



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 803
Behavioral and Social Science Research

Purpose

The purpose of this document is to explain Behavioral and Social Science research.

Scope

This policy covers Behavioral and Social Sciences research conducted under the auspices of the IRB. Behavioral and Social Sciences research involves surveys, observational studies, personal interviews, or experimental designs involving exposure to some type of stimulus or intervention.

Policy

To ensure that the appropriate type of review is conducted within the constraints of the federal regulations and the facility's policies and procedures.

Concerns in Social and Behavioral Research

Behavioral and Social Sciences research often involves surveys, observational studies, personal interviews, or experimental designs involving exposure to some type of stimulus or intervention.

1.0 Social and Psychological Harms

The IRB carefully examines the research to determine the probability of risk or harm to subjects. These considerations apply to medical/biological research as well as social and behavioral research.

- 1.1 The IRB considers the potential for participants to experience stress, anxiety, guilt, or trauma that can result in genuine psychological harm.
- 1.2 The IRB considers the risks of criminal or civil liability or other risks that can result in serious social harms, such as damage to financial standing, employability, insurability, reputation, stigmatization, and damage to social or family relationships.
- 1.3 If information is being collected on living individuals other than the primary “target” subjects the IRB considers the risk of harm to those “non-target” individuals, as well. The IRB reviews the proposal for appropriate preventive protections and debriefings, adequate disclosure of risks in the informed consent information, and mechanisms to protect the confidentiality and privacy of persons participating in or affected by the research.

2.0 Privacy and Confidentiality Concerns

The use of confidential information is an essential element of social and behavioral research. These considerations apply to medical/biological research as well as social and behavioral research.

- 2.1 The IRB ensures that the methods used to identify potential research subjects or to gather information about subjects do not invade the privacy of the individuals. In general, identifiable information may not be obtained from private (non-public) records without the approval of the IRB and the informed consent of the subject. This is the case even for activities intended to identify potential subjects who will later be approached to participate in research.
- 2.2 The IRB ensures that adequate measures are taken to protect individually identifiable private information once it has been collected to prevent a breach of confidentiality that could lead to a loss of privacy and potentially harm subjects.

3.0 Safeguarding Confidentiality

When information linked to individuals will be recorded as part of the research design, the IRB ensures that adequate precautions will be taken to safeguard the confidentiality of the information. The more sensitive the data being collected, the more important it is for the researcher and the IRB to be familiar with techniques for protecting confidentiality. These considerations apply to medical/biological research as well as social and behavioral research

- 3.1 If the IRB reviews research in which the confidentiality of data is a serious issue, the IRB will have at least one member (or consultant) familiar with the strengths and weaknesses of the different mechanisms available.
- 3.2 For survey and interview research, the IRB may waive the requirement for the

investigator to obtain a signed consent form for some or all subjects if it finds either:

- 3.2.1 That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality and the research is not FDA regulated. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- 3.2.2 The research presents no more than minimal risk of harm to participants, and the research involves no procedures for which written consent is normally required outside of the research context.
- 3.3 Coding of records, statistical techniques, and physical or computerized methods for maintaining the security of stored data are among the available methods for ensuring confidentiality.
- 3.4 A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- 3.5 Federal officials have the right to inspect and copy research records, including consent forms and individual medical records, to ensure compliance with the rules and standards of their programs. Although likely not applicable for this type of research, the FDA requires that information regarding this authority be included on the consent information for all research that it regulates. The provisions of the Privacy Act of 1974 protect identifiable information obtained by Federal officials during such inspections.
- 3.6 The IRB may require that an investigator obtain a Department of Health and Human Services (DHHS) Certificate of Confidentiality (CoC). The CoC protects against the involuntary release of sensitive information about individual subjects for use in Federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings.

4.0 **Types of Risk found with Social/Behavioral Research**

- A. Breach of confidentiality
- B. Violation of privacy
- C. Validation of inappropriate or undesirable behaviors of participants
- D. Presentation of results in a way that does not respect the participants' interests
- E. Possible harm to individuals not directly involved in the research, but about whom data are obtained indirectly (secondary participants), or who belong to the class or group from which participants were selected
- F. Harm to participants' dignity, self-image, or innocence as a result of indiscreet or age-inappropriate questions in an interview or questionnaire that results in embarrassment, harassment, or stigmatization

- G. Harm to a participant because of exposure to potential for criminal or civil liability and/or damage to financial standing or employability

5.0 Research Involving Deception or Withholding of Information

Where deception is involved, the IRB needs to be satisfied that the deception is necessary and that, when appropriate, the participants shall be debriefed. (Debriefing may be inappropriate, for example, when the debriefing itself would present an unreasonable risk of harm without a corresponding benefit.) The IRB will also make sure that the proposed subject population is suitable. The regulations make no provision for the use of deception in research that poses greater than minimal risks to participants. The IRB considers the following issues when reviewing research that involves deception:

- The scientific value and validity of the research.
- The ability to obtain the information without the use of deception.
- Whether the deception used will influence the participants' willingness to participate.
- The possibility of harm to the participant and a plan for debriefing which must be conducted as soon as possible after the conclusion of the study. Participants should be given the opportunity to withdraw their participation from the study after debriefing by requesting that any data collected from them be deleted and/or destroyed.
- The possibility that the deception may cause invasions of privacy.

This information is requested in the IRB application form.

The employment of deception by an investigator(s) for the purpose of securing subject participation and/or to prevent potentially biased reporting of data/information by the subject is permissible provided all of the following conditions exist:

- Deception is necessary due to the lack of alternative procedures for data collection not involving deception;
- The deceptive procedures will not place subjects at significant financial, physical, legal, psychological, or social risk;
- The data collection/experiment will be followed by careful debriefing sessions whereby the subjects are fully informed of the nature and purpose of the deception; and
- The procedures for deception must meet the guidelines established by the discipline of the investigator through its professional code of ethics.

6.0 Debriefing

In order for the IRB to adequately review the research, investigators should justify, in detail, in the protocol, the reasons for deceiving or withholding information from subjects, including an explanation of:

- the necessity for deceiving subjects;
- how potential benefits of the research justify the use of deception; and
- how the investigators will conduct the debriefing.

In addition, investigators should include a debriefing script or statement that indicates the information subjects will receive regarding their participation in the research. The IRB in collaboration with the investigator will determine whether subjects should be debriefed either after unwittingly participating in the research or after knowingly participating in research that involved deception. The IRB may require debriefing when it contributes to the subject's welfare, i.e., when it corrects painful or stressful misperceptions, or when it reduces pain, stress, or anxiety concerning the subject's performance. For example, if a subject is lead to believe through participation in deception research that she/he has committed a crime or has a disease, a debriefing session may correct the induced stress, pain, and/or anxiety.

7.0 Oral Histories

Oral history interviewing projects generally do not involve the type of research as defined by DHHS regulations and therefore are excluded from IRB oversight. However, if the project does not fall within the guidelines below it does require IRB review and routine application submission procedures apply.

For purposes of this SOP, projects fulfilling the following criteria are considered to be an oral history project and do not require IRB review:

- 7.1 Oral history projects involve interviews that are explicitly intended for preservation as a historical document.
- 7.2 Projects involving oral history interviews that are not designed to contribute to generalizable knowledge as the 45 CFR part 46 regulations describe. The project does not seek underlying principles or laws of nature that have predictive value nor can it be applied to other circumstances for the purposes of controlling outcomes.
- 7.3 Projects involving oral history narrators that are not anonymous individuals selected as part of a random sample for the purposes of a survey. Individuals are

selected due to their unique relationship to the topic and the questions are gradually developed and open-ended.

- 7.4 Projects involving oral history interviews where the historian (PI) follows the Oral History Associations Principles and Standards and Evaluation Guidelines as part of his or her work.
- 7.5 Oral history projects involve interviews in which those being interviewed fully understand the purposes, potential uses and their freedom not to answer questions. In most cases, the narrators are required to sign a release that addresses copyright and terms of access and reproduction (for interviews deposited in a library or archives), identification of narrators, and disposition of tapes

IRB Responsibilities Related to Exempt Research

The IRB ensures valid claims of exemption by reviewing the proposed research via an IRB application. A designated IRB member determines that the study is exempt from further IRB review and from applicable federal regulations governing human research, under 45 CFR 46.101(b) or according to University of Utah IRB policy. All research involving human subjects must be approved or exempted by the IRB before the research is conducted.

The IRB determines that the study is in compliance with applicable laws and regulations, including the HIPAA Privacy Rule, state law, and institutional policy.

The IRB determines that the study conforms to the principles of sound research ethics, in accordance with principles of the Belmont Report, as follows:

- 1.0 The research holds out no more than minimal risk to participants
- 2.0 The selection of subjects is equitable
- 3.0 If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data
- 4.0 If there are interactions with participants, there is a consent process that will disclose such information as:
 - 4.1 That the activity involves research
 - 4.2 A description of the procedures
 - 4.3 That participating is voluntary
 - 4.4 Name and contact information for the investigator
- 5.0 There are adequate provisions to maintain the privacy interest of participants
- 6.0 The research is conducted in an ethical manner which does not adversely affect the rights and welfare of the participants

Investigator Responsibilities Related to Exempt Research

- 1.0 The investigator submits proposed research to the IRB for review using the IRBNet online management system
- 2.0 The investigator begins research activities after documentation of IRB approval or exemption is received
- 3.0 The investigator ensures that the study is conducted in compliance with applicable laws and regulations, including the HIPAA Privacy Rule, state law, and institutional policy
- 4.0 The investigator ensures that the study conforms to the principles of sound research ethics, in accordance with principles of the Belmont Report, including but not limited to:
 - 4.1 Ensuring the research presents no more than minimal risk to participants
 - 4.2 Selecting subjects equitably
 - 4.3 If there is recording of identifiable information, maintaining the confidentiality of the data
 - 4.4 If there are interactions with participants, conducting a consent process that will disclose such information as:
 - 4.4.1 That the activity involves research
 - 4.4.2 A description of the procedures
 - 4.4.3 That participating is voluntary
 - 4.4.4 Name and contact information for the investigator
 - 4.4.5 Maintaining the privacy interest of participants
 - 4.4.6 Conducting the research in an ethical manner which does not adversely affect the rights and welfare of the participants
- 5.0 The investigator conducts the research in compliance with the protocol as submitted to and exempted by the IRB
- 6.0 The investigator obtains approval for all changes to the protocol prior to implementing the changes
- 7.0 The investigator adheres to IRB policy for reporting unanticipated problems and deviation

Regulated Documentation

[45 CFR 46.101\(b\)](#) – Categories of Exempt Human Subjects Research

References

[45 CFR 46.101\(b\) Categories of Exempt Human Subject Research](#)

[USA IRB: Getting Started- Determine Which Type of IRB Review Applies to Your Research](#)

[DHHS Office of Human Research Protections FAQs: Exempt Research Determinations](#)

HISTORY

Effective Date:

Revisions: November, 2018