

INSTITUTIONAL REVIEW BOARD
STANDARD OPERATING PROCEDURES
FAIRFIELD UNIVERSITY

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I. Institutional Review Board's Mandate to Protect Human Subjects

The University shall establish and maintain an Institutional Review Board (IRB) to ensure the protection of the rights and welfare of human research subjects pursuant to the federal regulations (45CFR Part 46 and 21CFR Part 56). The IRB performs prospective and continuing review of research protocols, the informed consent process, and the procedures used to enroll subjects to ensure research is conducted ethically and in compliance with the Belmont Report and all applicable federal, state, local and institutional requirements.

The Fairfield University IRB will apply those standards contained within the federal regulations which reflect the principles articulated in the Belmont Report. For research that is federally funded, the standards for ethical research by Fairfield University researchers follow the code of federal regulations. For research that is not federally funded, the IRB will not apply any review standard that exceeds the standards set by the Code of Federal Regulations, although the IRB may require ethics training for certain categories of research that is not federally funded.

Consistent with the federal regulations, decisions by the IRB to **not** approve research cannot be appealed to any authority outside the IRB. To the best of its ability the IRB will work with investigators to revise protocols that are not approved so as to meet the standards set forth in the regulations. On the other hand, the approval of research by the IRB does not guarantee permission to conduct any particular research project. IRB approval does not override other University policies or authorities.

All research involving human subjects conducted by University employees or students at Fairfield University, or outside of the University in their capacity as an employee/student, is subject to prospective review and approval by the IRB and may not proceed without it, unless specifically exempted by the IRB from review.

II. IRB Administration

The IRB will report to the Chief Academic Officer. The Chief Academic Officer will provide sufficient resources for the efficient conduct of IRB business, including an administrative staff person to serve as Administrative Liaison. The Administrative Liaison's duties include: 1) assisting in the development and implementation of procedures to ensure the efficient flow of all IRB records; 2) maintaining documentation and records in accordance with federal regulatory requirements; 3) tracking records and the progress of all studies; and 4) ensuring meetings are conducted according to federal regulations, i.e., recording attendance and preparing and distributing materials for meetings. The Administrative Liaison will attend all IRB meetings and report to the IRB Chairperson.

III. IRB Membership

The IRB will have sufficient expertise to review the broad variety of research in which the University becomes involved, will be knowledgeable about all relevant regulatory requirements, and will make every effort to be impartial and objective in its review (45 CFR 46.107(a) and 21 CFR 56.107(a)).

Appointment of IRB Chairperson and His or Her Duties.

The IRB Chairperson shall be appointed by the President. In addition to the responsibilities of IRB membership, the Chairperson has primary responsibility for conducting IRB meetings and directing the IRB staff to ensure operation of the IRB within all applicable regulatory requirements. The IRB Chairperson works with IRB members and investigators to ensure that the rights and welfare of research subjects are adequately protected. The Chairperson shall sign all official IRB correspondence, unless otherwise indicated or designated by the Chairperson, and shall report directly to the Chief Academic Officer.

Appointment of IRB Members and Their Duties.

The President will appoint members to the IRB, typically in consultation with current and past members' recommendations. Members are responsible for ensuring that the rights and welfare of research subjects are protected. Members vote to approve, require modifications in, disapprove, or table protocols. Members are expected to attend IRB meetings on a regular basis, serve as primary reviewers for research within their expertise, and serve as general reviewers on all research discussed at convened meetings. Members may be present in person or audio (telephone) or interactive teleconference. Members present via teleconference shall be noted as such in the meeting minutes. The IRB Chair may designate members of the IRB to review non-research, exempt, and expedited review protocols. The IRB may include members who serve as Alternate Members: An alternate member(s) may be designated, as needed, for a regular voting member(s). An alternate member may vote only when the regular voting member is not voting.

IRB Membership Requirements.

In accordance with the compositional requirements of section 46.107 of 45 CFR 46, the membership is composed of at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted at Fairfield. The IRB shall include at least one member whose primary concerns are in nonscientific areas, and one person who is not currently affiliated with Fairfield University, nor is part of the immediate family of a person who is currently affiliated with Fairfield University. Members will be drawn from diverse backgrounds, including consideration of their racial and cultural backgrounds, and sensitivity to such issues as community attitudes to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. When research is reviewed involving a category of people who may be vulnerable to coercion or undue influence (e.g., prisoners, children, individuals with impaired cognitive functioning), the IRB shall include in its reviewing body one or more individuals who have as a primary concern or professional expertise the welfare of these subjects.

Specific Duties.

The IRB is responsible for developing procedures for submitting research protocols for review, determining if research protocols are in conformity with the federal regulations

with regard to the use of human subjects in research, reviewing research projects approved through full board review on a continuing basis (at a minimum of once a year), reporting to the Chief Academic Officer of the University any serious or continuing noncompliance by University investigators with the conditions outlined in the project as approved, and reporting to the Secretary of Health and Human Services any serious or continuing noncompliance by University investigators who are funded by the Department of Health and Human Services.

Conflict of Interest.

No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. For example, when an IRB member is a principal investigator for a study being reviewed by the IRB, the member cannot vote on or otherwise participate in the IRB's review of his or her study.

Initial Training, Continuing Education, and Professional Development of IRB Members.

IRB members shall receive a copy of these IRB standard operating procedures to review research from an ethical and regulatory perspective. In addition, all IRB members must complete a training program and provide a completion certificate. The CITI training course for IRB members is suitable for this requirement. Specific information on training resources will be made available by the Administrative Liaison. Members are expected to become familiar with the Federal regulations and the Belmont Report.

Compensation of IRB Members.

IRB members are not provided monetary compensation for their service on the IRB. The Chair may be compensated (e.g., a stipend, course reduction) based on the agreement with the Provost's office.

IV. IRB Meetings

Schedule.

Meetings will be convened at the call of the chairperson when the chairperson judges the meeting to be necessary or advantageous, or upon the receipt of a joint written request of three or more members. The IRB committee should meet no less than four times per year. It is within the discretion of the IRB Chairperson to cancel or add a meeting in the event there is no business or additional business to conduct. Typically the IRB meets once a month during the academic year. Specific dates for scheduled IRB meetings will be posted on the IRB website within the first month of each new semester.

Quorum.

A majority of the membership, including at least one member whose primary concerns are in nonscientific areas, shall constitute a quorum and is required in order to convene a meeting for the review of research protocols. Members may be present in person or audio (telephone) or interactive teleconference. Members present via teleconference

shall be noted as such in the meeting minutes, which shall also indicate that the members received all pertinent information prior to the meeting and were able to actively and equally participate in all discussions.

Procedure.

All convened IRB meetings shall be conducted under and pursuant of the newest version of Robert's Rules of Order. For a research protocol to be approved it must receive the approval of a majority of those members present at the convened meeting. At a convened IRB meeting, any member may request that an activity that has been approved under the expedited procedure be reviewed by the IRB in accordance with non-expedited procedures. A vote of the members shall be taken concerning the request and the majority shall decide the issue. A tie vote will count as not approved. In cases where research activities were initially approved under expedited procedures and subsequently reviewed by non-expedited procedures, the decisions reached at the convened meeting shall supersede any decisions made through the expedited review.

V. Substance of IRB Review

Principal Investigators' Submission to IRB.

All research studies involving human subjects should be submitted for IRB review by the Principal Investigator. The Fairfield IRB system is entirely online. Submissions should be made through the Fairfield University IRB website, which has a link to the online submission system. Detailed information about submission requirements is provided on the website.

Undergraduate and graduate students are to follow submission procedures as outlined on the online system and must coordinate submission with their faculty mentor.

IRB Review and Approval of Research

Initial Review and Categorization of Study:

The Chair or the Chair's designee will review the submitted protocol and determine its status for IRB review (non-research, exempt, expedited review, or full board review). Unless the protocol does not meet the criteria for human subjects research (45 CFR 46.102(d) and (f)), all research using human subjects must be prospectively reviewed and approved by the IRB. For those studies that qualify as exempt or do not meet the criteria for IRB review, the Chair will designate the study as such and notify the PI. The IRB Chair may deem a protocol exempt after reviewing the information from the investigator submitted through the online system to determine whether the claimed exemption applies. The members of the IRB have access to all exempt protocols through the online system, and they are listed on the agenda for the next scheduled meeting. No action is required, though committee members can read exempt proposals and raise concerns. (No continuing reviews or renewals are required for exempt or non-research protocols.) All protocols will be closely reviewed with regards to inclusion of subjects from potentially vulnerable populations, children, fetuses, neonates, or prisoners, or

people with impaired decision making capacity; and the consent process, including requests for waivers or modification of informed consent.

Expedited Review Procedure:

For studies determined to be eligible for expedited review, the Chair or the Chair's designee from the IRB membership will review the proposed research and determine if the criteria for expedited review as described in the federal regulations ([56 FR 28012, 28022 June 18, 1991, as amended at 70 FR36328, June 23, 2005] have been met. If so, the decision is communicated to the PI and to the IRB committee members via the online system. IRB members are then expected to review the protocol and approval decision and alert the Chair if there is a question or potential issue of concern before or at the next scheduled meeting. Approved protocols will require the submission of an annual status update each year, or at the completion of the study if this occurs before the end of the year.

Full Review Procedure:

For studies that do not meet the criteria for exempt or expedited review, full board review is required. The IRB committee members will review the proposed research in preparation for discussion at the next meeting. The proposal is discussed at the meeting, and a majority vote from all present members is required for approval. The PI is notified by the Chair of approval, conditional approval pending minor changes, need for major changes before review, tabling, or disapproval (with explanation). Approved protocols are active for a period of up to one year as determined by the IRB. Approved protocols will require the submission of an annual report and request for continuation at the completion of the study or within one year of approval date, whichever comes first.

Continuing Review:

The IRB is required to conduct substantive and meaningful continuing review of all research that requires full board review. Such reviews shall be conducted at intervals appropriate to the degree of risk of the project, but not less than once per year. The IRB requires that the PI submit an annual report and request for continuation within the time period approved. Details about requested information appear on the IRB website. The IRB Chair shall review the protocol file at the time of the continuing review. The PI indicates on the continuing review report if he or she is requesting continuation of the proposal for up to one more year or is terminating the protocol. This must be done **before** the approval has expired. The request for continuation is discussed at the next meeting by the full board and can be affirmed or rescinded.

Criteria for IRB Approval of Research.

In order to approve any proposed research to be conducted at the University, the IRB shall determine that all of the following requirements (46.111(a) (1-7)) are satisfied, as quoted below.

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

Risks to subjects are reasonable in relation to anticipated benefits to subjects, if any, 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 the risks and benefits of therapies subjects would receive even if not participating in 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) as among those research risks that fall within the purview of its responsibility.

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 cognizant of the special problems of research involving individuals who may be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or the economically or educationally disadvantaged.

Informed consent shall be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116. Information required for informed consent is detailed on the IRB information page. Information about waivers of documentation of informed consent and waivers of informed consent are provided on the IRB Information page as well.

Actions Taken at Convened Meeting.

IRB actions for initial or continuing review of research will include the following:

- *Approved* with no changes or no additional changes. The research may proceed.
- *Approved contingent on minor changes* that are clearly delineated by the IRB so the investigator may simply concur with the IRB's revisions. The research may proceed **after** the required changes are made and verified by the IRB Chair.
- *Tabled*. Tabled research applications are approvable but require substantive changes or additional substantive information that must be reviewed at a subsequent convened subsequent meeting of the IRB. The research may proceed only **after** the convened IRB meeting has reviewed and approved the required changes to the research or the information provided.
- *Disapproved*. The IRB has determined that the research, as submitted, may not be conducted by the investigator(s). If the IRB disapproves a research protocol, it shall include in its written notification a statement of the reasons for its decision and afford the investigator an opportunity to respond in person or in writing.

VI. IRB Record Keeping and Required Documentation

IRB Records.

Federal regulations require that the IRB retain records for at least three years after the termination of the research protocol. All IRB records shall be kept in a secure place. Access to IRB records shall be limited to the Chairperson of the IRB, the administrative staff of the IRB, the IRB members, and officials of federal and state agencies. IRB records will include the following:

- IRB Standard Operating Procedures (SOP)
- IRB membership roster
- Curriculum Vitae for IRB members
- Record of certification of *human subjects training* for IRB members and Principal Investigators when required by federal grant award terms and conditions or IRB.
- IRB research application files for all submitted protocols, including all required documentation, continuing review reports, and correspondence.
- Minutes of the convened IRB meetings

The Administrative Liaison shall ensure that a current IRB membership roster is maintained pursuant to 45 CFR 46.103(b) (3).

Contents of Minutes.

The minutes of IRB meetings shall be compiled by the Administrative Liaison and approved by the IRB. The following specific information shall be included in the minutes:

- Attendees by name, absent members, alternate members and the name of the person for whom they are the alternate, consultants, invited investigators and guests, and whether quorum requirements have been met. Members present via teleconference shall be noted as such in the meeting minutes.
- Actions taken by the IRB on new and continuation applications; review of protocol and informed consent modifications or amendments; protocol deviations; adverse event reports; reports from sponsors; waiver or alteration of elements of informed consent; suspensions or terminations of research; and other actions. Votes on these actions are categorized as "for," "against," and "abstain." This section should also include the basis for requiring changes in or disapproving research.
- A list of research approved since the last meeting utilizing expedited review procedures and specific citation for the category of expedited review of the individual protocol, as well as a list of exempt and non-research protocols.
- Report of other business
- Members who absented themselves by name, along with the name of the protocol and reason for the conflict.

VII. Additional Considerations.

Certificates of Confidentiality.

The IRB may determine that special protections are needed to protect subjects from the risks of investigative or judicial processes. Research will be considered sensitive if it involves the collection of information in any of the following categories:

- Information relating to sexual attitudes, preferences or practices;
- Information relating to the use of alcohol, drugs or other addictive products;
- Information relating to illegal conduct;
- Information that if released could reasonably be damaging to an individual's financial standing, employability or reputation within the community;
- Information that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination;
- Information pertaining to an individual's psychological well-being or mental health.

For such sensitive information the IRB may require that the investigator obtain a Certificate of Confidentiality from the Department of Health and Human Services. Federal funding is not a prerequisite to such a determination that a Certificate of Confidentiality is necessary. The purpose of the Certificate of Confidentiality is to protect against any involuntary release of sensitive information about individual subjects for use in federal, state or local civil, criminal, administrative or other legal proceedings. The Certificate does not prohibit the disclosure of information by an investigator on issues including, but not limited to, child abuse or a communicable disease. The investigator must detail in the informed consent document what information will and will not be protected by the Certificate of Confidentiality.

Reporting Unanticipated Problems and Adverse Events.

Any adverse events or unanticipated problems involving subjects of any IRB-approved study must be reported to the IRB as soon as possible, but no later than thirty days from the event's occurrence. Deaths or other serious adverse events should be reported to the IRB as soon as possible, but no later than five days after the event's occurrence. If an adverse event occurs at a study site other than the University, the principal investigator must promptly notify all IRBs governing the protocol. Noncompliance issues will be first addressed by the IRB Chairperson and if a resolution is not found then the issue will be brought to the IRB Committee. If the IRB Committee cannot resolve the noncompliance, then the IRB Chair will bring the issue to the Chief Academic Officer for consultation and corrective action, including termination of the research protocol.

Review of Standard Operating Procedures (SOP).

The IRB shall review the IRB SOP at a minimum of every five years. Recommended revisions to the SOP will be discussed and decided on by the full IRB.

Protocol Amendments:

FAIRFIELD UNIVERSITY INSTITUTIONAL REVIEW BOARD
Standard Operating Procedures (Approved 2-7-19; prior version 3-13-12)

If a principal investigator would like to make a change to an already approved protocol or exempt protocol, he or she can submit an amendment to the protocol through the online system. Minor changes can be reviewed and approved by the Chair, and discussed at the next meeting. Major changes for non-exempt research are typically referred to the full IRB committee for discussion and action at the next meeting. Submission of Changes/Amendments to the research activity is the responsibility of the Investigator to ensure that changes in research are being reported to the IRB before they are initiated. All changes/amendments will be submitted through the Fairfield online IRB system and will follow the process as noted under section "IRB Review and Approval of Research."

Delegation of Protocols to Another IRB:

To avoid duplication of effort reliance on the review of another qualified IRB is allowable. Any protocol approved by another IRB will require the Investigator to submit the Approval letter through the Fairfield online IRB system in order for the IRB Committee to be informed of this research and its approval.