BEEC Share and Learn Report: September 2023

Presenters: Judy Cezeaux, Former Dean, Arkansas Tech University

Topic: IRB Fundamentals for Publishing in Engineering Education

Resources:

- 2018 Common Rule for Human Subjects (IRB Regulations): https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html
- Expedited Review: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html
- Judy Cezeaux Email Address: judy.cezeaux@gmail.com `

Presentation Overview:

- Discussed education research ONLY not medical devices, so following 45 CFR 46 regulations to evaluate the use of human subjects in research
- Subpart A of 45 CFR 46 outlines policies for human subjects research. Subparts B, C, D relate to pregnant women, children, fetuses, and prisoners. Subpart E relates to IRB administration
- Subpart A was modified in 2018
- What is research? – systematic investigation designed to develop or contribute to generalizable knowledge – want to share with world to allow others to use what you did. If you intend to publish, you
    - Surveys used for ABET or other internal administration surveys to use not for publishing purposes do not need IRB approval as it is not being used to contribute to generalizable knowledge
    - If you publish it, you need IRB approval
- What is a human subject? – living individual in which you collect data from and then analyze it
    - Students are considered human subjects
    - Don't forget about FERPA – some information is expected to remain private
    - IRB CFR 46.102
- Exempt Research – some research, a lot of what we do in education community, is considered exempt from IRB review
    - Research established in accepted educational settings (e.g. afterschool program with HS students counts as well)
    - Research on effectiveness or comparison among instructional techniques, curricula, or classroom management methods
    - Interviews, surveys, observations (including audio/visual recording) if at least one criteria is met:
        - Recordings are done such that human subject cannot be identified, e.g. link to identifiers and codes that are not directly linked to subjects – a survey in which Judy is Subject 1 but NOT JC 1 (can't be able to identify them)
    - Just because it is exempt doesn't mean you don't need to do anything! The investigator cannot make the determination, you MUST have this determination done by the procedures at your institution
        - Example: some IRBs at schools will have a questionnaire that you submit and the school then reviews it and determines whether it is IRB exempt, they need to agree or disagree whether or not it is exempt
- IRB Review Categories: Expedited vs. Full Review
    - If you are not determined to be exempt from IRB review, you may be able to go through Expedited Review
        - Subjects are exposed to no more than minimal risks, and reviews are conducted by IRB chair or a subset of the IRB
        - https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html

    - Full review – there is more than minimal risk and need to do a full IRB review
- Things to know – there is NO retroactive IRB approval. If you perform research without IRB approval or approved exemption, you can't use that data in publications
    - You can use archival data – data from previous years that you collected for other reasons
    - Students NOT 18 years old cannot give informed consent – so careful for first year college courses and HS program studies as parents need to give consent
    - Multiple institutions may require IRB approval from each institution – e.g. a center grant or getting data from multiple institutions
- Publications – if you publish at ASEE BED, as abstracts are due soon, you need to follow IRB approval. You need too provide the IRB number in the publication. E.g. This research was determined to be exempt under the MyUniversity IRB (MU E1234) or This research was approved by the MyUniversity IRB (approval number MU7689). You may also require a form that makes you include this if not directly in the manuscript (e.g. Nature Papers).
- Helpful Tips
    - Get to know your IRB chair, they can provide useful information prior to IRB proposal submission
    - Many require training before submitting to IRB. Many organizations use CITI to perform this training, make use of these opportunities
    - Consider serving on your IRB because it is useful to best write an IRB proposal and the statements IRBs want to see every time.

Discussion:

- Kemi Akintewe – getting permission before doing research, if you blind student's information and then publish some of their comments, do I need IRB approval?
    - Yes, because it's information from students. Comments for example from a course evaluation, even though was put together to be used internally, if published, it needs to be IRB approved.
    - It will likely be exempt or expedited IRB review but you need approval prior to getting those comments
- Kemi – if you have prior IRB approval, is it okay?
    - In general, yes, but it depends on when it was approved and whether it is not expired. If your co-author wrote the IRB approval, they need to write an IRB modification that includes a new investigator and new set of students they will be included in the study
    - This is done to ensure that students are being protected when we disseminate to the community
    - IRB modifications are usually like a notification and likely required even
- Rachel Childers – for data that is published about student data, in ASEE BED and J Biomedical Engineering Education, it is double blinded, do IRB rules apply to everyone including international institutions and how do you enforce this?
    - In general, what we talked about today is only applicable to any services who work for or with human health and services, so if you are working with a foreign institutions, the entity need to be strigent as the guidelines in the human health and services. So some journals need to say "IRB or equivalent" to ensure those outside of US are covered by that.
    - Our institutions require this even though they are not in human health and services
    - It may even have to go through the consulate?
    - Ann Saterbak – does research in Africa, places she worked at has separate systems and may require paying for IRB approval and can take 6-12 months which can delay work.
- Nicole Ramo – the IRB wants a lot of the research decisions to be made up front, but there were specific things not considered yet. At what point in the study design do you need to submit the IRB?
    - For example, power analysis for effect size, can be a bit of guess work, especially if we require informed consent. Give a strong protocol, once you have a research design in place, you need to

start IRB approval. E.g. you need to design focus groups vs surveys up front especially since that's something that can change how things are identifiable
        - At different institutions, they can have different review periods (some are monthly) so pay attention to when they meet to prevent delays
        - IRB can come back and still ask more questions, and it is meant to be a dialogue, but can also delay approval
- Kavon Karrobi – can you clarify archival vs. retroactive data for what you can access for research data?
    - Example: Judy taught engineering physiology for years and wanted to introduce active learning techniques into the course. If done in Fall 2016, got IRB approval in Fall 2016 to do intervention on students. But wanted to compare performance to previous years. The previous years final exam would be the archival data. Can use the archival data in an non-indentifiable form that was collected for a non-research purpose to use them to compare the new intervention.
    - If I collected data from Fall 2016 when the intervention was done before IRB approval, that's retroactive data that you cannot look at
- Kavon – if you have a colleague who made a change a prior year and you want to examine that, can you use it?
    - Would need to have a letter in the IRB application that the colleague is okay with examining it
- Kavon – to be able to deidentify subjects, if you are collecting demographics on top of data you want to have context with, does it go through exempt or now expedited review?
    - Depends on how you report it. If you put a table in for each individual and their demographics, may be expedited, but if do an aggregate (e.g. 59% females) data report may be exempt
    - Ann – if there was fewer than 6 students in any particular category, it may not be allowed to be published, but that was a general rule based on the institution. This was because you could technically still go back and identify the person. Good research practice is if you collect demographic data, always tell the IRB in your application.
- Nicole Ramo – wanted an anonymous survey but wanted to track student responses over time, is there a way to link them in your surveys?
    - If give pre and post surveys at same time, can put a unique identifier for each survey to be able to pair them, and make the identifier so that even you the investigator don't know the identifier
    - For pre and post tests, you need to get creative or give them at the same time with a unique identifier and let them come back to the survey later
    - Ann – to use surveys over time, used a person who supports educational research and linked it to their net ID, then had them deidentify it and send the data back to you
    - Anthony Felder: I've written down numbers on sticky notes and asked them to pick them up from a table and hold onto the note ghrough a course/program that's then their identifier they kept in notebooks. Not perfect, but worked for what we used
- Christine King – in large institutions, sometimes we use "blanket IRBs" where we do things like "active learning with survey assessments", what are your thoughts?
    - For mostly exempt or expedited IRBs, you may have more flexibility as they can be subsets of the IRB and allows less submissions to the Health and Human Services from the institution
    - Reach out to your IRB to discuss how they do it, and if you change institutions, reach out to them to discuss how they do it and what best practices they like to see.
- Kavon – do we need to put the IRB approval in the abstract for ASEE conference submission?
    - Nicole Ramo – as a reviewer, we were asked to check for it at the draft paper stage