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| University of Rochester | Office for Human Subject Protection | | |
| | Research Subjects Review Board | Effective Date: 12/10/2021 | |
| | RSRB Membership and Composition | Policy 302 | Version: 1.5 |

POLICY

1. Purpose

Describe the composition of the Research Subjects Review Board (RSRB), as well as the roles and responsibilities of the RSRB membership.

2. Scope

This policy applies to all members, administrators, and consultants of the Research Subjects Review Board.

3. Definitions

- 3.1. Board Chair/Vice Chair – An individual with relevant scientific/clinical background and expertise in research methods who is appointed by the Institutional Official to lead convened meetings and conduct administrative duties required for a successful operation of the Board.
- 3.2. Acting Board Chair – An individual with relevant scientific/clinical background and expertise in research methods who is named by the Chair and/or the RSRB Director, to lead convened meetings and conduct specific administrative duties in the absence of the Chair. This individual must be an experienced board member in order to fulfill this role.
- 3.3. Experienced Board Member – A member, as determined by the Chair, who has demonstrated during a period of active participation, a broad understanding and competency with human subject protection ethics, board operations, and regulatory requirements, including expedited and limited IRB review procedures.
- 3.4. Alternate Board Member – A member formally appointed and listed in the membership roster who may substitute for a primary member with whom the alternate has similar qualifications. Experienced members may be asked to continue as alternates when their terms expire or when their workload prevents them from carrying out their duties.
- 3.5. Consultant – An individual who may be requested to provide additional scientific and/or specialty expertise to the board as necessary. Consultants are not permissible as voting members.
- 3.6. Prisoner Representative – A member formally appointed and listed in the membership roster who has the appropriate background, experience and working knowledge to provide an understanding and appreciation of prison conditions from the prisoner's perspective.

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|--|--|--|-----------------------------------|
| University of Rochester | Office for Human Subject Protection | | |
| | Research Subjects Review Board | | Effective Date: 12/10/2021 |
| | RSRB Membership and Composition | | Policy 302 |
| | | | Version: 1.5 |

4. References

- 4.1. HHS 45 CFR 46.107; HHS 45 CFR 46.303(c); HHS 45 CFR 46.304; FDA 21 CFR 56.107
- 4.2. [Policy 201 Education Program](#)
[Policy 401 Functions of the RSRB Office](#);
[Policy 501 Levels of RSRB Review](#);
[Policy 504 IRB Reliance and Collaborative Research](#);
[Policy 802 Non-Compliance](#)
- 4.3. [Guideline for Board Member Terms of Appointment](#)

5. Responsibilities

- 5.1. The RSRB is responsible for serving the research community at the University of Rochester, and collaborating with unaffiliated institutions, in the processing, review, and approval of research activities. The determination of which board will be responsible for project review is based on the department of the submitting PI, the nature of the research, and the prospective subject population (*Policy 401 Functions of the RSRB Office*).
 - 5.1.1. The RSRB has five internal review boards, including three biomedical boards, an HIV/AIDS and oncology board, and a behavioral and social sciences board.
 - 5.1.2. In addition, the RSRB defers to external IRBs and acts as the Relying IRB as per *Policy 504 IRB Reliance and Collaborative Research*.
 - 5.1.3. RSRB board members are responsible for review determinations when limited IRB review is a condition for exemption (*Policy 501 Levels of RSRB Review*).
 - 5.1.4. There are designated RSRB staff members responsible for review and determination of exemption requests (*Policy 501 Levels of RSRB Review*).
- 5.2. The OHSP Director and RSRB Director are responsible for recommending to the Institutional Official (IO) individuals to serve as Board Chairs and Vice Chairs.
 - 5.2.1. Because the successful operation of the Board is critical to the Human Research Protection Program, the Chair/Vice Chair should possess:
 - 5.2.1.1. A broad knowledge regarding regulations for the protection of human research subjects, and the ability to apply these regulations consistently and appropriately.
 - 5.2.1.2. A commitment to devoting sufficient time to ensure an efficient RSRB review process.
 - 5.2.1.3. The ability to maintain a constructive, productive atmosphere at RSRB meetings.
 - 5.2.1.4. The ability to maintain productive working relations with the RSRB office staff.
 - 5.2.1.5. A commitment to maintaining a current knowledge of the human subject protection process.

| | | | |
|--|--|--|-----------------------------------|
| University of Rochester | Office for Human Subject Protection | | |
| | Research Subjects Review Board | | Effective Date: 12/10/2021 |
| | RSRB Membership and Composition | | Policy 302 |
| | | | Version: 1.5 |

- 5.3. The OHSP Director and the RSRB Director, in consultation with the respective Board Chair/Vice Chair, are responsible for identifying and recommending board member appointment and re-appointment to the IO.
- 5.3.1. The OHSP or the RSRB Director may request a representative from the Chair of a department that submits a high volume of studies.
- 5.3.2. An individual may express interest in board membership (self-nomination).
- 5.3.3. An individual may be referred by RSRB members, RSRB office staff, or OHSP staff.
- 5.3.4. Appointments of alternate members may be made in the same manner and for the same terms as primary members.
- 5.3.5. Selection of RSRB members by research investigators is not permitted.
- 5.4. The **Board Chair** (as well as the Vice Chair as a supportive role to each Chair) is responsible for overseeing RSRB review of research when the RSRB is the Reviewing IRB, including but not limited to the following:
- 5.4.1. Apply the basic ethical principles of respect for persons, beneficence and justice as articulated in the Belmont Report.
- 5.4.2. Uphold federal, state, and local regulations, University policies and procedures and with regard to the protection of human research subjects.
- 5.4.3. Be knowledgeable about, and have understanding of, ethical issues, federal research regulations, applicable state law, and Institutional policies.
- 5.4.4. Involvement as needed in discussions with federal authorities.
- 5.4.5. Promote a culture consistent with the objectives of the University of Rochester's Human Research Protection Program (HRPP), with special emphasis on the respect for and protection of individuals participating in research
- 5.4.6. Identify the expertise needed to comprise the RSRB and recommend potential members.
- 5.4.7. Direct the discussion and proceedings of the full-committee meetings, with the assistance of the RSRB Specialist, to keep discussion focused on the established agenda and ensure that guidelines for meeting procedures are followed.
- 5.4.8. Review protocols submitted for initial and continuing reviews as well as any amendments submitted.
- 5.4.9. Conduct review of research qualifying for exemption, as needed or as requested by RSRB staff.
- 5.4.10. Review projects that qualify for limited IRB review (this task may be delegated to an experienced board member).
- 5.4.11. Review projects that qualify as expedited (this task may be delegated to an experienced board member).
- 5.4.12. Review reportable events and take appropriate action as needed. This includes the authority of the Chair to take immediate action to suspend approval of a research project in order to protect research subjects from serious risks.

| | | | |
|--|--|--|-----------------------------------|
| University of Rochester | Office for Human Subject Protection | | |
| | Research Subjects Review Board | | Effective Date: 12/10/2021 |
| | RSRB Membership and Composition | | Policy 302 |
| | | | Version: 1.5 |

- 5.4.13. Ensure prompt reporting to the RSRB, institutional officials, and others, as needed, regarding research related events/problems, serious or continuing non-compliance with UR HRPP policy or the requirements or determinations of the RSRB, and any suspension or termination of RSRB approval.
 - 5.4.14. Determine if a consultant is needed to supplement the expertise of the RSRB (this task may be delegated to another member or RSRB staff, based on expertise and experience).
 - 5.4.15. Vote at full board meetings.
 - 5.4.16. Participate in the investigation of suspected non-compliance and the development of a plan of action to address the non-compliance.
 - 5.4.17. Designate individuals who have the expertise and experience to review protocols as sole designee for expedited reviews based on their experience with human subject research activities, credentials, and their experience reviewing protocols.
- 5.5. **RSRB members** are responsible for determining that the rights and welfare of human subjects in research are adequately protected, including but not limited to the following actions:
- 5.5.1. Apply his or her particular expertise, as well as the basic ethical principles of respect for persons, beneficence and justice as articulated in the Belmont Report, to the review of research.
 - 5.5.2. Be familiar with specific human subject protection regulations including HHS 45 Code of Federal Regulations 46 and its subparts and FDA 21 Code of Federal Regulations Parts 50, 56, 312, and 812.
 - 5.5.3. Conduct reviews as requested by the Chair/Vice Chair/RSRB staff member and provide feedback on all assigned review materials.
 - 5.5.3.1. A “primary reviewer” is responsible to review all the materials provided to the board and to lead the discussion and/or introduce the study at the convened meeting.
 - 5.5.3.2. An experienced board member may conduct reviews using the expedited procedure, as well as reviews requiring limited IRB review.
 - 5.5.4. Communicate directly with investigators and meet with them and study team as needed to advise on research and human subject protections.
 - 5.5.5. Prepare for and actively participate in board meetings.
 - 5.5.6. Meet HRPP education requirements (initial or continuing, as appropriate) according to *Policy 201 Education Program*.
 - 5.5.7. Report to the RSRB Director any perceived allegations of undue influence on the actions of RSRB members (*Policy 802 Non-Compliance*).
- 5.6. **Alternate RSRB members** will apply all the responsibilities of regular members when called upon by the RSRB Director (or designee) to serve at a convened committee meeting. The alternate member receives and reviews the same material that the primary member would have received. Alternates may be designated as a replacement for a

| | | | |
|--|--|--|-----------------------------------|
| University of Rochester | Office for Human Subject Protection | | |
| | Research Subjects Review Board | | Effective Date: 12/10/2021 |
| | RSRB Membership and Composition | | Policy 302 |
| | | | Version: 1.5 |

specific member with particular expertise or may be appointed for their general area of competency. Alternate members may attend any or all RSRB meetings, but may only vote and exercise the privileges of a primary member at such meetings when they are expressly substituting for an absent primary member. Any member of a board can be an alternate on any of the other boards as long as he/she is an appropriate alternate based upon affiliation, scientific status, and specialty.

- 5.6.1. If both the designated alternate and the regular member attend the same meeting, only the regular member may vote.
- 5.6.2. When an alternate member is used, the minutes will reflect who the alternate member is replacing.

5.7. **Consultants** are responsible for providing additional expertise that may be needed for reviewing a specific study as may pertain to his/her qualifications, scientific knowledge and ability to evaluate potential ethical concerns inherent to the study, potential risks or benefits of the study procedures, or concerns relative to the study population particularly when vulnerable subjects are involved.

5.8. The IO, in consultation with the OHSP Director and RSRB Director, may act to remove a member of the RSRB, including a Board Chair/Vice Chair, before the end of his/her term. This may occur if his/her participation in RSRB activities is deemed to be inadequate, inappropriate, or damaging to the reputation of the University and its research activities.

- 5.8.1. Removal of an RSRB member from service may occur under the concurrence of the RSRB Director and OHSP Director only.
- 5.8.2. Removal of an RSRB Chair/Vice Chair requires the concurrence of the IO and the OHSP Director and RSRB Director.
- 5.8.3. Members cannot be removed from RSRB because of their voting record, or in an attempt to alter the RSRB's membership for purposes of obtaining approval for a certain protocol or class of protocols.

6. Requirements

6.1. Research Subject Review Board Membership Composition

6.1.1. The membership of the RSRBs shall comply with federal regulations regarding membership composition [HHS 45 CFR 46.107; HHS 45 CFR 46.304; FDA 21 CFR 56.107] as follows:

- 6.1.1.1. Each RSRB shall be composed of at least five members who are qualified through their experience, expertise (i.e., professional competence), and diversity including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to review research projects in terms of regulations, ethical principles, applicable laws, standards of professional conduct and practice, and Institutional commitment.

| | | | |
|--|--|--|-----------------------------------|
| University of Rochester | Office for Human Subject Protection | | |
| | Research Subjects Review Board | | Effective Date: 12/10/2021 |
| | RSRB Membership and Composition | | Policy 302 |
| | | | Version: 1.5 |

- 6.1.1.2. Each RSRB shall consist of members of various professions including at least one scientist, one non-scientist, and one member who is not otherwise affiliated with the Institution (e.g., a community member), and who is not part of the immediate family of a person who is affiliated with the institution.
- 6.1.1.3. No RSRB shall consist entirely of men or entirely of women.
- 6.1.1.4. No RSRB shall consist entirely of members of one profession.
- 6.1.1.5. Each RSRB shall include representatives who represent the perspective of research subjects, as well as those who are knowledgeable about and experienced in working with populations that are vulnerable to coercion or undue influence such as children, prisoners, pregnant women, individuals with decisional impairment, or economically or educationally disadvantaged persons, if research involving such populations is regularly reviewed by that board. This information is documented using the *RSRB Board Member Representative Capacity* form (Appendix 7).
- 6.1.1.6. Each RSRB may include representation from affiliated institutions as appropriate.
- 6.1.1.7. No RSRB shall consist of members (or alternates) who are responsible for business development of the organization, nor should these individuals carry out any day-to-day operations of the review process (e.g., Institutional Official, Senior VP for Research, Vice Provost for Research).

- 6.1.2. New members are appointed for an initial term of one year at which time members are evaluated for continued service. Members will also be evaluated prior to the end of each subsequent term of service and Chairs/Vice Chairs will be evaluated on an annual basis to determine ongoing membership (see *Guideline for Board Member Terms of Appointment*). Members receive an appointment letter (see Appendix 2) to confirm membership on the RSRB and a re-appointment letter (see Appendix 3) to confirm continued service. Members are also acknowledged in writing at the end of their service as a board member (see Appendix 4).

- 6.1.3. Names and qualifications of board members, including changes in membership, are maintained in membership rosters as required by OHRP (Appendix 5).
 - 6.1.3.1. Information will be maintained by the RSRB office to document member expertise with vulnerable populations and representation by community members.
 - 6.1.3.2. The RSRB will not disclose its membership to researchers or sponsors ([Request for RSRB Membership Information](#)).
 - 6.1.3.3. Board members will be indemnified by the University for actions taken within the scope of duties as members of the RSRB. Indemnification is expressly extended to non-affiliated members of the RSRB while they are performing the duties of an RSRB member.

| | | | |
|--|--|-----------------------------------|---------------------|
| University of Rochester | Office for Human Subject Protection | | |
| | Research Subjects Review Board | Effective Date: 12/10/2021 | |
| | RSRB Membership and Composition | Policy 302 | Version: 1.5 |

6.2. Consultants

- 6.2.1. The Director of OHSP, Director of RSRB, or the board may determine whether additional expertise from an outside reviewer is required for the review of a particular protocol. Consultants may be from within the University or outside the institution.
- 6.2.2. Prior to receipt of review materials, the consultant will review and sign the Confidentiality Agreement for Consultants (Appendix 6).
- 6.2.3. The consultant will be provided documents relevant to the requested consultation and is expected to make recommendations regarding the study. Reviews provided in writing will be included in the meeting materials provided to board members.
- 6.2.4. If invited to attend the board meeting, consultant reviewer may participate in the deliberations, but may not vote.
- 6.2.5. Meeting minutes will document attendance of a consultant at board meetings as “guest”, indicate the specific study(ies) the consultant is reviewing, state any potential conflicting interests that may exist for the consultant, and capture any key information provided by the consultants.

6.3. Member Representation for Review of Vulnerable Populations

- 6.3.1. A prisoner representative with appropriate background and experience is assigned to each internal board to participate in the review of research involving incarcerated individuals. The prisoner representative will be appointed to the board in the same fashion as primary members.
- 6.3.2. A special board including the prisoner representative will meet to consider initial and continuing reviews of, as well as modifications to, research involving incarcerated individuals. The prisoner representative may assist with the review as an additional primary reviewer, and/or provide specific information related to the prisoner population. For federally funded research, these reviews will apply to either pre-planned or subsequent involvement of prisoners in the research. For all other research, the special board will review studies that intend to involve prisoners (per inclusion criteria), but will not be required to re-review previously approved studies that enroll a prisoner as an incidental subject (e.g., general population clinical trial for which a prisoner is eligible, or a general population study where an enrolled subject subsequently becomes incarcerated). The RSRB Chair/Vice Chair and staff may refer such studies to either the special board or to the prisoner representative for review if circumstances warrant. When the special RSRB reviews research that involves prisoners, a majority of the board (exclusive of the prisoner representative) will have no association with the prison(s) involved, apart from their membership on the RSRB.

| | | | |
|--|--|--|-----------------------------------|
| University of Rochester | Office for Human Subject Protection | | |
| | Research Subjects Review Board | | Effective Date: 12/10/2021 |
| | RSRB Membership and Composition | | Policy 302 |
| | | | Version: 1.5 |

6.3.3. Research involving children will be reviewed by a board that contains members with appropriate background and experience relevant to the research.

6.4. Initial Training and Education of RSRB of Prospective and New Members

6.4.1. Prospective members are provided with reference materials and meet with the RSRB Director to discuss the expectations of board membership and to assess qualifications.

6.4.1.1. The prospective member then will undergo regulatory training with the OHSP Director, or designee with appropriate regulatory experience and knowledge. This training provides an overview of human subject protection issues, including laws, federal regulations and ethical principles.

6.4.1.2. Additional training is provided by the Chair and Specialist of the Board to which the new member is assigned. This process provides further preparation in RSRB policies and procedures, how the meetings are conducted and how protocols are reviewed with the option to attend a meeting as a non-voting member.

6.4.1.3. Prospective members must also successfully complete the University's human subjects training program according to *Policy 201 Education Program*.

6.4.1.4. Completion of initial training is documented to verify that all elements have been covered prior to appointment.

6.4.2. New members may serve as primary reviewers at the Chair's discretion. The Chair, or another experienced reviewer, will support the new member in his/her first review as needed.

6.5. Ongoing Training and Education of RSRB Members

6.5.1. The Board Member Resources on the OHSP website provides members an area to access articles of interest, presentations from previous meetings, board meeting materials.

6.5.2. Ongoing interactions at meetings and individual discussions with staff, Chairs and members, as well as email communications distributed by OHSP or RSRB staff.

6.5.3. Attendance at university-sanctioned events pertaining to human subject protection, such as presentations or audio conferences.

6.5.4. Brief educational presentations during board meetings.

6.5.5. Attendance at the All Boards meeting or other training meetings provided through OHSP.

6.5.6. Attendance at the annual PRIM&R, or other national meetings, as selected.

| | | | |
|--|--|--|-----------------------------------|
| University of Rochester | Office for Human Subject Protection | | |
| | Research Subjects Review Board | | Effective Date: 12/10/2021 |
| | RSRB Membership and Composition | | Policy 302 |
| | | | Version: 1.5 |

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Appendices:

- Appendix 1: Board Member Appointment Template
- Appendix 2: Board Member Re-Appointment Template
- Appendix 3: RSRB Member and Alternate Member Roster Templates
- Appendix 4: Confidentiality Agreement for Consultants Template
- Appendix 5: RSRB Board Member Representative Capacity Template

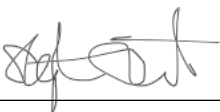
Revision History:

- 11/2014: Section 6.1.1.6 Add board member form; Appendix 6 update roster template; Add Appendix 8
- 01/2015: Add Sect 6.1.1.8 per AAHRPP
- 01/2018: Sect 3.1 add Vice Chair as member role and added throughout; Sect 4.2 add hyperlinks to references; Sect 5.1 reformatted with addition of 5.1.2 and language for Relying IRB; Sect 5.5.3.2 added; Appendix 6 current sample roster included; editorial changes
- 01/2019: Sect 3.3 added language for limited IRB review; Sect 5.1.3 and Sect 5.4.10 added re: limited IRB review; Sect 5.5.3.2 added language for limited IRB review; deleted Sect 6.1.3.2 requirement for reporting roster changes; additional editorial changes; Signatories change in IO and remove T. Gommel
- 08/2021: Sect 5.4.16 removed; additional editorial changes; updates to authors, Signatories and Appendices

Supersedes Date:

01/21/2019


Approved By:



Steve Dewhurst
Institutional Official, Vice President for Research

12/16/2021

Date



Kelley A. O'Donoghue
Director, OHSP

12/10/2021

Date

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|--|--|-----------------------------------|---------------------|
| University of Rochester | Office for Human Subject Protection | | |
| | Research Subjects Review Board | Effective Date: 12/10/2021 | |
| | RSRB Membership and Composition | Policy 302 | Version: 1.5 |

Appendix 1: Board Member Appointment Template

OFFICE FOR HUMAN SUBJECT PROTECTION

Research Subjects Review Board



Date

Name

Address

Dear Name:

It is my pleasure to appoint you as a scientific / non-scientific / community member of the Research Subjects Review Board for a one-year term effective Date.

I appreciate your willingness to serve the University in this capacity and I thank you for your contributions.

Sincerely yours,

Stephen Dewhurst, PhD
Vice President for Research & Institutional Official

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|--|--|-----------------------------------|---------------------|
| University of Rochester | Office for Human Subject Protection | | |
| | Research Subjects Review Board | Effective Date: 12/10/2021 | |
| | RSRB Membership and Composition | Policy 302 | Version: 1.5 |

Appendix 2: Board Member Re-Appointment Template

OFFICE FOR HUMAN SUBJECT PROTECTION

Research Subjects Review Board



DATE

Name

Address

Dear **Name**:

It is my pleasure to reappoint you as a **scientific/non-scientific/community member** of the Research Subjects Review Board for a **(years)** term effective **(date)**.

I appreciate your participation as a board member and want to thank you for your **(years)** years of service to the University of Rochester RSRB. I thank you for your continued contribution.

Sincerely yours,

Stephen Dewhurst, PhD
Vice President for Research & Institutional Official

| | | | |
|--|--|--|-----------------------------------|
| University of Rochester | Office for Human Subject Protection | | |
| | Research Subjects Review Board | | Effective Date: 12/10/2021 |
| | RSRB Membership and Composition | | Policy 302 |
| | | | Version: 1.5 |

Appendix 3: RSRB Member and Alternate Member Roster Templates

[Month / Year]

University of Rochester
IRB Registration
Board 0X - IRBREG#
Board 0XP - IRBREG#

| Member Name | Gender (M/F) | Earned Degree(s) | Scientific/ Non-Scientific | Primary Specialty [^] | Affiliation Status | Appt. Date |
|--------------------------|--------------|------------------|----------------------------|--------------------------------|--------------------|------------|
| [Last Name, First Name] | | | S | Psychology | Full-time Faculty | |
| [Last Name, First Name] | | | S | Obstetric/Gynecology | Part-time Faculty | |
| [Last Name, First Name]* | | | S | Surgery | Full-time Faculty | |
| [Last Name, First Name] | | | NS | Social Work / Criminal Justice | No Affiliation | |
| [Last Name, First Name] | | | S | Pharmacy | Full-time Faculty | |

ANY MEMBER OF BOARD 01 CAN BE AN ALTERNATE ON ANY OF THE OTHER BOARDS (2, 3, 4 OR 5) AS LONG AS THEY ARE AN APPROPRIATE ALTERNATE BASED UPON AFFILIATION, SCIENTIFIC STATUS AND SPECIALTY

KEY

* = Chair

= Vice Chair

** = Acting Chair

*** = Prisoner Representative (note all other board members are included on Board 0X and Board 0XP)

[^] = For representative capacity and experience description, see the RSRB Member Representation Form on file.

No Affiliation = Neither the member nor any of the member's immediate family member are affiliated with the institution

HHS Assurance No. FWA00009386

[Month / Year]

University of Rochester
IRB Registration
Alternate Members for all University of Rochester RSRBs

| Member Name | Boards to be Assigned | Gender (M/F) | Earned Degree(s) | Scientific/ Non-Scientific | Primary Specialty [^] | Affiliation Status | Comments |
|---------------------------|-----------------------|--------------|------------------|----------------------------|-----------------------------------|--------------------|----------|
| [Last Name, First Name] | [LIST BOARDS] | | | NS | Administration | Full-time Staff | |
| [Last Name, First Name] | | | | S | Law | Full-time Staff | |
| [Last Name, First Name]** | | | | S | Pediatric Medicine and Genetics | Full-time Faculty | |
| [Last Name, First Name] | | | | NS | Special Education | No Affiliation | |
| [Last Name, First Name] | | | | S | Neurology, Community & Prev. Med. | Full-time Faculty | |

KEY

** = Acting Chair

[^] = For representative capacity and experience description, see the RSRB Member Representation Form on file.

| | | | |
|--|--|-----------------------------------|---------------------|
| University of Rochester | Office for Human Subject Protection | | |
| | Research Subjects Review Board | Effective Date: 12/10/2021 | |
| | RSRB Membership and Composition | Policy 302 | Version: 1.5 |

Appendix 4: Confidentiality Agreement for Consultants Template

OFFICE FOR HUMAN SUBJECT PROTECTION

Research Subjects Review Board



Research Subjects Review Board (RSRB)
Confidentiality Agreement for Board Members

I, _____, the undersigned RSRB board member, hereby acknowledge that I understand that certain information acquired by me, in connection with my duties as an RSRB board member, is confidential and I agree to maintain the confidentiality of such information. Examples of such information include: identifying data or medical information about human subjects; proprietary information; trade secrets, medical or scientific data; research designs, concepts, discoveries or inventions; or any other information designated as, or which is reasonably understood to be, confidential. I agree that I will not disclose, or reproduce in any fashion, any confidential information that I obtain in connection with my duties as an RSRB board member or as otherwise requested unless required by law.

I understand that one of the reasons for not disclosing information I obtain in connection with my duties as an RSRB board member is to protect the privacy of research subjects and the confidentiality of their medical information. In addition, I understand that some information that is set forth in research protocols or other documents submitted to the RSRB may contain the proprietary or intellectual property of an investigator or a third party sponsor, and that disclosure of such information by me, outside the scope of my duties as a board member, could result in irreparable harm to the investigator or the funding sponsor.

Signature

Date

Saunders Research Building · 265 Crittenden Blvd, Suite 1.250 · Box CU420628 · Rochester, NY 14642-0628
585.273.4127 · 585.273.1174 fax

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|--|--|-----------------------------------|---------------------|
| University of Rochester | Office for Human Subject Protection | | |
| | Research Subjects Review Board | Effective Date: 12/10/2021 | |
| | RSRB Membership and Composition | Policy 302 | Version: 1.5 |

Appendix 5: RSRB Board Member Representative Capacity Template

OFFICE FOR HUMAN SUBJECT PROTECTION

Research Subjects Review Board



RSRB Board Member Representative Capacity

This form is intended to identify the areas of experience and knowledge of Research Subjects Review Board members that may be applied during the review of research to ensure appropriate representation and expertise at convened meetings.

Representative Capacity: Indicate below the group(s) or population(s) with whom you have knowledge or experience to bring to the board to advise as appropriate.

- | | |
|---|---|
| <input type="checkbox"/> Children (under 18 years) | <input type="checkbox"/> Research subjects – i.e., subject advocate or personal experience (self or others) |
| <input type="checkbox"/> K-12 students | <input type="checkbox"/> Terminally ill (life expectancy < 6 months) |
| <input type="checkbox"/> UR students (under 18 years) | <input type="checkbox"/> Nursing home residents |
| <input type="checkbox"/> UR students (18 years and over) | <input type="checkbox"/> Limited or non-reader |
| <input type="checkbox"/> UR employees | <input type="checkbox"/> Decisionally impaired |
| <input type="checkbox"/> Pregnant women | <input type="checkbox"/> Economically disadvantaged |
| <input type="checkbox"/> Prisoners | <input type="checkbox"/> Educationally disadvantaged |
| <input type="checkbox"/> N/A (no additional representation to note) | |

Indication of Experience: Provide a brief description of all relevant experiences contributing to the representative group(s) noted above (e.g., professions, life experiences with research or vulnerable populations, certifications, licensures).

Board Member Name

Board Member Signature

Date

v. 01/29/2019