



BOSTON COLLEGE
Office for Research Protections
Standard Operating Procedures for Researchers

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Standard Operating Procedures for Researchers

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I. Categories of Research Review and Review Procedures

The Boston College Institutional Review Board (BC IRB) is required to review all proposed research involving human participants and/or materials of human origin, whether funded or not, conducted by BC faculty, staff, or students. This applies to research conducted at other institutions in which BC faculty, staff, or students will be involved. Only one person is allowed to serve as the Principal Investigator on a BC IRB protocol. For protocols that are externally funded, the BC IRB will only review the protocol once the Principal Investigator has been notified that his/her project will be funded, unless pre-review IRB approval is required by the potential funding agency.

A. Definitions

Research: “A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge,” (45 CFR 46.102d).

Human Participant: “A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information,” (45 CFR 46.102e).

Intervention: “Includes both physical procedures by which data are gathered (for example venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes,” (45 CFR 46.102f).

Interaction: “Includes communication or interpersonal contact between investigator and subject,” (45 CFR 46.102f).

Private Information: “Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects,” (45 CFR 46.102f).

Minimal Risk: “The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests,” (45 CFR 46.102i).

However, the definition of “minimal risk” for the review of research involving prisoners is as follows:

“The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons,” (45 CFR 46.303d).

B. Guidelines for Determining When BC IRB Review/Approval is Required

The federal definitions for research involving human subjects/participants are described in Section I.A above. Since some research is not necessarily “systematic,” the BC IRB expands upon the federal definition for research to include projects for which there is any possibility that the results will be published or widely disseminated (e.g., presentation at a professional meeting or conference; submission for publication in a professional journal, either paper or electronic; and Internet postings).

Evaluation Programs

Evaluation programs do not require BC IRB review if the results will not be released outside of Boston College. However, BC IRB review/approval of an evaluation program would be required if there is an intent to publish the results.

Case Studies of Businesses/Corporations

Secondary data analyses of a business/corporation are likely to qualify for exempt status. However, interviewing employees regarding organizational change, for example and with the intent of publishing, would require BC IRB review/approval, and would likely qualify for expedited review.

Research on Secondary Historical Data

BC IRB review/approval is not required for research on secondary historical data because a human subject/participant is defined as “a *living* individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information,” (45 CFR 46.102e).

Restricted Data Sets

Definition of restricted data sets: “A number of federal agencies and research organizations distribute special files to investigators on which they impose use restrictions. These files generally contain data fields, such as social security numbers, names, or extensive life history markers that might enable an unauthorized user to identify a participant. The use restrictions vary, but they typically involve secure (locked) data storage and password protected computers, and forbid the storage of data on computer hard drives that may be accessed through a computer network connection. These agreements may also limit the type of analyses that are done by the investigator.”¹ (Cornell University Committee on Human Subjects (UCHS) website: <http://www.osp.cornell.edu/Compliance/UCHS/Secondary.htm>). A Principal Investigator who would like to work with a restricted data set for research purposes must complete a BC IRB

¹ Cornell University Committee on Human Subjects (UCHS) website:
<http://www.osp.cornell.edu/Compliance/UCHS/Secondary.htm>.

protocol application, which will likely be reviewed through expedited procedures. Agreements with other organizations covering the use of restricted data sets must be reviewed by the Office for Technology Transfer and Licensing.

Secondary Use of Data Sets

Any research that involves the secondary use of data in which individually identifiable information is included requires that the Principal Investigator completes the BC IRB protocol application, which will be reviewed through expedited procedures.

If the data set contains no individually identifiable information, or the data set is publicly available, the project may qualify for exempt status, in which case the Principal Investigator should complete the Exempt Status Form.

Meta-Analyses/Qualitative Meta-Syntheses

Meta-analyses do not require BC IRB review, as long as the researchers do not obtain or have access to individually identifiable human participant information.

C. IRB Training Requirement for Researchers

All individuals, including transcriptionists, who will interact with research participants and/or review research data are required to complete Human Participant Research Training. This requirement may be fulfilled by complying with the terms of the training policy which is available on the ORP website (<http://www.bc.edu/research/oric/human.html>). In addition, faculty advisors on student projects are required to take the training specified above.

D. Information the Principal Investigator Provides to the BC IRB

It is the responsibility of the Principal Investigator (BC faculty, staff, or student) to submit the Application for Review of Research Proposals Involving Human Participants that minimizes risks to participants while maximizing benefits. The Principal Investigator is also responsible for ensuring that every research participant's rights, welfare, and safety are protected and for following the applicable University policies and federal regulations regarding the use of human participants in research. The Principal Investigator's responsibilities regarding the consent process are outlined in Section II of these SOPs. In general, the Principal Investigator must also maintain all relevant research records for at least 3 years after the completion of the research and/or sponsored project, whichever is later. More specifically, if a project is funded by an external organization, there may be different (often longer) retention requirements, and the Principal Investigator must be familiar with those requirements.

Documents Required for Initial BC IRB Submission:

1. The Initial IRB Application Form signed by the PI and his/her Department Chair/Dean/Director of Research Center (faculty advisors need to sign BC IRB applications submitted by their students), which includes or addresses the following, as applicable:
 - a. Study Objectives

- b. Rationale/Justification for Study
 - c. Participant Population
 - d. Procedures
 - e. Analysis Plan
 - f. Inclusion Criteria
 - g. Exclusion Criteria
 - h. Recruitment Techniques
 - i. Vulnerable Populations
 - j. Informed Consent
 - k. Potential Risks
 - l. Minimizing Potential Risks
 - m. Potential Benefits
 - n. Alternatives
 - o. Confidentiality
 - p. Financial Components
 - q. Multi-site Research
 - r. Conflict of Interest
 - s. Reviews by other IRBs
 - t. Other Issues
2. Proposed informed consent document (and assent document, as applicable) that contains the elements of consent as identified in the Boston College Guide for Preparation of Consent Documents (see Section XI-A) and these SOPs, as well as a description of the consent process (and assent process, as applicable). However, if the Principal Investigator is requesting a waiver of the documentation of consent (see Section VI-D), a waiver or alteration of consent (see Section VI-E), or a waiver of parental consent (see Section VII-A) then additional justification is needed.
 3. Any and all advertising/participant recruitment materials (letters to professionals, letters to prospective participants, brochures, flyers, pamphlets, etc.) and procedures.
 4. Instrumentation (questionnaires, interview/focus group scripts, etc.).
 5. The Principal Investigator must submit a packet including the items listed in #1-#3 of this section. For expedited review, the PI must also include two copies of the packet and for full Committee review, the PI must also include 20 copies of the packet. Any excess copies will be shredded by the BC ORP Staff.
 6. Documentation of completion of required training.
 7. For externally funded research: documentation that the Principal Investigator has been notified that the project will be funded. As applicable, a copy of the federal grant or contract application must also be submitted. The term "federal" also includes subaward proposals submitted to another organization which is applying for federal funding.
 8. If the Principal Investigator will be working with health information, he/she must also complete and submit the Statement on HIPAA PHI Use form.

9. Research in Schools: Principal Investigators must also submit approval letters from the principal of each participating school or IRB of the school board, if applicable, before IRB approval will be granted.
10. Research at Other Institutions: If research is being performed at another institutions such as a hospital or another university, Principal Investigators should first submit a protocol application to the IRB of the participating institution, and at the same time contact the BC ORP to see if the BC IRB can rely upon the review/approval of the participation institution's IRB. If this is possible, an agreement will need to be signed between BC and the participating institution. In this case the BC IRB will only need to receive a copy of the participating institution's IRB protocol application, that IRB's approval letter, and that IRB's approved consent form.

The PI should then submit copies of all continuing review applications and amendments submitted to the participating institution's IRB as well as copies of all approvals.

Submissions to the BC IRB after Initial BC IRB Approval is Granted:

1. Requests for changes to the study after initial approval.
2. Reports of unexpected adverse events.
3. Continuing Review Report (annually or as required by the BC IRB).
4. Completion Form (at the end of the project).
5. Other forms or reports required by the BC IRB.

Note: If a Principal Investigator would like to conduct several projects that are similar, the PI should use distinguishing titles for each project protocol.

The BC ORP Staff will date stamp all documents received in the office.

E. Determination of Exempt Status

Only the BC IRB may decide whether a project is exempt from BC IRB review and approval. A Principal Investigator completes the Exemption Form if it is his/her judgment that the research qualifies for one of the following exempt status categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that

human subjects can be identified, directly or through identifiers linked to the subjects; **and** (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note: The exempt status categories listed above do not apply to research involving children, prisoners, fetuses, pregnant women, or in vitro fertilization. Category #2, as listed above, for research involving educational tests, survey or interview procedures or observation of public behavior does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Note: If the research involves college students or employees, the IRB may ask that the signature section of the consent form, if used for the exempt status protocol, be removed, as this will increase the anonymity of the participants.

Determination of exempt status will be made by the BC IRB Chair, in consultation with the Administrative Director, BC ORP, or by one or more qualified persons designated by the BC IRB Chair. If exempt status has been granted, the BC ORP Staff will send a Notice of Exempt Status to the Principal Investigator.

If the proposed research activity is judged not to qualify for exempt status, the Principal Investigator will be notified of this determination and informed that the BC IRB protocol application should be completed.

F. BC IRB Review

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 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.

Conducting Federal Grant Application Review

For federally funded research, the BC ORP will ask the PI to submit a copy of the federal grant application with the BC IRB protocol application. The ORP Director will review the federal grant application to ensure that the human participant research described in the grant application is consistent with the BC IRB protocol application being submitted for BC IRB review/approval.

Conflict of Interest

Neither the sponsor, nor the Principal Investigator, or any individual involved in the conduct of the research activity under review will participate in the BC IRB review process except to provide information. No IRB Member may participate in the BC IRB's initial or continuing review of any project in which the Member has a conflicting interest, except to provide information requested by the BC IRB. IRB Members having a conflict of interest shall announce the conflict and disqualify themselves from participating in the review of protocol except to provide information on request. Persons identified in this section shall leave the meeting during the discussion and the vote on any motion to approve or disapprove the research in question. When a person with a conflict of interest leaves the room he/she cannot be counted towards a quorum. If the quorum is lost, the protocol will be deferred.

Expedited Review

The BC IRB may utilize the expedited review process for the following types of research:

1. Minor changes in previously BC IRB approved research during the period of one year or less, for which approval is authorized; or,
2. Research activities involving no more than minimal risk and in which the only involvement of human participants will be in one or more of the categories identified on the current list of categories of research that may be reviewed by the BC IRB using expedited the categories cited below.

The BC IRB Chair or other BC IRB Members may conduct expedited review of protocols. In reviewing the research, the reviewer(s) may exercise all of the authorities of the BC IRB except disapproval. If the reviewer(s) do not approve the protocol being reviewed, ORP may refer it to the full BC IRB for review after consulting with the IRB Chair.

Expedited Review Categories

The federal expedited review categories are as follows:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat).
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally

eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\)](#) and [\(b\)\(3\)](#). This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
 - a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - b. where no subjects have been enrolled and no additional risks have been identified; or
 - c. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Full Committee Review

Research involving risks greater than “minimal risk” will require review at a convened meeting of the BC IRB.

- A quorum (a majority) of the Members of the BC IRB must be present at the convened meeting.
- At least one Member whose primary concerns are in nonscientific areas must participate in the review. BC IRB Members who have a conflicting interest in a research project cannot participate in the review except to provide information.
- Protocols scheduled for review will be distributed to all Members of the BC IRB in advance. When the BC IRB determines that consultants or experts will be required to advise the BC IRB in its review of a protocol, the protocol shall also be distributed to the consultants or experts prior to the review.

A primary and secondary reviewer will be assigned to all protocols that are reviewed by the full Committee. The primary reviewer will likely be a Committee Member with expertise in the researcher's field of study. All IRB Members are encouraged to contribute to the protocol discussion. The discussions that take place during BC IRB meetings are confidential and the identities of assigned reviewers are confidential.

1. Each BC IRB Member must be provided with sufficient information to be able to actively and constructively participate in the protocol review.
2. Review materials must be received by the Membership at least 5 business days in advance of the meeting to allow for adequate review of the materials.

Regularly scheduled meetings of the BC IRB will be held on the third Wednesday of each month, unless otherwise specified. Additional meetings may be scheduled as necessary. However, the BC IRB Chair may decide to cancel a BC IRB meeting if no greater than minimal risk protocols were submitted for review and no issues need to be discussed before the convened BC IRB. The BC IRB Chair or designee shall conduct all meetings of the BC IRB.

The BC IRB will use the same criteria for the full Committee review protocols as that used for the expedited review of protocols.

Notification of BC IRB Actions

The BC ORP Staff shall notify the Principal Investigator and University officials (when appropriate) in writing of its actions in approving, disapproving, or requiring changes to (in order to approve) the research. The BC ORP Staff will send the initial review notice to the Principal Investigator within one month of receiving the BC IRB protocol application. A disapproval notice shall include the basis for the disapproval and provide an opportunity for the Principal Investigator to address the BC IRB in person or in writing regarding its action. There is no appeal of BC IRB final decisions regarding the suspension or disapproval of protocols.

Withdrawal of Research

In order for a Principal Investigator to withdraw a BC IRB protocol application from BC IRB review, he/she must send written documentation of the withdrawal request, rationale for the request, and indicate that he/she will not be conducting the human participant research as described in the BC IRB protocol application being withdrawn. This information will be filed with the protocol file maintained by the BC ORP.

G. Conducting Continuing Review

The BC IRB shall conduct a continuing review of all approved protocols for which research activities (including data analyses) have continued. Continuing review is no longer needed once all participant identifiers have been destroyed.

1. Approved projects shall be reviewed again at intervals appropriate to the degree of risk to which participants are exposed. In all cases of non-exempt approval the interval between reviews will not exceed one calendar year. The IRB may decide that a protocol with a high risk-to-benefit ratio requires continuing review more often than annually.
2. Notification that continuing review is to take place will be sent to Principal Investigators 4-8 weeks before the protocol expires. Principal Investigators must complete the Continuing Review-Interaction Form for any situation in which the research will continue beyond the previously approved period. This includes situation in which the PI is only performing analysis on data collected from participants.
3. Continuing review reports for protocols that were initially reviewed through expedited procedures will be reviewed by the BC IRB Chair or the Chair's designee. Continuing review reports that satisfy one of the following categories will be reviewed through expedited procedures:
 - Continuing review of research previously approved by the convened BC IRB as follows:
 - (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - (b) where no subjects have been enrolled and no additional risks have been identified; or
 - (c) where the remaining research activities are limited to data analysis.
 - Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where the other expedited review categories do not apply but the BC IRB has determined and documented at a

convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Projects that may need verification from sources other than the Principal Investigator that no material changes have occurred since the previous IRB review may include projects conducted by investigators who previously have failed to comply with the requirements of federal regulations and University policies and projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.

H. Sanctions for Non-Compliance

1. Federal funds may not be expended for research involving human participants unless the requirements of 45 CFR 46, the BC Policy for the Protection of Human Research Participants, and these SOPs have been satisfied.
2. In instances of non-compliance, the individual(s) involved will be given notice by the BC IRB that research involving the use of participants must be suspended or terminated.
3. The BC IRB shall inform the Vice Provost for Research of instances of non-compliance, and, as appropriate, the BC Director of Research Integrity and Compliance and the DHHS Office for Human Participant Protection (OHRP).
4. In cases determined to be serious violations, the Vice Provost for Research and the BC Director of Research Integrity and Compliance, in consultation with the Dean and Department Chair, will recommend sanctions. The Provost will make the final decision with regard to appropriate action against the individual(s) involved.
5. Additional details regarding non-compliance are included in the BC policy "Ethical Conduct of Research and Research Misconduct."

VI. Informed Consent

The BC IRB shall require that information given to participants as part of informed consent is in accordance with the BC Policy for the Protection of Human Research Participants and 45 CFR 46.116.

The BC IRB has the authority to observe or have a third party observe the consent process and the research. The BC IRB shall ensure that informed consent is documented in accordance with and to the extent required by Boston College policies and federal regulations, unless documentation is waived by the BC IRB.

A. Consent Form General Requirements

The consent form must:

- conform to the format as outlined in the Boston College “Guide for Preparation of Informed Consent Documents” (see Section XI-A);
- be approved by the BC IRB;
- be signed and dated by the participant or the participant's legally authorized representative; and
- have a copy to be given to the person signing the form.

Principal Investigator Responsibilities

1. Principal Investigators shall be responsible for the process of informed consent in accordance with Boston College policies and 45 CFR 46.116, and for ensuring that no human participant will be involved in the research prior to giving and documenting such consent. Informed consent is encouraged, but not required for projects determined by the BC IRB to qualify for exempt status.
2. Unless otherwise authorized by the BC IRB, Principal Investigators are responsible for ensuring that legally effective informed consent shall:
 - a. be obtained from the participant or the participant's legally authorized representative;
 - b. be in language understandable to the participant or the representative;
 - c. be obtained under circumstances that offer the participant or the representative sufficient opportunity to consider whether the participant should or should not participate; and
 - d. not include exculpatory language which means that the PI may not include provisions by which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or release the Principal Investigator, the Sponsor, Boston College, the research sites, or its agents from liability for negligence.

Consent Form BC IRB Approval/Expiration Stamp

The BC IRB approval stamp indicates that the consent form document has been reviewed and approved by the BC IRB, and shows the approval date. The stamp is only used on finalized consent form documents, and must appear on each page of the consent form.

B. Consent Form Documentation Requirements

1. Unless otherwise approved by the BC IRB, the consent form must contain the elements of informed consent below,

Elements of Consent

Informed consent shall include the following elements (45 CFR 46.116a):

1. a statement that the study involves research;
2. an explanation of the purposes of the research;
3. the expected duration of the participant's participation in the research;
4. a description of the procedures to be followed;
5. identification of any procedures which are experimental;
6. a description of any reasonably foreseeable risks or discomforts to the participant;
7. a description of any benefits to the participant or to others which may reasonably be expected from the research;
8. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
9. a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained, and a statement of the possibility that OHRP may inspect the records;
10. for research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs; and whether any medical treatments are available if injury occurs; and if so, what they consist of, or where further information can be obtained;
11. an explanation of whom to contact for answers to pertinent questions about the research, and research participant's rights; and whom to contact in the event of a research related injury to the participant; and,
12. a statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

As applicable, one or more of the following ADDITIONAL (45 CFR 46.116b) elements of information shall also be provided to each participant:

1. a statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable;
2. anticipated circumstances under which the participant's participation may be terminated by the Principal Investigator without regard to the participant's consent;

3. any additional costs to the participant that may result from participation in the research;
4. the consequence(s) of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;
5. a statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue will be provided to the participant; and
6. the approximate number of participants involved in the study.

The BC IRB may require that information, beyond those elements listed above and in addition to that required in Federal Regulations (HHS 45 CFR Part 46), be given to research participants when in its judgment the information would meaningfully add to the protection of the rights and welfare of participants.

C. Waiver of Documentation of Informed Consent

For some or all research participants, the BC IRB may waive the requirement that the participant or the participant's representative sign a written consent document if it finds the following conditions:

1. the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or
2. the research involves no procedures for which written consent is normally required outside the research context.

If the BC IRB waives the requirement of documentation of informed consent as identified above, it may require the Principal Investigator to provide participants with a written statement regarding the research. When a Principal Investigator submits such a request, the IRB will assess this request and document the findings.

D. Waiver or Alteration of Informed Consent

The BC IRB may waive the requirement for informed consent per 45 CFR 46.116 (d) (or allow an alteration of some or all of the elements of informed consent) only if the BC IRB finds that each of the following four elements is met:

1. the research involves no more than minimal risk to participants; and
2. the waiver or alteration will not adversely affect the rights and welfare of the participants; and
 - a. the research could not practicably be carried out without the waiver or alteration; and

- b. whenever appropriate, the participants will be provided with additional pertinent information after participation (45 CFR § 46.116(d)).

When a Principal Investigator submits such a request, the IRB will assess this request and document the findings. This is different than waiving the requirement of documentation of informed consent, as identified directly in Section VI-C.

E. Research Participants for whom English is not their Primary Language

Subjects who do not speak English should be presented with a consent document written in a language understandable to them. The BC IRB should be given a copy of the original and an English language version that has been translated by a certified translator.

45 CFR 46.117(b)(2) permits oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary.

When this procedure is used with subjects who do not speak English, (i) the oral presentation and the short form written document (see sample attached) should be in a language understandable to the subject; (ii) the BC IRB-approved English language informed consent document may serve as the summary; and (iii) the witness should be fluent in both English and the language of the subject.

At the time of consent, (i) the short form document should be signed by the subject (or the subject's legally authorized representative); (ii) the summary (i.e., the English language informed consent document) should be signed by the person obtaining consent as authorized under the protocol; and (iii) the short form document and the summary should be signed by the witness. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

The BC IRB must receive all foreign language versions of the short form document as a condition of approval under the provisions of 45 CFR 46.117 (b)(2).

F. Consent Process for Participants who are Illiterate

A person who speaks and understands English, but does not read and write, can be enrolled in a study by "making their mark" on the consent document, when consistent with applicable state law, (FDA IRB Information Sheets: <http://www.fda.gov/oc/ohrt/irbs/faqs.html#Informed%20Consent%20Process>).

A person who can understand and comprehend spoken English, but is physically unable to talk or write, can be entered into a study if they are competent and able to indicate approval or disapproval by other means. If (1) the person retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally (still competent) and (2) is able to indicate approval or disapproval to study entry, they may be entered into the study. The consent form should document the method used for communication with the prospective subject and

the specific means by which the prospective subject communicated agreement to participate in the study. An impartial third party should witness the entire consent process and sign the consent document. A video tape recording of the consent interview is recommended.

G. Research with Children: Assent

Children (those under 18 years of age) should be given an explanation – at a level appropriate to the children’s age, maturity, experience, and condition – of the procedures to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research. Children should be asked if they wish to participate in the research or not. Mere failure to object on the part of the child should not, in the absence of affirmative agreement, be construed as assent. The child may either sign a very brief assent form or orally indicate a willingness to participate.

VII. Vulnerable Populations

Boston College recognizes the need for appropriate additional safeguards in research involving participants who are likely to be vulnerable to coercion or undue influence, such as children (under the age of 18), prisoners, students, pregnant women, mentally disabled persons or economically or educationally disadvantaged persons.

A. Research Involving Children (45 CFR 46, Subpart D)

The special vulnerability of children makes consideration of involving them as research subjects particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations are in place for reviewing research involving children. (Title 45 CFR Part 46, Subpart D provides for "Additional Protections for Children Involved as Subjects of Research.") Research that is contrary to the rights and welfare of child-subjects is prohibited.

Definitions

Assent: “A child's affirmative agreement to participate in research. Mere failure to object should not be construed as assent,” (45 CFR 46.402b).

Children: “Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted,” (45 CFR 46.402a).

Guardian: “An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care,” (45 CFR 46.402(3)).

Mature Minor: “Someone who has not reached adulthood (as defined by state law) but who may be treated as an adult for certain purposes (e.g., consenting to medical care),” (DHHS OHRP IRB Guidebook: http://www.hhs.gov/ohrp/irb/irb_guidebook.htm). Note

that a mature minor is not necessarily an emancipated minor.

Permission: “The agreement of parent(s) or guardian to the participation of their child or ward in research,” (45 CFR 46.402c).

Pediatric Research Risk/Benefit Categories

The four categories of research involving children that may be approved by IRBs, based on degree of risk and benefit to individual subjects, are as follows:

1. Research not involving greater than minimal risk (45 CFR 46.404).
2. Research involving greater than minimal risk, but presenting the prospect of direct benefit to an individual subject.

Research in this category is approvable provided:

- a. the risk is justified by the anticipated benefit to the subject; and
- b. the relationship of risk to benefit is at least as favorable as any available alternative approach (45 CFR 46.405).

3. Research involving greater than minimal risk with no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

Research in this category is approvable provided:

- a. the risk represents a minor increase over minimal risk;
- b. the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational settings; and
- c. the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subject's disorder or condition (45 CFR 46.406).

4. Research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Research that is not approvable under 45 CFR 46.404, 46.405, or 46.406 may be conducted or funded by DHHS provided that the BC IRB, and the Secretary, after consultation with a panel of experts, finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a significant problem affecting the health and welfare of children. The panel of experts must also find that the research will be conducted in accordance with sound ethical principles (45 CFR 46.407)

When a protocol involves children as a participant population, the IRB will determine which category the research fits into, assess whether or not the required stipulations have been met, and communicate the findings to the Principal Investigator.

Assent Determination

The child should be given an explanation of the proposed research procedures in a language that is appropriate to the child's age, experience, maturity, and condition. This explanation should include a discussion of any discomforts and inconveniences the child may experience if he or she agrees to participate. Among the assent possibilities the BC BC IRB can consider are the following:

- no assent;
- verbal assent, without documentation;
- verbal assent, with documentation by the Principal Investigator and/or the legally authorized representative(s);
- written assent form, with participant signature; or
- participant signature block on consent form (for older children only).

The requirement for parental permission may be inappropriate in some cases. Examples include research involving older adolescents who, under applicable law, may consent on their own behalf for selected treatments (*e.g.*, treatment for venereal disease, drug abuse, or emotional disorders). In other research (*e.g.*, research on child abuse or neglect), there may be serious doubt as to whether the parents' interests adequately reflect the child's interests. In these cases, IRBs should devise alternative procedures for protecting the rights and interests of the children asked to participate, including, perhaps, the court appointment of special guardians.

Waiver of Parental Consent

The following are the issues a Principal Investigator should address in requesting a waiver of parental consent:

- Specify why the research could not be practically conducted without a waiver and why parental permission is not a reasonable requirement.
- Specify whether the risks associated with this protocol minimal and provide justification.
- Assure that the waiver of parental permission will not adversely affect the rights and welfare of the subjects.
- Encourage adolescent participants to seek the support of a parent or another adult prior to participation. The PI should indicate how this will be accomplished. The informed consent must also address this issue.

- Establish procedures to allow adolescents to seek assistance on a confidential basis after completing surveys containing questionnaires that may raise issues for which adolescents may desire further information or assistance.
- Indicate when, how and under what conditions consent will be obtained from the adolescent.

Research Involving Minors and Exempt Status Categories

No research conducted by BC researchers that involves minors shall be considered exempt by the BC IRB.

Child Abuse Information

If there is a likelihood that evidence of abuse may be discovered over the course of the research, then the actions to be taken by the researcher must be explained in the protocol application and may be required to be inserted in the informed consent form. Mandated reporters are required to report, but this does not mean that the possibility of reporting must be included in the informed consent document. Chapter 119, Section 51A (Massachusetts law) includes information regarding mandated reporters: <http://www.mass.gov/legis/laws/mgl/119-51a.htm>.

B. Research Involving University Students

In reviewing research involving University students, the BC IRB will particularly ensure that (1) consent for participation is sought only under circumstances which minimize the possibility of coercion or undue influence and (2) that genuinely equivalent alternatives to participation are available. All University students are considered to be vulnerable research participants when participating in University research.

If a researcher would like to administer a minimal risk survey to University students in which the surveys will be completed anonymously, the research may qualify for exempt status, but the IRB will ask that the signature section of the consent form be deleted for the purpose of increasing the participant's anonymity.

C. Research Involving Individuals with Cognitive Impairment

Unlike research involving children, prisoners, pregnant women, and fetuses, no additional Department of Health and Human Services (DHHS) regulations specifically govern research involving persons who are cognitively impaired. While limited decision-making capacity should not prevent participation in research, it is important to keep in mind that additional scrutiny is warranted for research involving this population.

Following are issues to consider for research that involves participants who are, or may be, or may become decisionally impaired:

Assessing Capacity to Consent

Limited decision-making capacity covers a broad spectrum. A healthy person in shock may be temporarily decisionally impaired. Another may have been severely mentally retarded since birth, while yet a third who has schizophrenia may have fluctuating capacity. Researchers should be sensitive to the differing levels of capacity and use assessment methods tailored to the specific situation. Further, researchers should carefully consider the timing of assessment to avoid periods of heightened vulnerability when individuals may not be able to provide valid informed consent.

Decision making capacity may fluctuate, requiring ongoing assessment during the course of the research. The consent process should also be ongoing. The IRB, at its discretion, may require an outside witness to observe the consent process.

Second Signature on the Consent Document

There are many situations in which a subject should be encouraged to authorize the involvement of family members. However, the consent of another party will be required only when the patient is determined to lack the legal ability to provide an informed consent. This would include minors (persons under the age of 18) and persons adjudicated incompetent. This also includes persons who are not capable of understanding the nature of their illness or the risks, benefits, and natural consequences of participation.

D. Research Involving Prisoners (45 CFR 46, Subpart C)

The purpose of this section is to provide additional safeguards for the protection of prisoners involved in research. Prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as participants in research.

Definitions

Prisoner: “Means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing,” (45 CFR 46.303c).

Minimal risk: “The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons,” (45 CFR 46.303d).

Permitted Research Involving Prisoners

For research conducted or supported by DHHS to involve prisoners, two actions must occur:

1. The BC IRB must certify to the Secretary (OHRP) that it has reviewed and approved the research under 45 CFR 46.305; and

2. The Secretary (OHRP) must determine that the proposed research falls within one of the categories of permissible research specified in 45 CFR 46.306(a)(2):
 - study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
 - study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
 - research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research; or
 - research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the BC IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.

BC IRB Membership Requirements with Regard to Research Involving Prisoners

When the BC IRB reviews a protocol in which a prisoner is a participant, 45 CFR 46.304 requires that:

1. A majority of the BC IRB (exclusive of prisoner Members) shall have no association with the prison(s) involved, apart from their Membership on the BC IRB.
2. At least one Member of the BC IRB shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB only one IRB need satisfy this requirement. In the absence of choosing someone who is a prisoner or has been a prisoner, the BC IRB should choose a person who has a close working knowledge of prison conditions and the life of a prisoner. Suitable individuals could include present or former prisoners; prison chaplains; prison psychologists, prison social workers, or other prison service providers; persons who have conducted advocacy for the rights of prisoners; or any individuals who are qualified to represent the rights and welfare of prisoners by virtue of appropriate background and experience.
3. In addition, the BC IRB must notify OHRP of any change in the BC IRB roster occasioned by the addition of a prisoner or a prisoner representative and take into account the impact of roster changes on quorum requirements (46.108(b)). The BC IRB must meet the special composition requirements for all types of review of the protocol including, initial review, continuing review, review of protocol amendments, and review of reports

of unanticipated problems involving risks to participants.

Additional Duties of the BC IRB Where Prisoners are Involved in Research

When the BC IRB is reviewing a protocol in which a prisoner is a participant, the BC IRB must make SEVEN ADDITIONAL FINDINGS under 45 CFR 46.305 as follows:

1. The research under review represents one of the categories of research permissible under Section 46.306(a)(2).
2. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.
3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
4. Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the Principal Investigator provides to the BC IRB justification in writing for following some other procedures, control participants must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.
5. The information is presented in language which is understandable to the participant population.
6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.
7. Where the BC IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact. The institution shall be prepared to certify to the Secretary (OHRP), upon request, that the duties of the BC IRB under this section have been fulfilled and address any other requirements of the Secretary (OHRP).

Documentation of BC IRB Findings

All findings of the BC IRB, including additional findings under 45 CFR 46.305, category of permissible research and determination of minimal risk will be documented in the minutes of the meeting.

VIII. Special Topics**A. Maintaining Privacy and Confidentiality**

Confidentiality of the identity of research participants and of information from research participants is an important part of any research activity. Breach of confidentiality and invasion of privacy may pose the greatest risks of harm associated with the research. Wherever possible, research data should be retained without any identifiers. When this is not possible Principal Investigators must take steps to protect the confidentiality of the research participants and the data.

Principal Investigators who collect sensitive information from research participants who may be identifiable as study participants may apply for a federal Certificate of Confidentiality (<http://grants2.nih.gov/grants/policy/coc/>). The Certificates are available to all Principal Investigators, whether or not their research is funded by the federal government, and regardless of the kind of sensitive information being collected. The Certificate is intended to protect identifiable research data from disclosure through subpoena, warrant, or court order. There are exceptions to the Certificate's coverage. For further information about Certificates, please contact the BC ORP.

B. Health Insurance Portability and Accountability Act (HIPAA) and Research

The Health Insurance Portability and Accountability Act (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.

All applicants to the BC IRB who will be working with PHI are required to complete the Statement on HIPAA Protected Health Information Use as part of the BC IRB application process.

If BC serves as the Privacy Board of record then a written agreement will need to be signed between BC and the other institution prior to the initiation of the research.

C. Participant Recruitment/Research Advertisements

Any item which is intended to be used to encourage a potential participant to consider volunteering for a research study must be reviewed and approved by the BC IRB before being used. Federal Guidelines indicate that advertising is considered to be an extension of the informed consent process, and thus subject to BC IRB review.

The BC IRB defines advertising as research-related information that will be seen or heard by a potential participant before he or she has read and signed a consent form for the study. This includes any material intended to serve as recruitment material, beyond publication of the existence of a study.

Advertising may include:

- Printed items in newspapers, magazines, flyers, posters, etc.
- Radio
- TV
- Video
- Web/Internet recruitment advertisements
- Informational brochures
- Letters to potential participants
- Letters to professionals
- Imprinted items (notebooks, bags, etc.)

Information included in an advertisement should be limited to the information prospective participants need to determine their eligibility and interest. Following are guidelines for developing research advertisements:

- Include the purpose of the research and brief procedural information such as what will be involved (e.g., interviews, focus groups, etc), the location of the research, duration of participation, etc.
- Include brief eligibility criteria such as disease, condition, or age limits
- Must be quite clear that the project is “research”
- Benefits must be reasonably stated, should be straightforward and truthful
- Name of primary contact and phone number for calling
- Should not include terms such as “exciting new study,” “free,” etc. as these terms could be coercive
- Advertisements may state that subjects will be paid, but should not emphasize the payment or the amount to be paid, by such means as larger or bold type and compensation information should be added towards the bottom of the advertisement.

The BC IRB should also be informed of the following:

- Name or type of the media (e.g., The Boston Globe)
- The targeted audience of the selected media

The IRB must receive the final draft of printed advertisements to evaluate the relative size of type used and other visual effects. The IRB will review the information contained in the advertisement and the mode of its communication. The Principal Investigator must inform the IRB of every mode of communication that the text or advertisement will be used for.

D. Deception

Deception usually consists of merely failing to tell the research participant what the specific points of interest are in an attempt to prevent biasing the research results. Deception of this kind is reasonable and acceptable as long as the Principal Investigator provides justification for its use, and debriefs the research participants after their participation, when appropriate.

However, the use of deception imposes special responsibilities on the Principal Investigator. One of these responsibilities is to provide appropriate debriefing to the research participants. In each case, the BC IRB will require information sufficient to understand why deception is needed, how the potential benefits justify its use, and how debriefing will be done. Additional issues to consider include the following:

- Information that may affect the objectives of the study may not be withheld if it relates to the risks participants may face and hence might affect their willingness to participate.
- Does the presence of deception increase the risk of harm to the participants? If yes, this issue should be addressed.

The Principal Investigator will also need to address the regulatory requirements for the waiver or alteration of consent, which are as follows:

- the research involves no more than minimal risk to participants;
- the waiver or alteration will not adversely affect the rights and welfare of the participants;
- the research could not practicably be conducted without the waiver or alteration; and
- whenever appropriate, the participants will be provided with additional pertinent information after participation.

Depending upon the nature of the deception involved, the research will be reviewed through either expedited or full Committee review. This determination will be based upon whether or not the deception is risk-producing enough to raise the research above the “minimal risk” threshold.

E. Students as Researchers

Undergraduate honors theses, master’s theses, and doctoral dissertations involving human research participants or material of human origin require BC IRB review/approval. However, classroom projects that are conducted as a class assignment and will not be communicated beyond the classroom do not require BC IRB approval. In this situation, instructors are encouraged to introduce their students to the BC IRB process and discuss research ethics.

F. Research at Other Institutions

BC faculty, students, and staff who engage in human participant research at another institution (e.g. university or hospital) must first submit an IRB protocol application to the participating institution’s IRB. In this situation, it is likely that the BC IRB will rely on the participating institution’s IRB, in which case an agreement will be signed between the two institutions. However, the PI must inform the BC ORP of this situation as soon as conveniently possible. Once IRB approval has been obtained from the participating institution’s IRB, the PI needs to submit the participating institution’s IRB protocol application and approval documents (IRB approval letter and IRB approved consent form) to the BC IRB for review. If an agreement will

be signed between BC and the participating institution, then it is only necessary to submit the participating institution's IRB protocol application, IRB approval letter, and IRB approved consent form to the BC IRB for review and not the BC IRB protocol application.

G. Research at Schools

BC faculty, students, staff who engage in human participant research at schools will need to obtain approval from the principals of the participating schools or the school IRB, if applicable. Copies of these approval letters will need to be submitted to the BC IRB before the BC IRB can release BC IRB approval.

H. Research at Other Sites Not Having a Federalwide Assurance (FWA)

If the research is conducted at an institution not having a FWA approved by DHHS, the research must be reviewed and approved by the BC IRB before the research is initiated. In this case, an agreement may need to be signed between BC and the other site. However, if the other site will be receiving federal funds and is "engaged in research" as defined by the following OHRP Guidance document: <http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html>, the site must apply for an FWA with the DHHS OHRP.

I. Research in Other Countries

In order to enroll research participants in societies or cultures outside the United States, permission should be obtained from the host country (its government or delegated agency). Where written consent is appropriate, the form should be translated into the native language. The BC IRB must be given a copy of the original and an English language version that has been translated by a certified translator. Although a formal consent form may not be appropriate if contrary to national or local custom, full disclosure to research participants of all information as specified in the Federal regulations and by BC policy is required. A written statement containing the content of this disclosure should accompany applications for human research participant's approval.

When protocols involve research in foreign countries, the culture, customs, and laws of the host country must be taken into account in such matters as the design of the research, informed consent, and the need or possibility for local review in addition to the review conducted by the BC IRB.

Principal Investigators conducting research in foreign countries under a grant or contract from a Federal agency should consult that agency concerning any special requirements which may apply.

J. Conflict of Interest

The Office for Sponsored Programs maintains the University's conflict of interest policy. In order to meet the requirements of this policy, the BC IRB protocol application includes the following questions for the Principal Investigator to complete. These questions are designed to mitigate the possibility of a real or perceived conflict of interest

The BC ORP Staff will review the conflict of interest information provided by the Principal Investigator and refer any positive disclosures to the Director of the Office for Research Integrity and Compliance, who will then determine whether or not the University's Conflict of Interest Committee needs to review the disclosures and manage actual or potential conflicts of interest. Correspondence regarding the disclosures will be placed in the protocol folder. The BC ORP Staff will inform the BC IRB reviewer(s) as to the status of the review of disclosures: either the disclosure is currently being reviewed by the Conflict of Interest Committee or the Conflict of Interest Committee's requirements/recommendations.

Conflict of interest information pertaining to IRB Members is included in Section I-F.

K. Internet Research

The IRB's review of Internet research involving human participants includes an assessment of the same issues that apply to all research involving human participants (consent, risk/benefit, confidentiality, etc.). However, the technology used adds an additional layer of issues to consider.

Internet Research and the Consent Process

- Since Principal Investigators will not be able to obtain a participant's signature on consent forms, Principal Investigators will need to complete the "Waiver of Written Consent" form, which is electronically linked to the IRB protocol application.
- Also, if altering the consent process, Principal Investigators will need to complete the "Waiver of Informed Consent" form, which is also electronically linked to the IRB protocol application.
- An important aspect of the consent process is confirming that participants understand the research. For this reason breaking the on-line consent form into segments and requiring a "click to accept" before continuing will help to ensure that a participant understands the research.
- The on-line consent form should include information about how the data will be transmitted, how the data will be stored, etc in addition to all of the other "elements of consent" .

Internet Research and Privacy/Confidentiality

- For minimal risk Internet research, breach of confidentiality is the most common risk for data collected on-line and this issue should be addressed in the IRB protocol application.
- Some additional confidentiality issues to consider:
 - How will confidentiality be maintained if participants will be responding by e-mail? Participants could be sharing their e-mail account with other individuals, which could pose considerable problems if sensitive information is be transmitted in the e-mails.

- Issues with observational research, such as entering a “chat room” for research purposes, may include the fact that individuals may expect a certain degree of privacy in such an environment. As applicable, this issue should be addressed in the IRB protocol application.
- For Internet research that involves children under the age of 13, Principal Investigators should read the Children’s Online Privacy Protection Act (COPPA):
<http://www.ftc.gov/ogc/coppa1.htm>

Research Design Issues to Consider

- How to protect against individuals completing surveys multiple times?
- Will the participant be automatically referred to a debriefing screen if they quit in the middle of the study?
- It may also be helpful to include a debriefing page at the end of the study.
- It may be helpful to break the instrument into sections with the possibility of participants completing sections at different times.
- Participants should always be allowed to skip or not answer questions.
- Important to decide whether you will allow anyone to complete the survey or only individuals who have a particular password.

Technology Issues to Consider

- Who will be maintaining the Web site? Who will have access to the data that is collected and how will confidentiality be maintained during the electronic transmission of data?
- Will data only be collected when the participant hits the “submit” button, or before the participants decides that he or she is finished?
- It may be helpful to consult with an IT professional, such as the Director of Academic & Research Services: <http://www.bc.edu/offices/its/support/rs.html>.

V. Review of Adverse Events

A. Expected Adverse Events

Adverse events that may be reasonably anticipated to arise as a result of study procedures should be described in the consent form. Expected adverse events need not be reported to the BC IRB on an individual basis. At the time of renewal, the researcher must report the incidence of these adverse events.

If, in the course of conducting the study, the Principal Investigator finds that the expected adverse events are occurring with a greater frequency than anticipated or at a higher level of severity than expected, they should report this to the BC IRB as soon as the finding is noted. The consent form language describing the risks should be appropriately revised and participants already enrolled in the research should be appropriately advised. The Committee may request that the researcher to inform already enrolled participants of these changes.

B. Unexpected or More Serious than Expected Adverse Events

Occasionally, adverse events occur during the course of a research activity that were unanticipated or are more serious than expected. In these cases, the Principal Investigator

should contact the BC IRB within twenty-four hours of learning of an adverse event. The report will be sent to the BC IRB for a determination about whether the study should be modified to reduce the risks or the consent form should be revised to include the unanticipated adverse effects.

The death of any research participant should be reported immediately to the BC IRB. The only exception is when the study is conducted among participants who are expected to have a high rate of mortality from their underlying condition, and the Principal Investigator has absolutely ruled out any connection between any study procedure and the research participant's death.

C. Externally Funded Research

The Principal Investigator must contact the sponsor to determine their adverse event reporting requirements.