BOSTON COLLEGE
Office for Research Protections
Standard Operating Procedures for Researchers Using Human Participants in Research

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. There may be more than one Principal Investigator on a BC IRB protocol, however, the first PI listed will be the main point of contact for communications through the Cyber IRB system.

A. Definitions

Some of these definitions were revised as part of the Final Rule, which is the updated version of the Common Rule (45 CFR 46) governing human subjects protections.

Research: "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge," (45 CFR 46.102d). The following activities do not constitute research:

- Scholarly and journalistic activities (including oral history, journalism, literary criticism, historical scholarship, legal research, and biography)
- Public health surveillance activities
- Collection and analysis of information, biospecimens, or records for criminal justice or criminal investigative purposes
- Certain activities in support of intelligence, homeland, security, defense, or other national security missions

Human Participant: "A living individual about whom an investigator (whether professional or student) conducting research obtains (1) information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens," (45 CFR 46.102e).

Intervention: "Includes both physical procedures by which information or biospecimens 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

All BC faculty members, staff members and students must secure the prior, written approval of BC's IRB before undertaking any activity that constitutes "research" involving "human participants" as those terms are defined above. Determining whether a given activity constitutes "research" or involves "human subjects" is not always a straightforward exercise; projects that might appear at first not to call for IRB review may, upon closer analysis, fall within the definitions of "research" and "human subject" and therefore required IRB review. Moreover, even when a researcher correctly concludes that a planned activity would not call for IRB approval, other, practical considerations make some level of IRB review a *de facto* requirement. For example, some journals reflexively refuse to accept manuscripts in the absence of IRB review, regardless of whether the underlying activity truly constitutes "research" or involves "human subjects.'' Similarly, some sponsors or data set owners might have standard operating procedures requiring IRB review even when the sponsored activity does fall within the technical definitions of "research" or "human subjects."

For these reasons, ORP urges researches to err on the side of presuming that their planned projects *do* require IRB review and submit IRB applications. Alternatively, ORP encourages researchers to ask ORP in advance whether their proposed activities would require IRB review. Furthermore, to address the requirements of third-parties, such as journals or sponsors, that might demand evidence of IRB review even when it would not otherwise be required, the ORP may issue "Non-Human Subjects Research" determination letters, detailed in the following paragraph.

When ORP receives an email inquiring about a non-human subjects research determination, they will be asked to describe their project generally, and provide the following information: 1) How the data will be used; 2) What kind of data will be collected, and whether/how it is de-identified, 3) Procedures to obtain the data, and 4) Where/how the data will be stored. The ORP staff may discuss other relevant questions with the PI to determine whether the research does not require formal IRB review. If it does meet the requirements for non-human subjects research, a determination letter will be provided.

Presented below are examples of scenarios in which, before embarking on the process of

submitting a full application for IRB approval, researchers might appropriately ask ORP for guidance on whether IRB review is required.

Presence or Absence of Intent to Publish

A researcher's intent to publish suggests, but does not fully equate with, a purpose to develop generalizable knowledge. Therefore, one's intent to publish the outcome of his or her project does not necessarily mean that he or she is proposing to conduct "research," which requires IRB review. Conversely, the absence of an intent to publish does not categorically rule out the possibility that IRB review may be required. Accordingly, ORP cautions researchers not to ascribe undue weight to the question of whether they intend to publish. Instead, when researchers question whether IRB review is required, they should seek guidance from ORP.

Evaluation and/or Quality Improvement Programs

The federal Office for Human Research Protection (OHRP) has made clear that projects whose *sole* purpose is to evaluate or improve organizational performance at a particular institution does not constitute "research." On the other hand, OHRP recognizes that, in many instances, projects have dual purposes, including both evaluating or improving the performance of a particular organization *and* developing generalizable knowledge – i.e., conducting "research." See https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html. ORP encourages faculty, students and staff undertaking evaluation or quality improvement projects to consult with ORP staff to determine whether their planned projects would require IRB review.

Case Studies of Businesses/Corporations

For our purposes, a human subject/participant is "a living individual ***about whom*** an investigator (whether professional or student) conducting research obtains" data. If a research study collects data not about individual persons but about businesses or other organizations, the project might not require IRB review. Researchers planning such projects would likely benefit from a consultation with ORP before preparing their IRB applications.

Research on Deceased Persons or Publicy Available, Historical Data

BC IRB review/approval is not required for research concerning only deceased persons and no living individuals. Similarly, research utilizing only publicly available information does not require IRB review. Such projects do not involve a human subject/participant, which is defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens," (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.cornelll.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 protocol application, which will likely be reviewed as an exempt protocol. 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 as an exempt protocol.

If the data set contains no individually identifiable information, or the data set is publicly available, BC typically would not require the project to have IRB approval. The Principal Investigator can fill out a protocol form that will be processed as an exempt protocol. Nevertheless, in some situations, sponsors may require IRB approval as a condition of releasing funds. Additionally, the data at issue in such studies might constitute a restricted data set, which, as described above, might require special administrative processing. Accordingly, in such situations, the Principal Investigator can fill out a protocol form that will processed as an exempt protocol. The Principal Investigator will not need to fill out all sections, such as Informed Consent, as it will not be applicable.

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/office-for-research-protections/training.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

[1] Cornell University Committee on Human Subjects (UCHS) website: http://www.osp.cornelll.edu/Compliance/UCHS/Secondary.htm.

It is the responsibility of the Principal Investigator (BC faculty, staff, or student) to submit the IRB protocol 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 retention requirements regarding how and for how long records must be stored, and the Principal Investigator must be familiar with those requirements.

As long as there is no sensitive information on consent forms (such as social security numbers), consent forms may be stored electronically for the three year period rather than in a paper copy. However, PIs must ensure that the consent forms are stored in a secure place (with access restricted to researchers only) and in a location that is regularly backed up to prevent data loss. The BC secure servers are the best location to store scanned copies of consent forms given these requirements.

Protocols should be uploaded to Cyber IRB: www.cyberirb.us/bc. PIs may sign in with their BC username and password.

Documents Required for Initial BC IRB Submission:

1. The Initial IRB Application Form signed by the PI (faculty advisors also need to sign BC IRB applications submitted by their students), which includes or addresses the following, as applicable:

    a. Study funding
    b. Recruitment numbers
    c. Research summary
    d. Rationale/Justification for Study
    e. Materials, methods, and analysis
    f. Participant population & recruitment methods
    g. Informed Consent
    h. Confidentiality
    i. Potential Risks
    j. Minimizing Potential Risks
    k. Potential Benefits

2. Proposed informed consent document (and assent document, as applicable) that contains the elements of consent as identified in 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 II-C), a waiver or alteration of consent (see Section II-D), or a waiver of parental consent (see Section III-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.).

6. Documentation of completion of required training: training certificates for each member of the research staff, and the faculty advisor (if applicable), should be uploaded into Cyber IRB. These certificates are valid for 3 years.

7. As of July 2018, federal regulations no longer require that federal grant applications are submitted for review when submitting an IRB application.

8. If the Principal Investigator will be working with health information, he/she must also complete and submit a Statement on HIPAA PHI Use form. The exact form to be used may vary depending on the institution where the research takes place.

9. Research at Other Institutions: If research is being performed at another institutions such as a hospital or another university, Principal Investigators should seek to defer review to one of the two institutions, rather than going through a full IRB review at both institutions. This is called an Institutional Authorization Agreement, or IAA.

To initiate an IAA at Boston College, the PI should submit an application through Cyber IRB. Within the Cyber IRB system, the PI should click "Single IRB (IAA)" to begin the process. If BC will be the IRB of record (the institution to do the full IRB review), the PI should select "Institutional Authorization Agreement- BC." This application is almost identical to the Cyber IRB initial application, with one additional section asking for the relying institution's IRB information. If BC is relying on another institution for IRB review, select "Institutional Authorization Agreement – Other." This is a short form and simply asks for a brief description of the study and contact information for the other IRB.

Once the ORP receives this submission, an IAA form will be signed and sent between the institutions. We will send you the fully executed IAA via email.

11. Site Permission Letters: When research will be performed by a BC investigator at another organization, and no agreement as described in Paragraph 10 above is put in place, the BC investigator must obtain a Site Permission Letter from a person who is authorized to commit the other organization. The letter must be on the organization's letterhead or, if done by email, and it is strongly preferred that they are signed by hand. If this is not possible, an Adobe electronic signature is permissible.

The purpose of the Site Permission Letter is to provide tangible evidence of the other organization's willingness to host the research. It provides both parties written documentation of the agreement that could be useful in the event disputes occur in the course of or after the conclusion of the research. Site Permission Letters are required irrespective of the nature of the research or how the other organization is composed or managed.

The Site Permission letter is not a complicated document. It simply has to indicate that

the other organization agrees that the BC researcher may conduct his/her research project at the other organization's site. A sample letter can be found at http://www.bc.edu/research/office-for-research-protections/forms.html

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

1. Requests for changes to the study after initial approval. These are considered amendments, and can be initiated in Cyber IRB by first clicking on the title of the protocol under "My Approved" and then clicking the "Amendment" button on the left side of the screen.

2. Reports of unexpected adverse events. These can be initiated in Cyber IRB by first clicking on the title of the protocol under "My Approved" and then clicking the "Adverse Event" button on the left side of the screen.

3. Continuing Review Report (annually or as required by the BC IRB). This can be initiated in Cyber IRB by first clicking on the title of the protocol under "My Approved" and then clicking the "Continuing Review" button on the left side of the screen. Please note that as of July 2018 under the new Boston College Flex Policy, most expedited projects will no longer require Continuing Review (more details are in Section 1-F of this document).

4. Closure form. This must be submitted when a project is complete or is in the data analysis phase with no further access to individual identifiers. This can be initiated in Cyber IRB by first clicking on the title of the protocol under "My Approved" and then clicking the "Closure" button on the left side of the screen.

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

E. BC IRB Review

The policies and procedures outline here are used as a general guide for the ORP staff and IRB members to make decisions on protocol approvals. However, all studies are treated on a case-by-case basis with careful consideration for the protection of human subjects, the feasibility of processes outlined in the protocol, and the context of the research. Thus, the ORP staff and the IRB are expected to use their best judgment, which may include deviation from general policies when appropriate.

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, individuals with impaired decision making, 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, individuals with impaired decision-making capacity, 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.

F. IRB Flexibility Policy

The Final Rule (a change in the regulations governing IRB activities, called the Common Rule) was initially slated to go into effect in January 2018, but its implementation was delayed just before the official-roll out and postponed until July 18th, 2018. On June 19th, U.S. Department of Health and Human Services released a notice delaying the implementation of the Final Rule once again until January 21st, 2019, while allowing institutions to implement, at their discretion, three of the burden-reducing provisions of the Final Rule beginning on July 19th for all new studies. These provisions include:

- Use of the revised definition of "research," which deems four categories of activities as *not* research (certain journalistic, public health surveillance, and criminal justice or intelligence activities)
- Eliminating continuing review for most expedited studies and any full board studies that are in the Data Analysis Only phase
- Eliminating the requirement for IRB review of grant applications for research

The Boston College IRB adopted these provisions for all new studies submitted on or after July 19th, 2018, regardless of funding source.

Additionally, institutions were given some options for handling ongoing studies that were approved before July 19th, 2018. The BC ORP decided that all existing expedited Boston College studies (submitted before July 19th, 2018), will undergo one final continuing review, after which they will no longer require continuing review in subsequent years, unless the IRB determines on a case-by-case basis that they require additional monitoring (due to the risk profile of the protocol).

Overview of Boston College IRB Flexibility Policy

At BC, a small proportion of all active IRB protocols are federally funded, which are the only protocols that must follow the federal regulations governing IRB processes (the Final Rule). As an institution that has never "checked the box" on its Federal Wide Assurance with the Federal Office for Human Research Protections, Boston College has flexibility in how to treat its non-federally funded protocols. Until the summer of 2018, the Boston College Office for Research Protections chose to treat all federally funded protocols in the same way as all other protocols, i.e., federal guidelines have been applied to *all* protocols. This is burdensome for researchers. In response, the IRB implemented a more flexible set of IRB policies to be applied to all non-federally funded research protocols, which launched on July 19th, 2018.

Features of the IRB Flexibility Policy, Applicable to all non-federally funded protocols submitted on or after July 19th, 2018:

- Broadened existing categories of exempt research. Section 1-G in this document lists the full set of exempt categories of research under the Flexibility Policy.

  - In summary, the existing categories of surveys, interviews, educational tests, observations of public behavior (already exempt) have been expanded to include the collection of some kinds of sensitive and identifiable data. However, the following are still not allowed: interventions that do not fall into the definition of "benign behavioral intervention" (see below); the collection of biospecimens; linking to other personally-identifiable data; and research with children (except for educational tests)
  - The scope of secondary data research (already exempt) will be expanded to allow: maintenance of identifiers if all study data is protected health information (PHI), and prospective data review (meaning data do not need to be "on the shelf" at the time of the study, as required pre-2018).
- <u>Implementing a new category of exempt research.</u>
  - The new "benign behavioral intervention" category permits data collection via an interaction (e.g., survey, interview, audio/visual recording) from **adult** subjects with prospective agreement. A "benign behavioral intervention" is defined as one that is brief in duration, harmless, not physically invasive, painless, not embarrassing or offensive, and not likely to have a lasting adverse impact. Example: having subjects solve puzzles under various noise conditions.
  - However, the following are not included in this exempt category: research with children, deception, physiological data collection methods, linking to additional personally-identifiable data
- <u>Implementing minor changes to informed consent</u>
  - Informed consent documents that are more than 3 pages long should include a concise summary of the study on the first page of the consent form. New language is also available for studies that have been issued a Cerificate of Confidentiality.
- <u>Eliminating continuing review for most new studies</u>
  - Research that qualifies for expedited review no longer need annual review.
  - Studies in the Data Analysis Only phase typically do not need annual continuing review.
  - In rare cases, the IRB may require continuing review due to the risk profile of a protocol
  - In the place of continuing reviews, the BC ORP has developed a Quality Assurance Program which is detailed in section IV-L of this document.

Additionally, the Department Chair's signature is no longer required for protocol submission. The Department Chair will still receive notification of all submissions, but will not need to log into Cyber to electronically sign them.

The amendment process for staff changes or any other protocol alteration has not changed.

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.

G. 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. For all non-federally funded studies, these new definitions apply as of July 19, 2018 under the new BC Flexibility Policy. For any federally funded studies, these definitions will apply starting January 21st, 2019. Until that date, the old exempt categories apply, which can be found in Appendix 1 in this document.

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. **This category applies only normal educational research in regular educational settings.**

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, focus groups, or observation of public behavior (including visual or audio recording), if at least one of the following criteria is met: (i) information obtained is recorded in such a manner that human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; (iii) the information obtained is recorded in such a manner that the identity of the subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required. **This category does not apply to children or prisoners.**

(3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an **adult** subject (NOT child subjects) through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review. (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. (iii) If the research involves deception, it can be exempt under this category if the participants are told during the recruitment process that there is an element of deception in the study, and they agree to participate knowing this.

(4) Secondary data analysis using **identifiable** private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using governmentgenerated or government-collected information obtained for nonresearch activities

For this category, data do not need to be “on the shelf” at the time of the study. The data can be collected prospectively and still be used for exempt research.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, improve, or otherwise examine: Public benefit or service programs, including

procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs. Each Federal department or agency conducting or support the research must establish, on a publicly accessible Federal website, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision.

(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.

H. 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.

<u>Expedited Review Categories</u>

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. 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. This type of research may sometimes be exempt. Please see the Exempt Categories section to confirm.

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. 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.

    (NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

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.

I. 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 10days 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.

J. No IRB Review Needed

Occasionally, granting agencies request an official letter stating that the PI's project has been reviewed by the IRB. In cases where there is no human subjects involvement and therefore no IRB is required, the ORP will issue an official letter stating that the project does not require IRB review as determined by the BC ORP. In these situations, the PI should contact the IRB directly and should not submit an application through the Cyber IRB system.

K. IRB Meetings

Agenda and Meeting Materials for BC IRB Meetings

The agenda for BC IRB meeting is prepared by ORP and is distributed along with other meeting materials approximately seven days prior to the meeting. The meeting materials are sent to IRB members in a single PDF document. The materials include the agenda, minutes of the previous meeting, the report on protocol approvals done since the previous meeting, protocols being reviewed, and any documents scheduled for discussion at the meeting.

Voting Procedures at BC IRB Meetings

Voting on motions at BC IRB meetings is limited to the voting members of the BC IRB. In order for a vote to be held, a motion must be made by a voting member of the IRB, and seconded by another voting member of the IRB. The motion is then opened for discussion. Once discussion has satisfactorily reached its conclusion, the motion is voted on or the motion may be amended based upon the content of the discussion. The Chair asks for those voting for the motion, against the motion, and those who wish to abstain from voting. The results are recorded by the ORP representative taking the minutes of the meeting.

Minutes of BC IRB Meetings

The minutes of BC IRB meetings are recorded by a member of the ORP staff. The names of members and guests present and absent are noted. The results of motions, votes, and discussions are then recorded in the order in which they occur at the meeting. The recording of the discussion is done in summary fashion and is not intended to be a verbatim recording of the entire discussion.

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. These notices are sent at the earliest possible time after the decision has been made. There is no appeal of BC IRB final decisions regarding the suspension or disapproval of protocols.

Amendments

Proposed amendments are submitted using the IRB Amendment Form on Cyber IRB When ORP had determined that the proposed amendment is complete, a copy is sent to the ORP Associate Director for approval who has been delegated approval authority by the IRB. Simple amendments (e.g. those simply adding a person to the research staff) can be approved by the ORP staff as a means of expediting the process. Notices of approval are sent to the PI at the earliest possible time.

Pilot Studies

Generally, a pilot study is defined as a preliminary investigation to determine the feasibility of a larger study. It is usually done on a small scale (e.g. fewer that then participants) and is exploratory in nature. PIs should also consider whether they plan to present or publish their pilot study data. In most cases, pilot studies do still require IRB review, if they meet the definition of research (see section 1. A. of this document). PIs engaging in pilot studies should contact the ORP to help determine whether an IRB review is required.

L. Conducting Continuing Review

As explained in section 1G, the BC IRB will no longer routinely conduct continuing reviews of new studies submitted on or after July 19, 2018. The BC IRB shall conduct one final continuing review of all existing protocols approved before July 19, 2018, for which research activities (including data analyses) have continued. Continuing review is no longer needed once all participant identifiers have been destroyed. The IRB does reserve the right to require continuing reviews on an annual basis (or longer or shorter) due to the risk profile of the project, or adverse events that have been reported on the project in the past.

1. 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.

2. 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, or

      (d) where the IRB has determined during the initial full board review of the project that future continuing reviews can occur via the expedited procedure, however, this does not apply to federally funded studies.

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.

M. Project Closure

Exempt and expedited projects should be closed when (1) there will be no further interaction with human participants, (2) there will be no long-term follow-up with human participants, and (3) no further access to personally identifying information will be needed. All three criteria must be met in order for the project to be closed. Project closure is accomplished by the Principal Investigator completing the Closure Form on Cyber IRB. The Closure Form must be submitted prior to the protocol expiration date. If the review is in good order, the Office for Research protections staff will notify the Principal Investigator that the project will be closed on the expiration date (or earlier if requested by the Principal Investigator). Full board studies may be kept open indefinitely.

II. 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 Appendix 2 of this document.
- 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.

<u>Principal Investigator Responsibilities</u>

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.

For consent documents longer than 3 pages, a concise and focused presentation of the key information that is most likely to help potential subjects understand why they might or might not want to participate in the study. The key information must be presented first and must include the following:

a. Identification of the project as a research study and that participation is voluntary
b. Purpose of the research, duration of participation, and a description of research procedures

Foreseeable risks or discomforts, if any

c. Expected benefits to subjects or others, if any
d. Alternative procedures or treatments that might benefit the subject (Note: applies primarily to clinical research)

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.

H. Active & Reminder Consent

For studies involving data collection over multiple time points, PIs may collect active consent before the first data collection time point (with written or verbal consent), and may send a reminder during future data collection time points. This reminder would allow participants to contact the PI to opt out of the study if they wish, but would not require a new written or verbal consent.

III. 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,, individuals with impaired decision-making capacity, 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.

<u>Definitions</u>

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.

Child Abuse and Other Circumstances Involving Mandated Reporting

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.

Circumstances that may trigger reporting obligations include, but are not limited to, the following:

- Child Neglect and Abuse (see http://www.mass.gov/eohhs/docs/dcf/can-mandated-reporters-guide.pdf);
- Elder Neglect or Abuse (see http://www.mass.gov/elders/docs/reg-651cmr005.doc); and
- Abuse or neglect of disabled persons (see http://www.mass.gov/dppc/abuse-report/who-are-mandated-reporters.html)

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 researchers would be blind to the participants' identities, the research may qualify for exempt status.

C. Research Involving Individuals with Impaired Decision-Making Capacity

Additional safeguards should be included in studies of individuals with impaired decision-making capacity, to protect the rights and welfare of these subjects.

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

Secretary: "Means the Secretary of Health and Human Services and any other officer of employee of the Department of Health and Human Services to whom authority has been delegated." (45 CFR 46.303a).

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 (45 CFR 46.306)

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.

<u>Additional Duties of the BC IRB Where Prisoners are Involved in Research</u>

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.

IV. 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 (https://humansubjects.nih.gov/coc/index). These are automatically issued to all research funded by NIH on or after October 1st, 2017. Other researchers who are not funded by NIH but are interested in applying may follow the instructions at the CoC website in the link above. 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.

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. Participant Incentives

For any research incentives over $25, the Office for Research Protections will refer PIs to speak with a tax specialist in the Boston College Office of the Controller. Depending on the amount of the research incentive and type of funding for the project, PIs may be asked to include additional language regarding tax issues in their consent form.

E. 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. Deception may be passive (simply not telling the participant about the research hypotheses), also known as omission. Or it may be active (commission), which involves presenting misinformation about the study to participants.

The use of active 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.

F. 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. At least one of the faculty advisors on student projects must be faculty of Boston College, but a secondary advisor can be from another institution.

G. Recruitment of Family Members as Participants

The IRB generally discourages recruiting family members as a targeted population for the sake of convenience or because of their easy availability. Enrollment of individuals who are family members of the research team must be declared in an application to the IRB, and must include a strong justification for the inclusion of these subjects. The PI must also discuss how the possibility of coercion will be minimized, and the process for ensuring objective analysis of study results. The IRB will assess these requests on a case-by-case basis, ensuring that their inclusion is warranted, and that recruitment and consent procedures are free from undue influence. The consent process must not be conducted by someone with whom the potential subject has a status relationship (friend, family member, or employer).

H. 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.

I. 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.

J. 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.

K. Research in Other Countries

International research may pose special concerns for the IRB and for research teams. PIs are responsible for understanding and complying with the ethical and legal aspects of conducting human subjects research in an international setting. This often requires additional consideration for international participants' rights and welfare within different cultural context and local regulations.

PIs should consider the following issues when evaluating local context and address them in their IRB protocol:

- Scientific/ethical justification for conducting research in an international setting, including how the research will benefit the local population
- Societal and cultural beliefs that may impact the research
- Role of women and children in the society and their autonomy to make decisions
- Literacy rate of the population
- Details of the political, cultural, and economic environment, how these details impact the research in terms of design and special challenges, and the resources available to the research team for guidance on these topics

The HHS Office for Human Research Protections maintains an online compilation of international laws and regulations pertaining to human research protections. Additional resources on international research are also available. Before submitting an IRV application, PIs should first consult this compilation to determine whether there is a specific local review process in the country where data collection will occur.

If no local laws, regulations, or standards of practice require review by a local IRB or similar local review body, the PI* must include with their IRB application a letter from someone with knowledge of the local context stating that:
a) there is no formal local review process in the country, and
b) that the individual has reviewed the protocol and can attest to its cultural appropriateness and safety.
The PI should also provide information describing the person's qualification to comment on such matters.

If a specific local review is required in the country of study, the approval from that local governing board must be included in the BC IRB application. Please note that international approval processes often move slowly, so you should plan ahead and build potential delays into your timeline.

Regardless of whether local review is required, research conducted at or in collaboration with a specific site, such as a school, university, hospital, or clinic, the PI must include with their submission a letter signed by an appropriately authorized representative of the site indicate the site's support for the research to go forward.

The content, language, and method of consent should be carefully considered to ensure that it is culturally and contextually appropriate. A local contact must be included on the consent form with an appropriate contact method so that participants can reach out with concerns or questions. For example, if internet access is limited at the site, providing an email address would not be appropriate.

All personnel on the project, including those outside of the United States, must have human subjects training. Research assistants hired at the site are considered collaborators and must be included on the study protocol in most cases. If the BC-required CITI training is not culturally appropriate for local research team members, please contact the IRB to determine another training method that will meet the team's needs.

If your proposed international research will be done remotely (meaning you will only collect data through a virtual format or by phone), please contact the IRB as some of these requirements may be modified on a case-by-case basis.

L. GDPR

The General Data Protection Regulation (GDPR) is a European Law that went into effect on May 25, 2018, and establishes protections for privacy and security of personal data about individuals in European Economic Area (EEA) based operations and certain non-EEA organizations that process personal data of the EEA. It applies to the collection and use of personal information:

a. Through activities within the borders of EEA countries
b. That is related to offering goods and services to EEA residents, or
c. That involves monitoring the behavior of EEA residents.

If your study involves research activity that is accessing, using, collecting, or processing information or data in person or online from anyone who is present in one of the countries of the EEA, then your study may be subject to GDPR.

For any studies that fall into this category, the Office for Research Protections staff will forward your full protocol to the Boston College Office of the General Counsel. They may suggest minor changes to your consent forms if your study does indeed fall under

GDPR regulations. It may take 2-4 weeks for a GDPR determination from General Counsel, so please keep this in mind when determining your project timeline.

M. 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 Associate Director of Research Integrity, 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.

N. 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.

<u>Internet Research and the Consent Process</u>

- Since Principal Investigators will not be able to obtain a participant's signature on consent forms, Principal Investigators will need to select a partial waiver on the consent section of Cyber IRB.
- 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."

<u>Internet Research and Privacy/Confidentiality</u>

- 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 to 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: https://www.bc.edu/offices/researchservices.html.

Using Social Media for Data Collection

Investigators are allowed to use social media to recruit participants for their research studies, as long as the text of the communication and a description of how it will be disseminated is included in the IRB protocol.

The IRB does not consider sites that require a registration or log-in, such as Facebook, to be publicly available data. Therefore, posts on this website can only be used as research data if consent is obtained from participants. If a researcher feels that consent should be waived (see section II D of this document), he or she may make this argument to the IRB< and the full board will consider these requests on a case-by-case basis.

O. Technology Approval Process

Any technology (such as data collection platforms or transcription services) proposed in an IRB protocol must be approved by Boston College Information Technology Services through the "Get Tech" process. Please see this website for more information:

https://www.bc.edu/offices/help-secure/acquire-tech.html. Please note that you will need to use VPN if trying to access this website from off-campus. This site includes a list of software and other technology that is already approved at Boston College. At the bottom of the page, there is a link to request review and approval of any new technology. The Office for Research Protections cannot approve an IRB protocol with new technology until it has been approved through this process. Please note that this process typically takes a month or longer, so you should build this review time into your project timeline.

P. Quality Assurance Program

Given the elimination of Continuing Reviews for most expedited protocols under the Flexibility Policy, With the impeding changes to the Common Rule and our newly drafted flexibility policy, the BC ORP has developed a Quality Assurance Program (QAP) to provide internal oversight on compliance issues and record keeping with less administrative burden on researchers than the annual Continuing Reviews, which will be phased out for most expedited projects.

The QAP program consists of reviewing a small number of projects each month. Protocols will be chosen randomly, with a focus on expedited studies, although some exempt studies may be selected based on the risk profile of the research. Closed protocols or protocols in the data analysis only phase will not be selected for review. Once protocols for review are chosen at the beginning of each month, the PI on each protocol will be notified and asked to set up a short meeting with the ORP within 2 weeks of receipt of the email. The PI will be required to send the ORP a copy of all current consent forms and instruments being used on the project, as well as a current staff list. These documents will be compared to the approved documents on file with the IRB. All documents associated with submissions for the protocol (such as amendments, continuing reviews, etc.) will be reviewed by the ORP staff.

During the meeting, at least one member of the Office for Research Protections staff will meet with the PI or a research team member of the PI's choosing. The PI may invite any research staff of his or her choosing. The PI and/or research staff should be prepared to answer questions such as those listed in the Quality Assurance Worksheet (available on the ORP website and as Appendix 3 in this document). This is not an exhaustive list of questions, and you may not be asked all of these questions.
We will also solicit your feedback and ideas about the IRB process—what is working well and what could be improved—so that we can further refine our processes.

The Office for Research Protections will write up a report that details the findings of the review and meeting no later than 2 weeks after the meeting date. In this report, we will describe when the meeting took place, a list of significant findings, such as whether your research is compliant with BC and (if applicable) federal regulations and any discrepancies between the approved protocol and current practice. The report will also identify any areas where record keeping or practices could be improved, and will provide educational resources where necessary. If there are any discrepancies between

the approved protocol and the procedures or documents currently being used in the study, these will be detailed so that the PI can address them.

A draft of the report will first be sent to the PI for review. The PI can then approve it as is or suggest changes for accuracy. Once the ORP staff has drafted a final version of the report, a copy will be sent to the PI, the Vice Provost for Research, and the IRB Chair. If the PI has been asked to make any changes to the existing protocol or research practices, they must submit a letter detailing how those changes will be addressed within 2 weeks of receiving the report. If there are significant findings, the report may be reviewed either by the IRB staff, the IRB Chair, or convened IRB at its next meeting, as appropriate.

Q. Enrollment of Participants in Excess of the Number Approved by the IRB

Principal Investigators (PIs) are responsible for stating on the protocol form the number of participants they expect to recruit in the course of the research. It is IRB policy that the number stated in the approved protocol must be reasonable and must be derived from a realistic expectation based on the needs of the research, the PIs experience, the possible pool of participants, and the PI's recruiting methods.

The IRB recognizes that on occasion, the number will be exceeded even though no changes have been made to recruitment methods, site selection, or other factors. An example would be a PI recruiting participants from a social media site for an online survey and having more people signing on and completing the online survey that had been anticipated. While advance approval is no longer required for this type of situation, the PI still needs to explain in the annual Continuing Review why the number of participants exceeded the number in the approved protocol.

While the IRB recognizes the need for flexibility, there are cases in which the PI still must submit an amendment prior to recruiting participants in excess of the number in the approved protocol. The following are some examples of cases in which advance IRB is needed. Please note how these differ from the example given above – that is to say, the need for additional participants is linked to another change to the protocol that requires IRB approval:

1. The PI wants to add a new survey that will require a higher number of participants to be recruited.

2. The PI originally proposed recruiting only male participants, but now wishes to recruit women as well.

3. The PI originally proposed recruiting from one age grouping (e.g. 18-35 years), but now wants to expand recruitment to an additional age group (36-64 years).

4. The PI decides to either change or use additional recruitment methods in order to obtain the needed number of participants. The change results in a significant increase in the number of participants.

5. The PI is surveying individuals from three companies and wants to add a fourth company.

This will increase the number of participants.

6. The PI is conducting research with an affluent population but now wants to include additional participants from neighborhoods having a different socio-economic status.

As noted above, these are examples and in no way constitute a comprehensive set of situations requiring IRB approval. If you have any questions, please contact the Office for Research Protections (2-4778, irb@bc.edu) prior to recruiting additional human participants.

R. Data Storage

Whenever possible, PIs are encouraged to save data on the secure departmental servers. Each department's technology consultants are responsible for setting up server folders for faculty and other researchers. Although it is permissible to record audio data from interviews on handheld recorders or Iphones, these files must be promptly moved to a secure location such as the departmental servers. No human subjects data is allowed to be stored on unencrypted flash drives according to this policy from Boston College Information Technology Services.

V. Review of Adverse Events

Adverse events will be reviewed on a case-by-case basis. PIs should submit an adverse event report through Cyber IRB within 24 hours of any event that is considered adverse or unexpected, or may present a risk of harm to human subjects. This form can be accessed by clicking on the approved protocol within Cyber IRB and then selecting the "Adverse Event" button on the left side of the screen. The PI may be contacted by the ORP staff for clarifying questions or additional documentation of the incident. The adverse event report will be shared with IRB members and reviewed at the next full board meeting. The PI will receive an official determination letter outlining steps that need to be taken to rectify the situation and any amendments that need to be filed. The PI's department chair and the Vice Provost for Research will receive a copy of this letter. During the discussion of each adverse event that is reviewed at a full board IRB meeting, one of these definitions will be assigned to the event and referred to as such in the determination letter.

The Office for Sponsored Research may be contacted if the project is externally funded. If required by the terms of the granting agency, the funder will be notified of the noncompliance. In instances of serious non-compliance, the individual(s) involved will be given notice that research involving the use of participants must be suspended or terminated.

In any of the below situations, the BC IRB may inform the Vice Provost for Research, as well as the Executive Director for Research Administration, regarding details of the adverse event or noncompliance. As appropriate, the DHHS Office for Human Research Protections (OHRP) may be contacted. Additional details regarding non-compliance are included in the BC policy "Ethical Conduct of Research and Research Misconduct."

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 via the Adverse Event form on Cyber IRB. 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 inform already enrolled participants of these changes.

B. **Unanticipated Problem**

Any unanticipated problem related to the research that adversely affects the safety, rights, or welfare of subjects or others. Generally satisfies all of the following criteria: 1. Related to the research study itself; 2. Unanticipated (unexpected, not described in study docs); AND 3. Adversely affects the safety, rights, or welfare of subjects or others. For example, breaches of confidentiality are considered unanticipated problems even if they are described in the informed consent.

C. **Noncompliance**

Failure to comply with regulations, institutional policies, relevant state or federal laws, or the research plan as approved by the designated IRB. Noncompliance can be either minor or serious.

Minor Noncompliance

Any behavior, action, or omission in the conduct or oversight of research that constitutes noncompliance but is not persistent and does not adversely affect the rights and welfare of subjects, or result from willful, knowing, or intentional misconduct on the part of the research team. This type of noncompliance does not compromise the integrity or validity of the research and doesn't result in a detrimental change to a participant's condition or status. Examples of minor noncompliance may include, but are not limited to the following: lapses in continuing IRB approval, minor changes in or deviations from an approved protocol, or administrative errors.

Serious Noncompliance

Any behavior, action, or omission in the conduct or oversight of research that constitutes noncompliance, and in the judgment of a convened IRB, has been determined to significantly increase risk to participants, decrease potential benefits, compromise the integrity or validity of the research, or result from knowing misconduct on the part of the research team. Examples of serious noncompliance may include, but are not limited to the following: conducting or continuing non-exempt human subjects

research without IRB approval; lack of legally effective informed consent from research participants; failure to report or review serious adverse events, unanticipated problems, or substantive changes to research; or inappropriate oversight of the research to ensure the safety of human subjects and the integrity of the research/data.

D. **Continuing Noncompliance**

Any minor or serious noncompliance that occurs in a persistent or repeated pattern. This includes when the PI or research team makes the same or different mistakes on a single protocol or commits noncompliance events across multiple protocols. It suggests the likelihood that noncompliance will continue without intervention. It includes a failure to respond to a request from the IRB to resolve an episode or pattern of minor or serious noncompliance. Examples of continuing noncompliance may include, but are not limited to the following: repeated failures to provide or review progress reports resulting in lapses of IRB approval, inadequate oversight of ongoing research, or failure to respond to or resolve previous allegations or findings of noncompliance.

Please note that there may be other incidents related to a study that negatively impact (or could impact) the rights or welfare of subjects, regardless of whether the incident was unexpected or resulted from non-compliance. These events must also be reported through Cyber IRB. For example, in a study with diabetics involves placing a blood glucose monitor under the skin, the consent may disclose the risk of infection arising from insertion of the device. If an infection occurred, it would not be unexpected, and could happen in the absence of noncompliance.

E. Failure to Submit IRB Protocol

Retroactive IRB approval cannot be granted for research that has already been conducted. Accordingly, if one thinks that data involving human subjects may at some time be used for generalizable research, then IRB approval should be sought prior to data collection with this potentiality clearly noted. If data were collected for purposes that the IRB subsequently determines not to have constituted "research" involving human subjects, data analysis going forward would not require IRB approval.

According to the Boston College Ethical Conduct of Research and Research Misconduct Policy, the willful conduct of human research without having obtained IRB approval is a form of research misconduct. If this occurs, a report of the incident will be presented to the full IRB committee, and sent to the Director of Research Integrity for investigation.

F. Externally Funded Research

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

Appendix 1. Old exempt categories applying to federally-funded protocols only until January 21, 2019.

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.

   De-identified human cell lines and human specimens obtained from the American Type Culture Collection or other similar nationally-recognized repository do not require review and approval or determination of exemption from the BC IRB.

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.

Appendix 2. Consent Template

An annotated version of this template with tips on completing it is available at http://www.bc.edu/research/office-for-research-protections/forms.html

Boston College Consent Form
Boston College [*School or Department name***]**
Informed Consent to be in study [*Title of Study***]**
Researcher: [*name of PI*]
Study Sponsor: [*if any*]
Type of consent [Adult Consent Form or other applicable consent form such as **Parental Permission Form]**

Invitation to be Part of a Research Study

You are invited to participate in a research study. You were selected to be in the study because [eligibility criteria; e.g., age, gender, language, etc.]. Taking part in this research project is voluntary.

Note that if the subjects of your study are BC undergraduates, you must indicate here that the subjects have to be at least 18 years old to participate. Otherwise, you will need to collect parental consent.

Important Information about the Research Study

For research projects that involve numerous research procedures that will require more than a 2-3 page consent document, provide a concise and focused presentation of key information that is most likely to help potential subjects understand why they might or might not want to participate in the study. Organize information to facilitate comprehension.

Delete this section if not necessary for the study.

Things you should know:

- The purpose of the study is to [briefly describe study purpose]. If you choose to participate, you will be asked to [do what, when, where, and how]. This will take approximately [period of time].
- Risks or discomforts from this research include [briefly describe].
- The study will [description of potential direct benefits to subjects – or no benefits].
- Taking part in this research project is voluntary. You don't have to participate and you can stop at any time.

Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

What is the study about and why are we doing it?

The purpose of the study is [describe the study purpose]. The total number of people in this study is expected to be [insert number – optional if your study is an itnervention].

If you have used the summary above, provide additional details in this section.

What will happen if you take part in this study?

If you agree to take part in this study, you will be asked to [provide a detailed description of what the subject will be asked to do in chronological order (what, when, where, how). [Be sure to specify if audio/video recordings will be used to collect data]. We expect this to take about [duration, number of interactions]. [Indicate if information collected will be linked to other data (e.g., research data, protected health information, or administrative data such as US Census data).]

For projects involving the collection of sensitive information or the inclusion of questions that might be upsetting, include examples of the type of questions that will be asked or describe the sensitive topic areas that are involved.

If applicable, include a statement about whether clinically relevant research results will be shared with the subject and under what conditions. For example: "We may learn information about your health as part of the research. We will/will not share this information with you [how/why not]."

How could you benefit from this study?

Although you will not directly benefit from being in this study, others might benefit because [insert details]. **[OR]** You might benefit from being in this study because [insert details].

Please note that payment/compensation is **never** to be considered a benefit, but rather in recognition of the time and energy spent participating. As such, do not include any information about compensation in this section.

What risks might result from being in this study?

There are some risks you might experience from being in this study. They are [describe specific risks, and indicate what the study team will do to minimize those risks.]. **[OR]** We don't believe there are any risks from participating in this research.

Primary risks include physical, psychological, or informational risks. For informational risks (e.g., those involving breach of confidentiality), describe what you will do to protect the data during collection, while stored or during

transmission of the data in the section below. Psychological risks (e.g., those associated with the completion of a particularly sensitive survey or interview) could be mitigated by providing subjects with contact information for counseling resources. If resources will be given to participants, please include them in your application.

How will we protect your information?

The records of this study will be kept private. In any sort of report we may publish, we will not include any information that will make it possible to identify you. Research records will be kept in a locked file.

If you wish to use identifying information in a publication or presentation, including photographs, audio or video recordings, include the following, as appropriate:

"The results of this study may be published or presented at a scientific meeting. The researchers will ask for separate written permission to include your name [or pictures, recordings] or other information that could identify you."

If your project is NIH-funded and collects identifiable, sensitive information, it will be covered by a **Certificate of Confidentiality (CoC)** –**or**– if you will apply for a CoC for non-NIH-sponsored research collecting health-related, identifiable, sensitive information, insert the following language:

"This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it used for other scientific research, as allowed by federal regulations protecting research subjects."

Use the following language as applicable: "The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by [The Agency] which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connect with the research, you must provide consent to allow the researchers to release it."

The following language should be included if the researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws: "The Certificate of Confidentiality will not be used to

prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others]."

The following language should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants: "The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document."

Note: you should edit the suggested consent language as necessary for your study population, for example, lower literacy or non-English speakers, so long as all relevant points related to disclosure and consent are covered. See this site for more detail: ***https://humansubjects.nih.gov/coc/suggested-consent-language***

For projects not involving a CoC, if you are **a mandatory abuse** reporter and it seems likely you will encounter reportable events as part of the study, insert the following: "If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies."

If your project meets the definition of an **NIH clinical trial**, include the following: "A description of this study will be posted on a public website, http://ClinicalTrials.gov, and summary results of this study will be posted on this website at the conclusion of the research, as required by the National Institutes of Health (NIH), the study sponsor. No information that can identify you will be posted."

If you will **register your project on ClinicalTrials.gov** voluntarily or in order to meet journal or other sponsor requirements, include the following: "A description of this study will be posted on http://ClinicalTrials.gov, and summary results of this study may be posted on this website at the conclusion of the research. No information that can identify you will be posted."

All electronic information will be coded and secured using a password-protected file.

If at the time of data collection, subjects' research data will be linked to individual identifiers (such as names, email addresses, student ID numbers, etc.) then include the following:

"We will assign to each participant a unique, coded identifier that will be used in place of actual identifiers. We will separately maintain a record that links each participant's coded identifier to his or her actual name, but this separate record will not include research data."

If you will know the identities of the people who participate but will not have the ability to link any participant to the research data he/she provides (such as in the case where you are entering names into a raffle or need to give students credit for participating, include the following:

"The researchers will not be able to link your survey responses to you, but they will know that you participated in the research. This will enable the researchers to [insert reason for keeping track of who participated.]"

If you will remain blinded to the identities of the participants, include the following:

"The [survey/instrument] does not ask you to identify yourself, and the researchers will have no ability to learn the identities of the people who participate."

[If audio or video tape recordings are made, explain specifically who will have access to them, if they will be used for educational purposes, and when they will be erased/destroyed and indicate how they will be destroyed or erased.]

Mainly just the researchers will have access to information; however, please note that a few other key people may also have access. These might include government agencies. Also, the Institutional Review Board at Boston College and internal Boston College auditors may review the research records. Otherwise, the researchers will not release to others any information that identifies you unless you give your permission, or unless we are legally required to do so.

What will happen to the information we collect about you after the study is over?

I/We will/will not keep your research data to use for [future research or other purpose]. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project. **[OR]** Your name and other information that can directly identify you will be deleted from the research data collected as part of the project.

I/We may share your research data with other investigators without asking for your consent again, but it will not contain information that could directly identify you. [If data must or will be deposited in a public or other repository, briefly describe.] **[OR]** [We will not share your research data with other investigators.]

Sample text:

Data collected as part of this research will be provided to the XXX repository for future use by other researchers. This data will not contain information that could directly identify you.

How will we compensate you for being part of the study?

You will receive [nature and total amount of incentive/compensation] for your participation in this study.

Describe how compensation will be determined if the subject withdraws from the research before the end of the study. Compensation should not be contingent upon completion of the study. To avoid potential coercion, please pro-rate or give the amount in full if a participant ends the study early.

If there will be no compensation, state so.

What are the costs to you to be part of the study?

To participate in the research, you will need to pay for [indicate what costs, if any, subjects will have to pay – such as parking].

OR
There is no cost to you to be in this research study.

Your Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. If you decide to withdraw before this study is completed, [provide details about disposition of data]. [Describe anticipated circumstances, if any, under which the subject's participation may be terminated by the PI without the consent of the subject].

If you choose not to be in this study, it will not affect your current or future relations with the University or [if conducting research through a school or other institution, add the name here].

Getting Dismissed from the Study

The researcher may dismiss you from the study at any time for the following reasons: (1) it is in your best interests (e.g. side effects or distress have resulted), (2) you have failed to comply with the study rules [add if applicable: or (3) the study sponsor decides to end the study].

Contact Information for the Study Team and Questions about the Research

If you have questions about this research, you may contact [PI name, email, phone (and faculty advisor contact info if PI is a student)].

For International Studies: List the name, email and phone of the local collaborator, if any, first. Be sure to include the U.S. calling code and exit number for the country of origin.

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

Boston College
Office for Research Protections
Phone: (617) 552-4778
Email: irb@bc.edu

Your Consent

Required for projects obtaining a signature only – delete this paragraph for projects that will request a waiver of documentation. The document must be dated by the person signing.

For projects involving a waiver of documentation, include the following statement: Before agreeing to be part of the research, please be sure that you understand what the study is about. We will give you a copy of this document for your records [or you can print a copy of the document for your records]. If you have any questions about the study later, you can contact the study team using the information provided above.

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

_____
Printed Subject Name

_____
Signature Date

Parent or Legally Authorized Representative Permission

Delete this section if not applicable to the study.

By signing this document, you are agreeing to [your child's **OR** the person's named below] participation in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree for [my child **OR** the person named below] to take part in this study.*

_____
Printed Subject Name

_____
Printed Parent/Legally Authorized Representative Name and Relationship to Subject

_____
Signature Date

_____
Printed Parent Name and Relationship to Subject (when 2 signatures are required)

_____
Signature Date

You may also need to obtain dated consent for specific activities when those activities are ***optional*.** Whether an activity is required or optional must be clearly described in the main body of the consent above. Some common optional research activities are included below:

Consent to be Audio/video Recorded
I agree to be audio/video recorded.

YES_____ ***NO***_____

_____
Signature Date

Consent to Use Data for Future Research
I agree that my information may be shared with other researchers for future research studies that may be similar to this study or may be completely different. The information shared with other researchers will not include any information that can directly identify me. Researchers will not contact me for additional permission to use this information. (Note: This separate consent is not necessary if you will only store and share deidentified data.)

YES_____ ***NO***_____

_____
Signature Date

Consent to be Contacted for Participation in Future Research
I give the researchers permission to keep my contact information and to contact me for future research projects.

YES_____ ***NO***_____

_____
Signature Date

Appendix 3.

Boston College Office for Research Protections
IRB Quality Assurance Program Meeting Worksheet

When a researcher's protocol is selected for the Quality Assurance Program, he or she will be given notice two weeks in advance of their meeting with the Office for Research Protections staff. Researchers should be ready to discuss the following questions, but do not need to prepare written answers.

- How has the recruitment process been working so far? What methods of advertising and recruitment are you using?
- Where does the consent process take place? Who obtains consent from the subjects?
- Are you using the dated/stamped IRB-approved version of the consent form?
- How many subjects are currently enrolled?
- Have any subjects dropped out? How many? Why?
- Where do you store signed consent forms? If you collect consent electronically or orally, how are you storing this information?
- Where and how do you store your data? How is it de-identified? Is this consistent with your description of the process in the protocol?
- If you keep any video or audio recordings, when do you delete them? Have you deleted them according to the timeline you proposed in your protocol?
- Have any of your sources of funding for the project ended, and do you have any new funding sources?
- Do you compensate your subjects? If so, how? Have there been any issues with compensation?
- Have you received any complaints or questions about the consent form or research? (For example, if your study takes place in a school, have school administrators or parents contacted you?)
- Is your research staff list up to date? Is their required human subjects training up to date?
- Have there been any adverse events or unanticipated events?
- If so, have you reported them to the IRB and your sponsor (if applicable)?
- Where do you store the physical data? Do you have a timeline or plan for destroying or archiving the data?
- What process are you using to de-identify data (if applicable)?
- Have any data been lost (inadvertently) or deleted (on purpose)?
- Have you learned or developed any data handling or consent techniques that work well, and if so, would you be willing to share these techniques with other researchers?
- What feedback do you have on this process? Do you find this to be more or less burdensome than an annual continuing review?
- Do you have any suggestions to improve any IRB policies or procedures?