

# INSTITUTIONAL REVIEW BOARD (IRB) POLICY

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In 1974, as a result of national and international concerns regarding the protection and respect of human research participants, the federal government enacted the National Research Act that established the Institutional Review Board (IRB) system. The IRB standards are overseen by the Department of Health and Human Services (DHHS) in Title 45 Part 46 of the Code of Federal Regulations. The Federal Policy for the Protection of Human Subjects or the "Common Rule" was published in 1991 and revised in 2018, with a general compliance date of January 21, 2019. By federal law, institutions that accept research funding from the federal government must have an IRB to review all research involving human subjects (even if a given research project does not involve federal funds) and safeguard the rights and welfare of people (and animals) participating in research. In addition, the IRB at Bay Path University has the authority to approve or disapprove research proposals or require modification in research proposals to have the proposals meet the IRB guidelines. Proposals for research that have been approved by the Bay Path University IRB are further subjected to review and possible disapproval by the University administration but the administration cannot approve applications that have previously been denied approval by the IRB. Members of the IRB committee will not participate in the review of any research application to the IRB that may constitute a conflict of interest.

## The Role of the IRB

As part of that IRB system, the Institutional Review Board (IRB) at Bay Path University is a standing committee of at least five full-time faculty members who are familiar with human subjects research, and who value community and cultural sensitivities. Additionally, at least one member who is not otherwise affiliated with Bay Path University will also serve on the committee. The charge to the committee is to promote and protect respect for all research participants and research activity affiliated with the University. All research activities involving any Bay Path community members (including staff, administrators, faculty or students) or any Bay Path resources must comply with Bay Path IRB procedures and policy as stated below.

The policies and procedures of the Bay Path IRB apply to all research that meets all or any of the following conditions:

1. The research is conducted by one or more members of the Bay Path University community (including staff, administrators, faculty and students).
2. The research uses Bay Path University resources.
3. The goal of the research is to contribute to knowledge either through publication or report to an appropriate community beyond the boundaries of the University itself.

The policies and procedures of the Bay Path IRB *do not* apply if all of the following conditions are met:

1. The goal of the research is to teach and the research findings are not published or reported beyond the relevant course or classroom.
2. The research is designed so that no individual can be identified or linked to the collected data.
3. The subjects of the research are only students or personnel of Bay Path University.

4. The faculty overseeing the research project assumes full responsibility for adherence to all applicable laws, policies, ethical standards and regulations.

## IRB Procedures

An application for IRB Approval must be submitted by the principal investigator (PI) whenever IRB approval for research is required. The IRB will determine if the application requires IRB approval or if it is exempt from IRB review. There are three possible outcomes if the application is reviewed by the IRB:

1. The application for research may be approved and notification of approval sent to the PI.
2. The application for research may be subject to revision before approval, and will be returned to the PI requesting additional provisions, including clarification and/or recommended changes.
3. The application for research may be denied approval, and notification along with reasons for the denial sent to the PI.

Decisions regarding approval or disapproval of applications are usually made within two weeks (14 days) of submission. Under most circumstances, applications for IRB approval are to be submitted electronically. Questions or concerns regarding IRB procedures should be addressed to the IRB Committee chair or the Office of Academic Affairs. Records and documents relating to the Bay Path IRB, including applications and attachments, executed consent forms, waivers, and authorizations, as well as minutes and correspondence of the IRB committee, are kept confidentially in the Office of Academic Affairs. All records filed regarding the activities, decisions, and procedures of the IRB are property of Bay Path University.