POLICY

1. Purpose
Establish the requirements when University of Rochester (UR) researchers collaborate with an unaffiliated institution(s) or Investigator(s) to ensure UR ethical, regulatory and institutional requirements for the protection of human subjects are met. Reliance can pertain to either:
- the unaffiliated institution(s) or Investigator(s) deferring Institutional Review Board (IRB) review to the UR Research Subjects Review Board (RSRB);
- the RSRB deferring to another IRB.

2. Scope
This policy applies when a UR employee or agent conducting human subject research requests that the UR become the Reviewing IRB for an unaffiliated institution or investigator, or when the RSRB defers to another IRB.

3. Definitions
3.1. Reliance or IRB Authorization Agreement – A formal, written document that provides a mechanism for an institution engaged in research to delegate IRB review to another IRB, such as an independent IRB or another institution’s IRB. The agreement may apply to a single study or to certain categories of studies. Institutions may use different descriptive terms, e.g., reliance agreement, cooperative agreement, IRB authorization agreement (IAA), or memorandum of understanding (MOU).

3.2. Relying IRB – The IRB that delegates the responsibility of IRB review and approval to another IRB.

3.3. Reviewing IRB – The IRB designated to review and approve human subject research.

3.4. Unaffiliated Institution – An entity or organization that is external to the University of Rochester (e.g., another academic institution, another medical center or hospital, advocacy group).

3.5. Unaffiliated Investigator – A researcher who is not an employee or agent of the University of Rochester (e.g., private practice practitioner, faculty or staff at another academic institution or medical center).

4. References
4.1. HHS 45 CFR 46.103(e) and 46.115(a)(9); OHRP Step-by-Step Instructions for Filing a Federalwide Assurance; OHRP Guidance on Extending an FWA to Cover Collaborating Investigators
4.2. Policy 201 Education Program; Policy 901 Investigator Responsibilities; Guideline and Flow Charts When UR is the Reviewing IRB; Guideline and Flow Chart When UR Relies on Non-UR IRB

5. Responsibilities

5.1. The OHSP Director, with consultation from the RSRB Director, is responsible (as delegated by the Institutional Official) for deciding when the UR will become the Reviewing IRB for an unaffiliated institution or investigator, or when the UR will defer to another IRB. These determinations are reviewed on a regular basis with the Institutional Official.

5.2. The UR Investigator is responsible for contacting the RSRB Director, or delegate, to request that the UR become the Reviewing IRB for an unaffiliated institution or investigator, or that the UR defer to another IRB.

5.3. The Reviewing IRB is responsible for the review and approval of research (including initial and continuing review, and review of amendments) according to the authority granted under applicable federal regulations, state laws, and the policies and procedures of the Reviewing IRB. Additional responsibilities include, but are not limited to, the following:

5.3.1. Indicating the contact person and providing contact information for the Reviewing IRB.

5.3.2. Consideration of local context in the initial and continuing review of the research.

5.3.3. Notifying the unaffiliated institution in writing of review determinations upon request.

5.3.4. Making available relevant IRB minutes to the Relying IRB upon request.

5.3.5. Responsibilities and reporting requirements as outlined in the executed Reliance Agreement.

5.4. The Relying IRB is responsible for conducting an Institutional review to ensure compliance with Institutional policies and procedures, and for the responsibilities and reporting requirements as outlined in the executed Reliance Agreement.

6. Requirements When the RSRB is the Reviewing IRB

6.1. The OHSP Director and the RSRB Director will determine the requirements for when an unaffiliated institution is required to obtain a Federalwide Assurance (FWA).

6.1.1. If the research is federally funded, the unaffiliated institution must obtain an FWA from the Office for Human Research Protections (refer to OHSP Step-by-Step Instructions for Filing an FWA - Item #6).
6.1.2. In very rare instances, if a UR Investigator is collaborating with an unaffiliated Investigator without an FWA in a federally funded study, the UR may allow this unaffiliated Investigator to be added to the UR FWA through an Individual Investigator Agreement (refer to the OHSP Guidance for Extending an FWA to Cover Collaborating Investigators). In this instance, the UR Investigator must provide a plan for oversight of this collaborating site. This plan will outline the specific research activities that will occur at the collaborating site and the UR Investigator’s plan to ensure study and regulatory compliance, including notification to the unaffiliated researcher in writing of the RSRB review determinations. This plan will be uploaded as an amendment to an already approved protocol, or will be included with the initial protocol submission. OHSP may institute additional management strategies to oversee the conduct of this study.

6.1.3. If the research is not federally funded, the RSRB will request written documentation (letter of support) of administrative approval from the unaffiliated institution’s signatory official.

6.2. The UR Investigator who is collaborating with the unaffiliated institution(s) must provide a plan for oversight of this collaborating site(s). This plan will outline the specific research activities that will occur at the collaborating site(s) and the UR Investigator’s plan to ensure study and regulatory compliance, including notification to the unaffiliated researcher in writing of the RSRB review determinations. This plan will be uploaded as an amendment to an already approved protocol, or will be included with the initial protocol submission. Refer to the Guideline and Flow Charts when the University of Rochester is the Reviewing IRB.

6.2.1. The UR Investigator is responsible for following Policy 901 Investigator Responsibilities.

6.3. The UR will enter into an IRB Authorization or Reliance Agreement with the unaffiliated institution to defer IRB review to the RSRB.

6.4. The unaffiliated institution should conduct an institutional review of the research prior to approval of the study by the RSRB to provide any local context to the RSRB, as appropriate.

6.5. The RSRB will require the unaffiliated researchers to fulfill human subject training requirements, as described in Policy 201 Education Program.

7. Requirements When the RSRB is the Relying IRB

7.1. The UR will enter into a Reliance Agreement with the Reviewing IRB institution, if deemed appropriate, to defer IRB review to that institution. The Reliance Agreement must address the following:
7.1.1. The University of Rochester does not disclose individual or institutional conflict of interest management plans outside the institution, but will provide an outline of the management strategies implemented to mitigate the situation.

7.1.2. The UR will work with the Reviewing IRB to agree on the terms for reporting requirements related to reporting to sponsors/funding agencies, OHRP, FDA, and/or other oversight authorities for reports of unanticipated problems involving risks to subjects or others, serious or continuing non-compliance, and suspensions or terminations of IRB approval. The specific strategies to comply with this requirement will be outlined in the Reliance Agreement.

7.2. The RSRB will conduct an institutional review to ensure compliance with institutional policies, such as, scientific review, ancillary committee approval, human subject training requirements, compensation for injury, and conflict of interest.

7.3. If the Reviewing IRB is not accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), the RSRB will assess whether deferral is appropriate based on the type of research and level of risk involved in the research. If deemed acceptable to defer to another IRB, the RSRB may require additional activities to ensure an adequate IRB review is conducted (e.g., review of policies or relevant IRB minutes from the Reviewing IRB).
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<tr>
<th>University of Rochester</th>
<th>Office for Human Subject Protection</th>
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<tr>
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<td>Research Subjects Review Board</td>
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<td>Effective Date: 01/29/2018</td>
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<td>IRB Reliance and Collaborative Research</td>
<td>Policy 504</td>
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**Appendices:**
None

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12/2017: Sect 4 - Added references and hyperlinks; modifications throughout to reflect current practice and 2018 Common Rule changes; remove agreement templates from appendices
01/2018: Sect 5.3.5 remove reference to limited IRB review

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**Approved By:**

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