Template for InfoEd Initial Protocol Submission

The purpose of this template is to give you a sense of what you will be required to enter into InfoEd when submitting an initial IRB protocol. This may be a useful tool for graduate students and other staff to use while drafting IRB protocols, so that PIs may offer feedback on this word document before the information is copied and pasted into InfoEd.

Researchers may also find it helpful to save a draft of this document to keep an editable record of what they have submitted through InfoEd.

- Log into InfoEd (if off campus, connect to BC VPN first): rasprod.bc.edu
- Click "IRB Protocols" on the left side of the screen, then select "Initial Application"
- You will be prompted to fill in the following information:

I. **General Information**
   a. Study Title (must match sponsored title if funded)
   b. Legacy Protocol (yes/no)

II. **Application Type**
   a. Application Type: Research, Collaborative Research/Internal Review, Collaborative Research/External Review, Non-human Subjects Research Determination (select one)
   b. Does the research propose greater than minimal risk to participants (yes/no)
   c. Does the research include prisoners? (yes/no)
   d. Level of Review: Please select a level of review and the appropriate category that corresponds to that level of IRB review: (select Exempt, Expedited, or Full Board)
   e. Is this project a clinical trial? (yes/no)

III. **General Study Information**
   a. Do you have funding? (yes/no)
      i. If you click "yes," a number of follow-up questions appear. Please fill out all of them.
   b. Participant Recruitment Numbers: This number must be the maximum number you intend to recruit – it can be an estimate. You will not be allowed to recruit more than this number without first coming to the IRB to seek approval. Total number of participants: ____.
   c. Do you plan to include a larger proportion of one gender group, or omit any gender groups? (yes/no) (If you click yes, you will be prompted to explain).
   d. Are you conducting your research in an international research setting? (yes/no)
   e. Participant ages (please check all that apply): 0-7, 8-11, 12-17, 18-65, 65+
   f. Estimated Project Duration:
      i. Start Date____;
      ii. End Date_____.

For recruitment numbers: estimate your max sample. If you aren't sure about gender break down, you can just put half male and half female.

g. Why is this Project being conducted (please check): Faculty Research, Staff Research, Undergraduate Coursework, Master's Thesis, Doctoral Dissertation, Other
h. Will this study involve long-term follow-up with participants? (yes/no)
i. Special Study Populations (check all that apply): Minors (under 18 years); Pregnant Women/Fetuses or products of labor & delivery; Prisoners; Physically or mentally challenged; Diminished capacity for consent; Other; No special study populations
j. Does this study involve any of the following? (check all that apply): Deception or Punishment; Use of drugs, Covert observation; Induction of mental and/or physical stress; Procedures which may risk physical/mental harm to the participant; Information relating to sexual attitudes, orientation, or practices; Materials/issues commonly regarded as socially unacceptable; Information relating to the use of alcohol, drugs, or other addictive products; Procedures that might be regarded as an invasion of privacy; Information pertaining to illegal conduct; Genetic information that may be linked to a participant's health status, such as genetic markers for cancer, heart disease, etc.; Information normally recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination; Information pertaining to an individual's psychological wellbeing or mental health; Information that if released could reasonably damage an individual's financial standing, employability, or reputation within the community; None of the above procedures.

IV. **BC Personnel**
   a. Each person on the submission will need to be added here, including their:
      i. Role (PI, Co-I, Faculty, Faculty Advisor, Staff, Research Assistant, or Protocol Administrator
      ii. CITI certification (should be uploaded by the individual, but ensure that beginning and end dates are displaying correctly for the certification's validity)
      iii. Role in the University (Faculty, Staff, Graduate Student, Undergraduate Student, Other)

V. **Non-BC Personnel**
   a. Add non-BC personnel to the study by pressing "Add," and including their name, role, and attaching their CITI certification

VI. **Research Summary**
   a. Introduction and background:

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

b. Specific Aims/Study Objectives
   i. List the purpose(s) of the study (what are you hoping to learn as a result of the study)

c. Materials, Methods, and Analysis (quantitative and qualitative)
   i. List and describe all study procedures. For studies with multiple steps, present the steps sequentially or chronologically, and indicate when, where and how the step would be performed. For studies involving multiple categories of subjects, indicate the category of subject relevant to each step.
   ii. Describe the specific materials or tools that will be used to collect the data (be specific)
   iii. Describe the timeline of the procedures and how long each procedure will last
   iv. Describe how you will analyze your data (be specific)

Be as specific as possible in this section. The goal is to provide the reviewer a complete sense of what a participant will experience. For interviews: how long will they take? Individual or group? Specify that interviews will be in a private location and whether the data will be recorded. For surveys: will they be done online or hardcopy? How long will the survey take to complete? Specify the software you will use, if any, to collect data.

d. Research Population & Recruitment Methods
   i. Inclusion and exclusion criteria
      1. Describe in general terms the nature of the population of people you would like to have participate in this study.
      2. Please list all inclusion criteria.
      3. Please list all exclusion criteria (i.e., upper/lower age limits, decision making capacity, medical conditions, psychiatric conditions, etc.)
   ii. What is the scientific or scholarly justification for the number, gender, age, or race of the population you intend to recruit?
   iii. How did you choose the source of participants or data? (census records, BC students, Mass General Hospital records, etc.)
   iv. Recruitment procedure; including who will recruit participants and, if applicable, how any conflict of interest/coercion/undue influence will be mitigated
   v. Tools that will be used to recruit (payment, advertisements and flyers should be attached to the application)

In **Section D:** who are the participants and why did you choose them? If you are recruiting via email – how will you get the email addresses? Include a copy of your recruitment email or script as a separate document. If providing compensation, explain how you will document that participants received it. Describe how compensation will be pro-rated if a participant doesn't complete the study. For research with college students, remember that your criteria must state that participants must be 18 years or older; otherwise, parental consent is required.

e. Research Incentives and Payments: Please specify what form of payment you will be using and how it will be documented. (Note: participant payment beyond $600 must be reported to the IRS, and this requirement must be added to the consent form).

VII. **Informed Consent**

a. Who will perform the informed consent procedure, and how will that person be trained? (Note: undergraduates should specify their qualifications and describe how the faculty research supervisor will closely monitor.)
b. How will the prospective participant's competence or understanding of the procedures be assessed; will participants be asked questions about the procedures, or encouraged to ask questions?
c. Please describe the process by which informed consent will be obtained. Note: research involving minors requires consent from a parent/legal guardian and assent from the child.

If informed consent is online, specify that the consent form will be the first page of the study and there will be a check box for individuals to indicate consent. If subjects are under 18, explain how parent consent will be obtained. Describe how you will obtain child assent.

VIII. **Confidentiality**

a. Where will the data be stored, and who will have access to the data and the area? (Refer to our Research Data Policy for options).
b. How will the data be stored, and in what format (hard or electronic copy, identifiable or de-identified)?
c. Will the study entail the collection, storage or access of any of the following individually identifying data elements? Check all that apply and indicate how each would be stored in relation to the data.
    i. First name; Last name; Mailing address; Email address; Phone number; month, day, year of birth; month and year of birth only; year of birth (or age in years); Social Security Number; Medical record number; IP address; Biometric identifiers; Full face photo or video image; Other
d. Will you collect any individually identifiable information from third parties (organizations or individuals other than the subjects themselves)? (yes/no)
e. With respect to each category of information below, please indicate whether the study would collect, use, or access any of the information:
    i. Educational records (including FERPA-covered data; yes/no)
    ii. Medical Information (including data obtained from HIPAA-covered entities; yes/no)
    iii. Immigration Status (yes/no)
    iv. Criminal background/record (yes/no)
    v. Unlawful behavior (yes/no)
    vi. History of substance abuse (yes/no)
    vii. Current substance abuse (yes/no)
    viii. Domestic abuse (yes/no)
    ix. Child abuse (yes/no)
    x. Employment records (yes/no)
f. Please address whether the research plan would entail disclosing subjects' individually identifiable research information to any persons who are not Boston College faculty

If you have physical data including consent forms, specify where they will be stored and that consent forms will be stored separately from other data. If you have audio or video recordings, specify when they will be deleted (after transcription, after X years, etc.) and where the physical recording will be stored until then.

members, staff members or students or to any institutions or other organizations not owned or operated by Boston College. If so, please identify all such persons and entities.

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

IX. **Statement of potential research risks to subjects**

a. Indicate the type of risk that may result from participation. Consider psychological or emotional risks, social stigma, change in status or employment, physical risks or harms, information risks-breach of confidentiality and any effect loss of confidentiality may have on status, employment, or insurability. If the protocol involves treatment, what are the risks compared to other treatments in terms of "standard of care"? Please consider any populations who may be particularly vulnerable and may be triggered by this research topic and the risks they may face. Please check section IV.H. to ensure that you have considered how sensitive topics might lead to risks for some populations.

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

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

X. **Statement of potential research benefits to subjects (Note: compensation/ payments are considered a recruitment tool and should not be listed as benefits)**

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

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

XI. **Informed Consent**

a. Waivers of written documentation of informed consent may be requested as well as Full or Partial Waivers of Consent, if appropriate. Please indicate if you will be requesting a:

   i. Waiver of written documentation of consent
   ii. Full or partial waiver of consent
   iii. None of the above

If your study involved data collection that did not happen in person, you should request a waiver/alteration. For online surveys and phone interviews, you should request a partial waiver and a waiver of documentation of consent.

b. Depending on your answer to the above question, other questions about consent will populate to help justify why you are waiving documentation of consent or requesting a full/partial waiver.

XII. **Performance Sites**

a. If you are conducting research at a site, the site must provide the BC IRB with evidence that they support the research being conducted at their location. If the site has an IRB, consult with them to determine if they require IRB approval from their institution to conduct research at their location. **Are you conducting research at a site**? (yes/no)
b. If you click "yes," you should click the "add" button that appears and type in the name of the site.

A site permission letter should only be on the organization's letter head, physically signed by an administrator at the site. A typed signature is not permissible. Check our sample site permission letter in the "Sample Forms" section of the ORP website.

XIII. **Collaborating Institutions**

a. Would the proposed protocol entail a collaborative project involving not only Boston College faculty, students or staff as researchers but also the personnel of one or more institutions or entities external to BC? (yes/no). This section is filled out if you are planning an authorization agreement.

XIV. **Attachments**

a. All attachments must be uploaded **as PDFs**, with document names that clearly indicate what type of document it is. This includes:
    i. Recruitment materials
    ii. Consent forms
    iii. Instruments
    iv. HIPAA, FERPA, or other release forms
    v. External IRB approvals
    vi. Data Management and Sharing Plans (if applicable)
    vii. Other documents

XV. **Acknowledgements**

a. You will be asked to read a statement of scientific misconduct. You will also be asked to read a statement on conflict of interest and check a box (yes/no) stating whether you or a family member derived income within the past year of $5,000 or more in publicly traded or non-publicly traded entities.