Office of Research Services

2. Institutional Review Board

2.1. Policy

The University has established one Institutional Review Board ("IRB") to ensure the protection of human subjects in research under the auspices of the institution.

UMKC Institutional Review Board – UMKC IRB (IRB00000664): this IRB is delegated to review human subject research for the following areas:

1. Research involving the social sciences, such as sociology, psychology, anthropology, economics, political science, and history.
2. Clinical trials such as drug studies;
3. Research involving medical interventions; and
4. The prevention, treatment, or understanding of basic mechanisms of disease.

For the purposes of these SOPs, all on-site IRBs will be referred to as the "University IRB," "institutional IRB," or "IRB". Through the "Common Reciprocal agreement between the Frontier Partners for Designation of Institutional Review Board of Record" the University IRB may serve as the IRB of record for any of our frontiers partners (Children's Mercy Hospital (CMH), the University of Kansas Medical Center (KUMC), Saint Luke's Hospital of Kansas City, and Kansas City University (KCU). Research being conducted through the common reciprocal agreement will follow the general terms of that agreement.

All non-exempt human subjects research under the auspices of the institution must be reviewed and approved by an authorized IRB prior to the initiation (i.e., before any subject(s) can be enrolled in the study) of research activities.

The following describes the authority, role and procedures of the University IRB.

Regulations & Guidance: DHHS 45 CFR 46.103; AAHRPP I.2.B; and I.3.K.

2.2. IRB Authority

UMKC's policy authorizes the University IRB to:

- Approve, require modifications to secure approval, or disapprove all research activities overseen and conducted under the auspices of the University;
- Suspend or terminate approval of research not being conducted in accordance with the IRB requirements or that had been associated with unexpected serious harm to participants; and
- Observe or have a third party observe, ongoing research projects and the consent process, as well as conduct continuing review of the project, including audits of research records.

Research that has been reviewed and approved by the IRB may be subject to further review, suspension and termination by University officials consistent with University policy (see section 3.10). However, such officials may not approve research that has not been approved by the IRB. University officials may strengthen requirements and/or conditions, or add other modifications to secure University approval or approval by another University committee. Previously approved research proposals and/or consent forms must be re-approved by the IRB before initiating the changes or modifications. The IRB Chair and/or designee will make the determination whether the changes require convened IRB re-review or expedited review

Regulations & Guidance: DHHS 45 CFR 46.112; FDA 21 CFR 56.103; 21 CFR 56.109; 21 CFR 56.112; and 21 CFR 56.113.

2.3. Number of IRBs

There is currently one on-site IRB (the UMKC IRB). The Institutional Official (IO) and Research Compliance Office (RCO) Director will review the activity of the UMKC IRB on at least an annual basis and make a determination as to the appropriate number of IRBs that are needed for the institution. This determination will be based on the evaluation of the performance of the IRB as described in section 2.14.

2.4. Roles and Responsibilities--Chair of the IRB

The IO, in consultation with the RCO Director and, as appropriate, IRB members, appoints an IRB Chair and IRB Vice Chair to serve for renewable three-year terms. Any change in appointment, including re-appointment or removal, requires written notification from the IO. The IRB Chair and IRB Vice Chair must have previously served as members of an IRB.

The IRB Chair should be a highly respected Individual, fully capable of managing the IRB, and the matters brought before it with fairness and impartiality. The IRB must be perceived to be fair, impartial and immune to pressure by the institution's administration, the investigator whose protocols are brought before it, and other professional and nonprofessional sources.

The criteria used to select an IRB Chair include experience with, and knowledge of, applicable Federal and state laws and regulations, and institutional policies. This Individual must be willing to commit to the IRB; must have past experience as an IRB member; and must demonstrate excellent communications skills, along with an understanding of the research being conducted at the University and its affiliates. The IRB Chair must also be flexible and demonstrate a thorough understanding of ethical issues involved in research.

The IRB Chair convenes and Chairs the meetings of the IRB and is required to attend a majority of the convened meetings of the IRB. The IRB Chair may conduct or delegate expedited review of research that qualifies for such review; review the responses of investigators to contingencies of the IRB (to secure IRB approval); and to review and approve minor changes in previously approved research during the period covered by the original

approval. The IRB Chair may delegate such authority to the authorized IRB Vice Chair and/or designee as needed.

The IRB Chair is a signatory for correspondence generated by the IRB and may delegate signatory authority to the IRB Vice Chair and/or the RCO Director.

The IRB Chair advises the IO and the RCO Director about IRB member performance and competence.

The performance of the IRB Chair will be reviewed on an annual basis by the RCO Director in consultation with the IO.

If the IRB Chair is not functioning in accordance with the IRB mission, policies and procedures; has an undue number of absences; or is not fulfilling the responsibilities of IRB Chair, then he/she may be removed by the IO and replaced by a suitable alternative.

Regulations & Guidance: AAHRPP II.1.D.

2.5. Roles and Responsibilities - Vice Chair of the IRB

The Vice Chair of the IRB ("IRB Vice Chair") is an IRB member appointed by the IO to serve as IRB Chair in the absence of the IRB Chair. The IRB Vice Chair must have the same qualifications, authority, and duties as IRB Chair.

2.6. Chair of IRB Subcommittee

If the IRB Chair creates one or more IRB subcommittees, the Chair shall also appoint a Chair of the IRB subcommittee ("IRB subcommittee Chair").

2.6.1. Subcommittees of the IRB

The IRB Chair, in consultation with the RCO Director, may designate one or more IRB subcommittees to perform duties, as appropriate, to review and undertake other IRB functions, and to make recommendations to the IRB for research that is not expedited. The IRB Chair, in consultation with the RCO Director, will appoint IRB members to serve on each IRB subcommittee created under this section. The number and composition of the IRB subcommittee members shall depend on the authority delegated by the IRB Chair to such IRB subcommittee (e.g., merely making recommendations versus decision-making authority). Members of the IRB subcommittee must be experienced in terms of seniority on the IRB and must be matched as closely as possible with their field of expertise to the study assigned to the IRB subcommittee.

2.7. IRB membership

IRB members are selected based on appropriate diversity, including consideration of race, gender, and cultural backgrounds; varied community involvement and affiliations; knowledge and experience with vulnerable populations; and with multiple, diverse professions or

specialties, including both scientific members and non-scientific members. The structure and composition of the IRB must be appropriate to the nature of the research that is reviewed. Every effort is made to have member representation that has an understanding of the areas of specialty that encompasses the types of research performed at the University. The University IRB has procedures (see section 2.9) that specifically outline the requirements for protocol review by Individuals with appropriate scientific or scholarly expertise beyond or in addition to that available through the IRB members.

The IRB must promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects and possess the professional competencies necessary to review specific research activities. Ideally, a single member of the IRB could exhibit multiple professional competencies in executing their duties as a member of the IRB.

Regulations & Guidance: DHHS 45 CFR 46.107; FDA 21 CFR 56.107; AAHRPP II.1.A; & II.1.D.

2.7.1. Definitions

Affiliated: ***An employee or agent of UMKC or University Health (UH) (or any member of that person's immediate family). An emeritus faculty or retired staff member is also considered to be affiliated if he/she has been retired or involved in paid or unpaid University activities (including research or service) within the last 2 years. Current undergraduate, graduate, and postdoctoral students are also considered to be affiliated, as described by HRPP policy.***

Primary IRB member*:* Primary members include, but are not limited to Individuals who are: full- or part-time employees; current students; members of any governing panel or board of the institution; paid or unpaid consultants; health care providers holding credentials to practice at the institution; and, volunteers working at the institution on business unrelated to the IRB.

Alternate member: is an Individual who has the experience, expertise, background, professional competence, and knowledge comparable to that of the active IRB member(s) whom the alternate would replace.

Non-scientific member: is any IRB member who has formal education and training in a discipline generally considered to be non-scientific (e.g. Humanities, law, business) and/or is engaged in an occupation or role that is generally considered to be non-scientific (e.g. Law enforcement, minister).

Scientific member: is an Individual who has formal education and training as a physician or other medical professional, or MS and/or PhD level physical, biological, or social behavioral scientists.

2.7.2. Composition of the IRB

1. The IRB will have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

2. The IRB will be sufficiently qualified through the experience, expertise, and diversity of its members, including consideration of race, gender, cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

3. In addition to possessing the professional competence necessary to review specific research activities, the IRB will be able to ascertain the acceptability of proposed research in terms of institutional policies and regulations, applicable law, and standards of professional conduct and practice. The IRB will therefore include persons knowledgeable in these areas.

4. If the IRB regularly reviews research that involves a vulnerable category of subjects, consideration will be given to the inclusion of one or more Individuals on the IRB, who are knowledgeable about and experienced in working with these subjects. When protocols involve vulnerable populations, the review process will include one or more Individuals who are knowledgeable about or experienced in working with these participants, either as members of the IRB or as consultants (see section 2.9 and section 6).

5. Every effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes. The IRB shall not consist entirely of members of one profession.

6. The IRB includes at least one member whose primary concerns are in *scientific areas* and at least one member whose primary concerns are in *nonscientific areas*.

7. At least one member who is not otherwise affiliated with UMKC and who is not part of the immediate family of a person who is affiliated with UMKC.

8. One member may satisfy more than one membership category.

Members: the backgrounds of the members shall be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the IRB. Members must include:

A. Nonaffiliated member(s): the nonaffiliated member(s), who can be either scientific or nonscientific reviewer(s), should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should

be given to recruiting Individuals who speak for the communities from which the University of Missouri- Kansas city will draw its research subjects.

B. Scientific members: the IRBs will contain at least one member with scientific expertise appropriate and relevant to the research reviewed by that IRB. When an IRB encounters studies involving science beyond the expertise of the members, the IRB may use a consultant to assist in the review. However, if and when FDA regulated studies involving the use of an Investigational New Drug (IND) or Investigational Device Exemption (IDE) products are reviewed, the convened meeting must include a licensed physician member.

C. Nonscientific member: the intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Therefore, nonscientific members are Individuals whose education, work, or interests are not solely in medical or scientific areas.

D. Representatives of special groups of subjects: when certain types of research are reviewed, members or consultants who are knowledgeable about the concerns of certain groups may be required.

E. Chair: the Individual IRB Chair should be highly respected Individuals, from within or outside the University of Missouri-Kansas City, fully capable of managing the IRB and the matters brought before it with fairness and impartiality.

Note from OHRP answers: "How do I determine the various categories of members for the IRB roster?"

Regulations & Guidance: DHHS 45 CFR 46.107; FDA 21 CFR 56.107; AAHRPP II.1.A

2.7.3. Nomination & Appointment of IRB Members

The IRB Chair, IRB Vice Chair and/or the RCO Director identify a need for a new and/or replacement IRB member who may be either a primary or alternate member of the IRB.

2.7.3.1. Nomination of New IRB Members

New IRB members may be nominated as follows:

- By an IRB member;
- By University department Chairs or unit heads;
- By the RCO Director;
- By the IRB Chair; and/or
- By the IO.

The RCO Director will review all supporting documentation and information submitted to identify those nominees who can provide relevant technical expertise or other pertinent qualifications as needed by the IRB to review the types of research commonly presented to the IRB. All nominations and supporting documents will be forwarded for final selection by the IO.

2.7.3.2. Appointment of New IRB Members

The IO, in consultation with the I RCO Director, is responsible for selecting Individuals to serve as a new IRB member (and indicate whether primary or alternate). All appointments shall be documented, in writing, by the IO.

Appointments are made for a three-year or less period of service, after which the IO must elect to extend the member's appointment for another three-year period. Any change in appointment, including reappointment or removal by the IO, requires written notification. Members may resign by written notification to the RCO Director or IRB Chair.

2.7.3.3. Documentation and Information for New IRB Members

The following items are required from each member of the IRB at initial appointment and as directed and will be made available as appropriate, upon request for audit [DHHS 45 CFR 46.107]:

- Current *curriculum vitae* ("CV");
- Attendance at 50% (at minimum) of the convened IRB meetings during the course of a year. The member is to notify the RCO of any potential absence as far in advance as possible;
- Participation in the required initial training and new IRB member orientation must occur prior to review of any research; and
- Documentation of current institutional certification in compliance education in the conduct of Human Subjects Research (e.g., CITI training).
- Documentation of current institutional certification of Conflict of Interest CITI training.

Documents supporting final appointments along with records of continuing education will become part of the permanent membership records maintained by the RCO. The IRB membership will be reviewed at least annually. Required changes will be reported to the OHRP.

Regulations & Guidance: AAHRPP II.1.E.

2.7.3.4. Periodic Review of IRB Composition and Membership

On an annual basis, the IO and the RCO Director shall review the membership and composition of the IRB to determine if they continue to meet regulatory and institutional requirements. Required changes in IRB members will be reported to the OHRP.

2.7.4. Alternate IRB Members:

The appointment and function of alternate members is the same as that of primary IRB members; and the alternate's expertise and perspective are comparable to those of the primary member. The area of expertise of the alternates should match that of the primary member such that the Federal policy requirements are met if a primary member cannot attend an IRB meeting. The role of the alternate member is to serve as a voting member of the IRB when the primary member is unavailable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received.

The RCO maintains a roster of trained alternates who may vote in place of an absent voting member. In addition, all active members listed on the OHRP roster may be utilized as alternates for other active members as long as all applicable regulatory requirements and IRB policies are met.

The alternate member will have similar expertise as the regular committee member for whom s/he is serving as a replacement (physician to physician; other scientific to other scientific; and non-scientific to non-scientific).

The alternate member will assume all of the responsibilities of the committee member for whom s/he is serving as a replacement.

Alternate members may attend IRB meetings without serving as a replacement for a regular committee member; however, in this capacity, the alternate member may not participate in any of the final approval decisions of the committee.

IRB minutes will document if a member present at the meeting is an alternate as well as the IRB member for whom the alternate is substituting.

2.8. IRB Member Conflict of Interest

No IRB member may participate in the review (initial, continuing, or modification) of any research project in which the member has a Conflict of Interest ("COI"), except to provide information as requested.

IRB members may find themselves in any of the following COI scenarios when reviewing research:

1. Where the member or consultant is involved in the design, conduct, and reporting of the research;

2. Where an immediate family member of the member or consultant is involved in the design, conduct, and reporting of the research;

3. Where the member holds significant financial interests (see section 14) related to the research being reviewed; or

4. Any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a protocol.

It is the responsibility of each IRB member to disclose any COI with a study submitted for full board review, and recuse him/herself from deliberations and vote by leaving the room; departure is noted in the minutes. For studies reviewed under expedited review procedures the member is responsible for notifying the RCO of the conflict and requesting the application be reassigned to a non-conflicted IRB member.

The IRB Chair or designee, will poll IRB members at each convened meeting to determine if a COI exists regarding any protocols to be considered during the meeting and reminds the committee that members with conflicts should recuse themselves by leaving the room during the discussion and vote of the specific protocol. IRB members with a conflicting interest are excluded from being counted towards quorum (see 3.5.7 for definition of quorum). All recusals by members with COI are recorded in the minutes.

If the conflict of interest status of an IRB member changes during the course of a study, the IRB member is required to declare this to the IRB Chair and/or RCO.

Regulations & Guidance: DHHS 45 CFR 46.107(e); FDA 21 CFR 54; 21 CFR 56.107(e); AAHRPP II.1.C.

2.9. Use of Consultants

A "Consultant" is an Individual, not on the IRB roster, with competence in a special area that the IRB has invited to assist in the review of issues which require expertise beyond or in addition to the availability on the IRB. These Individuals do not count for IRB quorum purposes and cannot vote on any issue before the IRB [45 CFR 46.107(f)].

When necessary, the IRB Chair or the RCO Director may solicit advice or otherwise engage Individuals to assist the IRB in its review of issues or IRB proposals, which require appropriate scientific or scholarly expertise beyond or in addition to that available on the IRB.

The need for an outside reviewer is determined in advance of the IRB meeting by the RCO Director, RCO staff or IRB Chair by reviewing the IRB proposals scheduled to be reviewed at the convened meeting. The RCO will ensure that all relevant materials are provided to the outside reviewer prior to the convened IRB meeting.

Outside reviewers or consultants can be obtained either within or outside the University community. In the event that additional scientific or scholarly expertise cannot be obtained for

a research proposal the IRB Chair or RCO will postpone the proposal to the next IRB meeting in order that appropriate review may be obtained.

The RCO Director will review the COI policy for IRB members (see section 2.8) with consultants. Consultants must verbally confirm to the RCO Director that they do not have a COI prior to review. Individuals who have a COI or whose spouse or family members have a COI in the research will not be invited to provide consultation.

The consultant's findings will be presented to the convened IRB for consideration either in person or in writing. If in attendance, these Individuals will provide consultation but may not participate in or observe the vote.

Ad hoc or informal consultations requested by Individual members (rather than for convened IRB review) will be requested in a manner that protects the researcher's confidentiality and is in compliance with the IRB COI policy (unless the question raised is generic enough to protect the identity of the particular PI and research proposal).

To the extent that written statements or recommendations are provided by a consultant, a copy will be kept in IRB records. Key information provided by consultants at meetings will be documented in the minutes. Written reviews provided by the outside reviewer will be filed with the protocol.

Regulations & Guidance: DHHS 45 CFR 46.107(f); FDA 21 CFR 56.107(f); AAHRPP II.1.B.

2.10. Duties of IRB Members

Except for emergency IRB meetings, the agenda, submission materials, proposals, proposed consent forms and other appropriate documents are distributed to IRB members, ideally, 5 business days prior to the convened meetings at which the research is scheduled to be discussed.

For emergency IRB meetings, these written materials will be submitted as timely as possible in advance of the scheduled IRB meeting date and time.

IRB members will treat the IRB proposals, protocols, and supporting data confidentially. All copies of the protocols and supporting data are returned to the IRB staff at the conclusion of review for document destruction.

2.11. Attendance Requirements

If a member is unable to attend a scheduled meeting, they should inform the IRB Chair, IRB Vice Chair, or a RCO staff member prior to the scheduled meeting. In the case of an emergency, members should provide notification as soon as possible. If an IRB member is unable to attend IRB meetings for a prolonged period, then such notice should be given so that

the IO, the RCO Director and the IRB Chair can determine whether an alternate member is needed and, if so, the alternate member should be temporary or permanent.

If an IRB member is to be absent for an extended period of time, such as for a sabbatical, he or she must notify the IRB in advance so that an appropriate replacement can be obtained. The replacement can be temporary, for the period of absence, or permanent if the member is not returning to the IRB. If the member has a designated alternate (see section 2.7.1 and 2.7.4), the alternate can serve during the primary member's absence, provided the IRB has been notified in advance.

2.12. Training & education

The University is committed to providing initial and on-going training and education for the IRB Chair, IRB Vice-Chair, and IRB members, and RCO staff related to research ethics concerns, these SOPs, Federal and state regulatory requirements, and the University's policies for the protection of human subjects involved in research.

Regulations & Guidance: AAHRPP I.3.A; and I.4.A.

2.12.1. New IRB Members-Orientation

New IRB members, including alternate members, will meet with the RCO Director or designee for an informal orientation session. At the session, the new member will be given an IRB handbook (electronic or physical copy (if requested)) that includes copies of the following:

- UMKC's HRPP;
- IRB member handbook;
- Links to the applicable Federal & state regulations including:
- 45 CFR part 46 – the common rule
- 21 CFR part 50 – protection of human subjects
- 21 CFR part 56 – Institutional Review Boards;
- Links to the FDA information sheets Guidance[5] and links to the OHRP Guidance sheets [6]

[5] see FDA website at: http://www.FDA.gov/scienceresearch/specialtoPIcs/runningclinicaltrials/Guidancesinformationsheetsandnotices/ucm113709.htm

[6] see OHRP website at: http://www.HHS.gov/OHRP/policy/INDex.html

2.12.2. New IRB Members—Initial Education

Before serving, a new IRB member must receive and successfully complete the web-based initial education requirement, which consists of the CITI training modules for the protection of human subjects involved in research.

2.12.3. IRB Members—Continuing Education

To ensure that oversight of research involving human subjects is ethically grounded and the decisions made by the IRB are consistent with current regulatory and policy requirements, training is continuous for IRB members throughout their service on the IRB. Examples of educational activities include, but are not limited to:

- Continued attendance at IRB meetings
- Participation in IRB deliberations including reading and interpretation of IRB policies and Regulations
- In-service training at IRB meetings;
- Annual training workshops and sessions;
- Distribution of appropriate publications;
- Identification and dissemination by the RCO Director and/or RCO staff of new information that might affect the HRPP, including laws, regulations, policies, procedures, and emerging ethical and scientific issues to IRB members via e-mail, mail, or during IRB meetings;
- CITI refresher courses (required every four years);

2.12.4. RCO Staff – Orientation & Initial Education

New RCO staff will be given an orientation electronic binder that includes links to the following:

- UMKC's –FWA;
- UMKC's HRPP;
- *Belmont report*;
- Applicable Federal & state regulations including:
    - 45 CFR part 46 – the common rule
    - 21 CFR part 50 – protection of human subjects
    - 21 CFR part 56 – Institutional Review Boards;
- FDA information sheets Guidance (or a link to same at the FDA's website); and
- OHRP Guidance sheets (or a link to same at the FDA's website).

Each new RCO staff member is expected to successfully complete the following educational requirements:

- UMKC HIPAA privacy training; and
- The CITI training module for the protection of human subjects for both biomedical and social behavioral research.

2.12.5. RCO Staff—Continuing Education

Continuing training and education is provided to RCO staff through the following:

- Discussions of regulatory and ethical issues that arise during the processing of IRB proposals;
- Attendance at convened IRB meetings;

- Conferences on human subjects research protections; and
- Additionally, RCO staff members are encouraged to become CIP certified.

2.13. Insurance Coverage For Research Oversight Activity

The University maintains insurance that covers IRB members, the IRB Chairs, the IO, the RCO Director, institutional agents, the RCO, and RCO staff with respect to their acts and omissions taken within their scope of their employment/service or authorized activity taken under this document. The University should be timely notified of any potential or actual claims. See UM System Collected Rules and Regulations 490.010 Defense and Protection of Employees.

2.14. Review of IRB Member Performance

IRB member's performance will be reviewed on an annual basis by the IO and RCO Director. IRB members who are not acting in accordance with the IRB mission, the HRPP or IRB policies and procedures, or who have an undue number of absences will be replaced.

Regulations & Guidance: AAHRPP II.1.D.

2.15. Reporting and Investigation of Allegations of Undue Influence

If an IRB Chair, IRB member, or IRB staff person feels that the IRB or IRB member has been unduly influenced, then he/she shall make a confidential report to the RCO Director. The allegations shall be investigated by the RCO Director (who shall consult with the IO and IRB Chair as appropriate) to consider whether undue influence exists and, if so, determine what recommended corrective action should be taken. Such findings and recommendations will be reported to the IO for a final decision.

Approved by: Yusheng (Chris) Liu, PhD
Name of University Institutional Official

June 29, 2022

Signature of University Institutional Official Date