Office of Research Services

12. Investigator Responsibilities

12.1. Policy

PIs are ultimately responsible for the conduct of research including the investigational plan and applicable regulations for protecting the rights, safety, and welfare of subjects under the Principal Investigator (PI) care. PIs may delegate research responsibility. However, PIs must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility.

The following procedures describe the investigator responsibilities in the conduct of research involving human participants.

12.2. Definitions

Principal Investigator ("PI"): is an Individual who conducts research or under whose immediate direction research is conducted; or, in the event of an investigation conducted by a team of Individuals, is the responsible leader of that team. While the FDA considers a PI and an investigator to be synonymous, this document does not.

Researcher: is the PI and/or investigator.

12.3. Investigators

12.3.1. Principal Investigators

UMKC RCO has adopted a guidance document entitled "*Who Can Serve as a PI and Other Eligibility Requirements*" which sets forth the eligibility requirements and the duties and responsibilities of a principal investigator ("PI"). The IRB recognizes one PI for each study. The PI has ultimate responsibility for all research activities.

12.3.2. Change in Principal Investigator

If there is a change in the PI, the outgoing PI must submit an amendment to notify the IRB that he or she has relinquished the PI responsibilities to the person named in the amendment, or will do so on a specific date. In circumstances where the listed PI is unable to submit an amendment to change the PI, the IRB will request confirmation of such change from the Department Chair or Dean of the listed PI.

12.3.3. Student Investigators

Students (this includes residents and fellows) may not serve as PIs. Students must have a faculty advisor who fulfills the PI eligibility criteria and who will serve as PI and faculty advisor on the study. If a student's faculty advisor cannot serve as PI on the study the student must find a faculty member capable of serving as the PI.

12.3.4. Study Personnel

The University of Missouri Kansas City (UMKC) defines study personnel as persons who have direct contact with subjects, contribute to the research in a substantive way, have contact with subjects' identifiable data or biological samples (e.g., tissue, blood, urine, plasma, saliva), or use subjects' personal information.

12.4. Responsibilities

In order to satisfy the requirements of this policy, investigators who conduct research involving human subjects must:

- Develop and conduct research that is in accordance with the ethical principles in the Belmont report
- Develop a research plan that is scientifically sound;
- Have sufficient resources necessary to protect human subjects, including:
    - Access to a population that would allow recruitment of the required number of subjects.
    - Sufficient time to conduct and complete the research.
    - Adequate numbers of qualified staff.
    - Adequate facilities.
    - A process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.
    - Availability of medical or psychological resources that subjects might require as a consequence of the research.
- Assure that all procedures in a study are performed with the appropriate level of supervision and only by Individuals who are licensed or otherwise qualified to perform such under the laws of Missouri and the policies of UMKC;
- Assure that all key personnel are educated in the regulatory requirements regarding the conduct of research and the ethical principles upon which they are based;
- Protect the rights and welfare of prospective subjects;
- Ensure that risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (II) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes
- Recruit subjects in a fair and equitable manner
- Obtain and document consent as required by the IRB and ensuring that no human subject is involved in the research prior to obtaining their consent;
- Have plans to monitor the data collected for the safety of research subjects;
- Protect the privacy of subjects and maintain the confidentiality of data;
- 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, include additional safeguards in the study to protect the rights and welfare of these subjects;

- Have a procedure to receive complaints or requests for additional information from subjects and respond appropriately,
- Ensure that pertinent laws, regulations, and institution procedures and guidelines are observed by participating investigators and study personnel;
- Ensure that all non-exempt research that includes human subjects receives IRB review and approval in writing before commencement of the research;
- Ensure that all exempt research receives determination in writing before commencement of the research.
- Comply with all IRB decisions, conditions, and requirements;
- Ensure that protocols receive timely continuing IRB review and approval;
- Report Unanticipated Problems involving risk to subjects or others or any other reportable events to the IRB (see section 8);
- Obtain IRB review and approval in writing before changes are made to approved protocols or consent forms;
- Seek IRB assistance when in doubt about whether proposed research requires IRB review;
- Be familiar with regulations & guidelines covering the scope of their research:

Regulation and Guidelines: FDA 312.53(c)(1); 21 CFR 312.60; 21 CFR 312.61; 21 CFR 312.62; 21 CFR 812.43(c)(4); 21 CFR 812.100; 21 CFR 812.140; AAHRPP III.1.B – G; III.2.C and D.

12.5. Training / Ongoing Education of Investigators and Study Personnel

As stated above, one component of a comprehensive HRPP is an education program for all Individuals involved with research subjects. UMKC is committed to providing training and an on-going educational process for investigators and members of their study personnel related to ethical concerns, Federal and state regulatory requirements and UMKC policies for the protection of human subjects. It is the responsibility of the PI to ensure that the study personnel is compliant with all initial and ongoing education as required by UMKC polices and regulatory requirements.

This requirement is mandatory regardless of funding sources. The requirements also apply to research that is considered exempt from IRB review.

Regulations & Guidelines: DHHS 45 CFR 46.102(d): 45 CFR 46.102(f); FDA 21 CFR50.3(c); 21 CFR 50.3(g); 21 CFR 50.3(j); 21 CFR 56.102(c); 21 CFR 56.102(l); AAHRPP III.2.A.

12.5.1. Orientation

All PIs and study personnel are responsible for making themselves aware of the information found in the following sources:

1. UMKC's Standard Operating Policies and procedures for human research protection**;**
2. The Belmont Report: ethical principles and guidelines for the protection of human subjects of research;
3. Applicable Federal & State regulations

12.5.2. Initial Education

The PI and study personnel must complete and submit the following prior to review of research applications:

- UMKC requires CITI basic course (Biomedical Investigator or Social Sciences Investigator (whichever is applicable to the research being conducted) in the protection of human research subjects or other human subjects education that has been approved by the RCO

New research protocols and **Applications for Continuing Review** will not be reviewed or receive final approval until all investigators and study personnel have completed the education requirements.

12.5.3. Continuing Education and Recertification

All investigators and members of their study team must meet institution continuing education requirement every three (3) years after certification of initial education for as long as they are involved in human subject research. There is no exception to this requirement. Acceptable refresher modules at the CITI web-based training site must be completed.
Investigators must submit evidence of continuing education prior to the expiration of their training certification. New research protocols and **Applications for Continuing Review** will not be reviewed for PIs who have not submitted satisfactory evidence of continuing education in human subjects research from CITI.

Investigators who are also IRB Chairs, IRB members, or RCO staff will satisfy the training requirements for IRB members and staff described in this policy under section 2.12.

12.5.4. Additional Resources

The RCO will be available for scheduled in-services at departmental meetings. Also, human research protection information will be made available on the RCO website at
http://ORS.UMKC.edu/research-compliance/institutional-review-board-(IRB)
Including links to, UMKC Policies and Procedures and Federal and State regulatory sites.

12.5.5. Investigator Concerns

Investigators who have concerns or suggestions regarding UMKC's HRPP should convey them to the RCO Director, IRB Chair, IO, or other responsible parties (e.g. College Dean, Departmental Chair, etc.) regarding the issue, when appropriate. The IO or RCO Director will research the issue, and when deemed necessary, convene the parties involved to form a response

for the investigator or make necessary procedural or policy modifications, as warranted. In addition, the IRB Chair and/or the RCO Director will be available to address investigators' questions, concerns and suggestions.

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

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Signature of University Institutional Official Date