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)

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.

(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

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;

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 2310.01on 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.

(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

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.

  - 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.

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

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-

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.

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.

(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.

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.