Cleveland Clinic Akron General

Standard Operating Procedure
New IRRB Submissions for Human Subjects Research

PURPOSE

To provide investigator guidance on submitting newly proposed human subjects research to the Institutional Research Review Board (IRRB) for review and approval.

APPLICABILITY

The procedures in this document apply to all investigator(s) and research personnel conducting human subjects research at Akron General Medical Center (AGMC) or its affiliates.

RESPONSIBILITY

It is the responsibility of all investigator(s) and research personnel conducting human subjects research at Akron General Medical Center (AGMC) and its affiliates to follow the procedures set forth in this document.

DEFINITIONS

Human subject ***(45 CFR 46.102(f))****:* 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.

Research ***(45 CFR 46.102(d)):*** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

PROCEDURES

Training

All individuals involved in human subjects research at Akron General Medical Center (AGMC) must be knowledgeable of the regulations concerning the conduct of such research, and possess credentials qualifying them to carry out studies involving human subjects. This includes physicians, nurses, nursing students, medical students, staff members, graduate students, and others who will make use of AGMC resources or facilities during the course of a research study.

Training must be kept current through initial and continuing education. All credentials and documentation of training must be on file in the Department of Research before any research activities involving human subjects may begin

Minimum Requirements

At AGMC, the minimum requirement for human subjects research training is completion of CITI training module for Biomedical Research and the Conflict of Interest Module with an average score of 80% or greater on the quizzes.

- Go to: https://www.citiprogram.org/
- Follow directions for registration if you are a new user.
- Choose Akron General Medical Center as your affiliation. If you have ever been affiliated with another institution and completed some or all modules, sign in and ADD AN AFFILIATION with Akron General to your profile.
- Under **"Add a Course or Update Your Learner Groups for Akron General Medical Center"** choose Biomedical Research Investigators for question 1 and **YES** for question 6. (Other available training modules are optional.)
- Scroll to the bottom of the page and click "Continue", this will take you back to the main page where you can begin the training modules.
- The training does not need to be completed in one session.
- The IRRB Office will be notified when you have completed the training. You may wish to print your training certificate for your own records.

Human subjects research and conflict of interest training must be renewed by investigators and key personnel performing research every three (3) years.

Questions: Contact the Department of Research at 330-344-6947**.**

Training Requirements for Basic Science/Translational Research

Contact the Director of Research at 330-344-6001 to discuss training requirements for conducting other types of research at Akron General Medical Center.

Peer Review

Prior to submitting a new research study to the IRRB for review, protocols should be submitted to the department peer review committee or the central peer review committee for review of study design and clinical significance. The signatures of the person(s) performing the clinical and statistical reviews must be included on the completed application form in order for the IRRB to commence with review.

Application

The Principle Investigator must complete and return the Application to Perform Human Subjects Research, along with the applicable attachments, to the AGMC IRRB prior to commencement of IRRB review. Attachments required to be included in the application packet are as follows:

All Submissions

- Application to Perform Human Subjects' Research
- Protocol
- Instruments used to measure construct(s)
- Recruitment materials
- Informed consent (unless requesting waiver in application)
- HIPAA Authorization if collecting personal health information (unless requesting waiver in application)

- Updated curriculum vitae for all investigators and research personnel (if not currently on file)
- Conflict of Interest Disclosure Form for all research personnel who are involved in the design, conduct, or reporting of the proposed research
- Confidential Information Acknowledgement for all investigators and research personnel (if not currently on file)

Research Involving Vulnerable Populations

Prior to submission, investigators should familiarize themselves with the application materials required for vulnerable (i.e. Pregnant women, fetuses, and neonates; Children and Minors) and potentially vulnerable populations (i.e. Decision-impaired individuals, AGMC students and/or employees, socially and economically disadvantaged) prior to submission. Specific forms must be submitted when conducting research that may involve Pregnant Women, Fetuses, and Neonates and/or Children and Minors.

Collaborative Research

IRB/IEC Agreement if collaborating with an outside entity on research and AGMC is not the lead site (does not apply to sponsored research).

Sponsored / Externally-Funded Research

All contracts and budgets should be submitted to the Office of Sponsored Research prior to IRRB submission.

Drug Trials

- Investigational New Drug (IND) application approval (or justification of why it is not necessary)
- Investigator brochure
- FDA form 1572

Medical Device Trials

- Investigation Device Exemption (IDE) (or justification of why it is not necessary)
- 510(k) Premarket Approval (if applicable)

Prior to submission, the following signatures must be obtained:

- Investigator Assurance (Principal Investigator)
- Clinical Assurance (Department Chair or designated Peer Review Administrator)
- Scientific Assurance (Peer Review Administrator)
- Interdepartmental Research (Applicable Administrative Director(s))

- Sponsored / Externally Funded Research Contract / Budget Approval (Legal Counsel, Office of Sponsored Programs)

Protocol Requirements

The research protocol should include descriptions that are detailed enough for the reviewers to understand what is being done. The following sections should be included in the research protocol:

1. Specific Aims
   List the broad, long-term objectives and describe concisely and realistically what the research is intended to accomplish and the hypotheses to be tested.

2. Background and Significance
   Give a brief background that critically evaluates the current knowledge and identifies gaps in the knowledge that the proposed research is intending to address. Cite literature and include a reference list.

3. Research Design and Methods
   Describe the research design and procedures to be used to accomplish the specific aims of the project. Include the means by which the data will be collected, analyzed, and interpreted. When describing the design and methods, be sure to include: 1) New methodology used and its advantages over older methodology; 2) Potential limitations of the procedures and possible alternative approaches; 3) Tentative sequence or time table of events; and 4) Specific procedures, situations, or materials that may be hazardous to personnel and precautions to ensure their safety.

   Provide a description of the population sampling procedure. Justify the sampling procedure proposed as well as the sample size. Complete a statistical plan for analyzing the collected data.

   Identify all drugs and/or devices to be used, if applicable. Note the proposed dosage information including instructions for administering, adverse effects, compatibility, and stability. Provide handling instructions as well as storage and disposal procedures.

   Identify and clearly explain all procedures and/or interventions that will be performed in this protocol. When collecting biological samples, clearly explain how the samples will be collected as well as storage, testing, and disposal methods. For behavioral research, be sure to identify the instruments being used and who will be administering the instruments.

4. Study Population
   Describe the characteristics of the study population. Include the anticipated number of normal volunteers, age ranges, gender, ethnic background, and health status. Identify all inclusion/exclusion criteria and justify each criteria. Explain the use of special classes of subjects, including vulnerable and potentially vulnerable subjects; especially those in which ability to obtained informed consent may be questionable.

5. Human Subjects (Risk and Benefits)
   Identify the sources of research material obtained from the study subjects in the form of specimens, records, or data. Indicate whether or not the materials will be obtained prospectively, or if the materials will come from previously existing specimens, records, or data. Explain what information will be used to identify potential human subjects for inclusion in research.

   Describe the plan for recruitment of subjects as well as the informed consent process, including the circumstances under which consent will be obtained, who will be obtaining consent, and how consent will be documented. Be very clear about the consent process for vulnerable and potentially vulnerable populations. If requesting a waiver of consent, indicate why it is necessary.

6. Risks and Side Effects
   Describe any potential risks, including medical, psychological, legal, financial, and/or social risks; and assess their likelihood and/or seriousness. Describe any alternative treatments or procedures that may be advantageous to the participants.

   Describe the procedures for protecting against or minimizing the risks described above, including risks to confidentiality, and assess their likely effectiveness. Discuss provisions for medical and professional intervention in the case of an adverse event. Describe any provisions for monitoring the data for safety.

   Discuss why the risks are reasonable in relation to the benefits to the subject as well as in relation to the importance of the knowledge being gained.

7. Benefits
   Explain the expected benefits in relation to the subjects. If there are none, then state this. Explain the benefit to general science or others if applicable.

8. Costs/Compensation to Subjects
   Clearly describe the financial costs that the subject may incur. This should include any provisions for payment of travel, interventions, tests, labs, or medical care due to the research.

   Describe any compensation that is received by the subjects, whether monetary or otherwise. When determining compensation, keep in mind what is reasonable based on the time and effort required of the subject. The use of benefits to offset the burden due to participation in the research should be incremental and not based on study completion.

9. Confidentiality
   Describe appropriate provisions to protect the privacy of the subjects and maintain the confidentiality of the data; including safeguards to protect the rights and welfare of vulnerable populations. Information regarding who will have access to the data is required. Provide a plan for record retention and disposal once the study is complete.

Provide a clear description of how the data will be disseminated. Outline the sharing of data with others outside of the institution, and include provisions for maintaining confidentiality. Additionally, describe how the results of the data will be used (i.e. presentations at professional organizations, submission to professional journals).

All protocols should include a version number and date created and/or revised in the left-hand footer.

Informed Consent Requirements

The items below are required to be addressed in the informed consent. Language in the informed consent should be simple and the second person should be used whenever possible. While not required, it is suggested that investigators use the provided informed consent template.

1. Introduction to Research at Akron General Medical Center
   General introduction to research at AGMC and description of what informed consent is

2. Information about the Study
   Provide information for the following: 1) Why the subject is being asked to participate; 2) Who can participate in the study; 3) How many people will be asked to participate; 4) Who is performing the study; and 5) What is the purpose of the study?

3. Information about the Role of the Participant
   Explain what the subject is required to do if they participate. Include information regarding what they have to do, what will be done to them, and how long they will be involved.

4. Information about Possible Risks
   Explain the possible risks of participating in the research study. Make sure to include not only medical, but psychological, financial, legal, social, and risks to confidentiality.

5. Information about Possible Benefits
   Explain the benefit of participating in the research study. Describe both direct benefits and benefits to the scientific community as well as others.

6. What happens if the potential subject does not participate?
   Describe what happens if the potential subject does not participate. This is where you want to emphasize that participation is voluntary, and that no change in medical treatment or care will result from not participating.

7. Alternatives to Participating

Describe any alternatives should the subject decide not to participate in the proposed research study. Generally, this is just a statement that their alternative is to not participate and reiteration that they will receive the standard level of care.

8. Withdrawal
   Explanation that participation is voluntary, and that the subject is free to withdraw at anytime. If the subject withdraws from a study requiring medical follow-up, this needs to be explained and a plan to continue follow-up must be outlined.

9. Confidentiality
   Describe who will have access to the study data and how their confidentiality will be protected.

10. Cost of Participation
    Outline all possible costs to the participants. If there is no cost to the patient outside of routine care, state this.

11. Compensation
    Describe any compensation that the subject may receive for participation.

12. What happens if subject has been 'hurt' due to the study?
    Describe treatment options for study-related injuries. Include who will pay for their care and who to contact if they feel that they have been hurt.

13. Research Funding and Conflict of Interest Disclosure
    This is required for all sponsored research.

14. Rights as a Participant
    Statement outlining the legal rights of the subject as outlined in the federal regulations. Include contact information for the Principal Investigator, AGMC IRRB, and the sponsor (if applicable).

15. Signatures
    Subject (or representative) signature as well as the signature of person obtaining consent is required. The signature verifies that the subject read and understood the informed consent document and received a copy.

When research is performed in children and minors, parental permission (informed consent) as well as assent from the child may be required. Additionally, research involving the fetus and neonate may require consent of the father as well as the mother.

A copy of the informed consent/assent documents for Akron General Medical Center patients are required to be kept in the patient medical chart and in the Investigator's records. In order to facilitate auditing, the informed all informed consent documents are required to have a centered bar code in the footer of the document. This bar

code can be obtained by contacting the IRRB office. All informed consent/assent documents are required to include a version number and date of creation and/or revision in the left-hand footer.

HIPAA Authorization

HIPAA authorization must be obtained from the subjects enrolled in studies that collect personal health information. Investigators must submit a HIPAA authorization anytime personal health information will be recorded, unless a waiver is requested. It is required that investigators use the template for HIPAA authorization provided.

SUBMISSION

The completed application package is to be emailed to the IRRB Office (IRRB@akrongeneral.org). Please submit the protocol, Informed Consent, and HIPAA Authorization as Word documents (.doc, .docx). Other documents may be submitted as Word documents or PDFs. When submitting the application, please verify that all signatures have been obtained (digital signatures with a time and date stamp are acceptable). The IRRB Secretary will verify that all of the necessary attachments, training, and required signatures are present prior to forwarding the application to the IRRB for review. Incomplete applications will not be reviewed.

If additional information or changes are requested, the indicated contact person and the Principal Investigator will be notified of the requests. Please submit a tracked change copy as well as a clean copy of all changes.

Once the submission has been successfully completed, the IRRB Coordinator will notify the contact person of the progress of the review. A decision to approve, approve with conditions, or disapprove will be forwarded to the contact person and the Principal Investigator in the form of a letter. No research may begin until an approval letter has been received.