Pathway to "Approved": Optimizing IRB Submissions for Efficient Review

Back to the Bay

August 13, 2026: 1:00 PM - 1:50 PM

VBT 217

Session Description

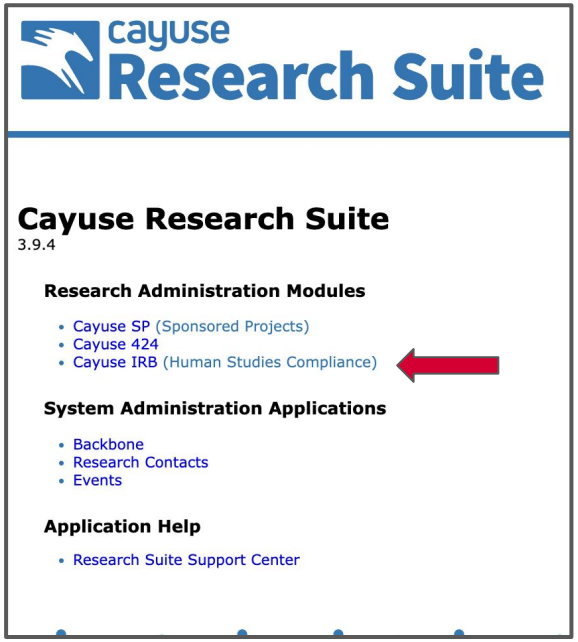
- This presentation will cover
  - Basic details of submission
  - Review pathways
  - Common reasons for delays,
  - Key IRB website resources to support investigators.
- Participants will learn how to craft IRB protocols that are positioned for timely approval.
- Presenters:
  IRB Co-Chairs Michelle Gravier, Ph.D. (Speech, Language, and Hearing Sciences) & Arnab Mukherjea, Dr.P.H. (Public Health)

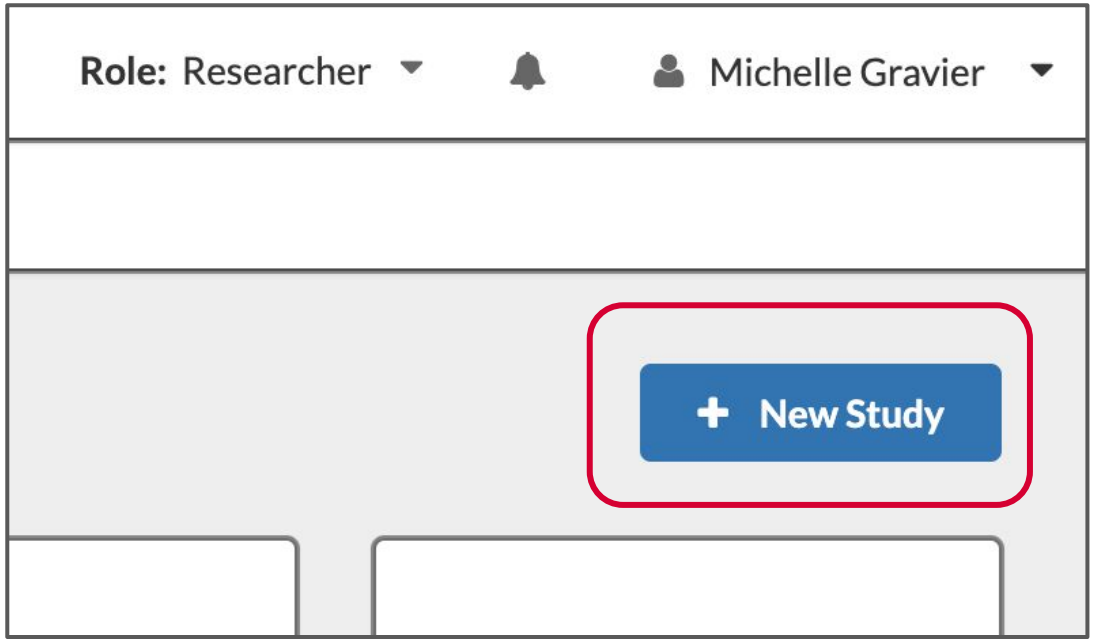
What is an Institutional Review Board (IRB)?

- **What the IRB does**
  - Protects research participants per the Code of Federal Regulations, Title 45 Part 46
  - Reviews human subjects research conducted by CSUEB faculty, staff, students, and investigators from other institutions/agencies who are working in conjunction with CSUEB in any capacity
  - Ensures ethical and regulatory compliance
  - Criteria for approval
- **What the IRB doesn't do**
  - Edit and/or proofread writing
  - Provide guidance on the research topic or study design
  - Provide approval for research that has already been carried out (post-hoc)

Submission Basics

- All research proposals are submitted on Cayuse (https://csueastbay.cayuse424.com/)





Submission Basics

- **What investigators need prior to submission**
  - *Research plan*
  - *Current CITI* for all researchers involved (including students)
    - https://www.csueastbay.edu/orsp/compliance/irb/training.html
    - Valid for 3 years
  - *Recruitment materials*
  - *Consent/assent forms*
    - Including translations (if applicable)
  - *Data collection instruments*
    - E.g., surveys, questionnaires
  - *Site permission* (if applicable)
    - E.g., Letter from approving individual at school or medical setting where research may be carried out

The IRB, not the investigator, determines the review category

Review Pathways

Even studies that may qualify as exempt still require IRB submission for determination.

- **Categories of Review**
  - Full board/full committee
    - More than minimal risk (e.g., invasive procedures such as x-ray) or research with special populations (e.g., prisoners)
    - Added to agenda at full IRB board meeting (held monthly)
  - Expedited (most common)
    - Minimal risk
    - Reviewed by IRB members and chair(s)
  - Exempt
    - Minimal risk and in one of eight exempt categories (e.g., anonymous survey, passive observation)
    - Usually administratively reviewed by IRB chair(s) only
  - Not human subjects research

https://www.csueastbay.edu/orsp/compliance/irb/review-categories.html

Review Pathways

- **What happens after investigator clicks “Submit” (expedited review)**
  - Make sure the Principal Investigator (PI) certifies the submission (even if the PI is submitting, still needs to be certified)
  - Administrative check (Tina Avilla - e.g., are all CITI certificates present)
  - Assignment of reviewers
  - Review + initial decision
  - Post-review by IRB chairs
  - Back to PI for revisions
  - Review + decision
  - Approval
  - ***Research can begin***

- Most protocols receive at least one round of requested revisions
- Allow 4 weeks on average for each review cycle

https://www.csueastbay.edu/orsp/compliance/irb/review-process.html

Common Reasons for Delays

- *Missing protocol elements*
  - E.g., recruitment flyer, translated consent form(s), etc OR not accessible to reviewer (sharing permissions, broken links)
  - PDFs preferred (versus links to shared documents)
- *Inconsistent info across various sections of the protocol*
  - E.g., number of participants, procedures
  - PI should ensure information on protocol matches consent form(s)
- *Information unclear to reviewers/potential participants*
  - IRB reviewers need to be able to understand the study entails without being a disciplinary expert
  - Consent form should be written at 6th-8th grade reading level
- *Missing Info on Consent Form*
  - E.g., IRB contact info
  - PIs should use templates

Common Reasons for Delays

- *Lack of detail or uncertain language*
  - E.g., “we might collect X data…” “Data will be analyzed.”
  - Research plan must be finalized. If changes are made, PI must submit a modification (cannot carry out changes until approved)
- *Draft versions of materials or incomplete materials*
  - E.g., “subset” or “sample” survey questions; “sample” recruitment flyer
  - Consent form doesn’t include securing permission for audio or video recording, or observational data collection in non-public settings
  - All materials need to be in final form
- *Not following guidance*
  - E.g., Not including assent form for research with children, not requesting waiver of documentation of consent for online studies, etc
  - PIs should read guidance for each section carefully!

Common Scenarios Faced by PIs

- *I'm working with another university*
  - Reliance agreements
- *I'm collecting data in a school district*
  - Site approval/letter from approval-granting individual (usually the PI, but submitter should check with the school/district because policies/procedures may vary).
  - Letter should have detail about the study and what the site is agreeing to, not just “blanket” approval
- *My students are helping with the project*
  - Faculty are still responsible for supervising/mentoring, ensuring IRB policies and procedures are followed
- *I want to study my own students*
  - Demonstrate how possible coercion is mitigated; cannot require participation in research as a condition of enrollment

Recommendations

- **Starting as early as possible!**
  - PIs should access Cayuse to become familiar with protocol sections
  - Timeline should account for at least two rounds of review
    - “Just-In-Time” for grants can be granted conditional approval
- PIs should find colleagues in their Department/College/Division with an approved IRB protocol and request access as an example
- PIs should have a colleague read through their protocol for anything that seems unclear/inconsistent
- Responding to reviewers quickly is key - PIs should make sure to “reply to” comments in Cayuse (and indicate where changes were made)
- Obtain ICT/VPAT review ASAP for any software/hardware being used that is not on the pre-approved list
- IRB website has numerous resources to facilitate successful submissions
- **PIs should email irb@csueastbay.edu with any questions**

Resources

- **IRB website: https://www.csueastbay.edu/orsp/compliance/irb/index.html**
- **IRB Email Address: irb@csueastbay.edu**

Make sure to click on the “+” plus sign to see all resources

Resources

- Does your Research Require Review:
  - https://www.csueastbay.edu/orsp/compliance/irb/research-review.html
- FAQs
  - https://www.csueastbay.edu/orsp/compliance/irb/frequently-asked-questions.html
- How to Facilitate IRB Protocol Review:
  - https://www.csueastbay.edu/orsp/compliance/irb/facilitate-review.html

(Hopefully)