

## **17. Collaborative Research and Off-Site Research**

### **17.1 Background**

Researchers at UMKC frequently interact with entities or Individuals outside the institution in furtherance of their human subjects research. The University (and its researchers’) regulatory obligations and alternatives for addressing them differ depending on the relationship with the entity or Individual outside the University in the context of the research project. In analyzing the many types of relationships that exist between the University and its researchers, on one hand, and outside entities and Individuals, on the other, a primary distinction is between those that are “engaged” in the human subjects research versus those that are not engaged. This distinction is important because each engaged institution is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable laws and regulations (including the common rule, as appropriate) and with its own human research protection program policies and procedures.

This policy ensures that the University can fulfill its affirmative obligation to assure appropriate oversight of non-exempt human subjects research in which the University is “engaged” and also, under certain circumstances, of other “engaged” entities associated with University research. This policy also describes the process for coordination of IRB research review and oversight for UMKC research involving human subjects which is conducted at off-site locations or at multiple sites.

This policy only applies to collaborative research and off site research not applicable to the Clinical and Translational Science Award (CTSA) master agreement. For CTSA partnering institutions see “Master Agreement”.

### **17.2 Policy**

Off-site research is subject to special procedures for coordination of research review and may involve more than one IRB responsible for research oversight. In these cases, UMKC has established additional procedures to define the responsibilities of each IRB, coordinate communication among responsible IRB, and manage information obtained in off-site or multi-site research to ensure protection of human subjects. In coordinating off-site research reviews, the IO, in consultation with the RCO, will utilize an algorithm to determine the appropriate reviewing IRB (appendix 1).

UMKC’s IRB requires additional information and documentation for research that meets the definition of off-site research. Institutional policies apply to all off-site research involving human subjects regardless of funding source including all unsponsored off-site research involving human subjects such as educational and other survey research. RCO staff is available to advise investigators on meeting the specific institutional and regulatory requirements for obtaining IRB approval of off-site research.

In addition, UMKC may enter into formal agreements with other non-UMKC facilities to provide research review (i.e., to act as the relied-upon IRB), to rely upon other institutions for research review, or to cooperate in review. UMKC enters into these types of arrangements through a Memorandum of Understanding, IRB Authorization Agreement, or contract with the institution(s) in question.

### 17.3 Definitions

**Cooperative research:** is defined as research conducted in cooperation with and at a performance site of an institution or facility that does not fall under UMKC IRB authority. An off-site institution or off-site facility may be domestic or international and may or may not have its own IRB.

**Engaged in research:** an institution is engaged in a human subjects research when its employees or institutional agents, for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; or (2) Individually identifiable private information about the subjects of the research or identifiable biological specimens; or (3) the consent of human subjects for the research.

*Obtaining individually identifiable private information includes, but is not limited to: (1) observing or recording private behavior; (2) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; and (3) using, studying, or analyzing for research purposes individually identifiable private information or identifiable specimens already in the possession of the investigators.*

The Office of Human Research Protections offers a detailed guidance document, “[Engagement of Institutions in Human Subjects Research \(2008\)](#)”.

**Off-site research (or “non-UMKC site,” “off-site institution” or “off-site facility” or “off-site location”):** is human subjects research conducted under the auspices of UMKC’s IRB at performance sites that are not owned or operated by UMKC.

**“On-site research” (or “UMKC site”):** is human subjects research conducted under the auspices of UMKC’s IRB at performance sites that are owned or operated by UMKC.

### 17.4 Types of Collaborations

UMKC researchers participate in a broad range of collaborative relationships with other investigators and institutions. They include:

- **UMKC-affiliated institutions**—many UMKC investigators collaborate with researchers at UMKC-affiliated entities, which includes any institution for which UMKC serves as the IRB-of-record (see OHRP’s website at <http://OHRP.cit.NIH.gov/search/> for confirmation purposes);

- **Other US-based academic institutions**—most if not all, academic institutions within the US, if they receive Federal funding, will have already obtained assurance of compliance through the FWA program. Investigators need to ensure that they or their collaborators meet the respective IRB-review requirements;
- **US-based, non-academic hospitals, clinics, and practices**—hospitals, clinics, and practices that are not affiliated with academic Medical Centers may not already have in place the IRB and FWA programs necessary for Federally-funded research to take place. If investigators are committed to working in these settings, they may be faced with finding a local IRB to review the study and with guiding the organization’s pursuit of assurance of compliance through the FWA program;
- **International entities and researchers**—researchers who wish to conduct human subjects research in countries outside the US or its territories generally must obtain approval from the host country’s ethics committee and from the UMKC IRB.

### **17.5 Research Involving Non-UMKC Performance Sites: Cooperative Research**

For cooperative research projects, the PI, in collaboration with the RCO, determines whether an off-site facility is “engaged” in research. An institution becomes "engaged" in particular non-exempt human subjects research when its employees or agents, for the purposes of the research project, obtain either:

- (1) Data about the subjects of the research through intervention or interaction with them;
- (2) Individually identifiable private information about the subjects of the research; or
- (3) The consent of human subjects for the research. [45 CFR 46.102(d)(f)].

An institution is automatically considered to be "engaged" in human subjects research whenever it receives a direct DHHS award to support such research. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award.

The PIs review should consider the nature of the involvement of off-site personnel in implementing research procedures and/or collecting data at the site. OHRP has issued Guidance (found at <http://www.HHS.gov/OHRP/policy/engage08.html>) that PIs may find helpful. The RCO staff will assist the PI in making determinations of whether the off-site facility is engaged in research.

**Coordinated or joint IRB review:** for Federally funded research, an institution with an FWA that is participating in a cooperative project may enter into a joint review agreement, rely upon (or defer) to another qualified IRB, or make similar arrangements to coordinate the joint review. The University permits similar arrangements for non-Federally funded research. In either case, the institutional official (or designee) must approve the arrangement for either Individual studies or categorically (e.g., facilitated review). Any coordinated or joint review effort requires a written agreement among the involved institutions, regardless of whether they maintain an FWA.

***Deferring to UMKC's IRB:***

- A. In some cases, an off-site facility may enter into an agreement with UMKC, allowing the facility to rely on UMKC's IRB to review, approve, and provide continuing oversight of the off-site research. UMKC may serve as the relied-upon IRB if the PI of the study is a UMKC employee and he/she conducts the study at an off-site facility. In such cases, the off-site facility may be asked to sign an IRB Authorization Agreement or Memorandum of Understanding, or Individual Investigator Agreement to abide by the decisions and determinations of the UMKC IRB in the conduct of the research. (See section on *Negotiation of IRB Authorization Agreements for Collaborating Institutions* for details.)
- B. When UMKC's IRB conducts research reviews for an off-site facility, as appropriate to the agreement and in accordance with its standard policies and procedures for research review and oversight, the IRB ensures sufficient knowledge of local research context for the off-site location as detailed in section on *IRB Knowledge of the Local Research Context*.
- C. The IO, in consultation with the RCO and, if appropriate, UM Office of General Counsel, makes the final determination whether UMKC's IRB will serve as the relied-upon IRB for another institution. Approval of such requests should not focus solely on avoiding duplicative effort and review. Factors to consider include:
- The time and resources required to accept the review, given the demands;
  - The expertise required for initial and continuing review;
  - The ability to comply with the requirements for "local" knowledge of the research;
  - The resources, ability, and willingness of the outside organization, the PI and the research sites to handle complaints, review Adverse Events, and to monitor compliance with applicable laws and regulations and IRB requirements; and
  - The ability and willingness to comply with any additional requirements the outside organization may impose on UMKC IRB's review.
- D. If authorized, documentation of deferred responsibility may take the form, as appropriate, of an **IRB Authorization Agreement, Memorandum of Understanding, etc.** (signed by UMKC's IO and the appropriate representative of the other institution), and a letter of cooperation from the non-UMKC facility administrator and/or an IRB approval from the non-UMKC IRB. The IO signs all agreements as the signatory official for UMKC under its FWA.
- E. The PI must coordinate with project personnel at the off-site locations to initiate any required off-site research review.

- F. The RCO staff will assist the PI in identifying required documentation on a case-by-case basis and maintain copies of all documentation from each off-site facility in the study file.
- G. The PI submits documentation of approvals for off-site research in the initial submission to UMKC's IRB or as it becomes available and may authorize research to start at a site once UMKC IRB approves the protocol. This information will be maintained in the UMKC IRB database and the study files.

***UMKC deferring to another IRB:***

- A. Under certain circumstances, UMKC also may agree to defer responsibility for IRB review to a non-UMKC institution's IRB. However, even when UMKC defers to another institution to serve as the IRB-of-record, UMKC remains responsible for maintaining a system to protect human subjects involved in the research. As the relying institution, UMKC continues to retain responsibility for safeguarding the rights and welfare of human subjects involved in research at the performance site(s) and for educating members of its research community to establish and maintain a culture of compliance with applicable laws and regulations with these SOPs and with institutional policies relevant to protection of human subjects involved in research. UMKC also remains responsible for implementing appropriate oversight mechanisms to ensure compliance with the determinations of the relying IRB.
- B. For UMKC to defer responsibility, the non-UMKC IRB must have an approved FWA. Other criteria taken under consideration when determining whether or not UMKC will defer responsibility to another IRB include whether the cooperating institution is willing to sign an agreement in which it assures UMKC that it complies with the same Federal regulations for the protection of human subjects. Examples of circumstances in which UMKC may defer IRB review may include cases where: the funding agency requires it; the UMKC employee role is limited (e.g., data analysis only); the research began at another institution prior to employment of the investigator at UMKC and remains active only at the other institution (and any funds supporting the research remain under the control of the non-UMKC institution). In cases where UMKC's IRB relies on another IRB, the PI must ensure that research activity does not begin prior to IRB review and approval of the documentation for each study site, as appropriate.
- C. The IO, in consultation with the RCO Director and, if appropriate, with the Office of General Counsel, makes the final determination as to whether UMKC's IRB will defer review and oversight responsibility to another IRB.
- D. Documentation of deferred responsibility may take the form, as appropriate, of an **IRB Authorization Agreement** (applicable to single projects) or **Memorandum of Understanding** (applicable to single project or ongoing IRB review), **Individual Investigator Agreement** (applicable to single projects), a letter of cooperation from

the non-UMKC facility administrator and/or an IRB approval from the non-UMKC IRB. The IO signs all agreements as the signatory official for UMKC under its FWA.

- E. The PI must coordinate with project personnel at the off-site locations to initiate any required off-site research review.
- F. The RCO staff will assist the PI in identifying required documentation on a case-by-case basis and maintain copies of all documentation from each off-site facility in the study file.
- G. The PI submits documentation of approvals for off-site research in the initial submission to UMKC's IRB or as it becomes available and may authorize research to start at a site once UMKC IRB approves the protocol. This information will be maintained in the UMKC IRB database and the study files.

#### **17.6 Research Projects Involving Multiple Sites Where UMKC is the Lead Site/Lead Investigator**

UMKC's default position on research performed at multiple locations is that each must review and approve its own participation in the research. Unless an exception is provided for in this policy, when the University is involved as the primary or coordinating research center or the overall PI of research conducted at multiple locations (see UMKC policy entitled "*who can serve as a PI and other eligibility requirements*"), the PI must assure UMKC's IRB that each performance location involved in the research has been properly approved at that location before the research is initiated there and must notify UMKC's IRB if any lapse or other change in approval status occurs.

If UMKC is the lead site in a multi-site study or the UMKC investigator is the lead investigator, the PI provides additional information to UMKC's IRB to ensure ongoing communication among the participating IRBs and sites. The UMKC investigator submits the following information along with the **IRB application**:

- For each non-UMKC site, a contact name and contact information (e.g., phone or e-mail) and name of Individual who is responsible for such contact;
- For each non-UMKC site, a letter from the appropriate administrator granting permission for the investigator to conduct the research at its site;
- For each non-UMKC site, the relied upon IRB and appropriate documentation as needed (if joint review, a copy of the non-UMKC site's IRB approval letter).

Additionally, the UMKC investigator may be asked to submit to the IRB a written plan for the management of information that is relevant to the protection of human subjects, such as reporting Unanticipated Problems, protocol modifications, and interim results from all participating sites.



UMKC does entertain requests to avoid duplicative reviews, although duplication of effort should not be the sole reason under which the University will agree to serve as the IRB-of-record for other engaged sites or to cede review of University research to other IRBs.

### **17.7 Research at Geographically Separate Off-Site Location with No Cooperating Institution/Facility/Organization**

In the **IRB application** the PI provides the necessary information, as appropriate, on the subject populations, the cultural context, and the languages understood by the human subjects.

If the IRB membership does not have the appropriate expertise to conduct the review, RCO staff and/or the PI assists the IRB in identifying cultural consultants. The PI may supply the name of an appropriate consultant in the IRB application.

Cultural consultants may review consent forms, provide verifications of translations, and provide Guidance on the impact of the research on subjects and the impact of the culture on the research to be conducted.

### **17.8 Research at Geographically Separate UMKC-Owned Site with Non-UMKC Employees**

RCO staff assists the PI in determining whether the non-UMKC employees will actively participate in the implementation of research procedures or will obtain individually identifiable private data about human subjects for research purposes. If the non-UMKC employees are engaged in the research, then the UMKC HRPP applies to those personnel. They must complete the appropriate human subjects protection training, and the PI lists them as study personnel in the **IRB application**.

The PI provides the IRB the necessary information, as appropriate, on the subject populations, the cultural context, and the languages understood by the human subjects.

If the IRB does not have the appropriate expertise to conduct the review, RCO staff and/or the PI assists the IRB in identifying cultural consultants. The PI may supply the name of an appropriate consultant in the **IRB application**.

### **17.9 Sites Operating Under a Formal Agreement with UMKC's IRB**

UMKC may enter into a formal agreement to serve as the relied-upon IRB for a single off-site facility by signing a Memorandum of Understanding, contract, or other official written agreement. Unlike the **IRB Authorization Agreement**, which applies to single projects, a formal agreement provides for ongoing IRB oversight of some or all of the research involving human subjects at the off-site facility.

In these cases, the formal agreement outlines the relationship between the institutions and documents the authority granted to the institution to serve as the relied-upon IRB for the off-site facility.

Sites operating under a formal agreement must file their own Individual assurance with the OHRP. The IO for UMKC and the authorized official for the off-site facility sign all formal agreements.

The terms of the formal agreement specify appropriate human subjects education and training resources for investigators at the cooperating site as well as education and training for UMKC IRB members pertaining to IRB knowledge of the local research context, including distinct subject populations (i.e., veterans, non-English speaking populations, etc.)

RCO maintains a record of current formal agreements on file.

#### **17.10 Negotiation of Federal Assurances for Collaborating Institutions (Applicable to Federally Funded Research)**

The institution is responsible for ensuring that all performance sites and investigators engaged in its Federally supported research involving human subjects operate under an appropriate OHRP or other Federally approved assurance. In general, institutions affiliated solely through professional or collaborative arrangements apply to OHRP for their own assurance. OHRP offers a number of different assurance mechanisms, including the FWA, **Individual Investigator Agreement** and **IRB Authorization Agreements**. If a Federal agency that is not a division of the DHHS supports the research, there may be additional requirements. Off-site facilities determine the appropriate assurance mechanism with assistance from the OHRP based on such issues as the funding source, nature of the research, ownership of the performance site, and affiliation of the Individuals collecting the data.

The PI assists performance sites without an IRB which are “engaged” in research in obtaining the appropriate assurance and IRB approvals. The RCO advises the PI throughout the process, as appropriate.

Off-site facilities submit an application for an assurance to OHRP and designate an institutional signatory official with authority to represent and commit the entire institution and all of its components to a legally binding agreement. If the signatory official is not legally authorized to represent an institution, it may not be covered under the assurance.

In some cases, an institution may operate under another institution’s assurance with the approval of the supporting agency. In such cases, UMKC may enter into a formal **IRB Authorization Agreement** with the collaborating institution for review, approval, and continuing oversight of the research in question.

The institution’s assurance may also cover Independent investigators who are not an employee of the institution only in accordance with a formal written agreement of commitment to relevant human subject protection policies and IRB oversight. The institutions may formalize such agreements under an **Individual Investigator Agreement** or by a commitment agreement developed by the institutions. The institution entering into the commitment agreement maintains the agreement on file and submits copies to OHRP upon request.



### **17.11 Negotiation of an IRB Authorization Agreement with Collaborating Institutions**

Cooperative research studies involving multiple institutions may rely on cooperative review. In such cases, participating IRBs enter into a written cooperative review agreement identifying the specific IRB designated to provide review and detailing the respective responsibilities of the IRB and each institution under the review agreement.

Under an **IRB Authorization Agreement** both institutions agree that one institution is responsible for providing IRB review and the second will rely on the other for IRB review for a single specified project. **IRB Authorization Agreements** list the Federal assurance number for each institution, designate the specific project to which the agreement pertains, and specify that the agreement applies to no other research projects.

The authorized officials for both institutions must approve the agreement in writing. The IO signs all **IRB Authorization Agreements** as the signatory official for UMKC under its FWA. Both institutions maintain an IRB Authorization Agreement on file and agree to submit the document to OHRP upon request.

The IRB which agrees to review the study conducted at another institution (i.e., the primary IRB) has the responsibility for initial and continuing review of the research. The primary IRB takes into account the required criteria for approval, the applicable regulations (e.g. FDA 21 CFR 50 or 56), the facilities and capabilities of the other institution, the measures to be taken by the participating institution to ensure compliance with the IRB's determinations, and community attitudes or local research context, as appropriate.

The primary IRB under an **IRB Authorization Agreement** is responsible for conveying approvals to all participating sites, either directly to the IRB or through the respective PI.

In cases in which UMKC relies on another designated IRB under an **IRB Authorization Agreement**, the PI, with assistance from the RCO, is responsible for providing information to the non-UMKC IRB assuring sufficient consideration of local research context for the UMKC component(s) of the study.

When UMKC's IRB relies on another IRB ("Reviewing IRB") for review of research under an **IRB Authorization Agreement**, it agrees to abide by the decisions and determinations made by the other IRB.

Likewise, Individual investigators agree to abide by those same decisions and determinations and may not modify or alter the research protocol without prior written approval of the Reviewing IRB.

The PI sends all required reports directly to the Reviewing IRB with copies to the UMKC IRB/RCO, as appropriate.

### **17.12 IRB Knowledge of Local Research Context**

In accordance with OHRP Guidance, when UMKC's IRB serves as the relied-upon IRB for another institution or when the research involves distinct subject populations (non-English speaking populations, veterans, etc.), UMKC's IRB must ensure that it possesses or obtains sufficient knowledge of the local research context even when the IRB is geographically removed from the off-site research location.

The PI supports the IRB in understanding the local research context by providing the IRB necessary information, as appropriate, on:

- The anticipated scope of the off-site facility's research activities;
- The types of subject populations likely to be involved;
- The size and complexity of the institution;
- Institutional commitments and regulations;
- Applicable law;
- Standards of professional conduct and practice;
- Method for equitable selection of subjects;
- Method for protection of privacy of subjects;
- Method for maintenance of confidentiality of data;
- Languages understood by prospective subjects;
- Method for minimizing the possibility of coercion or undue influence in seeking consent;
- Safeguards to protect the rights and welfare of vulnerable subjects.

In cases where UMKC's IRB conducts non-local review, members must have sufficient knowledge of the community from which the subjects are drawn to ensure protection of subject rights and appropriateness of the consent process for the subject population. In addition, the IRB must be sensitive to community laws and mores. The IRB may ensure the necessary expertise and knowledge to make appropriate determinations regarding the local research context through one or more of the following activities, as appropriate to the level of risk and in accordance with OHRP Guidance and FDA regulation:

- Personal knowledge of the local research context on the part of one or more IRB members, such knowledge obtained through extended direct experience with the research institution, its subject populations, and its surrounding community;
- Review of the proposed research by representatives from the facility or by one or more ad hoc or cultural consultants with knowledge of the local research context. Ad hoc or cultural consultants may provide comments or recommendations in writing to the IRB prior to the meeting or attend the convened meeting to participate in the deliberation, either physically or through audiovisual or telephone conference, when participation is deemed warranted by the consultant(s) or any one member of the IRB;

Any IRB member may identify the need for consultation with respect to local context considerations. Additionally, a request may be made to the IRB Chair to appoint a consultant in the following instances:

- By IRB members whenever the member determines the assigned protocol requires expertise in a special area in which he/she is unable to review a protocol adequately;
- By the IRB when it decides during its review that a consultant is needed to assist in the review of a protocol.

The IRB Chair (or designee) shall assess whether the local context review is satisfied. See section 2.9 for specifics with respect to use of consultants.

RCO staff will assist the PI in addressing the requirements for information on the local research context upon request.

RCO staff will assist the IRB in identifying appropriate consultants and distributing appropriate review materials pertaining to the local research context to IRB members, as appropriate.

RCO staff will maintain documentation in the database and the study file of the local research context and the measures taken to ensure sufficient IRB knowledge of that context.

The IRB includes the name and contact information for a RCO contact in the consent document for non-local IRB review or designates an Individual at the research site to serve as the contact to relay reports to the IRB.

In the minutes of the meeting or in the IRB file, RCO staff documents the procedures used to ensure that the IRB adequately considered community attitudes.

### **17.13 Responsibilities of Reviewing & Relying IRB & PI**

Where one IRB relies on or defers responsibility for IRB review to another IRB, the following responsibilities exist:

#### **17.13.1 Reviewing IRB**

The reviewing IRB will:

- Conduct initial and continuing reviews, and will review amendments to approved protocol and Unanticipated Problems or AEs that may arise, in accordance with all institutional policies and applicable Federal regulations.
- Have the authority to suspend or terminate the research for failure to comply with conditions of approval or regulatory requirements.
- Notify the relying IRB of any Unanticipated Problems, suspensions or terminations of research. The reviewing IRB will notify the Federal or funding agencies of these events consistent with their policies and procedures and cross copy the relying IRB on any such correspondence.

- Consider conflicts of interest and confirm, where appropriate, that the application or proposal for human subjects research submitted to DHHS matches the protocol submitted for IRB approval.
- Serve as the IRB of record.

### **17.13.2 Relying IRB**

The relying IRB will rely on the IRB review of the reviewing IRB. It will not re-review the study. Another IRB may refuse, on a case-by-case basis, to rely on the review of the reviewing IRB.

### **17.13.3 PI Duties**

**Investigators wishing to defer oversight to a non-UMKC IRB must:**

- Provide a detailed written request by submitting a request to rely form to UMKC's IRB describing the study and investigation.
- Submit a protocol package to the relying IRB that meets the submission requirements of that institution. Copies of the initial application, including all associated application materials should be furnished to UMKC's IRB.

**When a protocol has been approved by a non-UMKC IRB, the PI must:**

- Submit to UMKC's IRB copies of the reviewing IRB's approval letter as well as all forms approved by the reviewing IRB (e.g., **consent form**, recruitment materials, scripts, data collection tools, etc.), and contact information for reviewing IRB staff.
- Continuing reviews: continuing review will be conducted by the reviewing IRB. Copies of all applicable paperwork submitted to the reviewing IRB should also be sent to UMKC's IRB.
- Unanticipated Problems must be submitted to the UMKC IRB for all subjects enrolled through UMKC, in accordance with IRB policy.
- Any changes to the research submitted to the reviewing IRB in the form of an amendment and approved by the reviewing IRB should be copied to the UMKC IRB.
- Study closure: to close a study where UMKC's IRB has deferred to another IRB, the PI must submit to UMKC documentation from the reviewing IRB of study closure.

### **17.14 Special Topic—International Research**

In addition to the usual requirements for research involving human subjects, some unique issues are particularly vital for IRB review to protect human subjects in international populations. To this end, IRB review of research that involves human subjects in other countries must include appropriate expertise for evaluation of the study in the context of the specific international setting(s) and study population(s). In addition, all international research must be reviewed by either expedited review or convened IRB.

Procedures required in Federal and University policies may differ from those normally followed outside the US for research involving human subjects. These may stem from differences in language, cultural and social history, and social mores. In addition, foreign country policies such as the availability of national health insurance, philosophically different legal systems, and social policies may make US forms and procedures inappropriate. Additional laws, regulations, and international directive may apply to research conducted in foreign countries, and may require additional protections for research subjects.

If protections are deemed equivalent, requests to review or waive some standard elements of US approvals may be considered. However, protections afforded to subjects must approximate those provided to subjects in the US. Investigators are encouraged to contact the IRB Chair of the appropriate IRB to discuss these issues.

International research studies must adhere to recognized ethics codes such as: the Common Rule and the Declaration of Helsinki.

Consent and recruitment documents must be in the language that is readable and understandable by the subjects or an approved translation method may be used. Additionally, the following issues should be discussed in the **IRB application** or be addressed in the IRB discussion:

- Benefits to the subject;
- Community leader;
- Culturally-sensitive to local area;
- Paternalism;
- Potential coercion;
- Genetics/homogeneity/validity to other populations;
- Language sensitivity;
- “Helicopter” research (e.g., data/sample collection and leaving site with no follow-up);
- Infrastructure; and
- Justify use of this population.

#### **17.15 Additional Requirements for Department of Defense (DOD) or Department of Navy (DON) Collaborative Research**

UMKC must assure that research complies with additional US Department of Defense (DOD) or the US Department of Navy (DON) requirements in the following instances:

- UMKC conducts, reviews, approves, oversees, supports manages or otherwise is contractually subject to regulation by the DOD or DON; and/or
- Human subject research performed at UMKC using DOD or DON property, facilities, or assets.

Approved by: Lawrence Dreyfus, PhD  
Name of University Institutional Official

\_\_\_\_\_  
Signature of University Institutional Official

\_\_\_\_\_  
Date

## Appendix 1

a. Full committee review

i. Multiple sites

1. Magnitude of risk – the IRB responsible for oversight at the site where the research procedures being conducted pose the greater magnitude of risk will be the IRB of record for the study.
2. Site of majority of research procedures – if there is no clear difference in the magnitude of risks between sites, then the IRB of record will be the IRB responsible for the oversight at the site where the majority of research procedures are being conducted.
3. Site of majority of potential human subjects – if criteria 3(a)(i)(1) – 3(a)(i)(2) are equal, then the IRB of record will be the IRB responsible for the oversight at the site where the majority of potential subjects will be recruited.
4. Affiliation of the principal investigator – if criteria 3(a)(i)(1) – 3(a)(i)(3) are equal, then the IRB of record will be the IRB at the principal investigator’s affiliated institution.
5. Recipient institution of grant/funding – if criteria 3(a)(i)(1) – 3(a)(i)(4) are equal and the principal investigator(s) has a dual affiliation, then the IRB of record will be the IRB of the institution receiving and processing the funding for the study.
6. Special considerations – if criteria 3(a)(i)(1) – 3(a)(i)(5) are equal, then the principal investigator should contact their IRB to discuss any special considerations that may affect the decision as to which IRB should be the IRB of record. The final decision will be made the IRB Directors at the participating sites.

ii. Joint site

1. Affiliation of the principal investigator – the IRB of record will be the IRB at the principal investigator’s affiliated institution.
2. Recipient institution of grant/funding – if the principal investigator(s) has a dual affiliation, then the IRB of record will be



the IRB of the institution receiving and processing the funding for the study.

3. Special considerations – if criteria 3(a)(II)(1) – 3(a)(II)(2) are equal, then the principal investigator should contact their IRB to discuss any special considerations that may affect the decision as to which IRB should be the IRB of record. The final decision will be made the IRB Directors at the participating sites.

b. Expedited or exempt review

i. Multiple sites

1. Site of majority of procedures – the IRB of record will be the IRB responsible for the oversight at the site where the majority of research procedures are being conducted.
2. Site of majority of potential human subjects – if there is no clear difference in the amount of research procedures being conducted between sites, then the IRB of record will be the IRB responsible for the oversight at the site where the majority of potential subjects will be recruited.
3. Affiliation of the principal investigator – if criteria 3(b)(i)(1) – 3(b)(i)(2) are equal, then the IRB of record will be the IRB at the principal investigator’s affiliated institution.
4. Recipient institution of grant/funding – if criteria 3(b)(i)(1) – 3(b)(i)(3) are equal and the principal investigator(s) has a dual affiliation, then the IRB of record will be the IRB of the institution receiving and processing the funding for the study.
5. Special considerations – if criteria 3(b)(i)(1) – 3(b)(i)(4) are equal, then the principal investigator should contact their IRB to discuss any special considerations that may affect the decision as to which IRB should be the IRB of record. The final decision will be made the IRB Directors at the participating sites.

ii. Joint site

1. Affiliation of the principal investigator – the IRB of record will be the IRB at the principal investigator’s affiliated institution.
2. Recipient institution of grant/funding – if the principal investigator(s) has a dual affiliation, then the IRB of record will be the IRB of the institution receiving and processing the funding for the study.
3. Special considerations – if criteria 3(b)(II)(1) – 3(b)(II)(2) are equal, then the principal investigator should contact their IRB to discuss any special considerations that may affect the decision as to which IRB should be the IRB of record. The final decision will be made the IRB Directors at the participating sites.