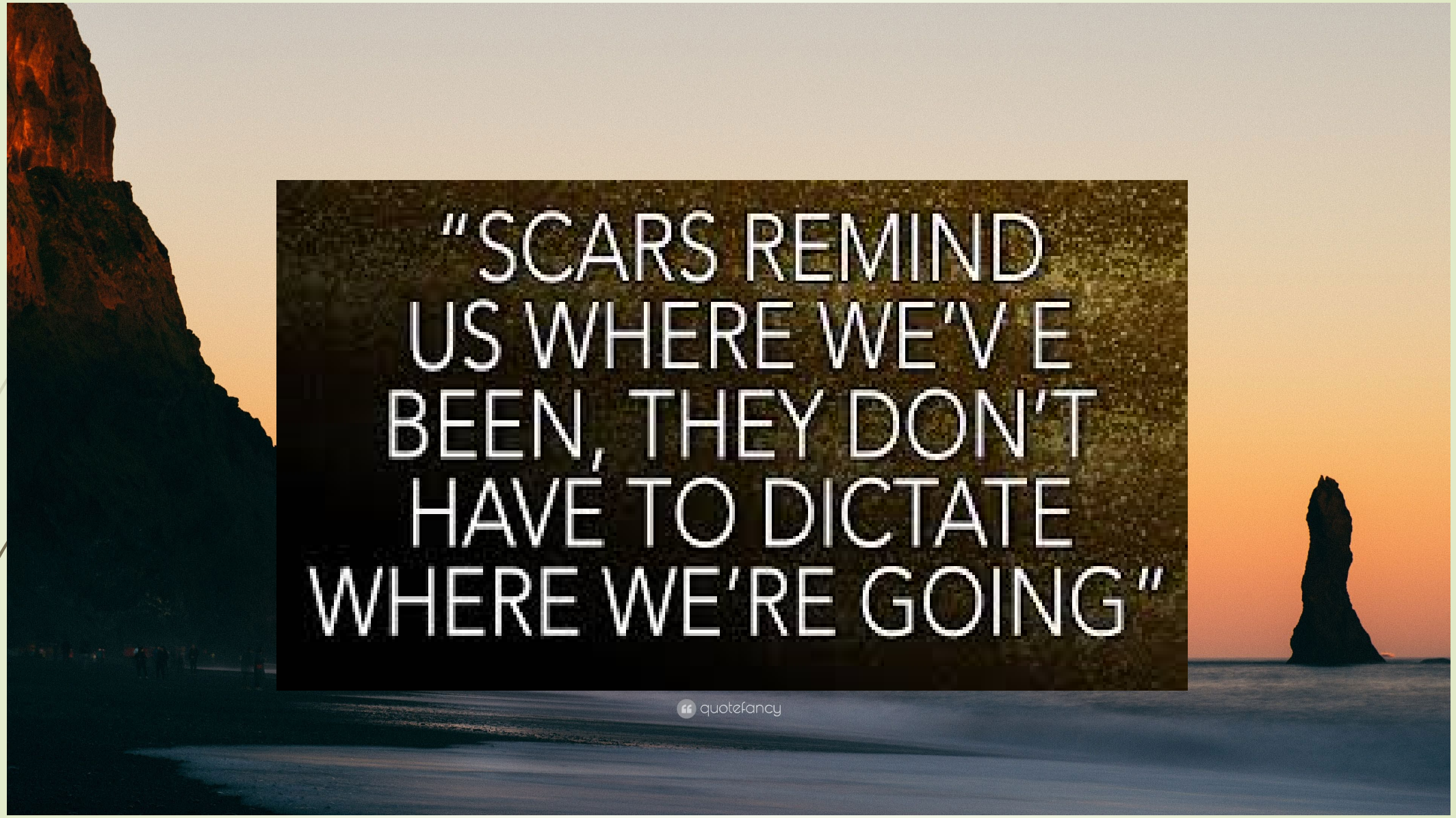
OHSRP Town Hall

January 13, 2022

NIH Office of Intramural Research
Office of Human Subjects Research Protections

Agenda

- Where we came from, where we are headed - Jonathan
- IRB year in review –Tiffany
- AAHRPP – Heather
- eIRB update – Meredith
- Q and A - all


"SCARS REMIND US WHERE WE'V E BEEN, THEY DON'T HAVE TO DICTATE WHERE WE'RE GOING"
quotefancy

NIH HRPP Background

- 1953: NIH IRP required review of clinical research
  - 1972-2000 Office of Protection from Research Risks (OPRR)
  - NIH registered first IRB (IRB 0000001 NCI IRB)
- 1991: Office of Human Subjects Research established to harmonize practices and oversee work of the IC IRBs
- 2001: AAHRPP visits NIH to beta test accreditation process
  - 2013: AAHRPP full accreditation (2017 reaccredited)
- 2015 Advisory Committee to DDIR recommended that NIH IRP:
  - Consolidate IRBs
  - Centralize and streamline IRB Operations
  - Have 1 electronic IRB system

NIH IRBs –BGG era (before Green/Gommel)

- 12 IRBs
- 12 administrative offices
- 12 different ways to do things
- IRBs accountable to IC leadership
- Limited role for OHSRP

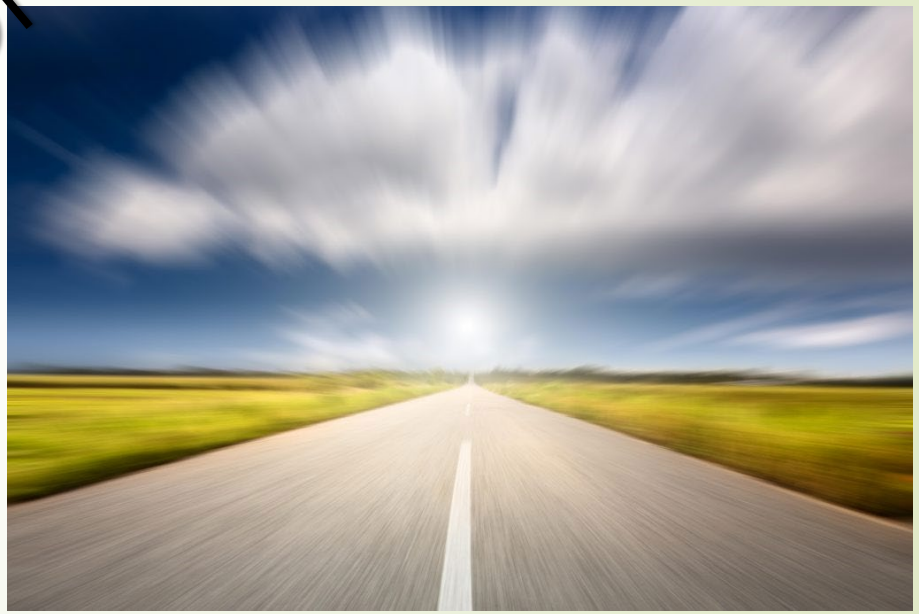
September 2018 – The G's arrive

- Mid-transition between 3 electronic systems
- Impending effective date of revised Common Rule
- Limited staff and space

Goals

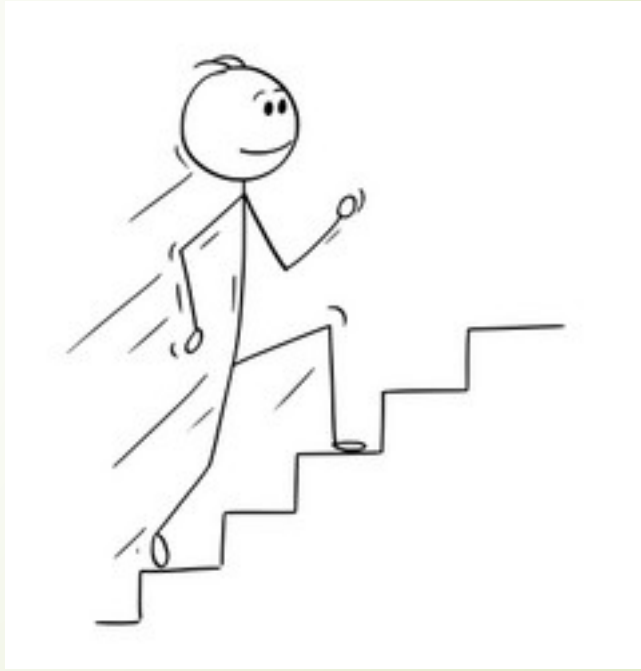
- Create a high quality, efficient IRB that provides optimal protections for the individuals that participate in our research studies and allows the best science to move forward in a safe, sound and ethical way.

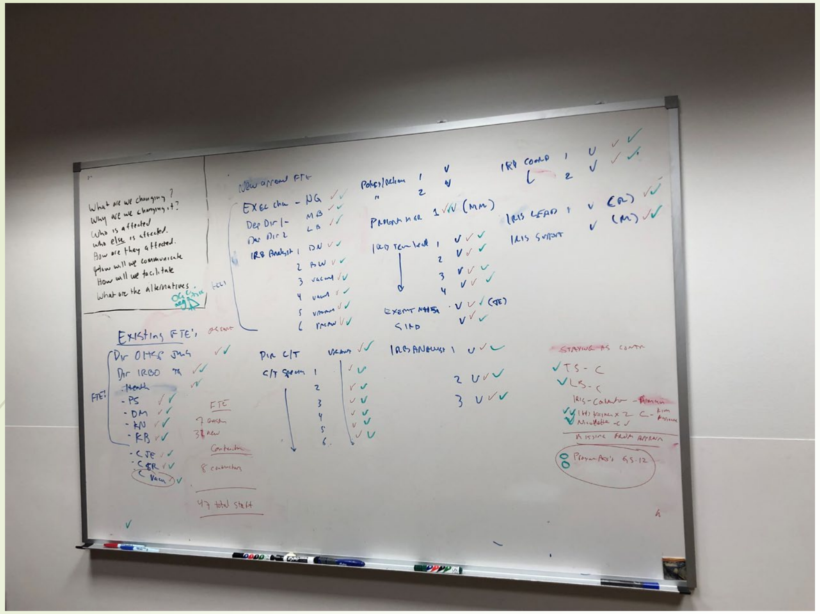
REVISED COMMON RULE

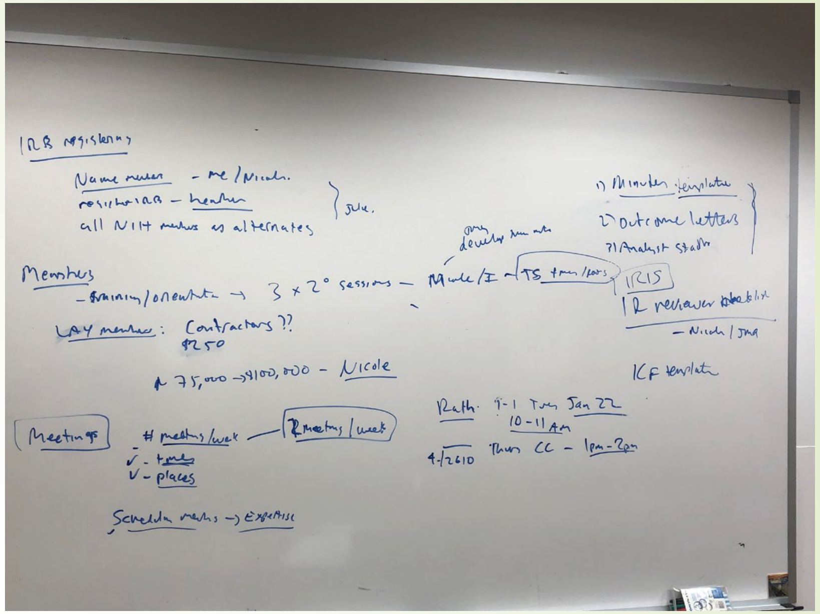


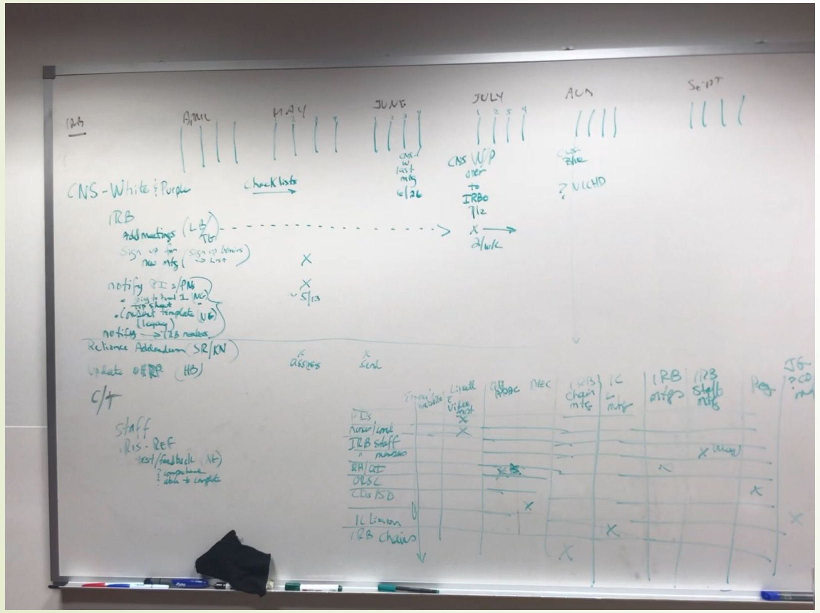
Steps to success

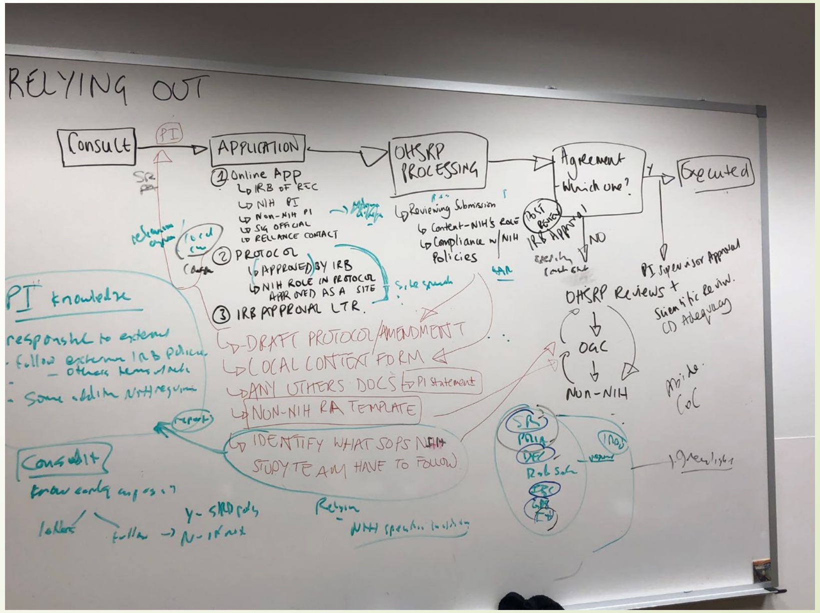
- Revise policies to reflect new organization and revised CR
- Stand up centralized administrative office
- Create new NIH intramural IRB
  - Flexible model
- Create standing compliance review committee (RCRC)
- Assume oversight of ~ 2000 active protocols from the 12 IRBs






IRB registering
Members
LAY members: Contractors ??
Meetings
IRIS
ICF template


APRIL
MAY
JUNE
JULY
AUG
SEPT


RELYING OUT
Consult
PI
APPLICATION
OHSRP PROCESSING
Agreement Which one?
Executed
① Online App
② PROTOCOL
③ IRB APPROVAL LTR.
PI knowledge
DRAFT PROTOCOL/AMENDMENT
LOCAL CONTEXT FORM
ANY OTHERS DOCS
NON-NIH RA TEMPLATE
IDENTIFY WHAT SOPS NIH STUDY TEAM HAVE TO FOLLOW
OHSRP Reviews
OGC
Non-NIH

Building 60 era
IRBO circa 11/2018 – 11/2019

Milestones

- December 2018: NIH Intramural IRB registered with OHRP
- January 20, 2019: NIH IRB begins reviewing all new protocols for the entire IRP
- July – December 2019: Sequentially rolled in all protocols from all IC-based IRBs

In addition

- 32 new staff onboarded
- Research Compliance Review Committee (RCRC) registered with OHRP, and first meeting of RCRC held
- Updated policies (35) consistent with new organizational structure and revised CR completed and published to NIH Manual Chapters, completed 1/2021.

In the meantime

- Designed and moved to new space in Rockledge
- Tested and adapted new workflows
- Create mountains of guidance, protocol templates, consent templates
- Built new website
- Took ownership of iRIS from the Institutes/Centers
- Increased communications with the community: Newsletters, Education program, new website, templates, dashboards, survey, etc.
- NIH signed onto SMART IRB Reliance
- Prepared for AAHRPP reaccreditation

COVID19

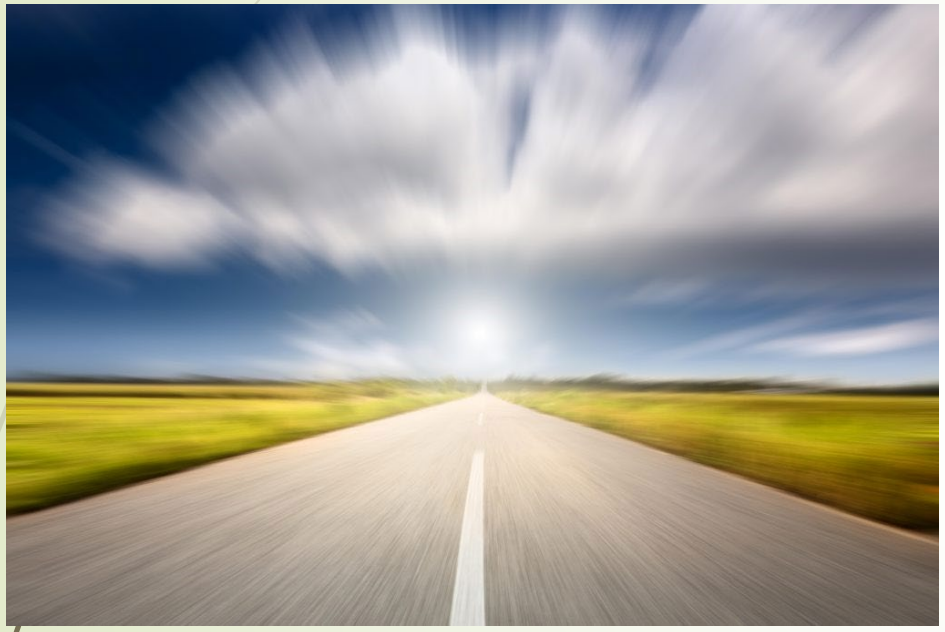
Goals


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


03/24/2015 16:03

NIH HRPP – Building our future

- Collaboration
- Continuous quality improvement
- Compliance



- We will promote the safe and ethical conduct of human subjects research by:
  - providing timely, consistent and compliant reviews
  - educating our community
  - communicating effectively and responsively
  - collaborating with stakeholders
- and thus, will be recognized as national leaders in human subjects protections.

IRB Year in review

Tiffany Gommel, Director; Office of IRB Operations

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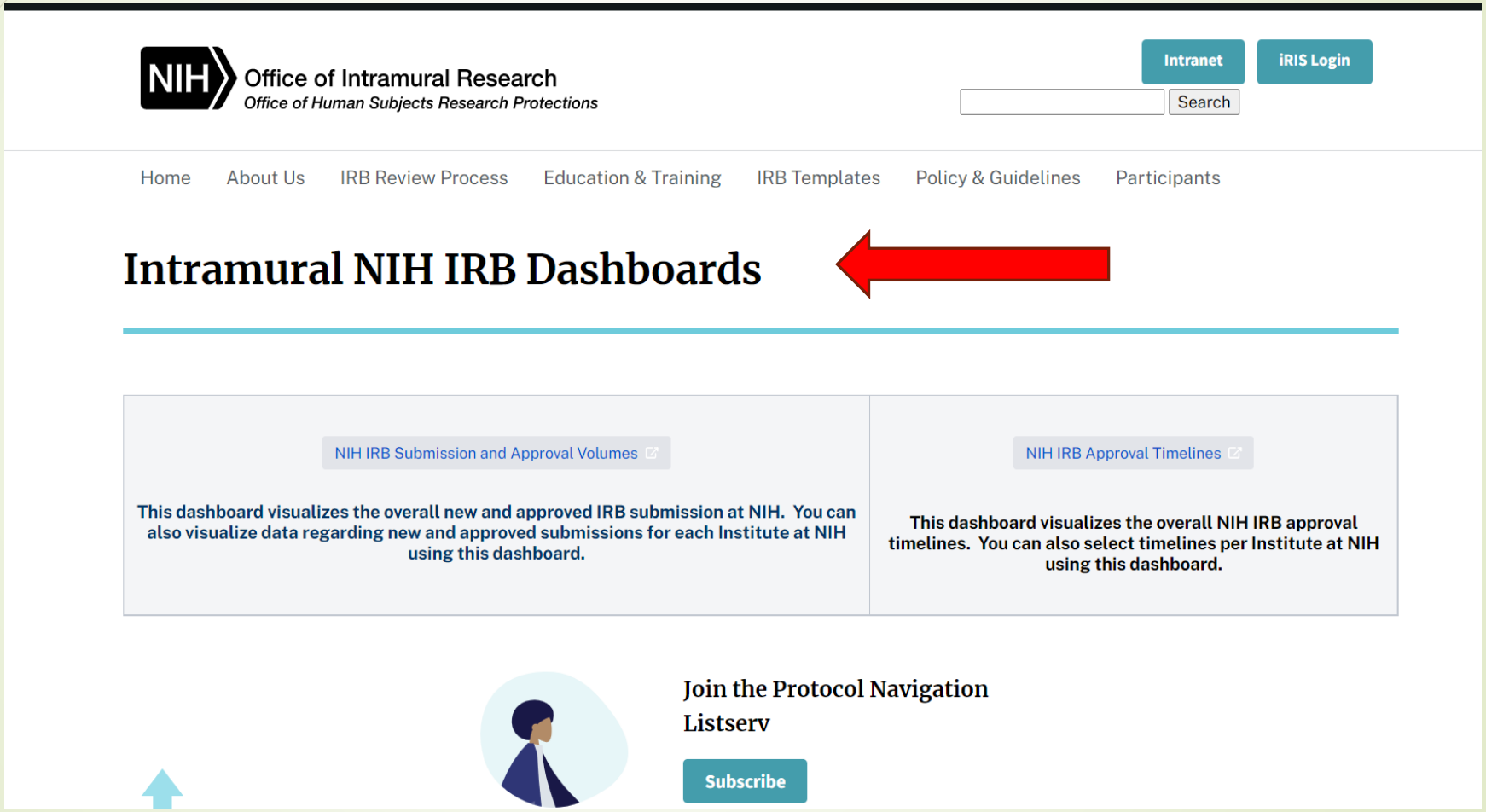
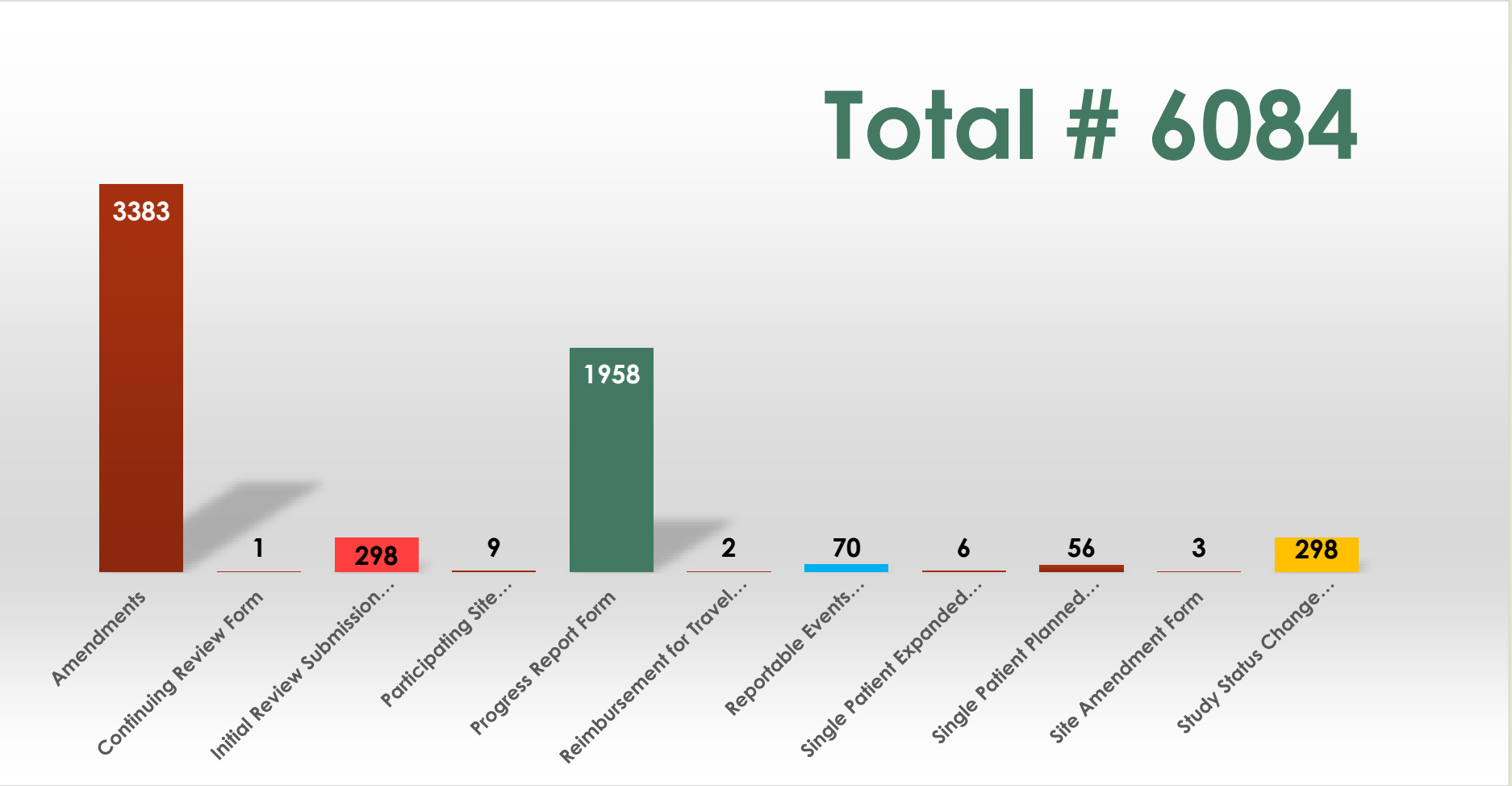
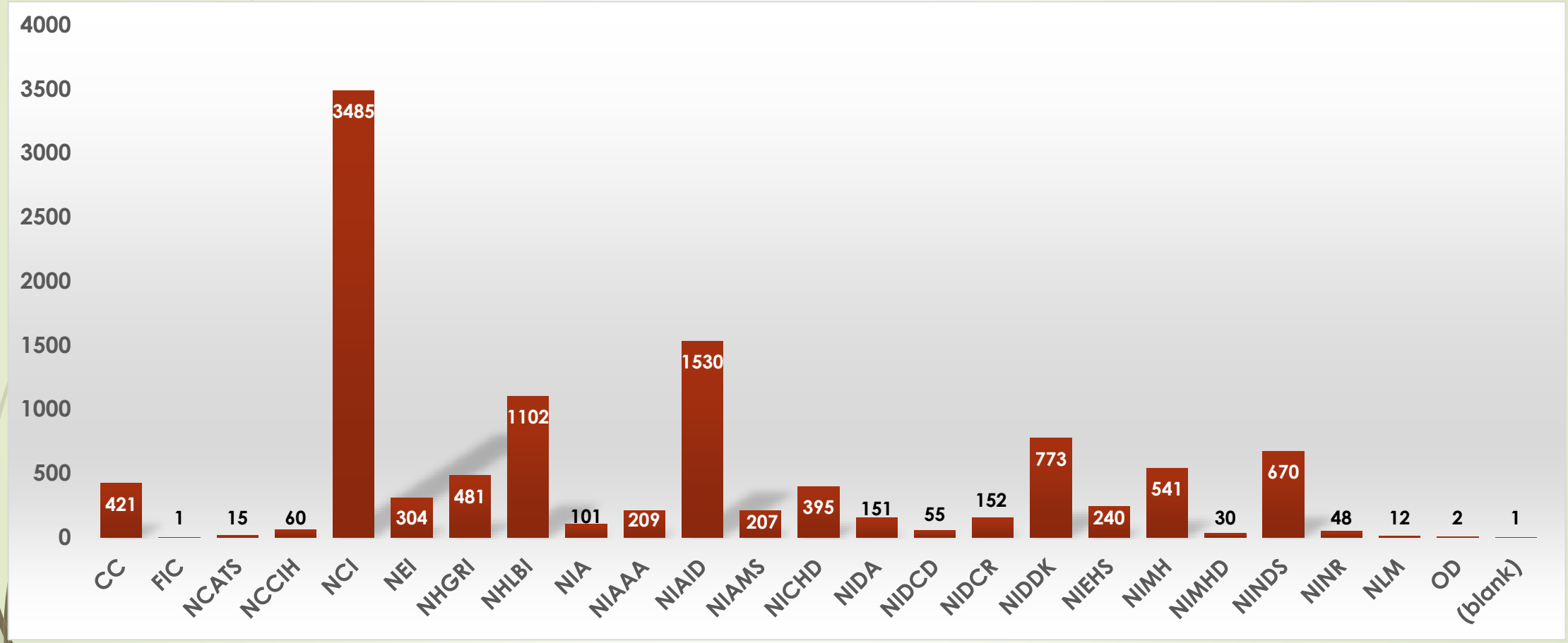
2021 Metrics



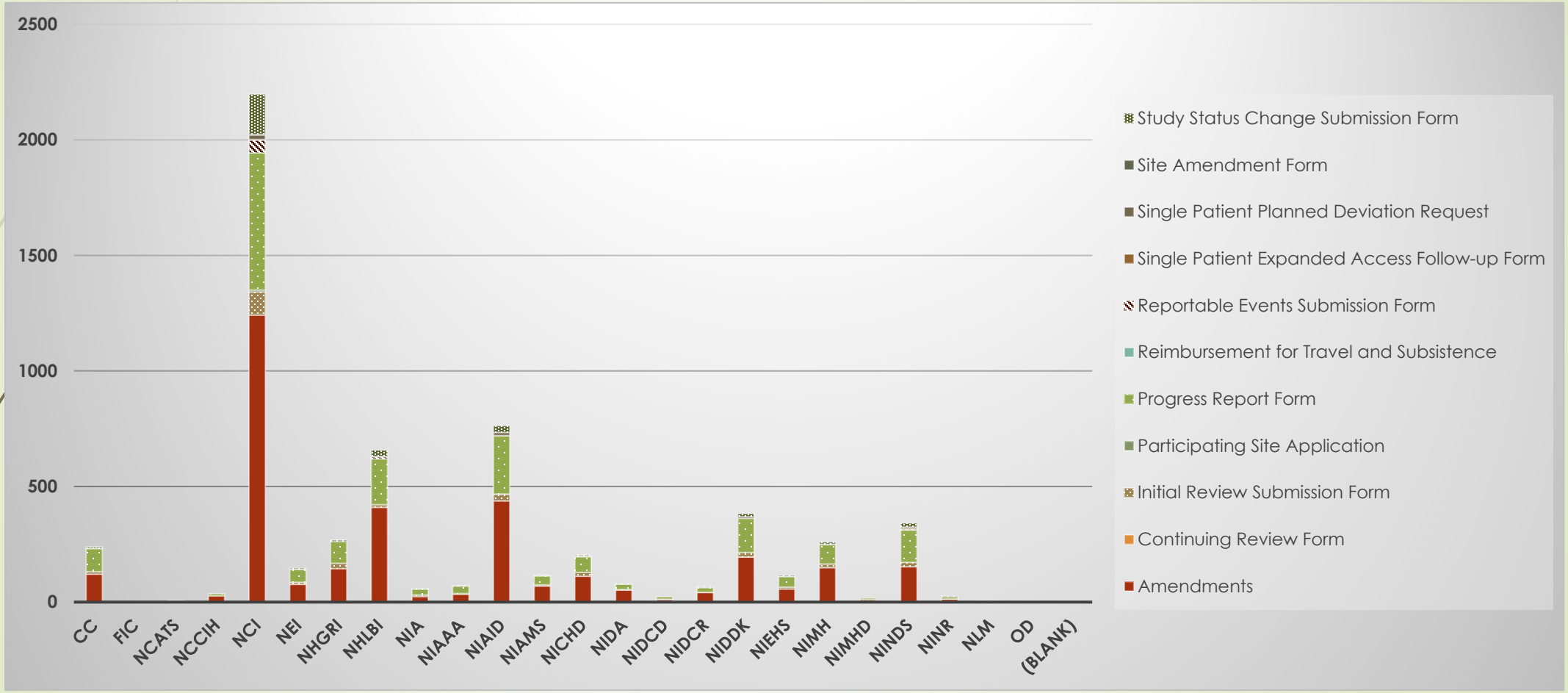
Forms Approved in 2021



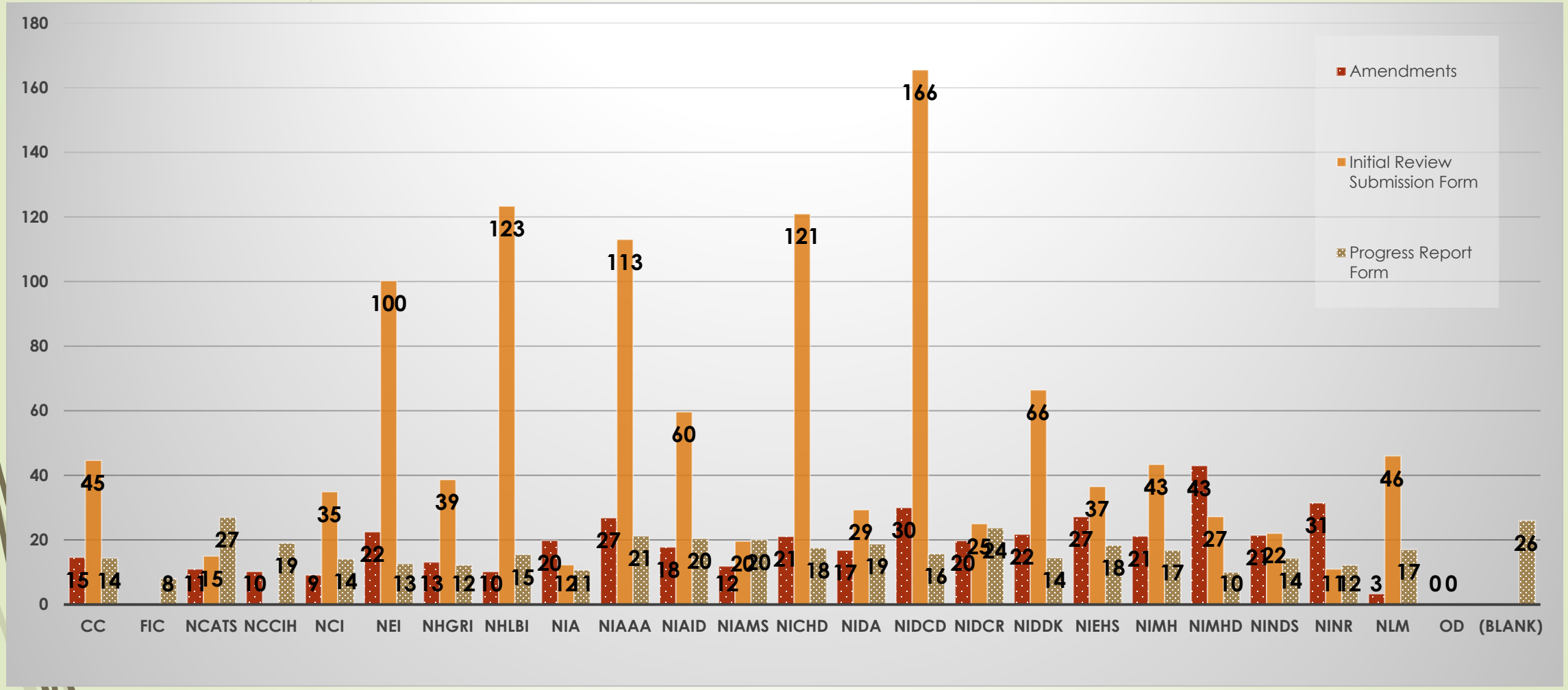
New forms submitted by IC



Total # of forms approved by IC



Average Review Time by IC



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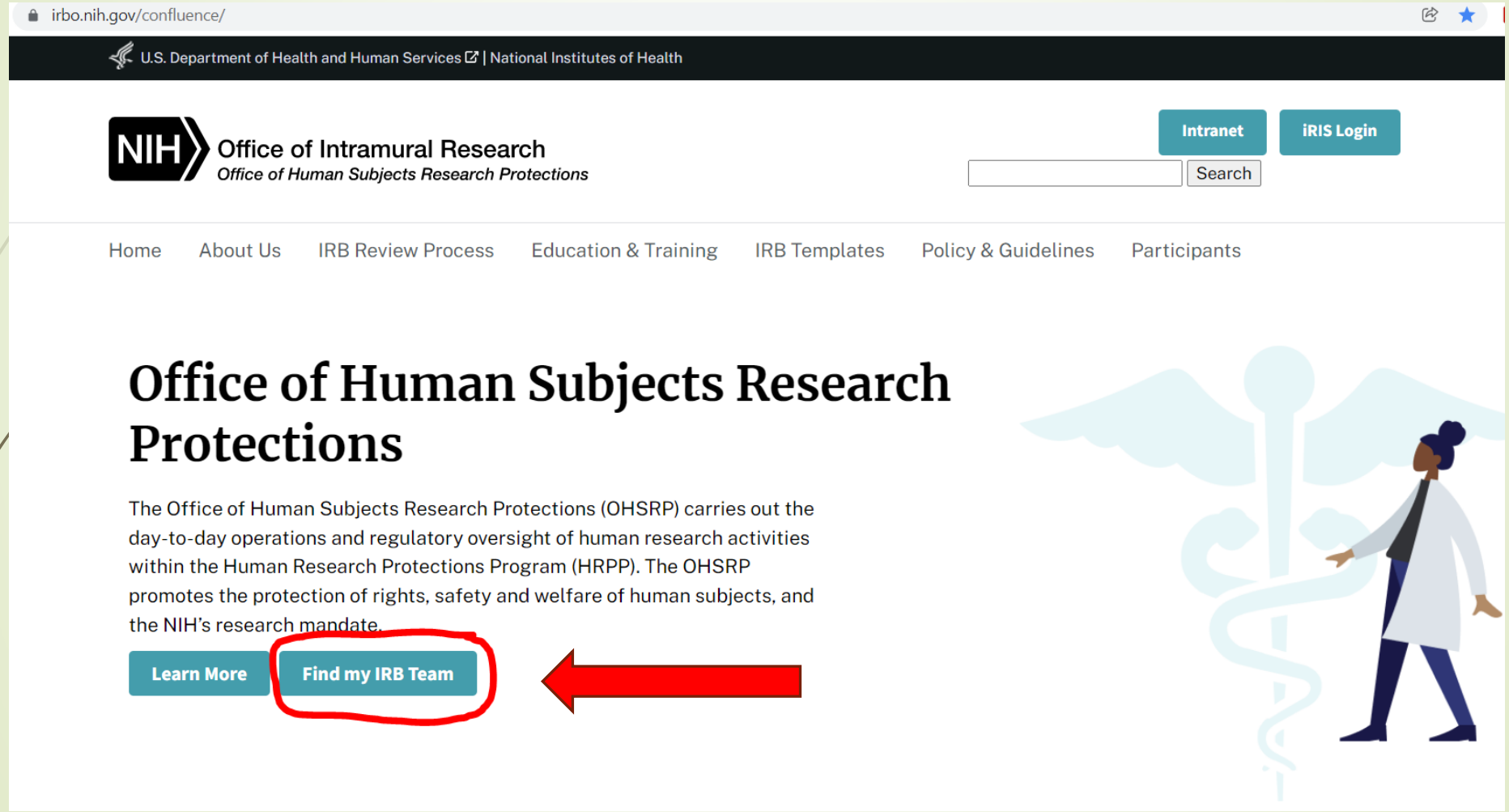
Creation of Teams per IC



Creation of Teams per IC

Find my IRB Team

Please note, you can also send an email to the IRB main inbox at IRB@od.nih.gov or call our main number 301-402-3713 to get in touch with IRB staff.

Select your Institute:

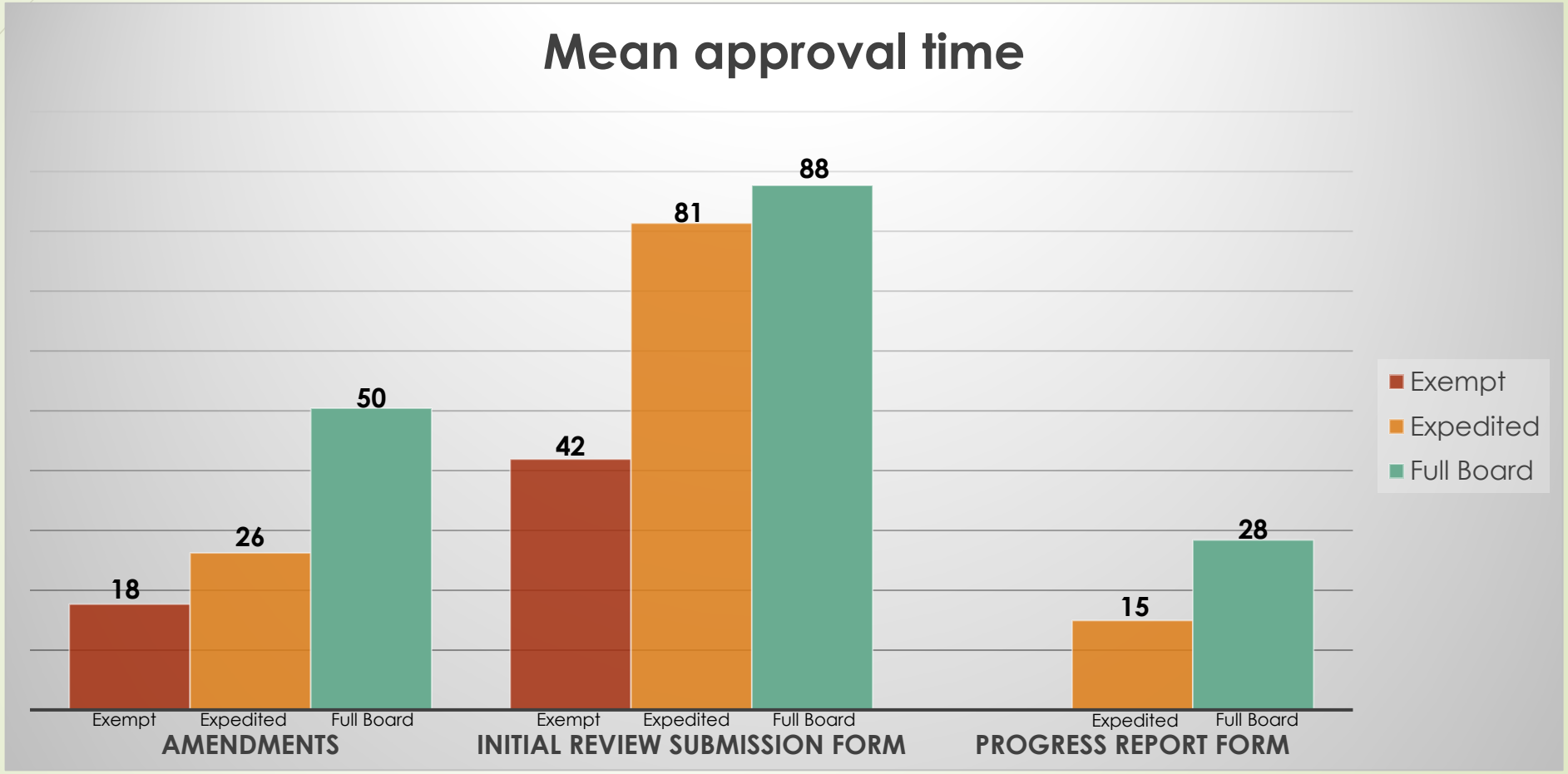
National Cancer Institute (NCI) −

- Team Lead: Patricia Sweet, RN MSN CCRP CIP; sweetp@nih.gov
  - Rochelle Day, MS CIP; rochelle.day@nih.gov
  - Annika Shuali, MS CCRC; annika.shuali@nih.gov
  - Emma Staller, RN BSN; emma.staller@nih.gov
  - Jason Wilson, MA CIP; jason.wilson3@nih.gov

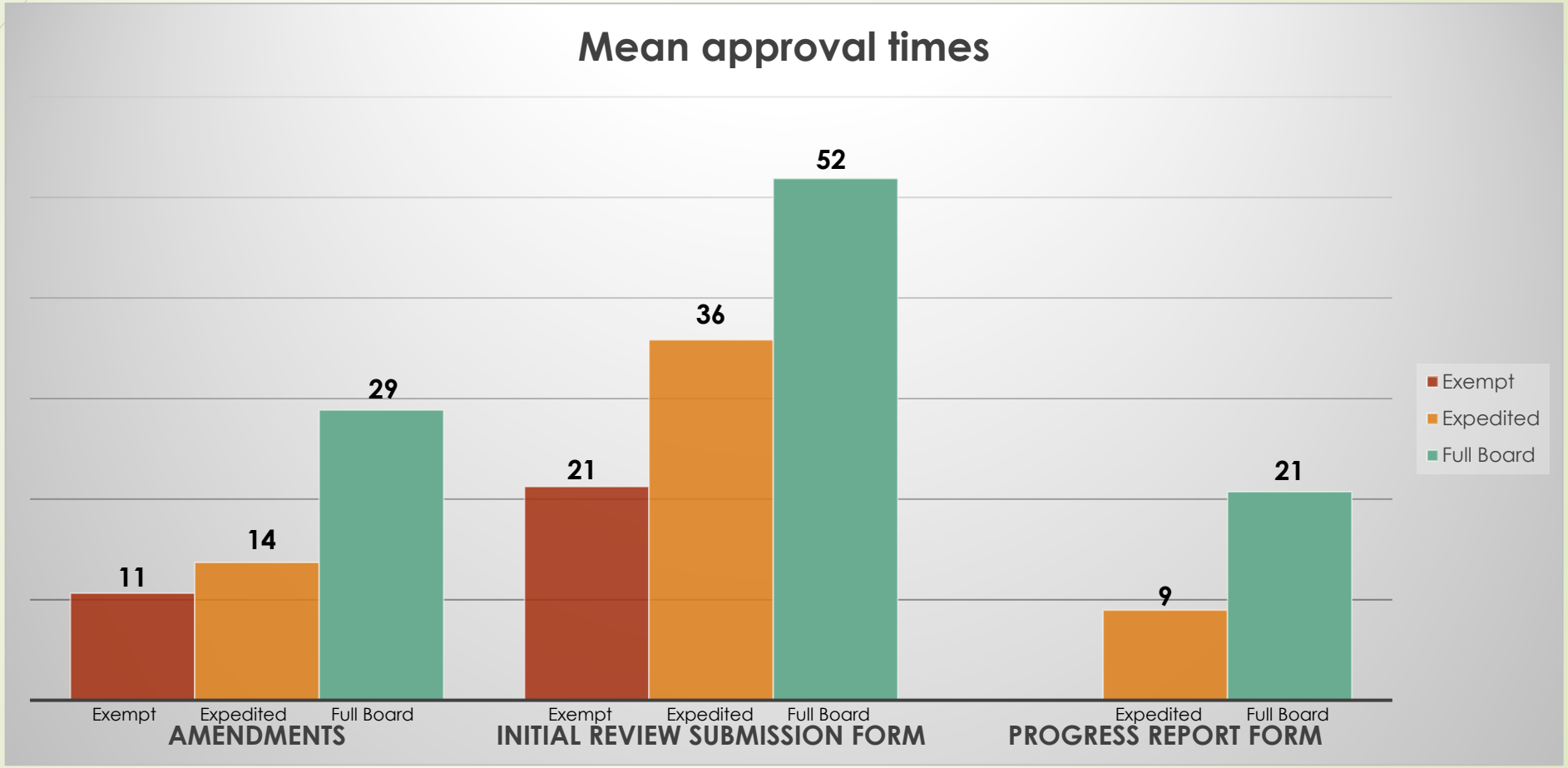
National Heart, Lung, and Blood Institute (NHLBI) +

National Institute of Child Health and Human Development (NICHD) +

Approval Times – prior to 6/1/2021



Approval Times – After 6/1/2021



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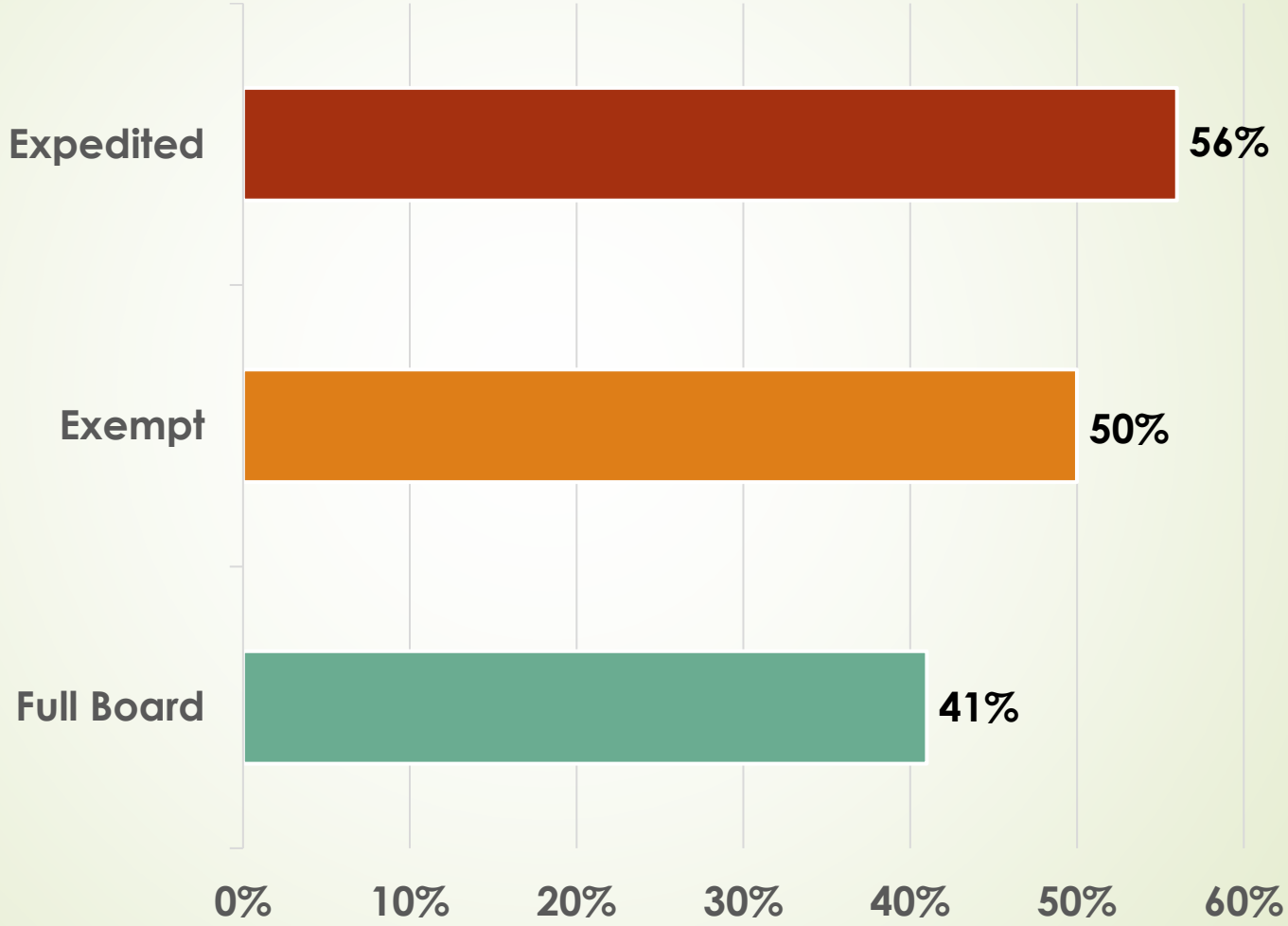
Initial Reviews – Decrease in Approval Times



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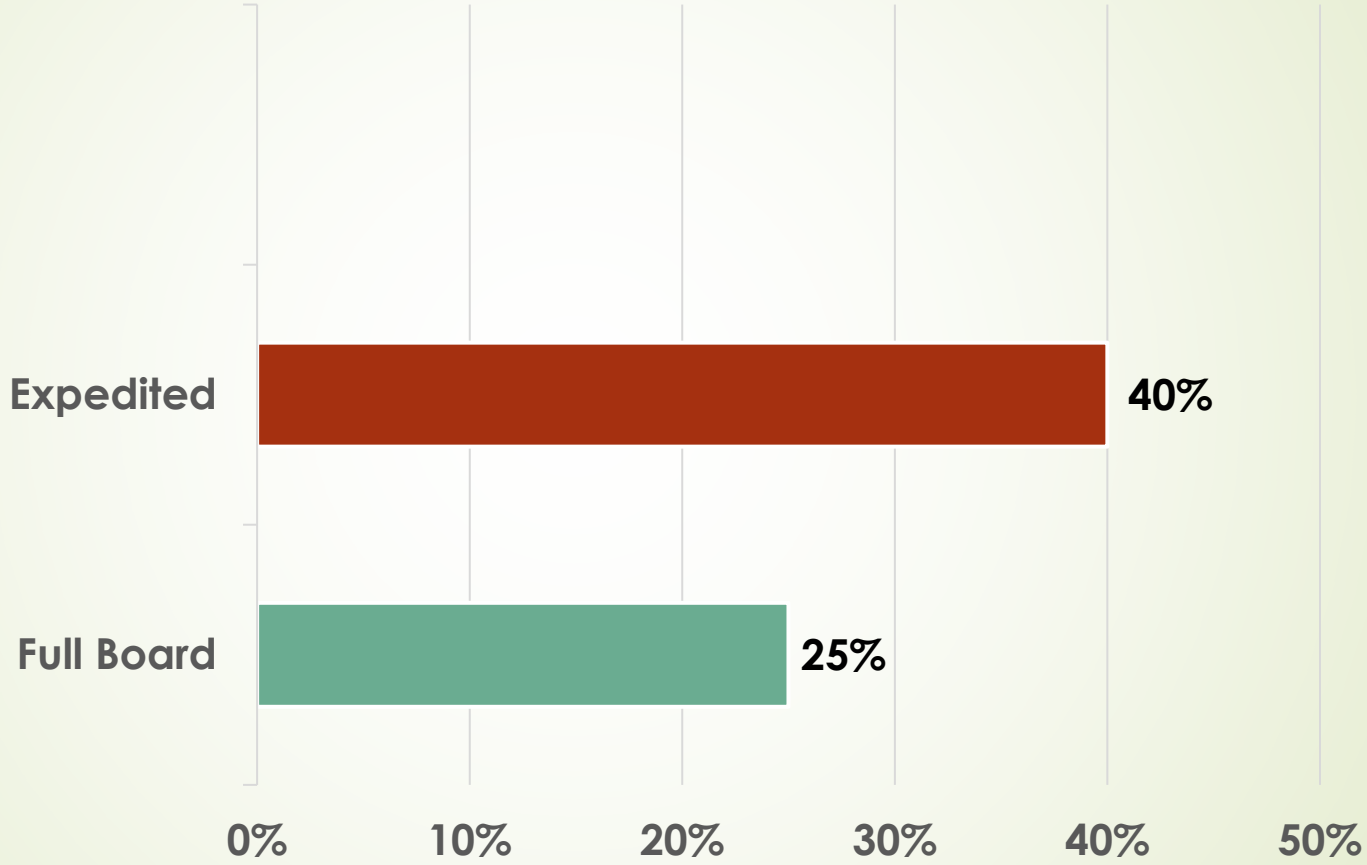
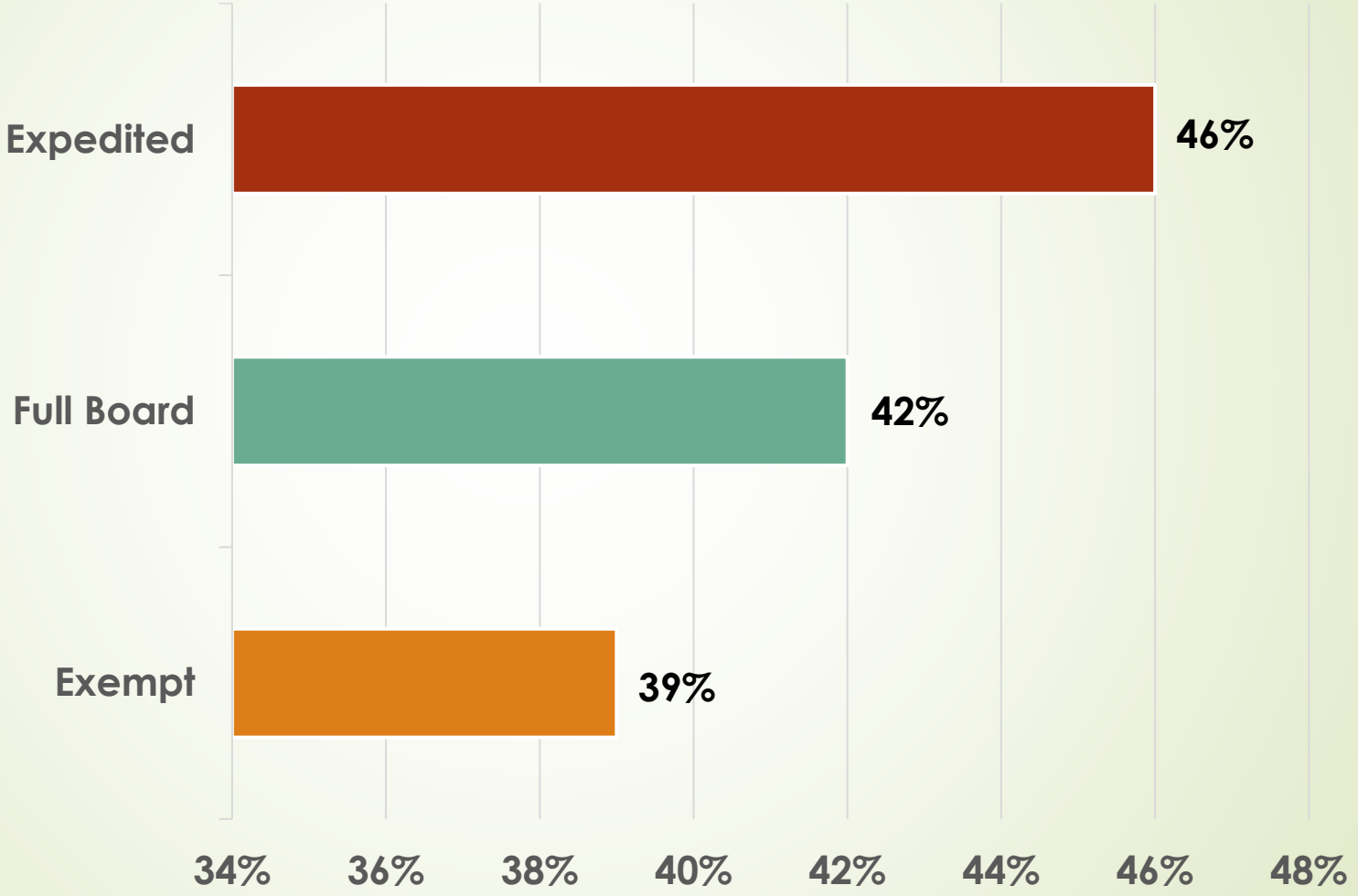
Progress Reports – Decrease in Approval Times



Amendments – Decrease in Approval Times



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AAHRPP Accreditation

Heather Bridge

OHSRP Director of Policy and Accreditation

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Office of Human Subjects Research Protections

The road to excellence - AAHRPP Accreditation

- What is AAHRPP Accreditation and why is it important?
- What happened at the recent Re-accreditation Site Visit?
- What is next?

Association for Accreditation of Human Research Protection Programs (AAHRPP)

- The Association for Accreditation of Human Research Protection Programs (AAHRPP) is our accrediting body
- It establishes commonly accepted standards for Human Research Protection Programs (HRPPs) (over 600 institutions worldwide are accredited based on these standards)
- The Accreditation Standards fall into the three (3) domains that make up an HRPP:
  - Domain I – The Institution
  - Domain II – The IRB
  - Domain III – Investigators
- It takes the entire HRPP to protect the rights, safety and welfare of research participants
- Being an accredited institution with AAHRPP indicates that our HRPP has the "Gold Seal" of approval

Accreditation of the NIH HRPP

Why accredit our HRPP?

- Accreditation establishes that the NIH has a high-quality HRPP and Institutional Review Board (IRB)
- It tells our prospective subjects that we prioritize their rights, safety and welfare when they participate in NIH research
- Being accredited promotes trust between research institutions which facilitates research collaborations

NIH Intramural Research Program (IRP) Accreditation

- Initial Accreditation – March 2014
- First Reaccreditation – March 2017
- NIH is seeking the second re-accreditation of its Human Research Protection Program (HRPP)

Outcome of the NIH Site Visit

THANK YOU!- We did it with Flying Colors!

- Purpose - To confirm our practices were consistent with our paper submissions
- **It took a Village:**
  - **4 Site Visitors** (Our peers from other accredited institutions)
  - **108 NIHers** from across the IRP were prepped over 4 weeks and were interviewed over 3 days
  - **13 enthusiastic team members** to support the site visit
  - **23 IC Liaisons**, and
  - **YOU!**
- Only 1 minor concern related to sharing results of IRB member surveys with members.

Reaccreditation Cycle

NIH Huron eIRB Implementation

Meredith Mullan

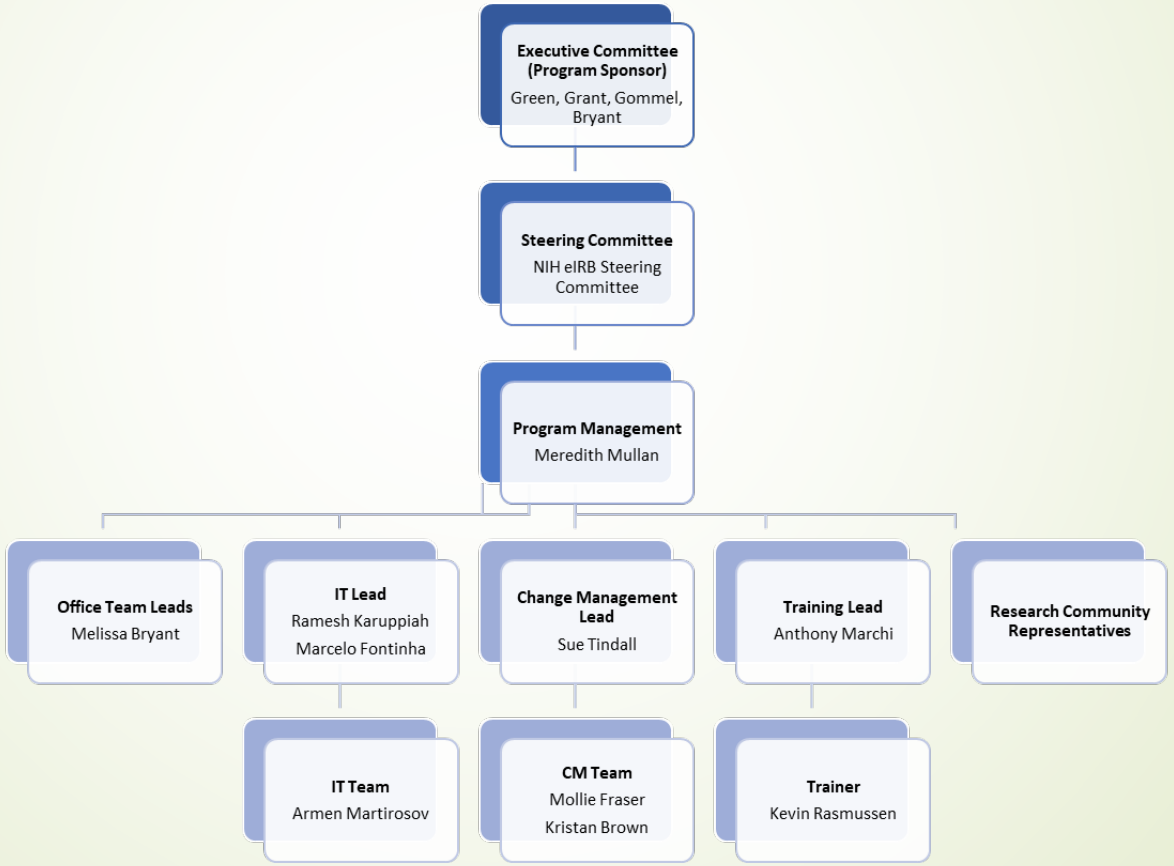
OHSRP Program Manager

NIH eIRB Project Lead

eIRB update

- Goal: Build a system that eases the administrative burden across the NIH research community
  - Facilitates submission and review processes
- Selected Huron Research Suite IRB software
- Process well underway
  - Through Onboarding, requirement review phase
  - Entering design phase

eIRB Project Organization



Project phases and approximate timelines

- Fall 2021-Spring 2022 - IRB Build
  - This includes functionality for the IRB office, researchers, and study teams
  - Currently, Core team is finalizing the design of the system before the build in Huron begins
- Winter 2022-Fall 2022 -Ancillary Build
  - Stakeholder engagement –started
    - 1/6 Initial meeting with Scientific Review
    - Currently scheduling initial meeting with Radiation Safety
- Testing - initial
  - After IRB build complete
  - Continues through ancillary build
- Final testing of entire system together occurs closer to go live

Project phases and approximate timelines

- Training
  - Targeted training pre go-live.
  - More information to be shared closer to when training will take place
- Data migration
  - Still being finalized, goal is to migrate:
    - Approved protocol and consent documents
    - Fields that are included in new Huron system that exist in iRIS
    - Other data: Expiration dates etc.
- Go-live
  - Goal late 2022, subject to change

Research Community Engagement

- eIRB Champions Identified and were contacted on 1/10
  - Convey the strategic vision of the product
  - Help future system users envision how the product will help them with their work
  - Extend the eIRB Implementation team outward to the community
  - Provide feedback to and from the research community
    - Gather and relay IC feedback/concerns to us as well as relay project timelines
    - Relay any IC-specific needs/scenarios that the eIRB Core Team may need to consider
  - Spread the word about the new system
- Testing of the system
  - Beyond champions, we will also engage other members of the research community in user acceptance testing

eIRB Naming Campaign

- Have ability to name new system something more in line with our goals for the new system
- Naming Campaign will be open to all current eIRB users
- The logo and name can be adapted to our choices: