IRB Initial Application Guide and Checklist

The IRB Application consistsof several parts:

- 1. The Forms
 - Handwritten forms will nobeaccepted.
 - a. The New ProtocolCover Sheet
- 2. The Protocol

The Protocol is adocumentwritten by the investigator that is an official account of the planned project.

Use the designated letter and BOLD Section Titles in this Guidefor each section fyour protocol. If a section does not apply to your research project, state n/a".

- a. Title of study
- b. Purpose of study describe the verarchinggoal of what you seek to discover through the proposed esearch project. Also include the expected benefits obtained by doing the study.
- c. Sponsorof study & COI list any externalor internal funding for the project. Also discussany conflicts of interest you may have with the sponsoor any other organization involved in your study.
- d. Personnel involved and theirqualifications 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 certificatioppirapriate. Also include any necessar support service and facilities that exist to support the project.
- e. Resultsof previous related research discussotherresearch undertakeny othersand/orby yourselfthatplaces your researchin context. This should include a brief discussion of how your project fits within the literature of your field and should include reference (listed in section). Help the reviewer to become part of the academic conversation Pleasekeep this section brief no more than 1-

Holy Cross Faculty, you will also need to obtain approval from the CampWisde Assessment Com

that your

work is consistent with itBata Collection, Use and Dissemination

- j. Proceduresto be performed describe howyou will go about youresearch activitiesWhatyou describe in this section shouldbe arealistic description of the steps and action syou will take asyou conductyour research. Be as detailed as possible. Be very specificabout the datayou will be collecting and what you will be doing with it. Specifically discuss you plansfor protecting the subjects privacy. Also discussyour plansfor 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 omplexyour procedure are. Lack of specificity in this section of the neads o required revision supon review, so think through and present your project carefully.
- k. Anticipated risks and benefitsto subjects-describe an potentialrisks that subjects magencounter by participating in your research project. Such risks may include but are not limited to psychological stress, losof privacy or confidentiality, social risks, legal risks, economic risks, or physical harm. If you do not feel that any specific risk to subject exists, please describe the risks as "minimal," meaning, "not greater than isks encountered in everyday

- m. Cost and compensation osubjects describe any costs participants of the study. Such costs may include participants' time, transportation etc. Also discuss an form of compensation subjects will receive, along ith the terms and conditions of the compensation.
- n. Plansfor obtaining and documentinginformed consent– describe the circumstances surrounding consent procedures, fo3Tw 0.253 0 Td [(w5.3.e)14.3(4)4(c)-/e

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