COLLEGE OF THE
Holy Cross

New Protocol Cover Sheet

Project Title

Principal Investigator	**Dept**	**Phone**	**E-mail**
***Student Researcher**	**Year** Select Year	**Phone**	**E-mail**

**For student-initiated research only*

Estimated Level of Risk Select One
Anticipated Start Date
Anticipated Date for Subject Recruitment

1. **Study Purpose**
   - ☐ Class Assignment Only
   - ☐ Presentation – on campus
   - ☐ Thesis
   - ☐ Presentation – off campus
   - Other

2. **Study Location**
   - ☐ **Yes** ☐ **No** This study will be conducted solely at College of the Holy Cross. **If no, briefly describe below:**

3. **Collaborations/Outside Researchers**
   - ☐ **Yes** ☐ **No** This study will be conducted solely by researchers affiliated with College of the Holy Cross
   - ☐ **Yes** ☐ **No** This study involves collaborators from other institutions or organizations. **If yes, briefly describe below.**
   - ☐ **Yes** ☐ **No** This study involves collaborators with an outside Institution or Vendor. **If yes, identify collaborators below.**

4. **Existing Data**
   - ☐ **Yes** ☐ **No** Study involves use of existing data, documents, records, pathological specimens, or diagnostic specimens. **If yes**:
   - ☐ **Yes** ☐ **No** Authorization to access the data (if not publicly available) is attached.
   - ☐ **Yes** ☐ **No** This study involves the use of Protected Health Information (PHI).
   - ☐ **Yes** ☐ **No** Will subject identifying information be recorded?
   - ☐ **Yes** ☐ **No** Will codes be used to link data to the subject's name?

5. **Participants to be Recruited**
   - ☐ Adults (18+)
   - ☐ Minors (<18)
   - ☐ Cognitively Impaired
   - ☐ Prisoners
   - ☐ Elderly/Aged
   - ☐ Minorities
   - ☐ Students (describe)
   - ☐ Others (describe)

6. **Number of Participants**

7. **Potential Risk(s)**
   - ☐ Social
   - ☐ Economic
   - ☐ Psychological/Emotional
   - ☐ Physical
   - ☐ Legal
   - ☐ Other

8. **Compensation**
   - ☐ **Yes** ☐ **No** Compensation will be offered to participants. **If yes, source of compensation ?**

9. **Informed Consent** (select all that apply)
   - ☐ This protocol will follow standard procedures for obtaining documented Informed Consent
   - ☐ This protocol seeks an alteration to documented Informed Consent Procedures
   - ☐ This protocol seeks a waiver of Informed Consent
   - ☐ This protocol involves Parental Consent/Child Assent

Investigator Assurance:

I certify the information provided in this application is complete and correct to the best of my knowledge.

I agree to comply with all federal, state, local and College of the Holy Cross policies and procedures for the protection of human subjects in research including:

a. **Accepting the responsibility for the conduct of the study, ethical performance of the project, and for protecting the rights and welfare of human subjects**
b. **Ensuring that all personnel on this project complete human subjects training**
c. **Obtaining consent from each subject using the approved consent form**
d. **Notifying the IRB of any changes and not initiating those changes until they have been approved**
e. **Notifying the IRB of any unanticipated events or significant adverse effects**

_____ _____

Principal Investigator Signature Date

_____ _____

Student Signature Date

Attached Documents

- ☐ **Protocol** (following the *Protocol Guide)*
- ☐ **Consent** Document(s)/Information Sheet(s)/Consent Script(s)
- ☐ **Recruitment** Materials (fliers, sample e-mails, postings, scripts, etc.)
- ☐ **Study** Instrument(s) (surveys, questionnaires, interview guides, etc.)
- ☐ **Permission** Letter(s), Data Use Agreement(s), MOU's, etc.
- ☐ **Other** _____