1. Purpose:

The purpose of this SOP is to outline educational requirements and training needed for KUMC research staff, for IRB members, and for IRB staff.

2. Regulation and Guideline Reference(s):

   45 CFR 46.107
   21 CFR 56.107
   45 CFR 164

3. Procedure:

15.0 Education and Training in Human Research Protections

I. Responsibility for the education and training program

   A. The HRPP Director, in conjunction with the Office of Compliance, is responsible for evaluating the adequacy of education and training resources for research personnel, IRB members and IRB staff.

   B. Education and training is maintained through in-person presentations, online tutorials, web resources such as IRB guidance documents, institutional broadcasts and newsletters. Fact Sheets and Frequently Answered Questions, and email reminders to research personnel.

   C. At least annually, the HRPP Director evaluates current training to update materials based on new developments in regulations and common compliance problems that have arisen during IRB review. The evaluation is communicated to the Institutional Official through the annual report from the Office of Compliance.

   D. Communicating routine changes in the policies and procedures to all individuals in the KUMC research community is accomplished through a range of media, including posts to the HRPP website, announcements in university newsletters, broadcast emails or in-person presentations to departments or the research community as a whole.

   E. If a critical issue arises, or if a serious compliance violation indicates the need for prompt dissemination of information, the research community may be notified by email, website, special
presentations or communications sent through Department Chairs and Center Directors.

II. Research personnel training

A. All KUMC research personnel, KUMC staff and affiliated staff whose role in the study involves human subjects research must pass and maintain current training in human subjects protection and privacy regulations. The requirement extends to personnel who engage intervene or interact directly with study participants or who access research data that contains any elements of Protected Health Information as defined by the HIPAA Privacy Rule.

B. The requirement extends to personnel who engage intervene or interact directly with study participants for research purposes or who access research data that contains any elements of Protected Health Information as defined by the HIPAA Privacy Rule.

C. Clinical personnel who perform standard clinical services related to a research project are generally not considered to be research personnel. However, if personnel perform the clinical procedure differently from standard practice, for the purpose of the study, they are considered research personnel.

D. KUMC uses courses from the CITI Program. Research personnel complete either the Biomedical Basic Course or the Social Behavioral Basic Course, depending on the nature of their research. Once the initial course has been completed, a refresher is required every three years.

E. The requirement to maintain current training also applies to collaborators from other institutions who are working on KUMC projects. Collaborators may demonstrate recent human subjects training from their home institution, CITI, NIH or other HRPP-approved mechanisms.

F. The KUMC Office of Compliance maintains a tracking system to confirm that all research personnel have current training.

G. The HRPP recognizes the need to adapt the content and delivery of human subjects training when representatives of the community serve as study team members. In these circumstances, the HRPP will work with investigators to develop training methods and materials that are appropriate to the community representatives' educational and cultural background and their role on the study.

H. No individual may be involved in the research study until the IRB has approved his/her involvement. After initial approval, updates to study personnel are submitted to the IRB through a personnel modification in electronic IRB system.

I. The IRB recognizes that maintenance of professional credentialing and training is an important component of ensuring subject safety. The principal investigator is responsible for assembling a team that has the proper qualifications to perform the research procedures. The Health System Medical Staff Office has policies that govern what procedures individuals are credentialed to perform. When questions arise, the IRB works closely with the credentialing offices to assure that these policies are followed in the conduct of research and expect credentialing offices to report any problems with credentialing to the IRB.

J. There may be additional educational requirements based on funding source and type of research. These additional requirements are identified at the time of protocol review.

III. IRB member training

A. New members undergo an orientation process. At an initial meeting with the Director or IRB Administrator, they are supplied with an IRB Member Handbook, local review tools and an overview of committee processes. After they are appointed to the IRB, new members observe at least two committee meetings before they are considered voting members and given studies to review.
B. After new members have served as voting members for approximately six IRB meetings, HRPP staff meet with them to learn their questions and suggestions and to discuss reviewer responsibilities that need further elaboration. The meeting is designed to help the new member improve their effectiveness and satisfaction with board membership. This conversation is repeated after the member has served for about one year.

C. HRPP staff members provide occasional training at IRB meetings by presenting articles or discussions on current topics in human research protection or KUMC research policy.

D. When new regulations or institutional policies are implemented, HRPP staff conduct targeted training for IRB members.

IV. IRB Chair training

A. IRB Chairs are provided additional training through the CITI modules, webinars, and attendance at national meetings

V. IRB staff training

A. IRB staff members are offered periodic opportunities to attend training conferences.

B. IRB staff members maintain their training through discussions at regular staff meetings and attendance at internal compliance presentations.

C. IRB staff who perform expedited reviews are IRB members and are qualified by training and experience.

References:

45 CFR 46.107
21 CFR 56.107
45 CFR 164

Attachments:

Approval Signatures

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<tr>
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<th>Date</th>
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<tr>
<td>Steffani Webb: Vice Chancellor for Administration</td>
<td>12/10/2019</td>
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<td>Lisa Hoebelheinrich: Chief Compliance Officer</td>
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Applicability

KU Medical Center, KU SoM Wichita