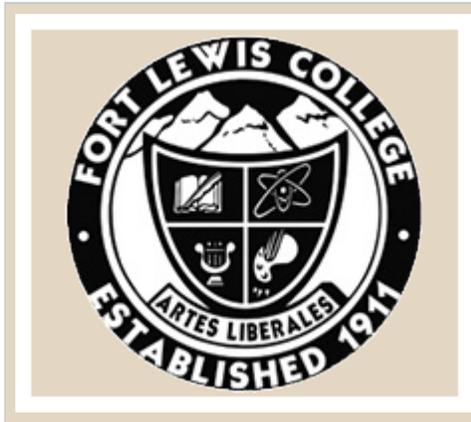


# Institutional Review Board



Policy identification number: **To come...**

File: **Academic Policies > Research Policies**

## Institutional Review Board

Policy Summary

**Governing the requirements of and procedures for the Institutional Review Board.**

Policy Owner	Approval Date	Effective Date
<b>Provost and Vice President for Academic Affairs</b>	<b>March 28, 2018</b>	<b>July 1, 2018</b>
Search Terms	Scheduled for Review	
<b>pvpa, i</b>	<b>Spring 2023</b>	

## Policy Statement

In accordance with its Federal-wide Assurance on file with the Department of Health and Human Services, Fort Lewis College has an Institutional Review Board (IRB) for review of the use of human participants in research. The IRB is a standing committee of the University Faculty. Its activities are overseen by the Provost and Vice President for Academic Affairs or designee (hereafter referred to as Provost).

### I. Definitions

- A. **Human Subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.
  - i. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
  - ii. Interaction includes communication or interpersonal contact between investigator and subject.
  - iii. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.<sup>2</sup>
- B. **Institutional Review Board**, or IRB, is the Fort Lewis College body established in accordance with and for the purposes expressed in Title 45 of the Code of Federal Regulations, Part 46.
- C. **IRB Approval** is the determination of the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional and federal requirements.<sup>3</sup>
- D. **Minimal Risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (see Appendix 3: Risks of Harm)
- E. **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.<sup>4</sup>
- F. **PI** means any Fort Lewis College faculty or staff member that submits a research protocol as the Principal Investigator. Students cannot serve as the PI.

<sup>1</sup> Material for this policy has been used with permission from Cornell University.

<sup>2</sup> 45 CFR § 46.102(f).

<sup>3</sup> 45 CFR § 46.102(h).

<sup>4</sup> 45 CFR § 46.102(d).

## II. Charge

The IRB shall ensure the protection of human participants as subjects of research at Fort Lewis College. The IRB shall:

- A. Determine what activities constitute research with human participants.
- B. Review, approve, require modifications or disapprove all research activities covered by this policy prior to the commencement of the research.
- C. Require that information given to participants as part of informed consent is in accordance with appropriate law, regulations, and international standards.<sup>5</sup> The IRB may require that additional information be given to the participants when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of participants.
- D. Require documentation of informed consent or waive documentation in accordance with federal laws and regulations. When research activities are being proposed to be conducted in other states, tribal nations, or countries by Fort Lewis College faculty, staff, and/or students, the research activities will be approved in compliance with the regulations for those specific research locations.<sup>6</sup>
- E. Notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification, a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
- F. Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year and have authority to observe or have a third party observe the consent process and the research.
- G. Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, the department or agency head, and Office of Human Research Protections (OHRP).

<sup>5</sup> 45 CFR 46.116

<sup>6</sup> 45 CFR 46.117

## III. Composition of the IRB<sup>7</sup>

- A. The FLC IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience, expertise and diversity of its members, including consideration of race, gender, and cultural backgrounds, to safeguard the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
- B. Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- C. Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

<sup>7</sup> 45 CFR §46.107

## IV. IRB Member Responsibility

- A. Training
  - i. All new IRB members will complete CITI Members Basic Training. CITI Training will include modules on "Cultural Competence" and "Research with Persons who are Socially or Economically Disadvantaged."
  - ii. All IRB members will complete CITI Refresher training every 3 years.
- B. Confidentiality
  - i. All IRB members will sign the Membership Responsibilities Form that outlines the need for confidentiality due to sensitive nature of the IRB decision making process. (see [Appendix 6: Membership Responsibilities Form](#)).
  - ii. Breaches of confidentiality by members IRB will be addressed by the IRB Committee. Breaches of confidentiality that cannot be addressed by the Committee will be referred to the Provost.

## V. Researcher Responsibility

- A. Training for PI and co-PI
  - i. **Before** the IRB can approve the research protocol, the PI and all co-PIs (including student researchers) must successfully complete the IRB online training addressing the appropriate conduct of human participant research. Proof of completion of this training is required by all PIs and co-PIs.
  - ii. All researchers named on a protocol are required to renew their training every 3 years.
- B. Online Submission guidelines can be found on the [IRB website](#).
- C. Data Handling
  - i. PIs will securely store data for at least 180 days after the study is completed.
  - ii. PI will securely store and/or destroy data 180 days after the study is completed.

## VI. Determining Whether Research Activity Needs IRB Review and Approval

- A. The researcher is responsible for ensuring full and continuing compliance with all FLC and IRB policies in the conduct of his/her research.
- B. A researcher may, in consultation with the IRB, or using the Decision Tree (see Appendix 7: Decision Tree) make a self-determination of whether the proposed research activity does or does not constitute human participant research.
- C. If the research activity **does not** constitute human participant research, the researcher may initiate the research without review or approval by the IRB.
- D. If the research activity **does** constitute human participant research, the researcher must submit a completed application to IRB for review. Research activities may not commence until the researcher receives a written letter of IRB approval or a notice of exemption from IRB.

## VII. Requests for Exemptions from IRB

- A. A PI **may not** self-determine that his or her own research protocol qualifies for exemption from IRB review.
- B. A PI requesting an exemption must submit a Request for Exemption from IRB Review. The IRB Chair will determine if the research project meets the eligibility requirements for exemption from IRB review. The Chair may also send the Request for Exemption to an IRB member for secondary review.
- C. If the research activities are not eligible for exemption, the research project must receive either expedited or full committee review by the IRB.
- D. Research activities may not commence until the PI receives a written notice of exemption from IRB.
- E. Changes to any of the research activities or materials made after submission must be reviewed by an IRB Chair and/or member to verify that the project continues to be eligible for exemption from IRB review.
- F. Researchers are responsible for ensuring full and continuing compliance with all FLC and IRB policies in the conduct of their research.

## VIII. Review and Decisions made by IRB

- A. If an IRB member is assigned to review an application submitted by a PI within their same department, the IRB Chair will serve as secondary reviewer to limit potential for bias and/or perceptions of bias.
- B. If a PI believes they have received a biased review of their work from an IRB member, they can request a second review by a different IRB member. The IRB Chair will consider both reviews and make a final decision.
- C. No research activity shall be initiated until the PI has received written notification from IRB that the protocol has been "approved" by the IRB.
- D. The PI shall be notified by IRB in writing that the IRB has made one of the following decisions after reviewing the research protocol application: (1) approved, (2) specific minor stipulations required for approval, (3) deferred, or (4) disapproved.
  - i. **Approved:** If the protocol is approved, the Chair will provide email notice of approval to the PI. Only after receiving the email notice of approval may the PI initiate the research activity.
  - ii. **Specific minor stipulations required for approval:** The Expedited Reviewer(s) or the convened IRB may stipulate that approval of the research protocol will be granted only after the PI makes specific minor revisions to the protocol, informed consent documents and/or process, recruitment materials, etc. The Chair of the IRB will send the PI a notification of the required changes. If the PI makes the revisions, he or she will then submit them for review via the Expedited Review process. After all specific minor revisions have been approved, the Chair of the IRB will send an email notice of approval to the PI. Upon receipt of the notice, the PI may initiate the research activity. If, however, the PI suggests or makes revisions that the Expedited Reviewer believes affect the risk-benefit ratio of the project, such revisions will be designated as major and referred for review by the convened IRB.

If the PI disagrees with any specific minor revisions that were required during the Expedited Review process, he or she may request a convened IRB meeting for additional review. However, that research protocol cannot begin until all specific minor stipulations have been satisfactorily addressed or the convened IRB has reviewed and approved the research protocol.

- iii. **Deferred:** A protocol is deferred when the Expedited Reviewer(s) or the convened IRB request additional information, substantive clarifications or modifications regarding the protocol, informed consent documents, etc. that are relevant to the evaluation of the risk/benefit ratio required for approval. The IRB may also table a protocol where it does not have a member with expertise adequate to assess the scope and complexity of the proposed research and thus seeks review by an expert in the appropriate field. The PI may suggest an expert to the IRB for this purpose.

A protocol requiring convened IRB Review may be tabled for lack of appropriate expertise in attendance, lack of time, loss of quorum, etc. In the event a research protocol application is tabled for such administrative reasons, IRB will assign it for review at a future meeting of the convened IRB.

When a protocol is deferred, IRB shall draft and transmit to the PI a memorandum setting forth the reasons for this action. The PI shall have up to approximately 90 days to respond to the concerns outlined in the memorandum and to make appropriate revisions to the documents in question. The PI will submit any revisions and responses to the concerns or questions outlined in the memorandum to the IRB Chair which will assign them for IRB review.

- iv. **Disapproved:** The IRB at a convened meeting may elect to disapprove a research protocol when it identifies significant concerns about potential risk to participants or a lack of scientific validity to support the proposed research activities. IRB will draft and transmit to the PI a written statement of the reasons for the IRB's decision. The PI will have the opportunity to respond with an internal appeal in person or in writing. The IRB at a convened meeting will review any written responses and make a decision about the appeal of the initial decision to disapprove the research protocol. As with all protocols, the PI may not initiate the corresponding research activity until the protocol has been approved by the IRB. The PI always has the right to submit a new protocol that addresses the concerns outlined during the initial review, and/or request an external appeal through a partnering institution.

## IX. Quorum Requirements for Votes on Convened IRB Decisions

- A. A convened IRB meeting is one at which a quorum is present (or participating via teleconference), which means that a majority (more than half) of the members of the IRB are present, including at least one member whose primary concern is in a non-scientific area. For studies that are FDA-regulated, the quorum must include at least one physician. Members attending by telephone- or video-conference count towards the quorum and may vote providing they have received all pertinent material prior to the meeting and they can participate actively and equally in the discussion of the protocols. The IRB minutes should document that these two conditions are met.
- B. Approval of research is by a majority vote of the IRB quorum, minus the Chair, who does not vote except to break a tie.
- C. A quorum can fail during a convened meeting, by inter alia loss of a majority through recusal of members with conflicts of interest, early departures, or the absence of a non-scientist member. In the case of quorum failure, the remaining group may continue discussion of protocols, but may not take further actions unless and until the quorum can be restored.

## X. Minimal Criteria for Approval of Research

- A. The IRB Expedited Reviewer(s) or the convened IRB may approve a research project only when they find that the project fulfills all of the following conditions, their consideration of which shall be documented on the IRB Review Checklist.
  - i. **Risks to participants are minimized.** The protocol uses procedures that (1) are consistent with sound research design and (2) do not unnecessarily expose participants to risks without the informed consent of the participants.
  - ii. **Risks to participants are reasonable in relation to any anticipated benefits to participants and to the importance of any knowledge that is expected to result.**
  - iii. **Selection of participants is equitable.** The IRB should consider the purposes of the research, the setting in which it will be conducted, and its inclusion/exclusion criteria, so as to maximize the equitable distribution of burdens and benefits. Moreover, the IRB should evaluate the recruitment practices and materials, as well as payments to participants. The IRB should consider particularly the special problems and additional safeguards posed by research involving vulnerable population participants such as children, prisoners, pregnant women, physically or mentally compromised individuals, or economically or educationally disadvantaged persons who may be vulnerable to coercion or undue influence in the context of the research (see Appendix 1: Definition of Vulnerable Populations).
  - iv. **Informed consent/assent.** Informed consent or assent will be sought from each participant or his or her legally authorized representative and appropriately documented, in accordance with and to the extent required by local, state, and federal regulations. (The PI can refer to the approved template of informed consent/assent here (link) and/or Appendix 2: Informed Consent and Assent).
  - v. **Privacy and confidentiality.** The protocol, if appropriate, will provide adequately for the protection of participants' privacy and the confidentiality of identifiable data.
- B. Criteria for Exempt and Expedited (forthcoming based on Common Rule)

## XI. Procedures for Prompt Reporting and Review of Unanticipated Problems within FLC: (see Appendix 5: Timeline)

- A. Unanticipated Problems Defined:
  - i. An unanticipated problem involving risk to human participants or others is one that (1) was unforeseen at the time of its occurrence, and (2) indicates that participants or others are at an increased risk of harm (See Appendix 3: Defining Risks of Harm). The Principal Investigator (PI) and/or any person familiar with the research project should promptly report to the IRB any harm experienced by a participant or another person which is both unanticipated and related to the research, regardless of whether the harm was an on-site or off-site event, and regardless of whether the harm was serious or non-serious. An unanticipated problem is related to the research if the problem was more likely than not caused by the research procedures or if it is more likely than not that the problem affects the rights and welfare of current research participants.

One type of unanticipated problem is the adverse event, which is any harm experienced by a participant regardless of whether the occurrence was on-site or off-site and which is both unexpected and related to the research. An adverse event is unexpected when its specificity and severity are not accurately reflected in the informed consent document.
  - ii. Serious adverse events requiring immediate reporting to the IRB within 24 hours of the first awareness of their occurrence, whether such awareness is first attained by the PI or another person or a member of the IRB:
    - a. death of a research participant;
    - b. serious injury to a research participant.
  - iii. Examples of non-serious unanticipated problems, including non-serious adverse events, requiring reporting as soon as possible and not later than 2 weeks of the first awareness of their occurrence, whether such awareness is first attained by the PI, another person familiar with the research, or a member of the IRB:
    - a. Negative, non-life threatening physical reactions in a research participant to drugs administered in a study.
    - b. Physical consequences to a research participant from dietary manipulations (e.g., fainting).
    - c. Negative, non-life threatening physical reactions in a research participant who has a chronic disease (e.g., diabetes, heart condition).
    - d. Unanticipated accident to a research participant (e.g., participant's falling off a treadmill during an exercise study).
    - e. Display of unanticipated emotional upset or degree of emotional upset by a research participant.
    - f. Accidental or unintentional change to the IRB-approved protocol that harmed research participants or others or that indicates that such persons may be at an increased risk of harm.
    - g. Release, including inadvertent release, of personal information of a research participant, or some other breach of confidentiality.
    - h. Sponsor-imposed suspension for risk.
    - i. Acquisition of information that indicates a change to the risk-benefit analysis of the research, such as publication of a paper from another study showing that risks or potential benefits of the Fort Lewis College research study may be different from what was presented to the IRB.
    - j. Failure of equipment during a study if such failure did or could have resulted in harm to a research participant.
    - k. Change to the protocol intended to eliminate an apparent immediate hazard to a research participant, without prior IRB review.
    - l. Complaint of a participant that indicates unanticipated risks .

## **B. Prompt Reporting of Unanticipated Problem**

- i. Serious adverse events must be reported to the IRB immediately, with a written report by either the PI, an IRB member or another person within 24 hours of the PI's becoming aware of the event. Serious adverse events are (1) death of a research participant; or (2) serious injury to a research participant. Even if such events are not related to the conduct of the research study, and, thus, are not required to be reported to OHRP, a PI should obtain documentation from the hospital or another appropriate source tending to show that the death or serious injury is not related to the research.
- ii. All other non-serious unanticipated problems should be reported to the IRB as soon as possible and not later than 2 weeks two of the first awareness of the problem by the PI, an IRB member, or another person. Prompt reporting is important, as unanticipated problems often require some modification of study procedures, protocols, and/or informed consent processes. Such modifications require the review and approval of the IRB.
- iii. A PI, IRB member, or another person should report an unanticipated problem to the IRB by completing and submitting an Unanticipated Problem Report Form. (See Appendix 4: Unanticipated Problem Report Form).

## **C. IRB Review of Unanticipated Problem Report Forms**

- i. Upon receipt of the Unanticipated Problem Report Form ("UP Report Form") the IRB Chair will review it within 5 days to determine whether the reported occurrence qualifies as an unanticipated problem, as defined above.
  - a. If the occurrence does not qualify as an unanticipated problem, no further action will be taken unless it is determined that serious or continuing non-compliance has occurred. (See Section 12)
  - b. If the occurrence does qualify as an unanticipated problem, the IRB will determine (1) whether the reported occurrence is a serious adverse event requiring review and modifications by the convened IRB; or (2) whether the reported occurrence is a non-serious unanticipated problem that can receive expedited review by the IRB Chair or the Chair's designated reviewer(s). The Chair of the IRB will ensure prompt and appropriate reporting of the occurrence to the OHRP, FDA and other regulatory agencies, as appropriate.
- ii. If the reported occurrence is determined to be a serious adverse event, as defined above, the Chair of the IRB can suspend the protocol for up to 2 weeks until the convened IRB reviews and acts on the protocol. The PI can request an extension to the 2 week suspension, if needed. The IRB Chair will place the UP Report Form on the agenda for the next meeting of the convened IRB for their discussion and resolution.
- iii. If the reported occurrence is determined to be an unanticipated problem, as defined above, the Unanticipated Problem (UP) Report Form will be assigned for Expedited Review, which should be completed within 5 days. The IRB Chair may assign the UP Report Form to himself or herself for review or to an Expedited Reviewer with the relevant expertise, or may obtain consultation to obtain that expertise. The Expedited Reviewer may suggest any action with respect to the protocol and place the UP Report Form on the agenda of the next meeting of the convened IRB for their discussion and resolution. The Expedited Reviewer may, however, request the Chair of the IRB to suspend a protocol until the convened IRB reviews and acts on the protocol. IRB will email the Expedited Reviewer's comments, questions, and/or decisions to the PI. The PI will respond in writing to IRB, and this response will be reviewed by the Expedited Reviewer and/or the Chair of the IRB. The PI, the Expedited Reviewer, or the Chair of the IRB may request that the UP Report Form be referred to the convened IRB for a decision, which will have 2 weeks to make and communicate the decision. If the UP form was submitted by an IRB member, the IRB member will recuse themselves from voting on whether the project meets UP criteria and/or corrective action. If the UP Report Form is not so referred, the IRB agenda will notify the other IRB members of the decision(s) made by the Expedited Reviewer with respect to the UP Report Form.
- iv. The range of possible actions that could be taken by the IRB with respect to the UP Report Form include:
  - a. Modification of the protocol.
  - b. Modification of the information disclosed during the consent process.
  - c. Providing additional information to past participants.
  - d. Notification to current participants when such information might relate to participants' willingness to continue to take part in the research.
  - e. Requirement that the current participants re-consent to participation.
  - f. Modification of the continuing review schedule.
  - g. Monitoring of the research.
  - h. Monitoring of any modified informed consent process.
  - i. Suspension of the research.
  - j. Termination of the research.
  - k. Referral to other organizational entities (e.g., Institutional Biosafety Committee).
  - l. Obtaining additional information.
  - m. Termination of a previously approved protocol, which occurs when the IRB permanently withdraws approval for all research activity.
- v. Following a final determination of an action with respect to the UP Report Form, the IRB will draft and email a letter to the PI on behalf of the Chair of the IRB, setting forth the IRB actions and any required modifications. The PI will provide written notification to the IRB when he or she has made the required modifications.

## XII. Defining and Managing Noncompliance with Approved Research Protocols (see Appendix 5: Timeline)

### A. Terms and Definitions

- i. **Allegation:** An assertion made by a party which has not yet been proven or supported by evidence.
- ii. **Confirmed Noncompliance:** An allegation of noncompliance that has been verified as a result of an investigation and/or a for-cause audit.
- iii. **Continuing Noncompliance:** A repeated pattern or un-rectified instance of noncompliance by an individual investigator or research staff member either on a single protocol or multiple protocols.
- iv. **Noncompliance:** Failure to comply with federal regulations; the policies or procedures of the IRB; or institutional policies governing human research. Examples of noncompliance include: (1) conducting human participant research without IRB approval (e.g., before approval; after expiration of approval and in the absence of a continuation application submitted to the IRB; during a suspension of IRB approval; after termination of IRB approval); (2) disregarding or otherwise violating IRB-approved informed consent procedures (e.g., failing to obtain consent/assent, using unapproved or outdated consent, assent, and information sheets, missing signatures, failing to document consent process); (3) deviating from the protocol approved by the IRB; (4) modifying an approved protocol without IRB consent; (5) failing to report or tardily reporting unanticipated problems; (6) failing to maintain adequate records; (7) failing to train research team members in the proper procedures; and (8) failing to follow recommendations by the IRB to ensure the safety of research participants. Noncompliance may constitute or may result in unanticipated problems.
- v. **Serious Noncompliance:** Noncompliance involving one or more of the following: (1) harming research participants; (2) exposing research participants to a significant risk of substantive harm; (3) compromising the privacy and confidentiality of research participants; (4) causing damage to scientific integrity of the research data that has been collected; (5) engaging in willful or knowing noncompliance; (6) impacting ethical principles adversely.

### B. Addressing Allegations of Noncompliance

The IRB may become aware of an allegation of noncompliance or of circumstances indicating noncompliance upon the receipt of a complaint from a participant, researcher, FLC employee, or member of the public; from the interpretation of information received during a Continuation, Amendment, Unanticipated Problems Review; or from the findings of a random or for-cause audit or other quality control activities.

Once it has received an allegation of noncompliance, the IRB will request the alleged to submit a written notification to the IRB. The IRB Chair will make the following initial determinations: (a) whether noncompliance is alleged; and (b) whether the allegation indicates that an immediate action such as suspension by the IRB is warranted. If it is determined that immediate action by the IRB is warranted (e.g., suspension), then the IRB Chair will initiate those proceedings in accordance with Section 13. The IRB will then initiate an investigation of the circumstances alleged. The IRB may elect to investigate informally by reading relevant documents and communicating with the affected parties. If the IRB Chair determine that the allegation is not credible or is unsubstantiated, then the inquiry ends. The IRB will document this finding in a written report; place the report in the study file; and notify the IRB of the finding on the agenda of the next available meeting. If, however, the inquiry yields evidence that noncompliance has occurred, then the IRB Chair will submit a corresponding report to the full IRB for discussion at the next available meeting.

### C. Confirming and Resolving Noncompliance

- i. If it is determined that the noncompliance is neither serious nor continuing, the IRB will devise a corrective plan, which generally will involve immediate remediation (e.g., obtaining signature of Protocol PI on submissions, providing missing documentation).
- ii. If it is determined that the noncompliance is serious or continuing, the IRB will conduct a for-cause audit. If it is determined that an unanticipated problem has occurred, the IRB Chair will address it in accordance with Section 11. The PI may request a meeting with the IRB Chair regarding their determination of serious or continuing noncompliance. As stated in Section 13, a PI may decide voluntarily to suspend or terminate some or all of the research activities that may be under current review or investigation. The PI should inform the IRB of this action, so that the IRB Chair can place the protocol on the agenda for the next available IRB meeting.
- iii. The IRB Chair will distribute its for-cause audit report to the PI, the members of the IRB, and, if appropriate, the Dean and/or Chair of the PI's Department. The PI may submit a response to the audit report in writing and/or may request to speak to the IRB at a convened meeting. The IRB will place the report and any written response from the PI as discussion items on the agenda of the next available IRB meeting. The IRB will make a final determination as to whether the evidence supports a finding of serious or continuing noncompliance and, if so, will determine a corrective plan, including timeframe for correction, and will, if necessary, initiate suspension or termination proceedings.
- iv. The IRB may invite the PI to a portion of the meeting to answer questions and to discuss the issue of noncompliance. If the PI requests, or is requested, to be present at the IRB meeting, he or she may be accompanied by a faculty representative, legal counsel, or another member of his or her department. The role of these individuals is limited to providing information and support to the PI; they will not participate in the discussion between the PI and the IRB.
- v. The PI must implement the corrective plan within the required timeframe. The IRB will monitor the PI's implementation of the corrective plan. Failure to implement the corrective plan on time will be reported by the IRB Chair for further action, including initiation of procedures for suspension or termination of IRB approval of the research protocol.
- vi. Upon full implementation of the corrective plan, the IRB will draft a final noncompliance report for discussion by the IRB at the next available meeting. After the report is finalized, the IRB will distribute this report to the following parties: (a) PI (b) Department Chair, Center Director, and/or College Dean of the PI, and (c) OHRP, when applicable.
- vii. While the IRB has the authority to take appropriate action concerning a research protocol, the IRB does not have the authority to take disciplinary action against any individual relating to a finding of confirmed noncompliance. Instead, disciplinary action shall be the responsibility of the institution. The Director of IRB shall report any termination of research to the appropriate institutional officials, and the IRB Chair will, if requested, assist in any disciplinary action process taken by the appropriate academic unit.
- viii. **Corrective Actions in Response to Noncompliance:** The actions taken to correct noncompliance vary and depend on the nature and seriousness of the noncompliance. The IRB may take any of the following actions:
  - a. Take no action.
  - b. Request a protocol and/or consent form modification.
  - c. Require that all participants be re-consented.
  - d. Require previous participants to be informed of any changes to the protocol and/or
  - e. Require observation of consent procedures.
  - f. Require more frequent review of the conduct of the research.
  - g. Require additional training for the research team.
  - h. Require follow-up audit(s).
  - i. Suspend the research.
  - j. Any other action deemed appropriate by the IRB to protect the rights and welfare of research participants.

### XIII. Suspensions and Terminations of IRB Approved Research Proposals

#### A. Definitions

- i. **Suspension** is defined as a temporary halt to all research activities. It occurs when the Chair of the IRB or the convened IRB places a temporary hold on the previously approved research, such that no research activities can be conducted, including recruitment/enrollment of new participants, further research interventions (unless necessary for the safety and well-being of the enrolled participants), follow-up (unless it is in the best interests of the participants and approved by the IRB), analysis of data, publications, and presentations. Suspended research is still subject to Continuing Review. Eventually, a notice of suspension is withdrawn by the IRB or the suspended protocol becomes subject to termination procedures by the IRB. A PI may resume research upon withdrawal of a suspension notice.
- ii. **Termination** is defined as a permanent halt to all research activities, including recruitment/enrollment of new participants, further research interventions, analysis of data, publications, and presentations. It occurs when the convened IRB, with impartiality and without prejudice votes to withdraw approval or stop all research activities permanently. However, future follow-up may be conducted with the approval of the IRB to monitor the well-being of and any potential risks to participants. Terminated research is no longer subject to Continuing Review. Resumption of a terminated protocol requires the submission of a new protocol application for review and approval by the IRB.

#### B. Circumstances Meriting Potential Suspension or Termination

- i. The IRB may suspend or terminate its prior approval of research that: (1) is not being conducted in accordance with IRB policies and procedures, the protocol as previously approved by the IRB, federal regulations, and/or institutional policies governing research and human participant protection (i.e., non-compliance); or (2) is associated with serious unanticipated problems.
- ii. Examples of non-compliance with IRB policies and procedures are: (a) conducting research using human participants without IRB review and approval; (b) deviating from the protocol submitted by the PI and approved by the IRB; (c) continuing to use human participants past the approved expiration date and in the absence of submitting a continuation application to the IRB; (d) failing to follow the IRB-approved consent process; (e) failing to report protocol changes to the IRB; and (f) failing to follow recommendations by the IRB to ensure the safety of research participants.
- iii. The IRB may become aware of such a circumstance upon the receipt of a complaint from a participant, researcher, Fort Lewis College employee, or member of the public; from the interpretation of information received during a Continuing Review; or from the findings of a random or for-cause audit.

#### C. Authority to Suspend or Terminate IRB Approval

- i. The convened IRB has the authority to suspend or terminate research activities, taking into consideration protections for current participants' rights and welfare. The IRB Chair also has the authority to suspend research until a convened IRB meeting and to report the suspension to the convened IRB at their next available meeting. The convened IRB must discuss suspensions of all protocols previously approved by the IRB. The Chair, however, does not have the authority to terminate IRB approval unilaterally.
- ii. A member of the IRB who is acting as the Expedited Reviewer of an Unanticipated Problem Report Form may request the IRB Chair to suspend a protocol until the convened IRB reviews and acts on the protocol.
- iii. The PI may request a meeting with the IRB Chair regarding any decision to suspend and/or terminate a protocol. In addition, the PI may be present during the question-and-answer period of the convened IRB's discussion of his or her suspended protocol.
- iv. A PI may decide voluntarily to suspend, withdraw, or terminate some or all research activities that may be under current review or investigation. The PI should inform the IRB Chair, and place the protocol on the agenda for the next available IRB meeting.
- v. The IRB does not have the authority to take disciplinary action against any individual relating to circumstances meriting suspension or termination of IRB approval. Instead, disciplinary action shall be the responsibility of the institution.

#### D. Criteria to Consider for Suspensions or Terminations

- i. In reviewing information, including complaints, that potentially shows non-compliance or unanticipated problems, the IRB should consider:
  - a. Whether the information supports a determination of non-compliance or increased risk;
  - b. Whether the information indicates that a serious unanticipated problem has occurred which warrants further investigation and/or suspension of research in order to protect human participants or others;
  - c. Additional actions to protect the rights and welfare of currently enrolled participants;
  - d. Whether procedures for withdrawal of enrolled participants account for their rights and welfare;
  - e. Whether participants should be informed of the termination or suspension; and
  - f. Whether to require any unanticipated problems or outcomes to be reported to the IRB.

#### E. Resolution of Suspensions by the Convened IRB

- i. Whenever the IRB Chair issues a suspension notice for a protocol, the IRB will place the suspension as a discussion item on the agenda for the next available convened meeting of the IRB and provide the IRB with all relevant information, including the protocol, any UP Report Form (link), and any investigation results. The Chair and members of the IRB will discuss the situation and recommend a plan of action. The PI may be invited or may request to attend part of the meeting to answer questions. The particular details of the discussion are documented in the minutes of the convened meeting.
- ii. The IRB will suggest a corrective plan that minimizes risks to participants or ensures compliance with all applicable policies and regulations and will establish a time frame for the implementation of the plan.
- iii. The IRB will monitor the PI's implementation of the corrective plan based on a pre-determined action plan. If the plan is implemented within the requisite timeframe, the convened IRB or the IRB Chair may withdraw the suspension notice and research may resume. If, however, the suspension has not been resolved by the PI after the expiration of the time frame, the IRB Chair may place the suspension on the agenda of the next available meeting of the Convened IRB in order to proceed with termination of IRB approval.

#### F. Terminations by the Convened IRB

- i. Criteria for Termination: The convened IRB may vote to terminate IRB approval of a research protocol when:
  - A. a corrective plan approved by the IRB has not been implemented in a complete and satisfactory manner; and/or
  - B. the IRB determines at any time that termination is in the best interests of the safety and welfare of the research participants.
- ii. Written Notifications: If the convened IRB votes to terminate a research protocol, IRB will notify within 7 days, in writing, the following:
  - A. PI
  - B. Department Chair, Center Director, and/or College Dean of the PI
  - C. Sponsoring federal agency, when applicable, OHRP, when applicable.
- iii. Appeal Process:
  - A. Time for Appeal: Within 10 days after notice of IRB decision, either party may request an appeal. The request shall be in writing, delivered to the Provost either in person or by mail, and shall include a statement of the reasons for appeal and the specific facts or circumstances which justify further review. If an appeal is not requested within 10 days, an appeal is deemed to be waived and the IRB's report and recommendation shall be forwarded to the Board for final action.
  - B. Grounds for Appeal: The grounds for appeal shall be limited to the following:
    - i. There was substantial failure by the IRB to comply with this Policy during the hearing, so as to deny a fair hearing; and/or
    - ii. the recommendations of the IRB were made arbitrarily or capriciously.
  - C. Nature of Appellate Review:
    - i. If the Provost approves an appeal, the case will be brought to an external institution's IRB that has an existing MOU with Fort Lewis College. The external IRB will consider the record of the hearing upon which the recommendation before it was made and recommend final action to the Board.
    - ii. Each party shall have the right to present a written statement in support of its position on appeal. The party requesting the appeal shall submit a statement first and the other party shall then have ten days to respond. In its sole discretion, the external IRB may allow each party or its representative to appear personally and make oral argument not to exceed 30 minutes.
    - iii. When requested by either party, the external IRB may, in its discretion, accept additional oral or written evidence. Such additional evidence shall be accepted only if the external IRB determines that the party seeking to admit it has demonstrated that it is relevant, new evidence that could not have been presented at the hearing, or that any opportunity to admit it at the hearing was improperly denied.
  - D. Final Action: A written report of the external IRB review will be presented to the Provost, who will make the final decision on whether or not the FLC research is terminated.

## XIV. Reporting Unanticipated Problems, Noncompliance, Suspensions, and Terminations

- A. **Federal Regulations and Fort Lewis College's Federal-Wide Assurance Registration (FWA):** require the Institutional Review Board (IRB) to report the following promptly to appropriate institutional officials; federal departmental or agency heads at the Office of Human Research Protections (OHRP) or the Food and Drug Administration (FDA); and sponsors: (1) unanticipated problems involving risk to human research participants or others (see Section 11); (2) instances of serious or continuing noncompliance (see Section 12); and (3) suspensions or terminations of IRB approval of research protocols (see Section 13).
- B. **Final Reports:**
  - i. A final report should include the following information: (1) the name of the PI; (2) the IRB's OHRP registration number, Fort Lewis College's FWA number; (3) protocol title; (4) sponsor<sup>8</sup> of the study; (5) any applicable grant numbers; (6) the date(s) and nature of the event(s); (7) details concerning how the event was discovered; (8) the IRB's and the Director of 's response to the event; (9) the PI's response to the event; (10) investigatory/audit findings; (11) the IRB's actions and rationale and any response by the PI; (12) details of the corrective plan; (13) any pertinent details concerning the PI's implementation of the corrective plan; (14) participants' response to corrective measures; (15) the IRB plan for monitoring the outcome of the event; (16) certification of destruction of data resulting from un-approved research activities, if applicable; (17) outcomes of withdrawal and follow-up of participants, if applicable; and (18) any general educational activities inspired by the incident.
- C. **Required Recipients of Reports:**
  - i. Final Reports: Copies of final reports concerning serious adverse events, other unanticipated problems, noncompliance, suspension or termination, will be sent to OHRP and/or FDA, as well as to the PI, appropriate institutional officials, department chair/center director /college dean of the PI, Office of Sponsored Programs, and if appropriate, the sponsor. The sponsor should always receive a final report relating to serious adverse events; serious or continuing noncompliance; and/or terminations of IRB approval of a research protocol.

<sup>8</sup> In the regulations (21 CFR 312.3(b)), a sponsor is defined as "a person who takes responsibility for and initiates a clinical investigation. A sponsor may be an individual or a pharmaceutical company..." For example, a sponsor may be the pharmaceutical or device company that initiates a clinical trial for one of its products.

## XV. Responsibilities

**For following policy:** Faculty, Staff and Students

**For enforcement of policy:** Provost and Vice President for Academic Affairs

**For oversight of policy:** Provost and Vice President for Academic Affairs

**For notification of policy:** Policy Librarian

**For procedures implementing the policy:** Faculty Chair(s) and IRB Members

## XVI. Appendix

[Appendix 1 - Definition of Vulnerable Populations](#)

[Appendix 2 - Informed Consent Template and Implied Consent Template](#)

[Appendix 3 - Risks of Harm](#)

[Appendix 4 - Unexpected Problem Report Form](#)

[Appendix 5 - Timeline for Reporting and Managing Unanticipated Problems and Non-Compliance of IRB Approved Research](#)

[Appendix 6 - IRB Membership Responsibilities Form](#)

[Appendix 7 - Decision Tree \(Forthcoming\)](#)

[Appendix 8 - IRB Guidelines for Research with Native American Communities](#)