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 letter 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-

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, fo3Tw 0.253 0 Td [(w5.3.e)14.3(4)4(c)-/e

with

p1]TJ 0 T6750 Tw 1.2y2(re0.00 Taij /TT0 1 Tf 0.241]TJ -0.004 dj /TTw)22.2(ith

cds30002 Tw 0.1.a]15.602(Taij / [(i)2.9-t)511LBod1.084