IRB Demo Questions

- Will you discuss the legacy protocols done in COEUS?
    - **COEUS legacy studies will not be migrated into the new PERA system. Please assess the status of your research and take the appropriate next steps. If you plan to continue this research. You are enrolling, interacting, or intervening with participants and/or analyzing private identifiable data, submit a new application in PERA once the system goes live on October 27th. You will need to use the protocol templates and appendices provided on the PERA IRB Go-Live website. Your COEUS legacy study in Cayuse is still active and research may continue until it is closed. However, it will need to be closed no later than March 2026 before Cayuse moves to read-only access. If your study is complete, you are only analyzing de-identified data or you have already submitted a study to replace this one and, it has received IRB approval, then log in to Cayuse IRB and close this study as soon as possible.**

- Can you share more about if/how protocols approved in Cayuse will be reviewed when resubmitted in PERA? For example, I need to submit personnel modifications. Will the full study be reviewed again or just the check that new personnel completed CITI retraining?
    - **The system will allow a modification for personnel only, which would only require the CITI check to be approved. There is another modification option for "other parts of the study" which would open up the whole study to modify and be reviewed**
- To clarify, this is a Q about protocols that are new to PERA as in there is no protocol in PERA yet to modify. So when I submit as a new protocol on Oct 27th bc I need to add new personnel will it go through a full review or the CITI check only?
    - **if your protocol was in Cayuse and approved/active.. there will be a record of it to modify your personnel, you will not start over. hopefully I am understanding the question (excluding Coeus, JIT, NHSR, Not Engaged)**

- I know Cayuse asked about all involved investigator but it looks like this template only asks about the principal investigator. Will there be somewhere to record other co-investigators?
    - **Yes, individuals will be added to the study in the PERA IRB SmartForm.**

- What about Co-PI's from other institutions?
    - **Adding external collaborators to a study is a more involved process than when you add Purdue personnel. If the external collaborators are engaged in human subjects research then you will need to change your study type to Collaborative/Multi-Site to create a Participating Site (p-site) for their institution in the PERA SmartForm. There will be instructions on how to do this posted on the PERA Training website.**

- I know Cayuse asked about all involved investigator but it looks like this template only asks about the principal investigator. Will there be somewhere to record other co-investigators?
    - **Yes, in the PERA SmartForm**
- So basically, we get to write our protocols via a word doc, and then use PERA to submit that document for review?
    - **Yes, a majority of the detailed information will be in the protocol templates word document**
- Will grad and undergrad students appear in the search to be added as local study team members? Or do they still need to request some kind of account?
    - **Yes, students should already be available in PERA to select when we are live. Please review the definitions of Key and Non-Key Personnel prior to submitting a personnel modification. (See my Notes at the end of this document…)**
- If we are recruiting from a Purdue classroom and the classroom hasn't been assigned yet, how do we handle that?
    - **The location listings will be only buildings. Details of the room can be provided, but will not be in the selection list. If the building is not available to select, you can use the manual entry**
- But if the class hasn't been assigned a building yet?
    - **We don’t need to know what the building is; course name in the protocol should be enough information.**
- Q: So no matter whether our study is exempt research or not, we have to fill in all the information you are showing us now?
    - **Yes, you are required to complete the PERA SmartForm.**
- If I collect data through online panels/crowdsourcing platforms (e.g., Prolific or Amazon Mturk) what do I put as a research location? Also, often these platforms allow to recruit participants from various countries, how do I deal with that?
    - **We no longer consider that a research location. Please put this detail into your protocol.**

- is there a template for the letter needed from the data custodian releasing FERPA data?
    - **We have a Letters of Collaboration template on our website that addresses FERPA.**
- If I am on research absentia and currently residing in another state within the U.S., what should I list as *research location*? My work primarily involves conducting online experiments and surveys (e.g., through Qualtrics). Would it be appropriate to indicate my advisor's office as the research location or sth else?
  Where do we upload letters of collaboration from community partner sites?
    - **Local Site Documents**.
- Under Local Study Team Members section, should we just include individuals who have access to the data?
    - **You should include anyone who is considered Key Personnel.**
- I may have missed this, but the word document we use to submit a study -- is the template within the library?
    - **Yes, and it is available on the PERA IRB Go-live site right now. PERA IRB Go-Live Information - Purdue Excellence in Research Administration**
- How will we receive feedback on the submitted protocol template in word?
    - **In a Word document**
- How do clarification requests come through, and how submit revised versions?
    - **This will be addressed on the PERA training website and in the Researcher Guide. You will receive most of the clarifications or modifications required in a Word document.**
- Will bookings be available for all campuses? I believe they have been limited to in-person meetings on the PWL campus, so my campus (PFW) has not been able to take advantage. Thanks!
    - **They will be all virtual and will be available to all campuses**
- does the managed guest list also get the messages from the IRB? So that when something comes back (revisions) the messages would go to both the primary contact and the guest list?
    - **Automated messages from the system will only go to the PI and the Primary Contact. Things like state changes, upcoming deadlines, etc. If a comment is added and Study Team is selected as the recipients, it will not go to the Guest List members, only the study team members added in "local study team members"**
- Is there a distinction between device and software? For example, if we have created an interactive ... IDK game like thing that participants engage with on their own devices...

Further, does the device section include review of any APIs the team may be using? Because like ... putting LLMs in every dang thing is a massive privacy risk.
    - **This is specific to Medical Devices.**
- For study members, if personnel change during the course of the study (for example if undergraduate research assistants turn over across semesters), do we need to resubmit the protocol?
    - **Most of the time undergraduate research assistants are not considered Key Personnel. Non-Key Personnel are research personnel who either interact with human subjects or access identifiable, private information but are <u>not</u> key personnel in the sense that they do not contribute in a substantive way to the scientific or scholarly development or execution of a project. For example, such personnel may assist in collecting data, but are always under supervision of the principal investigator and /or key personnel and do not act independently in the execution of the research project.**
    - **But yes, the system will allow for a modification just to the study team members that will not require the entirety of the study to be reviewed again**
- In Cayuse, we used to be able to collaboratively edit protocols with our students. For example, once our students had written some text, we used to be able to directly make edits to that text. Will this feature be available in PERA now?
    - **Yes, everyone on the study team has edit access to the smartforms while the study is open for editing (not being reviewed). The Compare function is very useful during collaboration in the smartforms. Similarly on the templates, you can collaborate on the word document for items not in the smartforms**
- Can you explain more about collaboration on word forms? Is there a way to do that in the system, or does this mean we can use onedrive or something outside of the study?
    - **Collaboration would be done outside of the system and then the protocol would be attached when its "final". If a reviewer requests modifications, the document can be edited in the same fashion collaboratively outside of the system and the latest version can be uploaded before you submit the clarifications/modifications**
- Is it easier to read the clarification questions than in the old system?
    - **Yes! They will be compiled into a Word document so you can see them all at once.**
- Is the IRB Reviewer still going to be hidden or will we know who is reviewing our protocol?
    - **It will still be anonymous**
- Is there a way to link your IRB protocol to grant proposal/grant award both for SPS and also for IRB reviewers, so there's easier 'cross-talk' between offices? And PERA modules?

    - **Yes, the functionality does exist. It is a bit clunky and is getting rereleased in early 2026. Once we are live and see how the functionality is in the live PERA site, we will put out some training on how to "link" your IRB study to your Grant**
- Do we still have aplace to see the previous determinations for these not study studies?
    - **Yes, you will be able to still see everything in Cayuse until March 31, 2029.**
- To clarify, I was under the impression from my previous interactions with IRB that I have to keep my protocols open as long as I keep analyzing the data (even if de-identified) or pursuing their publication. That is, I can only close the protocol if I no longer deal with the data in any way, and I published everything I wanted based on this data. Is this not correct?
    - **If you are not interacting or intervening with participants or their private identifiable data, then you are not conducting research with human participants and your study may be closed. Analysis of de-identified data does not meet the regulatory definition of research with human participants and does not require IRB oversight.**
- Will we have to enter everything from Cayuse again in the word form for simple modifications that do not lead to changes to the protocol (e.g., personnel amendment, amendment to a survey questionnaire without changing purpose or risk/benefit)
    - **We need to have a record of your entire approved study from Cayuse in PERA. The only way to do this is to manually move what you entered in the Cayuse text boxes into the Word protocol. We are working on materials to assist with this that will be posted on the PERA training website.**
- How would Just In Time submissions work in this system?
    - **We will be accepting JIT submissions in PERA, but are still working on the process. If you get a request from NSF or another agency for a 45 CFR 46.118 determination, please email irb@purdue.edu.**

  Is this system housed at Purdue or out on "the cloud" somewhere else?
    - **It is cloud based**
- Follow-up question, will sps have access to this irb module?
    - **To start, some members of SPS will have access, mainly from an administration side (PERA Help, Reporting, etc). SPS can be added to the guest list similarly to a Business Office person for access to specific studies. If business dictates more SPS staff needing access, it is something we're keeping in mind post go-live to make sure we add access where it makes sense**
- Will the notes from this session (and similar sessions) be shared after the sessions?
    - **Videos - Purdue Excellence in Research Administration**

- All very helpful. Can you elaborate on what the workflow is for international studies? E.g. EU sites where GDPR compliance needs to be documented, etc.
    - **Your study and consent documents will need to be reviewed by the Purdue Office of Legal Counsel (OLC) for compliance with those regulations prior to study approval. You may initiate the review by OLC or we will do it on your behalf during the review process.**
- Where are the slides for this presentation? I'm not seeing slides or a video for the previous IRB module presentation.
    - **Videos - Purdue Excellence in Research Administration**
- Do we have to manually migrate our active studies from Cayuse to PERA?
    - **Active studies in Cayuse will be migrated. However, you will need to complete the SmartForm and upload the Word protocol document of your protocol from Cayuse. See answer above about transferring your protocol details into the protocol template.**

Note on Administrative Check In

Only certain studies (greater than minimal risk, subject to pre-2018 Common Rule, FDA regulated) require annual continuing review and have a true expiration date.

Other studies that remain under IRB oversight, but do not require continuing review will have an administrative check-in due at some point. We are working on the process for that. For now, please do not stress over administrative check in dates from Cayuse. You will receive communication from us when we need something from you.

Studies that are exempt no longer have administrative check-in dates since exempt studies are not overseen by the IRB. Please do not submit renewals for exempt studies.

Notes on Personnel:

Principal Investigator- Tenured, tenure-track, research, and clinical faculty of Purdue University are eligible to be Principal Investigators (PIs) on an IRB protocol. Others requesting to submit protocols as the Principal Investigator must obtain approval from the Institutional Official or his/her designee.

Key Personnel Team members who contribute in a substantive way to the scientific or scholarly development, execution, or interpretation of a project. Key personnel MUST be added to the study in the PERA SmartForm

Non-Key Personnel Team members who either interact with human subjects or access identifiable, private information but **do not** contribute in a substantive way to the scientific or scholarly development or execution of a project. Such personnel may assist in collecting data but are always under supervision of the principal investigator and/or key personnel and do not act independently in the execution of the research project. A common example of non-key personnel is undergraduate research assistants. **They do NOT need to be added as a Study Team Member in PERA. They DO need to have the appropriate CITI training in Human Subjects Research.**