Cleveland Clinic Akron General

FOR IRRB USE ONLY
IRRB Number: _____
IRRB Reviewer: _____
☐ Exempt ☐ Expedited ☐ Full
☐ All Documents Received

Institutional Research Review Board Akron General Medical Center
Application to Perform Human Subjects Research

Please type all of the required information. HAND WRITTEN FORMS WILL NOT BE ACCEPTED. Submit completed and signed forms with all required attachments electronically to the Institutional Research Review Board IRRB@akrongeneral.org.Questions regarding IRRB submissions can be directed to (330) 344-6947, or by emailing IRRB@akrongeneral.org.

Project Title:

Protocol Version and Date:

Consent Version and Date:

Is this project trauma related? ☐ Yes ☐ No

Estimated Study Duration: Begin date End date
-If Chart Review, List Requested Dates to Review Start date End date

Principal Investigator

Name/Degree:
Email:
Address:
Department:
Residency Program:
Phone:
IronKey #:

AGMC Faculty Member (required to be completed for all student and/or resident initiated research)

Name/Degree:
Email:
Address:
Department:
Phone:

Student Advisor (required to be completed for all student initiated research)

Name:
Email:
Address:
Department:
Phone:
Organization:

Study Contact Person (Note: If you have an Akron General Outlook email address, that is the address that will be used for ALL communications from the IRRB.)

Name:
Email:
Address:
Department:
Phone:

Research Personnel (For individuals involved with the study; use additional sheet if necessary

Name/Degree	Research Role	Department	IronKey #
	Other Key Study Personnel		
	Other Key Study Personnel		
	Other Key Study Personnel		
	Other Key Study Personnel		
	Other Key Study Personnel		
	Other Key Study Personnel		
	Other Key Study Personnel		

Do all research personnel have an updated CV on file with the Department of Research?
☐ Yes ☐ No (If 'no', then a current CV must be submitted with this application)

Do all research personnel have a Confidential Information Acknowledgement document on file with the Department of Research?

☐ Yes ☐ No (If 'no', then a completed form(s) must be submitted with this application)

Have all personnel completed human subjects' research protection education in the last 3-years?
☐ Yes ☐ No (If 'no', then complete training at www.citiprogram.org)

Have all personnel completed conflict of interest training in the last 3-years?
☐ Yes ☐ No (If 'no', then complete training at www.citiprogram.org)

Have all research personnel completed a Conflict of Interest Disclosure form for this study and submitted them to the Department of Research?

☐ Yes ☐ No (If 'no', then a completed form(s) must be submitted with this application)

Does the proposed study require registration with ClinicalTrials.gov? ☐ Yes ☐ No
If unsure, contact the IRRB office for guidance at (330) 344-6947.

Performance Site(s):

☐ Akron General Medical Center

☐ Edwin Shaw Rehabilitation Center
☐ Lodi Community Hospital
☐ Other Sites (name sites):

Is the research collaborative (Non-AGHS)?
☐ Yes ☐ No

If yes, will AGMC be the IRRB of record?
☐ Yes ☐ No

Is Akron General the lead site? ☐ Yes ☐ No

Projected Enrollment (if chart review, include planned number of charts to be reviewed)**:**
This site: Other site(s):

Funding Source(s):

☐ Federal funding
Source:

☐ Departmental

☐ Drug/Device company
Name of Company:

☐ Akron General Grant

☐ Other source
Explain:

All contracts and budgets related to sponsored or funded research must be sent to the Director, Office of Sponsored Programs/Associate Legal Counsel Office of Sponsored Programs, prior to IRRB review. Signature of the Director of Office of Sponsored Programs is required for IRRB review of sponsored and/or funded research.

Type of Review: The type of review required depends on the level of risk of the proposed research as well as the characteristics of the study population. Studies will either be exempt, expedited, or require full board review. While the investigator can request a review status below, final recommendations on the type of review conducted will be decided by the IRRB administration. All research determined to be greater than minimal risk, or including potentially vulnerable study populations will require full board review.

Exempt Research: Check the category below that qualifies this research as exempt from review.

☐ 1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as i) research on regular and special education instructional strategies, and/or ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management strategies.

☐ 2) Research involving the use of educational tests (i.e. cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public health; UNLESS: i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subject, or ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation.

☐ 3) Research involving the use of educational tests (i.e. cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public health that is not exempt under 2 above, if: i) the human subjects are elected or appointed public officials or candidates for public office, or ii) federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and therafter.

☐ 4) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: i) public benefits or service programs; ii) procedures for obtaining benefits or services under those programs; iii) possible changes in or alternatives to those programs or procedures; or iv) possible changes in methods or levels of payment for benefits or services under those programs.

☐ 5) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject.

☐ 6) Taste and food quality evaluation and consumer acceptance studies, i) if wholesome foods without additives are consumed, or ii) if a food is consumed that contains a food ingredient at or below the level or for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expedited Research: Check the category below that qualifies this research for expedited review.

☐ 1) Research on individual or group characteristics or behavior (including, but not limited to, research on cognition, perception, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101 (b)(2) and (b)(3). This listing only refers to research that is not exempt.)

☐ 2) Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ 3) Research involving materials (i.e. data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from HHS regulations for the protection of human subjects 45 CFR 46.101 (b)(4). This listing refers to research that is not exempt.)

☐ 4) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 mL in an 8-week period, and collection may not occur more frequently than 2 times per week; or from other adults and children considering the age, weight, and health of the subjects, the collection procedure, the amount of the blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 mL or 3 mL per kilogram in an 8-week period and collection may not occur more frequently than 2 times per week.

☐ 5) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner, (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction, (c) permanent teeth if routine patient care indicates need for extraction, (d) excreta and external secretions (including sweat), (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue, (f) placenta removed at delivery, (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor, (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques, (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings, and (j) sputum collected after saline mist nebulization.

☐6) Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amount of energy into the subject or an invasion of the subjects' privacy, (b) weighing or testing sensory acuity, (c) magnetic resonance imaging, (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography, (e) moderate exercise, muscle strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Research not classified as exempt or expedited is subject to full board review.

WILL THE STUDY POPULATION INCLUDE ANY OF THE FOLLOWING? (Please check all of the following populations that may be included in your study)

☐ Fetuses
☐ Human *in vitro* fertilization
☐ Institutionalized (mentally infirmed)
☐ Comatose patients
☐ Terminally ill patients
☐ Minorities
☐ Children under 18 years old
☐ Normal healthy volunteers
☐ Other (please explain)

☐ Men
☐ Women
☐ Prisoners
☐ Cognitively impaired persons
☐ Elderly / Aged person >65 years old
☐ Students and/or residents
☐ Employees of the institution or principle investigator
☐ Pregnant women
☐ None of the above

If the protocol states that the study will enroll children under the age of 18, does the investigator intend to allow children under the age of 18 to be enrolled in the study at AGMC? ☐Yes ☐No

Additional forms need to be completed and submitted for the protection of the following vulnerable populations: Pregnant women and fetuses and/or children under 18 years of age.

SPECIAL CONCERN RESEARCH AREAS: (Please check all that apply)

☐ Drug trial
☐ Vaccine trial
☐ Medical device trial
☐ Radioactive materials and x-rays

☐ HIV/AIDS
☐ Alcohol and drug abuse
☐ Human genetics
☐ Transplants

An Investigator Brochure must be included with the submission of applications for all drug trials. Additionally, for drug trials an IND or explanation of why it is not necessary is required. Medical device trials require the submission of IDE information and/or 510(k) premarket approval.

INTERDEPARTMENTAL STUDIES

1. Departments providing a service beyond standard level of care: (check all that apply)

☐	Anesthesiology	☐	Oncology	☐	Calhoun Research Lab	☐	Cancer Registry
☐	Cardiology	☐	Orthopedic Surgery	☐	Information Systems	☐	Cardiac Registry
☐	Critical Care	☐	Psychiatry/Behavioral Sciences	☐	Health Information Management	☐	Trauma Registry
☐	Emergency Medicine	☐	Radiation Oncology	☐	Nutrition/Dietetics	☐	Other Registry
☐	Family Practice	☐	Radiology	☐	Pathology/Clinical Lab	☐	Other
☐	Internal Medicine	☐	Surgery	☐	Pharmacy	☐	Other
☐	Nursing	☐	Urology	☐	Patient Registration	☐	Other
☐	Obstetrics/Gynecology	☐	Biomedical Engineering	☐	Ambulatory Diagnostic Services	☐	Other

2. Have these departments agreed to provide resources for the study beyond standard level of care?
☐ Yes ☐ No

NOTE: Please see the signatory page of this document. A signature from the Administrative Director of EACH department at Akron General Medical Center providing resources beyond the standard level of care for this study, including your department, must be obtained prior to submitting this application to Research Administration.

PROTOCOL SUMMARY

Instructions: In order to review your proposal, the Institutional Research Review Board (IRRB) must receive a study protocol addressing each of the items outlined in the Standard Operating Procedure for IRRB Submission of Human Subjects' Research (SOP #). Provide sufficient information for effective review by all members of the IRRB, including non-clinicians. Wording should be in lay terms in order to be understood by non-scientific and non-clinicians alike. Define all abbreviations and terms that are not part of common language.

Summary: Summarize the proposed research project below. The following information should be included in the summary: i) a brief statement of the problem, ii) a statement regarding why this research is important, and iii) specific summary of the procedure(s) involving human subjects. This summary should not exceed one, single-spaced type written page.

INFORMED CONSENT

Please indicate the types of consent processes you will be using for this research. (Check all that apply)

☐ Prospective, written informed consent
☐ Waiver of informed consent
☐ Waiver of documentation of consent
☐ Alteration of consent
☐ Parental permission
☐ Waiver of parental permission
☐ Assent – written
☐ Assent – verbal
☐ Waiver of assent

1. If you are requesting a waiver or alteration of consent for all or part of the research, complete the information below.

Which are you requesting?

☐ Waiver for all of the research
☐ Waiver for recruitment purposes
☐ An alteration of consent

Note: For waivers of consent, please complete section (a) below. For alterations of consent, please complete section (a) and (b) below. For waivers of documentation of consent, please complete section (c) below.

(a) (i) Please provide an explanation of why the proposed research will present no more than minimal risk to the participants.

(ii) Please explain whether or not a waiver or alteration of informed consent would adversely affect the rights and welfare of the participants.

(iii) Please explain whether or not the research could practicably be carried out without a waiver or alteration of informed consent.

(iv) Please explain your plans, when appropriate, for providing any pertinent information to the subjects at a later date (e.g. after their participation in the study).

(b) If you are requesting an alteration to informed consent, please document how you plan to alter the informed consent and justify why the alterations are necessary.

(c) Are you requesting a waiver of documentation of informed consent? ☐ Yes ☐ No

If 'yes', please indicate which of the following justifications is being used to request a waiver of documentation, and then provide protocol specific justification for the waiver under each criteria.

☐ The only record linking the subject and the research would be a signed consent document, the principle risk or harm of the research would be breach of confidentiality, and each subject will be asked whether they want documentation linking themselves and the research, thus the subject's wishes will govern.
Explanation:

☐ The research involves no more than minimal harm or risk to the subject and involves no procedures for which written consent is normally required outside of the research context.
Explanation:

Note: If documentation of informed consent is waived, the IRRB requires that you provide the subjects participating in research with an oral or written description of the research, which contains all of the elements of traditional informed consent. Please include this information in written form with your application, and label the document "Research Participant Information Sheet."

HIPAA COMPLIANCE

Does your research use and/or disclose protected health information (PHI)? ☐ Yes ☐ No
If 'no', then you are done with this section and may skip to the signature page.

Check all that apply below regarding the authorization process:

☐ Patient (or representative) will provide authorization. (Please attach an authorization form)

☐ Waiver/alteration of authorization

1. Describe the identifiable PHI that will be accessed under this waiver.
   Please check all of the following identifiers which are to be used.

☐Names	☐Telephone Numbers
☐Fax Numbers	☐E-mail Addresses
☐Social Security Numbers	☐Medical Record Numbers
☐Health Plan Beneficiary Number	☐Account Numbers
☐Certificate/License Numbers	☐Vehicle Identifiers and Serial Numbers
☐Device Identifiers and Serial Numbers	☐Web Universal Resource Locators (URL)
☐Internet Protocol (IP) Address Numbers	☐Biometric Identifiers (finger and voice prints)

ANY GEOGRAPHIC SUBDIVISIONS SMALLER THAN A STATE:
☐Street ☐City ☐County ☐Precinct ☐Parish ☐Zip Code

ANY ELEMENTS OF DATES:

☐Birth Date ☐Admission Date ☐Discharge Date ☐Date of Death ☐Age Over 89

☐Full face photographic images

☐Any other unique identifying number, characteristic, or code, please specify:

Indicate the source(s) that will be used to obtain PHI

2. Explain how the use or disclosure of the PHI provides no more than minimal risk to the participant.

3. Describe the plan to protect the identifiers from improper use and disclosure (i.e. how will the PHI be stored, who will have access, etc.).

4. Describe how long the identifiers will be kept and how they will be destroyed at the conclusion of the study.

5. Explain why the research could not be practicably conducted without the waiver of alteration.

6. The Privacy Rule requires that when a waiver is granted that only the minimum necessary health information be used or disclosed. Provide justification that the PHI being requested is the minimum necessary to accomplish the objectives of the research.

Investigator Assurance

I certify that the information provided in this application is complete and correct. I understand as the Principal Investigator, that I am ultimately responsible for the protection of the rights and welfare of human subjects and the ethical performance of the research. I agree to comply with all applicable AGMC policies and procedures, and applicable federal, state, and local laws. I also agree to the following:

- The research will only be performed by qualified personnel as specified in the approved research application and/or protocol;
- No changes will be made to the research protocol (accept when necessary to alleviate apparent immediate hazards to the subject), or consent forms without the prior approval of the IRRB;
- Informed consent/assent will be obtained from all human subjects, unless the consent is waived by the IRRB, using only the approved consent/assent documents and recruitment materials approved by the IRRB. The potential benefits of participation will not be overstated and the risks will not be minimized. Additionally, precautions will be taken to ensure that participants are able to comprehend the consent process;
- Unanticipated problems involving risks to the subjects or others will be reported to the IRRB office in a timely manner; and
- If applicable, all research staff will complete required training and provide appropriate documentation of conflict of interest as well as confidentiality acknowledgement to the Department of Research.

I certify that the proposed research is not underway at this time and that the research will not begin until approval has been received by the IRRB.

_____ _____

Principal Investigator Signature Date

_____ _____

Printed Name of Principal Investigator Title

Peer Review Administrator (Clinical) Assurance

I have reviewed this protocol and evaluated the clinical and scientific merit of the research as well as the plan for protection of human subjects. Based on my review, I have determined that:

- The methods/practices of the protocol are acceptable to the discipline;
- The clinical objectives and endpoints of the protocol are clearly defined;
- The number of subjects available is adequate to meet the accrual goals of the protocol; and
- The use of any non-standard of care exams, procedures, and/or labs that should be charged to the study and not to the patient or the patient's insurance is clearly defined by the investigator.

I certify that the proposed research has clinical merit and that measures have been put into place to protect human subjects and am therefore approving this protocol for submission to the Institutional Research Review Board.

_____ _____

Peer Review Administrator (Clinical) Signature Date

_____ _____

Printed Name of Peer Review Administrator (Clinical) Title

Peer Review Administrator (Scientific) Assurance

I have reviewed this protocol and evaluated the scientific merit of the research, which included a review of the study design, methods, sample size / power analysis, and statistical analysis. I certify that the proposed research has scientific merit and I am therefore approving this protocol for submission to the Institutional Research Review Board.

_____ _____

Peer Review Administrator (Scientific) Signature Date

_____ _____

Printed Name of Peer Review Administrator (Scientific) Title

Participating Department Administrative Directors

The following department administrative directors have reviewed the protocol, and have agreed to departmental participation in this research:

Department	Administrative Director Signature	Date

Director, Corporate Tax and Grant Accounting

(Signature required if research is funded by an outside source)

The contract and budget for this research has been received by the Director, Corporate Tax and Grant Accounting and I certify that I have reviewed the contract and budget.

_____ _____

Director, Corporate Tax and Grant Accounting Date

_____

Printed Name of Director, Corporate Tax and Grant Accounting

Director, Department of Research

(Signature required if research is funded by an outside source)

The contract for this research has been received by the Director, Department of Research and I certify that negotiations for contract language have been finalized.

_____ _____

Director, Department of Research Date

_____

Printed Name of Director, Department of Research

Department Chair (or other Cognizant Official if Chair is the PI)

I have reviewed this protocol and evaluated the potential value of this proposed study as well as the plan for protection of human subjects research, and thus approve it for submission to the IRRB.

Department Chair or Cognizant Official Signature	Date
Printed Name of Department Chair or Cognizant Official	Title

IRRB Number:_____

DOCUMENT SUBMISSION CHECKLIST

Submitted	N/A	Document	Appendix
☐		Application (required)	
☐		Protocol (required)	
☐	☐	Instrument(s) used to measure construct(s)	
☐	☐	Informed Consent	
☐	☐	Assent Form	
☐	☐	Research Participant Information Sheet	
☐	☐	HIPAA Authorization	
☐	☐	Recruitment Materials (flyers, advertisements, brochures, letters, etc.)	
☐	☐	Use of Pregnant Women and Fetuses (required if research involves this population)	
☐	☐	Use of Children (required if research involves this population)	
☐	☐	IND/IDE (required for all investigational drug/device trials)	
☐	☐	510(k) Premarket Approval (required for device trials w/FDA approved devices)	
☐	☐	FDA form 1572 (required for all investigational drug trials)	
☐	☐	Investigator brochure (required for all pharmaceutical trials)	
☐	☐	Updated CV(s) (if not currently on file with research administration)	
☐		COI Training (www.citiprogram.org, no attachment required)	
☐		COI Disclosures for all personnel involved in the study (required)	
☐		Human Subjects' Research Training (www.citiprogram.org, no attachment required)	
☐	☐	Confidential Information Acknowledgement (if not on file with research administration)	
☐	☐	IRB/IEC Agreement (required if collaborating with an outside entity on research other than sponsored research and they are the lead site)	
☐	☐	Contract/Budget for Funded Research (submit to Office of Sponsored Programs)	