

## **1.0 HSC Authority and Institutional Commitment**

### **1.1 Ethical Principles of Human Research**

- I. All human subjects research conducted at 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 as stated in the KUMC's Federalwide Assurance document.
- II. Ethical principals and assurances to federal authorities apply to all human research at KUMC, regardless of funding source.
- III. 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, faculty, staff and students, the Human Subjects Committee and other compliance committees and staff of the KUMC Human Research Protection Program (HRPP).

### **1.2 KUMC Federalwide Assurance**

- I. It is the policy of the KUMC Human Subject Committee to uphold its Assurance as filed with the federal Office for Human Research Protections (OHRP).
- II. KUMC is engaged in research involving human subjects. The KUMC Human Research Protection Program (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.
- III. Federalwide Assurance (FWA) #00003411 has been approved for KUMC. The Associate Vice Chancellor for Compliance 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 includes two Human Subjects Committees, one which operates at the KUMC main campus in Kansas City, and one which operates at the School of Medicine-Wichita.

### **1.3 HSC Governing Regulations and Purpose**

- I. The Human Subjects Committee (HSC) is the institutional review board for the University of Kansas Medical Center (KUMC) and is an appropriately constituted administrative body established to protect the rights and welfare of human research subjects. 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 HSC 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) data through intervention or interaction with the individual, or (2) identifiable private information.
- 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 HSC 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 as required by federal law; 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, pregnant women, handicapped or mentally disabled persons, or economically or educationally disadvantaged persons).

#### **1.4 Activities Subject to HSC Jurisdiction**

- I. The Executive Vice Chancellor has granted the Human Subjects Committees (HSC's) on the Kansas City and Wichita Campuses the authority to oversee all human subjects research conducted or sponsored by KUMC.
- II. The HSC must review all research involving human subjects carried out by the KUMC faculty, students and employees, both on campus and at off-site locations. Additionally, the HSC reviews any 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 HSC oversight. All research conducted by full-time faculty is subject to HSC review (this extends to research studies performed at off-campus sites if the faculty member is the principal investigator or a listed co-investigator on the research study). Research conducted by part-time or volunteer faculty is subject to HSC review 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.
- III. The HSC in Kansas City oversees research conducted or sponsored by the Kansas City campus. The HSC in Wichita oversees research conducted or sponsored by the KU School of Medicine-Wichita campus. If an individual research project by a Kansas City or Wichita investigator involves a subject population at the campus that is not the home campus of the investigator, the HSC at the campus where subject population is located will be responsible for oversight of the study. If the research involves subject populations at both campuses, the Institutional Official will determine the HSC that will oversee the research, with input as needed from the HSC Chairs and other institutional officials. The decision will be documented in writing.
- IV. In exercising their delegated authority, the HSCs may:
  - A. Approve, require modifications in (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 to observe the informed consent process; or
  - D. Require third parties to observe or otherwise monitor the conduct of the research.

- V. 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 HSC-approved research but may not approve research that the HSC has disapproved.
- VI. 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. 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.

## **1.5 HSC Membership and Structure**

### **I. Composition of the Committee**

#### Primary Members

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

- The HSC 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 HSC members but may not be counted as votes or the quorum for convened meetings.
- The HSC must include at least one member and one alternate whose primary concern is in a scientific area. An HSC member who is a physician or PhD-level physical or biological scientist satisfies this requirement.
- The HSC must include at least one member and one alternate 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. Lawyers, clergy and ethicists have been cited as examples of persons whose membership will fulfill the regulatory requirement for representation of a non-scientific member. A non-scientific member or alternate must be present at each convened meeting in order to satisfy quorum requirements.
- The HSC 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. Although 21 CFR 56.108(c) does not specifically require the presence of a member not otherwise affiliated with the institution to satisfy quorum requirements, the FDA considers the presence of such members an important element of diversity; as such, frequent absence of a non-affiliated member is unacceptable. Acknowledging their important role, KUMC shall appoint at least two HSC members who are not otherwise affiliated with the institution.

- If the HSC regularly reviews research involving a vulnerable category of subjects (e.g., children, prisoners, pregnant women, or handicapped or mentally disabled persons) one or more individuals who possess knowledge of or experience in working with these subjects must be included in the HSC membership.
- The HSC 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 HSC 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 HSC may not consist entirely of members of one profession.
- In addition to possessing the professional competence necessary to review specific research activities, the HSC 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 shall therefore include persons knowledgeable in these areas (e.g., representatives from related compliance units, conflict of interest and data safety monitoring committees, and safety officers for radiation and biochemicals) as ex-officio members of the HSC.
- The HSC may, at its discretion and with approval of the Institutional Official, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the HSC. These individuals may not vote.

#### Alternate Members:

- are identified, selected and seated with the same procedures used for regular HSC members
- must be formally appointed and listed in the HSC membership roster
- hold qualifications comparable to the primary member(s) to be replaced

The HSC roster shall clearly identify the primary member(s) in whose absence an alternate member may attend HSC meetings. The HSC 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 HSC Members

Ad hoc substitutes for primary or alternate HSC members are not permissible. However, with proper advance notice to the IRB Administrator, regular members may request that ad hoc substitutes attend convened meetings as consultants. The ad hoc substitute may gather information for the absent member, but may not be counted toward the quorum, participate in HSC deliberations, or vote. The HSC may ask questions of the ad hoc substitute just as they could of any non-member consultant.

#### Conflict of Interest

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

#### Committee Roster

A current roster of HSC members is maintained by the Office of Compliance, and must be readily accessible to all interested parties (e.g., posted on the HSC website, or available in hard copy informational packets). The roster must include the following information:

- name and KUMC job title, if applicable
- earned degrees
- representative capacity (i.e., ex-officio, voting or non-voting, regular member or alternate member, non-affiliated member, non-scientific member, etc.)
- indications of experience such as board certifications, licenses, etc., sufficient to describe anticipated contributions to HSC deliberations
- any employment or other relationship between each member and KUMC; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant
- appointment dates (initial appointment dates, ending appointment, and any renewals approved by procedures listed below).

#### Changes in Composition of Committee

Changes in HSC membership shall be reported to the OHRP by the Associate Vice Chancellor for Compliance who serves as KUMC's Institutional Official.

## 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 HSC so that research proposals from their investigators may be reviewed. The EVC, in consultation with the Research Advisory Council (RAC) and Associate Vice Chancellor for Compliance, reserves the right to postpone reviews from areas with inadequate representation on the HSC.

### Identification and Selection of Ex-Officio Members

Ex-officio members of the HSC 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 who have voting privileges must be present at each convened HSC meeting, or ensure that a duly appointed and appropriately qualified alternate attends meetings in their absence.

Ex-officio members of the HSC hold the following positions:

- Associate Vice Chancellor for Compliance – non-voting member
- Director of Human Research Protection Program – non-voting member
- Director of Environment, Health and Safety – voting member
- HIPAA Manager – voting member
- Research Institute representative – non-voting member

The determination to add or delete ex-officio members shall be made by the Executive Vice Chancellor in consultation with the RAC and the Associate Vice Chancellor for Compliance.

### Identification/Selection of COIC and DSMB Representatives

The Conflict of Interest Committee (COIC) and the Data and Safety Monitoring Board (DSMB) shall be represented on the HSC to ensure that institutional considerations regarding conflicts of interest and data safety are efficiently incorporated into the review of human research. Representation on the HSC may be accomplished through shared membership between HSC, the COIC and the DSMB; alternatively, the Compliance Program Manager may serve in a non-voting, advisory capacity on behalf of the COIC and DSMB.

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

Voting or non-voting members and their alternates, the HSC Chair and the HSC 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, the Associate Vice Chancellor for Compliance, or any of the Vice Chancellors;
- Nomination by members of the HSC, DSMB, COIC, IRSC or Radiation Safety Committee.

Nominations and requests for re-appointment are submitted in writing to the Associate Vice Chancellor for Compliance, and shall include the following:

- Description of the nominee's qualifications for serving on the HSC;
- A current curriculum vita or resume;
- Additional support 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 HSC needs, the RAC will submit written recommendations to the Executive Vice Chancellor which specify the type of appointment that should be considered (i.e., voting, non-voting, Chair, Vice Chair), terms of appointment (in cases of renewals), and a brief explanation of the RAC's selection rationale.

The Executive Vice Chancellor (EVC) is responsible for the final selection of new members and for issuing re-appointments. Appointment letters which outline the HSC charge, member responsibilities and terms of appointment shall be issued by the EVC through the Associate Vice Chancellor for Compliance.

#### Identification and Selection of Consultants

When discipline-specific knowledge is required for the review of a given proposal and appropriate expertise is not represented on the HSC, the Associate Vice Chancellor for Compliance, in consultation with the HSC Chair and the HSC Administrator, shall identify and seat appropriate consultants who shall serve in non-voting, advisory capacities on an as-needed basis.

### III. Terms and Conditions of Appointment

#### Attendance

All regular and ex-officio committee members with voting privileges are expected

to attend each scheduled HSC meeting or provide adequate advance notice of their absence to the IRB Administrator.

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

Ex-officio committee members who do not have voting privileges are expected to attend most scheduled HSC meetings and provide advance notice of their absence to the IRB Administrator.

### Service

All members of the HSC will be expected to serve in good faith, receive initial and continuing education regarding human subjects protection requirements, conduct reviews according to established HSC 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.

### Length of Appointment

All ex-Officio members serve on the HSC until they no longer occupy the position to which ex-officio status has been assigned.

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

Terms of appointment for the HSC Chair and Vice Chair must overlap so that at least one year of service as a Vice Chair is accumulated before that individual can be named as Chair.

### Termination of Appointment

Recommendations for early termination of an HSC member's term shall be submitted to the Institutional Official, along with a written justification. Recommendations will be reviewed with the HSC Chair, Vice Chair and IRB Administrator. The final decision to terminate a member's appointment shall be made in consultation with the Associate Vice Chancellor for Compliance, the RAC and the EVC.

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

## **1.6 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 selects the AVCC, designates the Institutional Official for federal assurances, seats the RAC, appoints members of the HSC, 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:
  - Associate Vice Chancellor for Compliance (AVCC);
  - Research Integrity Officer (RIO), if different than the AVCC;
  - Director of the Human Research Protection Program;
  - Chair of the HSC and other compliance review boards as may be established;
  - All members of the HSC.
- Issue an official charge for each human research review board and formal appointments for all chairs and members;
- Delegate authority for development, oversight, implementation and maintenance of research protection programs to various individuals and offices;
- Serve as “Deciding Official” for the University’s Research Misconduct Complaint Procedure. It may be necessary to delegate this role under certain circumstance, i.e.,
  - When the EVC will be absent during the time period required to fulfill the role, s/he may designate another senior administrator as Deciding Official for a specific case by issuing a written notification to the AVCC.
  - When the EVC voluntarily discloses a potential conflict of interest, s/he shall request the Chancellor to designate another senior administrator as Deciding Official for a specific case.

### **II. Associate Vice Chancellor for Compliance**

The AVCC is delegated responsibility by the EVC to:

- serve as Institutional Official for the FWA filed with the Office for Human Research Protections (OHRP);
- 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;
- serve as RIO with the responsibility to receive and investigate allegations of research misconduct (including fraud, plagiarism, fabrication);
- 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.

### III. Research Advisory Committee

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

### IV. 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 officials (including but not limited to legal counsel, the RAC, the Faculty Assembly Research Committee, the committee chairs);
- create and maintain means of coordination for the OC units related to human research, including HSC, COI, DSMB, Radiation Safety Committee, IRSC and HIPAA;
- ensure coordination with other institutional entities that participate in the protection of human subjects, including the KUMC Research Institute, the General Clinical Research Center (GCRC) and the Protocol Review and Monitoring Committee (PRMC);
- develop and disseminate guidance on compliance requirements to institutional

- officials, HSC members and research personnel;
- ensure adequate monitoring of human research activities;
- make initial inquiries on potential compliance violations related to human research; as needed, refer non-compliance to the AVCC for further investigation;
- report serious non-compliance and for-cause study terminations 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 HSC 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.

#### V. IRB Administrator

The IRB Administrator serves as the University's primary technical resource regarding regulatory requirements governing human research protection programs and manages the operations of the HSC office. Responsibilities 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;
- serve as primary recording secretary for the HSC; ensure that minutes for each meeting are accurately recorded; finalize minutes for full HSC review and approval;
- develop written standard operating procedures (SOPs), data management systems and transaction forms to ensure efficient receipt, handling and tracking of each study submitted to the HSC for review;
- review all complete project submissions, determine review type, assign reviewers and authorize exempted status;
- work with the Chair to develop the agenda for each meeting and ensure that materials are distributed within established timelines;
- evaluate reports of unanticipated problems, amendments and continuing review forms and prepare recommendations to the full committee;
- facilitate communication between investigators and the HSC;
- ensure that HSC review decisions are accurately communicated to investigators in a timely manner; and
- participate in the orientation and training of new committee members.

#### VI. HSC Chair

The HSC Chair is appointed by the EVC, under recommendations from the RAC and the AVCC. Responsibilities include, but are not limited to:

- serve at least one year as Vice Chair of the HSC;
- understand regulations and guidelines governing the protection of human research participants, work closely with the IRB Administrator 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;
- in conjunction with the IRB Administrator, help develop the agenda for each HSC meeting, chair HSC meetings, ensure that the agenda is completed, facilitate adequate and meaningful discussion during the meeting, review and edit minutes;
- ensure that committee members who have potential conflicts of interest for a given project are recused during discussions of that project;
- consolidate the HSC's comments and concerns into concise and meaningful communications back to each investigator;
- serve as signatory authority for documentation requiring HSC Chair approval;
- work cooperatively with investigators, committee members and HSC support staff; foster dialogue between committee members and manage disputes when necessary;
- provide leadership to the HSC, 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; in conjunction with the IRB Administrator, develop and coordinate a team of experienced reviewers to provide expedited review;
- serve as faculty spokesperson for the HSC and uphold HSC decisions; and
- in conjunction with the IRB Administrator and other committee members, serve as a resource to researchers who are planning or conducting human research.

## VII. HSC Vice-Chair

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

- understand principles and regulations governing the protection of human research subjects; and
- act on behalf of the HSC Chair in his/her absence, and serve as delegated signatory authority for the Chair as needed

## VIII. HSC members

Individuals who serve on the HSC 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 by the IRB Administrator in time to present findings at the regularly convened HSC meeting;

- complete applicable review checklists;
- notify the IRB Administrator if a need is identified for an outside consultant to provide additional expertise;
- attend every scheduled HSC 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 HSC;
- maintain integrity of the HSC review process, recuse themselves from board discussions or deliberations when there is a conflict of interest, and avoid discussing HSC protocols with investigators outside of convened HSC meetings;
- review and approve meeting minutes; and
- notify the IO if members experience undue influence related to the review of research protocols

#### IX. Dean's Office

The Dean's 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;
- report discovered instances of non-compliance to institutional officials;
- 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.

#### 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 HSC have undergone appropriate review for scientific merit;
- 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.

#### XII. 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 HSC procedures regarding the safety and protection of human subjects
- provide HSC with complete and up-to-date study protocol
- ensure the protocol submitted to HSC is identical to the proposal for funding for extramural or intramural support
- conduct the study without deviation from the HSC-approved protocol, except in circumstances of direct threat of harm to the subject
- inform HSC of any updates or modifications to the protocol; secures HSC 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
- 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 HSC the events described in SOP 5.3
- report all adverse events to sponsors, data monitoring entities and appropriate federal agencies as required;
- submits continuing review reports to HSC in a timely fashion so that HSC 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
- store and handle research data in accordance with regulations on privacy and confidentiality
- after study completion, maintain study data in accordance with the KUMC Policy on Research Records Retention

**References:**

45 CFR 46.102, 107, 111

21 CFR 50.3

21 CFR 56.111

21 CFR 312.3  
21 CFR 812.3