

University of Rochester	Office for Human Subject Protection		
	Office for Human Subject Protection	Effective Date: 09/15/2024	
	Maintenance of Policies	Policy 101	Version: 2.1

POLICY

1. Purpose

This policy establishes the process for the creation and maintenance of the Office for Human Subject Protection (OHSP) policies.

2. Scope

This policy applies to all OHSP policies, inclusive of the related departmental divisions of the Research Education and Training (Education), Research Subjects Review Board (RSRB), and Research Quality Improvement (QI).

3. Definitions

None

4. References

None

5. Responsibilities

- 5.1 OHSP will oversee development, maintenance and training of policies created by the office as well as the divisions of Education, RSRB, and QI.
- 5.2 OHSP Associate Vice President for Human Subject Protection (AVP) reviews and approves all policies during creation and re-assessment.
- 5.3 The Institutional Official (IO), or designee, has access to approved policies through the [OHSP Policy/Guidance website](#). In addition, the IO will review and approve new and revised policies as deemed necessary by the IO and OHSP AVP (or designees).
- 5.4 University of Rochester Office of Counsel may review and approve new and revised policies as deemed necessary by Office of Counsel and OHSP AVP (or designees).

6. Requirements

All new policies and policy amendments must be approved by the OHSP AVP, in addition to the delegated division head (e.g., RSRB Director) for a specific policy, as applicable. Other signatories may be added for approval, as needed.

6.1 Creation of New Policy

- 6.1.1 Policy number will be assigned by OHSP AVP, or designee.
- 6.1.2 Author(s) will be assigned by OHSP AVP, or designee.
- 6.1.3 Author creates the policy following the “Policy Template” in Appendix 1.
- 6.1.4 Author distributes to reviewer(s) and any other appropriate subject matter experts for comment and revision.
- 6.1.5 Author revises the policy as appropriate.

University of Rochester	Office for Human Subject Protection		
	Office for Human Subject Protection	Effective Date: 09/15/2024	
	Maintenance of Policies	Policy 101	Version: 2.1

- 6.1.6 The document is finalized, indicating the Effective Date and version number 1.0, and then provided to the designated signatories for approval. If changes are noted during the approval process, a new Effective Date will be indicated prior to re-sending to designated signatories.
- 6.1.6.1 File the original with electronic signatures in the OHSP Policy folder on the shared drive.
 - 6.1.6.2 Post the approved policy on the OHSP website, as applicable to the research community.
 - 6.1.6.3 Notify affected individuals of the new policy per section 6.4 below.
- 6.2 Review of Existing Policy
- 6.2.1 Approximately every 5 years from the Effective Date, existing policies will be reviewed to determine if updates are necessary or desirable. A policy may be revised earlier, or revisions may be delayed, if deemed necessary or appropriate (e.g., due to changes in federal regulations/policy or institutional policy or procedure). The OHSP AVP, or designee, will assign the review as applicable.
 - 6.2.2 During the review process, changes will be tracked within the document. Revisions will be summarized in the “Revision History” section of the policy. If no revisions were made during a review period, “None” will be indicated with the date of review.
 - 6.2.3 Administrative/editorial changes will be reflected by a 1.X version change (e.g., 1.1, 1.2, etc.). Substantive changes, such as revisions to regulations, will be reflected by an X.0 version change (e.g., 1.0, 2.0, etc.). If there are no changes, version number remains the same.
 - 6.2.3.1 Should administrative changes be necessary during AAHRPP or other regulatory review process, the Effective Date should be updated; however, the Review Date may remain the same.
 - 6.2.4 The updated policy is distributed to reviewer(s) and any other appropriate subject matter experts for comment and revision.
 - 6.2.5 The Reviewer revises the policy as appropriate.
 - 6.2.6 The document is finalized, indicating the new Effective Date and date of prior Effective Date in the “Supersedes Date” section, and then signed by the designated signatories. If changes are noted during the approval process, a new Effective Date will be indicated prior to re-sending to designated signatories.
 - 6.2.6.1 File the original updated policy with electronic signature in the OHSP policy folder on the shared drive.
 - 6.2.6.2 Post the updated policy on the OHSP website, as applicable to the research community.
 - 6.2.6.3 Archive the tracked version of the document (if applicable) to the appropriate shared drive policy archive folder.

University of Rochester	Office for Human Subject Protection		
	Office for Human Subject Protection	Effective Date: 09/15/2024	
	Maintenance of Policies	Policy 101	Version: 2.1

6.2.6.4 Archive the replaced original document electronically (both Word and PDF with signatures).

6.2.6.5 Notify affected individuals of the updated policy per section 6.4 below.

6.3 Maintaining Policies

The current final electronically signed policies will be maintained electronically on the shared network for accessibility and reference as needed. As policies are replaced, they will be archived electronically according to Section 6.2.6 and the hard copy will not be retained.

6.4 Training

6.4.1 OHSP divisional staff, as well as RSRB board chairs and members, will be notified of new or revised policies. As applicable per their role and/or the nature of a revision, training and/or acknowledgement of receipt and review of the policy may be required, as deemed necessary by the OHSP AVP. When necessary, documentation of training and/or acknowledgement of receipt and review will be maintained.

6.4.2 The University of Rochester research community will be informed about new or revised policies, as applicable, and referred to the OHSP website for links to related documents. An informational seminar may be conducted, as deemed necessary by OHSP or division, to further communicate significant changes in policy.

6.5 Forms and Templates

6.5.1 Template documents and forms are developed, 1) to ensure that policies are integrated into the daily operations of the functional divisions, and 2) to enable staff to consistently implement processes and communications.

6.5.2 Template documents and forms are maintained on the office shared network and are also referenced within the applicable policy.

University of Rochester	Office for Human Subject Protection		
	Office for Human Subject Protection	Effective Date: 09/15/2024	
	Maintenance of Policies	Policy 101	Version: 2.1

Originator/Authors:

Kelley O'Donoghue, Director, OHSP
Emily Flagg, Senior Regulatory Specialist
Ann Marie Scorsone, Lead Regulatory Specialist

Appendices:

Appendix 1: Policy Template

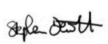

Revision History:

01/2015: Sect 6.2.3.1 added; editorial changes throughout to match practice; update IO and Director of Education signature lines; editorial changes to Appendices 1 and 3
06/2017: Administrative changes
10/2019: Administrative changes, including update signatories
05/2022: Remove requirement to send policies to IO every 4 years as policies are available on website; review of policies updated to occur every 3 years; add electronic signatures and electronic storage of original; and update signatories
09/2024: Sect 6.2.1, 6.2.3, and 6.4.1 revised; update signatories, editorial changes.

Supersedes Date:

05/09/2022

Approved By:


Signed by:

 Signer Name: Stephen Dewhurst
Signing Reason: I approve this document
Signing Time: 9/30/2024 | 2:37:32 PM EDT
E217A323058C451895F16072D41E27E0

9/30/2024 | 2:37:37 PM EDT

Stephen Dewhurst
Institutional Official

Date

Signed by:

 Signer Name: Elizabeth Kipp Campbell
Signing Reason: I approve this document
Signing Time: 9/13/2024 | 3:27:25 PM EDT
4320CFA25932487490F5DFB28FCC7D7C

9/13/2024 | 3:27:31 PM EDT



Elizabeth Kipp Campbell
Associate Vice President for Human Subject Protection

Date

(signatures continued next page)

University of Rochester	Office for Human Subject Protection		
	Office for Human Subject Protection	Effective Date: 09/15/2024	
	Maintenance of Policies	Policy 101	Version: 2.1

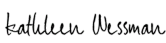

Approved By:

Signed by:

 Signer Name: Kelly Unsworth
 Signing Reason: I approve this document
 Signing Time: 9/13/2024 | 1:20:21 PM EDT
 38BA26DFB30A42DD991D31DED11A82EA

9/13/2024 | 1:20:27 PM EDT

Kelly Unsworth
 Director, Research Education and Training



Date

Signed by:

 Signer Name: Kathleen Wessman
 Signing Reason: I approve this document
 Signing Time: 9/13/2024 | 1:18:15 PM EDT
 23649B5586354D349599202232741C12

9/13/2024 | 1:18:27 PM EDT

Kathleen Wessman
 Director, Research Quality Improvement

Date

Signed by:

 Signer Name: Wendy Duncan
 Signing Reason: I approve this document
 Signing Time: 9/13/2024 | 1:24:51 PM EDT
 49FD24DE73D54EC683859794C6848D96

9/13/2024 | 1:25:00 PM EDT

Wendy Duncan
 Director, Research Subjects Review Board

Date

University of Rochester	Office for Human Subject Protection		
	Office for Human Subject Protection	Effective Date: 09/15/2024	
	Maintenance of Policies	Policy 101	Version: 2.1

APPENDIX 1 Policy Template

University of Rochester	Office for Human Subject Protection		
	[Insert Dept/Division]	Effective Date: [DATE FINAL FOR SIGN-OFF]	
	[INSERT TITLE]	Policy [INSERT POLICY #]	Version: [INSERT X.X]

POLICY

1. Purpose

- 1.1. [STATE THE PURPOSE OF THIS POLICY]
- 1.2. [IF MORE THAN ONE PURPOSE, LIST EACH OUT HERE]

2. Scope

[INDICATE TO WHOM OR WHAT THIS POLICY OR GUIDELINE APPLIES (E.G., INVESTIGATORS, ALL HUMAN SUBJECT RESEARCH, OR SPECIFIC UNIVERSITY DEPARTMENTS)]

3. Definitions

- 3.1. [LIST TERMS OR ACRONYMS USED WITHIN THIS DOCUMENT AS RELEVANT. INDICATE IF NONE.]

4. References

- 4.1. [LIST FEDERAL AND STATE LAW AND REGULATIONS TO WHICH THIS POLICY MAKES REFERENCE]
- 4.2. [LIST OTHER APPLICABLE UNIVERSITY OR OHSP POLICIES TO WHICH THIS POLICY MAKES REFERENCE]
- 4.3. [LIST ANY DOCUMENTS (e.g., TEMPLATES) REFERENCED WITHIN THE POLICY THAT ARE NOT INCLUDED IN THE APPENDIX]

5. Responsibilities

- 5.1. [DEFINE APPLICABLE RESPONSIBILITIES OF STAFF AND/OR DEPARTMENTS. INDICATE IF NONE]

6. Requirements

- 6.1. [OUTLINE THE PROCESS TO BE TAKEN TO ACCOMPLISH AND/OR MEET THE PURPOSE(S) OF THIS POLICY]
 - 6.1.1. [NOTE – IF ADDITIONAL EXPLANATION OR STEPS ARE NECESSARY TO DETAIL THE PROCESSES WITHIN A POLICY, A GUIDELINE MAY NEED TO BE DEVELOPED.]

University of Rochester	Office for Human Subject Protection		
	Office for Human Subject Protection	Effective Date: 09/15/2024	
	Maintenance of Policies	Policy 101	Version: 2.1

Originator/Authors:

INSERT AUTHOR(S), INCLUDING TITLES

Appendices:

Appendix 1: INSERT AND LIST ANY ATTACHMENTS OR INDICATE IF NONE

Revision History:

INDICATE DATE OF REVISIONS AND LIST SECTIONS CHANGED AND SUMMARIZE THE REVISION, OR INDICATE IF NONE

Supersedes Date:

INDICATE PREVIOUS EFFECTIVE DATE OR INDICATE NOT APPLICABLE IF NEW POLICY

Approved By: {Insert additional names/signatories as applicable}

 INSERT NAME
 Director, OHSP

 Date

 INSERT NAME
 INSERT TITLE

 Date

University of Rochester	Office for Human Subject Protection		
	Office for Human Subject Protection	Effective Date: 09/15/2024	
	Maintenance of Policies	Policy 101	Version: 2.1