) immediately (within 30 minutes of the end of the last non-consecutive scheduled appointment unless notified by the requesting person for additional visiting time). The PRs badge must be obtained for subsequent appointments.

8. It is the responsibility of each PR to make sure that his/her current address and telephone numbers are on file in the Pharmacy. This should be done through pharmacy personnel in the JJ1-201 Pharmacy area.

Identification badges at other CC facilities not located on the main campus

Follow individual registration and identification badge procedures at each of the various FHCs. At a minimum, representatives must wear a badge identifying their name and company.

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PRs are guests of CC and may not be present in any CC buildings or areas without an appointment. After the appropriate appointment and registration procedure, PRs are to proceed immediately to a scheduled appointment. They are to wait in a public waiting area until called/escorted to the requesting person's office.

PRs are prohibited from marketing, detailing or loitering in the following areas: halls and lobbies, hospital cafeterias or restaurants and the Medical Library. PRs are prohibited from visiting the following areas without an appointment: physician offices, work areas (pharmacy, microbiology, and laboratory), education areas (including Education and Lerner Buildings), research areas (including the Research and Lerner Buildings) administrative areas, patient care areas (examining rooms, patient rooms, nursing units). The PR may enter patient care areas only to access offices for scheduled business appointments or approved educational meetings only upon the specific invitation of a staff physician, pharmacy manager or nursing manager

Restricted Activities: Patient Contact

1. The formulation of treatment plans for patients at CC requires a confidential, candid exchange and assessment of confidential patient and treatment information among health care professionals, without the potential appearance of outside influence, especially from vendors. As such, PRs are prohibited from participating in physician, nursing or other health professional rounds, whether or not direct patient contact occurs.

2. Furthermore, PRs will not be permitted to observe or have direct contact with patients at CC. examples of contacts prohibited by this policy include making rounds on the inpatient units (including the intensive care units), being present when examinations are conducted in the outpatient setting and observing surgical and non-surgical procedures.

- 3. The only exception to this is as follows:
 - a. PRs may be permitted to participate in patient rounds as part of a formalized preceptorship performed under the guidance of the Center for Continuing Medical Education. Under these circumstances, representatives may have patient contacts only after the expressed written consent of each patient to be observed.

Drug and Product Provision

a. Samples: Samples are not permitted at CC. This includes the hospital, clinic areas and FHCs and ASCs.

b. Free Goods: All drug products must be procured and distributed through the Department of Pharmacy in order to comply with all applicable legislative, regulatory and accreditation issues.

c. Drugs for Clinical Investigation or Informal Evaluation - All drug products used for clinical investigation or informal evaluation, whether commercially available or investigational, must be procured and distributed through the Department of Pharmacy. Drugs used in this manner may require an IRB approved protocol.

Food and Beverages

Food and beverages may not be provided by PR's and/or their companies to any employee (including physicians, nurses, pharmacists) at any CC facility. PR's may sponsor educational conferences through CC Department or Institute Chairs. If food is part of the educational conference, it must be arranged and provided through the CC department only. The PR may not make food arrangements, orders, and deliveries or directly pay for delivered food. The hotels may not be used for pharmaceutical company sponsored educational programs during business hours (7 a.m. to 5 p.m.) unless part of a program coordinated through the Center for Continuing Medical Education.

Patient Education Materials

Patient education materials that are provided by the Pharmaceutical Manufacturers may only be available in public areas upon Staff Physician authorization. Materials must be placed in these areas by authorized CC personnel.

Displays

Displays are permitted only as a part of programming approved by the Center for Continuing Medical Education and only during the time specified by that program. <u>Presentations/Educational</u> Any company sponsored presentation must be approved by the Department or Institute Chairs. Provision of food is prohibited.

Infraction of PR Guidelines

A. Infraction Review Procedures

1. Compliance with Pharmaceutical Representative Rules of Conduct will be monitored by medical staff and CC personnel observation and feedback. All complaints are to be reported to a Pharmacy Director or the Chief Pharmacy Officer (CPO).

2. Violations and proposed actions to be taken will be formulated by the Pharmacy Director/CPO and approved by the Chairman of the Pharmacy and Therapeutics Committee. The record of the infraction and action taken will be filed in the Department of Pharmacy for a period of three (3) rolling years.

B. Disciplinary Procedures

1. If the infraction is determined to be unfounded, the Pharmacy Director/CPO will so inform the department or person responsible for the complaint as well as the PR involved.

- 2. If the infraction is valid, the following action(s) can be taken:
 - a. Letters from the Pharmacy and Therapeutics Committee to the PR, the representative's manager and the vice president of marketing of the representative's company stating that the PR is prohibited from conducting business at CC.

- 1. First violation: 3 month suspension
- 2. Second violation: 12 month suspension.

3. At the discretion of the Pharmacy Director/CPO and Chairman of the Pharmacy and Therapeutics Committee, all sales, marketing, education and account management personnel from the company in violation may be prohibited from conducting business at CC for the time of the suspension.

Use of Electronic Devices

Cellular Phones

It is the policy of the Cleveland Clinic to provide guidance on the appropriate use of business telephone and voicemail systems as well as cellular phones or similar devices.

The policy is intended to provide for a safe environment in patient care areas by avoiding inference between cellular phones and patient equipment by prohibiting use of cellular phones and all non-emergency use of radio transmitting devices in patient care areas.

Photographing

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.

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 activated.

Social Media Use

The purpose of this policy is to provide all Cleveland Clinic employees with rules and guidelines for participation in social media (also known as social networking). The intent of the Policy is not to restrict the flow of useful and appropriate information, but to safeguard the interest of Cleveland Clinic, its employees and its patients.

When communicating on Cleveland Clinic social media sites or communicating about Cleveland Clinic or as a representative of Cleveland Clinic on any social media site unaffiliated with Cleveland Clinic, Cleveland Clinic employees are expected to follow the same standards and policies that otherwise apply to them as a Cleveland Clinic employee. For example, social media activity is subject to Cleveland Clinic policies that strictly prohibit discrimination, harassment, threats and intimidation.

In the interest of guarding the privacy of our patients, employees must not publish any content including photos, names, likenesses, descriptions or any identifiable attributes or information related to any Cleveland Clinic patient. Postings that attempt to describe any specific patient and/or patient care situation or that contains any patient identifier or in combination may result in identification of a particular patient directly or indirectly, is inappropriate and strictly prohibited.

For the complete policy, refer to the HRConnect portal https://erc.enwisen.com/asi/page.aspx?alias=navigator&header=on

PATIENT SAFETY

Patient Safety is one of the Cleveland Clinic priorities. The Patient Safety Program is designed to support and promote the mission, vision and values of the Cleveland Clinic. The purpose of the program is to build a framework for the delivery of safe care, promulgate and support a culture of safety and improve patient care through the reduction of medical errors.

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

- •Review and evaluate actual and potential safety risks in current practice
- •Identify opportunities to enhance safe practice
- •Provide information to clinicians, administration and committees regarding identified risk
- •Provide an integrated, systematic and data driven approach to safety initiatives

•Implement education on the prevention and correction of medical errors to reduce the possibility of patient injury

•Support a Culture of Safety to promote awareness of patient safety and empower staff to raise and address related safety concerns

•Involve patients in decisions about their healthcare and promote open communication

•Encourage and promote the use of technology to support patient safety initiatives

•Report process and outcome measures to internal and external audiences in order to promote accountability and achieve value

The Patient Safety Program includes monitoring compliance with The Joint Commission National Patient Safety Goals (NPSG). Information regarding the NPSG can be found on the Quality and Patient Safety Institute website under Patient Safety & Clinical Risk/National Patient Safety Goals.

Culture of Safety

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

•Teamwork; acting as a unit

•High Reliability; doing the same thing for our patients every time - reluctance to simplify and pre-occupation with perfection

•Activated Patient; enlisting the patient & or family as part of the healthcare team - listening

•Just (Culture); establishing expectations and accountability for expected safety behaviors.

Encouraging '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.

The Cleveland Clinic Quality & Patient Safety Institute supports several committees, projects and resources providing opportunities for Cleveland Clinic 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 Quality and Patient Safety Institute, please refer to the Cleveland Clinic Quality and Patient Safety website located at http://intranet.ccf.org/qpsi/. Information is also available through COMET and CCLC on line learning.

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INFECTION PREVENTION

Clinical Trainees at the Cleveland Clinic will follow all infection prevention policies and procedures (available on the intranet in the Policy and Procedure Manager and the Infection Prevention web sites).

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 alcoholbased 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 Clinic employees. Healthcare workers will wash hands with soap and water:

- •When hands are dirty or visibly soiled with pertinacious material, blood, or body fluids
- •When caring for patients with Clostridium difficile
- •After using the restroom and before eating

If hands are not visibly soiled an alcohol-based hand rub may be used for routinely decontaminating hands in all clinical situations.

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) and ventilator-associated pneumonia (VAP). Bundles include daily assessment for need, and prompt removal of, indwelling devices as soon as clinically feasible.

SAFETY EVENT REPORTING (SERS)

Patient safety is a top priority. Reporting a safety event when it occurs is an opportunity to identify and learn about system failures, hazards and risks. 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.

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.

Cleveland Clinic practices a non-punitive approach to event reporting. Caregivers are encouraged to
report a safety event without fear of retribution. Disciplinary action is not taken with a caregiver
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involved in and/or reports an event. The only exceptions to this approach apply under the following circumstances:

- Intentional acts to harm or deceive
- Gross neglect
- Reckless or intentional disregard for standard operating procedures

Definitions

<u>Near miss</u>: any process variation that did not affect the outcome however for which a recurrence would carry a significant chance of a serious adverse outcome.

<u>Event</u>: any actual or potential happening that is not consistent with the routine care of a patient or any situation that is not consistent with the normal operations of the Cleveland Clinic. An event may involve a patient, visitor, employee or the physical environment within a Cleveland Clinic facility. It is associated with actual or potential harm, loss, or damage. An event may involve an error, but the term "event" is not synonymous with "error."

•An employee event is a work related injury or illness that occurs within the course and scope of employment

Harm: unintended injury resulting from or contributed to by the physical environment or by care.

<u>Sentinel Event</u>: any unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes the loss of limb or function. They are called sentinel because they signal the need for immediate investigation and response.

Please refer to the SERS web site accessible on the Cleveland Clinic intranet page for additional information at <u>http://intranet.ccf.org/sers/</u>. The SERS policy can be found on the Cleveland Clinic Policy tech site.

Allergy & Medication Reconciliation

The purposes of reconciliation are to maintain and communicate accurate patient medication and allergy information and to educate patients about the importance of having an accurate current medication list.

Reconciliation is the process of identifying and resolving medication and allergy discrepancies which may include omissions, duplications, contraindications, unclear information and changes pertinent to the care being delivered at that patient encounter. Allergy documentation and medication reconciliation is the physician/providers' responsibility. Patients are at risk during transitions in care across settings, services, providers, or levels of care. To provide safe, quality care we must develop, reconcile, and communicate an accurate medication and allergy list.

The Cleveland Clinic policy outlines the following allergy and medication requirements:

- Create a complete list of the patient's current medications with active patient involvement at entry into our organization or upon admission
- The medication list must include all prescribed medications, over-the-counter drugs, herbal and

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dietary supplements, vitamins, and other commonly used medications such as eye drops, inhalers, patches, and contraceptives

- Compare medications ordered for the patient to those on the list and resolve any discrepancies (e.g., omissions, duplications, potential interactions)
- At the time of discharge or transfer the provider must compare the medications to be continued post-discharge/post-transfer with the list of medications the patient was taking prior to entry into the organization

Additional information can be found on the Cleveland Clinic Policytech site: Medication Reconciliation.

Universal Protocol/Safety Checklist: A Team Approach to Patient Safety

The Safety Checklist is a powerful tool used to reduce the occurrence of preventable error during a procedure or surgery. It is designed to enhance communication among team members and identify potential issues or concerns related to the case.

The Safety Checklist is utilized for all procedures carrying more than minimal risk performed in the outpatient and inpatient settings. The Safety Checklist consists of the following:

Sign-In:

Pre procedure verification process to ensure all relevant documents, related information and equipment are:

- •Available prior to start
- •Correctly identified, labeled, and matched to the patient
- •Reviewed and consistent with teams' understanding of planned procedure

The conversation is led by the Staff attending. Each team member is empowered to communicate relevant patient information.

Site Marking:

Marking is required for sites with right/left distinction, multiple structures or levels. Site marked by LIP or provider ultimately accountable for procedure. The person marking the site must be involved directly in the procedure and be present at the time the procedure is performed

The following parameters apply to site marking:

- •Marked at or near the procedure site
- •Visible after skin prep & draping when patient in final position for procedure
- •Surgeon's or procedural list's initials
- •Permanent marker
- •Self-marking is not sufficient
- •Identify an alternative method of identifying correct site when anatomically impossible or impractical

Note: an alternative method of identifying the correct site must be in place when site marking is anatomically impossible or impractical

Time Out:

A final "time out" is to occur immediately prior to the start of the procedure or making the incision to confirm pre-procedure elements are completed/resolved prior to conducting the time out. All team

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members must stop what they are doing, listen and actively participate.

The Time Out includes verification of:

- •Correct patient
- •Correct side and site
- •Correct procedure
- •Correct position (if applicable)

Note: the "time out" must be documented in the medical record

Sign-Out:

Interactive communication among all team members to ensure key elements of the case are resolved to occur prior to the team disbanding or leaving the OR/procedure room.

Discussion to include

- •Name of procedure recorded correctly
- •Disposition of unused blood products
- •Manual and surgical counts completed and reconciled
- •Specimen(s) correctly labeled
- •Equipment issues addressed
- •Key concerns for the recovery and management of the patient

Website: <u>http://intranet.ccf.org/policy.asp</u> search by "universal protocol". For more information: <u>safety@ccf.org</u>, 4-SAFE (47233), or <u>http://intranet.ccf.org/qpsi/patientsafety</u>

Verbal Orders

The Facts

• Limit verbal orders to emergent or urgent situations when the physician cannot be present to write or enter the order in EMR and the quality of care will be diminished if order is delayed

• Verbal orders must be authenticated (signed, dated and timed) within 7 days

• Advanced Practice Nurses and Physician Assistants can authenticate verbal orders they give or are given by the physician they work with provided that the orders are within the APN or PA's prescriptive authority

Key Points

- Nurses cannot give nurses Verbal Orders
- Verbal orders for IV chemotherapy shall not be given or accepted

Action Required

• Use only in emergent situations when you cannot get to the unit/floor to write the order yourself.

- If you are on the floor, you are expected to write your own orders
- Ensure your order is "read back" to you before you hang up the phone
- Authenticate, date and time your signature within 7 days

Compliance Tip

• While on daily patient rounds, sign all verbal orders from the previous day

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https://ccf.policytech.com/dotNet/documents/?docid=5872&mode=view

Confidential Information

All employees of Cleveland Clinic may have during the course of their employment, access to confidential information concerning budgets, strategic business plans, patients or other employees. This information may be in the form of verbal, written, and/or computerized data. The safeguarding of this confidential information is a critical responsibility of each employee.

Unauthorized acquisition, use and/or disclosure (whether written or verbal) of any information relating to Cleveland Clinic Health System business, patient medical information, current and past employees, job applicants and computerized data is a most serious matter and will be grounds for disciplinary action up to and including discharge. (Refer to Policy #121- Corrective Action of the Supervisory Policy & Procedure manual.) Individual employees may also be subject to criminal prosecution for these violations.

Identity Theft (Protecting Patients)

In response to federal regulations that help prevent identify theft, Cleveland Clinic has created a systemwide policy to support our organization's commitment to patient confidentiality.

- As a Cleveland Clinic employee, please uphold this policy by notifying your supervisor if you observe any of the following situation or "Red Flags".
- Suspicious looking documents (i.e., altered ID)
- Suspicious activity on an account (i.e., frequent change of address)
- Alerts, notifications or warnings from a credit agency about identify theft
- Notice from patient, victim of identity theft or fraud, law enforcement, etc.
- Medical treatment inconsistent with physical exam

The regulation this policy supports were published by the Federal Trade Commission (FTC) and the federal financial regulatory agencies. These regulations are called "Red Flag Rules" and institutions were required to establish an Identity Theft Prevention Program to support them.

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

To review the entire Identity Theft Prevention and Mitigation Policy, refer to: <u>https://ccf.policytech.com/dotNet/documents/?docid=3918&mode=view</u>_____

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 in accordance with the wishes of the staff doctor in charge, unless the patient objects. Requests for copies of patient information must be directed to Health Information Management.

•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

Informed Consent is a legal and ethical issue, as well as necessary for compliance with Medicare regulations. It is the result of a discussion with the patient (or their representative) regarding inherent risks, benefits, alternatives and personnel related to a proposed procedure. Additionally, information must be conveyed to the patient in a manner that ensures their understanding.

To maintain regulatory compliance, Cleveland Clinic main campus utilizes a process where both the responsible practitioner and the patient sign an official consent document that includes language approved by our Law Department. In situations where the patient is unable to sign, it is important to ensure that the most appropriate representative sign the consent on the patient's behalf. The signature process for both practitioner and patient is primarily accomplished via the electronic medical record.

The Informed Consent policy describes major categories of operations and procedures that require informed consent, as well as supporting documents that describe the associated process. Currently, each clinical Institute has developed its own list of additional procedures that require informed consent.

http://intranet.ccf.org/rightthing/InformedConsent_list.asp https://ccf.policytech.com/docview/?docid=6755 https://ccf.policytech.com/docview/?docid=6754

HUMAN SUBJECT RESEARCH

All research involving human subjects requires 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. A human subject means a living individual about whom an Investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. Common types of human research involve retrospective chart reviews, surveys, questionnaires, innovative surgical procedures, drug and devices trials, registries and outcome research. 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, fellows, residents, students) as research volunteers. This recruitment must not involve direct faceto-face solicitation and is only permitted if the employee initiates interest in participation generally in response to a posted notice. 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 CITI course (Collaborative IRB Training Initiative). This is an online course on human subject protections at <u>www.citiprogram.org</u>. All employees participating in human subject research are also required to complete the HIPAA in Human Subject Research course available on COMET.

Completion of the Investigator Human Subject Research Education Course is also required for all Staff, Residents, Fellows and Scientists participating as PI or Co-Investigators in human research as of January 1, 2010. Courses are offered quarterly and registration is conducted through COMET.

Although clinical trainees and visiting researchers 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 (except cancer studies), regardless of who is conducting the research and includes the main campus, the family health and surgery centers, Cleveland Clinic Regional Hospitals, the Children's Hospital Shaker Campus and other components as listed on our Federal wide Assurance agreement. You can contact the CCF IRB at 216-444-2924 or access our email account IRB@ccf.org

CLINICAL RESEARCH

Research is a systematic investigation designed to contribute to generalizable knowledge. Research is most commonly associated with randomized trials, drug studies, and device studies. However, innovative surgical procedures, retrospective chart reviews, epidemiological studies, registries, and other records-based data analyses involve reviewable research if designed to contribute to generalizable knowledge.

Research Education Requirements

To conduct research at Cleveland Clinic Florida, all trainees must be certified within 3 months of stay by completing these courses:

- 1) CITI Course: Complete the online CITI course at www.citiprogram.org.
- 2) Cleveland Clinic's Investigator Human Subject Research Education Course: This 4-hour internal course is required for all Staff, Residents, Fellows, and Scientists participating as Investigators or Co-Investigators in human subject research (in addition to the CITI course).
- **3) HIPAA in Research Training**: All employees participating in human subject research are required to complete the HIPAA in Research course available on COMET.

<u>Research Process</u> Feasibility and Scientific Review

All human subject research to be executed at Cleveland Clinic Florida (CC Florida) must undergo advance review to ensure scientific merit and quality before submission to the IRB, particularly if it is not sponsored (i.e. not funded). This review will be conducted by the Cleveland based Institute Research Committees for each of the corresponding CC Florida departments and centers. The primary goal of this review is to assure that the conduct of research conforms to the highest standards of research methodology, while most effectively minimizing risks to volunteer subjects. It will also enable those with the most relevant scientific expertise to provide feedback on protocol development, scientific design, statistical data analysis and informed consent content.

including the following elements: enrollment expectations and adequate subject population, availability of appropriate staffing, equipment and resources to fulfill requirements of all time points of the protocol, and resources needed to perform the research are covered by the study budget.

• Scientific and Feasibility review: required for research projects presenting more than minimal risk or Intent to Treat (ITT)

• Feasibility review only: required for chart review or data registries with no more than minimal risk.

Procedure

Initial Review

- 1. The Investigator or designee delivers the new proposed research study and any related study materials to the CC Florida Department of Clinical Research which includes the following: A. Completed Institute Review Request Form⁽¹⁾
 - B. Completed Feasibility Checklist⁽²⁾
 - C. Complete protocol and investigational drug brochure (if applicable)
 - D. Informed consent document, institution or sponsor's consent (if applicable)
 - E. Budget and/or other funding commitment documents (if applicable)
 - F. Data collection tool (investigator-initiated studies only)
- 2. The documentation will be submitted via email to the Research Administrator who will forward to the appropriate Institute Review Committee to assess the study's scientific merit.
- 3. The Institute Review Committee will contact the Principal Investigator with the signed approval form.
- 4. Once the Institute Review Request Form and Feasibility Checklist have been approved, the Investigator may submit the study application to the IRB. The Institute Review Committee approval letter/form must be uploaded into the IRB application as confirmation that the protocol has been approved.
- 5. The research protocols and related documents will then undergo standard review by the IRB. All protocols that are deferred by the IRB for lack of scientific merit or lack of risk/safety monitoring will be returned to the Investigator.

Scientific ⁽¹⁾ and Feasibility ⁽²⁾ review: Required for research projects presenting more than minimal risk including chart review and registries, (For example, those projects with intent to treat (ITT))

⁽²⁾Feasibility review only: Required for chart review or data registries with no more than minimal risk.

Study Funding

You may require funding when:

- Your study includes a drug or device;
- You plan an intervention on a patient that is done solely for the purposes of research; or
- You need the expertise of someone who charges for his/her time.

Important Notes:

- If Cleveland Clinic patients/data is used, the Cleveland Clinic has ultimate authority over what you can publish. Hospital can review and recommend changes to your publication.
- If you get IRB approval for your study, you must also close it out with the IRB (via Amendment tab) when complete.
- If you are involving multiple non-Cleveland Clinic Institutions in your research, you may need

to gain IRB approval from each Institution.

Do I need to seek IRB approval for a case study?

- 1. Is the publication a case report or a case series?
 - Case report = An analysis of the clinical case of 1 patient
 - This is not considered research and does not require IRB review
 - Case series = An analysis of the clinical cases of 2 or more patients
 - This is considered to be research and requires IRB review
- 2. Case report: Is the PHI de-identified?
 - If no Patient authorization is required
 - If yes Patient authorization is not required, <u>but consider the de-identification</u> requirements (from 45 C.F.R. § 164.514):
 - Note that the list of PHI identifiers includes "any other <u>unique</u> identifying number, <u>characteristic</u>, or code" – if any of these identifiers are present, there are two options: (a) PHI identifiers must be removed, or (b) patient authorization must be obtained.
- 3. Case series: IRB process
 - If the data collected by the researcher contains identifiers, the IRB will determine if informed consent is required or if the criteria for waiver of informed consent is applicable.
 - If the collected data does not contain any identifiers, consent is not required.

Florida Department of Clinical Research (DOCR)

- Research Director: Dr. Marianna Berho (954) 689-5176, <u>berhom@ccf.org</u>
- Research Administrator: Avery Gottfried (216) 445-9440, gottfra@ccf.org
- Research Supervisor: Gregory Davis (954) 659-6204, <u>davisg3@ccf.org</u>
- Florida DOCR Intranet Page: http://portals.ccf.org/weston/Departments/Research/tabid/3123/Default.aspx

Research Compliance

- <u>http://intranet.ccf.org/compliance/Research_Compliance.htm</u>
- Contact: Tracy Shenk, (216) 445-5302
- System-Wide Anonymous Reporting Line (all areas including Florida): (800) 826-9294

Data Extraction

To be compliant in data extraction, please utilize Cleveland Clinic dedicated mechanisms and dedicated resources:

- eResearch <u>http://intranet.ccf.org/eResearch/requestservice.htm</u>
- QHS <u>http://www.lerner.ccf.org/qhs/</u>

Institutional Review Board (IRB)

All human subject research must be submitted to Cleveland Clinic's ethics committee, IRB, using the electronic system, Webkit.

• You will be given access to Webkit only after successful completion of the 3 research education requirements.

Frequency of IRB meetings: Weekly Day of IRB convened meetings: Fridays Deadline of research submissions: By 5 pm Wednesday for review the following week on Friday Timeframe for IRB approval letter: 2-3 business days after the convened IRB meeting

IRB Contact Information Cleveland Clinic Foundation Attn: Institutional Review Board 9500 Euclid Avenue Cleveland, OH 44195 Telephone: (800) 223 2273 Fax: (216) 445 4094 IRB Chairman: Alan Lichtin, MD Executive Director: Daniel Beyer, MS, MHA, CIP

IRB administrative questions: Deborah McCleave (216) 444-2359, mcclead@ccf.org

SAFETY & SECURITY (TRAINEE)

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 you are working late and feel the need to be escorted safely to your assigned parking location, contact the *Cleveland Clinic Police at 216-444-2250* for assistance. For your safety, "blue light emergency intercoms" blanket the Cleveland Clinic campus. The blue lights enable you to easily find them. Push the button once and you will be connected directly to the Cleveland Clinic Police Department and it will alert them to your 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 your car.

Hazardous Chemical Identification

Cleveland Clinic is committed to providing the safest, most healthful environment possible for its employees, patients and visitors. In support of this objective, Cleveland Clinic has established the following policy to comply with the Hazard Communication Standard (29CFR 1910.1200) of the Occupational Safety and Health Act and the City of Cleveland's Hazardous Chemical Right-to-Know Code (Ordinance No. 2704-B-83). For the complete policy, refer to the Intranet, Policy and Procedure Manager (Hazard Communication Program).

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. It is the responsibility of any physician who wishes to perform these tests on his or her patients to inform them about the appropriate interpretation of the tests, the ethical and potential legal implications associated with performing these tests, the need for appropriate counseling prior to and after the test results are conveyed to the patient, the need for medical follow-up if the test results are positive.

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 file a Safety Event Reporting System (SERS) form with their supervisor and contact the occupational health triage personnel by calling the Cleveland Clinic Bloodborne Pathogen (BBP) Hotline (216-445-0742) or Pager 23742 Monday – Friday 7:30 am – 5 pm. Pager 21132 evenings, weekends and holidays.

If the source patient from such an exposure is identified, consent to permit HIV testing will be sought. In the absence of consent, the request to test the patient will be referred to the Chairman of the Infectious Control Committee. Employees with exposure to source patients who are HIV-positive or whose HIV status cannot be determined will be immediately referred to an Infectious Disease Physician for evaluation for antiviral medication as deemed necessary and will be recommended for follow-up HIV testing at three, six, and twelve months after exposure. Depending on the degree of exposure and patient risk factors, they may also receive post exposure HIV prophylaxis (see post exposure protocol). Such employees should be advised to report and seek medical evaluation for any active illness that occurs during the follow-up period. For 24 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: 1) refraining from blood, semen, or organ donation, 2) refraining from sharing needles, and 3) abstaining from sexual intercourse.

If a source patient is identified as Hepatitis B positive it is recommended that the Health Care Worker 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 Health Care Worker will be referred immediately to Hepatology for evaluation and treatment.

After the tests results are available, the employee will be informed and counseled. If the test result is positive, a report will be submitted with the employee's knowledge, to a designated primary physician and the Chairman of the Infection Control Committee. If a non-Cleveland Clinic health care provider, emergency services worker, police officer or fire fighter sustains a significant exposure to the body fluids of a Cleveland Clinic patient, the exposed individual may request that the patient be tested for HIV by the Infection Control Department.

Confidentiality

All Cleveland Clinic employees must preserve the confidential nature of HIV testing and results. Breach of confidentiality is grounds for dismissal. For the complete policy, refer to the HRConnect

portal https://erc.enwisen.com/asi/page.aspx?alias=navigator&header=on

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: Cleveland Clinic employees who have a need to know; 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 non-Cleveland Clinic health care provider, EMS worker, peace officer or fire fighter who has sustained a significant exposure to a patient. If the patient receives post-exposure testing for HIV upon authority of the Infectious Control Committee, his or her identity may not be revealed.

Health Care Workers with HIV Infection

Effective July 31, 1996, all Ohio State Medical Board licensees are subject to new rules about HIV and HBV. The attached rules incorporate guidelines and procedures that the Ohio Department of Health (ODH) Task Force on the Transmission of Blood Borne Pathogens by Health Care Professional identified as necessary to minimize the risk of HIV/HBV transmission from health care providers to the public. The rules require:

• A physician to obtain testing if he/she has reason to suspect he/she is infected with HIV/HBV.

• A physician who learns he/she is infected is required to submit to assessment and monitoring by an appropriate review panel established or approved by the Ohio Department of Health (ODH). Any practice restrictions established by the panel must be observed to minimize risk to patients.

• A physician who learns that a colleague is seropositive is required to assure that he/she is referred to an appropriate entity for assessment and monitoring. If an infected colleague fails to self-report within seven days after being informed of his/her duty to do so, the physician is required to report their knowledge of the serosensitivity to the State Medical Board.

• Recognizing the deeply personal and sensitive nature of this information, the Medical Board rules encourage voluntary compliance to minimize the risk that a practitioner's seropositive status will be publicly divulged. The Medical Board believes that the majority of affected physicians will choose to be monitored exclusively by ODH or by an ODH-approved institutional panel.

<u>HIPAA</u>

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 CCHS Privacy &

Security policies, which may be accessed at http://intranet.cchs.net/policies/hipaa/

Additional information related to federal Privacy laws may be found under the Corporate Compliance section of this manual.

<u>OSHA</u>

Federal law mandates that all clinical trainees receive training annually regarding the Bloodborne Pathogen Standards. This is accomplished with an on-line course in COMET.

COMPENSATION & BENEFITS

Approved Absences (Time Away)

All time away from clinical responsibilities must be requested 30 days in advance via MedHub unless otherwise instructed by your program. Programs will notify the trainee if the request has been approved or denied.

The Program Director has final approval for time away and due to clinical responsibilities or short notice, may be unable to approve every request.

Vacation Time

Clinical 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. Vacation time is not cumulative and should be taken in the year earned; it does <u>not</u> carry over into the next academic year.

USMLE Exam Time

Clinical trainees are permitted two days off to take the USMLE III exam without using their vacation time.

Interview Days

In addition to vacation time, up to five interview days may be given during the program so that clinical trainees may interview for fellowships or practice opportunities.

Leave of Absence & Extension of Training

Please submit leave of absence requests via MedHub for department approval unless otherwise instructed by your department. Requests must be accompanied by documentation of purpose of leave (i.e. doctor's note, invitation for interview) which should be given to the program.

Some specialties may have specific requirements as to allowable time away during training as specified in The American Board of Medical Specialties (ABMS) guidelines. The Program Director, with input from other faculty members, determines specific guidelines depending upon the specialty, individual's performance and any specific needs that relate to an illness. Leave of absence(s) may extend the training period to comply with specific specialty board requirements to complete training or to reach an acceptable level of performance to progress to the next graduate level. At the time of request, the program director or his designee must meet with the trainee to apprise him/her of the requirements and the length of extension to training, if an extension is known to be

required at that time. If an extension is required due to a resident's performance or requirements to successfully complete the current year of the training program, the program director must advise the resident immediately.

Medical Leave of Absence

If a clinical 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 training program, salary and benefits will continue for 90 days, the duration of the illness or the remainder of the contract; whichever is shorter. If the illness continues and the trainee holds a valid appointment he/she will continue to receive Cleveland Clinic benefits; however, in lieu of a salary they will receive payments from the disability plan.

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 for further information.

Personal Leave

It is the policy of the Cleveland Clinic to grant residents and fellows a leave of absence (without pay) 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 personal leave of absence requests.

Maternity/Adoption Leave

If a clinical trainee/researcher is physically able to fulfill their training responsibilities and receives approval from their obstetrician and program director, they may work up to the date of delivery.

Six weeks paid leave are given for maternity leave; eight weeks if a caesarian section is necessary. Additional unpaid time (up to 12 weeks in total) may be taken under the Family Leave Act. Mothers are also granted six weeks leave when a child is adopted. Residents and fellows must complete and submit the appropriate forms to the Program Director at least 90 days in advance to allow arrangements for coverage.

After delivery of your baby, please contact Benefits Customer Service Center at 216-448-0600 to add the child onto your benefit health plan within 30 days from the birth of the baby or adoption.

Paternity Leave/Adoption Leave

Two weeks (10 working days) paid paternity leave is offered to our male clinical trainees for the natural birth or arrival of an adopted child. Under certain circumstances, additional time (up to 12 weeks total) may be taken under the Family Leave Act. Paternity leave MUST be taken within 30 days of the child's birth/adoption. Residents and fellows must complete and submit the appropriate forms to the program director at least 60 days in advance to allow arrangements for coverage.

Bereavement Leave

Per Cleveland Clinic Policy, Cleveland Clinic Employees are eligible for three (3) bereavement days for a death in the immediate family. Immediate Family is considered spouse, child, stepchild, mother, stepmother, mother-in-law, father, stepfather, father-in-law, sister, brother, grandmother, grandfather or grandchild. The complete policy can be found on the HRConnect portal https://erc.enwisen.com/asi/page.aspx?alias=navigator&header=on

FMLA

Basic Leave Entitlement

FMLA requires covered employers to provide up to 12 weeks of unpaid job protected leave, to eligible employees for the following reasons:

•For incapacity due to pregnancy, prenatal medical care or child birth;

•To care for the employee's child after birth or placement for adoption or foster care;

•To care for the employee's spouse, son, daughter or parent, who has a serious health condition

•For a serious health condition that makes the employee unable to perform the employee's job.

Military Family Leave Entitlements

Eligible employees with a spouse, son, daughter or parent on active duty or call to active duty status in the National Guard or Reserves in support of a contingency operation may use their 12-week leave entitlement to address certain qualifying exigencies. Qualifying exigencies may include attending certain military events, arranging for alternative childcare, addressing certain financial and legal arrangements, attending certain counseling sessions and attending post-deployment reintegration briefings.

FMLA also includes a special leave entitlement that permits eligible employees to take up to 26 weeks of leave to care for a covered service member during a single 12-month period. A covered service member is a current member of the Armed Forces, including a member of the National Guard or Reserves, who has a serious injury or illness incurred in the line of duty on active duty that may render the service member medically unfit to perform his or her duties for which the service member is undergoing medical treatment, recuperation, therapy in outpatient status or is on the temporary disability retired list.

Benefits and Protections

During FMLA leave, the employer must maintain the employee's health coverage under any "group health plan" on the same terms as if the employee had continued to work. Upon return from FMLA leave, most employees must be restored to their original or equivalent positions with equivalent pay, benefits, and other employment terms. Use of FMLA leave cannot result in the loss of any employment benefit that accrued prior to the start of an employee's leave.

Eligibility Requirements

Employees are eligible if they have worked for a covered employer for at least one year for 1,250 hours over the previous 12 months and if at least 50 employees are employed by the employer within 75 miles.

Definition of Serious Health Condition

A serious health condition is an illness, injury, impairment or physical or mental condition that involves either an overnight stay in a medical care facility, or continuing treatment by a health care provider for a condition that either prevents the employee from performing the functions of the employee's job or prevents the qualified family member from participating in school or other daily activities.

Subject to certain conditions, the continuing treatment requirement may be met by a period of incapacity of more than 3 consecutive calendar days combined with at least two visits to a health care provider or one visit and a regimen of continuing treatment, or incapacity due to pregnancy or incapacity due to a chronic condition. Other conditions may meet the definition of continuing treatment.

Use of Leave

An employee does not need to use this leave entitlement in one block. Leave can be taken intermittently or on a reduced leave schedule when medically necessary. Employees must make reasonable efforts to schedule leave for planned medical treatment so as not to unduly disrupt the employer's operations. Leave due to qualifying exigencies may also be taken on an intermittent basis.

Substitution of Paid Leave for Unpaid Leave

Employees may choose or employers may require use of accrued paid leave while taking FMLA leave. In order to use paid leave for FMLA leave, employees must comply with the employer's normal paid leave policies.

Employee Responsibilities

Employees must provide 30 days advance notice of the need to take FMLA leave when the need is foreseeable. When 30 days' notice is not possible, the employee must provide notice as soon as practicable and generally must comply with an employer's normal call-in procedures.

Employees must provide sufficient information for the employer to determine if the leave may qualify for FMLA protection and the anticipated timing and duration of the leave. Sufficient information may include that the employee is unable to perform job functions; the family member is unable to perform daily activities, the need for hospitalization or continuing treatment by a health care provider or circumstances supporting the need for military family leave. Employees also must inform the employer if the requested leave is for a reason for which FMLA leave was previously taken or certified. Employees also may be required to provide a certification and periodic recertification supporting the need for leave.

Employer Responsibilities

Covered employers must inform employees requesting leave whether they are eligible under FMLA. If they are, the notice must specify any additional information required as well as the employees' rights and responsibilities. If they are not eligible, the employer must provide a reason for the ineligibility.

Covered employers must inform employees if leave will be designated as FMLA-protected and the amount of leave counted against the employee's leave entitlement. If the employer determines that the leave is not FMLA-protected, the employer must notify the employee.

GME Institutional Manual

2015-2016

Unlawful Acts by Employers

FMLA makes it unlawful for any employer to:

- Interfere with, restrain or deny the exercise of any right provided under FMLA;
- Discharge or discriminate against any person for opposing any practice made unlawful by
- FMLA or for involvement in any proceeding under or relating to FMLA.

Enforcement

An employee may file a complaint with the U.S. Department of Labor or may bring a private lawsuit against an employer.

FMLA does not affect any Federal or State law prohibiting discrimination or supersede any State or local law or collective bargaining agreement which provides greater family or medical leave rights.

Long Term Disability

The Cleveland Clinic provides and fully pays for a group long-term disability policy for all clinical trainees appointed through the Graduate Medical Education Department. The plan covers 70% of salary to a maximum of \$3,000 Monthly Benefit. The plan includes Partial Disability Benefits, Survivor Benefits, and a Loan Payout Benefit of \$100,000 and a Delayed Cost of Living Benefit. A benefit is paid after you are disabled for 90 days and will continue for the length of the total disability until Social Security Normal Retirement Age. There is no health exam required for this coverage, nor are pre-existing conditions excluded from the policy.

Enrollment in the program is automatic and coverage begins on the first day of employment. The insurance is provided at no cost to the clinical trainees; premiums are paid by Cleveland Clinic.

As a Cleveland Clinic Graduate Medical Education Clinical Trainee, you also have the opportunity to purchase supplemental discounted individual disability income protection. The additional supplemental coverage is guaranteed with **NO** medical screening required. You may purchase a minimum of \$2,500/month of discounted individual disability income protection, with guarantees of up to \$10,000/month to protect future earnings. These policies include specialty-specific, own occupation coverage, residual (partial) disability protection, 3% compounded cost-of-living inflation protection, coverage for catastrophic disabilities, 90 day elimination period and to age 67 benefit period.

With medical underwriting, you may qualify for additional discounted benefits with potential coverage of up to \$25,000/month.

In both scenarios, you lock-in coverage for your medical specialty that you can personally customize to meet your specific needs. This disability program is exclusive to the Cleveland Clinic trainees at competitive discounted rates.

Please contact one of our Plan Representatives listed below with any questions.

Amy P. Dickenson Dickenson Group LLC 6001 Cochran Road, Suite 400 Solon, OH 44139 440-505-6007 – Office 440-349-8969 – Fax 216.375.2437 Cell amy@dickensoninsurance.com

Rory Bixel Lough The Bixel Organization, Inc. 8561 East Avenue Mentor, OH 44060 440.974.4040 Office 440.567.8949 Cell rory@thebixelorganization.com

HEALTHCARE BENEFITS

All individuals appointed through the Graduate Medical Education Department will be offered one of two health care plans through the CCHS Health Plan for themselves and any eligible dependents (as defined for their position in the Graduate Physician's Manual). *Benefits will be provided regardless of whether or not they are receiving a salary from Cleveland Clinic*. Trainees appointed through the GME Department CANNOT be required to provide their own medical insurance *OR* reimburse their department for medical insurance for themselves or their eligible dependents. Medical insurance provided by outside funding sources, such as a foreign government, are not acceptable as they may not be accepted by health providers in the U.S.

The Cleveland Clinic Benefits Program (BeneFlex) lets you select benefits that meet you and your family's needs including Health, Dental, Vision and Flexible Spending Accounts. The BeneFlex coverage you select begins on your actual start date. Select your benefits carefully as you can only change them once a year during the annual open enrollment

Funded Residents/Funded Fellows

Medical & Pharmacy	 Medical Insurance –One plan, two levels of coverage as follows: Tier I - Cleveland Clinic Florida – Covered services provided at Cleveland Clinic Florida at 100% with applicable co-pay, no deductible. Pediatrics and Obstetrics will be provided at level one coverage for services rendered in the UMR PPO network. Tier II – UMR PPO Provider Network – Covered services provided through UMR provider network physicians with applicable deductible and/or co- insurance. Coverage is effective on the date of hire provided online enrollment is completed within 31 days 			
	from the date of hire. Please refer to the schedule of benefits for coverage provisions. Pharmacy Benefit – Cleveland Clinic Florida Prescription Drug Benefit is administered through Caremark, one of the nation's leading independent Pharmacy Benefit Managers. The dedicated toll-free customer service number for Cleveland Clinic Florida Employee Health Plan (EHP) members to call is 1-866-804-5876. Operators are available 24 hours a day, 7 days a week. Caremark customer service is also available via e-mail at <u>customerservice@caremark.com</u> .			
	<i>Categories</i> Annual Deductible	Employee % Co- pay CCHS Outpatient Pharmacies \$100 Individual / \$	Employee % Co-pay Caremark Retail or mail order	
	Tier 1 Generic Rx	15% (deductible waived)	20%	
	Tier 2 Preferred Brands (Formulary) Tier 3	25%	30%	
	Non-Preferred Brands (Non- Formulary Tier 4	45%	50%	
	Specialized Drugs (Hi-Tech)	20%	20%	

Dental Options Traditional Only Dental (continued)	CIGNA Traditional Dental Insurance – Provides coverage for dental services. If you use network providers, your co-payments will be less due to discounted rates the CIGNA network providers have agreed to accept. \$50 deductible per calendar year per covered individual (waived for preventive services). Preventive services covered at 100% within the CIGNA network and 100% of the reasonable and customary charge for providers outside the CIGNA network. After satisfaction of annual deductible, basic services are covered at 80% within the CIGNA network and 70% of reasonable & customary for providers outside the CIGNA network and major services are covered at 50%. There is a \$1,250 maximum benefit per individual per calendar year and a \$1,250 lifetime maximum benefit for orthodontics for children to age 23. Please refer to the schedule of benefits for coverage provisions. Coverage is effective on the date of hire provided online enrollment is completed within 31 days from the date of hire. Please refer to the schedule of benefits for coverage provisions.
Vision	Vision Care Plan – A comprehensive vision insurance plan option that covers routine eye care, including eye exams and eyeglasses (lenses and frames) or contacts with referral. Coverage is effective on the date of hire provided online enrollment is completed within 31 days from the date of hire. To access care within the network, only need to provide name and date of birth to provider at time of service. Members will be issued Vision ID cards for convenience but not required to access network providers. Please refer to the schedule of benefits for coverage provisions.
FSA	 Flexible Spending Account – Employees may elect to set aside a certain portion of their salary, which otherwise would have been taxable income, into a personal reimbursement account. The Flexible Spending Account may be utilized to reimburse for eligible dependent child or adult daycare expenses at a maximum of \$5,000.00 and medical or dental expenses not otherwise covered by insurance plans at maximum of \$2,500.00. Any funds left in the account at the end of the year will be forfeited per IRS guidelines. Please refer to the Flexible Spending Account website at www.mypayflex.com or contact PayFlex Systems at 1-800-284-4885. Vacation- Each Resident/Fellow is entitled to 15 Days Vacation Time. Vacation must be taken in
Vacation Time	the year earned (July 1st-June 30 th).
Disability- Permanent	Disability -Cleveland Clinic Florida provides a separate disability policy for all clinical residents/fellows appointed by the Division of Education. (Enrollment is done quarterly from July 1 st .) A representative of the Bixel Organization will contact you regarding your specific coverage requirements. If a resident/fellow becomes permanently disabled due to illness or accident as determined by the primary care physician and the designated insurance company, a claim form must be filed with the insurance company. Salary and benefits will continue for the 90-day waiting period or until the end of the current contract, whichever is the shorter period of time. If the remaining time left is more than 90 days (once disability payment begins), benefits only will continue until the end of the current cOBRA.
Life Insurance	Life Insurance - Residents/Fellows on payroll are provided with up to \$25,000 in life insurance coverage at no cost.
SIP (403B Plan)	Savings and Investment Plans (403 B) - Employees will be automatically enrolled at a 3% Employee Savings Contribution rate. Employees may contribute the <i>lesser of</i> \$17,500 (IRS annual limit) or 50% of their pay. Employees over the age of 50 are permitted to make additional pre-tax deferrals over and above the limits set by the IRS (these additional deferrals would not be eligible for any additional match). You may contact Fidelity at 1-888-388-2247 or go online to www.fidelity.com/atwork to request a change in investment options, contribution rate, or to opt out.

Credit Union	Coral Community Federal Credit Union - Convenient payroll deductions to the employee's savings, checking, Christmas, and vacation club accounts. Loans and credit cards are also available. Effective immediately.* Membership eligibility is subject to credit union guidelines. Call 954-772-2330 for more information or visit: <u>www.coralcommunityfcu.org</u> .
Direct Deposit	Direct Deposit - Direct deposit of your paycheck into the bank account of your choice. Effective immediately. If you desire to elect direct deposit, complete a direct deposit form and submit it to the Payroll Department.

<u>Please Note</u>: The above stated coverage applies to covered services only and is subject to the provisions and exclusions established for each plan and is subject to change at any time.

Qualifying Life Events

The only time it is permissible to make changes to your benefits is within 31 days of a qualifying left event. If you qualify for a life event and wish to change your coverage you must contact the Benefits Department (216-448-0600) within 31 days of the event and provide the necessary supporting documentation. Please refer to your Benefit Program Summary for a detailed list.

Domestic Partner Benefits

Benefits for same gender partners are available to all eligible trainees. Specific criteria must be met and you and your domestic partner must complete and sign an Affidavit of Domestic Partnership. Under current federal and state law, the full cost of benefits coverage for your domestic partner is added to your income and subject to ordinary federal, FICA, state, local and other applicable payroll taxes.

COBRA

You may elect to continue your health coverage for up to 18 months upon termination from the Cleveland Clinic. If you elect to continue coverage, you pay the entire cost. Trainees will receive information to elect COBRA after they have left Cleveland Clinic. If COBRA is elected, your Benefit Plan(s) will be reinstated with no lapse in coverage. After completion of training program or at termination, all benefits will terminate on the last day of the month. (PayFlex Cleveland Clinic's COBRA administration-800-284-4885).

Dependent Care Flexible Spending Account

Eligible dependents are:

• Individuals under the age of 13 who you claim as dependents on your Federal income tax return

• Individuals (such as parents or children age 13 or older) who reside with you, are physically or mentally incapable of caring for themselves and can be claimed as dependents on your

- Federal income tax return
- Spouses who are physically or mentally unable to care for themselves

All benefits are maintained through the Cleveland Clinic Human Resources (HR) Department.

Cleveland Clinic Customer Service Unit

Any questions regarding the Cleveland Clinic Employee Health Plan should be directed to the CCHS Employee Health Plan Customer Service Unit at **216-448-0800 or toll free 1-866-811-4352**. You should also contact the Customer Service Unit regarding questions pertaining to billing or claims.

Cleveland Clinic Benefits Customer Service Center

The Benefits Customer Service Center is available to help obtain information related to eligibility issues, benefit plan coverage provisions, enrollment information and **qualified life events.** Contact the Benefits Customer Service Center at **216-448-0600**.

Cleveland Clinic Benefits Office/AC341 3050 Science Park Drive Beachwood, Ohio 44122

Social Security Number

A Social Security Number is **required** for enrollment into any of the Cleveland Clinic Health Care Plans. It takes approximately 45 days from your start date to receive your insurance card(s). Insurance card(s) are mailed to your home address that GME has on file. If you did NOT have a social security number when you processed in with GME, your ID card(s) will NOT be mailed out until Graduate Medical Education receives an actual copy of your social security card.

<u>Group Numbers</u> Employee Health Plan and Prescription Drug: 228250803 Cigna Dental Plans: 32153560000 EyeMed Vision Care Plan: 96599960

EMPLOYEE ASSISTANCE PROGRAM (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 you take care of yourself and maintain your ability to provide a world class patient experience.

The programs offer expert, confidential and free support through the:

- Physician Health Program
- Licensed Professionals Health Program
- CONCERN Employee Assistance Program
- Wellbeing Resource and Referral Service

Together these programs demonstrate the importance Cleveland Clinic places on caring for our caregivers.

Physician Health Program (PHP)

PHP offers physicians and other professional staff a spectrum of resources aimed at supporting wellness, prevention and personal/professional development. Services also extend to evaluation and treatment for issues that may lead to impairment.

- Prevention education
- Consultation, coaching, counseling and health services
- Referrals to resources within Cleveland Clinic and the community

To learn more about the Physician Health Program, seek assistance confidentially or schedule an appointment, call **216-445-6970**.

CONCERN Employee Assistance Program (EAP)

The CONCERN Employee Assistance Program (EAP) offers private and confidential assessment, short term counseling and follow-up services to employees and their immediate family members. You and your dependents do not need to enroll in any of the health care plans offered at the Cleveland Clinic in order to utilize the CONCERN benefit. Services are available at numerous locations throughout Northeast Ohio. All services are 100% confidential - not part of medical or GME records. The Clinic knows you are an important part of our team and provides this benefit to assist you in reaching your highest potential, both at work and in your personal life. For many issues (including workplace stress), you may want to consider the CONCERN program before using your insurance. To access CONCERN, please call **216-445-6970 or 1-800-989-8820**.

To receive more information, please refer to: http://portals.ccf.org/caregivers/

EMPLOYEE SERVICES

The following Clinic internet web site <u>http://intranet.ccf.org/employee.asp/</u> outlines a number of services provided to all trainees employed by the Cleveland Clinic. Please refer to this site to become familiar with; human resources policies, day care services, travel information, pastoral care and employee advantage discounts (for other programs and services offered to Cleveland Clinic employees contact Human Resources at 216-448-0400).

EDUCATION ALLOWANCE

A \$250.00 education allowance per year is available to all clinical trainees. Primary use it for books, electronic subscriptions, CD/DVD educational sets, journal subscription including on line journals. After required textbooks are acquired, clinical trainees are allowed to substitute journal subscriptions and educationally based computer programs. Clinic purchase procedures must be followed to ensure that ownership is documented. Submission of expense reimbursement request must be in the academic year of the purchase. Book allowances must be used during the academic year and money cannot be carried from year to year. Cell phones and IPODS of any type are not acceptable devices for reimbursement of educational allowance.

LOAN PROGRAM

An emergency loan fund is available for clinical trainees, not to exceed \$1200 a year. Outstanding loans must be paid in full before a new loan may be requested. Loans must be paid in full when clinical trainees leave Cleveland Clinic. Under extraordinary circumstances, a clinical trainee may ask the program director or department chair to contact the Director, Graduate Medical Education for consideration of a loan exceeding the \$1,200 limit. The Director, GME in conjunction with the Center Director, Education Center will take the request under consideration based on the extraordinary circumstances and the funding available. Please direct questions regarding this loan to the Graduate Medical Education Department.

ON-CALL MEALS

<u>Eligibility</u>

Clinical trainees that are in programs that require them to be on in-house overnight call are provided an on-call meal allowance. This does not include trainees taking call from home.

Meal Dollar Allowance

Cleveland Clinic uses a debit system through your ID Badge. Your on-call meal allowance was carefully calculated based on your training program, graduate level and your average in-house overnight calls. The on-call meal allowance is pre-loaded onto your ID Badge with six months' worth of on-call monies at a time. Updates to the amount occur in July and January of each year, which does reset your balance to your six month allowance.

Where to Use Your Allowance

Use your on-call meal allowance at any Aramark eatery including: the hospital cafeteria and Starbucks Kiosk.

How to Use Your Allowance

You must have your ID Badge to use your on-call meal allowance. Present your ID Badge to the cashier and indicate that you are "On-Call." You will receive a receipt after each purchase indicating the remaining balance of your on-call meal allowance. Any amount spent over your on- call meal allowance is your responsibility and will be charged to you via personal payroll deduction and taken out of a future paycheck.

You may use your on-call meal allowance as you choose, but when you have exhausted the allowance, no additional monies will be added. YOU are responsible for all charges made to your ID Badge. The on-call meal allowance is a benefit for you and shouldn't be used for family members, friends or visitors. Do not swipe your ID Badge for meals for other clinical trainees or allow them to use your ID Badge. If your training appointment ends early for any reason, the on-call meal allowance will be prorated based on the number of months within the 6 month period which were completed. Allowance monies which were already spent above the prorated amount will be deducted from your last paycheck.

Lost ID Badge

Please notify your program coordinator if you receive a new ID Badge. We will need the six-digit number on the back of your new badge to reactivate your account. Also, know that the balance in your account when your badge is reissued is the balance that you will have for on-call meals. In other words, if someone finds your badge and uses your account for meals, those dollars cannot be replaced.

Note: Refer to the Institutional Duty Hour Policy located on page 40 for information regarding on-call activities and frequency limitations.

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 the Cleveland Clinic. Outside rotations at participating sites that are a required component of your training program are included and covered under the professional liability coverage offered by Cleveland Clinic. **Elective rotations outside of the 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 you were in training. You do not have to purchase any "tail" coverage when you leave.

For more information, refer to the Enterprise Risk & Insurance website, at http://sharepoint.ccf.org/financedivision/eri/default.aspx. After you leave the Clinic, verification of professional liability insurance can be obtained via written request only by faxing to 216-445-7470.

SALARY & BENEFIT REQUIREMENTS

- 1. Funding Sources
- a. <u>By visa type</u>

<u>H-1B</u>: Salary and benefits must be paid by the employer (CC) and must be at or above prevailing wage as determined by the U.S. Department of Labor Office of Foreign Labor Certification. There are no exceptions to this rule. In addition, the employer is responsible for all costs (filing fees) associated with the filing of the H-1B petition.

<u>J-1</u>: Salary may be paid by CC, an outside source, partial personal funds or a combination of all three.

b. <u>Clinical Trainees</u>

Clinical trainees (resident, fellow, clinical fellow) being paid by Cleveland Clinic are to be paid at the PGY level required to enter the program. Clinical trainees may receive funding from a source outside Cleveland Clinic. However, they may not use personal funds. The source of funding must be verified in writing on letterhead and the amount must be equal (in U.S. dollars) to the salary paid to other trainees at the same PGY level in the individual's program.

- 2. Benefits
 - a. All individuals appointed through the Graduate Medical Education Department (fellow, clinical fellow, clinical scholar and resident) will be offered medical benefits through the CCHS Health Plan for themselves and any eligible dependents as defined for their position in the Graduate Physician's Manual. Trainees appointed through the GME Department cannot be required to provide their own medical insurance <u>or</u> reimburse their department for

medical insurance for themselves or their eligible dependents.

Withholding of Stipend

The Cleveland Clinic reserves the right to withhold part of a clinical trainee stipend, as recompense for:

•Any loss of or destruction to Cleveland Clinic Health System property, such as library books, pagers, uniforms, etc.

•Violation of Cleveland Clinic Health System parking regulations,

•Debts incurred to the Cleveland Clinic Health System or its subsidiaries,

•Overcharges to the on call meal system or as an inducement for the clinical trainee

to complete any delinquent professional or administrative

responsibilities/requirements.

Clinical Trainee Salaries

In keeping with the ACGME Guidelines for compensation of residents in training, Cleveland Clinic Florida Graduate Medical Education Committee formally institutes the following policy:

Salary levels shall be determined on an annual basis by the Graduate Medical Education Committee. This determination shall be based on review of the overall economic environment, the institutional adjustments for other employees and a comparison of other institutions of comparable size in this general geographic area.

The salary level for clinical trainees shall be determined by the postgraduate year required to enter the program. Clinical trainees, who enter a program that is approved for a given year of postgraduate level status after they have already exceeded that level of training themselves, will be appointed at the appropriate level according to number of years of training, and will be compensated at the level for which the position is approved. Clinical trainees at the same graduate level are paid at the same salary rate regardless of the specialty-training program.

Any variation from the compensation level, either above or below the standard, must be approved by the Graduate Medical Education Committee prior to institution of the salary adjustment.

Savings & Investment Plan (SIP)

Effective January 1, 2010, **all newly hired clinical and non-clinical trainees will automatically be enrolled in the Savings Investment Plan (SIP) from Fidelity**. The plan will automatically deduct 3% pretax deduction from each paycheck. Graduate physicians are *not* eligible to receive the employer matching contributions. Plan overview information as well as "opting out" instructions will be mailed from Fidelity to the home address that GME has on file. If you are <u>not</u> interested in participating in the SIP, you must contact Fidelity to "opt out" (but not earlier than 10 days from your start date to assure you are in their database). Any questions should be addressed to Fidelity at 1-888-388-2247 or long onto <u>www.fidelity.com/atwork</u>. Any employee currently employed by the Cleveland Clinic can simply call Fidelity at 1-888-388-2247 to begin their participation.

TRAVEL PRIVILEGES

Residents/Fellows at PGY3 or above are eligible for 5 meeting days **for a maximum of \$1, 200.00** reimbursement including registration fee per academic year.

Any additional travel cost shall be paid by the resident/fellow. Any additional working days needed for travel shall be counted, as vacation and no per diem shall be allowed for such vacation days.

Prior to a meeting, residents/fellows must complete an *Application for Meeting Attendance* and submit with appropriate documentation to their GME Coordinator no later than 30 days prior to the meeting. Requests for meeting attendance must also be submitted on MedHub no later than 30 days prior to the meeting. This must be done whether there is a registration fee or not. A check for the registration fee will be made out to the organization holding the seminar if the resident requests it in advance on the application form and submits a check request.

Airline tickets must be purchased through the CCF designated travel agent using CONCUR (for clinical trainees). Reimbursement for expenses up to the travel limit will be received after the meeting; the *"worksheet"* entitled *Travel Expense Report*, must be submitted with the original receipts to your GME Coordinator. All reimbursement forms to be paid must be submitted to the GME Coordinator no later than 30 days after the trip has been taken. **If complete reimbursement forms are not submitted within this time, the reimbursement will be denied.** Please contact your GME Coordinator for details.

In exceptional circumstances a resident/fellow who is eligible for travel may not be able to take his/her meeting due to staffing, etc. Permission to carry over a meeting to the next academic year may be granted prior to the end of the current academic year. The Program Director must request the carry over in writing to the Chair of the Graduate Medical Education Committee for review and final approval. **Travel time may not be carried over past one academic year**.

In cases where national meetings are a requirement of the Residency Review Committee (RRC) or a specific residency program requirement for a certain specialty, then the national meeting will be taken in lieu of the senior resident's/fellow's clinical tour.

GME sponsored travel is a privilege, not a right. Residents and Fellows are expected to be good stewards of the institution's resources and to treat funds as if they were personal resources. Expenses must conform to Cleveland Clinic policy in regards to limits and restrictions. Expense reports should be completed in a timely manner and receipts for all items over \$24.99 must be included.

Additional meeting time may be granted during the year at the program's discretion. The expenses for additional approved meetings will be covered either by the trainee or by the training program. Please refer to department policies and procedures for further information.

Presenting Papers

Residents/fellows who are to present papers or lectures, be faculty members at CME courses, or accompany an exhibit or poster presentation, that would incur travel expenses above the established limits, must have prior approval from their Program Director and must be in accordance to the funds available.

Eligibility

A resident/fellow is eligible to present a paper in person at a meeting if:

- He/she is an important contributor to a paper which has been accepted for presentation, and
- A staff member with knowledge of the subject also attends the meeting to assist in the discussion if necessary.
- Authorization is obtained from the Program Director, the Chair of the Department and the appropriate Division Chair. Abstracts submitted to a meeting scheduled for after the resident or fellow has left the Cleveland Clinic are subject to approval by the Program Director and the appropriate Division Chair, as well as any other signatures required by Department or CCF Policies. Abstracts submitted to any international meetings must have prior approval of the Department and Division Chair.
- The resident's time away for the presentation of papers or meeting attendance is approved at the discretion of the Program Director, is in accord with department guidelines, and follows RRC restrictions pertaining to the training program. The resident is responsible for notifying the Program Director before the paper or abstract is submitted of where the paper or abstract will be presented, the expected time away from training, and who will cover the service in his or her absence.

Any poster that would need printing would go to:

Poster Ordering Procedure:

1. Cleveland Clinic Center for Medical Art & Photography will prepare and print posters for Florida Residents and Fellows at no charge.

2. All Materials must be provided to <u>artphoto@ccf.org</u> 3 weeks prior to the requested due date.

3. Final word documents must be submitted via e-mail to <u>artphoto@ccf.org</u>, cc'ing Jim Reed <u>reedj@ccf.org</u> so he is aware that the submission is for CCF.

Failure to submit in the outlined timeframe will result in no financial coverage by Cleveland Clinic Florida.

The Resident/Fellow will be responsible for the printing cost of the poster.

Medical Editing Services

For publication advice and editing of your scientific article or abstract, please consult the Office of Medical Editing. There are two editors who can review scientific manuscripts before they are submitted to peer-reviewed journals. This office performs substantive editing on text, tables and illustrations to achieve clarity, precision, internal consistence and brevity. Also provided is guidance on visual and text presentations of quantitative data and on reporting research design and statistics. These services are fully funded by the Division of Education and thus are provided at no charge. Contact (216)-444-2661 for use of these services.

Exceptions to this policy in regard to <u>days away</u> and <u>expense limits</u> need to have prior approval via the *Application for Meeting Attendance* by the Program Director.

REIMBURSABLE EXPENSES

Clinical Trainees will be reimbursed for the following items. All receipts, including proof of payment, will need to be submitted to your residency coordinator. Money cannot be carried over from one academic year to the next.

- Training License
 - Initial All receipts for licensure must be submitted within 30 days of your start date for reimbursement.
 - Renewal- All receipts for licensure must be submitted
- Florida Permanent License (Limited Clinical Fellows, Colorectal, Plastic Surgery, and General Surgery Residents-PGY 4 and above-)
 - Initial All receipts for licensure must be submitted within 30 days of your start date for reimbursement.
 - Renewal All receipts for licensure must be submitted
- DEA Number (Limited Clinical Practitioners Billable Clinical Fellows) Cleveland Clinic Florida (Limited Clinical Fellows, Colorectal, Plastic Surgery, and General Surgery-PGY 4 and above-)
 - Initial All receipts for DEA reimbursement must be submitted within 30 days of your start date for reimbursement.
- Book Allowance- All Clinical Trainees are given \$250 book allowance per academic year. Reimbursement cannot be carried over from one academic year to the next

Clinical Trainees will be provided the following items free of charge:

- Lab Coats/ Scrubs
- Pager (fee applied only if lost or not returned)
- Access token (fee applied only if lost or not returned)
- Encrypted thumb drive (only given upon request. Clinical Trainee must complete sign release form and return before completing program and leaving institution)

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, Shape Up & Go!TM, 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.

For more updated details on the Employee Wellness program, please refer to www.clevelandclinic.org/employeewellness

Any additional questions can be directed to wellness@ccf.org.

RESOURCES

Appeal/Grievance Process

Procedure for Clinical Trainee/Research Fellow Appeal Process

When the individual clinical trainee is formally notified in writing(that he/she is being placed on performance warning status, being reappointed but not promoted to the next year of training, not reappointed or being dismissed from the program) he/she may initiate an appeal procedure.

When the individual research fellow is formally notified in writing (that he/she is being placed on performance warning status or being dismissed from the program) he/she may initiate an appeal.

Any of these appeal actions by the department will precipitate an interview/counseling session with the Center Director, Education Center & DIO or his/her designee. To initiate the appeal process, the involved clinical trainee/research fellow must provide written notification to the Center Director, Education Center & DIO within two weeks of this meeting of his/her decision to proceed or not to proceed with an appeal. Any clinical trainee, who initiates an appeal from a dismissal from the program, shall receive salary and benefits during the appeal. If the appeal is upheld, all documentation in the clinical trainees file regarding the non-reappointment/performance warning or termination will be removed. A copy of the complete appeal process is available in the GME Department.

Non-Appealable Adverse Actions considered Single Significant Events:

•falsification of records

•material omission of information on an application and/or official paperwork

•conviction of a felony

•loss of medical licensure

A thorough non-biased investigation shall be conducted by uninvolved parties. Structure An Appeal Task Force will be formed, as a subcommittee of the Graduate Medical Education Committee, to hear each appeal as it occurs. The Appeal Task Force is a peer review committee within the meaning of the Florida Revised Code and its members, proceedings, reports and minutes,

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shall be afforded the confidentiality guarantees and protections from discovery and immunities available to hospital peer review and quality management activities. The Appeal Task Force shall consist of five voting members who have no direct conflict of interest by way of being part of the teaching faculty in the house staff's training program, personal involvement with the house staff or a member of the involved faculty or any other situation which might cause the member to be prejudiced and have a preexisting opinion. The Center Director, Education Center shall guide final composition of the task force and he/she will not be eligible to participate. The membership of the task force shall consist of a member from the Graduate Medical Education Committee (serving as chair person), a house staff representative (a house staff committee officer or senior resident), a representative from the Graduate Medical Education Department (as a non-voting member) and the remainder of the task force filled by designation of three other faculty members who are not directly involved in the situation in question. Written documentation submitted to the task force for deliberation, reports and minutes generated by the task force shall not be made available to either the program director or the house staff member.

If the house staff member engages legal counsel to assist him or her with the preparation of the appeal, such legal counsel may not represent or accompany the house staff member or otherwise appear before the task force at any time. The task force may seek legal advice from the CCF Office of General Counsel as desired, but the Clinic's attorneys should not serve in a prosecutorial role before the task force.

Preliminary Preparation

Once the task force has been appointed and a chairman selected, the involved house staff member and program director will be solicited for documentation and general information relative to the action under appeal. The program director will be expected to submit documentation that justifies and explains the reason for the action that has been taken and is being appealed. This documentation may include but is not limited to, summaries of counseling sessions, department and 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. The house staff member is asked to submit any information and/or memos that he or she feels may help to explain the grounds for the appeal. Both the program director and the involved house staff member will be asked to provide a list of potential additional information sources at that time. That list may include fellow residents, 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 description of each individual recommended explaining why that person is identified and what their potential input would be to the overall process.

Process

• Under the guidance of the designated chairman, the Appeals Task Force will schedule a series of meetings that will comply with the availability of the members, program director and house staff member, to afford a prompt and fair resolution of the appeal. The initial meeting may be designated for the program director. The program director will summarize the events, issues and overall factors that have led to the appealed action. The Appeal Task Force may or may not question the program director at that time for additional facts and information and may choose to ask him or her to return if that is necessary to complete the information gathering process.

• The house staff member will be invited to appear before the task force, which may be either

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the initial meeting or at the next available scheduled session. The program director and the house staff member will not be present before the task force at the same time. The house staff member will be offered an opportunity to present information in his or her defense. The task force may or may not question the house staff member at that time and may or may not ask them to return to complete the explanation of and/or questioning of the house staff member.

• After the initial sessions with the program director and the involved house staff member, the task force will review the list of potential additional information sources and consider receiving testimony from any other individuals. They will then invite and interview those whom they have selected from the list and other relevant individuals. At the discretion of the task force, 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 or seem inappropriate. At any point throughout this process the program director and/or the house staff member may be invited to appear before the task force again in order to respond to information that has arisen during the interview of subsequent individuals or to clarify issues.

• When the Appeal Task Force feels that it has obtained all of the pertinent information available, it will take the matter under discussion until it is prepared to make a decision. A simple majority of the voting members of the task force present will be required to act on the appeal. That action may either be to sustain the appeal, which in effect negates the action taken by the training program, or reject the appeal and thereby sustain the action taken by the program. As part of its decision the Appeal Task Force may also enter specific stipulations and requirements governing the further involvement of the house staff member in the residency program. This may involve whether or not credit should be given for any or all training that has been done to date, whether or not psychiatric evaluation or counseling is appropriate and whether or not other means of remedial action should be taken.

Conclusion

When the Appeal Task Force has come to a majority decision, the information will be relayed to the Center Director, Education Center in writing within one week. The Center Director, Education Center will then inform both the house staff member and the program director. Reports and minutes of the meetings of the task force shall be prepared by a designated member of the task force in conjunction with the CCF Office of General Counsel, whereupon such reports and minutes will be maintained within the Department of Graduate Medical Education.

Complaint & Problem Resolution

Occasionally during training, clinical trainees experience problems and/or issues that are unable to be resolved within the channels available in their own training program. Such problems are best handled within the program and clinical trainees are encouraged to attempt all means of resolution through their chief resident, program director, department chairman, advisor or other designated individuals in the training program before utilizing the following alternative channel. The issues may involve a number of areas including but not limited to perceived harassment, unfair treatment, concerns regarding work environment, program noncompliance with ACGME, RRC and/or CC requirements and/or procedural discrepancies or inequities.

Once the resources and channels within a program have been exhausted, the clinical trainee is encouraged to contact the Graduate Medical Education Department 954-659-5882 to arrange a meeting. They will then have the opportunity to discuss their particular situation in detail with the Director of Graduate Medical Education, Center Director, Education Center, and/or the Administrator of Education. Every attempt will be made by the Director and Administrator of Graduate Medical GME Institutional Manual 2015-2016 110 Education to investigate and resolve the reported issues.

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

This policy is intended to provide clinical trainees with the opportunity to raise and resolve issues in their training program without fear of intimidation or retaliation.

DISABILITY ACCOMMODATION

Purpose

This policy confirms the commitment of Cleveland Clinic to comply with all state and federal laws regarding the employment of qualified individuals with disabilities and also establishes guidelines and procedures for the consideration of requests for reasonable accommodation by employees and applicants with known physical or mental impairments.

Policy

It is the policy of Cleveland Clinic to comply with the Americans with Disabilities Act ("ADA"), the Americans with Disabilities Act Amendments Act ("ADAAA") and all state and federal laws, rules and regulations concerning the employment of persons with disabilities. Cleveland Clinic will not discriminate against qualified individuals with disabilities in regard to application procedures, hiring, advancement, discharge compensation, training or other terms and conditions of employment. Furthermore, Cleveland Clinic will make, upon the request of a qualified individual with a disability, a reasonable accommodation to permit such person to perform the essential functions of the job, so long as such accommodation does not result in undue hardship to the business operations of Cleveland Clinic or cause a direct threat to the health and safety of the requesting person of others in the workplace.

For the complete policy, refer to the HRConnect portal <u>https://erc.enwisen.com/asi/page.aspx?alias=navigator&header=on</u>

Non-Discrimination (Harassment or Retaliation)

Purpose

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.

Policy

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 decimation or harassment on the basis of race, color, religion, gender, sexual orientation, gender identity, 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. All employees, regardless of position or title, will be subject to severe corrective action, up to and including discharge, for GME Institutional Manual 2015-2016 111 engaging in acts prohibited by this policy.

For the complete policy, refer to the HRConnect portal <u>https://erc.enwisen.com/asi/page.aspx?alias=navigator&header=on</u>

Chemical Dependency

Physicians are a high-risk group with regard to the potential for substance abuse. The Institution's chemical dependency recovery program is aimed at providing help to any clinical trainee/research fellow in need. Clinical trainees/visiting researchers identified as having a problem with chemical dependency will be offered a full course of treatment consisting of an intensive in-house treatment program at the Cleveland Clinic or another designated facility followed by outpatient treatment. The Institutional physician's health committee monitors the individual's progress and approves the return to training status as appropriate. Every effort is made to maintain complete confidentiality.

Referral and Assessment Procedure for Behavioral Health Issues

The Cleveland Clinic is committed to helping you and your family to stay healthy. Residency and fellowship training can be a stressful time in which some type of mental health care may help you optimize your personal and professional well-being. Behavioral health refers to and includes all services for mental health and substance abuse. Levels of behavioral health services are; outpatient visits, inpatient, partial hospitalization programs and intensive outpatient program. Most programs require prior authorization. Medical Management can be reached at 216-986-1050 or toll free 1- 888-246-6648 during regular business hours of 8 a.m. to 4:30 p.m. Monday through Friday. A confidential voicemail is available to accept non-urgent messages after hours.

This procedure is intended to be a guide and a resource to the Program Director as well as for the clinical trainee. A description of the plan coverage and treatment are administered through the Behavioral Health Program. For additional information, please call 216-986-1050 or 1-888-246-6648.

Reasons for referrals include but not limited to:

- Self-referral for mental health or wellness issues including substance abuse
- Disruptive physician behavior
- Chemical dependency, known or suspected
- Professionalism
- Performance issues
- Performance warnings

The role of the Caring for Caregivers Employee Assistance Program (EAP/CONCERN) and the Physician Health Committee (PHC) are also reviewed in this protocol. A separate section entitled psychiatric emergencies is also reviewed.

It is important to underscore that when a Program Director is considering the use of the protocol, he/she should ask the questions:

"Why am I not referring to the EAP?" GME Institutional Manual 2015-2016 "Why am I not referring to the PHC?"

Resources for Program Directors

- Employee Assistance Program (EAP/CONCERN)
- Physician Health Committee PHC
- Psychiatry Emergencies
- Disruptive Behavior Flags
- Algorithms for Referral
- Academic remediation and tutoring (Contact Alan Hull, M.D., Ph.D.)

<u>Caring for Caregivers Employee Assistance Program (EAP/CONCERN)</u> Telephone: Appointments 216-445-6970 (24 hour pager - 23411) Contacts: Kevin Peterca, LISW Location: Main Campus (nine other locations)

The role of the EAP is to provide a first entry and screening of wellness issues as well as limited (up to 10 sessions) follow up/counseling. The referral can be self-referred and referred by concerned supervisors (i.e. program directors). Confidentiality is maintained in the EAP (no entry into medical record/EPIC or computer appointment tracking).

The EAP personnel are licensed independent mental health and chemical dependency professionals with expertise in interpersonal stress management, substance abuse screening, mental illness, work relationships, personal relationships, performance issues, as well as life style management.

Historically, the EAP is the <u>first stop</u> in "getting help" and is of no cost to the clinical trainee. No insurance is billed. Issues of medical leaves and FMLA are also considered and the EAP counselors provide a balance of advocacy and institutional/patient risk management.

Following the initial assessment by the EAP counselor, 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

Strong consideration should be given by residency and fellowship directors in their collective orientation sessions and/or individual meeting with trainees the existence and usefulness of the EAP program and referral process. Equal awareness should be given to supervising residents and chief residents of the EAP role, as a timely referral by these supervisors is always encouraged and recommended.

Please refer to the section of the Graduate Physicians Manual on Benefits for additional information on the Caring for Caregivers Employee Assistance Programs.

Physician Health Committee Susan Rehm, M.D. Telephone 216-444-6846 Executive Director Location G2-142

Jeffrey Kolson, LISW-S Physician Health Coordinator Telephone 216-445-6972 Location C-14 Rm 38

or

LEAVING CLEVELAND CLINIC

Certificates of Completion of Training

Official Certificates of Completion of Training are issued to clinical trainees/researchers who have successfully completed a Cleveland Clinic residency or fellowship program in its entirety as determined by the program length approved by the GMEC. Visiting Researchers 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/visiting researchers who do not meet the above criteria will receive upon request, a letter, verifying completion of the actual training completed at Cleveland Clinic.

The Certificate of Completion of Training will include the legal name of the clinical trainee/visiting researcher, 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/ visiting researcher completes their training and leaves the Cleveland Clinic or leaves the Cleveland Clinic for any reason, they are required to process out through the Graduate Medical Education (GME) Department. The processing out procedure includes meeting all training program requirements, returning Cleveland Clinic property and obtaining the program director or coordinators signature on the Personnel & Data Release Form.

The Personnel & Data Release Form and the instructions on completing this form will be emailed to the clinical trainee/ visiting researcher before their final day. This form can also be found on the Cleveland Clinic GME Intranet site. After the form has been completed and returned to the GME Department, the final paycheck will be mailed to the forwarding address provided.

All clinical trainees who discontinue their appointment before their end date should submit a resignation letter to Graduate Medical Education. Please contact the GME Department (954-659-5815) for additional information.

MISCELLANEOUS TRAINEE INFORMATION

Facilities Operations / Security /Plant Operations

The personal safety and health of each employee, patient and visitor is a primary importance to the Cleveland Clinic Florida. 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 Florida that every effort will be made to exceed them whenever practical. Please keep the following numbers available for your reference:

Facilities Ope	rations/Security Office:			
General Office Hours – 8:00A.M. to 4:30P.M., Monday through Friday				
After normal business hours and on weekends dial extension 55025.				
X55030	- Info on Proximity Cards, ID Badges, Key requests and Parking Stickers			
X55025	- For Security officer to take a report, open doors, etc. 24-7			
X2222	– Security Emergencies			
9-911	– Medical Emergencies - initiated (if applicable) as Medical Alerts by			
	dialing			
	X7777 to advise Operator of Medical Emergency and location, then make			
	notification to Security Command Center at x2222.			
Plant Operations:				
X65025				

General Office Hours – 8:00A.M. to 4:30P.M., Monday through Friday Florida Intranet – Facility Engineering requests – *Work Order Forms* Florida Intranet – Bio-Medical Engineering requests – *Work Order Forms*

FACILITY OPERATIONS DEPARTMENT POLICIES

Parking

Employee parking sticker to be visible and placed on the driver's side lower left hand corner of front windshield. Parking will be in the general employee parking area located on the south side of the Clinic Building during normal business hours. After hours and weekends, parking is restricted to lot D & E. Sticker must be returned if vehicle is sold, or upon resignation or termination. A charge will be deducted from paycheck if sticker is not returned. Do not park in Physician Parking Only. Do not park in Clinic patient parking in Lots A, B, and C or the front lot of Hospital.

I.D. Badges

Employee's CLEVELAND CLINIC FLORIDA I.D. badge to be worn at all times while on CCFlorida premises. There will be a replacement charge for lost ID badges. Handmade alterations of name or photo are prohibited.

Key Control

Key requests must be submitted and approved on the appropriate "Key Request" form by the director/manager or your coordinator. These forms are available on line under "Information Forms Management" on the intranet.

Proximity Card

Proximity card is issued to each employee. The card is <u>not</u> transferable. Any card lost or stolen must be reported to Security immediately. There will be a replacement charge for lost cards.

Fire Alarm Systems & Procedures

- 1. Explanation of fire alarm policies
- 2. Fire extinguisher training review of use

It is each employee's responsibility to know the Fire Alarm Policy, location of nearest fire extinguisher, the number to call in case of a fire and where main and alternate evacuation routes are. Every employee is responsible to participate in fire training.

Florida's "Right to Know"

- 1. Employees have a right to know what chemicals and hazardous chemicals (materials) are in the work place.
- 2. Material Safety Data Sheets (MSDS) are located on the Florida Intranet.
- 3. Any questions should be directed to your supervisor or the Safety Officer at ext. 65020.
- 4. Yearly training is mandatory for all employees on the safe handling of hazardous materials.

Solicitation Policy

Solicitation by both employees and non-employees (self-employed sales personnel) within the Clinic and Hospital buildings or on its property is prohibited.

Weapons Policy

Carrying or possession of weapons/firearms by employees other than CCF Security personnel while on duty or on Clinic property is prohibited.

EMERGENCY CODES

When at Cleveland Clinic Florida, the campus number for **ALL** Codes and Medical Alert emergencies is **7777**. (Remove this statement: For code Blue in the Clinic only, you must activate **911 AFTER** calling **7777**). This is not always the case.

To contact Security for emergencies dial extension 2222.

Fire and Safety Codes at Cleveland Clinic Florida Codes –

Code Black – Bomb Threat Code Blue - Cardiopulmonary Arrest In clinic dial 7777, then activate 911 Code Brown – Severe Weather Code Green - Mass Casualty Disaster Code Grey - Violence / Security Alert Code Orange – Hazmat / Bioterrorism Code Pink – Infant/ Child Abduction Code Red – Fire/ Smoke Code Silver - Active Shooter Code White - Hostage Code Yellow - Lockdown Chest Alert - Cardiac Emergency in ED Brain Attack - Neurological Emergency (Hospital) Medical Alert – Patient in Medical Distress (Clinic) Rapid Response – Patient in Medical Distress (Hospital)

If you detect a fire follow these procedures:

Remember R-A-C-E	Remove patients in immediate danger.
	Alert others by pulling down lever of fire alarm.
	Contain the fire by closing the doors.
	Extinguish fire/evacuate

If you encounter a medical emergency (heart attack, severe shortness of breath, unconsciousness, and any other life or death incident), stay calm and dial **7777**.

PAGERS AND TELEPHONE REPAIRS

- X6-7213 Pager Service
- X5-5555 Telephone Repair
- X5-5555 Telecommunication requests (emergencies)
 - Non-emergencies forward request authorization forms to Telecommunications

All residents will be assigned a pocket page receiver. This pager will cover a 60-mile radius. Contact ITD, 4th Floor Clinic, for repairs and batteries. Batteries are also available in the Telecommunications Office on the 1st Floor of the Hospital. Clinical trainees are fiscally responsible for pager loss or irreparable damage.

TELEPHONE ACCESS (LONG DISTANCE)

Clinical trainees are given a long distance access code that allows them to make **CCF business and patient related** calls in the continental United States. The Division of Research and Education receives monthly reports of all long distance calls made using access codes; we review these reports and any calls that are not CCF official business will be charged to and paid by the individual assigned to that access code. Treat your access number the same as a credit card or bank access card. Do not give the number to anyone else to use. **You are financially responsible for calls made using your access number.**

RISK MANAGEMENT DEPARTMENT

Lee Ghezzi Risk Manager for Cleveland Clinic Florida Office: (954) 689-5265 Cell: (954) 591-7909

The Risk Management Department is responsible for assuring Patient Safety and reviews all Incident Reports submitted through the SERS (Safety Event Reporting System). The Risk Manager is on site or on-call at all times for consultation and to provide assistance to the Clinical Staff. The SERS system is accessed through the Cleveland Clinic Florida Intranet home page, by selecting the <u>Report Event/Injury (SERS)</u> hyperlink and logging in as you would to your e-mail.

PAYROLL DEPARTMENT

(216) 636-7111 Matthew Pruchnicki

Clinical trainees are paid semi-monthly via direct deposit. Direct deposit becomes effective at least a month after enrollment in the bank choice of the employee. All trainees not enrolled in direct deposit will receive a live check in their homes. W-2s are mailed to your home address at the end of the calendar year. If you move, please be sure to notify the GME Coordinator for your program of the change in address to ensure timely delivery of your paycheck.

All employees who are enrolled in direct deposit will receive electronic pay stubs. An additional benefit is the ability to view up to one year of payroll information, including W-2s. The benefits portal is available 24 hours a day/7 days a week. **First time portal users:** Access the portal at <u>https://hrconnect.ccf.org</u>

ON CALL ROOMS

Cleveland Clinic Florida maintains on call rooms for clinical trainees who are required to be inhouse overnight and for those clinical trainees who are called into the hospital at night. The rooms are located on the first floor of the Hospital near the Emergency Room. An additional on call room is located on the fourth floor of the hospital for the on-call ICU resident. Rooms are cleaned and bed linens are changed daily except on holidays

UNIFORMS AND LAUNDRY

Uniforms are available to all house staff and are ordered by the appropriate department. Uniforms will be laundered if they are placed in laundry bins in the Mailroom on the first floor of the Clinic Building and in Environmental Services Department on the ground floor at the Hospital building. Coats put in the laundry bins at the Clinic will be returned to the Residents Room in the Clinic Building and to individual departments. Those placed in laundry with Environmental Services at the Hospital must be picked up from the same location.

PASTORAL CARE

Clergy from numerous local religious organizations are available to visit with patients and family. Information is available at the hospital's switchboard.

CLEVELAND CLINIC PHARMACY

Hospital Pharmacy Services 2nd Floor, Southwest Corner

William Kernan - Director of Pharmacy	(954) 689-5520
Main Pharmacy	(954) 689-5280

The Hospital Pharmacy Department provides comprehensive pharmaceutical services 24 hours a day.

Pharmacy services include:

- **Dispensing** of oral, topical, and injectable medications and IV admixtures.
- **Compounding** and **manufacturing** of sterile and non-sterile dosage forms not commercially available including formulation of new dosage forms of existing drugs.
- **Maintaining** and **dispensing investigational drugs** in accordance with clinical research protocols.
- **Providing drug information** to physicians and allied health professionals. Our staff of registered pharmacists and pharmacy students is available to research any question you have regarding cost, availability, pharmacology, toxicology, drug interactions and related information. The pharmacy has computer databases, current medical literature files and on-line services on all aspects of drug therapy.

The **Pharmacy and Therapeutics Committee** of the medical staff is responsible for approving requests to add new drugs to the Cleveland Clinic Hospital Formulary. Since non-formulary drugs are not stocked in the Hospital Pharmacy and it may take 2-3 days to obtain from outside sources, it is recommended that formulary drugs be prescribed whenever possible. The Cleveland Clinic Hospital Formulary is listed on Lexicomp available at each computer.

Inpatient medication orders must be entered in EPIC by the Physician. Consults for total parenteral nutrition (TPN) must be entered no later than 11:00am daily. TPN consults completed after 11:00am will be processed the next day.

All known allergies to drugs and other substances must be entered into EPIC prior to the ordering and dispensing of any medication. Pharmacists will not dispense medications in the absence of

allergy information.

The Hospital Pharmacy does not routinely fill home-going (outpatient) prescriptions. The outpatient pharmacy is open from 8am to 7pm and does provide a bedside delivery service for discharged patients.

Medical and Surgical Residents with a temporary Florida training medical license must obtain a temporary D.E.A. number from the Hospital Pharmacy that may only be used when writing prescriptions in the normal scope of duties at Cleveland Clinic Hospital. Pharmacy will provide this number during orientation.

Outpatient Pharmacy Services 1ST Floor, Clinic Lobby,

Pharmacy: (954) 659-MEDS (6337) Hours: Mon-Fri, 8am-7pm

The Outpatient Pharmacy fills all home-going (outpatient) prescriptions for patients and employees (families included) of Cleveland Clinic Florida. A bedside delivery service is available for discharged patients.

CLINICAL PROCESS IMPROVEMENT DEPARTMENT

This department is an integrated function of Process Improvement, Risk Management, Case Management and Social Services.

Case Managers are registered nurses. Their combined functions of utilization management and discharge planning enable them to follow patients from admission through discharge to monitor the appropriateness of services, and to implement safe and timely discharge plans for the patients.

Social workers are uniquely qualified and responsible to recognize spiritual, emotional and attitudinal health issues of patients, families and hospital personnel. Such issues are addressed through provision of community referral information, crisis intervention and individual, family and/or group counseling. Spiritual problems are referred to the spiritual guidance person of patient/family's choice.

The office is open from 8:00 a.m. to 4:30 p.m., Monday through Friday. A case manager is on site on Saturdays; Sundays and Holidays an on-call case manager is available by beeper. The Director of Clinical Process Improvement is available by beeper after hours.

ALUMNI AFFAIRS

Cleveland, Ohio

Melinda Stroh Phone: (216) 444-2487 Fax: (216) 445-7442

Dedicated to supporting our constituency of former residents and fellows worldwide, the Alumni Affairs office also provides services to physicians and scientists currently in training.

Such activities include special events, such as the Annual "Welcome to Cleveland" GOODTIME Cruise, house staff TGIF parties, Annual GO-1 Award, THE HOUSE STAFF *CONNECTION* newsletter and career development programs.

BIOETHICS

The ethical aspect of patient care is addressed by the Ethics Committee of Cleveland Clinic Florida. The Ethics Committee provides consultations with physicians, nurses and other health providers, patients and families concerning therapeutic and diagnostic ethical dilemmas. The multidisciplinary Ethics Committee meets quarterly to discuss general issues related to ethical decision-making, policies and education.

Conflict resolution may be attempted to utilizing the resources of Cleveland Clinic Florida. Consultation regarding treatment refusal and conflicts in therapy is available with the Ethics Committee of Cleveland Clinic Florida by contacting the Director of Nursing.

CONTINUING MEDICAL EDUCATION 2950 Cleveland Clinic Blvd Weston, FL 33331 Phone: 954/659-5490 Fax: 954/659-5491 E-mail: <u>cme@ccf.org</u> Website: <u>www.clevelandclinicflorida.org/research/cme</u>

The CME department organizes continuing education programs for physicians throughout the year. Regularly scheduled conferences are in-house programs offered primarily to hospital and clinic physicians, nurses, and allied health professionals. Multi-day specialty symposia (covering topics including colorectal diseases, endorectal ultrasound, female pelvic disorders, hysterectomy, plastic surgery, surgery of the foregut, and bariatric weight loss surgery) are offered off-campus in area hotels. Residents and fellows may attend Cleveland Clinic Florida-sponsored continuing education courses upon approval by their department. Departmental funds will be used to offset the cost of attendance at the CCF sponsored symposia. (Most departments are willing to cover this cost.) A course registration form and meeting attendance form <u>must be completed</u> and submitted to the CME Department through a "CME Request" found on the department's intranet page.

Each program is accredited for 1 hour of Category 1 CME credit. Attendees must use the issued MyCME code to receive credit. (Lunch will be available when sponsored)

ANESTHESIA GRAND ROUNDS

When: 7:00 am – 8:00 am Quarterly (as announced)
Where: LOCATION AS ANNOUNCED
Program Director: Ira Ables, MD
Each program is accredited for 1 hour of Category 1 CME credit. Attendees must sign and complete an on-line evaluation form to receive credit. (Lunch will be available when sponsored)

IMAGING INSTITUTE GRAND ROUNDS

WHEN: 12:00 noon-1:00 p.m. Quarterly (as announced)
WHERE: Conference Rooms 1 & 2 – Jagelman Conference Center
Program Director: Jacobo Kirsch, MD
Each program is accredited for 1 hour of Category 1 CME credit. Attendees must sign and complete an on-evaluation form to receive credit. (Lunch will be available when sponsored)

MEDICAL GRAND ROUNDS

WHEN: 12:00 noon-1:00 p.m. on Wednesdays (as announced)
WHERE: Conference Rooms 1 & 2 – Jagelman Conference Center
Program Director: Carmen Villabona, MD
Each program is accredited for 1 hour of Category 1 CME credit. Attendees must sign and complete an on-evaluation form to receive credit. (Lunch will be available when sponsored)

SURGICAL GRAND ROUNDS

WHEN: 7:00-8:00 A.M. 3rd Tuesday of each month
WHERE: Conference Rooms 1 & 2 – Jagelman Conference Center
Program Director: Raul Rosenthal, MD
Each program is accredited for 1 hour of Category 1 CME credit. Attendees must sign and complete an on-line evaluation form to receive credit. (Lunch will be available when sponsored)

TRANSPLANT SURGERY GRAND ROUNDS

WHEN: 12:00 noon-1:00 p.m. on Wednesdays (as announced)
WHERE: Conference Rooms 1 & 2 – Jagelman Conference Center
Program Director: Nicolas Brozzi, MD
Each program is accredited for 1 hour of Category 1 CME credit. Attendees must sign and complete an on-evaluation form to receive credit. (Lunch will be available when sponsored)

THE LORRAINE AND SIGMUND GOLBLATT MEDICAL LIBRARY

Location: 1st floor in the Clinic Building General Information: Library hours: Monday-Friday 8:30 AM – 5:00 PM After hours: Proximity card access, **clinical staff only. Food and drink are not allowed in the Library**

Collections

The Library's collection of about 700 texts in medicine and nursing is arranged by the National Library of Medicine classification system. About 2,800 book titles are available in electronic format through AccessMedicine, AccessSurgery, ClinicalKey, StatRef, and other Web sites.

The Library subscribes to about 8,000 journal titles. About 20 journals are available in print; the rest of our journal subscription is available in electronic format through Ovid, EBSCO, ClinicalKey, or directly from publishers.

Services/References

The Library serves the staff, residents, students and employees of the Cleveland Clinic Florida, CCF patients, and the general public.

Photocopies A photocopier is available, with no fee, for **copying of library materials only.**

Interlibrary Loan

Materials not in our collection are requested from other institutions through interlibrary loan. Interlibrary loan costs are covered by the library budget, but careful selection of requested materials is recommended. Please use Ovid for searching, limit your search to full text, or check if the journal title is available in the Alumni Library or Weston collection.

Circulation

2. The Library Committee has designated the Library as a Reference/Resource Center. Books and journals do not circulate and are to be used in the Library only.

Computer Searches

The Library staff performs searches on Medline and other medical databases. You may also search Medline, ClinicalKey, UpToDate, AccessMedicine, AccessSurgery, and Cochrane Evidence-Based files directly from the Library, or from your department. Training in searching is available for all who wish to do their own computer searches.

Computers

Twenty three computer workstations are available in the Library for research and educational use. All computers have the same set-up. Any changes in our programs or software can be made only by our IT Department.

For more information please see the Library Web page: http://my.clevelandclinic.libguides.com/florida

INVENTION AND DISCOVERY POLICIES

CCF INNOVATIONS (216) 444-5757

POLICY ONE:



- As a condition of their affiliation with The Cleveland Clinic, all professional staff, employees and trainees agree to:
- 1) Assign all rights, title and interest in improvements, discoveries, ideas and innovations arising out of their professional activities while affiliated with the Clinic;
- 2) Communicate with Office of Technology Transfer (OTT) on matters relating to technology development, innovation and commercialization and cooperate with OTT in all commercialization efforts.

POLICY TWO: A

As an incentive for their inventive contributions, identified inventors who are professional staff, employees and trainees of the Foundation are collectively granted a 50% share of net revenues received from the commercialization of those technologies to which they contributed. Net revenues are defined as the balance of total revenues less Clinic out-of-pocket expenses for legal services, marketing activities and prototype development.

The inventorship share is distributed to inventors for the full commercial term of the technology, in accordance with the terms of an Inventor Royalty Sharing Agreement, without regard to the inventors' future employment status with the Clinic. If for any reason inventorship cannot be ascertained, right to the inventorship share will revert to the Foundation.

A copy of the entire policy for invention and discovery may be obtained from the Graduate Medical Education Department.

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 the General Counsel.

For detailed information, refer to Policy 514 in the CCF Supervisory Policy and Procedure Manual.

Guidelines for Investigating Scientific 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").

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 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.

All residents, fellows and visiting researchers are required by the Board of Governors to take a course on the Responsible Conduct of Research and Scientific Integrity (RCR) to meet PHS and NIH education requirements. Beginning in the Fall 2001, web-based instruction will be available to meet this requirement (currently done in two, one and one-half hour modules offered in the Spring and Fall of each year).

A copy of the entire policy for investigating scientific misconduct may be obtained from the department of OPSA Dean Richardson.

CONFIDENTIAL INFORMATION

All employees of Cleveland Clinic may have, during the course of their employment, access to confidential information concerning budgets, strategic business plans, patients or other employees. This information may be in the form of verbal, written, and/or computerized data. The safeguarding of this confidential information is a critical responsibility of each employee.

Unauthorized acquisition, release, and/or discussion of any information relating to Foundation business, patient medical information, current and past employees, job applicants and computerized data is a most serious matter and will be grounds for disciplinary action up to and including discharge. (Refer to Policy #121- Corrective Action of the Supervisory Policy & Procedure manual.)

Protected Health Information

Under the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), Protected Health Information (PHI) is any information that is created, received, and maintained by Cleveland Clinic related to an individual's health care (or payment related to health care) that directly or indirectly identifies the individual. Use of PHI refers to the sharing, applying or analyzing of PHI within Cleveland Clinic. "Disclosure" refers to the release of PHI outside Cleveland Clinic.

The use and disclosure of PHI by Cleveland Clinic employees shall occur only in accordance with HIPAA Privacy Policies. PHI may be accessed only by those individuals who, within the scope of the 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 Clinic policy, and may also be subject to criminal penalties.

The taking of photographs or any other electronic or recorded images, videotaping, audio taping, electronic or data recording by any mechanisms including but not limited to comers, video cameras, movie cameras, cell phones or cell phone cameras, personal digital assistants or any recording device without the express written consent of the individual is strictly prohibited. A copy of the entire policy (#510) for confidential information may be obtained from the Graduate Medical Education Department.

Release of Information

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 in accordance with the wishes of the staff doctor in charge, unless the patient objects. Requests for copies of patient information must be directed to Health (Data) Information Services.

TO REPORTERS: All inquiries from newspaper and television reporters regarding accidents, rumors, professional standing of doctors and nurses or anything that involves the Foundation 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.

PRINCIPLES OF CONSULTATION

- I. REQUESTING A CONSULTATION
 - A. Any staff physician has the privilege of requesting an indicated consultation. The appropriate form should be used when requesting a consult.
 - B. Each staff physician has the privilege of designating a specific consultant, but where practicable, he or she should refer patients to departments instead of individuals and thus facilitate scheduling of patients.
 - C. Consultations should be requested only when indicated.
 - D. The staff physician has the responsibility of completing any appropriate managed care referral forms prior to sending the patient for a consultation. If the requesting physician is not the patient's primary care physician, and the patient is covered under a managed care contract, it is the responsibility of the physician to ensure that the primary care physician both knows of and authorizes the additional consultation or service.
 - E. When it is desired that a consultant be authorized to order tests or treatment, the primary physician must give the authority in his or her written request for a consultation.
 - F. The type of consultation desired should be designated, e.g., diagnosis, treatment, transfer, scientific interest, etc.
 - G. The nature of the problem should be clearly stated for the benefit of the consultant.
 - H. The physician in charge should be first to report to the family doctor or other outside referring physicians
 - I. The physician in charge may request any of the consultants to send a supplemental report.
 - J. The patient should be informed of the nature and need for special consultation.

II. RESPONSIBILITIES OF A CONSULTANT

- A. The consultant must address the questions that have been raised in a thorough and timely manner.
- B. The consultant should not refer a patient for additional consultations without prior agreement with the physician in charge.
- C. The consultant should not under ordinary circumstances treat a referred patient without the knowledge and consent of the referring physician.
- D. The consultant must report back the results of the consultation to the referring physician, whether a Cleveland Clinic staff member or an outside referring physician.
- E. Prior to ordering any tests or procedures beyond those authorized in the original consultation, the consultant should check to see whether the patient requires any prior authorization for additional services via managed care or other certification procedures.
- F. If the consultant subsequently becomes the primary physician by reason of admitting the patient for specific therapy, the original physician should be notified, preferably by admitting on a joint service.
- G. The initial medical examiner should be called as consultant for any subsequent medical problem which arises while the patient is in the hospital.

Simple Preoperative Medical Clearance (Surgeons: Request Consultation Appointment)

Consultant may or may not be designated by surgeon – consists of evaluation of general operative risk in terms of heart, lungs, and kidney function – clearance given on provisional basis providing laboratory and x-ray studies are normal. The latter studies should be ordered by the surgeon. The internist or pediatrician may order others if indicated.

Designed for:

- Patients having minor procedures
- Seemingly healthy young adults
- Patients with known specific medical problems who are to have minor surgical procedures, but are returning to the care of their own physician at the conclusion of surgical treatment
- In and out procedures, when indicated

MEDICAL RECORD DOCUMENTATION AND HANDLING GUIDELINES FOR CLINIC RECORD

Purpose: To establish standards for the overall documentation of patient care at Cleveland Clinic Florida which will insure consistent, quality care to every patient seen at the Clinic.

Maintenance: The Health Information Management Department is the central repository for all medical information. All medical records are maintained in the Health Information Management Department until requested for reasons of patient care, research, or administrative purposes.

Organization of The Medical Record: Medical Record personnel are responsible for the organization and incorporation of all paper ancillary test reports in the medical record. The content of the paper record will be organized as follows:

Clinic notes

Laboratory test results: includes routine lab tests, pathology reports done at the Clinic. Radiology reports done at the Clinic.

- Other diagnostic test results: pulmonary, cardiology, neurophysiology, audiology, etc.
- Operative/procedures reports: includes all documentation of any procedure performed in the Endoscopy or Operating Room suite at the Clinic.
- Clinic Hospital information: includes any record of information from another facility, which is authored by a Clinic physician.
- Outside Records: includes information received from outside referring or primary care physician.
- Demo/consents: includes all registration information (face sheet), financial consent, advance notice of non-coverage, other consent forms.

All reports are filed in chronological order by date of service with the most recent as the last report. Electronic Medical Records are compiled in EPIC documentation system and can be retrieved appropriately via password protected pathway by practitioner(s). Refer to EPIC documentation guidelines.

Documentation of Patient Care:

Physicians and Professional staff are responsible for complete documentation in the medical record which accurately describes each patient contact, either physical encounter or by telephone.

Documentation should include any information which will impact the quality of the patient care, whether it is directly with the patient or other healthcare providers involved in the patient's care.

Each patient visit must be documented at the time of the visit and must include at least the following information:

Patient name	Chief complaint
Medical record number	Objective findings
Date of service	Diagnosis/Assessment
Clinical department	Treatment plan
Provider name and credentials	Signature of provider

Notes are dictated for the visit via direct input into EPIC of at least the medical impression and treatment plan is required at the time of the visit. A note must be made that a complete dictated note follows. A brief description of any procedure must be documented by the physician immediately following the conclusion of the procedure. A more thorough dictated summary must be completed following the procedure.

Some type of documentation must follow every date in the chart. If paper written note is continued on another page, the additional page must include the date and the physician's name and notation that it is continued from previous page.

Informed consent must be documented for each procedure. A record notation stating that the procedure, alternatives, and risk have been explained to the patient and that the patient understands and agrees to the procedure must be made.

TELEPHONE CONTACTS: Documentation for each telephone contact must include at least the following:

Name of patient Patient's medical record number Date of call. Printed name of physician called. Nature of contact (e.g. phone call from patient, relative, physician) Response to call. Name of person taking call (printed). Signature of person completing call. Date call completed.

All orders for diagnostic tests must be in writing and signed by the physician. Verbal orders must be documented in the medical record and signed by the ordering physician.

AMBULATORY SURGERY CENTER

As stated in the Condition of Participation Section 416.47, all medical records from ASC must include, at a minimum, the following:

- Patient identification
- Significant medical history and results of physical examination
- Pre-operative diagnostic studies (entered before surgery)
- Findings and techniques of the operation, including a pathologist's reporting all tissues removed during surgery, except those exempted by the governing body
- Any allergies and abnormal drug reactions
- Entries related to anesthesia administration
- Documentation of properly executed informed patient consent
 - Discharge diagnosis and follow-up plans.

In order to insure that the above criteria are met for all procedures performed at the Cleveland Clinic Florida licensed Ambulatory Surgery Center and to maintain consistency with JCAHO accreditation standards, the following documentation rules and regulations are adopted:

- 1. Patient identification in medical record shall consist of patient name, date of birth, current address and telephone number, legal representative (if applicable).
- 2. Significant medical history and physical examination performed immediately prior to procedure or within 30 days prior to procedure and updated as to any changes in physical status.
- 3. Pre-operative diagnostic studies to include at least UA, H&H, Chest x-ray and/or EKG.
- 4. Operative report to include pre- and post-operative diagnosis, surgeons and assistants, summary of findings, description of technique, specimens collected (if applicable, condition at end of procedure.
- 5. Allergies/abnormal drug reactions must be recorded on appropriate allergy form.
- 6. Anesthesia record.
- 5. Consent form completed for each procedure which must include name of procedure, date of procedure, type of anesthesia, explanation of risks, alternatives, benefits of procedure, patient signature, surgeon signature and date signed.
- 8. Discharge note must include diagnosis and condition at discharge, medication review, follow-up treatment plans.

If operative note is dictated, a brief written note must be documented in the clinic notes section describing the findings, technique, surgeons/assistants, specimens, condition at termination of procedure.

Corrections to documentation: Correction of errors in the paper medical record documentation must be made so that the original entry is legible. Reports/notes cannot be removed from the paper medical record once they have been bound in the record. Addendums or attachments must be made. Corrections to words or lines in the paper record must be made by crossing one line through the incorrect entry, writing the correct entry, initial and date new entry.

EXAMPLE: swelling in left leg

Handling: The medical record is clinic property. No original record may leave clinic property except by subpoena or Court order.

Records will not be transported from one department to another by the patient (including clinic employees transporting their own record).

Records, which are subpoenaed for trial or must be removed by court order, must be reviewed by the Health Information Management Department Manager or designee. No record may leave the property without the consent or knowledge of the HIMD Manager.

Outpatient electronic medical record (EpicCare) is the electronic medical record, replacing the paper medical record.

INFECTION CONTROL

Tuberculosis Control Program

Transmission of *M. tuberculosis* is a recognized risk in healthcare facilities. The magnitude of the risk varies considerably by the type of healthcare facility, the prevalence of TB in the community, the patient population served, the healthcare workers' occupation or group, the area of the healthcare facility in which the healthcare worker works, and the effectiveness of TB infection control interventions. The fundamentals of the CCF TB infection control program include early identification, isolation, and effective treatment of persons who have active TB. The first level of a hierarchy of control measures, which affects the largest number of persons, is administrative measures, intended primarily to reduce the risk of exposing uninfected persons to persons who have infectious TB.

- Developing and implementing effective written policies and protocols to ensure the rapid identification, isolation, diagnostic evaluation, and treatment of persons likely to have TB;
- Implementing effective work practices among healthcare workers in the healthcare facility (e.g., correctly wearing respirator protection and keeping doors and windows of airborne isolation rooms closed);
- Educating, training, and counseling healthcare workers about TB;
- Screening healthcare workers for TB infection and disease.

Policy

It is a condition of employment that all employees participate in the PPD skin testing program pre-employment and annually thereafter, during birth month. See pre-employment and annual Health screening policy on the Intranet (emp. Health).

Guideline for Isolation Precaution

The Cleveland Clinic Florida utilizes Standard Precautions/ Transmission Precautions System, which incorporates infection prevention practices for all patients. These include the use of barriers (gloves, masks, protective eye wear, and aprons) for contact with anybody substance, mucous membrane, or non-intact skin, regardless of the patient's diagnosis. These are REQUIRED precautions and use is not optional. All physicians MUST comply with all of the precautions at all times.

All barrier equipment is available in each patient care unit. Use of Standard and Transmission Precautions ensures a uniform standard of care for all patients and provides a safe working environment for caregivers.

Gloves

Gloves MUST be worn when touching or anticipating contact with mucous membranes or nonintact skin and when handling blood or anybody substances. Gloves MUST also be worn when handling patients or equipment which are visibly soiled with blood or other body substances. Gloves MUST be worn for handling any patient specimen when the outside portion is visibly soiled. Gloves MUST be worn when performing venipuncture and changed between each patient. Gloves are not necessary when touching intact skin or equipment not soiled with body substances. Hands must be washed when gloves are removed between each patient.

Eye Protection

Eye protection MUST be worn during any patient care activity where splashing of blood or body substances is likely to occur. If corrective eyeglasses are worn, SIDE SHIELDS MUST BE WORN or goggles worn over eyeglasses.

Masks

Masks MUST be worn during any patient care activity where splashing of blood or body substances is likely to occur. Masks MUST be worn when in contact with a patient with a known or presumed airborne infection who is in respiratory precautions. Particulate respirators must be worn for patients in airborne precautions.

Aprons/gowns

Aprons or gowns MUST be worn when patient is in contact precautions or when clothing is likely to become soiled with blood or other body substances.

Resuscitation equipment

One-use emergency resuscitation equipment will be available in all patient care areas. Mouth-tomouth resuscitation should not be performed in the hospital.

Red plastic bags

The use of red plastic bags is only necessary for items that are grossly soiled with blood or infectious material. The bags are disposed of in a designated container in each patient care area.

Red-lined boxes

Liquid biomedical waste, such as suction liners, paracentesis or thoracentesis fluids must be disposed of in red-lined boxes provided in each patient care area.

Needle/sharp disposal

Needle disposal boxes are available in all areas where needles or sharp instruments are used. Needles

are not to be recapped, bent, broken, removed from the syringe or otherwise manipulated. Place uncapped needles with attached syringes in the needle disposal container.

Human Immunodeficiency Virus Infections

Policy Statement

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 the limitations of the various laboratory diagnostic tests which are currently available. It is the responsibility of any physician who wishes to perform these tests on his or her patients to inform them about the appropriate interpretation of the tests, the ethical and potential legal implications associated with performing these tests, the need for appropriate counseling prior to and after the test results are conveyed to the patient, and the need for medical follow-up if the test results are positive.

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 must file an occupational injury report with his/her supervisor and contact the Employee Health Nurse immediately – within 1-2 hours (Pager: 954-992-0718). All follow up directions will be per Blood Borne Pathogen Significant Exposure Policy located on the Intranet under Weston Policies.

Healthcare Workers with HIV Infection

To ensure the safety and welfare of both patients and employees, and to prevent the transmission of HIV and opportunistic infections in the workplace, specific guidelines shall be developed and followed.

HIV status may not be requested or used as a pre-requisite or obstacle to employment. If the employee chooses to disclose his/her HIV status at the time of employment, a note from his/her personal physician regarding his ability to work will be provided. This information will be kept confidential. Any employee who becomes ill with HIV infection/AIDS will be referred to their private physician or an Infectious Disease physician, as appropriate, who will determine the employee's ability to work and any limitations to job performance or placement. At the employee sill be provided with AIDS education through in-services, updates and classes, according to licensing requirements.

An employee who tests HIV positive at Cleveland Clinic Florida should be referred to an Infectious Disease physician.

OSHA BLOOD-BORNE PATHOGEN STANDARD

Federal law mandates that all residents and fellows attend in-service training sessions annually regarding the Blood-borne Pathogen Standards. New residents will attend the in-service during the orientation sessions.

REGULATIONS FOR REPORTING COMMUNICABLE DISEASES

PHYSICIAN/HOSPITAL REPORT OF REPORTABLE COMMUNICABLE DISEASE (At CCF, the Laboratory reports communicable diseases.)

Link for information from the Department of Health

http://fac.dos.state.fl.us/faconline/chapter6.pdf

GENERAL INFORMATION ON HAND HYGIENE

www.cde.gov/handhygiene/training/interactiveeducation/courselaunch.

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