IRB SOP 14.0 Reliance On External IRBs, 2018 Requirements

Purpose:

It is the policy of the IRB when KUMC conducts multi-site research where an outside institution is conducting the IRB review for KUMC.

Background:

The IRB coordinates reviews with other academic institutions and universities. This policy outlines the requirements and staff responsibilities to have an external institution be the IRB of record for a project and what oversight that other sites has on the IRB activities.

Regulation and Guideline Reference(s):

KUMC References:

Attachment(s):

Definitions:

Procedure:

14.1 Principles about Collaborative Research

I. KUMC investigators frequently are involved in research that involves multiple research organizations. For any collaboration, the IRB staff will evaluate the activities of the KUMC investigator to determine if those activities engage our institution in human subjects research. IRB staff will refer to the OHRP document "Guidance on Engagement of Institutions in Human Subjects Research" (2008) in making the determination.

II. If the activities of the KUMC investigator cause the institution to be engaged in non-exempt human subjects research, the investigator’s involvement in the collaboration may not begin until the KUMC IRB
has approved the research or until a reliance agreement has been negotiated with an external IRB and
the external IRB has approved KUMC as a study site.

III. Whenever feasible, the HRPP will seek to avoid duplication by arranging a single IRB review for multisite
studies. This SOP discusses circumstances where KUMC chooses to rely on another IRB for oversight of
collaborative research. Refer to SOP 13 for information about requirements when the KUMC IRB serves
as the Reviewing IRB.

14.2 Criteria for Relying on an External IRB

I. Decisions on whether to rely on an external IRB will be based on the location of the principal investigator,
the risk level of the study, the location of the patient population, the extent of the procedures performed at
KUMC, the IRB resources and expertise at the collaborating institution(s), grant requirements and the
scope of existing agreements. The KUMC IRB will comply with the National Institutes of Health (NIH)
Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research effective
January 25, 2018 and with the requirements for single IRB review in the Revised Common Rule, effective

II. Investigators are encouraged to consult with the HRPP about new reliance arrangements. The HRPP will
confirm that the Reviewing IRB has relevant expertise to review the study.

III. When the research is greater than minimal risk, KUMC typically requires the Reviewing IRB to be
accredited or to demonstrate similar evidence of quality. Reliance on a non-accredited IRB will be
considered for minimal risk research if required by the funding source. In this circumstance, KUMC will
ensure additional quality assurance measures by the external organization or by the KUMC Quality
Assurance Program.

IV. The HRPP Director is responsible for facilitating and maintaining IRB reliance agreements, in consultation
with the Institutional Official, the Office of the General Counsel and the Research Advisory Committee.
Reliance agreements may pertain to individual studies, a defined group of studies or a defined group of
collaborators. Reliance agreements must specify the roles and responsibilities of all parties. It also must
specify communication and coordination plans for conflicts of interest, unanticipated problems, serious or
continuing non-compliance and notifications to federal agencies.

V. The HRPP provides the external IRB with local context information relevant to each study. HRPP staff
maintain current institutional profiles in the SMART IRB

14.3 Overview of the Reliance Process when KUMC is a Study Site

I. Investigators submit reliance requests in the electronic IRB system. The submission should include a
Request to Use an External IRB, the study protocol, overall IRB approval letter, approved master consent
form, proposed local informed consent documents (if available) and local recruitment materials, if
applicable. Additional study documents may be requested.

II. Eligibility for reliance is confirmed on a study-by-study basis unless an umbrella arrangement is in place.
The HRPP Director makes the decision about eligibility in consultation with the IRB Chair or Institutional
Official. The Reviewing IRB also may be designated by the funding agency.

III. If the study is eligible for reliance, IRB staff will perform an administrative review to consider local
requirements. Local requirements include, but are not limited to: current human subjects training and
conflict of interest disclosures for study team members, ancillary reviews (conflict of interest, radiation
safety and information security as applicable), local customizations to the consent form(s), and special
provisions for KUMC subjects who are non-English speaking or who are decisionally impaired.
IV. KUMC will not grant permission for reliance until all local requirements are met. IRB staff will communicate local context issues through the permission letter or local context questionnaires required by the Reviewing IRB.

V. When a study team member has a financial conflict of interest related to the study, reliance arrangements will not proceed until a management plan has been approved by the KUMC Conflict of Interest Committee. IRB staff will notify the Reviewing IRB about the management plan.

VI. The KUMC investigator and the Reviewing IRB will be notified of the reliance decision in writing. HRPP personnel will communicate with the Reviewing IRB about applicable state laws governing the research, local requirements for the informed consent document, approvals by ancillary committees and other topics related to local context.

VII. When reliance is finalized, the Reviewing IRB becomes responsible for initial review, reviews of amendments, continuing reviews, adverse events and other reportable information.

14.4 Overview of the Reliance Process when KUMC is a not a Study Site

I. The IRB must evaluate the research activities of KUMC personnel who collaborate with a non-KUMC institution, regardless of whether KUMC is a study site.

II. When KUMC personnel participate in research being conducted at an external site, the IRB staff evaluate the activities of the KUMC personnel to determinate if those activities engage KUMC in human subjects research. IRB staff will refer to the OHRP document "Guidance on Engagement of Institutions in Human Subjects Research" (2008) in making the determination.

III. If the activities of the KUMC investigator do not engage the institution in human subjects research, the IRB staff may issue a letter certifying that the KUMC IRB is not required to approve the research.

IV. If the activities of the KUMC investigator cause the institution to be engaged in human subjects research, the investigator's involvement in the collaboration may not begin until the KUMC IRB has approved the research or until an agreement to rely on the other IRB has been negotiated.

V. The request to be overseen by an external IRB is typically submitted in the eIRB system; exceptions may be made for student projects or research involving regional institutions. The request will be reviewed as described in 14.3 above. All local requirements must be met before final permission is granted.

14.5 Investigator Responsibilities

I. The KUMC investigator is responsible for knowing and complying with the requirements of the Reviewing IRB. Responsibilities include, but are not limited to, obtaining and documenting informed consent as required by the Reviewing IRB; reporting unanticipated problems or non-compliance; complying with requirements for study modifications, continuing reviews, data security and record retention; and allowing the Reviewing IRB to inspect research files.

II. The KUMC investigator must be aware of any KUMC requirements in addition to the approval of the Reviewing IRB. Examples include data use agreements, material transfer agreements or study contracts. The study may not be initiated at KUMC until all approvals have been obtained.

III. During the study, the KUMC investigator must update the KUMC IRB Office of any changes to study personnel or new financial conflicts of interest. The office will communicate these to the Reviewing IRB.

IV. The KUMC investigator must inform the KUMC HRPP if a KUMC subject experiences an injury or a serious and unexpected adverse event that is related to the research so that appropriate internal review can occur. The HRPP will confirm that any urgent actions for subject safety have been initiated. The HRPP will work collaboratively with the Reviewing IRB about follow-up actions.
V. The KUMC investigator must inform the KUMC HRPP of any non-compliance that potentially impacts the rights and welfare of subjects or integrity of study data. The HRPP will confirm that any urgent actions for subject safety have been initiated and determine whether local processes should be changed. The HRPP will work collaboratively with the Reviewing IRB about corrective actions.

14.6 Institutional Responsibilities

I. Regardless of whether KUMC reviews the research or relies on an external IRB, KUMC remains responsible for the safe and appropriate performance of the research. The KUMC Quality Assurance Program may conduct routine reviews to confirm that the study is being conducted in compliance with the protocol and the requirements of the Reviewing IRB.

II. If a KUMC subject experiences a study-related injury or if non-compliance occurs, the HRPP will confirm that a report has been made to the Reviewing IRB. The HRPP also may conduct an internal review to confirm that institutional and contractual responsibilities have been met. If the Reviewing IRB determines the event requires reporting to federal agencies, then the HRPP will work collaboratively with the reviewing IRB as outlined in the reliance agreement.

III. In the event of unanticipated problems or non-compliance related to collaborative research, the HRPP may consult with the Quality Assurance Program about local actions in addition to those specified by the Reviewing IRB. Considerations may be given to additional education of the study team, local monitoring or local adaptations for prevention.

IV. In the event of unanticipated problems or serious or continuing non-compliance related to collaborative research, the KUMC Institutional Official has the authority to suspend the involvement of KUMC and its investigators. If this occurs, the HRPP Director is responsible for notifying the Reviewing IRB.

Reference:

45 CFR 46.114

OHRP Guidance on Engagement of Institutions in Human Subjects Research

National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research

Attachments:

Approval Signatures

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<tr>
<th>Approver</th>
<th>Date</th>
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<tr>
<td>Steffani Webb: Vice Chancellor for Administration</td>
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Applicability

KU Medical Center, KU SoM Wichita