Minutes

IRB April Meeting
Apr 4, 2024 03:30 PM Eastern Time (US and Canada)

- Present: Mark Kostro; Eric Laws; Jackie Secoy; Evan Long; Kim Little; Larry Collins; Robert Nash; Jo Morrison
- March IRB meeting minutes approved.
- Report on March IRB activity (as of March 27)
    - Not HSR Determinations 1
    - Amendments 2
    - Exempt104(d)(1) 3
    - Exempt 104(d)(2)(i) 39
    - Exempt 104(d)(2)(ii) 4
    - Exempt 104(d)(2)(iii) 1* limited IRB review (2024-03-26)
    - Exempt 104(d)(3)(A)&(B) 4
    - Exempt 104(d)(3)(C) 1* limited IRB review (2024-03-32)
    - Expedited review (categories 4&7) 1
- Continued review of Exempt Research S&Ps. Psychology reviewed the section on deception and agreed that it would work for their student research projects. Dr. Laws will update the initial consent statement on the Sona System (Psychology Research Subject Pool) to include a statement about deception to ensure subjects are prospectively informed that they may be deceived. This will be updated in time for Fall 2024 semester. A justification for the use of deception in included in the IRB proposal.
- The IRB discussed how to provide and document consent for interview subjects. The federal requirement is a hard copy, signed consent form. For Exempt S&Ps we are able to alter this requirement. Based on their experience, Dr. Secoy and Dr. Long recommended that consent material may be provided electronically and a reply confirming consent documented electronically. Consent will be reaffirmed verbally and recorded as part of the interview. Investigators may apply for alterations or waivers of this requirement. The section on Informed Consent for interviews was revised. The IRB suggested providing templates and scripts for informed consent.
- The IRB discussed that consent is a continual process with researchers checking that subjects are comfortable answering questions and continuing and offering the opportunity to decline to answer questions.
- Dr. Long offered information about the interview technique of “Member Checking” where the participant is offered the opportunity to review the transcript of the interview and correct or clarify the information. It was decided that member checking would likely be a standard procedure for experienced faculty researchers but may be too onerous a requirement for student researchers with the goal of presenting at the semester research symposium.
- The group raised some other concerns about interview work that will need to be addressed in a S&P for interview based research.
- Dr. Morrison explained Broad Consent to the group. Broad consent is a separate and specific consent for the subject to allow researchers to send their identifiable information to any researcher for any research purpose without obtaining their consent for that purpose. There is little federal guidance for the use of Broad Consent and many institutions have chosen not to adopt Broad Consent. The IRB

agreed that Longwood would not use Broad Consent and would assist investigators in data sharing through other mechanisms. Data sharing is becoming standard practice and consent forms contain statements about data sharing.

- The IRB discussed the Consent Waiver and Alteration section and agreed that faculty do need the ability to apply for waivers or alterations of the documentation of consent if their research or study population needs it.
- Dr. Morrison explained that once active consenting and data collection is completed and the data are de-identified for data analysis, the protocol can be closed. This will reduce the number of active protocols and ensure an accurate accounting of the institution's HS research portfolio. An annual check in form will be created for faculty to let the IRB know that they are still in active data collection. If faculty do not respond the protocol will be administratively closed.
- The IRB discussed amendments and agreed that investigators need flexibility with interview questions and so changes that do not alter risk or the purpose of a question do not need to be submitted to the IRB but a change from an interview to a focus group should be noted with the IRB.
- The IRB did want any changes in payments (whether monetary or extra credit) to be documented with the IRB.
- Dr. Morrison explained that Limited IRB review is a review focused on data security where the primary risk to the subject is from a data breach
- Dr. Morrison explained that Exempt Category 4 allows for secondary use of data (both identifiable and de-identified) for other research. The IRB noted the overlap with Broad Consent.
- The IRB discussed the incorporation of Longwood Exempt Category 100 that will accompany Exempt Category 3. This will allow for benign behavioral intervention studies (e.g. Psychology and Kinesiology studies) that also collect non-invasive physical measurements (e.g. HR, BP etc.). At present the collection of physiological responses does not fit exempt categories and can be approved via expedited procedures. This change in categorization also changes consent form requirements. For the Longwood research portfolio this may not facilitate informed consent because of the length of the federal informed consent material. Although Longwood has 'checked the box' OHRP is moving towards a model where institutions can apply their own flexible policies more widely. Discarding the 'check the box' model has been widely discussed by OHRP. There was discussion about measures to include and exclude. It was decided to add electronic BP and plethysmography and exclude EKG and EEG measurements from this exempt category. The group agreed that multiple non-invasive physical measurements were acceptable in this category.
- Next meeting: May 2, 3:30 pm
- The IRB discussed ideas for increasing faculty engagement and awareness of the work of the IRB and the Standards & Procedures being developed.
- The meeting concluded at 4:37 pm

Minutes prepared 4/10/2024; Zoom audio recording and transcript deleted 4/25/2024