## Purpose:

Document the purview of the KUMC Human Research Protection Program, outlining the federal regulations and institutional standards that will be applied in the review of human subjects research at KUMC.

## Responsible Personnel:

Responsibility for ethical conduct rests with all parties involved in the review, oversight or conduct of human research. Parties include the Executive Vice Chancellor, Vice Chancellors, Deans, Department Chairs, Center Directors, investigators, the institutional review board (IRB) and other compliance committees and staff of the KUMC Human Research Protection Program (HRPP).

## Background:

All human subjects research conducted by the University of Kansas Medical Center (KUMC) is guided by the ethical principles of respect, beneficence and justice set forth in *The Belmont Report* and institutional commitments in KUMC's Federalwide Assurance document filed with the federal Office for Human Research Protections.

## Regulation and Guideline Reference(s):

45 CFR 46.102, 107, 111
21 CFR 50.3
21 CFR 56.111
21 CFR 312.3
21 CFR 812.3
KUMC References:

Attachment(s):

Definitions:

Research: as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subjects: as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens; or (2) uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

Human Subjects per FDA: FDA regulations define a "human subject" as an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. For research that involves medical devices a "human subject" is also an individual on whose specimen an investigational device is used.

Clinical Investigation: " as any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Food, Drugs, and Cosmetics Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. An experiment includes any use of a drug except for the use of a marketed drug in the course of medical practice.

Procedure:

1. Ethical Principles of Human Research
   I. All human subjects research conducted by the University of Kansas Medical Center (KUMC) is guided by the ethical principles of respect, beneficence and justice set forth in The Belmont Report and institutional commitments in KUMC’s Federalwide Assurance document filed with the federal Office for Human Research Protections.
   II. Responsibility for ethical conduct rests with all parties involved in the review, oversight or conduct of human research. Parties include the Executive Vice Chancellor, Vice Chancellors, Deans, Department Chairs, Center Directors, investigators, the institutional review board (IRB) and other compliance committees and staff of the KUMC Human Research Protection Program (HRPP).
   III. The KUMC (HRPP) is designed to ensure the rights, safety and welfare of all subjects recruited or enrolled in research projects, regardless of funding source. The purpose of the HRPP is to monitor, evaluate and improve the protection of human research subjects. The program includes institutional review and approvals of each protocol involving humans for ethical considerations, conflicts of interest, privacy and confidentiality, data integrity and safety. KUMC is responsible for assuring that all personnel involved in research activities understand and comply with the ethical standards and regulatory requirements governing all aspects of human research.

2. KUMC Federalwide Assurance
   I. KUMC is engaged in research involving human subjects. Federalwide Assurance (FWA) #00003411
has been approved for KUMC. The Vice Chancellor for Administration serves as Institutional Official for the FWA and is delegated authority by the Executive Vice Chancellor to serve as KUMC's primary contact with federal regulatory agencies. The FWA covers the two KUMC IRBs. The KUMC HRPP may designate other IRBs as reviewing IRBs.

II. KUMC applies the federal Common Rule (45 CFR Part 46, Subparts A) to all non-exempt human subjects research conducted or supported by any federal department or agency that has adopted the Common Rule. KUMC also applies Subparts B through D of the federal Common Rule to non-exempt human subjects research funded by the U.S. Department of Health and Human Services ("DHHS research").

III. KUMC applies protections equivalent to the federal Common Rule and its subparts to all research involving human subjects regardless of funding source. Where regulatory flexibility is allowed and appropriate to the research, adjustments based on funding source are noted in the applicable standard operating procedures.

3. IRB Governing Regulations and Purpose

I. The IRBs for the University of Kansas Medical Center (KUMC) are appropriately constituted administrative bodies established to protect the rights and welfare of human research subjects. KUMC includes the Medical Center campuses in Kansas City (Schools of Medicine, Nursing and Health Professions) and the KU School of Medicine in Wichita and Salina. For the purposes of these standard operating procedures, the two institutional review boards are collectively referred to as "the IRB." In accordance with the federal policy regulations (45 CFR 46) of the Department of Health and Human Services (DHHS) and the applicable regulations (21 CFR 50, 56) of the Food and Drug Administration (FDA), the IRB has the authority to approve, require modifications in (to secure approval) or disapprove research involving human subjects under its jurisdiction. KUMC defines "research involving human subjects" as any activity that either:

A. Is "research" and involves "human subjects" as these two terms are defined by DHHS regulations; OR

B. Is a "clinical investigation" and involves "human subjects" as these two terms are defined by FDA regulations.

II. DHHS regulations define "research" as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Regulations define a "human subject" as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens; or (2) uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

III. FDA regulations define "clinical investigation" as any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Food, Drugs, and Cosmetics Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. An experiment includes any use of a drug except for the use of a marketed drug in the course of medical practice. FDA regulations define a "human subject" as an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. For research that involves medical devices a "human subject" is also
an individual on whose specimen an investigational device is used.

IV. To approve human subjects research, the IRB must determine that risks have been minimized; risks are reasonable in relation to anticipated benefits; selection of subjects is equitable; informed consent will be sought, and documented, from each subject or a legally authorized representative unless the IRB has approved a waiver of consent; when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects; there are adequate provisions to protect the privacy of subjects and maintain confidentiality of data; appropriate additional safeguards have been included to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence (such as, children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons).

V. The IRB may be asked to advise investigators about the conduct of activities that do not constitute human subjects research. Examples may include: program evaluations, quality improvement activities, off-label use in medical practice, case reports, use of publicly available databases and tissues, research involving information about decedents, scholarly and journalistic activities, public health surveillance activities and other non-research categories outlined in the Common Rule. These activities are further summarized in SOP 2.1.IV.D.

4. Activities Subject to IRB Jurisdiction

I. The Executive Vice Chancellor has granted the KUMC HRPP the authority to oversee all human subjects research conducted or sponsored by KUMC.

II. The KUMC IRB must review all research involving human subjects carried out by the KUMC faculty, students and employees, both on campus and at off-site locations, unless arrangements have been approved to rely on an outside IRB. Additionally, the IRB evaluates proposed human subjects research that uses the physical or patient resources of the institution, to determine whether the activity engages KUMC in research and thus requires IRB oversight. All human subjects research conducted by full-time faculty is subject to IRB oversight whether it occurs through KUMC or as part of collaborative research with another organization. Research conducted by part-time or volunteer faculty is subject to IRB oversight when the individual is acting in his/her university capacity. "University capacity" shall mean that the individual is acting on behalf of KUMC in fulfillment of its clinical, education or research mission. Part-time faculty members may be operating in their university capacity if their research involves the university's institutional resources, facilities, patients, or trainees. The HRPP will consult with the Office of the General Counsel when there are questions about whether an individual is acting in a university capacity.

III. In exercising its delegated authority, the IRB may:

A. Approve, require modifications (to secure approval) or disapprove human research activities;
B. Suspend or terminate approval of research that is not being conducted in accordance with requirements of the Human Research Protection Program;
C. Require third parties other than the research team members to observe the informed consent process; or
D. Require third parties to observe or otherwise monitor the conduct of the research.

IV. Research covered by this policy may be subject to further institutional review and approval or disapproval by KUMC officials. KUMC officials may elect not to conduct IRB-approved research but may not approve research that the IRB has disapproved.

V. The HRPP remains independent within the organizational structure of the institution. Investigators
and administrative officials may ask questions or express concerns about the HRPP to the Institutional Official (IO). The IO will address these concerns while maintaining the independence of the HRPP. The processes to express concerns or request a re-consideration of an IRB decision are outlined in SOP 17.3 and 17.4.

VI. Attempts to inappropriately influence the HRPP should be reported to the IO. The IO will review the report and may request further information from the complainant or others. The IO is responsible for investigating the allegation and taking corrective action. The IO may consult with the Executive Vice Chancellor or other senior administrators in determining the appropriate corrective action.

5. Responsibility for Protection of Human Subjects

I. Executive Vice Chancellor

The EVC is ultimately responsible for the protection of human research subjects at KUMC. The EVC designates the Institutional Official for federal assurances, seats the Research Advisory Council (RAC), appoints members of the IRB, and authorizes adjustments or modifications in the University’s HRPP.

Specifically, the EVC shall:

▪ Utilize appropriate internal resources and mechanisms to identify qualified individuals to serve in the following roles:
  ▪ Vice Chancellor for Administration
  ▪ Director of the Human Research Protection Program;
  ▪ Chair of the IRB and other compliance review boards as may be established;
  ▪ All members of the IRB.
▪ Issue formal appointments for IRB chairs and members;
▪ Delegate authority for development, oversight, implementation and maintenance of research protection programs to various individuals and offices.

II. Vice Chancellor for Administration

The Vice Chancellor for Administration is delegated responsibility by the EVC to serve as Institutional Official (IO) for the FWA filed with the Office for Human Research Protections (OHRP). The IO ensures the fulfillment of institutional responsibilities outlined in 45 CFR 46.108, including adequate meeting space and staff for the IRB, provision of IRB members with sufficient expertise, policies and procedures and the required reporting to OHRP when there is an unanticipated problem involving risks to subjects or others, suspension or termination of IRB approval, or serious or continuing non-compliance.

III. Associate Vice Chancellor for Compliance

The Associate Vice Chancellor for Compliance has day-to-day oversight of the HRPP. Activities supporting the HRPP include:

▪ Serve as a non-voting, ex-officio member of the RAC;
▪ Monitor federal, state and funding source regulations to ensure that KUMC’s policies and procedures meet human research compliance requirements;
• Ensure that policies and procedures are disseminated to researchers, support staff and other university officials, utilizing appropriate outreach mechanisms;
• Ensure that policy changes are reviewed and approved through established internal review mechanisms;
• Oversee policy implementation through the use of appropriate procedures;
• With the guidance of the IO, enforce all requirements of the KUMC Human Research Protection Program (HRPP); and
• Annually, review the resources allocated to the HRPP to ensure protection for research participants

IV. Research Advisory Council

The RAC functions as primary counsel to the EVC regarding all issues relating to the conduct of research at KUMC. Specifically, the RAC serves as a direct resource to the EVC by evaluating research-related issues, including but not limited to:

• Research funding
• Research planning
• Allocation of resources, including space and personnel
• Development of new programs
• Policies, procedures and practices associated with research administration, compliance and peer review practices
• Applications and nominations for committee appointments

V. Director, Human Research Protection Program

The Director of the HRPP ensures that all aspects of the human research program meet federal, state, local and institutional requirements. Responsibilities include, but are not limited to:

• Develop human research protection policies in consultation with appropriate institutional leaders (including but not limited to the Institutional Official, Associate Vice Chancellor for Compliance, Office of General Counsel, the RAC, the Vice Chancellor for Research, and other faculty committees);
• Create and maintain means of coordination for the Compliance Services units related to human research, including IRB, Conflict of Interest, Radiation Safety Committee, Institutional Biosafety Committee, Privacy (HIPAA), and Quality Assurance;
• Ensure coordination with other institutional entities that participate in the protection of human subjects, including the KUMC Research Institute, the Cancer Center's Protocol Review and Monitoring Committee (PRMC) and department scientific reviewers and committees;
• Develop and disseminate guidance on compliance requirements to institutional officials, IRB members and research personnel;
• Coordinate with the KUMC Quality Assurance Program to ensure adequate monitoring of human research activities;
• Refer reports of potentially serious or continuing non-compliance as outlined in SOP 17.1;
• Report, or support the reporting by the IO, of IRB determinations of serious or continuing non-compliance, unanticipated problems involving risks to subjects or others, and suspensions or terminations of IRB approval to institutional officials for subsequent reporting to federal authorities;
• Annually, assess the effectiveness of the HRPP, based on factors such as the number of reviews accomplished, educational events, expertise of the IRB members, feedback from investigators, internal audit findings, unanticipated problems, subject complaints and reports to federal agencies; and
• Monitor the regulatory environment and recommend changes, as needed, to institutional officials.

VI. HRPP Staff

Responsibilities of the HRPP staff include, but are not limited to:
• Develop and implement procedures to ensure that human research review meets requirements established by regulators, sponsors and the institution;
• Ensure that minutes for each convened meeting are accurately recorded; finalize minutes for full IRB review and approval;
• Develop and implement written standard operating procedures (SOPs);
• Track each study submitted to the IRB for review;
• Review all complete project submissions, determine review type, assign reviewers and authorize exempted status;
• Prepare materials related to amendments, continuing reviews, potential unanticipated problems, potential serious or continuing non-compliance or other new information for review by the convened IRB or designated individual reviewers.
• Develop the agenda for each meeting and ensure that materials are distributed within established timelines;
• Facilitate communication between investigators and the IRB;
• Ensure that IRB review decisions are accurately communicated to investigators in a timely manner;
• Participate in the orientation and training of new committee members; and
• Ensure that committee members who have potential conflicts of interest for a given project are recused during discussion of controverted issues and voting of that project.

VII. IRB Chair

The IRB Chair is appointed by the EVC, under recommendations from the RAC and the IO. Responsibilities include, but are not limited to:
• Maintain current knowledge of regulations and guidelines governing the protection of human research participants, work closely with the Director and HRPP staff to ensure that requirements are consistently applied in the review process and that work of the committee is accomplished in an effective and timely manner;
• Chair the IRB meetings, facilitate adequate and meaningful discussion during the meeting;
• Work cooperatively with investigators, committee members and IRB support staff; foster dialogue between committee members and manage disputes when necessary;

• Provide leadership to the IRB, participate in training and orienting new members, and give input on related policies, procedures and educational materials governing the protection of human subjects;

• Conduct expedited reviews; designate other qualified reviewers to provide expedited review;

• Serve as faculty spokesperson for the IRB and uphold IRB decisions; and

• In conjunction with other committee members and the HRPP staff, serve as a resource to researchers who are planning or conducting human research.

VIII. IRB Vice-Chair

The Vice-Chair appointed by the EVC, under recommendations from the RAC and the IO. Responsibilities include, but are not limited to:

• Understand principles and regulations governing the protection of human research subjects; and

• Act on behalf of the IRB chair in his/her absence, and serve as delegated signatory authority for the chair as needed.

IX. IRB members

Individuals who serve on the IRB are responsible for understanding ethical, legal and regulatory issues related to the protection of human research subjects. Specific responsibilities include, but are not limited to:

• Conduct reviews as assigned in time to present findings at the regularly convened IRB meeting;

• Notify the HRPP staff if a need is identified for an outside consultant to provide additional expertise;

• Attend every scheduled IRB meeting or provide adequate notice to the IRB Administrator when absences will be necessary; help determine whether alternate members must be present on their behalf;

• Fully participate in discussions regarding each project reviewed by the IRB;

• Maintain integrity of the IRB review process, recuse themselves from board discussions or deliberations when there is a conflict of interest, and avoid discussing IRB protocols with investigators outside of convened IRB meetings;

• Review and approve meeting minutes;

• Provide, as needed, expertise to the IRB Chair or HRPP staff for expedited reviews; and

• Notify the IO if members experience undue influence related to the review of research protocols.

X. Department Chairs and Center Directors

The Chair and Center Directors’ responsibilities related to the protection of human subjects include:

• Promote compliance with federal, state, sponsor and KUMC regulations regarding the safety and welfare of human subjects;
• Ensure that protocols submitted to the IRB have undergone appropriate review for scientific merit when required by institutional policy;
• When required by institutional policy, review proposed projects to determine that investigator time, research space and adequate resources are available;
• As needed, participate in preliminary inquiry or investigation of non-compliance; and
• As needed, participate in corrective measures or disciplinary actions to address non-compliance.

XI. Principal Investigator

The Principal Investigator bears ultimate responsibility for the ethical conduct of the research project. Responsibilities include:
• Adhere to federal regulations, state and local laws, institutional policies, and IRB procedures regarding the safety and protection of human subjects;
• Provide IRB with complete and up-to-date study protocol;
• Ensure the protocol submitted to IRB is congruent with the proposal for funding for extramural or intramural support;
• Conduct the study without deviation from the IRB-approved submission, except in circumstances of direct threat of harm to the subject;
• Inform IRB of any updates or modifications to the protocol; secure IRB approval of any protocol changes prior to implementation except when a delay in implementation would place subjects at risk;
• Engage in recruitment practices that are fair and non-coercive;
• When required by the IRB, ensure that no subject is enrolled without adequate informed consent;
• Clarify to the subjects which study activities are standard of care and which are conducted for research purposes;
• Monitor study data to assess subject safety;
• Promptly report to the IRB the events described in SOP 5.3;
• Report all adverse events to sponsors, data monitoring entities and appropriate federal agencies as required;
• When required, submit continuing review reports to IRB in a timely fashion so that IRB approval does not lapse;
• Maintain documents as required by federal, state and university policies/procedures; make these records available for inspection by appropriate authorities;
• Personally conduct the study or supervise study conduct by sub-investigators;
• Assure that all sub-investigators are adequately trained not only to perform the assigned study procedures but also to protect human subjects;
• Comply with applicable regulations on handling and dispensing investigational drugs or devices;
• Complete periodic training, as required by the University, to remain up-to-date on federal regulations, KUMC policies and procedures, and compliance expectations;
6. **IRB Membership and Structure**

   I. **Composition of the Committee**

   **Primary Members**

   Composition of the IRB is governed by DHHS and FDA regulations (45 CFR 46 and 21 CFR 56), which include the following requirements:

   - The IRB must consist of at least five duly appointed voting members who possess varying backgrounds that will promote complete and adequate review of research activities commonly conducted by KUMC. A voting member who is unable to be present at the convened meeting may participate by video-conference or conference telephone call, when the member has received a copy of the documents that are to be reviewed at the meeting. Such members may vote and be counted as part of the quorum. Opinions of absent members that are transmitted by mail, telephone, fax or e-mail may be considered by the attending IRB members but may not be counted as votes or the quorum for convened meetings.

   - The IRB must include at least one member whose primary concern is in a scientific area. An IRB member who is a physician or PhD-level physical or biological scientist satisfies this requirement.

   - The IRB must include at least one member whose primary concern is in a nonscientific area. The FDA interprets the requirement for diversity of disciplines to include members who had little or no scientific or medical training and experience. A non-scientific member or alternate must be present at each convened meeting in order to satisfy quorum requirements.

   - The IRB must include at least one member who is not otherwise affiliated with KUMC and who is not part of the immediate family of a person who is affiliated with the institution. Acknowledging their important role, KUMC shall appoint at least two IRB members who are not otherwise affiliated with the institution.

   - If the IRB regularly reviews research involving a vulnerable category of subjects (e.g., children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons) one or more individuals who possess knowledge of or experience in working with these subjects must be included in the IRB membership.

   - The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members (including consideration of race, sex, and 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.

   - Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, and that due consideration is given to qualified persons of both sexes, so long as no selection is made solely on the basis of sex.

   - The IRB may not consist entirely of members of one profession.

   - In addition to possessing the professional competence necessary to review specific research
activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. KUMC may therefore include persons knowledgeable in these areas (e.g., representatives from related compliance units, conflict of interest, Privacy (HIPAA), and radiation safety) as ex-officio members of the IRB. These representatives may be asked to provide ad hoc consultation as needed.

- To maintain the independence of the IRB, individuals who are responsible for business functions or securing research funding will not be included as members.
- The IRB may, at its discretion and with approval of the Institutional Official, invite individuals with competence in special medical or regulatory areas to serve as consultants for the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote.

Alternate Members:

- Are identified, selected and seated with the same procedures used for regular IRB members
- Must be formally appointed and listed in the IRB membership roster
- Hold qualifications comparable to the primary member(s) to be replaced

The IRB roster shall clearly identify the primary member(s) in whose absence an alternate member may attend IRB meetings. The IRB minutes will document when an alternate member replaces a primary member. When an alternate member attends for a primary member, the alternate member must have received and reviewed the same material the regular member would have received.

Ad Hoc Substitutions for Regular IRB Members

Ad hoc substitutes for primary or alternate IRB members are not permissible.

Conflict of Interest

No member of the IRB may participate in the initial or continuing review of any project in which they have a conflicting interest, except to provide information requested or answer questions from the IRB.

Committee Roster

A current roster of IRB members is maintained by the Office of Compliance and is readily accessible upon inquiry by federal agencies. The roster must include the following information:

- Name
- Earned degrees
- Representative capacity (i.e., ex-officio, voting or non-voting, regular member or alternate member, non-affiliated member, non-scientific member, etc.)
- Primary scientific or non-scientific specialty
- Affiliation with the institution
Changes in Composition of Committee

Changes in IRB membership shall be reported to the OHRP by the HRPP.

II. Identification and Selection of Members

Responsibility for Ensuring Representation

Members of the committee shall be drawn from disciplines and specialties representing the types of human research conducted at KUMC. All unit heads are responsible for ensuring adequate representation on the IRB so that research proposals from their investigators may be reviewed. The EVC, in consultation with the Research Advisory Council (RAC) and Vice Chancellor for Administration, reserves the right to postpone reviews from areas with inadequate representation on the IRB.

Identification and Selection of Ex-Officio Members

Ex-officio members of the IRB are individuals whose service is required by virtue of their KUMC employment and that service is reflected as a job duty in their position descriptions. An ex-officio member may or may not have voting privileges, depending on the restrictions noted below.

Ex-officio members of the IRB in Kansas City hold the following positions:
- Director of Human Research Protection Program – non-voting member
- Radiation Safety Officer – voting member

The determination to add or delete ex-officio members shall be made in consultation with the Institutional Official.

Identification and Selection of All Other IRB Members (including the Chair and Vice-Chair)

Voting or non-voting members and their alternates, the IRB Chair and the IRB Vice-Chair are identified in one of the following ways:
- Self-nomination by interested candidates;
- Term renewal requests by members whose appointment term is ending;
- Nomination by department chairs, center directors or school deans;
- Nomination by the Faculty Assembly Research Committee, or any of the Vice Chancellors;
- Nomination by members of the IRB, Conflict of Interest Committee, Institutional Biosafety Committee or Radiation Safety Committee.

Nominations and requests for re-appointment are submitted to the Vice Chancellor for Administration, and shall include a current curriculum vita or resume, a description of the nominee’s qualifications for serving on the IRB and additional supporting documentation if needed.

Nomination materials and re-appointment requests are reviewed at regularly scheduled meetings of the RAC. The RAC may solicit additional information at its discretion. After evaluation of the
individual's qualifications and consideration of IRB needs, the RAC will submit written recommendations to the Executive Vice Chancellor through the RAC minutes.

Appointment letters which outline the IRB charge, member responsibilities and terms of appointment shall be issued by the EVC through the Vice Chancellor for Administration.

III. Terms and Conditions of Appointment

Attendance

All regular and ex-officio committee members with voting privileges are expected to attend each scheduled IRB meeting or provide adequate advance notice of their absence to the HRPP staff.

Alternate committee members who agree to attend an IRB meeting on behalf of a regular committee member are expected to fulfill that commitment.

Service

All members of the IRB will be expected to serve in good faith, receive initial and continuing education regarding human subjects protection requirements, conduct reviews according to established IRB principles and policies, meet review deadlines, ensure the confidentiality and security of materials released to them, recuse themselves when a potential conflict of interest exists and actively participate in committee discussions.

Evaluation of the IRB Chair and Members

The performance of the IRB Chair(s) and members is evaluated on a regular basis as needed but at least every two years. IRB members are periodically surveyed about their experience as members, their evaluation of the committee's expertise and workload and areas where committee meetings could be improved.

The Institution Official is responsible for communicating with the IRB Chair(s) to discuss his or her performance and to receive feedback from the Chair about the activities and needs of the IRB.

The participation of the IRB members is evaluated by the Chair and the HRPP Director. Members are evaluated on their attendance at meetings, their level of participation during the meetings, thoroughness of review, and their knowledge of regulations and institutional policy. As needed, the Chair and HRPP Director develop a plan to assist the member in improving his/her performance. After the evaluations, the Chair and HRPP Director send a letter to each member about their service. These evaluations of individual members are considered when committee appointments are renewed.

IRB members who are HRPP staff are evaluated according to the institution's human resources policies and procedures. Additional evaluation by the HRPP Director and IO is applicable when staff must possess unique requirements or knowledge for their role as IRB members.

Length of Appointment
All ex-officio members serve on the IRB until they no longer occupy the position to which ex-officio status has been assigned.

All other members, including the IRB Chair and Vice Chair, are initially appointed to three-year terms which are renewable at the discretion of the EVC, in consultation with the RAC and Vice Chancellor for Administration. Appointments may be renewed in increments of one to three years.

Early Termination of Appointment

Recommendations for early termination of an IRB member’s term shall be submitted to the Institutional Official, along with a written justification. Recommendations will be reviewed with the IRB Chair, Vice Chair and HRPP Director. The final decision is communicated to the member in writing.

Committee members who wish to resign before the end of their term shall notify the HRPP Director or Vice Chancellor for Administration in writing with adequate notice to ensure that a replacement can be named.

Approved By:
Vice Chancellor for Administration

Attachments:

Approval Signatures

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<tr>
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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>
<td>12/3/2019</td>
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<td>Karen Blackwell: Director HRPP</td>
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<td>Kyle Stephens: Assistant Director</td>
<td>11/19/2019</td>
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Applicability

KU Medical Center, KU Public Policies and Procedures, KU SoM Wichita