THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

State of the OHRE/IRB

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6/22/2023

Objectives

- Understand the current state of the OHRE office
- Explain the metrics related to "IRB review times" and the obligations of Investigators in contributing to, and improving, these review times
- Identify and understand ongoing initiatives and challenges

Brief background on me!

- Started in this role end of August 2022
- Been in clinical research for over 20 years
  - Served as coordinator for large coordinating center, study specific research coordinator, HRPP quality improvement manager, role as IRB/HRPO Director for 4 institutions
- Understand the challenges of clinical research in complex institution
- Still learning UNC infrastructure
- Some of my favorite things: travel, roller coasters, hiking, good food, music festivals, my 2 children!

OHRE Office

The Office of Human Research Ethics (OHRE) is responsible for ethical and regulatory oversight of research at the University of North Carolina at Chapel Hill that involves human subjects. OHRE supports and oversees the work of the Institutional Review Boards (IRBs).

OHRE currently has 29 FTEs.

IRB Committees

The IRB is the committee that is responsible for protecting the rights and welfare of participants in human research.

The 6 IRB committees (“full board review for greater than minimal risk studies”) include about 65 primary members and over 30 alternate members.

Leadership and Staffing Updates

Year in Review – Time of Transition

Operations Leadership Updates in 2022-2023

- Previous Associate Director of Operations & Education departed in 2021
- Dustin Yocum joined OHRE as the Associate Director of Operations & Education in April 2022
- Dustin Yocum resigned as of 5/1/23
- Celeste Cantrell appointed Interim Associate Director of Operations

Reliance Team Leadership and staffing 2021-2023

- Previous Reliance Manager departed November 2021
- Previous Associate Director of Regulatory Affairs & Compliance departed March 2022
- First Reliance IRB Analyst position created & filled by Ariana Peden July 2022
- Kristen Katopol joined OHRE as the Associate Director of Regulatory Affairs & Compliance in November 2022
- Ariana Peden promoted to Reliance Manager March 2023
- Second Reliance Analyst position approved; search committee formed for both Reliance Analyst positions April/May 2023

Other staffing 2022-2023

4 new staff hires in last year and 1 promotion

1 New position: Eric Schumacher, Education and Content Manager (1/23)

3 IRB Analysts replacements: Raquel Richard (10/22), Sarah Langensiepen (1/23), and Diane Towle (5/23)

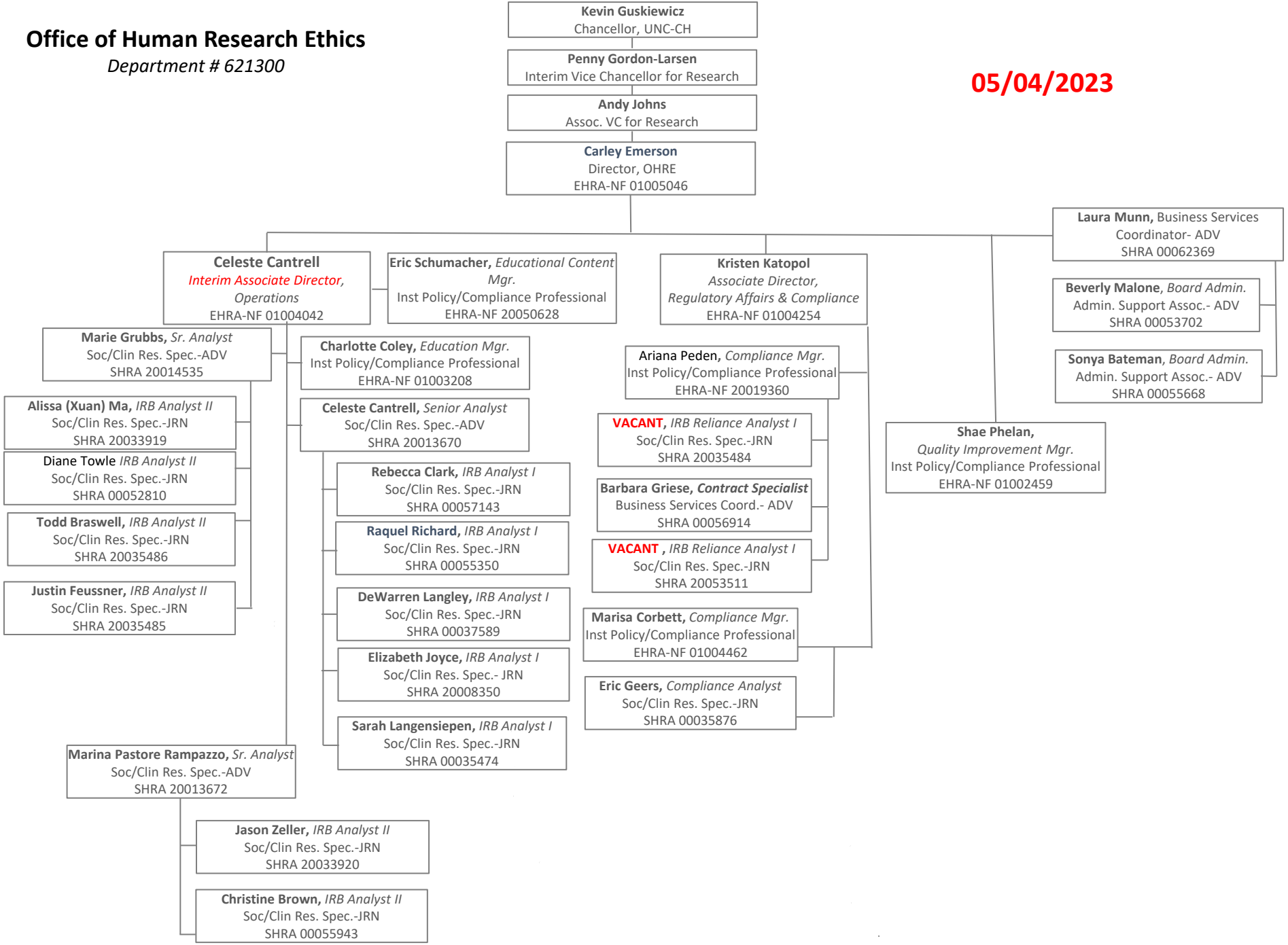
Still open: 1 Reliance Analyst and 1 Junior Analyst

1 Reliance Analyst starting next week!

Office of Human Research Ethics

Department # 621300

05/04/2023



AAHRPP Reaccreditation

AAHRPP

The **Association for the Accreditation of Human Research Protection Programs (AAHRPP)** promotes the highest quality research through an accreditation process that helps organizations worldwide strengthen their HRPPs

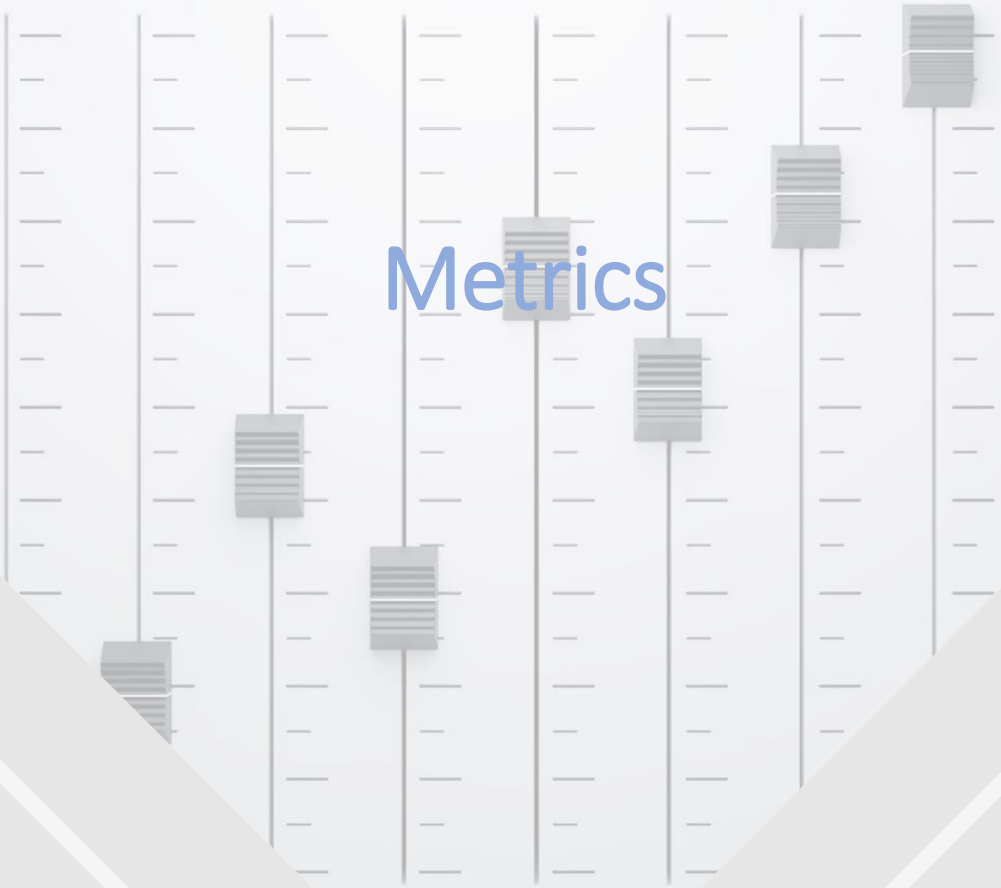
AAHRPP accreditation is the 'gold standard' for HRPPs, as it offers assurance to research participants, researchers, sponsors, government regulators, and the general public that the UNC HRPP is of the highest quality

The UNC HRPP was first accredited in 2009 and is undergoing its 3rd reaccreditation

AAHRPP Site Visit Agenda

- AAHRPP Site visit on 3/9/23 and 3/10/23
- Two full days of interviews with over 70 interviews (PIs, research team members, Research Support team members, IRB members, IRB Chairs, OHRE staff members)
- Review of IRB determinations for over 65 studies and 18 sets of IRB meeting minutes
- Still waiting for final determination but site visit went very well.

THANK YOU to all who participated!

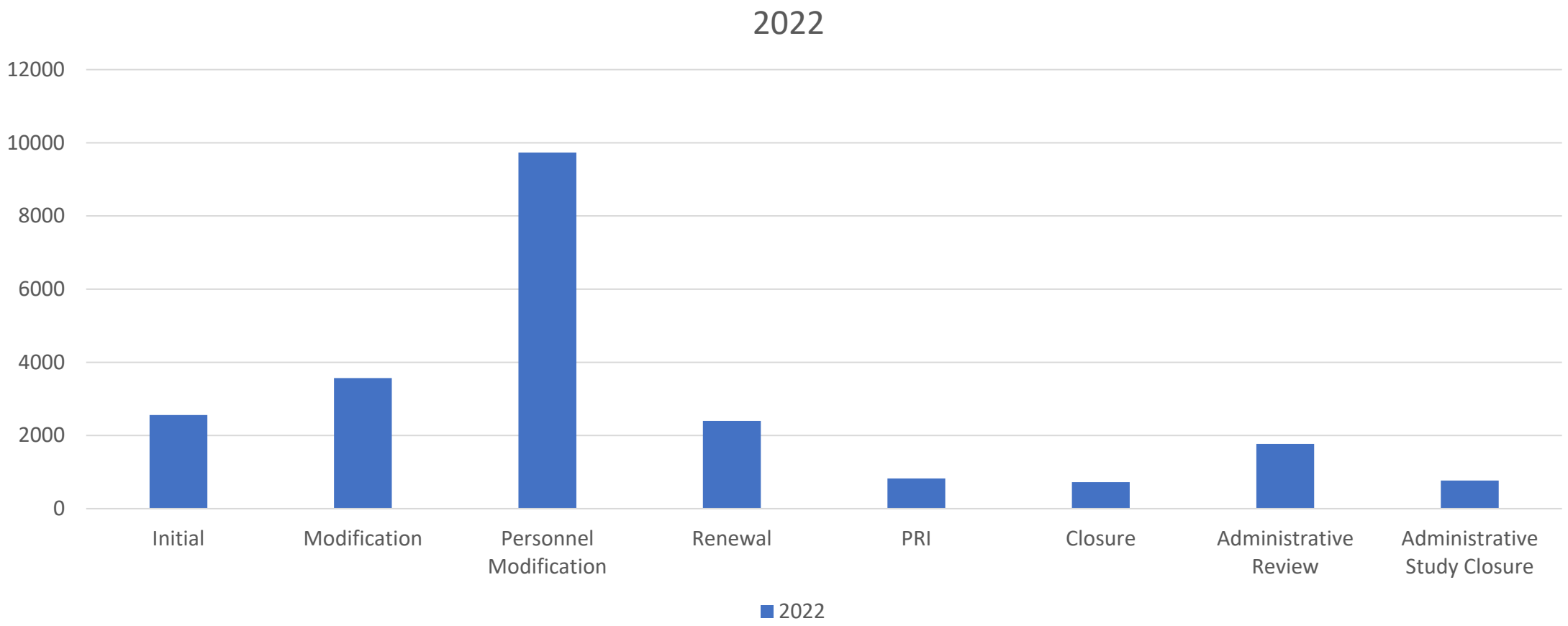


Metrics

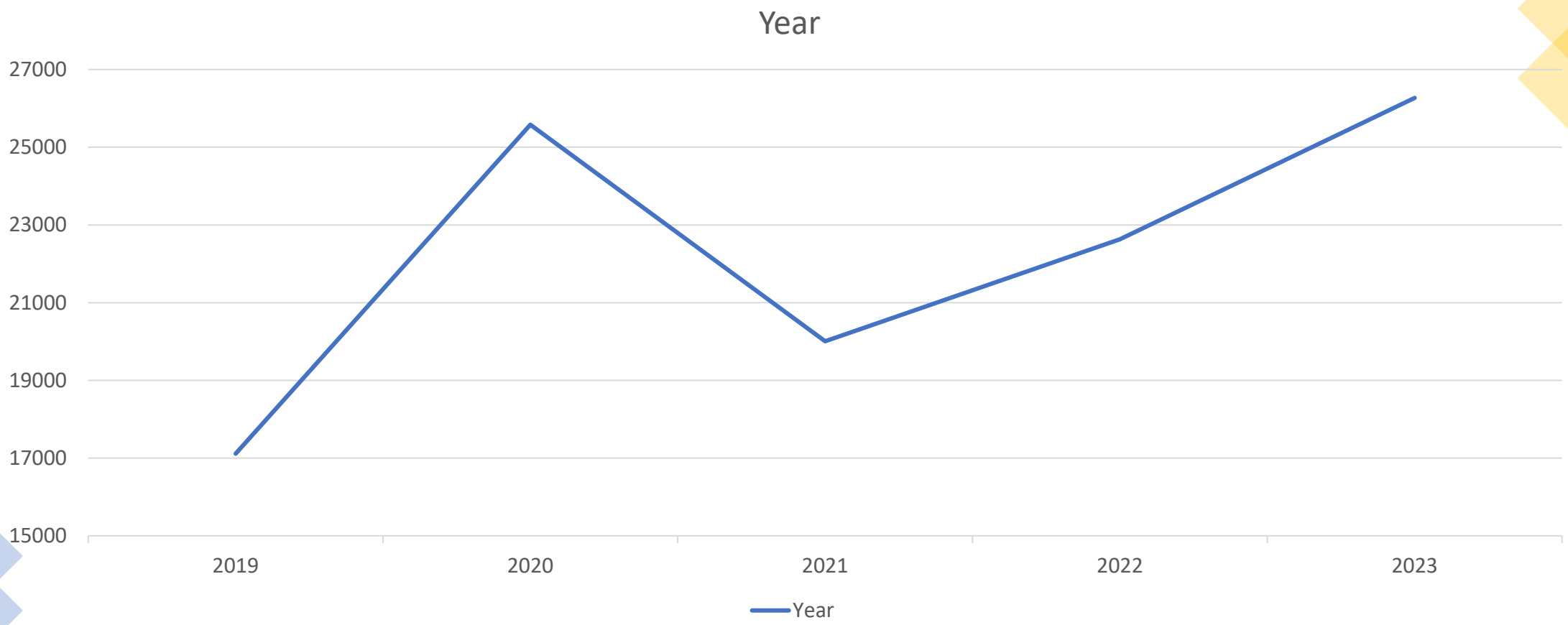
Annual Submission Volumes

SUBMISSION_TYPE	2019	2020	2021	2022	1/1/2023-5/31/2023
Initial	2708	3030	2776	2560	1196
Modification	6473	7405	4926	3569	1535
Personnel Modification	0	87	5333	9734	4251
Renewal	4497	2954	2514	2399	1070
PRI	565	369	458	824	285
Closure	642	731	737	725	374
Annual COI	177	286	295	279	184
Administrative Review	4	1095	1463	1768	895
Administrative Study Suspension	0	0	1	2	0
Administrative Study Closure	30	7602	1505	770	1153
Total	15096	23559	20008	22630	10943

Breakdown of Submissions in 2022



IRB Total Submissions Per Year (projected for 2023)



IRB Efficiency

- Is it all that matters?
- How can we improve the QUALITY and EFFECTIVENESS of reviews, while still being efficient?

GUIDING PRINCIPLES MOVING FORWARD

Efficiency:

Streamlined administrative processes and services that minimize response time and unnecessary administrative requirements

Organizational Effectiveness:

Accountability assigned to the most appropriate owners and responsible parties to strike an appropriate balance between investigator, study team, and IRB responsibilities

Compliance:

Policies, procedures, and systems will maintain compliance with federal and state regulations related to human subjects research.

High Service Levels:

The UNC OHRE will operate with a service orientation that emphasizes listening, understanding, and responding to the needs of the research community.

Data Transparency:

Clear and transparent performance metrics and measurable outcomes for research administration and management processes.

Edited from https://research.wisc.edu/research-compliance-and-ethics-oversight/irb-efficiency-project/irb-iep-goals/

Full Board Review Times

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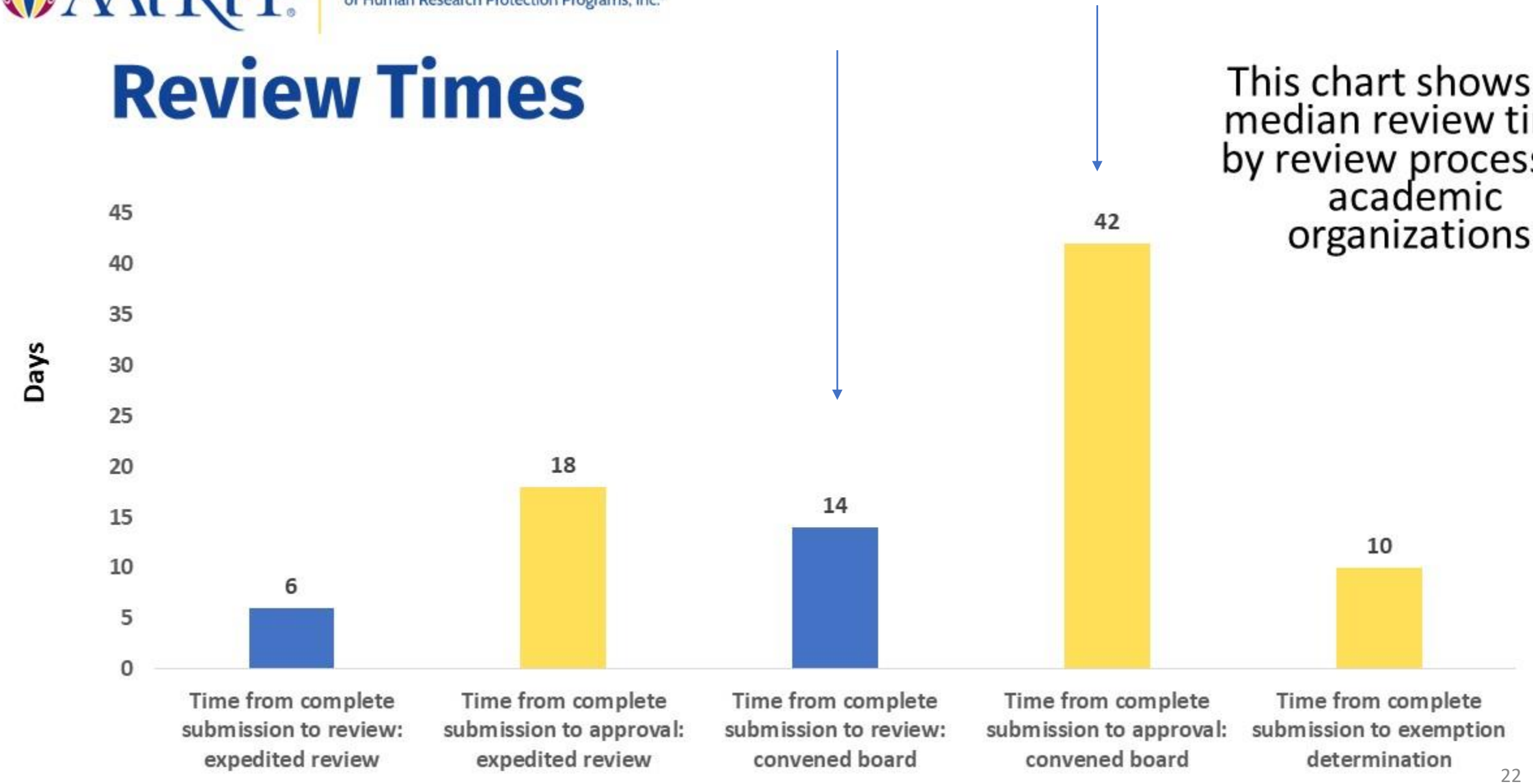
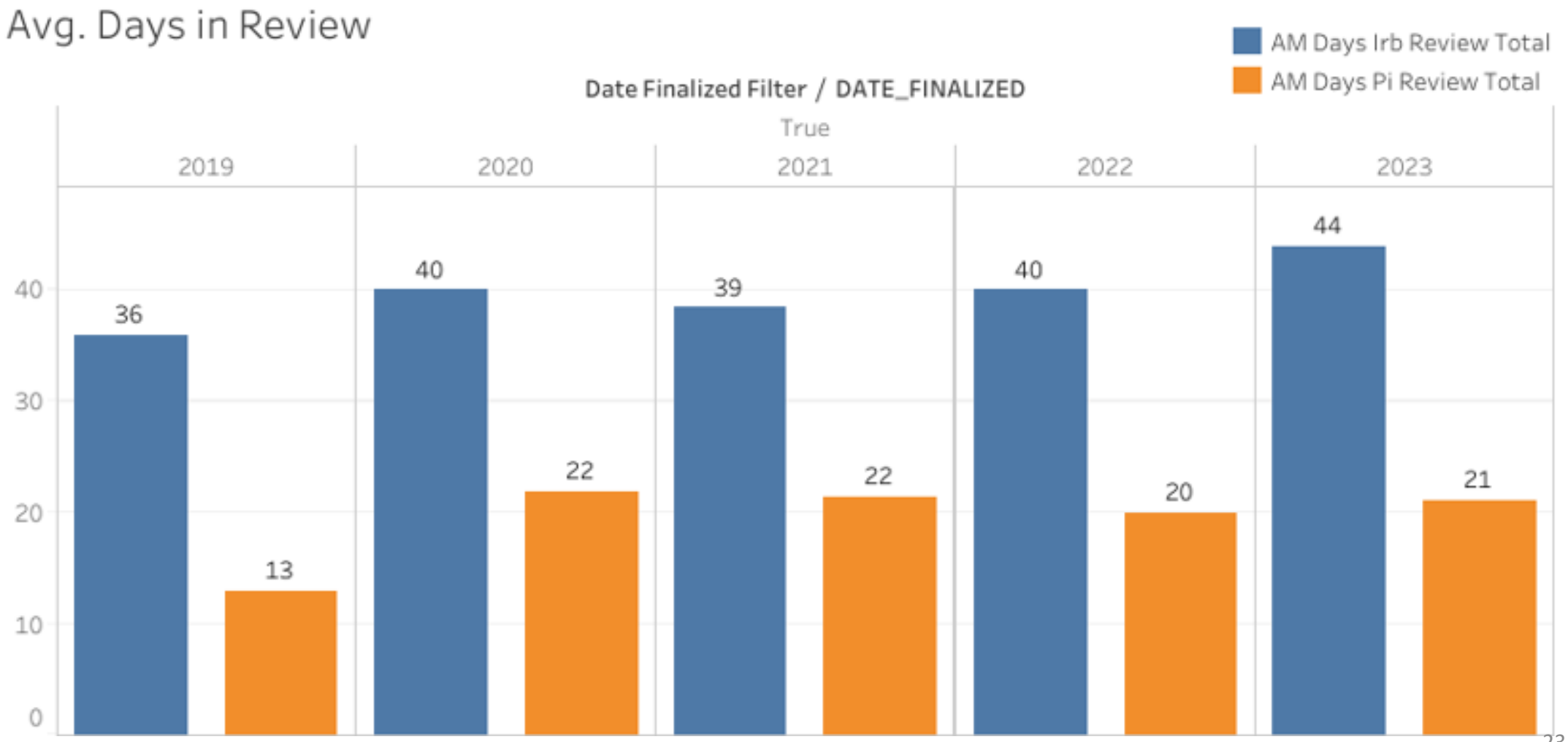
Review Times

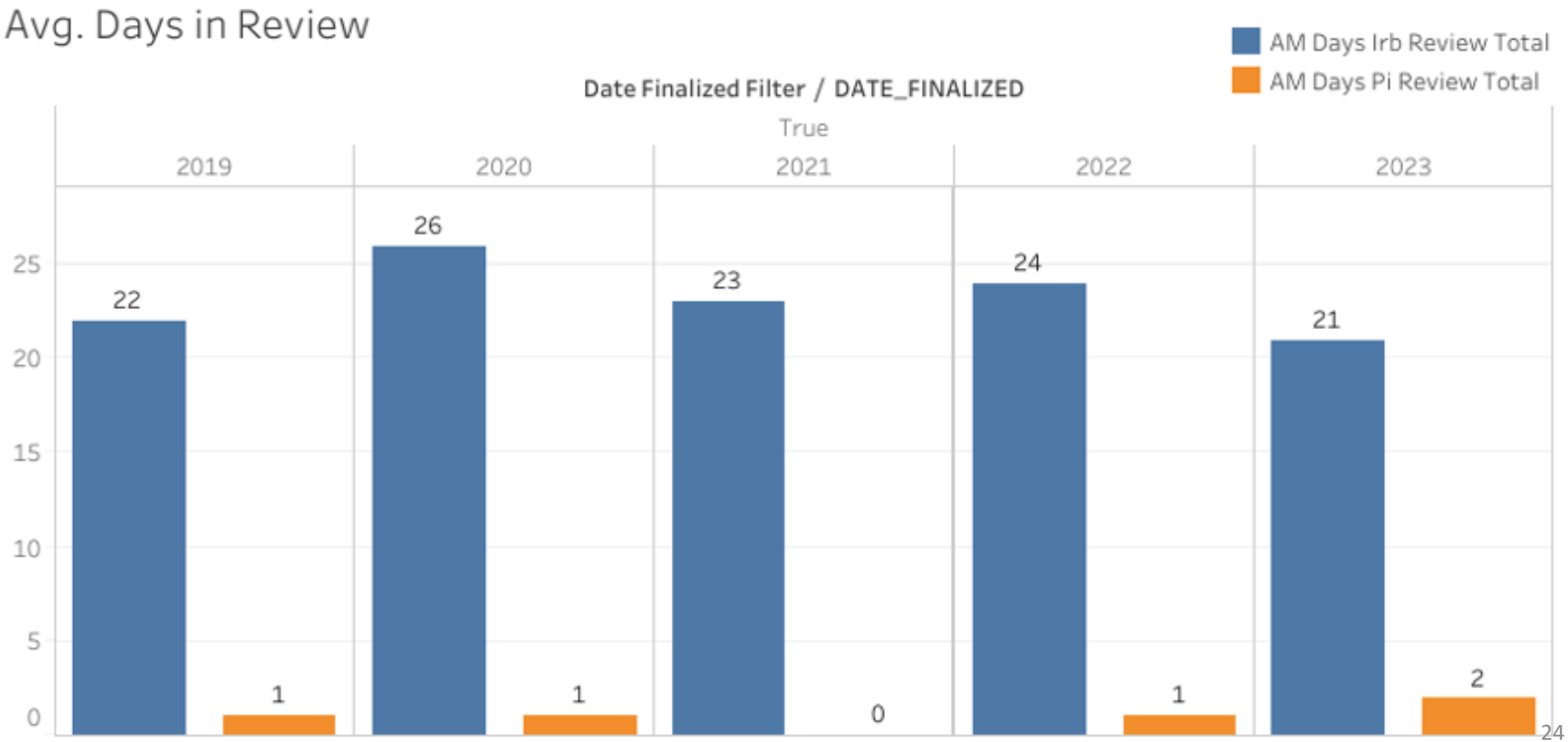


This chart shows the median review times by review process for academic organizations.

Initial Full Board Studies - Median



Renewal Full Board Studies - Median



Minimal Risk Review Times

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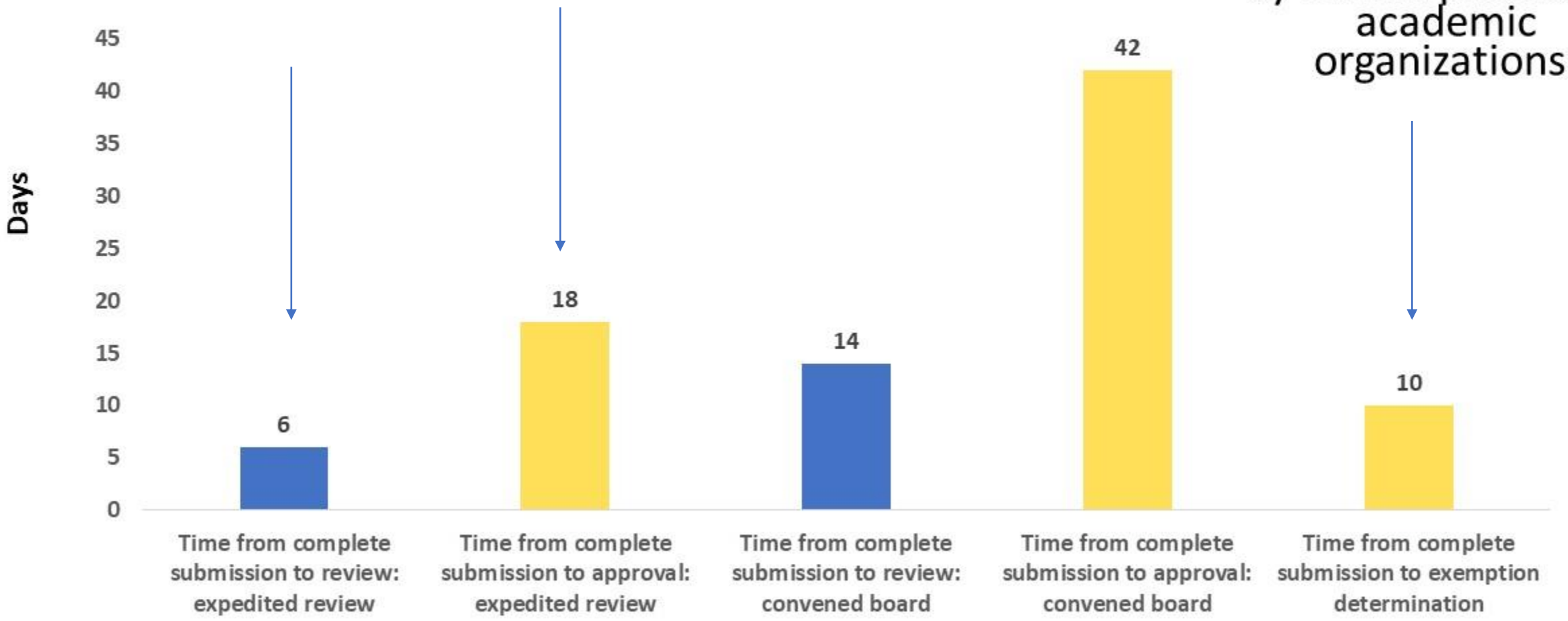
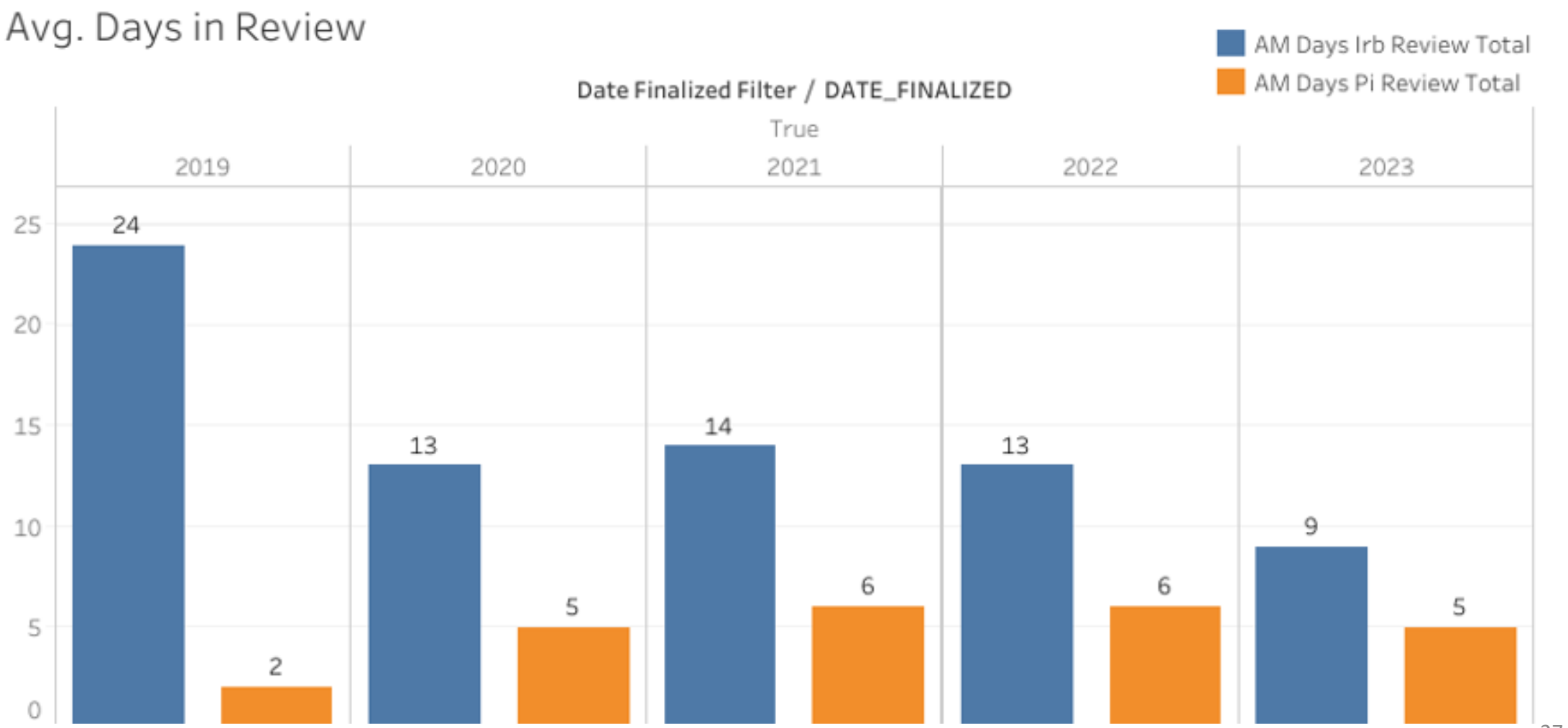
Review Times

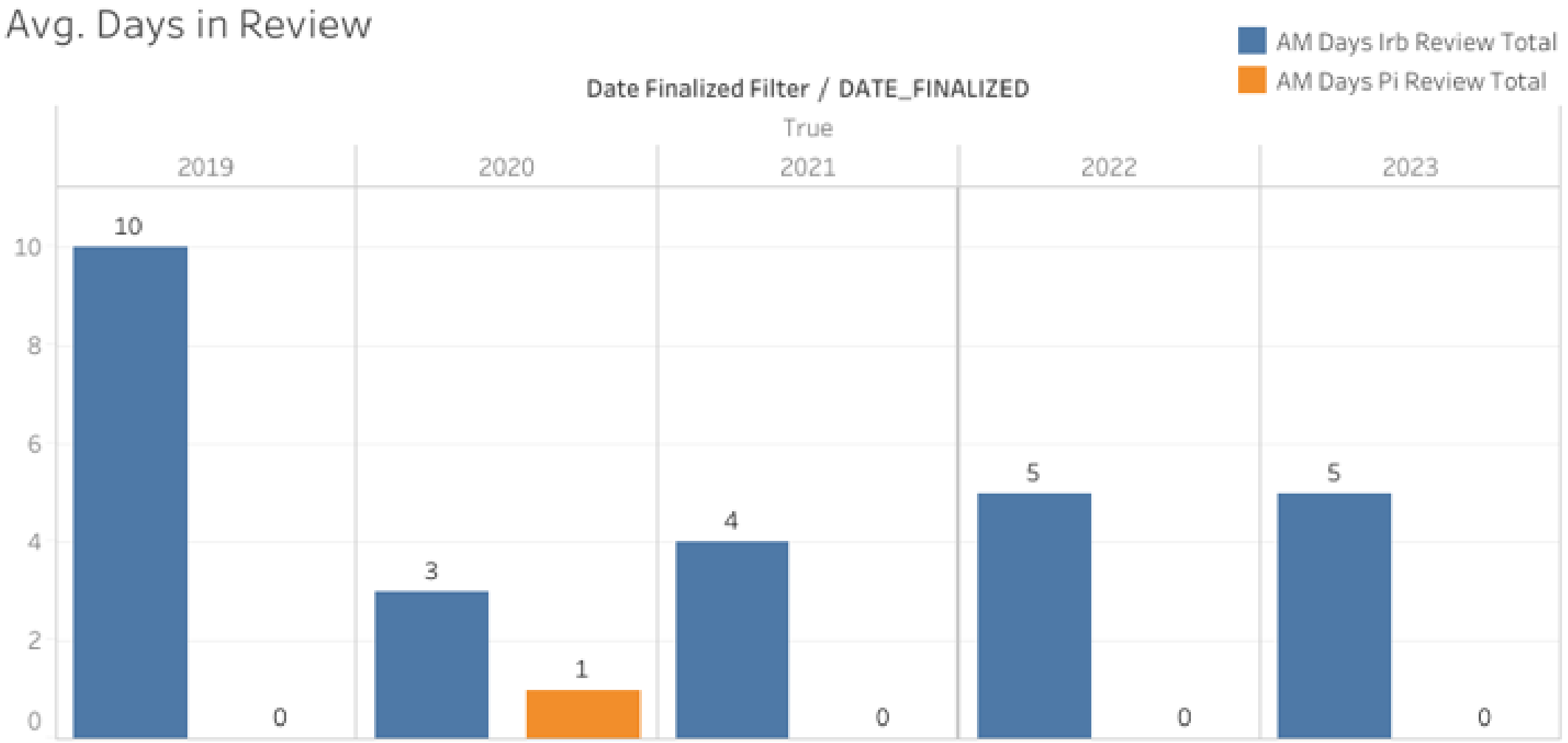
This chart shows the median review times by review process for academic organizations.



Initial Exempt/Expedited Studies - Median

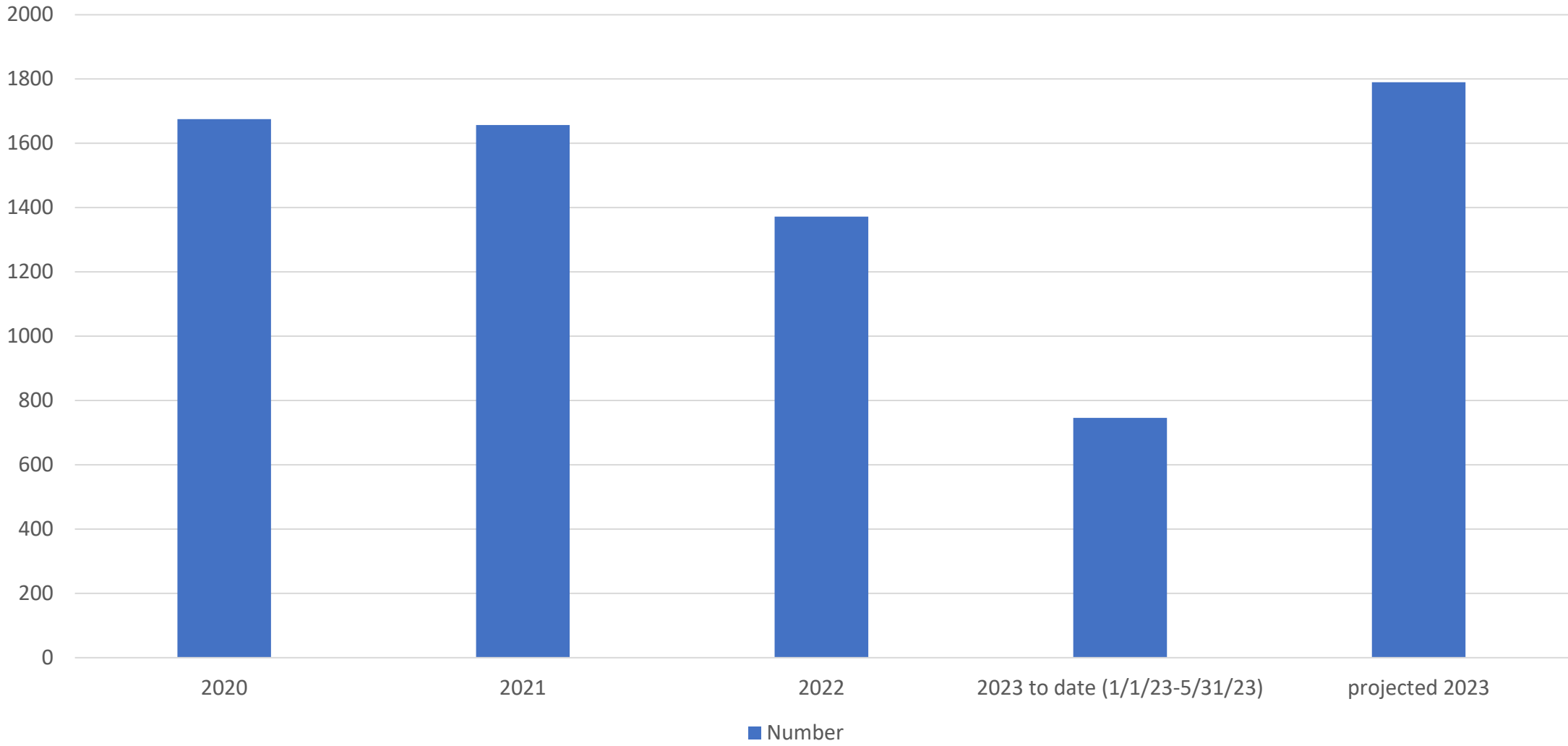


Renewal/Admin Review Expedited Studies - Median

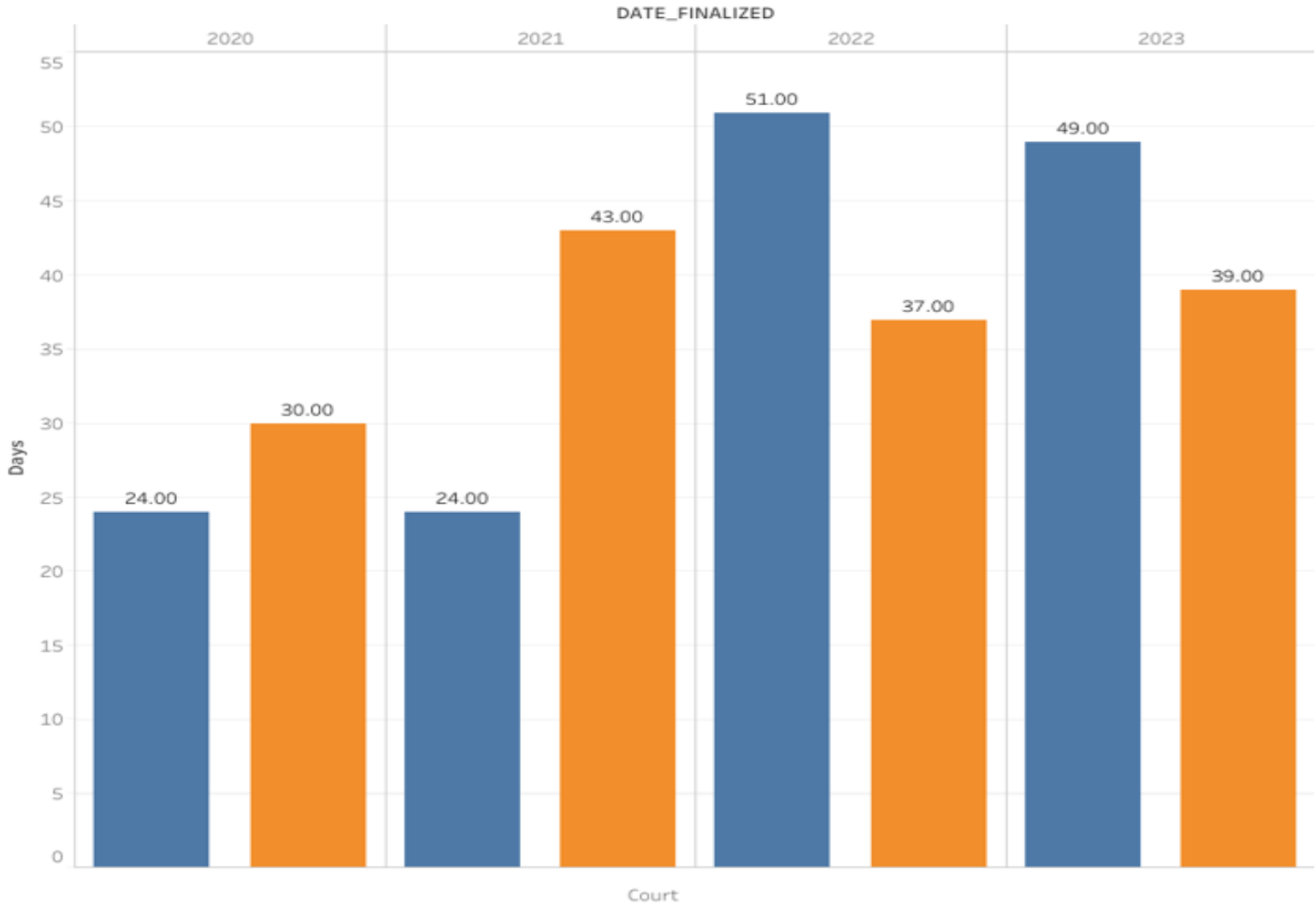


Reliance Metrics

Rely On External IRB Volumes- Total Reliance Submissions



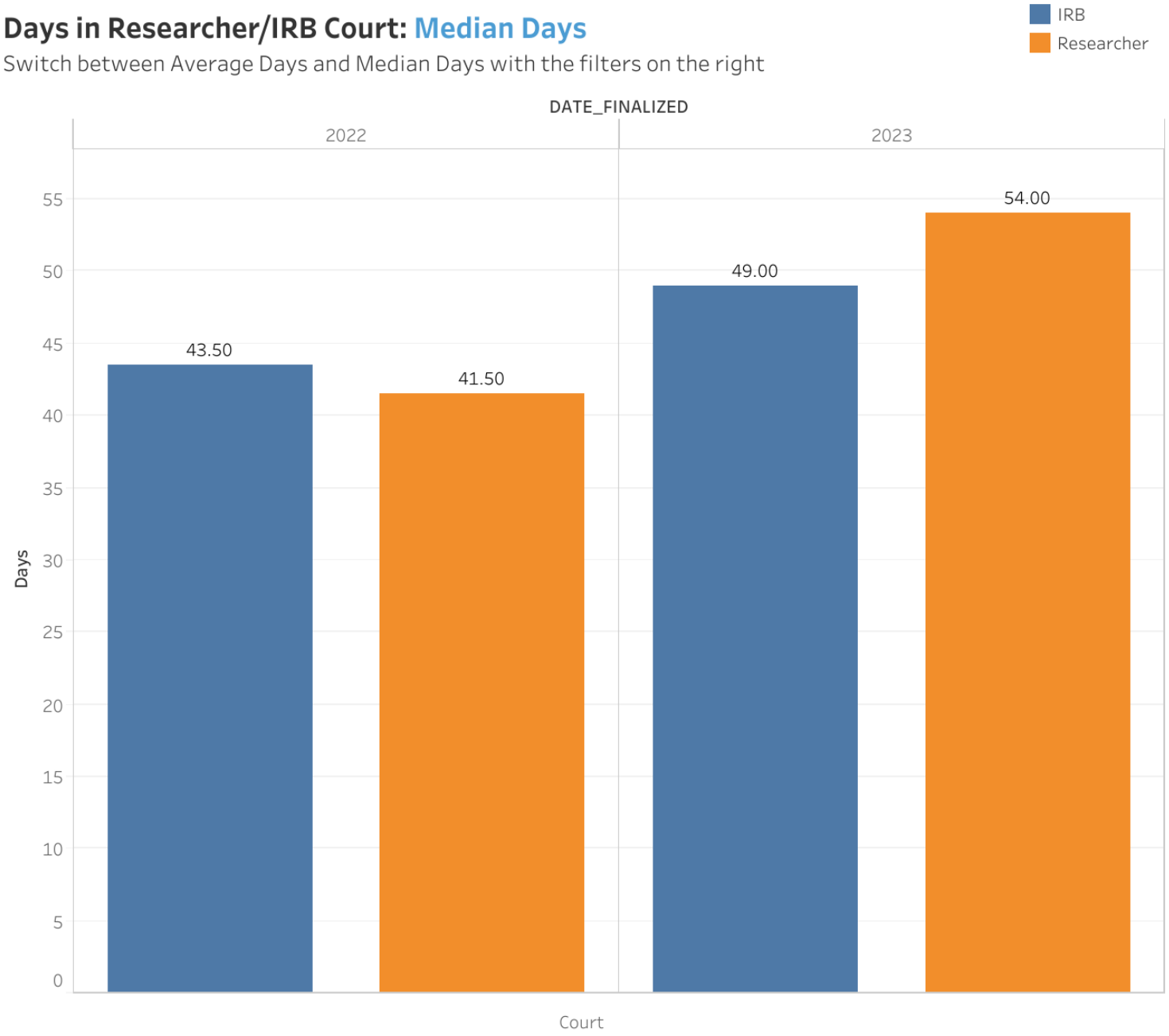
RELY ON EXTERNAL IRB (ALL)
Days in Researcher/IRB Court:
Median Days



AVG/Med Court Days

Days in Researcher/IRB Court: Median Days

Switch between Average Days and Median Days with the filters on the right



AM Court Days
Median

Past Years
2

RELY ON TYPE
Rely On Commercial IRB

SUBMISSION TYPE
Initial

PI NAME
All

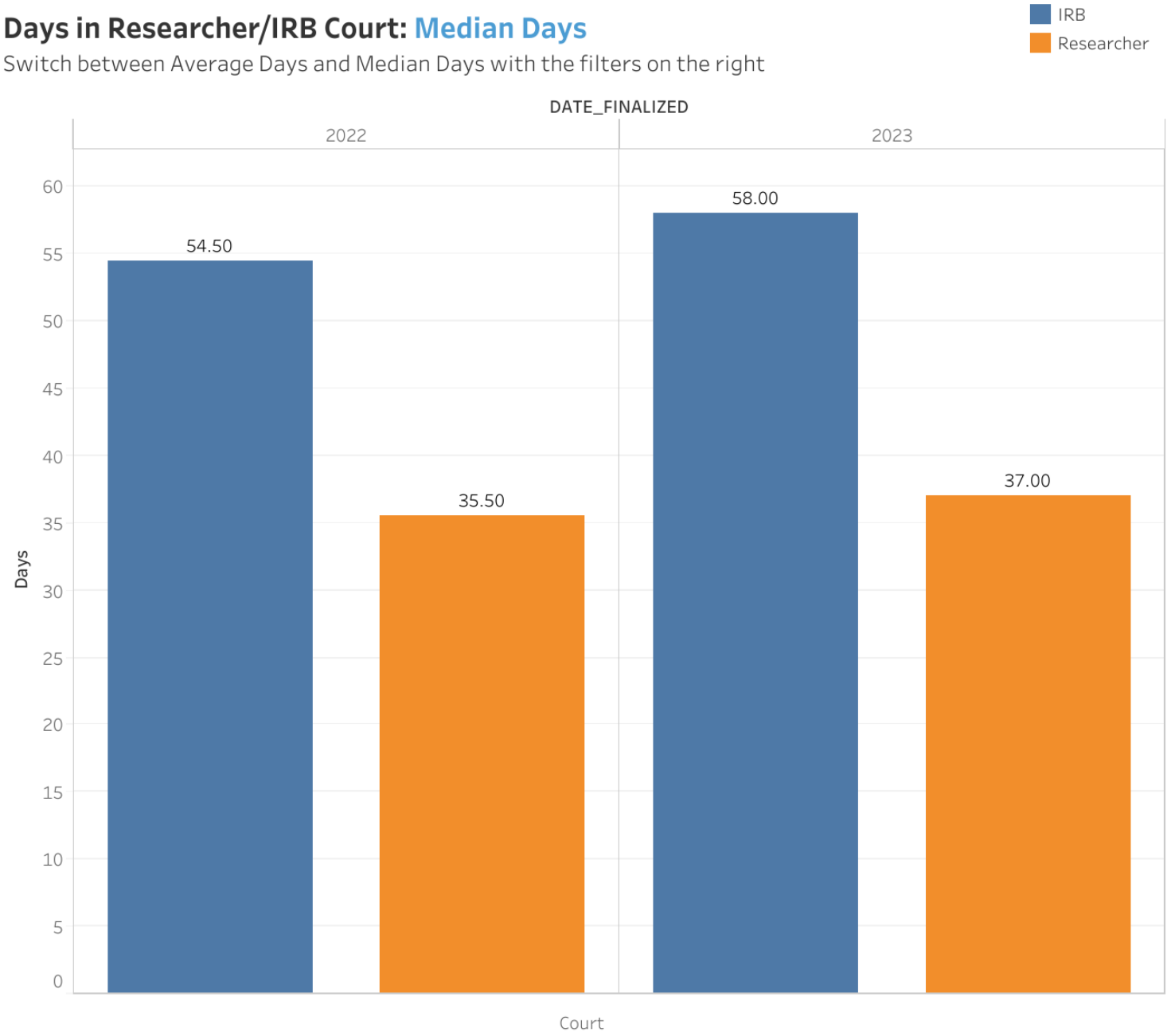
DEPARTMENT
All

ANALYST_NAME
All

AVG/Med Court Days

Days in Researcher/IRB Court: Median Days

Switch between Average Days and Median Days with the filters on the right



AM Court Days
Median

Past Years
2

RELY ON TYPE
Rely On Institutional IRB

SUBMISSION TYPE
Initial

PI NAME
All

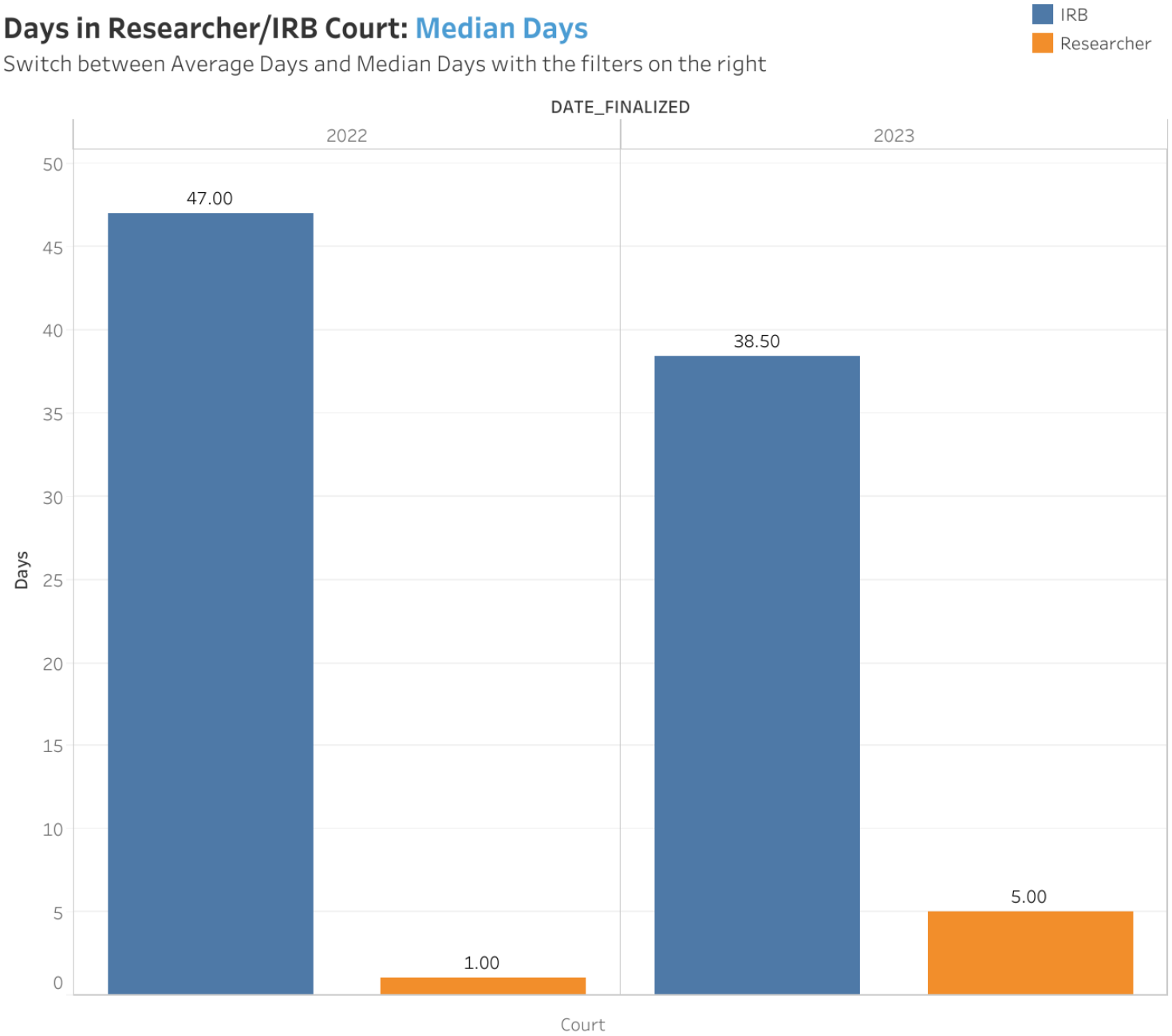
DEPARTMENT
All

ANALYST_NAME
All

AVG/Med Court Days

Days in Researcher/IRB Court: Median Days

Switch between Average Days and Median Days with the filters on the right



AM Court Days
Median

Past Years
2

RELY ON TYPE
Rely On NCI CIRB

SUBMISSION TYPE
Initial

PI NAME
All

DEPARTMENT
All

ANALYST_NAME
All

Additional Information on Reliance Data

- Previous slide includes only “RELY ON” reliance types (Commercial, Institutional, NCI) where UNC-CH is relying on another IRB
- This includes time that the study sits with UNC-CH IRB while an agreement is being executed or pending with another institution
  - Most delays arise when relying on other institutional IRBs
- Reliance team also handles onboarding external sites for which UNC-CH serves as the IRB of Record, each which take 2-6 hours per site
- UNC IRB is serving as the sIRB for over 419 studies and approximately 368 other sites

Addressing the delay time in review

- Hiring 2 FTEs for reliance analysts (1 is a new additional position)
- Since August 2022, brought on 1 consultant to help with reliance
- Brought on another 2 consultants to help with reliance in June 2023
- IRB Analysts and leadership are also helping with reliance submissions
- Developing researcher request form for UNC-CH to serve as sIRB
- Creating guidance documents to assist researchers in submissions
- Improving IRBIS platform for reliance processes
- Developing specific IRBIS admin mod to add external sites
- Saying no to serving as the sIRB for multi-site studies

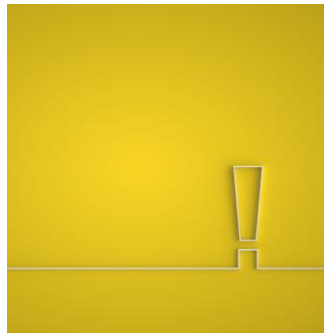
It takes a village!

Commonly seen issues with submissions

- CITI Training – required every 3 years
  - This should NEVER be a stip
- COI disclosure – as soon as the initial application is submitted, disclosure should be completed by all key personnel. Researchers also get notified to complete 45 days in advance of CR or Admin Review.
- Remove personnel in real time if they are no longer on the study so that renewals are not held up for their COI or CITI
- Congruency between application and supporting documents
- No Response to IRBIS questions – type N/A if not applicable
- Supporting Materials not included (data collection instruments, recruitment materials)
- Consent forms written higher than 8th grade reading level (use Flesch-Kincaid Grade Level test)
- Details are important!
  - Mods: please provide a very robust description of the change AND why. State specifically the document or section of the application that is being changed AND make the changes to the document/app.
- Consider the IRB reviewer a reasonably educated person, NOT a clinician
  - Write the IRB application using simple lay language and well-described concepts.
  - Be sure to define scientific and clinical terminology.
  - Clarify research procedures vs. SOC

Tips when submitting “Rely On” applications

- Submit the external IRB approval letter, as applicable (ex: multisite study with sIRB approval)
  - Will need to submit the approval letter specific to UNC to get final UNC IRB clearance
  - Mods and renewals: submit approval letter from the IRB of record specific to the Modifications and/or renewals
  - Know what modifications must be submitted to UNC-CH IRB
  - Closures: submit the closure letter from the IRB of record
- COI: If there COI management language for consent, must be implemented in consent sent to sIRB and sIRB should be alerted to this and given the COI management letter with the sIRB submission
- HIPAA: State where the data will come from and why it is needed, as well as the exact data points to be utilized
  - In some cases, the other IRB will serve as the Privacy Board. In some cases, the UNC will serve as the Privacy Board. It depends on the individual agreement.
- SIL language: If there are any changes to the standard language, signoff for the revised language must be included with the IRBIS app and for industry sponsored, will always be signoff letter
- UNC-CH IRB still have oversight of the CONDUCT of the research by UNC researcher



Tips when UNC may serve as sIRB

- Contact UNC OHRE Reliance Team early to discuss (get Letter of Support from OHRE when preparing grant!)
- Don’t assume the UNC IRB will serve as sIRB; there are multiple factors that are taken into consideration
- Discuss with collaborators to ensure their institutions are willing to rely or if their IRB wants to serve as the sIRB
  - Agreements can take a long time!
  - Other modifications cannot be submitted while a mod is open to execute an agreement
- If UNC agrees to serve as IRB of record, get initial approval for the UNC site first then add other sites as solo modifications
- If you are adding or updating external sites, please list the name of the site and the action you are requesting, whether it is to activate the site or update site materials or personnel
- **All** external sites need to complete the Local Context worksheet
  - Download the worksheet from Section 5, share with the other sites, and once complete, attach to submission
- Understand your responsibility when UNC is serving as the IRB of Record; you may need one FTE dedicated to facilitating communications between the UNC-CH IRB and UNC site, and communications with other IRBs and collaborators, and to manage regulatory requirements

Looking Forward

External Initiatives

- Improved researcher dashboard with swim lanes to view study statuses (DONE!)
- Email platform integrated into IRBIS (in process)
- Ticketing service for questions for improved tracking and response times (in process)
- Review of Unencrypted Communications guideline for recruitment (in process)
- Researcher satisfaction survey to be sent with outcome letter (in process)
- Revised OHRE/IRB website (in process)
- Educational resource library being built (in process)
- Return of open office hours – late summer
- Listening sessions with research community – fall 2023
- Increased transparency in turnaround times – fall/winter 2023
- Consent form overhaul – long term 2023-2024 project
- IRBIS Application revisions – long term 2023-2024 project
- COI improvement process with UNC Health (ONE UNC)
- NOT YET IMPLEMENTED: Considering stopping the verification of CITI training at CRs and Admin Review. **NOTE:** policy still exists for completion, but up to the research team to ensure compliance! (in process).

Assessment of IRBIS application and project plan for improvement

Create

Recent Internal Initiatives

- Designated phone lines for all OHRE staff
- More robust pre-review prior to full board assignments to reduce deferrals
- Utilization of SMART IRB for reliance to simplify process
- Amended Statement of Work contract with WCG to cover all research types (in process for Advarra)
- IRB Chair and IRB Member evaluations
- New IRB member form interest form online
- “Work smarter, not harder”

IRB committees and meetings

Roster revisions to permit more flexibility in member substitutions	Focus on increasing diversity	Increased representation from vulnerable populations representatives	Additional alternate members
Member self-evaluation and identification of training needs	Improved communications methods to members from OHRE office	Ongoing monthly member training	Additional worksheets as reference materials

Challenges

Challenges: To Be Addressed

- Data reliability from IRBIS and across research infrastructure
- Work volume and staffing
  - Takes time to train and change course
- Taking time to find out the “WHY”
- Consistency in reviews– many different types of research, OHRE staff with different backgrounds, research with UNC Health has own policies
- OHRE responsibility for areas outside our purview (COI disclosures)
- Reliance – working with many different institutions with different ways of doing things, volume
- Noncompliance of research teams
- Differing priorities: Researchers concerned with turnaround times vs effectiveness of IRB review

Discussion

Contact Information

Website:

https://research.unc.edu/human-research-ethics/

Staff contact information:

https://research.unc.edu/human-research-ethics/about/staff/

General questions: irb_questions@unc.edu

Reliance questions: IRBReliance@unc.edu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