Standard Operating Procedures

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<th>SOP #502.2 Revision 2</th>
<th>TITLE: Protection of Vulnerable Subjects</th>
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<td>Approved By: OIRB Director</td>
<td>Signature</td>
<td>Date 8/21/2016</td>
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<td>Approved By: IRB Chair</td>
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PURPOSE
To describe policies and procedures for reviewing research involving vulnerable subjects

REVISIONS FROM PREVIOUS VERSION
Administrative corrections; addition of reference to SOP 205

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 consent 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 study participation.

RESPONSIBILITIES
Execution of SOP: Researchers, IRB, OIRB Staff.

PROCEDURE
Screening and Educational Guidance

1. The PI identifies the categories of vulnerable participants (e.g. individuals with consent capacity impairment, children, prisoners, pregnant women, and students) involved in the research in the Project Information form and study 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 contacts UNM legal counsel for review and determination prior to approval 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 Initial Full Review and Initial Expedited 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 screen 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 study protocol includes enrollment of vulnerable subjects and whether appropriate safeguards are in place.

2. As applicable, the IRB considers the following elements when reviewing research involving vulnerable subjects:
   - Inclusion/exclusion criteria;
   - Over-selection or exclusion of certain groups based on perceived limitations (i.e. targeting prisoners as research subjects 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 subjects such as:
   - Pregnant Women, Human Fetuses and Neonates (45 CFR 46, Subpart B)
   - Research involving students (IRB Guidance on Research in the Classroom)
   - Review of Research Not Covered by Federalwide Assurance (SOP 205)

4. If a participant is pregnant, the IRB will determine whether approval criteria are met for consent and permission and documents that equivalent criteria for non-DHHS regulated research is used.

5. If a participant becomes a prisoner while enrolled in a research study that was not reviewed according to Subpart C and Subpart C applies:
   a. Confirm that the participant meets the definition of a prisoner.
   b. Terminate enrollment or review the research study under Subpart C if it feasible for the participant to remain in the study.
   c. Before terminating the enrollment of the incarcerated participant the IRB should consider the risks associated with terminating participation in the study.

6. If the participant cannot be terminated for health or safety reasons:
   a. Keep the participant enrolled in the study and review the research 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 in the study, keep the participant enrolled and inform OHRP of the decision along with the justification.
   c. Remove the participant from the study and keep the participant on the study intervention under an alternate mechanism such as compassionate use, off label use, etc.

7. The IRB considers each of the specific findings discussed in the IRB application forms for research involving vulnerable subjects, 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 exempt/expedited 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.

9. The IRB may require review more frequently than once a year for protocols involving vulnerable populations based on the nature of the research and the level of risk. Non-federally funded minimal risk faculty research involving vulnerable populations may qualify for continuing review every two years.

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