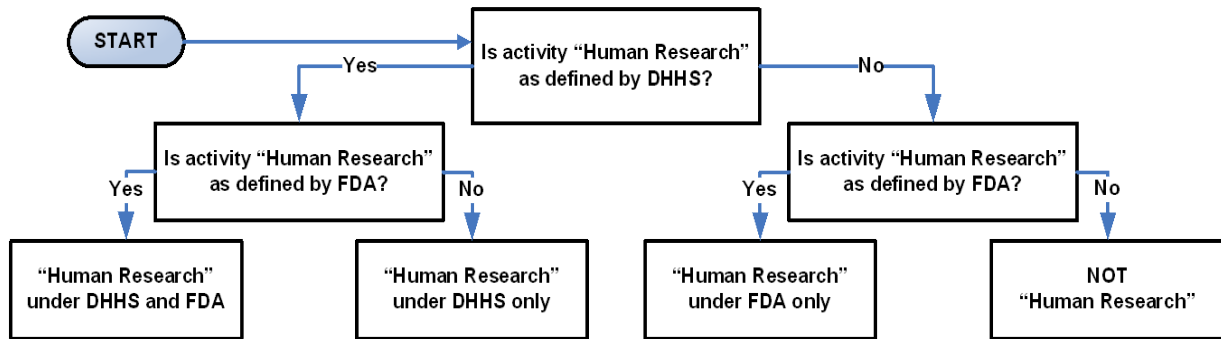




WORKSHEET: Human Research Determination

The purpose of this worksheet is to provide support for individuals in determining whether an activity is Human Research or how it is regulated ¹. **IRB review is not required for activities that are not Human Research.**

If you would like to obtain a formal assessment of Human Research from the IRB, then prior to the initiation of the activity, submit an application to the IRB. (Note: the IRB can only make this determination prior to the beginning of the research activity. The IRB will not make a determination after the activity has already begun).



1. Research as Defined by DHHS Regulationsⁱⁱ (Check if "Yes")

- Is the activity an investigation? (Investigation: a searching inquiry for facts; detailed or careful examination.)
- Is the investigation systematic? (Systematic: having or involving a system, method, or plan.)
- Is the systematic investigation designed to develop or contribute to knowledge? (Designed: observable behaviors used to develop or contribute to knowledge. Develop: to form the basis for a future contribution. Contribute: to result in. Knowledge: truths, facts, information.)
- Is the knowledge the systematic investigation is designed to develop or contribute generalizable? (Generalizable: universally or widely applicable.)

2. Human Subject Under DHHS Regulations (Check if "Yes")

- Is the investigator conducting the Research gathering information or biospecimens *about living* individuals?

3. Human Subject Under DHHS Regulations (Check if "Yes")

- Will the investigator use, study, or analyze information or biospecimens obtained through either of the following mechanisms? Specify which mechanism(s) apply, if yes:
 - Physical procedures or manipulations of those individuals or their environment for Research purposes ("Intervention").
 - Communication or interpersonal contact with the individuals. ("Interaction").

4. Human Subject Under DHHS Regulations (Check if “Yes”)

- Will the investigator gather data that is either? Specify which category(s) apply if yes:
 - The data are about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place (i.e. “Private information”).
 - Individuals have provided the data for specific purposes in which the individuals can reasonably expect that it will NOT be made public, such as a medical record (i.e. “Private information”).
- Can the individuals’ identities be readily ascertained or associated with the information by the investigator (i.e. “Identifiable Private Information”)?

5. Human Subject Under DHHS Regulations (Check if “Yes”)

- Will the investigator gather biospecimens?
- Can the individuals’ identities be readily ascertained or associated with the biospecimens by the investigator (i.e. “Identifiable Biospecimen”)?

If all items are checked under 1, 2, and 3 or 1, 2, 4 and/or 5, the activity is Human Research under DHHS regulations.

6. Human Research Under DHHS Regulations (Check if “Yes”)

- Has a department or agency head, covered by the Common Rule, retained final judgment (consistent with the ethical principles of the Belmont Report) that the activity is Human Research under DHHS regulations?

If checked, the activity is Human Research under DHHS regulations.

7. Human Research Under FDA Regulations (Check if “Yes”)

- Does the activity involve any of the following? (Check all that apply)
 - In the United States: The use of a drug ⁱⁱⁱ in one or more persons other than use of an approved drug in the course of medical practice ^{iv}.
 - In the United States: The use of a device ^v in one or more persons that evaluates the safety or effectiveness of that device.
 - Data regarding subjects or control subjects submitted to or held for inspection by FDA ^{vi}.
 - Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA ^{vii}.

If “Yes”, the activity is Human Research under FDA regulations.

8. Human Research under Organizational Policy

If the activity is Human Research under DHHS regulations or under FDA regulations, it is Human Research under organizational policy.

9. Engagement (Complete if the activity is Human Research. (Check if “Yes”)

- The organization is engaged in Human Research. Use HRP-311 - WORKSHEET - Engagement Determination.

10. Comments

Comments: Click or tap here to enter text.

11. Below are examples of activities that are generally considered not to be Human Research. If your activity is limited to the activities below, then it is likely not Human Research.

- Program Evaluation/Quality Assurance Review/Quality Improvement Project:** The activity is limited to program evaluation, quality assurance, or quality improvement activities designed specifically to evaluate, assure, or improve performance within a department, classroom, or hospital setting.

Note: The purpose of a Quality Assurance (QA) study is to assure known quality. The purpose of Program Evaluation (PE) is to assess that a program is doing what it is intended to do. Generally, Quality Improvement (QI) is designed for the purpose of improving the quality of a service, a program, a process, etc. These studies are mechanisms to assure that a service, a program or process functions optimally. Such projects are usually for internal auditing purposes only.

If you can answer "yes" to all the following questions, the activity is most likely not Human Research:

1. Will you simply monitor an existing process for which there will be no manipulation of the existing process?
2. For biomedical or social behavioral QA or PE studies, will physicians or caregivers (parents, teachers, therapists, etc.) provide usual and customary care regardless of the conduct of the study?
3. Does the study involve collection of data to which the investigator routinely has access as part of his or her responsibilities within the institution to monitor data associated with, for example: treatment, cost containment, performance, or compliance?

Note that an evaluation, assurance review, or improvement project designed specifically for a particular setting may yield useful information for similar entities, and may still not meet the definition of Human Research.

- Case Report:** The project consists of a case report or series which describes an interesting treatment, presentation, or outcome. A critical component is that nothing was done to the patient(s) with prior "research" intent.

Note that HIPAA or other state or local laws may still apply to this activity. Please consult the entity from which you received or accessed the information contained in the report for further guidance.

- Course-Related Activity:** The project is limited to one or more course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of routine class exercises or assignments and otherwise do not meet the definition of Human Research (e.g., course evaluations).

Most **classroom research projects** where the sole purpose at the outset is to be a learning experience and educational activity (for example, to teach research methods) do not meet the federal definition of Research; therefore, they do not require IRB review or approval.

Classroom research projects involving human participants do not need to be reviewed by the IRB if the following conditions are satisfied:

- The intent of the project is to teach research methods and not a systematic investigation designed to develop or contribute to generalizable knowledge.
- The results of the project will not be distributed outside the classroom and/or institutional setting or used for publication, although the results may be presented to instructors or peers for educational purposes or as part of a class assignment.
- The project involves Minimal Risk to participants (i.e., when the risks of harm anticipated in the proposed project are not greater considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).
- The project does not involve **sensitive topics** or collect information that could place a participant at risk if disclosed (e.g., illegal activities).
- The project does not involve people from **vulnerable populations** as participants (e.g., prisoners, minors, individuals lacking capacity to consent, or other at-risk populations).
- The project involves the **voluntary participation** of individuals without any undue influence or pressure being placed on the individuals to take part in the project.

Although the vast majority of classroom projects are “educational” activities and do not require IRB approval, faculty are responsible for assuring that students adhere to ethical principles while conducting their projects. Specifically, faculty overseeing classroom research projects are responsible for monitoring students’ activities and consent procedures and are advised to take [CITI training](#).

If the project does not adhere to these guidelines, contact the IRB prior to starting the project.

Note that some course-related activities, even those conducted by students, may yield information suggesting additional investigation or analysis. If an additional activity entails Human Research, then it must be submitted to the IRB for review.

- Journalistic or Documentary Activity (including Oral History):** The activity is limited to investigations or interviews (structured or open-ended) that focus on specific events (current or historical), views, etc. Such investigations or interviews may be reported or published in any medium, (e.g., print newspaper, documentary video, online magazine).

Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected are not considered Research as Defined by DHHS.

- Research Using Public or Non-Identifiable Private Information about Living Individuals:** The activity is limited to analyzing data about living individuals (1) where the data have been retrieved by the investigator

from public, non-restricted data sets or (2) where the private data have been provided to the investigator without any accompanying information by which the investigator could identify the individuals.

Note that “de-identified data” according to HIPAA may be identifiable according to the DHHS definition of “Human Subjects” above. Contact the IRB with any questions regarding research with data.

- Research Using Health Information from Deceased Individuals:** This activity is limited to analyzing data (identifiable or not) about deceased individuals.

Note that research with deceased individuals is not considered Research with Human Subjects as Defined by DHHS, but research using specimens from deceased individuals may be considered Research with Human Subjects as Defined by FDA. Note also that HIPAA and/or other state or local laws may still apply to this activity.

- Instrument/Questionnaire Development:** This activity is limited to interacting with individuals in order to obtain feedback on the types of questions which could or should be used to develop an instrument or questionnaire. The focus is on the development and construction of a data collection tool and not on the individuals who are providing the feedback on the questions being developed. This will be true even when the feedback may be specifically sought from an identified group of people most likely to be affected by the topic of the instrument, survey or questionnaire. The instrument/questionnaire development process will apply to many aspects of reliability and validity testing of the instrument or questionnaire. Note that once the process gets to the level of testing discriminant, concurrent or predictive validity, the activity may need to be reclassified as Human Research.

Note: If the participant is asked to provide additional information about themselves unrelated to instrument/questionnaire construction, such as demographic information, that will be analyzed as part of a research study, the project may need to be submitted to the IRB for review.

ⁱ This document satisfies AAHRPP elements I.1.A, III.1.A

ⁱⁱ The following activities conducted or supported by the Department of Defense (DoD) are NOT research involving human subjects: Activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel under force health protection programs of the Department of Defense, including health surveillance pursuant to section 1074f of Reference (g) and the use of medical products consistent with DoD Instruction 6200.02. Authorized health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of patient treatment. Activities performed for the sole purpose of medical quality assurance consistent with 10 USC 1102 and DoDD 6025.13. Activities performed solely for an OT&E project where the activities and project meet the definition of OT&E as defined in 10 USC 139(a)(2)(A). Activities performed solely for assessing compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units, including such activities as occupational drug testing, occupational health and safety reviews, network monitoring, and monitoring for compliance with requirements for protection of classified information. Activities, including program evaluation, customer satisfaction surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results of the evaluation are only for the use of Government officials responsible for the operation or oversight of the program being evaluated and are not intended for generalized use beyond such program. Survey, interview, or surveillance activities and related analyses performed solely for authorized foreign intelligence collection purposes, as authorized by DoDD 5240.01.

ⁱⁱⁱ The term “drug” means:

- (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
- (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

^{iv} “Other than the use of an approved drug in the course of medical practice” refers to a practitioner providing an approved drug to a patient because the practitioner believes the drug to be in the best interests of the patient. If the protocol specifies the use of the drug, it is not in the course of medical practice unless use of the drug is completely up to the discretion of the practitioner.

^v The term “device” means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

^{vi} This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

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