COLLEGE OF THE
Holy Cross

IRB Initial Application Guide and Checklist

The IRB Application consists of several parts:

1. **The Forms**

   Handwritten forms will not be accepted.

   a. **The New Protocol Cover Sheet**

2. **The Protocol**

   The Protocol is a document written by the investigator that is an official account of the planned project.

   Use the designated letters and BOLD Section Titles in this Guide for each section of your protocol. If a section does not apply to your research project, state "n/a".

   a. **Title of study**

   b. **Purpose of study** – describe the overarching goal of what you seek to discover through the proposed research project. Also include the expected benefits obtained by doing the study.

   c. **Sponsor of study & COI** – list any external or internal funding for the project. Also discuss any conflicts of interest you may have with the sponsor or any other organization involved in your study.

   d. **Personnel involved and their qualifications** – Identify all personnel directly interacting with human subjects, including the Principal Investigator, and list their relevant qualifications, including academic, professional, and/or volunteer activities with regard to the proposed research project. Specify their role in the project and document their training in human subjects research, including CITI certification if appropriate. Also include any necessary support services and facilities that exist to support the project.

   e. **Results of previous related research** – discuss other research undertaken by others and/or by yourself that places your research in context. This should include a brief discussion of how your project fits within the literature of your field and should include references (listed in section p). Help the reviewer to become a part of the academic *conversation*. Please keep this section brief—no more than 1-2 pages maximum.

   f. **Study design** – describe the scientific design of your study; include a discussion of the appropriateness of your chosen research methods.

   g. **Subject characteristics** – profile the participants you are seeking to be a part of your research. State the criteria for including or excluding subjects from the pool.

   h. **Justification for use of any special/vulnerable subject populations**, if applicable – vulnerable populations include children, the cognitively impaired, prisoners, pregnant women, etc.

   i. **Recruitment procedures** – describe how you will be finding your research subjects. If applicable, include the recruitment materials you intend to use such as fliers, text of e-mails or letters, scripts for phone calls, etc. in the supporting documents. If you will be working with an outside organization, you will need to attach a letter of permission (or include the promise of such a letter being sent to the IRB for your file before your research begins) from each organization that details their understanding of your project, their support and involvement in your project, and the duration of the involvement. If you wish to survey a large portion of either the Holy Cross student body or the Holy Cross Faculty, you will also need to obtain approval from the Campus-Wide Assessment Committee that your work is consistent with its Data Collection, Use and Dissemination policies.

   j. **Procedures to be performed** – describe how you will go about your research activities. What you describe in this section should be a realistic description of the steps and actions you will take as you conduct your research. Be as detailed as possible. Be very specific about the data you will be collecting and what you will be doing with it. Specifically discuss your plans for protecting the subjects' privacy. Also discuss your plans for data confidentiality and/or subject anonymity, if applicable. It may be helpful to include a timeline of your research project, flow charts, or a graph, depending on how complex your procedures are. Lack of specificity in this section often leads to required revisions upon review, so think through and present your project carefully.

   k. **Anticipated risks and benefits to subjects** – describe any potential risks that subjects may encounter by participating in your research project. Such risks may include but are not limited to psychological stress, loss of privacy or confidentiality, social risks, legal risks, economic risks, or physical harm. If you do not feel that any specific risk to subjects exists, please describe the risks as "minimal," meaning, "not greater than risks encountered in everyday life". (Do not say there are NO risks.) Also discuss any direct benefits subjects may receive from participation in your research project. Remember, compensation is not a benefit.

   l. **Provisions for managing risk** – describe steps you will take to manage the risks you identified and described in section k.

m. **Cost and compensation to subjects** – describe any costs to participants of the study. Such costs may include participants' time, transportation, etc. Also discuss any form of compensation subjects will receive, along with the terms and conditions of the compensation.

n. **Plans for obtaining and documenting informed consent** – describe the circumstances surrounding consent procedures, remembering that obtaining informed consent is a process, not just a moment in time. Describe the setting in which you will be obtaining informed consent, along with any special considerations you will make for vulnerable or non-English speaking populations (e.g. provisions of witnesses or translators). If you will be using children as subjects, please describe both the parental consent and the child assent process. If you would like to request a waiver of or alteration to standard documented informed consent procedures, please do so in this section, detailing the reasons why you are applying for the waiver and the conditions in your project that you believe allow you to request the waiver. For specific rules on this topic, see 45CFR46.116.c and d.

o. **Plans for data storage** – describe what you will do with the data you collect (including consent documents, surveys, notes, etc.), where they be stored, how long they will be kept, and when and how they will be destroyed.

p. **Bibliography/Citations** – include the works you cited in your protocol (particularly from section f.)

3. **Supporting Documents**
   a. **Consent documents** (Informed Consent Document(s), Information Sheet, Consent Script, Consent Screen, Assent Documents, etc.) following the instructions in the 45CFR46.116.
   b. **Recruitment materials** (fliers, sample e-mails, letters, notices, etc.)
   c. **Study instruments** (e.g. surveys, questionnaires, interview guides, tests, photographs, diagrams or photographs of equipment, etc.)
   d. **Permission Letters** Including memoranda of understanding or other assurances of collaboration both within the College of the Holy Cross and outside.
   e. **Grant proposal**, if applicable

After all forms and documents have been completed and signed where necessary and completed, please follow the directions in our Frequently Asked Questions How do I turn my IRB application into one pdf file? to turn your protocol into a .pdf for submission.

Before submitting your protocol, please make sure that

- ☐ **Spelling and grammar have been checked and are correct**
- ☐ **The Assurances have been signed**
- ☐ **The documents have been arranged in the proper order :**
  - **Cover Sheet**
  - **Assurance**
  - **PHI Form (if applicable)**
  - **Protocol**
  - **Consent Document(s)**
  - **Recruitment Materials**
  - **Study Instrument(s)**
  - **Permission Letters**
  - **Grant proposal**
- ☐ **The application has been made into one pdf**
- ☐ **The original hard copy of the application has ONE paper clip or binder clip—no staples, envelopes, report covers, etc.**
- ☐ **You have kept a copy of all application materials for your files**

Submit the electronic pdf of your application to hsc-irb@g.holycross.edu.

Remember, your application will not be considered complete until the electronic version of your application has been received.