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Date: Summer 2018 (June 1 through July 31, 2018)

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. 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

NOTE: Details about submitting research to the IRB in the ePAS system have changed since this course was developed. Please refer to the IRB’s website (www.researchcompliance.uc.edu/irb) for instructions about using the ePAS system. For this course, it is NOT necessary to get an account and submit through the ePAS system. However, it is recommended that you go to the IRB’s website and read the information posted about different kinds of research, and look on the Forms & Templates page to see forms that are mentioned in this course.

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 PROJECT
Prepare your own (pretend) IRB submission. Submit it as an attachment to an EMAIL to CLAUDIA.NORMAN@UC.EDU no later than midnight Tuesday July 31, 2018.

- 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.