Peru State College IRB Review Policy
August 2019

1.0 Scope

This policy applies to all non-exempt human subjects research and exempt human subjects research requiring limited institutional review board (IRB) review under the oversight at Peru State College. All research that involves human subjects must be submitted to the PSC IRB, including exempt research.

In accordance with §46.108, the institution must establish and follow written procedures for IRB functions and operations for the following:

(i) Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

(ii) Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and

(iii) Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject.

In accordance with §46.108, the institution must establish and follow written procedures for ensuring prompt reporting to the IRB; appropriate institutional officials; the department or agency head; and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency of

(i) Any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and

(ii) Any suspension or termination of IRB approval.

(b) Except when an expedited review procedure is used (as described in §46.110), an IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

2.0 Policy Statement

2.1 Guiding Principles

The PSC IRB is charged with protecting the rights and welfare of human research subjects, specifically ensuring that those individuals participating in research are not subject to undue or inappropriate risks, that participation remains a voluntary right, and that the conduct of research is upheld as a privilege.

PSC follows the ethical principles established by the Belmont Report to ensure the ethical conduct of research, including autonomy and respect for persons, beneficence, and justice.

PSC applies the federal regulations for protection of human subjects (45 CFR 46, Subpart A, Protection of Human Subjects) when research is sponsored or overseen by a federal agency.

When studies do not receive funding from and are not regulated by a federal agency, PSC has adopted policies and procedures to accommodate differences in types of research and to reduce unnecessary administrative burdens. In these instances, PSC has adopted protections for subjects equivalent to 45 CFR 46, Subpart A.

Additional federal, state, and local laws, regulations, and requirements may apply to human subjects research. When laws or regulations differ or conflict, the stricter requirements are followed.

Pursuant to 45 CFR 46.103(a), each institution engaged in research that is governed by the Common Rule (45 CFR 46) and conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in the regulations.

2.2 Authority of PSC IRB

The institutional official (IO) is designated by the Peru State College President for the protection of research subjects. In this federally mandated role, the IO assumes operational authority for the Institutional Review Board. The IO has authority to develop, implement, and monitor all human subjects protection programs. The PSC IRB is authorized by the IO to review human subjects research in accordance with the PSC IRB Review Policy. The IRB functions independently of other PSC organizational entities in protecting research subjects.

Prior to starting the research, the IRB review must find that all criteria for IRB approval outlined below are met, or grant exemption, as applicable. The IRB evaluates whether resources are adequate to protect subjects' rights and welfare.

The IRB may approve, require modification to secure approval, or disapprove research proposals covered by this policy, including exemptions requiring the IRB conduct a limited IRB review to make the determination.

No other official or office at PSC may approve a research activity that has been disapproved by the IRB, and no external body or official may override IRB disapprovals. There may be no undue pressure on the IRB to approve a research study or reverse a decision.

Research which is approved by the IRB may be disallowed by the institution. If research is approved by the IRB but not permitted by the institution, the appropriate institutional authority will promptly notify research personnel and the IRB that the research cannot be conducted, including the reasons for that determination.

The IRB may suspend, place restrictions upon, or terminate approval of research activities falling within its jurisdiction that are not being conducted in accordance with IRB requirements or that have been associated with unexpected serious harm to subjects.

The IRB may have the consent process or the research procedures of any research study under its jurisdiction observed by a third party if the IRB determines that such observation is indicated.

Deliberations, decisions, findings, and actions of the IRB associated with research activities are considered confidential. This information is reported to appropriate institutional officials as required by law and/or policies of the IRB. Failure to adhere to this provision may be cause for removal of a member from the IRB.

2.3 Criteria for Approval

Based on the IRB's review of information provided by the Principal Investigator (PI), and in accordance with appropriate regulations and PSC policies and procedures, the IRB may grant approval of research, including initial review, continuing review, and modifications to previously approved research, if it determines that all of the following requirements are satisfied:

- Risks to subjects are minimized by using procedures that (1) are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (2) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies/procedures/activities subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying

knowledge gained in the research (e.g. the possible effects of the research on public policy).

- Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly aware of the special problems that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, adult individuals lacking consent capacity, or economically or educationally disadvantaged persons.

- Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with and to the extent required by relevant regulations and PSC policies and procedures.

- Informed consent will be appropriately documented, or appropriately waived, in accordance with relevant regulations and PSC policies and procedures.

- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

- When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

- When some or all the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the research proposal to protect the rights and welfare of these subjects. These groups may include but are not limited to children, prisoners, pregnant women, adult individuals lacking consent capacity, or economically or educationally disadvantaged persons.

- Investigators will submit a site approval letter to the IRB from an appropriate organizational leader from cooperating organizations and/or study sites external to PSC, when appropriate. The IRB may request that the PI obtain such site approval letter.

2.4 Expedited Review

The IRB may use an expedited review procedure to review any of the following:

- Research which involves only procedures listed in one or more of the Expedited Research Categories below, unless the reviewer determines that the research involves more than minimal risk.
- Renewals or modifications to research previously approved under expedited procedures provided the research continues to meet the Expedited Research Categories below and any modifications do not substantially increase risk to subjects

- Minor changes in research previously approved by the convened IRB
- Research granted exemption but requiring a limited IRB review under the PSC IRB Policy on Exempt Research

The IRB may not use an expedited review procedure to review any of the following:

- Research in which identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal
- Classified research involving human subjects
- Studies involving randomized use of drugs, devices, or biologics. All of these studies will be reviewed by the convened IRB

Research involving prisoners may be reviewed via expedited procedures, unless subject to Department of Defense requirements, if:

- For research involving interaction with prisoners, the primary IRB reviewer and the prisoner representative determine the research is minimal risk for the prison population being studied or included.
- For research that does not involve interaction with prisoners, the primary IRB reviewer determines the research poses minimal risk for the prison population being studied or included.

2.5 Expedited Research Categories

Category 1

Clinical studies of drugs and medical devices only when either condition below is met:

a. Research on drugs for which an investigational new drug application (21 CFR 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review); or
b. Research on medical devices for which (1) an investigational device exemption application (21 CFR 812) is not required; or (2) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
b. From other adults and children, 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 50ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

Category 3

Prospective collection of biospecimens for research purposes by noninvasive means. Examples include:

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; or
j. Sputum collected after saline mist nebulization.

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 include:

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.

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). Note that some research in this category may be exempt from the federal regulations 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

Category 6
Collection of data from voice, video, digital, or image recordings made for research purposes.

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. Note that some research in this category may be exempt from federal regulations [45 CFR 46.101(b)(2) and (b)(3)] or PSC Policy and procedure. This listing refers only to research that is not exempt.

Category 8
Continuing review (i.e., renewal) of research previously approved by the convened IRB as follows:

a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions, and (iii) 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.

Category 9
Continuing review (i.e., renewal) 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.

2.6 Project Renewal

The IRB conducts continuing review of research at intervals appropriate to the degree of risk, but not less than once per year for:

- Non-exempt studies subject to FDA regulations
- Research requiring review by the IRB, except as described below

The IRB is not required to conduct renewal for the following:

- Research granted exemption, including exempt research requiring a limited IRB review per the PSC IRB Policy on Exempt Research
- Research that is not subject to FDA regulations and is eligible for expedited review under Categories 1-7 above

- Research that is not subject to FDA regulations and requires review by the convened IRB, but has progressed to the point that it involves only one or both of the following:
    - Data analysis, including analysis of identifiable private information or identifiable biospecimens (i.e., data analysis only)
    - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care (i.e., clinical follow-up)

The IRB may require renewal for this research on a case-by-case basis as it deems appropriate. If renewal is required, the IRB must document the rationale for such requirement.

2.7 Amendments to Approved Research

Any proposed changes in approved research must be reviewed and approved by the IRB prior to implementation to ensure that the modified research continues to meet the criteria for approval, except when it is necessary to implement changes to eliminate apparent immediate hazards to the subjects. In this situation, the changes must be promptly reported to the IRB.

2.8 Study Closure

Closure of all non-exempt research must be reported to the IRB within a reasonable time frame (i.e., prior to study expiration, when applicable).

For FDA-regulated research and greater than minimal risk research, research personnel must provide a final accounting of subject recruitment, withdrawals, adverse events, deviations, and changes to risk/benefit ratio. The closure is approved by an IRB member via the expedited review process and is reported to a convened IRB.

Minimal risk research which is not FDA-regulated may be closed by an IRB staff member and does not require reporting to the full IRB.

2.9 Research outside of the U.S.

The IRB is not expected to have expertise in regulations or cultures outside of the U.S. The IRB reviews issues with transnational research based on the information provided by the PI via the IRB application, including as applicable:

- Whether there is additional risk to subjects due to their location or inclusion in a culture
- Whether modifications to the informed consent document are appropriate
- Whether the study team has sufficient knowledge and understanding of the target country to conduct research

3.0 Procedures

3.1 IRB Administration and Support

The IRB has given PSC IRB Office staff the authority to conduct preliminary review of all research submitted to the IRB in order to ensure that it is in an acceptable form for the IRB to review; however, staff may consult with members of the IRB with any questions. The PSC IRB Office certifies the review and approval of human subjects research to external funding agencies, as required.

The PSC IRB Office staff notify the PI and students in writing of IRB actions taken on research.

3.2 IRB submission

All research involving humans at Peru State College is required to be submitted to the IRB.

The PI and the study team provides protocol-specific information via the human subjects application and submits the following additional materials, as applicable:

- Data collection instruments
- Recruitment materials
- Informed consent or assent documents, unless a waiver of consent or assent is being requested.

Research shall not begin until an approval letter is issued by the IRB, and all IRB reviewers concerns or required changes are addressed by the PI.

The PI must be a PSC faculty member that is up-to-date CITI training. PIs must have a valid CITI IRB training certificate on file at PSC's IRB office to submit an IRB. All student investigators must also go through appropriate training before IRB submission.

Students cannot serve as PI, but all students participating in research activities should be listed under participating research staff/students.

3.3 IRB Actions

The IRB may take appropriate action to protect human subjects when reviewing a research study or submission, including new studies, amendments, and renewals. All actions and determinations made by the IRB are conveyed to the PI and Student, Fellow, Resident PI in writing. Appropriate actions may include:

- **Approval** No changes are needed. The research may begin.
- **Conditional Approval** Specific revisions, stipulated by the convened IRB and requiring simple concurrence by research personnel need to be made. After revisions have been made, final approval may be granted by the IRB Co-chairs or designee. In the event of extensive changes or questions, reviewers may request subsequent review at a convened IRB meeting. The approval of research contingent on specific minor revisions is documented in the minutes of the first IRB meeting that takes place after the date of approval.
- **Table** Major concerns exist that impact the protection of human subjects, or clarifications or modifications regarding the research or consent process that are directly relevant to the determinations required by the convened IRB are necessary. This action can be taken only by the convened IRB, and the response must be reviewed by the convened IRB at a subsequent meeting.

- **Disapprove** Significant study concerns exist such that the IRB does not feel the project can be conducted as currently proposed. Specific reasons for disapproval are included in meeting minutes and communicated to the research personnel in writing. The study cannot be resubmitted in the same format. This action can be taken only by the convened IRB.
- **Accept** the item with no further action required (i.e., protocol continues as previously approved and/or the proposed corrective and preventative action plans are adequate)
- Refer to or consult with other institutional entities (e.g., department head; University General Counsel, Chief Compliance Officer, or Privacy Officer; IRB Executive Committee)
- Restrict use of research data collected
- Audit the research study(ies)
- Modify the research protocol and/or informed consent process/form
- Request notification to or re-consent of past and/or current subjects if the report may relate to their willingness to continue to take part in the study
- Withdraw currently enrolled subjects if it is determined to be in their best interest
- Require additional training of the research personnel and/or research team
- Modify the renewal schedule
- Require increased reporting by research personnel and/or increased monitoring of the research and/or informed consent process
- Restrict privileges of the PI or research personnel to conduct human subjects research

The PSC IRB may, upon the request of research personnel or on its own initiative, reconsider any proposal and reverse its own determination. Research personnel may appeal a decision made by the IRB by responding in writing to concerns posed by the IRB. These appeals should be addressed to the PSC IRB Office, which will provide this information to the convened IRB. The IRB may choose to invite research personnel to a meeting to address the concerns or may reject the appeal based on initial concerns with the research.

Research studies that are tabled or disapproved by the IRB cannot be resubmitted to a different IRB in an attempt to bypass the original IRB's decision.

Research that is not being conducted in accordance with the IRB's requirements or has been associated with unexpected serious harm to participants may also be suspended (temporary cessation of some or all research activities) or terminated (permanent withdraw of IRB approval for all research activities).

3.4 Expedited Review

Although research personnel make a preliminary determination about whether research meets the criteria for expedited review procedures, the IRB makes the final determination. If the IRB does not concur with the study team's determination, it may request modification to the research or require that the research be submitted for convened IRB review. If the

IRB determines that research appearing in the categories in 2.5 above is more than minimal risk, the IRB must document the rationale.

Individuals who are appointed as regular or alternate members of an IRB may be designated by the IRB Co-chairs to review research that qualifies for review under expedited procedures. Protocols are assigned to one or more IRB reviewers.

Any IRB member who has a conflicting interest in a submission cannot review that submission as an expedited reviewer. Examples of conflicting interests include:

- Participation in the project
- Financial interest
- Certain non-financial interests, including having supervision over the PI of the project or participating in a project that is in direct competition with the project
- Any other real or perceived conflict

In conducting an expedited review, the IRB reviewer may exercise all of the authorities of the convened IRB, except that he/she may not disapprove the research. Research may only be disapproved by the convened IRB.

Consultants with specific expertise may be utilized to assist in the review of expedited research, when appropriate. Their comments are documented and forwarded to an IRB member for review and final approval.

Approval of research under the expedited review procedure, including the relevant expedited category, is reported to the convened IRB.

In most, if not all expedited approvals, continuing review is not required. Investigators will be informed of a continuing review requirement if protocols meet certain criteria, including, but not limited to the following: inclusion of vulnerable populations, studies of criminal behavior, substance abuse and/or use of mental health data.

3.5 Scientific Review

Scientific review, which addresses whether the research uses procedures consistent with sound research design that will yield the expected knowledge, is conducted on all non-exempt human subjects research submitted to the IRB. The IRB conducts scientific review as part of determining that the research meets the criteria for IRB approval.

Scientific review may be conducted by external committees with expertise in study design.

3.6 Renewal and Expiration

If IRB renewal is required, the IRB approval will reflect the current expiration date for the protocol. Should an investigator need a renewal, they should contact the PSC IRB office, and

notify of the need to renew a study no later than 3 months in advance of the expiration date.

Upon notification, research personnel should submit for IRB review the appropriate renewal information, including any necessary protocol attachments.

Submission for renewal is made through the PSC IRB submission system. Research personnel will complete a questionnaire and, depending on the nature of the research, may also be required to provide additional materials for the IRB's review.

Review of Renewals

The following information must be provided by research personnel at time of renewal and is reviewed by the IRB, as applicable:

- The number of subjects accrued, including a summary of any withdrawal of subjects from the research since the last IRB review and the reasons for withdrawal, if known
- Summary of minor deviations and/or noncompliance since the last IRB review
- Statement whether adverse events have occurred in excess of the expected frequency and level of severity as documented in the research protocol, the informed consent document, and investigator's brochure and, if so, a summary
- Most recent data safety monitoring results, if applicable
- Summary of the progress of the research
- Any relevant information, published or unpublished, since the last IRB review, especially information about risks associated with the research. Relevant information may include literature publications, audits, subject complaints, interim findings.
- The latest version of the IRB-approved protocol and informed consent document(s)
- A brief summary of any amendments to the research approved by the IRB since the last IRB review
- Any proposed modifications to the informed consent document or protocol
- For Veteran Affair studies, the study team's assessment based on research results, the gender and minority status of those entered into the research, number of subjects considered as members of specific special populations, and an assurance that all serious or unexpected adverse events had been reported as required

When the IRB reviews the current informed consent/assent documents at the time of renewal, it ensures that they are still accurate and complete. If any significant new findings are identified that may relate to the subject's willingness to continue participation in the research, the IRB requires that the information be provided to subjects in accordance with regulations.

The IRB determines whether additional verification from sources other than the study team are necessary to ensure that no material changes have occurred since the last review based upon the type of research, risks to subjects, and/or previous noncompliance concerns.

Expiration

When renewal is required, there are no provisions for any grace period extending the conduct of the research beyond the expiration date of IRB approval. Additionally, where the convened IRB issues a provisional approval, renewal must occur no more than one year after the date the research was reviewed by the convened IRB. It is the study team's responsibility to ensure that the research is reapproved prior to the study's expiration date.

- If the study team fails to submit a renewal to the IRB or the IRB has not reviewed and approved a research study by 11:59 p.m. on the last date the protocol is approved, research activities must cease, including enrollment of new subjects, interventions on/interactions with current subjects, and analysis of identified data.
- If the study team is actively pursuing renewal with the IRB and the IRB believes that an overriding safety concern or ethical issue exists such that it is in the best interest of individual subjects for the research to continue, the IRB may permit this while the review process is completed. Enrollment of new subjects, however, cannot occur after the expiration of IRB approval.
- Lapse in IRB approval need not be reported to the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) as a suspension of IRB approval under HHS regulations.

3.7 Amendments to Previously Approved Research

Submissions for amendment are made through the PSC IRB submission system. The research personnel provide information about the proposed changes and submits revised IRB-approved documents or new materials, as applicable.

Amendments to Expedited Research

Amendments to research previously approved under expedited procedures are reviewed under expedited procedures provided the changes continue to meet the expedited categories. If the proposed changes to the research involve addition of procedures which are not described by the expedited categories or involve greater than minimal risk, the research must be reviewed by the convened IRB.

Amendments to Research Previously Approved by the convened IRB

Pursuant to 45 CFR §46.110(b)(2), minor changes in research previously approved by the convened IRB may be reviewed and approved under an expedited review procedure. Major changes (e.g., those that involve increased risks or discomforts to subjects or decreased potential benefit) are reviewed and approved by the convened IRB.

Personnel Changes

Changes in key personnel are considered amendments to previously approved research which require prospective IRB approval; however, study teams may make changes to the list of non-key research personnel by prospectively submitting a notification of the change to the IRB office. These notifications are not considered amendments and do not require prospective IRB review and approval. Key personnel should have up to date IRB training.

3.8 Reopening Research

Research personnel may request the IRB reopen a research study that was prematurely closed/expired. In reviewing this request, the IRB may require modifications to the research prior to reopening and/or enrolling subjects, as necessary. The PI may need to submit a new research application to restart/continue the previously closed/expired research study at the discretion of the IRB Office.

3.9 Suspensions, Terminations, and Post-Approval Events

The IRB has the authority to make determinations on post-approval events, including internal adverse events or protocol violations and incidents. PIs and research personnel are required to report such events/incidence to the IRB Co-chairs. The convened IRB must determine if the event qualifies as one or more of the following:

- An unanticipated problem involving risk to participants or others
- Noncompliance
- Serious noncompliance
- Continuing noncompliance

Suspensions of research are typically made at a convened IRB meeting. However, suspension can also be made on an urgent basis by either IRB Co-Chairs, if necessary. Any suspension or termination includes a statement of the reasons for the IRB's action and is reported promptly to the PI, appropriate institutional officials, the department or agency head and/or and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency, if acceptable.

Suspensions can be lifted only by the convened IRB. If an IRB Chair suspends research, it is reported to the full IRB for consideration and possible action. Termination of research can be made only by the convened IRB. Suspensions and terminations cannot be overturned by Institutional Officials.

When the IRB suspends or terminates a research study, it considers whether the suspension or termination requires that subjects be withdrawn from the study and/or places them at risk of harm.

- When subjects must be withdrawn from a study, the IRB considers the safety, rights, and welfare of subjects and determines necessary termination procedures (e.g., drug tapering, final visit, lab tests, other follow-up, and/or arrangements for continued care).
- If the IRB determines that the suspension or termination will place subjects at risk of harm and/or follow-up of subjects for safety reasons is permitted or required, the IRB determines which subjects are to be notified (e.g., current or past subjects) and the manner in which they are to be notified (e.g., in writing or by telephone).

Depending upon the reasons for the suspension or termination and the design of the study, the IRB may require that any of the following individuals be notified of the suspension or termination:
    - All subjects who have been or who are currently enrolled;
    - Only subjects who are currently enrolled and active; or
    - Only subjects who participated in a certain aspect of the study.
- Research personnel may request to attend an IRB meeting to discuss a suspension or termination in order to provide clarification of the issues.

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.