Purpose:
It is the policy of the IRB when KUMC conducts multi-site research.

Background:
The IRB coordinates reviews with other academic institutions and universities. This policy outlines the requirements and staff responsibilities to have KUMC be the IRB of record for a project and to have oversight on other sites that rely on the KUMC IRB review.

Regulation and Guideline Reference(s):

KUMC References:

Attachment(s):

Definitions:

Procedure:

13.1 KUMC Research conducted at non-KUMC locations

I. When a KUMC investigator is conducting research at a non-KUMC site, the HRPP will determine whether the non-KUMC site meets the federal definition of being "engaged" in human subjects research. The HRPP will refer to the OHRP document "Engagement of Institutions in Human Subjects Research" (2008). IRB staff also may consult with IRB representatives of the external site to confirm they do not consider their institution to be engaged. When the non-KUMC site is "not engaged" in human subjects research, the KUMC investigator must provide a letter of support from the site documenting approval for the research to occur.

II. If the non-KUMC site is engaged in human subjects research, the following actions will be taken:
A. The HRPP will inquire about whether the site maintains its own IRB. If so, both IRBs must review and approve the research unless an agreement has been negotiated whereby one IRB agrees to review the research on behalf of the other participating site(s).

B. If the non-KUMC IRB is reviewing the project and not relying on the KUMC IRB, then the study may not commence at that site until that IRB's approval has been secured.

C. Even when the participating sites are under their own IRBs, the KUMC protocol must describe coordination with the external sites, solicitation and evaluation of study-wide safety information, plans to security manage study data and strategies to ensure protocol compliance at all sites.

D. For each non-KUMC site that is under its own IRB, the KUMC investigator must submit a modification in the electronic IRB system that includes a protocol amendment indicating the new site (if needed), the site's IRB approval letter and the approved consent form to be used at that site. IRB staff will confirm that KUMC's leadership is appropriately represented in the external site's consent form and that the HIPAA authorization includes disclosure of protected health information to KUMC. The modification can be approved under expedited review.

E. After the non-KUMC IRB approves the project, the KUMC investigator is responsible for promptly notifying the KUMC IRB if there is a change in the approval status from the site's IRB.

13.2 KUMC IRB responsibilities when serving as the Reviewing IRB

I. Regulatory Background

A. To avoid duplication, two or more IRBs may enter into an arrangement whereby one IRB reviews the research on behalf of the other IRBs. When KUMC IRB serves as the Reviewing IRB, it shall document the collaborating institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of 45 CFR 46 via a written agreement.

B. 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 January 20, 2020. Non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States require a single reviewing IRB except where review by the proposed reviewing IRB would be prohibited by a federal, tribal, or state law, regulation, or policy.

II. Criteria for Serving as the Reviewing IRB

A. The decision for the KUMC IRB to serve as the Reviewing IRB for non-exempt research is made on a case-by-case basis. The HRPP Director makes the decision on whether to serve as the Reviewing IRB in consultation with the IRB Chair or Institutional Official. The Reviewing IRB also may be designated by the funding agency.

B. In determining whether to serve as the reviewing IRB, the HRPP Director considers requirements of funding agencies, available expertise on the IRB, study risks, number of sites, the experience of the study team and the administrative resources within the IRB office.

C. The HRPP Director will confirm there is, or will be, an appropriate reliance agreement prior to initial review by the IRB.

D. For research that involves international sites, the KUMC IRB will serve as the Reviewing IRB for US sites only.

E. The KUMC IRB typically will not serve as the Reviewing IRB if the study involves institutional
conflicts of interest. Exceptions may include pilot studies and other early phase studies if the KUMC Conflict of Interest Committee has determined adequate management strategies have been implemented.

III. Reliance Agreements

A. Each site that is engaged in human subjects research must be covered by an IRB reliance agreement that is signed by the institutional official. The agreement outlines the roles and responsibilities of the reviewing IRB and the relying site. It also specifies communication and coordination plans for conflicts of interest, unanticipated problems, serious or continuing non-compliance and notifications to federal agencies. If the site is not associated with the SMART IRB network, then a separate agreement must be negotiated. The agreement may be protocol-specific, may cover a specified group of protocols or may cover a defined group of collaborators.

B. If the site does not have its own IRB, a determination is made as to whether the site needs its own Federalwide Assurance (FWA) before the KUMC IRB serves as the Reviewing IRB.

C. If the research involves federal funding, the site must obtain an FWA.

D. If the research is minimal risk, the site does not typically conduct research, there is no federal funding and additional collaboration is not anticipated with that site, then KUMC may choose to extend its FWA to cover the site. Otherwise, the site must obtain an FWA before IRB review proceeds.

IV. Requirements for Lead Investigators

A. KUMC investigators who request the KUMC IRB to serve as the Reviewing IRB must consult with IRB representatives at the time of grant submission. During the consultation, representatives from the IRB will confirm the willingness of KUMC to oversee the research, discuss possible IRB review considerations and determine the proposed budget for single IRB services.

B. When the KUMC IRB serves as the Reviewing IRB, the HRPP will work with the KUMC study team to confirm that each relying site meets the qualifications necessary to conduct the research in a safe and ethical manner. Considerations may include the number and qualification of research staff, adequate facilities and equipment, secure storage for data, specimens and study records, languages spoken at the site and other study-specific factors that may impact the safety and welfare of participants.

C. The KUMC IRB uses a Local Context Questionnaire (LCQ) to confirm the considerations above. The LCQ covers state laws, institutional policies, community standards, demographics and cultural issues of the local population, and ancillary reviews required at the site. The LCQ is signed by the site investigator and by a local IRB representative. By their signature, the local IRB representative confirms that ancillary reviews are complete and that members of the local study team comply with their institutional requirements for training, conflicts of interest disclosure and credentialing.

D. The KUMC study team must demonstrate adequate plans for oversight of the study. Protocol documents must discuss the types of study activities that will occur at each site; plans for training on the protocol and on the requirements of the KUMC IRB; maintenance and distribution of IRB-approved documents; ongoing communication with the sites to receive updates and disseminate new information; identification of adverse events and other problems; and strategies for monitoring protocol compliance at the site. For studies involving greater than minimal risk, the oversight plan must be reviewed by the convened board.

V. Initial Review by the KUMC IRB
A. Initial review by the KUMC IRB includes all protocol materials as described in SOP2.0 as well as the principal investigator's plans for study oversight. The IRB confirms the study meets federal regulations applicable to the study. As part of the initial review of the protocol, the KUMC IRB confirms it is willing to oversee study conduct at relying sites.

B. At the time of initial approval, the KUMC consent form(s) is issued. The approved KUMC consent form is used as the template for consent forms to be issues for relying sites.

VI. Coordination with Relying Sites

A. After the protocol and KUMC consent form have been approved, IRB staff create a master consent template for relying sites. The master consent template differs from the approved KUMC version only in allowing space for site-specific changes. Relying sites may alter the local contact information, local cost language, payment for injury, local HIPAA/privacy information and other changes required by state law or written institutional policy.

B. Instead of a master consent template, the KUMC IRB may approve a study-specific overall consent form to be used at all sites and a consent addendum that contains site-specific information. The KUMC IRB typically will use a consent addendum process if there are more than 12 relying sites.

C. Investigators at relying sites are sent an introductory packet with the IRB-approved protocol, master consent template (or consent addendum), and the KUMC overview of single IRB review that highlights roles and responsibilities of all parties. The packet also includes the local context questionnaire, reliance documentation letter and instructions about working with their local IRBs.

D. The KUMC study team is responsible for communicating with site investigators and tracking the review status at the relying sites. They also collect the site-specific documents that the KUMC IRB will review.

E. IRB staff coordinate with IRB points of contact at relying sites to discuss questions about IRB processes or about issues of local context.

VII. IRB Review for Relying Sites

A. Study teams file a protocol modification in the electronic IRB system to request approval for a relying site. The submission must include a signed local context form, the proposed consent form or addendum for the site and site-specific documentation such as local recruitment materials or non-English consent forms.

B. IRB staff conduct a pre-review of the site-specific materials to determine whether state laws or institutional policies impact the review of the research. They may consult with the IRB Chair or Vice-Chairs for assistance in making the determination.

C. The modification may be reviewed under an expedited review if consent form changes are limited to the local customizations permitted in the master template and any differences in local context or local implementation do not impact the federal criteria for approval.

D. During the consideration of the site, reviewers confirm that local context requirements have been met and if changes are minor. If changes are not minor, review of the site is scheduled for a convened board meeting.

E. If a relying institution notifies the IRB that their investigator is under a conflict of interest management that relates to the study, the review of the site will be scheduled at a convened board meeting. The IRB has the prerogative to require additional elements to the management plan prior to approving the site.
F. Upon approval of the site, the IRB will issue a site-specific approval letter and the approved site-specific consent form or addendum. The KUMC study team is responsible for distributing IRB-approved documents to site investigators.

G. All persons under the authority of the KUMC IRB are responsible for compliance with the IRB's requirements. During initial communications, site investigators are provided with a link the KUMC IRB SOPs and an overview of roles and responsibilities of each party. As applicable to the project, they may be further trained through webinars, teleconferences or in-person sessions.

VIII. Ongoing Reviews and Reportable Events

A. Throughout the study, the IRB will review study-wide changes, changes that pertain to KUMC only and changes at relying sites. The KUMC study team is responsible for soliciting site-specific changes and reporting them to the IRB.

B. Modifications to the protocol or informed consents will be reviewed as outlined in SOP 5.2. If the modification involves study-wide consent changes, the IRB will issue new consent forms for all sites. The KUMC study team is responsible for informing site investigators about any re-consenting requirements.

C. All sites will follow the KUMC requirements for reportable events as specified in SOP 5.3 and SOP 17.1. Any event that occurs at a relying site is considered an 'internal' event for the sake of determining reportability.

D. If the IRB determines an event requires reporting to federal agencies, then the HRPP will work collaboratively with relying institutions as outlined in the reliance agreement.

IX. Continuing Reviews of Relying Sites

A. The continuing review for relying sites occurs simultaneously with the continuing review for the study as a whole. The KUMC IRB will determine if the study continues to federal criteria for approval. The continuing review is conducted as described in SOP 6.

B. At the time of continuing review, investigators at the relying sites must complete an addendum that describes enrollment at the site, changes to site personnel, updates to financial disclosures, updates to reportable events and any local changes in study implementation.

C. The KUMC study team is responsible for collecting information from the relying sites for the IRB's continuing review process. If a relying site does not provide local information prior to study expiration, approval for that site will lapse. Enrollment at the site must cease and any ongoing activities must be approved by the IRB as specified in SOP 6.7.

13.3 Unaffiliated Investigators Collaborating on KUMC Research

I. At times, KUMC research may involve collaboration with an individual who is not associated with an institution or organization. When such an unaffiliated investigator is involved in aspects of human subjects research on a KUMC project, the HRPP will negotiate an Unaffiliated Investigator Agreement.

II. The HRPP will provide documentation to the investigator as required by the federal OHRP. These include electronic copies of the Belmont Report, 45 CFR 46, other applicable federal regulations, applicable KUMC policies, and a copy of the terms of the KUMC FWA.

III. Prior to the unaffiliated investigator's involvement in the study, the investigator must demonstrate current training in human subjects protection and must have a current KUMC conflict of interest disclosure on file.
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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<th>Approver</th>
<th>Date</th>
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<tr>
<td>Steffani Webb: Vice Chancellor for Administration</td>
<td>12/10/2019</td>
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<tr>
<td>Lisa Hoebelheinrich: Chief Compliance Officer</td>
<td>12/10/2019</td>
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<td>Annie Fors: QA Director</td>
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<td>Karen Blackwell: Director HRPP</td>
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<td>Kyle Stephens: Assistant Director</td>
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Applicability

KU Medical Center, KU SoM Wichita