

<b>University of Rochester</b>	<b>Office for Human Subject Protection</b>		
	<b>Office for Human Subject Protection</b>	<b>Effective Date: 05/09/2022</b>	
	<b>Maintenance of Policies</b>	<b>Policy 101</b>	<b>Version: 2.0</b>

## 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), Quality Improvement (QI), and Clinical & Regulatory Systems (Systems).

### 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, QI, and Systems.
- 5.2 OHSP Director reviews and approves all policies during creation and biennial assessments.
- 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 Director (or designees).
- 5.4 The University of Rochester Office of Counsel (designee) will review and approve new and revised policies as deemed necessary by Office of Counsel and OHSP Director (or designees).

### 6. Requirements

All new policies and policy amendments must be approved by the OHSP Director, 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 Director, or designee.
- 6.1.2 Author(s) will be assigned by OHSP Director, 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.

<b>University of Rochester</b>	<b>Office for Human Subject Protection</b>		
	<b>Office for Human Subject Protection</b>	<b>Effective Date: 05/09/2022</b>	
	<b>Maintenance of Policies</b>	<b>Policy 101</b>	<b>Version: 2.0</b>

- 6.1.6 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 3 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, due to changes in institutional policy or procedure). The OHSP Director, or designee, will assign the reviewer(s) 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 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 Reviewer revises the policy as appropriate.
  - 6.2.6 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.

<b>University of Rochester</b>	<b>Office for Human Subject Protection</b>		
	<b>Office for Human Subject Protection</b>	<b>Effective Date: 05/09/2022</b>	
	<b>Maintenance of Policies</b>	<b>Policy 101</b>	<b>Version: 2.0</b>

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 members, will be trained (or acknowledge receipt and review) on new policies as applicable to their roles and responsibilities within the office (Appendix 2, Appendix 3). Staff and board members will also be responsible for acknowledging receipt and review of revised policies (in-person training will occur as necessary) [Appendix 3], as deemed necessary by the OHSP Director. Documentation of training 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: 05/09/2022	
	Maintenance of Policies	Policy 101	Version: 2.0

**Originator/Authors:**

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

**Appendices:**

Appendix 1: Policy Template  
Appendix 2: Policy Training Sign-In Template  
Appendix 3: Policy Review/Acknowledgement Form Template

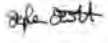
**Revision History:**

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

**Supersedes Date:**

10/25/2019

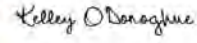
**Approved By:**

DocuSigned by:  
  
Signer Name: Stephen Dewhurst  
Signing Reason: I approve this document  
Signing Time: 5/22/2022 | 6:40:57 PM EDT  
F217A323058C451895F16072D41E27F0

5/22/2022 | 6:41:15 PM EDT

Stephen Dewhurst  
Institutional Official

Date

DocuSigned by:  
  
Signer Name: Kelley O'Donoghue  
Signing Reason: I approve this document  
Signing Time: 5/10/2022 | 7:59:21 AM EDT  
01BA85BD9A444F09983AC84603B8E36E

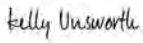

5/10/2022 | 7:59:33 AM EDT

Kelley A. O'Donoghue  
Director, OHSP  
(signatures continued next page)

Date

University of Rochester	Office for Human Subject Protection		
	Office for Human Subject Protection	Effective Date: 05/09/2022	
	Maintenance of Policies	Policy 101	Version: 2.0



**Approved By:**

DocuSigned by:  
  
 Signer Name: Kelly Unsworth  
 Signing Reason: I approve this document  
 Signing Time: 5/11/2022 | 1:18:39 PM EDT  
 38BA26DFB30A42DD991D31DED11A82EA

5/11/2022 | 1:18:47 PM EDT

Kelly Unsworth  
 Director, Research Education and Training

Date

DocuSigned by:  
  
 Signer Name: Kathleen Wessman  
 Signing Reason: I approve this document  
 Signing Time: 5/16/2022 | 5:03:45 PM EDT  
 23649B5586354D349599202232741C12

5/16/2022 | 5:07:18 PM EDT

Kathleen Wessman  
 Director, Quality Improvement

Date

<b>University of Rochester</b>	<b>Office for Human Subject Protection</b>		
	<b>Office for Human Subject Protection</b>	<b>Effective Date: 05/09/2022</b>	
	<b>Maintenance of Policies</b>	<b>Policy 101</b>	<b>Version: 2.0</b>

## APPENDIX 1 Policy Template

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

## 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.]

<b>University of Rochester</b>	<b>Office for Human Subject Protection</b>		
	<b>Office for Human Subject Protection</b>	<b>Effective Date: 05/09/2022</b>	
	<b>Maintenance of Policies</b>	<b>Policy 101</b>	<b>Version: 2.0</b>

**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

<b>University of Rochester</b>	<b>Office for Human Subject Protection</b>		
	<b>Office for Human Subject Protection</b>	<b>Effective Date: 05/09/2022</b>	
	<b>Maintenance of Policies</b>	<b>Policy 101</b>	<b>Version: 2.0</b>

**APPENDIX 2**  
**Policy Training Sign-In Template**

**Policy Training  
Sign-In Sheet**

**Date:**

**The following policies were reviewed: [LIST POLICY AND VERSION #]**

<b>Print Name</b>	<b>Signature</b>	<b>Division (OHSP, Education, RSRB, QI)</b>



<b>University of Rochester</b>	<b>Office for Human Subject Protection</b>		
	<b>Office for Human Subject Protection</b>	<b>Effective Date: 05/09/2022</b>	
	<b>Maintenance of Policies</b>	<b>Policy 101</b>	<b>Version: 2.0</b>

**APPENDIX 3**  
**Policy Review/Acknowledgement Form Template**

**Policy Review/Acknowledgement**

**Re: [LIST POLICIES THAT REQUIRE REVIEW AND ACKNOWLEDGMENT]**

This is to confirm my receipt, review and understanding of the policy or policies listed below.

<b>Policy #</b>	<b>Version #</b>	<b>Policy Name</b>	<b>Date Reviewed</b>
Policy XXX	X.X	[INSERT NAME]	

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date