1. POLICY

IRB members rely on the documentation submitted by Investigators for review of non-exempt protocols. This material must provide IRB members with enough information about a study to assess if it meets the criteria for IRB approval. Similarly, OPHS staff need adequate information to assess if a protocol meets the criteria for a determination of exemption.

When the OPHS staff have ascertained that the submitted application provides a sufficient baseline description of the proposed research and contains most, if not all, of the necessary supporting documentation, non-exempt protocols will be scheduled for IRB review.

Specific Policies

1.1 Submission Requirements

The Office for the Protection and Human Subjects, Research Administration and Compliance has undertaken development and implementation of an electronic, web-based IRB document submission, verification, distribution, review and approval project for human subjects research protocols which includes documentation and archiving. This software system is named Berkeley eProtocol.

eProtocol utilizes CalNet Authentification in lieu of original handwritten ink signatures for investigator acknowledgement of their rights and responsibilities per UCB policy governing the conduct of human subjects research.

All applications for research involving human subjects must be submitted using eProtocol.

1.2 Action Taken If Documentation is Inadequate

If the IRB or OPHS staff find that the submitted documents are not adequate, Investigators will be required to submit additional information, and/or their presence may be required at a convened meeting to answer questions or explain the details of the study.

2. SCOPE

These policies and procedures apply to all human subjects research applications submitted to the IRB and OPHS.

3. TRAINING

Training on the policies and procedures set forth in this document will be provided for the existing workforce of the OPHS, to the extent applicable to such workforce members. Training to investigators is provided through workshops, one-on-one consultations and the CPHS website.

Training and support on the use of eProtocol is provided to investigators through CPHS website instructions, HELP icons embedded in the software that are linked to information boxes and/or web pages; group and individual education sessions; and an email support help desk.

CPHS members and OPHS Staff will be trained on using eProtocol to the extent necessary for their roles and use of the program. At least two members of the OPHS staff - one of whom is the director of OPHS - will have overall Administrator Roles and Rights at all times. These individual OPHS staff members may also have other "user" roles with eProtocol.

New members of the OPHS workforce must receive such training, to the extent applicable, within a reasonable period of time after joining the OPHS. Generally, the training should take place no later than sixty (60) days after their hire date or assignment by their supervisor or another authorized by the Director to provide such training.

4. RESPONSIBILITY

The Principal Investigator is responsible for ensuring and attesting to the accuracy of the eProtocol submission by virtue of his/her submission of the protocol to OPHS.

The OPHS Director has primary responsibility in ensuring adequate IRB documentation of compliance for human subject research activities at UCB and in maintaining the systems used to support the functioning of the IRB.

OPHS staff are responsible for collection, review of exempt protocols and not human subjects research activities, pre-review of nonexempt protocols, documentation, management, and safekeeping of all IRB records and protocols files.

IRB Members are responsible for review of protocols and accurate completion of IRB records needed for documentation.

5. PROCESS OVERVIEW

Investigators are responsible for assembling research application materials. The application materials are submitted to the IRB for review using eProtocol. Investigators are referred to the CPHS web site for specific, current requirements pertaining to the different types of submissions.

Application materials submitted via eProtocol are automatically checked for completeness and receipt of documents acknowledged automatically. The OPHS Analysts/ Panel Managers assigned to the protocol conduct a pre-review. If there are missing elements, the assigned analyst contacts the Investigator to request missing documents or information as part of the pre-review process.

6. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.115

21 CFR 56.108

21 CFR 312, 812