POLICY

1. **Purpose**
   This policy establishes the core requirements for scientific review of protocols to ensure all proposed research has received an assessment of scientific merit, foreseeable risks to subjects, Investigator qualifications, and the availability of resources to conduct the research, prior to review of a new application by an Institutional Review Board (IRB).

2. **Scope**
   This policy applies to all human subject research conducted or supported by employees or agents of the University of Rochester (UR).

3. **Definitions**
   3.1. 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.
   
   3.2. Human Subject – A living individual about whom an investigator (whether professional or student) conducting research obtains:
   - Data through intervention or interaction with the individual, or
   - Identifiable private information
   
   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. Risk Category – Under the federal regulations, research is categorized as either “greater than minimal risk” or “minimal risk.” This category is based on the potential harm associated with the research that a reasonable person would likely consider to cause injury or discomfort.
   
   3.5. Scientific Reviewer – The individual(s) designated by the leadership of the Principal Investigator’s Center, Department, or School who conducts the scientific review. The individual who conducts scientific review may not be listed on the RSRB application under review to avoid any potential or perceived conflict of interest.
   
   3.6. Subject Engagement – Identifiable private information is acquired through intervention or interaction with the human subject.
3.7. No Subject Engagement – Identifiable private information is acquired without intervention or interaction with the human subject.

4. References
4.1. Policy 901 Investigator Responsibilities; Guideline for Scientific Review of Human Subject Research

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), and for obtaining scientific review of the proposed research, in accordance with Policy 901 Investigator Responsibilities.

5.2. Each Department, Center, or School is responsible for the following:
5.2.1. Establish a department-specific policy and procedure for conducting scientific review of human subject research protocols, inclusive, at minimum, of the core standards noted under Sections 6 – 8 (additional departmental requirements may be included);
5.2.2. Provide the RSRB with the policy;
5.2.3. Provide the scientific reviewer with sufficient resources to support scientific review;
5.2.4. Provide the scientific reviewer with any findings from related departmental reviews to ensure a robust assessment of Investigator qualifications;
5.2.5. Conduct scientific review prior to release of the protocol to the IRB for review (refer also to the Guideline for Scientific Review of Human Subject Research regarding detailed evaluation criteria for each core requirement); and,
5.2.6. Provide documentation of scientific review to the IRB within the RSRB On-line Submission System (ROSS). A Scientific Review Checklist template is provided in the Guideline for Scientific Review of Human Subject Research.

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

6. Requirements for Scientific Merit
6.1. The scientific reviewer must attest to the scientific merit of the proposed research, which includes the following elements:
6.1.1. Background supports the proposed study;
6.1.2. The protocol provides well-framed, testable hypotheses and/or well-framed study aims;
6.1.3. Study design and strategies are adequate to test the hypothesis and/or to achieve study aims;
6.1.4. The analysis plan and methods are adequate to test the hypothesis and/or achieve study aims;
6.1.5. The proposed research may provide societal benefits, as applicable.

7. Requirements for Risk Identification and Management
7.1. The scientific reviewer must assess risk to complement the regulatory charge of the IRB, which includes assessment of the balance of potential benefit to potential risk to human subjects:
7.1.1. Foreseeable risks to research subjects have been identified and described;
7.1.2. Reasonable means to mitigate risks have been employed; and
7.1.3. 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.

8. Requirements for Investigator Qualifications and Resources
8.1. The scientific reviewer must assess that the Investigator’s qualifications and resources are adequate to conduct the research, and in doing so must concur with the following:
8.1.1. The Investigator’s study team has the necessary skills, training, appropriate credentialing to perform procedures or testing, and experience to conduct the research as written in the protocol;
8.1.2. The Investigator has adequate time and resources to conduct the research, including any study treatments and/or data collection strategies;
8.1.3. The Investigator has a process to ensure adequate training and supervision of the study team.
<table>
<thead>
<tr>
<th>University of Rochester</th>
<th>Office for Human Subject Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Research Subjects Review Board</td>
</tr>
<tr>
<td></td>
<td>Effective Date: 02/06/2015</td>
</tr>
<tr>
<td></td>
<td>Scientific Review Standards</td>
</tr>
<tr>
<td></td>
<td>Policy 505</td>
</tr>
<tr>
<td></td>
<td>Version: 2.0</td>
</tr>
</tbody>
</table>

**Originator/Authors:**
- Eric Rubinstein, CTSI Executive Director for Research Services
- Tiffany Gommel, Director, RSRB
- Emily Flagg, Senior Regulatory Specialist
- Kelley O’Donoghue, Director, OHSP

**Appendices:**
None

**Revision History:**
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 (02/15)

**Supersedes Date:**
01/01/2013

**Approved By:**

<table>
<thead>
<tr>
<th>Kelley A. O'Donoghue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Director, OHSP</td>
</tr>
<tr>
<td>2/9/2015</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tiffany L. Gommel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Director, RSRB</td>
</tr>
<tr>
<td>2/9/2015</td>
</tr>
</tbody>
</table>

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.