HUMAN SUBJECT RESEARCH DETERMINATION GUIDE

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What is the purpose of this Guide?

This document describes the following:

- The process for determining whether an activity is human subjects research by (1) research self-determination or (2) formal determination made by the AMITA Health Institutional Review Board (IRB) Office.
- A description of how the AMITA Health Institutional Review Board (IRB) applies the Common Rule definition of research for all activities except those that are regulated by the Food and Drug Administration (FDA) and
- Promote consistency of determinations within AMITA Health and forward in time. Determinations based on this guidance may be inconsistent with some determinations made in the past.

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)”.

Context

Activities that do not meet the definition of research do not require (1) IRB review and approval, or (2) a determination of exempt status.

The Common Rule is the informal name given to a set of human subjects regulations initially developed in the 1970s. It was adopted by almost all federal agencies that fund human subjects research – in other words, it is the set of regulations they all have in common. The Common Rule describes responsibilities and requirements for Institutional Review Boards (IRBs), researchers, and the researcher’s institution. Most academic institutions apply the Common Rule regulations to all human subjects research, even if the research is not funded by a federal agency. This guidance includes the clarifying information provided in the revised Common Rule (implementation date: January 21, 2019).

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.

Who is authorized to make determinations?

The IRB Chair or designee are the only individuals authorized to make a formal determination that an activity does or does not involve human subjects research.

Institutions or funding agencies may differ regarding whether a specific activity is or is not human subjects research. Per AMITA Health, formal determination that a planned activity is human subjects research overrides a “Not Human Subjects Research” determination of another institution or a funding agency.

The IRB recognizes that some journals and funding agencies may require a formal “Not Research” determination from someone other than the manuscript author or lead researcher. The process for obtaining a formal determination from the AMITA Health IRB is described below “What do I need to submit for a determination”.

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**Prospective determination required**

When a formal determination has been requested from AMITA IRB, the research should not begin until the researcher has received the determination. When a determination indicates that the planned activity is human subjects research, IRB approval must be requested and granted before the research begins.

**What are my responsibilities as a Principal Investigator / Researcher?**

When an activity is determined to be Not Human Subjects Research, researchers continue to be responsible for:

- Complying with applicable federal and state laws, as well as AMITA Health policies. For example, a Materials Transfer Agreement or Data Use Agreement may be required.
- Ensuring that data/specimens/information are collected in an ethical manner.
- Acting in accordance with relevant professional standards and codes of conduct as generally accepted in the relevant academic and/or professional discipline(s).
- Promptly notifying the IRB of any new information about risks or relevant problems associated with the activity that might affect the human subjects research determination.

This responsibility starts with the protocol design. The PI / Researcher and all members of the research team must comply with the findings, determinations, and requirements of the IRB. [See PP-103 Investigators Guide for more detailed information]

**What do I need to submit for a determination?**

For a formal determination by the IRB, researchers must submit at a minimum the following materials:

- Human Research Determination (HRPP-214) form
- Initial application (HRPP-211) form
- IRB Protocol (HRPP-503) form

**IRB Determination**

IRB staff make human subjects research determinations as part of the routine pre-review process for all initial applications and modification requests, as well as in response to specific requests from researchers. Additional information or materials may be requested if needed to make the determination.

- If the activity is determined to be human subjects research that requires IRB review, the researcher will merely need to modify the determination by answering the non-circled questions (and perhaps submitting some additional materials) rather than preparing an entirely new application.
- Determinations are considered IRB records and are appropriately recorded.
- A formal determination letter is provided to the researcher. The researcher should file a copy of the determination letter with his/her records.
What if I need to make modifications after initial determination?

A determination applies only to the activity as initially described. A new determination should be made before implementing any changes to the activity (for example, changes in procedures, specimens, collaborators, etc.).

REFERENCES

45 CFR part 46
AMITA Health Policies and Procedures: [https://www.amitahealth.org/research/institutional-review-board](https://www.amitahealth.org/research/institutional-review-board)
Definitions (PP-001)
Investigator Guide (PP-103)