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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: 11-06-09

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, 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.

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 consent capacity impairment, children, prisoners, pregnant women, and students) involved in the research in the IRB application (e.g., General Information Sheet, Inclusion/Exclusion Criteria discussion in the Research Description).
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.

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3. In addition, the investigator completes specific forms in the IRB initial review application which focus on ethical and regulatory issues pertaining to conduct of research involving pregnant women, neonates, fetuses, prisoners, children, and individuals with impaired consent capacity.
4. Upon receipt of an IRB application, ORI staff conduct a preliminary screening. When applicable, ORI staff provide Protocol Specific Training (PST) materials to the IRB on the regulations pertaining to vulnerable subjects as outlined in the Initial Full Review and Expedited Initial Review SOPs. ORI staff reference in the agenda for individual studies the applicable PST materials in the IRB Survival Handbook.
5. 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.)
6. 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 children or prisoners. Depending upon the type of review, designated representatives either attend the convened meeting or provide comments in writing.

Protocol Review Process

1. The IRB reviews the IRB application 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:

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- Pregnant Women, Human Fetuses and Neonates (45 CFR 46, Subpart B) - (See guidance in the IRB Survival Handbook PST materials and Form U in the IRB application). Investigators may not conduct research involving fetuses or in vitro fertilization at the Veterans Affairs Medical Center (VAMC), and investigators may not include pregnant women as research subjects at the VAMC unless specific requirements are met;
 - Research Involving Prisoners (45 CFR 46, Subpart C) – (See guidance including the PST materials and Form V in the IRB application). Prisoner representatives review IRB applications involving prisoners. Investigators may not include prisoners in research conducted at the VAMC unless the Chief Research and Development Officer grants a waiver. 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 U.S. Department of Education, Subpart D) – (See guidance in the IRB Survival Handbook including PST materials, IRB Policy on Children in Research, Form W in the IRB application, and the Informed Consent SOP). VA investigators may not include children in research conducted while the investigators are on official duty or at VA-approved off-site facilities unless the Chief Research and Development Officer grants a waiver. (Prior to requesting a waiver, the investigator must ensure that the research meets certain criteria);
 - Research Involving Individuals with Impaired Consent Capacity – (See guidance in the IRB Survival Handbook including PST materials, UK Impaired Consent Capacity Policy, Form T of the IRB application, the VA Research: Reviewer Checklist, and the Informed Consent SOP);
 - 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 risk assessment of the protocol as described in the application by the PI. ORI staff document in the minutes discussions of controverted issues at convened meetings.
 5. ORI staff document specific findings in the meeting minutes, or exempt/expedited reviewers document determinations in accord with applicable IRB/ORI SOPs. The IRB does not

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reapply the categories during subsequent reviews unless changes to the protocol dictate otherwise.

6. 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.

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
Veterans Health Administration Handbook 1200.05