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,

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.

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

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

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

(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

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.

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

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

(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.

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

6. REFERENCES TO OTHER APPLICABLE SOPs

302 Initial Review

303 Expedited Review

320 Informed Consent Requirements

321 Waiver or Alteration of Informed Consent