SOP: 501
SPECIAL POPULATIONS

1. POLICY

The IRB shall review all research that involves special populations that is of minimal risk or that benefits these populations directly. The extent of protection required by the IRB depends upon the risk of harm and the likelihood of benefit to the special population participants. The IRB shall give special consideration to recruitment methods, oversight of the consent process, and the participant's capacity to consent. The IRB shall periodically reevaluate the judgment that any individual lacks autonomy.

The IRB shall invite members or consultants with special expertise and related competency to participate in the review when necessary.

The IRB minutes shall document that the IRB made the findings required in 45 CFR 46 Subparts B, C, & D.

The inclusion of research participants from vulnerable populations does not, in and of itself, necessitate review by the convened IRB. The IRB shall consider the level of risk involved in determining whether review by the convened Board is required. For example, research involving children that poses minimal risk may be expedited under 45 CFR 46.404.

Special populations include:

- Pregnant Women, Fetuses, & Neonates
- Children
- Cognitively Impaired Persons
- Prisoners
- Traumatized and Comatose Patients
- Terminally Ill Patients
- Elderly/Aged Persons
- Minorities (e.g., Native Americans)
- Students, Employees of the Sponsor or Investigator, and Healthy Volunteers
- Economically or Educationally Disadvantaged Persons

Specific Policies

1.1 Prisoners

1.1.1 If an investigator indicates in the study submission that prisoners will participate in the research or that participants may reasonably be expected to be incarcerated at some time point during the study, the IRB review of the project must comply with the following:

A. Local regulations: In addition to meeting federal regulations, the project must comply with local and state requirements for inclusion of prisoners as participants.

B. IRB composition: A majority of IRB members shall have no association with the prison(s) involved; and at least one member

shall be a prisoner or prisoner advocate with appropriate background and experience to serve in that capacity.

C. Additional duties where prisoners are involved: The IRB may approve research involving prisoners only if it finds that the following conditions are met:

1. The research falls into one of the following categories:

   i. Study of the possible causes, effects, and the processes of incarceration and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;

   ii. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;

   iii. Research on conditions particularly affecting prisoners as a class (e.g., vaccine trials on hepatitis, which is more prevalent in prisons) provided that the Secretary of DHHS or designee has published notice in the Federal Register of its intent to approve such research; or

   iv. The research under review involves solely research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. In cases where prisoners may not benefit from the research because they are assigned to a control group in a manner consistent with the protocol approved by the IRB, the study may proceed only after the Secretary of DHHS has consulted with experts and has published notice in the Federal Register of its intent to approve such research.

2. Any possible advantages accruing to the prisoner through participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison, are not of such a magnitude that the prisoner's ability to weigh the risks and benefits of the research in the limited-choice environment of the prison is impaired.

3. The risks involved in the research are commensurate with risks that would be accepted by non-prison volunteers.

4. Selection procedures within the prison are fair to all prisoners and immune from arbitrary intervention by prison authority or prisoners. Unless the investigator provides the IRB justification in writing for following some other procedures, control participants

must be selected randomly from the group of eligible prisoners for the research project.

5. Any information given to participants is presented in language that is appropriate for the participant population.
6. Adequate assurance exists that parole board(s) will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance via the informed consent that participation in the clinical investigation will have no effect on his/her parole.
7. Where there is need for follow-up examination or care of participants after the end of their participation in the research, while the participants are still prisoners, adequate provision is made for such examination or care, taking into account the varying lengths of prison sentences, and for informing participants of this fact.

1.1.2. If the IRB determines that the study meets the criteria in Section 1.1.1, the IRB documents that determination and sends a copy of the research proposal to the Prisoner Research Contact Person at OHRP.

The study shall not be initiated unless OHRP determines that the proposed research involves at least one of the categories of research permissible under 45 CFR 46.306(a)(2).

1.1.3 When Participants Become Prisoners During a Research Protocol

When any human participant in a research protocol becomes a prisoner at any time during the study; *e.g.,* after the research has commenced, because it is unlikely that review of the research and the consent document contemplated the constraints imposed by the possible future incarceration of participants, the investigator and the IRB shall comply with the following:

- If a participant becomes a prisoner after enrollment in research, the investigator must cease all research interactions and interventions with and obtaining identifiable private information about, the participant. The investigator shall report this situation in writing to the IRB immediately upon learning of the incarceration. In special circumstances in which the principal investigator asserts that it is in the best interests of the participant to remain in the research study while incarcerated, the IRB Chair may determine that the participant may continue to participate in the research until the requirements of 45 CFR 46 Subpart C are satisfied.
- At the earliest opportunity after receiving the investigator's notice or otherwise becoming aware of the incarceration of a participant, the IRB shall review the protocol again with a prisoner representative as a member of the IRB. The IRB shall take special consideration of the conditions of being a prisoner.
- Upon this review, the IRB can either (a) approve the involvement of the prisoner-participant in the research in accordance with this

policy or (b) determine that this participant must be withdrawn from the research.

- Additionally, the IRB shall confirm that, when appropriate, the informed consent includes information regarding subsequent incarceration which may result in termination of the participant's participation without regard to the participant's consent.

1.1.4 For VA Research:

Research involving prisoners as participants is not approved unless a waiver has been granted by the Chief Research and Development Officer.

1.1.5 For Department of Defense-sponsored research:

Research with prisoners of war (POW) is prohibited. This includes any person captured, detained, held, or otherwise under the control of Department of Defense personnel (military and civilian, or contractor employee). Such persons include: Enemy Prisoners, Civilian Internees, Retained Persons, and Lawful and Unlawful Enemy Combatants. Such persons do not include Department of Defense personnel being held for law enforcement purposes. For the definition of prisoners of war for the Department of Defense components, see SOP IV, Glossary.

1.2 Children

1.2.1 The IRB shall consider the following when reviewing research in a pediatric population.

- Probable risks
- Associated discomforts
- Possible benefits

<u>Determination of probable risks and associated discomforts:</u>
Procedures that usually present no more than minimal risk to a healthy child include urinalyses, obtaining small blood samples, EEGs, allergy scratch tests, minor changes in diet or daily routine, and/or the use of standard psychological or educational tests. The assessment of the probability and magnitude of the risk, however, may be different in sick children and vary depending on the diseases or conditions the participants have. For example, obtaining blood samples from a hemophiliac child may present more than minimal risk to the child. On the other hand, the IRB shall consider that children suffering from chronic illnesses who are accustomed to invasive procedures are placed at minimal risk by involvement in similar research procedures, in contrast to children who have not had such experiences. The IRB shall also consider the extent to which research procedures would burden any child, regardless of whether the child is accustomed to the proposed procedures.

Procedures that exceed the limits of minimal risk may be difficult to define in the abstract, but should not be too difficult to identify on a

case-by-case basis. Riskier procedures might include biopsy of internal organs, spinal taps, or the use of drugs whose risks to children have not yet been established. Behavioral interventions likely to cause psychological stress may also exceed minimal risk.

Determination of possible benefits: In assessing the possible benefits of research intervention, the IRB shall consider the variability in health statuses among potential participants. For example, a potential participant might be a normal, healthy child, or a child who has been exposed to a disease or a toxin (*e.g*., meningococcus or lead) where it is known that a percentage of the children exposed will actually experience untoward consequences. A child may also be in an early state of disease; *e.g.*, an HIV-infected child, or may actually suffer from disease or other significant medical condition. Thus, the IRB must take into account the current health status of a child and the likelihood of progression to a worsened state without research intervention.

1.2.2 Wards of the State: The special protections for children set forth in Subpart D of 45 CFR 46 include additional limitations on some research involving children who are wards of the state or any other agency, institution, or entity. Where the research involves greater than minimal risk to the participants with no prospect of direct benefit to individual participants (45 CFR 46.406), or requires DHHS Secretarial approval (45 CFR 46.407), the research must either be related to their status as wards, or be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards (45 CFR 46.409). The IRB shall require, for each child who is a ward, appointment of an advocate in addition to any other individual acting on behalf of the child as a guardian.

1.2.3. HIV-Infected Children: The IRB is particularly concerned with the involvement of HIV-infected children who are in foster care, but who are also not wards. Many of these children are from racial or ethnic minorities. The IRB shall give special attention to groups of children such as these who, while they need special protections, should not be denied the opportunity to participate in research that may potentially benefit them.

1.2.4. Institutionalized Children: When institutionalized children are involved in research, the IRB shall not allow the institutionalized children to be included as participants simply because of their availability to the investigator.

1.2.5. Determination of Risk: Federal regulations require the IRB to classify research involving children into one of four categories and to document the discussions of the risks and benefits of the research study. The minutes shall document how the research protocol meets the required criterion.

The four categories of research involving children based on degree of risk and benefit to individual participants are as follows:

1. **Research not involving greater than minimal risk.**

2. **Research involving greater than minimal risk, but presenting the prospect of direct benefit to individual participants**.

   Research in this category is approvable provided: (a) the risk is justified by the anticipated benefit to the participant; and (b) the relationship of risk to benefit is at least as favorable as any available alternative approach.

3. **Research involving greater than minimal risk with no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition.**

   Research in this category is approvable provided: (a) the risk represents only a minor increase over minimal risk; (b) the intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational settings; and (c) the intervention or procedure is likely to yield generalizable knowledge about the participant's disorder or condition that is of vital importance for the understanding or amelioration of the participant's disorder or condition.

4. **Research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children**.

   Research that is not approvable under 45 CFR 46.404, 46.405, or 46.406 may be conducted or funded by DHHS provided that the IRB and the DHHS Secretary, after consultation with a panel of experts, finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a significant problem affecting the health and welfare of children. The panel of experts must also find that the research will be conducted in accordance with sound ethical principles.

   If the IRB does not believe that a clinical investigation within the scope described in 21 CFR 50.1 and 21 CFR 56.101 and involving children as participants meets the requirements of 21 CFR 50.51, 21 CFR 50.52, or 21 CFR 50.53, the clinical investigation may proceed only if:

   - (a) The IRB finds and documents that the clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
   - (b) The Commissioner of Food and Drugs, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, determines either:

(1) That the clinical investigation in fact satisfies the conditions of 21 CFR 50.51, 21 CFR 50.52, or 21 CFR 50.53, as applicable, or

(2) That the following conditions are met:

(i) The clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) The clinical investigation will be conducted in accordance with sound ethical principles; and

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth in 21 CFR 50.55.

1.2.6 Parental Permission: Children may be participants of research only if informed consent/active parental permission is obtained from the parents or legal guardian. The IRB shall determine whether the permission of both parents is necessary, and the conditions under which one parent may be considered not reasonably available. For additional information, see SOP 701, Consent Process and Documentation.

1.2.7 Assent of Children: The IRB shall determine whether adequate provisions are made for soliciting the assent of the children when in the judgment of the IRB the children are capable of providing assent (21 CFR 50.55). For additional information, see SOP 701, Consent Process and Documentation.

1.2.8 Waiver of Assent: The assent of the child is not a necessary condition for proceeding with the clinical investigation. For additional information, see SOP 701, Consent Process and Documentation. The IRB may determine that assent is not necessary.

1.2.9 For VA Research: Research involving children as participants is not approved unless a waiver has been granted by the Chief Research and Development Officer.

1.3 Pregnant Women and Fetuses

1.3.1 The IRB may approve only research involving pregnant women and fetuses that satisfies <u>all</u> the conditions of 45 CFR 46, Subpart B as follows:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b)* The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; **OR**, if there is no such prospect of benefit, the risk to the fetus is not

greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

When the IRB applies Subpart B to non-biomedical research the IRB must carefully consider section (b) of this SOP since most social science research does not "hold out the prospect of direct benefit for the woman or the fetus: the research must have the purpose of "development of important biomedical knowledge."

(c) Any risk is the least possible for achieving the objectives of the research;

(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;

(e) If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or if the pregnancy resulted from rape or incest.

(f) Each individual providing consent under paragraph (d) or (e) above is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

(g) For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of 45 CFR 46;

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(j) Individuals engaged in the research will have no part in determining the viability of a neonate.

1.3.2 Research involving neonates:

A. After delivery: Neonates may be involved in research if all of the following conditions are met:

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates;
2. The individual(s) providing consent under the applicable regulations is/are fully informed regarding the reasonably foreseeable impact of the research on the neonate;
3. The regulatory requirements have been met as applicable.

B. Neonates of uncertain viability: After delivery, and until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by federal regulations unless the IRB has determined the following additional conditions are met:

1. The research holds out the prospect of enhancing the probability of survival of the particular neonate to the point of viability, and any risk is the least possible for achieving the objectives of the research; or
2. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the neonate resulting from the research; and
3. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with 45 CFR 46 subpart A, unless altered or waived in accord with 45 CFR 46.101(i) or 45 CFR 46.116(c) or (d).

C. Nonviable neonates: After delivery, a nonviable neonate may not be involved in research covered by federal regulations unless all of the following conditions are met.

1. Vital functions of the neonate will not be artificially maintained;
2. The research will not terminate the heartbeat or respiration of the neonate;
3. There will be no risk to the neonate resulting from the research;
4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

5. The legally effective informed consent of both parents of the neonate is obtained in accord with 45 CFR 46 Subpart A, except that the waiver and alteration provisions of 45 CFR 46.116(c) and (d) do not apply. However, if one parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of the other parent will suffice to meet the requirements except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of a nonviable neonate will not suffice to meet the requirements of the regulations.

1.3.3 Research involving after delivery; the placenta; the dead fetus, fetal material, cells, tissue, or organs excised from a dead fetus.

- Research involving after delivery; the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable federal, state, or local laws and regulations regarding such activities.
- Oklahoma law prohibits research on fetal tissue resulting from an abortion. An abortion is defined as the purposeful termination of a pregnancy with an intent other than to produce a live birth or remove a dead unborn child. 63 O.S. §1-735.
- If information associated with material described in Section 1.3.3 above is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research participants and all pertinent regulations apply.

1.3.4 VA Restrictions on Fetal and In Vitro Fertilization Research

- Research in which the subject is a fetus, in-utero or ex-utero (including human fetal tissue), must not be conducted by VA investigators while on official duty, at VA facilities, or at approved off-site facilities.
- Research related to in vitro fertilization must not be conducted by VA investigators while on official duty, at VA facilities, or at approved off-site facilities.

1.3.5 VA Research Involving Pregnant Women

VA research involving pregnant women as participants is not approved unless:

- The research includes adequate provisions to monitor the risks to the participant and the fetus.
- Adequate consideration has been given to the manner in which potential participants are going to be selected.
- Adequate provision has been made to monitor the actual consent process by procedures such as:
    - Overseeing the process by which the consent of individual is obtained either by:

- Approving enrollment of each individual.
- Verifying, perhaps through sampling, that approved procedures for enrollment of individuals into the activity are being followed.

o Monitoring the progress of the activity and intervening, as necessary, through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen.

1.4 Cognitively Impaired Participants

Although there are no federal regulations specifically written to address the needs of this special population, the IRB shall generally follow the recommendations governing the conduct of research in children and made by the *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*.

1.4.1 Cognitively impaired participants are defined as having a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests and therefore cognitively impaired.

1.4.2 Selection of Participants: Research involving individuals who are cognitively impaired to consent should have a direct relationship to their illness or condition unless the IRB determines there is a possibility of direct benefit to the participant that cannot be obtained outside of the research project. Particular attention should be paid to institutionalized individuals, as issues of dependence and coercion may be factors that may compromise the voluntary nature of their participation in research. For this reason, participants should be recruited from among noninstitutionalized populations whenever possible.

1.4.3 Risk Determination: The IRB shall determine the degree of risk of a research protocol involving cognitively impaired participants:

- a minor increase over minimal risk may be permitted in research involving those institutionalized as mentally disabled, but only where the research is designed to evaluate an intervention of foreseeable benefit to their care.
- for research that does not involve beneficial interventions and that presents more than minimal risk, the anticipated knowledge sought should be of vital importance for understanding or eventually alleviating the participants' disorder or condition.

1.4.4 Limiting Risks. The investigator shall include in the protocol, to limit a participant's exposure to risk:

- Description of appropriate psychological or medical screening criteria to prevent or reduce the chances of adverse reactions to the therapeutic and research procedures
- Specific diagnostic, symptomatic, and demographic criteria for participant recruitment
- Description of methods for assuring adequate protections for the privacy of the participants and the confidentiality of the information gathered
- Justification of plans to hospitalize participants or extend hospitalization for research purposes
- Measures to protect Individually identifiable information
- Measures to ensure that proposed research procedures will not be detrimental to ongoing therapeutic regimens.

1.4.5 Informed Consent: Generally, cognitively impaired adults who are competent to understand the issues of being a research participant should be allowed to either refuse or consent to participate in a research study. Cognitive impairment alone should not disqualify a person from consenting to participate in research and making an informed voluntary choice; rather, the investigator shall present specific evidence of cognitive impairment, such as in one of the following items below:

- Court of law declares participant incompetent
- Assessment by a physician not involved with the research project
- Mini Mental Health Exam

The IRB shall respect and observe the objection or refusal of a cognitively impaired adult participant to participate in a research study even if the intervention is expected to provide a direct health benefit to the participant, and the intervention is available only in the context of the research. This is in keeping with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research's recommendation that "despite the fact that consent may be obtained from a legally authorized representative or guardian, the feelings and expressed wishes of a 'cognitively impaired' should still be respected."

The IRB shall seek guidance from Legal Counsel to assess state law that might affect the participation of cognitively impaired persons and/or the role of guardians in the consenting process.

Studies involving participants who are cognitively impaired may take place over extended periods. The IRB shall consider whether periodic re-consenting of individuals is required to determine that a participant's continued involvement is voluntary. The IRB may require that investigators re-consent participants after taking into account the

study's anticipated length and the condition of the individuals to be included (e.g., participants with progressive neurological disorders). Additionally, the IRB shall consider whether and when it should require a reassessment of decision-making capacity.

1.4.6 VA research involving incompetent persons or persons with impaired decision making capacity: The IRB determines in writing each of the criteria indicated below. If these criteria are met, the IRB may approve the inclusion of incompetent persons or persons with impaired decision-making capacity in research projects on the basis of informed consent from authorized representatives as defined in paragraph 11 of the VHA Handbook.

- Only incompetent persons or persons with impaired decision making capacity are suitable as research subjects. Competent persons are not suitable for the proposed research. The investigator must demonstrate to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as participants. Incompetent persons or persons with impaired decision-making capacity must not be participants in research simply because they are readily available.

- The proposed research entails no significant risks, tangible or intangible, or if the research presents some probability of harm, there must be at least a greater probability of direct benefit to the participant.

- Incompetent people or persons with impaired decision-making capacity are not to be participants of research that imposes a risk of injury, unless that research is intended to benefit those participants and the probability of benefit is greater than the probability of harm.

- Procedures have been devised to ensure that participant's representatives are well informed regarding their roles and obligations to protect incompetent participants or persons with impaired decision making capacity. Health care agents (appointed under Durable Power of Attorney for Health Care) and next-of-kin or guardians must be given descriptions of both proposed research studies and the obligations of the person's representatives. They must be told that their obligation is to try to determine what the participant would do if competent, or if the participant's wishes cannot be determined, what they think is in the incompetent person's best interest.

1.5 Other Special Populations

Other special populations may include traumatized and comatose patients, terminally ill patients, students, normal volunteers, minorities, participants in AIDS research, employees of the sponsor or investigator,

the elderly, and Native American tribes and tribal organizations. The IRB defines the elderly as 65 years of age and older. The IRB shall determine special protections necessary for these groups on a case-by-case basis, taking into account the risks and benefits and other protections afforded by University policies and state and federal law.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. RESPONSIBILITY

The IRB Administrative Staff (or equivalent) is responsible for maintaining up-to-date tools for review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines.

The IRB Chair or designee is responsible for informing the IRB members of new and evolving regulations and guidelines pertaining to vulnerable populations, for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.

The IRB Reviewer is responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with appropriate experts and resources.

4. APPLICABLE REGULATIONS AND GUIDELINES

The Belmont Report

45 CFR 46: Subparts A, B, C, D

45 CFR 46.101, 46.115(B), 46.116, 46.122

21 CFR 50: Subpart D 50.51, 50.52, 50.53, 50.54, 50.55, 50.56

21 CFR 56.111

OHRP Guidance Document, IRB Guidebook

OHRP Guidance on the Involvement of Prisoners in Research, May 23, 2003

Department of Veterans Affairs, VHA Handbook 1200.5, July 15, 2003

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 402, Expedited Review
SOP 701, Consent Process and Documentation.

6. ATTACHMENTS

203-D	Reviewer Checklist for VA Research
203-E	Reviewer Checklist for Research Involving Pregnant Women, Fetuses & Neonates
203-F	Reviewer Checklist for Research Involving Prisoners
203-G	Reviewer Checklist for Research Involving Children
501-A	OHRP Prisoner Determination Letter

7. PROCESS OVERVIEW

7.1 Reviewer Process

The IRB Administrator reviews the submitted documents for the inclusion of special populations. The Reviewer Checklists pertaining to the special population are forwarded to the primary/secondary reviewers or to the IRB Chair or designee along with other applicable checklists.

7.2 Additional Meeting Requirements

Studies that include the following special populations have the following meeting requirements:

7.2.1 Prisoners: A prisoner representative must attend and participate in the discussion and vote of the study. All documents pertaining to the prisoner study are sent to the prisoner representative prior to the IRB meeting. If the prisoner study involves minors, attempts are made to obtain a child prisoner advocate if one is available.

7.2.2. Children: Studies involving children are assigned to an IRB with individuals who have pediatric expertise or will consult with a pediatric expert. The IRB shall determine the risk category and state this at the meeting.

7.2.3. Pregnant Women, Fetuses and Neonates: The IRB shall determine the risk category and state this at the meeting.

The IRB Reviewer examines the research, determines if additional necessary protective stipulations need to be applied, and reports the conclusions to the IRB Chair and other IRB members at the IRB meeting. The IRB Administrator notes the conclusions in the IRB meeting minutes.

7.3. Additional Minutes Requirements

Studies that include the following special populations have the following documentation requirements for the minutes:

7.3.1 Prisoners: The minutes shall reflect (1) the presence of the prisoner advocate; (2) whether the seven considerations of 45 CFR 46 Subpart A were met; (3) the category of research for the study; and (4) the protocol-specific findings justifying the IRB's determination.

7.3.2. Children: The minutes shall reflect (1) the category of research for the study; and (2) the protocol-specific findings justifying the IRB's determination.

7.3.2. Pregnant Women, Fetuses and Neonates: The minutes shall reflect that the IRB considered all of the conditions of 45 CFR 46 Subpart B and the protocol specific findings justifying the IRB's determination.

7.4 Additional Procedures for Research Involving Prisoners

7.4.1 If the research is conducted or supported by DHHS and is approved under 46 CFR 46.306(a), category iii or iv (see Section 1.1, 1 above), the IRB Administrator generates a letter to the investigator stating that the research requires approval from OHRP prior to opening study enrollment.

7.4.2 The IRB Administrator forwards the study documents along with the IRB correspondence to the IRB Director. The IRB Director sends the IRB approved protocol, any relevant HHS grant application or proposal, any IRB application forms required by the IRB, and any other information requested or required by the IRB to be considered during initial IRB review to OHRP Prisoner Research Contact Person, Office for Human Research Protections, Department of Health and Human Services, The Tower Building, 1101 Wooton Parkway, Suite 200, Rockville, MD 20852.

7.4.3 DHHS conducted or supported research involving prisoners as subjects may not proceed until OHRP issues its approval in writing to the University on behalf of the Secretary under 45 CFR 46.306(a)(2). The IRB Director notifies the investigator that the study has been either approved or disapproved. If OHRP approves the study, the IRB Administrator generates an approval letter noting the OHRP approval and forwards it to the investigator.

APPROVED BY:_____ **DATE: 01/15/2010**

NEXT ESTABLISHED REVIEW DATE: MAY 2012