



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 103
Activities Requiring IRB Review

Purpose

The purpose of this standard operating procedure (SOP) is to provide guidance on the type of research activities subject to review and approval. In order to ensure the rights, welfare, and protection of all subjects, all human subject's research, and all other activities, which in part involve human subject research, regardless of sponsorship, must be reviewed and approved by an IRB prior to initiation. This includes all interventions and interactions with human subjects for research, including advertising, recruitment and/or screening of potential subjects.

Scope

All USA IRB policies and procedures apply to all human subject's research conducted by the University of South Alabama faculty, staff or studies or by anyone conducting research in which the participation of University of South Alabama meets the definition of "engagement" as indicated by the Office of Human Research Protections (OHRP) (<http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html>) or the research is regulated by the Food and Drug Administration.

Definitions

IRB review and approval is required for projects that (i) meet the definition of research, (ii) involve human subject's and (iii) include any interaction or intervention with human subject's or involve access to identifiable private information. The definitions below should be utilized in assessing the requirements of IRB review.

Clinical Investigation any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.

Food and Drug Administration (FDA): The office responsible for implementing regulations governing the use of investigational drugs, biologics, devices and radiological procedures including radioactive drugs in clinical investigations with humans.

Human Subject (as defined by DHHS regulations): A living individual about whom an investigator (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individuals, and uses, studies or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Human Subject (as defined by FDA regulations): An individual who is or becomes a participant in research, either as a recipient of the test article or as a control and/or an individual on whose specimen a device is used. Under the FDA regulations and guidance, a human subject may include individuals whose de-identified tissue specimens are used in in vitro diagnostic medical device research.

Human Subjects Research is any research or clinical investigation that involves human subjects

Intervention includes both physical procedures by which data 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 or legal representative in the case of minors or other vulnerable populations.

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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Research (as defined by DHHS regulations): Any systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge.

Systematic: Activities must be systematic to be considered research. Activities that involve predetermined methods for answering a specific question, testing hypotheses or theories are systematic and might include interviews, program evaluations, and observational studies. Activities that are not normally systematic are training activities where an individual is trained to perform a certain technique or task or to teach proficiency in using a certain method.

Generalizable Knowledge: Activities must contribute to generalizable knowledge or be intended to extend beyond a department or internal use. Many thesis, dissertation or independent study projects are intended to extend beyond the graduate's department and therefore are considered research. Activities that are typically not generalizable are course evaluations that cannot be generalized to others, and quality assurance type activities that are only intended to improve the performance of a unit, division, or department.

Test article means 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 regulation under the Federal Food, Drug, and Cosmetic Act.

2.0 Examples of activities that are generally considered not to be Human Research

The following are examples of activities that are *generally* considered not to be Human Research according to the above definitions. If your activity is limited to one of the examples below, then it is likely not Human Research which would need to be reviewed by the IRB. *Note that **publication is not a determining factor** for whether an activity is Human Research.*

- **Grant-only Submission:** The submission includes a grant (without an accompanying protocol) for which you would like acknowledgement of receipt and "proof of concept" review by the IRB Office. Examples include Umbrella Grants, Training Grants, Just-In-Time Grants, etc., that themselves do not include all elements required in order to obtain full IRB approval.
- **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.
- **Case Report:** The project consists of a case report or series (up to 3 cases) which describes an interesting treatment, presentation, or outcome. A critical component is that nothing was done to the patient(s) with prior "research" intent.
 - **Classroom-Related Activity:** The project is limited to one or more classroom-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 either of the definitions of Human Research.
- **Scholarly and Journalistic Activities (e.g., oral history, journalism, biography, literary criticism, legal research):** 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.

- **Public Health Surveillance Activities**
- **Collection and analysis of information, biospecimens, or records for criminal justice or criminal investigation purposes**
- **Certain activities in support of intelligence, homeland, security, defense, or other national security missions**
- **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.
- **Research Using Health Information from Deceased Individuals:** This activity is limited to analyzing data (identifiable or not) about deceased individuals.

Policy

USA complies with the Code of Federal Regulations (CFR), the Common Rule, as it applies to human participant research. These include the regulations from DHHS [45 CFR 46] and its subparts, the FDA regulations [21 CFR 50 and 56], and all other relevant federal regulations.

The Common Rule and FDA regulations do not preempt other state and federal laws relating to the conduct of human research or to other aspects of the research itself. This guidance document describes related federal and state laws which may have bearing on the conduct of human research at USA. The descriptions provided below are intended to assist investigators and the IRB in determining when such laws and regulations may apply and are not intended to provide the detailed information required to ensure compliance with these laws/regulations. Investigators and IRB staff should consult the applicable regulation for additional guidance.

45 CFR 46 Common Rule: Describes the requirements for IRB review and approval of research involving human subjects. Subpart A is known as the “common rule” as it has been adopted by the following federal agencies:

- Department of Health and Human Services (45 CFR 46)
- Department of Agriculture (7 CFR 1C)
- Department of Energy (10 CFR 745)
- Department of Housing and Urban Development (24 CFR 60)
- Department of Justice (28 CFR 46)

- Department of Education (34 CFR 97)
 - Department of Veterans Affairs (38 CFR 16)
 - Environmental Protection Agency (40 CFR 26)
 - National Science Foundation (45 CFR 690)
 - Department of Transportation (49 CFR 11)
- (Note: Subparts B, C, and D have been adopted only by DHHS.)

Health Insurance Portability Privacy Act (HIPAA)

The IRB also serves as the HIPAA Privacy Board for all human participant research at USA and its affiliates. It must assure that HIPAA rules and all other privacy and confidentiality regulations are met for all research conducted at USA and its affiliates (45 CFR 46, Parts 160, 162, and 164; 38 CFR 46, Parts 160, 162, and 164).

State and Local Law

USA is committed to assuring that human participant research complies with all applicable state and local law. An attorney from USA's Office of the General Counsel serves as an advisory member of the IRB and therefore maintains updated knowledge of pertinent regulations and IRB policies.

1.0 Agreements to Provide IRB Review of Research Conducted by Unaffiliated Investigators

USA may be asked to provide IRB review for investigators who are unaffiliated with the University of South Alabama. Circumstances in which this arrangement might be considered would typically involve a study based at USA in which the unaffiliated investigator is collaborating in the study. It will generally not be considered appropriate to extend IRB oversight to research by unaffiliated investigators in which USA is not otherwise engaged.

All requests for USA to serve as the IRB of record for an unaffiliated investigator should be referred to the USA IRB office. This referral should include an "Unaffiliated Investigator Agreement" based on the USA approved agreement template included in IRBNet forms and templates. Usually, this agreement will apply to a single research project. Copies of the agreement will be provided to the unaffiliated investigator and maintained in IRB Office.

2.0 Human Research Activities Performed at Other Institutions

All research activities performed by, or under the direction of, USA personnel or which use University resources or facilities, must comply with applicable USA policies and

procedures, regardless of funding and whether performed in USA facilities or at offsite locations.

2.1 Requirements for Approval of Research at Non-USA Facilities

Any human subjects research conducted in whole or in part outside of USA facilities must be reviewed and approved by USA IRB prior to initiation if it satisfies any of the following criteria.

- It is conducted by or under the direction of USA personnel in connection with his or her USA responsibilities.
- It uses USA property, facilities, or resources to support or carry out the research.
- The name of the University of South Alabama is used in applying for funds (intra or extramural).
- The name of the University of South Alabama is used in explanations and/or representations to subjects.
- The investigator plans to use his/her University of South Alabama association in any publication or public presentation resulting from the research.
- Non-public information from USA will be used to identify or contact human research subjects or prospective subjects.

2.2 IRB Approval of Research to be Conducted at a Non-USA Institution

The researcher will need to obtain approval from the Non-USA IRB. Additionally, the local USA IRB may also require approval. This will be reviewed on a case-by-case basis.

Procedures

1.0 Determination of Human Subjects Research

- 1.1 When an investigator submits a new application; the IRB Office or designee will review the application and determine if the study meets the criteria for human subject's research.
 - 1.1.1 If the submission meets the criteria of human subject's research the application will be reviewed according to the applicable SOPs. The investigator will be notified and may be instructed to resubmit under an alternate review pathway.
 - 1.1.2 If the submission does not meet the criteria of human subject's research, the investigator will be notified.

Related Federal Regulations

[45 CFR 46](#) – 2018 Common Rule

45 CFR 46.102(l) – full description of the excluded categories of research activities

[21 CFR 56: FDA: Institutional Review Boards](#)

[21 CFR 50: Protection of Human Subjects](#)

Related Guidelines

[DHHS Office of Human Research Protections: Guidance – Scholarly and Journalistic Activities Deemed Not to be Research](#)

[DHHS Office of Human Research Protections: Guidance – Public Health Surveillance Activities Deemed Not to be Research](#)

HISTORY

Effective Date:

Revisions: January 2019