



CU IRB and Me:

MEET THE IRB TEAM

IRB Office Staff



IRB DIRECTOR

Nancy McCormick, MS, CIP, CCRC
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SENIOR IRB ADMINISTRATOR

Betsy Dancisak, MPH, CIP
Omaha, NE



SENIOR IRB ADMINISTRATOR

Eddie Mendoza, BS
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IRB ADMINISTRATOR

Teri Prentis, BA
Omaha, NE



Reaccredited in December 2024



Who and How to Contact

IRB Policy or Regulatory Questions

Nancy McCormick, *IRB Director*

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General IRB Questions

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IRB@Creighton.edu | 402.280. 2126

InfoEd Support

Rosa Seiffert, *InfoEd Administrator*

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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

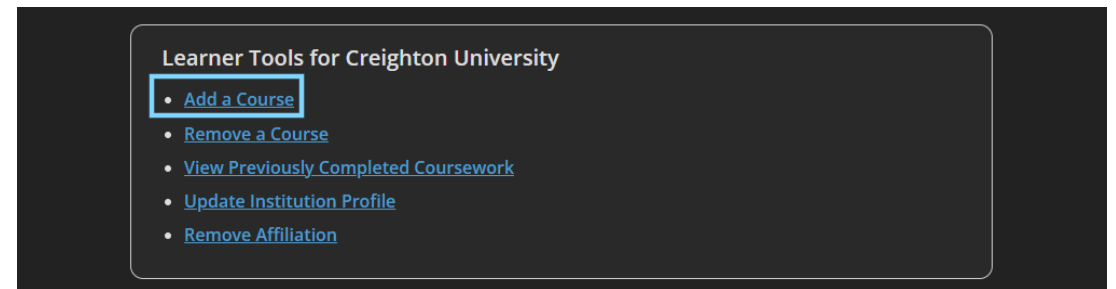
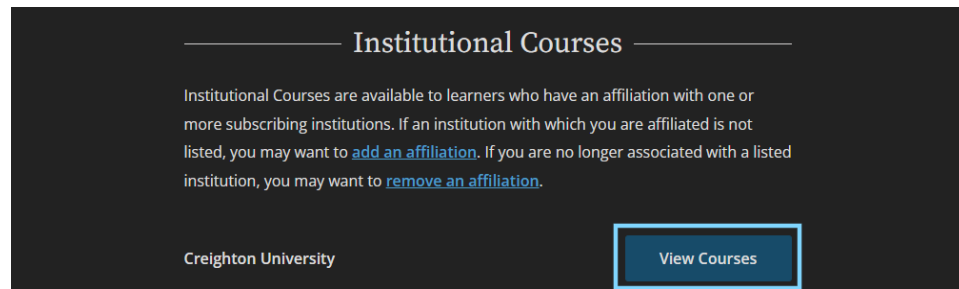
- The Collaborative Institutional Training Initiative (CITI) program has a catalog of webinars that all CU faculty, staff, and students can access through November 2025.

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**.

This question is required. Choose all that apply.

- ☐ I will be involved in research with **human subjects (IRB)**.
- ☐ I will be involved in research or teaching activities using **live animals (IACUC)**.
- ☐ I am listed on an **IBC** project. I work with bio-hazardous materials, Bloodborne pathogens, select agents and/or involved with shipping of biological materials and/or dry ice. I must complete one or more **Biosafety Courses**.
- ☐ I am one or more of the following and required to complete (RCR) CITI Responsible Conduct of Research Course; I have a class assignment to complete training and/ or I am involved in a research project.
- ☐ I am one or more of the following and required to complete **CITI (COI) Conflict of Interest**. I am listed on a federally funded project and/ or I have a current Management Plan from (CIRC) Conflict of Interest Review Committee with Creighton University.
- ☐ COI Institutional Conflicts of Interest (COI-Basic)
- ☐ I am working in a Creighton University Laboratory and I need to take the modules for New personnel: **Hazard Communication and Working Safely with Sharp Instruments**.
- ☐ I have previously completed CITI Training and need to select individual courses.
- ☒ **I will be taking Webinars**
- ☐ I am an **IRB Administrator** and required to complete the IRB Administrator Course.
- ☐ I am an IRB Chair and required to complete the IRB Chair Course.
- ☐ I am a Biomedical IRB Member and I am required to complete the **Biomedical IRB Member course**.
- ☐ I am a Social Behavioral IRB Member and I am required to complete the **Social Behavioral IRB Member course**

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6. Select the webinars you'd like to view.

7. Scroll to the bottom of the page.

8. Click **Next**.

Webinars

Please choose the Webinars you would like to review.

This question is required. Choose all that apply.

- ☐ A 21st Century Approach to ADA Compliance: Equity and Access
- ☐ A Beginner's Guide to Being a Sponsor Investigator
- ☐ AI in Higher Education: An Overview
- ☐ Accreditation 101 for New and Adjunct Faculty
- ☐ Addressing and Understanding Mental Health Challenges for Faculty and Staff
- ☒ **Advance Research Directives: Tools for Supporting People Who Lack Decision-Making Capacity**
- ☐ Artificial Intelligence (AI) and Human Subject Protections
- ☐ Artificial Intelligence: The Impact on Academic and Research Integrity
- ☐ Best Practices for Global Research Partnerships: Benefits and Challenges
- ☐ Blockchain and Higher Education
- ☐ Bring Your Own Device (BYOD) Studies
- ☐ Building a Laser Safety Program
- ☐ Building a ClinicalTrials.gov Compliance Program – Tips for Investigators and Institutions
- ☐ Burnout and Wellbeing in U.S. Higher Education
- ☐ COVID-19 and Human Research Protection Programs
- ☐ COVID-19: Supporting Ethical Care and Responding to Workforce Concerns in a Public Health Emergency
- ☐ Conducting a Literature Search for Animal Use Alternatives
- ☐ CRA Soft Skills, Time Management, and Effective Site Relationships
- ☐ CRAs and Interim Monitoring Visits
- ☐ CRA Relationships with CROs
- ☐ CRISPR Genome Editing: Rewriting DNA and the Future of Humanity
- ☐ Changing Security Requirements from U.S. Federal Research Funding Agencies
- ☐ Clinical Trial Staff Diversity and Cultural Humility
- ☐ ClinicalTrials.gov Enforcement: An Update
- ☐ Cost Allowability on Federally Sponsored Awards
- ☒ **Data Management and Security for Student Researchers: An Overview**
- ☐ Decentralized Clinical Trials (DCTs) and Your Workflow
- ☐ Design With the End in Mind
- ☐ Discrete Choice Experiments with Neurologic Disorders
- ☐ Disaster Response and Research Reactivation Effort
- ☐ Drives in Academia
- ☒ **Effectively Communicating Research Results to a Non-Scientific Audiences**
- ☐ Emerging Technologies and Homeland Security
- ☐ Ethics & Policy Issues in CRISPR Gene Editing New Content
- ☒ **Expanding Our Concept of Access: Universal Design in Online Course Design**
- ☐ Exploring the Global Campus: Navigating the Mental Health of International Students
- ☐ Expert Compliance for Staff, Students, and Faculty
- ☐ Facilitating Synchronous RCR Training Sessions
- ☐ FOIA and University Research: What Faculty and Administrators Need to Know
- ☐ FDA Inspections of GMP Facilities: How to Be Inspection Ready
- ☐ FERPA and Online Learning in the Time of COVID-19
- ☒ **FERPA: A Quick Review of the Law for Researchers and IRBs**

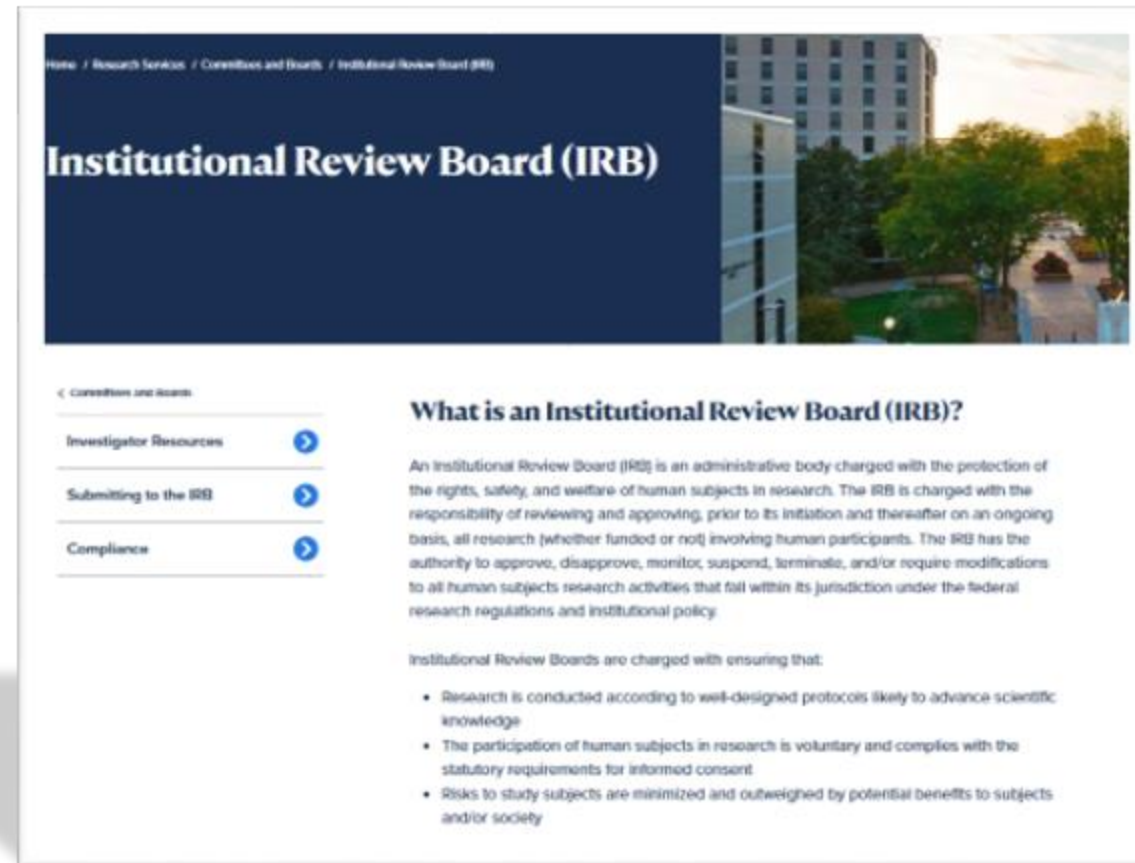
- ☒ **FCR and Grant Researchship**
- ☐ Race in Clinical Research: Ethics and IRB Decision Making
- ☒ **Remote Informed Consent: The Same, but Different, but Still the Same**
- ☐ Research Equity and the Part We Play
- ☐ Research in Wound Care
- ☒ **Research with Audio-Visual Mobile Data Collection Tools: Ethics and Regulations**
- ☐ Research with Native American Communities: Important Considerations When Applying Federal Regulations
- ☐ Revised Common Rule: Overview of Revisions
- ☐ Revised Common Rule: Revisions to Definitions
- ☐ Revised Common Rule: Revisions to Informed Consent
- ☐ Running a Virtual IRB Meeting
- ☐ Service Dog 101: Everything You Need to Know
- ☒ **Social Media and Research Recruiting**
- ☐ Space Exploration, the Outer Space Treaty, and the Future of Human Subjects Research Ethics
- ☒ **Successfully Developing and Deploying Digital Clinical Measures**
- ☐ Successfully Navigating Subrecipient Monitoring
- ☐ Supervision for Supervisors
- ☐ Sustainable Science How to Make Research Labs Greener
- ☐ The Challenge of Medicare Advantage Plans and Local Coverage Determinations
- ☐ The Dilemma Game App: How to Facilitate a Discussion on Research Integrity
- ☒ **The Importance of Mentorship in Biomedical and Behavioral Research**
- ☒ **The Process of Publishing a Scientific Paper**
- ☐ Title IX and the New Regulations
- ☐ Tips for Research Administrators: Working with Faculty and Research Teams
- ☐ Title IX: 50 Years and Modern Challenges
- ☐ Transitioning Research to the Revised Common Rule: The What, How, and Why
- ☐ U.S. Department of Defense (DoD) Regulations & Requirements for Human Subject Research
- ☐ U.S. Department of Energy Interim Policy on Conflicts of Interest
- ☒ **Understanding Consent Requirements and "Key Information" Under the Revised Rule**
- ☐ Understanding 483s and Surviving Them
- ☐ Understanding Decentralized Clinical Trials (DCTs) and Virtual Study Visits
- ☐ Understanding ISO 14155:2020 Revision
- ☐ Understanding and Addressing Mental Health on Campus: Opportunities and Challenges in Higher Education
- ☐ Utilizing Outside Experts on the IRB
- ☐ What Researchers Need to Know about Infection Prevention
- ☐ Why AI Companies Should Care About Ethics
- ☐ Why Sex Matters from Research to Patient Care
- ☒ **Working with Your IRB**
- ☐ Working with the FDA: Medical Devices and Regulatory Touchpoints
- ☐ Writing Your First R01

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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.

Expedited Review

- CU IRB TAT: 8 Days
- AAHRPP Standard: 24 days

Full Board Review

- CU IRB TAT: 52 Days
- AAHRPP Standard: 55 days

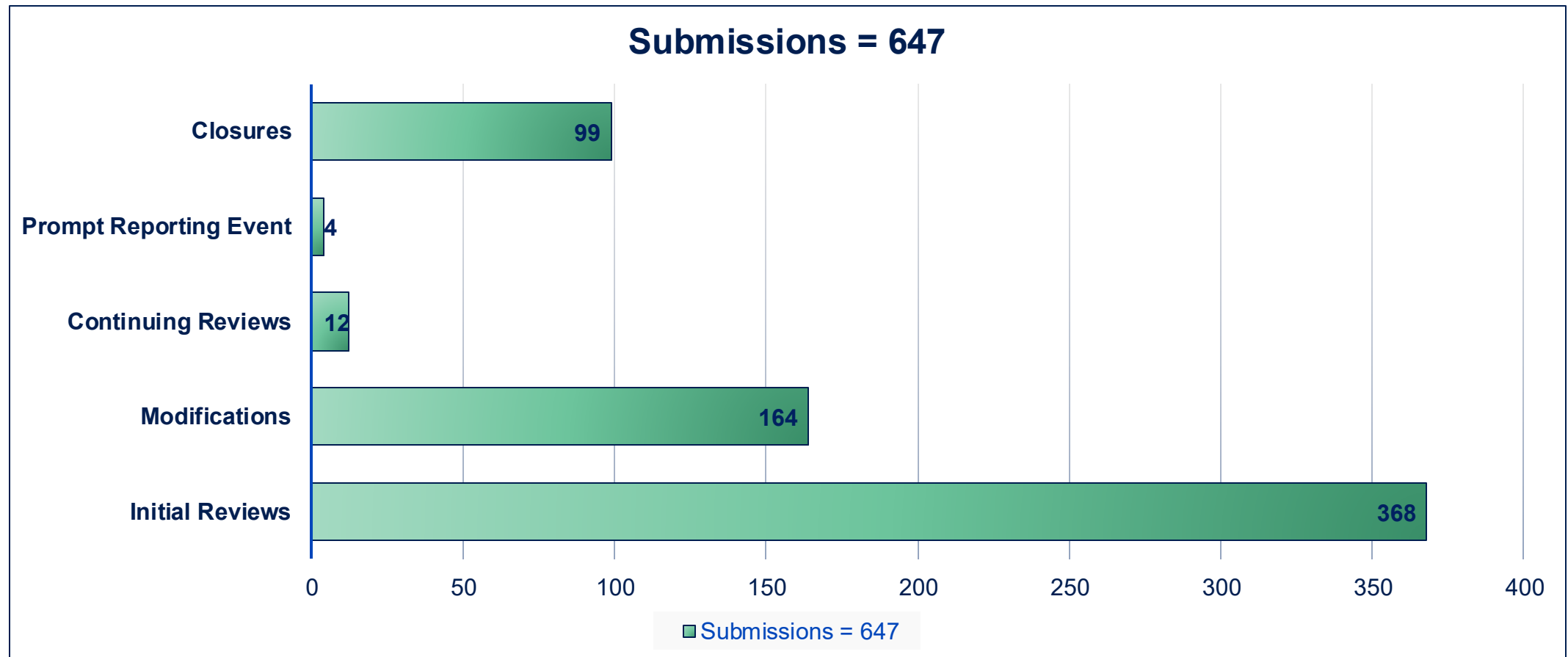
Exempt Determination

- CU IRB TAT: 14 Days
- AAHRPP Standard: 13 Days

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

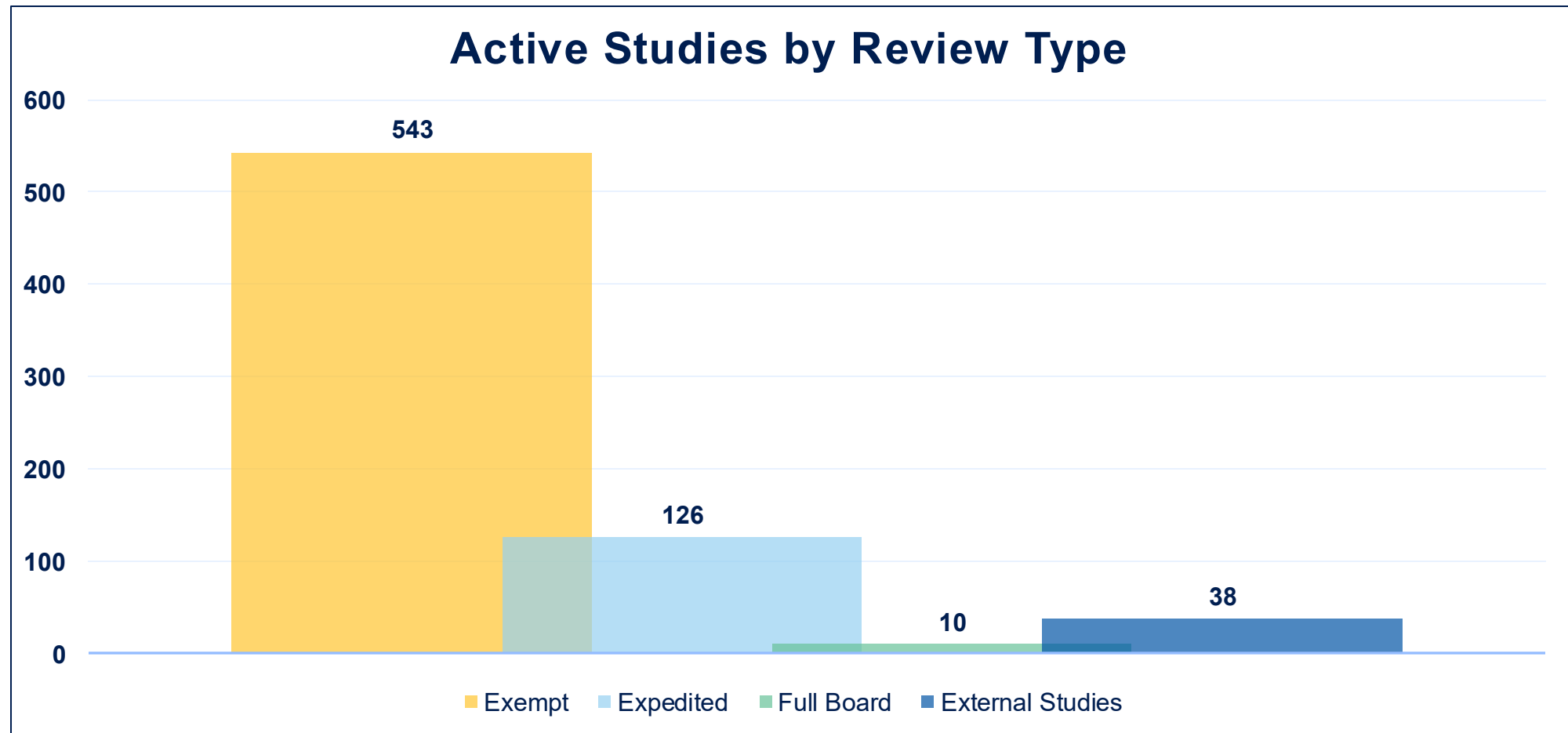
Recent Metrics

Total application submissions – to date January through today 2025:



Recent Metrics

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





Q & A



Thank you.

IRB Office | 402.280.2126 | IRB@creighton.edu