Creighton UNIVERSITY

CU IRB and Me:

MEET THE IRB TEAM

IRB Office Staff

IRB DIRECTOR
Nancy McCormick, MS, CIP, CCRC
Vail, CO

SENIOR IRB ADMINISTRATOR
Betsy Dancisak, MPH, CIP
Omaha, NE

SENIOR IRB ADMINISTRATOR
Eddie Mendoza, BS
Chicago, IL

IRB ADMINISTRATOR
Teri Prentis, BA
Omaha, NE

Reaccredited in December 2024

Dr. C.C. and Mabel L. Criss Health Sciences Complex I, Room 111
PHONE 402.280.2126 | **EMAIL** IRB@Creighton.edu

Who and How to Contact

IRB Policy or Regulatory Questions

Nancy McCormick, *IRB Director*

NancyMcCormick@creighton.edu | 402.280.3208

General IRB Questions

Teri Prentis, *IRB Administrator*

IRB@Creighton.edu | 402.280. 2126

InfoEd Support

Rosa Seiffert, *InfoEd Administrator*

RosaSeiffert@Creighton.edu | 402.280.3074

IRB Responsibilities

Human Research Protection Program (HRPP)

- Rights, safety, and welfare of research participants are protected
- Ethical treatment during recruitment and participation

Review and oversight

- Provide guidance to investigators on ethical, regulatory, and institutional matters
- Approve, require modifications to, or disapprove research
- Verify that studies comply with federal regulations, ethical guidelines, and institutional policies
  - Monitor approved studies to ensure they meeting ethical and regulatory standards
  - Report findings to investigators, relevant federal regulatory agencies, and the institution

IRB Responsibilities

Training

- Ensure that IRB members and investigators receive appropriate training

Maintain written procedures

- Includes conducting reviews, reporting findings, and handling noncompliance, unanticipated problems, and suspension or termination of research

What Falls Under the Purview of the IRB?

- **Research** (as defined by DHHS regulation 45CFR46.102(l)) is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- **Human Subject** (as defined by DHHS regulations 45CFR46.102(e)) is a living individual about whom an investigator (whether professional or student) conducting research:
  - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimen; or
  - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimen

Types of Review

- **Exempt Review:** Review of research determined to be exempt under DHHS regulations and FDA regulations, which do not require review and approval by the convened IRB.
  - ***Example: chart review, no identifiers kept***

- **Expedited Review**: Review of human subjects research by the IRB Chairperson or designee that involves no more than minimal risk and meets one or more of the categories authorized by 45 CFR 46.110.
  - ***Example: Questionnaire study, MRI study***

- **Full Board Review:** Review of proposed human subjects research by the fully convened IRB as defined by Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations which do not meet the federal criteria for expedited or exempt review of human subjects research.
  - ***Example: Drug, Device, Surgical Intervention, Children***

New Education Series

CU IRB and Me series

- These will be held monthly
- Virtual unless otherwise specified
- Research topic along with IRB updates on InfoEd and/or policy changes
- Time for questions

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

Required CITI Trainings

Biomedical human subjects research:

- Group 1: Biomedical Research
- CITI Health Information Privacy and Security (HIPS) for Clinical Investigators
- CITI Responsible Conduct of Research (RCR)

Social/Behavioral human subjects research:

- Group 2: Social & Behavioral Research
- CITI Responsible Conduct of Research

CITI Webinars

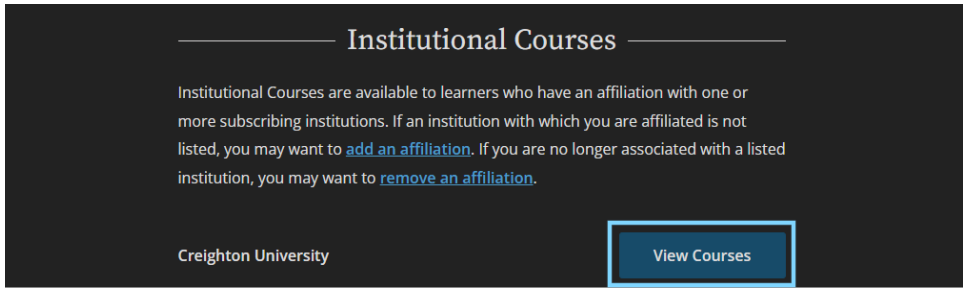
Webinar access

- The Collaborative Institutional Training Initiative (CITI) program has a catalog of webinars that all CU faculty, staff, and students can access through November 2025.

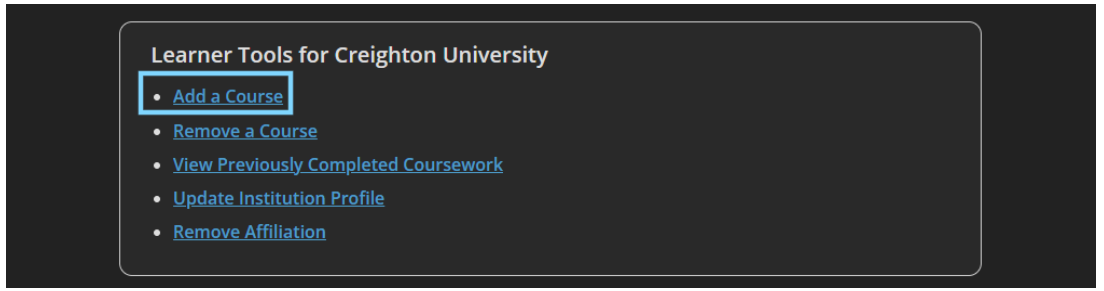
Instructions:

1. Once logged into CITI, click **View Courses** next to Creighton University under Institutional Courses.

Note: Your CITI account must be affiliated with Creighton University before you can access the webinars.

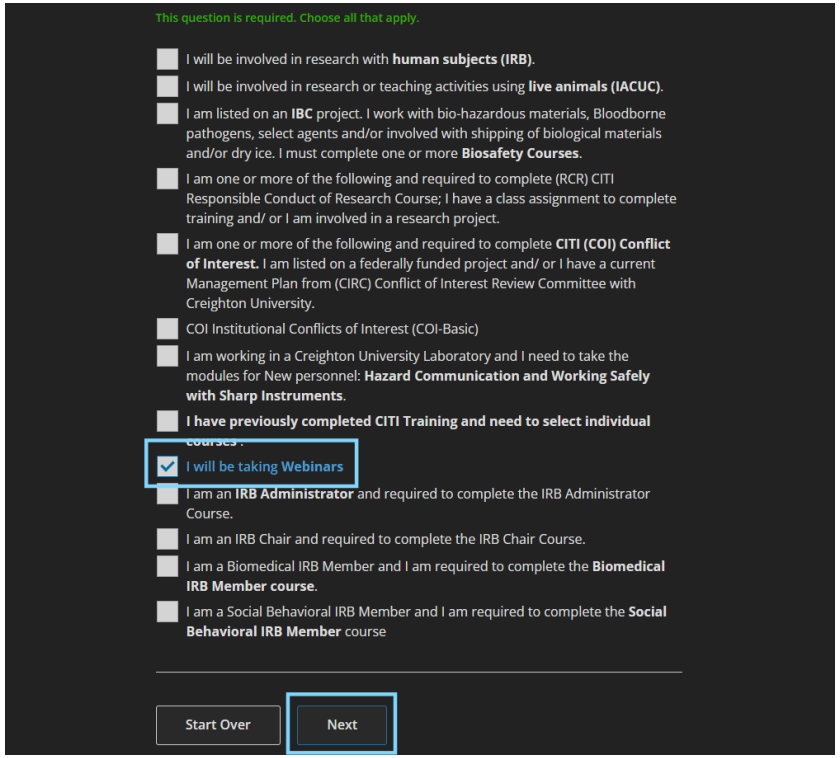


2. Scroll to the bottom of the page.
3. Click **Add Course** under Learner Tools for Creighton University.

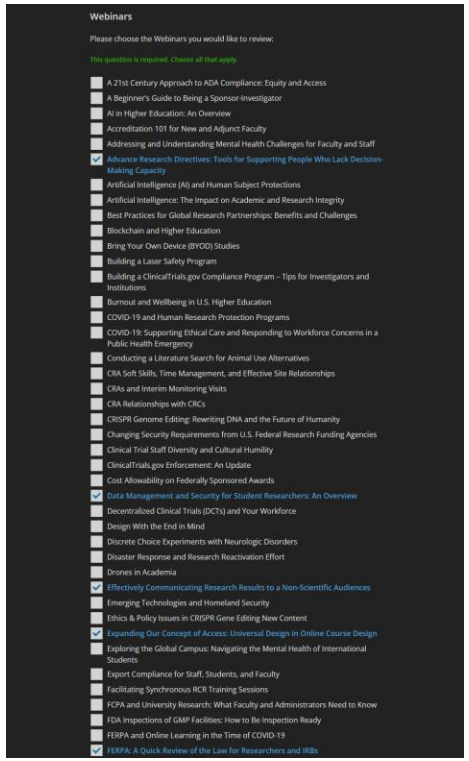


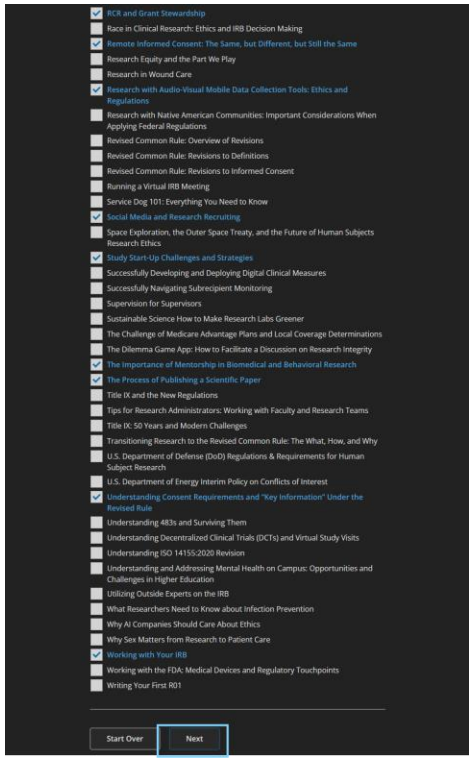
CITI Webinars

4. Select **I will be taking Webinars**.
5. Click **Next**.



6. Select the webinars you'd like to view.
7. Scroll to the bottom of the page.
8. Click **Next**.

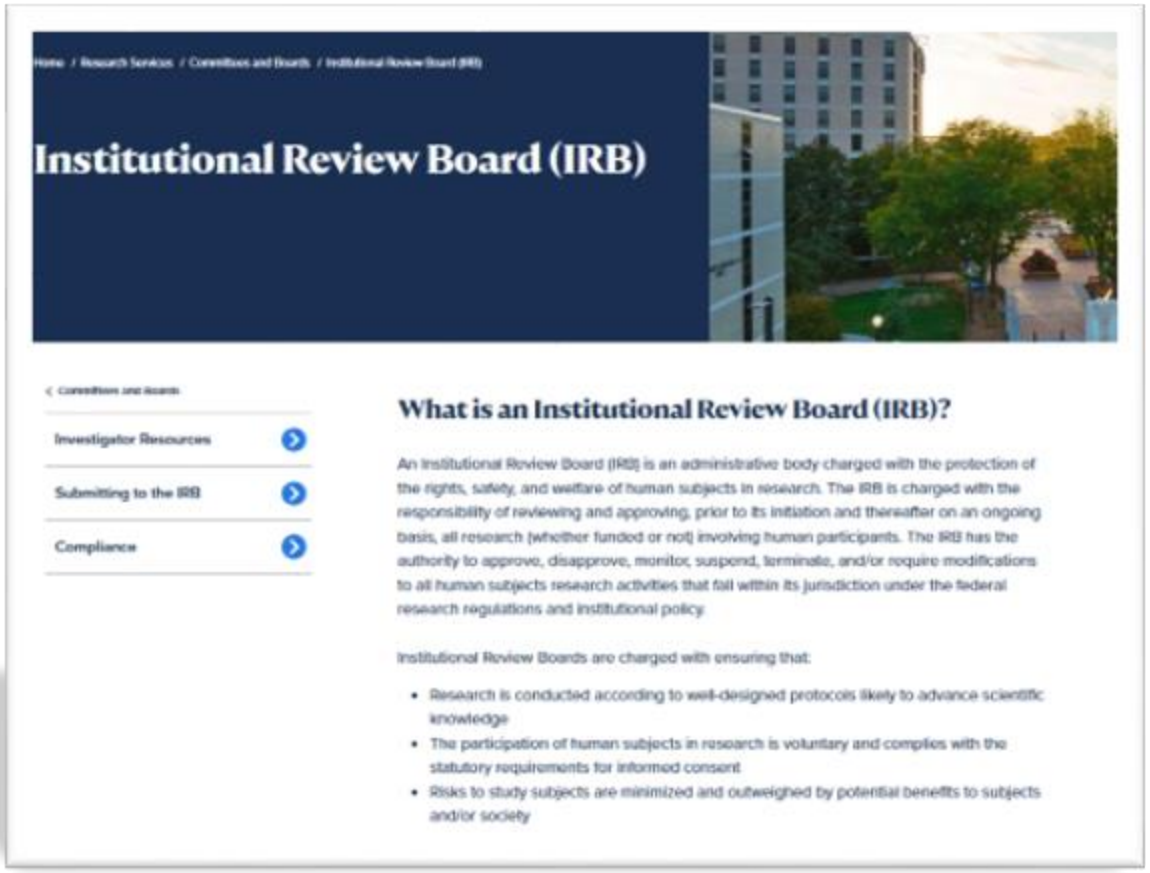




CU IRB Newsletter

- Distributed quarterly via email
  - Contact the IRB Office if you'd like to be added to this mailing list
- Include updates about InfoEd, policy changes, submission turnaround times

CU IRB Website



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

Full Board Review

BIOMEDICAL RESEARCH
(IRB-01)
3rd Tuesday each month

SOCIAL/BEHAVIORAL RESEARCH
(IRB-02)
3rd Thursday each month

Contact the IRB Office to confirm meeting dates and times

FULL BOARD REVIEW SUBMISSION DUE DATES	
Initial Applications	2 weeks prior to next convened IRB meeting
Continuing Review Applications	30 days prior to IRB protocol approval expiration

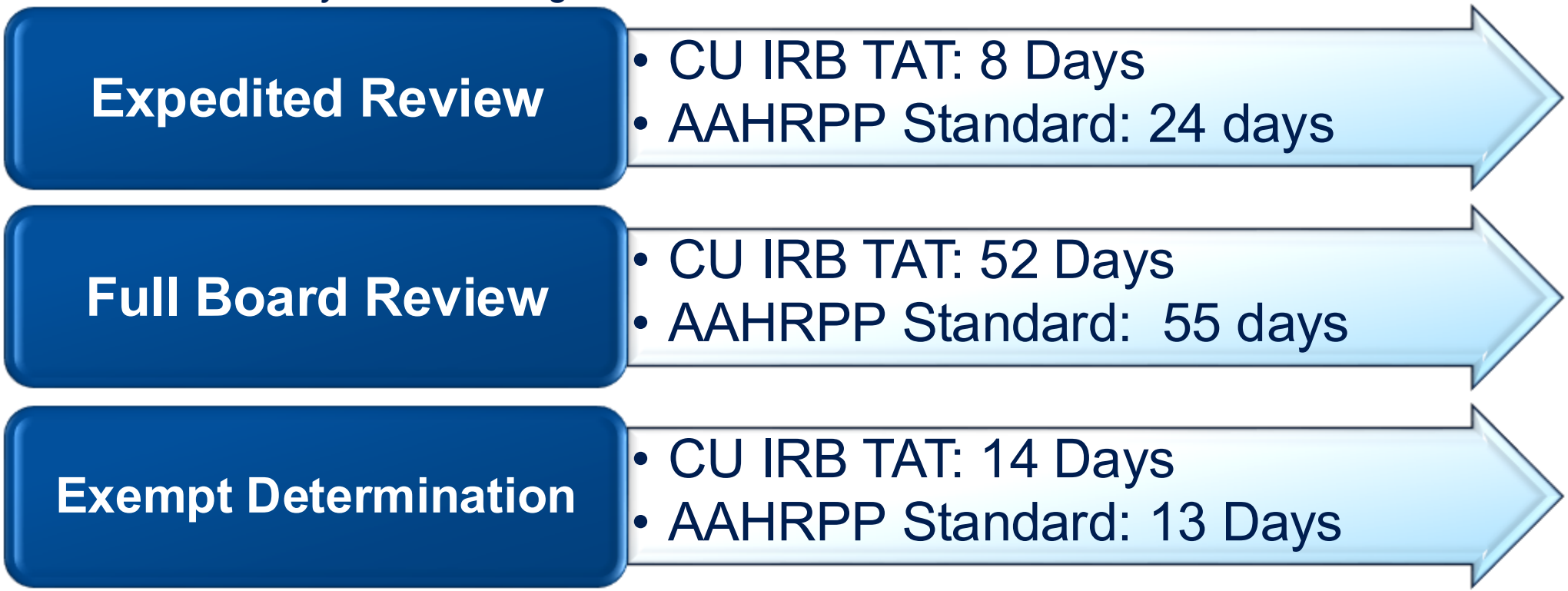
Helpful tips

- Contact the IRB Office by using central IRB email address (IRB@creighton.edu)
- Make sure all correspondence has the protocol number on it
- Utilize the provided templates
  - Templates can be found on the CU IRB website under **Investigator Resources**
  - Using the templates, *especially the protocol and consent templates*, is important for a more efficient IRB review process
- When writing the protocol, include enough detail so the reader could theoretically duplicate the study
- Make sure all study team members have their CITI training completed, signed and dated CVs uploaded, and FCOI Disclosures (if applicable) submitted
  - Required CITI courses and documentation requirements can be found on the CU IRB website under **Investigator Resources**
  - Instructions on how to upload CVs/professional licenses and how to submit an FCOI Disclosure in InfoEd can be found on the CU IRB website under **Submitting to the IRB**
- Submit early
  - The IRB review process almost always involves multiple rounds of addressing the IRB's requests for more information

Recent Metrics

Turnaround time (TAT) data from **submission** to initial approval (January through June 2025).

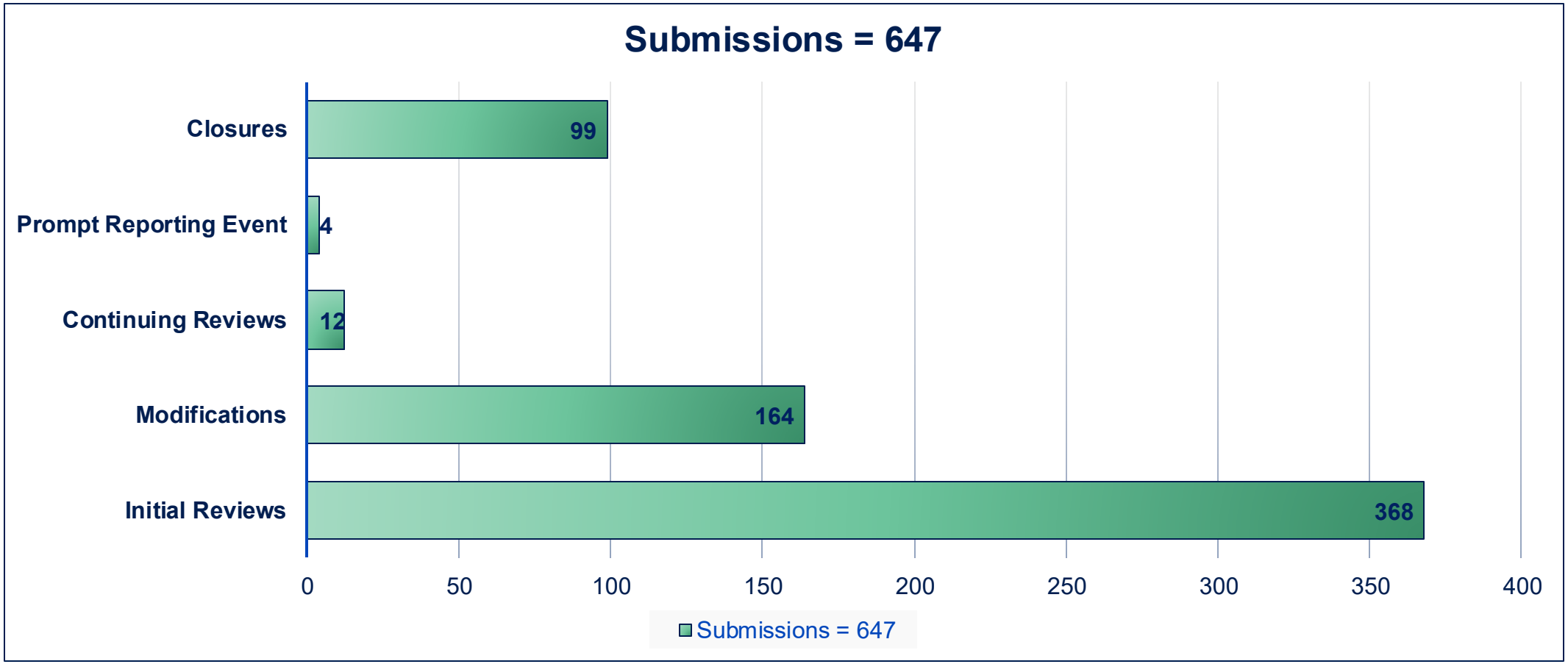
Note: TAT includes days with investigators.



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

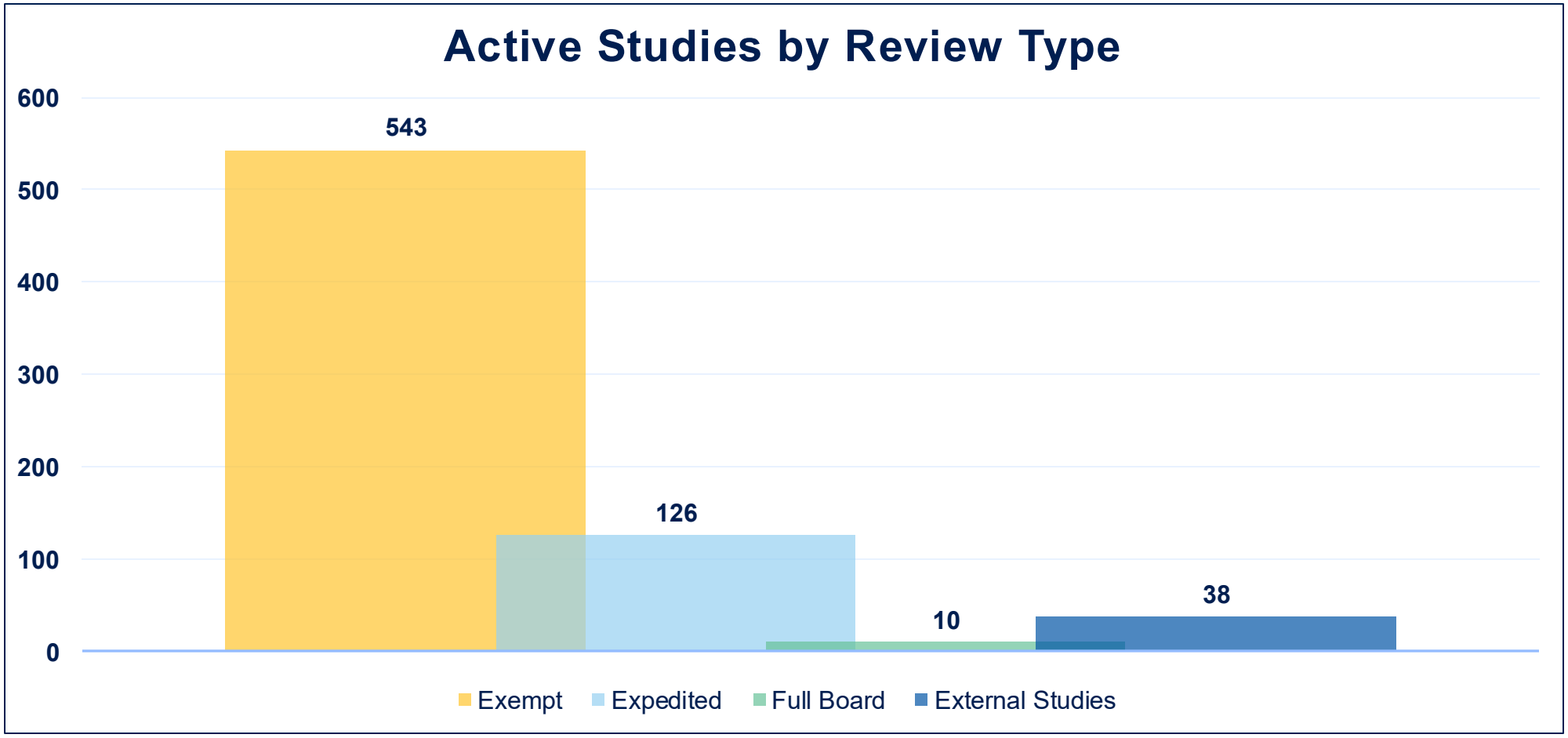
Recent Metrics

Total application submissions – to date January through today 2025:



Recent Metrics

The CU IRB currently reviews and monitors 717+ active studies.



Q & A

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Thank you.

IRB Office | 402.280.2126 | IRB@creighton.edu