University of	Office for Human Subject Protection		
	<b>Research Subjects Review Board</b>	Effective Date: 02/24/2020	
Rochester	RSRB Meetings	Policy 402	Version: 1.3

# POLICY

# 1. Purpose

To describe the procedures for preparation, conduct and review determinations of Research Subject Review Board (RSRB) convened board meetings.

# 2. Scope

This policy applies to the RSRB and RSRB office staff when the RSRB is the Reviewing IRB.

# 3. Definitions

None

# 4. References

- 4.1. HHS 45 CFR 46.108(b); FDA 21 CFR 56.108; HHS 45 CFR 46.111; FDA 21 CFR 56.111
- 4.2. Policy 104 Institutional Conflict of Interest; Policy 301 RSRB Scope and Authority; Policy 302 RSRB Membership and Composition; Policy 303 Board Member Conflict of Interest; Policy 403 Notification of RSRB Determinations; Policy 504 IRB Reliance and Collaborative Research; Policy 605 Research Involving FDA Regulated Drugs, Biologics, and Supplements; Policy 606 Research Using FDA Regulated Devices; Policy 606 Research Using FDA Regulated Devices; Policy 802 Non-Compliance in Human Subject Research; Policy 902 Investigator Financial Conflict of Interest

# 5. Responsibilities

- 5.1. The RSRB is responsible for the initial and continuing review (inclusive of re-approvals and modifications) of research at convened meetings at which quorum has been established.
  - 5.1.1. When the RSRB is the Reviewing IRB for non-UR institution(s), any additional responsibilities will be followed according to *Policy 504 IRB Reliance and Collaborative Research*.

# 6. Requirements

- 6.1. *RSRB Meetings* Each board will hold regularly scheduled meetings conducted by the RSRB Chair, or designated Acting Chair.
  - 6.1.1. The meeting agenda includes, but is not limited to: Review and approval of minutes, review of expedited reports, review of new applications, review of modifications, review of continuing reviews, review of reports of new information (i.e., reportable events), and other review items as applicable (Appendix 1). The

Page 1 of 15

University of	Office for Human Subject Protection		
	<b>Research Subjects Review Board</b>	Effective Date: 02/24/2020	
Rochester	RSRB Meetings	Policy 402	Version: 1.3

agenda indicates the date, the time, and the location of the meeting, as well as the items to be reviewed.

- 6.1.2. At the discretion of the Chair, or at the request of the RSRB, Investigators may be invited to attend a meeting for purposes of additional clarification or discussion of the proposed research. The Investigator (and any other study team members) involved in the presentation as guests are required to leave the meeting prior to subsequent discussion and voting by the board members.
- 6.1.3. Agendas are generated within the online review system where further information regarding each meeting and related review materials is located. All board members have access to all meeting materials on-line prior to the meeting. Laptops are available to board members who attend the meeting in person to follow through the agenda items and related materials during the conduct of the meeting. Members who join a meeting remotely have access to all materials through the online review system. A summary sheet that contains the criteria for approval, as well as the regulations that apply to the review of research involving vulnerable populations (e.g., children, pregnant women, prisoners), are available within the online review system library for reference as needed.
- 6.1.4. The RSRB Chair, RSRB Director, or RSRB Specialist, upon consultation, may cancel a scheduled meeting due to lack of items requiring convened board review, inability to secure quorum, holiday, or another reason that may arise.
- 6.1.5. The RSRB Chair, RSRB Director, or RSRB Specialist (upon consultation) may call a special meeting at any time to accommodate specific situations (e.g., single patient treatment protocols for which treatment is urgently needed). Related materials will be distributed as they become available. Special meetings will comply with regulatory requirements regarding review of human subject research.
- 6.2. *Selection of Primary Reviewers* The RSRB uses a primary review system for review of all agenda items (e.g., initial review, continuing review, modifications) to ensure that individuals with appropriate scientific or scholarly expertise conduct an in-depth review of the research.
  - 6.2.1. The RSRB Specialist assigns the primary reviewer prior to the convened board meeting. Primary reviewers are selected based on scientific and scholarly expertise, knowledge of the subject population, and/or experience in working with such populations. The primary reviewer must not have a conflict of interest regarding the research project under review.
  - 6.2.2. If a primary reviewer feels additional input is needed, he/she will notify the Chair and/or Specialist, as applicable, who will facilitate the identification of an appropriate consultant (e.g., studies with data security risks, gene therapy, or community based participatory research).
- 6.3. *Selection of Consultants* The Chair, Specialist, or RSRB Director may determine that knowledge or expertise beyond, or in addition to, that of a board member is necessary to

Page 2 of 15

University of	Office for Human Subject Protection		
	Research Subjects Review Board	Effective Date: 02/24/2020	
Rochester	RSRB Meetings	Policy 402	Version: 1.3

provide the board with sufficient information for the RSRB to make an approval determination. One or more consultants, with no undisclosed conflict of interest with the research activity under review, may be selected to obtain the expertise to adequately review a project. Information from consultants may be gathered by phone or written communication, or through participation at a convened meeting. Consultants may be asked to review an entire application or just a portion of an application, depending upon the needed knowledge or expertise. Consultants may not vote and are required to leave the meeting prior to voting by the board members. The consultant reviewer(s) responsibilities include the following:

- 6.3.1. Sign a Confidentiality Agreement to acknowledge the consultant will not disclose, or reproduce in any fashion, any confidential information reviewed.
- 6.3.2. Review the RSRB provided materials regarding the assigned project prior to the convened meeting.
- 6.3.3. Discuss any questions regarding the submission with the Chair and/or RSRB Specialist, as necessary.
- 6.3.4. Identify changes that may be needed in the application, protocol, consent, or other protocol documents, for discussion and consideration by the board.
- 6.3.5. Provide any written reviews to the RSRB Specialist for distribution to board members prior to the meeting and/or present a summary of findings and any concerns at the convened board meeting.
- 6.4. *Materials Provided to Reviewers* The RSRB Specialist prepares the information and materials provided to reviewers and board members in advance of the scheduled meeting to allow sufficient time for review (approximately five to seven days in advance). Any member or consultant with a real or perceived conflict of interest must disclose that information to the Specialist and/or the Chair in advance of the meeting, or at the meeting, regardless of the type of project reviewed by the RSRB and regardless of the level of RSRB review (*Policy 303 Board Member Conflict of Interest*).
  - 6.4.1. The primary reviewer and all board members have access to all review materials through the online review system, including applicable materials pertaining to individual participating sites when the RSRB is the Reviewing IRB for non-UR sites (see *Policy 504 IRB Reliance and Collaborative Research*). Hard copies of certain materials may be provided, as necessary or deemed appropriate by RSRB staff to facilitate the review. If hard copies are provided and not uploaded into the online review system after the meeting, these materials will be referenced in the board meeting minutes. The information distributed for each review activity may include, but is not limited to the following materials:
    - 6.4.1.1. Initial Review: RSRB new submission form, protocol, all consent documents, recruitment materials/advertisements, measures [e.g., surveys, assessments, Data and Safety Monitoring Plan, information related to potential conflicts of

Page 3 of 15

University of	Office for Human Subject Protection		
	Research Subjects Review Board	Effective Date: 02/24/2020	
Rochester	RSRB Meetings	Policy 402	Version: 1.3

interest (when they exist), investigational drug brochure or device information (when applicable)].

- 6.4.1.2. Continuing Review: RSRB continuing review form, protocol, all consent documents, recruitment materials/advertisements, copy of last signed consent documents(s), new risk/benefit information, as applicable.
- 6.4.1.3. Modification: RSRB modification form, materials updated or added as a result of the modification request.
- 6.4.1.4. Reportable Event: Report of new information form and any materials relevant to the reported event.
- 6.4.1.5. Other Items to Board: Documentation related to the report or item for review (e.g., OHSP Quality Improvement Reviews).
- 6.4.2. When an Investigator indicates a financial conflict of interest with the research under review (e.g. consulting with the sponsor of the research under review), a copy of the Individual Conflict Management Plan or Transparency Checklist will be included with the protocol, or other documentation as appropriate. The Specialist will review the information to ensure the protocol is consistent with the management strategies and the appropriate consent form disclosure language is included in the consent, as applicable. Details of the current plan will be included in the review materials provided to all board members, who will determine whether the potential conflict has been appropriately addressed. If the board is unable to resolve questions regarding the plan, it may choose to require clarification as a stipulation for approval (to be confirmed by the Chair) or defer the review of the research. See also *Policy 902 Investigator Financial Conflict of Interest*.
- 6.4.3. When a potential institutional conflict of interest is identified with the research under review, any information pertaining to the management plan will be included with the protocol submission and reviewed by the RSRB according to *Policy 104 Institutional Conflict of Interest*.
- 6.5. *Preparation for Meeting of RSRB Members* In preparation for RSRB meetings, board members (including alternates who may be attending) will conduct the following activities:
  - 6.5.1. Review all the application submission materials in enough depth to discuss the information at the convened meeting and determine if the project fulfills or continues to fulfill regulatory criteria for approval.
  - 6.5.2. If designated as a primary reviewer, review all materials prior to the meeting and provide any review comments in the online review system for all board members to review in advance of or at the convened board meeting. As an alternative, the primary reviewer can provide materials to the Specialist and the Specialist will upload the materials into the online review system, or issues can be identified by the reviewer during the meeting.

Page 4 of 15

University of	Office for Human Subject Protection		
	Research Subjects Review Board	Effective Date: 02/24/2020	
Rochester	RSRB Meetings	Policy 402	Version: 1.3

- 6.5.3. Be prepared to discuss any questions regarding submissions with the Chair (or Investigator if applicable), as appropriate.
- 6.5.4. Identify changes that may be needed in the application, protocol, consent or any other materials submitted for review for presentation to the board for discussion.
- 6.6. *Establishing a Quorum* The RSRB may not take any official vote on studies at a convened board meeting unless quorum is established. Quorum consists of more than half (i.e., the majority) of the total number of voting members listed on the RSRB roster, including at least one scientist, one non-scientific member and, at (per institutional policy) least one member who is not otherwise affiliated with the Institution [45 CFR 46.108(b) and 21 CFR 56.108]. See also *Policy 302 RSRB Membership and Composition*. In some cases, two members may share one position on the board (e.g., two pharmacists alternate attendance on the same board). When two members share one position on the board, this counts as one member towards quorum and thus, one vote. If both members are in attendance, only one of the two individuals may vote, unless the other person is attending as an alternate for another board member.
  - 6.6.1. The meeting is called to order when a quorum of members that includes a nonscientist, and a non-affiliated member is in attendance. Attendance of all members will be documented in the minutes. When reviewing studies regulated by the FDA, at least one physician member (or other qualified prescriber) will be in attendance.
  - 6.6.2. If quorum is lost during a meeting (e.g., resulting from recusal of a member with a conflict of interest, an early departure, absence of a non-scientist or non-affiliated member), the meeting may either end or the RSRB may halt discussion related to study review and not take votes involving study approval until quorum is restored. Loss of quorum and reason for the loss will be noted in the meeting minutes.
  - 6.6.3. An alternate member may only count towards meeting quorum requirements when present in place of a primary voting member, whether that primary voting member is unable to attend the meeting, or at any time during the meeting (e.g., when the primary voting member is unable to attend the whole meeting, or if the primary voting member must be recused from review of a particular study due to conflict of interest. Consultant reviewers do not count as voting members for purposes of determining a quorum.
  - 6.6.4. Research may only be approved if a majority of those members present at the meeting vote to approve.
  - 6.6.5. When the RSRB reviews research that involves categories of subjects vulnerable to coercion or undue influence (e.g., children, prisoners\*, pregnant woman), the Specialist and the Chair are responsible for ensuring that one or more individuals who are knowledgeable about or experienced in working with these subjects will be present at the meeting.
    - 6.6.5.1. \*When the RSRB reviews research that involves prisoners, the Specialist and the Chair are responsible for ensuring that one or more individuals who are

Page 5 of 15

University	Office for Human Subject Protection		
of	Research Subjects Review Board	Effective Date: 02/24/2020	
Rochester	RSRB Meetings	Policy 402	Version: 1.3

documented prisoner representatives on the roster will be present at the meeting, which will allow for the prisoner board to be convened.

- 6.7. *RSRB Voting Motions* Following presentation and discussion of an item on the agenda, the primary reviewer will recommend a motion to the board. All voting members present shall vote. Only individuals listed as voting members on the RSRB roster may vote. An alternate member may vote only when the regular member he/she is authorized to replace is not present. The Chair will ensure that no vote takes place without quorum. A majority vote of the members present at the meeting is required for a motion to pass. Proxy votes are not permitted. When members are attending through web-conference or teleconference, their vote must be indicated verbally.
  - 6.7.1. The possible voting motions taken by the convened board for initial reviews, continuing reviews, and review of modifications to previously approved research include the following:
    - 6.7.1.1. *Approve as submitted:* All criteria for IRB approval are satisfied, research study is approved as reviewed (i.e., without any modifications required by the board).
    - 6.7.1.2. *Approve with modifications required:* All criteria for IRB approval are satisfied, research study is approved pending minor modifications, consent document changes, or board directed changes, that require concurrence by the Investigator, and that can be confirmed by the RSRB Specialist; no additional review is required by the Board Chair or the convened board.
    - 6.7.1.3. *Defer:* Action on the research study is deferred to a subsequent convened board meeting pending resolution of one or more criteria for approval or other substantive issues (e.g., risks have not been identified, risks are significant and have not been adequately minimized, safety monitoring plan not adequate).
    - 6.7.1.4. *Disapprove*: A research study cannot be approved in its present form or is inappropriate in its present design (e.g., for reasons such as subject safety or scientific validity). The Investigator may respond to the disapproval in person or in writing. Studies modified by the Investigator to address the concerns leading to disapproval will be returned to the convened board for subsequent review.
    - 6.7.1.5. *Suspend or Terminate*: For previously approved research, the RSRB may suspend or terminate approval of research that is not being conducted in accordance with RSRB requirements or federal regulations (see Sections 6.9 and 6.10 below).
  - 6.7.2. Voting actions will be documented in writing through correspondence with the Investigator following a convened meeting (*Policy 403 Notification of RSRB Determinations*).

Page 6 of 15

University of Rochester	Office for Human Subject Protection		
	Research Subjects Review Board	Effective Date: 02/24/2020	
	RSRB Meetings	Policy 402	Version: 1.3

- 6.7.3. Minutes of all convened meetings are available to the IO or designee for review and can be accessed at all times through the online review system.
- 6.8. *RSRB Meeting Minutes* Federal regulations require that for research approved by the convened IRB, all required findings be fully documented in the minutes of the IRB meeting, including project-specific information justifying each regulatory criteria for approval at the time of initial and continuing review, and applicable criteria for approval for modifications (Appendix 2) [HHS 45 CFR 46.111; FDA 21 CFR 56.111]. Prior to distribution to the board members, the RSRB Director (or designee) reviews the meeting minutes to ensure that the minutes reflect proceedings of the convened board. Meeting minutes shall document the following, as appropriate:
  - Attendance at the meeting (including information about members entering and leaving the meeting, as well as indication of any members who participated via an alternative mechanism such as telephone or video conferencing), listing of voting members (the online review system contains documentation of the member's role on the committee and representative capacity for each member is documented on the RSRB Member Representation Form on file), RSRB staff members, guests, consultants (including brief description of consultant's expertise), and notation when an alternate replaces a primary member (including a statement that the reason is due to conflicting interest, if applicable);
  - Approval of any previous meeting minutes, and if the board required any changes to the minutes;
  - That the RSRB members received a report of expedited actions that occurred including new applications, continuing reviews, modifications, and closures (Note: this report is automatically generated in the online review system and included as part of each agenda);
  - When a quorum is lost during the meeting and when quorum is restored;
  - Action taken by the RSRB and the vote on the action (including number of members voting for, against, and abstaining), including any recusal;
    - Members abstaining from voting or those who vote to disapprove a study will be identified by their initials, with a brief description of the reason for their action.
    - Members who recuse themselves from the vote due to a conflicting interest with a particular project will be identified by name and a "conflict of interest" notation.
    - Minutes will reflect separate discussion and votes for each item on the agenda (i.e., batch discussion/voting is not permitted).
  - Separate specific comments and actions taken by the convened board on each study for initial and continuing review of research including:
    - A written summary of the discussion (e.g., the basis for requiring changes in or disapproving research and any controverted issues and their resolution).

Page 7 of 15

• Level of risk of the research.

University of	Office for Human Subject Protection		
	<b>Research Subjects Review Board</b>	Effective Date: 02/24/2020	
Rochester	RSRB Meetings	Policy 402	Version: 1.3

- Identification of any research for which there is a need for verification from sources other than the Investigator that no material changes are made in the research.
- The justification of any deletion or substantive modification of information concerning risks or alternative procedures;
- Specific comments and actions taken by the convened board regarding modifications, including if the modification changes the risk level of the study;
- Whether the study was approved, approved with modifications, deferred, or disapproved, including reason(s) for requiring changes, deferral, or disapproval; if the study was approved (either at initial review or at the time of continuing review), confirmation that approval criteria were met;
- Protocol-specific information justifying findings for approval of the following, as applicable:
  - A procedure which does not include, or which alters, some or all of the required elements of informed consent or when waiving the requirement to obtain informed consent.
  - A procedure which waives the requirement for the Investigator to obtain written documentation of consent.
  - Research involving vulnerable populations/groups requiring special consideration, including but not limited to research involving pregnant women, human fetuses, or neonates, prisoners, and children.
  - The board's agreement with the Investigator's/Sponsor's determination on the need for an Investigational New Drug application (see *Policy 605 Research Involving FDA Regulated Drugs, Biologics, and Supplements*).
  - The rationale for significant/non-significant risk device determinations (*Policy* 606 Research Using FDA Regulated Devices);
- Protocol-specific findings required by local policy (e.g., the RSRB's policy pertaining to research participation by decisionally impaired adults or research involving children);
- If are review item identified non-compliance, the board determination about whether or not the event was possibly serious or continuing non-compliance (*Policy 802 Non-Compliance in Human Subject Research*)
- Specific comments regarding suspension or termination of research;
- Actions taken by the board with regard to reportable events (e.g., unanticipated problem involving risk to human subjects or others);
- Whether/when any additional reports are required or any other business is considered by the convened board.
- 6.9. *Suspension of RSRB Approval* As indicated in *Policy 301 RSRB Scope and Authority*, the RSRB has the authority to suspend the research approval; meaning, there has been a determination made by the RSRB to temporarily or permanently stop approval for some or all of the research activities in a currently approved research study. This review

University of	Office for Human Subject Protection		
	Research Subjects Review Board	Effective Date: 02/24/2020	
Rochester	RSRB Meetings	Policy 402	Version: 1.3

determination may be made in response to unanticipated injuries or problems involving serious harm to subjects or others; serious or continuing non-compliance with the regulations or requirements of the RSRB or Institution; allegations/reports indicating that subjects are not being adequately protected; or allegations of scientific misconduct.

- 6.9.1. When a study is presented to the convened board for possible suspension of the study approval, the following considerations will be made:
  - What actions are needed to protect the rights and welfare of currently enrolled subjects (e.g., making arrangements for medical care, continue the research with a transfer to another investigator with or without independent monitoring).
  - Whether procedures for withdrawal of enrolled subjects are necessary to protect their rights and welfare.
  - Whether subjects (current and former) must be informed of the suspension.
- 6.9.2. When a study approval is suspended by the convened board, the following actions will be taken:
  - The board determinations will be made by way of a vote and will be recorded in the meeting minutes.
  - The Investigator and the appropriate department chair will be notified when the research approval is suspended.
  - The suspension will be promptly reported to the appropriate institutional officials, OHRP, FDA as appropriate, and study sponsor as appropriate (*Policy 403 Notification of RSRB Determinations*).
  - Any subsequent action taken by the convened board (e.g., to lift the suspension or to terminate the study) will be documented in the relevant meeting minutes.
- 6.9.3. If a particular issue poses an immediate threat to the safety of subjects, the RSRB Chair may suspend the study prior to notice to and review by the convened board. When study approval is suspended by the RSRB Chair, the suspension will be reported to the convened board for review and further action as listed under Section 6.9.1 above.
- 6.10. *Termination of RSRB Approval* As indicated in *Policy 301 RSRB Scope and Authority*, the RSRB has the authority to terminate the research approval; meaning, there has been a determination made by the RSRB to permanently withdraw approval of a research study and close the study. The same considerations and procedures apply as for study suspension indicated in Section 6.9. The termination will be promptly reported to the appropriate institutional officials, OHRP, FDA as appropriate, and the study sponsor as appropriate (*Policy 403 Notification of RSRB Determinations*).

University of	Office for Human Subject Protection		
	<b>Research Subjects Review Board</b>	Effective Date: 02/24/2020	
Rochester	RSRB Meetings	Policy 402	Version: 1.3

#### **Originator/Authors:**

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## **Appendices:**

Appendix 1: Sample RSRB Agenda Template Appendix 2: Sample RSRB Minutes Template

## **Revision History:**

- 11/2014: References corrected; Appendix 2 updated
- 03/2019: Sect 2 add Reviewing IRB language; Sect 3.1 ROSS definition removed; Sect 4.2 policies and hyperlinks added accordingly; Sect 5.1.1 Reviewing IRB language added; Former Sect 6.8 re: expedited review determinations moved to Policy 501; updates throughout according to OHRP Minutes of IRB Meetings Guidance (v. September 2017); Appendix 1 and 2 updated with current templates; additional updates throughout to reflect current workflow and documentation in IRB online review system; editorial changes; removal of T. Gommel as signatory.
- 02/2020: Clarification to section 6.2.2; update to signatories.

#### **Supersedes Date:**

03/05/2019

## **Approved By:**

Killing Rollonoghi

Kelley A. O'Donoghue Director, OHSP

\_03/20/2020 Date

MMaso

Nicole Mason Executive Director, RSRB

3/20/2020\_\_\_\_

Date

Page 10 of 15

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.

University of	Office for Human Subject Protection		
	Research Subjects Review Board	Effective Date: 02/24/2020	
Rochester	RSRB Meetings	Policy 402	Version: 1.3

University	Office for Human Subject Protection		
of	Research Subjects Review Board	Effective Date: 02/24/2020	
Rochester	RSRB Meetings	Policy 402	Version: 1.3

## Appendix 1: Sample RSRB Agenda Template

RSRB «committee.name» AGENDA

Page 1 of 1

AGENDA

«committee.name» «dateTimeStart» «location» Board Chair: «meetingCustomExtension.getChairName()»

#### REVIEW OF STUDIES

«TableStart:getAgendaItems();»

«TableStart.gen gendarteins(),//	
Type of Review:	«submissionType.name»
Title:	«project.name»
Investigator:	«project.getInvestigatorMergeString(name)»
Primary Reviewer:	«project.getPrimaryReviewer()»
Submission ID:	«project»
Funding:	«project.getFundingSourcesMergeString();»
IND or IDE/HDE:	«project.getDeviceOrDrugNumbersMergeStrin»
Documents reviewed:	«project.getAttachmentsMergeString();»

«TableEnd:getAgendaItems();»

#### REVIEW OF REPORTABLE NEW INFORMATION ITEMS

Type of Review:	«submissionType.name»
Title:	«project.name»
Reported By:	«project.getReportedBy»
Submission ID:	«project»
Date of Event:	< <iinsertdatemadeawareofevent>&gt;</iinsertdatemadeawareofevent>
Related projects:	«relatedProjects.getSet(ID,ID)»
Documents reviewed:	«project.getAttachmentsMergeString();»

### **REVIEW OF OTHER AGENDA ITEMS**

«TableStart:getOtherAgendaItems();»

1. «name»

Description:	«description»
Related projects:	«relatedProjects.getSet(ID,ID)»
Primary Reviewer:	«project.getPrimaryReviewer()»
"Table End: gat Other A gan de Itams (); "	

«TableEnd:getOtherAgendaItems();»

University	Office for Human Subject Protection		
of	Research Subjects Review Board	Effective Date	e: 02/24/2020
Rochester	RSRB Meetings	Policy 402	Version: 1.3

## **Appendix 2: Sample RSRB Minutes Template**

OFFICE FOR HUMAN SUBJECT PROTECTION



#### Research Subjects Review Board Meeting Minutes «committee.name» Meeting Start Time: «dateTimeStart» Meeting End Time: [Meeting End Time]

MEETING ATTENDANCE	
Members Present:	<< <u>getChairs+Members</u> >>
Members Absent:	[Enter "None" if no one was absent]
Staff Present:	< <getcommitteeadministrators>&gt;</getcommitteeadministrators>
Guests:	[INSERT Name and Title as appropriate, if no guests, delete this line]

All members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions.

Quorum was reached with Name and Name as our non-scientist members.

Non-affiliated members present were Name and Name.

INSERT of the INSERT voting members were present at the beginning of the meeting.

The RSRB Chair asked if any of the board members had a conflict of interest with the studies for review. There were no conflicts of interest voiced by the board members. OR INSERT NAME noted that she/he had a conflict with [Insert Submission ID].

Reports on expedited New Protocols, Re-approvals, Amendments, and Study Closures were presented and reviewed at the meeting.

#### REVIEW OF STUDIES

INSERT arrivesAeaves the meeting – Vote to INSERT, quorum remains.

«TableStart:getAgendaItems();»

1. Review of «project.irbSubmissionCustomExtension.get»:

SUBMISSION DETAILS	
Title:	1 5
Investigator:	
Funding:	«project.getFundingSourcesMergeString();»
IND or IDE/HDE:	
Documents Reviewed:	«project.getAttachmentsMergeString();»
Primary Reviewer:	«project.getPrimaryReviewer()»

University	Office for Human Subject Protection		
of	Research Subjects Review Board	Effective Date	e: 02/24/2020
Rochester	RSRB Meetings	Policy 402	Version: 1.3

Minutes for «name»

Page 2 of 3

MEETING DISCUSSION	
	«project.irbSubmissionCustomExtension.get»
Determination & Findings:	«project.irbSubmissionCustomExtension.get»

COMMITTEE REVIEW DETAILS		
Motion:	1	
Risk Level:	«project.preReviewChecklist.riskLevel»	
Recommended Changes	«project.requiredModification»	
& Reasons:		
Votes:	For:	«project.currentAgendaItem.voteInformation.v
		otesYesCount»
	Against:	«project.currentAgendaItem.voteInformatio»
	Abstain:	«project.currentAgendaItem.voteInformatio»
	Recused:	«project.currentAgendaItem.voteInformatio»

«TableEnd:getAgendaItems();»

#### REVIEW OF REPORTABLE NEW INFORMATION ITEMS

SUBMISSION DETAILS	
Type of Review:	«submissionType.name»
Title:	«project.name»
Reported By:	«project.getReportedBy»
Submission ID:	«project»
Date of Event:	< <iinsertdatemadeawareofevent>&gt;</iinsertdatemadeawareofevent>
Related projects:	«relatedProjects.getSet(ID,ID)»
Documents reviewed:	«project.getAttachmentsMergeString();»
Primary Reviewer:	«project.getPrimaryReviewer()»

MEETING	DISCUSSION
---------	------------

MEETING DISCUSSION	
Controverted Issues &	«project.irbSubmissionCustomExtension.get»
Resolutions:	
Determination & Findings:	«project.irbSubmissionCustomExtension.get»

RNI COMMITTEE REVIEW DETAILS				
Determinations:	«project.irbDetermination.name»			
Follow-up/Action Plan:	«project.requiredFurtherAction»			
Responsible Party:	< <pre>&lt;<pre>project.resposibleparty&gt;&gt;</pre></pre>			
Votes:	For:	«project currentAgendaItem voteInformation votesYesCount»		
	Against:	«project.currentAgendaItem.voteInformatio»		
	Abstain:	«project.currentAgendaItem.voteInformatio»		
	Recused:	«project.currentAgendaItem.voteInformatio»		

University	Office for Human Subject Protection			
of Rochester	<b>Research Subjects Review Board</b>	Effective Date: 02/24/2020		
	RSRB Meetings	Policy 402	Version: 1.3	

Minutes for «name»

Page 3 of 3

# REVIEW OF OTHER AGENDA ITEMS «TableStart:getOtherAgendaItems();» 2. Review of «name»: Description: «description» Related Projects: getSet(ID,ID)» Primary Reviewer: «project.getPrimaryReviewer()»

«TableEnd:getOtherAgendaItems();»

Notes: «notes»