

TITLE:	Guidance for Completing Reliance Agreements
SUMMARY:	Provides answers to frequently asked questions about IRB Reliance with rural clinic collaborators.
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1. Can rural clinics/organization rely on KUMC’s IRB?

Yes. Please see the [applicable policy on PolicyStat](#).

2. What kind of arrangement do I need?

The KUMC study team, relying rural site study team, and IRB reliance team will meet to determine engagement and what kind of agreement is needed. There are 3 different types of agreements, based on engagement.

- a. A Memorandum of Understanding (MOU) is needed when an entire site or clinic is involved in the research with KUMC and that clinic does not have their own IRB.
- b. If the site has their own IRB, a reliance agreement will be executed.
- c. An Unaffiliated Investigator Agreement is needed when just one person from the clinic is working on the study and working on behalf of KUMC and not their home clinic or site.

3. What does engagement mean? How do I know if others are engaged in research?

The KUMC IRB uses the Office for Human Research Protections’ definition of “engagement.” In general, an institution is considered engaged in a human subjects research project when its employees or agents, for the purposes of the research project, obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. See also, the [Office of Human Research Protection Guidance on Engagement of Institutions](#).

4. What is an MOU?

A Memorandum of Understanding is a legal document that broadly outlines the agreement between the KUMC IRB and the relying rural site. IRB staff can provide examples MOUs when requested.

- a. A Collaborator Attestation will also need to be completed for each rural site study team member.
 - i. A Collaborator Attestation is a description and statement of the collaborator's role and contribution to the study.
- b. If any part of the MOU is changed by the relying rural site, it will need to be approved by KUMC’s legal department.
- c. The MOU will need to be signed by the relying rural site’s CEO, COO or other party that is delegated the authority to sign contracts on their behalf.

5. The site has their own IRB. Can they still rely on the KUMC IRB?

If a relying site has their own IRB:

- a. If the site is a member of SMART IRB, a SMART IRB reliance agreement will be executed.
 - i. SMART IRB is a collaboration designed to ease challenges associated with initiating multisite research. It allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across the nation, regardless of funding status. It is free to join. Learn more on the [SMART IRB website](#).
- b. If the site is not a member of SMART IRB, a study specific reliance agreement will be executed.

6. Just one person at the site is working on the research. Do we still need some sort of agreement?

If a collaborator is unaffiliated, meaning the person does not have an affiliation with an IRB and is working on behalf of KUMC, and the rest of their clinic is not engaged in research:

- a. An Unaffiliated Investigator agreement needs to be completed.
- b. Documentation of Human Subjects Research training needs to be submitted to the KUMC study team.
- c. A paper Conflict of Interest disclosure needs to be submitted to the KUMC study team.

7. Who do I contact to start this process?

Please email the reliance team at IRBreliance@kumc.edu to set up a meeting to discuss.