IRB Submission Process for Researchers
Course # 219-F_26BE7081001 (19US-Flex) / BE-7081
219-F_26PH7081001 (19US-Flex) / PH-7081
1 Graduate Credit

Instructors: Angela Braggs-Brown, RAC, CIP, MA
Director, UC Human Research Protection Program
broag@uc.edu; 558-3005

Date: Summer 2019

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. 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.

Grading

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

Course Outline

1. Purpose of the IRB
   - Problematic studies in the past
   - International Guidance
   - The National Commission and the Belmont Report
   - The Belmont Principles (respect, beneficence, justice)
   - Independent review by an IRB
   - What requires IRB review/oversight?

2. IRB terminology and CITI training
   - 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)

CITI training:
How to register / fixing registration problems
What courses are required vs extra
Expiration dates / Refresher training
What if CITI was done elsewhere?
CITI training is required every 3 years

3. 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

4. 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

5. 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?

FINAL EXAM

Prepare your own (mock) IRB submission. Submit it as an attachment to an EMAIL to broag@uc.edu **no later than July 31, 2019**.

- 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 broag@uc.edu by the due date given above.
- Each submission will receive a review and reviewer comments.