OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #502.3 Revision 3	**TITLE: Protection of Vulnerable Populations**	Effective Date: 1/19/2018
Approved By: OIRB Director	Signature	Date 1/19/2018
Approved By: IRB Chair	Signature	Date 1/19/2018

PURPOSE

To describe policies and procedures for reviewing research involving vulnerable participants.

REVISIONS FROM PREVIOUS VERSION

Update to title and other administrative changes.

POLICY

The University of New Mexico (UNM) Institutional Review Board (IRB) gives special consideration to protecting the welfare of vulnerable research participants such as children, prisoners, fetuses/neonates, pregnant women, and individuals with decisional capacity impairment. The IRB also recognizes that additional populations such as students may qualify as vulnerable populations and need safeguards in place for their protection during participation in research.

RESPONSIBILITIES

Execution of SOP: Researchers, IRB, OIRB Staff

PROCEDURE

Screening and Educational Guidance

1. The PI identifies the categories of vulnerable participants involved in the research in the Project Information form and protocol.
2. When research on vulnerable participants is conducted outside the state of NM, the PI identifies the state law(s) applicable to the determination of legally authorized representative and age of majority and may contact UNM Office of University Counsel for review and determination prior to review by the IRB.
3. Upon receipt of an IRB submission, OIRB staff conduct a pre-review. When applicable, OIRB staff provide supplemental materials to the IRB on the regulations pertaining to vulnerable participants as outlined in the applicable review SOPs.
4. The OIRB, IRB Chair, or designee requests a consultant review if additional expertise is needed.
5. IRB membership includes representation with expertise in selected vulnerable populations routinely reviewed by the IRB, such as children or prisoners. OIRB staff pre-review the submission to ensure that designated representatives review research involving prisoners or research involving children that is greater than minimal risk or requires consultation for other issues. Depending upon the type of review, designated representatives either attend the convened meeting or provide comments in writing.

IRB Review Process

1. The IRB reviews the project to determine whether the protocol includes enrollment of vulnerable populations and whether appropriate safeguards are in place.
2. As applicable, the IRB considers the following elements when reviewing research involving vulnerable populations:
   - Inclusion/exclusion criteria;
   - Over-selection or exclusion of certain groups based on perceived limitations (i.e. targeting prisoners as research participants because they are a readily available "captive" population);
   - Knowledge of applicable or local laws that bear on the decision-making process (i.e. emancipated individuals, legally authorized representatives, age of majority for research consent).
3. The IRB follows applicable federal and state regulations and IRB policy to assist in reviewing and approving proposed research that involves vulnerable populations such as:
   - Pregnant Women, Human Fetuses and Neonates (45 CFR 46, Subpart B).
   - Research Involving Prisoners (45 CFR 46, Subpart C). Prisoner representatives review IRB applications involving prisoners. Note that non-federally funded research that would otherwise be subject to the requirements at 45 CFR 46.306 is handled locally, not through the Secretary of HHS.
   - Research Involving Children (45 CFR 46, Subpart D, 21 CFR 50, Subpart D and U.S. Department of Education, Subpart D) – note that non-federally funded research that would otherwise be subject to the requirements at 45 CFR 46.407 is handled locally, not through the Secretary of HHS.
   - Research involving students (Guidance on Research in K-12 Schools).
   - Review of Minimal Risk Research Not Covered by Federalwide Assurance (SOP 205).
   - Guidance on Assessing and Minimizing Risk in Human Research.
4. If a participant is pregnant, the IRB will determine whether approval criteria are met for consent and permission and document that equivalent criteria for non-DHHS regulated research is used. Non-federally funded projects involving pregnant women that are more than minimal risk are subject to the requirements at 45 CFR 46 Subpart B with the exception of the requirement at 45 CFR 46.204(d) which requires the research develop "important biomedical knowledge", which precludes most social and behavioral sciences research with pregnant women.
5. If a participant becomes a prisoner while enrolled in a research project that was not reviewed according to Subpart C and Subpart C applies:
   a. Confirm that the participant meets the definition of a prisoner.
   b. Withdraw the participant or review the project under Subpart C if it feasible for the participant to remain enrolled.
   c. Before withdrawing the incarcerated participant, the IRB should consider the risks associated with terminating participation.
6. If the participant cannot be withdrawn for health or safety reasons:
   a. Keep the participant enrolled and review the project under Subpart C.
   b. If some the requirements of Subpart C cannot be met, but it is in the best interests of the participant to remain enrolled, keep the participant enrolled and inform OHRP, if applicable, of the decision along with the justification.
7. The IRB considers each of the specific findings required by federal regulations and/or institutional policy for research involving vulnerable participants, as documented by IRB approval. IRB approval also documents that the IRB members acknowledge and agree with the preliminary description of

safeguards and risk assessment of the protocol as described in the application by the PI. OIRB staff document in the minutes discussions of controverted issues at convened meetings.

8. OIRB staff document specific findings in the meeting minutes, or IRB reviewers document determinations in accordance with applicable IRB SOPs. The IRB does not reapply the categories during subsequent reviews unless changes to the protocol dictate otherwise.

REFERENCES

45 CFR 46 Subpart B
45 CFR 46 Subpart C
45 CFR 46 Subpart D
21 CFR 50 Subpart D
34 CFR 97 Subpart D
34 CFR 98.4