POLICY

1. Purpose
Describe the institutional training requirements and educational opportunities for individuals involved in the University of Rochester’s Human Research Protection Program (UR HRPP) to ensure that the rights, safety and welfare of subjects are protected during the conduct of research.

2. Scope
This policy applies to all individuals responsible for protecting the rights and welfare of human subjects under the UR HRPP. This includes, but is not limited to: all research personnel engaged in human subject research, the Institutional Official (IO), Office for Human Subject Protection (OHSP) staff and Research Subject Review Board (RSRB) members.

3. Definitions
3.1. Internal Research Personnel – An employee or agent of the UR as defined by Policy 102 University of Rochester’s Human Research Protection Program.

3.2. External Research Personnel – Individuals not acting as an employee or agent of the UR as defined by Policy 102 University of Rochester’s Human Research Protection Program.

4. References
4.1. Policy 102 University of Rochester’s Human Research Protection Program;
Policy 302 RSRB Membership and Composition
4.2. Guideline for OHSP Education and Training Framework
Guideline for Professional Certification Reimbursement
RSRB Guideline for Determining Engagement in Research

5. Responsibilities
5.1. The OHSP Division of Research Education & Training is responsible for assisting researchers in protecting the rights, welfare and safety of human subjects by providing programs and educational resources in research ethics and human subject safety, with an emphasis on proper conduct of research. To accomplish this, the Division of Research Education & Training:
5.1.1. Administers and monitors the basic human subjects training requirements as conducted through the Collaborative Institutional Training Initiative (CITI). This includes:
5.1.1.1. Providing institution-specific certification letters to research personnel upon initial certification and re-certification (Appendices 1 & 2).
5.1.1.2. Maintaining research personnel certification information in the RSRB Online Submission System. (Note: Documentation of certifications obtained through the “Human Subjects Protection Program” and “Ethical Principles in Research Program” will be maintained for 6 years per record retention requirements set forth by the Accreditation Council for Continuing Medical Education.)

5.1.1.3. Notifying research personnel of pending certification expiration (Appendix 3).

5.1.1.4. Notifying research personnel of study members in need of certification and/or re-certification upon submission of new RSRB applications (Appendix 4).

5.1.2. Implements additional training opportunities designed to supplement the basic human subjects training requirements. This includes, but is not limited to:

5.1.2.1. Training seminars, workshops and classes intended for study team members engaged in human subject research.

5.1.2.2. Bi-annual education programs for OHSP staff and RSRB members.

5.1.2.3. Maintaining the information on the Division website, which provides internal and external training resources.

5.2. Individuals in the UR HRPP are responsible for:

5.2.1. Completing and maintaining the required basic human subjects training certification, including documentation of such certification, as described in section 6.0 below.

5.2.2. Complying with any additional internal training requirements set forth elsewhere within the UR (e.g., departmental training requirements), any board-requested training requirements, and any external research training requirements (e.g., sponsor training requirements, professional certification maintenance, etc.). Additional information regarding utilization of the OHSP Education and Training Framework to set forth training additional training requirements and professional certification reimbursement is included in the Guideline for OHSP Education & Training Framework and the Guideline for Professional Certification Reimbursement.

6. Requirements

6.1. Institutional Official & OHSP Staff

6.1.1. The IO and OHSP staff must successfully complete (with a score of at least 85%) and maintain the “IRB” basic human subjects training through CITI, as required by their job responsibilities. Re-certification (with a score of at least 85%) is required every 3 years.

6.1.1.1. Current “Greater than Minimal Risk” training will be accepted for an IO or OHSP staff member entering into their role; however, “IRB” training must be
completed with each re-certification while acting as IO or employed by OHSP.

6.1.2. For research sponsored by the Department of Defense (DoD), OHSP and RSRB leadership will review each DoD addendum/agreement to ensure adherence with any specific training requirements.

6.2. RSRB Members

6.2.1. All RSRB members must successfully complete (with a score of at least 85%) and maintain the “IRB” basic human subjects training through CITI. Re-certification (with a score of at least 85%) is required every 3 years.

6.2.1.1. Current “Greater than Minimal Risk” training will be accepted for any RSRB member entering into their role; however “IRB” training must be completed with each re-certification while serving as a RSRB member.

6.2.2. All RSRB members must comply with the initial and ongoing training and education policies set forth in Policy 302 RSRB Membership and Composition.

6.3. Internal Research Personnel

6.3.1. All internal research personnel must successfully complete (with a score of at least 85%) initial basic human subjects training through CITI prior to conducting to any human subject research.

6.3.1.1. CITI course completion requirements are based on the type of research being conducted: “Greater than Minimal Risk Biomedical”, “Greater than Minimal Risk Behavioral”, or “Minimal Risk”. Research personnel, regardless of role, must complete training that is commensurate with the risk level associated with the research conducted.

6.3.1.1.1. Personnel with “Minimal Risk” training certification are not permitted to work on greater than minimal research until they have completed the appropriate “Greater than Minimal Risk” training and received certification.

6.3.2. All research personnel must successfully re-certify (with a score of at least 85%) their basic human subjects training through CITI every 3 years.

6.3.2.1. Personnel whose certification lapses must cease all involvement in human subject research activities until re-certification can be completed. At the time of continuing review, the RSRB may withhold study renewals in cases where key research personnel certification has lapsed.

6.3.3. Under limited circumstances, sufficient justification, and approval by the OHSP, research personnel may be permitted to complete a modified or alternative basic human subjects training. If granted, the 3 year re-certification requirement will remain effective for this type of training.

6.4. External Research Personnel

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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.
6.4.1. External research personnel who collaborate with the UR on human subject research and are considered engaged in research per the *RSRB Guideline for Determining Engagement in Research*, must meet basic human subject training requirements prior to conducting research activities. If external research personnel are associated with an institution with training requirements (e.g., another academic medical center), OHSP will recognize the home institution’s training. Alternatively, external research personnel may complete OHSP’s basic human subjects training through CITI.
Originator/Authors:
Kelly Unsworth, Director of Research Education & Training

Appendices:
Appendix 1: Sample Human Subjects Training Initial Certification Letter
Appendix 2: Sample Human Subjects Training Re-certification Letter
Appendix 3: Sample Human Subjects Training Certification Pending Expiration Notification
Appendix 4: Sample RSRB Notification Regarding Study Team Members in Need of Certification

Revision History:
None

Supersedes Date:
Not Applicable

Approved By:

Robert Clark
Institutional Official and Senior VP for Research

Kelley A. O’Donoghue
Director, OHSP

Kelly Unsworth
Director of Research Education & Training, OHSP

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Appendix 1: Sample Human Subjects Training Initial Certification Letter

Office for Human Subject Protection

April 10, 2014

Re: Certification for Greater Than Minimal Risk Biomedical

Dear Dr. [Name]

Congratulations! This letter is to confirm you successfully completed the certification program to conduct greater than minimal research with human subjects at the University of Rochester.

You completed the GREATER THAN MINIMAL RISK BIOMEDICAL program.

Your certification will expire in three years (APRIL 8, 2017).

You have been assigned a certification number, which is your CITI Learner ID number. Your number is 4104997.

Please note that all research must be submitted to the RSB for review and approval before the research can begin. All research is reviewed through the RSB Online Submission System (ROSS), for additional information on the web-based submission system click: ROSS.

You will need to register for a ROSS account to submit a new study or to be added to a study. To register for an account, send an email to jason.warner@urmc.rochester.edu with the subject line “ROSS Account Request” and include your name, email address, the University of Rochester department name in which you are associated with, and your research role (PI, study coordinator, etc.). Your profile in the RSB Online Submission System (ROSS) will include the certification program you took, your certification number, and expiration date.

Monthly training sessions on this web-based system are offered through the RSB. To find out when the next class is and to sign up, go to the RSBP website.

If you are interested in a no-cost consultation about the informed consent process and its documentation requirements for research, contact the University's Research Subject Advocate, Nancy Needler, nneedler@urmc.rochester.edu or 275-1020.

Sincerely,

Kelly Draykovskiy, ME, CCRC, CIP
Director, Research Education & Training

PLEASE RETAIN A COPY OF THIS LETTER FOR YOUR FILES. ONLY DON'T USE A COPY OF THIS LETTER.

Saunders Research Building - 205 Crittenden Boulevard, Suite 1.250 - CU 420628 - Rochester, NY 14642-4268
585.273.4177 - 585.273.1674 fax

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: Sample Human Subjects Training Re-certification Letter

Office for Human Subject Protection

April 4, 2014

Re: Recertification for Greater Than Minimal Risk Biomedical

Dear [REDACTED]:

This letter is to confirm that you successfully completed the recertification program to conduct greater than minimal research with human subjects at the University of Rochester.

You completed the Greater than Minimal Risk Biomedical program.

Your certification will expire in three years (APRIL 2, 2017)

For recordkeeping purposes, you have been assigned a new certification number (your CITI Learner ID number). Your new number is 722579.

Your profile in the RSRE Online Submission System (ROSS) will be updated with the program you took, your certification number, and expiration date. This information is required for all RSRE and WIRE submissions.

Congratulations! Thank you for your continued commitment to human subject protections and compliance with research regulations and policies.

Sincerely,

[REDACTED]

Kelly Unsworth, MS, CRC, CIP
Director, Research Education & Training

PLEASE RETAIN A COPY OF THIS LETTER FOR YOUR FILES
OHSP DOES NOT KEEP A COPY OF THIS LETTER.

Appendix 3: Sample Human Subjects Training Certification Pending Expiration Notification

Dear Researcher:

The purpose of this notification is to inform you that your certification to conduct human subject research will expire within the next 30 days. If you are currently involved in studies with human subjects approved by the RSRB or WIRB, you must renew this certification before it expires. This is the only notice you will receive.

Instructions for renewing your human subjects research certification are available on our website at: http://www.rochester.edu/ohsp/education/certification/certificationRenewal.html

Please contact Kelly Unsworth at (585) 275-5344 or kelly_unsworth@urmc.rochester.edu if you have any questions or if you are unsure which recertification course to complete.

NOTE: If the Office for Human Subject Protection (OHSP) does not receive notification that you have successfully completed the program before your certification expires, you must stop all involvement in human subject research.

Thank you.
Appendix 4: Sample RSRB Notification Regarding Study Team Members in Need of Certification

University of Rochester Research Subjects Review Board

NOTIFICATION OF TEAM MEMBERS IN NEED OF CERTIFICATION

From: Auto Generated by RSRB Web Site
To: 
CC: 
Re: Study # RSRB00051203

This notification is to inform you that one or more team members listed for the above application: do not have an HSPP/FRPP number on record, are within 30 days of the certification date or their certification date has already passed. This study can not be approved by the RSRB until all team members have a current certification listed in the system.

Un-Certified Team Members:

<table>
<thead>
<tr>
<th>Team Member</th>
<th>Cert #</th>
<th>Cert Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Tue Oct 29 00:00:00 EDT 2013</td>
</tr>
</tbody>
</table>

The Department of Health and Human Services has approved a Federalwide Assurance (FWA) with the University of Rochester (FWA0000469), which is in effect through November 20, 2018.
289 Crittenden Blvd., Box CL410528, Suite 1-250
Rochester, New York 14642
(585) 275-2888

DO NOT REPLY TO THIS EMAIL
For questions or to provide a response, please go into the RSRB Online Submission System (ROSS) or contact your RSRB Specialist: RSRB staff page.