



| <b>GUIDANCE: Human Subject Research Determination</b> |            |        |
|---|------------|--------|
| NUMBER  | DATE       | PAGE   |
| HRP-901   | 12/15/2021 | 1 of 4 |

## **GUIDANCE: Human Subject Research Determination**

This information for the Icahn School of Medicine at Mount Sinai (ISMMS) research community explains which activities may meet the definition of human subjects research (HSR). Activities that are not human subjects research (NHSR) do not fall under the purview of the ISMMS Institutional Review Board (IRB).

The IRB recognizes that these definitions are broad and it can be difficult to determine what constitutes human subjects research. To help, we've provided examples of studies that typically do or do not qualify as human subjects research, and our office is available to assist help investigators make a determination when needed.

### **What is Research?**

Department of Health and Human Services (DHHS) defines research as “a systematic investigation designed to develop or contribute to generalizable knowledge.” [45 CFR 46.102(d)].

### **What is a Human Subject?**

A Human Subject is a living individual about whom an investigator conducting research obtains:

- (1) data through intervention or interaction with the individual, OR,
- (2) identifiable private information [45 CFR 46.102(f)].

### **What is a Systematic Investigation?**

A systematic investigation is usually recognized by the fact that there is a predetermined and organized method [of data collection and analysis] to study a specific topic, answer a specific question, test a hypothesis, or develop a theory. It is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.

### **How is Generalizable Knowledge defined?**

To be considered *generalizable knowledge*, the activity includes one or more of the following:

- Information will expand the knowledge base of a scientific discipline or other scholarly field of study;
- Results are expected to be generalized to a larger population beyond the site of data collection or population studied; or
- Results are intended to be replicated in other settings.

### **What is meant by Individually Identifiable Private Information or Specimens?**

In general, the Office for Human Research Protections (OHRP) considers private information or



| GUIDANCE: Human Subject Research Determination |            |        |
|--|------------|--------|
| NUMBER   | DATE       | PAGE   |
| HRP-901  | 12/15/2021 | 2 of 4 |

specimens to be individually identifiable as defined at 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Conversely, OHRP considers private information or specimens not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. For example, OHRP does not consider research involving **only** coded private information or specimens to involve human subjects as defined under 45 CFR 46.102(f) if the following conditions are both met:

1. the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals;  
AND
2. the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain, because, for example:
  - a) the investigator and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased {note that the HHS regulations do not require the IRB to review and approved this agreement}; or
  - b) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
  - c) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased

Examples of activities that are Human Subject Research (HSR):

- Clinical studies that utilize test subjects or their specimens for new devices, products, drugs, or materials.
- Research studies that collect data through intervention or interaction with individuals.
  - Interaction may include surveys, interviews, questionnaires, and focus groups.
  - Intervention may include physical procedures (e.g., drawing blood), or manipulation of a subject's environment (e.g., hot/cold stressors).
- Research studies using private information or biological specimens where the investigators can readily ascertain the identity of the individuals to whom the information or specimens pertain, even if the information/specimens were not collected specifically for the currently proposed project.



| <b>GUIDANCE: Human Subject Research Determination</b> |            |        |
|---|------------|--------|
| NUMBER  | DATE       | PAGE   |
| HRP-901   | 12/15/2021 | 3 of 4 |

- Studies that produce generalizable knowledge about categories or classes of subjects.
- Pilot or feasibility projects that will be used to develop or evaluate research procedures or design for a project that will involve human subjects.

When an activity does not meet both definitions of *research* and *human subjects*, it is not considered human subjects research and no IRB review/approval is required.

#### Examples of activities that are NOT Human Subjects Research (NHSR)

- Service surveys issued or completed by medical center personnel for the intent and purposes of improving services and programs of the ISMMS or for developing new services or programs for students and employees. If data are re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB
- Research involving cadavers, autopsy material or biospecimens from now deceased
- Quality assurance or improvement projects and program evaluations that are approved by the appropriate institutional committees and are generally not considered research unless there is a clear intent to contribute to generalizable knowledge. If the data are re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB.
- Research involving publicly available datasets or information.
- Research involving only analysis of data or biological specimens that are not individually identifiable and were not collected specifically for the currently proposed project

#### **Who at Mount Sinai is authorized to make a determination about whether an activity is Human Subjects Research?**



## GUIDANCE: Human Subject Research Determination

| NUMBER  | DATE       | PAGE   |
|---------|------------|--------|
| HRP-901 | 12/15/2021 | 4 of 4 |

- Ultimately, an NHSR determination rests with the IRB however, the Principal Investigator (PI) and research team can make this determination using the appropriate determination worksheet: HRP-310 ([located here in the RUTH Library](#)).
- Each activity undertaken on behalf of ISMMS must be evaluated by the individual most familiar with the planning and development of the activity. Therefore, it is the responsibility of
- The PI or delegate to make appropriate determinations based on this policy. When an individual makes a self- determination that an activity does not constitute human research, the ISMMS IRB recommends that the individual document in writing how the determination was made (e.g., via the HRP-310 Human Research Determination Worksheet) and retain this with his/her study records.

### **What if a formal determination is required or the PI is uncertain about making this determination independently?**

- In these circumstances, the activity/project **must be submitted to the PPHS through the IRB's** electronic application system RUTH.
- After creating your submission in RUTH, add a comment to the main workflow page requesting a "Not-Human Subjects Research" determination from the IRB or upload a short memo within the submission.

### **The Decision Trees and References below are useful tools for making your HSR or NHSR determination:**

- OHRP Department of Health and Human Services (HHS) Decision Charts: Is an Activity Research Involving Human Subjects?: [Human Subject Regulations Decision Charts | HHS.gov](#)
- NIH Decision Tool, [Decision Tool: Am I Doing Human Subjects Research? | grants.nih.gov](#)
- Data/Specimen Decision Tree, Office for Human Research Protections (OHRP) Department of Health and Human Services: [Issues to Consider in the Research Use of Stored Data or Tissues \(1996, 1997\) | HHS.gov](#)
- OHRP Department of Health and Human Services (HHS): [Coded Private Information or Specimens Use in Research, Guidance \(2008\) | HHS.gov](#)