What Needs IRB Review – Determination of Human Subjects Research

Table of Contents: What Needs IRB Review – Determination of Human Subjects Research

Policy Statement

Any UIW employee or agent who engages in human subjects research under a UIW appointment or affiliation is required to follow UIW policies governing human subjects research. This includes obtaining UIW IRB approval or exemption prior to beginning any research activities involving human subjects unless the UIW IRB cedes IRB oversight to another institution.

Definitions

For the purposes of this policy, the following definitions apply:

Agent: any individual performing institutionally designated activities (including students) or exercising institutionally designated authority or responsibility. See the HHS guidance on engagement of institutions in human subjects research.

Engagement: an institution is considered engaged in human subjects research when its employees or agents for the purpose of research obtain: (1) data about the subjects of research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. See the HHS guidance on engagement of institutions in human subjects research.

Human Subject (DHHS): a living individual about whom an investigator (whether professional or student) conducting research:

> (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
> (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. [45 CFR 46.102(e)]
>
> **Intervention:** Includes both physical procedures by which information are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction: includes communication or interpersonal contact between investigator and subject.

Private information: includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information: private information for which the identity of the subject is or may be readily ascertained by the investigator or associated with the information.

Human Subject (FDA): an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient [21 CFR 56.102(e)]. In addition, a human subject includes an individual on whose specimen an investigational device or control is used, even if the specimen is anonymous [21 CFR 812.3(p)].

Research: a systematic investigation designed to develop or contribute to generalizable knowledge [45 CFR 46.102(l)]. Includes clinical investigations that support applications for research or marketing permits for products regulated by the FDA, including food and color additives, drugs, medical devices, biological products, or electronic products for human use (i.e., test articles). [21 CFR 56.102]

Note: The terms "systematic investigation" and "generalizable knowledge" are not defined in the federal regulations, but for the purposes of determining whether an activity is considered to be human subjects research at UIW, the following definitions apply:

Systematic investigation: an inquiry that is characterized by 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.

Generalizable knowledge: includes one or more of the following – information that will expand the knowledge base of a scientific discipline or other scholarly field of study; knowledge from which conclusions may be drawn that can be applied to a larger population beyond the site of data collection or the population studied; results that can be replicated in other settings.

Description and Procedures

A. Research Subject to IRB Review

Only those activities that meet the definitions of research with human subjects under the DHHS or FDA regulations require prior review and approval by the UIW IRB or one of the IRBs relied upon by UIW. Examples of human subjects research include, but are not limited to:

- research studies that collect data about individuals through intervention (e.g., physical procedures such as drawing blood, or manipulation of a subject's environment) or interaction with individuals (e.g., surveys, focus groups, and interviews);

- clinical studies that utilize test subjects or their specimens to investigate new devices, products, drugs, or materials;

- research studies using private information or biological specimens where the investigators can readily ascertain the identity of the individual to whom the information or specimens pertain; and/or

- pilot or feasibility projects that will be used to develop or evaluate research procedures for a research project that will involve human subjects.

B. Activities Deemed Not Regulated Research (NRR)

When an activity does not meet both definitions of research and human subjects, no IRB review and approval is required. Examples of *not regulated research* include, but are not limited to:

- observational studies of public behavior **ONLY** where there is **no intervention or interaction with the subjects**, the **behavior is not private**, and there is **no manipulation of the environment** in order to stimulate certain types of behavior;

- data collected for internal departmental, school, or other University administrative purposes, such as teaching evaluations and customer service surveys;

- information gathering interviews or surveys where questions focus on things, products, or policies rather than on individuals or their personal thoughts, perceptions, or feelings (e.g., surveying university administrators about institutional admission policies, or interviews with company managers about how a product is made);

- course-related activities designed specifically for educational or teaching purposes, where data are collected as part of a class exercise or course requirement, and are not intended to contribute to generalizable knowledge (see IRB Guidance on Student Class Projects);

- scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), when the collection and use of information focuses directly on the specific individuals about whom the information is collected [45 CFR 46.102(l)];

- quality assurance or improvement projects and program evaluations, unless the project is designed to contribute to generalizable knowledge (see IRB Guidance on QI/QA projects);

- medical case histories or case studies if the case is limited to a description of the specific features/outcome of the case and do not contribute to generalizable knowledge;

- research involving publicly available de-identified datasets or information, such as the U.S. Census, National Center for Health Statistics, or National Center for Educational Statistics;

- research involving only retrospective secondary analysis of data or biological specimens that are not individually identifiable and were not collected for the current research project (see IRB Guidance on Secondary Data Analysis);

- public health surveillance activities, **ONLY** when conducted, supported, requested, ordered, required, or authorized by a **public health authority**, limited to those activities necessary to identify monitor, assess, or investigate conditions of public health importance (e.g., the San

Antonio Metropolitan Health District, the Texas Department of State Health Services, the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Occupational Safety and Health Administration) [45 CFR 46.102(l)];

- collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes [45 CFR 46.102(l)]; and/or

- authorized operational activities in support of intelligence, homeland security, defense, or other national security missions [45 CFR 46.102(l)].

C. Authorization to Make NRR Determinations

It is the responsibility of investigators to make appropriate determinations based on UIW IRB policy. Each activity undertaken by UIW employees or agents must be evaluated by the individual most familiar with the planning of the activity. When an individual makes a self-determination that an activity does not constitute regulated research, the UIW IRB recommends that the individual documents in writing how the determination was made and retain this with the project records for at least three years after the conclusion of the project. The IRB has the authority to overrule an investigator's self-determination or the determination of other institutions. If a determination cannot be made, the investigator must submit the activity/project to the Office of Research and Sponsored Projects Operations for a determination. Investigators may also request a formal determination letter from the Office of Research and Sponsored Projects Operations by submitting the online Human Subjects Research Determination Questionnaire. The request should describe the activity in sufficient detail and provide adequate documentation for the ORSPO to make a determination.

D. Additional Guidance for NRR Activities

Regardless of whether a project is determined to be NRR or human subjects research requiring IRB review and approval, all UIW faculty, staff, and students are expected to follow adequate, discipline-specific guidelines to assure that projects are being conducted in a responsible, professional, and ethical manner. In addition, there may be other federal, state, local, or institutional laws and policies (e.g., HIPAA, FERPA) that may need to be considered even if federal regulations for human research protections do not apply. If a project is not regulated research, and the investigator intends to utilize a consent form or to publish/present the results, no references to IRB oversight should be included. When funding agencies, publishers, or external collaborators require documentation that the activity is not regulated research, the investigator should submit a request using the Human Subjects Research Determination Questionnaire for formal documentation.

More specific guidance is provided for the following activities that commonly lead to questions about whether the activities meet the definitions of research in the following guidance documents:

- Student Class Projects
- Quality Improvement/Quality Assurance Projects
- Secondary Data Analysis

Effective Date

August 24, 2020

Revision History

References

HHS Guidance on Engagement of Institutions in Human Subjects Research
45 CFR 46
21 CFR 56
21 CFR 812
Human Subjects Research Determination Questionnaire
IRB Guidance on Student Class Projects
IRB Guidance on Quality Improvement/Quality Assurance Projects
IRB Guidance on Secondary Data Analysis