OHSRP Town Hall

August 29, 2024

NIH Office of Intramural Research
Office of Human Subjects Research Protections

Agenda

- Intro and Review of translation policy and preview of new policy on enrolling AI/AN persons in IRP research – Jonathan Green
- Other policy review – Heather Bridge
- IRBO metrics and updates – Tiffany Gommel
- PROTECT and website update – Nicole Grant
- Q and A – everyone

Policy goals

- Ensure all persons that enroll in research conducted by the NIH IRP receive information in their preferred language
  - Fairness
  - Equity
  - Inclusion
- Compliance with Common Rule and FDA requirements for informed consent.

Translation requests to NIH library

Requests by group

IC/Agency	Mar	Apr	May	Jun	Jul	**Total**
CC			1	1		**2**
NCI	12	10	15	3	28	**68**
NEI	7	2	4		1	**14**
NHGRI	2	3	6	3	2	**16**
NHLBI	13	11	5	3	6	**38**
NIAID	6	16	7	4	4	**37**
NIAMS	13					**13**
NICHD	1	1	1	2	1	**6**
NIDCR	3		2	1		**6**
NIDDK	12	2	12	4	3	**33**
NIMH		1		1		**2**
NINDS	2	9	3	2	2	**18**
Total	**71**	**55**	**56**	**24**	**47**	**253**

Average cost: $639/ consent
Average length: 4,707 words

Number of consents translated by language

July 2024

Translation From and To w/ Other	Requests	Word Count
English to Spanish	16	98320
English to Arabic	5	33779
English to Vietnamese	4	36466
English to French	3	4399
English to Korean	3	7210
English to Portuguese	3	14696
English to Nepali	2	26989
English to Romanian	2	17761
English to Amharic	1	5071
English to Chinese	1	
English to Chinese (traditional)	1	
English to Dari	1	
English to Hindi	1	4549
English to Russian	1	4739
English to Simplified Chinese - Mandarin	1	14623
English to Somali	1	
English to Urdu	1	
Total	**47**	**268602**

June 2024

Translation From and To w/ Other	Requests	Word Count
English to Arabic	8	20334
English to Spanish	8	45160
English to French	2	15130
English to Nepali	2	
English to Amharic	1	3036
English to Chinese	1	
English to Chinese - Mandarin	1	25467
English to Farsi	1	3777
English to Hindi	1	9450
English to Mongolian	1	7803
English to Portuguese	1	
English to Romanian	1	
English to Serbian	1	7063
English to Urdu	1	10179
English to Vietnamese	1	
English to Wolof	1	5218
English to Xhosa	1	2746
Total	**33**	**155363**

Translation Turnaround Times

Translation	Days
English to Afrikaans	9
English to Amharic	9
English to Arabic	11
English to Bengali	6
English to Cantonese	9
English to Chinese	9
English to Chinese - Mandarin	14
English to Chinese (simplified) Mandarin	10
English to Chinese Traditional	8
English to Czech	12
English to Farsi	9
English to French	8
English to German	15
English to Gujarati	16
English to Hebrew	15
English to Hindi	10
English to Indonesian	8
English to Italian	12
English to Korean	8
English to Krio	4
English to Mongolian	11
English to Nepali	11
English to Pashto	27
English to Polish	14
English to Portuguese	10
English to Romanian	11
English to Russian	9
English to Serbian	11
English to Simplified Chinese	14
English to Spanish	11
English to Swedish	11
English to Tagalog	8
English to Thai	9
English to Turkish	8
English to Twi - Asante	10
English to Ukrainian	14
English to Urdu	7
English to Vietnamese	7
English to Wolof	6
English to Xhosa	8
English to Yiddish	8
Overall Average	**10**

Great job NIH Library!

To the investigators and study teams of the intramural program

Enrolling AI/AN persons in IRP research

- Sovereign nation within the US
- Laws and culture should be respected
- History of exploitation in research
- NIH has not always done this well

Policy Workgroup

- OHSRP
- Tribal Health Research Office (THRO)
- Investigators/study teams
- IC leadership
- Office of Science Policy
- Others

Purpose of the policy

- To describe the additional protections and considerations that apply when conducting or reviewing NIH IRP research that enrolls AI/AN persons or uses samples/data collected from AI/AN persons.
- To ensure that Tribal sovereignty is respected, and measures are taken in the design, implementation, and review of the research to promote community-based protections and to mitigate the potential for group harm, while also recognizing the autonomy of individuals who choose to enroll in research, including that expected by the Common Rule (45 CFR 46).
- These measures are in addition to the protections afforded by the Common Rule (45 CFR 46), other applicable laws and NIH policies.

DRAFT

Scope/Applicability

- Exempt, non-exempt and some NHSR if:
  - the research is likely to include AI/AN communities and/or persons,
  - make inferences about AI/AN populations or communities
  - or will use data and/or biospecimens in secondary research that are known to have been collected from AI/AN persons and the secondary research will make inferences about AI/AN populations or communities.
- For example
  a. Any aspect of the research, including recruitment, takes place entirely or in part on tribal land.
  b. The research will intentionally recruit AI/AN persons as participants and/or AI/AN populations are the focus of the research.
  c. Secondary research using data and/or biospecimens known to have been collected from AI/AN persons that were originally collected for other purposes and will make inferences about AI/AN populations or communities.
  d. Secondary research using data and/or biospecimens that were originally collected on Tribal land is subject to this policy, regardless of the aims of the secondary research.

DRAFT

Scope/Applicability

- This does not include research that may incidentally include AI/AN persons as part of the research, if not intentionally recruited as participants, and the research will not make inferences about tribal communities or populations.
- Nothing in this policy is intended to prevent AI/AN persons from being considered for enrollment in NIH Intramural research for which they are otherwise eligible.

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Draft policy in a nutshell

- Any protocol subject to the policy needs to be looked at by THRO
- THRO will provide written recommendations as to whether tribal engagement is needed and will facilitate.
- When Tribal authority approval is required by the tribe, this must be obtained and submitted to the NIH IRB. This could be Tribal government approval or a designated research review board.
  - NIH IRB will not approve without this.
- If not subject to the single IRB policy, and Tribal IRB review is required, this must be obtained and approval submitted to the NIH IRB
  - NIH IRB will not approve without this.
- If subject to the single IRB policy, and the tribe requests Tribal IRB review, this must be obtained and submitted to the NIH IRB, which will incorporate the review into its local context determinations.
- NIH review will be by an IRB panel with a majority of AI/AN members.

DRAFT

Goal

- Engage with Tribal communities throughout the research lifecycle.
- Conduct and review research in an ethical and culturally sensitive manner.

AI/AN Policy Implementation

- Policy is under final review
  - Hope is to publish Fall 2024
- Implementation is for new research following the effective date of the policy
  - Will apply to existing research when it is modified such that it becomes subject to the policy
- There will be an OHSRP Education Session dedicated to this policy and accompanying guidance from the IRB

Policy Updates – Triennial Review of Policies

- **What:** OHSRP must review its entire policy series on a regular cycle (at least every 5 years)
- **When:** Due to accreditation cycle, we start our reviews at year 3 (Summer 2024)
- **Why:** Because it is required by NIH policy, and to see if:
  - The policy is still needed
  - Any changes are needed
- **What to expect:**
  - Most policies will only have minor technical changes (link removal/fixes, formatting or grammatical fixes)
  - Some policies will have minor policy changes (Partial Revisions)
  - Look for descriptions of policy changes in our newsletter and/or by eblast for major or time-sensitive policy changes.

IRBO Metrics & Updates

Tiffany Gommel, MS, CIP

Director, IRBO

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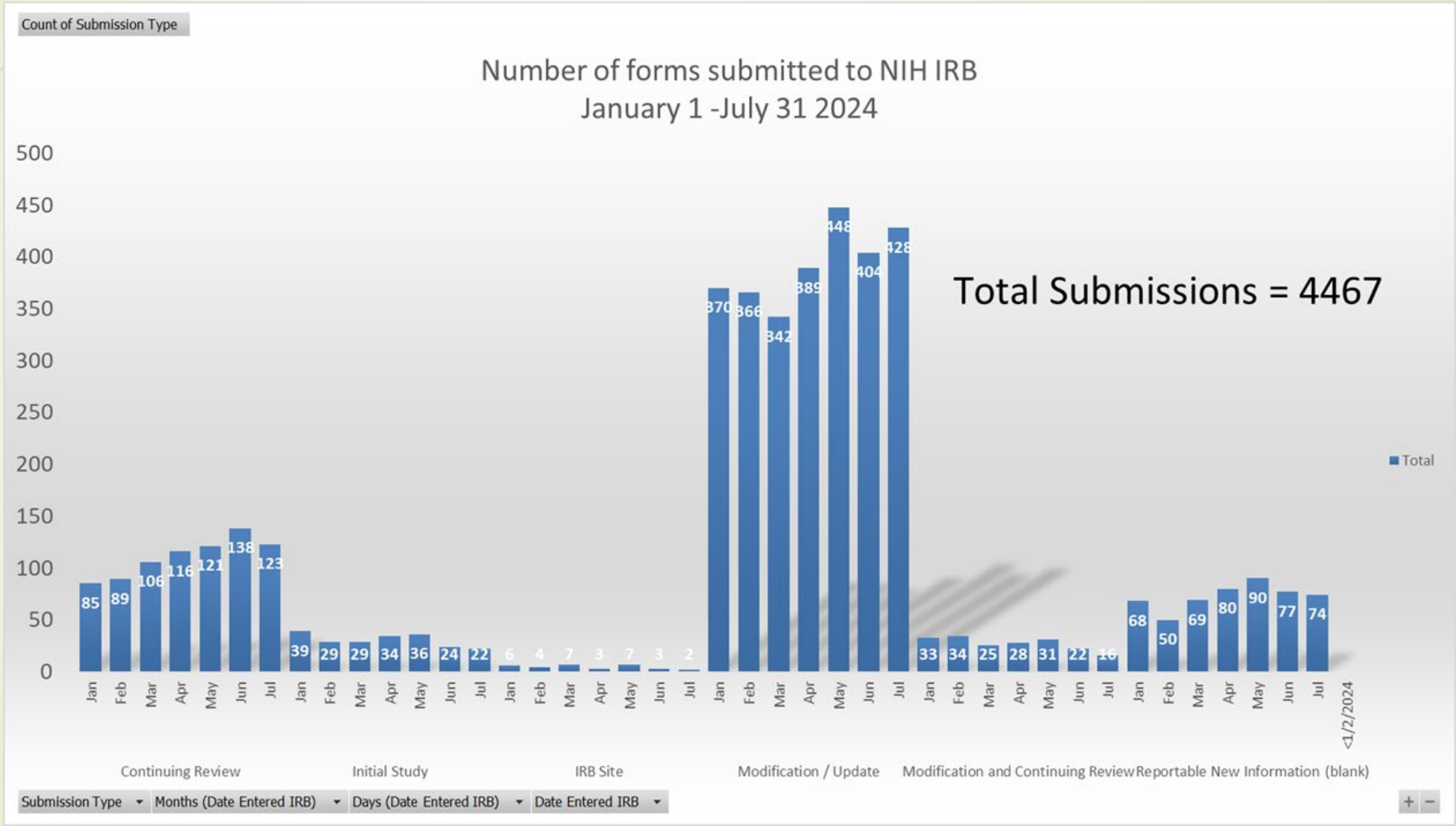
Office of Human Subjects Research Protections

Submissions to NIH IRBO



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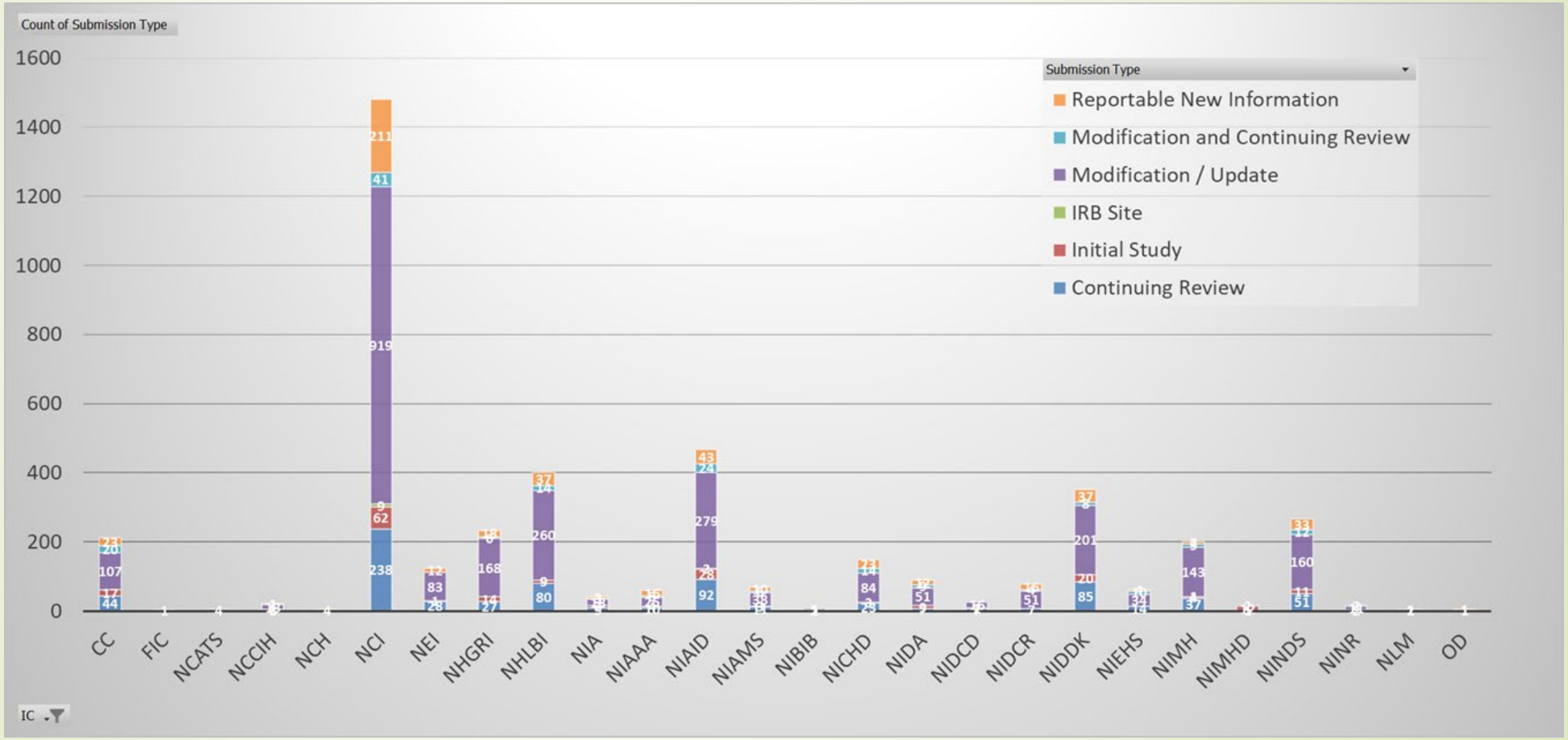
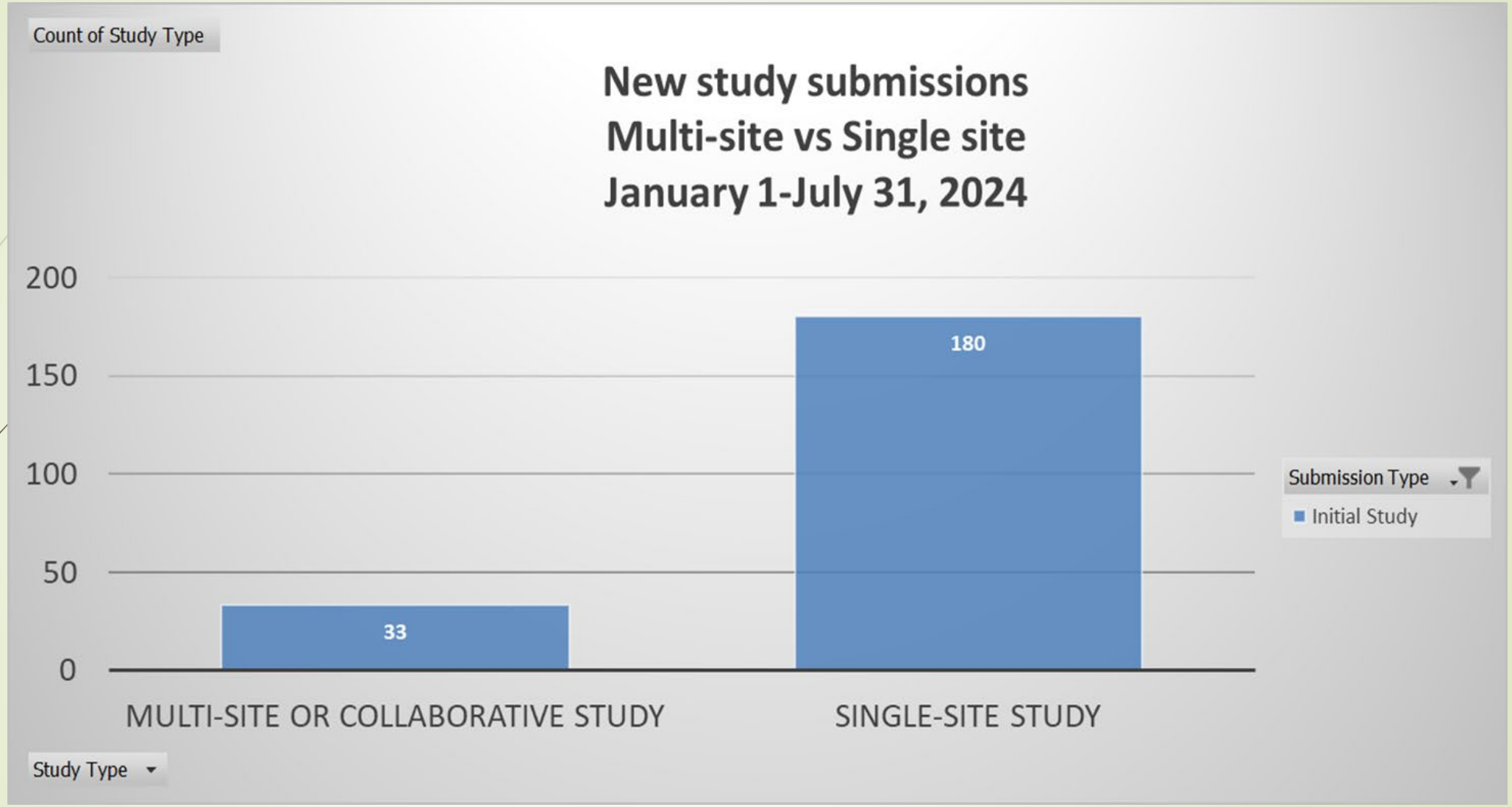
Submission of form types by IC January 1 – July 31, 2024





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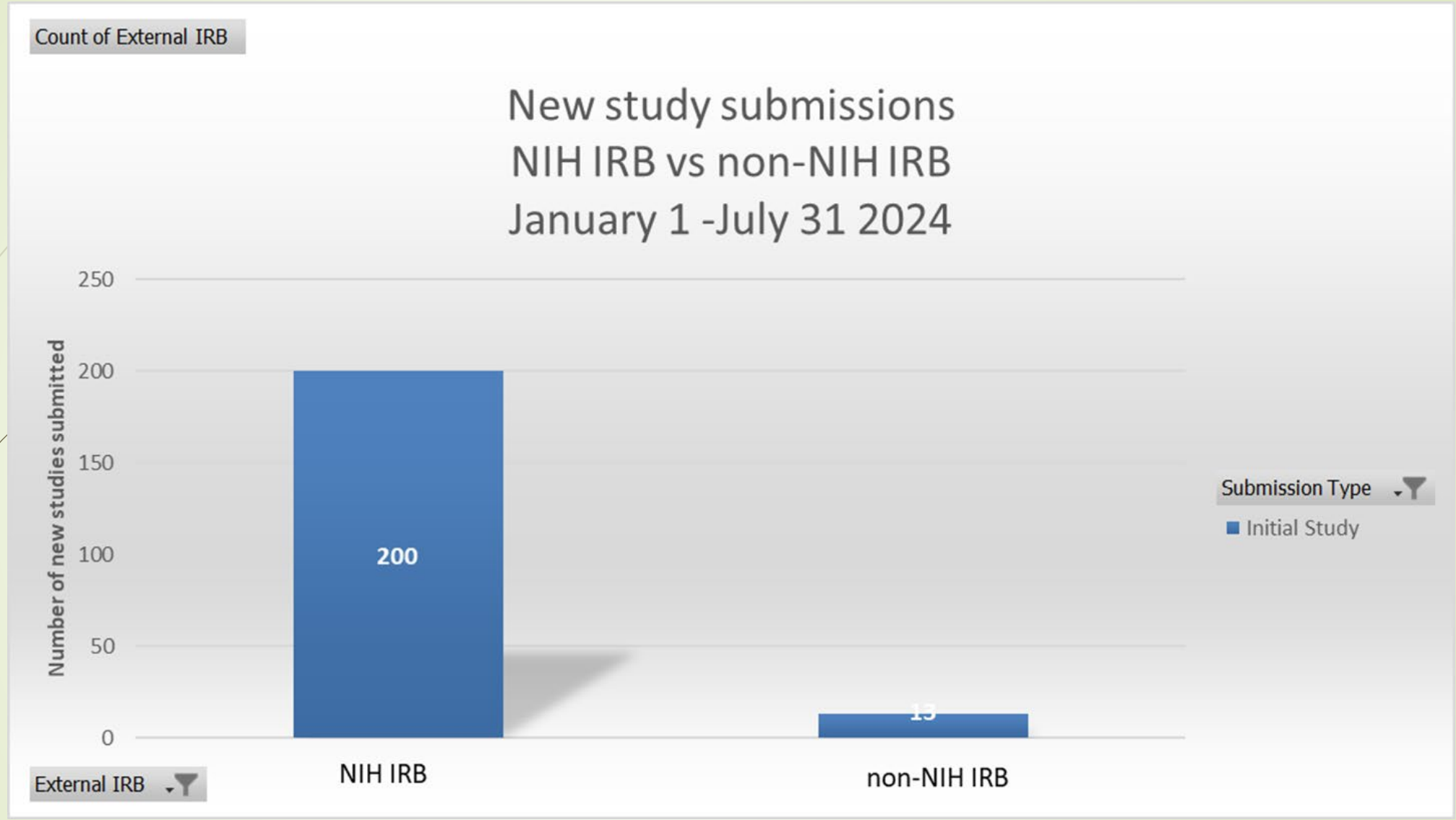
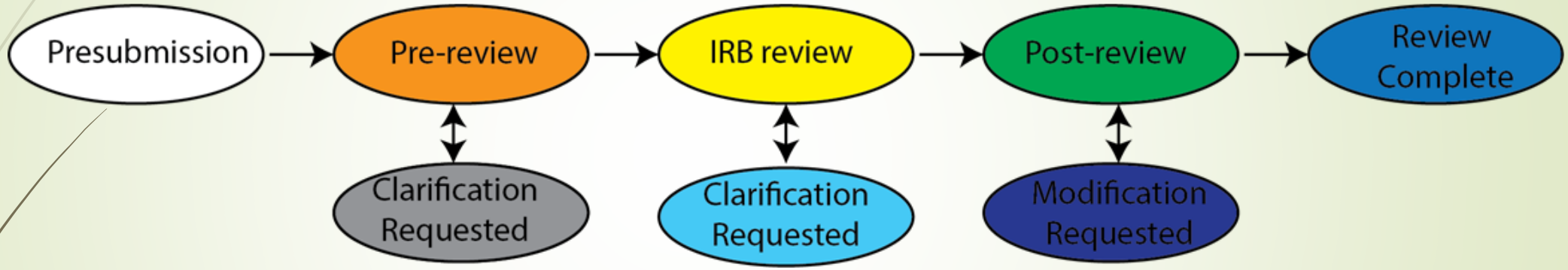
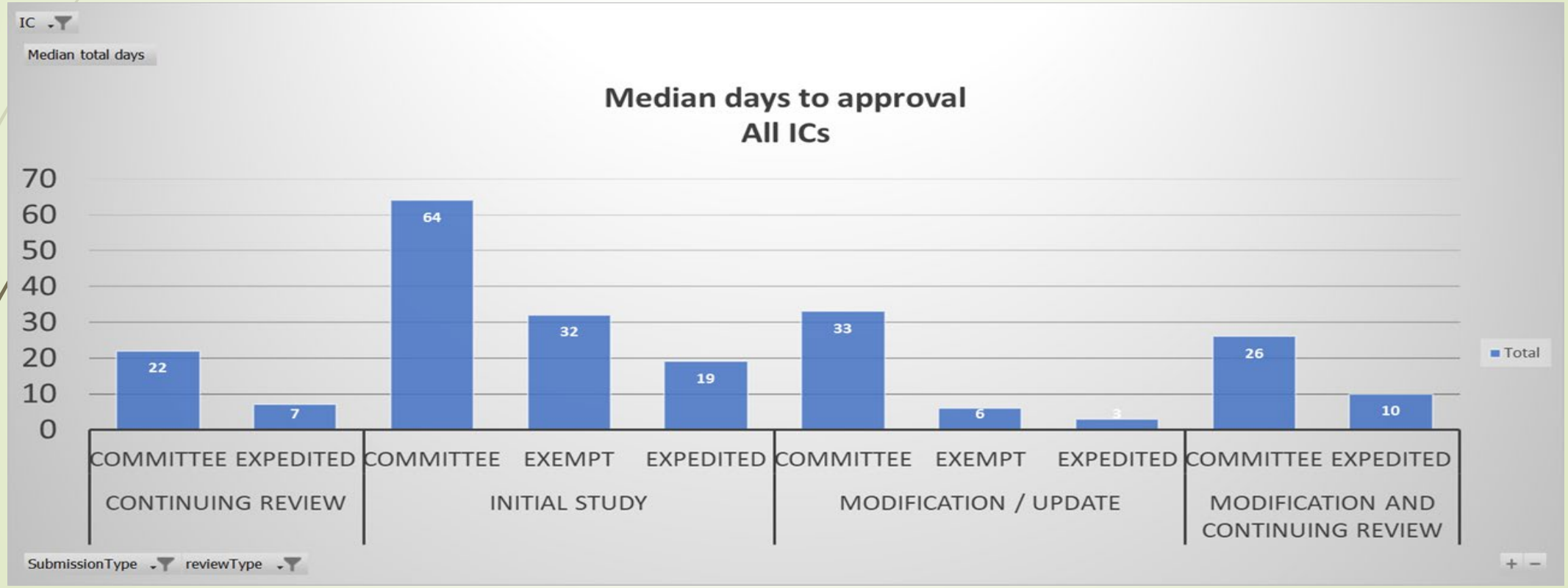

Count of External IRB
New study submissions
NIH IRB vs non-NIH IRB
January 1 -July 31 2024
250
200
150
100
50
0
Number of new studies submitted
200
13
NIH IRB
non-NIH IRB
External IRB
Submission Type
Initial Study

IRB review intervals/workflow



Median days to approval All NIH Jan 1- July 31, 2024



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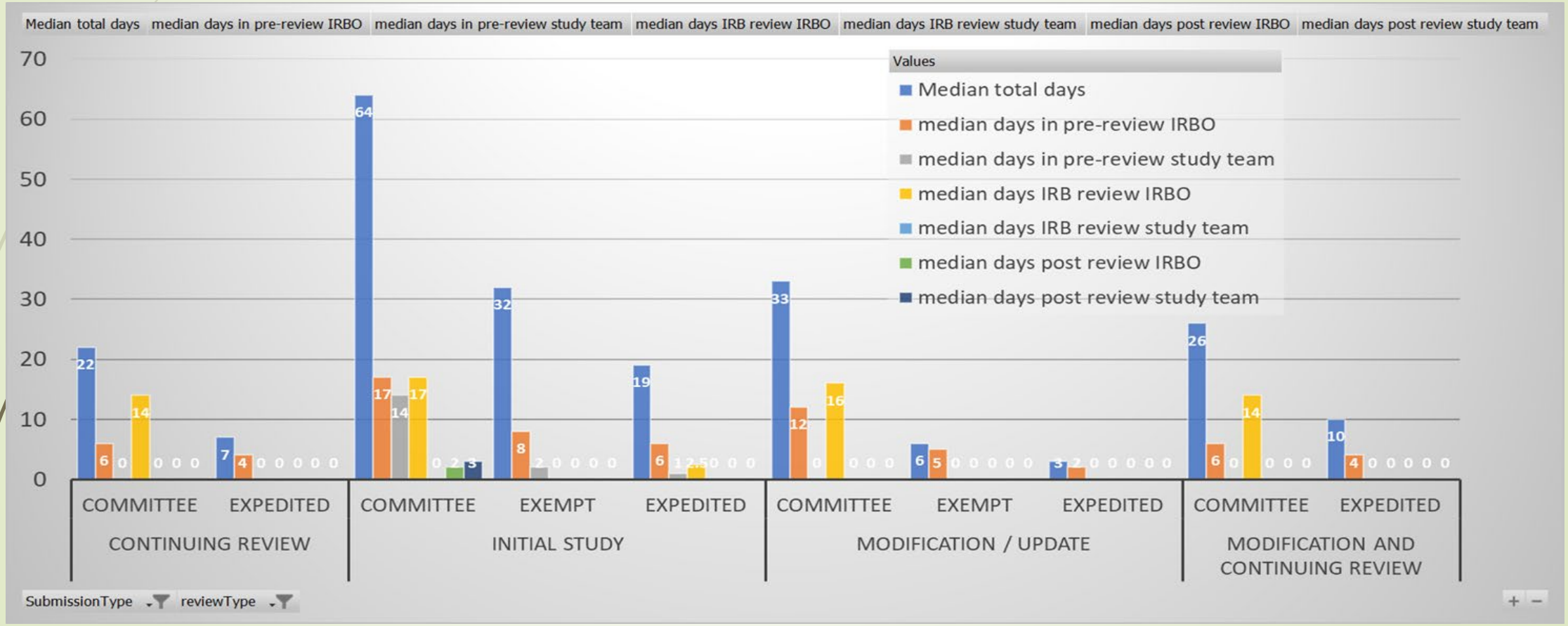
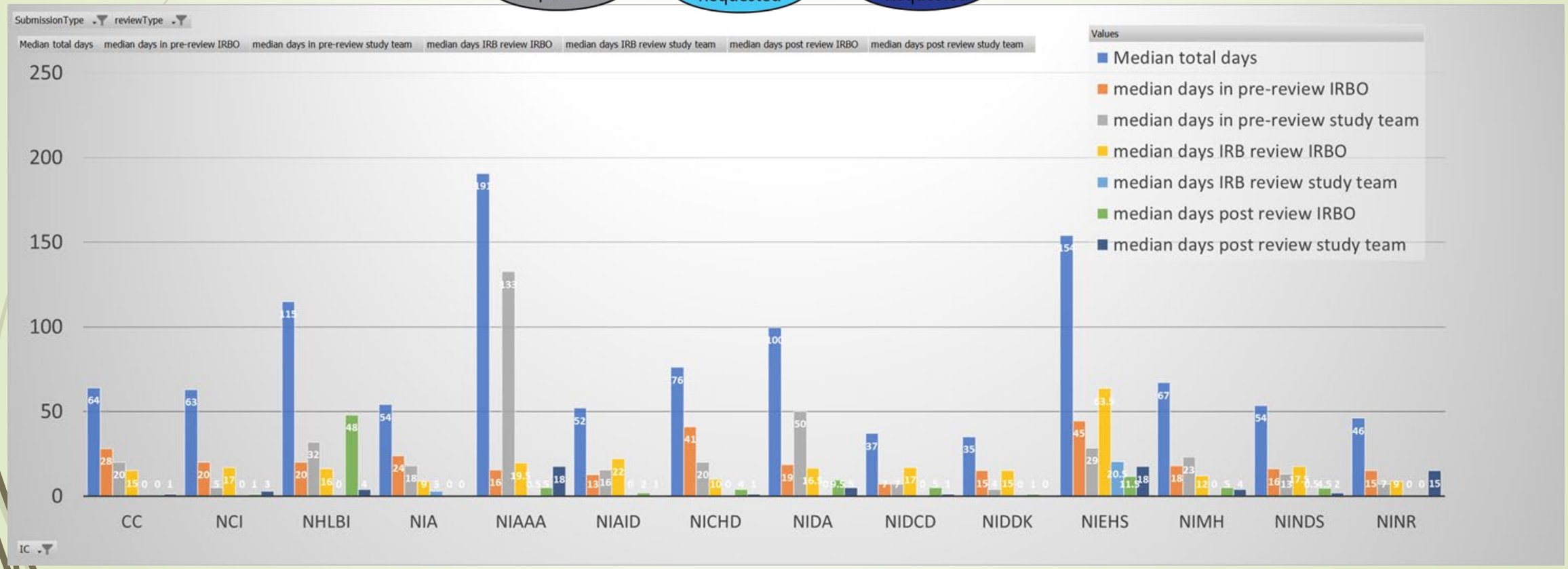
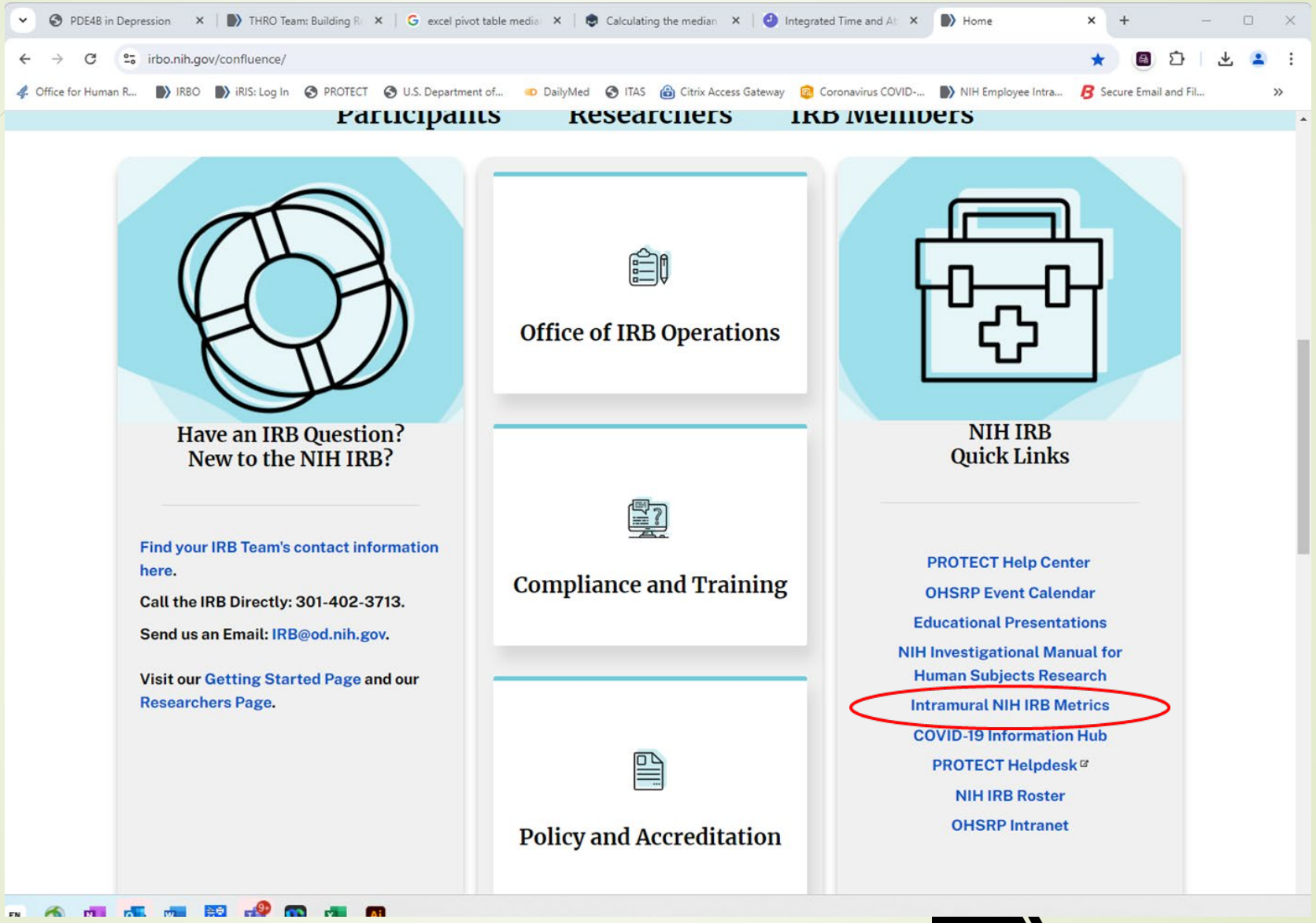
Review intervals – all NIH

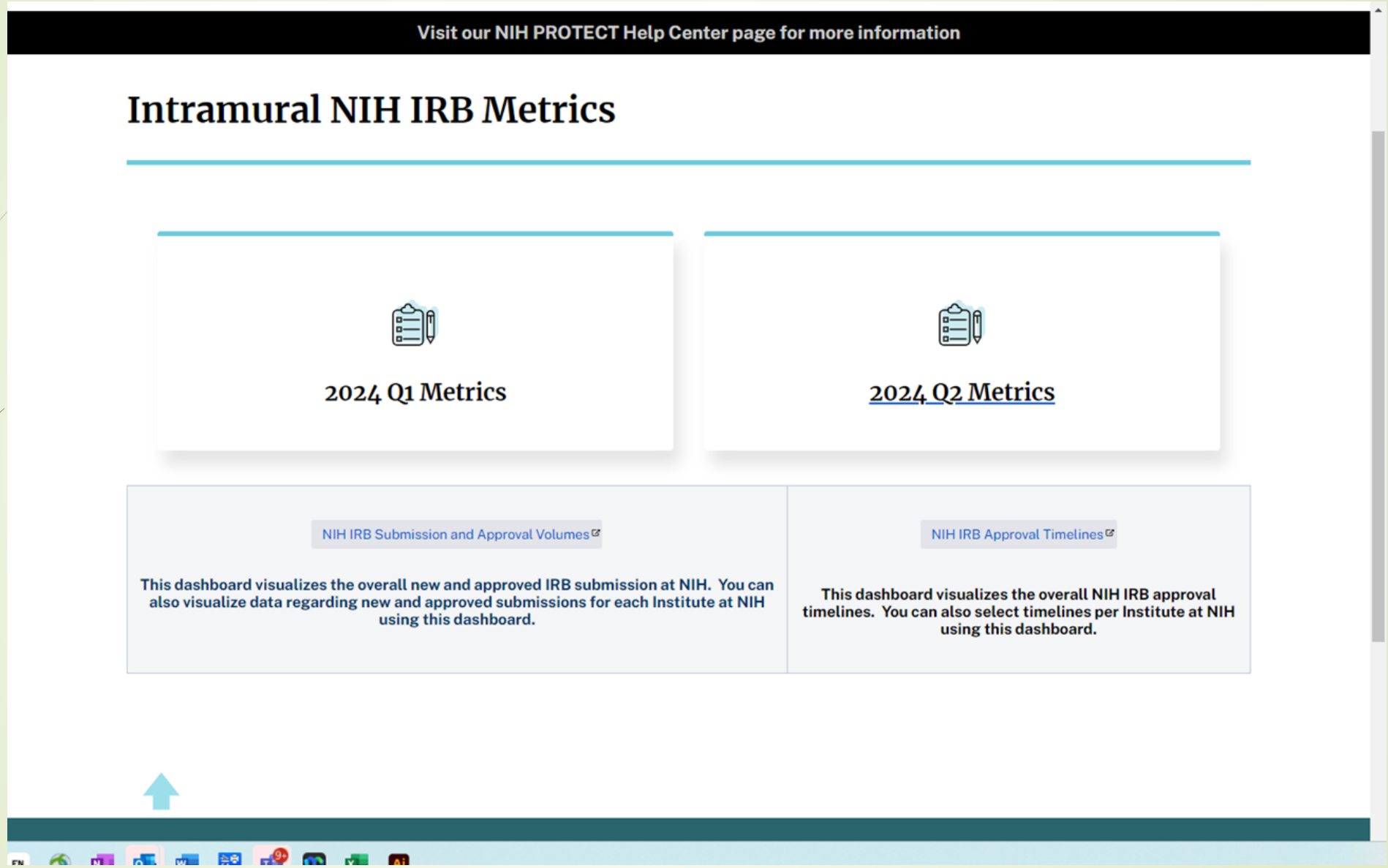


Review intervals-Full Board Initial review Jan 1-July 31, 2024



Where can you find quarterly metrics?




Visit our NIH PROTECT Help Center page for more information
Intramural NIH IRB Metrics
2024 Q1 Metrics
2024 Q2 Metrics
NIH IRB Submission and Approval Volumes
This dashboard visualizes the overall new and approved IRB submission at NIH. You can also visualize data regarding new and approved submissions for each Institute at NIH using this dashboard.
NIH IRB Approval Timelines
This dashboard visualizes the overall NIH IRB approval timelines. You can also select timelines per Institute at NIH using this dashboard.

OHSRP Staff Updates

- We are hiring!
- Compliance Analyst
  - Responsible for the assessment of all initial reports of non-compliance or unanticipated problems (RNIs); coordinates non-compliance submissions for RCRC full board meetings; 5. coordinates a plan to execute a routine GCP audit of human subject research protocols; perform a Partnership for Informed Consent Optimization (PICO) review of informed consents for initial reviews.
- IRB Analyst
  - Reviews protocol submissions for IRB completeness and accuracy; prepares IRB submissions for IRB full board review; drafts IRB correspondence to study teams; and coordinates with Investigators to facilitate their IRB requests.

PROTECT Satisfaction Survey

Results & Response

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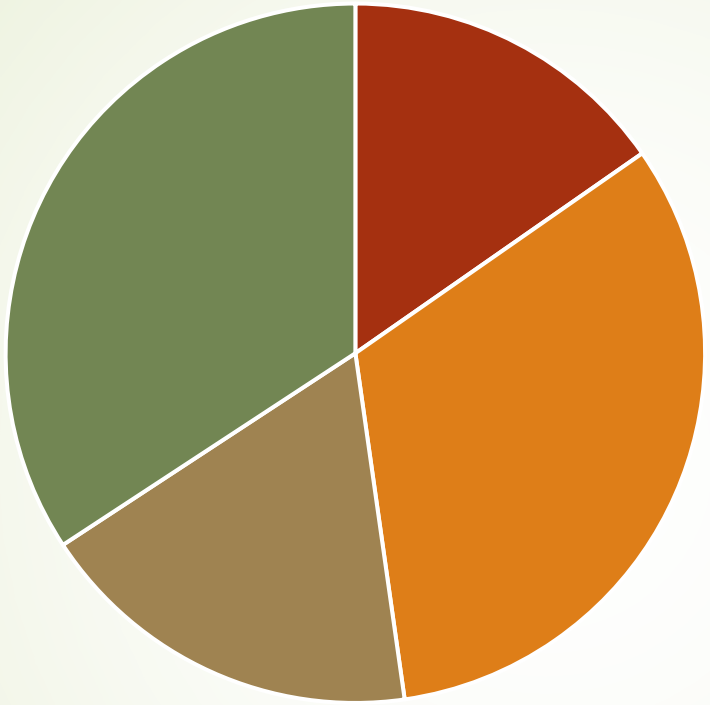
PROTECT Customer Satisfaction Survey

- Purpose: To understand user experience with the PROTECT system, as well as the training and support provided by our PROTECT Training team
- Issued June 2024 *(will re-issue annually)*
- 20-question survey
- Targeted all PROTECT system users (N=3975)
- 142 responses

Respondents



- Principal Investigators (17%)
- Protocol Navigators (36%)
- Study Team Members (20%)
- Other (27%) Committee Staff, Committee Reviewers, Ancillary Reviewers, pSite Users, Branch Chiefs, Clinical Directors

Overall System Experience

On a scale of 1 to 5, how satisfied are you with the *overall experience* with the PROTECT system?

1 - Very Dissatisfied	18
2 - Dissatisfied	20
3 - Neutral	33
4 - Satisfied	62
5 - Very Satisfied	9

PROTECT Support & Training

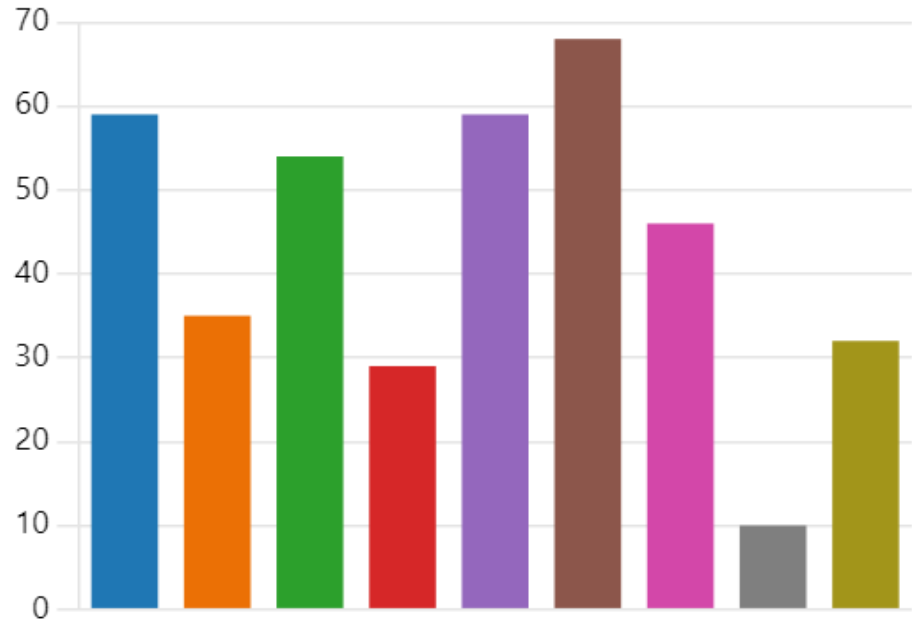
On a scale of 1 to 5, how satisfied are you with the overall experience with the PROTECT support that is offered (ongoing classes, live help desk hours, ticketing system for support, 1:1 assistance)?

1 - Very Dissatisfied	5
2 - Dissatisfied	4
3 - Neutral	37
4 - Satisfied	58
5 - Very Satisfied	38

What you felt was improved

Which of the following do you feel HAVE IMPROVED since the replacement of iRIS with the PROTECT system?

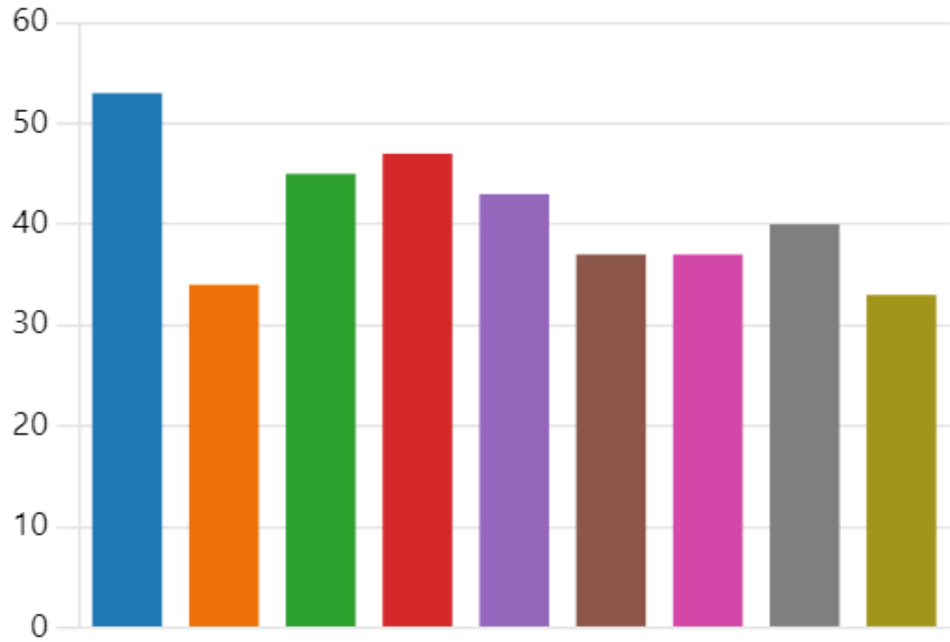
Navigation	59
Inboxes	35
Workflow	54
Ancillary Reviews	29
Locating protocols and submissi...	59
Locating documents	68
Document management	46
Reports	10
None of the above	32



What you felt was not improved

Which of the following do you feel HAVE NOT IMPROVED since the replacement of iRIS with the PROTECT system?

Navigation	53
Inboxes	34
Workflow	45
Ancillary Reviews	47
Locating protocols and submissi...	43
Locating documents	37
Document management	37
Reports	40
None of the above	33



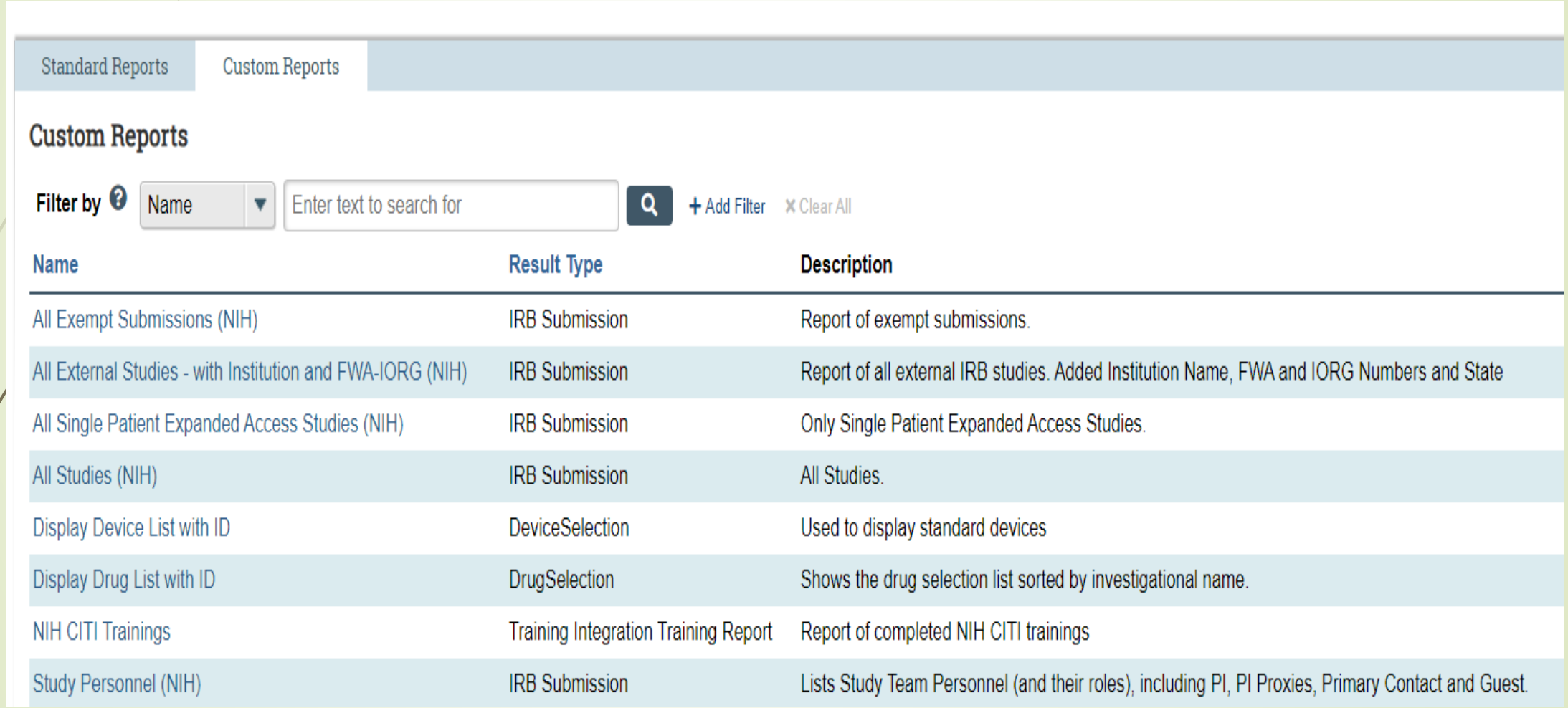
What you want more of:

- Robust, more useful reports
- Document deletion
- Ease of searching/filtering
- Ease of navigation/use of dashboards
- Ease of Scientific Review workflow
- Ease of Ancillary Review workflow

How we can help improve satisfaction

What users asked for	PROTECT Team Response
Robust, more useful reports	<u>Upcoming Reports session:</u> • Recently created new custom reports (Training and Personnel) • Overview of Basic and Custom reports • Opportunity to hear users' additional reporting needs
Document deletion Ease of searching/filtering Ease of navigation/use of dashboards	<u>Upcoming Classes:</u> • Optimizing your dashboard • Tips & Tricks for navigation/workspaces • Tips & Tricks for a clean document "cabinet" in PROTECT
Ease of Scientific Review workflow Ease of Ancillary Review workflow	<u>Outreach initiative:</u> Reaching out to SRCs, RSC, and Ancillary Review community to offer in-person face time (gather questions, feedback, and ensure optimization of workflow)

New custom reports in PROTECT



Standard Reports | Custom Reports

Custom Reports

Filter by Name | Enter text to search for | + Add Filter | x Clear All

Name	Result Type	Description
All Exempt Submissions (NIH)	IRB Submission	Report of exempt submissions.
All External Studies - with Institution and FWA-IORG (NIH)	IRB Submission	Report of all external IRB studies. Added Institution Name, FWA and IORG Numbers and State
All Single Patient Expanded Access Studies (NIH)	IRB Submission	Only Single Patient Expanded Access Studies.
All Studies (NIH)	IRB Submission	All Studies.
Display Device List with ID	DeviceSelection	Used to display standard devices
Display Drug List with ID	DrugSelection	Shows the drug selection list sorted by investigational name.
NIH CITI Trainings	Training Integration Training Report	Report of completed NIH CITI trainings
Study Personnel (NIH)	IRB Submission	Lists Study Team Personnel (and their roles), including PI, PI Proxies, Primary Contact and Guest.

OHSRP Website

Working to update on a continuous basis

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Thank you for your participation!

We look forward to seeing you face-to-face soon!
PROTECT Training & Support Team

OHSRP Website
PROTECT Help Center
Upcoming Trainings/Recordings

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Q&A