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.

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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