Research Support Guidance

Document:
This document provides information as to how UMKC School of Medicine (SOM) faculty clinicians, residents/fellows and students may obtain guidance from designated TMC clinical research study coordinators (known as the Research Support team) on how to submit research protocols to the applicable University compliance committees such as the UMKC Institutional Review Board (IRB) and complete hospital affiliate requirements such as the Truman Medical Center (TMC) Research Application Form, St. Luke's Hospital (SLH) IRB submission, complete Children's Mercy Hospital (CMH) IRB requirements, and obtain appropriate department signature approvals to conduct the research at the SOM or hospital affiliates.

Purpose:
To ensure that research is conducted and reviewed in compliance with the institutions' policies and procedures, applicable federal regulations including relevant U.S. Food and Drug Administration (FDA) regulations located throughout 21 CFR, FDA Good Clinical Practice Standards (GCP), U.S. Department of Health and Human Services (DHHS) regulations at 45 CFR Part 46, and the Health Insurance Portability and Accountability Act (HIPAA) of 1996 known as the Privacy Rule that protects the confidentiality of patient health information. This is important for the safety and welfare of research subjects participating in research, that subjects provide consent to participate in research, and to ensure that patient data used for research purposes is conducted in accordance with the federal regulations. Research Support is familiar with human subjects of research regulations, the IRB submission process, and hospital affiliate requirements for conducting research.

Scope:
All researchers, workforce members, residents, fellows and medical students that will conduct or do conduct research activities.

Guidance:
Research Support may provide input on the following items listed below. Research Support is not responsible for writing research protocols, completing the IRB submission, preparing the TMC Research Application Form or other clinical affiliate

required documents, or preparing articles for publication - as those functions are the responsibility of the principal investigator.

I. Brief review of a research protocol (after review or before review by the faculty mentor) including referencing a protocol template. This includes guidance on the need for data collection forms with the protocol.

   A. Direction on how to locate and contact the SOM Research and Statistics Consult Service located within the Department of Biomedical and Health Informatics before the final protocol is written.

   B. Suggesting edits to IRB submission documents before final submission to the IRB.

II. Direction on how to register for required human subjects of research training that is required by the UMKC IRB and hospital affiliates.

   A. Inform Research Staff conducting research to complete Collaborative Institutional Training Initiative (CITI) training on the protection of human Subjects (e.g., UMKC Group 1-Biomedical Investigator training course). More info about the CITI training and courses are located at: *http://med.umkc.edu/ora/human_subjects/*

III. Guidance on how to complete a UMKC IRB submission.

   A. Direct individuals to the UMKC IRB website.

   B. Demonstrate or show a submission to the UMKC IRB via the online submission system known as eProtocol for full-board, expedited, and exempt research project submissions.

   C. Provide suggestions for submissions to the UMKC IRB for determinations of research activity (non-human subjects research determination request).

   D. Assist to interpret if a project is a quality improvement (QI) or quality assurance (QA) activity and whether the QI or QA project requires a determination from the UMKC IRB.

   E. Guide on how to complete a submission to the Privacy Board, as appropriate per project, to ensure compliance with HIPAA and the Privacy Rule.

IV. For research protocols conducted at TMC, research protocols that include TMC employees as research staff, or research that uses, accesses, reviews, or

records TMC patient information - suggestions and guidance on how to complete the TMC research application form and obtain the appropriate department signatures required.

A. Demonstrate and guide how to complete the TMC research application form and submit to Research Administration.

B. Show individuals the location of current TMC research policies and intranet site as necessary.

C. Guide on how to complete and submit a request to TMC Information Technology for data requests and data queries of patient health information for research protocols.

V. For SOM student research activities at CMH, guide students on how to complete documentation to ensure CMH and UMKC IRB requirements are met.

A. Show students the CMH IRB request-to-rely process to ensure the UMKC IRB is aware of the students' research activities.

VI. For research conduted at St. Luke's Hospital, guide on how to complete documentation to ensure SLH and UMKC IRB review requirements are met.

A. Show students the IRB submission and IRB request-to-rely process to ensure the appropriate IRB reviews the students' research activities.

Definitions:

Clinical Trial/Study: Any investigation in Human Subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an Investigational Product(s) or medical device, and/or to identify any adverse reactions to an Investigational Product(s) or medical device, and/or to study absorption, distribution, metabolism, and excretion of an Investigational Product(s) with the object of ascertaining its safety and/or efficacy. For purposes of this policy, a Clinical Trial refers to Research that is funded or sponsored by an organization, e.g., National Institutes of Health, industry, etc., and regulated under applicable FDA regulations located throughout 21 CFR.

Good Clinical Practice: A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of Clinical Trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of Subjects are protected.

Human Subject: A living individual about whom an Investigator (whether professional or student) conducting Research obtains (a) data through Intervention or Interaction with the individual or (b) identifiable Private Information.

Informed Consent: A process by which a Subject voluntarily confirms his or her willingness to participate in a particular Research study, after having been informed of all aspects of the study that are relevant to the Subject's decision to participate. Informed Consent is documented by means of a written, signed, and dated Informed Consent form.

Institutional Review Board (IRB): An independent, academically based committee mandated by the National Research Act constituted of medical, scientific and non-scientific members whose goal and responsibility is to ensure the safety, well-being, and the protection of the rights of Human Subjects who take part in Research studies. The IRB reviews Research in accordance with the Department of Health and Human Services and FDA regulations.

Protocol: A document that describes the objective(s), design, methodology, statistical considerations, and organization of a Research study project. The Protocol usually also gives the background and rationale, but these could be provided in other Protocol referenced documents

Research: A systematic investigation designed to develop or contribute to generalizable knowledge as defined in 45 CFR Part 46.

Research Staff: Includes investigators, study coordinators, and others who conduct Research activities, or persons who have direct contact with Human Subjects, contribute to the Research in a substantive way, have contact with Human Subjects' identifiable data or biological samples (e.g., tissue, blood, urine, plasma, saliva), or use Human Subjects' personal information.