Pennington Biomedical Research Center
Louisiana State University

GUIDANCE #: G-001
GUIDANCE: HUMAN RESEARCH DETERMINATION

Guidance: Determining Which Activities Require Pennington Biomedical Research Center IRB Review

Overview

This guidance document assists Pennington Biomedical investigators with determining which activities require IRB review. All activities that constitute "human research" performed by Pennington Biomedical investigators must be reviewed and approved by the IRB or be certified exempt from IRB review prior to initiation.
IMPORTANT NOTE: This includes preparatory to research activities that involve interventions or interactions with living individuals, e.g., advertising, recruitment, and/or screening of potential subjects for research, and/or accessing or obtaining identifiable, private information from or about living individuals for the purpose of conducting research, e.g., review of medical records.

Pennington Biomedical Research Center IRB approval always is required if the human research activities will be supported by federal funding (e.g., NIH, DOE, DOD, FDA) that is awarded directly to Pennington Biomedical.

Human Research Definitions

Investigators should review the following definitions to determine whether an activity is human research. They may also contact a member of the IRB staff for assistance with this determination. Human Research is any research or clinical investigation that involves human subjects as defined below.

RESEARCH:
DHHS regulations define research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)).
Systematic Investigation:

- A systematic investigation is an activity that involves a prospective plan that incorporates data collection (quantitative or qualitative) and data analysis to answer a question.
- Activities are not research if they do not involve a systematic approach involving a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory.

Determining Which Activities Require IRB Review

- Examples of activities that typically are systematic investigations:
  - interviews and focus groups

    - surveys and questionnaires
    - analysis of data and specimens
    - observational studies
    - epidemiological studies
    - social or educational program evaluations
    - cognitive and perceptual experiments
    - medical chart reviews
    - test development

- Examples of activities that typically are not systematic investigations:
    - Training activities provided the activities are not designed to develop or contribute to generalizable knowledge.
    - Classroom activities where the objective of the activity is to teach proficiency in performing certain tasks or using specific tools or methods and the activity is not designed to develop or contribute to generalizable knowledge.

Generalizable Knowledge:

- Activities designed (with intent) to develop or contribute to generalizable knowledge are those designed to draw general conclusions, inform policy, or generalize finding beyond a single individual or an internal program (e.g., publication or presentation). IMPORTANT NOTE: The intent to develop or contribute to generalizable knowledge makes an activity research. Results do not have to be published or presented to qualify the activity as research.

- Examples of activities that typically are **not** designed to develop or contribute to generalizable knowledge:
    - Biographies
    - Oral histories that are designed solely to create a record of specific historical events
    - Service or course evaluations, unless they can be generalized to other individuals
    - Services, courses, or concepts where it is not the intention to share the results beyond the PBRC community
    - Classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices
    - Quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the PBRC community

FDA regulations define a clinical investigation as any experiment that involves a test article and one or more human subjects, and that either subject to the requirements for prior submission to the FDA under section 505(i) or 520(g) of the Act, or need not subject to the requirements for prior submission to the Food and Drug Administration under these sections of the Act, but the results of which are intended to be later submitted to, or held for inspection by

the FDA as part of an application for a research or marketing permit (21 CFR 50.3(c), 21 CFR 56.103(c), 21 CFR 312.3(b), and 21 CFR 812.3(h)).

- A test article is any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulations.

Please see the attached form for additional support in making a human research determination.

The purpose of this worksheet is to provide support for the Investigators, support staff, IRB Staff, convened IRB or designated reviewers when making a determination on whether a project is considered research. This worksheet is to be used as guidance. It does not have to be completed or retained.		
Y	**N**	**1. Research as Defined by DHHS Regulations[i] .** *All must be checked yes to be considered "research".*
☐	☐	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.)
Y	**N**	**2. Human Subject under DHHS Regulations.** *All must be checked yes to be considered Human Subjects.*
☐	☐	Is the investigator conducting the research gathering data about *living* individuals?
Y	**N**	**3. Human Subjects under DHHS Regulations.** *All must be checked yes to considered human subjects research.*
		Will the investigator gather that data through either of the following mechanisms (specify which mechanism(s) apply):
☐	☐	Physical procedures or manipulations of those individuals or their environment for research purposes ("intervention").
☐	☐	Communication or interpersonal contact with the individuals ("interaction").
Y	**N**	**4. Human Subject under DHHS Regulations.** *All must be checked yes to considered human subjects research.*
		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 information")?
If all items are checked under 1, 2, and 3 or 1, 2, and 4, the activity is Human Research under DHHS regulations.		
Y	**N**	**5. Human Research under FDA Regulations.** *All must be checked yes to be considered Human Subjects Research under FDA regulations*.
		Does the activity involve any of the following?
☐	☐	In the United States: The use of a drug[ii] in one or more persons other than use of an approved drug in the course of medical practice[iii].

☐	☐		In the United States: The use of a device[iv] 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[v].
			Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA[vi].
If the activity is Human Research under DHHS regulations or under FDA regulations, it is Human Research under institutional policy.			

[i] 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.

[ii] 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).

[iii] “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.

[iv] 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

(3) 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.

[v] 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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