Franklin Pierce University Institutional Review Board
Policies and Procedures
(Updated and Approved 9.20.23)

Mission Statement

Franklin Pierce recognizes the need for investigations in which human beings serve as research subjects and acknowledges its responsibility for ensuring that the privacy, safety, health, and welfare of such subjects are adequately protected. Consequently, Franklin Pierce has established an Institutional Review Board to review and approve the adequacy of human subject protection during such research. The IRB may approve, disapprove, or state conditions for the conduct of human subject research. The ethical principles and guidelines utilized are primarily drawn from the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (The Belmont Report).

IRB Philosophy and Responsibilities

Franklin Pierce University believes strongly in research and the use of human subjects in the advancement of science and knowledge. As such, there are judgments to be made to ensure that cautious investigation is conducted that maximizes benefits of research while reducing risks to human subjects.

The IRB will review all human-subjects research proposals from faculty, students, and staff associated with Franklin Pierce University. Requests from individuals who are not part of a Franklin Pierce program, but who wish to conduct research within the Franklin Pierce community, will be reviewed on a case-by-case basis.

Before initiating any research on human subjects, investigators will be required to obtain the approval of the Institutional Review Board. The IRB will review and approve all Franklin Pierce research involving human participants. If researchers are not sure whether their project qualifies as human-subjects research, they should reach out to the IRB for guidance.

Classifying a project for exempt, expedited, or full-board review status will be the responsibility of the IRB chair or co-chair. This means that even “minimal risk” studies using human subjects must complete and submit an IRB application.

All research will adhere to ethical, state, federal, and professional standards for research. This will include the use of accepted ethical principles established by professional organizations or societies that are applicable. This includes complying with all applicable federal, state, and local laws and regulations.

Current Policies and Procedures of Franklin Pierce University IRB

All research projects, including Action Research Projects, are currently reviewed by IRB. Mandates for Institutional Review Boards can be found at the National Institute of Environmental Health Sciences - http://www.niehs.nih.gov/about/boards/irb/

- The Office of Human Research Protection (OHRP) defines research as: 46.102 "*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities."

- The OHRP defines a human subject as: (45 CFR 46) "a living individual about whom an investigator (whether professional or student) conducting research:
  - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
  - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

- The IRB assesses risk to human research subjects and ***does not assess design***; however, where there exists design problems that do not allow for assessment of risk to human subjects, the protocol and supporting documents will be sent back to the researcher for revision and consultation with their faculty sponsor (if applicable). (Note: the reviewer should not be responsible for articulating the specifics of the design problem…that should be left to the work of the researcher).

- Before initiating any research on human subjects, investigators will be required to obtain written approval of the Institutional Review Board. <u>The IRB will review and approve all Franklin Pierce research involving human participants.</u> Research needs to be submitted to the FPU IRB when it involves human subjects and:
  1) Is funded by FPU.
  2) Is conducted by a FPU faculty, student, or staff using the FPU relationship when publishing. Per OHRP statute 46.114 Cooperative Research- Cooperative Research statute can be considered when an FPU faculty is involved in a research project overseen by another qualified IRB.
  3) Is conducted at any of the FPU locations.
  4) Involves FPU subjects amongst others.

- If a researcher is unsure whether their project counts as "human-subjects research," they should reach out to the IRB chair for clarification.

- For undergraduate or graduate student projects, the IRB expects the faculty research sponsor to review the application and provide guidance to their student before the application is submitted to the IRB for official review.

- Chair and co-chair will communicate with the principal investigator listed on the application.

- Upon receipt of an IRB application, the chair or co-chair will designate the application as exempt, expedited, or full-board.

- **Exempt Reviews**: The Chair will read the initial application and decide if the research meets exempt status. The Co-Chair will be consulted if a second opinion is needed.
  - Exempt status as defined by the Code of Federal Regulations is included in the below URL §46.101(b)(1)(2)(3)(4)(5)(6) and in more detail in Appendix A http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101%28b%29

- **Expedited Reviews**: Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).
  - See Appendix B or the following link for detailed information on Categories of Research found under Expedited Review - http://www.hhs.gov/ohrp/policy/expedited98.html
  - According to §46.110, the following pertains to expedited research:
    - An IRB may use the expedited review procedure to review either or both of the following:
      - (1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,
      - (2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

- **Full-board reviews:** Any applications that do not qualify for exempt or expedited status will undergo a full-board review. The Chair will assign the review to the full committee. A quorum of IRB members will need to sign off on the application for it to be approved.

- **Retrospective Research**--In an effort to review retrospective research projects, which use existing data, and which did not initially go through the Franklin Pierce University Institutional Review Board, the following two regulations shall be used to provide guidance. If the research included a consent form, the consent form must reflect the participant/s' or guardians/s' approval to use the results for a variety of purposes, to include publication or sharing with multiple audiences, etc. If the consent form does not reflect the researcher's new intentions, the researcher must provide evidence that a new consent form was developed and signed, reflecting new permissions that allow for the use of the results in ways not originally intended.
  - **Important Note:** Although such research can be reviewed under OHRP regulations, it should be viewed by the Franklin Pierce community as the exception, not the rule.

- In any applications where the distinction between exempt and expedited status is unclear, the FPU IRB will use the Expedited review process.

- **Education Requirement for All Applicants:** All IRB applicants/investigators will be required to take and pass a protection of human subjects tutorial. A ***copy of the certificate of completion must be sent to the IRB chair along with the IRB application.***
    - *Faculty and Graduate Students must complete a paid online training through phrptraining.com, Citi, or another approved service. Renewal of training should be completed according to any expiration date on training certificate.*
    - *Undergraduate students will complete the FPU in-house IRB training. This training is given by the faculty sponsor to the undergraduate student conducting the research. Contact the IRB chair to obtain the reading materials and the quiz for students to pass.*

- Up to four weeks may be allowed for processing and response to submissions. If applications are submitted during a university break, it may affect turnaround time. In the event the Chair is absent for a period of time, which extends beyond the time frame above, the Co-Chair will serve as an interim Chair.

- Revisions to an application may be requested. Researchers will be instructed via email that they may or may not need to resubmit a final version of protocol to the Chair for review.

- **Proposal approvals expire one year** from the date listed on the official approval form. Researchers should apply to the Chair for an extension two months prior to the expiration date. The researcher will complete an **Application for an Extension of IRB Approval form** and submit it to the Chair. The Chair will determine whether or not an extension will be granted. For questionable cases, the Chair may will consult with the Co-Chair.

- If changes need to be made to an already-approved IRB application, researchers should fill out and submit the **IRB Addendum form**. All IRB forms are located on the IRB's eRaven page. http://eraven.franklinpierce.edu/s/dept/academicaffairs/committees/IRB/

- **In the event of an adverse or unexpected event/issue** causing harm to a subject after research has been approved, it is the responsibility of the PI to inform of this incidence this IRB in writing immediately, or at the earliest feasibility.

- When a research study involving the treatment of patients utilizes **control groups**, the following information must be addressed in the consent form: 1) participants could be randomly assigned to the control or placebo group in a blinded manner, 2) if participants are in the control group, they may be offered access to the treatment at the end of the study, 3) if participants' symptoms worsen during the course of the study, they should alert the principal investigator and contact their health care provider immediately.

- In some instances, this IRB may choose to accept IRB approval for research through **Institutional Agreement** between another institution. Please refer to the following for more information. https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html

- **The IRB** will be comprised of the following members: Chair, Co-Chair, and members. According to hhs.gov/ohrp, members shall be a mix of scientists and non-scientists and one member non-employed by the University. The IRB will make every effort to have members who have expertise in the fields we are receiving applications from.

- **IRB full committee meetings** will be held twice yearly (once per Rindge semester) to discuss IRB issues/policies/etc. Meetings will be held on an "as needed" basis for full-board reviews. Reports and meeting minutes will be recorded and filed by the Chair or Co-Chair.

- **Membership Replacement or the Addition of new Members**
    - The IRB needs to have representation/expertise in many different fields, and will make every effort to have expertise from the fields we are receiving applications from.
    - If an IRB member leaves, or a member with new specific expertise needs to be added, the process used for member replacement will include a full committee review and majority committee approval. Prospective replacements or additional members to be added to the IRB committee must submit background information and credentials in the form of a written faculty biography to the Chair, including human subjects' tutorial certificates. These documents will then be distributed to the remaining IRB committee members for review and majority approval.
    - If the IRB needs a new member, but does not need specific expertise, the normal Academic Senate nomination and full faculty vote process will be utilized.
    - Co-Chairs will be a member who has been nominated by another member of the committee. Co-Chairs will act as ex-officio two months prior to the end of the Chair's position within the committee taking on all responsibilities of the Chair.

- **Membership, including the Chair, incurs for a 3-year term**. (No term limits) Members will remain as such until they have been replaced by new members as described above. All members are required to stay current in their knowledge of IRB policies and information. They are encouraged to frequently review information at https://www.hhs.gov/ohrp/.

- When assigning reviewers for a faculty IRB application, the chair and co-chair will make every effort to maintain impartiality by sending applications to reviewers outside of the applicant's program; however, the IRB acknowledges that sometimes expertise, knowledge, and experience in a particular field are necessary to review for safety, ethics, and standards of practice.

IRB Committee Structure

- Chair and Co-Chair: Chair or Co-Chair will each oversee one section of IRB: Faculty/graduate student applications or undergraduate applications.
- Chair and Co-chair each have discretion to facilitate their section.
- Chair is also responsible for maintaining OHRP status (annual certification) and organizing/running bi-yearly meetings.
- Both Chair and Co-chair classify IRB applications as exempt, expedited, or full-board, assign reviewers (including themselves) to IRB applications as they deem appropriate.
- Chair and Co-chair divide other responsibilities among themselves as necessary.
- Committee Members- review IRB applications and attend bi-yearly meetings, maintain knowledge pertinent to IRB matters.
- Chair and Co-Chair are elected by current members whenever the current terms expire.
- IRB membership is elected via Academic Senate similar to other committees; however, in circumstances where particular expertise or representation is needed, a new IRB member can join with a majority IRB member vote.
    - IRB needs a provision to add a member in case of the sudden departure of a member with particular expertise (e.g., knowledge of which procedures are safe to perform on fetuses or prisoners' rights).
- IRB committee terms are three years without limits.
- It is customary for Co-Chair to assume the Chair position after Chair term.
- Note: IRB structure varies from standard FPU committee structure. The main reason is that we have to have one IRB with two different functional groups: one facilitating graduate/faculty proposals and the other facilitating undergraduate proposals. The current structure is working and meeting needs of faculty and students. This is on line with Office of Human Research Protection (OHRP) standards.

Helpful Information to be provided to Researchers upon Request

PI's are encouraged to read carefully through the application and the policies or the IRB to fully understand the application process. They may also email the IRB (irb@franklinpierce.edu) for specific questions. Listed below are a few frequently asked questions.

1. ***What do I do to submit to the IRB for review?***

   First ensure that all researchers have completed their Human Subjects Certification. The IRB recommends this free training: https://www.hhs.gov/ohrp/education-and-outreach/human-research- protection-training/human-research-protection-foundational-training/index.html
   All five module certificates must be included with the application for each researcher. The files must be labeled with Researcher Last Name First Name Human Subjects Certification.

   Complete an IRB application that can be located at the IRB Canvas page and at the eRaven page http://eraven.franklinpierce.edu/s/dept/academicaffairs/committees/IRB/ and upload it to the IRB Canvas page.

2. ***How do I know if my research is exempt from IRB review?***
   There are several categories of studies that may need no IRB review at all. Examples are:
   a. Activities that are not "your research" according to Federal guidelines because you are not taking part in the design, the analysis, or the publication.
   b. Research that does not involve humans (e.g. animal studies).

c. Research that poses no risk to humans because
    i. The participants are dead OR
    ii. The participants who contributed the data absolutely cannot be identified by anyone in the world. (Note that an identifier instead of a name won't do if there is a code anywhere that could link the two.) Note: These data must already exist. No new collections can be exempted from review.
    iii. Research conducted in established or commonly accepted educational settings, involving normal educational practices
    iv. For a more complete description of what can be considered exempt, please see Appendix A

3. ***What do I do if I think my research satisfies one of these "exempt" criteria?***
   You will submit your completed IRB application to the IRB Chair who will make that determination based on your application.

4. ***How do I know if my research has the status of "expedited"?***
   If your research presents minimal risk to the participants, it may be eligible for an expedited review. There are many rules that determine eligibility, but the following cases may generally be expedited:

    a. Studies where small amounts of blood are drawn from healthy adults except in cases where genetic assays may be done, and the investigator wishes to keep identifiers for participants
    b. Collection of data using non-invasive means.
    c. Collection of information using survey research instruments such as questionnaires, focus groups, etc.
    d. Research that was formerly approved by the full IRB but now is in the data analysis phase, with all research interventions finished.
    e. For a more complete description of what can be considered expedited, please see Appendix B

5. ***What do I do if I think my research may be eligible for expedited review?***
   You will submit your IRB application to the IRB Chair who will determine whether or not your research falls under expedited review.
   Note: Research that cannot be exempt or expedited must be reviewed by the full Institutional Review Board. The Chair will notify you about this status and may request additional documents, such as your research proposal.

6. ***What needs to be included in my application/informed consent to describe how I would store data?***
   Researchers should consult the informed consent checklist, which is located on the IRB's eRaven page. There are also sample informed consent documents located there. Applicants should articulate how data will be stored, e-form or hard copy, and protected. Indicate how subjects will remain anonymous if applicable. The names of individuals with access to the data should be indicated. Indicate how long the data will be kept and when data will be destroyed. All data, electronic or hard copy should be kept for a minimum of 36 months after completion of the research project.

7. ***What if I need to make a change to my research proposal after I have been approved?***

   It is the responsibility of the PI to request approval for any changes after research has been approved. This can be done by completing the addendum form found at http://eraven.franklinpierce.edu/s/dept/academicaffairs/committees/IRB/

Appendix A

Exempt Review

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101%28b%29

Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Appendix B

Expedited Review

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101%28b%29

Applicability

A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

B. The categories in this list apply regardless of the age of subjects, except as noted.

C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= 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.

D. The expedited review procedure may not be used for classified research involving human subjects.

E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 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.)

    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is

cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. (a) from healthy, nonpregnant 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[2], 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 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

    Examples: (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; (j) sputum collected after saline mist nebulization.

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: (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.

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: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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

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: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review 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.

9. Continuing review 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.

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[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

[2] Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).