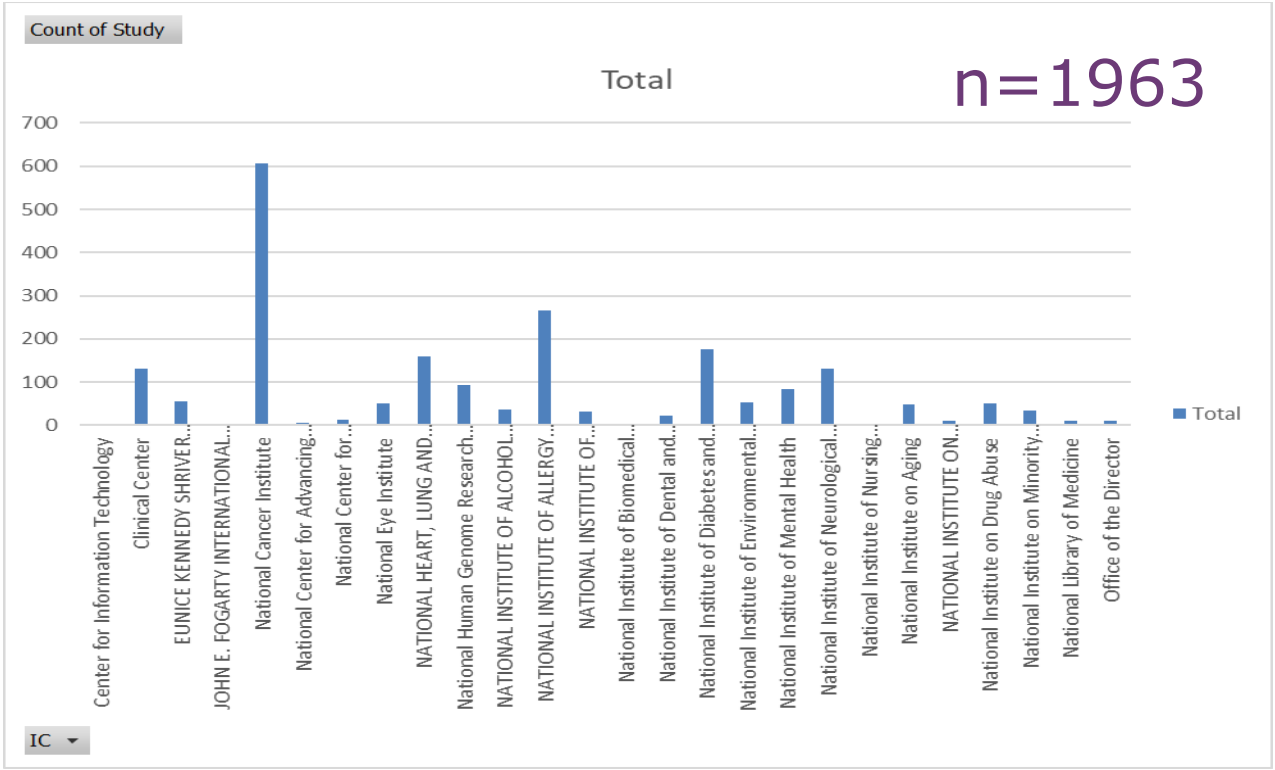
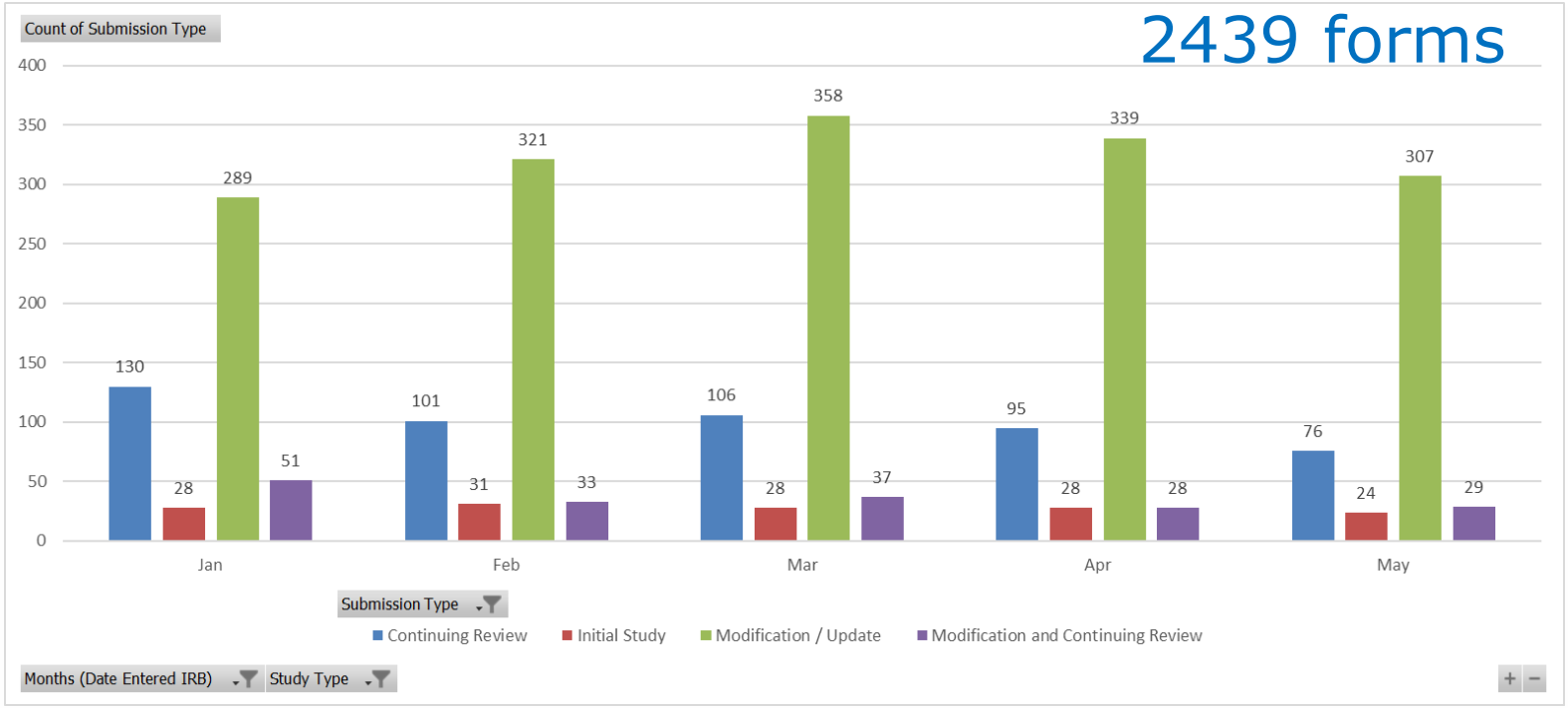
NIH IRB Metrics

Tiffany Gommel, MS CIP
IRB Director
28 May 2026

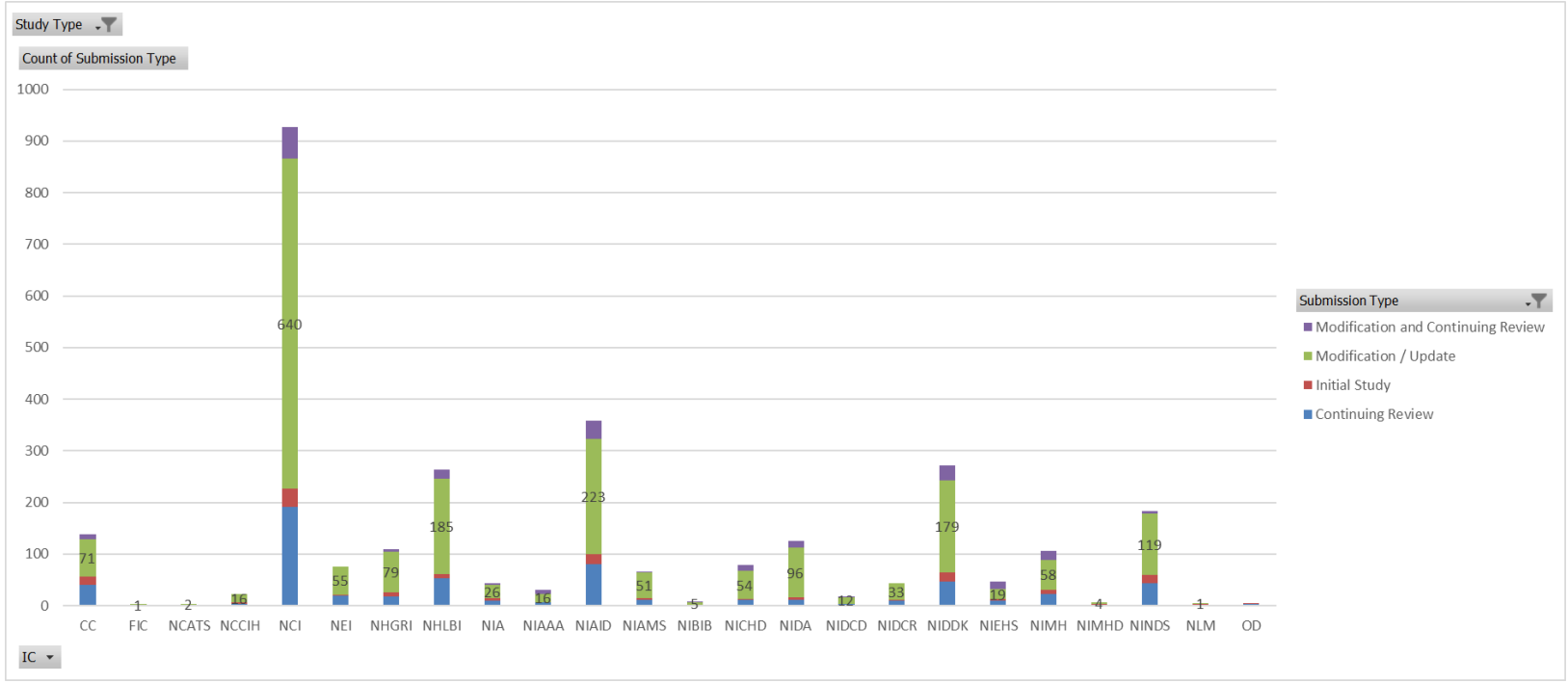
Active studies by IC as of 5/27/2026



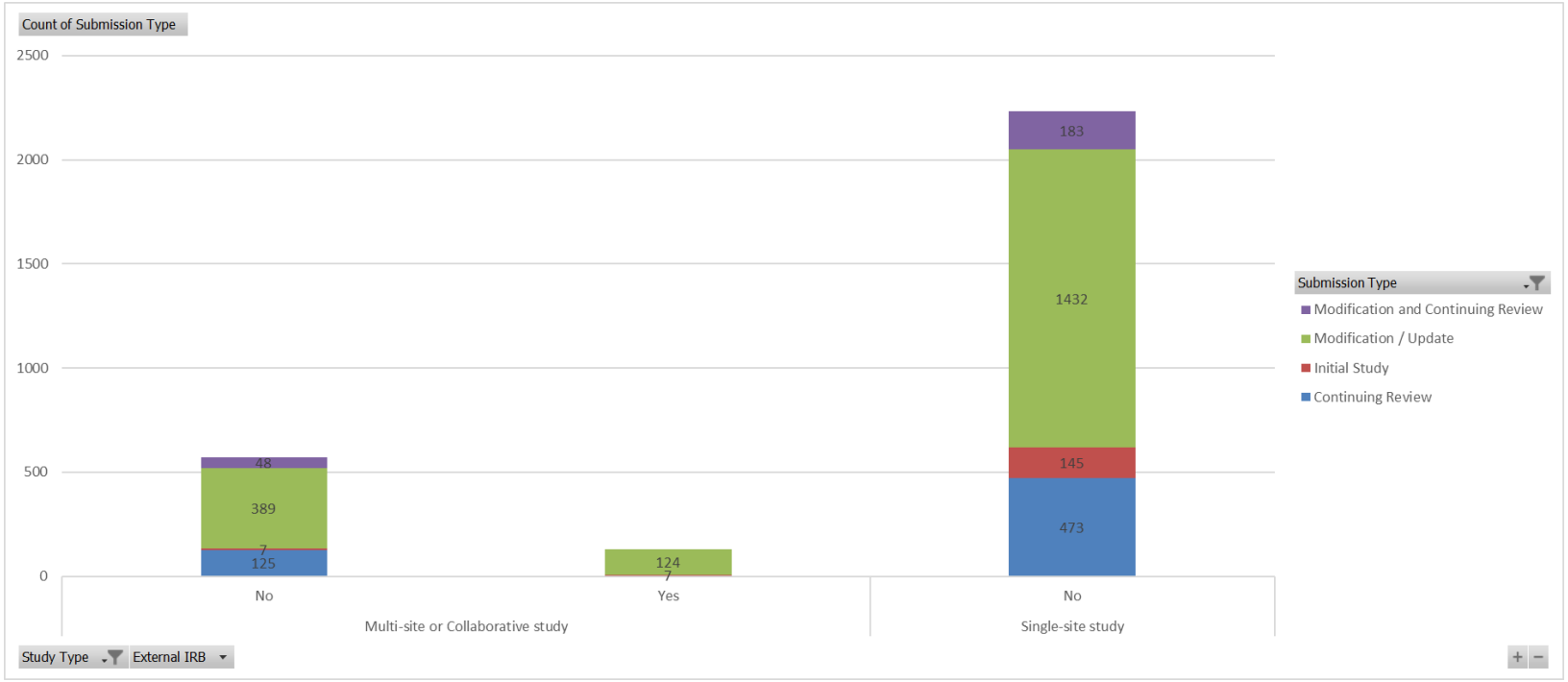
Submissions to IRBO: Jan – May 27, 2026



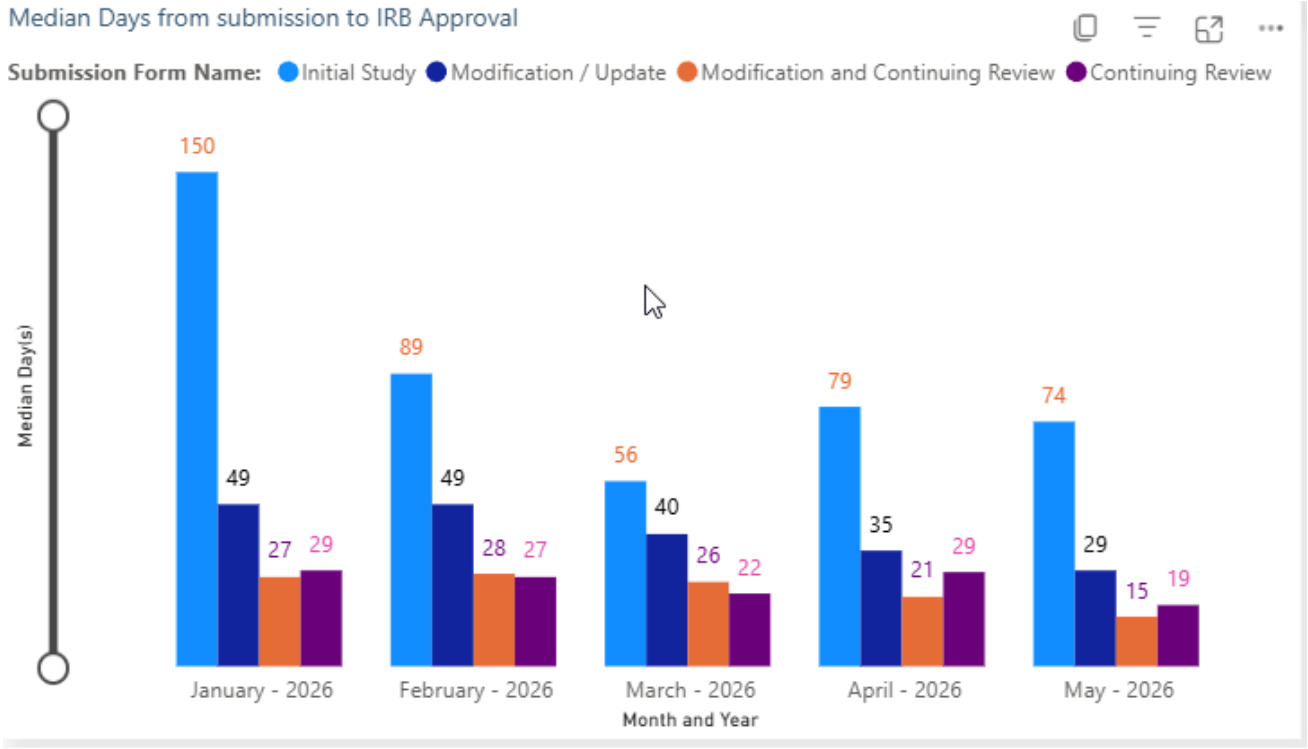
Submission Form Types by IC: Jan – May 27, 2026



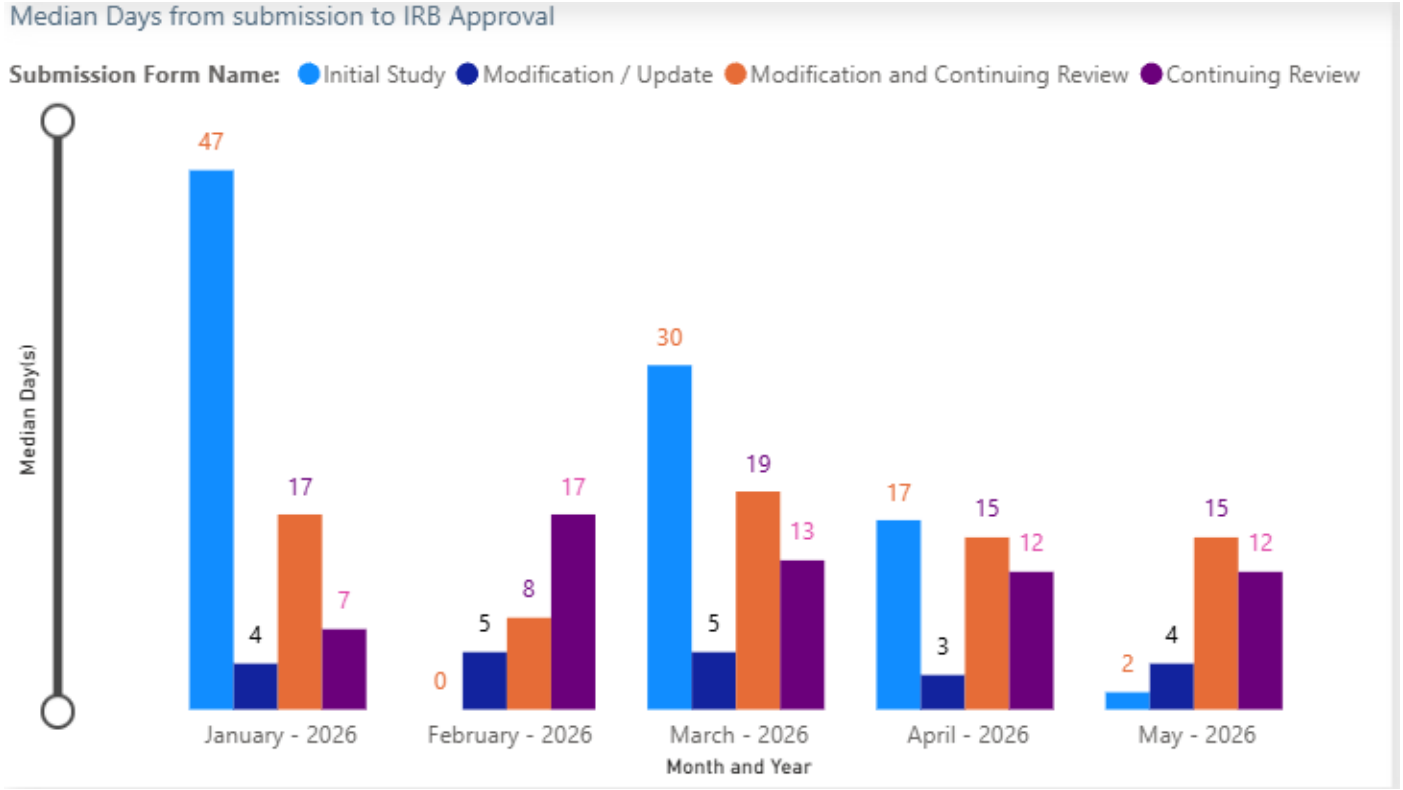
Submission Form Types for Single vs Multi-site: Jan – May 27, 2026



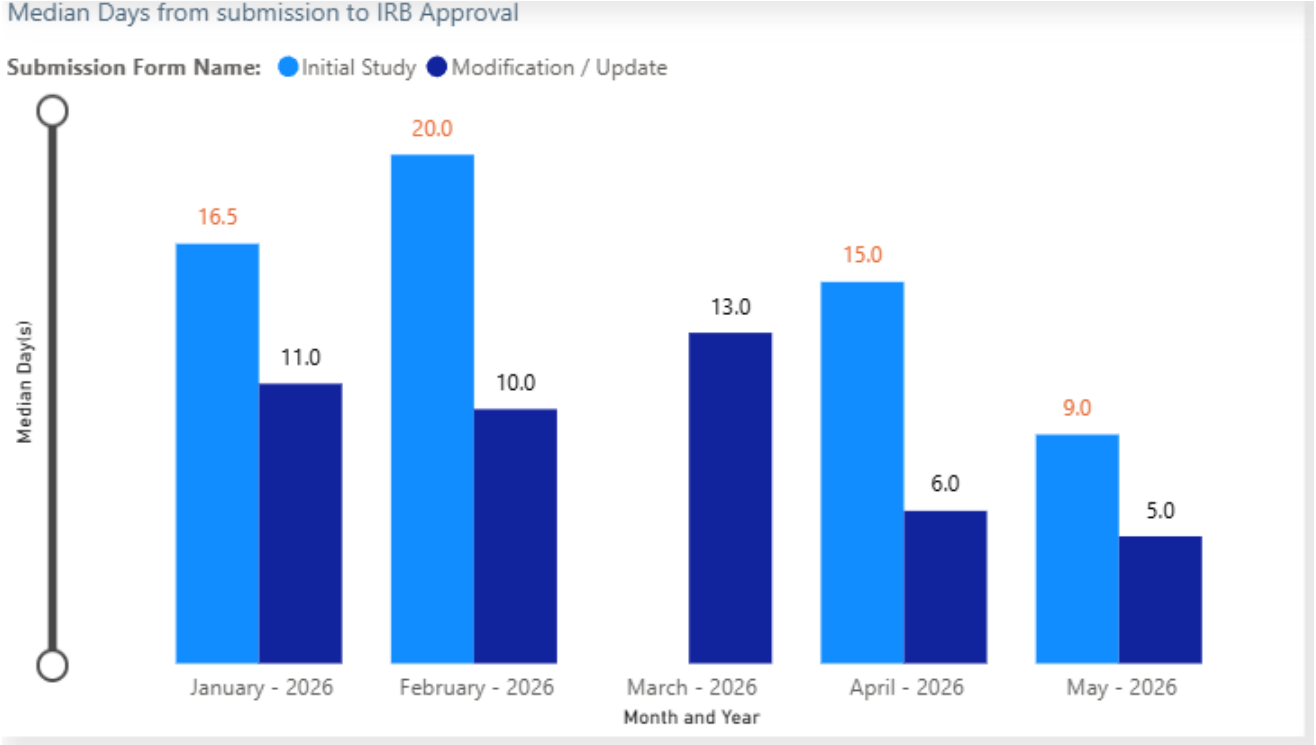
Median days to approval – Full Board: Jan – May 2026



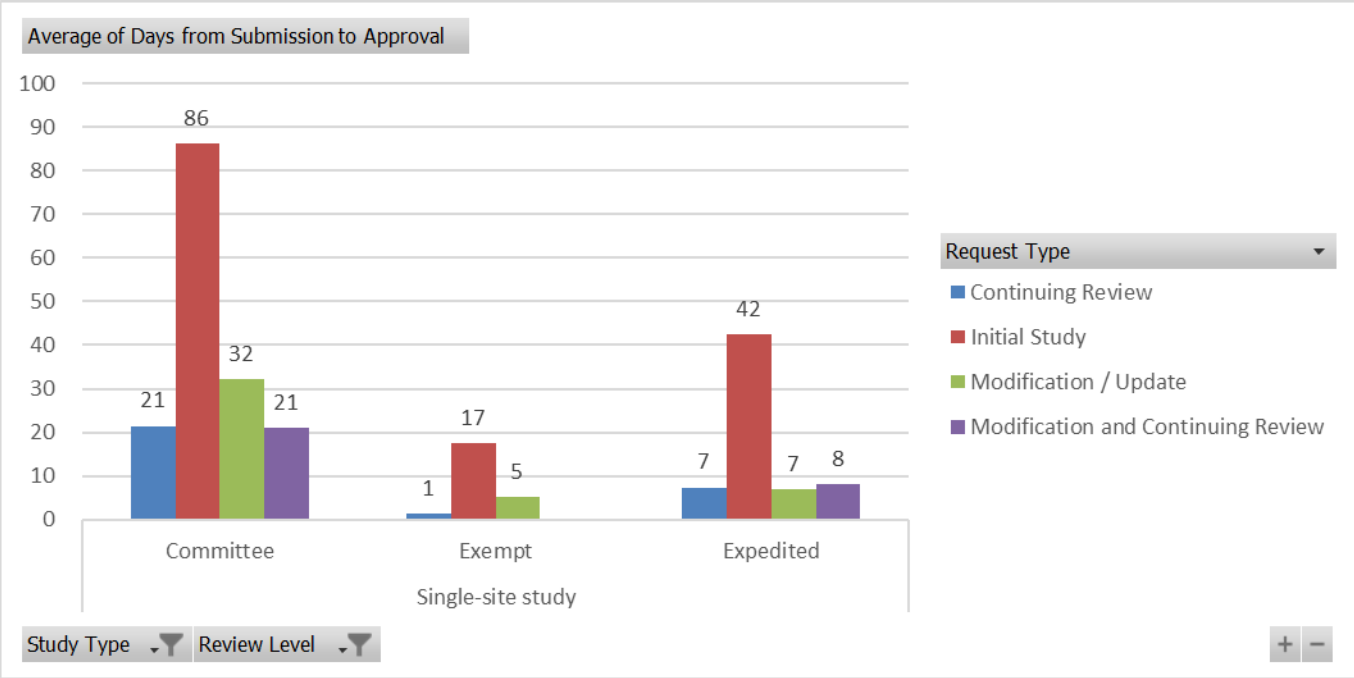
Median days to approval – Expedited: Jan – May 2026



Median days to approval – Exempt: Jan – May 2026



Average Days to Approval: Jan – May 2026



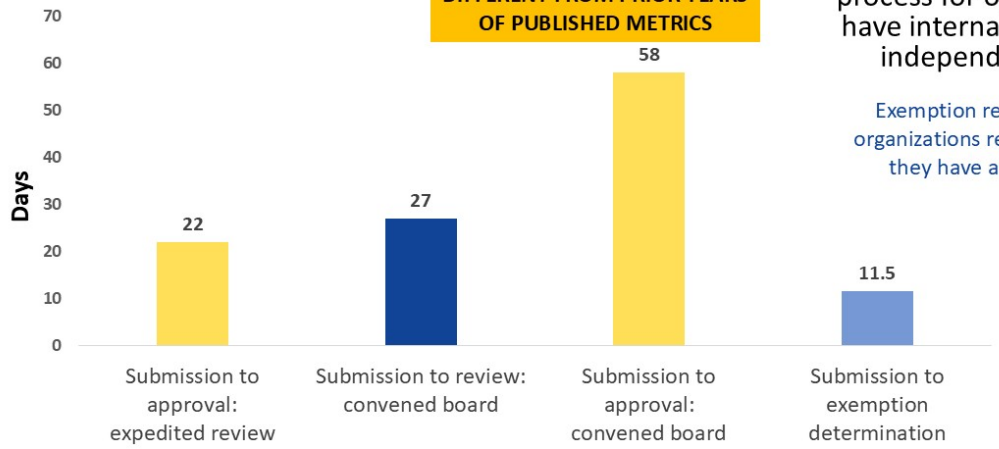
How do we measure up?

How do we measure up?

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

Review Times

NOTE: THE WAY REVIEW TIMES WERE CALCULATED IS DIFFERENT FROM PRIOR YEARS OF PUBLISHED METRICS

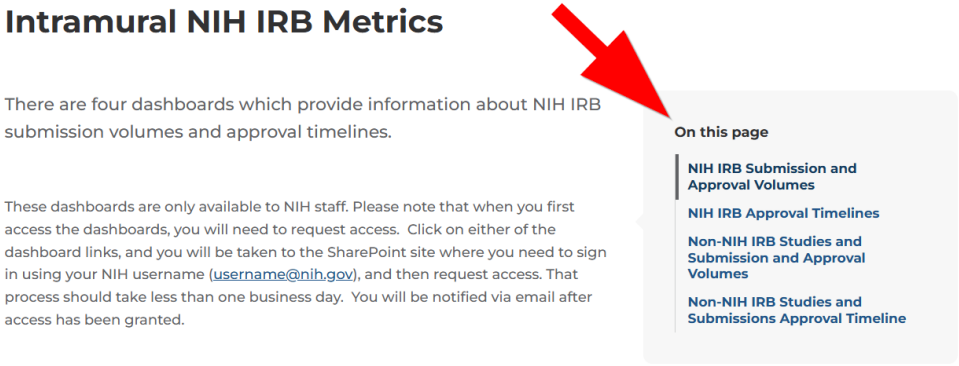


Data corrected December 2025

This chart shows the median review times by review process for organizations that have internal IRBs/ECs or are independent IRBs/ECs.

Exemption review times are for organizations regardless of whether they have an internal IRB/EC

Where can you find OHSRP metrics?



OHSRP Website Updates

Nicole Grant, RN, BSN, MPH
Acting Director/Executive IRB Chair

New information posted on OHSRP website

- The OHSRP website has been updated with several new resources and tools to support your work. We regularly update our website—please bookmark the homepage and check back often.

- https://irbo.nih.gov/ohsrp-news-updates/new-information-on-website/

IND Safety Reports

Nicole Grant

Purpose of This Update

- Explain new FDA guidance regarding IND safety reports
- Clarify NIH IRB expectations for investigators
- Review submission timelines and procedures
- Highlight investigator responsibilities for participant protection

What are IND Safety Reports?

- Communications from sponsors providing important safety information about an investigational drug
- May describe events from other sites or other studies using the same investigational product
- Even when events do not occur in your study, they may still impact participant safety on your study

Key FDA Guidance

- In December 2025, the FDA issued 2 new guidance documents related to safety reporting: Investigator Responsibilities-Safety Reporting for Investigational Drugs and Devices and Sponsor Responsibilities - Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies.

- In the guidance for investigators, it states in section VI: *The investigator must submit IND safety reports to the IRB (§ 312.66) because FDA considers safety information that meets the IND safety reporting criteria under § 312.32(c) to be an unanticipated problem involving risk to human participants or others.*

Important Change in NIH Guidance

- Previous NIH guidance allowed investigators to submit only reports that they determined met the definition of an unanticipated problem (UP) or new information (NI) at the NIH site.

- FDA clarified that all IND safety reports are a UP and should be submitted to the IRB

- Current NIH guidance now requires submission of all IND safety reports to the IRB

Investigator Responsibilities

- Review each IND safety report received from a sponsor for potential impact on your study

- Determine whether actions are needed, including:
  - Updating the consent form
  - Modifying the protocol
  - Informing participants

- Document your assessment within the RNI submission

Submission Requirements

- Submit all IND safety reports through a Reportable New Information (RNI) submission
- Submission timeline: within 7 calendar days of your receipt
- Choose the appropriate RNI category:
  - Unanticipated Problem
  - New Information
  - IND safety report that does not meet the description of UP or NI criteria at the NIH site.

Additional Operational Guidance

- One RNI may cover multiple protocols if the assessment is the same
- One RNI may include multiple IND safety reports related to the same event
- Protocols overseen by a non-NIH IRB generally do not require NIH RNI submission unless the event affects the NIH site

Protocol Template Update

- The NIH interventional protocol template has been updated
- The previous section limiting IND safety report submissions has been removed
- Investigators should delete outdated language during their next planned protocol modification
- Protocols already in data analysis do not need to be updated

Key Takeaways

- All IND safety reports received from sponsors must be submitted to the NIH IRB
- Submission must occur within 7 calendar days via RNI
- Investigators remain responsible for assessing impact on participant safety
- Appropriate actions should be taken when reports affect study risk or participant willingness to continue

Association for Accreditation of Human Research Protection Programs (AAHRPP) Accreditation

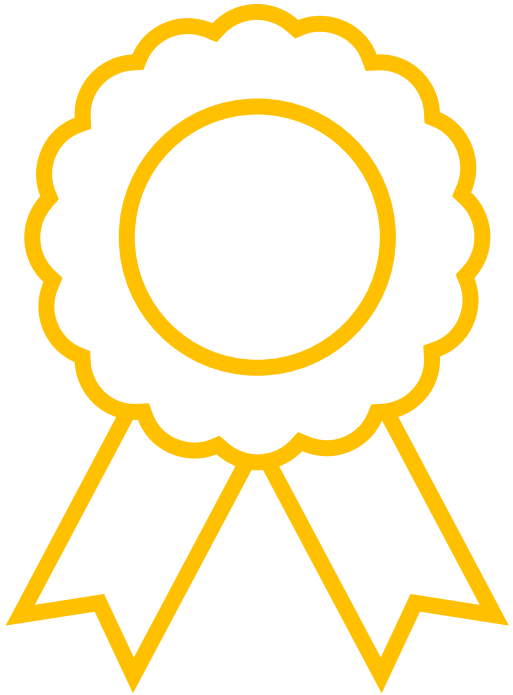
Heather Bridge

Agenda

- What is AAHRPP
- What to expect during the Site Visit
- What if you are selected to be interviewed

Why Accreditation Matters

- Strengthens public trust
- Mitigates risk and strengthens compliance
- Demonstrates institutional accountability
- Affirms human research participant protection as an institutional priority
- Supports scientific collaboration (and funding opportunities)



Accreditation Framework

Domain I –

The Institution

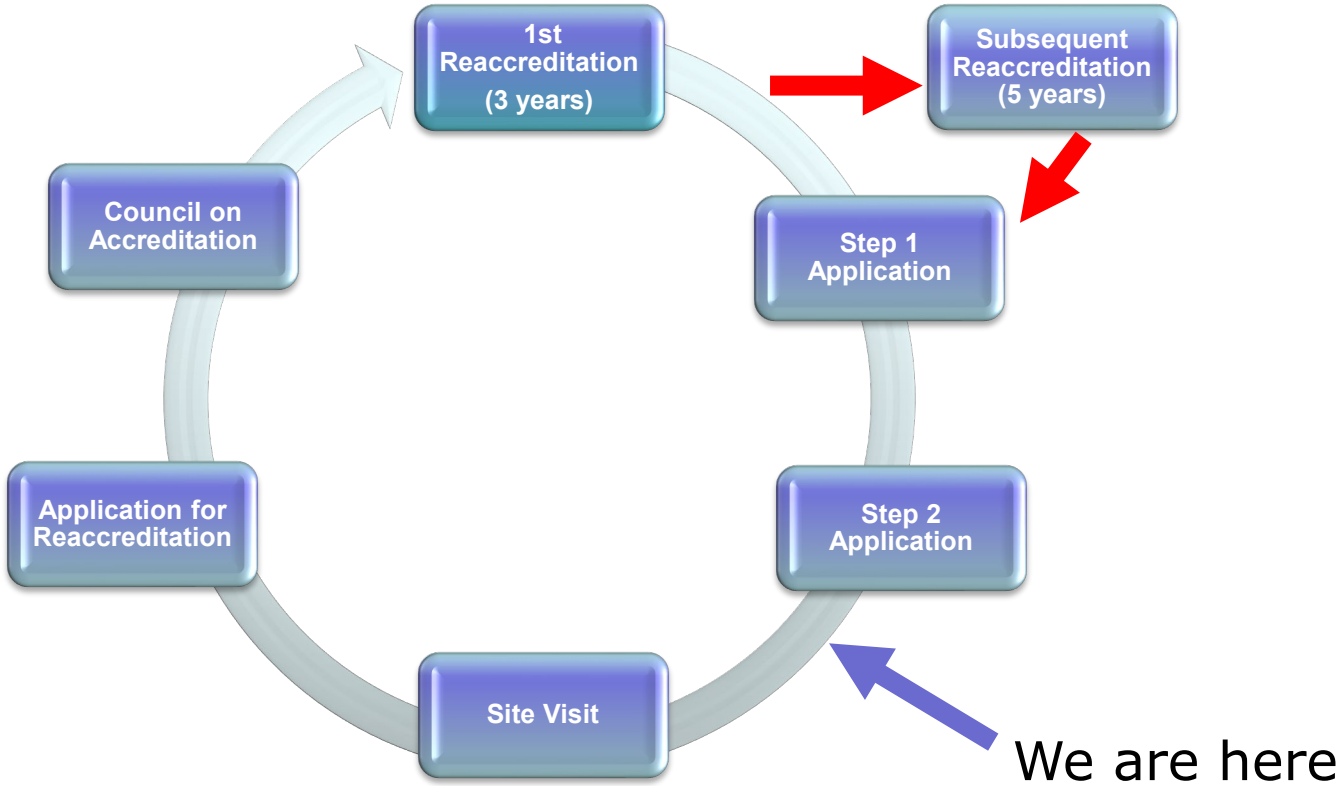
Domain II – The Institutional Review Board/Ethics Committee

Domain III – Researchers

The Accreditation Process

- **Step 1 Application** – Demonstrates that the HRPP documentation, structure and resources align with AAHRPP standards
- **Step 2 Application** – Provides of additional materials (protocol and staff lists) for the site visit
- **Step 3 -** AAHRPP Site Visit - Evaluation of practice
  - Review of records – Protocols, IRB Minutes, etc.
- **Step 4** – Response to Site Visit concerns
  - Final Application for Reaccreditation
- **Step 5** – Council on Accreditation – Accreditation status

The Accreditation Cycle



Accreditation Status So Far

AAHRPP has already:

- Accepted the Step 1 Application
- Accepted the Step 2 Application
- Selected NIH staff to interview
- Started the draft agenda for the site visit

AAHRPP needs to:

- Set the final site visit dates
- Select protocols and documents to review
- Identify the Site Visitors
- Provide NIH materials to site visitors to pre-review

What is the Purpose of the Site Visit?

The site visit is a confirmatory process. Site visitors verify that our practices comply with our policies, regulations and AAHRPP Standards.

It is NOT an assessment of individuals or an audit. It is an assessment of our institution's HRPP.

What happens during the interviews?

Site visitors:

- Assess core competencies based on a role (person) or function (office/committee)
- Ask you questions based on your particular role or office/committee function
- Verify that what we do in practice matches what is described in our written application

Interviews are grouped by role/function

- Senior HRPP Leaders are interviewed individually
- All other interviews are group interviews of 2-4 staff

Who Are The Site Visitors

They are:

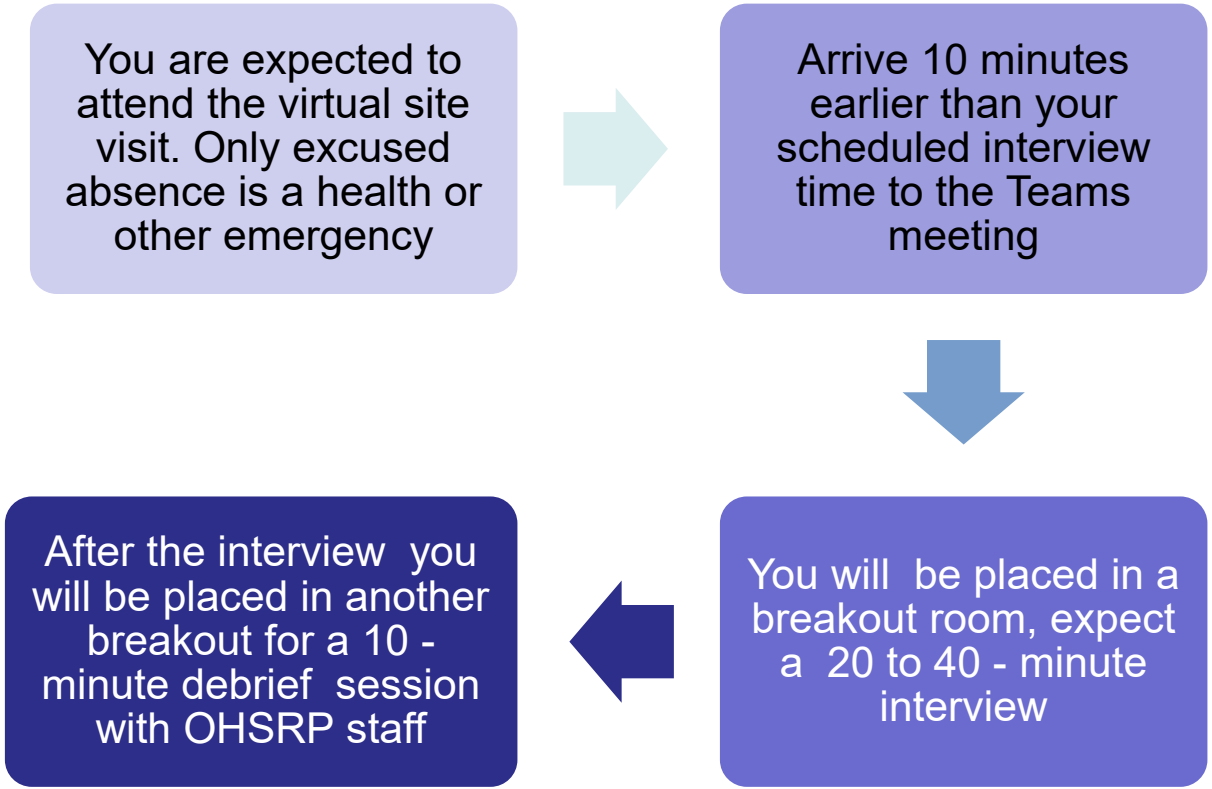
- Our peers: They are from other AAHRPP accredited institutions.
- Knowledgeable about research and IRB procedures based on their own experience
- Collegial, respectful and open
- Not bothered if you don't understand a question – Ask them to clarify
- Not worried if you as an individual don't know the answer to a particular question or scenario

What if I am selected to be interviewed

We will prepare you for the interview. You can relax because:

- This is NOT an audit. Site visitors are merely confirming our practices.
- AAHRPP is focused on how you arrive at outcomes and the processes that get you there - how you do your job.
- It's not about you - it's about your role or function within the HRPP.
- You don't have to cram or learn something new - You know who to ask, and where to find more information if you need it.

Virtual Site visit flow for interviewees



Next Steps

- We will finalize the agenda with AAHRPP
- Confirm the site visit dates
- Gather records for records review
- This Summer, we will prep those of you selected to be interviewed (and some alternates)
- Conduct the site visit in September

Questions???

ONE PROGRAM,
MANY PEOPLE,
INFINITE POSSIBILITIES
irp.nih.gov