University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
Revision #9	**TITLE: Protection of Vulnerable Subjects**		**Page 1 of 3**
Approved By: ORI Director	Signature	Date	Date First Effective: 06-27-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 02-15-19

OBJECTIVE

To describe policies and procedures for reviewing research involving vulnerable subjects

GENERAL DESCRIPTION

The University of Kentucky (UK) Institutional Review Board (IRB) gives special consideration to protecting the welfare of vulnerable subjects such as children, prisoners, fetuses/neonates, individuals with impaired decision-making capacity, and/or economically or educationally disadvantaged persons. 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.

RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/Study Personnel, IRB, Office of Research Integrity (ORI) Staff

PROCEDURES

Screening and Educational Guidance

1. The PI identifies the categories of vulnerable subjects (e.g., individuals with impaired decision-making capacity, fetuses/neonates**,** economically or educationally disadvantaged persons, children, prisoners, and students) involved in the research in the IRB application.

2. When research on vulnerable subjects is conducted outside the state of Kentucky, the PI identifies the state law(s) applicable to the determination of legally authorized representative and contacts UK legal counsel for review and determination prior to approval by the IRB. If the PI is unable to identify applicable state law(s), the PI contacts UK legal counsel for assistance prior to approval by the IRB.

3. The investigator also provides specific information in the IRB initial review application which focuses on ethical and regulatory issues pertaining to conduct of research involving vulnerable subjects.

4. ORI staff conduct a preliminary screening of an IRB application upon receipt.

5. IRB membership includes representation with expertise in selected vulnerable populations routinely reviewed by the IRB, such as children or prisoners. ORI staff screen the application to ensure that designated representatives review research involving prisoners, children, or if the application requires consultation for other issues. Depending upon the type of review, designated representatives either attend the convened meeting or provide comments prior to the meeting.

6. The ORI, IRB Chair, or designee requests a consultant review if additional expertise is needed. (See Initial Full Review, Expedited Initial Review, Continuing Review, or Modification, Deviations, and Exceptions IRB Review of Changes SOPs.)

Protocol Review Process

1. The IRB reviews the IRB application to determine whether the 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;
   - 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 context/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 Prisoners (45 CFR 46, Subpart C) Prisoner representatives review IRB applications involving prisoners. Under the Kentucky Administrative Regulations applicable to county jails (not federal prisons), inmates may not participate in medical research (i.e., drug, device, biologic clinical trials);
   - Research Involving Children (45 CFR 46, Subpart D, 21 CFR 50, Subpart D and 34 CFR 97, Subpart D) – (See guidance in IRB Policy on Children in Research and the Informed Consent SOP).

- Research Involving Individuals with Impaired Decision-Making Capacity – (See guidance in the UK Impaired Decision-Making Capacity Policy, and the Informed Consent SOP);
- Research involving economically or educationally disadvantaged persons;
- Research involving UK students – (See the IRB Guidance for Enrolling University Students as Subjects);
- Research involving K-12 students – (See the IRB Guidance for Enrolling K-12 Students as Subjects).

4. 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 the risk assessment of the protocol as described in the application by the PI. ORI staff document discussions of controverted issues at convened meetings in the meeting minutes.

5. Specific findings are either documented by ORI staff in the meeting minutes (i.e., for protocols reviewed by the convened board) or by exempt/expedited reviewers in their determinations in accord with applicable IRB/ORI SOPs. The IRB does not reapply the categories during subsequent reviews unless changes to the protocol warrant such review.

6. The IRB requires more frequent review (i.e., issue an approval period shorter than 12-months) for protocols involving vulnerable populations based on the nature of the research and the level of risk.

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