



# 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** from 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**

## 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:


# 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

# CITI Webinars

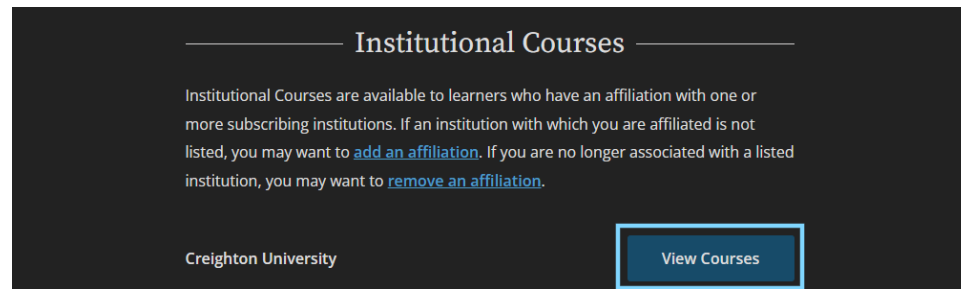
## Webinar access

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

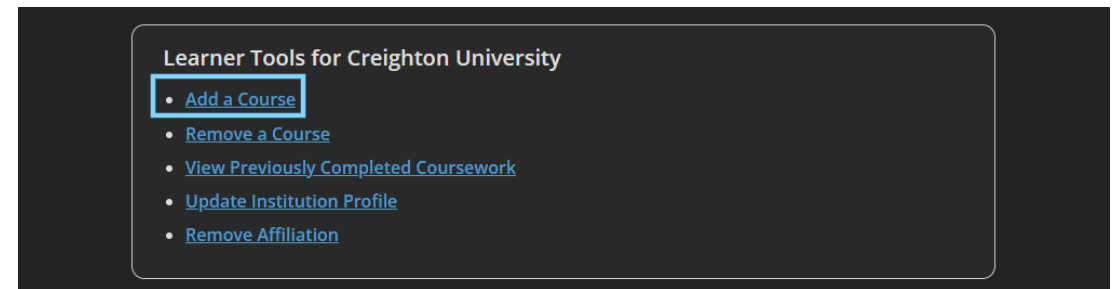
## Instructions:

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**.

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**

[Start Over](#) [Next](#)

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 CRIs
- ☐ 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 Workforce
- ☐ Design With the End in Mind
- ☐ Discrete Choice Experiments with Neurologic Disorders
- ☐ Disaster Response and Research Reactivation Effort
- ☐ Drones 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
- ☐ Export Compliance for Staff, Students, and Faculty
- ☐ Facilitating Synchronous RCR Training Sessions
- ☐ FCRA 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**

- ☒ **RCR and Grant Stewardship**
- ☐ 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
- ☒ **Study Team Up Challenges and Strategies**
- ☐ Successfully Developing and Deploying Digital Clinical Measures
- ☐ Successfully Navigating Subscriptions 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

[Start Over](#) [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


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## Institutional Review Board (IRB)




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### What is an Institutional Review Board (IRB)?

An Institutional Review Board (IRB) is an administrative body charged with the protection of the rights, safety, and welfare of human subjects in research. The IRB is charged with the responsibility of reviewing and approving, prior to its initiation and thereafter on an ongoing basis, all research (whether funded or not) involving human participants. The IRB has the authority to approve, disapprove, monitor, suspend, terminate, and/or require modifications to all human subjects research activities that fall within its jurisdiction under the federal research regulations and institutional policy.

Institutional Review Boards are charged with ensuring that:

- Research is conducted according to well-designed protocols likely to advance scientific knowledge
- The participation of human subjects in research is voluntary and complies with the statutory requirements for informed consent
- Risks to study subjects are minimized and outweighed by potential benefits to subjects and/or society

# Recent Metrics

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

## Expedited Review

- CU IRB TAT: 19 days
- AAHRPP Standard: 24 days

## Full Board Review

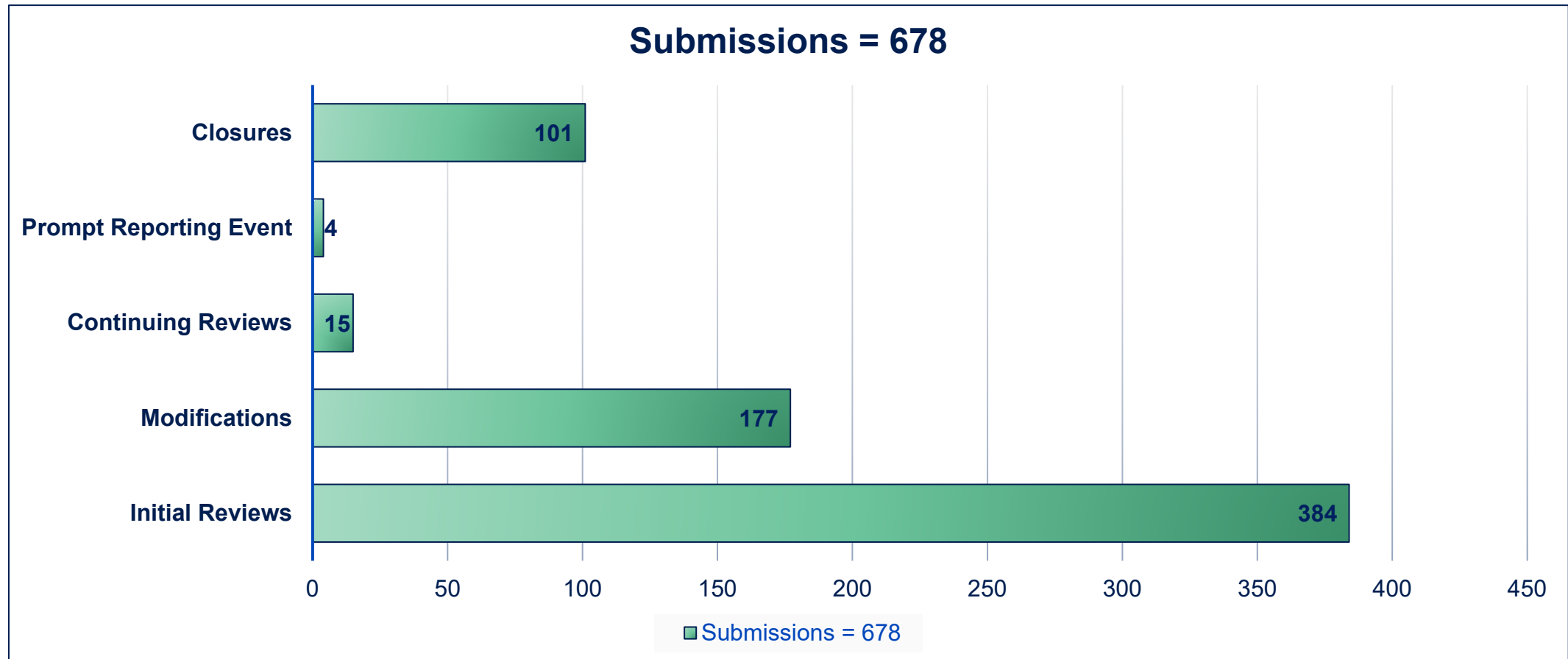
- CU IRB TAT: 49 days
- AAHRPP Standard: 55 days

## Exempt Determination

- CU IRB TAT: 16 days
- AAHRPP Standard: 13 days

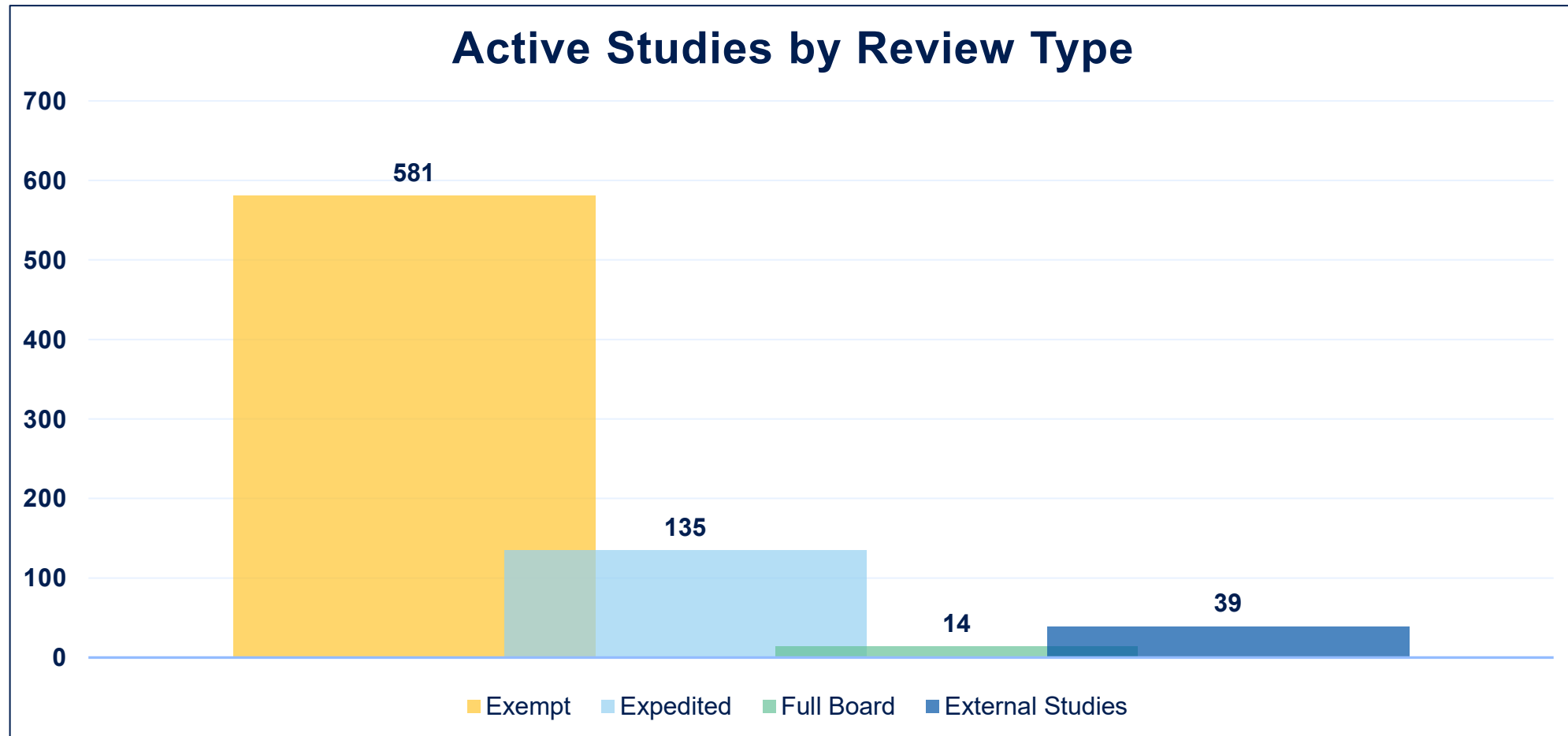
# Recent Metrics

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





*Thank you.*

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