POLICY

1. Purpose

This policy establishes the requirement to evaluate the:

- Scientific or scholarly soundness of the research design in minimizing risk to subjects; that risks to subjects are reasonable in relation to any anticipated benefits, if any; the importance of the knowledge that may reasonably be expected to result;
- Investigator qualifications; and;
- Availability of resources to conduct the research.

2. Scope

This policy applies to all human subject research (see *Guideline for Determining Human Subject Research*) conducted or supported by employees or agents of the University of Rochester (UR).

3. Definitions

3.1. Scientific Reviewer – The individual(s) designated by the leadership of the Principal Investigator's Center, Department, or School, or other delegated entity as allowed in this policy, who conducts the scientific review.

3.2. Human Subject – A living individual about whom an investigator (whether professional or student) conducting research:

3.2.1. Obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; **OR**

3.2.2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

3.3. Minimal Risk – The probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

3.4. Greater Than Minimal Risk – The probability and magnitude of harm or discomfort anticipated in the research are greater than those ordinarily encountered in everyday life or during the performance of routine physical or psychological examinations or tests.

4. References

4.1. Guideline for Determining Human Subject Research;
Guideline for Scientific and Resource Review of Human Subject Research;
University Policy on Faculty Conflict of Commitment and Interest

5. Responsibilities

5.1. The Investigator is responsible for providing a research protocol that contains sufficient information to meet the standards established by federal and state regulations and University policies (see RSRB Protocol Templates).

5.2. Each Department, Center, or School is responsible for ensuring completion of scientific review of the proposed research (see *Guideline for Scientific Review of Human Subject Research* regarding evaluation criteria and examples) and that documentation of such review is provided to the RSRB (the *Scientific and Resource Review Checklist* template may be used as documentation).

5.3. The RSRB is responsible for ensuring that documentation of scientific review is completed prior to initiating review of the protocol submission and to consider that scientific review during review of the protocol.

6. Requirements for Completing Scientific Review

6.1. Each Department, Center and School must develop a department-specific policy for conducting scientific review of human subject research protocols, which addresses, at minimum, an assessment of scientific merit, risks in relation to any potential benefits, and adequacy of resources. A copy of the policy must be provided to the RSRB office.

6.2. All human subject research must undergo internal scientific review by a departmental chairperson (or designee) within the primary scientific discipline relevant to the research.

6.2.1. Alternatively, scientific review requirements may be completed by an internal institutional research committee (e.g., Cancer Center Peer Review Committee, Neonatal Clinical Trials Group) or other external committee or review group (e.g., NCI CIRB), in which case no additional internal review is required.

6.2.2. Scientific review may be completed by more than one department, when necessary.

6.2.3. When the RSRB is the Reviewing IRB for multi-center research, documentation of scientific review for participating external sites will be waived.

6.3. The scientific reviewer must not have any identified potential conflict of interest (see *University Policy on Faculty Conflict of Commitment and Interest*)

6.4. The individual(s) completing the scientific review must be independent of the proposed study (i.e., not listed as a study team member).

6.5. Documentation of scientific review will be included within the study application of the IRB review system.

7. Requirements for Scientific Merit

7.1. The scientific reviewer must assess the scientific merit of the proposed research, which includes the following elements:

7.1.1. Background supports the purpose(s) of the proposed study;

7.1.2. The protocol provides a well-framed, testable hypothesis, secondary hypotheses, and/or well-framed study aims;

7.1.3. Study design and methods are adequate to test and validate the hypothesis and/or to achieve study aims;

7.1.4. A description of the statistical analysis plan that is adequate to test the hypothesis and/or achieve study aims;

7.1.5. A description of any societal benefits, as applicable.

8. Requirements for Risk Identification and Management

8.1. The scientific reviewer must assess the risks associated with the proposed research, as well as the balance of potential benefit to the potential risks to human subjects, to complement the regulatory charge of the Reviewing IRB. This assessment includes the following elements:

8.1.1. Foreseeable risks to research subjects are identified and described;

8.1.2. Reasonable means to mitigate risks are described; and,

8.1.3. Data and safety monitoring procedures are appropriate to the design, specific risks and risk level of the study, and are adequate to safeguard the rights and welfare of study subjects.

9. Requirements for Investigator Qualifications and Resources

9.1. The scientific reviewer must assess that the Investigator's qualifications and resources are adequate to conduct the research, which includes the following elements:

9.1.1. Adequacy of Investigator and the study team member's credentials and time to conduct the study;

9.1.2. Adequacy of institutional resources and facilities.

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Appendices:

None

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02/2015: Revised format of policy template consistent with Policy 101; Policy number assigned; Section 3 added the definitions from the appendix; Section 4 references added; Sections 5.1 and 5.3 responsibilities added; Sections 6, 7 and 8 formatted and revised; addition of Emily Flagg and Kelley O'Donoghue as Authors
11/2019: New policy title; Reorganization of definitions and update human subject definition, and creation of new section "6. Requirements for Completing Scientific Review"; administrative and editorial changes, update signatories

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11/12/19
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