

Title:	Research Involving Vulnerable Populations
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director
	<i>Signature/date</i>
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POLICY STATEMENT

The Institutional Review Board (IRB) and the IRO staff shall follow special procedures with respect to inclusion of vulnerable populations in research studies. A systematic evaluation of initial applications, continuation reviews, and modifications to research studies will be conducted to determine if part or all of the targeted population is or may be considered to be a vulnerable population. In all cases where a vulnerable population is identified, additional safeguards will be followed. The IRB review will include the review by IRB members and if necessary, consultants to the IRB that have the specific scientific or scholarly knowledge and expertise of the identified vulnerable population to protect the rights and welfare of the vulnerable population and assure that there is no undue influence or coercion.

DEFINITIONS

Children: Persons who have not attained the legal age to consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In most states, including Washington State, the legal age at which a person is able to consent to participate in research is 18 years. Investigators should check appropriate State laws and regulations before conducting research to determine the definition of a child for the purposes of participation in research studies. In the case of research studies conducted outside the United States, the relevant laws and regulations of the research participants' country of residence should be applied.

Decisionally Impaired: Persons whose decision-making capacity is restricted, wholly or in part, due to illness, mental disability or other circumstances.

Fetus: The product of conception from implantation until delivery.

Neonate: A living newborn infant.

Prisoners: An individual involuntarily confined or detained in a penal or correctional institution. The term is intended to encompass individual's sentenced to such as 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.

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

Vulnerable populations: Prospective research participants who lack the capacity to provide informed consent or who are likely to be vulnerable to coercion or undue influence. Examples include children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

REFERENCES

45 CFR 46 Subpart A
45 CFR 46 Subpart B
45 CFR 46 Subpart C
45 CFR 46 Subpart D
45 CFR 46.107(a)
45 CFR 46.111(b)
45 CFR 46.204
45 CFR 46.205
45 CFR 46.304
21 CFR 50
21 CFR 50.3
21 CFR 56.107(a)
21 CFR 56.111(b)
21 CFR 56.111(c)
OHRP Common Findings 3 & 47 & 48 & 74
OHRP Guidance Prisoners in Research
Revised Code of Washington (RCW), Section 7.70.065
Revised Code of Washington (RCW), Section 11.88.010
Revised Code of Washington (RCW), Section 26.28.010

PRINCIPLES/OVERVIEW

1. Inclusion of Children in Research

It is the policy of the FHCRC to require adherence to federal regulations regarding the additional responsibilities assigned to the IRB under DHHS regulations and FDA regulations, as applicable. These regulations protect children who are the participants of research. Investigators, IRB Members, and the IRO staff shall consider the involvement of children in research only after all additional safeguards are considered and in place related to children as research participants as outlined in *IRB Research Involving Vulnerable Population: Children Procedures*.

Research involving Pregnant Women, Human Fetuses, or Neonates is very rare at FHCRC. If this population has been identified as potential research participants the FHCRC IRB, IRO staff, and investigators will consider all safeguards needed in research activities involving, pregnant women, human fetuses, and neonates set forth in DHHS and FDA regulations when developing, reviewing and approving the research. The FHCRC IRB will carry out their review as outlined in 45 CFR 46 Subpart B and will request expert consultation as necessary for adequate review. The IRB Members will use the *IRB Member Checklist* to carry out this review.

2. Inclusion of Decisionally Impaired in Research

Research involving decisionally impaired individuals is very rare at FHCRC. If this population has been identified as potential research participants the FHCRC IRB, IRO staff, and

investigators will consider all safeguards needed in research activities involving, decisionally impaired individuals set forth in DHHS and FDA regulations when developing, reviewing and approving the research. The FHCRC IRB will request expert consultation as necessary for adequate review.

In seeking to enroll a decisionally impaired individual in a human subjects research study, informed consent must be obtained from a legally authorized representative acting on behalf of the research participant. The determination as to who is the legally authorized representative for a decisionally impaired individual must be made in accordance with the applicable law of the jurisdiction in which the research will be conducted. See IRB Policy 2.25 Policy on Identification and Use of Legally Authorized Representatives.

3. Inclusion of Prisoners in Research

It is the policy of the FHCRC that an IRB member who qualifies as a prisoner representative must be present during the presentation, discussion, and vote of any study which involves individuals who meet the regulatory definition of “prisoner” under 45 CFR 46.303(c). For the purposes of human subject research, this definition includes any person who enrolls in a research study, and then becomes a prisoner while in the study. It is also the policy of the FHCRC that the majority of the IRBs (exclusive of the prisoner representative) have no association with the prison involved.

It is the policy of the FHCRC that the additional responsibilities for IRB review of prisoner research under 45 CFR 46 Subpart C must be fulfilled. The Subpart C criteria will be considered for all research involving prisoners, regardless of funding source. The FHCRC IRB must make the required determinations when reviewing an application involving prisoner research and will use a *Prisoner Certification Checklist for Investigator* to document the determinations required by the regulations noted in the *Research Involving Vulnerable Populations - Prisoners Procedure*.

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to Institutional Review Office (IRO) staff, IRB members, employees of FHCRC and investigators from other institutions who submit research studies to the FHCRC IRB for review and approval.

PROCEDURES

1. Principal Investigator (PI)

- a. Must complete the Initial New Application, Modifications, or the Continuation Review Report and note if a vulnerable population will be involved in the research.
- b. Include the *Prisoner Certification Checklist for Investigator* when prisoners are involved in the research.
- c. Contact the IRB office for specific information needed if on a rare occasion they may include, pregnant women, human fetus, neonates, or decisionally impaired.

2. IRB Members

- a. Must consider the following at the time of initial review, when modifications to the study are requested, and at the time of continuing review when making determinations as to the possible inclusion of a vulnerable population in research studies:
 - Inclusion and exclusion criteria for selecting and recruiting
 - Informed consent process

- Criteria for selection and recruiting research participants
 - Willingness of the research participant to volunteer
 - Possible coercion and undue influence
 - Confidentiality of data
 - Economic, social, physical and environmental conditions
- b. Use the *IRB Member Checklist* when reviewing New Applications, Continuation Review Reports, and Modifications.
- c. The IRB Member or consultants to the IRB (e.g., General Counsel) must be knowledgeable about applicable state or local laws that address potentially vulnerable populations.
- d. Determine if additional safeguards must be taken to protect the potential vulnerable populations.
- e. Follow the *Research Involving Vulnerable Populations - Children Procedures*; and the *Research Involving Vulnerable Populations - Prisoners Procedures*.

3. IRO Staff

- a. Screening the completed New Application, Modifications, or the Continuation Review Report and note for the IRB Members if a vulnerable population will be involved in the research by using the following *Screeners*:
- i. *Protocol Modification Form*
 - ii. *New Application*
 - iii. *CRR*
 - iv. When prisoners are involved the *Research Involving Prisoners Form*
- b. Provide additional regulatory requirements and considerations to the PI and the IRB Members if on a rare occasion the study might include, pregnant women, human fetus, neonates, or decisionally impaired research participants.
- c. The IRO staff will document the findings of the IRB and communicate those findings to the PI and study staff as outlined in *IRB Policy 1.6 Meeting and Meeting Records* and screeners noted above.
- d. Follow the *Research Involving Vulnerable Populations - Children Procedures*; and the *Research Involving Vulnerable Populations - Prisoners Procedures*.

SUPPORTING DOCUMENTS

IRB Policy 1.6 Policy Meeting and Meeting Records
IRB Policy 2.1 Policy New Application
IRB Policy 2.11 Policy Informed Consent Documents
IRB Policy 2.25 Policy on Identification and Use of Legally Authorized Representatives
IRB Member Checklist
Research Involving Vulnerable Populations - Children Procedures
Research Involving Vulnerable Populations - Prisoners Procedures
Prisoner Certification Checklist For Investigator
Screener: Research Involving Prisoners
Modification To On Going Activities Procedure
Screener: Protocol Modification Form
Application For Review
Screener: New Application

New Minimal Risk Screener Form
CRR Form
Screener: Continuation Review Report