

PARKVIEW HEALTH	INSTITUTIONAL REVIEW BOARD MANUAL
Policy & Procedure Title: Vulnerable Populations Category: IRB Review Process	

I. Policy Statement

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, PH IRB shall determine that additional safeguards have been included in the study to protect the rights and welfare of these subjects. If a Protocol requires, or an Investigator wishes to include members of a Vulnerable Population, then the Investigator must demonstrate how adequate protections will be provided for these subjects.

II. Definition of Terms

Vulnerable Population: Those individuals who may have diminished autonomy related to certain social, legal, psychological, intellectual, economic, or physical conditions to a degree that leaves them susceptible to coercion or undue influence. Vulnerable Populations as designated by regulations are:

- Children
- Pregnant women
- Human Fetuses
- Neonates
- Prisoners
- Handicapped persons
- Mentally disabled persons
- Economically disadvantaged persons
- Educationally disadvantaged persons

There may be additional Vulnerable Populations as determined by study specifics, such as the elderly, racial minorities, the very sick, and the institutionalized.

Coercion or undue influence: Some degree of force or encouragement to do something that may not be good for oneself, thereby compromising one's ability to control one's own destiny. In the absence of coercion or undue influence, study participation is "voluntary".

Children: Persons who have not reached the age of majority. In Indiana this is anyone under the age of 18.

Handicapped/Physically Impaired: Having physical impairment(s) (visual, hearing, speech) that would prevent normal communication.

Mentally Disabled/Cognitively Impaired: Having diminished capacity to understand verbal and/or written information.

Educationally Disadvantaged: Persons who are illiterate or unable to comprehend the information presented to them.

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Economically Disadvantaged: Persons who may lack access to adequate income, housing, or health care, such that badly needed benefits may seem to be only available through research.

Pregnant Women: Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

Fetus: The product of conception from implantation until delivery.

Neonate: A newborn (less than one month old).

Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Legally Authorized Representative (LAR): A person who, by relation or legal appointment, acts in the best interest of an individual who is deemed incapable, by law, of giving informed consent.

III. Procedure

- A. The PH IRB New Protocol Submission Form and Protocol will be reviewed to determine if the study targets a Vulnerable Population or if the possibility exists for enrolling members of Vulnerable Populations. If additional safeguards are not specified, the PH IRB will determine if additional safeguards must be implemented to include the enrollment of a Vulnerable Population(s) in the study.
- B. During the review of any study involving Vulnerable Populations, in addition to normal review procedures, the PH IRB will consider the following:
 1. Specific Considerations: Are there special vulnerabilities unique to each particular class of Vulnerable Populations that are included in this study that have yet to be addressed?
 2. Information concerning these considerations for Pregnant Women, Prisoners, and Children can be found in the Code of Federal Regulations [21 CFR 56.111\(3\)](#), [45 CFR 46.111\(3\)](#), [45 CFR 46.Subpart B](#), [45 CFR 46.Subpart C](#), [45 CFR 46 Subpart D](#).

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- C. Information concerning the above may be contained in the Protocol and PH IRB New Protocol Submission Form as part of the study submission. Other specific information may be sought from the Investigator.
- D. Individuals with experience and competence in special areas may be invited to assist in the review of complex issues which require expertise beyond or in addition to that available on the PH IRB. These individuals may not vote with the PH IRB.
- E. The following table demonstrates certain Vulnerable Populations and special precautions that will be employed if, in the opinion of the Investigator or designee, a potential or existing subject has compromised autonomy related to research participation. An opportunity will be provided on the PH IRB New Protocol Submission Form to add other Vulnerable Populations and the special precautions that will be implemented. The Investigator may also specify other special precautions in addition to those which are listed in the table.

Vulnerable Population	Special Precautions
Mentally Disabled/Cognitively Impaired	A LAR will be present to aid in the decision making process and, when applicable, throughout the study. Ample time will be allowed for discussion and to consider study participation. The LAR's signature will be required on the ICF.
Handicapped/Physically Impaired	A subject advocate who is not affiliated with the research or the investigator will be present to aid in the decision making process and, when applicable, throughout the study. Ample time will be allowed for discussion and to consider study participation.
Economically Disadvantaged	PI or designee will ensure that the compensation is reasonable and not so large as to induce subjects to enroll or stay in the study, and will not be presented in a manner that may be coercive. Payment will not be contingent upon completion of the entire study. There is a plan to pro-rate payments.
Educationally Disadvantaged	Person conducting consent discussion will review each section of the ICF with the potential subject and pose questions after each section to ensure an adequate understanding. For an illiterate subject, a subject advocate who is not affiliated with the research or the Investigator, will be present to aid in the decision making process during the presentation of and signing of the ICF and when applicable, throughout the study. The subject advocate will also sign the ICF as a witness.
Non-English Speaking	If the PI consents a non-English speaking subject, a PH IRB approved, translated ICF or Short Form will be used. The PI will also provide someone who is capable of answering questions in the language of the non-English speaking subject during the consent process and throughout the study.
Children (Under age 18)	A child's parent(s) or legal guardian(s) will accompany a child during the informed consent process, and when applicable, throughout the study. Assent will be obtained for children 7 years or older unless assent is waived by the PH IRB. The child will be

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	given ample opportunity to decide, independently, whether or not to participate in the study.
Pregnant Women	Pregnant women will be fully informed regarding the foreseeable impact of the research on the fetus or resultant child. In addition, the individuals engaged in research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy and will have no part in determining the viability of the fetus. No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
Prisoners	PH IRB does not review studies in which prisoners are the targeted population. If a subject becomes a prisoner while participating in a study, the PI will promptly notify the PH IRB and all study procedures and interactions will be suspended until the requirements of 45 CFR 46 Subpart C are met.

- F. The PH IRB may determine additional safeguards are needed for vulnerable subjects. Additional safeguards may include:
1. Ensuring subjects' understanding by requiring prospective subjects to take a test or to independently write or dictate their understanding of the research and its risks;
 2. Obtaining an independent assessment by a physician not involved in the case;
 3. Employing a consent monitor to independently verify that informed consent has taken place;
 4. Providing prospective subjects with an advocate during the consent process;
 5. Providing additional opportunities for prospective subjects to decline to participate or to end their participation in the study;
 6. Asking for certification of the financial billing / costs of the study in writing from providers (institution or office);
 7. Other actions as decided by the PH IRB.
- G. PH IRB shall determine if the monitoring plan for the study is adequate to the degree of risk involved and appropriate to ensure that this Vulnerable Population is protected.
- H. When a Vulnerable Population is involved in a study, the special precautions implemented shall be documented in the patients' medical record.

IV. References

- A. FDA: 21 CFR 56 Institutional Review Boards:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=56>
- B. OHRP: 45 CFR 46 Protection of Human Subjects:
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

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C. Amdur, Robert J. & Bankert, Elizabeth A., 2007, Institutional Review Board-Member Handbook, Second Edition, Sudbury, MA, Jones and Bartlett Publishers.

D. Indiana Code 16-36: Medical Consent:
<http://www.in.gov/legislative/ic/code/title16/ar36/ch1.html>

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