Guideline and Flow Charts When University of Rochester is the Reviewing IRB

The University of Rochester (UR) may review human subject research that requires expedited or convened board review for another institution’s IRB when the research involves more than one site, or when the study received federal funding, as per OHSP Policy 504 RSRB Reliance for Review. When this occurs, UR becomes the Reviewing IRB.

When the UR is the Reviewing IRB, the UR Investigator has specific responsibilities as outlined in Policy 901 Investigator Responsibilities.

The UR PI should follow the steps outlined on the UR Reviewing IRB Flow Chart, which includes completing the eReliance Request form (see Appendix 1). The process for RSRB review will vary depending on whether this is a new study or an existing study (see Appendix 2 entitled “Click IRB Submission Process When the RSRB is the Reviewing IRB”).

After the protocol materials and model consent documents are approved by the RSRB, the UR PI will distribute these materials to the non-UR sites. Documentation of institutional review and site-specific consent forms, as applicable, will need to be obtained from each non-UR site. Once site materials are submitted and Reliance is determined the participating sites will be added to the IRB Review System.
Request for The RSRB to be the Reviewing IRB - Appendix 1

1. UR PI fills out and submits the eReliance Request form.

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2. Funding Proposal Submission Request for the UR to act as the Reviewing IRB for a multi-site research study.

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3. UR PI attends budget meeting with OHSP Staff to create budget. OHSP provides letter of support for grant.

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4. UR to act as the Reviewing IRB Funding received or an unfunded project. Request includes the multi-site study management list of participating sites.

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5. Reliance Specialist confirms a study-specific budget has been created or requests UR PI attend budget meeting with OHSP Staff to create budget.

6. UR PI submits study in Click IRB for RSRB review (See Appendix 2)
Click IRB Submission Process When the RSRB is the Reviewing IRB
Appendix 2

RSRB confirms UR will serve as the Reviewing IRB. UR PI completes Click IRB submission.

New Study

UR PI submits initial application in Click IRB. Question #6 should be answered “yes.” Application should include protocol, measures, and model consent form(s), as applicable. PI must include a plan for PI oversight of non-UR sites.

Existing Study

UR PI submits a modification in Click IRB to indicate that the RSRB will be the reviewing IRB for the multi-site study. In the basic information section, question #6 must be answered “yes.” PI must include a plan for PI oversight of non-UR sites and creates model consent form(s), as applicable.

RSRB reviews the protocol documents and model consent form(s). Edits are requested as needed.

RSRB approves protocol documents and model consent form(s). Reliance coordinator creates pSites in Click IRB.

UR PI sends approved materials to sites with a request to complete a non-UR institutional review memo, local context survey, and to create site-specific model consent form(s) based on the approved models (as applicable).

Site Materials are submitted to the site in Click IRB:
1. Signed Reliance Agreement or SMART IRB determination letter.
2. Completed Non-UR site institutional review memo.
3. Site specific consent form(s) and other site specific materials.

UR PI receives an approval letter when review is complete and distributes approved materials to non-UR sites.
Request for The RSRB to be the Reviewing IRB - Appendix 3

Does the Relying Institution participate in SMART IRB?

YES

UR PI requests SMART IRB access at smartirb.org and submits study for reliance determination. The UR institutional profile is provided to the Relying IRB.

Reliance is determined and the UR PI receives determination letter designating UR as the Reviewing IRB.

NO

Reliance Specialist works with the site’s IRB to execute a Reliance agreement. The UR institutional profile is provided to the Relying IRB.

Reliance is determined when the Reliance Agreement is executed. UR PI receives a PDF of the signed agreement.