IRB Submission Process for Researchers
Course # BE-7081 / PH-7081
1 Graduate Credit

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Date: Summer 2017 (June 1 through July 31, 2017)

Location: Online through Blackboard

Course Description
The course provides hands-on experience with preparing a human subject research study and submitting it to the IRB, including use of the IRB's online submission site, ePAS. Students will become familiar with the University's electronic submission system and will prepare an IRB submission on a study of their choice.

Student Learning Outcomes
• Students will learn why IRB review is required for human subject research.
• Students will learn what items must be submitted to the IRB for review.
• Students will create a sample protocol, consent document and other attachments similar to those that are submitted to the IRB for review.
• Students will learn how to use the IRB's online submission system, ePAS.

Grading
This course is graded Pass / Fail. Students are expected to listen to all modules posted in Blackboard and then complete and submit an IRB proposal. An IRB reviewer will review each proposal and provide feedback. Students must successfully complete both the attendance requirement and the IRB proposal in order to receive a Pass.

Course Outline
1. IRB terminology
   Generalizable
   Anonymous / confidential / identifiable / de-identified
   Not Human Subject Research determination (different from "exempt")
   Exempt (a type of human subject research)
   Expedited review (not "faster")
   Protocol (document vs packet)
   Consent (types of documents)

2. Writing a protocol
   Template to use / medical or SBR
   Required information / Not Applicable parts
   Examples of wording in the sections
   What if there is a sponsor's protocol?
   What if parts have not been developed yet?
   What if it is a Step 1, Step 2, Step 3 kind of project?
   What if it is "participatory"?
What if it is only a chart review?
Attachments to provide

3. Writing a consent
   Consent / Permission / Assent / Oral script
   Templates to use / medical or SBR
   Required information / Additional information
   Examples of wording in the sections
   What if there is a sponsor's consent?
   Waiver of documentation
   Waiver of process / EFIC
   Re-consenting

4. Submitting a new proposal to the IRB
   ePAS site / logging on
   Overview of pages and choices
   Attaching documents / Document name vs filename
   Printing the ePAS submission
   Responding to reviewer comments
   Receiving approval

5. Submitting an amendment / continuing review / reportable event to the IRB
   Overview of pages and choices for each kind of item
   Printing the ePAS submission
   Responding to reviewer comments
   Receiving approval

6. CITI training
   How to register / fixing registration problems
   What courses are required vs extra
   Expiration dates / Refresher training
   What if CITI was done elsewhere?

7. Special situations
   HUD / Emergency use
   Other IRB of Record (tandem review / reliance) / Central IRBs
   Multiple institutions (peers, not one IRB of Record)
   Getting IRB approval in a different country
   IRB approval expired but study needs to continue
   What if there are concerns / problems with IRB review or reviewer comments?

8. Final project
   Prepare your own (pretend) IRB submission. Submit it as an attachment to an EMAIL to
   CLAUDIA.NORMAN@UC.EDU no later than midnight Monday July 31, 2016.
   • Select a topic in your own field.
   • Write a mock protocol and mock consent(s) that are appropriate for it.
   • Make adjustments to what was discussed in class, as needed.
   • Submit your protocol and consent(s) by EMAIL to CLAUDIA.NORMAN@UC.EDU by the due
     date given above.
   • The instructor will do an "IRB review" and send back "reviewer comments" (my comments).
   • Because the purpose of the exercise is educational, all submissions and comments will be
     available for all class members to see.