Minutes

IRB February Meeting
Mar 14, 2024 03:30 PM Eastern Time (US and Canada)

- Present: Mark Kostro; Eric Laws; Jackie Secoy; Evan Long; Dan Michael; Robert Nash; Jo Morrison
- February IRB meeting minutes approved.
- February IRB Report
    - Not HSR Determinations 1
    - Amendments 2
    - Exempt 104(d)(2)(i) 5
    - Exempt 104(d)(2)(ii) 13
    - Exempt 104(d)(3) 2
- Update on the development of the electronic system (Key Solutions)
    - Dr Morrison shared an update on the development of the eProtocol system. Training has begun and IRB members were invited to join the training if they wished. IRB members can be added to the training system and experiment with the basic protocol that is already in the system. This basic protocol will be substantially edited to better fit the Longwood research environment. Rather than creating a more complex system that requires the researcher to identify the research category, it has been decided to create a form for Student-led research and faculty led research with the goal of having the student form be simple enough for students to complete independently and reduce faculty workload. The system will integrate directly with the CITI Training system and will indicate if the correct training has been completed. An investigator will not be able to submit until the training is complete.
- Review of Definitions S&P
    - The IRB completed a final review of the Standards and Procedures Definitions document. It was clarified that human subjects research does not encompass cadaver research or historical research on deceased individuals. The regulations are silent on obtaining information on deceased individuals that may have implications for the privacy of living family members. The IRB discussed whether case studies require IRB review. Dr. Morrison explained that case studies that report the treatment or experiences of an individual generally do not meet the definition of 'research.' The IRB discussed capturing the breadth of research, largely qualitative, done at Longwood within our definition of 'generalizable.' The IRB decided to keep the language as written.
    - Vote to approve: Definition Standard and Procedures approved unanimously.
- Review of Class Projects Involving Human Subjects Data Collection Best Practices
    - The IRB reviewed a revised version of the Best Practices for Classroom Based Research Assignments that was submitted by a member of the Psychology Department. This version has formatting changes and simplified language. The IRB agreed that this version was an improvement on the draft that was initially sent out. There was discussion about the recommendation to use as few demographic questions as possible. The IRB decided to keep the language as is, as the research question may be to determine the effect of sampling procedures on data collection. It was brought up that this document is a Best Practices document and so faculty are not required adhere to these recommendations.

- The IRB removed the recommendation that data are not stored on students' devices as this would be unnecessarily burdensome to the faculty. Instead the language emphasizes the faculty responsibility to ensure data security.
- The IRB edited the recommendation that faculty are responsible for the safety and welfare of student researchers. The spirit of this recommendation was to ensure that research methodologies don't place the student researchers at undue risk.
- The IRB discussed the responsibility of faculty who are using research as a pedagogical tool are not only responsible for ethical research that prioritizes the rights and welfare of the subjects but also the safety and welfare of the student researchers.
- The IRB discussed a comment that the recommendation that faculty use informed consent should not be placed under faculty responsibilities. It was noted that Best Practices are not a requirement and we are hoping that faculty will follow these Best Practices.
- Vote to approve: Class Projects Involving Human Subjects Data Collection Best Practices: approved unanimously.

- Development of S&Ps for Exempt Research
  - The IRB began to revise the Standards and Procedures for Exempt Research.
  - Dr. Morrison explained that when Longwood University established the IRB and obtained a Federalwide Assurance (FWA) we "checked the box." The Common Rule is required for all HHS funded human subjects research, but institutions that carry out non-federally funded human subjects research can elect to apply the common rule requirements to this research. Longwood also checked the box for Subparts A, B, and C that cover special protections for children, prisoners, pregnant women, neonates, and fetuses.
  - When determining if a project requires IRB review three questions are asked: is it research; is it human subjects; is it exempt?
  - Exempt research means exempt from Common Rule requirements. If a project fits into one of the federally defined exempt categories it can be reviewed according to institutional Standards and Procedures. We need to build our Standards and Procedures for Exempt Research.
  - Most of the research done at Longwood fits into Exempt categories.
  - Vulnerable subjects, sensitive topics, research involving greater than minimal risk will come in front of the full IRB and will continue to be subject to common rule requirements.
  - The IRB felt that the language of the Standard was fine. No revisions were made.
  - The IRB agreed that we can rely on other institutions exempt determinations for collaborative research. We will maintain a record but do not need to make the determination here. A reliance agreement transfers oversight of the research activities and personnel to a single IRB.
  - There are eight exempt categories, including research with food. Research with food can be greater than minimal risk and still meet exempt requirements (Federal language).
  - There are exclusions from exempt categories. Research with prisoners as the target subject population does not qualify for exempt, some research with children can be exempt, research with pregnant women can be exempt.
  - We are not bound to apply the exempt categories. Any research that needs more review will likely come in front of the full IRB.
  - We have added a requirement that all research that specifically targets Longwood student-athletes must receive clearance from the Faculty Athletics Representative prior to IRB review. This research is eligible for exempt determination and rapid review.

- The IRB will continue to allow focus groups to undergo exempt determination and rapid review with appropriate safeguards in place for subject privacy and confidentiality.
- The Standards and Procedures for Deception in Research was reviewed in light of the use of mild deception in Psychology student research. Dr. Laws was tasked with canvassing the Psychology faculty for best practices. Dr. Laws will add language about deception to the Sona Systems consent to fulfil the requirement for prospective agreement to deception.
- The IRB will review the general consent for Psychology research studies for regulatory requirements while keeping in mind the principles of academic freedom.
- We discussed whether the consent including deception is informed consent. It was determined that this does not conform to the requirements of informed consent because the subjects are not fully informed. An additional signature will be obtained after the study and debrief so that subjects are able to consent to the use of their data once fully informed.
- The IRB reviewed the section on Informed Consent requirements for exempt research. We determined that obtaining informed consent needs to be more flexible and align with the research methodology. Members of the IRB with experience in interview research are going to examine this section and develop informed consent requirements that can be incorporated into interview methodology.
- The IRB agreed that student-led research cannot waive the collection of informed consent. There may be situations in faculty-led research where a waiver of informed consent is appropriate. Many of the situations where informed consent is waived, or not documented are greater than minimal risk or with a vulnerable or sensitive population and may not qualify for exempt determination. In that case the Common Rule requirements hold.
- There were no comments on the Criteria for Approval language. This section is federal language.
- The IRB agreed with the following approval periods:
  - Student-led class research: 3 months (undergraduate), 1 year (graduate)
  - Faculty-led research, exempt or expedited: 3 years
  - Full board review: 1 year
- While some institutions do not require continuing review, monitoring, or approval periods for exempt research, this would mean that Longwood would not know what is happening to the majority of our research portfolio.
- It was emphasized that we will probably return to the Exempt Research Standards and Procedures repeatedly as the IRB works to develop other Standards and Procedures.

- Next meeting: April 4, 3:30 pm
- The meeting concluded at 5:00 pm

Minutes prepared 3/20/2024; Zoom audio recording and transcript deleted 3/27/2024