# POLICY

## 1. Purpose

Describe the criteria for approval of research projects that will be followed by the Research Subjects Review Board (RSRB) when the RSRB is the Reviewing IRB.

## 2. Scope

This policy applies to all review boards, board Chairs/Vice Chairs and RSRB members.

## 3. Definitions

3.1. *Research Risk* – The probability of harm or injury occurring as a result of participation in a research study. The type of the risk/s (physical, psychological, social, legal, or economic) as well as probability and magnitude are variables that determine the overall risk exposure.

3.2. *Minimal Risk* – The probability and magnitude of harm or discomfort anticipated in the proposed 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. [HHS 45 CFR 46.102(j); FDA 21 CFR 50.3(k)]

3.2.1. For research involving prisoners, the definition is modified by a restriction to the daily lives of healthy (non-incarcerated) persons. [HHS 45 CFR 46.303(d)]

## 4. References

4.1. HHS 45 CFR 46.102(j); FDA 21 CFR 50.3(k); HHS 45 CFR 46.111; FDA 21 CFR 56.111; HHS 45 CFR 46.303(d); HHS 45 CFR 46 subparts B, C, and D

4.2. Policy 503 Ancillary Committee Reviews;
Policy 504 IRB Reliance and Collaborative Research;
Policy 505 Scientific Review of Research;
Policy 506 Data & Safety Monitoring;
Policies 601 – 606 Reviews Requiring Special Consideration;
Policy 604 Research Involving Adults with Decisional Impairment;
Policy 701 Informed Consent;
Policy 702 HIPAA Privacy Rule

## 5. Responsibilities

The RSRB is responsible for determining that the requirements of HHS 45 CFR 46.111 and, when applicable, FDA 21 CFR 56.111, are satisfied when approving research (initial or continuing review) or modifications to approved research.

## 6. Requirements

6.1. The RSRB will review the project application, protocol, consent form(s), recruitment material(s) and all other related protocol materials, for initial and continuing review or

modifications to approved research, to determine that the regulatory requirements for approval of research are met.

6.2. The RSRB must apply the criteria for IRB approval of research according to HHS 45 CFR 46.111 and FDA 21 CFR 56.111, as applicable:

A) In order to approve research, the RSRB must determine that all of the following requirements are met:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed in non-research activities, e.g., for educational, diagnostic, or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the RSRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The RSRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

- Risk/Benefit Assessment – The RSRB will consider the range of risks identified below in Section 6.1.1 when assessing whether research risks identified in the protocol have been minimized to the extent possible. The RSRB may identify additional risks and require that the Investigator develop a plan to minimize those risks. The RSRB will consider whether a study's research design maximizes any potential benefits and determine whether exposure to a study's risks is justifiable when considered in relation to any potential benefits. When no direct benefits to the subject are anticipated, the RSRB must evaluate whether the risks presented by procedures performed solely to obtain generalizable knowledge are ethically acceptable.

(3) Selection of subjects is equitable. In making this assessment the RSRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, individuals with impaired decision making capacity, or economically or educationally disadvantaged persons. This assessment will take into account the purposes of the research, the setting in which the research is conducted, the inclusion/exclusion criteria, the

recruitment/enrollment procedures, and subject payments for participation (if applicable).

- Equitable Selection of Subjects – The RSRB will consider whether there is fairness in distribution of any risk and benefit across the study population, is reflected in the composition of the proposed study population(s) in terms of age, sex, social group, and physical or psychological condition. The RSRB will consider whether the protocol adequately describes and provides rationale for inclusion of the proposed population (or exclusion of a population if applicable).

(4) Informed consent will be sought from each prospective subject, or the subject's authorized representative, in accordance with and to the extent required by federal regulations and institutional policies.

(5) Informed consent will be appropriately documented, or appropriately waived, in accordance with and to the extent required by federal regulations and institutional policies.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

- *Privacy* is defined as having the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. RSRB application materials must adequately describe proposed access to subject information and how the privacy of subjects will be protected. If the Investigator is part of a covered entity, additional privacy protections are required under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (*Policy 702 HIPAA Privacy Rule*).

- *Confidentiality* is the process or method for ensuring that information collected from a subject is protected from inadvertent disclosure to persons/entities not authorized to have access to such information. It pertains to handling information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the original disclosure. When information linked to individuals will be recorded as part of the research design, the RSRB will consider whether the Investigator has described adequate precautions to safeguard the confidentiality of that information. In making this assessment, the RSRB will consider the type,

probability, and magnitude of harms that would likely result from a disclosure of confidential information obtained through the research to unauthorized individuals or organizations.

(8) When conducting limited IRB review required for storage or maintenance for secondary research for which broad consent is required [45 CFR 46.104(d)(7)], the RSRB need not make the review determinations required under (A)(1) through (A)(7) above, rather, the following determinations shall apply:

i. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of 45 CFR 46.116(a)(1)–(4), (a)(6), and (d);

ii. Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with 45 CFR 46.117; and

iii. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

B) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

6.2.1. Research Involving Vulnerable Populations – The RSRB will consider whether adequate provisions have been made to protect the safety, rights, and welfare of the subjects and to minimize research risks unique to the population.

- Examples of mechanisms for additional protective provisions may include, but are not limited to, use of: consent process witness; ombudsman/advocate oversight; "time-out" before signature; non-research team member as person obtaining consent.

6.2.1.1. Should additional expertise or knowledge be required beyond that of the Chair or board members when a research project involves a population requiring special protections, the Chair may request a consultant. In its review, the RSRB shall consider:

- Whether the inclusion of that population is justified.
- The ability of subjects to provide voluntary informed consent.
- Whether adequate safeguards are provided for risks unique to that population.
- The regulatory requirements specific to the vulnerable population/group, if any.

6.2.1.2. For federally-funded research under 45 CFR 46 subparts B (research involving pregnant women, fetuses, neonates), C (prisoners), and D (children), the RSRB follows the regulatory criteria for approval for such research to determine whether adequate safeguards are in place to protect the specific subject group. Although federal regulations identify special protections only for specified populations, each project reviewed by the RSRB is evaluated for populations and circumstances that may place subjects in vulnerable situations (coercion or undue influence) that call for special consideration. (For additional information *see Policies 601 – 606 for reviews requiring special consideration*.)

6.2.2. Research Risks – The RSRB shall identify potential risks to human subjects, both physical and non-physical, associated with the research project under review. The following are examples of types of risks that should be considered:

- **Physical:** Physical risks involve the potential for physical discomfort, pain, injury, illness or disease brought on as a result of methods or procedures involved in the research. These risks to subjects cover a wide range and may be minor and transient or may hold the prospect of permanent injury or death. Risk of physical harm caused to the subject by another person may also be considered.
- **Psychological:** Psychological risks involve the potential for undesired changes in thought processes and emotion including embarrassment or episodes of depression and confusion resulting from feelings of stress, guilt, or loss of self-esteem. These effects are usually, but not always, transient. Psychological effects may be experienced at the time of research participation or later, after participation.
- **Social:** Social risks involve the potential for stigmatization to the subject or others, or loss of respect of others within a social group or place of employment.
- **Legal:** Legal risks involve the potential for putting the subject or others at risk of civil liability or criminal prosecution if information collected as part of the research is revealed.
- **Economic:** Economic risks include the potential for the subject or others to lose employment or the ability to work due to stigmatizations, psychological or physical injury as a result of participation in the research. Less severe economic risks include loss of wages and failure of medical insurance companies to cover costs for participation in research.
- **Invasion of Privacy:** Risk associated with the invasion of privacy involves the intrusion of the research into information or behavior that the subject considers to be private, without their knowledge and consent. Invasions of privacy have the potential for placing the subject at psychological, social, economic, and legal risk as described above.

- **Breach of Confidentiality:** Breaches of confidentiality due to inadequate safeguarding of information that has been voluntarily given by one person to another have the potential for placing the subject at psychological, social, economic, and legal risk as described above.

6.2.3. Minimal Risk or Greater Than Minimal Risk – Once risks have been identified, the RSRB shall determine whether the research risks to subjects are minimal risk or greater than minimal risk.

6.2.4. Sound Research Design/Scientific Validity – The RSRB will conduct a general assessment of the project's research design; however, the primary responsibility for this assessment belongs to the submitting Principal Investigator's department (or as delegated), according to OHSP *Policy 505 Scientific Review Standards*, by considering the purpose of the research, scientific design, data analysis, qualifications of the research personnel, and adequacy of resources to conduct the research.

6.3. When conducting limited IRB review, the RSRB need not make the review determinations required under (A)(1) through (A)(7) above, rather:

6.3.1. For exempt categories 45 CFR 46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), the IRB conducts a limited IRB review to make the determination required by §__.111(a)(7).

6.3.2. For storage or maintenance for secondary research for which broad consent is required [45 CFR 46.104(d)(7)], the following determinations shall apply:

6.3.2.1. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of 45 CFR 46.116(a)(1)–(4), (a)(6), and (d);

6.3.2.2. Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with 45 CFR 46.117; and

6.3.2.3. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

6.4. The RSRB will assess the Investigator's description of the consent process as part of the review. In order for the RSRB to approve the project, the RSRB must determine whether the Investigator will obtain the legally effective consent of the subject or the subject's authorized representative. For additional information, see *Policy 701 Informed Consent Process* and *Policy 604 Research Involving Adults with Decisional Impairment*.

6.5. The RSRB will consider the Investigator's plan for collection, monitoring, storage, and analysis of data. The level of monitoring required is related to the degree of risk posed by the research (*Policy 506 Data & Safety Monitoring*).

6.6. The RSRB will review the submitted documents to evaluate whether the research plan has adequate provisions in place to protect subject's privacy and to maintain the confidentiality of the subject's data.

6.7. The designated University of Rochester oversight/ancillary committee will review and approve research projects, as required by the submitting Investigator's department and resources used by the project (*Policy 503 Ancillary Committee Reviews*).

6.8. When the University of Rochester relies on an external IRB, the requirements regarding IRB criteria for approval of research must be determined by the Reviewing IRB. The RSRB will conduct an institutional review to ensure compliance with institutional requirements. See *Policy 504 IRB Reliance and Collaborative Research*.

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**Appendices:**

None

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02/2016: Sect 4.2 hyperlinks added; Sect 6.5.1-6.5.9 replaced with reference to policy; editorial changes
01/2018: Sect 1 Reviewing IRB language added; Sect 2 Vice Chair added; Sect 4.2 references added; Sect 6.3 Policy 604 reference added; Sect 6.7 regarding IRB reliance added; editorial and administrative changes.
01/2019: Sect 6.2(A)(3) and (8) and Sect 6.3 revisions for the Common Rule pertaining to limited IRB review; editorial changes; remove T. Gommel as signatory
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**Approved By:**

Kelley A. O'Donoghue

Kelley A. O'Donoghue
Director, OHSP

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Date