

Recruitment of Vulnerable Populations  
Policy Number 2876.43



**Campus Institutional Review Board**  
University of Missouri-Columbia


**Recruitment of Vulnerable Populations**

Policy Number 2876.43

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Effective Date: December 12, 2007

Board Review

  
Signed \_\_\_\_\_  
IRB Chair

Date December 12, 2007

Administrative Review

  
Signed \_\_\_\_\_  
Associate Vice-Chancellor for Research

Date December 12, 2007

Recruitment of Vulnerable Populations  
Policy Number 2876.43

**1.0 Policy**

The Campus Institutional Review Board (Campus IRB) requires research proposing to recruit vulnerable subject populations to provide special protection and adequate safeguards to protect their safety and welfare.

**2.0 Scope**

The guidelines of this policy for recruiting subjects apply to all human subject research being conducted under the jurisdiction of the Campus IRB.

**3.0 Purpose**

Federal regulations require that the Campus IRB gives special consideration to protecting the welfare of particularly vulnerable subject populations. Research involving vulnerable subjects requires the investigator and the Campus IRB to take the necessary measures to ensure special protections are incorporated into the research methodology to assure the subjects safety and welfare.

**4.0 Standard Operating Procedure**

**I. RECRUITMENT METHODS**

A rigorous examination is applied to all proposed recruitment methods submitted to the Campus IRB in an effort to determine if the proposed research could include vulnerable populations. The Campus IRB will review all files to require the special protections required for vulnerable subject populations. When the board does not have at least one person on the IRB with the appropriate scientific and scholarly expertise to conduct an in-depth review of the protocol, a consultant or guest may be invited to provide information to the board in compliance with the “Requesting Information from Consultants or Guests” policy.

The Campus IRB must take into account the inclusion/exclusion criteria, participant recruitment and enrollment procedures, and the influence of payments on participants. The review process must be conducted with enough information from the investigator, so that the IRB can determine whether prospective participants are vulnerable to coercion or undue influence. Any proposed activity requesting to include vulnerable subjects, must receive careful consideration during the review process.

Investigators proposing to recruit vulnerable subject populations must comply with the “Recruitment Process” Policy. See Policy.

**II. RECRUITMENT OF VULNERABLE SUBJECT POPULATIONS**

**A. Identifying Potential Vulnerable Subjects**

An investigator must take special precautions when recruiting vulnerable subject populations for research. The Campus IRB recognizes that some or all of the participants are susceptible to coercion, undue influence and may require additional safeguards. When research involves pregnant women, fetuses, or neonates, prisoners or children, the Campus IRB must assure compliance with Subparts B, C, and D respectively, and require a process that provides adequate safeguards as a condition precedent to approval. The Campus IRB will implement a rigorous assessment process to consider specific criteria for approval of such research and shall have a process by which the IRB considers these criteria.

Recruitment of Vulnerable Populations  
Policy Number 2876.43

Not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Some persons are in need of extensive protection, even to the point of excluding them from activities that may harm them. Other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. Indeed, some types of research may, in and of themselves, create a vulnerable group – that is, the subjects lose their autonomy or are exposed to unknown risks. In addition, when an IRB regularly reviews research involving a vulnerable population, consideration will be given to inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects. The IRB will apply additional protections as necessary to protect potentially vulnerable research subjects.

1. VULNERABLE GROUPS SPECIFIED IN THE REGULATIONS:

- Prisoners
- Children
- Pregnant women, fetuses or neonates
- Economically/ Educationally Disadvantaged Persons

The Campus IRB is charged with assuring special categories receive protection as identified in Subpart B, C, and D. The Investigator proposing to include vulnerable subjects must comply with all of the Campus IRB policies. This objective is confirmed in the IRB process through the requirement that the reviewer complete the applicable “Reviewer Checklist” as follows:

- Review of Research Involving Pregnant Women, Fetuses or Neonates Subpart B
- Review of Research Involving Prisoners Subpart C
- Review of Research Involving Children Subpart D

The Campus IRB Compliance Officer is charged with assuring that one or more individuals who were knowledgeable about or experienced in working with participants vulnerable to coercion or undue influence would be present at the meeting when the IRB reviewed research that involved such participants. All activities proposing to research participants vulnerable to coercion or undue influence requires an individual knowledgeable about or experience in working with such participants to be present at the meeting when the IRB reviews the research. The researcher must comply with the following policies: See Administrative Staff Policy; CIRB Review Process; “Application Submission Process”; “Recruitment Process”; “Assessing the Level of Risk”, “Assessing Scientific Merit”, “Informed Consent”; “Continuing Review Report”; and “Amendment Review Process” policies.

2. OTHER VULNERABLE GROUPS

Although federal regulations list specific subject categories requiring special protections, other vulnerable groups may include subjects in certain circumstances or activities. The IRB will determine if special protections for these groups are appropriate on a case-by-case basis, taking into account the risks and benefits and other protections afforded by institutional policies, state and federal law. The Campus IRB recognizes that the following subjects may be considered a vulnerable subject in certain circumstances. The list includes, but is not limited to:

- Cognitively Impaired Persons
- Illiterate or Uneducated Persons
- Students
- Employees
- Low-Income Persons
- Minorities
- Elderly Persons
- International Persons
- Terminally ill patients

Recruitment of Vulnerable Populations  
Policy Number 2876.43

- Subjects of genetic research
- Minority groups
- Special Populations

**B. REGULATORY GUIDANCE FOR IRB APPROVAL**

Institutions with HHS-approved assurances on file will abide by provisions of Title 45 CFR part 46 subparts A-D. Some of the other departments and agencies have incorporated all provisions of Title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

**C. PROCESS FOR IRB APPROVAL**

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects in compliance with federal regulations outline in 45 CFR 46.111(b), 45 CFR 46 Subpart, B, C and D. The Campus IRB process for IRB approval will comply with the “Application Submission”, “Recruitment Process,” “CIRB Review Process”, “Assessing the Level of Risk”, “Assessing Scientific Merit”, “Informed Consent”, “Board Meeting Procedures” policies. The process will include assessment of the proposed activities and investigator responses to determine if they meet the following criteria for IRB approval.

**D. APPLICABILITY OF STATE, FEDERAL AND LOCAL LAWS**

In determining applicability of the regulations, the Campus IRB will take into consideration the subject’s capacity to consent to treatments or procedures involved in the proposed research, under the applicable law of the jurisdiction in which the research will be conducted. In instances where research will take place in jurisdictions outside of Missouri (including other states and other nations), the Campus IRB will consult with MU’s General Counsel’s office to determine if the proposed procedures/treatments are compliant with the laws within the specific jurisdiction.

If the research is to take place outside of Missouri and will involve subjects unable to consent for themselves, the Principle Investigator will supply the IRB with documentation (such as relevant statutes, regulations, Attorney General’s or other legal opinions by practicing attorneys from the jurisdiction) regarding who is legally authorized to provide consent on behalf of the subject under the applicable law of the specific jurisdiction. The Campus IRB may consult with Legal Counsel for review and a determination as to whether the proposed method would provide legally effective consent under applicable law.

In determining who other than parent may consent on behalf of a child to their participation in research, the Campus IRB will take into consideration who under the applicable law of the jurisdiction in which the research will be conducted meets the DHHS definition of a “guardian.” A guardian is an individual who under the applicable law of the jurisdiction in which the research will be conducted is authorized to consent to general medical care on behalf of the child. In instances where research will take place in jurisdictions outside of Missouri (including other states and other nations), the Campus IRB will consult with MU General Counsel to determine the who is authorized to consent to general medical care on behalf of the child within the specific jurisdiction.

Recruitment of Vulnerable Populations  
Policy Number 2876.43

In research involving adults who are cognitively impaired or decisionally-impaired, the Campus IRB will determine who under state or local law meets the DHHS and FDA definition of “legally authorized representative” under the applicable law of the jurisdiction in which the research will be conducted. In instances where research will take place in jurisdictions outside of Missouri (including other states and other nations), the IRB will consult with legal counsel to determine the requirements within the specific jurisdiction.

**III. RESEARCH INVOLVING PREGNANT WOMEN, FETUSES AND NEONATES**

**A. RESEARCH INVOLVING PREGNANT WOMEN, FETUSES OR NEONATES**

Pregnant women may be involved in research under the jurisdiction of the Campus IRB if all of the following conditions are met:

1. 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;
2. The risk to the fetus is not greater than minimal, or any risk to the fetus, which is greater than minimal, is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus.
3. Any risk is the least possible for achieving the objectives of the research;
4. The woman's consent or the consent of her legally authorized representative is obtained in accord with the informed consent provisions of subpart A of 45 CFR 46, unless altered or waived in accord with Sec. 46.101(i) or Sec. 46.116(c) or (d);
5. The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child;
6. For children as defined in 45 CFR 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of 45 CFR 46 subpart D;
7. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
8. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy;
9. Individuals engaged in the research will have no part in determining the viability of a fetus.
10. Research involving observation activities of a newborn and their family members.

**NOTE:** The Campus IRB Compliance Officer may consult with the Health Sciences Compliance Officer regarding researching activities involving a non-hospitalized neonate to determine the appropriate forum for IRB review.

**B. RESEARCH INVOLVING ACTIVITIES AFTER DELIVERY, THE PLACENTA, THE DEAD FETUS, OR FETAL MATERIAL.**

The following activities must be reviewed by the Health Sciences IRB:

- Research involving a delivered fetus, the delivery process, placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, or hospitalized neonates.

**NOTE:** The Campus IRB Compliance Officer will consult with the Health Sciences Compliance Officer regarding researching activities involving an undelivered fetus to determine the appropriate forum for IRB review.

Recruitment of Vulnerable Populations  
Policy Number 2876.43

**IRB REVIEW REQUIREMENTS**

- (1) Where scientifically appropriate, preclinical studies, including clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses:
  - i. The principal investigator shall attach a copy of supportive research literature
  - ii. The principal investigator shall provide a list of reasonable risks to subjects and what additional safeguards will be implemented to minimize those risks.
  - iii. The principal investigator shall propose a plan to monitor the risks
- (2) Where 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;
  - i. The principal investigator shall provide a copy of supportive research literature or authentic documentation from a licensed treating physician in support of participation
- (3) Any risk is the least possible for achieving the objectives of the research;
  - i. The participant is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.
- (4) 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;
  - i. The participant must be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.
- (5) 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 the pregnancy resulted from rape or incest.
  - i. The participant must be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate. If the father is unable to consent, the investigator must show that a reasonable attempt was made to obtain consent but due to unavailability, incompetence, or temporary incapacity or pregnancy resulted from rape or incest.
- (6) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
  - i. The participant must be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.
- (7) 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 this part;
  - i. The participant must be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.
  - ii. Assent is legally effectuated.
  - iii. Permission is obtained as provided in Subpart D.
- (8) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
  - i. No incentives will be allowed to support a termination of pregnancy
  - ii. All incentives must not be coercive
- (9) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy;
  - i. Assurances must be provided indicating researchers have no involvement in any aspects of procedures used to terminate a pregnancy.
- (10) Individuals engaged in the research will have no part in determining the viability of a neonate.
  - i. Assurances must be made to assure that researchers have no involvement with the viability of the neonate.

Recruitment of Vulnerable Populations  
Policy Number 2876.43

**C. RESEARCH INVOLVING PRISONERS**

**NOTE:** The exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C.

The Campus IRB requires all research involving prisoners to be reviewed by a convened board in compliance with the regulations found in Title 45 CFR Part 46 Subpart C. Research involving prisoners will only be approved when the conditions outlined in 45 CFR 46.305 and 45 CFR 46.306 have been met.

A “prisoner” is defined as any individual(s):

- involuntarily confined or detained in a penal institution;
- sentenced to an institution under a criminal or civil statute;
- detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution;
- detained pending arraignment, trial, or sentencing.

**Prisoners who are Children**

A child, who is also imprisoned (detained), is a highly vulnerable subject. Research involving a child prisoner subjects must meet both 45 CFR 46 Subpart C and Subpart D.

If the child is tried, “and convicted”, and sentenced as an adult, and the research is conducted in Missouri, the Campus IRB will look to State law in consultation with General Counsel to determine if the consent process is legally effective in compliance with 45 CFR 46 Subpart C and Subpart D. Consultation with the General Counsel’s office will be solicited to consider the child’s developmental age, and whether the parent’s rights have been subjugated to the State Department of Corrections.

If the research is conducted outside Missouri, the Principle Investigator will supply the IRB with documentation (such as relevant statutes, regulations, Attorneys General or other legal opinions by practicing attorneys from the jurisdiction) regarding who is legally authorized to provide consent on behalf of the child under the applicable law of the specific jurisdiction. The Campus IRB may consult with Legal Counsel for review and a determination as to whether the proposed method would provide legally effective consent under applicable law.

**1. REQUIREMENTS FOR REVIEW**

If an Investigator indicates in the proposed study submission that prisoners will participate in the research, or that subjects may reasonably be expected to be incarcerated at some time point during the study, the following additional requirements will apply to IRB review of the project:

- a. If the research involving prisoners is neither conducted nor supported by DHHS then the IRB’s will include in its minutes that the research falls into one of the four categories of research 45 CFR 46.306(2)(A)-(D).
- b. If the research involving prisoners is either conducted or supported by DHHS then the IRB’s will certify to the Secretary of DHHS, in such a manner as the Secretary may require, that the duties of the IRB’s under this section have been fulfilled. The IRB’s will include in its minutes that the research falls into one of the four categories of research 45 CFR 46.306(2)(A)-(D).
- c. Local regulations: In addition to meeting federal regulations, the project must comply with local and state requirements for inclusion of prisoners as subjects.
- d. Composition of each IRB: A majority of IRB members will 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.

Recruitment of Vulnerable Populations  
Policy Number 2876.43

2. ADDITIONAL DUTIES WHERE PRISONERS ARE INVOLVED

IRB's may review research involving prisoners if it finds that the following conditions are met:

The research falls into one of the following categories:

- The study of possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subject. (“Minimal risk “is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.)
- The 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 subjects
- Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere
- Research on social and psychological problems such as alcoholism, drug addition, and sexual assaults) provided that the study may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research; or
- Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.
  - In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB's to control groups which may not benefit from the research, the study may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research.
- 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.
- The risks involved in the research are commensurate with risks that would be accepted by non-prison volunteers.
- 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's justification in writing for following some other procedures, control subjects must be selected randomly from the group of eligible prisoners for the research project.
- Any information given to subjects is presented in language that is appropriate for the subject population.
- 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 that participation in the clinical investigation will have no effect on his/her parole.
- Where there is need for follow-up examination or care of subjects after the end of their participation in the research, adequate provision has been made for such examination or cares, taking into account the varying lengths of prisoner sentences, and for informing subjects of this fact.

Recruitment of Vulnerable Populations  
Policy Number 2876.43

3. INVESTIGATOR RESPONSIBILITIES WHEN SUBJECTS BECOME PRISONERS  
DURING A RESEARCH ACTIVITY

If a subject becomes a prisoner at any time during the protocol or after the research has commenced the Principal Investigator is required to:

- a. Contact the Campus IRB immediately and submit a written report of the situation in writing to the IRB immediately.
- b. Submit the IRB requested documents immediately so that the IRB can review the protocol again by the convened IRB with a prisoner representative as a member of the IRB. The IRB will take special consideration of the conditions of being a prisoner.
- c. The IRB will review the submission in accordance with the "CIRB Review Process", "Agenda", "Continuing Review", "Amendments to Approved Projects", "Vulnerable Subjects", "Board Meeting Procedures" and "Minute Policies," along with all Standard Operating Procedures and determine what action to take and provide the investigator with a written decision to either (a) approve the involvement of the prisoner-subject in the research in accordance with this policy; or (b) determine that this subject must be withdrawn from the research.
- d. If involvement of the prisoner subject is approved, a special addendum to the consent document must be created that informs the subject of the impact incarceration may have on his or her continued participation.

4. THE CAMPUS IRB WILL APPROVE RESEARCH INVOLVING "PRISONERS" IF ALL  
OF THE FOLLOWING CONDITIONS ARE MET:

NOTE: Research involving prisoners will only be approved when the conditions outlined in 45 CFR 46.305 and 45 CFR 46.306 have been met.

At the time of initial and continuing review of research that involves prisoners, the IRB will meet the following specific requirements in addition to satisfying the requirements for IRB membership outlined in 45 CFR 46.107:

- (a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.
  - At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.
- (b) The research under review represents one of the categories of research:
  - Involves the study of possible causes, effects, and process of incarceration, and of criminal behavior and presents no more than minimal risk or inconvenience to the participants; OR
  - Involves the study of prisons as institutional structures or of prisoners as incarcerated persons and presents no more than minimal risk or inconvenience to the participants; OR
  - Involves conditions particularly affecting prisoners as a class and is either conducted or supported by DHHS; or the Secretary has consulted with experts including penology, medicine and ethics; or has published notice in the Federal Register of intent to approve such research; OR

Recruitment of Vulnerable Populations  
Policy Number 2876.43

- The research is on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant;  
OR
  - The sole purpose of the research is to describe the prevalence or incidence of a disease by identifying all cases and/or to study the risk factor associations for a disease and provides no more than minimal risk without prisoners being a particular focus of research.
- (c) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
- Financial incentives must be approved by the University of Missouri Business Services Accounting Department
  - Prison Officials must give permission in writing to the investigator to conduct the research and also approve the incentive plan.
- (d) The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- Provisions must be proposed that do not place prisoner subjects in a more vulnerable position as a result of participation in research.
- (e) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.
- Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
- (f) The information is presented in language which is understandable to the subject population;
- The Recruitment documents, instruments, Consent, and Information Pamphlets or materials must be written at a sixth grade level or lower if applicable.
  - Provisions must be in place to accommodate illiteracy.
  - Provisions must be in place to orally translate for subjects with poor reading and writing skills
  - Provisions must be made that permit the subject to ask questions about the research activities. Examples include, but are not limited to self-addressed stamped post cards, envelopes, or drop boxes. The investigator must take into consideration efforts to avoid proposing methods that afford the subjects more privileges than would normally be encountered in the prison population.
- (g) Adequate assurance exists that parole boards 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 that participation in the research will have no effect on his or her parole
- The Consent form should include a statement that participation will have no effect on the outcome of a parole hearing.

Recruitment of Vulnerable Populations  
Policy Number 2876.43

(h) Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

- Provisions for follow-up must be approved by the institution
- Provisions should be included in the Informed Consent Documents
- Provisions should be included to make the institution aware of IRB procedures requiring Continuing Review Reports, Audit activities, or complaint follow-ups.

(i) The University of Missouri Columbia is responsible for the conduct of the research and has certified to the Secretary that the Institutional Review Board has approved the research.

- The IRB record must document that all conditions have been met.

APPROVAL OF MINOR CHANGES TO RESEARCH INVOLVING PRISONERS

The Campus IRB will employ the use of the expedited review mechanism only for minor modifications to ongoing research involving prisoners. Such expedited review will be conducted by the prisoner representative who will confirm that the request meets the criteria for expedited review and that the research continues to meet the regulatory criteria for inclusion of prisoners.

ADDITIONAL CONSIDERATIONS IN RESEARCH INVOLVING PRISONERS

INVESTIGATOR RESPONSIBILITIES: Research involving prisoners raises the issue of whether the subject's situation prohibits the exercise of free choice to participate in research and whether the prisoner's confidentiality will be adequately maintained.

- a. An investigator shall consider the benefit in relation to the risk to the subject, including the potential for retaliation for receiving a research benefit. The risks must be commensurate with risks that would be accepted by non-prisoner research volunteers. An investigator must inform the prisoner that participation will not affect parole decisions, and assure that parole boards will not consider the research in making their decisions.
- b. An investigator must provide documentation of a fair selection process.
- c. The subjects must be immune from arbitrary intervention by prison authorities or prisoners.
- d. An investigator must take the necessary measures that provide the subject the opportunity to participate without coercion, undue influence, or deprivation of privacy or confidentiality of responses during the subject's completion of instruments, interviews, or designated research activity.
- e. Inform the prisoner subject that participation will not affect parole decisions, and that the parole boards will not consider the research in making their decisions;
- f. Obtain a permission letter certifying that the proposal has been approved by an authorized Institutional official;
- g. Appreciate that the risks inherent in conducting research with prisoners;
- h. Take the necessary measures that provide the subject with the opportunity to participate without coercion, undue influence, or deprivation of privacy or confidentiality of responses during the subject's completion of instruments, interviews, or designated research activity.

Recruitment of Vulnerable Populations  
Policy Number 2876.43

SPECIAL CONSIDERATIONS TAKEN BY THE CAMPUS IRB:

When reviewing research involving prisoners, the Campus IRB shall:

- a. Solicit a prisoner representative with the appropriate level of expertise to appreciate the inherent risks associated with the research to review the proposal and consult on behalf of the prisoner's rights;
- b. Assure that no member of the board is affiliated with the prison institution.
- c. Ensure that the proposal fits into one of the four categories of permissible research under 45 CFR 46.306(a)(2):
  1. Studies of the possible cause, effects, and processes of incarceration and criminal behavior and involves no more than minimal risk;
  2. Studies of prisons as institutional structures or of prisoners as incarcerated persons and involves no more than minimal risk;
  3. Studies on particular conditions affecting prisoners as a class;
  4. Studies involving a therapy likely to benefit the prisoner;

Full Board Applications involving Prisoners:

The Campus IRB reviews all research involving prisoners at the full board level.

1. If the project includes the possibility of including prisoners, a copy of the application and all supplemental materials will be sent to the designated prisoner advocate for review and action recommendation;
2. The advocate will review and make a recommendation, which will be sent to the assigned primary reviewer;
3. The proposal will be reviewed in accordance with the "Meeting Procedures", "CIRB Review Process", "Continuing Review", "Amendments to Approved Projects", "Vulnerable Subjects", and policies governing Full Board Review.
4. No further action will be taken on the application until the review is complete and a recommendation of action has been made to the Board;
5. The primary reviewer will conduct a substantive review and a Campus IRB authorized individual will communicate the review to the investigator(s);
6. The investigator(s) will respond to the substantive review requests in a timely manner;
7. The primary reviewer will present a summary of the application and advocate's comments at the convened Board meeting;
8. The Board may invite the advocate to the convened meeting for additional information;
9. The primary reviewer will present the recommended action to the board ;
10. The board activities should proceed in compliance with the Campus IRB Meeting Procedures policy.
11. Consider the benefit in relation to the risk to the subject, including a potential for retaliation for receiving a research benefit;
12. Ensure that any possible advantages accruing to the subject through research participation, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such magnitude that it could be considered coercive due to the limited choices in the prison environment;
13. Assess whether the risks involved in the research commensurate with risks that would be accepted by non-prisoner volunteers;
14. Unless the principal investigator provides written justification, control subjects must be selected randomly from the group of available prisoner subjects who meet the characteristics need for that particular proposal;

Recruitment of Vulnerable Populations  
Policy Number 2876.43

15. Ensure that selection processes of subject participants are fair and immune from arbitrary intervention by prison authorities or prisoners;
16. The information must be presented in language which is comprehensible at an appropriate level to the subject population;
17. The documents should not be higher than the 8<sup>th</sup> grade reading level
18. The investigators should develop an alternate method for obtaining data from the prisoner a subject population that is illiterate.
19. The board will take whatever measures are necessary to assure the safety of research participants.

**REQUIREMENTS for DHHS Certification of Prisoner Research**

IRB Reporting Requirements: The IRB notifies OHRP of prisoner research that *is supported by DHHS*, and provides the following documentation:

- provide the name and qualifications of the prisoner representative
  - provide a reasonably detailed description of the research
  - document the category of research
  - document the additional seven protections required by 45 CFR 46.305
  - Assurance that the research represents one of the approved categories of 45 CFR 46.306(a)(2)
  - Statement of the advantages to the subject are not of such a magnitude that the decision to participate is impaired due to the limitations of the prisoner environment
  - Statement that the risks commensurate with that would be accepted by the non-prisoner volunteers.
  - Statement that the Selection procedures are immune from arbitrary intervention by prison authorities or prisoners.
  - Statement that the information is presented in a language understandable to the subject population.
  - Adequate assurances must exist that the parole boards will not take participation in research into account when making decisions regarding parole. Assurance that the prisoner is also notified of this prior to consent.
  - Assurance that follow-up examination or care is provided when appropriate.
- (a) DHHS sponsored research may not proceed until OHRP has reviewed the IRB's determination in accordance with Subpart C of 45 CFR 46.
  - (b) If a Secretary of DHHS panel is required, OHRP will act on behalf of the Secretary to convene the panel.
  - (c) NOTE: If the research is not funded by the DHHS, the IRB is not required to notify OHRP, but should document the record to show it has met all criteria.

Specific guidelines for this vulnerable subject population are set forth in 45 CFR 46.301.

**D. RESEARCH INVOLVING CHILDREN**

NOTE: The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Enrolling children into research studies presents challenging considerations for the IRB. Two factors make a case for research in children.

- Children differ markedly from both animals and adults, and therefore, these models cannot substitute as alternatives to testing in children.

Recruitment of Vulnerable Populations  
Policy Number 2876.43

- Lack of appropriate research in children will increase their risk of harm from exposure to practices and treatments untested in this population. In addition, new therapies could not be developed for diseases that specifically affect children.

The determination of risk and possible benefit to the child is at the core of the concept of beneficence when considering research in a pediatric population. Therefore, the IRB must consider the degree of risk and discomfort involved in the research in relation to the direct benefits it offers to the child before it can determine whether or not the IRB has the authority to approve the study.

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

The Campus IRB shall take into account special ethical and regulatory considerations regarding the special vulnerability of children, and require the investigator to consider the benefits and risks inherent in the proposed research. The Campus IRB will also require the investigator to assess and justify the risks in light of the expected benefits to the child or to society as a whole.

Definitions

(a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

**1. DETERMINATION OF RISK:**

When reviewing research proposing to include children, risk is defined in terms of minimal and greater than minimal risk, and may only be approved by the IRB's as follows:

<b>Risk determination</b>	<b>Benefit assessment</b>	<b>IRB's action</b>
Minimal	With or without direct benefit	Approvable *
Greater than minimal risk*	Potential benefit to child	Approvable *
Greater than minimal risk *	No direct benefit to individual offers general knowledge about the child's condition or disorder	Approvable case-by-case*
Greater than minimal risk**	No direct benefit to child offers potential to, "understand, prevent, or alleviate a serious problem affecting the health and welfare of subjects"	Not approvable**

Recruitment of Vulnerable Populations  
Policy Number 2876.43

\* Risk may not be more than a minor increase over minimal risk, consent of both parents required under normal circumstances.

\* Respect for persons require oral communication with children younger than age 7 about the research and what they will experience to the extent of their development permits.

\*\**Special Note:* Approval to proceed with this category of research must be made by the Secretary of the HHS with input from selected experts, and following opportunity for public review and comment.

- Children may be subjects of research only if informed consent is obtained from the parents, legal guardian or legal representative. Children over the age of 7 must agree to participate in the research and provide assent. When appropriate the researcher and child will sign the form in accordance with the “Child Assent” section of this policy.
- The Campus IRB notes that the “No Child Left Behind Act of 2001” identified 8 categories of protected information for survey, questionnaires, interview materials, or other testing instruments responses:
  1. Political affiliations of student or student’s parents;
  2. Mental or psychological problems of student or student’s family;
  3. Sex behavior or attitudes;
  4. Illegal, anti-social, self-incriminating or demeaning behavior;
  5. Critical appraisals of others with whom students have close family relationships;
  6. Legally recognized privileged or analogous relationships;
  7. Religious practices, affiliations or beliefs of student or student’s parents; and
  8. Income.

NOTE: The Campus IRB mandates that research involving any of the eight identified categories requires Written Parental Informed prior to participation of a child.

## 2. IRB APPROVAL REQUIREMENTS

All research involving children with comply with the “CIRB Review Process” and all other applicable CIRB policies. The Campus IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

- a. The IRB finds that no greater than minimal risk to children is presented and that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.
- b. The IRB will approve research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
- c. The IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, but **ONLY** if the IRB finds that:
  - The risk is justified by the anticipated benefit to the subjects;
  - The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
- d. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians
- e. The IRB may approve research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

Recruitment of Vulnerable Populations  
Policy Number 2876.43

f. The IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

- The risk represents a children increase over minimal risk;
- The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
- The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
- Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

g. The IRB may approve research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children only if:

- The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
- The research will be conducted in accordance with sound ethical principles;
- Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

### **PERMISSION FOR PARTICIPATION**

#### Requirements for permission by parents/or guardians and for assent by children.

(a) The IRB shall determine that 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. In determining whether children are capable of assenting, the IRB shall take into account the:

1. Ages
2. Maturity
3. Psychological state of the children involved.

This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate.

#### Limited Capabilities

If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, *the assent of the children is not a necessary condition for proceeding with the research*. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived.

(b) The IRB shall determine that adequate provisions are made for soliciting the PARENTAL OR GUARDIAN PERMISSION for each child. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted. Where permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

Recruitment of Vulnerable Populations  
Policy Number 2876.43

(c) In addition to the provisions for waiver, the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with Campus IRB policies.

**E. RESEARCH INVOLVING CHILDREN AS WARDS**

Children who are wards of the state or any other agency, institution, or entity can be included in research ONLY if such research is:

- (1) Related to their status as wards, and the investigator provides permission from the court or Guardian that the child may participate in research
- (2) The assent form contains a statement that participation in research does not affect the disposition of the court's decision.
- (3) The Parental Consent or Guardian Consent form must contain a statement that participation in research does not affect the disposition of the court's decision.
- (4) Research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.
- (5) The investigator must provide assurance that the child who is a ward will not be singled out or placed in a more vulnerable position as a result of participation in research.
- (6) The IRB may require the appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. Written documentation must be provided to assure that the advocate has no affiliation or association with the researchers, the research or guardian organization.

NOTE: One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

**ADDITIONAL INFORMATION REGARDING THE INVESTIGATOR'S RESPONSIBILITY**

The Campus IRB will require the investigator to comply with the principles of the *Belmont Report* (Respect, Beneficence, and Justice) and respectfully honor a child's affirmative agreement to participate in research. An investigator must recognize that a child does not have the legal capability of giving informed consent, but does possess the ability to assent or dissent to participate. The regulations define "assent" as the affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. The Campus IRB also requires the investigator to respect the child's "dissent", which would indicate the intent to decline participation in research.

The Investigator should communicate directly with the child's parents (in accordance with the regulations) when securing a child's assent.

Recruitment of Vulnerable Populations  
Policy Number 2876.43

The Campus IRB will comply with the regulations governing children involved in research, by requiring the investigator to not only obtain “assent” from the child, but obtain permission from both parents unless one parent is not reasonably available.

1. Documentation of Assent

The assent document must include 1) an explanation of the proposed research project in an understandable language *appropriate to the child’s age, experience, maturity, and condition* of the child; 2) explanation of benefits; and 3) explanations of the risks, discomforts, and inconvenience associated with the research. The activities must comply with the “Informed Consent” Policy. See Policy.

2. Parental Permission

All processes must comply with the “Informed Consent” Policy. See Policy.

The investigator shall:

- A. Respect the child’s ability to dissent from participation in research, but understand that the child’s parent may overrule dissent at the discretion of the Campus IRB. If the child is a mature adolescent and death is imminent, it is recommended that the child’s wishes be respected
- B. Obtain the permission of both parents if possible or determine the conditions under which one parent may be considered “not reasonably available” (see 45 CFR 46.408). This requirement may be waived by the Campus IRB on a case-by-case basis.
- C. The Campus IRB may consider alternative procedures for protecting the rights and interests of the child (e.g., court appointment of a special guardian);
- D. If a parent’s permission is insufficient, inappropriate, or in opposition to the best interests of the child, the Campus IRB may consider asking for a court to review the parent’s decision;
- E. The Campus IRB may consider inviting a legal consultant to serve as a secondary reviewer on the proposal;

Specific guidelines for this vulnerable subject population are set forth in 45 CFR 46.401.

**F. OTHER VULNERABLE GROUPS THAT MIGHT REQUIRE SPECIAL PROTECTIONS IN**

1. Cognitively Impaired Persons:

Cognitively impaired adults are individuals who have a diminished capacity for judgment and reasoning. Certain situations may render other individuals to be considered cognitively-impaired or decisionally-impaired or have limited decision-making ability. Other individuals may be considered cognitively-impaired or decisionally impaired because they are either under the influence of drugs or alcohol, suffering from degenerative diseases affecting the brain, are terminally ill, or have disabling physical handicaps.

The Campus IRB appreciates the ethical concerns in research involving individuals that are cognitively impaired which may compromise their capacity to understand the information presented, and their ability to make a reasoned decision about participating in research. All processes involving Cognitively Impaired Persons must comply with the “Informed Consent” Policy. See Policy.

### **PROCESS FOR IRB APPROVAL**

The Campus IRB will comply with the “Application Submission”, “Recruitment Process” and “CIRB Review Process” policies when reviewing research proposing to involve cognitively impaired individuals. The process will include assessment of the proposed activities and investigator responses to determine if they meet the criteria for approval.

#### **Criteria for Approval**

In addition to considerations associated with the criteria for approval, the Campus IRB will take into consideration the following points when reviewing research involving adults with impaired cognitive or decision-making capacity:

1. Whether the research could be conducted without these individuals.
2. How the protocol addresses the needs of this vulnerable population.
3. Adequacy of the proposed initial and ongoing consent and assent processes.
4. Who, under state or local law, meets the DHHS definition of “legally authorized representative” under the applicable law of the jurisdiction in which the research will be conducted. In instances where research will take place in jurisdictions outside of Missouri (including other states and other nations), the Campus IRB will consult with MU legal counsel to determine the requirements within the specific jurisdiction.

#### Additional considerations for approval:

The Campus IRB assures that protections for this population should be broadly applied to all decisionally impaired persons, regardless of the source of their impairment. The Campus IRB suggests that this category of research be conducted only when the following guidelines have been met:

- (i) Confidentiality and protection of the subject’s privacy are maintained;
- (ii) Research focuses on an issue unique to the subject population;
- (iii) Research involves no more than minimal risk, unless the purpose is therapeutic;
- (iv) Special review considerations are required for institutionalized individuals and must be reviewed by the convened Campus IRB;
- (v) Description of the psychological or medical screening must be provided;
- (vi) The Investigator meets the guidelines for proper Informed Consent. The process should also:
  1. Presume the subject is competent when disclosing information regarding participation, unless there is evidence of serious mental disability that would impair reasoning or judgment for participation purposes; and
  2. Obtain consent from the legally authorized individual who has been appointed to act on behalf of the subject, cautioning the use of 1) institutional officials; 2) family members; and 3) financial administrators;
- (vii) The Campus IRB may seek legal advice to determine the applicable laws of the State, if needed;
- (viii) Seek the subject’s assent where applicable and determine whether the subject’s dissent shall override the legal representative’s consent.
- (ix) The investigator must make every effort to:
  - 1) protect the subject’s confidentiality and privacy;
  - 2) conduct research that focuses on an issue unique to the subject population;
  - 3) consider the benefits and risks to the subjects

Recruitment of Vulnerable Populations  
Policy Number 2876.43

Additional Notifications to Research Participants Lacking Sufficient Capacity to Consent:

To the extent possible, the researcher should do the following:

1. Inform the subject about the study and seek an agreement to participate;
2. Notify the subject that there is the “right” to object and/or leave the study at any time;
3. Notify the subject in a sensitive way the he/she lacks the sufficient capacity to consent and provide an opportunity for the subject to contest the decision;
4. Explain surrogate consent procedures and options.

2. Student and Employees:

Research involving students or employees may require special attention in certain circumstances. The Campus IRB requires that investigator(s) take special precautions to exercise measures that will ensure the safety and welfare for these subjects.

- Students: An investigator must protect the student in the academic community from coercion by incorporating special protections in the recruitment processes. In an effort to avoid offending the voluntary participation requirement for research, faculty researchers should broadly solicit participants through general announcements rather than direct in-class contact to a specific student group.

*Course Credit:* In the case where course credit is offered, the investigator must assure that coercion is absent. In the case where extra credit is offered, the investigator must offer a comparable alternate method to obtain the credit points for those who decline to participate in the research project. The risk must be minimal to the subject.

*Payment:* Payment in the form of money, gifts, privileges, or other resources, can only be offered as a “recruitment incentive”, not as a benefit of participation. Therefore, the Campus IRB will assess the incentive proposal to assure that it commensurates with the time, effort and risks involved in the research.

*Child Students:* Some college students may be children, for whom parental consent is required. Many high school students take advance placement courses for college credit and may be included in the campus student environment. The investigator must be aware that parental consent is required for children to participate in research in compliance with federal regulations.

- Employees: An investigator must assure that the decision to include employees in research will employ special consideration to protect the subject from adverse actions based on participation.

The proposal must include methods to address:

- 1) Maintaining confidentiality
- 2) Avoidance of coercion
- 3) the right to withdraw without penalty
- 4) disclosure of the potential risks.

The investigator shall assure the subject that participation will not affect their performance evaluations or opportunities for job advancement.

3. Economically or Educationally Disadvantaged Persons:

Research involving economically or educationally disadvantaged persons may require special attention in certain circumstances. The Campus IRB will review research

Recruitment of Vulnerable Populations  
Policy Number 2876.43

involving individuals who are economically or educationally disadvantaged to assure that participation is voluntary, free of coercion, duress, or undue inducement. The Campus IRB requires that investigator(s) take extra measures to ensure achieving an equitable representation of this category of subjects involved in research. All processes involving Low-Income Persons must comply with the "Informed Consent" Policy. See Policy.

In reviewing research in which economically or educationally disadvantaged individuals are likely to be recruited, the Campus IRB will specifically consider the following.

1. Recruitment and consent processes provide sufficient detail for members to assess the voluntary participation of participants.
2. All study documents, including materials read to participants or provided in writing, are appropriate to the population and will be easily understood.
3. Any reimbursement for participation is reasonable in relation to the time required.

An investigator must 1) avoid coercion and undue influence upon subjects to participate; 2) assess and justify the mechanism for offering incentives of value; 3) protect the privacy and confidentiality of the subjects; and 4) provide an opportunity for reasonable alternatives.

4. Minorities:

Research involving members of racial and ethnic minority groups may require special consideration in certain circumstances and raise issues about whether appropriate levels of inclusion or exclusions are appropriately assessed. Issues about whether the methodology supports scientific merit, or will result in generalities unsupported by scientific results should be examined. All processes involving Minority Populations must comply with the "Informed Consent" Policy. See Policy.

The involvement of minorities in research will require the investigator to assess the equitability of the selection process of subjects, the possibility of special vulnerability on the part of some prospective subjects, and informed consent and the relative strengths and weaknesses of vulnerable groups in the consent process.

An investigator must 1) provide a clear rationale for subject exclusions; 2) select an equitable choice of a geographic area for recruitment that must be representative of the racial and ethnic groups in research populations; 3) safeguard the consent process to ensure open and free communication; and 4) consider cultural norms when instituting the consent procedure.

5. Elderly Persons:

Research involving the participation of elderly subjects in research poses several issues for consideration and under certain circumstances requires special protections are employed. There is no age requirement at which time prospective subjects should become ineligible to participate in research: therefore, the inclusion of elderly subjects in research is very important. All processes involving Elderly Persons must comply with the "Informed Consent" Policy. See Policy.

The investigator should take careful consideration to assure the subject can comprehend the information they receive, the length of time required for participation, the need for breaks during the process, the hearing ability of the subject, and whether a proposed monetary incentive plan could be perceived as coercion if the subject is in a fixed income bracket. Special protections will be considered by the Campus IRB on a case-by-case basis.

Recruitment of Vulnerable Populations  
Policy Number 2876.43

6. International Subjects:

International research requires the IRB to assure that the proposal employs special protections in circumstances where foreign subjects are vulnerable. Issues that are considered routine for domestic IRBs can become more complicated when encountered in an international setting. Many international research sites are conducted in less developed countries, where interaction with sponsored research or the regulations of the United States is either unfamiliar or non-existent. All processes involving Foreign Subjects must comply with the “Informed Consent” Policy. See Policy.

The Campus IRB is expected to have knowledge of the proposed local international research context, and will request that the investigator provide supportive documentation or information through local consultation to address any concerns. The IRB may have to resort to receiving information from Ethic Review Committees, Independent Consultants, or other resources.

The Campus IRB is aware that the design and implementation processes may be impacted by local international conditions and situations, and will take that into consideration when reviewing the proposal. However, the Campus IRB will not relax its standards as a matter of convenience for the investigator in an effort to move the proposal forward in the review process. The IRB will expect the investigator to exhibit the same ethical standards and professional mannerisms while conducting research internationally, as it would if the project were conducted in the United States.

The investigator should carefully scrutinize the recruitment and informed consent processes to assure they are absent of practices that could be construed as coercive, based on the limitations of the international host site conditions or environment

The Campus IRB will expect the investigator to develop a mechanism for communicating in a language that is appropriate for the international research community. The investigator must also provide the Campus IRB with translated documents that are prepared in the foreign language. The investigator must provide the Campus IRB with English and back translation version for comparison. The investigator must provide the Campus IRB with a contact individual that can confirm the contents of the translation, should questions arise.

#### IV. IRB RESPONSIBILITIES

1. Campus IRB: Responsible for maintaining current knowledge of the appropriate tools necessary for review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines. Monitoring of processes will comply with the “Quality Assessment and Improvement” Policy. Responsible for review of the research in enough depth to participate in the discussion and voting at the convened IRB meeting.
2. Chairperson and Campus IRB Compliance Officer: Responsible for ensuring the IRB members are well versed in new and evolving regulations and guidelines pertaining to vulnerable populations. The Campus IRB Chair and Compliance Officer will be responsible for selecting primary reviewers who possess the appropriate expertise to conduct reviews of research involving vulnerable categories, and for securing appropriate consulting expertise as needed for selected reviews.
3. Primary Reviewer: Responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources.

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