Creighton UNIVERSITY

CU IRB and Me:

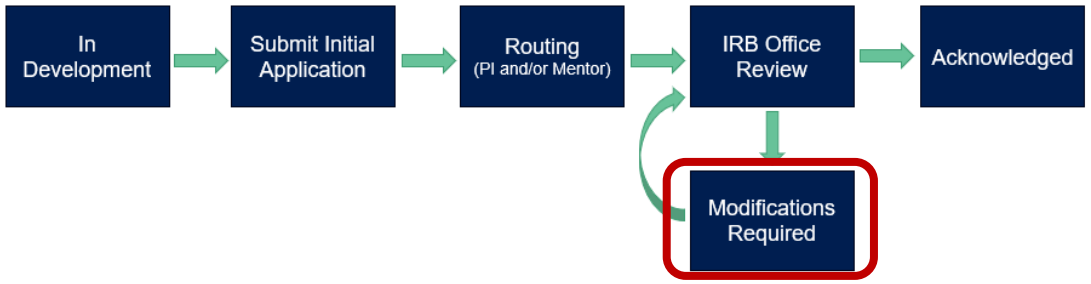
COMMON ISSUES WITH IRB SUBMISSIONS

Agenda

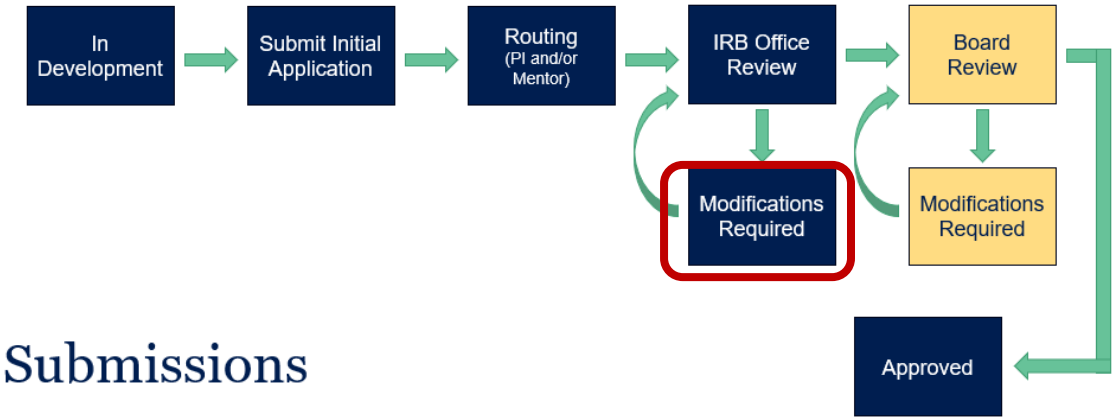
- Materials required with IRB submissions
- Common issues and how to avoid delays
- IRB expectations
- CITI webinars
- IRB website
- Revised guidance documents
- Metrics
- Q & A

Workflows

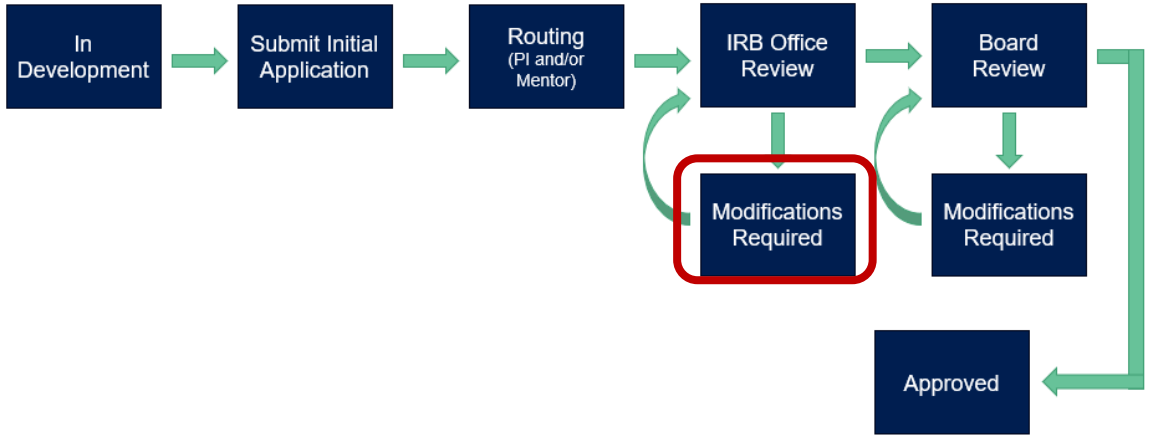
Workflow for Exempt Submissions



Workflow for Expedited Submissions



Workflow for Full Board Submissions



Materials Required with IRB Submissions

Core Documents

- Initial Application**
- Study protocol*
- Consent materials*
  - Information sheet
  - Informed consent form
- Recruitment materials
  - Flyers
  - Emails
  - Announcement scripts
- Data collection instruments
  - Surveys
  - Interview guides

Supplementary Documents

- Site permission letters*
  - If the research is conducted at an external location
- Conflict of Interest Disclosures** and Managements Plans*
- Licensed instrument permissions
  - If the research involves the use of any copyrighted, proprietary, or licensed instruments
- Local ethics approval for international research

* Template available on the Investigator Resources page of the IRB website
** Found on InfoEd

IRB Submissions: Common Issues and How to Avoid Delays

Common Issues	How to Avoid Delays
• Study personnel training requirements not met	• Refer to Requirements Based on Research Type on the Investigator Resources page of the IRB website; ensure training is complete **before** submitting.
• Study personnel CV/Resume not dated and/or not uploaded to InfoEd profile	• Refer to these instructions; ensure documentation is dated and uploaded **before** submitting. • To date a CV/resume, it is recommended that the Biosketch Name (Step 4 in the instructions) include the date. For example, "Date First Name Last Name CV/Resume."
• Mentor is not listed on student-led research	• Undergraduate students may not be designated as the PI. • Designate a faculty advisor as the mentor and add them to the personnel list within the Initial Application when submitting. • Advise mentor to review Routing assignment.

IRB Submissions: Common Issues and How to Avoid Delays

Common Issues	How to Avoid Delays

• Missing, incomplete, or inconsistent information on protocol	**PROTOCOL**
	• Use CU IRB protocol template.
	• Describe the role of CU investigators vs external investigators.
	• Define acronyms the first time they are used in the document.
	• List identifiers to be collected, even if temporarily.
	• Describe whether identifiers will be attached to participant data or is the data coded or rendered de-identified?
	  • If coded, is the code key stored separate from other study data?
	  • When will the identifiers be scrubbed from the study data, (if applicable)?
	• Clearly describe how data is securely stored and protected.

IRB Submissions: Common Issues and How to Avoid Delays

Common Issues	How to Avoid Delays

• Misuse of terms in the protocol and informed consent form (ICF): Coded and De-identified	• **Coded:** Personal identifiers (e.g., name, medical record number, email address) are removed and replaced with a unique assigned code made up of words, letters, figures, or symbols that are not generated from or related to personal information.
	  • Data that is coded is associated with a code key (aka “code breaker” or “linker file”) which includes a list of each code assigned to a personal identifier.
	  • Example: An Excel spreadsheet that lists the code assigned to each subject’s medical record number.
	  • Coding protects the identity of subjects, but it’s still possible to identify the subject if the code key exists.

• Misuse of terms in the protocol and ICF: Coded and De-identified	• **De-identified:** Personal identifiers are permanently removed, no code key exists to link the data/specimens to their original source, and the remaining information cannot be used to identify the source.

IRB Submissions: Common Issues and How to Avoid Delays

Common Issues	How to Avoid Delays

• Misuse of terms in the protocol and ICF: Anonymous and Confidentiality	• **Anonymous:** The identity of individual responses is completely unknown and cannot be linked to their responses.
	  • Data collected during an interview is not anonymous.
	  • Anonymity ensures that even the researchers are unable to connect specific responses to specific individuals.
	  • Researchers deliberately avoid collecting any identifying information including names, contact details, IP address, or personal identifiers.

IRB Submissions: Common Issues and How to Avoid Delays

Common Issues	How to Avoid Delays
• Misuse of terms: Anonymous and Confidentiality	• **Confidentiality:** Identifiable information is collected but is kept secure and is not disclosed to any unauthorized individuals. Final reports do not contain any combination of factors such as race and gender that could expose the subject's identity.

IRB Submissions: Common Issues and How to Avoid Delays

Common Issues	How to Avoid Delays
• Not following recruitment best practices	• **Snowball recruitment:** Investigators should not ask others to provide the names of potential subjects or release private information about them, unless you obtain permission from that individual. See the CU HRPP Policy Manual, Section 3.6 (Subject Recruitment Through Direct Invitation) for guidance.
	• **Cold calling:** In the spirit of the Belmont Report's "respect for persons" principle, sending an email first that informs individuals they may receive a recruitment call is preferred, as it promotes transparency and supports informed, voluntary participation.

IRB Submissions: Common Issues and How to Avoid Delays

Common Issues	How to Avoid Delays
• Recruitment materials missing required content	• Refer to Sections 3.5 and 3.6 of CU HRPP Policy Manual. • Refer to IRB Requirement for Recruitment Materials. • Include required content: Investigator name and contact information, information identifying CU as the research institution, IRB protocol number, clear statement that the activity is research, and purpose of the research. • Avoid prohibited content (e.g., promises of “free” treatment; more that one reference to compensation per advertisement, intentionally drawing attention to the value or availability of compensation, exculpatory language)

IRB Submissions: Common Issues and How to Avoid Delays

Common Issues	How to Avoid Delays
• Missing, incomplete, or inconsistent information on consent form	**INFORMED CONSENT FORM AND RESEARCH INFORMATION SHEET** • Use CU IRB ICF template (signature required) or CU IRB Research Information Sheet template (signature not required) • Use the second person writing style (i.e., participant addressed as “you” and investigators as “I/we”). • Technical and scientific terms should be explained or substituted with common terms. • Acronyms should be written out the first time they are used. • Break long sentences into two or more shorter, direct sentences.

IRB Submissions: Common Issues and How to Avoid Delays

Common Issues	How to Avoid Delays
• Missing documents	• Upload all participant-facing materials including recruitment emails, interview scheduling emails, follow-up emails, phone scripts, advertisements, consent form, surveys/questionnaires, etc.
• One document containing protocol, consent forms, recruitment materials, etc. is uploaded	• Remove appendices from the protocol document and save all documents as separate files. • Upload separate documents to the Creighton University HS eForm in the corresponding sections.
• Required modifications go unaddressed	• Watch for emails from IRB staff and check the Assignments section of InfoEd. • Respond promptly to IRB requests and verify that the application has been submitted.

IRB Expectations

Status in InfoEd	Application Type	Deadline to Send to IRB Office*
In Development	Initial Applications	6 months
	Request for Modifications	90 days
	Annual, Continuing, or Project Termination	90 days
Modifications Required**	Initial Applications	90 days
	Request for Modifications	
	Annual, Continuing, or Project Termination	
Approved with Conditions (Full Board only)	Initial Applications	10 days
	Request for Modifications	
	Annual, Continuing, or Project Termination	
Tabled (Full Board only)	Initial Applications	Dependent on Board requests
	Request for Modifications	
	Annual, Continuing, or Project Termination	

* Extensions will be granted with proper communication to the IRB Office before the deadline.
** InfoEd generated email reminders will be sent to study team members with 80, 60, 30, and 7 days before the expiration date.

CITI Webinars

Available webinars relevant to today's topics

- Working with Your IRB (ID: 317832)
- Informed Consent and Clinical Investigations: A Focus on the Process (ID:317830)
- Informed Consent and Research with Wearable Tech (ID:317836)
- Paying Participants in Research: Regulations, Ethics, and Practical Considerations (ID:317792)
- Remote Informed Consent: The Same, but Different, but Still the Same (ID:317840)
- Social Media and Research Recruiting (ID:317823)
- Study Start-Up Challenges and Strategies (ID:317756)
- Understanding Consent Requirements and "Key Information" Under the Revised Rule (ID:317820)

CU IRB Website

https://www.creighton.edu/research-services/committees-and-boards/institutional-review-board-irb

Revised Guidance Documents

Training, Documentation, and Disclosure Requirements for HSR

- The training and disclosure requirements have not changed.
- Curriculum vitae (CV) no longer require a signature. A date on the document is still required.
  - Recommended: Name the document *[DATE] [FIRST NAME] [LAST NAME] CV*; save to InfoEd Biosketch.
  - CVs still required to be updated every two years for all study team members.

Guidance Document

- Quality Improvement Projects and Not Human Subjects Research Requirements
- Checklist: Case Study or Human Subjects Research?
- Flowchart: Human Subjects Research Decision Tree **NEW**
- Guidance Document: Do I Need to Submit to the IRB?
- Guidance Document: IRB Requirements for Recruitment Materials

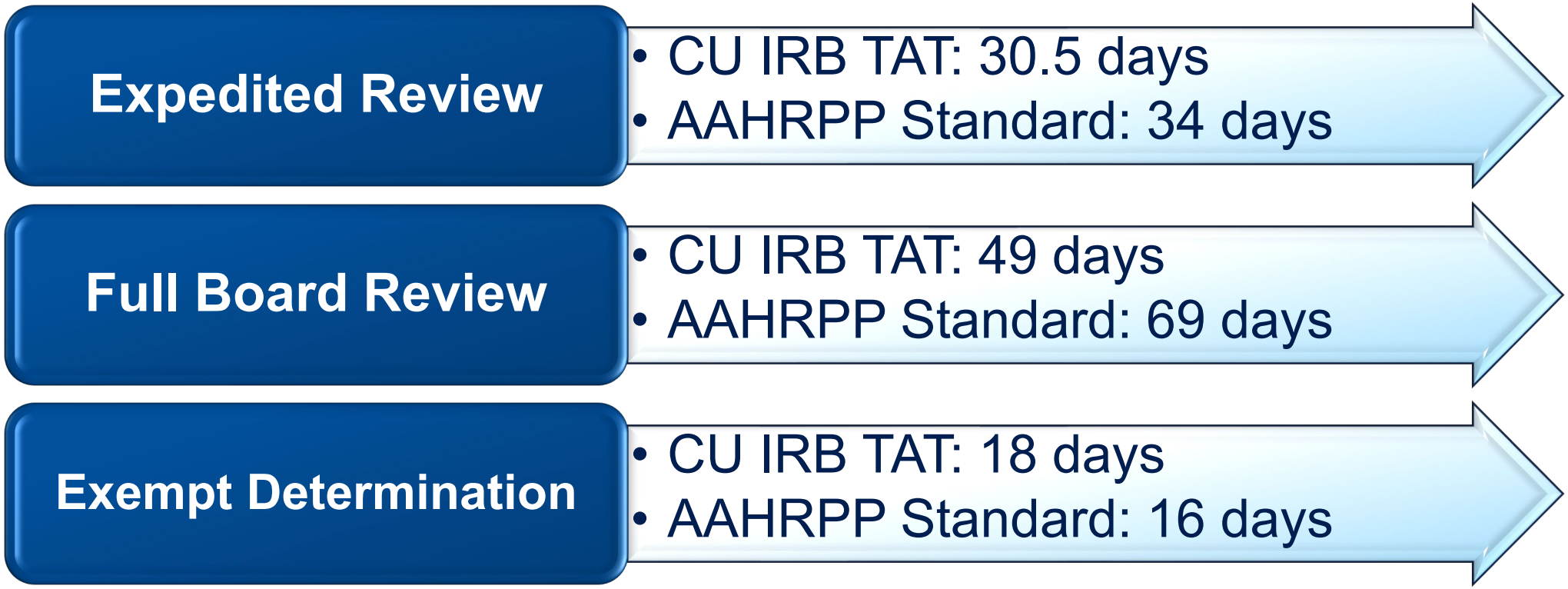
Templates

- Certificate of Translation

https://www.creighton.edu/research-services/committees-and-boards/institutional-review-board-irb/investigator-resources

Recent Metrics

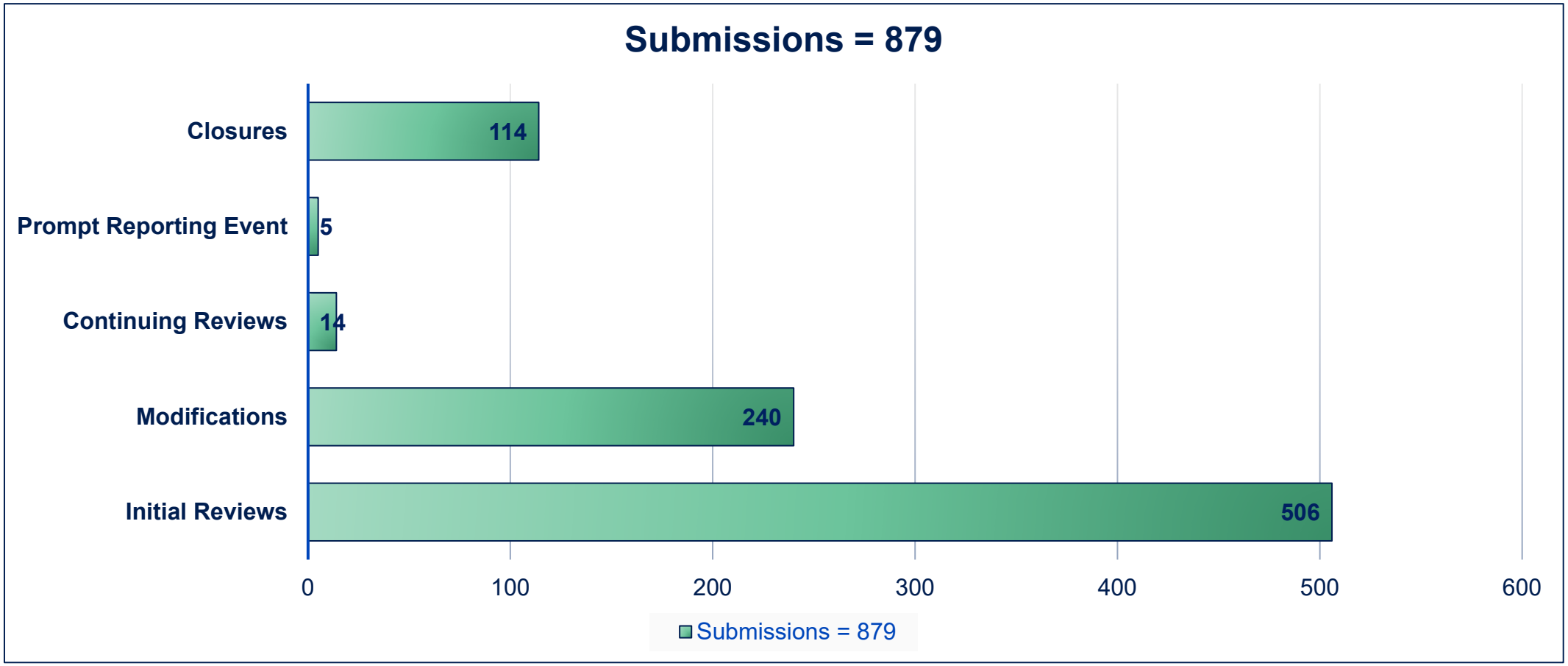
Turnaround time (TAT) data from **submission** to initial approval (January 2025 through December 2025). *Note: TAT includes days with investigators.*



AAHRPP = Association for Accreditation of Human Research Protection Programs, Inc.

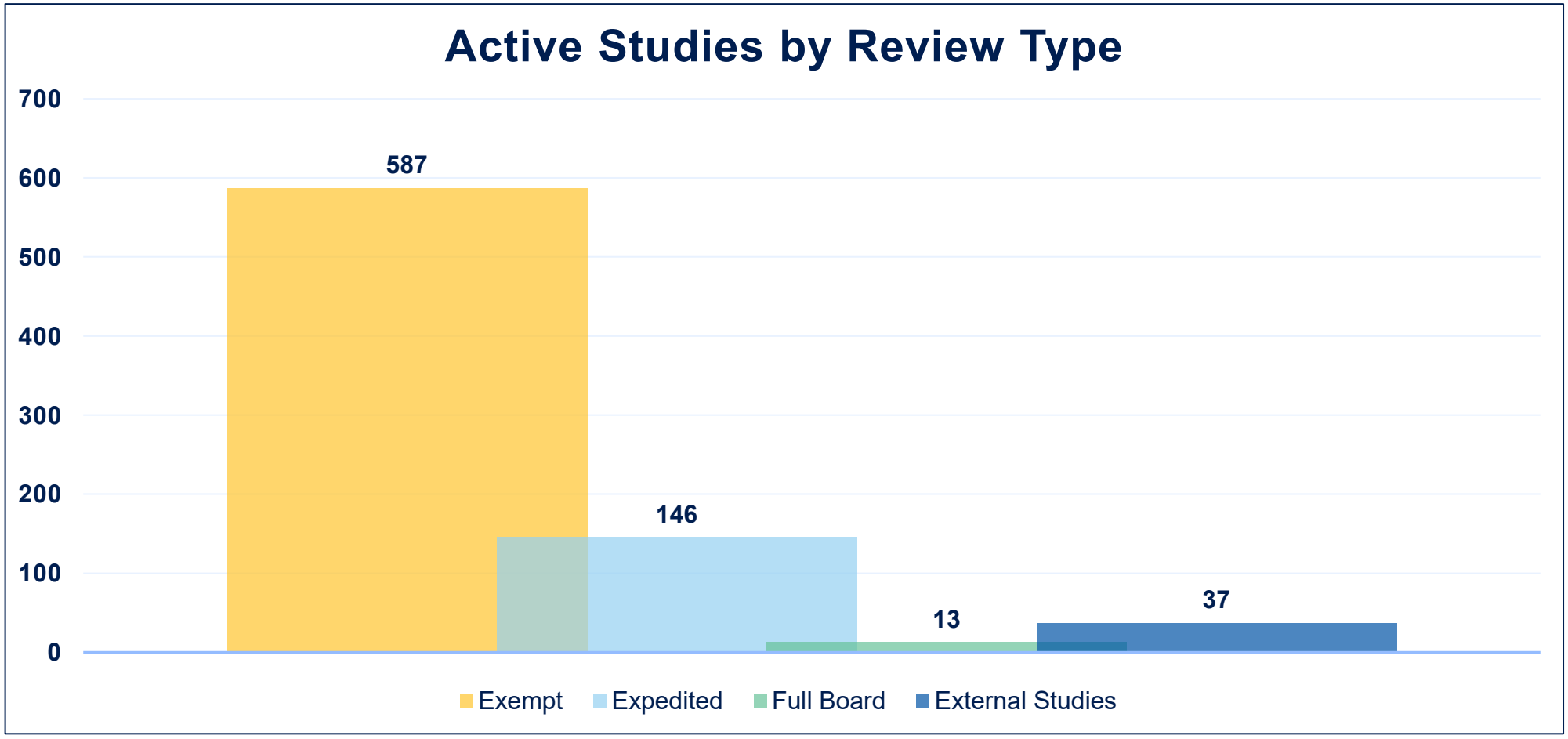
Recent Metrics

Total application submissions – to date January 2025 through December 2025:



Recent Metrics

The CU IRB currently reviews and monitors 783+ active studies.



Q & A

Help us help you

Our goals

- Provide meaningful education and guidance to the research community
- Support researchers for the lifetime of their studies

IRB Booking Page

Suggestions for future CU IRB and Me sessions

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Thank you.

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