



BOSTON COLLEGE

Policy for the Protection of Human Research Participants

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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.d, “*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.”

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, (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>).

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).

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

The BC IRB has the responsibility and the authority to review the progress of protocols at least annually and more often when deemed necessary. It also has the authority to observe or have a third party that the BC IRB determines is qualified and appropriate to observe the consent process or any aspect of the research.

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

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

E. Authority of the BC IRB to Restrict Protocols

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

III. Organizational Responsibilities

A. IRB Reporting Structure within the University

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

B. The Vice Provost for Research

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

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

The BC IRB requires that Deans, Department Chairpersons, and Center Directors (or designees of the foregoing) review and sign each protocol application that is submitted to the BC IRB for review indicating that scientific review has occurred. Deans, Department Chairs, and Center Directors shall ensure that the determinations of the BC IRB are followed and that the applicable University policies and Federal regulations regarding the use of human participants in research are followed by their faculty, staff, and students.

D. Faculty Advisors

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

E. Principal Investigators

Only BC faculty, staff, and students may serve as Principal Investigators on protocols. For those individuals

having less than full affiliation with BC (e.g., part-time faculty), the BC IRB may require that the protocol be overseen or supervised by a full-time BC faculty member. The BC IRB recognizes only one Principal Investigator for each protocol. The Principal Investigator has ultimate responsibility for his/her protocol and all official BC IRB correspondence is addressed to the Principal Investigator.

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

F. Other Institutions

The BC IRB may act as a liaison with the IRBs of other institutions, as necessary, to assist in the approval of joint and cooperative projects involving multiple sites and/or Principal Investigators. Conversely, the BC IRB may agree to permit another federally sanctioned IRB with an approved Federalwide Assurance (FWA) to act as the IRB of record for studies to be conducted by, or with the assistance of BC personnel, at the facilities of a second institution. The BC IRB may agree to function as the IRB of record for another Principal Investigator and/or institution if the project involves collaboration with BC personnel. Such agreements will require written letters of agreement and may include the completion of additional documentation under the FWA Process.

G. Regulatory Agencies

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

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

A. BC IRB Chairperson

Selection and Appointment

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

Duties

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

It is the responsibility of the BC IRB Chairperson to convene meetings of the BC IRB, moderate the BC IRB discussion, and if necessary, assist in resolving disagreements among BC IRB Members. The BC IRB Chairperson is also responsible for ensuring that the appropriate type of review is conducted in a timely manner in accordance with all University policies, and federal laws, regulations, and policies. The BC IRB Chairperson determines if projects qualify as human subject research and if protocols qualify for an exemption from IRB review, expedited review, or full Committee review in accordance with regulations at 46 CFR 46. Aside from

protocols requiring full-board review, the BC IRB Chairperson also reviews and may approve all protocol amendments and modifications to previously approved protocols, and reviews and may approve continuing review reports.

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, Lynch School of Education faculty member(s), Connell School of Nursing faculty member(s), Graduate School of Social Work faculty member(s), School of Arts and Sciences (Psychology Department faculty member(s), Sociology Department faculty member(s), and faculty members from other departments), Boston College Law School faculty member, Carroll School of Management faculty member, and Vice Provost for Research appointees. The Director of ORP serves as ex-officio Member of the BC IRB. The Director of ORP also serves as the Executive Secretary of the BC IRB. The Executive Secretary is responsible for maintaining an accurate record of IRB proceedings.

Qualification of Members

The Membership of the BC IRB will include individuals with varying backgrounds. The BC IRB will possess appropriate professional competence to review the diverse types of protocols that are received. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The BC IRB will be able to ascertain the acceptability of the research in terms of institutional commitments and regulations, all applicable laws, and standards for professional conduct and practice. Membership is selected to assure appropriate diversity, including representation by multiple ethnic backgrounds, both genders, and to include both scientific and non-scientific Members. At all times, the IRB will include at least one member who is not otherwise affiliated with Boston College and who is not part of the immediate family of a person who is affiliated with Boston College.

Selection and Appointment

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

Duties

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

for exempt status and expedited review.

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

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

Training of BC IRB Chairperson and Members

The BC IRB Chairperson and BC IRB Members will complete a core educational program prior to serving on the BC IRB. The core-training track consists of training in Federal Regulations and BC IRB SOPs. Regulatory training provides the basic foundation for protecting human participants in research, and includes HHS Regulations, the historical background to the Federal Regulations, and the Belmont Report. This requirement may be satisfied by complying with the BC IRB Training Policy found in Attachment 3 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.

Compensation of BC IRB Members

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

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

C. BC Office for Research Protections (ORP) Staff

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

BC ORP Staff Requirements

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

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 has been given the authority to sign all documents that formalize action taken at a convened meeting at which the BC IRB Chairperson, or her/his delegate has presided, all documents that formalize expedited reviews (new protocols, continuations, amendments) and approvals and exemptions.

The ORP Director has also been given the authority to sign the following documents:

- All Notices of Committee Review;
- All Notices of Approval;
- Notices relaying BC IRB action;
- Health Insurance Portability and Accountability (HIPAA) Research Agreements; and
- Statement on HIPAA Protected Health Information (PHI) Use.

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.

D. Use of Consultants

The BC IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond or in addition to that available on the BC IRB. These individuals do not have IRB voting rights.

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

Appendix 1

BC IRB Forms

1. Initial IRB Application Form
2. IRB Continuing Review Form
3. IRB Request for Exemption Form
4. Research with Minors Form
5. Informed Consent Waiver/Alteration Form
6. IRB Adverse Event Form

These forms can be downloaded from the following webpage:

<http://www.bc.edu/research/oric/human/irbappforms.html>

Samples of informed consent can be downloaded from the following webpage:

<http://www.bc.edu/research/oric/human/irbsampleforms.html>

Appendix 2

BC HIPAA Forms

1. Use of HIPAA Protected Health Information Form
2. HIPAA Authorization Form
3. Application for Research on Decedents' Information
4. HIPAA De-Identification Certification Form
5. Limited Data Set Agreement
6. Application for Waiver of Individual Authorization for Use or Disclosure of Protected Health Authorization

These forms can be downloaded from the following webpage:

<http://www.bc.edu/research/oric/human/irbappforms.html>

Appendix 3

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

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

Consumer Product Safety Commission

16 CFR Part 1028

http://www.access.gpo.gov/nara/cfr/waisidx_09/16cfr1028_09.html

Department of Agriculture

7 CFR Part 1c

http://www.access.gpo.gov/nara/cfr/waisidx_00/7cfr1c_00.html

Department of Commerce

15 CFR Part 27

http://www.access.gpo.gov/nara/cfr/waisidx_99/15cfr27_99.html

Department of Defense

32 CFR Part 219

http://www.access.gpo.gov/nara/cfr/waisidx_09/32cfr219_09.html

Department of Education

http://www.access.gpo.gov/nara/cfr/waisidx_00/34cfr97_00.html

Department of Energy

10 CFR Part 745

http://www.access.gpo.gov/nara/cfr/waisidx_09/10cfr745_09.html

Department of Housing and Urban Development

24 CFR Part 60

http://www.access.gpo.gov/nara/cfr/waisidx_98/24cfr60_98.html

Department of Justice

28 CFR Part 46

http://www.access.gpo.gov/nara/cfr/waisidx_09/28cfr46_09.html

Department of Veteran Affairs

38 CFR Part 16

http://www.access.gpo.gov/nara/cfr/waisidx_09/38cfr16_09.html

Environmental Protection Affairs

40 CFR Part 26

http://www.access.gpo.gov/nara/cfr/waisidx_99/40cfr26_99.html**Department of Transportation**

49 CFR Part 11

http://www.access.gpo.gov/nara/cfr/waisidx_00/49cfr11_00.html**Agency for International Development**

22 CFR Part 225

http://www.access.gpo.gov/nara/cfr/waisidx_01/22cfr225_01.html**National Aeronautics and Space Administration**

14 CFR Part 1230

http://www.access.gpo.gov/nara/cfr/waisidx_99/14cfr1230_99.html**National Science Foundation**

45 CFR Part 690

http://www.access.gpo.gov/nara/cfr/waisidx_00/45cfr690_00.html**B. Family Educational Rights and Privacy Act (FERPA)**

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

http://www.access.gpo.gov/nara/cfr/waisidx_00/34cfr99_00.html

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

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

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

http://www.access.gpo.gov/nara/cfr/waisidx_98/34cfr98_98.html

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

http://www.access.gpo.gov/nara/cfr/waisidx_98/34cfr98_98.html

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

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

E. HIPAA

The Health Insurance Portability and Accountability Act (HIPAA) (<http://www.hhs.gov/ocr/hipaa/>) is the federal legislation that governs all uses and disclosures of Protected Health Information (PHI), for both the living and the dead, in order to protect individual privacy. While Boston College is not a Covered Entity, some research projects may take place within other organizations that are Covered Entities. In such cases, researchers must be prepared to use and control PHI in compliance with the provisions of HIPAA and any commitments the University has agreed to accept in support of its researchers and their research projects.

Appendix 4



Boston College
Office for Research Protections

Human Participant Research Training Policy

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

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

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

Approved by the IRB 10/15/08
Minor Revisions 03/27/09, 1/8/10 and 3/22/10

Appendix 5

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, pregnant women, students, handicapped or mentally disabled persons, 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.