# BOSTON COLLEGE

Policy for the Protection of Human Research Participants

Approved by the IRB 10/15/08
Revisions 03/27/09, 1/8/10,3/22/10, 7/18/11, 8/31/18, 1/6/26

**Table of Contents**

## 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 determined by the IRB to observe the consent process or any aspect of the research.

All human subjects research conducted under the University's jurisdiction is subject to quality assurance (QA) Monitoring. The QA program is designed as a proactive, collaborative, and educational process that supports researchers in maintaining compliance and promotes high-quality research practices through routine (not-for-cause) and directed (for-cause) monitoring.

**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 participants in research.

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

The BC IRB requires that Department Chairpersons are notified of each protocol application that is submitted to the BC IRB for review indicating that scientific review has occurred. Emails are automatically sent via InfoEd to department chairs for all faculty research.

### 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. This review and approval is completed electronically through InfoEd. The faculty advisor's signature indicates that they have 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. In the InfoEd IRB module, the first person listed as the PI will be the primary contact person for all IRB communications. The Principal Investigator has ultimate responsibility for their 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. 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. ORP makes determinations regarding whether BC is engaged in the research per federal definitions, when considering these collaborative agreements. Please see this link for information on "engagement" in research, and this webpage for more information on collaborations with other institutions.

### 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 3-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 researchers may discuss any questions or concerns regarding the BC IRB review process with the IRB Chair.

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 reports 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 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. Deans may request that nominees from their schools serve shorter or longer terms.

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 their own protocols being reviewed by the full BC IRB (either for initial review or continuing review), that person must recuse themself 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 their 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 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, as well as an overview of the InfoEd IRB module.

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. The community representative on the committee, who is not an employee of BC, is 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 is 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, 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.

Director, ORP

The ORP 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**

**General Information**

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

Submission Type *
Initial Application
- Legacy Protocol

If this box is checked, you are submitting an amendment or continuing review for a protocol that was initially submitted and approved under the previous IRB platform (CyberIRB). In such cases, the user will not need to update the protocol eform in InfoEd.

**Application Type**

- Research: This means you are submitting a new human research protocol for review by BC's IRB, and no external institutions would regard BC's IRB as their IRB of record for the protocol (most applications fall into this category).
- Collaborative Research/Internal Review: This means you are collaborating with another institution(s) and propose that BC's IRB would serve as the IRB of record for not only BC but also for the other institution(s).
- Collaborative Research/External Review: This means you are collaborating with an external institution and propose that BC cede review to the IRB of the external institution.
- Non-human Subjects Research Determination: To be used if you believe your study does not meet the definition of "research" involving "human subjects," and you request that ORP confirm your belief. *
- Research Collaborative Research/Internal Review Collaborative Research/External Review Non-human Subjects Research Determination

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

Is this project a Clinical Trial? *

Yes No

General Study Information

A. Do you have funding? *
Yes No

B. Participant Recruitment Numbers: This number must be the maximum number you intend to recruit - it can be an estimate. You will not be allowed to recruit more than this number without first coming back to the IRB to seek approval.
Total # of participants:

Do you plan to include a larger proportion of one gender group, or omit any gender groups?
Yes No

Are you conducting your research in an international research setting? *

Yes No

C. Participant Ages (please check)
- 0-7 (parental consent and oral child assent)
- 8-11 (parental consent and child written consent)
- 12-17 (parental consent and child written consent)
- 18-65
- 65+

D. Estimated Project Duration

Start Date:
End Date:

E. Why is this Project being conducted? (please check) *
Faculty Research/Staff Research/Undergraduate Coursework/Master's Thesis/Doctoral Dissertation/Other

F. Will This Study Involve Long-Term Follow-Up with participants:
Yes No

G. Special Study Populations *
- Minors (under 18 years)
- Pregnant Women/Fetuses or products of labor & delivery
- Prisoners
- Physically or mentally challenged
- Diminished capacity for consent
- Other
- No Special Study Populations

H. Does this study involve any of the following? *
- Deception or Punishment
- Use of drugs
- Covert observation
- Induction of mental and/or physical stress
- Procedures which may risk physical/mental harm to the participant
- Materials/issues commonly regarded as socially unacceptable
- Information relating to sexual attitudes, sexual orientation or practices
- Information relating to the use of alcohol, drugs or other addictive products
- Procedures that might be regarded as an invasion of privacy
- Information pertaining to illegal conduct
- Genetic information that may be linked to a participant's health status, such as genetic markers for cancer, heart disease, etc.
- Information normally 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.
- Information that if released could reasonably damage an individual's financial standing, employability, or reputation within the community.
- None of the above Procedures

BC Personnel
Name
Email
Department
Username
Title

End Date

Role
Faculty AdvisorPIStaffFacultyResearch AssistantCo-IProtocol Administrator

Certifications

Certification Begin End
- - -

This person is a:
Faculty member/Staff member/Graduate student/Undergraduate student/Other

Non-BC Personnel
To enter Non-BC Personnel, click the “Add” button. Type the person’s name, role, and upload their training certificate.

Investigators
Add

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”. Hover over the question mark icons for helpful tips to complete that section.

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. List and describe all study procedures. For studies involving multiple steps, please present the steps sequentially or chronologically, and indicate when, where and how the step would be performed. For studies involving multiple categories of subjects, indicate the category of subject relevant to each step. *

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:

Please describe the population you plan to recruit.

1. Inclusion and Exclusion Criteria (what participant traits are needed to be included, what traits exclude participants?)
a. Please briefly describe in general terms the nature of the population of people you would like to have participate in this study.
b. Please list all inclusion criteria.
c. Please list all exclusion criteria (examples: upper and lower age limits, decision making capacity, medical conditions, neuropsychiatric conditions, etc.)
*

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). See the BC participant payment policy here. *

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 our Research Data Policy for data storage options). *

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

3. Will the study entail the collection, storage or access of any of the following individually identifying data elements? Check all that apply and indicate how each would be stored in relation to the data.

- First name
- Last name
- Mailing address
- Email address
- Phone number
- Month, day, year of birth
- Month and year of birth only
- Year of birth (or age in years)
- Social security number
- Medical record number
- IP address

Biometric identifiers

Full face photo or video image

Other

4. Will you collect any individually identifiable information from third parties (organizations or individuals other than the subjects themselves)?

Yes No

5. With respect to each category of information below, please indicate whether the study would collect, use, or access any of the information:

Educational Records (including FERPA-covered data)

Yes No

Medical Information (including data obtained from HIPAA-covered entities)

Yes No

Immigration Status

Yes No

Criminal background/record

Yes No

Unlawful Behavior

Yes No

History of Substance Abuse

Yes No

Current Substance Abuse

Yes No

Domestic Abuse

Yes No

Child Abuse

Yes No

Employment Records

Yes No

6. Please address whether the research plan would entail disclosing subjects' individually identifiable research information to any persons who are not Boston College faculty members, staff members or students or to any institutions or other organizations not owned or operated by Boston College. If so, please identify all such persons and entities. *

7. Please present your plan for disposition of (a) individually identifiable data and (b) coded, individual-level data (i.e., data in which actual identifiers have been replaced with a coded identifier. With respect to the latter, it may be acceptable simply to destroy the cross-reference mechanisms linking actual and coded identifiers.

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"? Please consider any populations who may be particularly vulnerable and may be triggered by this research topic and the risks they may face. Please check section IV.H. to ensure that you have considered how sensitive topics might lead to risks for some populations. *

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?

Informed Consent
Waiver of Written Documentation of Informed Consent:

The default is for participants to sign a written document that contains all the elements of informed consent. Under limited circumstances, the requirement for a signed consent form may be waived by the IRB. For example, this might occur for phone or internet surveys, when a signed consent form is either impractical or unnecessary, or in circumstances where a signed consent form creates a risk for the participant.

Full or Partial Waiver of Consent:

- The standard is for participants to give informed consent.
- There are times in which the consent form can be waived in full (not just the waiver of signature) or waived in part.
- A waiver may be requested for research involving only existing data or human biological specimens.
- More rarely, it may be requested when the research design requires withholding some study details at the outset (e.g., behavioral research involving deception).
- In limited circumstances, parental permission may be waived. •

1. Please select all that apply. *

- Waiver of documentation of consent
- Full or partial waiver of consent
- None of the above

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 on the Attachments page. Site permission letters should be written on the letterhead of the institution and physically or electronically signed by an administrator (email does not suffice except for extenuating circumstances).

A. Are you conducting research at a site? *

Yes No

Collaborating Institutions

Collaboration with Researchers Affiliated with other Institutions

A. Would the proposed protocol entail a collaborative project involving not only Boston College faculty, students or staff as researchers but also the personnel of one or more institutions or entities external to BC? *

Yes No

Attachments

Please click the "Add" button to upload all supplemental materials under the appropriate section. Under "Document Name" in each section, please clearly label the type of document (ex. Child Assent, Interview Questions, Survey, etc.). IMPORTANT NOTE: ALL ATTACHMENTS MUST BE UPLOADED AS PDFs. We cannot accept Word documents.

Recruitment Materials

Add

Consent Forms

Add

Show list of requirements for what should be in a consent form

Instruments (surveys, interviews, etc.)

Add

If obtaining information from the third party requires the use of documentation such as authorizations for the release of medical information (e.g., HIPAA forms), educational records (e.g., FERPA forms) or the like, please upload such forms here.

Add

External IRB Approvals

Add

Other

Add

Data Management and Sharing Plan

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:

- Fabrication, falsification, plagiarism or other unaccepted practices in proposing, carrying out or reporting results from research;
- Material failure to comply with Federal requirements for the protection of human participants, researchers and/or the Public;
- Failure to meet other material legal requirements governing research;
- Failure to comply with established standards regarding author names on publications;
- 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 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 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 No

**2. IRB Continuing Review Form**

Study Status:

A. Recruitment/Enrollment Status (check one, and only one, of the following):
The researchers have not started recruitment.
The researchers have started recruitment, but have not enrolled any subjects.
The protocol has enrolled one or more subjects and continues to recruit additional subjects.
The protocol has enrolled one or more subjects, but the protocol is closed to new enrollment.

B. Data Collection and Use (check one, and only one, of the following):

Data collection has not yet begun.

Data collection has begun and is not complete.

Data collection is complete, but the researcher(s) will continue to (a) interact with subjects for purposes related to this research protocol (e.g., to effect agreed-upon payment or other reasons specified in the approved protocol) or (b) analyze or otherwise work with subjects' individually identifiable research information.

Data collection is complete, and the researchers will neither (a) interact further with any subjects NOR (b) analyze or otherwise work with subjects' individually identifiable research information.

General Study Information

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 the information suggest an increased risk to participants?
Yes No N/A

2. Should the information be added to the consent form?
Yes No N/A

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

D. Complaints: Have you received any complaints about the research?
Yes No

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 result of research participation, loss of data, breach of privacy or security)?
Yes No

F. Deaths: Have any subjects enrolled in your study died (either as a result or not)?
Yes No

G. Changes: Are you making any NEW changes at this time?
Yes No

Participant Consent Information

A. Number of participants currently approved by the IRB:

B. Number of Participants Consented

1. Number of participants consented since protocol first received IRB approval:

2. Number of participants consented since last continuing review:

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

C. Participant Withdrawals.

1. Number of participant withdrawals since protocol first received IRB approval:

2. Number of participant withdrawals since last continuing review:

Please explain each participant withdrawal (dissatisfaction, relocation, etc.) since the last continuing review.

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

Study Title:
(If funded must match the sponsored title) *
Submission Type *
Continuing Review
Legacy Protocol
If this box is checked, you are submitting an amendment or continuing review for a protocol that was initially submitted and approved under the previous IRB platform (CyberIRB). In such cases, the user will not need to update the protocol eform in InfoEd.

Application Type

- Research: This means you are submitting a new human research protocol for review by BC's IRB, and no external institutions would regard BC's IRB as their IRB of record for the protocol (most applications fall into this category).
- Collaborative Research/Internal Review: This means you are collaborating with another institution(s) and propose that BC's IRB would serve as the IRB of record for not only BC but also for the other institution(s).
- Collaborative Research/External Review: This means you are collaborating with an external institution and propose that BC cede review to the IRB of the external institution.
- Non-human Subjects Research Determination: To be used if you believe your study does not meet the definition of "research" involving "human subjects," and you request that ORP confirm your belief. *
- Research Collaborative Research/Internal Review Collaborative Research/External Review Non-human Subjects Research DeterminationResearch

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 category descriptions here
Expedited category descriptions here *

Exempt Expedited Full Board Exempt

Exempt Category Number(s)
- 1 - Data collected in educational settings
- 2 - Research that only includes educational tests, surveys, interviews, observation of public behavior
- 3 - Benign behavioral interventions
- 4 - Secondary data analysis
- 5 - Public benefit/service program research
- 6 - Taste and food quality

Is this project a Clinical Trial? *

Yes No

General Study Information

A. Do you have funding? *
Yes No

B. Participant Recruitment Numbers: This number must be the maximum number you intend to recruit - it can be an estimate. You will not be allowed to recruit more than this number without first coming back to the IRB to seek approval.
Total # of participants:

Do you plan to include a larger proportion of one gender group, or omit any gender groups?
Yes No

Are you conducting your research in an international research setting? *

Yes No

C. Participant Ages (please check)

- 0-7 (parental consent and oral child assent)
- 8-11 (parental consent and child written consent)
- 12-17 (parental consent and child written consent)
- 18-65
- 65+

D. Estimated Project Duration

Start Date:
End Date:

E. Why is this Project being conducted? (please check) *
Faculty ResearchStaff ResearchUndergraduate CourseworkMaster's ThesisDoctoral DissertationOtherFaculty Research

F. Will This Study Involve Long-Term Follow-Up with participants:
Yes No

G. Special Study Populations *

- Minors (under 18 years)
- Pregnant Women/Fetuses or products of labor & delivery
- Prisoners
- Physically or mentally challenged
- Diminished capacity for consent
- Other
- No Special Study Populations

H. Does this study involve any of the following? *

- Deception or Punishment
- Use of drugs
- Covert observation
- Induction of mental and/or physical stress
- Procedures which may risk physical/mental harm to the participant
- Materials/issues commonly regarded as socially unacceptable
- Information relating to sexual attitudes, sexual orientation or practices
- Information relating to the use of alcohol, drugs or other addictive products
- Procedures that might be regarded as an invasion of privacy
- Information pertaining to illegal conduct
- Genetic information that may be linked to a participant's health status, such as genetic markers for cancer, heart disease, etc.
- Information normally 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.

- Information that if released could reasonably damage an individual's financial standing, employability, or reputation within the community.
- None of the above Procedures

BC Personnel
Add Personnel
Name
Email
Department
Username
Title
End Date
Role
Faculty Advisor/PI/Staff/Faculty/Research Assistant/Co-I/Protocol Administrator
Certifications
Certification Begin End
Alternate Phone
CV
Additional CITI Training Documentation

This person is a
Faculty member/Staff member/Graduate student/Undergraduate student/Other

Non-BC Personnel
To enter Non-BC Personnel, click the “Add” button. Type the person’s name, role, and upload their training certificate.

Investigators

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”. Hover over the question mark icons for helpful tips to complete that section.

A. Introduction and Background:

1. State the problem and hypothesis *
n/a

2. Provide the scientific or scholarly reason for this study and background on the topic *
n/a

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) *
n/a

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

1. List and describe all study procedures. For studies involving multiple steps, please present the steps sequentially or chronologically, and indicate when, where and how the step would be performed. For studies involving multiple categories of subjects, indicate the category of subject relevant to each step. *
n/a

2. Describe the specific materials or tools that will be used to collect the data (be specific): *
n/a

3. Describe timeline of the procedures and how long each procedure will last *
n/a

4. Describe how you will analyze your data (be specific): *
n/a

D. Research Population & Recruitment Methods:

Please describe the population you plan to recruit.

1. Inclusion and Exclusion Criteria (what participant traits are needed to be included, what traits exclude participants?)
a. Please briefly describe in general terms the nature of the population of people you would like to have participate in this study.
b. Please list all inclusion criteria.
c. Please list all exclusion criteria (examples: upper and lower age limits, decision making capacity, medical conditions, neuropsychiatric conditions, etc.)
*
n/a

2. What is the scientific or scholarly justification for the number, gender, age, or race of the population you intend to recruit?
n/a

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 *
n/a

5. Tools that will be used to recruit (payment, advertisements and flyers attach copies to this application) *
n/a

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). See the BC participant payment policy here. *

n/a

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.) *
n/a

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? *
n/a

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. *
n/a

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 our Research Data Policy for data storage options). *

n/a

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

3. Will the study entail the collection, storage or access of any of the following individually identifying data elements? Check all that apply and indicate how each would be stored in relation to the data.

First name

Last name

Mailing address

Email address

Phone number

Month, day, year of birth

Month and year of birth only

Year of birth (or age in years)

Social security number

Medical record number

IP address

Biometric identifiers

Full face photo or video image

Other

4. Will you collect any individually identifiable information from third parties (organizations or individuals other than the subjects themselves)?

Yes No

5. With respect to each category of information below, please indicate whether the study would collect, use, or access any of the information:

Educational Records (including FERPA-covered data)

Yes No

Medical Information (including data obtained from HIPAA-covered entities)

Yes No

Immigration Status

Yes No

Criminal background/record

Yes No

Unlawful Behavior

Yes No

History of Substance Abuse
Yes No

Current Substance Abuse
Yes No

Domestic Abuse
Yes No

Child Abuse
Yes No

Employment Records
Yes No

6. Please address whether the research plan would entail disclosing subjects' individually identifiable research information to any persons who are not Boston College faculty members, staff members or students or to any institutions or other organizations not owned or operated by Boston College. If so, please identify all such persons and entities. *
n/a

7. Please present your plan for disposition of (a) individually identifiable data and (b) coded, individual-level data (i.e., data in which actual identifiers have been replaced with a coded identifier. With respect to the latter, it may be acceptable simply to destroy the cross-reference mechanisms linking actual and coded identifiers.

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"? Please consider any populations who may be particularly vulnerable and may be triggered by this research topic and the risks they may face. Please check section IV.H. to ensure that you have considered how sensitive topics might lead to risks for some populations. *
n/a

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? *
n/a

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

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. *
n/a

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

Informed Consent
Waiver of Written Documentation of Informed Consent:

The default is for participants to sign a written document that contains all the elements of informed consent. Under limited circumstances, the requirement for a signed consent form may be waived by the IRB. For example, this might occur for phone or internet surveys, when a signed consent form is either impractical or unnecessary, or in circumstances where a signed consent form creates a risk for the participant.

Full or Partial Waiver of Consent:
- The standard is for participants to give informed consent.
- There are times in which the consent form can be waived in full (not just the waiver of signature) or waived in part.
- A waiver may be requested for research involving only existing data or human biological specimens.
- More rarely, it may be requested when the research design requires withholding some study details at the outset (e.g., behavioral research involving deception).
- In limited circumstances, parental permission may be waived. •

1. Please select all that apply. *
- Waiver of documentation of consent
- Full or partial waiver of consent
- None of the above

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 on the Attachments page. Site permission letters should be written on the letterhead of the institution and physically or electronically signed by an administrator (email does not suffice except for extenuating circumstances).

A. Are you conducting research at a site? *
Yes No

Collaborating Institutions

Collaboration with Researchers Affiliated with other Institutions

A. Would the proposed protocol entail a collaborative project involving not only Boston College faculty, students or staff as researchers but also the personnel of one or more institutions or entities external to BC? *

Yes No

Attachments

Please click the "Add" button to upload all supplemental materials under the appropriate section. Under "Document Name" in each section, please clearly label the type of document (ex. Child Assent, Interview Questions, Survey, etc.). IMPORTANT NOTE: ALL ATTACHMENTS MUST BE UPLOADED AS PDFs. We cannot accept Word documents.

Recruitment Materials

Consent Forms

Show list of requirements for what should be in a consent form

Instruments (surveys, interviews, etc.)

If obtaining information from the third party requires the use of documentation such as authorizations for the release of medical information (e.g., HIPAA forms), educational records (e.g., FERPA forms) or the like, please upload such forms here.

External IRB Approvals

Other

Data Management and Sharing Plan

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:

- Fabrication, falsification, plagiarism or other unaccepted practices in proposing, carrying out or reporting results from research;
- Material failure to comply with Federal requirements for the protection of human participants, researchers and/or the Public;
- Failure to meet other material legal requirements governing research;
- Failure to comply with established standards regarding author names on publications;
- 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 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 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 No

**3. Amendment Form**

☰List all personnel being removed from the project

Add an "End Date" to the personnel on the Personnel page

List all personnel being added to the project.

Add the personnel to the Personnel page

Are you increasing recruitment numbers?

Yes No

Describe the proposed changes and explain why they are being made:

Click the Add button for each change you are making with this amendment, assign a number to each change with the change number dropdown, and describe each change.

Please list any study documents that will be revised because of this amendment, such as consent forms, recruitment materials, questionnaires, and attach a copy of these revised documents to this application.

For each new document, please indicate:

- Type of document that is changing (consent, recruitment, instrument, etc.)
- Whether this represents a brand new document, or just a change to an existing document
- If a new document, explain circumstances in which it would be used
-

**Application Type**

Research: This means you are submitting a new human research protocol for review by BC's IRB, and no external institutions would regard BC's IRB as their IRB of record for the protocol (most applications fall into this category).

Collaborative Research/Internal Review: This means you are collaborating with another institution(s) and propose that BC's IRB would serve as the IRB of record for not only BC but also for the other institution(s).

Collaborative Research/External Review: This means you are collaborating with an external institution and propose that BC cede review to the IRB of the external institution.

Non-human Subjects Research Determination: To be used if you believe your study does not meet the definition of "research" involving "human subjects," and you request that ORP confirm your belief. *

Research Collaborative Research/Internal Review Collaborative Research/External Review Non-human Subjects Research DeterminationResearch

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 category descriptions here

Expedited category descriptions here *

Exempt Expedited Full Board Exempt

Exempt Category Number(s)

- 1 - Data collected in educational settings
- 2 - Research that only includes educational tests, surveys, interviews, observation of public behavior
- 3 - Benign behavioral interventions
- 4 - Secondary data analysis

- 5 - Public benefit/service program research
- 6 - Taste and food quality

Is this project a Clinical Trial? *

Yes No

General Study Information

A. Do you have funding? *

Yes No

B. Participant Recruitment Numbers: This number must be the maximum number you intend to recruit - it can be an estimate. You will not be allowed to recruit more than this number without first coming back to the IRB to seek approval.

Total # of participants:

Do you plan to include a larger proportion of one gender group, or omit any gender groups?

Yes No

Are you conducting your research in an international research setting? *

Yes No

C. Participant Ages (please check)

- 0-7 (parental consent and oral child assent)
- 8-11 (parental consent and child written consent)
- 12-17 (parental consent and child written consent)
- 18-65

- 65+

D. Estimated Project Duration

Start Date:

End Date:

E. Why is this Project being conducted? (please check) *

Faculty ResearchStaff ResearchUndergraduate CourseworkMaster's ThesisDoctoral DissertationOtherFaculty Research

F. Will This Study Involve Long-Term Follow-Up with participants:

Yes No

G. Special Study Populations *

- Minors (under 18 years)
- Pregnant Women/Fetuses or products of labor & delivery
- Prisoners
- Physically or mentally challenged
- Diminished capacity for consent
- Other
- No Special Study Populations

H. Does this study involve any of the following? *

- Deception or Punishment

- Use of drugs
- Covert observation
- Induction of mental and/or physical stress
- Procedures which may risk physical/mental harm to the participant
- Materials/issues commonly regarded as socially unacceptable
- Information relating to sexual attitudes, sexual orientation or practices
- Information relating to the use of alcohol, drugs or other addictive products
- Procedures that might be regarded as an invasion of privacy
- Information pertaining to illegal conduct
- Genetic information that may be linked to a participant's health status, such as genetic markers for cancer, heart disease, etc.
- Information normally 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.
- Information that if released could reasonably damage an individual's financial standing, employability, or reputation within the community.
- None of the above Procedures

**BC Personnel**

Add Personnel

Name

Email

Department

Username

Title

End Date

Role

Faculty Advisor/PI/Staff/Faculty/Research Assistant/Co-I/Protocol Administrator

Certifications

Certification Begin End

Alternate Phone

CV

Additional CITI Training Documentation

This person is a

Faculty member/Staff member/Graduate student/Undergraduate student/Other

Non-BC Personnel

To enter Non-BC Personnel, click the “Add” button. Type the person’s name, role, and upload their training certificate.

Investigators

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”. Hover over the question mark icons for helpful tips to complete that section.

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. List and describe all study procedures. For studies involving multiple steps, please present the steps sequentially or chronologically, and indicate when, where and how the step would be performed. For studies involving multiple categories of subjects, indicate the category of subject relevant to each step. *

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:

Please describe the population you plan to recruit.

1. Inclusion and Exclusion Criteria (what participant traits are needed to be included, what traits exclude participants?)

a. Please briefly describe in general terms the nature of the population of people you would like to have participate in this study.

b. Please list all inclusion criteria.

c. Please list all exclusion criteria (examples: upper and lower age limits, decision making capacity, medical conditions, neuropsychiatric conditions, etc.)*

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). See the BC participant payment policy here. *

**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 our Research Data Policy for data storage options). *

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

3. Will the study entail the collection, storage or access of any of the following individually identifying data elements? Check all that apply and indicate how each would be stored in relation to the data.

First name

Last name

Mailing address

Email address

Phone number

Month, day, year of birth

Month and year of birth only

Year of birth (or age in years)

Social security number

Medical record number

IP address

Biometric identifiers

Full face photo or video image

Other

4. Will you collect any individually identifiable information from third parties (organizations or individuals other than the subjects themselves)?

Yes No

5. With respect to each category of information below, please indicate whether the study would collect, use, or access any of the information:

Educational Records (including FERPA-covered data)

Yes No

Medical Information (including data obtained from HIPAA-covered entities)

Yes No

Immigration Status

Yes No

Criminal background/record

Yes No

Unlawful Behavior

Yes No

History of Substance Abuse

Yes No

Current Substance Abuse

Yes No

Domestic Abuse

Yes No

Child Abuse

Yes No

Employment Records

Yes No

6. Please address whether the research plan would entail disclosing subjects' individually identifiable research information to any persons who are not Boston College faculty members, staff members or students or to any institutions or other organizations not owned or operated by Boston College. If so, please identify all such persons and entities. *

7. Please present your plan for disposition of (a) individually identifiable data and (b) coded, individual-level data (i.e., data in which actual identifiers have been replaced with a coded identifier. With respect to the latter, it may be acceptable simply to destroy the cross-reference mechanisms linking actual and coded identifiers.

**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"? Please consider any populations who may be particularly vulnerable and may be triggered by this research topic and the risks they

may face. Please check section IV.H. to ensure that you have considered how sensitive topics might lead to risks for some populations. *

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?

**Informed Consent**

Waiver of Written Documentation of Informed Consent:

The default is for participants to sign a written document that contains all the elements of informed consent. Under limited circumstances, the requirement for a signed consent form may be waived by the IRB. For example, this might occur for phone or internet surveys, when a signed consent form is either impractical or unnecessary, or in circumstances where a signed consent form creates a risk for the participant.

Full or Partial Waiver of Consent:

- The standard is for participants to give informed consent.
- There are times in which the consent form can be waived in full (not just the waiver of signature) or waived in part.
- A waiver may be requested for research involving only existing data or human biological specimens.
- More rarely, it may be requested when the research design requires withholding some study details at the outset (e.g., behavioral research involving deception).

- In limited circumstances, parental permission may be waived. •

1. Please select all that apply. *

- Waiver of documentation of consent
- Full or partial waiver of consent
- None of the above

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 on the Attachments page. Site permission letters should be written on the letterhead of the institution and physically or electronically signed by an administrator (email does not suffice except for extenuating circumstances).

A. Are you conducting research at a site? *

Yes No

Collaborating Institutions

Collaboration with Researchers Affiliated with other Institutions

A. Would the proposed protocol entail a collaborative project involving not only Boston College faculty, students or staff as researchers but also the personnel of one or more institutions or entities external to BC? *

Yes No

Attachments

Please click the "Add" button to upload all supplemental materials under the appropriate section. Under "Document Name" in each section, please clearly label the type of document (ex. Child Assent, Interview Questions, Survey, etc.). IMPORTANT NOTE: ALL ATTACHMENTS MUST BE UPLOADED AS PDFs. We cannot accept Word documents.

Recruitment Materials

Consent Forms

Instruments (surveys, interviews, etc.)

If obtaining information from the third party requires the use of documentation such as authorizations for the release of medical information (e.g., HIPAA forms), educational records (e.g., FERPA forms) or the like, please upload such forms here.

External IRB Approvals

Other

Data Management and Sharing Plan

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 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 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 No

**4. IRB Adverse Event Form**

Form
PIs complete this report as soon as possible after the discovery of any incident that, per the definitions appearing below, would constitute one or more of the following:

- An Adverse Event
- An Unanticipated Problem; or
- Non-Compliance

Definitions

Adverse events are any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (the event can be physical and/or psychological)

Unanticipated problems are any incident, experience, or outcome that is 1) related or possibly related to participation in the research study, 2) unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents and the characteristics of the subject population being studied and 3) adversely affects the safety, rights, or welfare of participants.

Non-Compliance means a significant failure to follow the IRB approved procedures, any laws or regulations, or Boston College institutional policies.

The report must contain sufficient information for the IRB to make an assessment of risk.

TYPE OF INCIDENT
Please check all that apply

A. Unanticipated Problem

Unanticipated harm or risk of harm (including not only harm to one's physical or psychosocial wellbeing but also to one's privacy, social standing, employability, economic interests or the like) to one or more individual participants possibly resulting from study participation

Unanticipated circumstance that gives rise to risk for participating subjects not anticipated in terms of type, severity or frequency

B. Adverse Event

Please describe the nature, severity and consequences of the harm experienced by the affected subject(s):

Please indicate the nature of the treatment or assistance, if any, that affected subject(s) have required, or reasonably could be expected to require, as a result of the harm they experienced.

Please indicate the prognosis of the affected subject(s). If not known, please so indicate.

C. Non-Compliance

Please describe the non-compliance and address whether, in your view, the non-compliance has exposed participating subjects to risk of harm.

Please describe any actions you have undertaken thus far to correct the non-compliance and/or mitigate its consequences.

Please describe any actions you plan to undertake in the future to correct the non-compliance and/or mitigate its consequences, and please present an estimated timeline within which such actions would commence and reach their completion .

Description of the Event or Problem

Location of the Adverse Event:

Date(s) of the Adverse Event:

Date(s) of the onset of the actual event or problem:

Brief Summary of the Event: (be specific) *

Estimated Severity of the Event?
Insignificant (likely that no participants were harmed)Moderate (enough discomfort to interfere with usual activity)Severe (incapacitated the subject; hospitalization)Fatal

In your judgment, was the event caused by procedures associated with this protocol?
Not RelatedPossibly RelatedProbably RelatedDefinitely Related

Was this event anticipated in the initial protocol?
Yes No

Please address whether and how the informed consent document, or informed consent process addressed the risk that materialized for the affected subject(s)

In your judgment, should the informed consent process any part of the protocol be modified as a result of this event?
Yes No

**5. Project Closure Form**

**Protocol Number** **Submission Number**

**Principal Investigator**

**I. Study Title:**

**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**. Check All 3 Boxes: *

- No further interaction with human participants will occur.
- No long term follow up will be needed.
- No access to personally identifying information will be needed.

**Section II: Reason for study closure** Select at least 1: *

- Data analysis is complete.
- PI is moving to another institution.
- Lack of enrollment.
- There is no more funding, time or personnel to conduct the study.
- Other:

**Section III: What will be done with the data** You MUST select the "Required" item plus at least 1 other: *

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

## 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://www.ecfr.gov/current/title-34/subtitle-A/part-99?toc=1

Conditions the availability of federal funding to any educational agencies or institutions upon adherence to 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://www.ecfr.gov/current/title-34/subtitle-A/part-98

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, they 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) 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.

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 or any other accepted training certificates will be regarded as being active for three years from the date of completion recorded on the certificate.

4. At the expiration of the CITI 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.