Peru State College IRB Policy on Exempt Research
August 2019

1.0 Scope

This policy applies to the conduct of human subjects research granted exemption under the PSC IRB.

2.0 Policy Statement

Human subjects research activities must be reviewed to determine whether the research meets one or more of the exemption categories described below and, if so, whether the research complies with applicable ethical standards.

Research personnel and the Principle Investigator(s) cannot certify their own study as exempt, and do not have the authority to make an independent determination that research involving human subjects is exempt. Research personnel and the Principle Investigator(s) must obtain determination of exemption prior to beginning the research. 45 CFR 46.104 (Common Rule) identifies several different categories of minimal risk research as being exempt from federal policy for the protection of human subjects. Exempt research must be minimal risk AND fit into one (or more) of the following categories outlined below in 2.1. Federal HIPAA regulations, state laws and institutional policies can further limit exempt research categories.

Research qualifies as exempt only if it falls into one or more of the exempt categories described below and meets these additional requirements:

- The research must present no more than minimal risk to subjects.
- The research is consistent with the ethical principles established by the Belmont Report to ensure the ethical conduct of research: autonomy/respect for persons, beneficence, and justice.
- As appropriate, there are adequate provisions to maintain the privacy interests of participants and the confidentiality of data.
- The research does not involve a test article regulated by the FDA
- The research does not involve prisoners.

  Exempt Research may undergo expedited review: **https://www.hhs.gov/ohrp/regulations-and-policy/guidance/exempt-research-and-research-expedited-review/index.html**.

Exempt research studies that involves human subjects **must be submitted to the PSC IRB**. The IRB will review the application and certify that the study qualifies for the exemption. You will receive an exempt certification letter, not a letter of approval.
The IRB will NOT certify the following types of research as exempt at PSC:

- FDA regulated
- Involves the collection of Protected Health Information (PHI)
- Involves inpatients or prisoners as subjects
- Taste tests

Other notes about exempt studies:

- Exempt studies have no expiration date and do not require continuing review. Provide expected study closure on IRB submission. Upon completion of the study, submit a Study Closeout Report.

2.1 Exempt Human Subjects Research Categories according to Federal Regulations

Research activities in which the only involvement of human subjects will be in one or more of the following categories, described at 45 CFR 46.104(d) are exempt from IRB review unless noted below.

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**. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

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 criteria is met:

- The information obtained is recorded by research personnel in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects
- 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
- The information obtained is recorded by research personnel in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to 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

This exemption does not apply to research involving children that uses survey procedures, interview procedures, or observation of public behavior when research personnel participate in the activities being observed. Research may qualify for exemption if it involves children as subjects and their participation is limited to educational tests (cognitive, diagnostic, aptitude, achievement) and observation of public behavior when research personnel do not participate in the activities being observed.

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:

- The information obtained is recorded by research personnel in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects
- 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
- The information obtained is recorded by research personnel in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subject, 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

Benign behavioral interventions are brief in duration (generally a few hours and within one day), harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and research personnel have no reason to think the subjects will find the interventions offensive or embarrassing.

If the research involves deceiving the subjects regarding the nature or purposes of the research, the subject must authorize the deception through a prospective agreement to participate in the 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.

Note: The Federal advisory committee has published examples

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:

- The identifiable private information or identifiable biospecimens are publicly available
- Information, which may include information about biospecimens, is recorded by research personnel in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, research personnel do not contact the subjects, and research personnel will not re-identify subjects
- The research involves only information collection and analysis involving use of identifiable health information when that use is regulated under the HIPAA Privacy

Rule (45 CFR parts 160 and 164, subparts A and E) for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b).

- The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and compliance with section 208(b) of the E-Government Act of 2002, 44 USC 3501 note, if all the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 USC 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 USC 3501 et seq.

Category 5

Research and demonstration projects that are conducted by or subject to the approval of a Federal department or agency, or otherwise subject to the approval of department or agency heads, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

Research in this category must be published on a list of such research by the Federal department or agency prior to commencement pursuant to 45 CFR 104(d)(5)(i).

Category 6

Taste and food quality evaluation 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 the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. (See also 21 CFR 56.104[d])

Research supported by the Department of Justice is not eligible for exempt review under the above-listed categories. However, the research may be granted exemption under the categories described in 28 CFR 46.101.

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 the determinations required by §46.111(a)(8).

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 the following criteria are met:

- Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
- Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
- An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
- 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.

3.0 Procedures

3.1 Human Subject Submission and Review

For proposed exempt research, the PI will provide protocol-specific information via the human subjects application and submits the following additional materials, as applicable:

- Data collection instruments, including surveys, questionnaires, interview questions, etc.
- Recruitment methods and materials
- Other documents as applicable, e.g., letters of approval/cooperation from research sites

3.2 Granting Exempt Status

Exemption may be granted by at least 1 IRB member after submitted through the PSC IRB submission process. Qualified IRB members are those who have been involved in the review of human subjects research for more than one (1) year, have signed the PSC IRB Confidentiality Agreement, and have completed applicable CITI training. The IRB co-chairs will delegate to appropriate IRB member(s) based on qualifications and expertise.

When the exemption requires the IRB conduct a limited IRB review, an IRB member(s) must review and grant the exemption and determine whether there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

If the research is subject to HIPAA and research personnel request a waiver of authorization, a member of the IRB will determine whether it is appropriate to waive the requirement to obtain authorization or documentation of authorization for the study in accordance with HIPAA Privacy Rule: **https://privacyruleandresearch.nih.gov/pdf/IRB_Factsheet.pdf**.

Exemption is documented in the PSC IRB Office and Exemption Certification will be sent via email to the PI which describes the specific categories under which exemption is granted and any applicable IRB determinations.

3.3 Ongoing Review

Exempt research is not required to undergo renewal.

Minor modifications to exempt studies do not require review and approval unless the modification may change the study's eligibility for exemption or may change the level of risk to participants.

Substantive modifications that have the potential to change the nature of the research and, therefore, the study's eligibility for exemption, require review and approval prior to implementation of the modification.

Research personnel request review of substantive changes by submitting an amendment via PSC IRB online submission system. The changes are reviewed to ensure that they do not affect the exempt status of the research. If the changes do not affect the exempt status, research personnel will be notified. If the changes result in the research no longer qualifying for exemption, research personnel will be notified accordingly and instructed to submit an appropriate expedited or full board IRB submission.

Research personnel should notify the PSC IRB Office that exempt research is complete with the submission of the Study Closeout Report.

4.0 Sanctions

Individuals found to be in violation of this policy may be subject to sanctions relating to their participation in research with human subjects, up to and including permanent suspension or debarment from engaging in research with human subjects at Peru State College.

5.0 History/Revisions

This policy was created in August 2019.