Purpose:

It is the policy of the IRB to work in conjunction with other KUMC committees to provide protections to research subjects.

Background:

The IRB coordinates reviews with other institutional committees and communicates with them regarding the status of review and conditions of approval. Though other institutional committees contribute to the protection of human subjects, the final authority for approval of research rests with the IRB. For the institutional committees described below, final approval for the research will be held until documentation of approvals has been forwarded to the IRB.

Regulation and Guideline Reference(s):

45 CFR 46.111
21 CFR 56.111

KUMC References:


Attachment(s):

Definitions:

Procedure:

3.0 IRB Relation to Other KUMC Committees

It is the policy of the IRB to work in conjunction with other KUMC committees to provide protections to research subjects. The IRB coordinates reviews with other institutional committees and communicates with them regarding the status of review and conditions of approval. Though other institutional committees contribute to the protection of human subjects, the final authority for approval of research rests with the IRB.
I. The Conflict of Interest Committee (COIC) is charged with reviewing potential cases of individuals, research personnel or affiliated institutions with any financial interest that may affect or appear to affect research. The COIC provides management plan recommendations that may be considered in addressing conflicts. Management plan strategies range from informed consent disclosure, to that of disqualification of the investigator, research personnel or affiliated institutions from participating in the project.

II. Before a proposed study is approved, each member of the research team must have on file a current annual Conflict of Interest Disclosure that meets the federal Public Health Service, Kansas Board of Regents and KUMC requirements. The disclosure is used as a resource in identifying potential conflicts of interest.

III. Additional information about individual conflicts of interest is gathered through the IRB application process. Protocol applications solicit information about potential conflicts of interest among study team members that are specifically related to the proposed study.

IV. In addition to disclosures about individuals, the COIC periodically receives a report of any institutional investments or licenses that may create a conflict of interest related to research. Any human research projects associated with an institutional ownership interest are reviewed to determine whether or not a management plan is required.

V. If potential conflicts of interest are identified, either through annual reporting, through disclosure on an IRB application, or from current information held by the COIC, the proposed study is reviewed in accordance with KUMC’s COIC policies and procedures.

VI. If full review by the COIC is warranted under KUMC’s COI policies and procedures, the COIC evaluates the reported interests in accordance with its policies and procedures. The COIC works collaboratively with the individual investigator and institutional officials to manage the conflict through a management plan according to the COIC policies and procedures.

VII. Management plans may include divestiture of the interest, modification of the protocol to ensure objectivity, additional auditing and monitoring of the research, disclosure of the interest to research subjects or recusal from consenting for conflicted individuals.

VIII. COI disclosures are housed in the same electronic system as the electronic IRB so that interests related to each study can be monitored. The COI program reviews the status of COI reporting for study team members listed in the electronic IRB system. Financial interests related to any agenda items are noted during the IRB meeting.

IX. For research that involves more than minimal risk, proposed conflict management strategies are discussed at a convened IRB meeting. The convened IRB decides whether the management strategy is sufficient for determining conditions of approval. The IRB has the prerogative to add further elements to a proposed management plan. Final IRB approval is withheld until a management plan is agreed upon. When the management plan includes a disclosure to subject in the consent form, the IRB assures that the disclosure is added to the informed consent document prior to IRB approval.

X. If a proposal that qualifies for expedited or flexible IRB review is associated with a potential conflict of interest, the COI program informs the HRPP staff through the eIRB system when they complete the ancillary review. Expedited reviewers are made aware of the potential conflict, and final IRB approval of the proposal or modification is withheld until the conflict has been managed.
3.2 Radiation Safety Committee

I. The Hospital Radiation Safety Committee (HRSC) must approve research involving radiation on hospital premises or otherwise occurring under the hospital's registrations. The KUMC Radiation Safety Committee (RSC) approves research for which the radiation use solely involves devices under the university's registrations. The university's Radiation Safety Officer serves as the contact point for receiving all proposals that involve the use of radiation. The Radiation Safety Officer distributes the proposal to the appropriate oversight committee.

II. Review Projects

A. All projects that involve the use of radioactive materials or radiation-producing devices require submittal of the radiation application (form RS06) in addition to the protocol and consent form(s). The submission should be sent by email to the University Radiation Safety Officer.

B. Projects are reviewed on an individual basis. The risk associated with the radiation exposure differs by the type of procedure and the portion(s) of the body that will be exposed.

III. Coordination with IRB Review

A. Human subjects research involving radiation must have review and approval from the health systems RSC or the university RSC, as applicable, prior to implementation. The IRB does not grant final approval until approval for the use of radiation is secured. Risks of radiation are discussed in a distinct section of the consent form as directed by the RSC review.

B. Studies conducted in Wichita that need radiation safety review are referred to the Radiation Safety Officer/Official at the community hospital or clinic where the research will occur. The investigator must provide written proof of approval prior to IRB approval.

3.3 Institutional Biosafety Committee

I. Institutional oversight of all research involving: recombinant DNA (rDNA); synthetic DNA; select pathogenic agents and/or toxins; or etiological agents follows institutional policy.

II. The IBC communicates with the IRB, for human subject research, and the IACUC, for research in animals, to ensure that such research is conducted in a manner consistent with the biosafety practices outlined in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and the CDC/NIH publication of the Select Agent and Toxins Regulations (42 CFR Part 73).

III. The IBC reviews the science, safety and ethics of research involving the above mentioned hazards and establishes policies that provide for the safe conduct of laboratory work practices and procedures that involve such hazardous research.

IV. Researchers submitting expedited and full-review proposals indicate whether the project involves recombinant DNA or biohazards. Projects that do not qualify as low risk are referred to a convened IBC. IBC approval is required before IRB review begins.

3.4 Protocol Review and Monitoring Committee

I. The University of Kansas Cancer Center's Protocol Review and Monitoring Committee (PRMC) scientifically reviews human subject cancer or cancer-related protocols if the study uses Cancer Center resources. It also establishes their relative priority to the institutional mission. The PRMC is responsible for reviewing the appropriateness of data and safety monitoring plans, monitoring accrual and patient safety for all cancer or cancer-related studies within the institution.

II. All human subject cancer or cancer-related protocols (therapeutic/treatment, prevention, ancillary/comppanion and correlative), must be reviewed, approved, and monitored by the PRMC. For investigator-
initiated and industry-sponsored studies, PRMC approval must be obtained prior to IRB submission. For NCI cooperative group studies, submission to PRMC can happen parallel to IRB review. For the cooperative group studies, final IRB approval is held until the PRMC approval is submitted.

III. PRMC monitoring of the ongoing research will take place after all compliance approvals have been completed. Monitoring intervals are based on the class of the protocol. Monitoring may be the same frequency or more frequent than continuing review by the IRB.

IV. The PRMC may recommend closure of a trial that does not meet adequate safety standards, scientific merit or accrual goals. If the PRMC recommends closure, the principal investigator is notified. The principal investigator may appeal the PRMC’s decision. If the PRMC makes a final determination for closure, the principal investigator files a closure request with the IRB. Upon receipt of the closure request, the IRB ensures that former subjects have been safely transitioned off the study and then closes the trial.

References:

45 CFR 46.111
21 CFR 56.111

Attachments:

Approval Signatures

<table>
<thead>
<tr>
<th>Approver</th>
<th>Date</th>
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<tbody>
<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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<tr>
<td>Annie Fors: QA Director</td>
<td>12/3/2019</td>
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<tr>
<td>Karen Blackwell: Director HRPP</td>
<td>11/26/2019</td>
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<tr>
<td>Kyle Stephens: Assistant Director</td>
<td>11/19/2019</td>
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Applicability

KU Medical Center, KU SoM Wichita