KU RESEARCH ADMINISTRATION
The University of Kansas Medical Center

TITLE:	Guidance for Identifying Rural Researchers, Their Training, Disclosure Requirements, and HIPAA Requirements for Human Subjects Research Projects
SUMMARY:	Provides definitions of who is identified as a researcher and the steps these individuals should take to satisfy their human subjects research training and conflict of interest disclosure.
CONTACT:	Human Research Protection Program- IRBreliance@kumc.edu

1. **Identifying Who is a Rural Researcher**
   Who is and who is not a researcher may be difficult to determine when engaging a rural site. There are three main activities that would make a person a researcher. The KUMC IRB classifies researchers as anyone who:
   - **a.** Consents a participant into a research project
   - **b.** Collects research data
   - **c.** Analyzes identifiable data

   If a person is helping with a study, but not conducting one or more of the activities listed above, they are not considered a researcher. They would not need to be listed on the KUMC IRB application. Non-research activities may include identifying subjects to be contacted, handing out surveys where all questions come to the KUMC research team, analyzing a de-identified dataset, and helping write journal articles or other publications.

2. **International Research Teams**
   While some research can be conducted in other countries, the KUMC IRB cannot extend its authority outside of the United States. In these instances, international rural care providers and other types of research collaborators working with the KUMC research team will need to meet any local ethical requirements that apply to that country.

3. **Human Subjects Training Requirements**
   - **a.** Rural researchers not affiliated with KUMC:
     A major responsibility of researchers working on a human subjects research study is training. Once the research team is identified, researchers are required to complete human subjects training. KUMC recognizes CIRT training provided by the University of Illinois-Chicago for individuals who are not associated with KUMC. Rural researchers should complete the Community Involvement in Research training. Once completed, the training report/certification should be saved and given to the PI/study coordinator to upload into the KUMC IRB submission system. To complete this training:
     - **i.** Go to the CIRT training site.
     - **ii.** Click “Register” (top righthand corner).
     - **iii.** Select “I am not from UIC.”

iv. Complete the registration form. When asked to select a site, select "University of Kansas Medical Center."
v. Click "Register" to finish.
vi. Email the completion certificate to the KUMC study team contact.

Other training options do exist; please contact the IRB reliance staff should CIRT training not work for your research situation.

Initial training and any refresher course expire in 3 years from the date they are completed.

b. Researchers affiliated with KUMC:
Anyone affiliated with KUMC will complete the Collaborative Institutional Training Initiative (CITI) Biomedical Researchers- Basic Course for general training. For projects that include pregnant women, children or prisoners, additional advanced training is needed. Please see the KUMC CITI training guidance.

4. Conflict of Interest (COI) Financial Disclosures
Conflict of Interest (COI) disclosures are needed from all research staff working on a KUMC research project. KUMC faculty and staff complete this via the COI system. Rural researchers need to complete a paper COI form. This document can be requested by contacting the COI office at coi@kumc.edu. Once the forms are complete, they should be given to the PI/study coordinator and documented in the study files to be uploaded into the KUMC IRB submission system.

COI disclosures should be completed each fiscal year.

5. HIPAA requirements for small clinics or covered entities
Healthcare providers are going to be considered a HIPAA covered entity and may have to meet some HIPAA requirements. These collaborators may need to make a HIPAA waiver determination or collect HIPAA authorization from their patients if patient data will be used for research or if their patients may be interacted/contacted with by KUMC research staff. Please reach out to KUMC IRB staff should the project engage healthcare providers outside of KUMC or the University of Kanas Health System.

6. If the collaborating site is not a clinic, there may be other rules and regulations that must be followed such as FERPA. Please contact the IRB when one of these sites may be used.