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 members. The IRB shall give special consideration to recruitment methods, the consent process, and the research participant’s capacity to consent. The IRB may require investigators to periodically reevaluate the judgment of any participant who 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 the special population findings made by the IRB or the IRB reviewer, as required in 45 CFR 46 Subparts B, C, & D.

The inclusion of research participants from special 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 and/or 45 CFR 46.110.

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, University Employees, Employees of the Sponsor or Investigator, and Healthy Volunteers
- Economically or Educationally Disadvantaged Persons

Specific Populations

1.1 Prisoners

Federal regulations require additional protections for prisoners involved in research. If prisoners will participate in the research projects or it is reasonable to expect that research participants may become incarcerated during the research project, the IRB review of the project must comply with federal, state, and local requirements for inclusion of prisoners as research participants. In addition, review of these studies must comply with the following:

NOTE: Department of Justice, Bureau of Prisons research that consists of pilot projects of programmatic or operational initiatives are not considered to be human participant research.
1.1.1 IRB composition: A majority of IRB reviewers shall have no association with the prison(s) involved. At least one reviewer shall be a prisoner or prisoner advocate with appropriate background and experience to serve in that capacity.

1.1.2 The IRB may approve research projects involving prisoners only if it finds that the research falls into one of the following categories:

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

B. Research of prisons as institutional structures or of prisoners as incarcerated persons, provided that the research project presents no more than minimal risk and no more than inconvenience to the participants;

C. 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

D. 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 research project 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.

1.1.3 Any possible advantages accruing to the prisoner through participation in the research project, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison, should not be 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.

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

1.1.5 Selection procedures within the prison must be 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.

1.1.6 Any information given to participants is presented in language that is appropriate for the participant population.

1.1.7 Adequate assurance must exist that parole board(s) will not take into account a prisoner's participation in the research project when making decisions regarding parole, and each prisoner must be clearly informed in advance in the informed consent process and related documents that participation in the research project will have no effect on his/her parole.

1.1.8 Where there is need for follow-up examination or care of participants after the end of their participation in the research project, adequate provision is made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing research participants of this fact.
1.1.9. For prisoner research conducted or supported by DHHS, the IRB determines that the
research project meets the criteria in Section 1.1, documents that determination, and
sends a copy of the research proposal to the Prisoner Research Contact Person at
OHRP.

The research project 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).

Studies previously authorized by OHRP with prisoner involvement do not require
recertification if modified unless the change to the research alters the applicability of the
approved category of research.

1.1.10 When a Participant Becomes a Prisoner During a Research Protocol:
The IRB shall comply with the following if a participant becomes a prisoner after
enrollment in research:

A. The investigator must cease all research interactions and interventions with and
obtaining identifiable private information about the participant. The investigator shall
report this to the IRB immediately upon learning of the incarceration. In special
circumstances in which the investigator asserts that it is in the best interests of the
participant to remain in the research project while incarcerated, the IRB Chair or IRB
designee may determine that the participant may continue to participate in the
research until the requirements of 45 CFR 46 Subpart C are satisfied.

B. At the earliest opportunity after receiving the investigator's notice or otherwise
becoming aware of the incarceration of a research 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 when
considering whether to let the participant continue in the research project.

C. When reviewing the continuation of research participation, the IRB can either (a)
approve the continued involvement of the prisoner as a participant in the research
project in accordance with this policy or (b) determine that the participant must be
withdrawn from the research project.

D. Additionally, when appropriate, the IRB shall confirm that the informed consent
documents include information regarding incarceration that may result in termination
of the participant's participation without regard to the participant's consent.

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

1.1.12 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.

For research involving prisoners not meeting the definition of POW, expedited review
procedures are prohibited.
1.2 Children

1.2.1 Federal regulations require additional protections for children involved in research. The IRB shall consider the following when reviewing research involving children:

- **Determination of probable risks and associated discomforts:** 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 of the child participants. 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 for the investigator to define in the research protocol but should not be too difficult for the IRB 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 interventions, 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 for purposes of the research study 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 of the State. 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 project. 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.** (45 CFR 46.404, 21 CFR 50.51)

2. **Research involving greater than minimal risk, but presenting the prospect of direct benefit to individual participants.** (45 CFR 46.405, 21 CFR 50.52)

   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.** (45 CFR 46.406, 21 CFR 50.53)

   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.** (45 CFR 46.407, 21 CFR 50.54)

   Research that is not approvable under categories one, two, or three may be conducted or funded by DHHS provided that the IRB and the DHHS Secretary, after consultation with a panel of experts convened in accordance with OHRP Guidance on the 46.407 review process, 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.

   For FDA-regulated research: If the IRB determines that risk categories one, two, and three are not met, the research project may proceed under category four only if:

   a) The IRB finds and documents that the research project 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 research project 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 research project presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
   ii.) The research project 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 research participants only if permission is obtained from the parent(s) 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 necessity of obtaining the assent of the child shall be determined by the IRB. For additional information, see SOP 701, Consent Process and Documentation.

1.2.9 VA Research: Research involving children as participants may not be approved unless a waiver has been granted by the VA Chief Research and Development Officer. Research involving children may not pose greater than minimal risk to the child.

1.3 Pregnant Women and Fetuses

1.3.1 Federal regulations require additional protections for pregnant women, fetuses, or neonates involved in research. The IRB may approve research involving pregnant women and fetuses only if the research satisfies all 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 non-pregnant 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;
   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 Pregnant Women That Is Not Federally Funded:

The IRB may be flexible in applying Subpart B to non-federally funded research involving pregnant women that is social/behavioral in nature, presenting minimal risk to the pregnant women and fetus, and creates generalizable scientific knowledge.

1.3.3 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; and

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 one of 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.
Additionally, 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.

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

A. 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.

B. Oklahoma law prohibits research on fetal tissue resulting from an abortion. An abortion is defined as the purposeful termination of a pregnancy with the intent other than to produce a live birth or remove a dead unborn child. 63 O.S. §1-735 and SOP 1101: Oklahoma State Laws Pertaining to Research

C. 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.

1.3.5 **VA Restrictions on Fetal and In Vitro Fertilization Research**

A. 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.
B. 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.

C. Research involving stem cells shall be governed by the policy set by NIH, "Guidelines for Human Stem Cell Research".

D. Interventional research involving neonates is not allowed. Prospective observational or retrospective record review studies that involve neonates or neonatal outcomes are permitted.

E. Research involving the creation of a human embryo or embryos solely for research purposes or research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in-utero under 45 CFR 46.208(a)(2) Section 498B of the Public Health Service Act (42U.S.C.289g(b)) cannot be conducted by VA investigators, at VA facilities, or at VA approved off-site facilities.

1.3.6 VA Research Involving Pregnant Women

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

A. The research includes adequate provisions to monitor the risks to the participant and the fetus;

B. Adequate consideration has been given to the manner in which potential participants are going to be selected;

C. The facility where the research will be conducted has staff with sufficient expertise in women’s health to conduct the proposed research; and

D. Adequate provision has been made to monitor the actual consent process by procedures such as:

1. 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.

2. 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.

1.3.7 DOD Research Involving Subpart B

A. The phrase “biomedical knowledge” must be replaced with “generalizable knowledge”.

B. The applicability of Subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and included interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as participants.

C. Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.
1.4 Cognitively Impaired Research 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 participants having a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia) or a developmental disorder (e.g., intellectual disability) 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 disabilities, may also be compromised in their ability to make decisions in their best interests and are therefore considered to be cognitively impaired.

1.4.2 Selection of Participants: When involving individuals who are cognitively impaired, the research should have a direct relationship to the participant’s 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 (e.g., staff and interventions in the institution, addiction, and/or those legally authorized to give permission to be a research participant) 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 non-institutionalized populations whenever possible.

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

A. 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.

B. 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: To limit a participant’s exposure to risk, the investigator shall include in the protocol:

A. A description of appropriate psychological or medical screening criteria to prevent or reduce the chances of adverse reactions to the therapeutic and research procedures.

B. The specific diagnostic, symptomatic, and demographic criteria for participant recruitment.

C. A description of methods for assuring adequate protections for the privacy of the participants and the confidentiality of the information gathered.

D. Justification of plans to hospitalize research participants or extend hospitalization for research purposes.

E. Measures to protect individually identifiable information.
F. 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 process, risks, and benefits of being a research participant should be allowed to either refuse or consent to participate in a research project. Cognitive impairment alone should not disqualify a person from consenting to participate in research. The investigator shall also present specific evidence of cognitive impairment, such as one of the following items:

- Declaration of incompetence by a court of law
- Assessment by a physician not involved with the research project
- Scoring from a Mini Mental Health Exam or equivalent assessment instruments

The IRB shall respect and observe the objection or refusal of a cognitively impaired participant to participate in a research project, 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 may seek guidance from the Office of 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 research project’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 and require re-consent of the participant.

1.4.6 VA Research Involving Persons Who Lack Decision-Making Capacity: Refer to SOP 603A: Veterans Affairs Health Care System.

1.5 Other Special Populations

Students and employees recruited as research subjects are more vulnerable to coercion because of the possibility that they may perceive grades, employment, or other benefits as dependent upon or affected by their participation in research. Students and employees are at greater risk of experiencing negative ramifications related to an inability to maintain strict confidentiality and because more information is known about these individuals than is collected during the course of the research project.

The IRB considers these individuals to be more vulnerable to coercion (real or perceived) and to issues related to confidentiality than individuals not affiliated with the University and, therefore, will apply additional safeguards to protect their rights and welfare.
1.5.1 **Students as Research Participants**

Note: For Classroom-Based Research Projects Conducted by University Students, refer to SOP 401: Research Exempt from Federal Regulations.

A. **Justification for Targeting Students**: Investigators who plan to conduct research with only students as participants must be able to provide a rationale, *other than convenience*, for restricting the research project population to students and must show that the recruitment method does not lead potential subjects to think they will be penalized by not participating or receive preferential treatment by participating. Examples of such rationale include: a) participation as a valuable educational experience demonstrated by a substantive plan for debriefing, b) the need for an alternative mechanism for research project compensation (e.g. class credit or extra credit) due to lack of monetary resources, c) the existence of a formal student subject pool and related departmental policy. Neither Investigators nor Class Instructors may impose penalties on students who fail to attend scheduled research-related appointments.

Recruitment materials must minimize the potential for undue influence or coercion.

B. **Direct Recruitment**: Investigators may make research project-related announcements (such as research project title and investigator contact information) or provide recruitment materials (such as fliers) to students in University classrooms, so long as the investigator is not also the class instructor. Recruitment methods must permit students to self-identify as potential research participants outside of the classroom so as to maintain confidentiality and minimize the potential for peer pressure. For example, students should be provided with contact information for a research project team member who they may contact after class, rather than be asked to express interest at the time of the announcement.

C. **Indirect Recruitment**: The investigator must obtain appropriate permission from University campus locations before posting IRB-approved recruitment materials.

D. (For Norman Campus only) **Mass Email Recruitment**: Investigators seeking approval to email recruitment materials or research project announcements to students must explain this recruitment method in the protocol and include this language: “The OU IRB has approved the content of this research recruitment message, but the investigator is responsible for obtaining authorization to distribute this research recruitment message by mass email.”

E. **Consent**: A student may not be compelled to participate in research as part of a course requirement. Investigators must ensure that students know that they may choose not to participate in the research and that their decision will not affect their grade, class standing, or relationship with any instructor. Similarly, research participants must be made aware that their participation will not lead to any preferential class-based treatment.

F. **Course Credit**: If research participation is required as part of the course assignments, an alternate means of earning equivalent course credit for an equivalent commitment of time and effort must be made available for those who cannot or choose not to participate in a research project.
If extra credit is offered for participation in a research project, the opportunity to participate must be made available to all students. The amount of extra credit must reflect the amount of time required for research participation and cannot exceed 5% of the overall course grade calculation.

G. Use of Class Time: IRB submissions proposing the use of class time for research should include an explanation of the benefit of the research to all of the students, especially those who choose not to participate in the research project. Specifically, the investigator should explain how participation in the research would be a learning experience for the students and how the research project is relevant to the course being taught in that class. An alternative activity should be provided for students who choose not to participate.

H. Use of Class Assignments in Research: Instructors who use their students' class assignments (e.g., journals, term papers) in research projects will be required by the IRB to obtain consent from the students who are willing to be research participants. The investigator must make arrangement for the consent process to occur after the class grades are posted or to be conducted by another member of the research team.

I. Additional safeguards may be required to protect the privacy and confidentiality of University student research participants. Certain additional protections for students and parents are required by federal regulations. For example, the proposed use of student education records for research must comply with the requirements of the Family Educational and Rights Privacy Act (FERPA). If any University records of the research participants are to be used, then the research participant must give permissions for records access in the consent documents. It is the responsibility of the investigator to comply with any additional federal, state, or local regulations.

1.5.2 Student Research “Pools”

A. In some departments, University students are offered the opportunity to participate in research projects. Examples include participation for course credit as part of a course requirement, participation for “extra credit” in a course, or participation in exchange for compensation.

B. A University student may not be required to participate in research for course credit unless a comparable non-research alternative is also offered. To minimize the potential for coercion, alternatives to participating in research for course credit that are offered must be comparable in terms of time, effort, and fulfillment of course requirements. Examples may include reading and/or writing research papers, attending research presentations offered by faculty, or observing performance of research studies.

C. All research participants, including University students, must be free to withdraw from participation at any point in research project without penalty. University students who withdraw from a research project offered for course credit must receive the full course credit offered for participation. When compensation is offered, a pro-rated amount of compensation must be given to any University student who does not complete the entire research project.

D. Every University student participating in a research project must give informed consent for that specific research project as described by SOP 701: Consent Process and Documentation; federal regulations; and IRB policies. Parental permission and
assent are required for any University students (including high school students taking University courses) who meet the regulatory definition of minors.

1.5.3 Recruitment of Employees

A. Justification for Targeting Employees: Investigators who plan to include only University employees must be able to provide a rationale, other than convenience, for restricting the research project population to employees and must show that the recruitment method does not lead potential subjects to think they will be penalized by not participating.

B. Direct Recruitment: Investigators may make research project-related announcements or provide recruitment materials to employees at regular meetings. However, recruitment methods must permit employees to self-identify as interested in participation in a way that maintains confidentiality. For example, employees should be provided with contact information for a research project team member whom they may contact for more information.

C. Indirect Recruitment: The investigator must obtain appropriate permission from University campus locations before posting IRB-approved recruitment materials.

D. (For Norman Campus only) Mass Email Recruitment: Investigators seeking approval to email recruitment materials or research project announcements to employees must explain this recruitment method in the protocol and include this language: “The OU IRB has approved the content of this research recruitment message, but the investigator is responsible for obtaining authorization to distribute this research recruitment message by mass email.”

E. Consent: An employee may not be required to participate in research as a condition of employment. Investigators will ensure that employees know that they may choose not to participate in the research and that their decision will not affect their employment or benefits at the University. Similarly, research participants must be made aware that their participation will not lead to any preferential employment treatment.

1.5.4 Other Special Populations

A. There are other groups of persons that receive special consideration and may include traumatized and comatose patients, terminally ill patients, normal volunteers, minorities, participants in AIDS research, employees of the sponsor or investigator, the elderly, and American Indian 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 laws.

B. For purposes of VA Research, individuals or populations that might be temporarily or permanently vulnerable include, but are not limited to, those who:

1. Are susceptible to coercion or undue influence (e.g., the homeless, prisoners, students, patients with limited or no treatment options, socially and economically disadvantaged).
2. Lack comprehension of the research and its risks (e.g., educationally disadvantaged, dementia, schizophrenia, or depression).

3. Have increased susceptibility to harm from the procedures of the specific study under review (e.g., individuals who would have to answer study survey questions about their sexual assault).

4. Are at risk for economic, social, or legal consequences from the study (e.g., individuals who would have to answer study survey questions about their drug use or HIV status).

2. SCOPE

This SOP applies to all human research submitted to the IRB.

3. RESPONSIBILITY

3.1 The IRB Staff is responsible for maintaining adequate information for review of research pertaining to special populations based on applicable regulations and guidance.

3.2 The IRB Chair or IRB designee is responsible for informing IRB members of applicable regulations and guidance pertaining to special populations, for selecting IRB reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.

3.3 The IRB reviewer is responsible for conducting appropriate review of research including special populations with attention to the assessment of potential for coercion or undue influence, in consultation with appropriate experts and resources as necessary.

4. APPLICABLE REGULATIONS AND GUIDELINES

The Belmont Report

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

45 CFR 46.101, 45 CFR 46.110, 46.115(B), 46.116, 46.122, 46.404, 46.405, 46.406, 46.407, 46.409

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

NIH Guidelines for Human Stem Cell Research, July 7, 2009

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP IV: Glossary

SOP 301: Research Submission Requirements

SOP 401: Research Exempt from Federal Regulations

SOP 402: Expedited Review
7. PROCESS OVERVIEW

7.1 Review Process

A. The IRB Administrator reviews the submitted documents for the inclusion of special populations.

B. Research projects that include special populations may require that the IRB or IRB reviewer stipulate that additional protective measures be included in the research project as described in this policy. The revised protocol will then be considered in light of the regulations in 45 CFR 46 A, B, C, and D (as applicable) prior to IRB approval of the research project.

C. Following this, the Review Process will be carried out as described in SOP 301: Research Submission Requirements.

7.2 Additional Review and Meeting Requirements

Research projects that include special populations have the following meeting requirements:

7.2.1 Prisoners: A prisoner representative must attend and participate in the discussion of and vote on research projects that recruit from or that include participants who become incarcerated during the conduct of the research project. All documents pertaining to the prisoner research project are provided to the prisoner representative prior to the IRB meeting. If the prisoner research project involves minors, attempts are made to obtain a child prisoner advocate if one is available. The IRB shall determine that all the conditions for approval are met.

Additionally, research involving prisoners may fall into one of three categories:

1. For research involving interactions with prisoners reviewed by the convened IRB:
   a. Minor modifications to research may be reviewed using the expedited procedure, as documented in SOP 402: Expedited Review and SOP 405: Modifications.
   b. Modifications involving more than a minor change reviewed by the convened IRB must use the same procedures for initial review including the responsibility of a prisoner representative to review the modification and participate in the meeting (as described above).
   c. Continuing review must use the same procedure for initial review including the responsibility of a prisoner representative to review the continuing review materials and participate in the meeting (as described above).

2. Research involving interactions with prisoners reviewed by the expedited procedure:
a. Research involving interaction with prisoners may be reviewed by the expedited procedure if a determination is made that the research involves no greater than minimal risk for the prison population being studied.
   i. The prisoner representative must concur with the determination that the research involves no greater than minimal risk.

b. Review of modifications and continuing review must use the same procedures for initial review using this expedited procedure, including the responsibility of a prisoner representative.

3. Research not involving interactions with prisoners (e.g., existing data, record review) reviewed by the expedited procedure:
   a. Research that does not involve interaction with prisoners may be reviewed by the expedited procedure if a determination is made that the research involves no greater than minimal risk for the prison population being studied.
   b. Review by a prisoner representative is not required. However, the prisoner representative may review the research as a reviewer or consultant if so designated by the IRB Chair.

7.2.2. Children: Research projects requiring a convened IRB review are assigned to an IRB with individuals who have expertise with this population. Alternatively, the IRB will consult with a child expert. The IRB or IRB reviewer shall determine the risk category and appropriate level of review.

7.2.3. Pregnant Women, Fetuses, and Neonates: The IRB shall determine the risk category and appropriate level of review.

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 or prisoner advocate; (2) that all the seven considerations of 45 CFR 46 Subpart A were met; (3) the level of review for the research project; and (4) the protocol-specific findings justifying the IRB’s determination.

7.3.2 Children: The minutes shall reflect (1) that one of the four approval categories of research for children 45 CFR 46 Subpart D were met; (2) the level of review for the research project; and (3) the protocol-specific findings justifying the IRB’s determination.

7.3.3 Pregnant Women, Fetuses, and Neonates: The minutes shall reflect (1) that all of the conditions of 45 CFR 46 Subpart B was met; (2) the level of review for the research project; and (3) 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 participant recruitment.
7.4.2 The IRB Administrator forwards the research project 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 submission materials required by the IRB, and any other information requested or required by the IRB to be considered during IRB review to OHRP Prisoner Research Contact Person.

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

APPROVED BY:_________________________ DATE: 01/06/2020

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020