Creighton UNIVERSITY

CU IRB and Me:

INVESTIGATOR REPORTING REQUIREMENTS

Agenda

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Investigator Reporting Requirements

Adverse Events (AEs)

What is an AE?

- Any unexpected or unfavorable occurrence in a human subject associated with the subject's participation in the research. AEs may be physical, psychological, social, legal, or economic.

Types of AEs

- Serious AE
- Internal AE: An AE experienced by a subject in a study conducted at Creighton or at an external site under the jurisdiction of the CU IRB.
- External AE: An AE experienced by a subject in a study conducted at an external site (not under the jurisdiction of the CU IRB).

Examples of AEs

- AEs: Rash, arrythmia, nausea or vomiting, abnormal labs, altered cognitive state, dizziness, breach of confidentiality or privacy.
- Serious AEs: Death, a life-threatening event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Events may also be considered serious when they require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Unanticipated Problems (UAPs)

What is a UAP?

- An event that meet the following three criteria:
  - Event is unexpected in terms of specificity, severity, or frequency, considering the nature of the research, the characteristics of the subject population, and the information contained in the protocol, protocol-related documents, and the ICF. Events consistent with the expected natural progression of any underlying disease, disorder, or condition of the subject are not unexpected.
  - Event is related, or possibly related, to subjects' participation in the research or procedures involved in the research.
  - A subject or others suffered harm or were placed at greater risk of harm (including physical, psychological, economic, social, or legal) than was previously anticipated under the IRB approved protocol and other study documents.

* Though not a required criterion for definition of an event as a UAP, an event that is a UAP generally warrants substantive changes in the research protocol or informed consent process/document or other corrective actions to protect the safety, welfare, or rights of subjects or others

Examples of UAPs

- Identification of a new or increased risk related to the use of an investigational product or technique; malfunction of a research device; breach of confidentiality or privacy; lost or stolen laptop or USB drive containing subjects' PHI; any event, discovery, or condition which results in a change to the study protocol or consent in order to protect the rights, safety, or welfare of subjects.

Noncompliance

What is noncompliance?

- Any failure to follow federal regulations (including but not limited to 45 CFR 46, including any applicable subparts), HRPP policies, the requirements or determinations of the IRB or the provisions of the IRB approved research study.

Types of noncompliance

- Serious Noncompliance: A violation of applicable federal regulations, HRPP policies, or the determinations of the IRB which (a) significantly increases the risk to subjects or otherwise compromises the rights and welfare of research subjects; or (b) appreciably decreases the potential direct benefit to subjects; or (c) compromises the scientific integrity of the research.
- Continuing Noncompliance: Repeated incidents of the same or substantially similar noncompliance after the investigator or staff has been notified that the action represents non-compliance or despite appropriate retraining and/or a specific corrective action plan; or repeated incidents of the same or substantially similar noncompliance of such a nature that the investigator should have reasonably known that such an action was noncompliance.

Noncompliance *(continued)*

Examples of noncompliance

- Serious noncompliance: Conducting non-exempt human subjects research without IRB approval; failure to obtain informed consent; implementing changes to the study protocol without IRB approval when the change is not required to address an emergency; failing to adhere to eligibility criteria, timely perform safety assessments, communicate new information to subjects, or adhere to conditions of IRB approval resulting in an increase in risks to subjects' rights, safety, or welfare; a finding from an auditor or inspector that an event or condition resulted in increased risks to subjects' rights, safety, or welfare; arrest or other criminal action against an investigator and/or a suspension of the investigator's medical license or privileges; failure to timely submit Reportable New Information to the IRB; giving an investigational product to the wrong study subject.
- Continuing noncompliance: Repeated violations of the study protocol or institutional policies; ongoing failure to renew an active study prior to expiration; ongoing failure to respond to IRB inquiries, contingencies, or requests for information; failure to implement or adhere to corrective action plans; ongoing inadequate oversight of research; multiple instances of serious or minor noncompliance; a pattern of repeated protocol deviations over a period of months or across study protocols; repeated protocol deviations after retraining.

Other Reportable Events

Types of Events

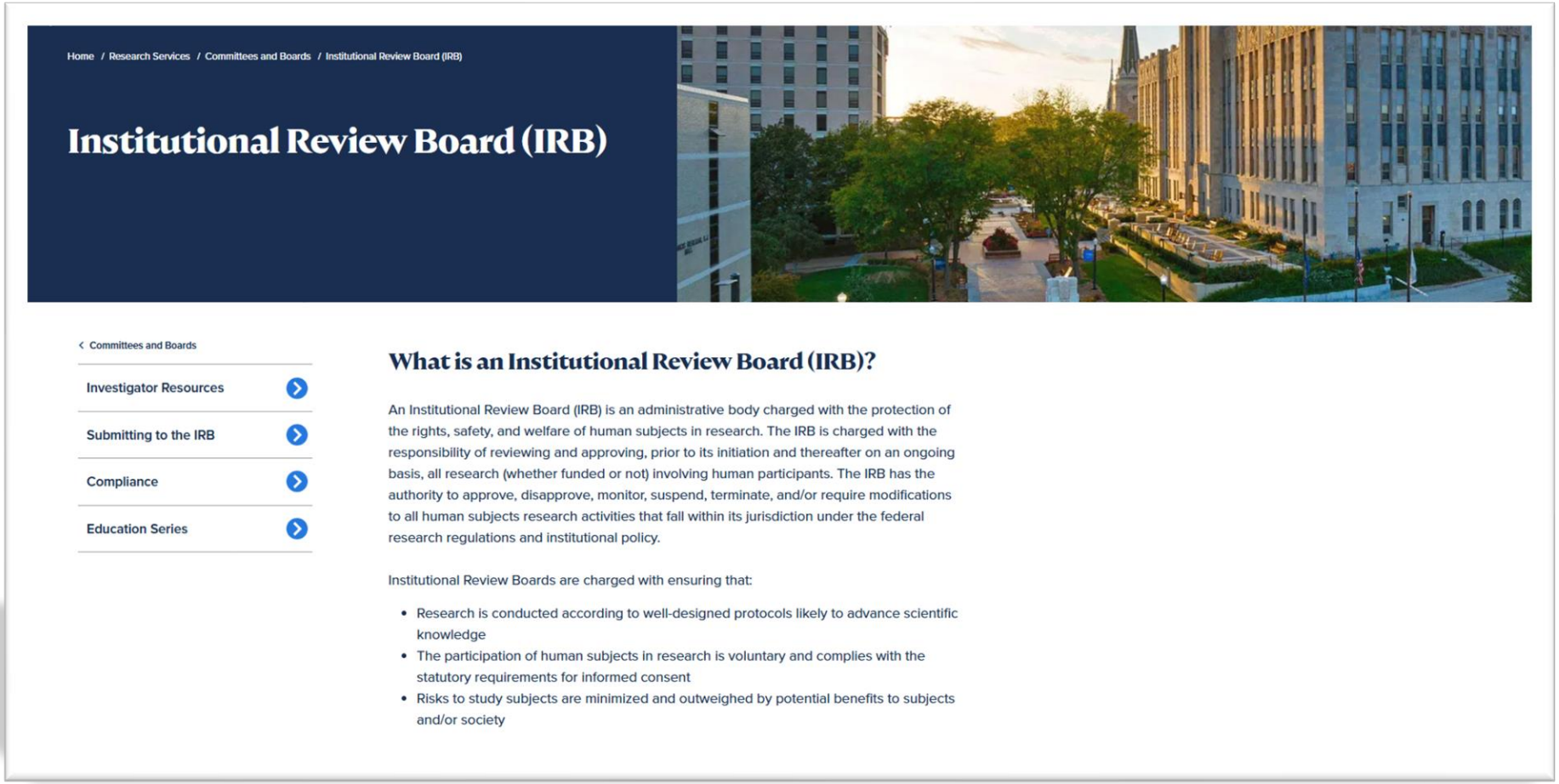
- Data Safety Monitoring Board (DSMB) Reports
- Investigational New Drug (IND) Safety Reports
- Participant Complaints: Problems, concerns, or questions raised by current, prospective, or past research participants or their representatives regarding their participation in human subjects research.

Reporting Deadlines

Investigator Reporting Deadlines	
Event	**Report due within**
Fatal internal adverse events (AEs) including fatal unanticipated adverse device effects (UADEs)	24 hours of PI awareness
All other internal AEs including UADEs that are unexpected and related or possibly related to participation in the study	2 business days of PI awareness
Unanticipated problems to subjects or others (UAPs)	2 business days of PI awareness
Serious external adverse events	5 business days of PI awareness
Research study complaints	5 business days of PI awareness
Possible PI/study team noncompliance resulting in harm to a subject or subjects	5 business days of PI awareness
DSMB or IND safety reports including information on serious risks to the welfare of subjects or recommending substantive changes to study documents	5 business days of PI awareness
Possible PI/study team noncompliance not resulting in harm to subjects	10 business days of PI awareness
All other DSMB and IND safety reports	At continuing review
All other AEs and protocol deviations	At continuing review

Resources

CU IRB Website



Creighton University Institutional Review Board website

Revised Guidance Documents

Templates

- Revised Informed Consent Template
- Revised Parent/Guardian Permission Template
- Revised Assent for Ages 7-12 Template
- Revised Assent for Ages 13-18 Template
- Revised HIPAA authorization
- Protocol Template
- NHSR/QI Proposal Template **NEW**
- Checklist: Does my Project Require IRB Review?

Forms

- Post-Approval Monitoring (PAM) Forms section **NEW**
  - Delegation Log **NEW**
  - Protocol Deviation Log **NEW**
  - Adverse Event Log **NEW**

Investigator Resources page

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

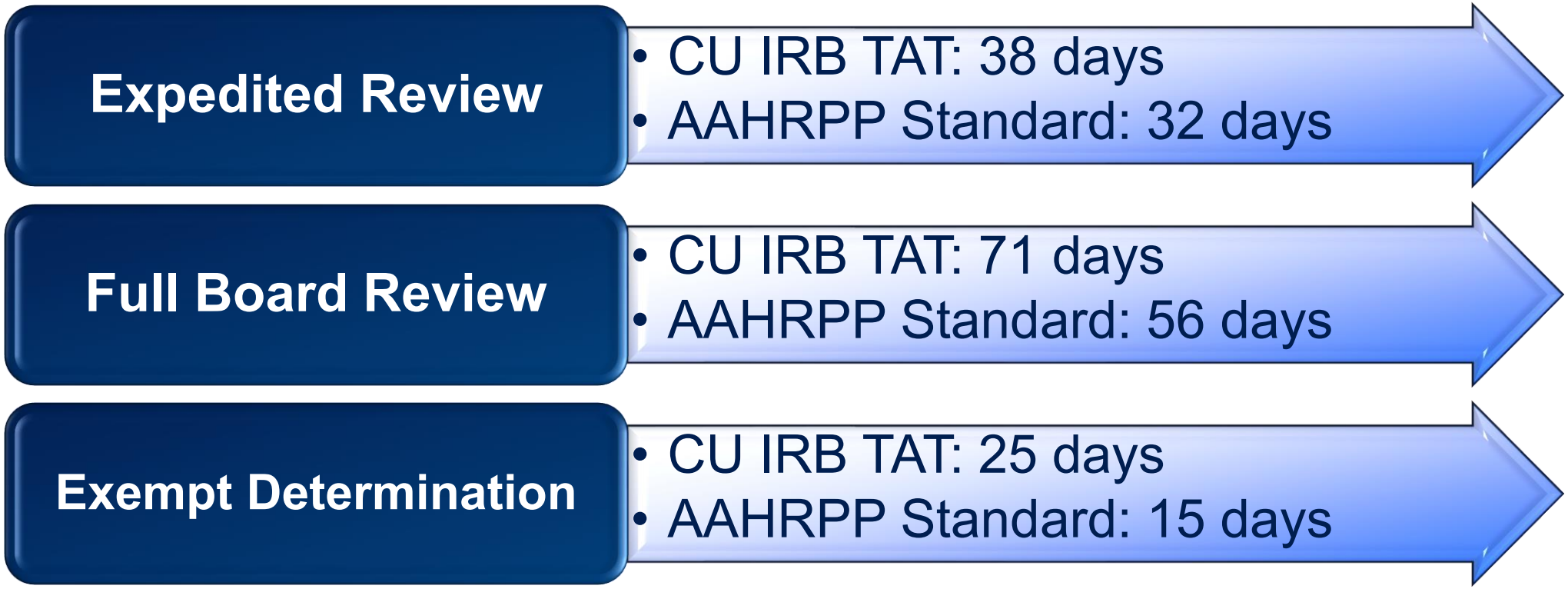


Next CU IRB and Me Session: 23-Dec-26 at 12 PM (Central)

Metrics

Turnaround Times

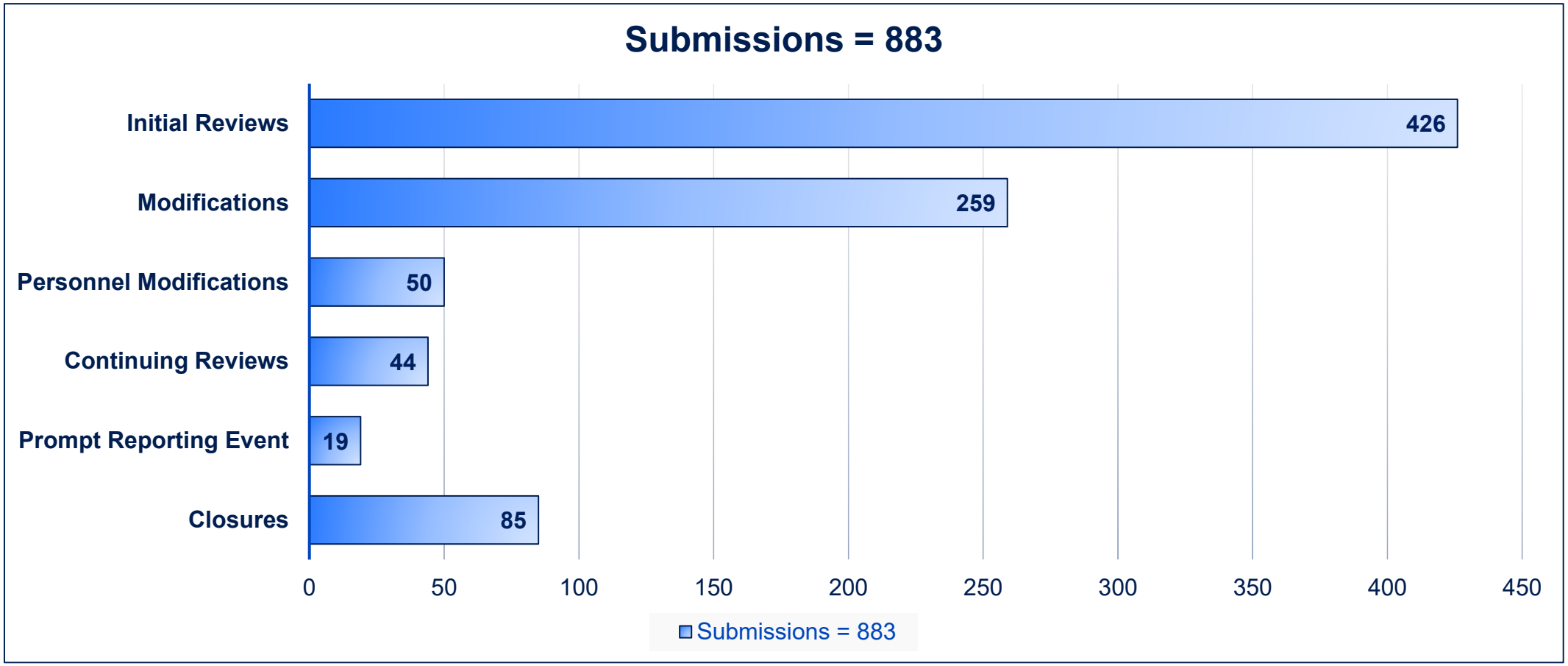
Turnaround time (TAT) data from **submission** to initial approval (January 2026 through September 2026). *Note: TAT includes days with investigators; TAT is calculated in median days.*



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

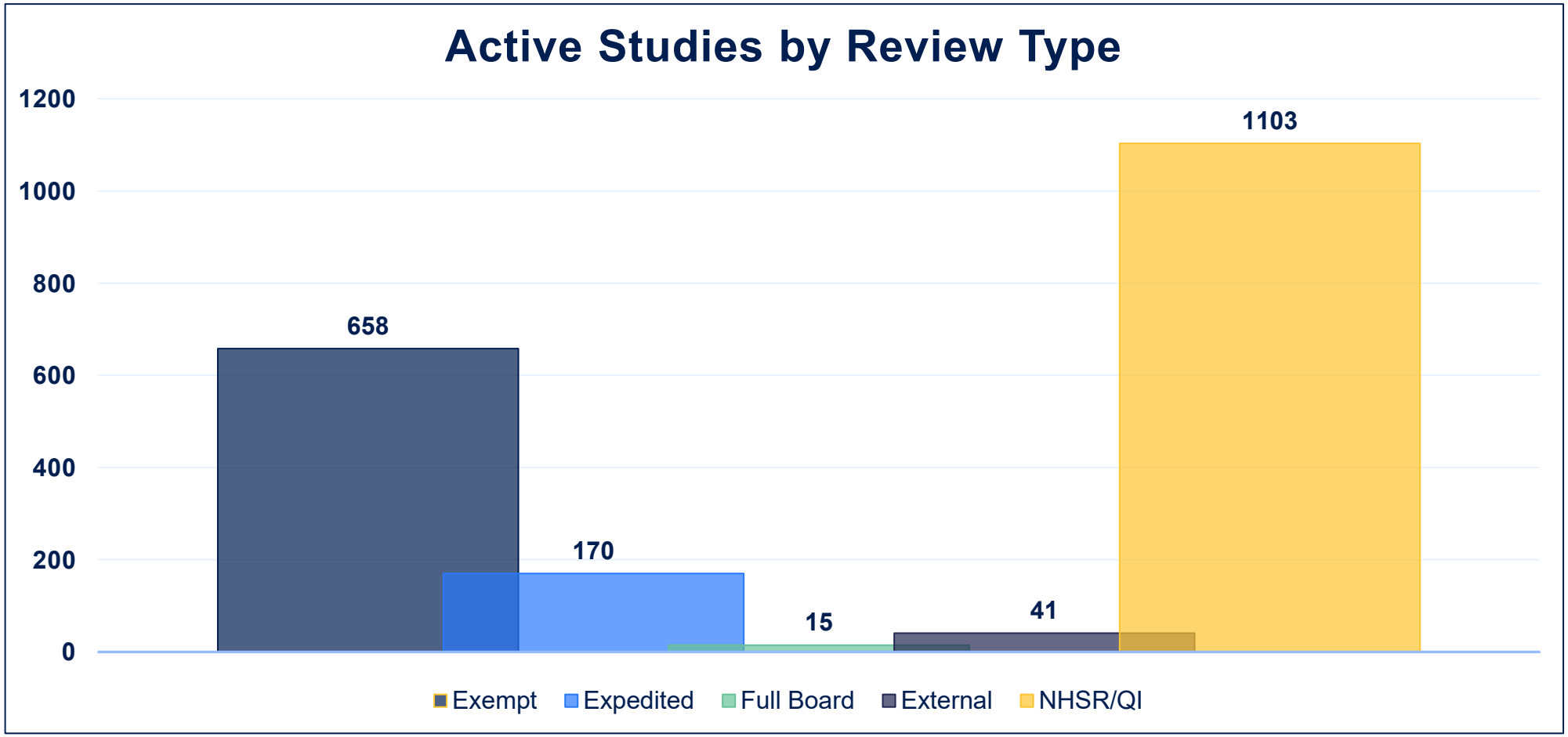
Application Submissions

Total application submissions to date January 2026 through September 2026:



Active Studies

The CU IRB currently reviews and monitors 1987+ active studies.



Q & A

Creighton
UNIVERSITY

Thank you.

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