Creighton UNIVERSITY

CU IRB and Me:

INFORMED CONSENT

Agenda

- Informed consent
  - Requirements
  - Elements
  - Tips
  - Research information sheet
- Revised guidance documents
- CITI webinars
- Website changes
- Metrics
- Q & A

Informed Consent

§ 46.116 General requirements for informed consent

There are specific general requirements for Informed Consent that are outlined in the HHS regulation.

(1) Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR).

(2) An investigator shall seek informed consent only under circumstances that

(1) provide the prospective subject or LAR sufficient opportunity to discuss and consider whether or not to participate and

(2) that minimize the possibility of coercion or undue influence.

(3) The information that is given to the subject or LAR shall be in language understandable to the subject or the legally authorized representative.

Informed Consent

§ 46.116 General requirements for informed consent (continued)

- Provide the information needed to make an informed decision
- Facilitate the understanding of the information provided
- Promote the voluntariness of the decision about whether or not to participate in the research.
- No informed consent may include any exculpatory language

Informed Consent

(b) Basic elements of informed consent

The following information shall be provided to each subject or LAR:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(2) Any reasonably foreseeable risks or discomforts to the subject;

(3) Any benefits to the subject or to others;

(4) A disclosure of appropriate alternative procedures or courses of treatment;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For more than minimal risk studies, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs;

Informed Consent

(b) Basic elements of informed consent (continued)

(7) Who to contact if the subject has questions about the research and research subjects' rights, and who to contact in the event of a research-related injury to the subject;

(8) A statement that participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, ***after such removal***, the information or biospecimens ***could be used for future*** research studies or ***distributed to another investigator*** for future research studies ***without additional informed consent f***rom the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, ***even if identifiers*** are removed, ***will not be used or distributed*** for future research studies.

Informed Consent

(c) Additional elements of informed consent

One or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

(6) The approximate number of subjects involved in the study;

Informed Consent

(c) Additional elements of informed consent (continued)

(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.116

Informed Consent Process: It's more than just a signature!

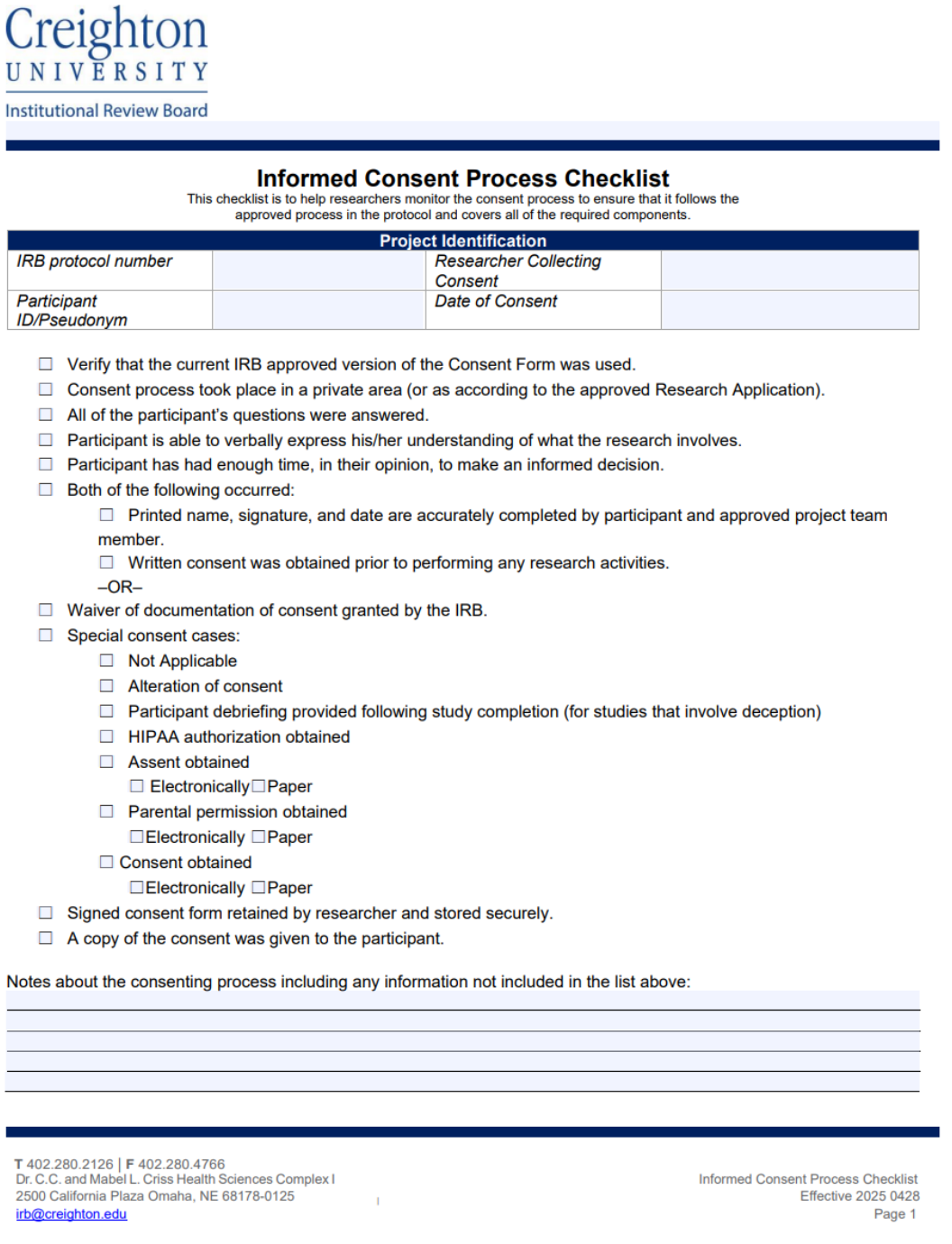
- When informed consent is required, it must be sought prospectively and documented as required by the HHS regulations.
- Informed consent is an ongoing process.
- Begins with the initial approach (recruitment) and continues until the completion of the research study.
- Should be conducted in a manner and location that ensures participant privacy.
- Provide the opportunity for potential participants to ask questions.
- Confirm an adequate understanding of the research study for making an informed decision.
- Ensure the potential participant can freely decide whether or not to participate.

Tips for Informed Consent

- Use formatting to break up dense information or to highlight important information.
- If you have multiple visits, use a table to convey what will happen at each visit.
- Define/Describe medical terms and acronyms.
- Identify who will obtain consent and add this to your study delegation log.
  - If the PI is not consenting, they must delegate who will consent.
- Always use the CU IRB consent templates located on our website.
- Store consents in a confidential manner.
- Utilize the Informed Consent Process Checklist to document your consent process with each participant
  - This tool is **optional**.

Informed Consent Process

The fillable PDF version of the checklist can be found on our website under ***Investigator Resources*** > ***IRB Templates and Forms*** > ***Consent***



Creighton UNIVERSITY
Institutional Review Board

Informed Consent Process Checklist

This checklist is to help researchers monitor the consent process to ensure that it follows the approved process in the protocol and covers all of the required components.

Project Identification			
IRB protocol number		*Researcher Collecting Consent*	
Participant ID/Pseudonym		*Date of Consent*	

- ☐ Verify that the current IRB approved version of the Consent Form was used.
- ☐ Consent process took place in a private area (or as according to the approved Research Application).
- ☐ All of the participant's questions were answered.
- ☐ Participant is able to verbally express his/her understanding of what the research involves.
- ☐ Participant has had enough time, in their opinion, to make an informed decision.
- ☐ Both of the following occurred:
  - ☐ Printed name, signature, and date are accurately completed by participant and approved project team member.
  - ☐ Written consent was obtained prior to performing any research activities.

  –OR–
- ☐ Waiver of documentation of consent granted by the IRB.
- ☐ Special consent cases:
  - ☐ Not Applicable
  - ☐ Alteration of consent
  - ☐ Participant debriefing provided following study completion (for studies that involve deception)
  - ☐ HIPAA authorization obtained
  - ☐ Assent obtained
    - ☐ Electronically ☐ Paper
  - ☐ Parental permission obtained
    - ☐ Electronically ☐ Paper
  - ☐ Consent obtained
    - ☐ Electronically ☐ Paper
- ☐ Signed consent form retained by researcher and stored securely.
- ☐ A copy of the consent was given to the participant.

Notes about the consenting process including any information not included in the list above:

T 402.280.2126 | **F** 402.280.4766
Dr. C.C. and Mabel L. Criss Health Sciences Complex I
2500 California Plaza Omaha, NE 68178-0125
irb@creighton.edu

Information Sheet

Definition

- A document given to potential participants that provides comprehensive details about a study to help them make an informed decision about participating. No signature is required.

When to use

- Exempt research

Information Sheet: In-person interaction

When a researcher and a potential subject interact, the subject gives their consent to participate verbally. The researcher and the subject can be in the same location or communicating via an electronic means (i.e., phone, Zoom).

- Step 1: Present the Research Information Sheet
- Step 2: Allow subject time to think
- Step 3: Answer any questions
- Step 4: Document verbal consent

Information Sheet: No in-person interaction

- Researcher presents the contents of the research information sheet to potential subjects prior to subjects participating in the research activity (i.e., inserted in the introduction section of the survey).
- Consent is inferred: “By choosing to participate in this online survey, you consent to participating in this study.”

Information Sheet

Tips on how to use

- Use plain/lay language
  - Keep it respectful and conversational, not legalistic.
- Use second person writing style
  - Address participants as “you.”
- Keep sentences short and active
  - “You will be asked to complete a survey. The research survey will take 10 minutes.”
- Keep it brief
  - Encourages the individual to actually read it, not just skim.

Information Sheet

Tips on how to use (continued)

- Start with a short summary
  - Briefly explain the background and purpose.
- Explain what participation involves
  - Clearly outline research procedures.
- Inform participant if any recording that will occur
  - Disclose plans to audio/video record (interviews/focus groups).
- Explain what happens to their data
  - Explain data recording and storage plans.
- Ask yourself, “Would I consent to this research?”
  - Is it clear, honest, and free from coercion?

Revised Guidance Documents

Training, Documentation, and Disclosure Requirements for HSR

- The requirements have not changed; the guidance document has been revised.

Who Needs to be Included on IRB Protocols?

- Specified for students and faculty

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

CITI Webinars

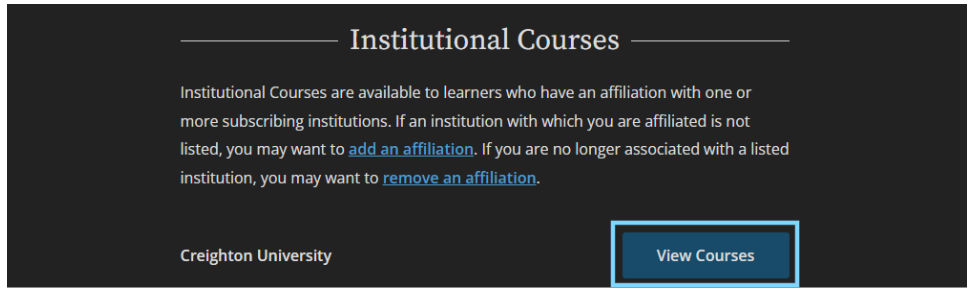
Webinar access

- The Collaborative Institutional Training Initiative (CITI) program has a catalog of webinars that all CU faculty, staff, and students can access through November 2026.

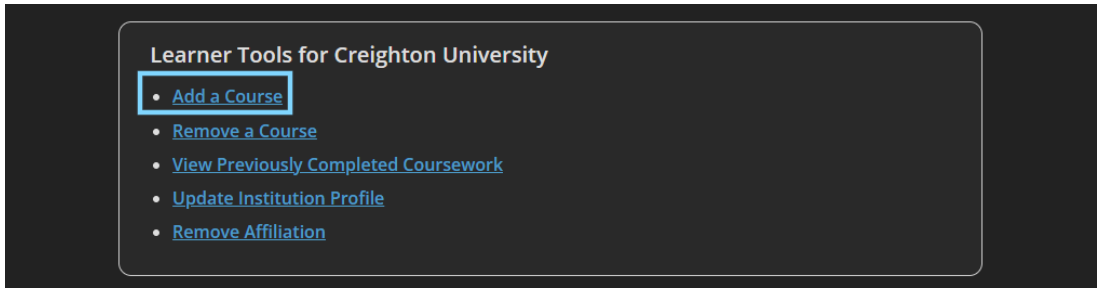
Instructions:

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.

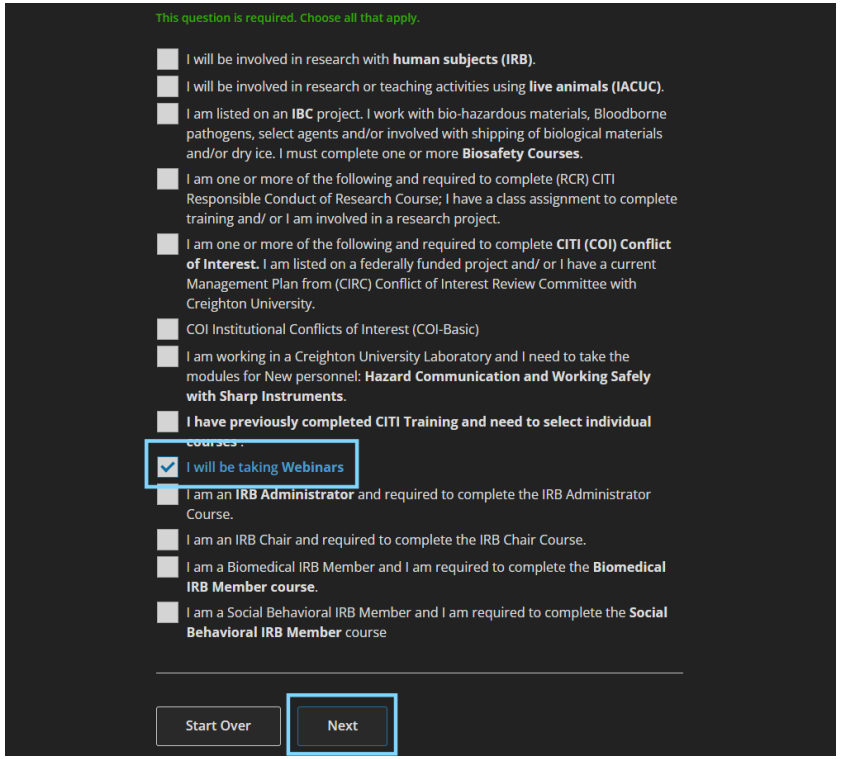


2. Scroll to the bottom of the page.
3. Click **Add Course** under Learner Tools for Creighton University.



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**.

CITI Webinars

Available webinars about informed consent

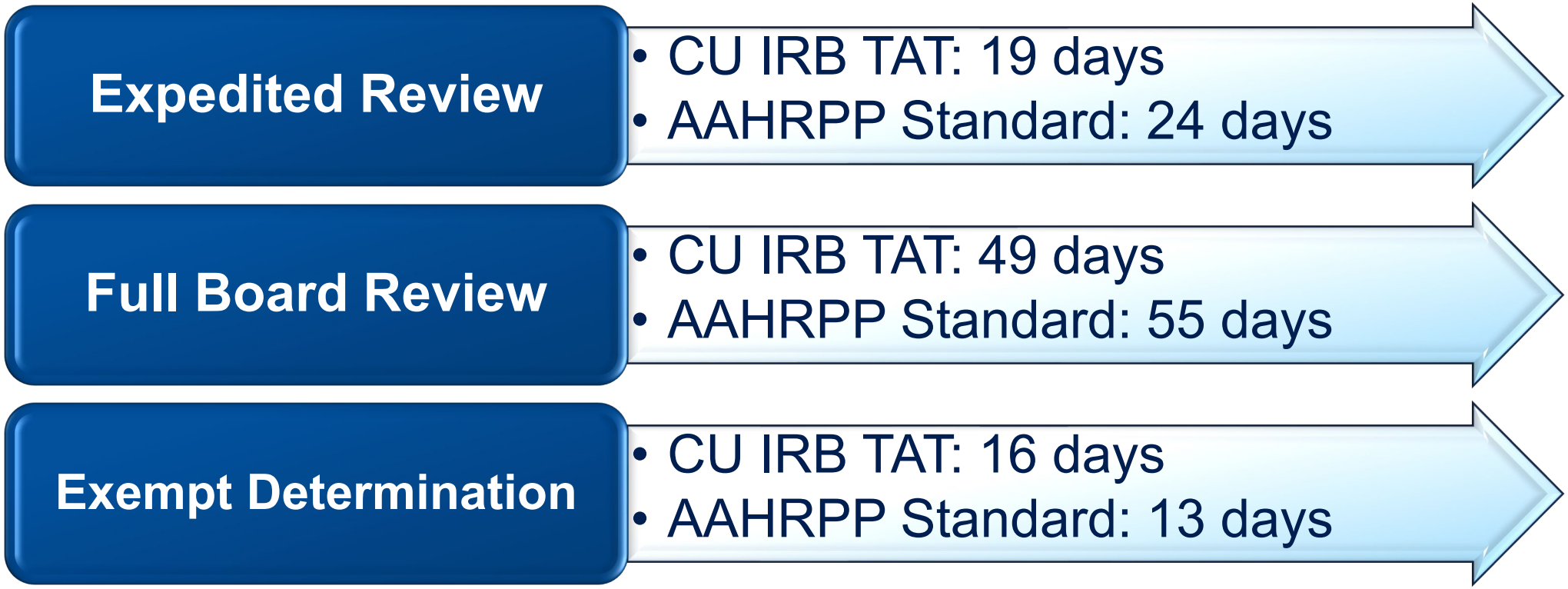
- Informed Consent and Clinical Investigations: A Focus on the Process (ID: 317830)
- Informed Consent and Research with Wearable Tech (ID: 317836)
- Remote Informed Consent: The Same, but Different, but Still the Same (ID: 317840)
- Revised Common Rule: Revisions to Informed Consent (ID: 317817)
- Understanding 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

Recent Metrics

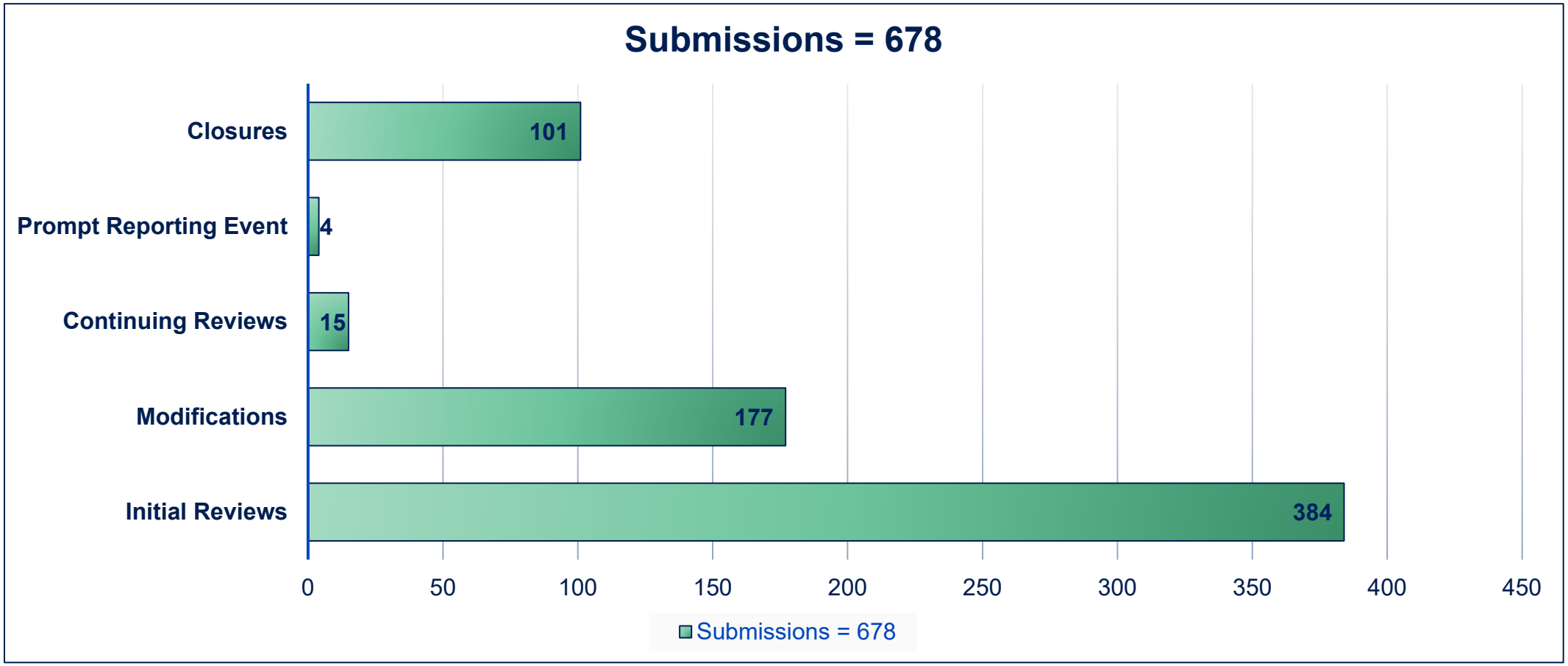
Turnaround time (TAT) data from **submission** to initial approval (January 2025 through September 2025). *Note: TAT includes days with investigators.*



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

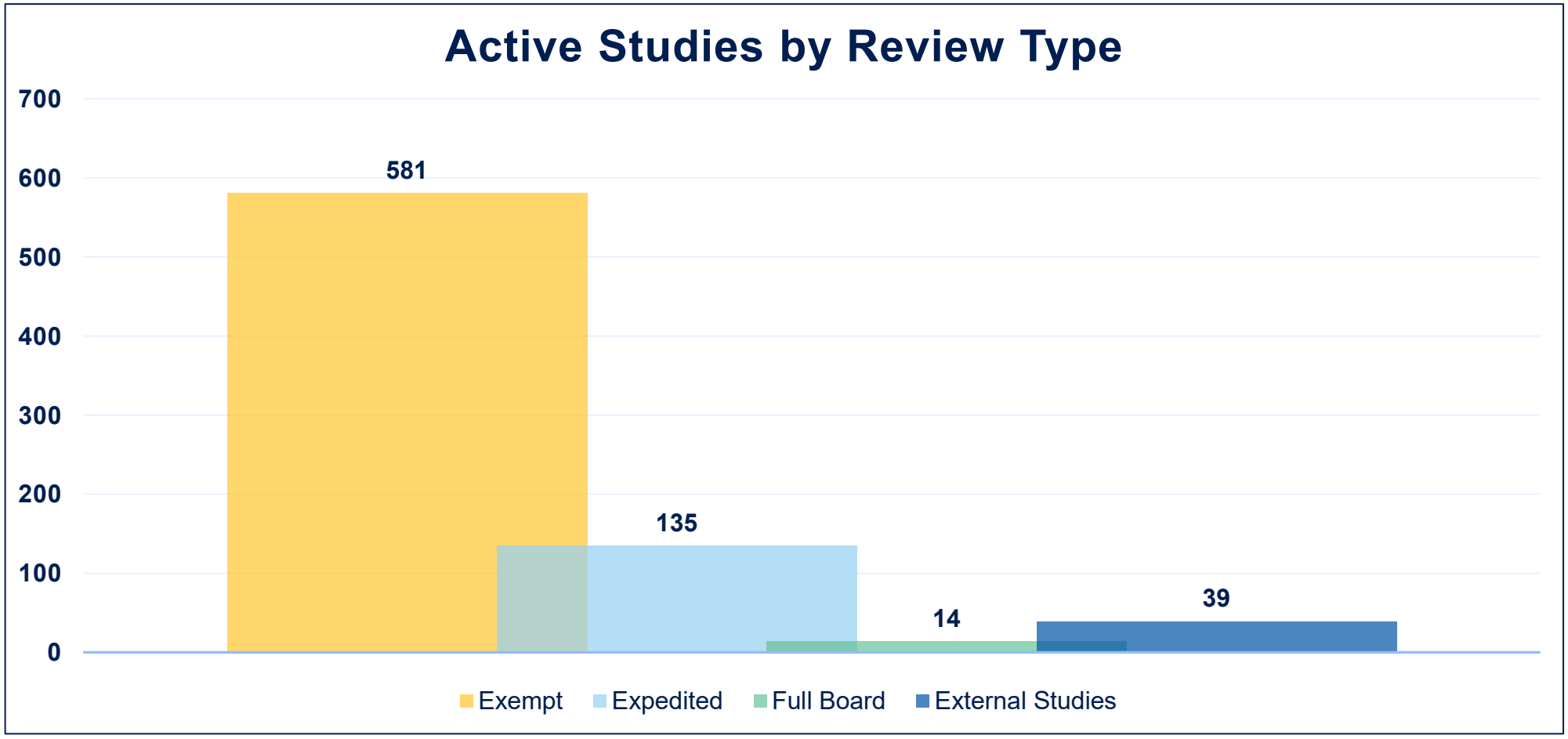
Recent Metrics

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



Recent Metrics

The CU IRB currently reviews and monitors 769+ 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.

IRB Office | 402.280.2126 | IRB@creighton.edu