1. **POLICY:**

Except when an expedited review procedure is used, the IRB will review proposed research at convened meetings at which a quorum is present. The IRB will meet twice per month, or at a frequency determined by the IRB Chair and the IRB Administrator.

These policies and procedures apply to all research submitted to the IRB.

2. **PROCEDURES**

2.1 Quorum

2.1.1 A quorum is defined as greater than 50% of the voting Members of the IRB.

2.1.2 A quorum consists of regular and/or alternate Members and includes at least one Member whose primary concerns are in scientific areas, one Member whose primary concerns are in nonscientific areas.

2.1.3 For convened meetings, a Member unaffiliated with Purdue University should be present for at least 50% of meetings in an appointed term, but is not required for quorum.

2.1.4 When FDA-regulated research is reviewed, there shall be one Member who is a physician.

2.1.5 A regular Member may designate his or her alternate Member to attend in the regular Member's place in order to meet the quorum requirements outlined above.

2.1.6 A Member present via telephone, video, or other instantaneous electronic connection can be used to establish a quorum.

2.1.7 Special consultants cannot be used to establish a quorum.

2.1.8 Members who recuse from the review of a protocol cannot be used to establish a quorum.

2.2 Primary and Secondary Reviewers

2.2.1 Prior to the meeting, the IRB Chair or designee will designate primary and secondary reviewers for each research protocol undergoing review. At least one primary or secondary reviewer must be present at the IRB meeting in order for the IRB to act on the protocol. The primary reviewer provides a summary of the protocol, and the initial set of comments. A secondary reviewer also provides comments on the review, and leads

discussion of the protocol if the primary reviewer is unable to attend the meeting.

2.2.2 Review worksheets will be collected from the Primary Reviewer prior to or immediately after a fully-convened meeting. Collection will be conducted by the IRB Chair, IRB Administrator, or a Protocol Analyst. These documents will be retained electronically or in hard copy as needed, and may be considered confidential to the IRB. See SOP 203: Documentation and Recordkeeping.

2.2.3 Should the review worksheet contain different opinions from the reviewer that require resolution, the IRB Chair, IRB Administrator, or a Protocol Analyst must document in either the IRB meeting minutes or a memo to file, the reconciliation of any controverted issues.

2.3 Use of Special Consultants

The IRB Chair may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals will be required to sign a confidentiality agreement before they review a protocol or attend an IRB protocol discussion. They shall not vote. The consultant will provide the IRB Chair with a written report to be shared with all reviewers summarizing relevant information. The summary will be retained with the protocol file.

2.4 Meeting Materials Sent Prior to IRB Meetings

The IRB Administrator prepares a preliminary agenda for each IRB meeting and submits the draft agenda to the IRB Chair prior to the meeting for review and revision. Agenda preparation may be delegated by the IRB Administrator to a Protocol Analyst. Once approved by the IRB Chair, the final agenda, monthly reports (e.g., Activities Deemed Exempt, Expedited Review Report), the previous meeting minutes, and documentation required for review will be distributed to all IRB Members no fewer than three (3) business days in advance of the meeting.

2.4.1 Agenda. A copy of the agenda will be maintained on file with the meeting minutes. The meeting agenda will remind Members to declare any potential Conflict of Interest (COI) they may have with research that is about to be reviewed at the outset of each meeting. Members who declare a COI on any matter will recuse themselves from participating in the discussion (except as requested by the IRB Chair) and voting on that matter. The IRB minutes will reflect such recusals as they occur during meetings.

2.4.2 Questions and comments made by Members will be sent to the IRB Administrator and appropriate IRB Chair. After the IRB Chair reviews

them, the IRB Administrator may compile and email the questions to Investigators in advance of the meeting, to enable them to address issues proactively. A copy of Investigators' responses to these early comments will be sent electronically to all Members prior to the meeting, time permitting.

2.5 Minutes

The Federal regulations for the protection of human subjects require that "Minutes of IRB meetings...shall be in sufficient detail to show attendance at the meeting; actions taken by the IRB; the vote on these actions including the number of Members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution." 45 CFR 46.115(a)(2)

2.5.1 Recording: The Protocol Analyst or designee will take written minutes of each meeting. Minutes will be written in sufficient detail to show the following:

2.5.1.1 Date and time of meeting;

2.5.1.2 Identity of the minutes taker;

2.5.1.3 Meeting attendance, including status of each attendee (regular Member, alternate for a named regular Member, non-scientist, unaffiliated Member, consultant, etc.) and COIs, if any;

2.5.1.4 Verification of a quorum;

2.5.1.5 Actions taken by the IRB on each agenda item requiring full IRB action, including, the basis for requiring changes in or disapproving the research;

2.5.1.6 Summary of the discussion of controverted issues and resolution;

2.5.1.7 Determination of the level of risk, and the study specific reasons for the determination;

2.5.1.8 Other regulatory determinations required, and the study specific reasons for the determination;

2.5.1.9 Duration of IRB approval; and

2.5.1.10 Motion and voting results, including number for, against, Members abstaining, and Members who recused

themselves (with recused members listed by name), including the reason for recusal.

2.5.2 Approval: Draft minutes will be distributed to Members prior to the next IRB meeting for review and approval.

2.5.2.1 Corrections requested by IRB Members will be made by the Protocol Analyst who authored the minutes or designee. The IRB Chair and office member who authored the minutes document their name and date the final, approved minutes. The minutes will be printed in final form and made available to Members by email.

2.5.2.2 The Protocol Analyst will maintain electronic copies of the minutes, the agenda and other pertinent materials.

2.6 Voting

2.6.1 For each application, IRB Members will vote upon the merits of the application in conjunction with the issues raised and discussed during the meeting, and the criteria for approval established by 45 CFR 46.111 (See SOP 302: Initial Review) , 116, and 117, and when appropriate Subparts B, C, and/or D. IRB Members also will determine level of risk, the frequency of review for each protocol; and, if appropriate to the protocol, monitoring of the investigative site, and whether third party assessment and follow-up will be needed.

2.6.2 Members with a COI will recuse themselves from the review of applications with which they have a COI, except to answer specific questions posed by the IRB. Members with a COI will recuse themselves from the discussion and voting and such will be noted in the minutes. Members who are recused from the vote are not counted towards quorum.

2.6.3 A majority of Members must vote in favor of an action for that action to be accepted by the IRB. Only regular Members, and designated alternate Members acting in place of regular Members, may vote. The vote, including any abstentions, will be recorded in the minutes.

2.6.4 If quorum is lost during a meeting (due to the number of Members or the required Member(s) leaving the room), the IRB cannot take votes until quorum is restored.

3. RESPONSIBILITY

The Protocol Analyst assigned to the meeting is responsible for recording the minutes of the meeting, and acts as a technical consultant when necessary.

The IRB Chair (or designee) presides over the meeting, using the agenda as a guide. The IRB Chair is responsible for procedural conduct, the review of the protocols, and providing leadership throughout the IRB meeting. IRB Chair is responsible for ensuring the appropriateness of all IRB decisions and actions.

Investigators of protocols under discussion are invited to attend the meeting for the purpose of providing further clarification or answering any questions the IRB may pose. However, Investigators must not be present during deliberation and voting on any protocol.

The HRPP Director is responsible for ensuring that all IRB decisions and actions are based on institutional requirements.

The IRB Administrator is responsible for ensuring that all IRB decisions and actions are based on regulatory requirements.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.107, 46.108, 46.109, 46.111, 46.115

21 CFR 56.108, 56.109, 56.111, 56.113

5. REFERENCES TO OTHER APPLICABLE SOPs

SOP 203 Documentation and Recordkeeping.

Purdue University Policy III.B.2, Individual Financial Conflicts of Interest

This SOP affects all other SOPs.