

## Minutes

IRB February Meeting  
Feb 1, 2024 03:30 PM Eastern Time (US and Canada)

- Present: Larry Collins; Mark Kostro; Eric Laws; Kim Little; Jackie Secoy; Evan Long; Dan Michael; Robert Nash; Jo Morrison
- January IRB Report
  - Not HSR Determinations 2
  - Exempt 104(d)(2)(i) 1
  - Exempt 104(d)(2)(ii) 6
  - Exempt 104(d)(2)(iii) 1
  - Amendments 2
- Welcome and introductions
  - IRB members introduced themselves and we all welcomed Dr. Robert Nash, community member of the IRB. Dr. Nash has been part of the Farmville community for 48 years. He has served with the Navy and Naval Reserve, worked for the VA Medical Center, and worked with the Piedmont District of the VA Department of Health during COVID. Dr. Nash has an extensive background in research and is familiar with IRB operations.
- January IRB work
  - Amendments
  - Not HSR determinations
  - Exempt determinations
- Update on the development of the electronic system ([Key Solutions](#))
  - Longwood has purchased software to manage IRB submissions, and the lifecycle of proposals. This system is built on smart forms and we will be able to customize the system for the Longwood environment. Training will begin shortly. The electronic IRB management system will go live in Fall 2024.
  - The system is single sign on for students and faculty and will integrate with CITI training. We set the required CITI training and the system will identify whether the appropriate certification has been completed.
  - There may be the potential to develop an 'IRB-Lite' process within the system for class projects.
- The task ahead – development of Standards and Procedures for Human Subjects Research (HSR) at Longwood
  - The Office of Human Research Protections (OHRP) requires IRB's to have written Standards and Procedures (S&Ps) for Human Subjects Research. Longwood does not have any Standards and Procedures for HSR which is an area of vulnerability but also an area where the IRB can provide guidance and best practices to faculty and students.
  - A list of needed S&Ps is available on Canvas. This is a list in progress and IRB members are invited to add to the list.
  - Dr. Morrison explained that it will probably take a few years to develop the S&Ps that are needed and the IRB will be working to shape the human research protections at Longwood University.

- Motion: All IRB members are voting members for the purposes of IRB Standards and Procedures, best practices, structure, and functions. We will retain the subset of five protocol review/voting members for review and approval of full review proposals.
  - Dr. Nash seconded the motion
  - Motion passed.
- Longwood definitions for Systematic Investigation and Generalizable
  - Dr. Morrison explained that the federal definitions for ‘research’ and ‘human subjects’ are used to determine if the IRB should be reviewing a project. While the definition for ‘human subjects’ is well defined, the definition for ‘research’ is vague. It is recommended that institutions develop their own definitions for the terms ‘generalizable’ and ‘systematic investigation’ that apply to the specific institutional environment.
  - The IRB reviewed a draft of the definitions for ‘research’ ‘systematic investigation’ generalizable’ and ‘human subjects’ with language that originated from a biomedical IRB.
  - Dr. Secoy identified that the definition did not capture the breadth of qualitative research at Longwood.
  - Dr. Morrison clarified that the definition is used to determine if the IRB needs to be involved and is not intended to imply that the scholarly work of some disciplines that does not meet these definitions is not research.
  - Dr. Laws recommended providing examples of research that does not fall under the purview of the IRB. It was determined that the examples provided in 45 CFR 46 could be moved within the document so that these examples appear immediately after the revised definition for ‘research’ with a clarification in the introductory language that these were examples of research that did not need IRB oversight.
  - Dr. Long and Dr. Secoy offered thoughts about the draft definition of ‘systematic investigation.’ The language was revised to be more inclusive of academic disciplines.
- Review of Guidance/Best Practices on Class Projects
  - Dr. Morrison introduced this item by explaining that class projects that involve human subjects but do not meet the definition of generalizable (therefore do not require IRB review) carry as much risk for the participant as IRB reviewed research.
    - Individuals are often asked for private information
    - Informed consent may be lacking
    - Data security is a concern, there is a lot of private information about individuals on student google accounts.
  - A previous Guidance for Class Projects was long, confusing, and contradictory.
  - The IRB reviewed examples of class project guidance from five institutions and decided to rewrite the Class Projects Guidance into a Best Practices document that provide a clear and concise list of the limits on class projects involving humans subjects.
  - The IRB discussed the responsibility of faculty to ensure that the standards of ethical research design are adhered to and an additional responsibility to ensure the safety and welfare of the student researchers.
  - Dr. Collins raised the issue of data storage and security. Many people do not understand that Google Drive is not a secure place to store data. It was suggested that the IRB consult IT experts for guidance.
  - The IRB is aware of and respects academic freedom.

- Dr. Secoy asked if all HSR projects that are presented at research day and symposium would need to be reviewed by the full IRB. Dr. Morrison clarified that almost all of these projects fall into the exempt category and can be reviewed and approved by the IRB chair.
- Dr. Secoy used an example of a student project that was presented at a discipline specific University talk. The students were presenting sensitive information obtained from a marginalized population. While the project should have come before the IRB for review, it did not. However, at present, this same type of project, with the same sensitive information could reasonably be a class project with no IRB oversight. The risks to the subjects are the same.
- The IRB decided to list specific subject areas and types of research that should not be undertaken in class projects without IRB review.
- Members expressed concerns about the use of demographic questions in surveys and identifiability in the small Longwood community. It was decided to add specific guidance related to demographic questions to keep these questions to the bare minimum required to directly answer the research question.
- The IRB recommends CITI training in Human Subjects Research for students undertaking class projects involving human subjects.
- The IRB discussed the use of videotaping in research, class projects, and evaluation. Video data is identifiable. After much discussion, it was decided that videotaping should not be allowed for class projects unless reviewed and approved by the IRB. Dr. Long shared that student teachers will record themselves teaching then conduct data analysis on their activity. This activity generally falls into a category of program evaluation and dissemination to an accrediting body would not meet the definition of research.
- Dr. Morrison will email IRB members with drafts of the definitions S&P and the Class Projects Best Practices by 2/8/2024.
  - IRB members are encouraged to share these drafts with colleagues and departments to solicit feedback.
- The meeting concluded at 4:37 pm

Minutes prepared 2/2/2024; Zoom audio recording and transcript deleted 2/8/2024