

Guidance: The Streamlined, Multisite, Accelerated Resources for Trials IRB Reliance platform (SMART IRB)

The Streamlined, Multisite, Accelerated Resources for Trials IRB Reliance platform (SMART IRB), is designed to streamline the IRB review process for multisite studies. SMART IRB is **not an IRB**, but a master reliance agreement in which institutions across the United States, including RFUMS, participate. The SMART IRB master reliance agreement replaces the need to have an individual Institutional Authorization Agreement (IAA).

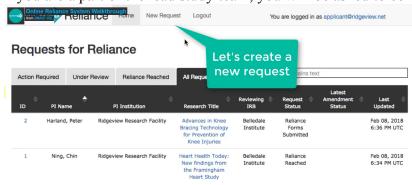
SMART IRB can be used to complete the reliance process for a study being conducted with another SMART IRB participating institution. Please review the list of <u>Participating Institutions</u> to see if your collaborator is a member of SMART IRB. Additional resources are available on the <u>SMART IRB Learning Center</u> webpage.

Guidance for PIs for using the SMART IRB for reliance agreements

The SMART IRB online reliance system allows research teams to submit an electronic request to execute reliance under the terms of the SMART IRB master reliance agreement. The request is typically initiated by the lead study team whose IRB will be serving as the IRB of Record for all sites. Each person requiring access to the online reliance system will need to submit a separate request for access to the system.

- To request access to the SMART IRB online reliance system, click <u>here</u>.
 - o If you've requested access and haven't received confirmation within a week please contact irb@rosalindfranklin.edu.
- Once you have access, sign in here.

If you are a part of the lead study team, you will be asked to complete a reliance request



Upon creating a new request, you will provide the following information in the online system:

- Basic information about the research (title of study and a brief description)
- Name of Principal Investigator
- List the engaged sites which are requesting to cede review to the IRB of Record

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- Identify activities and study team personnel at each site
- Upload the research protocol (e.g., RFUMS application) and consent form templates

<u>IMPORTANT.</u> Once you submit that information to the SMART IRB system, email <u>irb@rosalindfranklin.edu</u> with the name of your study to initiate the reliance review process at RFUMS.

Once the PI completes the SMART IRB submission, the RFUMS IRB will review your request for RFUMS to serve as the reviewing IRB and make a determination about whether it is appropriate.

- If RFUMS agrees to serve as the reviewing IRB, the relying institutions will then need to agree to cede review RFUMS.
- If they agree, then RFUMS will serve as the reviewing IRB for those sites and all IRB documentation will need to be submitted to RFUMS for review.
- If they do not agree, they may request to serve as the relying IRB, and RFUMS may decide to cede review to their IRB, or continue to serve as the reviewing IRB for the RFUMS PI, and any other sites that agreed to cede IRB review to RFUMS.

Once the reliance review is complete, the RFUMS IRB will inform you of the outcome.

If RFUMS will be the reviewing IRB, you will then submit your full application and all relevant information (e.g., consent form, recruitment advertisements, appendices, study forms, documentation from the IRB of the approved reliance agreement...) to irb@rosalindfranklin.edu. Some relying IRBs may request site specific information, or consent form modifications. All of these documents should be submitted to the RFUMS IRB.

If RFUMS agrees to cede IRB to a different institution, you will work with the PI from that institution to secure IRB approval. See our guidance document on the <u>RFUMS IRB website</u> when RFUMS serves as the relying institution for more information.

Version: 01-21-22