POLICY

1. Purpose
   To describe the procedures for preparation, conduct and review determinations of RSRB meetings.

2. Scope
   This policy applies to RSRB and RSRB office staff.

3. Definitions
   3.1. RSRB On-line Submission System (ROSS): The web-based submission and review system used to manage all aspects of research review for the RSRB.

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 302 RSRB Membership and Composition
         Policy 303 Board Member Conflict of Interest
         Policy 403 Notification of RSRB Determinations
         Policy 606 Research Using FDA Regulated Devices
         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 amendments) of research at convened meetings at which quorum has been established.

6. Requirements
   6.1. RSRB Meetings – Each RSRB will hold regularly scheduled meetings conducted by the RSRB Chair. The meeting agenda includes, but is not limited to: Approval of minutes, review of expedited reports, review of new applications, review of amendments, review of continuing reviews, review of reportable events, reports to board/other business (Appendix 1). The agenda indicates the date, time, and location of the meeting, as well as the items to be reviewed.

       6.1.1. 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 presentation and discussion is included in the agenda and minutes. Investigator guests are required to leave the meeting prior to subsequent discussion and voting by the board members.
6.1.2. Agendas are generated within ROSS where further information regarding each meeting and related review materials is located. All board members have access to the meeting materials on-line prior to the meeting. Laptops are provided at the meeting for board members to follow through the agenda items and related materials during the conduct of the meeting. In order to meet the regulatory requirements for approval of research, handouts and posters are made available to the board that contain the criteria for approval, as well as the regulations that apply to the review of research involving vulnerable populations.

6.1.3. In consultation, the RSRB Chair, RSRB Director, or RSRB Specialist 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.

6.1.4. In consultation, the RSRB Chair, RSRB Director, or RSRB Specialist 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, amendments) to ensure that individuals with appropriate scientific or scholarly expertise conduct an in-depth review of the research.

6.2.1. The RSRB Specialist determines 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 Specialist, who will facilitate the identification of an appropriate consultant.

6.3. Selection of Consultants – The Chair, Specialist, or RSRB Director may determine that knowledge or expertise beyond that of a board member is necessary to 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. Review the RSRB provided materials regarding the assigned project prior to the convened meeting.
6.3.2. Discuss any questions regarding the submission with the Chair, as necessary.
6.3.3. Identify changes that may be needed in the application, protocol or consent document for discussion and consideration by the board.
6.3.4. 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 Specialists will prepare 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, 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 ROSS. Hard copies of certain materials may be provided, as necessary or deemed appropriate by RSRB staff to facilitate the review. 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, Conflict Management Plan (when one exits), investigational drug brochure or device information (when applicable), grant application (when applicable).

6.4.1.2. Continuing Review: RSRB continuing review form, protocol, all consent documents, recruitment materials/advertisements, copy of last signed consent(s), new risk/benefit information, as applicable.

6.4.1.3. Amendment: RSRB amendment form, materials updated or added as a result of the amendment request.

6.4.1.4. Reportable Event: RSRB reportable event form and any materials relevant to the reported event.

6.4.1.5. Report to Board: Documentation related to the report.

6.4.2. When an Investigator indicates a financial conflict of interest with the research under review, the RSRB will obtain a copy of the Conflict Management Plan. The Specialist will ensure that the plan is current and has been signed by both the Investigator and the Dean. Details of the 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 table the review of the research. See also Policy 902 Investigator Financial Conflict of Interest.

6.4.3. When an Investigator indicates a financial interest (e.g. consulting with the sponsor of the research under review), the Specialist will review a copy of the Transparency Policy Checklist to ensure that the appropriate consent form disclosure language is included in the consent. Details of the Investigator’s compliance with the transparency policy will be included in the review materials provided to all board members, who will determine whether the Investigator’s interest has been appropriately addressed. If the board is unable to resolve questions regarding the compliance with the policy, it may choose to require clarification as a stipulation for approval (to be confirmed by the Chair) or table the review of the research. See also Policy 902 Investigator Financial 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 materials prior to the meeting and upload any written review materials into ROSS 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 ROSS.

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 of the total number of voting members listed on the RSRB roster, including at least one scientist, one non-scientific member and, at 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.

6.6.1. The meeting is called to order when a quorum of members that includes a non-scientist 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 nonscientist 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 voting member. 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 prisoner representatives 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 at the meeting. The Chair will ensure that no vote takes place without quorum present. A majority vote of the members present at the meeting is required for a motion to pass. Proxy votes are not permitted.

6.7.1. The possible voting motions taken by the convened board for initial reviews, continuing reviews, and review of amendments to previously approved research include the following:

6.7.1.1. Approve as submitted: Research study is approved as reviewed (i.e., without any stipulations required by the board).

6.7.1.2. Approve with stipulations: Research study is approved pending minor modifications or consent document changes that require concurrence by the Investigator and that can be confirmed by the board Chair or experienced board member; no additional review required by the convened board.

6.7.1.3. Table: Action on the research study is deferred to subsequent board review pending resolution of more substantive issues (e.g., risks have not been identified, risks are significant and have not been adequately minimized, there are questions raised by the RSRB that await response from the Investigator).
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 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. These voting actions will be documented in writing through correspondence with the Investigator following a convened meeting (Policy 403 Notification of RSRB Determinations).

6.7.3. Minutes of the convened meetings are forwarded to the IO or designee for review and notification.

6.8. **RSRB Review Determinations for Expedited Review** – The possible review determinations that may be made by an RSRB expedited reviewer for initial reviews, continuing reviews, and review of amendments to previously approved research include the following, which will be documented in writing through correspondence with the Investigator following expedited review (Policy 403 Notification of RSRB Determinations).

6.8.1. **Approve as submitted**: Research study is approved as reviewed (i.e., without any stipulations required by the expedited reviewer).

6.8.2. **Approve with stipulations**: Research study is approved pending minor modifications or consent document changes that require concurrence by the Investigator and that can be confirmed by the expedited reviewer.

6.8.3. **Request changes or additional information**: Research study requires additional information in order to determine whether the study may be approved or requires referral to convened board.

6.8.4. **Refer to convened board**: The expedited reviewer may choose to defer any action to a meeting of the convened board. Disapproval is not permitted under the expedited review procedure.

6.9. **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 amendments (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): listing of voting members, guests and notation when an alternate replaces a primary member;
- Approval of minutes of the previous meeting(s), and if the board required any changes to the minutes;
- That the RSRB members received a report of expedited actions that occurred since the last convened board meeting including new applications, continuing reviews, amendments, and closures (Note: these reports are typically distributed with the meeting minutes or agendas);
- When a quorum is lost during the meeting and when a 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).
  - Level of risk of the research.
  - Approval period for the research including identification of research that warrants review more often than at least annually.
  - 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 amendments, including if the amendment changes the risk level of the study;
- Whether the study was approved, approved with stipulations, disapproved, or tabled, including reason(s) for requiring changes, tabling or disapproval;
- Protocol-specific information justifying findings for approval of the following, as applicable:
O 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.
O A procedure which waives the requirement for the Investigator to obtain written documentation of consent.
O Research involving vulnerable populations/groups requiring special consideration, including but not limited to research involving pregnant women, human fetuses, or neonates, prisoners, and children.
O The board’s agreement with the Investigator’s/Sponsor’s determination on the need for an Investigational New Drug application.
O 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);
- Specific comments regarding suspension or termination of research;
- Actions taken by the RSRB with regard to reportable events;
- Whether/when any additional reports are required or any other business considered by the convened RSRB.

6.10. Suspension of RSRB Approval – As indicated in OHSP Policy 301, 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 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; allegations/reports indicating that subjects are not being adequately protected; or allegations of scientific misconduct.

6.10.1. 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.

6.10.2. 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).

6.10.3. 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 and 6.9.2 above.

6.11. Termination of RSRB Approval – As indicated in OHSP Policy 301, 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 6.10. 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).
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<th>University of Rochester</th>
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Originator/Authors:
Kelley O’Donoghue, Director OHSP
Emily Flagg, Senior Regulatory Specialist

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

Revision History:
References corrected; Appendix 2 updated

Supersedes Date:
10/07/2013

Approved By:

Kelley A. O’Donoghue
Director, OHSP

Tiffany Gommel
Director, RSRB

Supersedes Date: 10/07/2013

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Appendix 1: Sample RSRB Agenda

RESEARCH SUBJECTS REVIEW BOARD
AGENDA FOR BOARD [XX – TYPE]

DATE: [Insert Date]
LOCATION: OHSP Board Room (SRB 1.275)
SCHEDULED TIME: 4:00 PM
Board Chair: [Insert Name]

1 Minutes from Previous Meetings
[Listing of any expedited reports or minutes]

2 New Applications

RSRB0000000X [Insert Study Title]
Principal Investigator: [Insert Name]
Primary Reviewer: [Insert Name]

Review Materials: [Listing of materials included for review]

3 Amendments

RSRB0000000X [Insert Study Title]
Principal Investigator: [Insert Name]
Primary Reviewer: [Insert Name]

Amendment Reason: [Listing of requested changes]
Review Materials: [Listing of materials included for review]

4 Continuing Reviews

RSRB0000000X [Insert Study Title]
Principal Investigator: [Insert Name]
Primary Reviewer: [Insert Name]

Review Materials: [Listing of materials included for review]

5 Reportable Event

RSRB0000000X [Insert Study Title]
Principal Investigator: [Insert Name]
Primary Reviewer: [Insert Name]

Review Materials: [Listing of materials included for review]
Appendix 1: Sample RSRB Agenda (Continued)
Appendix 2: Sample RSRB Minutes

RESEARCH SUBJECTS REVIEW BOARD
MINUTES FOR BOARD 00

DATE

Members Present:

Members Absent: IF NO ONE IS MISSING ENTER “None”

Staff Present: Name, Regulatory Specialist
T. Gommel, Director, RSRB

Guest(s): INSERT Name and Title as appropriate, if no guests, delete this line

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

Non-affiliated members present were Name and Name.

The meeting was called to order by Name, RSRB Chair, at Time.

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

The minutes from the Date meeting were reviewed and approved as submitted OR with minor editorial changes.

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 RSRB #INSERT.

INSERT ANY ANNOUNCEMENTS OR TRAINING

Order of the studies was changed to accommodate reviewers’ schedules.

NEW APPLICATIONS

RSRB #XXXXX Insert the full study title
PI NAME

Review Materials: {INCLUDE VERSION NUMBERS/DATES ON ALL ITEMS. FOR NEW STUDIES ENSURE THAT THE FOLLOWING ARE INCLUDED AS A MINIMUM: RSRB APPLICATION, PROTOCOL, ALL CONSENT FORMS. THE FOLLOWING ITEMS MAY BE INCLUDED IF APPLICABLE: DRUG PROFILES (INCLUDE DRUG NAME IN FILE NAME), IB (INCLUDE DRUG NAME IN FILE) RECRUITMENT MATERIALS AND STUDY MEASURES.}
Primary Reviewer: Name

Discussion:

The reviewer presented this new study and the review materials noted above to the board. The purpose of the study is… The study will recruit individuals who are INSERT AGE in the following INSERT STUDY POPULATION(S).

This study will enroll XX subjects with XX at the University of Rochester (IF MULTI-CENTER INCLUDE “This study will enroll XX subjects across XX sites in the United States and XX at the University of Rochester.”)

Each subject will have XX study visits over about XX. INCLUDE BRIEF DESCRIPTION ABOUT STUDY PROCEDURES OR SOMETHING PARTICULARLY INTERESTING ABOUT THE STUDY.

INCLUDE SUMMARY OF DISCUSSION ABOUT ITEMS THE BOARD DEBATED (THE REVIEWER NOTED… OR THE BOARD DISCUSSED…)

IF STUDY INVOLVES AN INVESTIGATIONAL DRUG OR DEVICE THE FOLLOWING LANGUAGE SHOULD BE ADDED TO THE MINUTES IF AN IND/IDE IS REQUIRED: The use of [Drug/Device Name] is considered investigational in this study and will be given under an IND/IDE (IND/IDE# XXXX) held by the [Principal Investigator/study sponsor].

IF STUDY INVOLVES AN INVESTIGATIONAL DRUG OR DEVICE THE FOLLOWING LANGUAGE SHOULD BE ADDED TO THE MINUTES IF AN IND/IDE EXEMPTION IS GRANTED: The use of [Drug/Device Name] is not approved for the [indication under study]; however the [study sponsor/Principal Investigator] received a letter from the FDA stating that this study meets all of the requirements for exemption from the IND/IDE regulations. Therefore, an IND/IDE will not be required to conduct this study.

OR

The use of [Drug/Device Name] is approved by the FDA as a treatment for [provide treatment it is used for]. The board reviewed the [Drug package insert or Device brochure] and the [study sponsor's/Principal Investigator's] justification for IND/IDE Exemption and agreed with the assessment.

The reviewer recommended tabling the study and the board concurred. The board tabled this study because…
[RECORD VOTE TO TABLE BELOW.]

OR

The board concurred that the eligibility criteria are appropriate, risks to subjects are reasonable in relation to the anticipated benefits and the importance of the knowledge
that may result. OR The board concurred that the eligibility criteria are appropriate, risks to subjects are minimal, are reasonable in relation to the anticipated benefits and the importance of the knowledge that may result and agreed that future review of this study can be expedited (Category 9).

In its deliberations, the board considered all elements of 45 CFR 46.111. (for Board 02 only)

In its deliberations, the board considered all elements of 45 CFR 46.111 and 21 CFR 56.111. (for board 01, 03, 04 and 05)

BRIEFLY DESCRIBE HOW THE FOLLOWING CRITERIA FOR APPROVAL ARE SATISFIED:

(1) Risks to subjects are minimized –
(2) Risks to subjects are reasonable in relation to anticipated benefits –
(3) Selection of subjects is equitable –
(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative –
(5) Informed consent will be appropriately documented
(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 –
(8) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects –

The reviewer recommended approval. The board concurred, pending the following stipulations:

Regarding the Application
- Section XX;

Regarding the Protocol
- INSERT SECTION: 1)….2)

Regarding the Consent Documents (tracked version provided to PI):
- Consent Form
  - Page X “INSERT SECTION”: 1)…2)
  - Additional administrative changes.
- Parental Permission Form
  - Page X “INSERT SECTION”: 1)…2)
  - Additional administrative changes.
- Assent Form
  - Page X “INSERT SECTION”: 1)…2)
  - Additional administrative changes.

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Recruitment Materials
- INSERT: 1)…2)
- INSERT: 1)…2)

The specialist will forward these stipulations to the investigator. The Chair will confirm compliance with the stipulations required by the board.

OR

The reviewer recommended approval as submitted and the board concurred.

OR

The specialist will forward the rationale for tabling the study and the changes requested to the investigator. The investigator’s response and revised application will be submitted to a subsequent meeting of the board.

Vote to Approve: 
Vote Against: 
Abstained: 
Review Period: Yearly OR INSERT OTHER TIME PERIOD OR NUMBER OF SUBJECTS 
Non-significant risk OR Significant Risk Risk: INSERT RISK FROM OPTIONS BELOW:
Minimal Risk (Adults)
Minimal Risk (Adults) – Future review expedited (Category 9)
Greater than Minimal Risk (Adults)
Minimal Risk – Children (45 CFR 46.404 and 21 CFR 50.51)
Minimal Risk – Children (45 CFR 46.404 and 21 CFR 50.51) – Future review expedited (Category 9)
Greater than Minimal Risk but presenting the prospect of direct benefit to the individual subjects – Children (45 CFR 46.405 and 21 CFR 50.52)
Greater than Minimal Risk – no prospect of direct benefit to the individual subjects but likely to yield generalizable knowledge about the subject’s disorder or condition – Children (45 CFR 46.406 and 21 CFR 50.53)
Greater than Minimal Risk – Pregnant Women & Fetuses (In its deliberations, the board considered all elements of 45CFR46.204) 

Adults with Decisional Incapacity Assessment: INSERT CATEGORY FROM OPTIONS BELOW:
Category A - Minimal Risk.
Category B – Greater than Minimal Risk, but presenting the prospect of direct benefit to the individual subjects.
Category C – Research involving a minor increase over Minimal Risk, with no prospect of direct benefit to individual subjects, but may produce knowledge about the subjects’ disorder or condition.

IF A VULNERABLE POPULATION (CHILDREN, PREGNANT WOMEN AND FETUSES)…MUST INCLUDE MORE DETAIL SURROUNDING RISK ASSESSMENT INCLUDING CITATIONS FROM THE PROTOCOL/OTHER REVIEWED MATERIALS (SEE APPENDIX FROM RSRB POLICY AND PROCEDURES a46a-e).
EXAMPLE FOR CHILDREN:

**Protocol Rationale:** INCLUDE DESCRIPTION OF WHY CHILDREN ARE INCLUDED IN THIS PROTOCOL.

**Risk/Benefit Relationship:** INCLUDE DESCRIPTION OF THE RELATIONS OF THE ANTICIPATED BENEFITS TO THE RISK IS AT LEAST AS FAVORABLE TO THE SUBJECTS AS THAT PRESENTED BY AVAILABLE ALTERNATIVE APPROACHES.

**Parental Permission/Consent Form/Assent:** INCLUDE THE BOARD’S DETERMINATION OF PARENTAL PERMISSION and ASSENT…ADJUST THE WORDING BELOW AS NEEDED FOR YOUR STUDY (Example… “As this therapy would not be available outside of this research study, only parental permission will be obtained.” Or “Adequate provisions have been made for obtaining parental permission from at least one parent and for soliciting assent of children ages 7 to 12 (verbal assent) and 13 to 17 (written assent).” Or “Adequate provisions have been made for obtaining parental permission from at least one parent. Assent not required based on… (insert reason - e.g., based on subjects’ age).” [NOTE: TWO PARENT SIGNATURES ARE REQUIRED FOR 406 AND 407 STUDIES.]

EXAMPLE FOR PREGNANT WOMEN AND FETUSES

**Protocol Rationale:** INCLUDE DESCRIPTION OF WHY FETUSES AND/OR PREGNANT WOMEN ARE INCLUDED IN THIS PROTOCOL.

**Consent Form:** INCLUDE THE BOARD’S DETERMINATION OF WHETHER BOTH PARENTS MUST SIGN (Example… “The research holds out the prospect of direct benefit solely to the fetus, therefore the consent of the pregnant woman and the father will be obtained.” Or “The research holds out the prospect of direct benefit to the pregnant woman {OR the prospect of a direct benefit both to the pregnant woman and the fetus OR no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means}, therefore only the consent of the pregnant woman will be required.”

**INSERT arrives/leaves the meeting – Vote to INSERT, quorum remains.**

**AMENDMENTS**

- **RSRB #XXXXX**
- **PI NAME**

**Amendment Reasons:** INSERT SUMMARY OF CHANGES AND RATIONALE

**Review Materials:** {FOR AMENDMENTS ENSURE THAT THE FOLLOWING ARE INCLUDED AS A MINIMUM: RSRB AMENDMENT FORM, THE FOLLOWING ITEMS MAY BE INCLUDED IF APPLICABLE: PROTOCOL (TRACKED OR NOT), TRACKED CONSENT DOCUMENTS, ETC.;} INCLUDE TRACKED DOCUMENTS IF AT ALL POSSIBLE

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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.
Primary Reviewer: Name

Discussion:
The reviewer presented this amendment and the review materials noted above to the board. The purpose of this amendment is to…

INCLUDE DISCUSSION ABOUT ITEMS THE BOARD DEBATED (THE REVIEWER NOTED… OR THE BOARD DISCUSSED…)

DOCUMENT IF THIS AMENDMENT CHANGED THE RISK TO SUBJECTS
(This amendment did not increase the risk to subjects who participate; the study remains greater than minimal risk OR This amendment did not increase the risk to subjects who participate; the study remains minimal risk and the board determined that the review of this study can continue to be expedited (Category 9).

In its deliberations, the board considered all elements of 45 CFR 46.111. The elements of the criteria for approval have not changed with this amendment and are still applicable as initially determined by the Board. (for Board 02 only)

In its deliberations, the board considered all elements of 45CFR46.111 and 21CFR56.111. The elements of the criteria for approval have not changed with this amendment and are still applicable as initially determined by the Board. (for board 01, 03, 04 and 05)

BRIEFLY DESCRIBE ONLY THE FOLLOWING CRITERIA FOR APPROVAL THAT PERTAIN TO THE AMENDMENT:

(1) Risks to subjects are minimized –
(2) Risks to subjects are reasonable in relation to anticipated benefits –
(3) Selection of subjects is equitable –
(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative –
(5) Informed consent will be appropriately documented
(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 –
(8) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects –

The reviewer recommended approval. The board concurred, pending the following stipulations: OR The reviewer recommended tabling this study because…. The board concurred and requested the following additional changes:
Regarding the Amendment Form
  - Page XX Section XX:

Regarding the Protocol
  - INSERT SECTION: 1)….2)

Regarding the Consent Documents (tracked version provided to PI):
  **Consent Form**
  - Page X “INSERT SECTION”: 1)…2)
  - Additional administrative changes.
  **Parental Permission Form**
  - Page X “INSERT SECTION”: 1)…2)
  - Additional administrative changes.
  **Assent Form**
  - Page X “INSERT SECTION”: 1)…2)
  - Additional administrative changes

**Recruitment Materials**
  - INSERT: 1)…2)
  - INSERT: 1)…2)

The specialist will forward these stipulations to the investigator. The Chair will confirm compliance with the stipulations required by the board.

OR

The reviewer recommended approval as submitted and the board concurred.

Vote to Approve:
Vote Against:
Abstained:
Risk: Non-significant risk OR Significant Risk

**INSERT RISK FROM OPTIONS BELOW:**
  Minimal Risk (Adults)
  Minimal Risk (Adults) – Future review expedited (Category 9)
  Greater than Minimal Risk (Adults)
  Minimal Risk – Children (45 CFR 46.404 and 21 CFR 50.51)
  Minimal Risk – Children (45 CFR 46.404 and 21 CFR 50.51) – Future review expedited (Category 9)
  Greater than Minimal Risk but presenting the prospect of direct benefit to the individual subjects – Children (45 CFR 46.405 and 21 CFR 50.52)
  Greater than Minimal Risk – no prospect of direct benefit to the individual subjects but likely to yield generalizable knowledge about the subject’s disorder or condition – Children (45 CFR 46.406 and 21 CFR 50.53)
  Greater than Minimal Risk – Pregnant Women & Fetuses (In its deliberations, the board considered all elements of 45CFR46.204)

**INSERT CATEGORY FROM OPTIONS BELOW:**
  Category A - Minimal Risk.
  Category B – Greater than Minimal Risk, but presenting the prospect of direct benefit
to the individual subjects.
Category C – Research involving a minor increase over Minimal Risk, with no prospect of direct benefit to individual subjects, but may produce knowledge about the subjects’ disorder or condition.

**INSERT arrives/leaves the meeting – Vote to INSERT, quorum remains.**

**CONTINUING REVIEWS**

<table>
<thead>
<tr>
<th>RSRB #XXXXX</th>
<th>Insert the full study title</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI NAME</td>
<td></td>
</tr>
</tbody>
</table>

**Review Materials:** {FOR CONTINUING REVIEWS ENSURE THAT THE FOLLOWING ARE INCLUDED AS A MINIMUM: RSRB PROGRESS REPORT AND CLEAN CONSENT IF REAPPROVING THE FORM. THE FOLLOWING ITEMS MAY BE INCLUDED IF APPLICABLE: LAST SIGNED CONSENT DOCUMENTS, DSMC REPORTS, ANY SPECIFIC REPORTABLE EVENTS, PUBLICATIONS}

**Primary Reviewer:** Name

**Discussion:**

The reviewer presented this continuing review and the review materials noted above to the board.

**INCLUDE THE FOLLOWING ITEMS IN THE DISCUSSION:**
- NUMBER OF SUBJECTS ENROLLED
- NUMBER OF SUBJECTS REQUESTED
- NUMBER OF SUBJECTS WITHDRAWN
- STATUS OF THE STUDY (ACCRUAL CONTINUES, ETC.)
- DSMC REVIEWED
- REPORTABLE EVENTS

**DISCUSSION ABOUT ITEMS THE BOARD DEBATED (THE REVIEWER NOTED… OR THE BOARD DISCUSSED...)**

In its deliberations, the board considered all elements of 45 CFR 46.111. (for Board 02 only)

In its deliberations, the board considered all elements of 45 CFR 46.111 and 21 CFR 56.111. (for board 01, 03, 04 and 05)

All of the elements of the criteria for approval are still applicable as initially determined by the Board.

**OR**

**IF THERE WAS A CHANGE IN THE CRITERIA FOR APPROVAL IDENTIFY WHICH ONE THE CHANGE PERTAINS TO AND PROVIDE RATIONALE:**
(1) Risks to subjects are minimized –
(2) Risks to subjects are reasonable in relation to anticipated benefits –
(3) Selection of subjects is equitable –
(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative –
(5) Informed consent will be appropriately documented
(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 –
(8) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects –

The reviewer recommended re-approval of this study. The board concurred, pending the following stipulations:

**Regarding the Progress Report**
- Section XX:

The specialist will forward these stipulations to the investigator. The Chair will confirm compliance with the stipulations required by the board.

**OR**

The reviewer recommended re-approval of this study as submitted and the board concurred.

Vote to Re-Approve: 
- Vote Against: 
- Abstained: 
- Review Period: Yearly OR INSERT OTHER TIME PERIOD OR NUMBER OF SUBJECTS
- Risk: Non-significant risk OR Significant Risk

**INSERT RISK FROM OPTIONS BELOW:**
- Minimal Risk (Adults)
- Minimal Risk (Adults) – Future review expedited (Category 9)
- Greater than Minimal Risk (Adults)
- Minimal Risk – Children (45 CFR 46.404 and 21 CFR 50.51)
- Minimal Risk – Children (45 CFR 46.404 and 21 CFR 50.51) – Future review expedited (Category 9)
- Greater than Minimal Risk but presenting the prospect of direct benefit to the individual subjects – Children (45 CFR 46.405 and 21 CFR 50.52)
- Greater than Minimal Risk – no prospect of direct benefit to the individual subjects but likely to yield generalizable knowledge about the subject’s disorder or condition – Children (45 CFR 46.406 and 21 CFR 50.53)
- Greater than Minimal Risk – Pregnant Women & Fetuses (In its deliberations, the board considered all elements of 45CFR46.204)
Adults with Decisional Incapacity Assessment:

**INSERT CATEGORY FROM OPTIONS BELOW:**
- Category A - Minimal Risk.
- Category B – Greater than Minimal Risk, but presenting the prospect of direct benefit to the individual subjects.
- Category C – Research involving a minor increase over Minimal Risk, with no prospect of direct benefit to individual subjects, but may produce knowledge about the subjects’ disorder or condition.

**INSERT arrives/leaves the meeting – Vote to INSERT quorum remains.**

**REPORT TO BOARD**

RSRB #XXXXX

**PI NAME**

Insert the full study title

**Review Materials:** { REPORT TO BOARD REVIEW MATERIALS CAN VARY, ENSURE THAT APPROPRIATE MATERIALS ARE INCLUDED AND VERSION DATES ARE IN THE FILE NAMES WHEN APPLICABLE}

**Primary Reviewer:** Name

**Discussion:**

The reviewer presented this **INSERT** and the review materials noted above to the board.

**DISCUSSION ABOUT ITEMS THE BOARD DEBATED (THE REVIEWER NOTED… OR THE BOARD DISCUSSED…) THIS WILL NEED TO BE CUSTOMIZED BASED ON THE ISSUE.**

A vote was neither required nor taken. **OR INSERT THE VOTE BELOW**

**SAMPLE OHSP AUDIT LANGUAGE:**

The reviewer presented this OHSP Final Quality Improvement Report to the board. This investigator-initiated study was randomly selected for routine review.

The purpose of this study is to... Participating subjects undergo... **DESCRIBE STUDY PROCEDURES.**

The review found no reportable findings or observations. Therefore, in accordance with OHSP standard operating procedures, the review findings for this site resulted in a rating of “Commendable”.

No additional concerns were raised. No additional follow-up is required at this time.

A vote was neither taken nor required.

**OR**

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The review found minor reportable findings regarding …DESCRIBE FINDINGS. Therefore, in accordance with OHSP standard operating procedures, the review findings for this site resulted in a rating of “Acceptable”. The Principal Investigator provided an appropriate preventative action plan in response to the findings.

No additional concerns were raised. No additional follow-up is required at this time.

A vote was neither taken nor required.

OR

The review of the study noted the following:

- INSERT FINDINGS

None of the review findings revealed an increased risk to human subjects. Therefore, in accordance with OHSP standard operating procedures, the review findings for this site resulted in a rating of “Acceptable with Follow-Up”.

The board felt the corrective and preventative action plan implemented by the study was appropriate; no further actions were required. OR The board found the corrective and preventative action plan acceptable; however the board expressed concern over…DESCRIBE DISCUSSION ITEMS. As such, the board requested that the study team…DESCRIBE ANY ADDITIONAL ACTIONS REQUESTED BY THE BOARD

SAMPLE UPIRTSO LANGUAGE:
The reviewer presented this reportable event and the review materials noted above to the board.

This reportable event notifies the RSRB of…DESCRIBE INCIDENT AND ANY CORRECTIVE/PREVENTATIVE ACTIONS PROVIDED BY THE STUDY TEAM.

The board felt the corrective and preventative action plan implemented by the study was appropriate; no further actions were required. OR The board found the corrective and preventative action plan acceptable; however the board expressed concern over…DESCRIBE DISCUSSION ITEMS. As such, the board requested that the study team…DESCRIBE ANY ADDITIONAL ACTIONS REQUESTED BY THE BOARD

The board also discussed whether the incident met the definition of an unanticipated problem involving risks to subjects or others (UPIRTSO) (defined as any incident, experience, or outcome that meets all of the following criteria: 1. unexpected [in terms of nature, severity, or frequency] given [a] the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and [b] the characteristics of the subject population being studied; 2. related or possibly related to participation in the research; and 3. suggests that the research places subjects or others at a greater risk of harm [including physical,
psychological, economic, or social harm] than was previously known or recognized). The board agreed that the incident did meet the definition of UPIRTSO. The RSRB Director will report the incident to the OHRP as required by the federal regulations and University policy.

Vote to Acknowledge:
Vote Against:
Abstained:

OLD BUSINESS

RSRB #XXXXX
PI NAME

Review Materials: [INCLUDE VERSION NUMBERS ON ALL ITEMS. FOR NEW STUDIES ENSURE THAT THE FOLLOWING ARE INCLUDED AS A MINIMUM: RSRB APPLICATION, PROTOCOL, ALL CONSENT FORMS. THE FOLLOWING ITEMS MAY BE INCLUDED IF APPLICABLE: DRUG PROFILES (INCLUDE DRUG NAME IN FILE NAME), IB (INCLUDE DRUG NAME IN FILE) RECRUITMENT MATERIALS AND STUDY MEASURES.]

Primary Reviewer: Name

Discussion:

This INSERT was tabled by the board at the INSERT DATE meeting. The board tabled this INSERT because…

USE THE TEMPLATES ABOVE TO CREATE WHATEVER IS APPROPRIATE BASED ON THE ITEM THAT WAS TABLED. IF IT IS AN AMENDMENT DO NOT INCLUDE “REVIEW PERIOD” BELOW.

Vote to Approve:
Vote Against:
Abstained:
Review Period:
Risk:

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

The meeting was adjourned at TIME.