

Bylaws of the Boston College Institutional Review Board
January 2022

Article I. NAME

The name of the board is the Boston College Institutional Review Board (hereinafter referred to as “BC IRB.”)

Article II. PURPOSE

The purpose of the BC IRB is to ensure compliance with Federal Policy for the Protection of Human Subjects (45 CFR 46 “Final Rule”) for federally funded studies, and observances of the policies of Boston College regarding the protection of human subjects in all research conducted by faculty, students or staff at Boston College.

Article III. AUTHORITY

The BC IRB is empowered to:

- 1) Review all funded and unfunded research by faculty, staff, or students that involves the use of human subjects, prior to the beginning of the research.
- 2) Determine the type of review (exempt, expedited, or full board) the research requires.
- 3) Disapprove, modify, or approve research protocols based upon consideration of the protection of human subjects.
- 4) Suspend or terminate a research project if it violates federal or university policies for the protection of human subjects, or if it does not follow the protocols submitted to and approved by the IRB.

Article IV. RELATIONSHIP TO THE UNIVERSITY

The BC IRB shall coordinate its actions and policies with the Office of the Vice Provost for Research.

Article V. MEMBERSHIP

The BC IRB shall include the following members:

- 1) At least one non-affiliated member (also known as a “community representative”), who can be either a scientific or non-scientific reviewer, who has no affiliation with Boston College.
- 2) Scientific members: these include faculty members across schools and departments at Boston College. Although the composition may change based on the volume of IRB protocol applications from each school, this usually includes four representatives from the Lynch School of Education and Human Development, one representative from Boston College Law School, two representatives from the Connell School of Nursing,

two representatives from Psychology, one representative from Sociology, and one representative from the Boston College School of Social Work.

- 3) At least one non-scientific member, whose education, work, or interests are not primarily in scientific areas.
- 4) The Chair, who must be employed by Boston College as a faculty member.
- 5) At least one prisoner representative who is able to be present when research involving prisoners is being proposed.
- 6) IRB alternate members, who must complete the same training as new IRB members prior to serving as an alternate and through their expertise, training, and/or affiliation, are designated to serve as an alternate for one or more IRB members.

Deans and department Chairs nominate members, who are then appointed by the Vice Provost for Research. Members serve for 3 years, unless their Dean or Chair requests otherwise.

All members must complete the CITI online course for IRB members. Members may serve multiple terms.

Article VI. OFFICERS

The Vice Provost for Research shall appoint a chairperson of the BC IRB for a three year term. The chairperson may appoint an acting chairperson to function in his or her absence. The Chair is a voting member of the IRB and presides over all convened meetings. The Vice Provost for Research, with input from the research and administrative community, evaluates the Chair annually and may adjust the length of term. The Chair has authority to sign all IRB action items. The Chair may serve multiple terms.

Article VII. RESPONSIBILITIES

The BC IRB members shall be responsible to:

- 1) Review applications and evaluate them in accordance with Federal Policy for the Protection for Human Subjects (45 CFR 46 "Final Rule") and policies of Boston College regarding the protection of human subjects;
- 2) Participate in BC IRB deliberations and make recommendations for reduction of risk, improved informed consent process, or other aspects of protection of human subjects;
- 3) Attend all BC IRB meetings unless there are extenuating circumstances for absence;
- 4) Inform the BC IRB Chair of human subjects research about noncompliance problems or ethical issues of which they become aware;
- 5) Maintain the confidentiality of all BC IRB deliberations.

Article VIII. MEETINGS

The BC IRB will meet on the third Wednesday of each month from 11:30 a.m. to 1 p.m. every month of the year, including the summer months. Meetings may be conducted in person, by

phone, or by Zoom. Notice of meeting time and place shall be given at least one week in advance. The Chair may call a special meeting upon three days' written notice.

A quorum shall consist of half of the board members plus one. The board members consist of the chair, the scientific members, the non-scientific member, and the non-affiliated member. If any of these people are absent, an alternate may count toward quorum in their place. Alternate members do not count toward quorum unless they are needed to fill in for a member; non-voting members are not counted toward quorum. If there are ten members, the quorum shall consist of 6 people. If there are eleven members, the quorum shall consist of 7 people.

Minutes of each meeting shall be kept, and a list of actions taken since the previous meeting shall be attached to the meeting minutes.

Article IX. DECISIONS OF THE IRB

Full review by the BC IRB shall consist of all members, or alternates, who attend the meeting reviewing each protocol. The BC IRB shall be empowered to approve or disapprove a protocol, and to give conditional approval. It may also table protocols whose review requires more information.

In the review process, the BC IRB shall have as its primary criteria: the degrees of physical, social and psychological risk; the need for a degree of confidentiality; the presence, absence, or adequacy of informed consent; and the protection of particularly vulnerable subjects. The contribution of methodological quality to the risk-benefit ratio will be informed primarily by the expertise of the Principal Investigator; however, the IRB will consider evaluations by its members and can also solicit review from outside experts as needed.

In deciding whether a full board protocol shall be approved, disapproved, tabled, or conditionally approved, the BC IRB shall seek input from all members. The action taken shall be determined by a simple majority vote of those voting members present at the meeting. A member with a conflict of interest may not vote on the protocol. When a member or alternate is barred from voting because of a conflict interest, said member or alternate shall not be counted in determining the number of votes needed for a majority, notwithstanding that the presence of said member or alternate has been counted to determine a quorum. Each BC IRB member shall have one vote. Voting shall proceed openly, after an opportunity for full discussion and debate.

Individuals whose protocols have been reviewed shall be notified of the BC IRB's decision in writing within five working days.

The BC IRB, upon the request of an investigator or on its own initiative, may reconsider any protocol and reverse its own determination.

Any investigator may resubmit a protocol for re-review once it has been modified in such a way as to remove the BC IRB's objections. There shall be no mechanism for appeal by investigators beyond the IRB.

Article X. PARTICIPATION OF NON-MEMBERS

Meetings of the BC IRB may be attended by persons who are not members with the consent of the chairperson. Such persons ordinarily would be (1) persons with special expertise needed by the BC IRB, (2) persons who have submitted protocols and whom the IRB has invited for oral explanation and questioning, (3) persons whose research in progress requires monitoring, or (4) office staff, administrators of the University, and special guests.

Article XI. MONITORING

The BC IRB will conduct a continuing review of research for full board protocols at intervals appropriate to the degree of risk, but not less than once per year. In some circumstances, a shorter review interval may be required. In the event that the BC IRB (1) becomes aware of any serious or continuing non-compliance with federal or BC IRB regulations, or (2) suspends or terminates a BC IRB approval, written notice of such noncompliance, suspension, or termination will be given to the Vice Provost for Research and the appropriate federal funding agency.

Article XII. RECORDS

The chairperson or Office for Research Protection staff shall ensure that proper records are maintained, specifically:

- 1) Minutes of each meeting with the names of those present, the protocols acted upon, a general summary of the discussion of protocol issues, other BC IRB actions, and all vote counts.
- 2) Copies of all protocol submission documentation, documentation or review, notification of the BC IRB action and any other relevant data.

Meeting minutes shall be kept in perpetuity; all protocols shall be kept for three years after completion of the research.

Article XIII. CONFLICT OF INTEREST

An IRB member is said to have a conflicting interest whenever that IRB member, or his/her spouse, domestic partner, or first degree relative:

- Is an investigator or key personnel on the protocol under consideration;
- Acts as an officer or a director of the sponsor or an agent of the sponsor;
- Is involved in the research as a coordinator, protocol consultant, co-investigator, and/or primary advisor;
- Has a financial interest, including a compensation arrangement or receipt of income, equity interests, or intellectual property rights, from, with, or in an investigator or sponsor of the protocol under consideration;

- Has identified him/herself for any other reason as having a conflicting interest (e.g., having a close personal or professional association with the submitting investigator, serving as co-investigator and/or the primary mentor for a student or postdoc investigator).

It is the responsibility of each IRB member to disclose any COI in a study submitted to the IRB and recuse him/herself from the review of that protocol. No member may participate in the discussion of any research project in which the member has a conflict of interest, except to provide information or answer questions from the IRB as requested. Members with a COI for a protocol may not be present during IRB voting on that protocol.