Marshfield Clinic

Vulnerable Populations

1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. **Vulnerable Populations**: Vulnerable populations include at a minimum, pregnant women, human fetuses, neonates, prisoners, children, mentally disabled persons or economically or educationally disadvantaged persons, institutionalized individuals, and persons in emergent care settings. Other groups may, depending on specific circumstances of the study be considered vulnerable. An individual is not considered part of vulnerable population if the researcher is unaware of or would not reasonably be expected to be aware of subject's vulnerable status.

LIVE

3. PROCEDURE BODY

Purpose is to define vulnerable populations, to note additional approval criteria and safeguards that must be met prior to IRB approval of research involving certain vulnerable populations, and to suggest additional safeguards for investigators and the IRB to consider for research involving other vulnerable populations.

3.1. Background

a. 45 CRF 46.111(b) requires that when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, additional safeguards must be included in the study to protect the rights and welfare of these subjects. Three subparts of these regulations add to this requirement by providing distinct approval criteria and additional safeguards that must be in place prior to IRB approval of a research activity involving **pregnant women, human fetuses and neonates, prisoners and children.**

3.2. Process

a. When it is evident that vulnerable populations will be involved in a research project, the investigator and the Institutional Review Board (IRB) must give special consideration to the research in an effort to ensure that appropriate additional safeguards are in place for subjects who are likely to be vulnerable to coercion or undue influence. The investigator and the IRB will consider special protections for studies targeting vulnerable populations on a case-by-case basis. In general, the extent of additional safeguards implemented will depend upon the risk of harm, the likelihood of benefit, and other protections afforded by state and federal law.

PROCEDURE

b. For research supported by Department of Health & Human Services (DHHS) and involving pregnant women, human fetuses, neonates, prisoners, and children, the investigator must ensure that the required safeguards within the applicable Subparts of 45 CFR 46, as outlined in the IRB Application form, are part of the research plan and so conveyed in the material submitted to the IRB. The IRB will then make a determination that the specific approval criteria are met and required safeguards are planned prior to approving the study.

c. No standard safeguards or approval criteria exist for research that targets other vulnerable populations (e.g., mentally disabled, economic or educationally disadvantaged, persons in emergent care settings, etc.). Therefore, for any of these other vulnerable populations, the investigator must propose additional safeguards and the IRB will determine whether those safeguards are adequate. The IRB may, depending on the circumstances of the study, determine that subjects beyond those proposed by the investigator are also vulnerable and may dictate additional safeguards.

d. Additional safeguards (beyond those dictated by Subparts) to consider include:

   - The IRB is given the authority by federal regulations (.109(e)) to observe or have third party observe the consent process and the research. The use of a consent monitor or an otherwise uninvolved individual to witness the consent process and verify the subject's understanding and willingness to participate should be considered, especially when the research is of high risk or involves no direct benefit to the vulnerable subjects.
   - Assent by individuals who may not have the capacity to give legal informed consent in addition to the consent of their legal guardian.
   - Co-consent of an immediate family member
   - When a vulnerable population's capacity to understand the risks, benefits and alternatives of the research is in question, consideration should be given to requiring a formal assessment of the potential subject's decision-making capacity. This should include consideration of how the assessment will be made (e.g., with a validated instrument vs another technique), who may make the assessment, whether the assessment must be documented, and the need for periodic re-evaluation of decisional capacity and/or re-consent of subjects at key study intervals.

e. If a study did not originally propose to involve pregnant women, human fetuses, neonates, children or prisoners, but the investigator later wishes to enroll these subjects, an amendment must be submitted and approval obtained prior to their involvement in the research. A study that did not originally plan but is later revised to target other vulnerable populations (mentally disabled, economically or educationally disadvantaged persons, persons in emergent care setting, etc.) must also be re-submitted in the form of an amendment to the IRB for review and prior approval.

Live
PROCEDURE

4. ADDITIONAL RESOURCES

4.1. References:
- None

4.2. Forms:
- Change or Update to Original Submission Form

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control transferred from Policy & Handbook Library - #1717.0 (format changes made due to new DC system)
2.0	
3.0	

6. DOCUMENT PROPERTIES

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