



SOP Title	Protection of Vulnerable Subjects				
Date Last Revised	12/06/2018	Date Created	08/22/2018	Revision #	2.0
SOP Number	25	Required by:	<input checked="" type="checkbox"/> OHRP <input type="checkbox"/> Funding Agency <input type="checkbox"/> OLAW		
Applicability	<input type="checkbox"/> RGC Internal <input type="checkbox"/> Researcher		<input checked="" type="checkbox"/> Institutional		
Subgroup	<input type="checkbox"/> NKU Compliance	<input checked="" type="checkbox"/> IRB	<input type="checkbox"/> IACUC	<input type="checkbox"/> IBC	

1.0 PURPOSE

To describe policies and procedures for reviewing research involving vulnerable subjects

2.0 GENERAL INFORMATION AND SCOPE

The Northern Kentucky University (IRB) 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 decision-making or consent capacity impairments. 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.

3.0 PROCEDURES

A. SCREENING AND EDUCATIONAL GUIDANCE

1. The Principal Investigator (PI) identifies the categories of vulnerable subjects (e.g., individuals with decision-making or consent capacity impairments, children, prisoners, pregnant women, and students) involved in the research in the IRB application within Mentor IRB.
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 NKU 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 NKU legal counsel for assistance prior to approval by the IRB.
3. Upon receipt of an IRB application, the IRB Administrator conducts a preliminary screening. And, when applicable, provides Protocol Specific Training (PST) materials to the IRB on the regulations pertaining to vulnerable subjects.
4. The IRB Administrator, IRB Chair, or Manager of Research Compliance 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. The IRB Administrator screens the application 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.

B. 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 for all research submitted to the IRB to assist in reviewing and approving proposed research that involves potentially vulnerable subjects such as:
 - [Subpart B](#) - Pregnant Women, Human Fetuses and Neonates ([45 CFR 46, Subpart B](#))
 - [Subpart C](#) - Biomedical and Behavioral Research Involving Prisoners as Subjects ([45 CFR 46, Subpart C](#))
 - [Subpart D](#) – Children Involved as Subjects in Research ([45 CFR 46, Subpart D](#) and [U.S. Department of Education, Subpart D](#))
 - Research Involving Individuals with Impaired Decision Making Capacity
 - Research involving NKU students
 - Research involving K-12 students
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. The IRB Administrator documents in the minutes discussions of controverted issues at convened meetings
5. IRB 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 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.

4.0 REFERENCES

- [45 CFR 46 Subpart B](#)
- [45 CFR 46 Subpart C](#)
- [45 CFR 46 Subpart D](#)
- [34 CFR 97 Subpart D](#)

5.0 FORMS OR ATTACHMENTS

6.0 DEFINITIONS

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	11/15/2018	<input type="checkbox"/>
IRB Chair	<input checked="" type="checkbox"/>	11/15/2018	<input type="checkbox"/>
Institutional Official	<input checked="" type="checkbox"/>	11/15/2018	<input type="checkbox"/>

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	<input checked="" type="checkbox"/>	12/06/2018	<input type="checkbox"/>	Addition of revised common rule information.
IRB Chair	<input checked="" type="checkbox"/>	12/06/2018	<input type="checkbox"/>	
Institutional Official	<input type="checkbox"/>		<input type="checkbox"/>	