# INVESTIGATOR GUIDE

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What is the purpose of this Guide?
This document is designed to guide you through the IRB submission process at AMITA Health. All Policies, Standard Operating Procedures (SOPs), Worksheets, Forms, Templates and other documents referenced in this guide can be found on the AMITA Health website which is accessible at https://www.amitahealth.org/research/institutional-review-board. Definitions of specialized terms used in this document, or in any of the Policies, SOPs, Worksheets, Forms, and Templates, may be found in Policy “Definitions (PP-001)”.

What are my responsibilities as a Principal Investigator?
As the individual responsible for the implementation of research, the Principal Investigator (PI) bears direct responsibility for protecting the rights and welfare of research participants. This responsibility starts with protocol design, which must minimize risks to subjects while maximizing research benefits. In addition, the PI and all members of the research team must comply with the findings, determinations, and requirements of the IRB. The PI must also be responsible for the adequacy of both the informed consent document and the informed consent process, regardless of which members of the research team actually obtain and document consent. If you have any specific questions, contact the IRB office.

What training does my staff and I need in order to conduct Human Research?
All members of the research team as listed on the application who are involved in the design, conduct, or reporting of the research are required to complete training in human subject protections. Certificates or other evidence of completion of training must be submitted before final approval by the IRB.

Human subjects protection training can be completed through the CITI Program at http://www.citiprogram.org/. Contact the AMITA Health IRB office for instructions on how to access the training.

Training is valid for a three-year period, after which time the training must be repeated.

Note that there may be additional requirements from research sponsors, institutions or other regulatory bodies.

What if I think my project does not meet the definition of Human Subjects Research?
Contact the AMITA Health IRB Office in cases where it is unclear whether an activity meets the regulatory definition of Human Research.

How do I write an Investigator Protocol?
Use the “TEMPLATE: PROTOCOL (HRPP-503)” as a starting point for drafting a new protocol. Here are some key points to remember when developing an Investigator Protocol:

- The italicized bullet points in the “TEMPLATE: PROTOCOL (HRPP-503)” serve as guidance to investigators when developing an Investigator Protocol for submission to the IRB. All italicized comments are meant to be deleted prior to submission.
For any items described in the sponsor’s protocol or other documents submitted with the application, investigators may simply reference the page numbers of these documents within the Investigator Protocol rather than repeat information.

When writing a protocol, always keep an electronic copy. You will need to modify this copy when making changes to the protocol.

Depending on the nature of your research, certain sections of the template may not be applicable to your protocol. Indicate this as appropriate.

How do I create a consent document?
Use the “TEMPLATE: CONSENT DOCUMENT (HRPP-502)” as a starting point for creating a consent document.

What are the different regulatory classifications that research activities may fall under?
Research activities may fall under one of the following four regulatory classifications:

- **Not “Human Research”:** Activities must meet federal definitions of “research” involving “human subjects” for the activities to require IRB review and oversight. If you are unsure if your project meets this definition, please contact the AMITA Health IRB Office.

- **Exempt:** Certain categories of Human Research may be exempt from regulation but require IRB review. It is the responsibility of the IRB, not the investigator, to determine whether Human Research is exempt from IRB review.

- **Review Using the Expedited Procedure:** Certain categories of non-exempt Human Research may qualify for review using the expedited procedure, meaning that the project may be approved by a single designated IRB reviewer, rather than the convened board.

- **Review by the Convened IRB/Full Board Review:** Non-Exempt Human Research that does not qualify for review using the expedited procedure must be reviewed by the convened IRB.

What are the decisions the IRB can make when reviewing proposed research?
The IRB may approve research, require modifications to the research to secure approval, table research, or disapprove research:

- **Approval:** Made when all criteria for approval are met. See “How does the IRB decide whether to approve human research?” below.

- **Modifications Required to Secure Approval:** Made when IRB members require specific modifications to the research before approval can be finalized.

- **Tabled:** Made when the IRB cannot approve the research at a meeting for reasons unrelated to the research, such as loss of quorum. When taking this action, the IRB automatically schedules the research for review at the next meeting.

- **Deferred:** Made when the IRB determines that the board is unable to approve the research and the IRB suggests modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision, describes modifications that might make the research approvable, and gives the investigator an opportunity to respond to the IRB in person or in writing.
**Disapproval:** Made when the IRB determines that it is unable to approve the research and the IRB cannot describe modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to respond to the IRB in person or in writing.

**What will happen after IRB review?**
The IRB will provide you with a written decision indicating that the IRB has approved the human research, requires modifications to secure approval, or has disapproved the human research.

- **If the IRB has approved the human research:** The human research may commence once all other Ministry approvals have been met, all appropriate contracts have been put into place, and any other applicable regulatory approvals have been obtained (e.g., FDA). The IRB approval period will be noted in the approval letter.

- **If the IRB requires modifications to secure approval and you accept the modifications:** Make the requested modifications and submit them to the IRB. If all requested modifications are made, the IRB will issue a final approval. Research cannot commence until this final approval is received. If you do not accept the modifications, respond as such to the IRB.

- **If the IRB defers the human research:** The IRB will provide a statement of the reasons for deferral and suggestions to make the study approvable, and give you an opportunity to respond in writing. In most cases if the IRB's reasons for the deferral are addressed in a modification, the human research can be approved.

- **If the IRB disapproves the human research:** The IRB will provide a statement of the reasons for disapproval and give you an opportunity to respond in writing.

In all cases, you have the right to address your concerns to the IRB directly at an IRB meeting.

**What are my obligations after IRB approval?**
The PI must agree to follow and abide by all policies and procedures of the AMITA Health IRB, as well as all federal, state and local laws pertaining to the protection of human subjects research, including but not limited to:

- Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.

- Conducting the research as approved by the AMITA Health IRB.

- Implementing no changes in approved expedited or full board research without prior approval of the AMITA Health (IRB), unless such changes are necessary to protect the safety of human participants.

- Conducting the research using only the qualified and trained personnel only, and ensuring that research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials and, when relevant, privileges) to perform procedures assigned to them during the study.

- Obtaining informed consent from all subjects without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate (unless Waiver of Consent is specifically approved or research is exempt).

- Submitting a timely continuing report as requested by the IRB (unless research is exempt).
Notifying the IRB of any unanticipated problems involving risks to participants or others within 5 business days.

Promptly reporting and/or respond to all inquiries by the IRB concerning the conduct of the approved research when so requested.

Immediately notifying the IRB upon termination of the study or prior to the departure of the Principal Investigator from this Institution.

The Principal Investigator assumes full responsibility for the conduct of the study and for the protection of the rights and welfare of human subjects involved in the research. The PI is ultimately responsible for all activities related to the research protocol including the quality and timeliness of submission to the AMITA Health IRB.

The PI must be qualified by education, training, and experience in the area in which the research is being conducted. The PI must be familiar with the IRB-approved protocol, all applicable regulations and guidelines, federal, state and local laws, the Ethical and Religious Directives for Catholic Health Care Services (ERDs), and institutional policies and guidelines pertaining to his or her human subject research and clinical investigations.

What should happen if I am no longer able to carry out my duties as Principal Investigator?

Contact the AMITA Health IRB for guidance.

How do I submit a modification?

Complete the FORM: Modification (HRPP-213) and all requested documents. Maintain electronic copies of all information submitted to the IRB in case revisions are required. Please note that research must continue to be conducted without inclusion of the modification until IRB approval is received.

How do I submit a continuing review for full board studies?

Complete the FORM: Continuing Review (HRPP-212) form and all requested documents. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

If the continuing review involves modifications to previously approved research, submit those modifications as a combined Modification and Continuing Review submission.

If the continuing review application is not received by the date requested in the approval letter, you will be restricted from submitting new Human Research until the completed application has been received.

If the approval of human research expires, all human research procedures related to the protocol under review must cease, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information. Continuing human research procedures after expiration of IRB approval is a violation of federal regulations. If current subjects will be harmed by stopping Human Research procedures that are not available outside the human research context, immediately contact the IRB office for guidance.
**How do I submit unanticipated events and protocol deviations?**

An incident that meets the definition of an unanticipated problem involving risk to subjects or others must be promptly reported to the IRB within five (5) working days of when it is known. Refer to AMITA IRB policy “Unanticipated Problems (PP-213)” and complete the FORM: Unanticipated Problem Report (HRPP-221).

**How do I close out a study?**

Complete the FORM: Closure Report (HRPP-216) and all requested documents. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

**What if I need to use an unapproved drug, biologic, or device and there is no time for prior IRB review?**

Contact the AMITA Health IRB Office immediately to discuss the situation.

**How do I request to rely on an external IRB?**

Complete the Form: Central IRB Submission (HRPP-215) and attach all requested documents. Maintain electronic copies of all information submitted to the IRB in case revisions are required, refer to AMITA Policy “Use of Non-Local IRB (PP-221)” for further information. Ensure that human subject training has been completed by all research personal prior to submission to the IRB.

**How do I get additional information and answers to questions?**

This document and the policies and procedures for the Human Research Protection Program are available on the AMITA Health website.

If you have any questions or concerns, about the Human Research Protection Program, contact the AMITA Health IRB Office at:

Lorrie Holland  
IRB Coordinator  
800 Biesterfield Rd. Brock room 3008  
Elk Grove Village, IL 60007  
Email: Dolores.Holland@amitahealth.org  
(815) 741-7693

**REFERENCES**

DHHS OHRP Investigator Responsibilities – FAQs [http://answers.hhs.gov/ohrp/categories/1567](http://answers.hhs.gov/ohrp/categories/1567)  
FDA: Good Clinical Practices and Running Clinical Trials [http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm)  