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1. POLICY:

The IRB will review all submitted research protocols and may decide to approve or disapprove the proposed research activity, or to specify modifications required to secure IRB approval of the research activity. When reviewed by the convened IRB, these actions will be taken by a vote of a majority of the voting IRB Members present (physically or via approval channel of mediated communication; see SOP 202: IRB Meeting Administration), except for those Members present but unable to vote in accordance with Purdue University's conflict of interest policies. When reviewed via expedited review, the IRB Chair (or designee) can take any of the following actions except to disapprove a study.

These policies and procedures apply to all research reviewed by the IRB.

2. DEFINITIONS

- 2.1** *Administrative Review.* A review conducted by a Human Research Protection Program (HRPP) Protocol Analyst to determine if a submission contains all of the necessary paperwork and supporting documents and ensures that all required elements are complete.
- 2.2** *Exempt Research.* Research that qualifies for one of the exemption categories specified at 45 CFR 46.104 and/or 21 CFR 56.
- 2.3** *Expedited Review.* Review procedures for certain categories of research established by the Department of Health and Human Services and the Food and Drug Administration that do not require review by a convened quorum of the full IRB. The IRB Chair (or designated expedited reviewer) has the authority to review the information via expedited review unless the IRB requires that the material be reviewed by the full IRB.
- 2.4** *Full Review.* Level of review pertaining to research activities that must be evaluated by a quorum of the convened IRB.
- 2.5** *Information Sheet.* The information sheet is a document written to contain all of the elements of the consent form template that communicates to the study participant information about the research study. The information sheet does not have signature lines for study participants to sign as does a consent form.
- 2.6** *Key Personnel.* The Principal Investigator and any project staff, students, postdoctoral staff, internal or external to Purdue University who contribute in a substantive way to the scientific development or execution of a project (including, but not limited to, consent, data collection or analysis).

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- 2.7** *Minimal Risk.* Level of risk in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of a normal healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests.
- 2.8** *Primary and Secondary Reviewers* – Reviewers who are voting IRB members assigned to conduct, initial review, continuing review, or review of revision requests.
- 2.9** *Principal Investigator* – Tenured, tenure-track, research, and clinical faculty of Purdue University are eligible to be Principal Investigators (PIs) on an IRB protocol. Others requesting to submit protocols as the Principal Investigator must obtain approval from the Institutional Official or his/her designee.

3. PROCEDURES

Research activities with human subjects/participants that do not qualify for exemption from the full requirements of 45 CFR 46 or 21 CFR 56 must receive IRB review and approval prior to their initiation.

3.1 Submission Requirements

- 3.1.1 Investigators submitting an application for initial review are required to provide:
- (a) Documented or electronic system authorization/certification by the Principal Investigator
 - (b) Initial Study form with complete answers to all questions
 - (c) Consent documents
 - (d) Assent documents, if applicable
 - (e) Recruitment materials including, but not limited to, advertisements, flyers and letters
 - (f) Data collection instruments, surveys, tests, questionnaires, debriefing information, etc.
 - (g) If the research or the recruitment will occur in or through schools, businesses, care facilities or other organizations, please include a letter from an appropriate administrator or official permitting the conduct of research activities on their premises.

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- (h) Confirmation or evidence of training in the appropriate field of Human Subjects Research.

3.1.2 Additionally, investigators may be required to submit:

- (a) An information sheet for participants
- (b) Documentation that the study has been reviewed and approved by other committees charged with oversight of research at Purdue University (e.g. review from Radiological and Environmental Management (REM)).
- (c) Information on collaborating Investigators from other institutions.
- (d) Documentation of review from an appropriate ethics board in a foreign country or other appropriate individual with expertise in the respective culture.
- (e) Translations of consent forms into a foreign language appropriate for the intended subject population and certification of the accuracy of the translation.
- (f) Authorization for release or use of Personal Health Information (PHI).
- (g) Evidence of prior training or certification when specialized biomedical or social behavioral procedures will be conducted as a component of a research protocol (e.g. venipuncture or administration of psychological testing).

3.2 Review Procedures for Initial Review

3.2.1 The Protocol Analyst conducts administrative review of the protocol application submission to determine if the Investigator has submitted all of the necessary paperwork and supporting documents and ensures that all required elements are complete. If it is determined that the submitted documents are not adequate, the Investigators may be required to submit additional information, answer questions and/or explain the details of the study. Incomplete submissions will not be routed for IRB review.

3.2.2 The Protocol Analyst determines if the protocol application qualifies for expedited review. This determination may also be made by, or in consultation with, the IRB Chair, HRPP Director, IRB Administrator, or an Expedited Reviewer (see SOP 303: Expedited Review). If the consulting parties cannot reach consensus on the appropriate level of

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review, the protocol application will be reviewed via full convened IRB procedures.

- 3.2.3 Once the administrative review is complete, the protocol application is either reviewed according to expedited procedures or assigned by the Protocol Analyst to a primary reviewer from the appropriate IRB, depending on the research proposed in the application, and placed on a meeting agenda.
- 3.2.4 Copies of the complete protocol application are distributed to all IRB Members. The Primary Reviewer receives a copy of the Administrative Review. The Primary Reviewer is responsible for documenting the review.
- 3.2.5 The Protocol Analyst will compile questions and comments received from IRB members and forward them to the Investigator requesting a response to the comments. Additionally, the Protocol Analyst will extend an invitation to the Investigator to attend the meeting in order to answer any remaining questions the IRB may have about the protocol application.
- 3.2.6 When the Protocol Analyst receives the Investigator's response to the IRB's comments, the response is forwarded to IRB members.

3.3 Review Criteria

The IRB will conduct a review of the research which includes, but is not limited to, the criteria outlined in 45 CFR 46.111 and/or 21 CFR 56.111:

- 3.3.1 A determination that risks to participants are minimized;
- 3.3.2 A determination that risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result;
- 3.3.3 A determination that selection of participants is equitable;
- 3.3.4 A determination that informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by 46 CFR 46.116 and/or 21 CFR 50;
- 3.3.5 A determination that informed consent will be appropriately documented, in accordance with and to the extent required by 46.117 and/or 21 CFR 50.27;

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- 3.3.6 A determination that when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
- 3.3.7 A determination that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;
- 3.3.8 A determination that when some or all subjects are likely to be vulnerable to coercion or undue influence (such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons), additional safeguards have been included in the study to protect the rights and welfare of subjects; and
- 3.3.9 A determination of the scientific or scholarly validity of the research.
 - (1) Such validity is determined by the experience of an Investigator, a review by a funding agency, a separate peer review process, or by a thesis/ dissertation committee (in the case of graduate student research). These processes help to ensure that:
 - A. The research procedures are consistent with sound research design;
 - B. The research design is sound enough to reasonably expect the research to answer its proposed question; and
 - C. The knowledge expected to result from the research is of importance to the scientific or scholarly discipline.
 - (2) Should IRB Reviewers disagree with the scientific or scholarly validity assessment, the application should be reviewed either by an IRB Member with appropriate expertise or a consultant whose expertise is germane to the research.

3.4 IRB Convened Meeting

- 3.4.1 At a convened meeting, the IRB will conduct an initial review of the protocol in accordance with the aforementioned review criteria in section 3.3. If the Investigator accepted the IRB's invitation to attend the meeting, she/he will be given the opportunity to answer the IRB's questions and clarify any concerns regarding her/his protocol application.

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- 3.4.2 After the Investigator has addressed questions and concerns and has left the meeting, the IRB will deliberate on the protocol, make findings as appropriate, and decide on an action.
- 3.4.3 The IRB may make one of the following determinations as a result of its review of research submitted for initial review:
- (a) *Approval.* The protocol and accompanying documents are approved as submitted. IRB approval will commence on the day the study is approved by an action of the convened IRB or IRB Chair or designee and expire within a defined time period based on risk assessment and regulations. Approvals are always conditional. If specific conditions are stipulated in the approval letter, those conditions must be met by the designated date or approval may be withdrawn. See SOP 306: Post-Approval Monitoring and SOP 410: Suspension or Termination of Research for more information on the conditional nature of approval.
 - (b) *Revisions to Submission Required:* Minor modifications of, or addition to, a protocol or accompanying document(s) is required. The Investigator will be informed in writing of the required changes and requested information and must provide the IRB with the changes or information.
 - (c) *Tabled:* Significant questions are raised by the proposal requiring its reconsideration after additional information is received from the Sponsor and/or Investigator. The proposal is assigned for review at a specific, future meeting.
 - (d) *Deferred:* Significant questions are raised by the proposal requiring its reconsideration after additional information is received from the Sponsor and/or Investigator. The proposal is postponed to an unspecific future meeting.
 - (e) *Disapproval:* The proposal fails to meet one or more criteria used by the IRB for approval of research. This disapproval determination cannot be made through the expedited review mechanism and may only be made by majority vote at a convened meeting of the IRB.

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- 3.4.4 After the meeting adjourns, the Protocol Analyst creates the meeting minutes and generates correspondence to the Investigator informing her/him of the IRB action taken on the protocol application. The Protocol Analyst consults as needed with the IRB Administrator, IRB Chair or his/her designees, on the content of the correspondence to investigators.
- 3.4.5 If the protocol is approved at the convened IRB meeting, the IRB Chair or designee, will document the approval by electronically certifying the Protocol Review Form. The HRPP Support then generates an approval letter and informs the Investigator to include the IRB Protocol Number and Approval Expiration Date in the header or footer of all approved consent documents.
- 3.4.6 If the protocol is approved with Revisions to Submission Required, the Investigator is notified via the generated correspondence referenced in Section 3.4.4. When the Investigator's revised protocol application is received, it is reviewed by the Protocol Analyst and the IRB Chair or designee. If the revised application is in order, the IRB Chair or designee may approve the protocol by electronically submitting the Protocol Review Form. The HRPP Staff then generates the approval letter and processes the approval as referenced in Section 3.4.5.
- 3.4.7 If substantive revisions are requested, the Investigator is notified via the generated correspondence referenced in Section 3.4.4. When the Investigator's revised protocol application is received, it is reviewed by the Protocol Analyst and the IRB Chair or designee (who must be an Expedited Reviewer) to ensure it adequately addresses the IRB's concerns. The Protocol Analyst then assigns the protocol to a meeting agenda and distributes the revised protocol application to the IRB members. The protocol will be reviewed in accordance with Section 3.3.
- 3.4.8 If the protocol is deferred, the Investigator is notified via the generated correspondence referenced in section 3.4.4. The Protocol Analyst then assigns the protocol to a meeting agenda at which time the protocol will be reviewed in accordance with Section 3.3.
- 3.4.9 If the protocol is disapproved, the Investigator is notified via the generated correspondence referenced in Section 3.4.4. The correspondence includes a statement of the reasons for the IRB's decision and instructs the investigator that s/he can respond in writing to the determination within 30 days of her/his notification.

Investigators may appeal an IRB decision to disapprove a study. Investigators may also appeal the revisions required by the IRB in the protocol and/or informed consent form. Appeals must be in writing and submitted to the IRB. Appeals will be reviewed by the full IRB at a

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convened meeting. If an appeal is denied and the study disapproved, the decision is final. IRB decisions to deny research protocols cannot be overturned by any other agent of the University.

3.5 Notification of IRB Findings to Organizational Offices and Officials

3.5.1 The IRB, through its operational staff (e.g. HRPP Director, IRB Administrator, Protocol Analysts, and Clerical Staff) will communicate the findings of each IRB initial review. Notices are sent electronically or by hard copy to:

- (a) The Principal Investigator (PI);
- (b) The designated Primary Contact (PC) in the electronic system;
- (c) Key Personnel- All current key personnel on a protocol will be informed of the IRB findings. A PI or PC may request that specific Key Personnel do not receive notification if study design requires blinding from research methods or results. The PI and PC must receive notification. If an exception is granted by the HRPP, all IRB findings will still be sent to the PI and PC and be available in the electronic system and file hard copy as available;

3.5.2 When appropriate, the IRB operational staff will communicate findings with other members of the organization. The IRB, through its operational staff (e.g. IRB Administrator, Protocol Analysts, and Clerical Staff) may opt to communicate the findings of each IRB initial review with:

- (a) The Institutional Official (IO);
- (b) Study Sponsor (via Research Regulatory Affairs and/or Sponsored Program Services; approval documents may be made available to Sponsored Program Services through the Research Regulatory Affairs team via direct system access, electronically, or hard copy;
- (c) University Legal Counsel and/or designated outside counsel;
- (d) IRBs or Ethics Committees collaborating with or relying on Purdue University IRB;
- (e) The IRB Chair, IO, HRPP Director or his/her designee may determine other appropriate entities to notify of the IRB findings. These may be internal or external to Purdue University.

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- (f) Notifications pertaining to Unanticipated Problems and Adverse Event Reporting will follow reporting procedures described in SOP 409.

4. RESPONSIBILITY

Principal Investigators must accept overall responsibility for directing and overseeing the research and adhering to University policies, federal and state regulations, IRB SOPs, and approved IRB protocols.

HRPP Support Staff (including Project Assistants, Clerical, and student support) is responsible for receipt of the protocol application submissions, entering data into the electronic system, forwarding the request to a Protocol Analyst for administrative review.

Protocol Analysts are responsible for conducting administrative review of protocol application submissions, assigning them to meeting agendas and overseeing the review process, recording meeting minutes into the data management system, and generating correspondence.

The IRB Administrator in consultation with the IRB Chair and HRPP Director is responsible for establishing and implementing processes for conducting review of research. Additionally, she/he participates in the conduct of initial reviews for protocols reviewed by the convened IRB. If necessary, she/he may conduct administrative or expedited reviews.

The IRB Chair or his/her designee is responsible for providing consultation in the evaluation of protocol application submissions, review revised protocol applications submitted in response to requests for specific minor revisions, and grant approval on behalf of the IRB.

IRB Members are responsible for participating in the initial review of protocol application submissions.

Primary Reviewer is responsible for documenting the initial review and findings on the Protocol Review Form and, if applicable, special Review Form(s).

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.109; 45 CFR 46.111

21 CFR 56.109; 21 CFR 56.111

[Purdue University Policy III.B.2, Individual Financial Conflicts of Interest](#)

[Purdue University Policy III.B.6, Institutional Conflicts of Interest](#)

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6. REFERENCES TO OTHER APPLICABLE SOPs

303 Expedited Review

320 Informed Consent Requirements

409 Unanticipated Problems and Adverse Event Reporting