

University of Rochester	Office for Human Subject Protection		
	Research Subjects Review Board		Effective Date: 11/15/2024
	RSRB Scope and Authority		Policy 301
			Version: 1.5

POLICY

1. Purpose

Define the role and responsibilities of the University of Rochester’s (UR) Institutional Review Board (IRB), the Research Subjects Review Board (RSRB), established under the Human Research Protection Program, to ensure oversight of the UR as a research institution.

2. Scope

This policy applies to all human subject research conducted by University of Rochester employees or agents.

3. Definitions

3.1. *Clinical Investigation* – Sometimes referred to as a clinical trial, is a study in which one or more human subjects are prospectively assigned to one of more interventions (inclusive of placebo or other control) to evaluate effects of the interventions(s) on biomedical or behavioral health-related outcomes. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of this part.

- When the intervention is the use of a study drug; in which a drug is administered or dispensed to, or used, involving one or more human subjects (i.e., an experiment is any use of an approved or unapproved drug, except for the use of a marketed drug in the course of medical practice). A “marketed drug” is a drug that has been approved by the FDA and cleared for sale.
- When the intervention is the use of device, it is research involving one or more subjects to determine the safety or effectiveness of the device.

3.2. *Employee or Agent* – An individual who (1) acts on behalf of the institution; (2) exercises institutional authority or responsibility; or (3) performs institutionally designated activities, including but not limited to staff, students, contractors, and volunteers, regardless of whether an individual receives compensation.

3.3. *Human Subject Research* – any activity that either:

- Meets the Health and Human Services (HHS) definition of research and involves human subjects as defined in the HHS regulations (see 3.4 and 3.6 below), **OR**
- Meets the Food and Drug Administration (FDA) definition of research and involves human subjects as defined in FDA regulations (see 3.5 and 3.7 below).

3.4. *Research (HHS Regulations)* - A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

University of Rochester	Office for Human Subject Protection		
	Research Subjects Review Board		Effective Date: 11/15/2024
	RSRB Scope and Authority		Policy 301
			Version: 1.5

- 3.5. *Research (FDA Regulations)* - Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the FDA under these sections of the Food, Drug and Cosmetics Act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.
- For research involving drugs, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.
 - For research involving in vitro diagnostics and unidentified tissue specimens, the unidentified tissue specimens are considered to meet the definition of “human subject.”
- 3.6. *Human Subject (HHS Regulations)* – A living individual about whom an investigator (whether professional or student) conducting research:
- Obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens. **OR**
 - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- 3.7. *Human Subject (FDA Regulations)* - An individual who is or becomes a participant (“subject”) in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. For research involving medical devices, a human subject is also an individual on whose specimen an investigational device is used.
- 3.8. *Identifiable Biospecimen* – A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
- 3.9. *Identifiable Private Information* – Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- 3.10. *Institutional Review Board* – The committee formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, research involving human subjects. The IRB at the University of Rochester is the Research Subjects Review Board (RSRB).
- 3.11. *Intervention* - Includes both *physical procedures* by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

University of Rochester	Office for Human Subject Protection		
	Research Subjects Review Board		Effective Date: 11/15/2024
	RSRB Scope and Authority		Policy 301
			Version: 1.5

- 3.12. *Interaction* - Includes *communication or interpersonal contact* between the investigator, the research team, and the subject.
- 3.13. *Principal Investigator* – An individual who meets the qualifications and requirements outlined in the University of Rochester “[Principal Investigator Eligibility Policy](#)” (regardless of funding source) and who has the full and final responsibility for the conduct of the approved research. Although the PI may delegate tasks to investigators/members of their research team, the PI retains the ultimate responsibility for the conduct of the study.
- 3.14. *Private Information* - Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., medical, employment, or educational records).
- 3.15. *Test Article* - Any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Food, Drug and Cosmetics Act or under sections 351 or 354-360F of the Public Health Service Act.

4. References

- 4.1. [HHS 45 CFR 46](#); [FDA 21 CFR 50](#); [FDA 21 CFR 56](#)
- 4.2. [Policy 102 University of Rochester Human Research Protection Program](#);
[Policy 103 Organizational Structure of the HRPP](#);
[Policy 402 RSRB Meetings](#);
[Policy 403 Notification of RSRB Determinations](#);
[Policy 504 IRB Reliance and Collaborative Research](#);
- 4.3. [Guideline for Determining Engagement in Research](#);
[Guideline for Determining Human Subject Research](#);
[Human Subject Research Determination Checklist](#)

5. Responsibilities

- 5.1. When the RSRB is the Reviewing IRB, the RSRB is responsible for the review and approval of all human subject research, regardless of sponsorship, to protect the rights and welfare of human subjects, including:
- 5.1.1. Research conducted by or under the direction of any staff or faculty member (employee or agent) of the UR or its affiliates in connection with their institutional responsibilities.
- 5.1.2. Research involving UR faculty/staff use of the UR’s non-public information to identify or contact human subjects.

University of Rochester	Office for Human Subject Protection		
	Research Subjects Review Board		Effective Date: 11/15/2024
	RSRB Scope and Authority		Policy 301
			Version: 1.5

- 5.1.3. Research for which the UR has accepted responsibility for review under the terms of a Reliance Agreement (see *Policy 504 IRB Reliance and Collaborative Research*).
- 5.2. When the RSRB is the Reviewing IRB, the RSRB will apply the Common Rule 2018 Requirements only to research approved on or after January 21, 2019.
- 5.3. When the RSRB is the Relying IRB, the RSRB is responsible for oversight of the human subject research, regardless of sponsorship, as outlined in *Policy 504 IRB Reliance and Collaborative Research*.
- 5.4. At the request of an employee or agent of the UR, the RSRB has the authority to determine whether a project meets the criteria for human subject research.
- 5.5. At the request of an employee or agent of the UR, the RSRB has the authority to determine whether a project causes the UR to become engaged in human subject research.
- 5.6. As governed by federal regulations for the protection of human subjects [*HHS 45 CFR 46* and *FDA 21 CFR 56*], and as delegated by the Institutional Official, the RSRB has the authority and responsibility to:
- 5.6.1. Approve, require modifications, or disapprove any research activities overseen by the UR or its affiliates based upon whether human subjects are adequately protected, including exempt research activities for which limited IRB review is a condition of exemption [*HHS 45 CFR 46.109(a)*].
- 5.6.1.1. UR officials with supervisory authority, including Faculty Advisor, Department Chair or Chief, Deans, and President, may subsequently disapprove research that was approved by the RSRB. However, these officials may not override the RSRB's decision to disapprove a project [*HHS 45 CFR 46.112* and *FDA 21 CFR 56.112*].
- 5.6.2. Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or federal regulations (see *Policy 402 RSRB Meetings* and *Policy 403 Notification of RSRB Determinations*).
- 5.6.3. Suspend or terminate approval of research that has been associated with serious events/problems. This includes the authority of the Chair to take immediate action to suspend a research project to protect research subjects from serious risks.
- 5.6.4. Observe, or have a third party observe, the consent process.
- 5.6.5. Observe, or have a third party observe, the conduct of the research.
- 5.7. The RSRB Director is responsible for registering the Institutional Review Boards associated with the University of Rochester, when required by regulatory agencies.

University of Rochester	Office for Human Subject Protection		
	Research Subjects Review Board		Effective Date: 11/15/2024
	RSRB Scope and Authority		Policy 301
			Version: 1.5

5.7.1. The process is completed consistent with instructions provided by the Office for Human Research Protections on [Register IRBS & Obtain FWAs](#) and in advance of the expiration date.

6. Requirements

6.1. The RSRB staff determines when a project “engages” the UR in human subject research and, therefore, requires UR RSRB review (see *Guideline for Determining Engagement in Research*).

6.1.1. If the RSRB determines that a project does not engage the UR in human subject research, notification to the Investigator shall be made.

6.2. The RSRB staff determines when a project “engages” non-UR and Affiliates facilities or sites (if applicable) in human subject research and the additional requirements that may be necessary to conduct the research activities (see *Guideline for Determining Engagement in Research*).

6.2.1. Researchers from other institutions (non-UR and Affiliates faculty/staff) requesting to use UR or its affiliates as a site are responsible for contacting the appropriate department to obtain approval for access.

6.3. The RSRB staff determines that a project qualifies as human subject research (see *Guideline for Determining Human Subject Research and Human Subject Research Determination Checklist*), based on whether the activity represents “research” and involves “humans” as subjects [as defined by *HHS 45 CFR 46*], and, when applicable, whether the activity represents a “clinical investigation” involving one or more humans as subjects [as defined by *FDA 21 CFR 50.3c and FDA 21 CFR 56 102.c*].

6.3.1. If additional RSRB review is not applicable, a notification to the Investigator shall be made. Activities that qualify as human subject research will be processed by the RSRB office and assigned for additional reviews as applicable.

6.4. The RSRB will interface as necessary with other departments in the UR that are involved in research (see *Policy 102 University of Rochester Human Research Protection Program* and *Policy 103 Organizational Structure of the HRPP*).

6.5. RSRB Chairs, members, or staff, who perceive undue influence, experience undue influence, or have knowledge of an attempt at undue influence on the actions of the RSRB, should report such allegations promptly to the RSRB Director, or another appropriate leader in the HRPP.

6.5.1. In instances where a faculty member is the alleged source of undue influence, the RSRB Director and Associate Vice President for Human Subject Protections (AVP) will conduct an initial assessment of the allegation and report their findings to the Institutional Official (IO).

University of Rochester	Office for Human Subject Protection		
	Research Subjects Review Board	Effective Date: 11/15/2024	
	RSRB Scope and Authority	Policy 301	Version: 1.5

6.5.2. Depending on the level and/or topic of concern, the IO may be notified to conduct further investigation. The IO may conduct the investigation or may form a panel. If there appears to be evidence to substantiate that inappropriate and unethical inducement occurred, the IO, in consultation with the Director of RSRB and the AVP, and others as appropriate, will determine the course of action. This may include, but is not limited to no action, dismissal, letter of caution, administrative suspension or termination of studies, requirement for remedial action.

University of Rochester	Office for Human Subject Protection		
	Research Subjects Review Board		Effective Date: 11/15/2024
	RSRB Scope and Authority		Policy 301
			Version: 1.5

Originator/Authors:

Emily Flagg, Senior Regulatory Specialist
Ann Marie Scorsone, Lead Regulatory Specialist

Appendices:

None



Revision History:

02/2016: Sect 4.2 and 4.3 hyperlinks added to references; editorial changes
01/2018: Language throughout pertaining to Reviewing/Relying IRB; Sect 5.1.4 deleted; Sect 5.2 Relying IRB language added; editorial changes
01/2019: Sects 3.1, 3.5, 3.7, 3.8, 5.2, and 5.6.1 added/revised per Revised Common Rule; Sect 3.4 added second bullet re: unidentified tissue specimens; change in IO and removed T. Gommel for signatories
11/2019: Add section 5.8 registration of IRBs; update Signatories
11/2024: Sect 3 reorganized; Sect 4.1 and throughout policy hyperlinks added; editorial changes and update of signatories

Supersedes Date:

11/15/2019

Approved By:

Signed by:

 Signer Name: Stephen Dewhurst
Signing Reason: I approve this document
Signing Time: 12/5/2024 | 9:14:17 AM EST
E217A323058C451895F16072D41E27E0

12/5/2024 | 9:14:21 AM 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: 12/2/2024 | 5:29:42 PM EST
4320CFA25932487490F5DFB28FCC7D7C

12/2/2024 | 5:29:57 PM EST

Elizabeth Kipp Campbell
Associate Vice President for Human Subject Protection, OHSP

Date

(signatures continued next page)

University of Rochester	Office for Human Subject Protection		
	Research Subjects Review Board		Effective Date: 11/15/2024
	RSRB Scope and Authority		Policy 301
		Version: 1.5	

Signed by:

Wendy Duncan



Signer Name: Wendy Duncan

Signing Reason: I have reviewed this document

Signing Time: 12/2/2024 | 5:35:08 PM EST

49FD24DE73D54EC683859794C6848D96

12/2/2024 | 5:35:26 PM EST

Wendy Duncan
Director, RSRB

Date