I. Purpose:
The purpose of this SOP is to explain IRB staff roles and responsibilities, to provide internal staff practices pertaining to reviewing submissions to the IRB, and to outline practices for maintaining the IRB processes.

II. Regulation and Guideline Reference(s):
45 CFR 46.107
21 CFR 56.107
45 CFR 46.115
21 CFR 56.115

III. Procedure:
16.1 Roles and Responsibilities

I. General Requirements: All staff members in the KUMC Human Research Protection Program are responsible for learning and following federal human subjects regulations and KUMC SOPs. They must meet institutional requirements for conflict of interest disclosure and training in human subjects protection, privacy and confidentiality. Staff members are responsible for timely response to requests for information from investigators and study personnel. Staff members must report to the HRPP Director or Institutional Official if they experience any attempts to unduly influence the decisions of the IRB, whether those attempts are from investigators, research personnel or administration. Staff members should inform the HRPP Director if they have a personal or professional relationship with physicians or faculty who may serve as principal investigators on studies; a potential conflict of interest will be avoided by assigning pre-reviews and expedited reviews to unconflicted staff members.

II. IRB Generalist:
A. The IRB Generalist duties include, but are not limited to:
   1. managing approval process of new research projects from initial submission to final approval,
   2. analyzing submissions to ensure compliance with federal regulations,
3. performing administrative reviews to determine readiness for committee review,
4. identifying other compliance components that impact the project,
5. communicating with investigators regulatory requirements and committee's review,
6. managing proviso process until final approval is obtained, determining review type,
7. processing and management of materials submitted through the eIRB system,
8. compiling review comments, receiving and evaluating proviso responses before submitting to the chair or full committee for final approval,
9. establishing meeting calendars,
10. assigning reviewers in eIRB,
11. sending documents to investigator,
12. daily processing of other Committee actions,
13. and facilitating communication between investigators and the IRB.

B. After study approval, the IRB Generalist provides pre-review on modifications and continuing reviews. The IRB Generalist is expected to work closely with the IRB Administrator and office support staff to ensure that all required application materials are received, appropriately processed, disseminated for review, and retained according to university requirements. Also, the generalist may coordinate arrangements for IRB meetings, process IRB agenda items, and process results of IRB reviews, letters, and committee minutes.

C. Generalists who have sufficient IRB experience (typically at least two years) may be designated as alternate, non-scientific members of the IRB. As non-scientific members, they may review and approve modifications and responses to provisos that do not require scientific expertise as well as expedited continuing reviews. With sufficient experience and designation as a certified IRB professional, an IRB Generalist can be promoted to the status of Senior IRB Generalist. Additional responsibilities include reviewing minimal risk studies, flexible IRB projects and responses to conditional approvals that do not require additional scientific or medical expertise.

III. IRB Administrator:

A. IRB Administrators serves as a secondary resource regarding regulatory requirements governing human research protection programs. The IRB Administrators' main responsibilities include

1. determining review type;
2. assign reviewers;
3. authorize exempted status,
4. develop written standard operating procedures (SOPs);
5. facilitate communication between investigators and the IRB;
6. ensure that IRB review decisions are accurately communicated to investigators in a timely manner;
7. help develop educational programs and resources for investigators, study coordinators, and other research staff;
8. and work closely with the educational and outreach specialist to provide readily accessible informational resources.
B. IRB Administrators serve as alternate IRB members. With sufficient experience, an IRB Administrator can be promoted to the status of Senior IRB Administrator. Additional responsibilities include overseeing the convened meeting process, managing other IRB administrators and training new personnel.

IV. **Compliance Specialist:**

A. The Compliance Specialist screens the submission of reportable events, to determine whether the submission is complete and the nature of additional IRB review that may be needed. The Compliance Specialist consults with the HRPP Director, IRB Chair or members of the KUMC Quality Assurance Program in evaluating the submissions. The Compliance Specialist also supports the workload of the IRB office by screening minimal risk research, requests for flexible IRB review and requests for not human subjects research determinations.

V. **IRB Reliance Manager:**

A. The IRB reliance manager coordinates the administrative reviews of research being submitted to external IRBs. The reliance manager ensures ancillary reviews are complete and the proposed local consent forms reflect state law and institutional policies. The reliance manager also facilitates new research for which the KUMC IRB will be the Reviewing IRB. Along with the HRPP Director, the manager provides training and support for lead study teams at KUMC, develops budgets for single IRB review, coordinates with IRB representatives of relying institutions, evaluates site-specific materials prior to the IRB review and informs site investigators about the requirements of conducting research under the KUMC IRB.

VI. **HRPP Assistant Director:**

A. The Assistant Director serves as KUMC’s primary resource regarding regulatory requirements governing human research protection programs. Specific responsibilities of the Assistant Director include, but are not limited to, the following:

1. serve as primary recording secretary for the IRB;
2. ensure that minutes for each meeting are accurately recorded;
3. finalize minutes for full IRB review and approval;
4. monitor whether IRB members fail to meet attendance or performance expectations;
5. develop and implement procedures to ensure that human research review meets requirements established by regulators, sponsors and the institution; develop written standard operating procedures (SOPs);
6. pre-screening all complete greater than minimal risk project submissions before review by the IRB;
7. triage reports of unanticipated problems, amendments and continuing review forms;
8. prepare recommendations to the full committee;
9. facilitate communication between investigators and the IRB;
10. ensure that IRB review decisions are accurately communicated to investigators in a timely manner;
11. participate in the orientation and training of new committee members;
12. and help develop educational programs and resources for investigators, study coordinators, and other research staff.
B. The Assistant Director serves as an alternate IRB member.

16.2 Submission Deadlines

I. There are no submission deadlines for convened board reviews. Items for review by the convened board are placed on the next available agenda when the submission is complete. The meeting agenda is generally finalized a week in advance. At times, certain holidays may alter when the next available meeting will be convened.

II. There is no submission deadline for items which qualify for exemption or for expedited review. Those items are reviewed on a rolling basis.

16.3 Categorizing Submissions

I. The Investigator submits his/her proposal through the electronic IRB system. When these items are submitted to the IRB office, the IRB Generalists and Administrator will categorize the submission as Exempt, Expedited, Full Committee or Flexible IRB review, or consult with the Assistant Director or HRPP Director to help the appropriate categorization.

II. Items which are not new submissions (e.g., modifications and continuing reviews) are classified by the IRB Generalist as to whether or not those items require full committee review. Consultation of the IRB Assistant Director and Director can be sought to assist making a final determination. Items not requiring full committee review are then reviewed using an expedited review procedure.

III. Items which are reports of new information are classified by the IRB Compliance Specialist or by the Assistant Director and/or Director as to whether additional information is needed and whether they should be submitted to the convened board or to the QA Program in the Office of Compliance. SOP 5.3 and 17.1 provide the guidelines for classifying a report.

IV. Whenever feasible, new initial studies where a member of the IRB is also the Principal Investigator will be assigned to the IRB where that PI is not a primary member. For example, if a member of IRB 1 is a Principal Investigator on a study, that study will be reviewed by IRB 3.

16.4 Electronic IRB (eIRB)

I. The KUMC IRB has adopted an electronic submission system (eIRB). This system is used by investigators to create IRB actions, upload study documents, and submit actions to the IRB.

II. Submissions are only received after the Principal Investigator or proxy clicks on the "Submit" icon on the main page of the action.

III. IRB policy dictates the individuals who can make submissions to the eIRB system. Initial submissions and continuing reviews must be made by the Principal Investigator. A "proxy" for the Principal Investigator can be named upon request. A proxy may submit the items outlined in the PI Proxy policy that is posted on the IRB website.

IV. The eIRB system logs all actions by the study team and IRB staff. The recorded history of the project including any Continuing Review and Modification action can be seen on this History Tab. These actions are added in chronological order to the History Tab. Reports of new information can be found on the Follow-on Submissions Tab. The determination (mods required, clarifications requested, deferred, approved, etc.) can be found for each action on the top of the page for that action, highlighted in yellow.

V. All correspondence between the IRB and the investigator is uploaded to eIRB within the History Tab corresponding to the particular submission. Correspondence from other compliance committees is uploaded to the Review Tab for a particular submission and a History Tab record is automatically
created.
VI. IRB staff conduct pre-review on all submission to determine completeness and make an initial
determination about required level of review. IRB staff members will not be assigned a pre-review if they
have disclosed a personal or professional relationship with the principal investigator to the HRPP Director.
VII. IRB staff add an Administrative Note indicating the Exempt, Expedited, Full Committee or Flexible IRB
review status after the determination is made.
VIII. Full committee review submissions are screened for completeness and once complete are placed onto
the next available meeting. Any ancillary reviewers are notified to review the project and IRB committee
reviewers are assigned. As applicable to the project, ancillary reviews may include HIPAA, radiation
safety, biosafety, data security or conflict of interest. The minutes and provisos are finalized by the
Assistant Director. A letter with conditions for approval is generated and sent to the Principal Investigator.
IX. Expedited actions are screened for completeness, and once completed, are assigned to the Chair or
designee for Designated Review. Ancillary reviewers are notified to review the project. Expedited actions
are indicated as expedited in the eIRB system once the chair/designee has submitted the designated
review.
X. The Assistant Director creates a list of all staff-approved actions and adds these actions to the Convened
board minutes that are currently under review. Staff-approved actions include expedited actions,
exemptions, HIPAA privacy waivers and approvals under the Flexible IRB Policy.
XI. Clarification requests and letters (disapproval, deferred, modifications required, and approval) for Full
Committee and Expedited actions are housed in the eIRB system and are then available for Investigators
to download. Investigators are notified when a letter or a clarification request is generated in the system.

16.5 Assignment to IRB meetings
I. The Assistant Director or Generalists assign at least two reviewers to each initial study that requires full
committee review. Reviewers are assigned for other actions including continuing review, modifications,
and reports of new information (regarding unanticipated problems or non-compliance.)
II. Primary and secondary reviewers will be assigned based on factors including but not limited to related
professional expertise, subject matter of the research, and prior experience with review of similar projects.
The Assistant Director or Generalist checks whether at least one reviewer has the appropriate scientific or
scholarly expertise to review the research. If not, the Assistant Director or Generalist will consult with the
IRB Chair to arrange for a consultant with appropriate expertise to review the research. Alternatively, the
review may be moved to a meeting in which a member has the appropriate expertise.
III. Reviews will not be assigned to a member who has an investigative role in the research or has some
other conflict of interest. If a member with a conflict of interest is the only member who has relevant
expertise for a particular IRB meeting, the study will be re-assigned to a meeting where a different
member can provide unconflicted expertise.
IV. When making reviewer assignments, the Assistant Director or Generalist will consider the vulnerable
populations involved in the research and, when possible, assign the protocol to at least one individual
who has experience with this population when needed. If there is no IRB member with experience
working with this population, the Assistant Director or Generalist will consult with the IRB Chair to arrange
for a consultant with appropriate experience.
V. In general, studies whose principal investigator is also a member of one of the boards will be assigned to
a different board meeting, to avoid the appearance of conflict of interest or undue influence. Exceptions
may be made in circumstances such as a compassionate use protocol or if an IRB meeting is canceled.
VI. Whenever possible, either the primary or secondary reviewer will have a terminal degree in a related field.

VII. If one of the reviewers assigned to the submission is absent from the convened meeting, the IRB chair may, at his/her discretion, serve as the primary/secondary reviewer. Alternatively, the Assistant Director may present the absent member's written comments for the committee's consideration. The absent member's recommendations do not constitute a vote. If both primary and secondary reviewers are absent, the protocol will be deferred to the next available meeting. If both the original primary and secondary reviewers have commented on the submission, these notes will be provided to the new reviewers.

16.6 Creating the IRB Meeting Agenda

I. IRB meetings are held the first through the fourth weeks of each month. The IRB staff creates the agenda for upcoming meetings. Items are added as they are received and pre-reviewed to determine completeness of the submission. The volume of the agenda is typically limited to about 20 items to allow adequate time for review and discussion during the meeting.

II. At a convened IRB meeting, the following items will be placed on the agenda for review:

A. New IRB Proposals Submitted for Review. All newly proposed research involving human participants, excluding those projects that meet one or more of the exemption categories as authorized in 45 CFR 46.101(b) and 21 CFR 56. 104(d) or one or more of the expedited categories as authorized in 45 CFR 46.110;

B. Continuing Review Applications. When required, continuing review of all human participants research at intervals appropriate to the degree of risk, but not less than once per year, excluding those projects that meet one or more of the exemption categories as authorized in 45 CFR 46.104(d) and 21 CFR 56. 104(d) or one or more of the expedited categories as authorized in 45 CFR 46.101(b) (8) or (9);

C. Modifications. All modifications to currently approved human participants research activities that materially affect an assessment of the risks and benefits of the study or substantially change the specific aims or design of the study; excluding those projects that would continue to meet one or more of the exemption categories as authorized in 45 CFR 46.104(d) and 21 CFR 56. 104(d) or one or more of the expedited categories as authorized in 45 CFR 46.101(b) (8) or (9) with the amended changes.

D. Reports of New Information. The following items may be placed on the IRB meeting agenda.

   1. Reported problems that may constitute an unanticipated problem involving risks to subjects or others, as defined in SOP 5.3.

   2. Activities that may constitute serious or continuing non-compliance, after preliminary evaluation described in SOP 17.1.

   3. The results of any auditing or monitoring process that indicate a potential risk of harm to subjects or compromise to the integrity of the data.

E. Education/Committee Discussion. Periodically, a member of the HRPP will schedule an education or discussion item on the agenda, which may include:

   1. Federal regulations;

   2. Local policies and procedures;

   3. Any changes in Federal regulations;

   4. Any changes in local policies and procedures; or
5. Other items as requested by the IRB.

III. IRB Staff Responsibilities

A. It is the responsibility of IRB office staff to place all scheduled items for Committee review on the next available agenda.

B. IRB office staff will assure that all relevant sections appear on the agenda that will be discussed during the Committee meeting.

C. When an addition to a finalized agenda is warranted, the IRB office staff will assign the action to the agenda and re-notify attending members.

16.7 Recording the Meeting Minutes

I. Minutes of the IRB Meeting document the following:

A. Attendance at meetings
   1. Members in attendance that voted during the meeting;
   2. That a member removes themselves during the vote due to a conflict of interest; and
   3. Initial and continued presence of a majority of members, including at least one nonscientist.
   4. Members who attend as alternates are noted.

B. Actions taken by the Committee
   1. Vote on these actions (including the number of members voting to approve, disapprove, or abstaining from the motion).
   2. Basis for requiring modifications or disapproving the research, and a summary of controverted issues and their resolution.
      a. Minutes are distributed to the Committee in the eIRB system. Approval of the minutes is conducted at the IRB meeting. Comment is accepted from any member who may have revisions during the discussion at the IRB meeting.
      b. Modifications of full board minutes that occur after committee approval will be communicated to members via email distribution of an addendum to the minutes where the changes are outlined. Approval of the addendum by the Committee members is indicated by their absence of response within five days of the IRB request for comments or their approval of the changes.

II. IRB Office Responsibilities.

A. The IRB Administrator and any IRB staff attending the convened IRB meeting will document the IRB discussions and determinations. IRB Staff attending the meeting maintain a log containing the names of attendees and noting times for each arrival, departure, and recusal due to conflict of interest.

B. At each meeting, IRB staff is responsible for determining when quorum is reached and assuring that quorum is maintained. Quorum is documented on attendance sheets.

C. If quorum is lost at any time during a meeting, the IRB does not take any votes until quorum is restored.

D. The minutes of all IRB meetings must be in sufficient detail to demonstrate:
   1. Attendance at the meeting, to include initial and continued presence of a majority of members, including at least one nonscientist.
2. If an IRB member is a member of the study team or has disclosed a conflict of interest related to the study, the member leaves the meeting room during discussion and voting of the protocol. The member's absence is noted in the minutes, and the member does not count towards quorum. This member can be asked questions about the protocol should the IRB need to address any concerns.

3. For each protocol discussed, the minutes detail:
   a. Actions taken by the IRB;
   b. Discussion of any controverted issues and resolutions and issues needing to be addressed by the investigator;
   c. If discussing a suspension or notification of expiration, issues that arise where treatment may be continued for safety purposes;
   d. The vote on these actions including the number of voting "for," "against," or "abstaining"; and
   e. Separate deliberations for each action.
   f. Votes for each protocol as numbers for, against, or abstaining.
   g. When an alternate member replaced a primary member.
   h. Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.
   i. The names of IRB members who recused themselves from the meeting due to a conflicting interest along with the fact that a conflicting interest was the reason for the absence.

4. When a protocol is approved, the minutes note the Committee's determination that the project meets federal criteria for approval.

5. When a protocol is approved, the approval period (review interval) appropriate to the level of risk is determined for initial studies and for continuing reviews.

6. When protocol revisions are requested or a proposal is disapproved, the basis for the revisions and the disapproval is included as well as discussion of the controverted issues and their resolution.

7. When protocol revisions are requested, a determination of whether minor conditions can be reviewed by the Chair or designee, or whether the project is to be returned to the convened committee due to the need for substantive modifications.

8. The minutes also include the list of staff approvals as noted above.

9. The minutes of IRB meetings reflect the IRB's determination regarding which protocols require continuing review more often than annually, as appropriate to the risk, and the approval period.

E. **Specific Findings.** When specific findings on the part of the convened IRB are required, these findings are documented in the IRB minutes and include protocol-specific information justifying each. For example:

   1. **Alteration or Waiver of Informed Consent.** When approving a procedure that alters or waives the requirements of informed consent, the minutes must document that the Committee made the determinations in accordance with IRB policy and protocol-specific findings justifying each determination.
2. **Research Involving Children.** When approving research involving children, the minutes must document that the Committee made the determinations in accordance with IRB policy and protocol-specific findings justifying each determination about approval, number of parents/guardians to give permission, and the requirement for assent of the child.

3. **Research Involving Pregnant Women, Fetuses, and Neonates** When approving research involving pregnant women, fetuses, and neonates, the minutes must document that the Committee made the determinations in accordance with IRB policy and protocol-specific findings justifying each determination.

4. **Research Involving Prisoners** When approving research involving prisoners, the minutes must document that the Committee made the determination in accordance with the IRB policy and protocol-specific finding justifying each determination.

5. **Research Involving Medical Devices** When approving research involving medical devices, including investigational in vitro diagnostic devices, the minutes must document the rationale for significant risk/non-significant risk device determinations.

6. **Research Involving Adults with Decisional Impairment** When approving research involving adults with decisional impairment, the minutes must document the approval for the use of a surrogate decision-maker.

**F. Distribution of Minutes**

1. IRB staff utilizes the eIRB system for completing a draft of the IRB meeting minutes.
2. The Committee members will vote for approval of the minutes at the next convened meeting of that board.
3. A copy of the approved minutes is made available electronically to the Institutional Official.
4. Finalized minutes are stored in IRB office's network drive.

**16.8 Project Approvals**

I. Components of the HRPP

A. In June 2004, KUMC formalized a comprehensive Human Research Protection Program to coordinate oversight for all human research studies.

B. Office of Compliance components that support the HRPP include:
   1. Institutional Review Board. All new projects that involve research with human subjects are given exempt, expedited or full committee review in accordance with federal regulations at 45 CFR 46.
   2. HIPAA compliance review. All new projects are initially screened to determine if HIPAA regulations apply. Further information is outlined in SOP 4.0.
   3. Conflict of Interest (COI) Committee review. Personnel from the COI Program confirm that all study team members have a current conflict of interest disclosure on file. Projects are referred to the COI Committee for review if a disclosure form indicates a potential conflict. Further information is outlined in SOP 3.1.
   4. Institutional Biosafety Committee (IBC) review. Projects are referred to an IBC for review if they involve hazardous chemicals, recombinant DNA, human etiologic agents classified as BL2 or higher, tissues or blood that are classified as BL3, and human gene therapy. Further information is outlined in SOP 3.3.
5. Radiation Safety Committee (RSC) review. All research involving the use of radiation is subject to review by an RSC. Further information is outlined in SOP 3.2

6. Quality Assurance (QA) Program. The QA program provides routine and for-cause audits of human subjects research along with investigator education and support on good clinical practice, federal regulations and institutional policies.

II. Approvals from other Components
   A. For new studies, confirmation of approval, through review comments in the eIRB system or email, are obtained for each of the applicable components.
   1. IRB: Each project requires a confirmation of approval from the IRB Chair or Vice-Chair or designee, indicating that all IRB conditions are satisfied.
   2. HIPAA: At the time of IRB review, IRB staff members confirm that all relevant requirements related to HIPAA have been completed. IRB staff consult with the HIPAA Privacy Program as needed.
   3. COI: Each project requires a confirmation of approval from a representative of the COI Program, indicating that disclosures for all study personnel are on file and approved. The COI approval is not confirmed if the project has been referred to the COI Committee for review. In that case, the COI confirmation occurs after the COI Committee and the Investigator have agreed to a satisfactory management plan and the plan has been approved by the IRB.
   4. RSC: If the IRB has referred the project to the RSC, confirmation RSC approval is required prior to IRB approval.

B. After all applicable confirmations are obtained, the IRB Office will issue a project approval letter through the electronic IRB (eIRB) system. The effective date of approval is the date that the IRB Administrator or Generalist confirms that all IRB and ancillary requirements have been satisfied.

C. The electronic letter will have the typed name of the IRB director or other IRB staff member. The auto-generated letter is considered the official approval from the IRB.

16.9 IRB Record Retention

I. KUMC Policy for Investigators
   A. KUMC investigators must comply with the current Records Retention Policy. Investigators should consult the KUMC Policy Library for the current version.
   B. Records involving research with human subjects must be retained for a minimum of 7 years. Longer retention periods apply when the research involves children or neonates. For research that is funded by contract, the term of the Contract/Agreement may require a longer time of storage. In that case, the Contract/Agreement would supersede the policy requirement.

II. Retention of IRB Records
   A. IRB records (including records for protocols that are cancelled without subject enrollment) will be maintained for the greater of 7 years or three years after completion of the research.
   B. Paper records of terminated projects are stored at a secure off-site facility.
   C. Projects submitted through the eIRB system are stored indefinitely.
   D. Records of all retained projects are accessible for inspection and copying by personnel authorized by the IRB and Institutional Official and his/her designees.
I. The HRPP is responsible for creating and maintaining policies and procedures that meet federal requirements and institutional standards. Policies are evaluated and approved by the Research Advisory Council. The HRPP informs research personnel about updates to policies and standard operating procedures (SOPs) by website and email announcements, seminars and presentations. All policies and SOPs are maintained on the KUMC website. HRPP personnel review policies and SOPs to ensure currency at least annually and whenever new federal regulations or guidance documents are released.

References:

45 CFR 46.107
21 CFR 56.107
45 CFR 46.115
21 CFR 56.115

Attachments:

Approval Signatures

<table>
<thead>
<tr>
<th>Approver</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steffani Webb: Vice Chancellor for Administration</td>
<td>12/10/2019</td>
</tr>
<tr>
<td>Lisa Hoebelheinrich: Chief Compliance Officer</td>
<td>12/10/2019</td>
</tr>
<tr>
<td>Annie Fors: QA Director</td>
<td>12/4/2019</td>
</tr>
<tr>
<td>Karen Blackwell: Director HRPP</td>
<td>11/26/2019</td>
</tr>
<tr>
<td>Kyle Stephens: Assistant Director</td>
<td>11/21/2019</td>
</tr>
</tbody>
</table>

Applicability

KU Medical Center, KU SoM Wichita