SOP 502J: Categories of Research – Social Behavioral

1. POLICY

The IRB shall review social/behavioral research involving human participants. Methods employed to carry out this type of research often involve direct/indirect participant observation, questionnaires or surveys, interviews, or review and analysis of existing data.

Specific Policy

1.1 Social/Behavioral Research

The review of studies involving social/behavioral research may be appropriate for either expedited review or convened IRB review. Additional review by other University committees, such as the Cancer Institute Scientific Review Committee (SRC), may be required.

The IRB considers the methods used in the research project and storage of data. Audiotaping, videotaping, and photography may be used in social/behavioral research. Plans to store and ultimately destroy these forms of data must be clearly described in the research protocol as well as in the informed consent documents.

Deception in social research is a method sometimes used in social/behavioral research. The IRB considers the following issues when reviewing research that involves deception:

A. The scientific value and validity of the research.
B. The ability to obtain the information without the use of deception.
C. Whether the deception used will influence the participants’ willingness to participate.
D. The possibility of harm to the participants and a plan for debriefing, which must be conducted as soon as possible after the conclusion of the research project. Participants shall be given the opportunity to withdraw from the research project. After debriefing, the participant may request that any data collected from them be deleted and/or destroyed.
E. The possibility that the deception may cause invasions of privacy.

1.2 Community-Based Participatory Research (CBPR)

The HRPP is committed to supporting the active engagement of communities in University research and to promoting research designed to engage the communities served by the University. Community-based participatory research (CBPR) is a form of community engaged research involving a collaborative approach for protocol development, community member participation, shared decision-making, dissemination of research results, and mutual ownership in all aspects of the research processes among communities affected by the issue being studied, investigators, and organizational representatives.

IRB members and/or consultants with CBPR expertise are asked to review community-based participatory research projects at the University. The IRB
reviewer will consider regulatory requirements related to investigator engagement, performance sites, and involvement of special populations, including, as appropriate:

1. Key Study Personnel Training requirements
2. Institutional and/or individual investigator agreements
3. Involvement of community advisory boards
4. The process for conducting a formative assessment with community members to develop the research protocol
5. Involvement of participant advocates
6. Establishing collaborations with community-based organizations
7. Discussion in the research protocol of the process that will be used to disseminate any changes to the research project, any protocol deviations or unanticipated results and the research results.

1.3 Types of Risks 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 participants because of exposure to potential criminal or civil liability and/or damage to financial standing or employability

1.4 Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research-Application of Subpart B in Social Behavioral Research

For additional guidance on pregnant women in social/behavioral research, see SOP 501, Special Populations.

1.5 Deception (for OU Norman campus only)

Deception in social research is a method sometimes used in social/behavioral research. Generally, deception falls into one of two categories:

1. Concealment, which involves withholding information about the specific purpose or procedures of the research without providing false or misleading information to the research participant, or
2. **Direct Deception**, which involves providing false or misleading information to the research participant.

In studies in which deception is proposed, the IRB considers the following issues when determining risk related to the use of deception in the research:

A. The scientific value and validity of the research. For example, does the deception improve the internal or external validity of the research project?

B. The ability to obtain the information without the use of deception. Why is deception a necessary and unavoidable component of the experimental design?

C. Whether the deception used will influence the participants’ willingness to participate.

D. The possibility of harm to the participants because of exposure to the deception.

E. The quality of the plan for debriefing, which must be conducted as soon as possible after the conclusion of the research project. As a component of debriefing, participants should be given the opportunity to withdraw their consent to participate in the research project by requesting that any data collected from them be deleted and/or destroyed.

F. The possibility that the deception may cause invasions of privacy.

The OU NC IRB policy allows for studies that involve concealment to be reviewed by expedited procedures provided that the study involves no greater than minimal risk and does not involve protected groups or special populations. However, the IRB reviewer has the option of requesting that a determination of the level of deception be made by a convened IRB. Debriefing is always required in cases of direct deception; however, it may not be required in cases of concealment.

The debriefing is to be provided to the participants at completion of the research project and shall include a full explanation of the purpose of the research project. At the debriefing, the participant is given the opportunity to withdraw participation by means of requesting that his/her data be withdrawn from the research project.

2. **SCOPE**

This SOP applies to all social/behavioral research.

3. **RESPONSIBILITY**

3.1 The HRPP Director is responsible for maintaining up-to-date tools for review of this type of research and to notify the appropriate entities if the IRB disapproves the human research protocol.

3.2 The IRB Chair or IRB designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting one Primary and one Secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select Primary and Secondary reviewers with the relevant expertise, the IRB Chair or IRB designee shall defer
the review to another IRB with Primary and Secondary reviewers with the relevant expertise or obtain consultation for that expertise.

3.3 The IRB Reviewer is responsible for conducting appropriate review of research planned for these categories in consultation with appropriate experts and resources.

3.4 The IRB Administrator is responsible for requesting changes to the study protocol from the investigator and sending the results of the IRB review to the investigator.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46
21 CFR 50, 56
OHRP Guidance Document, IRB Guidebook

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements.
SOP 401: Research Exempt from IRB Review
SOP 402: Expedited Review
SOP 403: Initial Review – Criteria for IRB Approval

6. ATTACHMENTS

203-A  HSC Reviewer Checklist
502J-A-1  Debriefing Template

7. PROCESS OVERVIEW

7.1 The Investigator or Investigator’s staff submits a new study application and uploads all applicable documents into the IRB electronic information system.

7.2 The submission is received in the IRB Office and processed (see SOP 301: Research Submission Requirements and SOP 403: Initial Review – Criteria for IRB Approval). The submission with all applicable documents made available to all IRB members.

7.3 The IRB Administrator conducts a pre-review of the submission and verifies all necessary documents are received.

7.4 The IRB Administrator assigns the submission either to (1) the appropriate Board agenda or (2) to the IRB Chair/IRB designee (b).

7.5 If assigned to an IRB agenda, the process follows SOP #403: Initial Review – Criteria for IRB Approval
7.6 If assigned to IRB Chair / IRB Designee, the process follows SOP #402: Expedited Review

7.7 Following review of the submission, the IRB Administrator updates the outcome of the IRB review and communicates the outcome and any stipulations to the Investigator. The IRB Administrator posts the final IRB approval to the next appropriate IRB agenda.

7.8 Enrollment into the research project may not commence until all required institutional committees have completed their review and the contract is signed, if applicable

APPROVED BY: ________________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016