

## **9.0 Vulnerable Populations**

### **9.1 Research Involving Children**

#### **I. HSC Review and Approval of Research Involving Children**

- A. The special vulnerability of children makes consideration of involving them as research participants particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving children. The HSC may approve research involving children only if special provisions are met.
- B. Federal regulations define “children” as persons who have not attained the legal age for consent to treatment or procedures involved in the research. In the States of Kansas and Missouri, “children” are those persons who are less than eighteen (18) years, unless they have been classified as emancipated minors.
- C. Federal regulations define “guardian” as an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care. In Kansas, “guardian” means an individual or corporation who is appointed by a court to act on behalf of a ward. Among the guardian’s duties and responsibilities is to assure that the ward receives any necessary and reasonably available medical care. Regarding research, a legal guardian may consent to research that involves a significant risk of harm only if (a) the research is intended either to preserve the life of the ward, or to significantly improve the quality of life of the ward, or to assist the ward to develop or regain significant skills or abilities; and (b) the guardian has been fully informed concerning the potential risks and benefits of the proposed research and has specifically consented to the research. In Missouri, “guardian” means one appointed by the court to have care and custody of a minor or an incapacitated person. A guardian may consent to medical care or treatment. Missouri law does not address guardian’s permission for research.
- D. When KUMC researchers conduct research involving children or guardians in states other than Kansas or Missouri, the HSC will obtain the opinion of University Legal Counsel as to protections and requirements applicable in that state.
- E. When the HRPP performs random or for-cause study audits on research involving children, the HRPP will confirm that study records include documentation of guardianship, when applicable.
- F. The HSC must classify research involving children into one of four categories and document their discussions of the risks and benefits of the research study. The four categories of research involving children that may be approved by the HSC are based on degree of risk and benefit to individual subjects.

## II. Categories of Research Involving Children

- A. **Category 1: Research Not Involving Greater than Minimal Risk to Children (45 CFR 46.404)**. When the HSC finds that no greater than minimal risk to children is presented, the HSC may approve the research only if the HSC finds that adequate provisions are made for soliciting the assent of the children and permission of their parents or legal guardians.
- B. **Category 2: Research Involving Greater than Minimal Risk but Presenting the Prospect of Direct Benefit to the Individual Child (45 CFR 46.405)**. If the HSC 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 child, or by a monitoring procedure that is likely to contribute to the child's well-being, the HSC may approve the research only if the HSC determines that:
1. The risk is justified by the anticipated benefit to the children;
  2. The relation of the anticipated benefit to the risk is at least as favorable to the children as that presented by available alternative approaches; and
  3. Adequate provisions are made for soliciting the assent of the children and permission of their parents or legal guardians.
- C. **Category 3: Research Involving Greater than Minimal Risk and No Prospect of Direct Benefit to the Individual Child, but Likely to Yield Generalizable Knowledge about the Child's Disorder or Condition. (45 CFR 46.406)**. If the HSC 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 child, by a monitoring procedure which is not likely to contribute to the well-being of the child, the HSC may approve the research only if the HSC determines that:
1. The risk represents a minor increase over minimal risk;
  2. 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 situations;
  3. The intervention or procedure is likely to yield generalizable knowledge about the participants' disorder or condition which is of vital importance for the understanding or amelioration of the participants' disorder or condition; and
  4. Adequate provisions are made for soliciting assent of the children and permission of their parents or legal guardians.
- D. **Category 4: Research Not Otherwise Approvable, which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Children (45 CFR 46.407)**. If the HSC finds the research does not meet the requirements set forth in categories 46.404, 46.405 or 46.406 as described above, the HSC may approve the research only if:

1. The HSC 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
2. If Federally funded, the Secretary of the Department of Health and Human Services (DHHS), after consultation with a panel of experts in pertinent disciplines and following opportunity for public review and comment, has determined either:
  - a. That the research in fact satisfies the conditions of categories 46.404, 46.405, or 46.406; or
  - b. The following:
    - i. The research 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 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 legal guardians.
3. For non-funded research, the investigator is responsible for providing a written rationale for use of this vulnerable population, including supporting documentation (e.g., literature search) of study design, safety monitoring, and risk/benefit ratio justification.
  - a. The investigator will provide additional documentation or materials as requested by the HSC in order to support the justification for research under category 45 CFR 46.407.
  - b. The investigator will, as requested, assist the HSC in preparation for review by providing any additional materials and documentation required for adequate review.
  - c. The investigator will be available and may be required to present the proposed study to the Committee.
  - d. The investigator cannot initiate the research, including screening and recruitment, until all reviews (including any expert panel reviews) and a complete evaluation of additional safeguards are complete and all requested revisions or recommendations are satisfied and final approval has been granted by the HSC.

III. Requirements for Permission by Parents or Legal Guardians and for Assent by Children (45 CFR 46.408)

- A. Adequate Provisions for Child's Assent. The HSC must find that adequate provisions are made for soliciting the assent of child participants when in the judgment of the HSC the children are capable of providing assent.
  1. In determining whether children are capable of assenting, the HSC takes into account the ages, maturity, and 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 HSC deems appropriate. The child should be given an explanation of the proposed research procedures in a language that is appropriate to the child's age, experience, maturity, and condition. For healthy children, assent is generally appropriate for ages 7 and older. For children whose age and maturity level limits their ability to fully comprehend the nature of the research activity but who are still capable of being consulted about participation in research, the assent procedure should reflect a reasonable effort to enable the child to understand, to the degree they are capable, what their participation in research would involve. For research activities involving adolescents whose capacity to understand resembles that of adults, the assent procedure should likewise include information similar to what would be provided for informed consent by adults or for parental permission.

2. **Waiver of Assent.** If the HSC determines either of the following to be true, then the assent of the children is not a necessary condition for proceeding with the research:
  - a. The capability of some or all of the children is so limited that they cannot reasonably be consulted; or
  - b. 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; or
  - c. The research involves no more than minimal risk to the child; the waiver will not adversely affect the rights and welfare of the child; the research could not practicably be done without waiving the child's assent; and when appropriate, the child will be provided with additional pertinent information after participation.

- B. Adequate Provisions for Parents' or Legal Guardians' Permission. The HSC must find that adequate provisions are made for soliciting the permission of each child's parents or legally authorized representative.
  1. Research not involving greater than minimal risk to children. When research is approved under this category and parental permission is to be obtained, the HSC may find that the permission of one parent, or permission of the legal guardian, is sufficient for research.
  2. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child. When research is approved under this category and parental permission is to be obtained, the HSC may find that the permission of one parent, or permission of the legal guardian, is sufficient for research.
  3. Research involving greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield

generalizable knowledge about the child's disorder or condition. When the research is approved under this category, and 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. Children participating in this category of research must be in the custody of at least one parent. Children in the custody of a legal guardian of state agency may not participate in this category of research due to limitations in Kansas law. See section I.C. above.

4. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. When the research is approved under this section, and 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.

C. Waiver of Parental or Legal Guardian Permission. If the HSC determines that a research protocol is designed for conditions or for a participant population for which parental or legally authorized representative permission is not a reasonable requirement to protect the participants (for example, neglected or abused children), it may waive the consent requirements described above, provided that:

1. An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted; and
2. 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 participants, and their age, maturity, status, and condition.
3. The research is not subject to FDA regulations.

D. Permission by parents or guardians shall be documented in accordance with and to the extent required by §46.117 of subpart A and in accordance with the requirements of 21 CFR 50.27.

E. When the HSC determines that assent is required, it shall also determine whether and how assent must be documented.

F. Wards of the State or Other Agency. Children who are wards of the state or any other agency, institution, or entity can be included in research approved under Categories 2 above. Children who are wards of the state cannot be included in research that is Category 3 above due to limitations in Kansas law. See section I.C. above.

## 9.2 Research Involving Pregnant Women, Human Fetuses, and Neonates

- I. The HSC is required to review and approve all research involving pregnant women, human fetuses, and neonates of uncertain viability or nonviable neonates based on the Federal regulations at 45 CFR 46 Subpart B and in addition to those imposed under other HSC policies, procedures, and other applicable Federal, State, and local laws. Procedural protections beyond the basic requirements for protecting human participants are prescribed in the Federal regulations for research involving pregnant women.
- II. §46.204: Research Involving Pregnant Women or Fetuses. Pregnant women or fetuses may be involved in research if all of the following conditions are met:
  - A. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses; and
  - 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; and
  - C. Any risk is the least possible for achieving the objectives of the research; and
  - 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 45 CFR 46 Subpart A; and
  - 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 45 CFR 46 Subpart A, 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; and
  - F. Each individual providing consent under (D) or (E) above, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate; and
  - G. 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; and
  - H. No inducements, monetary or otherwise, will be offered to terminate a pregnancy; and

- 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.
- III. §46.205: Research Involving Neonates.
- A. Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are satisfied:
    - 1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates; and
    - 2. Each individual providing consent under paragraph B.2 or C.5 below is fully informed regarding the reasonably foreseeable impact of the research on the neonate; and
    - 3. Individuals engaged in the research will have no part in determining the viability of the neonate; and
    - 4. The requirements of paragraph B or C of this section have been satisfied, as applicable.
  - B. Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this policy unless the following additional conditions have been satisfied:
    - 1. The HSC must determine that:
      - a. The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective; or
      - b. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
    - 2. The legally effective informed consent of either parent of the neonate, or if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with 45 CFR 46 Subpart A, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.
  - C. Nonviable neonates. After delivery a nonviable neonate may not be involved in research unless all of the following conditions are satisfied:
    - 1. Vital functions of the neonate will not be artificially maintained; and

2. The research will not terminate the heartbeat or respiration of the neonate; and
3. There will be no added risk to the neonate resulting from the research; and
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 alteration provisions of §46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (C)(5), 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 either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph.

D. Viable neonates. If a neonate is judged viable (i.e. likely to survive to the point of sustaining life independently, given the benefit of available medical therapy), it is then called an infant and should be treated as a child for purpose of research participation. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of 45 CFR 46 Subparts A and D.

IV. §46.206: Research Involving, After Delivery, the Placenta, the Dead Fetus, or Fetal Material.

- 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 accord with any applicable Federal, State, or local laws and regulations regarding such activities.
- B. If information associated with material described in paragraph A of this section 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 subjects and all pertinent subparts of the regulations are applicable.

V. §46.207: Research Not Otherwise Approvable Which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Pregnant Women, Fetuses, or Neonates. The Secretary of the Department of Health and Human Services (DHHS) will conduct or fund research that the HSC does not believe meets the requirements of 45 CFR 46.204 or 45 CFR 46.205 only if:

- A. The HSC 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 pregnant women, fetuses, or neonates; and
- B. The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:
  - 1. That the research, in fact, satisfies the conditions of §46.204, as applicable; or
  - 2. The following:
    - a. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates; and
    - b. The research will be conducted in accord with sound ethical principles; and
    - c. Informed consent will be obtained in accord with the informed consent provisions of 45 CFR 46 Subpart A and other applicable subparts of 45 CFR 46.

VI. Studies in Which Pregnancy is Coincidental to Subject Selection.

- A. Any study in which women of childbearing potential are possible subjects may inadvertently include pregnant women. Federal regulations require that, when appropriate, subjects be provided a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable as part of the informed consent process.
- B. The HSC must judge whether the mother's participation would pose any risk to the fetus or nursing infant. In some studies, the HSC may need to assure that nonpregnant subjects are advised to avoid pregnancy or nursing for a time during or following the research. Furthermore, where appropriate, subjects should be advised to notify the Investigator immediately should they become pregnant. In some instances, there may be potential risk sufficient to justify requiring that pregnant women either be specifically excluded from the research or studied separately.

VII. Exemption from Review. Note that with the revision of Subpart B on November 13, 2001, the exemptions from HSC review listed at 45 CFR 46.101(b) may be applied to research involving pregnant women, human fetuses, and neonates in accordance with 45 CFR 46.201(b).

### **9.3 Research Involving Prisoners**

#### **I. Review and Approval of Research Involving Prisoners**

- A. Research involving prisoners as participants must be reviewed and approved in accord with both standard regulatory provisions and additional considerations for prisoners, as determined by federal regulations.
- B. The Human Subjects Committees at KUMC do not review prisoner research.
- C. If incarceration of a KUMC subject occurs, investigators are instructed to report the incarceration as an unanticipated problem on Problem Report – Form G. If the subject wishes to continue participation and the investigator confirms that participation is feasible, then the HRPP Director will be responsible for securing the re-review of the research to comply with federal regulations.
- D. KUMC may rely on another academic institution, or an independent IRB, to accomplish the research review in accordance with the additional prisoner requirements.

### **9.4 Research Involving Decisionally-Impaired Subjects**

#### **I. General principles in research with decisionally-impaired subjects.**

- A. Whenever feasible, KUMC investigators must conduct research with subjects who have decisional capacity to give legally-effective informed consent on their own behalf.
- B. Decisional capacity is generally thought to include the following four elements:
  - 1. The ability to comprehend information about the nature and purpose of the study, the procedures involved and the risks and benefits of participating versus not participating;
  - 2. The ability to appreciate the significance of the information presented about the potential risks and benefits for one's own situation and condition;
  - 3. The ability to engage in a reasoning process about the risks and benefits of participating versus the alternatives, and;
  - 4. The ability to express a choice about whether or not to participate.
- C. The HSC will consider decisionally-impaired subjects to include mentally disabled persons, those with diagnosed psychoses, persons with dementia or other cognitive disorders and subjects with temporary incapacity due to extreme trauma, duress or pain. The HSC recognizes that some persons in these categories may retain the capacity to consent to research, and these persons' rights would be compromised if they were not allowed to consent for themselves.

- D. Investigators who propose to conduct research with subjects who are not capable of informed consent must demonstrate the scientific justification. Either the purpose of the research is relevant to the specific reason the individual is decisionally impaired, or the research holds out the prospect of direct benefit to the individual subject.
  - E. When subjects are not capable of giving legally-effective informed consent, the HSC will ensure that additional safeguards protect the rights and welfare of subjects.
  - F. The primary safeguards are the assessment of decisionally capacity and the provision of surrogate consent, when approved by the HSC. Other safeguards may include the use of an independent consent monitor, use of waiting periods to decide about research participation or assent to participation by the individual.
  - G. Subjects who are not capable of giving informed consent must be excluded from the research unless the HSC has approved a surrogate consent process.
- II. HSC requirements specific to projects using decisionally-impaired subjects
- A. Proposals for research that likely will include decisionally-impaired subjects must address the following issues:
    - 1. The reasons that these subjects must be included in the research;
    - 2. A discussion of who will determine capacity to consent;
    - 3. Description of the method by which capacity will be evaluated, and;
    - 4. The criteria for identifying incapable subjects.
  - B. The HSC recognizes that there are no universally-accepted standards on assessing capacity. Informal assessment may be approved when the study involves only minimal risk. In general, more rigorous methods will be required when the study involves greater than minimal risk.
  - C. Methods of assessing capacity may include a standardized test, post-consent questions to document comprehension, assessment by a third-party or other protocol-specific measures.
- III. Informed consent process
- A. When investigators have justified the need for inclusion of decisionally-impaired subjects and proposed acceptable methods of determining capacity, the HSC may approve a surrogate consent process accompanied by an attempt to obtain assent of the subject when feasible.
  - B. At its discretion, the HSC may choose not to approve a surrogate consent process when risks to subjects are high and not sufficiently offset by direct benefit to the individual. The availability of acceptable alternative therapies also will be weighed.
  - C. The HSC and investigators will follow Kansas state law regarding the selection of surrogate decision makers. This law supports the priority of

decisions made by either a legal guardian or an attorney-in-fact with the authority to make health care decisions for the individual. However, if neither such role exists, or if the person acting in the capacity cannot be contacted using reasonably diligent efforts, informed consent for research participation may be granted by a family member in the following order:

1. The adult or emancipated minor's spouse, unless they are legally separated;
  2. An adult child;
  3. A parent;
  4. An adult relative by blood or marriage.
- D. The state of Missouri uses the same hierarchy for surrogate decision makers as does the state of Kansas. When KUMC researchers conduct research involving decisionally-impaired subjects in states other than Kansas or Missouri, the HSC will obtain the opinion of University Legal Counsel as to protections and requirements applicable in that state.
- E. For clinical research, the ability of the above four groups of decision-makers to consent on another's behalf only applies when the research is being conducted by a licensed physician with medical staff privileges and when the research has been reviewed and approved by an institutional review board.
- F. The law places a caveat on surrogate decision-making, in that no decision in favor of research participation may be made if the potential subject has previously expressed contrary wishes, either orally or in writing.
- G. When the investigator determines that the subject lacks decisional capacity, the investigator will inform the subject of the investigator's intent to seek surrogate consent, as feasible. If the subject expresses resistance or dissent to participation or to the use of the surrogate decision maker, by word or gesture, the subject will not be enrolled.
- H. Investigators are responsible to ensure that surrogates understand the potential risks, benefits, procedures and available alternatives, understand their decision-making role, and are willing to serve in a surrogate capacity.
- I. Potential subjects must be evaluated on an individual basis. Those who demonstrate the capacity to consent for themselves must be allowed to do so. Subjects who initially demonstrate decisional capacity, but who may lose capacity in the future, should be monitored during the course of the study. If in the course of the study the subject no longer demonstrates decisional capacity, surrogate consent should be obtained.
- J. Copies of instruments used to assess decisional capacity, and other assessment notes, should be kept in the research file along with the informed consent document.

## **9.5 Research Involving Non-English Speaking Populations and Translation of Consent Document**

- I. The HSC requires that consent forms be understandable to the subject population. The HSC may require principal investigators to have the consent form translated into the language most commonly used by the target study population. The two possible cases in which translation may be required include:
  - A. on site recruitment in a foreign location where English is not the primary language;
  - B. in the U.S. where there are known populations to be recruited at a site where there are non-English speakers (for example, Hispanic or Korean populations).
- II. The HSC will accept translations from consultants who provide certification of their expertise in the specific language.

## **9.6 Research involving Students and Employees**

- I. Research involving Students
  - A. Recruitment of students by Investigators who are also faculty members or instructors at KUMC.
    1. Investigators are to advertise and recruit student participants generally, rather than recruiting individual students directly.
    2. An exception to this rule may be allowed when the use of one's own students is integral to the research. For example, research into teaching methods may be allowed by the HSC when sufficient precautions have been taken to protect the student-participant (e.g., using a third party to obtain informed consent).
  - B. Student Participation as a Class Component
    1. The HSC may approve the giving of course credit or extra credit to students who are expected to participate in research activities as part of a class curriculum only when alternative means of obtaining course credit or extra credit is made available to students who do not wish to volunteer as research participants. Students must be given other options for fulfilling the research participation component that are comparable in terms of time, effort, and educational benefit. For example, short papers, special projects, book reports, and brief quizzes on additional reading may be offered in lieu of research participation.

2. These research studies may not involve more than minimal risk and students must be told that they can withdraw from the study at any time without losing the extra credit.
  3. Students should be recruited through general announcements, bulletin board postings or advertisements, rather than individual solicitations.
  4. Research interventions should not be conducted during class time.
- C. Medical School Students
1. Medical school students may only participate in research involving minimal risk and minimal interruption of time.
  2. The HSC has the authority to review and approve research involving medical students. However, proposals regarding the use of medical students shall be approved by the appropriate Dean prior to HSC review.
- D. Student Recruitment
1. Although HSC approval is granted, research activities that are targeted for or designed specifically to address students from a particular Department or School may require the approval of the appropriate Dean before the study may commence.
- E. Student Records
1. KUMC is subject to the provisions of Federal law known as the Family Educational Rights and Privacy Act (also referred to as the Buckley Amendment or FERPA). This act affords matriculated students certain rights with respect to their educational records.
  2. Generally, students have the right to consent to disclosures of personally identifiable information contained in the student's education records to third parties (such as researchers). Therefore, Investigators must obtain student's consent to access personally identifiable information in the student's educational records, even if consent to participate in the research may have been waived by the HSC.

## II. Research involving Employees

- A. Investigators should minimize the likelihood that employees who participate in research programs perceive that the decision will affect performance evaluations or job advancement.
- B. Employees should be recruited through general announcements or advertisements, rather than individual solicitations.
- C. Employees of a particular Investigator or laboratory should not be directly recruited for participation in any study conducted by that Investigator or laboratory, although such employees may, on their own, volunteer to participate.
- D. Investigators who include colleagues or subordinates as research participants should be able to provide a rationale other than convenience for selecting those individuals and should show that the recruitment

methods do not lead colleagues to think that they will be compromised by not participating.

- E. Investigators or other members of the study team may not participate in the study because of the inherent conflict of interest with the outcome. If an investigator desires an exception from this policy, he or she must seek prior approval from the Human Subjects Committee. The investigator should file a Request for Amendment requesting permission from the HSC to add himself/herself or another study team member to the subject population pool and provide adequate rationale for the request. Decisions will be made on a case-by-case basis.

## **9.7 Research in Foreign Countries**

### **I. HSC Review of International Research**

- A. When the foreign institution or site is a performance site “engaged” in research.
  - 1. The HSC will review all international research involving human subjects to assure adequate provisions are in place to protect the rights and welfare of the participants.
  - 2. Because KUMC holds an assurance with OHRP, the foreign institution or site must file an Assurance of compliance (FWA) with OHRP if the study is federally funded.
  - 3. Approval of research is permitted if “the procedures prescribed by the foreign institution afford protections that are at least equivalent to those provided in 45 CFR 46.”
  - 4. The HSC must receive and review the foreign institution or site’s ethics review and approval of each study prior to the commencement of the research at the foreign institution or site.
- B. When the foreign institution or site is a performance site “not engaged” in research.
  - 1. When the foreign institution or site has an established IRB or other ethics committee, the Investigator must obtain approval to conduct the research at the "not engaged" site from the site’s IRB or other ethics committee or provide documentation that the site’s IRB or other ethics committee has determined that approval is not necessary for the Investigator to conduct the proposed research at the site.
  - 2. When the foreign institution or site does not have an established IRB or other ethics committee, a letter of cooperation must be obtained demonstrating that the appropriate institutional or oversight officials are permitting the research to be conducted at the performance site.
  - 3. HSC approval to conduct research at the foreign institution or site is contingent upon receiving documentation of the performance

site's IRB's or other ethics committee's determination, or letter of cooperation, as applicable.

4. It is the responsibility of the KUMC Investigator and the foreign institution or site to assure that the resources and facilities are appropriate for the nature of the research.
5. It is the responsibility of the KUMC Investigator and the foreign institution or site to notify the HSC promptly if a change in research activities alters the performance site's engagement in the research (e.g., performance site "not engaged" begins consenting research participants, etc.).

## II. HSC Considerations for Approval

- A. For Federally funded research, approval of research for foreign institutions or sites "engaged" in research is only permitted if the foreign institution or site holds an Assurance with OHRP and local IRB review and approval is obtained.
- B. The HSC will consider local research context when reviewing international studies to assure protections are in place that are appropriate to the setting in which the research will be conducted. The HSC may require an expert consultant to address issues of local research context if the HSC does not have a committee member with the expertise or knowledge required to adequately evaluate the research in light of local context.
- C. The informed consent documents must be in a language understandable to the proposed participants. Therefore, translated documents in a non-English language may be required.

## III. Monitoring of Approved International Research

- A. The HSC is responsible for the ongoing review of international research conducted under its jurisdiction.
- B. The HSC may require documentation of regular correspondence between the Investigator and the foreign institution or site.
- C. The HSC may require verification from sources other than the Investigator that there have been no substantial changes in the research since its last review.

### **References:**

45 CFR 46.111

21 CFR 56.111

45 CFR 46, Subparts B, C, D

21 CFR 50.20, 25, 27