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 subjects 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 students 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).

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 (45 CFR 46): 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.

Human Subject (21 CFR 50): 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

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.

x Public Health Surveillance Activities

x Collection and analysis of information, biospecimens, or records for criminal justice or criminal investigation purposes

x

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

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.