

Human Research Protection Program

Institutional Review Board



Standard Operating Procedures (SOPs)

Updated December 6, 2021

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Statement of Purpose, Authority, and Responsibility

Updated December 06, 2021

INTRODUCTION

1. Purpose

The Purdue Human Research Protection Program (HRPP) implements Purdue's commitment to protect human research participants through application of Belmont Report principles (Respect for Persons, Beneficence, and Justice).

The HRPP organizational structure exists as an extension of the Office of Research and Partnerships. As a component of HRPP, the Purdue University Institutional Review Board (IRB) is charged with ethical review of proposed research with human subjects.

2. Authority

HRPP and the associated IRB has the support of the Purdue University administration under Purdue University Policy I.C.1, "Research Involving Human Subjects". Purdue University requires that all research projects involving humans as subjects, human material, or personally identifiable data be reviewed and approved by the IRB prior to initiation of any research related activities, including recruitment and screening activities. Congruent with federal guidance, a Purdue University is considered engaged in a human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

The IRB is established to review research involving human subjects regardless of the source of funding and location of the study. The IRB has the authority to ensure that research is designed and conducted in such a manner that protects the rights and welfare of participating subjects. Specifically:

- The IRB may disapprove, modify or approve studies based upon consideration of human subject protections;
- The IRB reviews, and has the authority to approve, require modification in, or disapprove, all research activities that fall within its jurisdiction;
- The IRB has the authority to conduct continuing review as it deems necessary to protect the rights and welfare of research subjects, including requiring progress reports from the Investigators, monitoring the conduct of the study, observing the informed consent process, and/or monitoring the progress of any study under its jurisdiction as it deems necessary to protect the rights and welfare of human subjects;
- The IRB may suspend or terminate approval of a study; and
- The IRB may place restrictions on a study or disallow use of collected data from human subjects.
- The IRB may request review from the Purdue University Office of Legal Counsel to assist in determinations of international, national, and local laws that influence IRB determinations within a particular locality where research is conducted.

Statement of Purpose, Authority, and Responsibility

The IRB functions independently of, but in coordination with, other institutional research review committees appropriate for consultation and guidance on issues related to protection of human subjects (e.g., with respect to exposure to radiation). Research that has been reviewed and approved by the IRB may be subject to review and disapproval by institutional officials, other committees, or Purdue University's Office of Legal Counsel to assist with resolution of conflicts in federal/national law and other applicable laws. However, those officials or committees may not approve research if it has been disapproved by an IRB.

Failure to submit a research project for IRB review will be treated as noncompliance with university and federal regulations, and is subject to consequences determined by the IRB and, as deemed necessary, by Purdue University. Results from such studies may not be shared or published unless IRB approval had been obtained prior to collecting the data.

3. Responsibility

All research involving human subjects conducted by Purdue employees or affiliates must be reviewed and approved by the Purdue IRB. No intervention or interaction with human subjects in research, including recruitment, may begin until the IRB has reviewed and approved the research protocol. Specific determinations relevant for the definition of "Research" or "Human Subjects," and their implications for the jurisdiction of the IRB under institutional policy are determined by the HRPP and IRB.

The IRB's sole responsibility is to protect the rights and welfare of human subjects. The IRB reviews and oversees such research to ensure that it meets well established ethical principles and that it complies with federal regulations at 45 CFR 46 and 21 CFR 50 and 56, that pertain to human subject protection, as well as any other pertinent regulations and guidelines.

Except for research in which the only involvement of humans is in one or more of the categories exempted or waived under 45 CFR 46, all research involving human subjects, and all other activities, regardless of sponsorship, are subject to IRB review and approval if the activity meets the definitions of Human Subjects Research as outlined in the federal regulations and Standard Operating Procedures (SOP) detailed herein.

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1. POLICY

The Institutional Review Board (IRB) shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB should also be able to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

Therefore, each IRB shall consist of at least five regular, voting Members. Qualified persons from multiple professions shall be considered for membership. The institution will make every effort to have as diverse as possible membership appointed to the IRB, within the scope of available expertise needed to conduct its functions.

The management of the membership of the IRB and oversight of Member appointments, IRB related activities, communications, and other administrative details are the responsibility of the Human Research Protection Program (HRPP). The IRB Executive Committee of the HRPP shall be the primary policy-making body of the HRPP with respect to IRB matters. The IRB Executive Committee will develop and implement policies related to the function of the HRPP, including SOPs, procedures, forms and implementation of federal regulations. The IRB Executive Committee shall be comprised of the IRB Chair, IRB Associate Chair, IRB Administrator, Human Research Protection Program (HRPP) Director, and a Protocol Analyst representative. The Institutional Official (IO) may participate as an ex officio member of the Executive Committee.

These policies and procedures apply to the membership of the Purdue University IRB.

2. PROCEDURES

2.1 Membership Selection Criteria

The Members of the IRB shall be sufficiently qualified, through experience and/or expertise, to review research proposals in terms of regulations, applicable law and standards of professional conduct and practice, and institutional commitments. Therefore, the IRB shall include persons knowledgeable in these areas.

The membership shall be diverse, so selection shall include consideration of race, gender, cultural backgrounds, clinical experience, healthcare experience and sensitivity to such issues as community attitudes to assess the research submitted for review. Those individuals involved directly in Purdue University business development may not serve as members of the IRB and may not carry out the day-to-day operations of IRB review or exemption processes.

2.2 Composition of the Board

2.2.1 Regular Members: The backgrounds of the regular Members shall be varied (e.g., representing more than one area of expertise, not composed solely of males or females) in order to promote appropriate reviews of the types of

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research activities commonly reviewed by each IRB. Regular Members must include:

- (a) **Scientific Member:** The IRB must include at least one Member whose primary concerns are in the scientific area. Most IRBs include physicians and doctoral level physical, biological, or social-behavioral scientists. Such Members satisfy the requirement for at least one scientist. However, when FDA-regulated products are reviewed (such as investigational new drug studies), the convened meeting must include a licensed physician Member.
- (b) **Nonscientific Member:** The intent of the requirement for diversity of disciplines is to include Members whose main concerns are not in scientific areas. Therefore, nonscientific Members are individuals whose education, work, or interests are not solely in medical or scientific areas.
- (c) **Nonaffiliated Member:** The nonaffiliated Member(s), who can be either scientific or nonscientific reviewers, should be knowledgeable about the local community, represent the perspective of research participants, and be willing and able to discuss issues and research from that perspective. Nonaffiliated Members must not themselves be affiliated with Purdue University or be part of the immediate family of a person who holds a current affiliation with Purdue. Consideration should be given to recruiting individuals who speak for the communities from which Purdue University routinely draws its research subjects. The nonaffiliated Member(s) should not be vulnerable to intimidation by the affiliated Members on the IRB, and their knowledge and expertise should be fully utilized by the IRB.
- (d) **Representatives of special groups of subjects:** When certain types of research are reviewed, Members or consultants who are knowledgeable about the concerns of certain groups may be required. For example, if an IRB reviews research involving prisoners, an individual who can represent this group (e.g., an ex-prisoner or an individual with specialized knowledge about this group) must be included in the IRB discussion.
- (e) **IRB Chair:** The IRB Chair must be employed by Purdue University and be fully capable of providing leadership to the IRB and the matters brought before it with fairness and impartiality.
- (f) **Associate Chair:** The Associate Chair provides the Purdue HRPP with leadership and coordination of activities that contribute to the overarching goal of promoting ethical human subjects research. This

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includes (but is not limited to), presentations to faculty groups, hosting researcher seminars and assisting researchers with IRB applications. This role may also chair convened IRB meetings when the IRB Chair is unavailable.

2.2.2 Alternate Members: The IRB may formally select alternate Members to substitute for a regular Member who is unavailable. (The use of ad hoc alternates is not permitted.) The IRB Member roster should clearly indicate which regular Member(s) for whom each alternate Member is permitted to substitute. To ensure maintaining an appropriate quorum, the alternate Member's qualifications should be comparable to the regular Member to be replaced. When an alternate Member substitutes for a regular Member, the alternate Member should have received and reviewed the same material that the regular Member received or would have received.

2.2.3 Non-Member Consultants: When an IRB encounters studies involving specific topics beyond the expertise of the Members, the IRB may use a consultant with competence in such matters to assist in the review. Such consultants are not Members of the IRB and may not vote with the IRB.

2.3 Appointments

Members of the IRB are appointed by the Institutional Official (IO) upon recommendation of the IRB Chair(s), HRPP Director, and IRB Administrator. Members will be solicited from Purdue University and surrounding communities. Regular Members and alternate Members are appointed using the same process.

2.4 Member Expectations

2.4.1 Meeting Attendance

- (a) A majority of IRB Members eligible to vote must be present at a meeting to establish quorum, therefore Scientific IRB Members are expected to attend greater than one half (1/2) of convened meetings per fiscal year (e.g., 13 of 24 scheduled meetings). A minimum attendance of one meeting must occur during the summer. Nonscientific IRB members will rotate board meeting responsibilities among the scheduled meetings. The IRB Chair is authorized to make exceptions to this expectation as appropriate in coordination with the Institutional Official.
- (b) The IRB Chair and Associate Chair are expected to attend at least 75% of regular convened IRB meetings during the one-year term.
- (c) Voting IRB Members are expected to arrive promptly and stay at convened meetings until all board business has been completed.

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- (d) IRB Members can attend meetings by telephone or other electronic means. Participating members will receive all pertinent material prior to the meeting and will be able to actively and equally participate in the discussion of all protocols.
- (e) When attendance is not possible, IRB Members must notify the IRB Administrator or designee (e.g., Protocol Analyst), allowing sufficient time in advance of the meeting to locate an alternate IRB Member to ensure a quorum.

2.4.2 Knowledge of Regulations, Policies and Procedures

In order to gain and increase knowledge of the ethical, regulatory and procedure requirements for reviewing and approving research involving human subjects, IRB Members are expected to:

- (a) Be familiar with the Belmont Report and its application.
- (b) Be familiar with 45 CFR 46 and 21 CFR 56 and their application, including OHRP and FDA guidance documents.
- (c) Participate in HRPP training and ongoing education as provided by the HRPP.
- (d) Attend ongoing education for IRB Members and HRPP Staff provided by PRIM&R, AAHRPP, OHRP, or other nationally recognized bodies.
- (e) Be familiar with and abide by Purdue University HRPP policies, procedures and guidance documents governing the IRB, including all SOPs.
- (f) Mentor new IRB Members.
- (g) Serve as a resource for Investigators about Human Subjects Research.
- (h) Promote respect for the advice and counsel of the IRB in safeguarding the rights and welfare of human subjects.
- (i) IRB members (excluding Nonscientific Members) must perform a portion of expedited reviews equal to one calendar month each year. IRB members with less than one year of experience must receive sufficient in-person training by the HRPP Staff, IRB Chair or Associate Chair before performing expedited review.

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2.4.3 Maintaining Confidentiality

Members are expected to respect and maintain the confidentiality of the research studies reviewed and the IRB deliberations thereon.

2.4.4 Conflict of Interest Disclosure

Members are expected to disclose a real or perceived conflict with any study under review by the IRB, and not participate in the IRB review of such studies.

2.4.5 Reports of Undue Influence

If a Member encounters attempt of undue influence or incidence to unduly influence a determination, the Member is expected to report to the Institutional Official or the Office of Ethics and Compliance as appropriate.

2.4.6 Subcommittee or *Ad hoc* Service

Members may be asked to participate in a subcommittee of the IRB as a service on behalf of the IRB. Members may also be asked to attend meetings convened to address immediate participant risk concerns.

2.5 Terms

2.5.1 The IRB Chair will serve in this capacity for a term of one year. Reappointment by the IO for additional terms may occur, with input from the HRPP Director, IRB Administrator, and IRB Chair.

2.5.2 The IRB Associate Chair will serve in this capacity for a term of one year. Reappointment by the IO for additional terms may occur, with input from the HRPP Director, the IRB Administrator, and the IRB Chair.

2.5.3 IRB Members will serve on the IRB for a term of one year. Reappointment by the IO for additional terms may occur, with input from the HRPP Director, the IRB Administrator, the IRB Chair, and the IRB Member.

2.6 Resignations and Removals

2.6.1 If a Member resigns before the conclusion of their term, the vacancy will be filled as quickly as possible by the IO.

2.6.2 With reasonable cause, the IRB Executive Committee may recommend to the IO the removal of a Member at any time. Acting upon the recommendations of the IRB Executive Committee, the IO has the authority to remove a Member.

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2.6.3 The IRB Executive Committee may recommend to the IO removal of an IRB Chair at any time. Each voting member of the IRB Executive Committee has the authority to convene a meeting with or without the presence of the IRB Chair. Acting upon the recommendation of the IRB Executive Committee, the IO has the authority to remove the IRB Chair.

2.7 Compensation

Participation by Purdue University faculty or staff, or students is considered a component of their job responsibilities as established by their supervisors. Regular voting members may be modestly compensated for the time spent in IRB-related activities. Regular Members who are not affiliated with Purdue University may receive appropriate reimbursement as consultants and miscellaneous expenses (e.g., parking).

2.8 Liability Insurance

Regular and alternate Members acting consistent with their charge as IRB Members have liability insurance coverage as part of their IRB membership in their capacity as agents of Purdue University as described by University Policy.

2.9 Records

The HRPP shall maintain a current list of IRB Members, along with each Member's CV or qualifications.

3. IRB EXECUTIVE COMMITTEE

3.1 Meetings

3.1.1 The Executive Committee shall be co-chaired by the IRB Chair, and the HRPP Director.

3.1.2 The Executive Committee shall meet no fewer than four times per academic year and more frequently as determined by need. Need shall be determined by the IRB Chairs and HRPP Director with input from the Board membership and HRPP staff. The calendar for these meetings shall be published at the beginning of the IRB term, though ad hoc meetings may occur.

3.1.3 Meeting minutes shall be recorded by a staff member designated by the HRPP Director or IRB Administrator.

3.1.4 A quorum is defined as 50% or greater of the voting membership.

3.1.5 A member present via telephone or electronic connection can be used to establish a quorum.

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- 3.1.6 Emergency meetings may be conducted via telephone conference calls, provided all members receive all relevant materials in advance of the meeting, each member can actively participate, and that all other regulatory requirements are met.
- 3.1.7 Minutes will be reviewed and approved by the co-chairs, and distributed to the committee members at the next convened meeting.
- 3.1.8 Any changes to SOPs approved at meetings will be uploaded to the HRPP website prior to the next meeting, following approval signatures from the IRB Chairs and the IO.

3.2 Finalizing and Distributing SOPs

- 3.2.1 The HRPP Director or IRB Administrator will ensure that IRB Chairs and the IO sign updated and approved SOPs.
- 3.2.2 The HRPP Director or IRB Administrator will ensure that updated and approved SOPs are published on the HRPP website.

4. RESPONSIBILITY

The IO is responsible for ensuring the IRB has adequate resources to identify and recruit qualified potential members. The IO appoints IRB Members for each term.

The HRPP Director is responsible for arranging for compensation as needed for consultants and nonaffiliated Members.

The IRB Administrator is responsible for recruiting and training new IRB Members in consultation with the IRB Chair and Associate Chair.

The IRB Chair and Associate Chair are responsible for mentoring and evaluating new IRB Members. The IRB Chair is responsible for management of the activities of the IRB Members relevant to meeting conduct and review of research.

IRB Members (including IRB Chair and Associate Chair) are responsible for fulfilling the IRB Member Expectations outlined in Section 2.4 above. IRB Members are also required to provide a current CV to the HRPP Office at the time of their initial appointment, and annually thereafter.

5. PROCESS OVERVIEW

The IRB Chair and IRB Administrator, in consultation with the HRPP Director, may identify members of Purdue University's faculty and staff and members of the local community to serve on the IRB.

Approximately ninety (90) days prior to the end of an appointment term, the IRB Administrator will query each current Members' interest in serving for an additional term. The results of this query will be sent to the IRB Chair, HRPP Director, and IO for

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reappointment considerations and to identify the number of vacancies anticipated in the next term.

Recommendations for new appointments may also be made by any IRB Member to the IO or IRB Chair. The IRB Chair and IRB Administrator will discuss the responsibilities and time commitment of IRB membership with interested parties. If the person is interested, his or her name is submitted by the IRB Chair or designee to the IO recommending appointment of the individual to the IRB. If the IO concurs with the recommendations, he or she sends an appointment letter to the interested party, with copies to his or her department head and the IRB Administrator.

The IO and HRPP Director ensure the overall diversity of the IRB membership (e.g., gender, race, ethnicity, community affiliation, and professional experience) through establishing non-discriminatory selection methods.

The IRB Administrator, IRB Chair, and HRPP Director select new Members to replace Members who resign or otherwise leave IRB service, and recommend such Members to the IO for potential appointment.

The HRPP Support Staff maintains a roster of all regular and alternate Members, a file on all Members (to include their curriculum vitae or other evidence of professional ability), and a roster of available consultants who are eligible and qualified to review protocols and attend meetings as invited consultants.

6. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.107

21 CFR 56.107

[FDA Institutional Review Boards Frequently Asked Questions - Information Sheet](#)

7. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

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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

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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

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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

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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.

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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.

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1. POLICY

The IRB's files must be maintained in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, including continuing reviews, amendments, adverse event reports, and reports of non-compliance. All records regarding a submitted study (regardless of whether it is approved) must be retained by the Human Research Protection Program (HRPP) in an appropriate manner as required by regulatory requirements and/or Purdue University institutional policy.

Records must be accessible for inspection and copying by authorized representatives of the sponsor, funding department or agency, regulatory agencies, and institutional auditors at reasonable times and in a reasonable manner.

Required documents must be submitted to the appropriate funding entity as required.

These policies and procedures apply to all controlled documents used in research reviewed by the IRB.

2. PROCEDURES

2.1 Document Retention

2.1.1 Study-specific documents. Adequate documentation of the IRB's activities will be prepared, maintained, and retained in a secure location. Documents to be retained include:

- (a) Copies of all original research protocols reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by Investigators, and reports of adverse events occurring to subjects, and reported deviations from the protocol;
- (b) The rationale for an expedited reviewer's determination under 45 CFR §46.110(b)(1)(i) that research appearing on the expedited review list described in § 46.110(a) is more than minimal risk (See SOP 303: Expedited Review).
- (c) Copies of all continuing review activities, including submitted monitoring reports and site visit reports;
- (d) For all human subjects research conducted at Purdue University but reviewed by an IRB operated by another institution, Purdue University and the organization operating the other IRB shall document Purdue University's reliance on the IRB for oversight of the research. The documentation can be achieved through a written agreement between Purdue University and the IRB, as set forth in a

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multi-institutional research protocol, or by implementation of a Purdue University-wide policy providing the allocation of responsibilities between Purdue University and IRBs operated by other institutions;

- (e) Copies of correspondence between the IRB and Investigators relevant to the study risks and clarifications (e.g., phone minutes, e-mail conversations, memos to file). These documents will be utilized to document resolution of controverted issues or requested revisions of the IRB. Documents must be versioned or paginated in a manner that allows obvious evidence of reconciliation of concerns expressed by a Primary and/or Expedited Reviewer;
- (f) Review worksheets will be collected from the Primary Reviewer prior to or immediately after the fully convened meeting. This collection will be conducted by the IRB Chair, IRB Administrator, or a Protocol Analyst. Expedited or exempt review sheets will be provided to an IRB office member prior to initiating an action toward revision or approval. These documents will be retained electronically or in hard copy as needed and may be considered confidential to the IRB.
- (g) Statements of significant new findings provided to subjects; and
- (h) Reports of any complaints received from subjects.

2.1.2 Administration Documents. Adequate documentation of the HRPP and IRB's internal operations will be prepared, maintained, and retained in a secure location. Documents to be retained include:

- (a) Agendas and minutes of all IRB meetings, which shall be in sufficient detail to show attendance at the meetings; 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;
- (b) A current list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant;

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(c) Copies of all required policies and procedures of the HRPP and IRB.

2.2 Duration of Retention

- 2.2.1 The HRPP must retain all records regarding a research application (regardless of whether it is approved) for at least three (3) years.
- 2.2.2 For all applications that are approved, and the research initiated, the HRPP must retain all records regarding that research for at least three (3) years after completion of the research.
- 2.2.3 The HRPP will treat denied applications as terminated files and retain records for three (3) years after the denial of the research.
- 2.2.4 For all applications that use or obtain Protected Health Information (PHI), pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the HRPP must retain all records regarding that research for at least six (6) years after the completion of the research.

2.3 Manner of Retention

Federal IRB regulations permit records to be stored either electronically or in hard copy. The Purdue University HRPP maintains documentation in electronic format, but may elect to store files in hard copy as deemed necessary.

2.4 Destruction of Materials

IRB Members are required to return, destroy, and/or delete all IRB-related research protocol review material that is considered confidential and in excess of the required original documentation and appropriate controlled forms. Master files are kept on file as described in Sections 2.2 and 2.3.

2.5 Archiving and Destruction

All documents and materials germane to IRB applications will be retained as described in Section 2.2. After the required retention period has elapsed, archiving policies of Purdue University will determine when such archived records may be destroyed and the method of destruction.

2.6 Informed Consent Documentation

For clinical trials supported by a federal agency, a copy of the IRB-approved informed consent form must be made publicly available as described in SOP 320: Informed Consent Requirements.

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3. PROCESS OVERVIEW

HRPP Support Staff will log incoming applications into the IRB electronic system. Once the application has been approved, the application/protocol folder is filed in the electronic system utilized by the HRPP office. The HRPP is responsible for maintaining complete files on all research reviewed by or submitted to the IRB and for all applicable regulatory compliance requirements.

Upon closure or termination of a protocol, files are archived within the electronic system. Any hard copy files are grouped by termination month and year and are stored for three years or six years depending on the retention requirements described in Section 2.2. If an application does not receive approval and/or the Investigator withdraws the application during the review process, it the record remains in the electronic system. Files are periodically purged after expiration of the retention period, in accordance with Purdue University policy.

In the case that either the HRPP Director or Institutional Official withhold institutional approval, the files will be retained by that official until the issue is resolved (e.g., through amendment of the protocol, withdrawal of the protocol by the Investigator, or denial of the protocol by the official).

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 46.115

21 CFR 56.115

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

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1. POLICY:

The closure of a protocol is a change in the status of an approved research activity from active to closed. Protocol closure must be reported to the IRB by the Investigator. The Closure Date establishes the record-keeping period of 3-years (or more, as applicable) post closure, and allows the IRB to collect pertinent information as needed, as well as close its files.

These procedures apply to all human subject research reviewed by the IRB, and exempt research.

2. DEFINITIONS

2.1 *Exempt Research.* Research that qualifies for one of the exemption categories specified at 45 CFR 46.104 and/or 21 CFR 56.

2.2 *IRB Reviewed Research.* Human subject research that does not qualify for an exempt determination (or which requires limited IRB review as a condition of an exempt determination) must be reviewed and approved by the IRB before it can be undertaken. While the research study is open, it remains under the oversight of the IRB.

2.3 *Protocol Closure.* The point at which research activities cease and the study is reported as “closed” to the IRB.

2.4 *Closure Date.* The date the study status is changed to “closed” with the IRB.

3. PROCEDURES

3.1 Requirements to Close a Protocol

3.1.1 No further interventions/interactions with subjects, no follow-ups, nor access to personally identifiable information for research purposes are occurring; and

3.1.2 All data analysis involving the research site(s) under this study is complete¹; or data have been de-identified and no direct identifiers or code keys (if data are coded) exist that would allow for the potential identification of subjects; and

3.1.3 Grant funds associated with the protocol are no longer being accessed; or an associated grant remains active, the human subjects research activities have ended.

¹ Note that identifiable data may be stored securely for future research purposes if authorized by the IRB-approved data collection protocol and/or appropriate consent has been obtained from subjects.

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3.1.4 Alternatively, an Investigator separating from Purdue may:

- (a) identify a Purdue Investigator to oversee the study, or
- (b) transfer oversight to an IRB at another institution, thereby closing the study with the Purdue IRB.

3.2 Procedure to Close a Protocol

- 3.2.1 Investigators can close a protocol for IRB reviewed research by submitting study closure materials through the electronic system. This must be submitted prior to the expiration of IRB approval.
- 3.2.2 Protocols that are transferred to another IRB are closed when the new IRB assumes jurisdiction.
- 3.2.3 HRPP Support Staff record the closure in the data management system and notify the Investigator of the closure by issuing a closure notice.
- 3.2.4 HRPP Support Staff archive the closed protocol. The protocol is retained for a minimum of three (3) years. If other regulations and policies apply to a particular protocol, the protocol is retained in accordance to the applicable record retention requirements (e.g., a minimum of six (6) years for research covered by HIPAA). At the end of the record retention period, the protocol is destroyed.

3.3 Administrative Closure of Protocols

- 3.3.1 Approved protocols that pass their designated “end date” may be closed administratively by the IRB if the Investigator fails to renew the protocol following established renewal procedures relevant to the given protocol.
- 3.3.2 Investigators who separate from Purdue with open protocols will have the active protocols at Purdue closed administratively.

3.4 Reactivation of a Closed Protocol

- 3.4.1 The IRB recognizes that occasionally Investigators or the IRB may inadvertently close a protocol that was intended to remain in approved status.
- 3.4.2 An Investigator has up to 60 days after the date of closure to notify the IRB Office of the mistaken closure and request reactivation.
- 3.4.3 Once an Investigator requests reactivation, continuing review is conducted on the protocol. To facilitate this process, the investigator must submit

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any continuing review materials requested for the IRB to complete continuing review.

- 3.4.4 Protocols expired longer than 60 days cannot be reactivated. The Investigator must submit a new protocol application.

3.5 Investigator Duties After Protocol Closure

- 3.5.1 Investigators must retain research records pertaining to a research protocol for a period of three (3) years after the closure date. If other regulations and policies apply to a particular protocol, the protocol is retained in accordance to the longest applicable record retention requirements (e.g., a minimum of six (6) years for research covered by HIPAA). Such research records include, but are not limited to, signed informed consent forms, the approved protocol, and correspondence with the IRB.
- 3.5.2 Such records may be preserved in hardcopy, electronic or other media form and must be accessible for inspection and copying by authorized representatives of the HRPP, the Department of Health and Human Services, the Food and Drug Administration (FDA), and research sponsors.
- 3.5.3 Once a research protocol has been closed, Investigators may keep the data they collected, including identifiable private data, in a manner consistent with the IRB- approved protocol and subject consent. Investigators must continue to honor any confidentiality protections of the data.
- 3.5.4 Investigators must honor any other commitments that were agreed to as part of the approved research, for example, providing information about the study results to research subjects, or honoring commitments for compensation to research subjects for research participation. Additionally, if an Investigator becomes aware of risks to subjects from their participation in the research for which the subjects have not been informed, the investigator must notify the IRB via the submission of an Unanticipated Problem and/or Adverse Event Report.
- 3.5.5 Investigators who leave the Institution must deposit their research records with their Department Head prior to their departure from the institution.

4. RESPONSIBILITY

HRPP Support Staff are responsible for recording Investigator initiated protocol closures and administrative closures in the data management system, sending Closure Notices to Investigators, archiving closed protocols, and destroying protocols at the close of the applicable record retention period.

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The IRB Administrator is responsible for supervising and advising the HRPP Support Staff.

The IRB Chair or designee is responsible for reviewing the final Continuing Review or Closure Report and confirming closure of the protocol.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108(a)(3); 21 CFR 56.109(f)

45 CFR 46.103; 45 CFR 46.109; 45 CFR 46.115(b)

6. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

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1. POLICY

All Purdue University faculty, students, and staff involved in activities that fall under the federal definitions of Human Subjects Research are required to comply with federal and state laws as well as University policies and procedures for the protection of human research subjects.

This guideline serves to clarify types of activities that are determined to be Human Subjects Research in order to assist investigators in the Institutional Review Board (IRB) process at Purdue University.

2. DEFINITIONS

Health and Human Services Definitions

2.1 *Research.* A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

2.2 *Human Subject.* A living individual about whom an investigator (whether professional or student) conducting research:

2.2.1 Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

2.2.2 Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(a) *Intervention* includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(b) *Interaction* includes communication or interpersonal contact between investigator and subject.

(c) *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

(d) *Identifiable Private Information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

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- (e) An *Identifiable Biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

2.3 *Clinical Trial.* A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Food and Drug Administration Definitions

2.4 *Research.* Clinical investigation activities that include:

2.4.1 Use of a drug other than the use of a FDA approved drug in the course of medical practice (21 CFR 312.3(b)).

2.4.2 Use of a medical device other than the use of a FDA approved medical device in the course of medical practice (Food, Drug and Cosmetic Act 530(g)(3)(a)(i)).

2.4.3 Gathering data that will be submitted to or held for inspection by FDA in support of a FDA marketing permit for a food, certain dietary supplements, an infant formula, a food or color additive, a drug, biologic or medical device for human use, or an electronic product. (21 CFR 50.1(a))

2.5 *Human Subject.* An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. (21 CFR 56.102(e)).

3. GUIDELINES

The Human Research Protection Program has developed the following guidelines to assist Investigators in determining which activities are subject to IRB review.

3.1 Any activity that qualifies as Research (as defined above) and includes one or more Human Subjects (as defined above) must be reviewed and approved (or declared exempt) by the IRB prior to the commencement of the study.

3.2 Human Subject Research activities must be reviewed by the IRB irrespective of funding.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46

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21 CFR 50

21 CFR 56

5. REFERENCES TO OTHER APPLICABLE SOPs

301 Exemption Determinations

302 Initial Review

303 Expedited Review

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1. POLICY:

Research activities in which the only involvement of human subjects will be in one or more specific categories listed below may be exempt from the full requirements of 45 CFR 46 or 21 CFR 56. The determination to grant an exemption from these requirements will be made by the Purdue University Human Research Protection Program (HRPP), Institutional Review Board (IRB), or its designees based on regulatory and institutional criteria, and its rationale for the determination will be documented. Investigators are not authorized to make this determination entirely independently. However, the institution may elect to task the IRB with crafting procedures for Investigator-based determination of compliance with federal regulations, as long as such procedures will ensure human subject protections, mitigation of investigator conflicts of interest, and compliance with federal regulations. For example, an institution might task its IRB with creating a decision tree, to be completed by an Investigator, to determine whether a given research project fits a given exemption category, with decision-tree questions written by the HRPP/IRB and with certain IRB-determined answers leading to a clear conclusion with respect to exemption status.

These policies and procedures apply to Investigator claims for Exemption from the full requirement of IRB review pursuant to federal regulations.

2. DEFINITIONS

- 2.1** *Benign Behavioral Interventions.* Interventions that are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
- 2.2** *Clinical Investigation.* An experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.
- 2.3** *Exempt Research.* Research that qualifies for one of the exemption categories specified at 45 CFR 46.104 and/or 21 CFR 56.104. Requests for exemption (excluding Limited IRB review) may be completed by the IRB Chair, HRPP Director, IRB Administrator, Expedited Reviewers or Protocol Analysts or specifically named designee termed "Reviewer" herein,

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- 2.4** *Expedited Review.* Review procedures for certain categories of research established by the US Department of Health and Human Services (DHHS) that do not require review by a convened quorum of the full IRB.
- 2.5** *Full Review.* Level of review pertaining to research activities that must be evaluated by a quorum of the convened IRB.
- 2.6** *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.
- 2.7** *Limited IRB Review.* A level of review required as part of the exemption determination process for certain categories of research studies. The IRB Chair, IRB Associate Chair, or IRB Members serving as Expedited Reviewers may complete requests for Limited IRB Review (excluding those requiring review by the convened IRB), termed “Limited Reviewer” herein, Limited IRB Review may be conducted via expedited review or by the full IRB, as appropriate.

3. PROCEDURES

3.1 Exempt Research Activities

3.1.1 Exempt research fulfills Purdue University’s ethical standards, such as:

- (a) The research holds out no more than minimal risk to participants.
- (b) Selection of participants is equitable.
- (c) If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.
- (d) If there are interactions with participants, the HRPP/IRB should determine whether there should be a consent process that will disclose such information as:
 - (i) That the activity involves research.
 - (ii) A description of the procedures.
 - (iii) That participation is voluntary.
- (e) Name and contact information for the researcher.

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3.1.2 Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from the full requirements of 45 CFR 46:

- (a) **Category 1:** Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, including:
 - i. Research on regular and special education instructional strategies.
 - ii. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (b) **Category 2:** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording), if at least one of the following criteria is met:
 - i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or
 - ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. (*Caveat:* This limited IRB review option may not be used for research involving children. See Section 3.2.3 below.)
 - iv. The information obtained is the result of straight-forward survey, testing, or interview procedures which do not

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employ an intervention, application of independent variables, or experimental or quasi-experimental design.

(c) **Category 3:** Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

- i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or
- ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- iv. However, if the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(d) **Category 4:** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- i. The identifiable private information or identifiable biospecimens are publicly available; or

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- ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; or
 - iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated HIPAA, for the purposes of health care operations, research, or public health activities and purposes as defined at 45 CFR 164; or
 - iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with federal regulations.
- (e) **Category 5:** Research and demonstration projects which are conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - i. Public benefit or service programs;
 - ii. Procedures for obtaining benefits or services under those programs;
 - iii. Possible changes in or alternatives to those programs or procedures; or
 - iv. Possible changes in methods or levels of payment for benefits or services under those programs.
- (f) **Category 6:** Taste and food quality evaluation and consumer acceptance studies:
 - i. If wholesome foods without additives are consumed, or
 - ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration

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(FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture.

(g) **Category 7:** Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes all of the following determinations:

- i. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens was obtained in accordance with federal requirements for broad consent (See SOP 320: Informed Consent Requirements); and
- ii. Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § 45 CFR 46.117 (See SOP 320: Informed Consent Requirements and SOP 321: Waiver or Alteration of Informed Consent); and
- iii. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(h) **Category 8:** Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if all of the following criteria are met:

- i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with federal requirements for broad consent (See SOP 320: Informed Consent Requirements); and
- ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 45 CFR 46.117 (See SOP 320: Informed Consent Requirements and SOP 321: Waiver or Alteration of Informed Consent); and
- iii. An IRB conducts a limited IRB review and makes the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data and makes the determination that the research to be

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conducted is within the scope of the broad consent obtained by the Investigator; and

- iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

- (i) **Purdue Exemption Category 100 ([P-100] Must not be utilized for research involving federal funds or regulations [e.g. NIH, NSF, DoD])** Research meeting all of the criteria of a Benign Behavioral Intervention under federal guidelines (Exemption Category 3 above), but also involving data collection of a single physical measurement intended to assess the effect of a Benign Behavioral Intervention. Measurements must be obtained with low risk, commercially-available automated measurement technology. Examples include but are not limited to: commercial eye-tracking sensors, wearable activity trackers, and heart rate monitors used by appropriately trained Key Personnel under supervision of the Principal Investigator.

P-100 studies must not involve collection of biospecimens (e.g. saliva, blood), use of virtual reality headsets, or any procedures requiring non-exempt review referenced under 45 CFR 46 or 21 CFR 56. Examples that do not qualify for P-100 review include, but are not limited to: Magnetic Resonance Imaging, exercise studies, electrocardiography, electroencephalography, thermography, ultrasound, use of radiation, clinical investigations of experimental drugs/devices, venipuncture, echocardiography.

- (j) **Purdue Exemption Category 101 ([P-101] Must not be utilized for research involving federal funds or regulations [e.g. NIH, NSF, DoD])** Non-federally funded research where the research activities do not conform to one of the eight DHHS exempt categories provided that both of the following criteria are met:
 - i. Activities are limited to data analysis where participants have completed research-related intervention or interaction and follow-up has been completed,
 - ii. Remaining research activities are limited to only data analysis that may require access to identifiable records and/or specimens identified directly or via code with existing code key.

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- iii. No unanticipated problems involving risks to subjects or others, adverse events, protocol deviations, subject complaints, or noncompliance occurred since the date of last IRB review/renewal.

3.1.3 The following categories of clinical investigations are exempt from the requirements of 21 CFR 56:

- (a) Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.
- (b) Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under FDA regulations before that date.
- (c) Emergency use of a test article, provided that such emergency use is reported to the IRB within five (5) working days. Any subsequent use of the test article at the institution is subject to IRB review.
- (d) Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

3.2 Applicability of Exemptions to Research Involving Special Populations

- 3.2.1 Research involving Pregnant Women, Fetuses, and/or Neonates: Each of the above exemption categories may be applied to research subject to 45 CFR 46, subpart B if the conditions of the exemption are met.
- 3.2.2 Prisoners: The above exemptions do not apply to research subject to 45 CFR 46, subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.
- 3.2.3 Children: The exemptions for Category 1, 4, 5, 6, 7, and 8 may be applied to research subject to 45 CFR 46, subpart D if the conditions of the exemption are met. The exemption for Category 2 may apply to research subject to 45 CFR 46, subpart D involving educational tests or the observation of public behavior only when the Investigators do not

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participate in the activities being observed; *provided however*, that research involving children may not rely on limited IRB review to obtain an exempt determination under Category 2.

3.3 Submission Requirements for Requesting an Exempt Determination

3.3.1 Investigators submitting a request for exemption determination are required to provide the following via the appropriate electronic system

- (a) Exemption Determination form;
- (b) Documented or electronic system authorization by the Principal Investigator;

3.3.2 Investigators must utilize the electronic submission system to obtain an initial categorization of their proposed exempt research. Electronic systems contain a form developed with the intent to have certain IRB-determined answers lead to a clear conclusion of a study's exemption status.

- (a) Information supplied in exemption applications is subject to routine monitoring (See SOP 306). The HRPP will administer criteria along with assignment of the reviews for alignment with the proper exemption category;
- (b) Investigators whose studies are not exempt will be promptly contacted (typically within 3 business days of determination) in the event that the study does not fit exemption criteria or requires Limited IRB review.

3.3.3 Following Submission of a request for exemption determination Investigators *may* be required to submit:

- (a) An Information Sheet;
- (b) Documentation that the study has been reviewed and approved by other committees charged with oversight of research at Purdue University;
- (c) Documentation regarding collaborating Investigators at other institutions;
- (d) Documentation of review from an appropriate ethics board in a foreign country and translated consent forms or other appropriate individual with expertise in the respective culture that assists in the exemption determination; and

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- (e) Documentation from administrator(s) permitting investigator to conduct research in settings such as schools, businesses, and care facilities, etc.
- (f) Proposed subject instructions;
- (g) Questionnaires and assessment instruments;
- (h) Clarification to the answers submitted to questions in the electronic application system.
- (i) Any other supporting material, such as recruitment advertising, etc.; and
- (j) Evidence of Purdue administered training or equivalent substitute training in research with human subjects.

3.4 Evaluation of Research Exemption Requests

- 3.4.1 HRPP Support Staff will receive a completed Exemption Determination form as submitted via the electronic system, conduct a review for completion and training, and forward the request to a Protocol Analyst for administrative review.
- 3.4.2 A Protocol Analyst conducts an administrative review on the request to determine if the Investigator has submitted all of the necessary paperwork and supporting documents and ensures that all required elements are complete. The Protocol Analyst documents any concerns and the appropriate category of exemption if appropriate, on the form and in the data management system. Protocol Analysts are authorized to make exemption determinations on behalf of the Purdue HRPP provided adequate training and experience are confirmed. If necessary, the request is routed for review by the IRB Chair or designee for assistance on review type category.
- 3.4.3 The assigned Reviewer evaluates the request to determine if it is exempt under 45 CFR 46 and/or 21 CFR 56.
- 3.4.4 Where Limited IRB Review is a component of the exemption determination it may be conducted by the Limited Reviewer, or by the full IRB, as appropriate.
- 3.4.5 If it is determined that the submitted documents are not adequate, the Investigator may be required to submit additional information or answer questions or explain the details of the study. Incomplete submissions will not be granted Exemption.

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- 3.4.6 If the research is determined to be exempt, the assigned reviewer completes the Review Checklist, and documents the applicable exemption category.
- 3.4.7 Following the determination of exemption, the determination is recorded in the electronic system, and the Exemption Granted notification is generated and sent to the Investigator and Key Personnel.
- 3.4.8 If the Protocol Analyst or assigned reviewer determines that the proposed research does not meet the criteria for Exemption status, the Investigator will be contacted and asked to submit the appropriate application and documentation for either Expedited or Full Board review.
- 3.4.9 If there are any possible institutional concerns related to the proposed research, the Human Protections Administrator and/or Institutional Official are notified of those concerns.
- 3.4.10 If the research does not qualify for Exemption, the reason is documented on the form, data management system and in correspondence to the Investigator. Additionally, the PI is requested to submit an application for Expedited or Full Board review.

4. RESPONSIBILITY

HRPP Support Staff is responsible for intake of the initial application requests, performing a brief training and completion check, and forwarding the request to a Protocol Analyst for administrative review or confirmation of exemption.

The Reviewer is responsible for conducting administrative review of exemption requests, confirming exemption determinations, and/or routing them as necessary for further evaluation in order to make a determination of exemption from 45 CFR 46 and/or 21 CFR 56.

The IRB Chair or designee is responsible for making exemption determinations or for ensuring that any Investigator-based exemption determination decision-tree has been approved by the IRB. The HRPP Director and The IRB Administrator are responsible for providing consultation in the evaluation of exemption requests. The IRB Chair or designee has final authority in determining a finding of exemption and has the authority to revoke determinations.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.104, 46.111

21 CFR 56.104

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6. REFERENCES TO OTHER APPLICABLE SOPs

302 Initial Review

303 Expedited Review

320 Informed Consent Requirements

321 Waiver or Alteration of Informed Consent

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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

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1. POLICY:

The Secretary of the Department of Health and Human Services and the Food and Drug Administration have established and published in the Federal Register a list of categories of research that may be reviewed by the IRB through an expedited review procedure. (See Section 5 below for links to the current list of expedited review categories.) An IRB may use the expedited review procedure to review either or both of the following:

- A. Some or all of the research appearing on the list, unless the reviewer determines that the study involves more than minimal risk. (If the reviewer determines that the study involves more than minimal risk, the reviewer's rationale for this determination shall be documented in accordance with applicable HRPP policies. See SOP 203: Documentation and Records Management.)
- B. Minor changes in previously approved research appearing on the list during the period for which approval is authorized.

These policies and procedures apply to all Human Subjects Research activities regulated by the Food and Drug Administration and the Department of Health and Human Services that qualify for expedited review categories.

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** *Expedited Review.* Review procedures for certain categories of research established by the Department of Health and Human Services and the Food and Drug Administration which do not require review by a convened quorum of the convened IRB. Categories eligible for Expedited Review are outlined in Section 3.1 of this SOP.
- 2.3** *Expedited Reviewers* – Experienced (by serving one year or more on the IRB, training by HRPP staff or a board member, or through daily job duties) reviewers who are voting IRB members assigned to conduct Expedited Review. All voting and alternate IRB members serving for one year or more on the IRB are automatically Expedited Reviewers, unless indicated to the IO by the IRB Chair.
- 2.4** *Full Review.* Level of review pertaining to research activities that must be evaluated by a quorum of the convened IRB.
- 2.5** *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

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environment or during the performance of routine physical or psychological examinations or tests.

- 2.6** *Minor Changes.* Changes to a protocol that do not increase risk or burden to participants.

3. PROCEDURES

3.1 Expedited Review Procedures for Initial Protocol Applications

- 3.1.1 HRPP Support Staff, enters a submitted protocol into the data management system, records training status of the research team members, and forwards the request to a Protocol Analyst.

- 3.1.2 A Protocol Analyst conducts administrative review on the Application. The Protocol Analyst documents any concerns and the appropriate category of Expedited Review, if appropriate, on the Checklist, special review form(s) as appropriate, and in the data management system. Once complete, the request is routed to an Expedited Reviewer, depending on the research proposed in the protocol application.

(a) The assigned Expedited Reviewer will determine if the protocol qualifies for Expedited Review under any of the following categories for Initial Review:

- (i) **Category 1:** Clinical studies of drugs and medical devices only when condition (A) or (B) is met.

A. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.

B. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

- (ii) **Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

A. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period

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and collection may not occur more frequently than 2 times per week; or

B. From other adults and children, as defined in 45 CFR 46.402(a), considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(iii) **Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

A. hair and nail clippings in a nondisfiguring manner;

B. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

C. permanent teeth if routine patient care indicates a need for extraction;

D. excreta and external secretions (including sweat);

E. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;

F. placenta removed at delivery;

G. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

H. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

I. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

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J. sputum collected after saline mist nebulization.

(iv) **Category 4:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

A. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

B. weighing or testing sensory acuity;

C. magnetic resonance imaging;

D. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

E. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(v) **Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

(vi) **Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes.

(vii) **Category 7:** - Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

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(b) The assigned Expedited Reviewer will determine if the protocol qualifies for Expedited Review under any of the following categories for Continuing Review:

(i) **Category 8:** Continuing review of research previously approved by the convened IRB as follows:

A. where (1) the research is permanently closed to the enrollment of new subjects; (2) all subjects have completed all research-related interventions; and (3) the research remains active only for long-term follow-up of subjects; or

B. where no subjects have been enrolled and no additional risks have been identified; or

C. where the remaining research activities are limited to data analysis.

(ix) **Category 9:** Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

3.1.3 The Expedited Reviewer can choose to consult with another IRB Member or an outside consultant with appropriate expertise. The Expedited Reviewer must have experience in terms of professional competence related to human research protections or conduct of research with human subjects.

3.1.4 The Expedited Reviewer 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:

- (a) A determination that risks to participants are minimized;
- (b) 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;
- (c) A determination that selection of participants is equitable;
- (d) 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;

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- (e) 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;
- (f) A determination that when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
- (g) A determination that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;
- (h) 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
- (i) 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.

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- 3.1.5 If it is determined that the submitted documents are not adequate, the Investigators may be required to submit additional information, answer questions, or explain the details of the study and/or revise the application. Incomplete or inadequate submissions will not be approved.
- 3.1.6 A PI's responses to a request for additional information and/or application revisions are reviewed by a Protocol Analyst and an Expedited Reviewer. If the application is in order, the IRB Reviewer may approve the protocol by signing the Protocol Review Form.
- 3.1.7 Expedited Reviewers may exercise all the authority of the IRB in reviewing the research, except they may not disapprove the research. Research that cannot be approved via expedited procedures must be reviewed by the convened IRB.
- 3.1.8 If an issue requiring institutional approval (e.g., legal matter, public relations, payment), the IRB approved application is then routed to the Institutional Official (IO) or his/her designee to be reviewed for institutional approval. If approved, the IO or his/her designee will indicate approval through memo or an electronic message.
- 3.1.9 Once an initial protocol application is approved, HRPP Support Staff will enter the approval in the electronic system and add the protocol to the agenda for the next meeting of the appropriate IRB as a reported item. Staff will archive the approved consent document(s) and generate the approval letter. Copies of the approval letter and approved consent document(s) will be sent via e-mail or electronic data management system to the Investigator and Key Personnel.

3.2 Expedited Review Procedures for Revision and Continuing Review Requests

- 3.2.1 Beginning July 19, 2018, annual Continuing Review is no longer required by default for ongoing research originally approved through Expedited Review. This release from pre-2018 Common Rule requirements also applies to studies that have completed study interventions and are merely analyzing study data or involve only observational follow up in conjunction with standard clinical care. However, the Purdue IRB maintains the authority to mandate Continuing Review on these protocols if necessary for purposes of monitoring risk to participants and/or in cases of noncompliance.
- 3.2.2 No less than every (3) years, the PI will receive notification from the HRPP regarding the open study. At this time the PI will be notified of his/her responsibilities and provided with the most up to date processes and forms. The IRB or the Expedited Reviewer may elect to require more

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frequent continuing review as a condition of initial approval or may impose such requirement at a subsequent time.

- 3.2.3 For studies undergoing Continuing Review, HRPP Support Staff completes intake of the revision or continuing review request, enters it into the data management system, records training status of the research team members, and forwards the request to a Protocol Analyst.
- 3.2.4 A Protocol Analyst conducts administrative review on the submission. The Protocol Analyst documents any concerns and the appropriate category of Expedited Review, if appropriate, on the Checklist and in the electronic system. Once complete, the request is routed to an Expedited Reviewer.
- 3.2.5 Expedited Reviewers can be the IRB Chair or other experienced IRB member. The Expedited Reviewer can choose to consult with another IRB Reviewer or an outside consultant with appropriate expertise.
- 3.2.6 The Expedited Reviewer 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 and is stated in sections 3.1.2. and 3.1.4 of this SOP as well as procedures included in SOP 304: Continuing Review and SOP 305: Amendments Requests.
- 3.2.7 If it is determined that the submitted documents are not adequate, the Investigators may be required to submit additional information, answer questions, or explain the details of the study and/or make revisions to the application. Incomplete or inadequate submissions will not be approved.
- 3.2.8 The Investigator's responses to a request for additional information and/or application revisions are reviewed by a Protocol Analyst and an Expedited Reviewer. If the application is in order, the Expedited Reviewer may approve the revision request or continuing review request in the electronic system.
- 3.2.9 If necessary, the IRB approved revision request or continuing review request is then routed to the IO or his/her designee to be reviewed for institutional approval. If approved, the IO or his/her designee will indicate approval by memo or electronic message.
- 3.2.10 Once the revision request or continuing review request is approved, HRPP Staff will enter the approval in the electronic system and assign the protocol to the agenda for the next IRB meeting as a reported item. HRPP Staff will also finalize the approved consent document(s), if any, and generate the approval letter. Copies of the approval letter and approved consent document(s) will be sent via e-mail or available in the electronic data management system to the Investigator.

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4. RESPONSIBILITY

HRPP Support Staff is responsible for completing intake processes of the protocol submissions (initial applications, revision requests and/or continuing review requests), entering it into the data management system, forwarding the request to a Protocol Analyst for administrative review, entering the approval into the data management system, placing the approved submission on the next IRB meeting agenda and notifying the Investigators of the submission's approval.

Protocol Analysts are responsible for overseeing the review process for expedited review as well as conduct administrative review on protocol submissions.

The IRB Chair or other experienced IRB member designated by the IRB Chair to conduct expedited review are responsible for conducting review and granting IRB approval of all submissions that qualify for expedited review. Additionally, they are responsible for determining the need for consultation with other IRB Members, HRPP Support Staff or consultants.

The IO or his/her designee is responsible for conducting further appropriate review and granting institutional approval when required.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.110

21 CFR 56.110

6. REFERENCES TO OTHER APPLICABLE SOPs

302 Initial Review

304 Continuing Review

305 Amendment Requests

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1. POLICY:

In accordance with 45 CFR 46.109(e), Institutional Review Boards (IRBs) must conduct continuing review of approved research at intervals appropriate to the degree of risk. Continuing review must be substantive and meaningful. When considering whether to renew a study, the IRB revisits the same criteria used to grant initial approval. For a detailed description on review criteria, see SOP 302: Initial Review.

These policies and procedures apply to all reviewed research conducted under the jurisdiction of the Purdue University IRB.

2. DEFINITIONS

- 2.1** *Continuing Review* - Review of a protocol conducted for purposes of determining the appropriateness of granting continued approval and renewal.
- 2.2** *Expedited Review* - Review procedures for certain categories of research established by the Department of Health and Human Services and/or the Food and Drug Administration which do not require review by a convened quorum of the full IRB.
- 2.3** *Expedited Reviewers* - Experienced (by serving one year or more on the IRB, training by HRPP staff or a board member, or through daily job duties) reviewers who are voting IRB members assigned to conduct Expedited Review. All voting and alternate IRB members serving for one year or more on the IRB are automatically Expedited Reviewers, unless indicated to the IO by the IRB Chair.

3. PROCEDURES

3.1 Continuing Review Notification to Investigators

- 3.1.1** HRPP Support Staff generate a continuing review reminder notice and sends to Principal Investigators, ideally two months prior to the study's expiration date, with a due date approximately 1 month prior to current study approval expiration. The Principal Investigator is ultimately responsible for completing a Continuing Review form and submitting it to the HRPP Office for processing by the due date.
- 3.1.2** If a Continuing Review form is not submitted by the return due date, a second notice is sent to the PI along with a memo noting this is a final notice and that without return of a Continuing Review form, the protocol's approval will expire at the end of the day (11:59 p.m.) on the expiration date.

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- 3.1.3 On the protocol's expiration date, or as soon as possible thereafter, an Expiration Notice is sent to the Principal Investigator notifying him/her to cease and desist from all research activities.

3.2 Submission Requirements for Continuing Review

In order to ascertain the current status of the study, the following materials are required for submission and review:

- 3.2.1 Completed Continuing Review form;
- 3.2.2 Documented or electronic system authorization by the Principal Investigator;
- 3.2.2 A copy of the current informed consent document(s) or any newly proposed consent document(s) if enrollment is ongoing;
- 3.2.3 A copy of current recruitment material(s) or any newly proposed recruitment material(s) if enrollment is ongoing;
- 3.2.4 A summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
- 3.2.5 A summary of any relevant information about risks associated with the research; and
- 3.2.6 Any relevant multi-center trial reports.

3.3 Continuing Review – General Review Procedures

- 3.3.1 Beginning July 19, 2018, annual Continuing Review is no longer required by default for ongoing research originally approved through Expedited Review. This release from pre-2018 Common Rule requirements also applies to studies that have completed study interventions and are merely analyzing study data or involve only observational follow up in conjunction with standard clinical care. However, the Purdue IRB maintains the authority to mandate Continuing Review on these protocols if necessary, for purposes of monitoring risk to participants and/or in cases of noncompliance.
- 3.3.2 No less than every (3) years, the PI will receive notification from the HRPP regarding the open study. At this time, the PI will be notified of his/her responsibilities and provided with the most up to date processes and forms. The IRB may elect to require more frequent continuing review

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as a condition of initial approval or may impose such requirement at a subsequent time.

- 3.3.3 For those studies requiring Continuing Review, HRPP Support Staff forwards a Continuing Review form and relevant materials to a Protocol Analyst or Expedited Reviewer for administrative review. Either the HRPP Support Staff or Protocol Analyst enters the submission data into the data management system.
- 3.3.4 A Protocol Analyst conducts administrative review on the submission to determine if the Investigator has submitted all of the necessary documentation and ensures that all the required elements are complete. The Protocol Analyst documents any concerns in the data management system. Once complete, the Protocol Analyst routes the submission and protocol to the IRB for review.
- 3.3.5 The continuing review submission and the protocol are reviewed by the convened IRB or an Expedited Reviewer (if necessary, for an Expedited Review). The criteria for approval of research with continuing review are the same as for initial review (see SOP 302: Initial Review). The IRB considers any significant new findings that may relate to participant's safety or willingness to continue participation.
- 3.3.6 For review of multi-center trials monitored by a Data Safety Monitoring Board, Data Monitoring Committee, other similar body, or sponsor whose responsibilities include review of adverse events, interim findings, and relevant literature, the IRB may rely on a current statement from the DSMB or sponsor indicating that it has reviewed study-wide adverse events, interim findings, and any recent literature that may be relevant to the research, in lieu of requiring that this information be submitted directly to the IRB.

3.4 Continuing Review – Full Board Review Procedures

- 3.4.1 For continuing review requests, a primary reviewer and a secondary reviewer are assigned to the protocol submission. The primary reviewer is responsible for conducting the continuing review, reporting his/her assessment to the convened IRB and documenting their review. The secondary reviewer is responsible for conducting the continuing review, reporting their assessment to the convened IRB and, in the event the primary reviewer cannot fulfill his/her responsibilities, documenting their review.
- 3.4.2 Both the primary and secondary reviewers receive copies of the original continuing review request and access to the original protocol file.

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- 3.4.3 All IRB members receive a copy of the continuing review request including all submitted materials and, as needed access to the original protocol file.

3.5 Lapse in Continuing Review

- 3.5.1 If an Investigator fails to provide a completed continuing review submission to the IRB, or the IRB has not reviewed and approved a research study by 11:59 p.m. on the continuing review date specified by the IRB, the current approval expires automatically and research activities including (but not limited to) recruitment, enrollment, data collection, and data analyses must stop, unless the IRB finds that there is an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating in the research interventions or interactions.
- 3.5.2 Such expiration of IRB approval does not need to be reported to federal regulators at the Office of Human Research Protections (OHRP) within the US Department of Health and Human Services (DHHS) as a suspension of IRB approval under DHHS regulations.
- 3.5.3 For an expired protocol to regain approved status, the IRB must conduct continuing review within 60 days of the protocol's expiration date and approve the protocol in accordance with Section 3.

3.6 Exceptions to Continuing Review Requirement

- 3.6.1 Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances:
- (a) The research is eligible for expedited review, as described in SOP 303: Expedited Review;
 - (b) The research was reviewed by the IRB in accordance with Limited IRB Review, as described in SOP 301: Exemption Determination; or
 - (c) The research has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
 - (i) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 - (ii) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

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4. RESPONSIBILITY

HRPP Support Staff is responsible for generating Continuing Review reminder notices, Final Notices, and Expiration Notices and sending them to Principal Investigators. Additionally, HRPP Support Staff is responsible for processing of the Continuing Review form and forwarding the request to a Protocol Analyst for administrative review.

The Protocol Analyst is responsible for conducting administrative review of Continuing Review submissions and routing them to the full board for review.

The IRB Administrator in consultation with the IRB Chair and HRPP Director is responsible for establishing and implementing processes for conducting continuing review of research.

The Primary Reviewer is responsible for conducting the continuing review, reporting their assessment to the convened IRB, and documenting the review on the Checklist.

The Secondary Reviewer is responsible for conducting the continuing review, reporting their assessment to the convened IRB and, in the event the primary reviewer cannot fulfill his/her responsibilities, documenting the review on the Checklist.

The Institutional Official or designee is responsible for conducting further appropriate review and granting Institutional approval.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108, 56.109, 56.110, 45.111

45 CFR 46.108, 46.109, 46.110, 46.111

[OHRP Guidance on Continuing Review](#)

6. REFERENCES TO OTHER APPLICABLE SOPs

302 Initial Review

303 Expedited Review

204 Protocol Closure

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1. POLICY:

In accordance with 45 CFR 46.108(a)(3), Institutional Review Boards (IRBs) must review changes to previously approved research. Such changes must be reviewed and approved by the IRB prior to implementation of the changes. Approval of an Amendment does not change the expiration date of the protocol.

1.1 Exceptions

- 1.1.1 When an immediate change is necessary to eliminate a hazard to research participants, the proposed change does not need to be reviewed by the IRB prior to its implementation. However, Investigators must notify the IRB of the change in the protocol immediately thereafter using the Unanticipated Problem Report and/or Adverse Event form as a formal mechanism of reporting to the Human Research Protection Program.
- 1.1.2 Some specific changes have been determined to present no increased risk or burden to research participants, nor result in decreased benefits to them. These changes represent momentary deviations from a set schedule required by the irregularities of life that do not alter the integrity of the study or the rights of the subjects. These changes do not require IRB review and approval prior to implementation; however, updated forms (if applicable) must be provided to the IRB to ensure the accuracy of of the IRB research study file. See Section 3.3 below.

These policies and procedures apply to all IRB reviewed research conducted under the jurisdiction of the Purdue University IRB.

2. DEFINITIONS

- 2.1 *Amendment or Modification:* A change to IRB-approved research that must have IRB review and approval prior to implementation. Note: The term Amendment and Modification are used synonymously in the processing of protocols.
- 2.2 *Minor Change:* A change that does not introduce new risks to the subject population or negatively alter the risk/benefit analysis. Minor changes may be reviewed using expedited procedures. Examples: changes in funding source that do not trigger a conflict of interest, revision of project title, removal of research personnel (other than the Investigator), alteration of recruitment media, updating of contact information, reduction of subject interventions or interactions that do not change the risk/benefit ratio of the study as originally reviewed by the IRB.

3. PROCEDURES

3.1 Modification Submission Requirements

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The following materials are required for the submission and review of an Amendment (forms available at www.irb.purdue.edu):

- 3.1.1 Completed electronic Modification form.
- 3.1.2 Documented or electronic system authorization by the Principal Investigator.
- 3.1.3 A revised application that documents the modified protocol, using tracked changes.
- 3.1.4 A copy of all altered study materials using tracked changes (i.e., recruitment materials, consent forms, data collection forms, supporting agreements).
- 3.1.5 For externally sponsored projects involving procedural changes, the HRPP may request confirmation that the project has received the sponsor's approval for a change to the research.

3.2 Amendment Submissions – Office Procedures and Review Process

- 3.2.1 HRPP Support Staff accepts the complete submissions, and rejects incomplete submissions. The request is forwarded to a Protocol Analyst for administrative review prior to IRB review. Complete submissions may be forwarded directly to the IRB in the event of heightened risk or legitimate need for expedient processing.
- 3.2.2 The Protocol Analyst documents review considerations and routes the submission for IRB review.
- 3.2.3 The submission is reviewed either via expedited procedures (for minor changes) or via full IRB review (for all other changes). The criteria for approval are the same as for initial review. See SOP 302: Initial Review. In order to approve the Modification, the expedited review or convened IRB must determine that all of the approval criteria will continue to be met following the implementation of the change. Additionally, the Board considers any significant new findings that have been reported that may relate for participant's safety or willingness to continue participation.

3.3 Changes Not Requiring Review

The changes listed below do not require IRB review and approval prior to implementation. However, any updated forms must be provided to the IRB for completeness of the IRB study file.

- 3.3.1 Study Procedures

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- (a) Rescheduling of a data collection when a research participant misses an appointment or data collection is incomplete due to unforeseen circumstances that do not increase risk to the participant (e.g., equipment failure resulting in data collection cancellation, etc.). However, such deviations from the protocol must be reported at continuing review.
- (b) Rescheduling of specimen collections (identified below) of an adult subject when that subject misses an appointment or specimen collection is incomplete, due to unforeseen circumstances that do not increase risks to the subject but increase the total amount of specimen collected than what was approved. However, such deviations from the protocol must be reported at continuing review. Specimen collections that qualify for this category are as follows:
 - (i) collection of blood via finger, heel or ear stick;
 - (ii) hair and nail clippings collected in a non-disfiguring manner; excreta and external secretions (including sweat);
 - (iii) uncannulated saliva collected either in an instimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
 - (iv) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; and
 - (v) sputum collected through expectoration.
- (c) Removal of study instrument(s) so long as it does not reduce any previously found direct benefit to participants or decrease the validity of the study.
- (d) Minor editorial changes to study instruments (e.g., corrections of grammar/language to increase participant understanding).

3.3.2 Recruitment Materials

- (a) Changes within the approved recruitment material medium (e.g., changes within print medium, for example, flyer to newspaper advertisement). If changes are made to a different medium (e.g., from print medium like a flyer to phone solicitations) the changes are substantive and must be submitted to the IRB for review and approval.

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- (b) Changes in contact information, except where a new Investigator or other Key Personnel is added to the study. The addition of new Investigator or other Key Personnel is a substantive change to the study and must be submitted to the IRB for review and approval.
- (c) Minor editorial changes (e.g., corrections of grammar/language to increase participant understanding).
- (d) Updating dates and times related to when research activities will occur (so long as such dates/times and number of data collection activities are within the approved protocol period and do not increase duration of a subject's participation).

3.3.3 Consent/Assent Documents

- (a) Minor editorial changes (e.g., corrections of grammar/language to increase participant understanding).
- (b) Changes in contact information except where a new Investigator or other Key Personnel is added to the study. The addition of new Investigator or other Key Personnel is a substantive change to the study and must be submitted to the IRB for review and approval.
- (c) Changes noting removal of a study instrument and resulting change of duration of participation. Changes adding study measures are substantive and must be submitted as an amendment to for IRB review and approval.

3.3.4 Changes to non-key personnel. When non-key personnel are added to a study, it is the Investigator's responsibility to keep records of study personnel changes, study personnel's fulfillment of education requirements and be able to produce those records upon request. Non-key personnel may not engage in any aspect of human subjects research until they have passed all required training. Should non-key personnel become key personnel later, this change is substantive and must be submitted as an amendment for IRB review and approval.

4. RESPONSIBILITIES

4.1 Investigator Responsibilities

- 4.1.1 An Investigator must submit change(s) to an approved protocol using an electronic modification form and receive IRB approval for the change(s) prior to implementing the changes to the protocol.

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- 4.1.2 An Investigator must re-consent currently enrolled subjects should the IRB determine that the changes to the protocol require currently enrolled subjects to be re-consented.
- 4.1.3 Consent Forms: Investigators making minor changes not requiring review to consent/assent documents for non-exempt studies must submit proposed modifications on these documents to the HRPP office to secure IRB approval.
- 4.1.4 Exempt Studies: Investigators making any change to an exempt study must submit a request to modify the exempt study submission, to ensure that the regulatory status of the activity has not been altered by the change in the activity.

4.2 IRB Responsibilities

- 4.2.1 HRPP Support Staff and Protocol Analysts are responsible for managing the submission through the IRB review process, and communicating directly with the investigator. The Principal Investigator is responsible for the actions of his/her staff and should be the primary respondent to IRB submission questions.
- 4.2.2 The IRB Administrator supervises and advises on the processes for review of revision requests. May review or approve amendments as necessary as an expedited reviewer
- 4.2.3 IRB (either by convened IRB or expedited reviewer, as appropriate) reviews and approves or denies an Amendment request. The reasons for a denial must be communicated to the investigator in writing.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.108(a); 45 CFR 46.110(b)

21 CFR 56.108(3) and (4); 21 CFR 56.110(b)

6. REFERENCES TO OTHER APPLICABLE SOPs

302 Initial Review

303 Expedited Review

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1. POLICY

The primary purpose of these procedures is to assess and enhance the protection of human subjects involved in research by providing education to Investigators and research team members and determining that proper procedures are followed regarding the conduct of Human Subjects Research. Additionally, these procedures are used for directed monitoring.

These policies and procedures apply to all Human Subjects Research protocols approved, or exempted by the Purdue HRPP or the Purdue University Institutional Review Board (IRB). The monitoring process may also be conducted on any protocols for which Purdue University's IRB has responsibility for oversight. These procedures apply to all research protocols.

2. DEFINITIONS

- 2.1** *Directed Monitoring.* Monitoring activities conducted on a "for-cause" basis which include, but are not limited to, reported complaints and request by the IRB due to anomalies related to a protocol.
- 2.2** *Monitor.* An Office of Research and Partnerships Post-Approval Monitor, a Protocol Analyst, IRB Administrator, IRB Chair, IRB Associate Chair, IRB Member, or a team consisting of any of the preceding who are selected to conduct monitoring activities.
- 2.3** *Random Selection Procedure.* Manner of selection based on review type without Investigator identifiers.

3. PROCEDURES

3.1 Protocol Selection

3.1.1 Reasons for selection to undergo post-approval monitoring include:

- (a) For cause selection which includes reported complaints and/or requests by the convened IRB of record.
- (b) Projects where continuing review or reports from other sources have indicated that material changes may have occurred without IRB approval.
- (c) Projects conducted by an Investigator who had previous instances of noncompliance.
- (d) Projects involving vulnerable populations that raise cause for concern.

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- (e) Complex projects involving unusual levels or types of risks to subjects.
- (f) Upon request by the Investigator.
- (g) In response to inquiries from external regulatory agencies.
- (h) Random selection procedure.

3.1.2 The decision to initiate directed Post-Approval Monitoring (PAM) may be made by an IRB Chair, IRB Associate Chair, HRPP Director, or IRB Administrator, but all, collectively must be informed unless a conflict of interest is cited.

3.2 Who Conducts Monitoring Activities

- 3.2.1 Post-Approval Monitoring activities are generally conducted by a Post-Approval Monitor (assigned EVPRP staff member), Protocol Analyst, and/or the IRB Administrator under the guidance of the HRPP Director and/or Institutional Official.
- 3.2.2 In addition to the above referenced personnel, IRB Chairs, IRB Associate Chairs, and IRB Members may be selected to conduct or assist with monitoring activities on the basis of expertise.

3.3 Monitoring Procedures for Research Protocols

- 3.3.1 Once a protocol is selected for monitoring, the Monitor conducting the visit will contact the Investigator notifying them that their protocol has been selected for review and to expect a second contact within the next five (5) business days to schedule the visit. Information about the monitoring program and what will be reviewed will be provided.
- 3.3.2 Within five (5) business days after the initial contact with the Investigator, the Monitor will contact the Investigator to schedule the visit. If the Investigator has a conflict with the proposed visit schedule, she or he may request the visit be rescheduled. The Investigator may elect to have key personnel from the research team present.
- 3.3.3 Prior to the visit, the Monitor will verify the research team's training, review the protocol, and prepare the monitoring materials as required.
- 3.3.4 On the day of the visit, the Monitor will conduct an introductory meeting with the Investigator and research team. At this meeting, the Monitor will inform the Investigator if the visit is for directed Monitoring. The Monitor will interview the Investigator and other research team present about their

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procedures and will ask for a verification of security procedures. Additionally, the Monitor will address any questions from the Investigator and research team.

- 3.3.5 After the interview(s) the Monitor will review the requested materials and request any additional materials from the Investigator
- 3.3.6 The Monitor will prepare a draft report and provide it to the Investigator within fifteen (15) business days.
- 3.3.7 The Monitor will conduct a debriefing interview with the Investigator and research team and provide an overview of preliminary findings and answer any questions that may occur.
- 3.3.8 The Investigator will have fifteen (15) business days to respond to the draft report and advise of changes. If no response is forthcoming in that time frame, the report will be considered to be accurate and will be finalized. If for some reason the Investigator cannot respond within the fifteen (15) business day time frame, she or he can request an extension.

3.4 Reporting Monitoring Results

- 3.4.1 The Monitor will submit the final report to the IRB Chair, IRB Associate Chair, HRPP Director, or the IRB Administrator.). The final report may include recommendations for corrective actions. The IRB Chair or Associate Chair reviews the final report and may request revisions to the research protocol from the Investigator based on the information and recommendations provided.
- 3.4.2 If the monitoring uncovers serious or continuing noncompliance, the matter will be handled in accordance with the procedures outlined in SOP 408: Noncompliance.
- 3.4.3 The final report will be filed in the Investigator's protocol file maintained in the HRPP office as well as in the Monitor's database.
- 3.4.4 No less than twice per year, a report of recent PAM processing will be provided to the IRB for inclusion at a fully convened meeting.

3.5 Additional Monitoring Procedures

- 3.5.1 Due to the diversity of research, monitoring procedures must remain flexible to accommodate the various research procedures utilized in protocols. The Monitor will have the discretion to skip procedures and/or questions identified on the Monitoring Form if they are inappropriate for

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the research design and the reasons for conducting the monitoring activities (e.g. random, directed, etc.).

- 3.5.2 In some situations, observation of the consent process with subjects and/or the research procedures may be required.

4. RESPONSIBILITY

Monitor is responsible for conducting monitoring activities including, but not limited to, Random Selection Procedures, notification of Investigators, scheduling site visits, conducting interviews, conducting document reviews and drafting timely reports.

The IRB Chair (or his/her designee) may serve as the original reviewer of Post Approval Monitoring Reports.

The HRPP Director and IRB Administrator coordinate the monitoring activities, receive and route PAM reports, and supervise the HRPP and Office of Research and Partnerships Post-Approval Monitoring staff involved in the process.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.108, 46.109

21 CFR 56

6. REFERENCES TO OTHER APPLICABLE SOPs

304 Continuing Review

408 Noncompliance

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1. POLICY:

Unless an exception applies, an Investigator may not enroll a human subject in a research study until informed consent has been obtained. Informed consent must be legally effective, prospectively obtained and in understandable language. Securing and maintaining consent is an ongoing process that begins with recruitment and continues through the end of the subject's involvement in the study.

These procedures apply to all non-exempt research protocols. At times, other institutional approvals may be required prior to enrolling a participant in research.

2. DEFINITIONS

- 2.1 *Assent.* An Individual's affirmative agreement to participate in research obtained in conjunction with permission of the individual's parents or legally authorized representative. Failure to object should not be construed as assent.
- 2.2 *Clinical Trial.* A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
- 2.3 *Cognitively Impaired.* Having a condition that impairs the capacity for judgment and reason. This may include individuals under the influences of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and individuals with severely disabling mental handicaps, all of whom may be compromised in their ability to make decisions in their best interest.
- 2.4 *Consenter.* The Investigator or a designated member of the research team on the approved protocol who has the appropriate training and knowledge to conduct the informed consent process.
- 2.5 *Delegated Authority to Consent on Behalf of Incapable Party.* Per Indiana Code 16-36-1-6, an individual authorized to consent to health care for another who for a time will not be reasonably available to exercise the authority may delegate the authority to consent during that time to another individual. The delegation: (1) must be in writing; (2) must be signed by the delegate; (3) must be witnessed by an adult; and (4) may specify conditions on the authority delegated. Unless the writing expressly provides otherwise, the delegatee may not delegate the authority to another individual. It is the position of the Human Research Protection Program that this authorization to consent to health care extends to participation in research.
- 2.6 *Enroll.* To enter into a research study by means of signing an informed consent document.

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- 2.7** *Funding Source.* The source of funding may be through external (e.g., grants, contracts, gifts) or internal (University/department) sources. Projects which are internally funded should be acknowledged as funded by Purdue University.
- 2.8** *Identifiable Biospecimen.* A biospecimen for which the identity of the subject is or may readily be ascertained by the Investigator or associated with the biospecimen.
- 2.9** *Identifiable Private Information.* Private information for which the identity of the subject is or may readily be ascertained by the Investigator or associated with the information. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
- 2.10** *Informed Consent.* A person's affirmative agreement to participate in a research study after achieving an understanding of what is involved.
- 2.11** *Informed Consent Document.* A document that certifies a person's informed consent.
- 2.12** *Informed Consent Process.* The process of informing a potential subject or a potential subject's Legally Authorized Representative which includes, but is not limited to, explanation of the protocol, review of the consent document, and answering research- related questions.
- 2.13** *Legally Authorized Representative (LAR).* An individual or a judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. In Indiana, a health care representative (appointed in accordance with Indiana Code 16-36-1-7) is the equivalent of the federally defined LAR.
- 2.14** *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.
- 2.15** *Persons Authorized to Consent for Incapable Parties.* Per Indiana Code 16-36-1-5, if an individual incapable of consenting has not appointed a health care representative or the health care representative is not reasonably available or declines to act, consent to health care may be given by:
- 2.15.1 A judicially appointed guardian of the person or a representative appointed; or

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2.15.2 By a spouse, a parent, an adult child, or an adult sibling, if:

- (a) There is no guardian or other representative described in 2.14.1 above;
- (b) The guardian or other representative is not reasonably available or declines to act; or
- (c) The existence of the guardian or other representative is unknown to the health care provider.

2.15.3 The individual's religious superior, if the individual is a member of a religious order and:

- (a) There is no guardian or other representative described in 2.14.1 above;
- (b) The guardian or other representative is not reasonably available or declines to act; or
- (c) The existence of the guardian or other representative is unknown to the health care provider.

2.15.4 It is the position of the Human Research Protection Program that this authorization to consent to health care extends to participation in research.

2.16 *Risk.* The possibility of harm to a subject in a research study.

2.17 *Short Form.* Written consent document allowing use of an oral consent process.

2.18 *Witness.* A witness is a person who is physically present to observe the consent process and can attest to what actually occurred. Should the subject not speak English, the witness should be fluent in both English and the language of the subject.

3. PROCEDURES

3.1 General Requirements of Informed Consent

3.1.1 Except as described in SOP 321: Waiver or Alteration of Informed Consent, no Investigator may enroll a research subject into a research protocol unless s/he has obtained legally effective informed consent of the subject or the subject's LAR. Consent shall be sought only under circumstances that provide the prospective subject or the LAR sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information given to

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the subject or LAR must be in language understandable to the subject or the LAR and include all required elements of informed consent.

- 3.1.2 The prospective subject or LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
- 3.1.3 Except in the case of broad consent, informed consent must:
 - (a) Begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research; and
 - (b) Present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the subject's or LAR's comprehension.
- 3.1.4 Informed consent may not contain any exculpatory language through which the subject is made to waive or appear to waive legal rights, or releases or appears to release the Investigator, the Sponsor, or Purdue University from liability for negligence.

3.2 Required Elements of Informed Consent

- 3.2.1 A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- 3.2.2 A description of any reasonably foreseeable risks or discomforts to the subject.
- 3.2.3 A description of any benefits to the subject or to others that may reasonably be expected from the research.
- 3.2.4 A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.
- 3.2.5 A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained and, for research regulated by the Food and Drug Administration (FDA), a statement noting the possibility that the FDA may inspect the records.

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- 3.2.6 A statement noting the possibility that study records may be inspected by the IRB (or its designees) and the study sponsor, if the research is sponsored by a Funding Source.
- 3.2.7 For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- 3.2.8 An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- 3.2.9 A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- 3.2.10 For research that involves the collection of identifiable private information or identifiable biospecimens, one of the following must be included in the informed consent:
 - (a) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 - (b) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

3.3 Additional Elements

When appropriate, one or more of the following elements of information shall also be provided to each subject.

- 3.3.1 A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant), which are currently unforeseeable.
- 3.3.2 Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.

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- 3.3.3 Any additional costs to the subject that may result from participation in the research.
- 3.3.4 The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- 3.3.5 A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.
- 3.3.6 The approximate number of subjects involved in the study.
- 3.3.7 A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
- 3.3.8 A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
- 3.3.9 For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

3.4 Broad Consent

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements in paragraphs 3.2 and 3.3 above. If the subject or LAR is asked to provide broad consent, the following shall be provided to each subject or LAR:

- 3.4.1 A description of any reasonably foreseeable risks or discomforts to the subject.
- 3.4.2 A description of any benefits to the subject or to others that may reasonably be expected from the research.
- 3.4.3 A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- 3.4.4 A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time

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without penalty or loss of benefits to which the subject is otherwise entitled.

- 3.4.5 When appropriate, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
- 3.4.6 For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
- 3.4.7 A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted.
- 3.4.8 A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens.
- 3.4.9 A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite).
- 3.4.10 Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies.
- 3.4.11 Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject.
- 3.4.12 An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable

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private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

3.5 Documentation of Informed Consent

3.5.1 Unless waived as described in SOP 321: Waiver or Alteration of Informed Consent, the informed consent document must be either of the following:

- (a) A written consent document that embodies the elements of informed consent described in Sections 3.1, 3.2, and 3.3 above and complies with the IRB consent template. This form may be read to the subject or the subject's LAR, but, in any event, the Investigator shall give either the subject or the LAR adequate opportunity to read it before it is signed, or the Investigator shall read it to the subject of the LAR. The subject or the LAR must also be given a copy of the signed form. The IRB consent template requirement may be waived with appropriate justification.
- (b) A short form written consent document stating that the elements of informed consent as required above have been presented orally to the subject or the subject's LAR. The elements must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. The IRB must approve a written summary of what is to be said to the subject or representative. When this method is used, there shall be a witness to the oral presentation. The subject or the LAR signs only the short form itself. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the LAR in addition to a copy of the short form.

3.5.2 A subject or his/her LAR must sign and date a copy of the current IRB-approved consent form prior to enrollment into the study, including screening procedures conducted solely to determine eligibility, unless the requirement is waived by the IRB as described in SOP 321: Waiver or Alteration of Informed Consent. The subject and/or his or her LAR must also be given a copy of the signed document.

3.5.3 The written informed consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent as described in Sections 3.1, 3.2, and 3.3 of this SOP. The informed consent document should be written in simple language free of technical, scientific and/or scholarly jargon. Any

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complex terminology should be explained using common or lay terminology.

3.5.4 It is preferred that the informed consent document should be written in the second-person (e.g., “You will be asked to...”). This voice is intended to convey a dialogue between the researcher and the subject. However, the IRB will consider use of a different voice if appropriate given the subject population and the local context as well as any other relevant factors in the research.

3.5.5 Exculpatory language is not permitted in the consent document.

3.6 Informed Consent Documents for Subjects Who Do Not Speak English

3.6.1 When subjects in a research protocol do not speak English, the written informed consent document should be translated into a language understandable to the subject.

3.6.2 In addition to the English version of the consent form, copies of the consent document translated into a language understandable by the participant should be submitted to the IRB. The consent form should contain the required elements in Sections 3.1, 3.2, and 3.3. The foreign language version must be congruent in substance and intent with the English version. The Investigator must be able to document that the content accurately reflects the English version of the consent form and that it is in a language appropriate to the local context for the target subject population.

(a) Investigators can certify the appropriateness of a translation by use of a translator who is on the approved list of translators offered by Purdue University’s Department of Languages and Cultures.

(b) Alternate procedures to certify a translation may include, but are not limited to, written verification either from a researcher or from a third party with demonstrated expertise in both that language and English. At the IRB’s discretion, a computer program may be used to certify a translation.

3.5.2.3 All translations are subject to verification by the HRPP/IRB and may require a confidentiality agreement for any translation services.

3.6.3 Oral Presentation with Short Form

Where informed consent is documented using a short form procedure for non-English speaking subjects, the written informed consent document

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should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. When this procedure is used with subjects who do not speak English,

- (a) The oral presentation and the short form written informed consent document should be in a language understandable to the subject;
- (b) The IRB-approved English language informed consent document may serve as the summary; and
- (c) The witness should be fluent in both English and the language of the subject.

Expedited review of these forms is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.

3.7 Use of Facsimile or Mail to Document Informed Consent

The IRB may approve a process that allows the informed consent document to be delivered and returned by mail, e-mail, or facsimile to the potential subject or the potential subject's LAR and to conduct the consent interview by telephone when the subject or the LAR can read the consent document as it is discussed. If the consent form is provided in an electronic format, it may be signed electronically by the subject or LAR. All other applicable conditions for documentation of informed consent must also be met when using this procedure.

3.8 Review of Informed Consent Processes and Documents

3.8.1 A Protocol Analyst will conduct administrative review of protocol applications and supporting documents to ensure that the informed consent procedures and consent document(s) are appropriate. If warranted, s/he will notify the Investigator of any omissions or necessary corrections prior to review by an IRB Chair, designee or the convened IRB. Otherwise, the Protocol Analyst will identify any existing issues and will forward the protocol application to the appropriate IRB Chair, designee, or the convened IRB, as appropriate.

3.8.2 If eligible for expedited review, the protocol application and supporting documents including the informed consent procedures and informed consent document(s) will be conducted by the IRB Chair or designated expedited reviewer. If the protocol application requires full IRB review, it will be reviewed by the convened IRB. The informed consent procedures and consent form document will be evaluated to ensure

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compliance with regulatory requirements and IRB guidelines and instructions.

- 3.8.3 Any required changes will be communicated to the Investigator in writing and noted in the protocol file.
- 3.8.4 After the application is approved, the Investigator must add the IRB Protocol Number and the Expiration Date to the header or footer of all approved informed consent document(s). Only approved consent forms can be used by Investigators to document subjects' informed consent.
- 3.8.5 When minor revisions occur in informed consent documents for approved protocols, a Protocol Analyst can review and approve the revision. In such cases the revisions to the consent form can only involve procedures that have been previously approved by the IRB. Any major changes or new procedures to the protocol must be submitted to the IRB for review and approval. See SOP 305: Amendment Requests. The revised consent documents will be forwarded to the IRB for filing in the protocol file.

3.9 Posting of Clinical Trial Informed Consent Materials

- 3.9.1 For each clinical trial supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the Responsible Party on a publicly available Federal web site that will be established as a repository for such informed consent forms.
- 3.9.2 If the Federal department or agency supporting the clinical trial determines that certain information should not be made publicly available on a Federal web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.
- 3.9.3 The informed consent form must be posted on the Federal web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

3.10 Informed Consent Considerations for Special Populations

- 3.10.1 For additional considerations regarding informed consent of pregnant women, see SOP 501: Research Involving Pregnant Women, Fetuses, and Neonates
- 3.10.2 For additional considerations regarding informed consent of Children, see SOP 502: Research Involving Children.

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3.10.3 For additional considerations regarding informed consent of Prisoners, see SOP 503: Research Involving Prisoners.

3.10.4 Provisions of Assent for Adults Unable to Give Legally Effective Informed Consent

- (a) Should the IRB determine that adult subjects are cognitively impaired, whether temporary, progressive, or permanent, or are otherwise unable to give legally effective informed consent, the IRB will further determine if an assent process is required or it may waive assent when all of the waiver criteria are met as described in SOP 321: Waiver or Alteration of Informed Consent.
- (b) If the IRB determines that an assent process is required, the IRB must determine whether that process occurs verbally or if that process should be documented by means of an assent form.
- (c) When adults who are unable to give legally effective informed consent are subjects in research, the IRB determines the process for obtaining informed consent from LAR in accordance with this SOP, or the IRB may waive this consent when all of the waiver criteria are met as described in SOP 321: Waiver or Alteration of Informed Consent.

4. RESPONSIBILITY

4.1 Investigator Responsibilities Regarding Informed Consent

- 4.1.1 Unless informed consent is waived or altered, the Investigator must ensure that the subject or the subject's LAR sign a copy of the stamped IRB- approved informed consent document before any study related procedures are initiated.
- 4.1.2 The Investigator is responsible for assuring an appropriate informed consent process is approved and carried out. The Investigator may delegate the duty of obtaining informed consent to members of the research team listed on the approved protocol. The Investigator is responsible for assuring that any such designee is knowledgeable about the specific research study and the process of informed consent.
- 4.1.3 The Investigator or designee conducting the consent process must sign the informed consent document as the "Researcher," as well as obtain the signature of the subject or his/her LAR.
- 4.1.4 The Investigator or designee will file the original signed consent document with the project's research records. A copy of the consent

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document will be provided to the subject or the subject's LAR at the time of consent. Ideally, an original consent document should be provided to the subject or the subject's LAR signed by all parties.

4.1.5 The Investigator is responsible for assuring that the content of the written consent document, if required, is in compliance with IRB requirements.

4.1.6 Upon identification of a potential subject, the Investigator or designee is responsible for identifying who is legally authorized to consent for the subject, if consent is required. If the subject is physically or mentally unable to provide consent, then the LAR may be approached to give informed consent for the subject. The Investigator or designee should be sensitive to any potential impairment to informed consent.

4.1.7 Required Signatures on Consent Documents

- (a) Written consent should be signed and personally dated by the subject or subject's LAR and by the Consenter. Other signatures must be provided as required by the IRB and/or the sponsor if specified on the IRB approved consent document. If the consent form is provided in an electronic format, it may be signed electronically by the subject or the subject's LAR. Physical signatures may be required for certain research protocols, at the discretion of the IRB.
- (b) The Consenter's signature confirms that the informed consent process was conducted, not that the subject's signature was witnessed. The signature of the Investigator is not required on the consent document, unless s/he is the Consenter.
- (c) The subject is not required to sign the consent document at the same time as the Consenter. The subject may take the consent form in order to review and/or consider it further before signing. The Consenter may sign the consent form documenting the consent process was completed prior to the subject taking it for further consideration. Hence the date of the Consenter's signature may precede that of the subject's signature.

4.1.8 Revisions to the Informed Consent Document

- (a) The Investigator is responsible for assuring that the written consent document and any other written information to be provided to subjects is revised whenever important new information becomes available that may be relevant to the subject's willingness to participate (e.g., new procedures, new anticipated problems/adverse events, etc.). The Investigator may delegate to

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appropriate members of the research team the development and processing of the revised consent document or any other written information to be provided to subjects. Any such revisions must receive IRB approval prior to use. Immediate hazards should be communicated to the subject right away and reported to the IRB as soon as possible (see SOP 409: Unanticipated Problems and Adverse Event Reporting).

- (b) The informed consent process must be revised any time the risk-benefit ratio changes or when new information becomes available that alters information previously reported to subjects (e.g., new procedures, new anticipated problems/adverse events, etc.). If a written consent document is revised during the course of a subject's participation in the research, then the subject may need to be re-consented with the revised IRB-approved consent document. The original newly obtained revised signed consent document should be filed with the subject's research records. A copy of the newly obtained revised signed consent document should also be provided to the subject or subject's LAR at the time of consent. The initial previously signed consent should be retained by the Investigator.
- (c) In situations where consent documents have been revised and approved by the IRB, the newly approved revised consent document will be authorized with the same expiration date. It is important for the Investigator or designee to assure that newly enrolled subjects sign the current IRB-approved version of the consent document.
- (d) While some changes to the consent document may require re-consenting of all subjects currently enrolled in the research study (e.g., discovery of serious unanticipated problems), not all changes to the consent document require re-consenting of currently enrolled subjects. Some examples might include grammatical error corrections or any revisions that do not change the risk-benefit ratio.
- (e) In cases where subjects have completed active study or follow-up procedures and new safety information is discovered that may affect a subject's participation or long-term risks from the research, the subject must be informed of this new information. This may be accomplished through re-consenting subjects with a revised consent document which explains this new information or by other methods of notification approved by the IRB. The timeliness of

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informing subjects and re-consenting them will depend on the degree of risk associated with the new information.

4.1.9 When the Subject or the Subject's LAR is Unable to Read or Understand the Consent Document

- (a) If written consent is required and the subject or the subject's LAR is unable to read, then the IRB-approved consent document must be read in its entirety in the presence of a witness. This should be documented directly onto the consent document and signed by the subject or the subject's LAR, as well as the witness.
- (b) If the subject or the subjects' LAR or witness, if involved, is unable to speak or understand the written informed consent document because of the language in which it is written, the IRB-approved process and written consent document, if required, must be conducted in a language the subject understands and documented in the subject's record and reported to the IRB at each occurrence. If these situations can be anticipated, prior IRB approval of a translated consent form should be obtained. Translators or sign language interpreters should be part of the ongoing communication throughout the research study and may be used to assist with verbal and written translation. See Section 3.6.

4.1.10 Obtaining Informed Consent Remotely

- (a) Informed consent may only be obtained via telephone when written documentation of informed consent has been waived by the IRB. In these situations, the consentor must document the informed consent process took place by making appropriate notation regarding the process in the research records.
- (b) There may be situations when obtaining signed informed consent documentation from subjects via fax, mail, or email is appropriate. This is acceptable in situations where the informed consent process has already been appropriately conducted in person or when it is conducted over the phone. The consentor should sign and date the consent document prior to faxing, mailing, or emailing it to the subject, or giving it to the subject should the consent process take place in person. If the consent process occurs over the phone, the consentor should note in the subject's records that it took place. The subject should return the original signed consent document to the researcher either at the next scheduled research session, provide a copy of the signed consent document via fax, mail, or email. The research team member receiving the signed original document should note the received date on the document and file it

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with the research records and make appropriate notes to the research records explaining how the consent process occurred.

4.2 IRB Responsibilities Regarding Informed Consent

- 4.2.1 A Protocol Analyst is responsible for conducting administrative review of informed consent procedures and informed consent documents, communicating required changes to Investigators and advising Investigators on appropriate procedures and requirements. A Protocol Analyst is responsible for reviewing and approving minor revisions in informed consent documents for previously approved procedures and forwarding the newly approved revised consent documents to the IRB.
- 4.2.2 The IRB Administrator is responsible for advising Investigators on appropriate procedures and requirements. Additionally, s/he is responsible for assisting Protocol Analysts with administrative reviews.
- 4.2.3 IRB Members are responsible for reviewing informed consent procedures and documents as well as communicating required changes to Investigators.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.25; 21 CFR 50.27

45 CFR 46.116; 45 CFR 46.117

[OHRP, Frequently Asked Questions on Informed Consent](#)

6. REFERENCES TO OTHER APPLICABLE SOPs

321 Waiver or Alteration of Informed Consent

409 Unanticipated Problems and Adverse Event Reporting

501 Research Involving Pregnant Women, Fetuses, and Neonates

502 Research Involving Children

503 Research Involving Prisoners

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1. POLICY:

There are instances in which it may be appropriate to waive or alter the requirement to obtain informed consent or documented (signed) informed consent from subjects. All requests for such waivers or alterations must meet federal regulatory requirements and must be approved by the Institutional Review Board (IRB).

These procedures apply to all non-exempt research protocols.

2. DEFINITIONS

- 2.1** *Assent.* An Individual's affirmative agreement to participate in research obtained in conjunction with permission of the individual's parents or legally authorized representative. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- 2.2** *Enroll.* To enter into a research study by means of signing an informed consent document.
- 2.3** *Information Sheet.* A document conveying information typically required in an informed consent document absent signature lines for subjects.
- 2.4** *Informed Consent.* A person's affirmative agreement to participate in a research study after achieving an understanding of what is involved.
- 2.5** *Informed Consent Document.* A document that certifies a person's informed consent.
- 2.6** *Informed Consent Process.* The process of informing a potential subject or a potential subject's Legally Authorized Representative (LAR) which includes, but is not limited to, explanation of the protocol, review of the consent document, and answering questions.
- 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** *Not Practicable.* Incapable of being put into practice or of being done or accomplished. The term "not practicable" means more than simple inconvenience, it means the research could not be otherwise conducted.
- 2.9** *Risk.* The possibility of harm to a subject in a research study.
- 2.10** *Test Article.* Any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or

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any other article subject to regulation under the Federal Food, Drug and Cosmetic Act or under §351 or 354-360F of the Public Health Service Act.

3. PROCEDURES

3.1 Waiver or Alteration of Informed Consent

- 3.1.1 To obtain a waiver or alternation of informed consent, the Investigator must include the request (and provide justification for the waiver or alternation) in the protocol submission process.
- 3.1.2 The request for waiver or alteration will be reviewed by the convened IRB (see SOP 302: Initial Review) or by the IRB Chair or designated expedited reviewer (see SOP 303: Expedited Review).
- 3.1.3 The IRB reviewer may approval the waiver or alteration of informed consent pursuant to 45 CFR 46.116(e) (Public Benefit and Service Programs), if the IRB reviewer determines and documents that:
 - (a) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 - (i) Public benefit or service programs;
 - (ii) Procedures for obtaining benefits or services under those programs;
 - (iii) Possible changes in or alternatives to those programs or procedures; or
 - (iv) Possible changes in methods or levels of payment for benefits or services under those programs; and
 - (b) The research could not practicably be carried out without the waiver or alteration.
- 3.1.1 The IRB reviewer may approval the waiver or alteration of informed consent pursuant to 45 CFR 46.116(f) (General Research), if the IRB reviewer determines and documents that:
 - (a) The research involves no more than minimal risk to the subjects;
 - (b) The research could not practicably be carried out without the requested waiver or alteration;

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- (c) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- (d) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- (e) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

3.1.2 The IRB reviewer will document the findings for Waiver or Alteration of Informed Consent.

3.1.3 An alteration to informed consent may apply when conducting a study where there is deception or an incomplete disclosure. Examples of such research would be certain types of ethnographic research, and studies that require deception because the study would be compromised if participants were told the true purpose.

3.2 Screening, recruiting, or determining eligibility.

An IRB may approve a research proposal in which an Investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's LAR, if either of the following conditions are met:

3.2.1 The Investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

3.2.2 The Investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

3.3 Subject Refusal to Grant Broad Consent

If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with SOP 320: Informed Consent Requirements, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

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3.4 Waiver of Signed Consent Form

- 3.4.1 A waiver of a signed informed consent form may be appropriate for some research studies. Examples of such studies are survey or interview studies that contain highly sensitive questions (e.g., health status, sexual practices, criminal behavior, etc.), or surveys containing non-sensitive information.
- 3.4.2 To obtain a waiver of documented (signed) informed consent, the Investigator must include the request (and provide justification for the waiver or alternation) in the protocol submission process.
- 3.4.3 The request for waiver or alteration will be reviewed by the convened IRB (see SOP 302: Initial Review) or by the IRB Chair or designated expedited reviewer (see SOP 303: Expedited Review).
- 3.4.4 The IRB reviewer will consider the Investigator's request and review the request to determine either:
 - (a) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
 - (b) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
 - (c) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
- 3.4.5 The IRB reviewer will document the findings for Waiver or Alteration of Informed Consent.
- 3.4.6 In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research, such as an information sheet, in lieu of an informed consent document.

3.5 Waiver or Alternation of Informed Consent in FDA Research

- 3.5.1 When research is subject to the Food and Drug Administration (FDA) regulations, a waiver or alteration of informed consent will be allowed

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only in certain emergency situations that meet the criteria in 21 CFR 50.23 or 21 CFR 50.24.

- 3.5.2 In most FDA research, the obtaining of informed consent will be deemed feasible, unless both the Investigator and a physician who is not otherwise participating in the research certify in writing all of the following:
- (a) The human subject is confronted by a life-threatening situation necessitating the use of the test article.
 - (b) Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.
 - (c) Time is not sufficient to obtain consent from the subject's legal representative.
 - (d) There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.
- 3.5.3 If immediate use of the test article is, in the Investigator's opinion, required to preserve the life of the subject, and time is not sufficient to obtain the independent determination required in Section 3.4.2 in advance of using the test article, the determinations of the Investigator shall be made and, within 5 working days after the use of the article, be reviewed and evaluated in writing by a physician who is not participating in the research.
- 3.5.4 The documentation required in Section 3.5.2 or 3.5.3 shall be submitted to the IRB within five (5) working days after the use of the test article.

4. RESPONSIBILITY

4.1 Investigator Responsibilities

- 4.1.1 The Investigator request waiver or alternation of informed consent as part of the protocol submission process.
- 4.1.2 The Investigator must conduct the informed consent process in accordance with the IRB approved protocol.
- 4.1.3 The Investigator must use the IRB approved consent form unless that requirement has been waived.
- 4.1.4 If a waiver of signed informed consent is granted in accordance with Section 3.4 above, the Investigator must ask the subject whether the

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subject wants documentation linking the subject with the research, and the subject's wishes will govern.

4.2 IRB Responsibilities

- 4.2.1 HRPP Protocol Analysts are responsible for conducting administrative review of requests for waiver or alteration of informed consent and signed informed consent, informed consent forms and debriefing informed consent forms, information sheets and communicating requests for clarification and required changes to investigators.
- 4.2.2 The IRB Administrator is responsible for advising Investigators on appropriate procedures and requirements. Additionally, s/he is responsible for assisting the Protocol Analysts with administrative reviews.
- 4.2.3 IRB Members are responsible for reviewing informed consent procedures and documents, requests for waivers and alterations and making findings and determinations for full review protocols.
- 4.2.4 IRB Chair or his/her designee is responsible for reviewing informed consent procedures and documents, requests for waivers and alterations and making findings and determinations.
- 4.2.5 IRB Reviewer is responsible for documenting findings for granted waivers and alterations on the Review Form for Waiver or Alteration of Informed Consent.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.116; 45 CFR 46.117

21 CFR 50.23; 21 CFR 50.24

[OHRP Guidance on Informed Consent](#)

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6. REFERENCES TO OTHER APPLICABLE SOPs

302 Initial Review

303 Expedited Review

320 Informed Consent Requirements

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1. POLICY

Federal regulations 45 CFR 46.108(a)(4) and 21 CFR 56.108(b)(2) require institutions to have written procedures for ensuring prompt reporting to the Institutional Review Board (IRB), appropriate institutional officials, and the department or agency head of serious or continuing noncompliance with the governing regulations or the requirements or determinations of the IRB.

When the Purdue HRPP is in pending or active accreditation status from the Association for the Accreditation of Human Research Protection Programs (AAHRPP), Purdue University must report to AAHRPP within 24 hours after the university or any researcher (if the researcher is notified rather than Purdue University) becomes aware of:

- 1.1 Any negative actions by a government oversight office, including, but not limited to, OHRP determination letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA restrictions placed on IRBs or ECs or researchers, and corresponding compliance actions taken under non-US authorities related to human research protections.
- 1.2 Any litigation, arbitration, or settlements initiated related to human research protections.
- 1.3 Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding Purdue University's HRPP.

These policies and procedures apply to all reviewed research activities that fall under the jurisdiction of the Purdue University Human Research Protection Program (HRPP).

2. DEFINITIONS

- 2.1 *Allegation* - An unconfirmed report.
- 2.2 *Complaint* - A report made by a party who either experienced or witnessed an event of potential noncompliance.
- 2.3 *Continuing Noncompliance* - Repeated noncompliance that, in the opinion of the IRB Chair or designee, suggests the likelihood that noncompliance will continue without intervention.
- 2.4 *Noncompliance* - Failure to comply with any of the federal or state regulations or institutional policies governing Human Subjects Research or the requirements or determinations of the IRB.
- 2.5 *Report* - Notification to the IRB that an incident of potential noncompliance has occurred.

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- 2.6** *Serious Noncompliance* - Failure to comply with any of the federal or state regulations or institutional policies governing Human Subjects Research that increases risks, or decreases benefits to subjects, and/or significantly affects the subject's rights, safety or welfare and/or integrity of the data. An example of serious noncompliance includes conducting Human Subjects Research without appropriate IRB approval.

3. PROCEDURES

Investigating complaints, allegations and self-reported noncompliance is integral to the IRB's ability to protect the safety, rights and welfare of human subjects. The IRB is authorized to receive, investigate and make determinations about allegations and/or incidents of noncompliance associated with all Human Subjects Research, including both IRB-reviewed protocols and covered activities which should have been submitted to the IRB for review. The IRB is authorized to take action to protect human subjects and promote compliance with the University's Federalwide Assurance and HRPP policies.

3.1 Handling Reports of Noncompliance

- 3.1.1 Reports, complaints or allegations of noncompliance should be made to the HRPP. Any event meeting the definition of noncompliance should be reported to the HRPP within 48 hours after the Investigator first learns of the event. Initial reports can be made either orally or in writing; however, a written follow up may be requested by the HRPP. Specifically, reports should be sent to irb@purdue.edu or delivered in person to the office.
- 3.1.2 When HRPP Staff receive reports, complaints, or allegations of noncompliance, they must immediately report it to the IRB Administrator, IRB Chair, or IRB Associate Chair (or designees).
- 3.1.3 The IRB Administrator, IRB Chair, or IRB Associate Chair will compile the information regarding the allegation, complaint or report and will work with the IRB Chair to submit the information to the IRB for further review and processing as needed.

3.2 Initial Inquiry

- 3.2.1 The IRB Chair and/or IRB Associate Chair will serve as the primary designee for inquiry unless another IRB Member is specifically named by the IRB Chair or Institutional Official or a conflict of interest prevents this duty. The IRB Chair, Associate Chair, or their designee, may request additional information, as needed, in order to verify that an incident of noncompliance has occurred as well determine the degree of noncompliance. An individual with a potential conflict of interest may not

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participate in the initial inquiry. All communication between the IRB and the Investigator will be documented and recorded in the IRB study file. The IRB Chair (or designee) may secure critical documents at any time during the investigation, as necessary to assure the protection of human subjects.

- 3.2.2 In case of emergency, the IRB Chair (or designee) may temporarily suspend approval of the investigator's research in accordance with SOP 410: Suspension or Termination of Research, until the matter can be presented to the convened IRB for further review.
- 3.2.3 If the IRB Chair (or designee) determines that no incident of noncompliance occurred or the investigation cannot proceed due to lack of information/evidence, the allegation or complaint will be dismissed. Such determination will be made in consultation with the IRB Associate Chair, HRPP Director or an IRB Member. This determination will be documented and filed in the IRB study file. The determination will be promptly communicated to the complainant and Investigator as appropriate.
- 3.2.4 If the IRB Chair or designee determines that the reported events is neither Serious Noncompliance nor Continuing Noncompliance and did/does not have a significant impact on subjects' rights, safety or welfare, and/or the integrity of the data, the incident will be reviewed via expedited procedures. The IRB Chair (or designated expedited reviewer) will determine and implement appropriate corrective action(s). If such corrective action includes more than a minor modification to previously approved research, the modifications must be reviewed via the convened IRB. See SOP 305: Amendment Requests. The determination will be filed in the IRB study file and will be reported to the full IRB at its next convened meeting. After the matter is reported at the convened meeting, the Investigator will be promptly notified of the outcome.
- 3.2.5 If the IRB Chair or designee determines that the reported event requires additional fact finding, the IRB Chair can refer the matter to an Investigative Subcommittee or the Institution (e.g. Post-Approval Monitor), to further investigate the matter in order to make a recommendation to the full IRB.
- 3.2.6 If the IRB Chair (or designee) determines that the reported event is Serious Noncompliance or Continuing Noncompliance, or determines that the incident cannot be adequately resolved via the expedited review process, she or he can refer the matter either to an Investigative Subcommittee or to the convened IRB for review. A summary report of the investigation including the initial incident report and the information reviewed by the IRB Chair (or designee) will be provided to the members of the Investigative Subcommittee. The status will be promptly reported to the Investigator and,

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if appropriate, to the department head, the complainant, and applicable federal agencies.

3.2.7 The HRPP Director and IO must be notified within 48 hours of all reports that include any of the following conditions:

- (a) Any substantiated reports of Serious Noncompliance or Continuing Noncompliance;
- (b) Any action that results in the constitution of an Investigative Subcommittee;
- (c) Any act by the IRB to secure critical documents.
- (d) Any suspensions or terminations resulting from the report and/or investigation.

3.3 Assignment to Investigative Subcommittee or Post-Approval Monitor

3.3.1 Assignments to the Post-Approval Monitor are conducted utilizing procedures detailed in SOP 306. If the initial inquiry of the incidence requires additional fact finding, the IRB Chair can assign the matter to an Investigative Subcommittee, consisting of, at a minimum: the IRB Chair or Associate Chair, the IRB Administrator, and 2 IRB Members (regular or alternate). At least one Investigative Subcommittee member should possess expertise appropriate for review of the allegation. Any individual with a potential conflict of interest shall not participate in the investigation. The IRB Chair or Associate Chair, or designee, will lead the investigation. The IRB Administrator will act as secretary to the Investigative Subcommittee. The Investigative Subcommittee will meet as necessary to ensure timely review of pending allegations.

3.3.2 The Investigator, and if appropriate the complainant, will be informed in writing of the allegation and investigation. If additional information is required to facilitate review of the investigation, the Investigator will be asked to respond in writing within ten (10) days. The Investigator, other research team members, and/or others may be interviewed and/or an audit of the Investigator's research may be conducted, as necessary.

3.3.3 On behalf of the IRB, the Investigative Subcommittee may suspend IRB approval of the Investigator's research in accordance with SOP 410: Suspension or Termination of Research, until the matter can be reviewed by the convened IRB. The Investigative Subcommittee may also secure critical documents at any time during the investigation, as necessary to assure the protection of human subjects. A written report of the investigation including the initial incident report, information reviewed by the Investigative

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Subcommittee, determination of whether the incident constitutes Serious Noncompliance and/or Continuing Noncompliance, and its conclusions and recommendations will be submitted to the IRB Chair (if not a member of the Investigative Subcommittee) and the IRB responsible for reviewing the research.

3.4 IRB Convened Meeting

- 3.4.1 At a convened meeting, the IRB responsible for reviewing the research will review the summary report and all relevant materials submitted by either the IRB Chair or designee or the Investigative Subcommittee.
- 3.4.2 After consideration of the report, the IRB can move take the following actions:
 - (a) Request additional information.
 - (b) Accept the recommendation(s) of the report.
 - (c) Accept the recommendation(s) of the report with modifications.
 - (d) Refer the event to the appropriate University process (e.g., misconduct).
- 3.4.3 The IRB will make its final determination(s) by majority vote of a quorum of the IRB Members at the convened meeting.
- 3.4.4 If there is a finding of Serious Noncompliance or Continuing Noncompliance or a suspension or termination of IRB approval, the Investigator will be notified in writing within five (5) business days of the IRB's final determination and a due date for corrective actions to be implemented. If appropriate, the Investigator will be instructed to notify the funding agency upon receipt of the IRB's final determination. If appropriate, the complainant will also be notified of the determination.

3.5 IRB Determinations

- 3.5.1 In the event of a determination of Serious Noncompliance and/or Continuing Noncompliance or any suspension or termination of IRB approval, the IRB will report the event to the IO. The IO is then responsible for reporting the event to the Office for Human Research Protections and/or the Food and Drug Administration, as appropriate.
- 3.5.2 The IRB may take additional actions as it deems necessary and appropriate. Possible actions include, but are not limited to, the following:

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- (a) Require corrective actions such as modifications to the research protocol and/or informed consent documents.
- (b) Restrict use of research data.
- (c) Require past and/or current subjects to be informed of the incident and/or be re-consented.
- (d) Modify the continuing review cycle.
- (e) Require increased reporting by the Investigator and/or increased monitoring of the research and/or informed consent process.
- (f) Suspend or terminate the protocol's approval or suspend specific research activities in accordance with SOP 410: Suspension or Termination of Research.
- (g) Require mentoring and/or educational measures.
- (h) Recommend sanctions to the IO.
- (i) Referral to other appropriate University processes.

3.5.3 Determinations will be documented in the IRB study file as well as in the minutes of the convened IRB meeting.

3.6 Further Actions

- 3.6.1 If the Investigator does not comply with the IRB determination(s) by the time specified in the notification to the Investigator, the IRB Chair or the Investigative Subcommittee may recommend additional action, including suspension or termination of IRB approval(s) for ongoing Human Subjects Research activities. The need for additional action(s) will be considered by the full IRB at a convened meeting.
- 3.6.2 The Investigator will be promptly notified in writing of any further IRB review and will be given an opportunity to respond in writing.
- 3.6.3 The Investigator will be notified in writing within five (5) business days of the final decision of the IRB.

3.7 Appeals

Although the determinations of the IRB are final, the convened IRB may consider an Investigator's response or appeal to the IRB's determination if new information or unusual circumstances are presented. All appeals must be made no more than thirty (30) days after the receipt by an Investigator of the IRB's determination, with

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the exact number of days determined by the IRB based on determined severity of Noncompliance. The IRB will review an Investigator's appeal within thirty (30) days of receipt of the appeal, and the Investigator will be notified in writing of the IRB's response to the appeal within five (5) business days.

4. RESPONSIBILITY

- 4.1** HRPP Staff members are responsible for receiving reports and forwarding them immediately to the IRB Administrator (or designee).
- 4.2** The IRB Administrator or designee is responsible for pre-reviewing reports, compiling related information, and forwarding to the IRB Chair and/or Associate Chair.
- 4.3** The IRB Chair (or designee) is responsible for reviewing reports, conducting investigations, making determinations regarding the nature of the event, requiring corrective actions for deviations, constituting Investigative Subcommittees, and, if appropriate, making recommendations to the full IRB.
- 4.4** IRB Members are responsible for reviewing reports, making determinations, requiring corrective actions, when appropriate, serving on Investigative Subcommittees to conduct investigations and make recommendations to the IO.
- 4.5** The IRB Administrator administratively supports and participates in investigations into Serious Noncompliance and Continuing Noncompliance. The IRB Administrator is responsible for communicating with appropriate federal agencies and sponsors as needed and ensuring that other parties are informed of IRB actions (e.g. suspensions or terminations) on an as needed basis.
- 4.6** The IO is responsible for evaluating the IRB's report and considering its recommendations. The IO is responsible for submitting reports to the Office for Human Research Protections or the Food and Drug Administration as appropriate.
- 4.7** Investigators are responsible for self reporting noncompliance to the IRB. Additionally, they are responsible for training research team members in the recognition and reporting of noncompliance.
- 4.8** Purdue University Office of Legal Counsel is responsible for reporting Any litigation, arbitration, or settlements initiated related to human research protections to the IO and/or the HRPP Director (who will report to AAHRPP) or to AAHRPP directly, as appropriate.

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5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.25(b)(5), 21 CFR 56.108(b)(2)

45 CFR 46.108(a)(4), 45 CFR 46.116(c)(5)

6. REFERENCES TO OTHER APPLICABLE SOPs

306 Post-Approval Monitoring

410 Suspension or Termination of Research

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1. POLICY

Purdue University Investigators and Human Research Protection Program (HRPP) Staff have an obligation to report unanticipated problems involving risks to subjects or others and certain types of Adverse Events.

Investigators must report applicable Unanticipated Problems and Adverse Events to the HRPP as outlined in this SOP. The HRPP will then review the report and consider corrective actions or substantive changes, as necessary, in order to protect the safety, welfare, and rights of subjects or others. The HRPP also has an obligation to report identified Unanticipated Problems to the Office for Human Research Protections (OHRP).

These policies and procedures apply to all Human Subject Research under the jurisdiction of the IRB.

2. DEFINITIONS

2.1 *Adverse Event.* Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Adverse events encompass both physical and psychological harms.

2.2 *Serious Adverse Event.* Any Adverse Event that:

2.2.1 results in death;

2.2.2 is life-threatening (places the subject at immediate risk of death from the event as it occurred);

2.2.3 results in inpatient hospitalization or prolongation of existing hospitalization;

2.2.4 results in a persistent or significant disability/incapacity;

2.2.5 results in a congenital anomaly/birth defect; or

2.2.6 based upon appropriate medical judgment, may jeopardize the subject's health, and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not

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result in inpatient hospitalization, or the development of drug dependency or drug abuse).

2.3 *Unanticipated Problem.* An incident, experience, or outcome that meets all of the following criteria:

2.3.1 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;

2.3.2 related or possibly related to a subject's participation in the research; and

2.3.3 suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, legal, or social harm) than was previously known or recognized.

2.4 *Possibly Related.* There is a reasonable possibility that the problem, event, incident, experience, or outcome may have been caused by the procedures involved in the research.

Adverse events may be caused by one or more of the following:

2.4.1 the procedures involved in the research;

2.4.2 an underlying disease, disorder, or condition of the subject; or

2.4.3 other circumstances unrelated to either the research or any underlying disease, disorder, or condition of the subject.

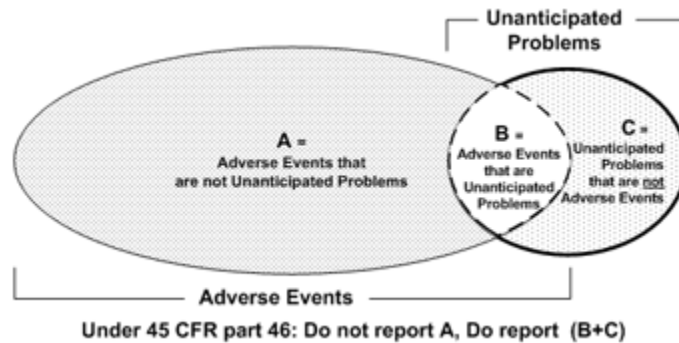
In general, Adverse Events that are determined to be at least partially caused by (1) would be considered related to participation in the research, whereas Adverse Events determined to be solely caused by (2) or (3) would be considered unrelated to participation in the research.

3. PROCEDURES

3.1 Identifying Unanticipated Problems

3.1.1 As shown in the OHRP guidance diagram below, Investigators must report all Unanticipated Problems (including the subset that is also Adverse Events) to the HRPP.

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- 3.1.2 OHRP guidance recognizes that the vast majority of Adverse Events occurring in human subjects research are not Unanticipated Problems, in light of (1) the known toxicities and side effects of the research procedures; (2) the expected natural progression of subjects' underlying diseases, disorders, and conditions; and (3) subjects' predisposing risk factor profiles for the Adverse Events. Thus, most individual Adverse Events do not meet the first criterion for an Unanticipated Problem and do not need to be reported.

3.2 Reporting Requirements and Procedures

- 3.2.1 The Investigator must promptly report any Unanticipated Problems to the IRB. The HRPP requires Investigators to report in accordance with the following guidelines in order to satisfy the prompt reporting requirement:
- (a) Unanticipated Problems that are Serious Adverse Events must be reported to the IRB within five (5) business days of the Investigator becoming aware of the event. The IRB strongly recommends that a preliminary report be submitted by the researcher within 48 hours of learning of the Serious Adverse Event with a formal follow-up report submitted within the above timeline. Investigators should not include identifiable information in the report(s).
 - (b) Any other Unanticipated Problem should be reported to the IRB within two (2) weeks of the Investigator becoming aware of the problem. The IRB strongly recommends that a preliminary report be submitted by the researcher within five (5) business days of learning of the Unanticipated Problem with a formal follow-up report submitted within the above timeline. Investigators should not include identifiable information in the report(s).

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- (c) All Unanticipated Problems should be reported to the Institutional Official (IO), the supporting agency head (or designee), and OHRP within one month of the IRB's receipt of the report of the problem from the Investigator.
- (d) In some cases, the requirements for prompt reporting may be met by submitting a preliminary report to the IRB, the IO, the supporting HHS agency head (or designee), and OHRP, with a follow-up report submitted at a later date when more information is available. Determining the appropriate time frame for reporting a particular unanticipated problem requires careful judgment by persons knowledgeable about human subject protections. The primary consideration in making these judgments is the need to take timely action to prevent avoidable harms to other subjects.
- (e) The HRPP/IRB will respond to participant complaints, Purdue hotline reports, self-disclosures, reputable reports from another source, or requirements for clarification from an investigator in the same manner as an Unanticipated Problem Report.

3.2.2 Content of Unanticipated Problem Report. When making a report to the IRB, an Investigator should include the following information:

- (a) appropriate identifying information for the research protocol, such as the title, Investigator's name, and the IRB project number;
- (b) a detailed description of the Adverse Event, incident, experience, or outcome; however, to preserve confidentiality, subject names and identifiable information should not be included in the report);
- (c) an explanation of the basis for determining that the Adverse Event, incident, experience, or outcome represents an unanticipated problem; and
- (d) a description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

3.2.3 The Investigator is responsible for assessing and documenting unanticipated problems and reporting to the HRPP, as required by this policy, regardless of who observed or became aware of the event.

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- (a) The Investigator should use his or her judgment when determining if an event is considered reportable. When in doubt, the investigator should contact the HRPP for guidance.
- (b) In the absence of the Investigator, a co-researcher can fulfill these requirements to meet the reporting timeline.
- (c) In the absence of either the Investigator or a co-researcher, a student member of the research team or other research personnel must contact the HRPP for direction.

3.2.4 For collaborative research, Unanticipated Problems should be reported to the IRB of record.

- (a) When a Purdue University IRB is the IRB of record, Unanticipated Problems must be reported in accordance with this SOP, regardless of where the Unanticipated Problem occurred. The Purdue University Investigator is responsible for coordinating the reporting.
- (b) When a Purdue University Investigator is relying upon IRB review from another institution, Unanticipated Problems must be reported in accordance with the policies and procedures of that institution.

3.2.5 The IO is responsible for reporting Unanticipated Problems to OHRP and/or the Food and Drug Administration (FDA), as required.

3.2.6 The Investigator must fulfill the reporting requirements of other organizations (e.g., Sponsor), which are not satisfied nor precluded by submitting an Unanticipated Problem report to the HRPP. Likewise, submitting Unanticipated Problem or Adverse Event reports to other organizations (e.g., Sponsor) does not satisfy the reporting requirement to HRPP.

3.3 IRB Review and Response

3.3.1 Initial review of Unanticipated Problems will be conducted by the IRB Chair, Associate Chair, or designee.) unless another IRB Member is specifically named by the IRB Chair or Institutional Official or a conflict of interest prevents this duty. The IRB Chair (or designee) is authorized to take the following actions in response to any incident report:

- (a) Conduct an administrative review of the report, including assessing whether the incident constitutes an Unanticipated Problem and by

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whom it should be reviewed (e.g., the IRB Chair only, IRB Associate Chair only, an IRB subcommittee, or the convened IRB).

- (b) If convened IRB review is needed, the IRB Chair or designee assigns the incident report for review at the next available regularly scheduled IRB meeting. Assignment to a convened meeting will occur by the processes found in SOP 302: Initial Review.
- (c) Alternately, the IRB Chair may convene an emergency meeting of the IRB to review the report.
- (d) If the IRB Chair (or designee) finds that the rights, safety, and welfare of subjects are jeopardized by the research, the IRB Chair may suspend research until such time that the full IRB can convene to review the report.

3.3.2 When reviewing a report of an Unanticipated Problem, the IRB should consider whether the affected research protocol still satisfies the criteria for IRB approval under regulations at 45 CFR 46.111. See SOP 302: Initial Review. In particular, the IRB should consider whether risks to subjects are still minimized and reasonable in relation to the anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result.

3.3.3 When reviewing a particular incident, experience, or outcome reported as an Unanticipated Problem by the Investigator, the IRB may determine that the incident, experience, or outcome does not meet all three criteria for an Unanticipated Problem. In such cases, further reporting to appropriate institutional officials, the department or agency head (or designee), and OHRP would not be required.

3.3.4 After reviewing the Unanticipated Problem report, the IRB may require the following actions, in order to protect the ongoing safety of research subjects:

- (a) Modification of subject inclusion or exclusion criteria to mitigate the newly identified risks;
- (b) Implementation of additional procedures for monitoring subjects;
- (c) Modification of informed consent documents to include a description of newly recognized risks;
- (d) Provision of additional information about newly recognized risks to previously enrolled subjects;

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- (e) Suspension of enrollment of new subjects;
- (f) Suspension of research procedures in currently enrolled subjects;
- (g) Suspension of the entire study; or
- (h) Termination of approval for the entire study.

3.3.5 If the response to an Unanticipated Problem requires an amendment of the research protocol and/or informed consent forms, an amendment request must be submitted to the IRB in accordance with SOP 305: Amendment Requests. If the changes are minor they may be reviewed by expedited review procedures. If the changes are more than minor, they must be reviewed and approved by the convened IRB. Any such proposed changes in response to an Unanticipated Problem must be reviewed and approved by the IRB before being implemented, except when implementation is necessary to eliminate apparent immediate hazards to subjects.

4. RESPONSIBILITY

The IRB Chair, Associate Chair, or designee is responsible for reviewing all reports of unanticipated problems and ensuring the appropriateness of all IRB decisions and actions.

The IRB Administrator is responsible for advising the IRB Chair on relevant institutional and regulatory requirements.

The IO is responsible for reporting unanticipated problems to the OHRP or other outside institutions as needed.

5. PROCESS OVERVIEW

Unanticipated Problems must be reported to the HRPP as promptly as possible, within two (2) weeks of the Investigator learning of the incident, or five (5) business days in the case of a Serious Adverse Event. All reports must be made in writing, except in the event of an emergency, in which case an initial report may be made by telephone or in person, with a formal written report to follow within the required timeframe.

In the event that HRPP Support Staff receive Unanticipated Problem Reports, they must forward to the appropriate IRB Chair for review. HRPP Support Staff also notify the IRB Administrator, Human Protections Administration, and the IO that an Unanticipated Problem report has been submitted.

The IRB Chair or designee reviews the reports. S/he evaluates the incoming report determines what actions, if any, may be needed to protect the rights, safety, and welfare of research subjects due to the nature or frequency of the reported unanticipated problem.

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If the IRB Chair finds that additional review is necessary, the IRB Chair assigns the Unanticipated Problem report for review at the next regularly scheduled IRB meeting or convenes an emergency meeting of the convened IRB. The IRB Chair may also opt to follow procedures outlined in SOP 408 if Noncompliance with an approved protocol may be a factor.

HRPP Support Staff assist the IRB Chair in communicating the results of the review, discussion, and outcome to the Investigator and other appropriate parties.

6. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103; 46.109; 46.111; 46.113

21 CFR 56.108; 312.32; 312.64; 812.3(s); 812.46; 812.150

[OHRP Guidance, Unanticipated Problems Involving Risks & Adverse Events \(2007\)](#)

7. REFERENCES TO OTHER SOPs

302 Initial Review

408 Noncompliance

410 Suspension or Termination of Research

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1. POLICY:

The Institutional Review Board (IRB) may to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, the Institutional Official (IO), the HRPP Director, and if the research is externally funded, to the sponsor. The IRB has authority to suspend or terminate human subject research activities that have never been reviewed by the IRB upon learning of such activities.

These policies and procedures apply to all Human Subjects Research conducted by Investigators affiliated with Purdue University, regardless of whether the protocol was ever submitted, reviewed, or approved by the IRB.

2. DEFINITIONS

- 2.1** *Department or Agency Head.* The head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.
- 2.2** *Suspension.* Temporary cessation of some or all activities in a currently approved research study.
- 2.3** *Termination.* Determination made by the IRB to permanently withdraw approval for some or all activities of a currently approved research study.

3. PROCEDURES

- 3.1** Federal regulations give an IRB the authority to terminate or suspend approval of research under its jurisdiction.
 - 3.1.1** An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.
 - 3.1.2** A research study may be suspended or terminated for a variety of reasons, including but not limited to:
 - (a) Failure to obtain appropriate consent or keep appropriate study-related paperwork;
 - (b) Conduct of research activities without prior IRB approval;
 - (c) Serious adverse event(s);
 - (d) Detrimental change in the risk-benefit ratio of the study;

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- (e) Failure of investigators to complete required training; or
- (f) Other noncompliance issues.

3.2 Authority

- 3.2.1 The convened IRB is authorized to suspend or terminate research protocols.
- 3.2.2 The IRB Chair (or his/her designee) is authorized to suspend research protocols in emergency situations (i.e., when the rights, safety, or welfare are in immediate jeopardy).
- 3.2.3 The HRPP Director, IO, and the IRB Chair are authorized to suspend or terminate human subject research activities that were not properly reviewed and approved (or determined to be exempt) by the IRB.

3.3 Process and Notification for Suspension or Termination

- 3.3.1 When potential cause for further investigation is demonstrated, an inquiry into the specific circumstances giving rise to concern with a specific protocol will be conducted. The initial inquiry and investigation procedures are described in SOP 408: Noncompliance and SOP 409: Unanticipated Problems and Adverse Event Reporting. If a protocol is determined to be in noncompliance or if an adverse unanticipated problem has occurred, further action will be taken by the IRB.
- 3.3.2 In most cases, the IRB will review the circumstances of the case and make a determination of suspension or need for termination. The IRB Administrator and/or consultants will be consulted as needed in the decision-making process. Under normal circumstances and when the severity of the event is low, the determination will be made at the next regularly-scheduled IRB meeting.
- 3.3.3 In emergency situations (that is, severe noncompliance that puts the rights, safety, or welfare of human subjects at immediate risk), the IRB Chair (or designee) may make the determination to suspend a study after consulting with at least one of the following: an IRB Associate Chair, IRB Administrator, an IRB Investigative Subcommittee, or the HRPP Director. If an IRB Chair (or designee) suspends research, the matter will be reported and reviewed by the convened IRB at the next regularly scheduled meeting. The convened IRB will review the circumstances of the case and make a determination to continue the suspension, to lift the suspension and reinstate active approval, or to terminate the protocol.

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3.3.4 Once action has been taken by the IRB Chair or the convened IRB, the IRB Chair (or his or her designee) will send a letter that includes the following:

- (a) a description of the event
- (b) the determination of the IRB (i.e., suspension, termination)
- (c) justification for the determination
- (d) requirements of the investigator (e.g., cease all data collection)

3.3.5 The letter will be forwarded to the Investigator, IO, any Sponsor(s), and applicable federal agencies (e.g., FDA, OHRP), and any other individuals or entities deemed appropriate by the IRB Chair. A copy of the form is filed with the protocol's IRB file.

3.3.6 The Investigator is responsible for notifying (in a timely manner) all co-PIs, key personnel, and other research staff associated with the protocol as well as any subcontract grantees if the protocol has been suspended or terminated.

3.4 Points to Consider When Suspending or Terminating Research Activities. When suspending or terminating a research activity, the following should be considered:

- 3.4.1 Whether the suspension or termination protects the rights and welfare of participants;
- 3.4.2 Whether procedures for withdrawal of enrolled participants take into account their rights and welfare (e.g., continuation of medical care after cessation of the research study, continuation in the research under independent monitoring);
- 3.4.3 Whether to inform current participants of the suspension or termination;
- 3.4.4 Whether to require participant follow-up for safety concerns; and
- 3.4.5 Whether to inform current participants of reported matters (unanticipated problem, adverse events, noncompliance, etc.).

3.5 Consequences of Suspension or Termination

3.5.1 When a protocol is suspended or terminated, the Investigator must stop all activity on the protocol, including subject recruitment and enrollment, treatment, and analysis and/or publication of existing data. If any data was collected between the date of the termination notice and receipt of the termination notice, the Investigator must discard that data. Additionally,

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data that were collected during the study approval period may no longer be used since approval for the study has been terminated.

3.5.2 When the suspension or termination of a research protocol involves the withdrawal of current participants from the research, the Investigator will be required to:

- (a) inform enrolled participants that the study has been suspended or terminated; and
- (b) develop procedures for withdrawal that protect the rights, safety, and welfare of participants, and describe those procedures to participants.

3.5.3 In certain circumstances, project activities may continue if stopping study procedures/treatment would adversely affect the welfare of a subject. When the suspension or termination of a research protocol does not involve the withdrawal of current participants from the research, the Investigator will be required to:

- (a) notify the IRB office immediately of the need to continue any procedures/treatment;
- (b) inform enrolled participants that the study has been suspended or terminated; and
- (c) report any adverse events or unanticipated problems involving risks to participants.

3.5.4 When the IRB suspends or terminates any research activities, the Institutional Official shall report the event to the Office for Human Research Protections and/or to the Food and Drug Administration, promptly. Though prompt reporting is dependent on factual details and the severity of the event, a preliminary report should be made to OHRP within 30 calendar days of the IRB's notification.

3.6 Reinstatement of Protocols

3.6.1 *Suspended Studies.* To reinstate a project that has been suspended, the Investigator must satisfactorily resolve any pending issues as required by the IRB. After six months, if adequate progress has not been made on the pending issues then the IRB will close the study. The Investigator must contact the HRPP in writing within thirty (30) days of the suspension, and must address the following issues:

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- (a) Reason for requesting the study be reinstated;
- (b) Short summary of the purpose of the study and intended objectives/outcomes;
- (c) Description of how the study has changed, if any, since initial approval;
- (d) Summary of status of the study, including:
 - (i) how many subjects were enrolled
 - (ii) at what point in the treatment/procedures were the subjects
 - (iii) any adverse events or amendments since last continuing review, including a description of each
 - (iv) any additional relevant information;
- (e) Documented plan to ensure that reason for suspension will not happen again and that the study will be in compliance with all applicable laws and regulations; and
- (f) Anticipated enrollment, if the study is reactivated.

In the case that IRB-approval of a protocol is reinstated, the IRB may require that subjects who were previously enrolled be re-consented.

3.6.2 *Terminated Studies.* Terminated studies cannot be reinstated. Instead, Investigators must submit a new research study application.

4. RESPONSIBILITY

4.1 Investigator Responsibilities

- 4.1.1 Submit all research proposals to the IRB for approval or exemption determination prior to the commencement of any research.
- 4.1.2 Conduct research according to the approved IRB protocol.
- 4.1.3 Report any unanticipated problems or adverse events according to SOP 409: Unanticipated Problems and Adverse Event Reporting.
- 4.1.4 Report any deviations or noncompliance according to SOP 408: Noncompliance.

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- 4.1.5 Notify (in a timely manner) all co-researchers, key personnel, and other research staff associated with the protocol as well as any subcontract grantees if the protocol has been suspended or terminated.

4.2 IRB Responsibilities

- 4.2.1 HRPP Support Staff and Protocol Analysts should report matters to the IRB Chair or designee according the reporting procedures for noncompliance, unanticipated problems and adverse events.
- 4.2.2 IRB Chair (or designee) or IRB considers reported events and, if necessary, suspends research activities and reports those suspensions to the Investigator, IO, and convened IRB.
- 4.2.3 Convened IRB considers event reports, lifts suspensions, and if necessary, terminates research activities and reports those terminations to the Investigator and IO.
- 4.2.4 Institutional Official reports any suspensions or terminations of research activities to the Office for Human Research Protections and/or to the Food and Drug Administration in accordance with their requirements.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.113

21 CFR 56.113

6. REFERENCES TO OTHER APPLICABLE SOPs

408 Noncompliance

409 Unanticipated Problems and Adverse Reporting

SOP: 501 Effective Date: 07/01/2019	RESEARCH INVOLVING PREGNANT WOMEN, FETUSES, AND NEONATES	Supersedes Document Dated: 12/05/2017
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1. POLICY

A central principle of Human Subjects Research is that participants should grant informed consent prior to the commencement of any research. This process is complicated in research involving pregnant women, fetuses, and neonates, as one party that will be affected the research is incapable of granting consent.

As a result, the Institutional Review Board (IRB) must take additional criteria into account when evaluating proposed research involving pregnant women, fetuses, and neonates, and the IRB should consider engaging experts or consultants to assist with the review. An IRB may only approve research involving pregnant women, fetuses, or neonates that fulfills the criteria listed below, in addition to the standard approval criteria found in SOP 302: Initial Review.

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

2. DEFINITIONS

- 2.1 *Fetus.* The product of conception from implantation until delivery.
- 2.2 *Neonate.* A newborn.
- 2.3 *Pregnancy.* Encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.
- 2.4 *Viable (as it pertains to the neonate).* Being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of this SOP.

3. PROCEDURES

- 3.1 **Pregnant Women and Fetuses.** Pregnant women or fetuses may be involved in research if all of the following conditions are met:
 - 3.1.1 Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

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- 3.1.2 The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of specific benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means
- 3.1.3 Any risk is the least possible for achieving the objectives of the research;
- 3.1.4 If the research holds out the prospect of direct benefit to the pregnant woman, 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, her consent is obtained in accord with the informed consent provisions of SOP 320: Informed Consent Requirements;
- 3.1.5 If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions SOP 320: Informed Consent Requirements, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- 3.1.6 Each person providing consent under paragraph 3.1.4 or 3.1.5 above is fully informed regarding the reasonably foreseeable impact of the research on the fetus and/or resultant child;
- 3.1.7 For children who are pregnant, assent and permission are obtained in accord with the provisions of SOP 502: Research Involving Children;
- 3.1.8 No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- 3.1.9 Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
- 3.1.10 Individuals engaged in the research will have no part in determining the viability of a fetus.

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3.2 Neonates.

3.2.1 Neonates of Uncertain Viability. After delivery, a neonate of uncertain viability may not be involved in research unless all of the following additional conditions are met:

- (a) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates;
- (b) The individual(s) providing consent under the applicable regulations is/are fully informed regarding the reasonably foreseeable impact of the research on the neonate;
- (c) Individuals engaged in the research will have no part in determining the viability of a neonate.
- (d) The IRB determines that:
 - i. The research holds out the prospect of enhancing the probability of survival of the particular neonate to the point of viability, and any risk is the least possible for achieving that objective; or
 - ii. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the neonate resulting from the research; and
- (e) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with SOP 320: Informed Consent Requirements, unless altered or waived in accordance with SOP 321: Waiver or Alteration of Informed Consent

3.2.2 Nonviable Neonates: After delivery, a nonviable neonate may not be involved in research unless all of the following additional conditions are met:

- (a) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates;

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- (b) The individual(s) providing consent under the applicable regulations is/are fully informed regarding the reasonably foreseeable impact of the research on the neonate;
- (c) Individuals engaged in the research will have no part in determining the viability of a neonate.
- (d) Vital functions of the neonate will not be artificially maintained;
- (e) The research will not terminate the heartbeat or respiration of the neonate;
- (f) There will be no added risk to the neonate resulting from the research;
- (g) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
- (h) The legally effective informed consent of both parents of the neonate is obtained in accordance with SOP 320: Informed Consent Requirements, except that the waiver and alteration provisions of SOP 321: Waiver or Alternation of Informed Consent do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of the regulations.

3.2.3 Viable Neonates. A neonate, after delivery, that has been determined to be viable is a child and may be included in research only to the extent permitted by and in accord with the requirements of SOP 502: Research Involving Children.

3.3 Research Involving, After Delivery, the Placenta, the Dead Fetus, or Fetal Material.

3.3.1 Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.

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- 3.3.2 If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent regulations apply.

4. RESPONSIBILITY

When proposed research involves special populations, the IRB must take precautions to ensure research participants' rights, safety, and welfare. In all cases involving special populations, the IRB Administrator must stay abreast of applicable regulations and guidelines. IRB Chair and Members must be cognizant of the subjects' needs when evaluating the protocol and are responsible for determining any additional protective stipulations to be applied to the research.

When proposed research involves pregnant women, fetuses, and neonates, HRPP Support Staff, IRB Chair, and IRB Members will ensure that the protocol contains consent and assent documents, as appropriate.

IRB Administrator is responsible for maintaining up-to-date review tools for review of research pertaining to special populations based on new and evolving applicable regulations and guidelines.

IRB Chair, IRB Associate Chairs, and IRB Administrator are responsible for ensuring the IRB Members are well versed in new and evolving regulations and guidelines pertaining to special populations, for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.

IRB Members are responsible for conducting appropriate review of research planned for special populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources.

5. APPLICABLE REGULATIONS AND GUIDELINES

The Belmont Report

45 CFR 46; Subpart B

45 CFR 46.122

21 CFR 56.111

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6. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

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1. SCOPE

Pursuant to 45 CFR 46, Subpart D (Additional Protections for Children Involved as Subjects in Research), the Purdue University Institutional Review Board (IRB) must review all non-exempt research involving children and may approve only research which satisfies the conditions listed in this policy.

The procedures below apply to Investigator requests to conduct non-exempt research that involves children as research subjects. The following definitions and procedures apply to research conducted within the state of Indiana. Other laws may apply if an Investigator conducts research involving children outside the state of Indiana.

2. DEFINITIONS

2.1 *Assent.* An individual's affirmative agreement to participate in research obtained in conjunction with permission of the individual's parents or legally authorized representative. Mere failure to object should not, absent affirmative agreement, be construed as assent.

2.2 *Benefit.* A valued or desired outcome; an advantage.

2.3 *Children.* According to the federal regulations, children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. Per Indiana State Law, "minors" (that is, persons less than 18 years of age) are considered "children" for purposes of this policy.

EXCEPTION: Per Indiana Code 16-36-1-3, a minor may consent for medical treatment on his/her behalf if certain conditions are met. Accordingly, it is the position of the Human Research Protection Program (HRPP) that a minor may consent to participate in research, if any of the following are true:

2.3.1 The minor is emancipated;

2.3.2 The minor is at least fourteen (14) years of age, not dependent on a parent for support, is living apart from parents or from an individual *in loco parentis*; and is managing the minor's own affairs;

2.3.3 The minor is or has been married;

2.3.4 The minor is in the military service of the United States; or

2.3.5 The minor is authorized to consent to their health care by any other statute.

2.4 *Dissent.* An individual's negative expressions, verbal and/or non-verbal, that they object to participation in the research or research activities.

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- 2.5** *Greater Than Minimal Risk.* The probability and magnitude of harm or discomfort anticipated in the research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- 2.6** *Guardian.* An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. The FDA includes in its definition that this individual can also consent on behalf of a child to participate in research.
- 2.7** *In loco parentis.* Someone who acts in the place of a parent.
- 2.8** *Legally Authorized Representative (LAR).* Defined in the federal regulations as an individual or a judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. In Indiana, a health care representative (appointed in accordance with Indiana Code 16-36-1-7) is the equivalent of the federally defined LAR.
- 2.9** *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.
- 2.10** *Parent.* A child's biological or adoptive parent.
- 2.11** *Permission.* The agreement of parent(s) or guardian(s) to the participation of their child or ward in research.
- 2.12** *Persons authorized to consent for incapable parties (children).* Per Indiana Code 16-36-1-5, consent to health care for a minor not authorized to consent may be given by any of the following:
- 2.12.1 A judicially appointed guardian of the person or a representative appointed.
- 2.12.2 A parent or an individual *in loco parentis* if:
- 2.12.2.1 There is no guardian or other representative described in 2.12.1 above;
- 2.12.2.2 The guardian or other representative is not reasonably available or declines to act; or
- 2.12.2.3 The existence of the guardian or other representative is

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unknown to the health care provider.

2.12.3 An adult sibling of the minor if:

- 2.12.3.1 There is no guardian or other representative described in 2.12.1 above.
- 2.12.3.2 A parent or an individual *in loco parentis* is not reasonably available or declines to act; or
- 2.12.3.3 The existence of the parent or individual *in loco parentis* is unknown to the health care provider after reasonable efforts are made by the health care provider to determine whether the minor has a parent or an individual *in loco parentis* who is able to consent to the treatment of the minor.

2.12.4 A grandparent of the minor if:

- 2.12.4.1 there is no guardian or other representative described in 2.12.1 above;
- 2.12.4.2 a parent, an individual *in loco parentis*, or an adult sibling is not reasonably available or declines to act; or
- 2.12.4.3 the existence of the parent, individual *in loco parentis*, or adult sibling is unknown to the health care provider after reasonable efforts are made by the health care provider to determine whether the minor has a parent, an individual *in loco parentis*, or an adult sibling who is able to consent to the treatment of the minor.

2.12.5 An individual delegated authority to consent has the same authority and responsibility as the individual delegating the authority.

2.12.6 An individual authorized to consent shall act in good faith and in the best interest of the individual incapable of consenting.

2.13 *Risk.* The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study.

2.14 *Secretary.* The Secretary of the Department of Health and Human Services (DHHS) and any other officer or employee of the DHHS to whom authority has been delegated.

3. PROCEDURES

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3.1 IRB Review and Approval – General Requirements

3.1.1 The IRB must apply special considerations to all reviewed research in which children are the target population or may constitute some of the subject population. When the IRB reviews research involving children as subjects it must consider the benefits, risks, and discomforts inherent in the proposed research and assess their justification in light of the expected benefits to the child-subject or to society as a whole. In calculating the degree of risk and benefit, the IRB should weigh the circumstances of the subjects under study, the magnitude of risks that may accrue from the research procedures, and the potential benefits the research may provide to the subjects or class of subjects.

3.1.1.1 Procedures that usually present no more than minimal risk to a healthy child include urinalyses, obtaining small blood samples, EEGs, allergy scratch tests, minor changes in diet or daily routine, and/or the use of standard psychological or educational tests. However assessing the probability and magnitude of risk in sick children may be different and varied depending on the diseases or conditions the subjects may have.

3.1.1.2 Although assessing the limits of minimal risk needs to be done on a case-by-case basis, the IRB should consider biopsy of internal organs, spinal taps, or use of drugs whose risks to children have not yet been established as among the riskier procedures (greater than minimal risk).

3.1.1.3 In assessing the possible benefits of research participation for children, the IRB should consider the variability in health statuses among potential subjects (e.g., normal, healthy child vs. a child suffering from a disease or significant medical condition). Therefore, the IRB should consider the health status of a child and the likelihood of progression to a worsened state without research intervention.

3.1.2 The IRB must classify research involving children into one of four categories and document its discussion of the risks and benefits of the research study in order to approve such research. The four categories of research involving children that may be approved are based on degree of risks and benefit to the individual subjects. These categories are:

3.1.2.1 **Research not involving greater than minimal risk to children (45 CFR 46.404)**

When the IRB determines that no greater than minimal risk to children is presented, the IRB may approve the research only if

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the IRB finds that adequate provisions are made for soliciting the assent of the children and permission of their parents or legal guardians.

3.1.2.2 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child (45 CFR 46.405)

When the IRB determines that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual child, or by a monitoring procedure that is likely to contribute to the child's well-being, the IRB may approve the research if it finds that

- (a) the risk is justified by the anticipated benefit to the children;
- (b) the relation of the anticipated benefit to the risk is at least as favorable to the children as that presented by available alternative approaches; and
- (c) adequate provisions are made for soliciting the assent of the children and permission of their parents or legal guardians.

3.1.2.3 Research involving greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield generalizable knowledge about the child's disorder or condition (45 CFR 46.406)

When the IRB determines that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual child but is likely to yield generalizable knowledge about the child's disorder or condition, the IRB may approve the research if it finds that:

- (a) the risk represents a minor increase over minimal risk;
- (b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
- (c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or improvement of the subjects' disorder or condition; and

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(d) adequate provisions are made for soliciting the assent of the children and permission of their parents or legal guardians.

3.1.2.4 Research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45 CFR 46.407)

When the IRB determines that the research does not meet the requirements in any of the above three categories, the IRB may only approve the research if it finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children. Additionally, if the research is conducted or supported by the DHHS, the Secretary (through the Office for Human Research Protections (OHRP)) after consultation with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law and following opportunity for public review and comment, must determine that the research either:

(a) does in fact satisfy the conditions of 45 CFR 46.404, 45 CFR 46.405, 45 CFR 46.406; or

(b) presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, will be conducted with sound ethical principles and finds adequate provisions have been made for soliciting the assent of children and the permission of their parents or legal guardians.

Important Note: Research that is conducted or supported by DHHS that the IRB determined met 45 CFR 46.407 cannot be finally approved until a determination by the Secretary of DHHS (through OHRP) is received.

3.2 Adequate Provisions for Assent of Children

3.2.1 In accordance with 45 CFR 46.408(a) and 21 CFR 50.55(a), the IRB must determine that adequate provisions are made for soliciting the assent of children, when in the judgment of the IRB the children are capable of providing assent. Assent is typically required for children ages seven and older, but may be appropriate for younger children depending on their aptitude/ability.

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- 3.2.2 In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved in a particular research study, or for each child, as the IRB deems appropriate. The child should be given an explanation of the proposed research procedures in language that is appropriate to the child's age, experience, maturity, and condition. This explanation should include a discussion of any discomforts and inconveniences the child may experience if s/he agrees to participate.
- 3.2.3 While children may be legally incapable of giving informed consent, they may have the ability to assent to or dissent from participation. Out of respect for children as developing persons, children should be asked whether or not they wish to participate in the research, particularly if the research does not involve interventions likely to be of benefit to the subjects and they can comprehend and appreciate what it means to be a volunteer for the benefit of others.
- 3.2.4 When the IRB determines that assent is required, the Investigator (or his/her designee) and the child (when appropriate) will sign the study consent form to document that the subject has been given a verbal explanation of the proposed research in language that is appropriate to the child's age, experience, maturity, and condition. In other instances, the IRB may require that the Investigator develop a separate assent form. Such instances will be documented in the protocol file. When it is inappropriate to expect the signature of the child (due to age or ability) either on the consent form or the separate assent form, the IRB requires that the document be signed by the Investigator (or his/her designee) and the parent(s).
- 3.2.5 Waiver of Assent

The IRB may determine that assent is not necessary if:

- 3.2.5.1 The capability of some or all of the children is so limited that they cannot reasonably be consulted; or
- 3.2.5.2 The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.

It should be noted that, in such circumstances, a child's dissent which should normally be respected, may be overruled by the child's parents at the IRB's discretion. When research involves the provision of experimental therapies for life-threatening diseases such as cancer, however, the IRB should be sensitive

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to the fact that parents may wish to try anything, even when the likelihood of success is marginal and the probability of extreme discomfort is high. Should the child not wish to undertake such experimental therapy, difficult decisions may have to be made. In general, if the child is a mature adolescent and death is imminent, the child's wishes should be respected.

- 3.2.5.3 Even where the IRB determines that the child subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived for adults. (See SOP 321: Waiver or Alteration of Informed Consent)

3.3 Permission of Parents or Legal Guardians

- 3.3.1 The IRB must find that adequate provisions are made for soliciting the permission of each child's parents, guardian or LAR. Although the regulations require the permission of each parent or guardian, there are circumstances in which the IRB may determine that permission from only one parent or guardian is sufficient. The following provisions apply based on the category of research in which the research falls:

- 3.3.1.1 **Research not involving greater than minimal risk to children.** Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research not involving greater than minimal risk.
- 3.3.1.2 **Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child.** Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

Important Note: Although the regulations allow permission of only one parent or guardian for research involving children which falls into categories 1 or 2 above, the IRB must determine that the permission of one parent or guardian is sufficient. The research falling into category 1 or 2 is not sufficient reason in and of itself. For example, it may be inappropriate to allow permission of only one parent or guardian in a standard therapeutic trial for childhood cancer where one has time to consult with, and obtain permission from, both parents (unless one is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child)

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just because the research falls into category 2.

3.3.1.3 **Research involving greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield generalizable knowledge about the child's disorder or condition.** When the research is approved under this category, and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

3.3.1.4 **Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.** When the research is approved under this category and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

3.3.2 Waiver of Parental or Legal Guardian Permission.

If the IRB determines that a research study is designed for conditions or for the subject population for which parental, or guardian or LAR permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children), it may waive the consent requirements. In order to protect the rights and welfare of the children, it may be appropriate for the IRB to consider the involvement of a court appointed guardian. Additionally, the requirement for parental permission may be inappropriate in cases involving older adolescents who, under applicable law, may consent on their own behalf for selected treatments (e.g., treatment for venereal disease, drug abuse, or emotional disorders).

3.4 Wards of the State or Other Agency

3.4.1 Children who are wards of the state or any other agency, institution, or entity are provided additional protections under the federal regulations. These additional protections for wards apply to two categories of research:

3.4.1.1 Research involving greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield generalizable knowledge about the child's disorder or condition (3.1.2.3 above); or

3.4.1.2 Research not otherwise approvable, which presents an

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opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (3.1.2.4 above).

3.4.2 Children who are wards of the state or any other agency, institution, or entity can be included in either of the above referenced research categories only if the IRB finds and documents that such research is:

3.4.2.1 Related to their status as wards; or

3.4.2.2 Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

3.4.3 The IRB must require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardians or *in loco parentis*. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or IRB Member) with the research, the investigators, or the guardian organization.

3.5 IRB Expertise When Reviewing Research Involving Children

3.5.1 An IRB considering a protocol involving children as subjects should:

3.5.1.1 Assess its needs for pediatric expertise among the voting IRB Members to assure that it possesses the professional competence necessary to review the specific research activities.

3.5.1.2 Consider inclusion of one or more individuals who are knowledgeable about and experienced in working with children. To fulfill this requirement, the IRB may invite nonvoting individuals to assist in the review of issues which require expertise beyond, or in addition to, that available among voting IRB Members.

4. RESPONSIBILITY

4.1 Investigator Responsibilities When Involving Children in Research

4.1.1 With any new study submission in which children will be a target population or may constitute some of the subject population, the investigator must obtain approval from the IRB before any children may be enrolled in the study.

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4.1.2 Additionally, within the protocol, plans should be described regarding if and how assent will be obtained and documented for IRB review and approval. Guidance on assent can be found in section 3.2 of this document.

4.1.2.1 In establishing this plan, the investigator should take into account the ages, maturity, and psychological state of the children. Although typically an assent would be appropriate, the following is also recommended:

4.1.2.1.1 Parental permission utilizing an informed consent document.

4.1.2.1.2 Ages less than 7 years: An oral script in very simple language appropriate for children in this age range.

4.1.2.1.3 Ages 7 to 12 years: An assent form written simply and at a comprehension level appropriate for children in this age range.

4.1.2.1.4 Ages 13 to 17 years: An assent form which may be in the same language as the adult consent document or the informed consent document itself with appropriate subject signature lines.

4.1.2.2 In situations where the potential benefits of the study are such that the investigator and parents will enroll the child regardless of the child's wishes, the child should simply be told what is planned and should not be solicited for his/her assent to participate. In such cases, the investigator should request a waiver of assent from the IRB.

4.1.2.3 If a waiver of assent has been approved by the IRB, the investigator will still obtain parental permission unless a waiver from parental permission has been granted.

4.1.2.4 The investigator may only approach the child to assent to the research study after the parents or legal guardians have given written permission.

4.2 IRB Responsibilities When Involving Children in Research

4.2.1 HRPP Support Staff is responsible for receipt of the protocol application submissions, entering it into the data management system, forwarding the request to a Protocol Analyst for administrative review, and notifying the Investigator of the submission's approval.

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- 4.2.2 Protocol Analysts are responsible for conducting administrative review of protocol application submissions, overseeing the review process for expedited review of eligible submissions, assigning protocols ineligible for expedited review to meeting agendas and overseeing the review process, recording meeting minutes into the data management system, ensuring findings are documented and generating correspondence
- 4.2.3 IRB Administrator in consultation with the IRB Chair and HRPP Director is responsible for establishing and implementing processes for conducting review of research. Additionally, s/he participates in the conduct of reviews in an ex-officio capacity for protocols reviewed by the convened IRB. If necessary s/he may conduct administrative reviews in lieu of an available Protocol Analysts or consult on administrative reviews.
- 4.2.4 IRB Chair or designee is responsible for providing consultation in the evaluation of protocol submissions, review revised protocol submissions in response to requests for revisions, and grant approval on behalf of the IRB. The IRB Chair or other experienced IRB Member designated by the IRB Chair to conduct expedited review are responsible for conducting and documenting the review and findings on the Protocol Review Form and special Review Form(s) as well as granting IRB approval of all submissions that qualify for expedited review. Additionally, they are responsible for determining the need for consultation with non-IRB Members.
- 4.2.5 IRB Members are responsible for participating in the review of protocol submissions reviewed at convened meetings.
- 4.2.6 Primary Reviewer is responsible for documenting the initial review and findings on the Protocol Review Form and, if applicable, special Review Form(s).
- 4.2.7 Institutional Official or his/her designee is responsible for conducting further appropriate review and granting Institutional approval.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46, Subpart D, Additional Protections for Children Involved as Subjects in Research 21

CFR 50, Subpart D, Additional Safeguards for Children in Clinical Investigations

Indiana Code, Article 36, Medical Consent

6. REFERENCES TO OTHER APPLICABLE SOPs

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303 Expedited Review

302 Initial Review

321 Waiver or Alternation of Informed Consent

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1. POLICY

Prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research. Therefore, the Institutional Review Board (IRB) is required to provide additional safeguards for the protection of prisoners involved in human subject research activities.

These procedures apply to all research involving prisoners as defined by 45 CFR 46 Subpart C.

2. DEFINITIONS

- 2.1** *Informed Consent.* A person's affirmative agreement to participate in a research study after achieving an understanding of what is involved.
- 2.2** *Minimal Risk.* Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.
- 2.3** *Prisoner.* Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Common examples of the application of the definition of prisoner are as follows:

- 2.3.1** Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners.
- 2.3.2** Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are prisoners; however, individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to nonpenal institutions for treatment because their illness makes them a danger to themselves or others, are not prisoners.
- 2.3.3** Parolees who are detained in a treatment center as a condition of parole are prisoners; however, persons living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners.

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2.3.4 Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned subject population.

2.4 *Risk.* The possibility of harm to a subject in a research study.

2.5 *Secretary.* The Secretary of the Department of Health and Human Services (DHHS).

3. PROCEDURES

3.1 Research that would otherwise qualify for exemption from IRB review is not exempt when the research involves prisoners.

3.2 Due to the vulnerability of prisoners, DHHS strongly recommends that research involving prisoners be reviewed by the full convened IRB. However, if the research is reviewed under the expedited review procedure, the IRB Member(s) reviewing the research must include a prisoner or prisoner representative.

3.3 An IRB may only approve research projects involving prisoners if the research falls under one of the following categories:

3.3.1 Study of possible causes, effects and processes of incarceration, and of criminal behavior, provided that the study present no more than minimal risk or inconvenience to subjects;

3.3.2 Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study present no more than minimal risk and no more than inconvenience to the subjects;

3.3.3 Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults); or

3.3.4 Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

3.4 In addition to all other responsibilities prescribed for the Institutional Review Boards, the IRB shall review research involving prisoners and approve such research only if it finds that:

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- 3.4.1 The research under review represents one of the categories of research permissible under 3.3 of this document;
- 3.4.2 Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
- 3.4.3 The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
- 3.4.4 Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
- 3.4.5 The information is presented in language which is understandable to the subject population;
- 3.4.6 Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
- 3.4.7 Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

3.5 Research Conducted or Supported by DHHS – Additional Requirements

- 3.5.1 Research involving prisoners that is conducted or supported by DHHS must fulfill the following requirements before it is conducted:
 - (a) The institution engaged in the research must certify to the Secretary (via the Office for Human Research Protections (OHRP)) that the IRB designated under its assurance of compliance has reviewed and approved the research under this SOP; and

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- (b) The Secretary (through OHRP) must determine that the proposed research falls within the categories of research permitted to involve prisoners; and
- (c) The Secretary (through OHRP) must review and provide written approval before any research activities may begin, including screening and enrollment; and
- (d) If the research falls under Section 3.3.3, the study may proceed only after the Secretary (through OHRP) has consulted with the appropriate experts including experts in penology, medicine and ethics, and published notice, in the Federal Register, of his/her intent to approve such research.
- (e) If the research falls under Section 3.3.4, and in cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary (through OHRP) has consulted with the appropriate experts including experts in penology, medicine and ethics, and published notice, in the Federal Register, of his/her intent to approve such research.

3.5.2 Investigators must provide any additional documents or materials required for certification to the Secretary (through OHRP).

3.6 Minors

3.6.1 Research involving prisoners who are minors (e.g., an individual detained in juvenile detention center) must also be reviewed and conducted in accordance with SOP 502: Research Involving Children.

3.7 Additional Approvals and Permissions

3.7.1 For research within a penal institution or other facility in which prisoners will be subjects, the Investigator must obtain written permission from the institution or facility and submit that with the protocol application to the IRB.

3.7.2 Indiana Department of Corrections

- (a) All requests for access to offender or juvenile records for research purposes shall be made to the director of planning services in written form. Such requests shall include the name of the agency or organization performing the research, the names of the persons directly responsible for the following:

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- (i) Conducting such research.
 - (ii) The purpose of such research.
 - (iii) How the research is to be performed.
 - (iv) What measures will be taken to assure the proper protection of classified information.
- (b) Approval of such requests will then be granted or denied consistent with provisions of Indiana Code 4-1-6-8.6 and department procedures.

3.7.3 Federal Bureau of Prisons. The Federal Bureau of Prisons places special restrictions on research that takes place within the Bureau of Prisons under 28 CFR 512. This rule specifies additional requirements for prospective researchers to obtain approval to conduct research within the Bureau of Prisons and responsibilities of Bureau staff in processing proposals and monitoring research projects.

4. RESPONSIBILITY

4.1 Investigator Responsibility

- 4.1.1 For any new protocol application in which prisoners will be the target population or may make up part of the subject population, the Investigator must obtain approval from the IRB prior to recruiting or enrolling any prisoners in the study.
- 4.1.2 Investigators proposing to conduct research with prisoners must complete and submit the appendix with their protocol application.
- 4.1.3 For research within a penal institution or other facility in which prisoners will be subjects, the Investigator must obtain written permission from the institution or facility and submit that with the protocol application to the IRB.
- 4.1.4 For research conducted within the Federal Bureau of Prisons or Indiana Department of Corrections, the Investigator must obtain approval from the Bureau or Indiana Department of Corrections prior to initiating the recruitment of subjects and supply a copy of the approval to the IRB.
- 4.1.5 When an enrolled research subject becomes a prisoner and the research was not previously reviewed and approved for the inclusion of prisoners by the IRB (and DHHS, as appropriate), the Investigator must promptly inform the IRB in writing of the change in subject's status.

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- (a) All research interactions and interventions with, and obtaining identifiable private information about, the prisoner-subject must cease until the protocol has been reviewed and approved for the inclusion of the prisoner-subject.
- (b) If research interactions and interventions or obtaining identifiable private information will not occur during the incarceration period, or if the Investigator wishes to withdraw the now prisoner-subject from the research, the Investigator must notify the IRB of such in writing.
- (c) If continued participation of the prisoner-subject is needed, the Investigator must submit a revision request for the protocol requesting inclusion of prisoners in the research and address the requirements in Section 3.4, including protocol specific information justifying each requirement. The revision request will be reviewed by the convened IRB (or by the IRB Chair or expedited reviewer, if the study is otherwise eligible for expedited review).

4.2 IRB Responsibility

4.2.1 Composition of the IRB

The following IRB composition requirements must be met for all types of review for protocols involving prisoners as subjects: initial review, review of amendment requests, continuing review, or in the event a subject becomes a prisoner while participating in the research. Review of reports of noncompliance, and unanticipated problems and adverse events will be conducted according to the procedures documented in those SOPs.

- (a) 4.2.1.1 A majority of IRB Members (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB.
- (b) 4.1.1.2 At least one IRB Member shall be a prisoner, former prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity.

- 4.2.2 For research involving prisoners, the IRB and HRPP staff are responsible for conducting initial review, continuing review, review of amendment requests, review of reports of noncompliance, and reports of unanticipated problems and adverse events in accordance with the procedures documented in this SOP as well as all applicable Purdue University policies and HRPP procedures.

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4.2.3 Should a subject become a prisoner (see section 4.1.5 above) and the research protocol has not yet been reviewed and approved by the IRB and DHHS for compliance with this SOP, where the Investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the subject may continue to participate in the research until the requirements of this SOP are satisfied. The IRB Chair or his/her designee can make that determination and report it to the IRB at the next scheduled meeting.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46 Subpart C

28 CFR 512

Title 210. Department of Correction, Article I. General Provisions IAC 1-6-7

[OHRP, Prisoner Involvement in Research \(2003\)](#)

[OHRP Guidance, FAQ on Prisoner Research](#)

6. REFERENCES TO OTHER APPLICABLE SOPs

302 Initial Review

304 Continuing Review

305 Amendment Requests

502 Research Involving Children

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1. POLICY:

Certain US Federal agencies require additional protections for human subjects research that extend beyond those found in the Common Rule. The Purdue University Human Research Protection Program and reviewing IRB must review in a manner consistent with these regulations should research at Purdue University be funded or otherwise supported by the Department of Defense (DoD), Department of Justice (DoJ), Department of Education (DoEd), Environmental Protection Agency (EPA), and Department of Energy (DoE).

2. DEFINITIONS

- 2.1** *Education Program.* Any program that is principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, postsecondary education, special education, job training, career and technical education, and adult education, and any program that is administered by an educational agency or institution. This definition is applicable to research subject to FERPA.
- 2.2** *Education Records.* Records that are directly related to a student and maintained by an educational agency or institution or by a party acting for the agency or institution. This definition is applicable to research subject to FERPA.
- 2.3** *Experimental Subject.* An activity, for research purposes where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. This definition is applicable to research subject to DoD Instruction 3216.02.
- 2.4** *Instructional Material.* Includes teachers' manuals, films, tapes, or other supplementary instructional material which will be used in connection with any research or experimentation program. This definition is applicable to research subject to US Department of Education requirements.
- 2.5** *Personally Identifiable Information.* Any information collected or maintained about an individual, including but not limited to, education, financial transactions, medical history and criminal or employment history, and information that can be used to distinguish or trace an individual's identity, such as his/her name, Social Security number, date and place of birth, mother's maiden name, biometric data, and any other personal information that is linked or linkable to a specific individual. This definition is applicable to research subject to US Department of Energy requirements.

3. PROCEDURES

3.1 Research Activities Supported by the US Department of Defense (DoD)

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- 3.1.1 Beyond the requirements found in 45 CFR 46, and the Purdue University IRB SOPs, the Department of Defense requires inclusion of contractual clauses related to DoD Instruction 3216.02 “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research”. Unless otherwise stated in this section, Purdue IRB SOPs mirror DoD requirements.
- 3.1.2 All research subject to DoD Instruction 3216.02 must undergo secondary review by the DoD Human Research Protections Office (HRPO), or other delegated DoD Component prior to implementation unless explicitly specified or waived. HRPO must concur with any IRB determination of not human subjects research or approval before research with human participants can begin. As a non-DoD entity, Purdue University is subject to the guidelines with the DoD Instruction 3216.02 related to Non-DoD Institutions. DoD may require additional education, certification, and qualification credentials for those personnel who conduct, review, approve, oversee, or manage human participants research.
- 3.1.3 Special considerations related to DoD Instruction 3216.02 include:
- (a) **Limitation On Use Of Humans as Experimental Subjects:** Per 10 USC 980, Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless informed consent for the subject is obtained in advance. The LAR may consent on behalf of the subject provided that the research is intended to be beneficial to the subject and is obtained in advance. Waivers for this requirement must be obtained per criteria defined in 10 USC 980 (b).
 - (b) **Scientific Merit Consideration:** When Purdue University researchers conduct non-exempt research subject to DoD Instruction 3216.02, the IRB review must consider the scientific merit of the research.
 - i. The IRB Chair of the reviewing committee will communicate any requests for the outcome of scientific review.
 - ii. The IRB may choose to rely on experts or consultants outside of the IRB to provide evaluation of scientific merit.
 - (c) **Existing Data or Biospecimens:** Research involving human subjects considered non-exempt using materials (e.g. data, documents, records, or specimens) that have been previously collected for any purpose (outside of the currently proposed research) may be reviewed by the IRB by expedited procedures.

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- (d) **Notification to DoD:** In addition to the reporting requirements outlined in the Common Rule, Purdue must promptly (within 30 days from learning of the occurrence) notify DoD HRPO when:
- i. The IRB approves significant changes to the research protocol;
 - ii. The outcome of continuing review of an applicable protocol;
 - iii. If Purdue is notified by any Federal department or agency or national organization that any part of its HRPP is under investigation for cause involving a DoD-supported research protocol;
 - iv. In the event of an Unanticipated Problem Involving Risk to Subjects or Others (UPIRTSO), suspensions, terminations, and serious or continuing noncompliance regarding DoD-supported research involving human subjects.
- (e) **Evaluating Risk in DoD-supported Research:** The Purdue IRB must consider different definitions when considering risk supported by DoD. The phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests” in the definition of minimal risk shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).
- (f) **Monitoring:** For research determined to be greater than minimal risk by the Purdue IRB and HRPO, the IRB Chair or IO must designate one or more specific research monitor(s). The monitor(s) must be an independent clinical research monitor (e.g. not part of the study team), or a member of the Purdue University Office of Research and Partnerships staff. The number of monitors will be based on research study design, risk, and the experience and skill sets needed. Expertise of the monitor must be consonant with the nature of risk(s) identified within the research protocol. The IRB must approve a written summary of the monitors’ duties, authorities, and responsibilities.
- i. Duties of the monitor must be outlined with consideration to DoD Instruction 3216.02. The monitor may perform

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oversight functions (e.g. observe recruitment enrollment procedures, and the consent process for individuals, groups or units; oversee study interventions and interactions; review monitoring plans and UPIRTSO reports; and oversee data matching, data collection, and analysis) and report their observations and findings to the IRB or a designated official.

- ii. The monitor has the authority described in DoD Instruction 3216.02. The research monitor may discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research. The research monitor shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report. Research monitors shall have the responsibility to promptly report their observations and findings to the IRB or other designated official.

(g) **Additional Protections for Human Subjects:** In addition to the protections described in Purdue University SOPs and the Common Rule, the Purdue IRB must review DoD-supported research with certain populations in a convened meeting. The reviewing IRB must consider the review criteria found in DoD Instruction 3216.02 when reviewing subject populations that include:

- i. Pregnant Women, Fetuses, and Neonates
- ii. Prisoners, including those who become prisoners or detainees, in addition to allowable categories of research on prisoners found at 45 CFR 46, Subpart C, epidemiological research is also allowable when:
 - The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor associations for a disease.
 - The research presents no more than minimal risk.
 - The research presents no more than an inconvenience to the human subject.
 - Prisoners are not a particular focus of the research.
- iii. Children, including Service members under age 18;

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- iv. DoD Personnel including military personnel,
 - Per section 4 of DoD Instruction 3216.02, superiors of service members (e.g., unit officers, senior noncommissioned officers [NCOs] and equivalent DoD Civilians) are not permitted to influence the decision of their subordinates or be present at the time of recruitment or consent.
 - When applicable, officers and NCOs so excluded shall be afforded the opportunity to participate as research subjects in a separate recruitment session.
 - During recruitment briefings to a unit where a percentage of the unit is being recruited to participate as a group, an ombudsman not connected in any way with the proposed research or the unit shall be present to monitor that the voluntary nature of individual participants is adequately stressed and that the information provided about the research is adequate and accurate.
- v. Detainees- DoD prohibits research involving detainees as human participants. The IRB shall be aware of and consider the definitions found in DoD Directive 2310.01 on a case by case basis when reviewing DoD-supported research involving potential detainees.
- (h) **Limitations on Waiver of Informed Consent:** The IRB can only consider waivers of informed consent pursuant to Section 9 of Instruction 3216.02
- (i) **Compensation for Participation in Research:** DoD places limitation on the compensation amounts and procedures for federal (on-duty and off-duty) and non-federal personnel. The IRB must review that compensation practices align with DoD Instruction 3216.02 for DoD-supported research.
- (j) **Confidentiality:** Should the IRB encounter review when a Certificate of Confidentiality (CoC) is appropriate to protect participants, the processes to obtain a CoC is congruent with all NIH policies and guidelines (for non-NIH sponsored research) referenced in Purdue SOPs.

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- (k) **Recordkeeping:** DoD guidelines match the retention requirements of other agencies and require records to be retained for at least three (3) years after the completion of the research, provided that no other Federal regulation imposes longer record keeping requirements. Records documenting compliance with DoD regulations must be made available upon request of DoD reviewing components within a reasonable time frame and manner.
- (l) **Informed Consent:** In line with Purdue SOP 320, informed consent documents must identify that DoD or a DoD organization is funding the study and that the representatives of the DoD are authorized to review research records associated with DoD-supported research.
- (m) **Research Activities sponsored by the US Department of Navy**
Beyond the requirements found in 45 CFR 46 and DoD Instruction 3216.02 the Department of Navy requires inclusion of contractual clauses related to SECNAVINST 3900.39D outlining requirements from the Department of Navy Human Research Protection Program. Though referenced in SECNAVINST 3900.39D, effective February 1, 2016, DoN no longer requires the Navy Addendum to the FWA referenced in SECNAVINST 3900.39D for non-DoD institutions. As applicable, these projects will be reviewed on a case-by-case basis for congruency with SECNAVINST 3900.39D.

3.2 Research Activities sponsored by the US Department of Justice (DoJ)

- 3.2.1 Beyond the requirements found in 45 CFR 46, and the Purdue University IRB SOPs, the Department of Justice requires adherence to 28 CFR 512. Unless otherwise stated in this section, Purdue IRB SOPs mirror DoJ requirements.
- 3.2.2 Special considerations related to 28 CFR 512 include:
 - (a) **Research Conducted within the Bureau of Prisons:** Additional clarifications and requirements exist when prospective researchers seek to conduct research within the Bureau of Prisons:
 - i. Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research;
 - ii. In addition to researchers having adequate academic preparation or experience in the area, projects must have an

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adequate research design and contribute to the advancement of knowledge about corrections;

- iii. Selection of participants within any one organization must be equitable;
- iv. No incentives may be made to persuade inmates to participate. However, reasonable accommodation (such as monetary compensation for time and effort) may be offered to non-confined research participants who are both no longer in Bureau of Prisons custody and participating in authorized research being conducted by Bureau employees or contractors.
- v. Confidentiality and informed consent must be completed in accordance with 28 CFR 512.11 (a) and 28 CFR 512.16 respectively.
- vi. Content of research proposals must include criteria found in 28 CFR 512.12. For research conducted within the Bureau of Prisons, when submitting a research proposal, the applicant shall provide the following information:
 - A summary statement, which includes:
 - Names and current affiliations of the researchers.
 - Title of the study.
 - Purpose of the study.
 - Location of the study.
 - Methods to be employed.
 - Anticipated results.
 - Duration of the study.
 - Number of participants (staff or inmates) required and amount of time required from each; and
 - Indication of risk or discomfort involved as a result of participation.
 - A comprehensive statement, which includes:
 - Review of related literature.
 - Detailed description of the research method.
 - Significance of anticipated results and their contribution to the advancement of knowledge.
 - Specific resources required from the Bureau of Prisons.

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- Description of all possible risks, discomforts, and benefits to individual participants or a class of participants, and a discussion of the likelihood that the risks and discomforts will actually occur.
- Description of steps taken to minimize any risks.
- Description of physical or administrative procedures to be followed to:
 - Ensure the security of any individually identifiable data that are being collected for the study.
 - Destroy research records or remove individual identifiers from those records when the research has been completed.
- Description of any anticipated effects of the research study on organizational programs and operations.
- Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.
- A statement regarding assurances and certification required by 28 CFR 46, if applicable.

(b) **Research Supported by National Institute of Justice (NIJ)**

Additional clarifications and requirements exist when prospective researchers seek to conduct research supported by NIJ:

- i. All applicants and awardees must submit a Privacy Certificate to NIJ. The Privacy Certificate must be approved by the NIJ Human Subjects Protection Officer prior to engaging in research activities with human subjects.
- ii. The confidentiality statement on an IRB-approved consent form must state that confidentiality can only be broken if the participant reports immediate harm to participants or others.
- iii. Under a privacy certificate, researchers and research staff do not have to report child abuse unless the participant signs another consent form to allow child abuse reporting. The Purdue IRB may opt to engage appropriate entities (e.g., IO, University Legal Counsel), prior to approving IRB protocols with NIJ Privacy Certificates.

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- iv. NIJ requires signature of an employee confidentiality statement by all researchers and research staff. This must be maintained and retained by the Principal Investigator.
- v. Identifiable data must be destroyed after proper retention timelines have passed. Researchers must submit progress reports, research instruments, and deidentified datasets to the entities identified in contractual agreements or grant proposals.
- vi. For National Institute of Justice-funded research, a copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.
 - At least once a year, the researcher shall provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.
 - At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The researcher shall include an abstract in the report of findings.
 - In any publication of results, the researcher shall acknowledge the Bureau's participation in the research project.
 - The researcher shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
 - Prior to submitting for publication the results of a research project conducted under this subpart, the researcher shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

3.3 Research Activities subject to Department of Education (DoED) Requirements

- 3.3.1 Beyond the requirements found in 45 CFR 46, and the Purdue University IRB SOPs, research subject to DoED regulations must follow criteria

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outlined in Family Educational Rights and Privacy Act (FERPA) and Protection of Pupil Rights Act (PPRA).

3.3.2 Special considerations related to DoED include:

- (a) **Student Record Release:** Research activities requiring access to Education Records from an Education Program are subject to the terms defined in FERPA. Purdue IRB relies on the disclosing institution to determine if personally identifiable or deidentified student data requires consent, exception, or disclosure for use in research.
 - i. If Education Records are required from Purdue University, Principal Investigators must receive written permission from the Purdue University Office of the Registrar prior to IRB approval.
 - ii. Education Records from non-Purdue sites subject to FERPA must verify compliance with FERPA by written authorization by the Responsible Official at the site. Such sites must confirm compliance with FERPA.
- (b) **Access and Inspection to Instructional Material Used in a Research or Experimentation Program:** Research materials are subject to DoED and PPRA Requirements and must include the provision of inspection and access to materials. Parents and guardians must have access to all Instructional Material used in connection with research or experimentation programs or project shall be available for inspection by the parents or guardians of the children engaged in such program or project per terms of 34 CFR 98.3 and PPRA.
- (c) **Additional Protections:** In addition to the provisions associated with 45 CFR 46 and its subparts, research subject to DoED requirements must ensure that:
 - i. Per the terms and definitions in 34 CFR 98, no student shall be required, as part of any program specified subject to DoED regulations to submit without prior consent to psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following: (1) Political affiliations; (2) Mental and psychological problems potentially embarrassing to the student or his or her family; (3) Sex behavior and attitudes; (4) Illegal, anti-social, self-

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incriminating and demeaning behavior; (5) Critical appraisals of other individuals with whom the student has close family relationships; (6) Legally recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers; or (7) Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.

For the purposes described above, prior consent means either: Prior consent of the student, if the student is an adult or emancipated minor; or prior written consent of the parent or guardian, if the student is an emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any DoED-funded survey, analysis, or evaluation.

- ii. When an IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research subjects, the IRB must include at least one person primarily concerned with the welfare of these research subjects.
- (d) For research not funded by US DoED: The IRB must verify compliance with US DoED regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:
 - (i) The administration of physical examinations or screenings that the school or agency may administer to a student.
 - (ii) The collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure, or use.

3.4 Research Activities subject to US Environmental Protection Agency (EPA) Requirements

- 3.4.1 Beyond the requirements found in 45 CFR 46, and the Purdue University IRB SOPs, research subject to EPA regulations must follow criteria outlined in 40 CFR 26 and respective subparts.

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3.4.2 Special review criteria related to EPA regulations include:

- (a) **Review by EPA of Proposed and Completed Human Research:** Prior to the onset of research subject to EPA regulations, the IRB protocol and approval must be secondarily reviewed and approved by the EPA Human Studies Review Board. Criteria for the review process are articulated by EPA and follow the requirements found in 40 CFR 26, Subpart P.
- (b) **Substance Exposure:** Under no circumstances shall EPA conduct or support research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child. Research intended or supported by the EPA meeting this definition must not be approved by the IRB.
- (c) **Observational Research:** EPA requires application of 40 CFR 26 Subparts C and D to for additional protections to pregnant women, children as participants in observational research as defined in 40 CFR 26.
 - i. For children, observational research not involving greater than minimal risk must ensure that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.
 - ii. For children, observational research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects must have IRB documentation that the activity meets special criteria outlined in 40 CFR 26.405.
 - iii. Parental permission by parents or guardians and for assent by children must follow EPA criteria in outlined in 40 CFR 26.406.
- (d) **Extended Protections Regarding Intentional Exposure:** EPA extends the provisions of the 40 CFR 26 to human research involving the intentional exposure of non-pregnant, non-nursing adults to substances.

3.5 Research Activities subject to US Department of Energy (DoE) Requirements

- 3.5.1 Beyond the requirements found in 45 CFR 46, and the Purdue University IRB SOPs, research subject to DoE regulations must follow criteria outlined in 10 CFR 745 and DoE 443.1B "Protection of Human Research Subjects." as applicable to unclassified research.

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- (a) **Personally Identifiable Information:** Research activities involving PII must comply with DoE requirements for protection of data. Research involving human subjects must also comply with Federal and DOE-specific requirements for protecting the personally identifiable information (PII) generated in such research. Methods for protecting such data must be specified in the application.
- (i) The IRB uses the “Checklist- Reviewing Protocols that use PII” to verify compliance with the DOE requirements for the protection of Personally Identifiable Information.
 - (ii) Researchers are required to follow DOE requirements for the protection of personally identifiable information by completing and complying with the requirements of the “Checklist-Reviewing Protocols that use PII”, as outlined at: <https://science.osti.gov/ber/human-subjects> Researchers must also ensure they are following DOE Order 206.1, DOE Privacy Program, and its Contractor Requirements Document.
 - (iii) Requirements include: keeping PII confidential; releasing PII only under a procedure approved by the responsible IRB and DOE; using PII only for purposes of the IRB-approved project; handling and marking documents containing PII as “containing PII or containing Protected Health Information (PHI)”; establishing and documenting safeguards to prevent unauthorized use or disclosure of PII and PHI; protecting PII stored on removable media using encryption procedures that are compliant with Federal standards (FIPS-140-2 certified); sending removable media containing PII by express overnight service with signature and tracking capability; sending passwords to encrypted files separately from the files; and using 2-factor authentication for log-on access for remote systems.
- Additional information can be found at:
<https://science.osti.gov/ber/human-subjects>
- (b) **Reporting:** HSP Program Managers must be notified within 48 hours with a description of corrective actions following significant adverse events, unanticipated problems, and complaints about the research, suspension or termination of IRB approval of research or known or potential incidents of noncompliance with requirements of DoE requirements or the Common Rule.

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3.6 Exception

Federal agencies may grant case-by-case exceptions to these additional review requirements through specific written correspondence or through inclusion of specific contractual terms in an agreement.

4. RESPONSIBILITY

PIs are responsible for disclosing any funding applicable support through the agencies to the IRB through the application narrative or amendment process. PIs must also adhere to additional review by the agencies' IRB or equivalent committee charged with protection of human subjects.

HRPP Support Staff is responsible for identifying factors related to the research protocol support that may apply in addition to 45 CFR 46 and Purdue SOPs.

A Reviewer is responsible for conducting review of a protocol supported by these agencies and applying principles to the review.

APPLICABLE REGULATIONS AND GUIDELINES

Department of Health and Human Services, 45 CFR 46

Department of Defense, 32 CFR 219; DoD Directive 3216.02, 10 USC 980

Department of the Navy, SECNAVINST 3900.39D

Department of Education, 34 CFR 99; 34 CFR 98

Department of Justice, 28 CFR 22; 28 CFR 512

Environmental Protection Agency, 40 CFR 26 and associated Subparts

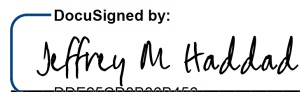
Department of Energy, 10 CFR 745; DoE O 443.1B

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

The Purdue University Human Research Protection Program Standard Operating Procedures (SOPs) are acceptable and current in the versions represented in this compiled document.

<u>SOP #</u>	<u>SOP Name</u>	<u>Date of Approved Version</u>
201	IRB Membership	08/21/2020
202	IRB Meeting Administration	07/01/2019
203	Documentation and Records Management	08/21/2020
204	Protocol Closure	07/01/2019
300	Determination of Human Subjects Research	07/01/2019
301	Exemption Determinations	08/21/2020
302	Initial Review	12/06/2021
303	Expedited Review	12/06/2021
304	Continuing Review	08/21/2020
305	Amendment Requests	08/21/2020
306	Post-Approval Monitoring	08/21/2020
320	Informed Consent Requirements	07/01/2019
321	Waiver or Alteration of Informed Consent	07/01/2019
408	Noncompliance	08/21/2020
409	Unanticipated Problem & Adverse Event Reporting	08/21/2020
410	Suspension or Termination of Research	07/01/2019
501	Research Involving Pregnant Women, Fetuses, and Neonates	07/01/2019
502	Research Involving Children	07/01/2019
503	Research Involving Prisoners	07/01/2019
600	Additional Protections Beyond The Common Rule	12/06/2021

DocuSigned by:

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 Jeff Haddad, Ph.D.
 IRB Chair
 12/5/2021
 Date

DocuSigned by:

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 Christopher R. Agnew, Ph.D.
 Institutional Official for Human Subjects Research
 12/6/2021
 Date