



BOSTON COLLEGE
Policy for the Protection of Human Research Participants

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Table of Contents

<u>Section</u>	<u>Page</u>
I. Introduction	4
Authority Under Which the Boston College Institutional Review Board (BC IRB) is	
A. Established and Empowered	4
B. Purpose of the BC IRB	4
C. Statement of Ethical Principles	4
D. Boston College Federalwide Assurance (FWA)	5
II. Authority of the BC IRB	5
A. Scope of Authority Defined	5
B. Authority of the BC IRB to Act on Proposed Protocols	5
C. Authority of the BC IRB to Require Progress Reports and to Oversee Protocols	5
D. Authority of the BC IRB to Suspend or Terminate Approval of Protocols	6
E. Authority of the BC IRB to Restrict Protocols	6
III. Organizational Responsibilities	6
A. IRB Reporting Structure within the University	6
B. The Vice Provost for Research	7
C. Deans, Department Chairpersons, and Directors of Research Centers at Boston College	7
D. Faculty Advisors	7
E. Principal Investigators	7
F. Other Institutions	7
G. Regulatory Agencies	7
IV. BC IRB and the BC Office for Research Protections Personnel	8
A. BC IRB Chairperson	8
B. BC IRB Members	8
C. BC Office for Research Protections (ORP) Staff	10
D. Use of Consultants	10

Appendices	12
1. Appendix 1 - BC IRB Forms	12
2. Appendix 2 – Federal Regulations	29
3. Appendix 3 – Human Participant Research Training Policy	31
4. Appendix 4 – BC IRB Review Criteria	33

I. Introduction

Federal and University regulations require that all faculty, staff, and student research projects involving human participants and/or materials of human origin be reviewed and approved by the Boston College(BC) Institutional Review Board (BC IRB) before initiation.

For the purposes of this Policy, BC adopts the federal definition of research found in 45 CFR 46.102, most recently amended on June 19, 2018 (83 FR 28497):“*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. For purposes of this part, the following activities are deemed not to be research:

- (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products).
- (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

This Policy and the BC IRB Standard Operating Procedures for Researchers (SOPs) govern human participant research conducted at, or sponsored by Boston College, and human participant research conducted at other institutions in which BC faculty, staff, or students will be involved.

A. Authority under which the Boston College Institutional Review Board (BC IRB) is Established and Empowered

The Boston College Institutional Review Board (BC IRB) is a standing Committee at Boston College. The BC IRB acts under the authority of the Vice Provost for Research.

B. Purpose of the BC IRB

The purpose of the BC IRB is to protect the rights, safety, and welfare of humans who are participants in research. Additionally, the BC IRB aims to protect human participants in their privacy, dignity, and value and to protect them from manipulation, embarrassment, disrespect, and insult, among other things. The BC IRB shall review and has the authority to approve, disapprove, or require modifications to all research activities involving human participants.

The BC IRB has adopted this Policy and SOPs to comply with the United States Department of Health and Human Services (DHHS) Regulations on research with human beings: Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).

The University affirms its commitment to maintaining the integrity, traditions, and identity of the University as a

Jesuit institution devoted to the development of character, advancement of learning, and service to humanity in the research the BC IRB approves on behalf of the University,

C. Statement of Ethical Principles

The BC IRB is guided by the ethical principles regarding all research involving humans as participants as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled, *The Belmont Report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, April 18, 1979, (<https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html>).

The BC IRB subscribes to the basic generally accepted ethical principles governing human participant research, as outlined in the Belmont Report: respect for persons, beneficence, and justice. The BC IRB is also committed to ensuring the dignity of human participants in research.

The ethical guidelines of the Belmont Report are considered in the review of all research activities, including informed consent, risk/benefit analysis and the selection of participants for research. University researchers are expected to commit themselves independently to truthfulness, honesty, trustworthiness, and charity. The BC IRB strives to maintain sensitivity to community attitudes and to take into consideration the racial, ethnic, and cultural backgrounds of research participants so as to ensure an optimal level of protection for all participants in our research programs.

D. Boston College Federalwide Assurance (FWA)

A guarantee that all federally funded human participant research will be reviewed by the BC IRB has been filed with the United States Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) through a Federalwide Assurance (FWA00001461). As an institution that has never “checked the box,” Boston College has a legal obligation to comply with The Final Rule for all protocols that are federally funded. Furthermore, as a matter of institutional policy, Boston College follows the Common Rule in its review of all non-federally funded protocols. However, by not “checking the box,” we have some discretion for handling non-funded studies, and thus apply these regulations in a more flexible manner for this group of protocols. Our Flexibility Policy, which is detailed in the Boston College Office for Research Protections Standard Operating Procedures, is used to review all non-federally funded protocols.

II. Authority of the BC IRB

A. Scope of Authority Defined

The BC IRB has the authority to protect all human participants involved in non-exempt research at BC, or in all other activities which even in part involve such research, regardless of sponsorship, if one or more of the following apply:

1. The research is sponsored by the University;
2. The research is conducted by or under the direction of any faculty, staff, or student of the University; and/or,
3. The research is conducted at other institutions in which BC faculty, staff, or students will be

involved.

Research studies involving human participants and/or materials of human origin must receive BC IRB approval before being initiated.

B. Authority of the BC IRB to Act on Proposed Protocols

The BC IRB has the authority to approve, require modifications in (to secure approval) or disapprove all research activities involving human participants and/or materials of human origin. The regulatory basis for this authority is the U.S. Department of Health and Human Services (DHHS) regulations (45 CFR 46) pertaining to rights and welfare of participants and/or patients. Additional federal regulations are listed in Appendix 3 of this Policy.

C. Authority of the BC IRB to Require Progress Reports and to Oversee Protocols

Under the Final Rule, beginning July 19th, 2018 and ending January 20th, 2019, the BC IRB no longer has the responsibility to annually review the progress of new expedited studies. Under the [BC IRB Flexibility Policy](#), most new studies submitted on or after July 19th, 2018, will not require an annual continuing review, regardless of funding source. All existing expedited studies will have one final Continuing Review, and then the majority will no longer require annual reviews. The BC IRB reserves the right to continue to monitor certain studies via continuing review based on the risk profile of the study. The BC IRB also has the authority to observe or have a third party that the BC IRB determines is qualified and appropriate to observe the consent process or any aspect of the research.

D. Authority of the BC IRB to Suspend or Terminate Approval of Protocols

The BC IRB has the responsibility and the authority to suspend or terminate approval of any previously approved protocol that has an unanticipated problem involving risks to human participants, serious or continuing noncompliance with any federal regulation or serious or continuing noncompliance with the requirements or determinations of the BC IRB. Such instances will be discussed at a convened meeting of the BC IRB and communicated to the Vice Provost for Research.

E. Authority of the BC IRB to Restrict Protocols

The BC IRB has the responsibility and the authority to restrict any protocols involving human participants and/or materials of human origin if it determines circumstances warrant such action. If one aspect of a study fails to comply with federal regulations or BC IRB requirements or determinations, the BC IRB must restrict the protocol so as to restrict the portion found in noncompliance until it is brought into compliance. Such instances will be discussed at a convened meeting of the BC IRB and communicated to the Vice Provost for Research.

III. Organizational Responsibilities

A. IRB Reporting Structure within the University

The Chairperson of the BC IRB reports directly to the Vice Provost for Research, who reports to the Provost on

BC IRB matters. The Director, Office for Research Protections (ORP), also reports to the Vice Provost for Research.

B. The Vice Provost for Research

The Vice Provost for Research serves as the Institutional Official for Boston College regarding matters involving human participant in research.

C. Deans, Department Chairpersons, and Directors of Research Centers at Boston College

The BC IRB requires that Department Chairpersons review each protocol application that is submitted to the BC IRB for review indicating that scientific review has occurred

D. Faculty Advisors

BC students must request that their faculty advisor reviews and signs the protocol application before submitting it to the BC IRB for review. The faculty advisor's signature indicates that he/she has reviewed the protocol application and will oversee the protocol in its entirety, including any final or termination report.

E. Principal Investigators

Only BC faculty, staff, and students may serve as Principal Investigators on protocols. For those individuals having less than full affiliation with BC (e.g., part-time faculty), the BC IRB may require that the protocol be overseen or supervised by a full-time BC faculty member. On the Cyber IRB system, the first person listed as the PI will be the primary contact person for all IRB communications. The Principal Investigator has ultimate responsibility for his/her protocol and all official BC IRB correspondence is addressed to the Principal Investigator.

The Principal Investigator and other individuals who will interact with participants and/or review research data, must complete IRB training that has BC approval and/or meets its requirements (see Appendix 4).

F. Other Institutions

The BC IRB may act as a liaison with the IRBs of other institutions, as necessary, to assist in the approval of joint and cooperative projects involving multiple sites and/or Principal Investigators (Institutional Authorization Agreement, or IAA). Conversely, the BC IRB may agree to permit another federally sanctioned IRB with an approved Federalwide Assurance (FWA) to act as the IRB of record for studies to be conducted by, or with the assistance of BC personnel, at the facilities of a second institution. The BC IRB may agree to function as the IRB of record for another Principal Investigator and/or institution if the project involves collaboration with BC personnel. Such agreements will require written letters of agreement and may include the completion of additional documentation under the FWA Process. For studies that are not grant-funded, the BC IRB is willing to review the possibility of granting IAAs with institutions that do not have an approved FWA, on a case-by-case basis.

G. Regulatory Agencies

The BC IRB is subject to regulation by federal oversight agencies, including the federal Office for Human Research Protection (OHRP) and all other applicable federal, state and local agencies with oversight of research

involving human participants and materials of human origin.

IV. BC IRB and the BC Office for Research Protections Personnel

A. BC IRB Chairperson

Selection and Appointment

The Vice Provost for Research appoints the BC IRB Chairperson who serves a 2-year term. Only individuals with sufficient expertise and experience will be considered for this BC IRB position. The BC IRB Chairperson will be remunerated for services as appropriate.

Duties

The BC IRB Chairperson serves as the liaison between the BC IRB and the Vice Provost for Research and is also responsible for assisting the Vice Provost for Research in maintaining the membership of the BC IRB. The BC IRB Chairperson is a person with whom researchers may discuss any questions or concerns regarding the BC IRB review process.

It is the responsibility of the BC IRB Chairperson to convene meetings of the BC IRB, moderate the BC IRB discussion, and if necessary, assist in resolving disagreements among BC IRB Members. The BC IRB Chairperson is also responsible for ensuring that the appropriate type of review is conducted in a timely manner in accordance with all University policies, and federal laws, regulations, and policies. Aside from protocols requiring full-board review, the BC IRB Chairperson also reviews continuing review report and amendments as necessary. The BC IRB Chairperson is also the signatory official on IAAs.

If necessary, the BC IRB Chairperson may delegate the responsibility for convening and moderating a BC IRB meeting to another BC IRB Member. The BC IRB Chairperson may also delegate determination of exemption from IRB review and delegate the review and possible approval of amendments and continuing review reports to a qualified appropriately trained designee.

B. BC IRB Members

The BC IRB will consist of the following categories of representatives: Community Members, faculty members across the various schools at Boston College, particularly from departments with the largest volume of IRB applications, and Vice Provost for Research Appointees. The ORP staff and Associate Director are responsible for organizing logistics and maintaining an accurate record of IRB proceedings.

Qualification of Members

The Membership of the BC IRB will include individuals with varying backgrounds. The BC IRB will possess appropriate professional competence to review the diverse types of protocols that are received. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, 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. The BC IRB will be able to ascertain the acceptability of the research in terms of institutional commitments and regulations, all applicable laws, and standards for professional conduct and practice.

Membership is selected to assure appropriate diversity, including representation by multiple ethnic backgrounds, both genders, and to include both scientific and non-scientific Members. At all times, the IRB will include at least one member who is not otherwise affiliated with Boston College and who is not part of the immediate family of a person who is affiliated with Boston College.

Selection and Appointment

The Vice Provost for Research selects and appoints new IRB Members in consultation with Deans and Department Chairpersons, the BC IRB Chairperson, and the ORP Director. BC IRB Members will serve up to a three-year term, which is renewable.

Duties

It is expected that BC IRB Members will attend as many convened meetings of the BC IRB as possible. When assigned to review a particular protocol, BC IRB Members must apply the review criteria as outlined in Appendix 5. Members independently evaluate project submissions prior to the BC IRB meeting, participate in appropriate discussions, and vote to approve, disapprove, require modifications, or defer each submission during the BC IRB meeting. Members also review and vote on other pertinent business that the BC IRB Chairperson includes on the agenda. Members may also be appointed by the BC IRB Chairperson to review research activities that qualify for expedited review.

In those situations where an IRB Member has one of his or her own protocols being reviewed by the full BC IRB (either for initial review or continuing review), that person must recuse himself or herself from any and all meetings or processes which pertain to that review. Additionally, that person will not be eligible to cast a vote in any procedure which has to do with his or her research.

IRB Members are expected to be sensitive to other types of potential conflicts. For instance, if the IRB Member has collaborated on projects with the Principal Investigator, or if the IRB Member and the Principal Investigator are close personal friends, the IRB member, in consultation with the IRB Chair, should evaluate whether it is possible to give an objective review of the protocol.

Training of BC IRB Chairperson and Members

The BC IRB Chairperson and BC IRB Members will complete a core educational program prior to serving on the BC IRB. This requirement may be satisfied by complying with the BC IRB Training Policy found in Appendix 4 to this Policy. The basic training module provided by the CITI Program is the minimum and should be supplemented by CITI training module(s) directed at IRB member responsibilities. The Director or other qualified staff from ORP will provide orientation for new BC IRB Members at the beginning of their appointment. That orientation will address internal BC procedures and how they link to external policies and regulations.

Compensation of BC IRB Members

Except for the IRB Chair, BC IRB Members who are BC employees are not provided additional compensation for their BC IRB work. BC IRB Members who are not employees of BC are compensated monetarily for their time and effort.

A list of the names and qualifications of the BC IRB members will be maintained by the BC ORP and has been filed with the regulatory agencies as required.

C. BC Office for Research Protections (ORP) Staff

In conjunction with the BC IRB Chairperson, the Boston College ORP is responsible for coordinating the activities of the BC IRB. The BC ORP informs Principal Investigators of the BC IRB decisions and administrative processing affecting their protocols. The BC ORP is also responsible for maintaining the documentation of the activities of the BC IRB. In conjunction with Deans, Department Chairpersons, Center Directors, and the BC IRB, ORP is responsible for distributing pertinent literature and educating faculty, staff, and students on the requirements for the use of human participants in research.

BC ORP Staff Requirements

As required by the University's Federal-wide Assurance, the Vice Provost for Research will provide sufficient secretarial/administrative support and adequate resources to ensure that all University, federal, and state regulations are followed. Adequate meeting and office space shall be provided for the BC IRB and the ORP Staff. Adequate office equipment and supplies shall be made available to the BC IRB and the BC ORP Staff.

BC ORP Staff Duties

The ORPs staff will prepare an agenda, maintain minutes of each BC IRB meeting, coordinate the process for obtaining approval of the meeting minutes, and store records according to regulations. The ORP staff will distribute materials to all BC IRB Members, as applicable and appropriate, at least 5 business days in advance of a convened IRB meeting. The ORP staff shall prepare, store, and maintain files required by regulation and the SOPs pertaining to its activities and responsibilities. The ORP staff also does the initial screening review of IRB initial protocol and amendment submissions, requesting changes to be made by the PI as needed, until the protocol is ready to be submitted to the Chair, Associate Director, or IRB member.

BC ORP Staff Training

The ORP staff will complete the same core educational program as that provided to BC IRB Members. This includes training on the policies, regulations, this Policy and SOPs. The ORP Staff will also be provided and/or offered opportunities for ongoing and continuing education opportunities.

Associate Director, ORP

The ORP Associate Director is responsible for maintaining an approved FWA with DHHS. The ORP Director must also update the IRB registration information when Members are added or removed from the BC IRB. The Associate Director reviews and approves amendments for existing protocols, and initial exempt projects. If an IRB committee member is unable to complete an expedited review by the deadline, the Associate Director may also complete this review in place of the committee member.

D. Use of Consultants

The BC IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of

complex issues that require expertise beyond or in addition to that available on the BC IRB. These individuals do not have IRB voting rights.


When conducting a review, a BC IRB reviewer may request the assistance of a consultant. The BC IRB reviewer should contact the ORP Director who will discuss this matter with the IRB Chairperson.

Appendix 1

BC IRB Forms

1. Initial IRB Application Form
2. IRB Continuing Review Form
3. Informed Consent Waiver/Alteration Form
4. Amendment Form
5. IRB Adverse Event Form
6. Project Closure Form

(For ORP use only) BC IRB
Protocol#:

 <p>INITIAL IRB APPLICATION FORM</p> <p>For Initial IRB Review Only</p>	<p>Boston College Institutional Review Board Office for Research Protections 140 Commonwealth Ave., Waul House Chestnut Hill, MA 02467 (617) 552-4778 Fax: (617) 552-0498 E mail: irb@bc.edu</p>
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<p>I. Study Title: (If funded must match the sponsored title)</p>	<p>Today's Date:</p>
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II. Principal Investigator Information

III. Research Risk

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 (45 CFR 46. 102). Research must present no more than minimal risk to human subjects in order to qualify for exempt or expedited review. Research must fit within one of the categories of review in order to qualify for that level of review.

Projects that propose greater than minimal risks to human subjects are considered full board protocols and they must be reviewed by the IRB at a convened meeting. The IRB meetings are held every third Wednesday of the month. Full board protocols must be submitted ten business days in advance of an IRB meeting in order to be reviewed at that month's meeting. **NOTE: Research involving prisoners is always considered a full board protocol and must be reviewed at an IRB meeting.**

A. Does the research propose greater than minimal risk to participants? Yes No

B. Does the research include prisoners? Yes No

C. Level of Review

Please select a level of review and the appropriate category that corresponds to that level of IRB review:

Exempt

Expedited

Full Board

IV. General Study Information

Is this project a *Clinical Trial*? Yes No

A. Funding

1. **None** (Go on to Section B)

2. **University Funded**

<p>3. <input type="checkbox"/> External</p> <p>4. <input type="checkbox"/> Federal</p> <p><input type="checkbox"/> Sponsor Award Number (if known)</p> <p><input type="checkbox"/> BC Project Number (if known)</p> <p>5. Is BC the primary awardee for the grant? <input type="radio"/> Yes <input type="radio"/> No If No Please list Primary Awardee:</p> <p>6. Are there subcontracts? <input type="radio"/> Yes <input type="radio"/> No If Yes Please list sub-contractors:</p>	
<p>B. Participant Recruitment Numbers: This number must be the maximum number you intend to recruit. You will not be allowed to recruit more than this number without first coming back to the IRB to seek approval. Females: Males:</p> <p>C. Participant Ages (please check)</p> <p><input type="checkbox"/> 0-7 (parental consent and oral child assent)</p> <p><input type="checkbox"/> 8-11 (parental consent and child written consent)</p> <p><input type="checkbox"/> 12-17 (parental consent and written consent)</p> <p><input type="checkbox"/> 18-65</p> <p><input type="checkbox"/> 65+</p>	<p>D. Estimated Project Duration Start Date: End Date:</p> <p>E. Why is this Project being conducted? (please check)</p> <p><input type="checkbox"/> Faculty/Staff Research</p> <p><input type="checkbox"/> Undergraduate Coursework</p> <p><input type="checkbox"/> Master's Thesis</p> <p><input type="checkbox"/> Doctoral Dissertation</p> <p><input type="checkbox"/> Other:</p>
<p>F. Will This Study Involve Long-Term Follow-Up with participants: <input type="radio"/> Yes <input type="radio"/> No If Yes, please describe:</p>	
<p>G. Special Study Populations</p> <p><input type="checkbox"/> Minors (under 18 years) If including minors, also complete Research with Minors Form</p> <p><input type="checkbox"/> Pregnant Women/Fetuses or products of labor & delivery</p> <p><input type="checkbox"/> Prisoners</p> <p><input type="checkbox"/> Physically or mentally challenged</p> <p><input type="checkbox"/> Diminished capacity for consent</p> <p><input type="checkbox"/> Other:</p> <p><input type="checkbox"/> No Special Study Populations</p>	
<p>H. Does this study involve any of the following?</p> <p><input type="checkbox"/> Deception or Punishment</p> <p><input type="checkbox"/> Use of drugs</p> <p><input type="checkbox"/> Covert observation</p> <p><input type="checkbox"/> Induction of mental and/or physical stress</p> <p><input type="checkbox"/> Procedures which may risk physical/mental harm to the participant</p> <p><input type="checkbox"/> Materials/issues commonly regarded as socially unacceptable</p> <p><input type="checkbox"/> Information relating to sexual attitudes, sexual orientation or practices</p> <p><input type="checkbox"/> Information relating to the use of alcohol, drugs or other addictive products</p> <p><input type="checkbox"/> Procedures that might be regarded as an invasion of privacy</p> <p><input type="checkbox"/> Information pertaining to illegal conduct</p> <p><input type="checkbox"/> Genetic information that may be linked to a participant's health status, such as genetic markers for cancer, heart disease, etc.</p> <p><input type="checkbox"/> Information normally recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination.</p> <p><input type="checkbox"/> Information pertaining to an individual's psychological well being or mental health.</p> <p><input type="checkbox"/> Information that if released could reasonably damage an individual's financial standing, employability, or reputation within the community.</p> <p><input type="checkbox"/> None of the above Procedures</p> <p>Please provide details on all procedures checked above: How are they integral to the study?</p>	

V. Research Summary:

Instructions: A research summary is a narrative that provides the IRB with important information about a study. Please provide a thoughtful response to each section using simple language and avoid technical jargon. If a specific question is not applicable to your study, please state "not applicable" or "n/a".

A. Introduction and Background:

1. State the problem and hypothesis
2. Provide the scientific or scholarly reason for this study and background on the topic

B. Specific Aims/Study Objectives:

1. List the purpose(s) of the study (what are you hoping to learn as a result of the study)

C. Materials, Methods and Analysis (quantitative and qualitative)

1. Describe data collection methods (Procedures) (be specific):
2. Describe the specific materials or tools that will be used to collect the data (be specific):
3. Describe timeline of the procedures and how long each procedure will last
4. Describe how you will analyze your data (be specific):

D. Research Population & Recruitment Methods:

Describe:

1. Inclusion and Exclusion Criteria (what participant traits are needed to be included, what traits exclude participants?)
2. What is the scientific or scholarly justification for the number, gender, age, or race of the population you intend to recruit?
3. How did you choose the source of participants or data? (census records, BC students, Mass General Hospital records, etc.)
4. Recruitment procedure; including who will recruit participants and, if applicable, how any conflict of interest/coercion/undue influence will be mitigated
5. Tools that will be used to recruit (payment, advertisements and flyers attach copies to this application)
6. Research Incentives and Payments: Please specify what form of payment you will be using and how it will be documented. (Note: participant payment beyond \$600 must be reported to the IRS, and this requirement must be added to the consent form)

E. Informed Consent Procedure:

1. Who will perform the informed consent procedure, and how will that person be trained? *(Note: undergraduates should specify their qualifications and describe how the faculty research supervisor will closely monitor.)*

2. How will the prospective participant's competence or understanding of the procedures be assessed; will participants be asked questions about the procedures, or encouraged to ask questions?

3. Please describe the process by which informed consent will be obtained. *Note: research involving minors requires consent from a parent/legal guardian and assent from the child.*

F. Confidentiality:

Describe the Provisions for participant and data confidentiality:

1. Where will the data be stored, and who will have access to the data and the area? *(Please refer to the [References Tab](#) for the latest BC Research Data Policy.)*

2. How will the data be stored, and in what format *(hard or electronic copy, identifiable or de-identified)*

3. Will you collect the names, email addresses, phone numbers, student ID numbers, and/or any other data elements that individually identify the subjects of the research? Will the participant's identity be coded? Will the codes to identify participants be stored with the data?

4. Will you collect any identifiable information from any organizations or individuals other than the subjects *(or potential subjects) themselves?* *(e.g., a hospital or school)* Yes* No

4.a: If so, please identify such organizations or individuals and, if not widely known, briefly indicate what they do. *(e.g., "XYZ Primary Care, LLC -- This is a physician practice").*

Please note that, depending on the entity (usually some kind of institution) from which you receive identifiable information, you may need to address additional regulatory requirements, such as FERPA with respect to educational institutions and HIPAA with respect to health plans and most health care providers. The IRB staff can help you address such issues.

Please upload the applicable HIPAA forms here

G. Statement of potential research risks to subjects *(e.g. breach of confidentiality, treatment complications)*

1. Indicate the type of risk that may result from participation. Consider psychological or emotional risks, social stigma, change in status or employment, physical risks or harms, information risks-breach of confidentiality and any effect loss of confidentiality may have on status, employment, or insurability. If the protocol involves treatment, what are the risks compared to other treatments in terms of "standard of care"?

2. Consider the likelihood and magnitude of the risks or discomforts occurring? Are they unlikely, or likely to occur and what effect would the discomforts or risks have on the individual should they occur?

3. How will you minimize the risks? Some examples include informed consent, adequate staff training and experience, debriefing, and monitoring adverse effects on participants

H. Statement of potential research benefits to subjects (Please note that compensation/ payments are considered a recruitment tool and should not be listed as a benefit)

1. Indicate the type of benefit that may result from participation. Consider psychological or emotional benefits, learning benefits, physical benefits and discuss if participant will benefit directly or if the benefit is largely to gather generalizable knowledge or provide scientific or social information on a topic that may benefit society. **DO NOT OVERSTATE** the benefit.

2. Consider the likelihood of the benefits. Will all or some participants benefit?

I. Investigator experience. Please attach a current copy of your C.V. unless a current copy is on file. Note: the IRB only needs the C.V. from the PI, not the faculty advisor.

VI. Informed Consent

Are you requesting an alteration or waiver? Yes* No Both - I have a consent form, but will be asking for a waiver for some cases

VII. Research with Minors

Instructions: Please complete this section only if you are using minors in your research. Otherwise, you may proceed to the next section. Research with minors requires either expedited or full board review.

Federal regulations recognize children as vulnerable subjects in research and require that special consideration be given to protecting their welfare. IRBs consider the potential benefits, risks, and discomforts of the research to children as well as their circumstances (e.g. age, health status, ability, etc.) and assess the justification for their inclusion in the research (www.hhs.gov).

Guidance on Remuneration: Minors may receive small gifts of appreciation for participation. Gifts should rarely be cash and should never be contingent upon study completion. Parents and guardians may be compensated for travel or time lost from work.

VIII. Performance Sites:

If you are conducting research at a site, (e.g. hospital, school, organization), the site must provide the BC IRB with evidence that they support the research being conducted at their location. If the site has an IRB, you should consult with that IRB to determine whether they require IRB approval from their institution in addition to IRB approval through BC. If they do not have an IRB, please provide a site permission letter. Site permission letters should be written on the letterhead of the institution and signed by a Principal or Administrator.

- A. Are you conducting research at a site? Yes No
 B. Do they have an IRB? Yes No Will IRB approval be sought from that institution? Yes No
 C. Name of site:

IX. Acknowledgement

SUBMISSION OF A PROPOSAL TO THE BC IRB REQUIRES THAT THE PRINCIPAL INVESTIGATOR (AND MENTOR IF THE PI IS A STUDENT OR FELLOW) SIGN THIS PAGE AND READ COMPLETELY THE DEFINITION OF "SCIENTIFIC MISCONDUCT" AND ANSWER ALL "CONFLICT OF INTEREST" QUESTION GIVEN BELOW.

A. Scientific Misconduct

"Scientific Misconduct" shall be considered to include:

1. Fabrication, falsification, plagiarism or other unaccepted practices in proposing, carrying out or reporting results from research;
2. Material failure to comply with Federal requirements for the protection of human participants, researchers and/or the Public;
3. Failure to meet other material legal requirements governing research;
4. Failure to comply with established standards regarding author names on publications;
5. Failure to adhere to issues of confidentiality as provided in the participant consent form, the study protocol, and as outlined in the Code of Federal Regulations (**45 CFR 46**).

Conflict of Interest

1. Are you or any member of your immediate family (spouse or domestic partner and/or dependent children) an officer, director, partner, trustee, Employee, advisory board member, or agent of (a) the external organization funding this Sponsored Project or (b) any external

organization from which goods and services will be obtained under this Sponsored Project (including those to which you may be subcontracting a portion of the project work), (c) any external organization whose financial condition could benefit from the results of this Sponsored Project, or (d) any external organization having business dealings in an area related to the work under this Sponsored Project?

- Yes (if so, describe in detail the nature and extent of the association on an attached sheet).
- No

2. Publicly-Traded Entities: Have you or any member of your immediate family derived income within the past year of \$5,000 or more in a publicly-traded entity, or in the past year have you or any member of your immediate family owned equity interests in a public-traded interest, the fair market value of the equity being \$5,000 or more?

- Yes (If any of the following pertain, provide a full description on a separate sheet):
- (a) The entity is co-funding this Sponsored Project;
 - (b) The income or equity is related the your university responsibilities (e.g. research, teaching, and service);
 - (c) The entity may provide goods and services under this Sponsored Project (including those to which you may be subcontracting a portion of the project work);
 - (d) The entity's financial condition may benefit from the results of this Sponsored Project; or
 - (e) The entity has business dealings in an area related to the work under this Sponsored Project?

No

3. Non-Publicly Traded (i.e. Privately Held) Entities: Have you or any member of your immediate family derived income within the past year of \$5,000 or more in a non- publicly traded entity, or in the past year have you or any member of your immediate family owned any equity interests in a non-publicly traded entity?

- Yes (If any of the following pertain, provide a full description on a separate sheet):
- (a) The entity is co-funding this Sponsored Project;
 - (b) The income or equity is related the your university responsibilities (e.g. research, teaching, and service);
 - (c) The entity may provide goods and services under this Sponsored Project (including those to which you may be subcontracting a portion of the project work);
 - (d) The entity's financial condition may benefit from the results of this Sponsored Project; or
 - (e) The entity has business dealings in an area related to the work under this Sponsored Project?

No

Research Assistants

SIGNATURE OF PRINCIPAL INVESTIGATOR

The undersigned accept(s) responsibility for the study, including adherence to the ethical guidelines set forth in the Belmont Report, Declaration of Helsinki, the Nuremberg Code, the ethical principles of your discipline, the Common Rule and Boston College policies regarding protection of the rights and welfare of human participants participating in this study. In the case of student protocols, the faculty supervisor and the student share responsibility for adherence to policies.

SIGNATURE OF FACULTY RESEARCH SUPERVISOR- REQUIRED FOR STUDENT RESEARCH

By signing this form, I certify that:

(For ORP use only) BC IRB
Protocol#:



IRB CONTINUING REVIEW FORM

For research previously reviewed by the IRB

**Boston College Institutional Review Board
Office for Research Protections**
140 Commonwealth Ave., Waul House
Chestnut Hill, MA 02467
Phone: (617) 552-4778
Fax: (617) 552-0498
E mail: irb@bc.edu

IRB Protocol Number (assigned at initial review)

I. Study Title:
(If funded must match the previous title in the initial review)

II. Principal Investigator Information

A. Name of Principal Investigator		B. E-mail Address:	
C. Primary Phone Number:		D. Department:	

III. Research Staff (All research staff must have a current training certificate. Training certificates must comply with the IRB s Training Policy. They are valid for three years after which they must be renewed.)

Name and credentials	Research Role	Last Training Date	Training Type (e.g. CITI, NIH)
	Principal Investigator		

III. Study Status:

<input type="checkbox"/> Not Started	<input type="checkbox"/> Actively Recruiting	<input type="checkbox"/> Long Term Follow up	<input type="checkbox"/> Data Analysis Only
No subjects recruited, research has not started	We will be recruiting new subjects and/or private identifiable information exists	No longer recruiting subjects, the only interaction with subjects is long term follow-up	Complete this form only if further interaction with human participants or access to identifiers is needed. Otherwise, use the Project Closure Form to close your study.

IV. General Study Information

A. Funding: Is the Study Funded? Yes No
List Sponsor Name, if Federally funded list Agency, Department and Grant Number:

B. Observations/Findings: Please describe your significant preliminary observations/findings. If there are no significant findings, please summarize what work has been conducted in the last year on the study.

1. Does this information suggest an increased risk to participants? Yes No NA
2. Should this information be added to the consent form? Yes No NA
- C. Additional Information: Since the last protocol approval date is there any new information, either through the study itself, or through outside sources (e.g. journal articles, conferences, communication with colleagues, etc.) that may indicate an increased risk of social, psychological, or physical harm to subjects in this study? Yes* No
- *Please explain:

- D. Complaints: Have you received any complaints about the research? Yes* No
- *Please explain:

- E. Unanticipated Problems: Have there been any unanticipated problems (examples include social, financial, occupational, psychological, physical or other problems that participants may have had as a result of research participation, loss of data, breach of privacy or security)? Yes* No
- *If yes, please explain:

- F. Deaths: Have any subjects enrolled in your study died (either as a result or not)? Yes* No
- *If yes, please explain:

- G. Changes:
1. Are you making any NEW changes at this time: Yes* No

V. Participant Enrollment Information

A. Number of participants currently approved by the IRB:

B. Number of participants who consented to participate:

If the number of participants enrolled (B) exceeds the number approved by the IRB (A) please explain why:

C. Number of participant withdrawals since the initial IRB approval:

Please explain each participant withdrawal (dissatisfaction, relocation, etc.)

Have a greater than expected number of participants withdrawn from the study? Yes* No

*Please revise the informed consent document to include this information

D. Have you asked any participants to withdraw from the study? Yes* No

* How many:

* Why:

E. Current Consent Form: *Please attach a copy of the consent and assent (if applicable) that you are currently using. Kindly note that the consent/assent documents are required regardless of the study status.*

SIGNATURE OF PRINCIPAL INVESTIGATOR

The undersigned accept(s) responsibility for the study, including adherence to the ethical guidelines set forth in the Belmont Report, Declaration of Helsinki, the Nuremberg Code, the ethical principles of your discipline, the Common Rule and Boston College policies regarding protection of the rights and welfare of human participants participating in this study. In the case of student protocols, the faculty supervisor and the student share responsibility for adherence to policies.

SIGNATURE OF FACULTY RESEARCH SUPERVISOR- REQUIRED FOR STUDENT RESEARCH

By signing this form, I certify that:

I have read the protocol, this research will be conducted under my supervision and guidance and I will assume responsibility for overseeing the conduct of this protocol while the student is at Boston College in accordance with Boston College policies.

VI. Informed Consent

Are you requesting an alteration or waiver? Yes* No Both - I have a consent form, but will be asking for a waiver for some cases

A. Standard Elements of Consent

The informed consent document should include all required elements of consent (See BC Consent Guide for informed consent samples <http://www.bc.edu/research/oric/human/irbsampleforms.html>) . Confirm that each element is included in your consent form :

- A statement that the study involves research
- The purpose of the research in lay terms (in language understandable to the participant)
- A statement that they are being asked to participate in research, and how they were selected to participate
- The expected duration of the participant's participation "You will be asked to complete a survey every month for 1 year"
- The total time commitment of participation in the procedures "the survey will take 20 minutes to complete"
- A brief but complete description of all procedures to be followed (if research includes treatment describe which procedures are experimental and alternatives to those procedures)
- The risks or discomforts that are reasonably expected from the research, and a statement that "There may be unknown risks"
- The benefits to the participant or others that are reasonably expected from the research
- A statement of confidentiality that provides the participant a contact at the institution who may be reached if injury occurs or confidentiality is breached (this should be someone other than the researcher)
- A statement that participation is entirely voluntary and may be discontinued at any time
- A statement that withdrawal from participation will not result in denial of entitled benefits
- Invasive biological, clinical or behavioral interventions require specific descriptions of the procedure (Do NOT check this box if your study does not involve invasive biological, clinical, or behavioral interventions)
- The consent form must be signed and dated, or oral consent must be witnessed and signed and dated by the witness
- A statement and check box that indicates the participants have a copy of the informed consent document

Note: Individuals with added protections require both permission of a legal representative and assent of the individual.

B. Consent Waiver/Alteration: In rare circumstances, the IRB may consider altering the informed consent requirements. In order for the IRB to approval a waiver of the informed consent process or a partial waiver of any of the required elements of consent, require that: ([Federal Regulations: 45 CFR 46.116\(d\)\(1-4\)](#))

1. The research involves no more than "minimal risk;"
2. The waiver will not adversely affect the rights and welfare of the research participants;
3. The research could not practicably be carried out without the waiver; and
4. Whenever appropriate, the research participants will be provided with additional pertinent information after participation.

Are you asking for a partial waiver of consent: Yes No

Please indicate which elements you are asking to waive::

- A statement that the study involves research
- The purpose of the research in lay terms (in language understandable to the participant)
- A statement that they are being asked to participate in research, and how they were selected to participate
- The expected duration of the participant's participation "You will be asked to complete a survey every month for 1 year"
- The total time commitment of participation in the procedures "the survey will take 20 minutes to complete"
- A brief but complete description of all procedures to be followed (if research includes treatment describe which procedures are experimental and alternatives to those procedures)
- The risks or discomforts that are reasonably expected from the research, and a statement that "There may be unknown risks"
- The benefits to the participant or others that are reasonably expected from the research
- A statement of confidentiality that provides the participant a contact at the institution who may be reached if injury occurs or confidentiality is breached (this should be someone other than the researcher)
- A statement that participation is entirely voluntary and may be discontinued at any time
- A statement that withdrawal from participation will not result in denial of entitled benefits
- Invasive biological, clinical or behavioral interventions require specific descriptions of the procedure
- The consent form must be signed and dated, or oral consent must be witnessed and signed and dated by the witness
- A statement and check box that indicates the participants have a copy of the informed consent document

Note: Individuals with added protections require both permission of a legal representative and assent of the individual.

Are you asking for a total waiver of consent: Yes No

Are you asking for a waiver of the documentation of consent Yes No

Are you asking for a waiver of the documentation of consent to waive the requirement for signature and name because this study will be conducted online: Yes No

Please describe what elements of consent you wish to waive and provide a strong rationale for this alteration/waiver.

C. The PI is responsible for ensuring that the consent form is written at a reading level that is appropriate to the population being studied. The comprehension level of the consent document must be verified by choosing one of the three readability tools below. Mark which tool you used to check the readability level of the consent form and insert the readability comprehension level (**the grade level, 8.0,8.1, not the larger number**) in the box below:

<http://www.readability-score.com/>

http://www.online-utility.org/english/readability_test_and_improve.jsp

Microsoft Word Readability Statistics

Insert Readability Comprehension Level

VII. Research with Minors

Instructions: Please complete this section only if you are using minors in your research. Otherwise, you may proceed to the next section. Research with minors requires either expedited or full board review.

Federal regulations recognize children as vulnerable subjects in research and require that special consideration be given to protecting their welfare. IRBs consider the potential benefits, risks, and discomforts of the research to children as well as their circumstances (**e.g. age, health status, ability, etc.**) and assess the justification for their inclusion in the research (www.hhs.gov).

Please provide a scientific or medical rationale for the inclusion of minors:

Federal regulations classify research with minors into four categories based on the degree of risk. Please pick the appropriate category for your research.

Category 1 (**45 CFR 46.404**): Research involving minimal risk to minors

Category 2 (**45 CFR 46.405**): Research involving greater than minimal risk to minors with the prospect of direct benefit to the child:

Category 3 (**45 CFR 46.406**): Research involving greater than minimal risk with no direct benefit to the minors but it is likely to yield generalizable knowledge about the subject's disorder or condition

Category 4 (**45 CFR 46.407**): Research not meeting the criteria for Categories 1-3 that involves greater than minimal risk to healthy minors and presents no direct benefit to them but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare. **Please note: this fourth category of research with minors requires a special level of DHHS review after BC IRB review.**

Guidance on Remuneration: Minors may receive small gifts of appreciation for participation. Gifts should rarely be cash and should never be contingent upon study completion. Parents and guardians may be compensated for travel or time lost from work.



IRB AMENDMENT FORM

**Boston College Institutional Review Board
Office for Research Protections**
140 Commonwealth Ave., Waul House
Chestnut Hill, MA 02467
(617) 552-4778 Fax: (617) 552-0498 E mail: irb@bc.edu

IRB Protocol Number (assigned at initial review)

I. General Information

Instructions Investigators who wish to make any revisions to their original approved protocols (**exempt, expedited or full board approvals**) must seek IRB review and obtain approval before initiating changes. Attach changed research documents or any supportive materials (**such as subject recruitment advertising, questionnaires, surveys, results from related studies, etc**) to this form. You will be notified of IRB review results.

A. Study Title:

B. Principal Investigator:

C. Date:

D. Contact Email:

E. Mailing Address:

F. Phone:

G. Original Level of IRB Review: Exempt Expedited Full Board

H. Research Status (**Check one; provide # of subjects as requested**):

- Currently in progress (**subjects being recruited**)
- Project not yet started (**no subjects recruited**)
- Closed to new subject entry (**long term follow-up only**)

II. Describe Changes

- Application
- Research Summary
- Consent Form
- Recruitment
- Instruments (**measures, scales, questions, etc.**)
- Add Research Staff
- Add Recruitment Site
- Other

III. Amendments

A. Please provide a detailed summary of the changes you are making to the original approved protocol and state your rationale for these changes. Attach a copy of revised documents with specific changes in bold. If you are adding research staff, include name, date of IRB training and copy of certificates.


B. Does this revision/ amendment revise or add a genetic component? Yes No

C. Does the change affect subject participation (e.g. procedures, risks, costs, etc)? Yes No NA

D. Does the change affect the consent document? Yes No NA

SIGNATURE OF PRINCIPAL INVESTIGATOR
The undersigned accept(s) responsibility for the study, including adherence to the ethical guidelines set forth in the Belmont Report, Declaration of Helsinki, the Nuremberg Code, the ethical principles of your discipline, the Common Rule and Boston College policies regarding protection of the rights and welfare of human participants participating in this study. In the case of student protocols, the faculty supervisor and the student share responsibility for adherence to policies.
SIGNATURE OF FACULTY RESEARCH SUPERVISOR- REQUIRED FOR STUDENT RESEARCH
By signing this form, I certify that:

(For ORP use only) BC IRB
Protocol#:

 <p>BOSTON COLLEGE</p> <p>IRB Adverse Event Form</p>	<p>Boston College Institutional Review Board Office for Research Protections 140 Commonwealth Ave., Waul House Chestnut Hill, MA 02467 (617) 552-4778 Fax: (617) 552-0498 E mail: irb@bc.edu</p>
---	---

Instructions: All adverse events of physical or psychological harm or injuries, complaints, threats to privacy or safety or unexpected attrition of human subjects or data collected without IRB approval must be communicated to the Office for Research Protections within 10 days of the adverse event (if at BC) or within 10 days of notification for events at other sites. Submit reports of all fatal or lifethreatening events to the ORP within 24 hours of the event (if at BC) or within 24 hours of receiving notification for events at other sites. All unanticipated adverse events that include human research subjects in federally sponsored research will be reported to the Department of Health and Human Services, Office of Human Subjects Protections as well as any federal agency or sponsor that provides funding for the research study. Adverse events in non-federally funded or unfunded research will be reported to the Vice Provost for Research, and the IRB.

Please attach supporting documents, and a copy of the current informed consent form. For expected events, please highlight the section of the consent form that lists the event. If you wish to change the informed consent form, please submit it with a Protocol Amendment Form, with the changes highlighted. Federal regulations (45 CFR 46.117(a)) requires IRB approval for informed consent form alteration.

1. Investigator Information

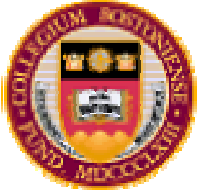
A. Name of Principal Investigator			B. Date:	
C. Address:		D. Department:	E. Protocol Number:	
F. E-mail address:		G. Phone:	H. Alternate Phone:	
I. Study Title: (If funded must match the sponsored title)				

2. Description of the Event

<p>Check one:</p> <p><input type="checkbox"/> Initial report</p> <p><input type="checkbox"/> Follow-up report Please black out all identifying information about the subject from all pages</p>
--

3. Location of the Adverse Event:	
4. Date(s) of the Adverse Event:	
5. Brief Summary of the Event: (be specific)	
6. Estimated Severity of the Event?	<input type="checkbox"/> Insignificant (likely that no participants were harmed) <input type="checkbox"/> Moderate (enough discomfort to interfere with usual activity) <input type="checkbox"/> Severe (incapacitated the subject; hospitalization) <input type="checkbox"/> Fatal
7. In your judgment, was the event caused by procedures associated with this protocol?	<input type="checkbox"/> Not Related <input type="checkbox"/> Possibly Related <input type="checkbox"/> Probably Related <input type="checkbox"/> Definitely Related
8. Was this event anticipated in the initial protocol?	<input type="radio"/> Yes <input type="radio"/> No
9. Should the informed consent process any part of the protocol be modified as a result of this event?	<input type="radio"/> Yes <input type="radio"/> No * Please explain:

SIGNATURE OF PRINCIPAL INVESTIGATOR
The undersigned accept(s) responsibility for the study, including adherence to the ethical guidelines set forth in the Belmont Report, Declaration of Helsinki, the Nuremberg Code, the ethical principles of your discipline, the Common Rule and Boston College policies regarding protection of the rights and welfare of human participants participating in this study. In the case of student protocols, the faculty supervisor and the student share responsibility for adherence to policies.
SIGNATURE OF FACULTY RESEARCH SUPERVISOR- REQUIRED FOR STUDENT RESEARCH
By signing this form, I certify that:



Boston College Institutional Review Board
 Office for Research Protections
 140 Commonwealth Avenue | Waul House
 Chestnut Hill, MA 02467
 (Tel) 617-552-4778 (Fax) 617-552-0498

IRB PROJECT CLOSURE FORM

Instructions and Information: When approved human subject's research has concluded, the IRB protocol should be closed. Closure of a protocol means that there will be no further interaction with human subjects, no long-term follow-up will be conducted, and no access to personally identifying information will be needed.

Principal Investigator

I. Study Title:
 (If funded must match the sponsored title)

Protocol Number:

Faculty Advisor (if applicable):

Sponsor:

	Sponsor Award Number:

Section I: The following three criteria must be met in order to close a protocol. By checking the boxes below, you agree to the following statements:

<input type="checkbox"/>	No further interaction with human participants will occur.
<input type="checkbox"/>	No long term follow up will be needed.
<input type="checkbox"/>	No access to personally identifying information will be needed.

Section II: Reason for study closure:

<input type="checkbox"/>	Data analysis is complete.
<input type="checkbox"/>	PI is moving to another institution.
<input type="checkbox"/>	Lack of enrollment.
<input type="checkbox"/>	There is no more funding, time or personnel to conduct the study.

<input type="checkbox"/>	Other:
--------------------------	--------

Section III: What will be done with the data:

<input type="checkbox"/>	Data will be stored at BC per BC policy and sponsor requirements.
<input type="checkbox"/>	Copies of data will be taken with PI to new institution.
<input type="checkbox"/>	Required: Informed consent documents (if applicable) will be kept for three years beyond the conclusion of the research.
<input type="checkbox"/>	Other

SIGNATURE OF PRINCIPAL INVESTIGATOR
By signing this form, the undersigned acknowledges that any further interaction with the participants in this study or personally identifying information has not been approved by the Boston College IRB.
SIGNATURE OF FACULTY RESEARCH SUPERVISOR- REQUIRED FOR STUDENT RESEARCH
By signing this form, I certify that:

Appendix 2

A. Federal Regulations

Codification of the Federal Policy for each of the departments and agencies adopting it is as follows:

Department of Health and Human Services

45 CFR Part 46

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>**Consumer**

B. Family Educational Rights and Privacy Act (FERPA)

20 USC § 1232g; 34 CFR §§ 99.1 – 99.67

<https://www2.ed.gov/legislation/FedRegister/finrule/2004-2/042104a.html>

Conditions the availability of federal funding to any educational agencies or institutions upon adherence on the policies and procedures outlined regarding the protection of privacy of parents and students. An educational institution must follow the Department of Education regulations pertaining to inspection and review of education records; specific Information that must be made available; procedures for access to education records; reasonableness of time for such access; hearings; and written explanations by parents. The regulations under FERPA control the use, dissemination, and protection of any data gathered In connection with any surveys or research activities. A prior written consent is required by the parent or eligible student before an educational agency or institution discloses personally identifiable information from the student's education record.

C. Student Rights in Research, Experimental Programs, and Testing (Hatch Act)

20 USC § 1232h; 34 CFR §§ 98.1 – 98.10

<https://www.ecfr.gov/cgi-bin/text-idx?SID=393301a7cdccca1ea71f18aae51824e7&node=34:1.1.1.1.32&rgn=div5>

Mandates that a parent or legal guardian shall have the right to inspect all materials that will be used in connection with any survey, analysis, or evaluation of his/her child. Outlines the limits, mandating that no student shall be required to submit to such a survey, analysis, or evaluation that reveals private information (as listed in the statute) without the prior consent of the student (if the student is an adult), or without prior written consent of the parent.

D. Protection of Pupil Rights Amendment (PPRA)

20 U.S.C. § 1232h; 34 CFR Part 98

<https://www2.ed.gov/policy/gen/guid/fpco/ppra/index.html>

The Protection of Pupil Rights Amendment (PPRA) (20 U.S.C. § 1232h; 34 CFR Part 98) applies to programs that receive funding from the U.S. Department of Education (ED). PPRA is intended to protect the rights of parents and students in two ways:

- It seeks to ensure that schools and contractors make instructional materials available for inspection by parents if those materials will be used in connection with an ED-funded survey, analysis, or evaluation in which their children participate; and
- It seeks to ensure that schools and contractors obtain written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation that reveals information concerning:
 1. Political affiliations;
 2. Mental and psychological problems potentially embarrassing to the student and his/her family;
 3. Sex behavior and attitudes;
 4. Illegal, anti-social, self-incriminating and demeaning behavior;
 5. Critical appraisals of other individuals with whom respondents have close family relationships;
 6. Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers; or
 7. Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

E. HIPAA

The Health Insurance Portability and Accountability Act (HIPAA) (<http://www.hhs.gov/ocr/hipaa/>) is the federal legislation that governs all uses and disclosures of Protected Health Information (PHI), for both the living and the dead, in order to protect individual privacy. Notably, HIPAA prohibits covered entities from using or disclosing persons' individually identifiable health information for purposes of research unless the covered entities satisfy certain requirements and conditions. Boston College does not meet the criteria for being a covered entity under HIPAA. This means that Boston College does not have a regulatory obligation to comply with HIPAA. Regardless, Boston College has an ethical obligation to safeguard all information collected concerning research subjects, especially information generally regarded as private, such as health information. Additionally, if a researcher is planning to do research with a HIPAA covered entity, such as a hospital or health care plan, he or she likely will have to abide by HIPAA regulations in order to satisfy the covered entity's requirements.

Appendix 3



Boston College
Office for Research Protections

Human Participant Research Training Policy

Appropriate training is required for all research personnel who participate in the conduct of human participant research. In the past, a variety of training programs were accepted to satisfy this requirement. In order to achieve consistency in training quality and continuity, this policy applies to human participant research performed by research personnel on projects approved by the Boston College IRB. For the purpose of this policy, the term “research personnel” includes anyone (e.g., faculty, post-docs, students, research staff) who is engaged in the conduct of research. It also includes faculty advisors on student research protocols.

1. . Effective July 1, 2008, unless an exception in Point 2 below applies the CITI training program (<http://www.citiprogram.org/default.asp?language=english>) or the National Institutes of Health training program, (<http://phrp.nihtraining.com/users/login.php>) will be the only training program that is considered to satisfy the training requirement for human participant research conducted by research personnel on projects approved by the Boston College IRB. The only modules in the CITI training program that meet the requirement are the Biomedical and Social/Behavioral module. The Responsible Conduct of Research (RCR) module *does not* satisfy this requirement. **Please note that the NIH will no longer offer its online training program as of September 27, 2018. We will still accept certificates from the program that are less than 3 years old, but all future training must be through the CITI Program.**
2. Other training certificates will be accepted under the following conditions:
 - a. If a research personnel have recently joined the Boston College community and has a training certificate awarded by an institution having an active Federal-Wide Assurance, or a training certificate issued by the National Cancer Institute (NCI), dated no more than two years prior to the submission of an IRB application; or
 - b. If Boston College research personnel have an NCI training certificate with a recorded date falling between September 1, 2006 through June 30, 2008; or

- c. If a researcher located at another institution participates on a project approved by the Boston College IRB, and has a training certificate from his/her institution or NIH, and the certificate is regarded as active by his/her institution.
3. The CITI, NIH, or any other accepted training certificates will be regarded as being active for three years from the date of recorded on the certificate.
4. At the expiration of the CITI or NIH training certificate (i.e., three years from the recorded date on the certificate), research personnel are required to take the CITI Refresher Course in order for an IRB application to be approved.
5. Notwithstanding the foregoing, the Boston College IRB, at its sole discretion, may require that researchers complete specific training. This may include, but is not limited to, high-risk research projects.
6. Exception to this policy: Those researchers who are working solely with de-identified data sets *and* are not conducting research using federal funding are exempt from this training policy.

Appendix 4

BC IRB Review Criteria

The BC IRB must determine that the following requirements are satisfied before it approves research:

1. Risks to participants are minimized by:
 - a. using procedures which are consistent with sound research design;
 - b. using procedures that do not expose participants to excessive, unreasonable and/or unacceptable risks;
 - c. whenever appropriate, using procedures already being performed on the participants for diagnostic or treatment purposes.
2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants; and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the BC IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies, care, or interaction with the researcher that participants would receive even if not participating in the research). The BC 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.
3. Selection of participants is equitable, taking into account the purposes of the research and the setting in which the research will be conducted. The BC IRB must determine that necessary additional safeguards have been included to protect the rights and welfare of vulnerable participants, if all or some of the participants are children, prisoners, pregnant women, students, handicapped or mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective participant or the participant's legally authorized representative (as defined in the laws/regulations of the legal jurisdiction in which the research takes place) unless modified or waived by the BC IRB.
5. Informed consent will be appropriately documented or the IRB may waive the requirement for documentation.
6. There are adequate provisions in the research plan, where appropriate, for monitoring the data collected to ensure the safety of participants.
7. There are adequate provisions to protect privacy of participants and to maintain the confidentiality and physical security of data, where appropriate.
8. There are appropriate additional safeguards included in the study to protect the rights and welfare of participants who are likely to be vulnerable to coercion or undue

influence e.g., children, prisoners, students, individuals with impaired decision-making abilities, persons with acute or severe physical or mental illness, persons who are economically or educationally disadvantaged, or persons who are vulnerable because they are institutionalized.

BC IRB Members follow the criteria listed above in reviewing research through expedited and full Committee procedures. These criteria are included in a Reviewer Checklist used by BC IRB Members in reviewing BC IRB protocols.