POLICY

1. Purpose

1.1. Describe the responsibilities and requirements of a Principal Investigator (PI) to ensure research is conducted in accordance with the Office for Human Subject Protection (OHSP) and University policies and guidelines, as well as federal regulations, as applicable.

1.1.1. To ensure that the rights, safety, and welfare of research subjects are protected during the conduct of the research and after the research is completed.

1.1.2. To ensure the integrity of the data collected during the conduct of the research.

2. Scope

This policy applies to any individual designated as a Principal Investigator conducting human subject research governed by the Research Subjects Review Board (RSRB) under the University of Rochester Human Research Protection Program.

- For research that is deferred to an external IRB and the University of Rochester is the Relying Institution, responsibilities and requirements are outlined in *Policy 504 IRB Reliance and Collaborative Research.*

3. Definitions

3.1. *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.

3.1.1. A Principal Investigator on a proposal confirmed to be not human subject research, confirmed that the UR is not engaged in the human subject research, or determined to be exempt by the RSRB need not hold a faculty position (e.g., students).

3.1.2. Individuals not meeting the criteria of Principal Investigator include: adjunct professors, residents, fellows, students, or staff members, ***even if*** they are identified as the Principal Investigator by the funding source or regulatory body (e.g., National Institute of Health (NIH)/National Science Foundation (NSF) grant, Food & Drug Administration approved Investigational New Drug (IND) or Investigational Device Exemption application).

3.1.2.1. Such individuals may serve as a Co-Principal Investigator under the aegis of a UR-recognized and approved PI who assumes ultimate responsibility for the research.

3.1.3. Individuals not meeting the criteria who are conducting unfunded or internally funded, minimal risk research, may hold the position of Principal Investigator at the discretion of the RSRB (e.g., Pharm D).

3.2. *Clinical Trial* – A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to

evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

3.3. *Sponsor-Investigator* (or Investigator-held IND) – An Investigator who is responsible for the initiation and conduct of a clinical investigation, as well as the responsibility for the direct oversight of the administration, dispensing and/or use of the test item across all sites (e.g., regulatory Sponsor). For example, when a physician submits an IND application to the FDA to propose a study of an unapproved product or of an approved product for a new indication or patient population.

4. References

4.1. HHS 45 CFR 46; FDA 21 CFR 56; FDA 21 CFR 50; FDA 21 CFR 312; FDA 21 CFR 812; FDA Guidance for Industry Investigator Responsibilities

4.2. University of Rochester Principal Investigator Eligibility Policy;
University of Rochester Clinical Research Billing Policy;
UR Clinical Research Standard Operating Procedures Regarding Financial Oversight and Billing Compliance;
University of Rochester HR Policy 339 Short-Term Disability Plan
Policy 501 Levels of RSRB Review;
Policy 502 Types of RSRB Submissions;
Policy 503 Ancillary Committee Reviews;
Policy 504 IRB Reliance and Collaborative Research;
Policy 505 Scientific Review Standards;
Policy 605 Research Involving FDA Regulated Drugs, Biologics, and Supplements;
Policy 606 Research Involving FDA Regulated Devices;
Policy 701 Informed Consent;
Policy 702 HIPAA Privacy Rule;
Policy 801 Reporting Research Events;
Policy 902 Investigator Financial Conflict of Interest

4.3. Guideline for Investigators Leaving the Institution;
Guideline for Principal Investigator Oversight For Multi-Site Research
Guideline for Reporting Research Events;
RSRB Protocol Templates;
OHSP Study Documentation Tool Box;
Summary of Responsibilities for Investigators Conducting EXEMPT Research;
Summary of Responsibilities for Investigators Conducting Non FDA-Regulated Research;
Summary of Responsibilities for Investigators Conducting FDA-Regulated Research

5. Responsibilities

Responsibilities are described within the Principal Investigator requirements under Sections 6 – 10 below, as well as the Summary of Responsibility documents listed under Section 4.3 above. Investigators are responsible for complying with all applicable University and OHSP policies and guidelines, in addition to any of those specified within this document.

6. Requirements for All Principal Investigators

6.1. Oversee the conduct of all research activities, including the training and education of research staff (as applicable).

6.1.1. PIs may delegate responsibilities and functions of research activities to appropriately trained, capable, and licensed, as appropriate, research staff; however, the PI must maintain all oversight responsibilities.

6.1.2. Ensure only IRB-approved research staff conduct the research (e.g., obtain consent, conduct study procedures).

6.2. Obtain scientific review of the proposed research (see *Policy 505 Departmental Scientific and Resource Review*) prior to submission to the RSRB.

6.3. Provide a research protocol that contains sufficient information to meet the standards established by federal and state regulations, University policies, and to ensure an effective review by the RSRB (see *RSRB Protocol Templates*).

6.3.1. For studies supported by grant funds, a separate protocol must be created based upon the grant proposal, as the grant does not provide sufficient detail to substitute for the RSRB research protocol.

6.3.2. For multi-site research, the University of Rochester PI may be required to provide a site-specific protocol addendum to address institution-specific requirements.

6.4. Implement and conduct research in compliance with federal and state regulations, the Office for Human Subject Protection (OHSP) and University policies and guidelines, the ethical principles and standards appropriate for the PI's discipline, and determinations of the Reviewing IRB, only after the following conditions have been met:

6.4.1. IRB approval is obtained (or a review determination as applicable);

6.4.2. Required ancillary committee approvals are obtained, as applicable, according to *Policy 503 Ancillary Committee Reviews*;

6.4.3. For research involving the use or disclosure of protected health information (PHI), the protection of subjects' privacy and confidentiality is in compliance with *Policy 702 HIPAA Privacy Rule*; and,

6.4.4. For sponsored research, a fully executed contract is in place before enrolling subjects.

6.4.5. For research involving the transfer of data and/or specimens to external entities, an agreement (e.g., Material Transfer Agreement, Data Use Agreement) is executed before transmitting data/specimens.

6.5. For each study reviewed by the RSRB, ensure sufficient resources are available to conduct the research, including:

6.5.1. Access to the study population and a sufficient number of eligible subjects to complete the research;

6.5.2. Sufficient time to conduct and complete the research;
6.5.3. Adequate numbers of qualified staff;
6.5.4. Adequate facilities including a place and process for secure data and study record storage;
6.5.5. Any medical and/or psychological resources that subjects might require as a consequence of the research.

6.6. Individuals who mentor a non-faculty Investigator (e.g., student, resident, fellow) are also responsible for the following:
6.6.1. Advise the non-faculty Investigator throughout protocol development, submission to RSRB, and implementation of the research protocol, as appropriate.
6.6.2. Ensure the non-faculty Investigator meets appropriate training and education requirements regarding human subject research.
6.6.3. Ensure the non-faculty Investigator is aware of and meets the responsibilities and requirements of this policy as an Investigator.
6.6.4. Conduct activities necessary to maintain appropriate oversight and guidance for the non-faculty Investigator during the conduct of the research.
6.6.5. Ensure the non-faculty Investigator research activity is closed in a timely fashion.

6.7. Comply with the requirements of *Policy 902 Investigator Financial Conflict of Interest*.

6.8. If a PI on a study that received convened board or expedited review is out of the office on disability (*University of Rochester HR Policy 339 Short-Term Disability Plan*), on a leave of absence, or any other reason where applicable law prevents the individual from working, the PI must name an experienced individual to take responsibility for the study. The only exception would be if the PI confirms through a Report of New Information that there are no active subjects enrolled and no enrollment will occur during this time. If an emergent situation arises, the PI's supervisor (e.g., Department Chair, Division Chief, Department Head) will need to work with the RSRB to identify the interim PI.
6.8.1. When the RSRB is the Reviewing IRB:
6.8.1.1. Submit a modification to change the name of the PI to the interim PI. The interim PI will provide a letter stating their agreement to serve as the PI, but study documents may not require a change in the named PI.
6.8.1.2. When the PI returns from disability, an additional modification will be submitted to change the PI back to the original PI

7. Requirements for Principal Investigators Conducting Research Exempt from Federal Regulations

In addition to the requirements listed under Section 6 above, the following apply to Investigators conducting research that is exempt from federal regulations (see *Policy 501 Levels of RSRB Review*):

7.1. Maintain documentation to support RSRB determination of materials reviewed.
   7.1.1. For exempt research this includes, at minimum, the finalized protocol, the RSRB application, and the RSRB letter regarding the exempt determination.

7.2. Use consent forms (or information letters) bearing a current "RSRB Approved" watermark with the first page printed on UR letterhead.
   7.2.1. For research including the requirement for signed consent, study documentation includes all pages of the original signed consent form for at least 3 years after the research is completed (6 years if HIPAA Authorization used as part of the research).

7.3. Conduct research in compliance with the finalized RSRB approved protocol.

7.4. Submit all changes to the research (including the protocol and all other study documents) for review and approval by the RSRB prior to implementation of those changes.

7.5. Obtain approval of recruitment materials and/or recruitment methods prior to use and/or implementation, at the time of initial RSRB review or during the conduct of the study.

7.6. Maintain adequate and accurate subject study records and documentation to demonstrate compliance with the IRB-approved protocol. Changes to study records should be traceable, should not obscure the original entry, and should be explained if necessary (e.g., written revisions to study records should be made with a single line through the original entry and the correction should be initialed and dated with indelible ink).

7.7. Ensure that any subject questions, concerns, and complaints are properly addressed and that resolution to any of these reports is documented and retained in the study record. Report concerns and complaints per the *Guideline for Reporting Research Events*.

7.8. Report research events according to *Policy 801 Reporting Research Events* and the *Guideline for Reporting Research Events*.

8. Requirements for Principal Investigators Conducting Non-FDA Regulated Research When the RSRB is the Reviewing IRB

In addition to the requirements listed under Sections 6 and 7 above, the following apply to Investigators conducting non-FDA regulated greater than minimal risk or minimal risk research:

8.1. If applicable, follow the *UR Clinical Research Billing Policy* to ensure compliance with regard to the following activities (refer to the *Office of Research and Project Administration Clinical Trial Resources* for related materials):
- 8.1.1. Development of a compliant billing plan and budget, independent of the sponsor (if applicable);
- 8.1.2. Oversight of expenditure completeness and accuracy, and revenue realization (if there is a sponsor);
- 8.1.3. Timely programmatic and financial closeout.

8.2. Maintain a study site file with current and accurate records of all study documentation as required by applicable regulatory requirements (see *OHSP Quality Improvement Study Documentation Tool Box* for study site file guidance).

8.3. Ensure the registration for all "applicable clinical trials" and the submission of study results on ClinicalTrials.gov (www.ClinicalTrials.gov) consistent with funding and regulatory requirements.

8.4. Conduct RSRB approved research in compliance with Department of Health and Human Services (HHS) regulations 45 CFR 46.

8.5. Obtain and document informed consent according to the RSRB-approved protocol and *Policy 701 Informed Consent*.

8.6. Obtain and document HIPAA authorization according to *Policy 702 HIPAA Privacy Rule*, unless the requirements for authorization or documentation of authorization have been waived or altered.

8.7. Ensure the data and safety monitoring plan outlined in the approved protocol is followed and documented. This includes timely submission of data and safety monitoring reports, as applicable, per the *Guideline for Reporting Research Events*.

8.8. For those studies requiring continuing review, ensure timely submission of the progress report, i.e., Continuing Review Report, to ensure continued RSRB approval during the

conduct of the study (see *Policy 502 Types of RSRB Submissions*). Reports should be submitted 6 to 8 weeks prior to study expiration to allow adequate time for review/processing.

8.8.1. If RSRB approval of the study expires, ensure all research activities (including recruitment, enrollment, interventions, interactions, and data analysis on current subjects) are stopped.

8.9. For those studies meeting the definition of a "clinical trial," as defined by 45CFR46.102(b), ensure that one consent form used to enroll subjects is posted on a publically available federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit consistent with 45CFR46.116(h).

8.10. Submit a final progress report, i.e., Continuing Review Report, when a study is completed or closed.

8.10.1. For those studies that do not require continuing review, the Investigator will receive an annual notification as a reminder to submit the study for closure when the research is completed.

8.11. Maintain all study records (e.g., study site files, data collection forms, source documentation) for at least 3 years after the research is completed, or for a longer term if required by other contractual agreements.

8.11.1. If the consent form includes HIPAA Authorization, it must be maintained for 6 years.

8.12. When new information or findings related to subject safety or welfare are identified after a study has closed, provide the RSRB with a report of the new information/findings.

8.13. Notify the RSRB if departing the University (temporarily or permanently) and follow additional procedures according to the *Guideline for Investigators Leaving the Institution*.

9. Requirements for Principal Investigators Conducting FDA Regulated Research When the RSRB is the Reviewing IRB

In addition to the requirements listed under Sections 6, 7 and 8 above, the following apply to Investigators conducting greater than minimal risk or minimal risk research regulated by the Food and Drug Administration (FDA):

9.1. Conduct the approved research in compliance with FDA regulations 21 CFR 56 and 21 CFR 50, as well as, 21 CFR 312 (drugs and biologics) and 21 CFR 812 (devices), as applicable.

9.1.1. Oversee the control of the investigational product (IP), ensuring the IP is dispensed/administered to enrolled subjects in accordance with the RSRB-approved protocol.

9.1.2. Conduct research involving an Investigational New Drug (IND), Investigational Device Exemption (IDE), or abbreviated IDE in compliance with *Policy 605 Research Involving FDA Regulated Drugs, Biologics, and Supplements* and *Policy 606 Research Involving FDA Regulated Devices*, as applicable.

9.2. Conduct the approved research according to the FDA "Guidance for Industry – Investigator Responsibilities" and the signed Form 1572, when applicable.

9.3. PIs may delegate responsibilities and functions of research activities to appropriately trained and capable research staff; however, the PI must document this delegation and must maintain all oversight responsibilities.

9.4. Maintain all study records consistent with 8.11 or for a longer term if required by FDA regulations.

9.5. Investigators with the role of sponsor-investigator will comply with the responsibilities and requirements for both the "Investigator" and "Sponsor" defined by the FDA [21 CFR 312] and FDA [21 CFR 812].

10. Requirements for Principal Investigators Conducting Multi-Site Research When the RSRB is the Reviewing IRB

In addition to the requirements listed under Sections 6, 8, and 9 above, the following apply to Investigators conducting greater than minimal risk or minimal risk multi-site research:

10.1. Ensure all Reliance Agreements are negotiated and executed (see *Policy 504 IRB Reliance and Collaborative Research*).

10.2. Include a plan for oversight of the non-UR sites in the protocol (see *Guideline for Principal Investigator Oversight For Multi-Site Research*), including, as applicable:
- 10.2.1. The specific research activities that will occur at each non-UR collaborating site(s).
- 10.2.2. Collection of institutional reviews.
- 10.2.3. Distribution of RSRB approved materials.
- 10.2.4. Protocol training for research staff prior to and throughout study conduct.
- 10.2.5. Ensuring compliance with the approved protocol, IRB determinations, policies, and guidelines, as applicable.
- 10.2.6. Submission of required information for reporting, progress reports, reportable events, and any other required documentation and information.

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Appendices:

None

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12/2017: Revised Common Rule (continuing review), Multi-site research, and editorial and administrative changes, addition of author

11/2019: Include posting on clinicaltrials.gov (section 8.3), requirement to document data and safety monitoring (8.7), and posting of consent forms (section 8.10); Update signatories

10/2023: Include requirements when PI is on disability; Remove annual update when no Continuing Review is required; Add only IRB-approved research staff conduct research; Confirm who can be PI on a not human subject or not engaged research determination; Additional Editorial and Administrative Changes, Update Signatories

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