Creighton UNIVERSITY

CU IRB and Me:

IRB PROCESSES AND EXPECTATIONS

Agenda

- Review types
- IRB processes
- IRB expectations
- Risk levels
- Revised guidance documents
- Website changes
- Metrics
- Q & A

Is the Activity Human Subjects Research (HSR)?

- Does it meet the definition of **research** as defined in the federal regulations?
- Does it meet the definition of **human subjects** as defined in the federal regulations?

RESEARCH as defined at 45 CFR 46.102(l):	**HUMAN SUBJECTS** as defined at 45 CFR 46.102(e):
A systematic investigation that involves research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge	Involves a living individual whom researchers: (1) Obtain data/biospecimen through intervention or interaction and then studies/analyzes/tests the collected data/biospecimen **OR** (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

The CU IRB offers a determination checklist that can be used by the research community in assessing whether their project is considered research involving human subjects.

Levels of IRB Review

- A direct relationship between the level of research-related risk and the required level of review.

Exempt Review

Exempt Review Categories

(1) Research in established or commonly accepted educational setting

(2) Educational tests, surveys, interviews, observations of public behavior

(3) Benign behavioral interventions with adults

- Minors cannot be included in this exemption category

(4) Secondary research for which consent is not required

(5) Research and projects conducted or supported by a U.S. department or agency

(6) Taste and food quality evaluation or consumer acceptance

(7) Storage for secondary use for which broad consent is required

(8) Secondary research for which broad consent it required

Question: Is the following considered **research** involving **human subjects**?

A graduate student at Creighton University plans to submit a new initial application to the IRB. The student wants to invite individuals aged 19 and older who live in Omaha, Nebraska to participate in a one-on-one interview. During the interview, participants will be asked about their personal experiences using A.I. tools over the past week.

The objective is to collect and analyze this information to identify common patterns in how people in Omaha are using A.I. in their daily lives.

1. **Is this research?**
    a. Is this a systematic investigation?
    b. Is the intent to draw generalizable conclusions?

2. **Is this research involving human subjects?**
    a. Is there an interaction?

Question: Is the following considered **research** involving **human subjects**?

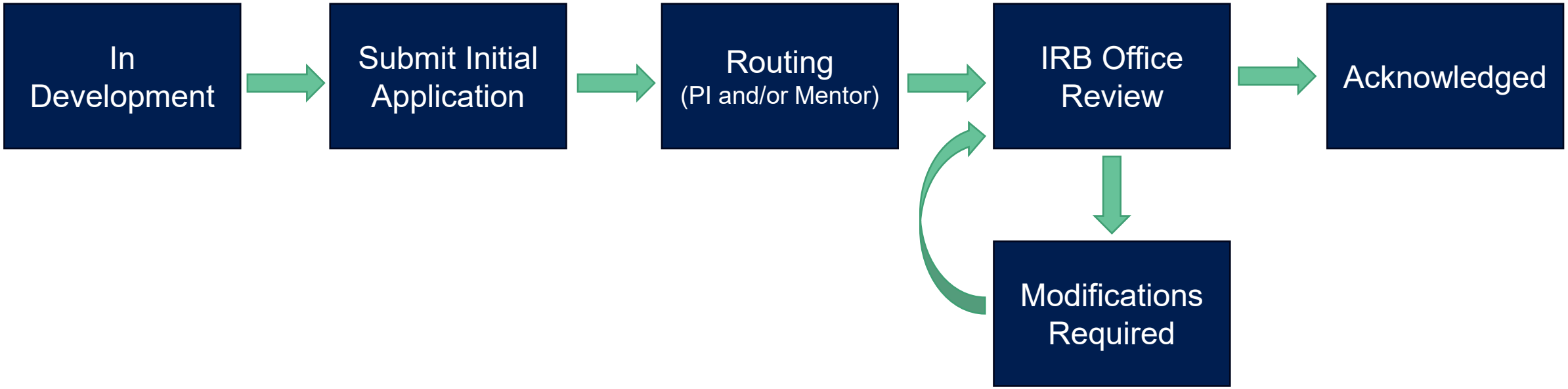
A graduate student at Creighton University plans to submit a new initial application to the IRB. The student wants to invite individuals aged 19 and older who live in Omaha, Nebraska to participate in a one-on-one interview. During the interview, participants will be asked about their personal experiences using A.I. tools over the past week.

The objective is to collect and analyze this information to identify common patterns in how people in Omaha are using A.I. in their daily lives.

1. **Is this research?** Yes
    a. Is this a systematic investigation? Yes
    b. Is the intent to draw generalizable conclusions? Yes

2. **Is this research involving human subjects?** Yes
    a. Is there an interaction? Yes

Workflow for Exempt Submissions



Poll: True or False?

An Expedited review is a procedure through which certain kinds of research may be reviewed and approved more quickly.

Poll: True or False?

An Expedited review is procedure through which certain kinds of research may be reviewed and approved more quickly.

False

Expedited Review

- Does not fit within the Exempt categories
- Minimal Risk research only
- Reviewed/Approved by an individual IRB member
- May or may not require annual renewal
- 45 CFR 46.111 approval criteria must be met in order to approve the research
  - Minimizing risks
  - Ensure risks are reasonable in relation to benefits
  - Equitable selection of subject
  - Ensure informed consent is properly obtained
  - Adequate provisions for monitoring the data, protecting the privacy of subjects and the confidentiality of data
  - Additional safeguards to protect the rights and welfare of vulnerable subjects
- Must fit within one of the nine Expedited categories of research

Minimal Risk

Federal regulations define 45 CFR 46.102 (j) ***Minimal Risk*** as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Risk Levels: Minimal Risk

Examples of Minimal Risk Studies
• Collection of blood samples by venipuncture from adults and children (within limits)
• Collection of data through non-invasive means (excluding studies that require general anesthesia or sedation for research purposes) routinely employed in clinical practice, including MRI (3 Tesla or under), ECG, ultrasound
• Research involving materials (data, documents, records — including medical records — or biological specimens) that have been collected or will be collected solely for nonresearch purposes
• Collection of data from voice, video, digital, or image records made for research purposes
• Research on individual or group characteristics or behavior (e.g., focus groups, surveys, interviews)
• Mobile applications that only track information and do not directly inform care of the research subject
• Observational research on Standard Treatment(s): Observational research on standard treatment(s) where the treatment(s) is (are) determined clinically and not assigned by research methodology (e.g. randomization)

Expedited Review

Expedited Review Categories: Initial Review

(1) Clinical studies of drugs and devices that do not require an Investigational New Drug or Investigational Device Exemption application. FDA regulated*

(2) Research that collects blood samples by finger stick, heel stick, ear stick or venipuncture from health, non-pregnant adults and sometimes children (limited amount of blood)

(3) Prospective non-invasive collection of biological specimens for research purposes only

(4) Collection of data through non-invasive standard of care procedures

(5) Review of data, documents, records, specimens that have been or will be collected solely for non-research purposes

(6) Collection of data from voice, video, digital or image recordings made for research purposes

(7) Research performed on individual or group characteristics or behaviors or involves employing surveys, interview, oral histories, focus groups, etc.

* At this time, CU IRB does not review FDA-regulated research. External IRB review is required.

Expedited Review Example

Expedited Category 7: Research performed on individual or group characteristics or behaviors or involves employing surveys, interview, oral histories, focus groups, etc.

Study purpose: Identify common patterns in how people in Omaha, NE are using A.I. in their daily lives.

Population: Individuals aged 18+ years

Study activity: Interview participants about their personal experiences using A.I. tools.

Why isn't it Exempt category 2 (educational tests, surveys, interviews, observations of public behavior)?

Expedited Review Example

Expedited Category 7: Research performed on individual or group characteristics or behaviors or involves employing surveys, interview, oral histories, focus groups, etc.

Study purpose: Identify common patterns in how people in Omaha, NE are using A.I. in their daily lives.

Population: Individuals aged 18+ years

Study activity: Interview participants about their personal experiences using A.I. tools.

Why isn't it Exempt category 2 (educational tests, surveys, interviews, observations of public behavior)?

- Individuals aged 18 years are considered children in Nebraska.
  - Age of majority in Nebraska is 19 years.
- Exempt category 2 cannot involve children unless it involved educational tests or observation of public behavior when investigators do not participate in activities being observed.

Expedited Review

Expedited Review Categories: Continuing Review

(8) **Continuing review** of research previously approved by the convened IRB as follows:

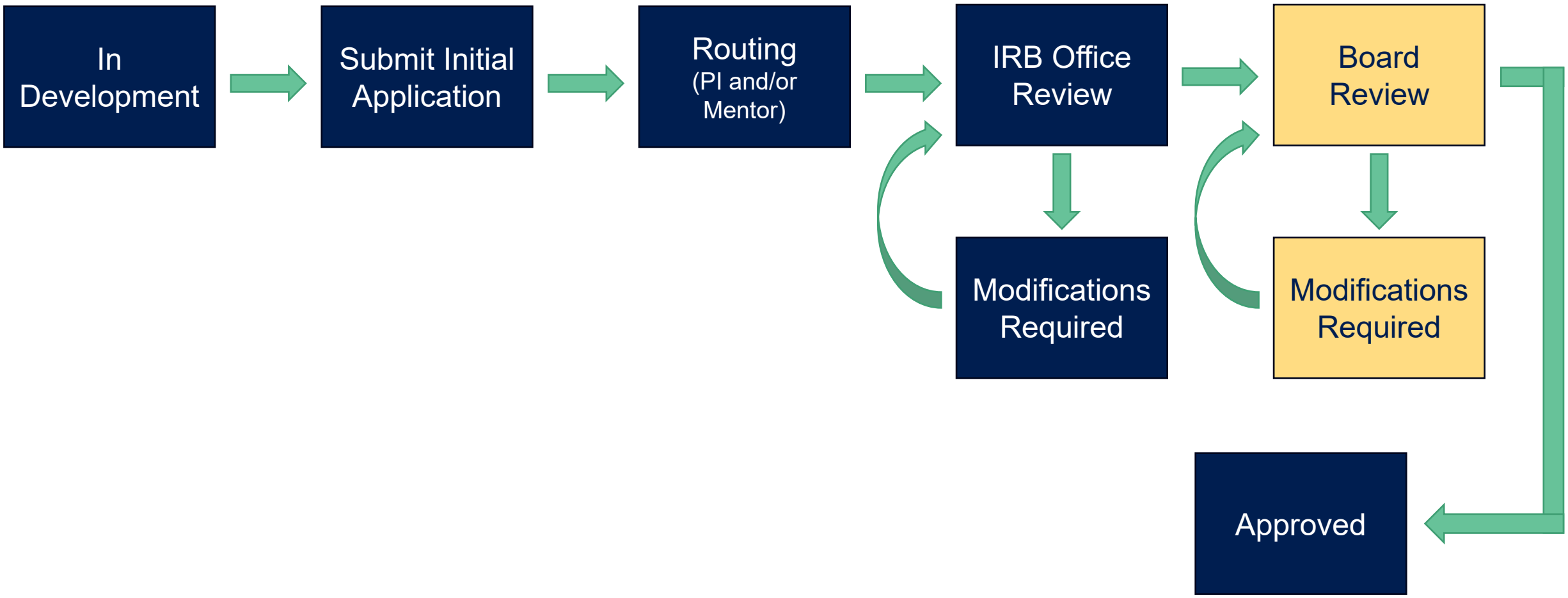
a. Where (i) the research is permanently closed to the enrollment of new participants (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; OR

b. Where no participants have been enrolled and no additional risks have been identified; OR

c. Where the remaining research activities are limited to data analysis.

(9) **Continuing review** of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Workflow for Expedited Submissions



Full Board Review

- Minimal Risk research that does not fall into either the Exempt or Expedited categories
- Greater than Minimal Risk research
- Requires annual review by the IRB

Greater than Minimal Risk

Greater than Minimal Risk is any study that does not meet the definition of Minimal Risk*. Greater than Minimal Risk studies require adequate monitoring plans be in place to help minimize the risk and deal with situations should they arise.

*Minimal risk is the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Risk Levels: Greater than Minimal Risk

Examples of Studies that Are Not Minimal Risk Studies
• Punch biopsies
• An extra biopsy when other biopsies are already being taken for standard diagnostics
• X-rays, DEXA scans
• MRIs when contrast media and/or sedation is used for research purposes
• Research on investigational drugs or devices
• Research in which the identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to their reputation or be stigmatizing to their group
• Mobile medical applications that use health information to directly inform care of the research subject (e.g., applications that provide insulin dosing recommendations)

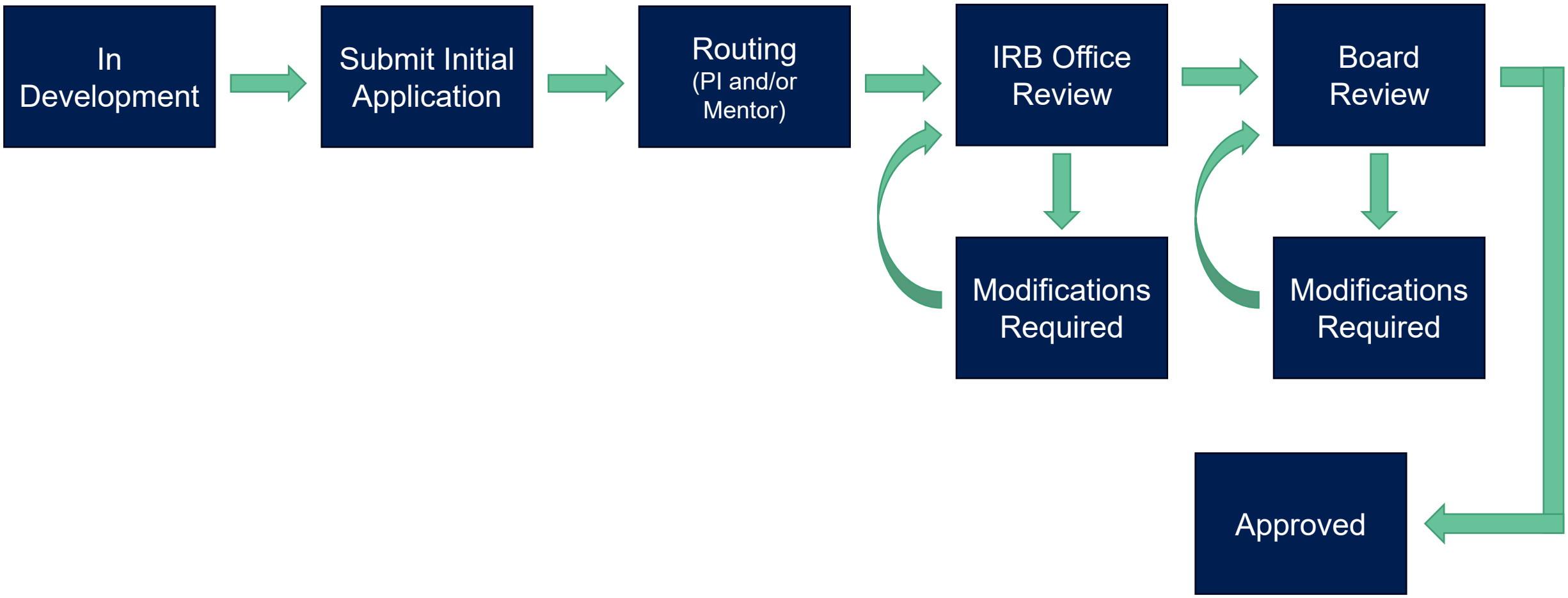
Full Board Review

- 2 Board types
  - Social/Behavioral research
  - Biomedical research
- 45 CFR 46.111 approval criteria must be met in order to approve the research
- Full Board meets monthly, contact the IRB Office (irb@creighton.edu) for confirmation of meeting dates

Possible Determinations

- Approved
- Approved with Conditions
  - Minor modifications required; to be reviewed by Chair
- Tabled
  - Significant modifications required; to be reviewed by Full Board
- Disapproved

Workflow for Full Board Submissions



Materials Required with IRB Submissions

Core Documents

- Initial Application (in InfoEd)
- Study protocol
- Consent materials
  - Information sheet
  - Informed consent form
- Recruitment materials
  - Flyers
  - Emails
  - Announcement scripts
- Data collection instruments
  - Surveys
  - Interview guides
  - Case forms

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

IRB Submissions: Common Issues and How to Avoid Delays

Common Issues	How to Avoid Delays
• Missing, incomplete, or inconsistent study materials • Protocol does not make a distinction between roles of CU investigators and external investigators • Data management plans are not clearly described • Minimum CITI training requirements not met • CV/Resume not dated and/or not uploaded to InfoEd profile	• Respond promptly to IRB requests • Use current CU IRB templates • Upload each study material as a separate file • Ensure a faculty advisor is listed as a Mentor on student-led research • Ensure research procedures are consistent across all study documents

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)
- Revised Common Rule: Revisions to Definitions (ID: 317816)
- Study Start-Up Challenges and Strategies (ID: 317756)
- The Importance of Mentorship in Biomedical and Behavioral Research (ID: 317742)

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

- Minimal Risk Compared to Greater than Minimal Risk

Informed Consent Checklist

- Optional tool for researchers

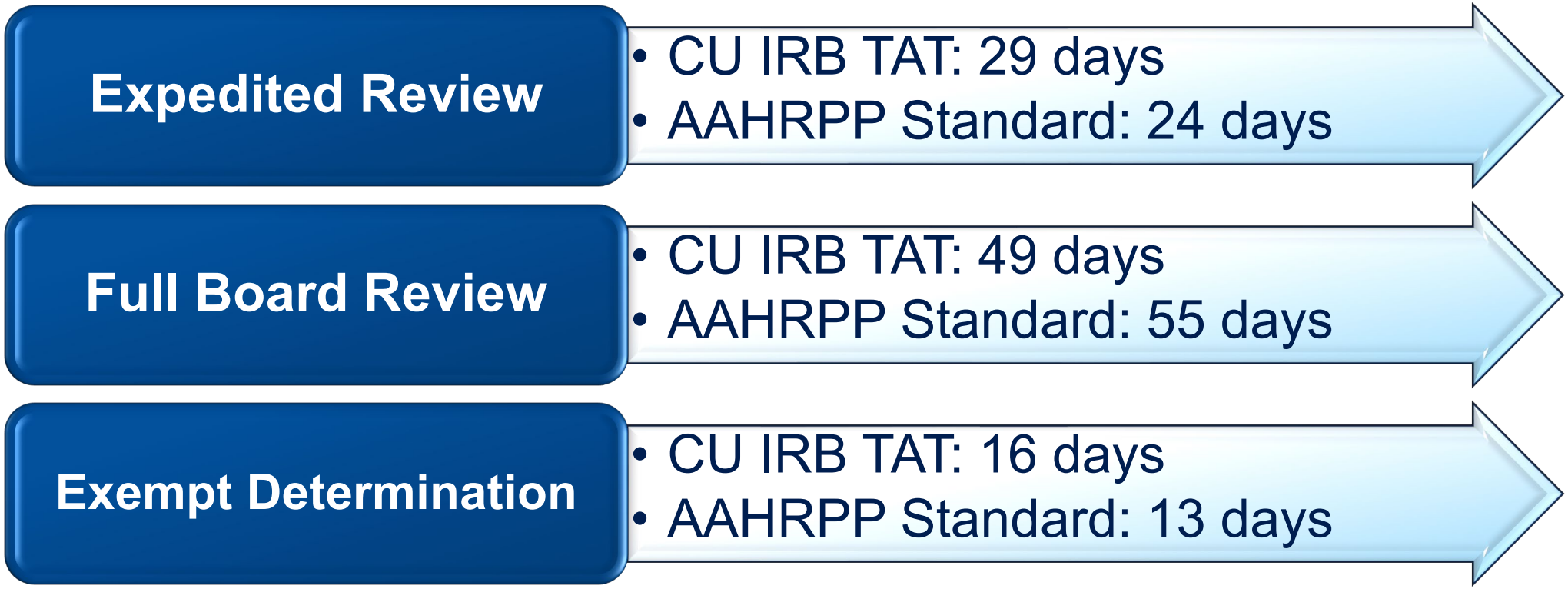
Templates

- Information Sheet
- Informed Consent Form
- Parent/Guardian Permission

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

Recent Metrics

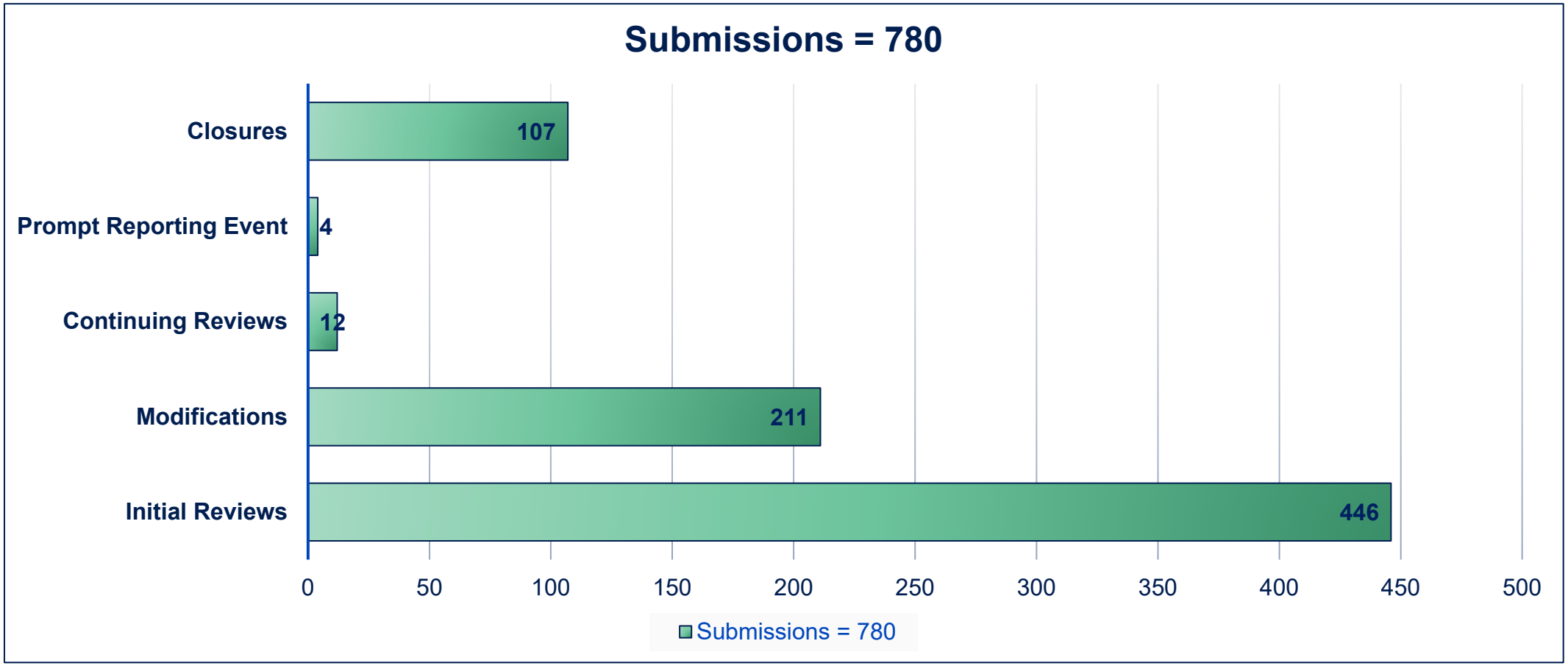
Turnaround time (TAT) data from **submission** to initial approval (January 2025 through October 2025). *Note: TAT includes days with investigators.*



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

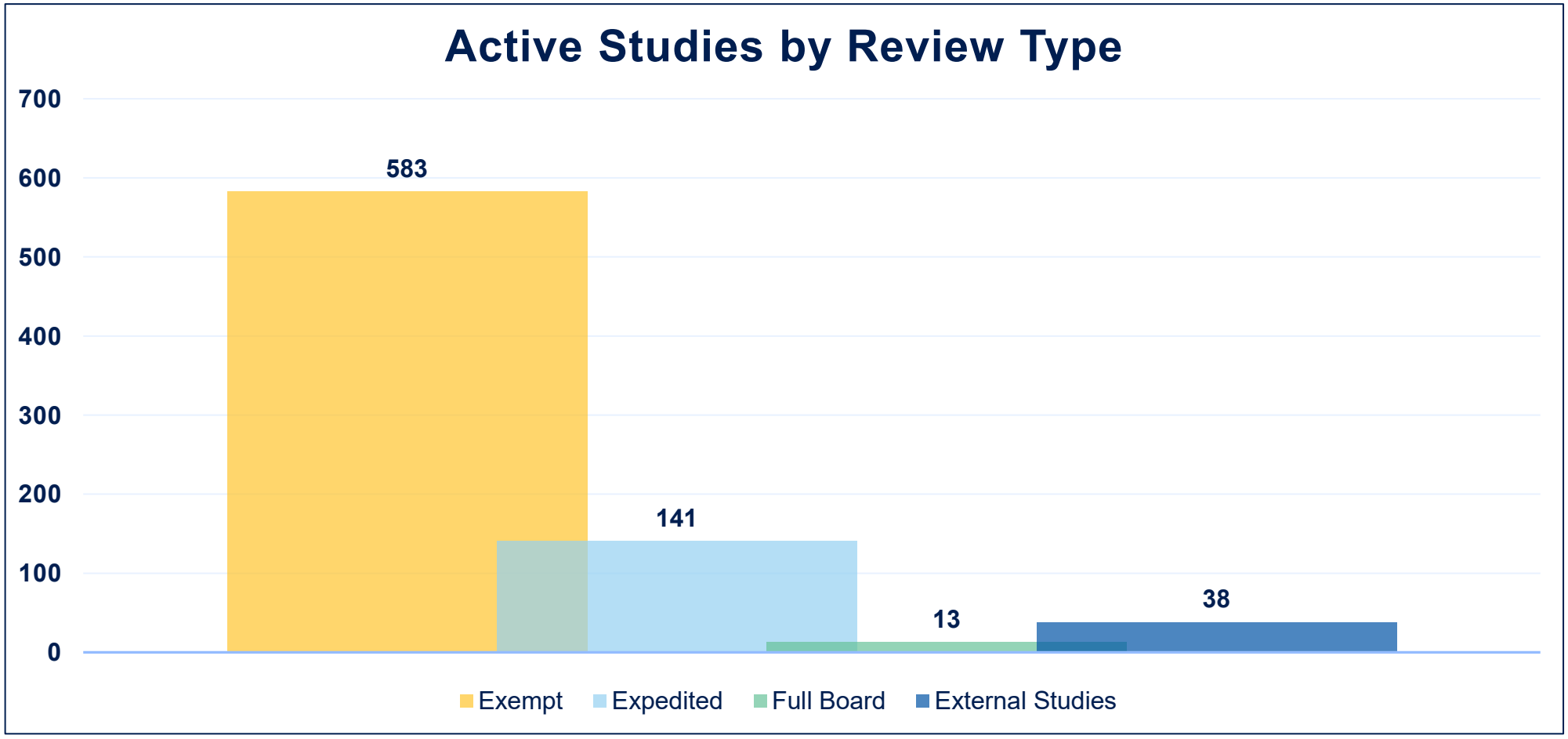
Recent Metrics

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



Recent Metrics

The CU IRB currently reviews and monitors 775+ 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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