POLICY

1. Purpose
   Establish the requirements for utilizing reliance models when University of Rochester (UR) researchers collaborate with an unaffiliated institution(s) or Investigator(s), and the unaffiliated institution(s) or Investigator(s) defers Institutional Review Board (IRB) review to the UR Research Subjects Review Board (RSRB) or the RSRB defers to another IRB to ensure that the UR ethical, regulatory and institutional requirements for the protection of human subjects are met.

2. Scope
   This policy applies when a UR employee or agent conducting human subject research requests that the UR become the Reviewing IRB (IRB of record) 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 Institutional Review Board (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).
     - The IRB Authorization Agreement is used for studies with minimal subject engagement or studies with limited data access or data analysis.
     - The Reliance Agreement is used for research where the study conduct will take place at the unaffiliated institution or by the unaffiliated investigator.

   3.2. Relying IRB – The Institutional Review Board (IRB) that delegates the responsibility of IRB review and approval to another IRB.

   3.3. Reviewing IRB (IRB of Record) – The Institutional Review Board (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. OHRP Step-by-Step Instructions for Filing a Federalwide Assurance - Item #6-


5. Responsibilities

5.1. The UR Institutional Official (IO), with consultation from the OHSP Director and RSRB Director, is responsible for deciding when the UR will become the Reviewing IRB (IRB of Record) for an unaffiliated institution or investigator, or when the UR will defer to another IRB.

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

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. Notifying the unaffiliated institution in writing of review determinations upon request.
5.3.3. Making available relevant IRB minutes to the Relying IRB upon request.
5.3.4. Conducting monitoring or auditing activities, as appropriate.

5.4. The Relying IRB is responsible for ensuring compliance with Institutional policies and procedures, and for the responsibilities and reporting requirements as outlined in the IRB Authorization (Appendix 1) or Reliance Agreement (Appendix 2).

6. Requirements When Each IRB Conducts the Review

6.1. The RSRB conducts a regulatory and institutional review per operating procedures for the activities of the UR researcher.
6.2. The Unaffiliated Institution’s IRB conducts a regulatory review per operating procedures for the activities of the collaborating researcher.

7. **Requirements When the RSRB is the Reviewing IRB**

7.1. When an unaffiliated institution with an established Federalwide Assurance (FWA) would like to defer IRB review to the RSRB, the following must occur:

7.1.1. The UR Investigator who is collaborating with the faculty member at 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.

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

7.1.3. 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.

7.1.4. The RSRB will require the unaffiliated researchers to fulfill their institution’s human subject training requirement, or if one does not exist, they will be required to fulfill the UR training requirements.

7.2. When an unaffiliated institution without an established FWA would like to defer IRB review to the RSRB, the following must occur:

7.2.1. If the research is federally funded, the unaffiliated institution should obtain an FWA from the Office for Human Research Protections.

7.2.2. 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.

7.2.3. The UR Investigator who is collaborating with the faculty member at 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.

7.2.4. The UR will enter into an IRB Authorization or Reliance Agreement with the unaffiliated institution to defer IRB review to the RSRB.
7.2.5. 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.

7.2.6. The RSRB will require the unaffiliated researchers to fulfill their institution’s human subject training requirement, or if one does not exist, they will be required to fulfill the UR training requirements.

7.3. 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. 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.

7.3.1. OHSP may institute additional management strategies to oversee the conduct of this study.

7.3.2. The RSRB will require the unaffiliated researchers to fulfill the UR human subject training requirements.

8. Requirements When the RSRB is the Relying IRB

8.1. The UR will enter into an IRB Authorization or Reliance Agreement with the Reviewing IRB institution, if deemed appropriate, to defer IRB review to that institution. The IRB Authorization or Reliance Agreement must address the following:

8.1.1. 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.

8.1.2. The University of Rochester will retain all required 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 UR will work with the Reviewing IRB to agree on the terms of the report; however, the primary report will be from the University of Rochester. The specific strategies to comply with this requirement will be outlined in the IRB Authorization or Reliance Agreement.

8.2. The RSRB will conduct an institutional review to ensure compliance with institutional policies, such as, human subject training requirements, compensation for injury, and conflict of interest.
8.3. 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).
### Originator/Authors:
Kelley O'Donoghue, Director OHSP
Emily Flagg, Senior Regulatory Specialist

### Appendices:
- Appendix 2: Reliance Agreement Sample Template

### Revision History:
None

### Supersedes Date:
Not Applicable

### Approved By:

<table>
<thead>
<tr>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robert Clark</td>
<td>11/4/14</td>
</tr>
<tr>
<td>Kelley A. O'Donoghue</td>
<td>11/3/2014</td>
</tr>
<tr>
<td>Tiffany L. Gomme</td>
<td>11/3/2014</td>
</tr>
</tbody>
</table>

Robert Clark
Institutional Official and Senior VP for Research

Kelley A. O'Donoghue
Director, OHSP

Tiffany L. Gommel
Director, RSRB

---

Paper copies of the Policy may not be the current version. The current version of this Policy is maintained and available on the OHSP shared network.

Name of Institution Providing IRB Review: UNIVERSITY OF ROCHESTER (Institution A)
Federalwide Assurance #: FWA00009386

INSERT AS APPROPRIATE

IRB Registration #: Board 01 - IRB00000462 and Board 01P - IRB00001226
Board 02 - IRB00000463 and Board 02P - IRB00000464
Board 03 - IRB00000465 and Board 03P - IRB00000466
Board 04 - IRB00000467 and Board 04P - IRB00001227
Board 05 - IRB00007740 and Board 05P - IRB00007741

Name of Institution Relying on the Designated IRB: insert name of Institution B (Institution B)
Federalwide Assurance #: insert FWA of Institution B

The Officials signing below agree that (insert name of Institution B) may rely on the designated IRB for review and continuing oversight of its human subjects research described below: (check one)

(___ ) This agreement applies to all human subject research covered by Institution B’s FWA

(___ ) This agreement is limited to the following specific protocol(s):
Name of Research Project:
Name of Principal Investigator:
Sponsor or Funding Agency: _____________ Award Number, if any: ___________________

(___ ) Other (describe): ______________________________________________________

The review performed by the designated IRB will meet the human subject protection requirements of Institution B’s OHRP-approved FWA. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B within [INSERT A TIMEFRAME AS APPROPRIATE]. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB’s determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Institution A): __________________________   Date: ____________
Print Full Name:  _Robert Clark, PhD_ Institutional Title:  _Sr. VP for Research and Institutional Official_

Signature of Signatory Official (Institution B): __________________________   Date: ____________
Print Full Name: _____________________________ Institutional Title: _______________________

Paper copies of the Policy may not be the current version. The current version of this Policy is maintained and available on the OHSP shared network.
Appendix 2
Reliance Agreement Sample Template

Office for Human Subject Protection

Reliance Agreement

Name of Institution Providing IRB Review: UNIVERSITY OF ROCHESTER (Institution A)
Federalwide Assurance #: FWA00009386

Name of Institution Relying on the Designated IRB: insert name of Institution B (Institution B)
Federalwide Assurance #: insert FWA of Institution B

The Officials signing below agree that (insert name of Institution B) may rely on the designated IRB for review and continuing oversight of its human subjects research described below: (check one)

(____) This agreement applies to all human subject research covered by Institution B’s FWA

(____) This agreement is limited to the following specific protocol(s):
Name of Research Project:
Name of Principal Investigator:
Sponsor or Funding Agency: _____________ Award Number, if any: ___________________

(____) Other (describe): __________________________________________

The review performed by the designated IRB will meet the human subject protection requirements of Institution B’s OHRP-approved FWA. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B within this Reliance Agreement. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB’s determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Institution A): __________________________ Date: ______________
Print Full Name: Robert Clark, PhD Institutional Title: Sr. VP for Research and Institutional Official

Signature of Signatory Official (Institution B): __________________________ Date: ______________
Print Full Name: ___________________________ Institutional Title: _____________________

Paper copies of the Policy may not be the current version. The current version of this Policy is maintained and available on the OHSP shared network.
1) PURPOSE & SCOPE
This Reliance Agreement sets forth the responsibilities of the University of Rochester (UR) and insert name of Institution B concerning the utilization of UR’s Institutional Review Boards for initial review and continuing oversight of its human subject research, as described above.

2) BACKGROUND:
UR and Institution B maintain separate, active Federalwide Assurances (FWA) from the Office for Human Research Protections (OHRP) under the U.S. Department of Health and Human Services (HHS). Both institutions use OHRP’s current policy guidance on defining when an institution is engaged in research covered by the Common Rule and each institution’s assurance. The review and continuing oversight performed by the designated UR IRBs will meet the human subject protection requirements of Institution B’s OHRP-approved FWA.

3) RIGHTS, DUTIES, AND RESPONSIBILITIES OF THE UR IRB:
a) The UR IRB will perform all of the functions required under 45 CFR Part 46, 21 CFR Parts 50, 56, and 312 and 812 (where applicable), 45 CFR Parts 46.160 & 164 HIPAA Privacy Rule (where applicable), and the human subjects protection requirements of Institution B’s OHRP-approved FWA for the review and continuing oversight of human subjects research conducted under the auspices of the research outlined in this Reliance Agreement.
b) In concert with Institution B, the UR IRB will consider conflicts of interest and confirm, where appropriate, that the application or proposal for human subject research submitted to the federal Department of Health and Human Services (HHS) matches the protocol submitted for IRB approval.
c) The UR IRB will have the authority to suspend or terminate the research for failure to comply with conditions of approval or regulatory requirements.
d) The UR IRB will review all unanticipated problems involving risks to subject or others, and incidents of serious or continuing non-compliance related to the research noted above.
e) The UR IRB will notify Institution B in writing of any unanticipated problems involving risks to subject or others, serious or continuing non-compliance, and terminations or suspensions of research within [INSERT AS TIMEFRAME AS APPROPRIATE].
f) The UR IRB, or its authorized representatives, including the FDA and HHS to the extent permitted by law, will be permitted to conduct on-site or remote post approval monitoring, including but not limited to the following:
   i. Examine and inspect the local Institution’s facilities used for the performance of the research, including storage and use of any investigational products.
   ii. Observe the conduct of the research.
   iii. Inspect and copy all documents relating to the research, including research records, patient medical records, informed consent documents, Investigational Product logs, and other research specific data.
   iv. Interview, as necessary, all necessary personnel involved in the research or patient care-related to the research.
g) The UR IRB shall maintain all documents reviewed in connection with the human subject research outlined on the attached IRB Authorization Agreement, including any relevant communication with investigators.
h) The UR IRB will make its records for research approved under this agreement available upon written request to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request.

4) RIGHTS, DUTIES, AND RESPONSIBILITIES OF THE INSTITUTION RELYING ON THE UR IRB (INSTITUTION B):
a) Institution B is ultimately responsible and bears full responsibility for all research covered under its Federalwide Assurance. Institution B is responsible for ensuring compliance with the terms of its OHRP approved Federalwide Assurance.
b) Institution B is responsible for maintaining a Human Research Protection Program (HRPP) to include a formal process to monitor, evaluate, and continually improve the protection of human research subjects; educating investigators and research staff about their ethical responsibility to protect research subjects; and, when appropriate, providing a mechanism to intervene in research and to respond directly to concerns of research subjects. The HRPP will also monitor compliance with the determinations and requirements of UR IRB’s approval, including the OHSP Policy 901 Investigator Responsibilities, when appropriate.

c) Institution B assures and warrants that all investigators participating in research above are and will remain members of the Institution’s staff in good standing and are credentialed and privileged to perform the procedures outlined in the research.

d) Institution B will notify, within [INSERT A TIMEFRAME AS APPROPRIATE], the UR IRB Director of the termination, suspension, or modification of any clinical privileges of members of its Staff who are participating in the research authorized by the UR IRB.

e) Institution B will notify, within [INSERT A TIMEFRAME AS APPROPRIATE], the UR IRB Director of the any:
   1) unanticipated problems involving risks to subjects or others; or
   2) any serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB(s).

f) Institution B will inform the UR IRB of any contact by the FDA, HHS, or any other persons or entities regarding any of the research specified above within [INSERT A TIMEFRAME AS APPROPRIATE] of contact. Institution B will also notify the UR IRB within [INSERT A TIMEFRAME AS APPROPRIATE], in the event that the FDA or other governmental agency issues the institution any “Notice of Inspectional Observations”, “Warning Letters”, or other communications citing improper or inadequate research practices with respect to the research outlined in the attached IRB Authorization Agreement.

g) Institution B will maintain this Agreement as part of the institution’s HRPP records.

h) Following the UR IRB approval, Institution B may require additional review as determined by the Institution B Institutional Official and may be subject to additional administrative requirements as determined by Institution B policy, but the Institution B may not approve research covered under this agreement that is not already approved by the UR IRB

2) REPORTING

a) The UR IRB Office will report to the Institution B HRPP Office the following within [INSERT A TIMEFRAME AS APPROPRIATE]:
   i. Reports of serious or continuing non-compliance
   ii. Reports of unanticipated problems involving risks to subjects or others
   iii. Suspension of IRB approval
   iv. Terminations of IRB approval
   v. Allegations of scientific misconduct
   vi. Disclosure of significant conflicts of interest by Institution B investigators engaged in research
   vii. Oversight agency or other organization initiates any action (including audits, compliance monitoring, and reporting)
   viii. Any modification to the Federalwide Assurance or changes to the status of the Assurance documents

b) The Institution B will report to the UR IRB Office the following within [INSERT A TIMEFRAME AS APPROPRIATE]:
   i. Reports of serious or continuing non-compliance
   ii. Reports of unanticipated problems involving risks to subjects or others
   iii. Suspension of Institution B IO approval
   iv. Terminations of Institution B IO approval
   v. Allegations of scientific misconduct
   vi. Disclosure of significant conflicts of interest by Institution B investigators engaged in research

Paper copies of the Policy may not be the current version. The current version of this Policy is maintained and available on the OHSP shared network.
vii. Oversight agency or other organization initiates any action (including audits, compliance monitoring, and reporting)
viii. Any modification to the Federalwide Assurance or changes to the status of the Assurance documents
ix. Changes in the IRB Point of Contact information

c) In the event of any required reporting to sponsors/funding agencies, OHRP, FDA, and/or other oversight authorities of unanticipated problems involving risks to subjects or others, serious or continuing non-compliance, and suspension or termination of IRB approval in connection with the research included as part of this Agreement, the University of Rochester and Institution B will work together to determine which one of them will make the report. The party making the report will provide the other parties with an opportunity to review and comment on a draft of such report before it is sent to the sponsor/oversight authority, and will copy the other parties’ institutional official(s) and designees on the final report. Nothing in this Agreement shall prevent any party from making its own additional report to such entities. In such event, the party making the additional report will provide the other parties with an opportunity to review and comment on the draft report before it is sent to the sponsor/oversight authority, and will copy the other parties’ institutional official(s) and designees on the final report.

3) CONTACTS

Any notifications or reports required as part of this Reliance Agreement shall be delivered by hand, by overnight carriers (such as FedEx or UPS), by first-class mail, or scanned and emailed, as follows:

If to the University of Rochester:

<table>
<thead>
<tr>
<th>Name</th>
<th>Kelley O'Donoghue MPH, CIP</th>
<th>Tiffany Gommel, MS, CIM, CIP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Director, OHSP</td>
<td>Director, RSRB</td>
</tr>
<tr>
<td>Address</td>
<td>University of Rochester</td>
<td>University of Rochester</td>
</tr>
<tr>
<td></td>
<td>Saunders Research Building</td>
<td>Saunders Research Building</td>
</tr>
<tr>
<td></td>
<td>265 Crittenden Blvd, Suite 1.250</td>
<td>265 Crittenden Blvd, Suite 1.250</td>
</tr>
<tr>
<td></td>
<td>Box CU420628</td>
<td>Box CU420628</td>
</tr>
<tr>
<td></td>
<td>Rochester, NY 14642</td>
<td>Rochester, NY 14642</td>
</tr>
<tr>
<td>Phone</td>
<td>(585) 273-4631</td>
<td>(585) 273-4574</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:Kelley_odonoghue@urmc.rochester.edu">Kelley_odonoghue@urmc.rochester.edu</a></td>
<td><a href="mailto:Tiffany_gommel@urmc.rochester.edu">Tiffany_gommel@urmc.rochester.edu</a></td>
</tr>
</tbody>
</table>

If to Institution B:

| Name: | |
| Title: | |
| Address: | |
| Phone: | |
| Email: | |

4) MODIFICATIONS

Any modifications to this Reliance Agreement must also be in writing and with the concurrence of all parties to the agreement.