

University of Rochester	Office for Human Subject Protection		
	Research Subjects Review Board		Effective Date: 12/01/2024
	IRB Reliance and Collaborative Research		Policy 504
			Version: 3.2

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);
- or,*
- the RSRB deferring to another IRB (institutional IRB or independent IRB).

2. Scope

This policy applies when a UR employee or agent conducting expedited or convened board review 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.

- As confirmation of not human subject research and exemption are institutional responsibilities, not IRB responsibilities, this policy is not applicable to this type of research.

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, and document respective authorities, roles, responsibilities, and communication between the Reviewing IRBs and Relying Institutions. 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 Institution* – The Institution 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 as per 45 CFR 46.111 and in accordance with the Reliance Agreement. This can either be another institutional IRB or an independent IRB.
- 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).

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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(b), 45 CFR 46.103(d), 45 CFR 46.103(e) 45 CFR 46.109(d), 45 CFR 46.114; DoD DoDI 3216.02 3.5; and FDA 21 CFR 56.109(e), 21 CFR 56.114
[OHRP Step-by-Step Instructions for Filing a Federalwide Assurance](#);
[OHRP Guidance on Extending an FWA to Cover Collaborating Investigators](#)
- 4.2. [Policy 104 Institutional Conflict of Interest](#);
[Policy 201 Education Program](#);
[Policy 301 RSRB Scope and Authority](#)
[Policy 302 RSRB Membership and Composition](#)
[Policy 303 Board Member Conflict of Interest](#)
[Policy 501 Levels of RSRB Review](#)
[Policy 503 Ancillary Committee Reviews](#);
[Policy 505 Departmental Scientific and Resource Review](#);
[Policy 801 Reporting Research Events](#)
[Policy 901 Investigator Responsibilities](#);
[Policy 902 Investigator Financial Conflict of Interest](#);
[Guideline for Human Genomic Data Sharing](#);
[Guideline and Flow Charts When UR is the Reviewing IRB](#);
[Guideline and Flow Chart When UR Relies on Non-UR IRB](#);
[Guideline for Principal Investigator Oversight for Multi-Site Research \(RSRB is the Reviewing IRB\)](#)
[University of Rochester IRB Reliance Request Form](#)

5. Responsibilities

- 5.1. The OHSP 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. The OHSP Director may consult with the RSRB Director, as appropriate. These determinations are reviewed on a regular basis with the Institutional Official.
- 5.2. The UR Investigator is responsible for submitting a request through the *University of Rochester IRB Reliance Request Form* for the UR to become the Reviewing IRB for an unaffiliated institution or investigator, or for the UR to defer to another IRB.
 - 5.2.1. When the UR has a master reliance agreement in place with an independent IRB, this request is not required.

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- 5.3. The Reviewing IRB is responsible for the review and approval of research (including initial and continuing review, and review of modifications) 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:
- 5.3.1. Indicating the contact person and providing contact information for the Reviewing IRB.
 - 5.3.2. Providing Reviewing IRB policies and procedures, and updates as appropriate.
 - 5.3.3. Consideration of local context in the initial and continuing review of the research.
 - 5.3.4. Notifying the unaffiliated institution in writing of review determinations upon request.
 - 5.3.5. Making available relevant IRB minutes to the Relying Institution upon request.
 - 5.3.6. Requesting an audit of the research being reviewed.
 - 5.3.7. Conducting monitoring of research activities, in addition to or in collaboration with the Relying Institution, as appropriate.
 - 5.3.8. Reviewing potential non-compliance to determine whether there is a basis in fact, and to determine if incidents meet the definition of serious or continuing, consistent with policy and procedures.
 - 5.3.9. Reviewing potential unanticipated problems to determine whether there is a basis in fact, and to determine if incidents involve an increased risk to subject or others, consistent with policy and procedures.
 - 5.3.10. Responsibilities and reporting requirements as outlined in the executed Reliance Agreement [HHS 45 CFR 46.103(e)].
- 5.4. The Relying Institution 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 [HHS 45 CFR 46.103(e)].

6. Requirements When the RSRB is the Reviewing IRB

Refer to the *Guideline and Flow Charts when the University of Rochester 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 have or obtain an FWA from the Office for Human Research Protections (refer to *OHRP Step-by-Step Instructions for Filing an FWA*).
 - 6.1.1.1. In very rare instances, if an 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 *OHRP Guidance for Extending an FWA to Cover Collaborating Investigators*). OHSP will

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institute additional management strategies to oversee the conduct of this study. See the *Guideline for Principal Investigator Oversight for Multi-Site Research (RSRB is the Reviewing IRB)*.

- 6.1.2. 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 the collaborating site(s). This plan, at a minimum, 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. See the *Guideline for Principal Investigator Oversight for Multi-Site Research (RSRB is the Reviewing IRB)* for additional information.
 - 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 conduct the review and approval of research and:
 - 6.5.1. Ensure the board is properly constituted consistent with *Policy 302 RSRB Membership and Composition* and Board Member conflicts are disclosed consistent with *Policy 303 Board Member Conflicts of Interest*.
 - 6.5.2. Suspend or Terminate approval consistent with *Policy 301 RSRB Scope and Authority*.
 - 6.5.3. Review research events consistent with *Policy 801 Reporting Research Events*
 - 6.5.4. Conduct the review of Participating sites to previously approved research consistent with *Policy 501 Levels of Review*.
 - 6.5.5. Review Participating sites conflict of interest management plans, as applicable, consistent with *Policy 104 Institutional Conflict of Interest* and *Policy 902 Investigator Conflict of Interest*.

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

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7. Requirements When the RSRB is the Relying Institution

Refer to the *Guideline and Flow Chart When University of Rochester Relies on a Non-UR 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 will provide individual or institutional conflict of interest management plans to the Reviewing IRB.

7.1.2. The UR will work with the Reviewing IRB to agree on the terms for reporting requirements related to obtaining any additional approvals from DHHS when the research involves pregnant women/fetuses/neonates, children, or prisoner.

7.1.3. 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.

7.1.4. The UR will provide the Reviewing IRB with the University of Rochester Institutional Profile at the time of initial reliance and with major updates to related policies. The Institutional Profile provides:

7.1.4.1. Descriptions of UR HRPP and community composition;

7.1.4.2. Descriptions and hyperlinks to applicable policies, laws; and

7.1.4.3. UR HRPP Contact Information

7.2. The RSRB will assess whether deferral to a Reviewing IRB that is not accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) is appropriate based on the type of research and level of risk involved in the research.

7.2.1. If deemed acceptable to defer to another non-AAHRPP accredited IRB, the RSRB may require additional activities to ensure an adequate IRB review is conducted.

7.2.2. The process and criteria for ensuring the research will be reviewed appropriately and in compliance with ethical standards and applicable law and regulations by the non-AAHRPP accredited IRB will be addressed in the Reliance Agreement.

7.3. The RSRB will conduct an institutional review to ensure compliance with institutional policies, such as, scientific review as described in [Policy 505 Departmental Scientific and Resource Review](#), ancillary committee approval as described in [Policy 503 Ancillary Committee Reviews](#), human subject training requirements as described in [Policy 201 Education Program](#), compensation for injury, and conflict of interest as described in [Policy 902 Investigator Financial Conflict of Interest](#) and [Policy 104 Institutional Conflict of Interest](#).

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- 7.4. The RSRB, nor any institutional officials, will not approve research under a reliance agreement that has not been approved by the Reviewing IRB.
- 7.5. Investigators and research staff, as applicable, must follow the requirements outlined below when the RSRB is the Relying Institution, in addition to the responsibilities outlined in *Policy 901 Investigator Responsibilities*:
- 7.5.1. Adhere to the Reviewing IRB's policies and procedures regarding initial and continuing review, record retention, and reporting, as well as providing information requested by the Reviewing IRB in a timely manner.
- 7.5.2. Identify and disclose financial interests according to *Policy 902 Investigator Financial Conflict of Interest*.
- 7.5.3. Promptly report any proposed changes to the approved research to the Reviewing IRB and ensure changes are not implemented prior to IRB approval, except where necessary to eliminate immediate hazards to subjects.
- 7.5.4. Ensure that no subjects are enrolled in research prior to review and approval by the Reviewing IRB and having met any other applicable requirements or approvals for the study.
- 7.5.5. Obtain, document, and maintain records of consent for each subject, or each subject's legally authorized representative, as applicable to the approved research.
- 7.5.6. Report research events in accordance with policies of the Reviewing IRB, including but not limited to unanticipated problems involving risks to subjects or others, non-compliance, subject complaints, and protocol deviations.
- 7.5.7. Provide data safety monitoring reports, or other study related reports or updates, in accordance with the policies of the Reviewing IRB.
- 7.5.8. Reporting requirements to the RSRB as the Relying Institution:
- 7.5.8.1. Submit modifications that may affect the institutional review conducted initially, e.g., study team member changes, additional ancillary committee reviews, changes to any financial interests or compensation for injury.
- 7.5.8.2. After the Reviewing IRB has reapproved the study at continuing review, submit a modification with the new approval letter and approved consent documents.
- 7.5.8.3. Submit Reports of New Information for any event that results in the Reviewing IRB making a determination of Serious Non-Compliance, Continuing Non-Compliance, an Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) or Suspending or Terminating the research.
- 7.5.8.3.1. There may be special circumstances when the RSRB requires reporting of Reports of New Information, in those instances this will be communicated to the Principal Investigator.

8. Requirements When Following the NIH Single IRB Policy

- 8.1. When a University of Rochester researcher participates in multi-site studies involving human subjects that require expedited or convened board review and are funded by the

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National Institutes of Health (NIH), a single Institutional Review Board (sIRB) will be used to conduct IRB review and approval according to the Department of Health and Human Services regulations for the Protection of Human Subjects [HHS 45 CFR 46].

8.1.1. This requirement applies to research awardees in the United States, as well as participating sites in the United States. It does not apply to organizations outside the United States.

8.2. The awardee organization(s) will ensure that reliance agreements are in place and documentation maintained.

8.3. The Reliance agreement will document responsibilities pertaining to additional requirements of the NIH Genomic Data Sharing Policy and according to the RSRB [*Guideline for Human Genomic Data Sharing*](#), as applicable.

8.4. Participating sites will rely on the sIRB for review and approval of the research, in addition to applicable institutional reviews that might be required by the relying sites.

8.5. Participating sites may conduct their own review should any exceptions from the sIRB review NIH policy apply.

9. Requirements For Federally Funded Cooperative Research Consistent with 45CFR46.114 Cooperative Research

9.1. When a University of Rochester researcher participates in multi-site studies involving human subjects that require expedited or convened board review and are funded by a Federal Department or Agency, a single Institutional Review Board (sIRB) will be used to conduct IRB review and approval according to the Department of Health and Human Services regulations for the Protection of Human Subjects [HHS 45 CFR 46].

9.1.1. This requirement applies to research in the United States, as well as participating sites in the United States. It does not apply to organizations outside the United States.

9.1.2. This requirement does not apply to cooperative research when IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); and

9.1.3. This requirement does not apply when the Federal Department or Agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate.

9.2. Participating sites will rely on the sIRB for review and approval of the research, in addition to applicable institutional reviews that might be required by the relying sites.

9.3. The RSRB will apply 45CFR46.114 only to federally funded research approved on or after January 20, 2020.

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10. Requirements for research conducted or supported by the Department of Defense (DoD)
- 10.1. When a University of Rochester researcher participates in multi-site studies involving human subjects that require expedited or convened board review and are conducted or supported by the Department of Defense, a single Institutional Review Board (sIRB) will be used to conduct IRB review and approval according to the Department of Health and Human Services regulations for the Protection of Human Subjects [HHS 45 CFR 46] and the Department of Defense regulations [DODI 3216.02].
- 10.1.1. This requirement applies to research in the United States, as well as participating sites in the United States. It does not apply to organizations outside the United States.
- 10.2. The awardee organization(s) will ensure that reliance agreements are in place and documentation maintained.
- 10.3. The Reliance agreement will document responsibilities pertaining to the DoD organization and non-DoD reviewing IRBs.
- 10.4. Participating sites will rely on the sIRB for review and approval of the research, in addition to applicable institutional reviews that might be required by the relying sites.

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Appendices:

None

Revision History:

- 12/2017: Section 4 - Added references and hyperlinks; modifications throughout to reflect current practice and 2018 Common Rule changes; remove agreement templates from appendices
- 01/2018: Section 5.3.5 remove reference to limited IRB review
- 11/2019: Entire policy updated per AAHRPP standard I-9: Update scope and sections 3.1, 5.3, 6.1.2, 6.2 corrections to reflect current process in new IRB Review system; added Section 8 regarding NIH sIRB; Section 9 regarding Common Rule Cooperative Research; Update signatories
- 05/2022: Add Guideline for PI Oversight and eReliance Request Form; Clarify when modifications and Reports of New Information must be submitted to RSRB as the Relying Institution; Change “Relying IRB” to “Relying Institution”; Administrative Changes; Update Signatories
- 12/2024: Revised Section 4.1; added Section 10; updated Signatories

Supersedes Date:

9/14/2022

Approved By:


Signed by: 


 Signer Name: Stephen Dewhurst
Signing Reason: I approve this document
Signing Time: 12/10/2024 | 6:35:18 PM EST
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12/10/2024 | 6:35:21 PM EST

Stephen Dewhurst
Institutional Official, Vice President for Research

Date

Signed by: 

 Signer Name: Elizabeth Kipp Campbell
Signing Reason: I approve this document
Signing Time: 12/9/2024 | 12:50:46 PM EST
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12/9/2024 | 12:50:51 PM EST

Elizabeth Kipp Campbell
Associate Vice President for Human Subject Protections

Date