

OHSRP AND THE NIH INTRAMURAL IRB

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DIRECTOR: OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

Who I am

Clinician

Researcher

IRB professional



- To protect the rights, welfare and safety of human subjects participating in research conducted by the NIH Intramural Research Program.
- To promote the ethical conduct of human subjects research by collaborating with investigators throughout the research lifecycle.



HRPPs are a Partnership

Investigators

Institution

Sponsors

IRBs

Participants





Build upon the existing strengths of the NIH IRP to create a human research protection program that fosters research by providing:

- Optimal participant protections
- Efficiency and consistency
- Regulatory compliance
- Educational outreach

Complex Regulatory Environment

Common Rule (pre-2018 and 2018)

FDA regulations

DoD regulations

Privacy Act

HIPAA

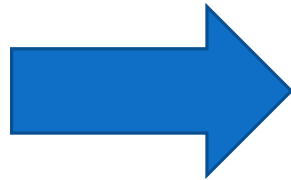
NIH policy

ICH-GCP

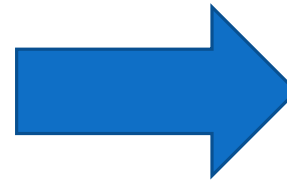
Single IRB mandate

Back to the future

27 ICs
12 IRBs
12 administrative offices
12 different processes
Oversight by IC leadership



Inefficiency
Inconsistency
Variable Quality
IC control



1 IRB
1 Central administrative office
1 way of doing things
Independence

Steps

Revise HRPP policies -- Stand up centralized administrative office

Reorganize IRBs under OD



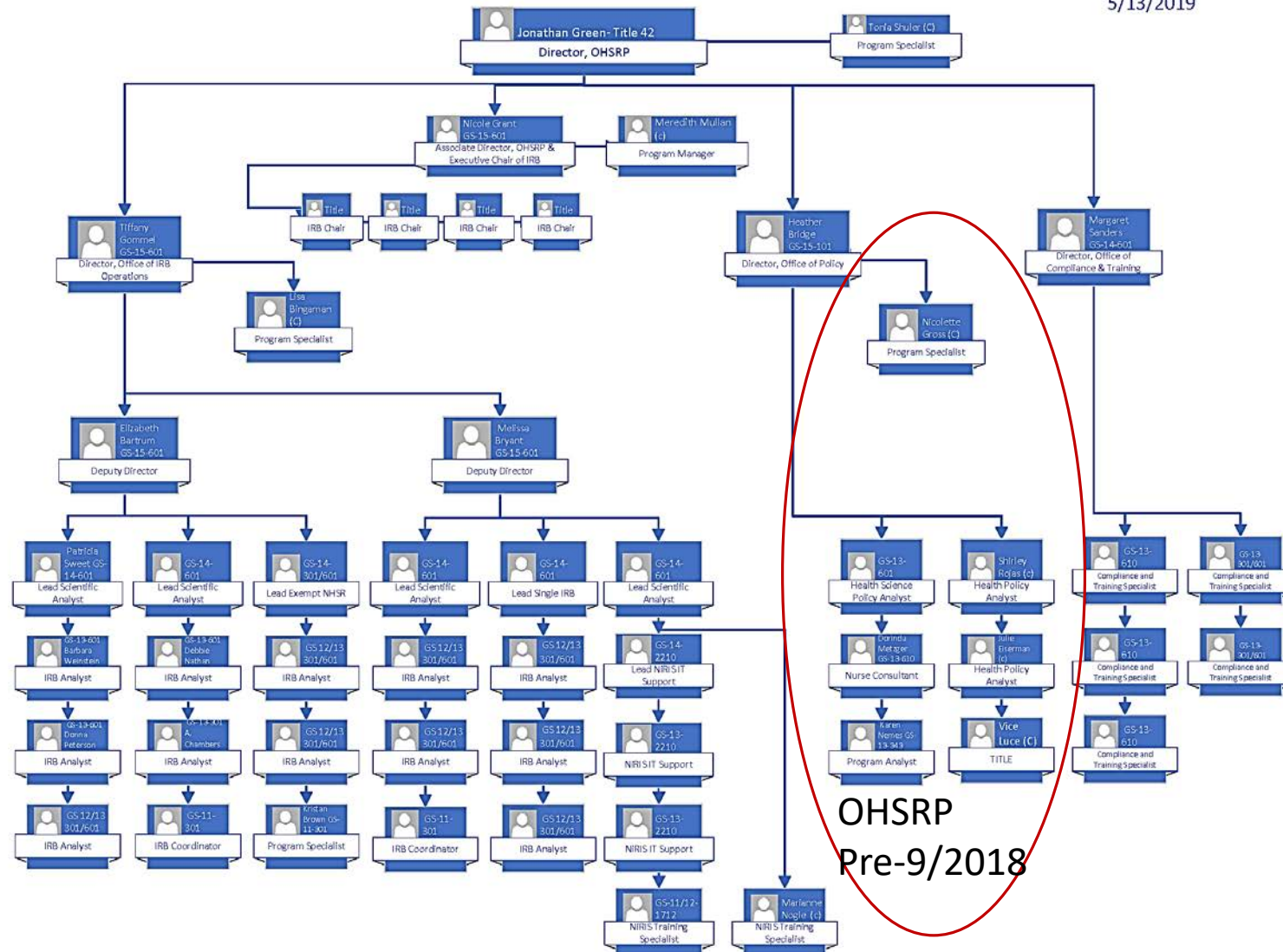
Policy Revisions

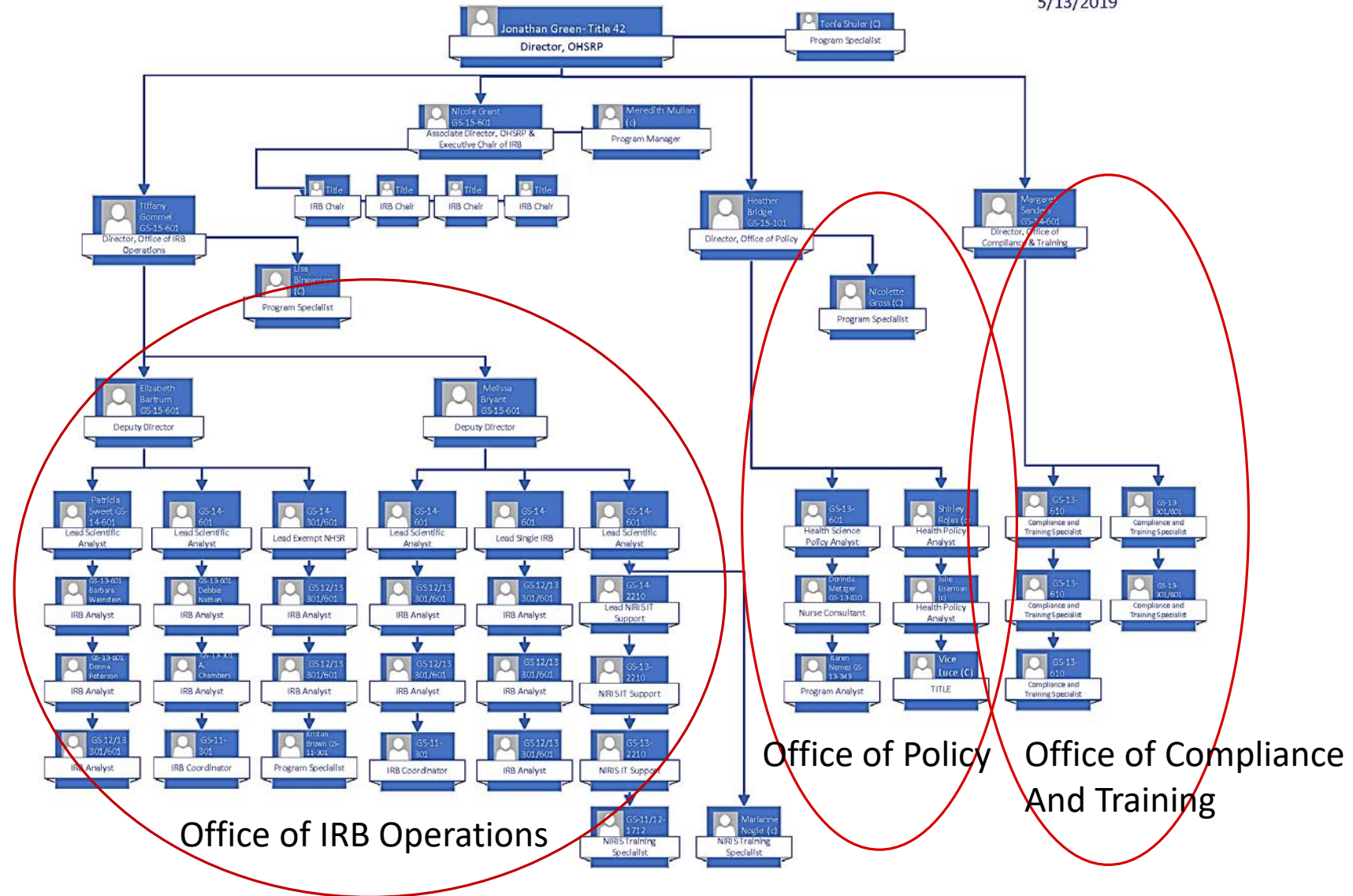
Simplify

Keep focus on policy not operations

Compliance with revised Common Rule









Office of IRB Operations (IRBO)

Director: Tiffany Gommel

Functions

- Exempt/NHSR determinations
- Expedited Review
- Administrative screening and support for Full Board Review
- NIH iRIS system
- Coordinate sIRB activity
- Investigator support
- IRB member support

Website: irbo.nih.gov



Office of Policy

Manager: Heather Bridge

Continual evaluation and development of policy

- Functionality
- Compliance
- Address new regulatory and ethical challenges

Office of Compliance and Training

Manager: Peg Sanders

Triage reportable events

Manage non-compliance investigations

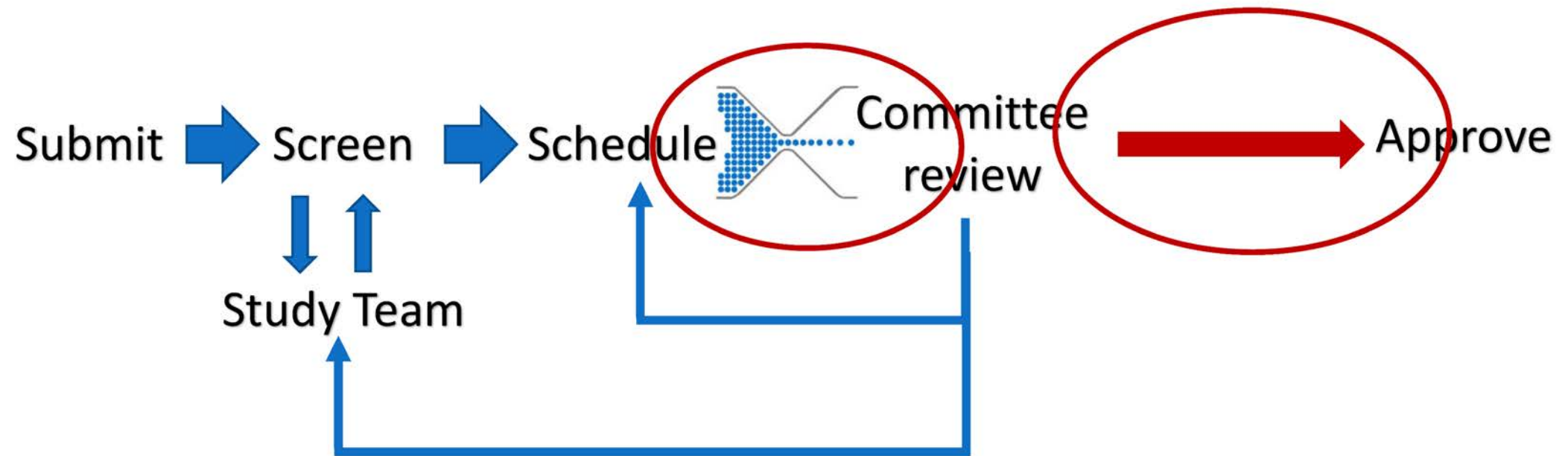
Support Research Compliance Review Committee

Create and implement educational programs for investigators and IRB members

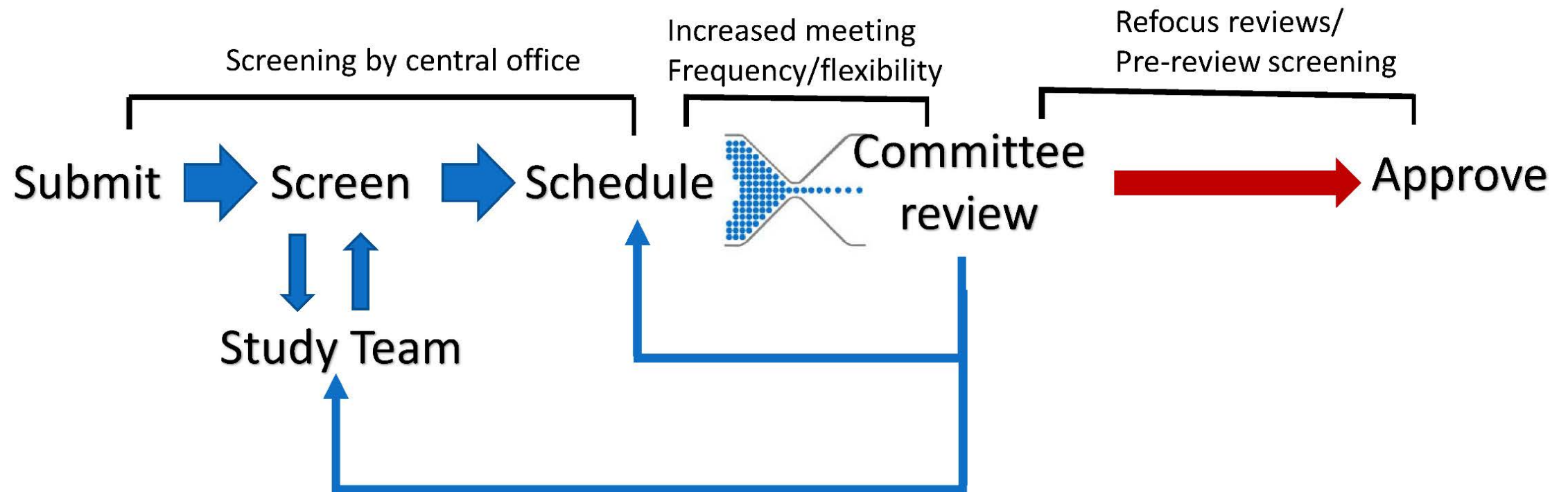
IRB Restructuring



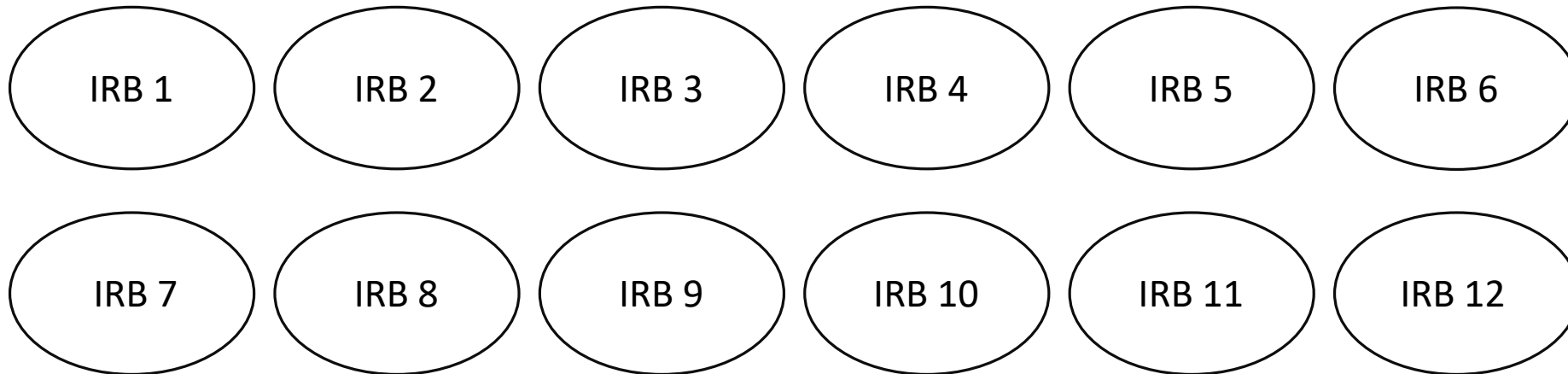
System inefficiencies and bottlenecks



System inefficiencies and bottlenecks



Committee reorganization



15-20 members/committee
Meet monthly for 2-6 hours
??? agenda items

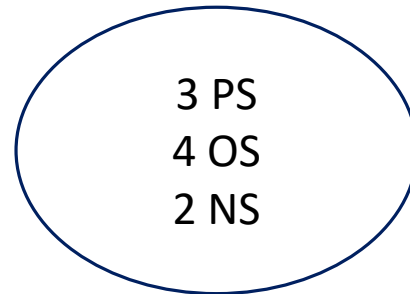
Penguins and Platypuses



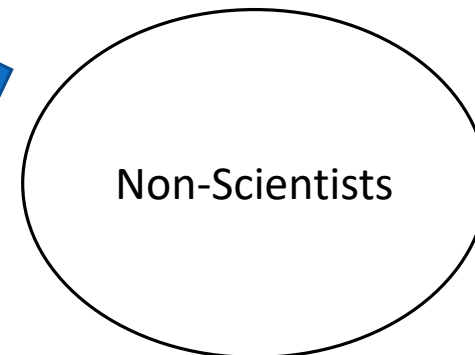
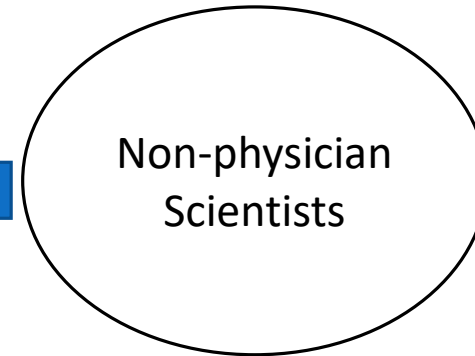
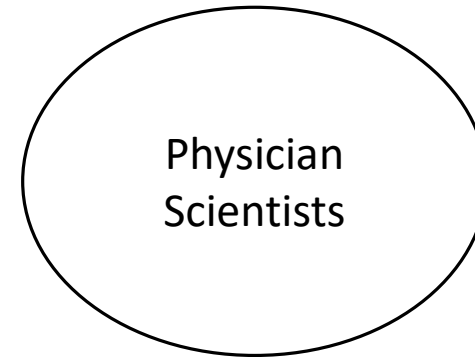
Flexible IRB

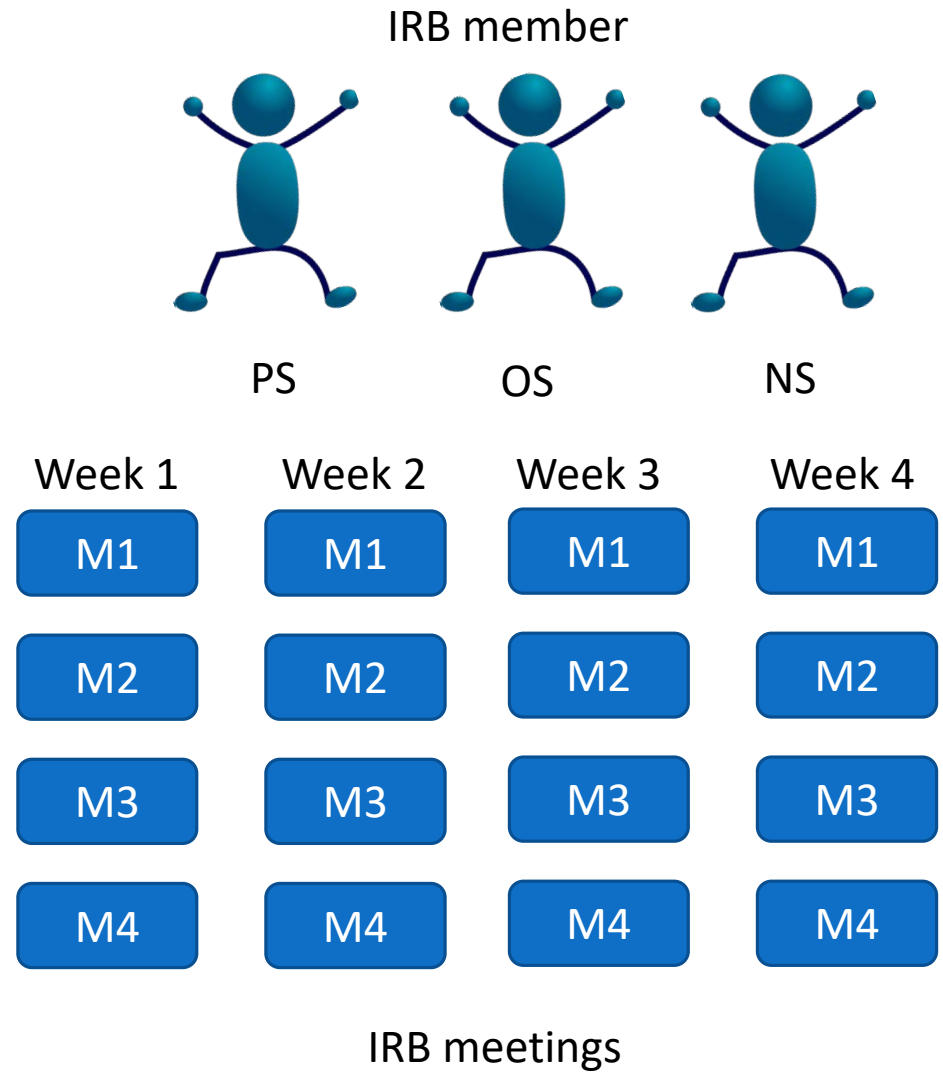
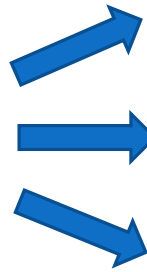
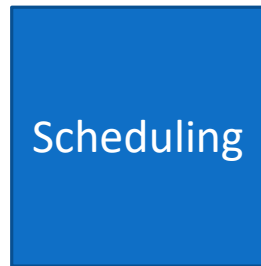
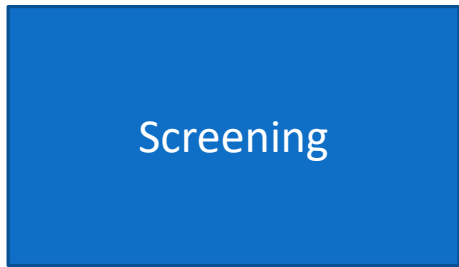
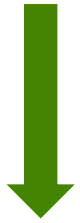
Committee makeup

- 9 primary members
- remainder alternates



6 meetings per week
~ 1 hour per meeting
6-8 agenda items (1 IR)





IRB Chairs

Executive Chair: Nicole Grant

- Regulatory authority for approval
- Provides leadership to FB committee chairs
- Delegates authority to expedited review staff
- Provides consultation as needed to expedited review staff

Team of FB chairs

- Provide overall leadership to FB
- Lead one meeting per week (in general)
- Work together to achieve consistency across meetings

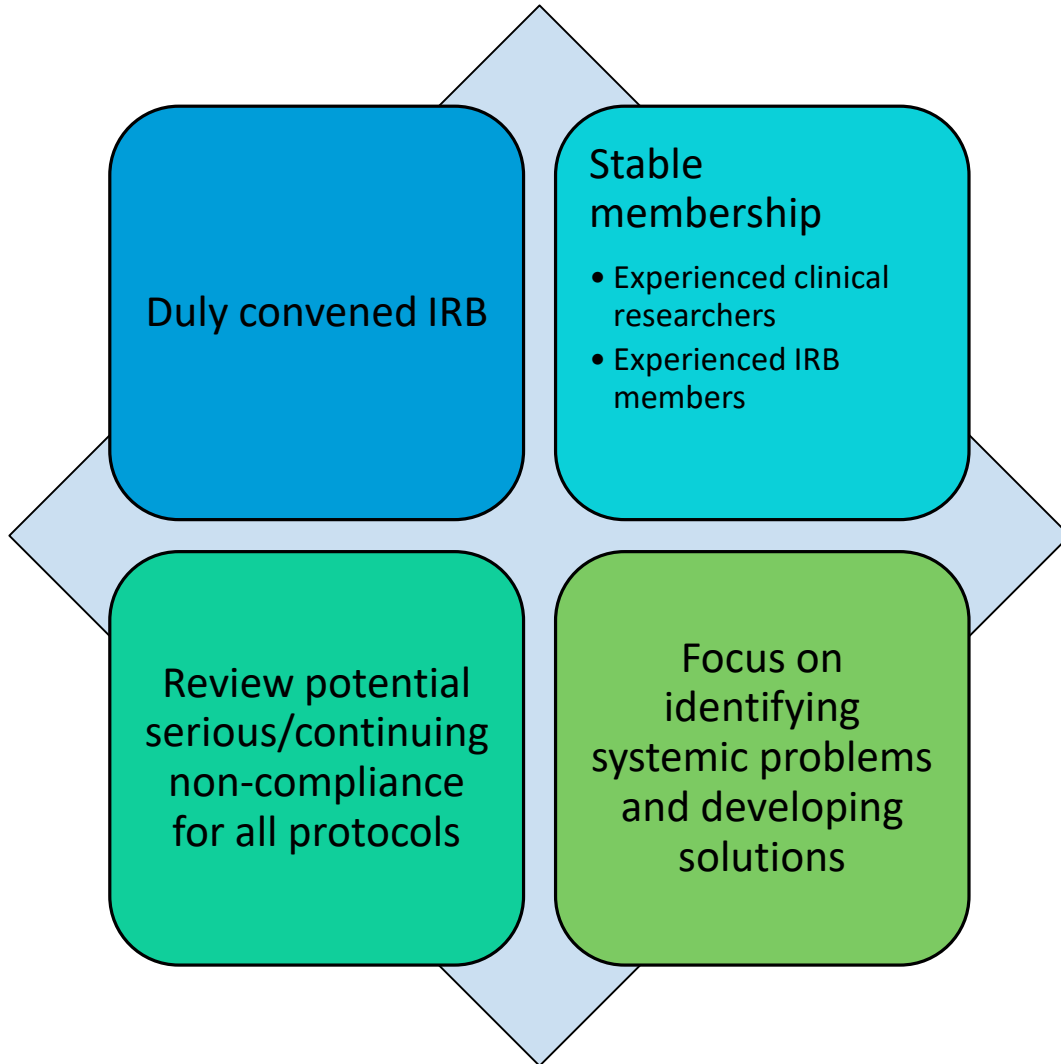
Benefits

Increased efficiency

- Maximal flexibility in scheduling = minimal time in the holding pen
- Capacity can be easily matched to demand

Improved reviews

- Dynamic committee membership = diverse and fresh perspectives
- Dedicated chairs committed to the process provide consistency



Research Compliance Review Committee

Progress to date.....



IRBO

~50% hired (not onboarded)
Supporting new NIH IM IRB



NIH Intramural IRB

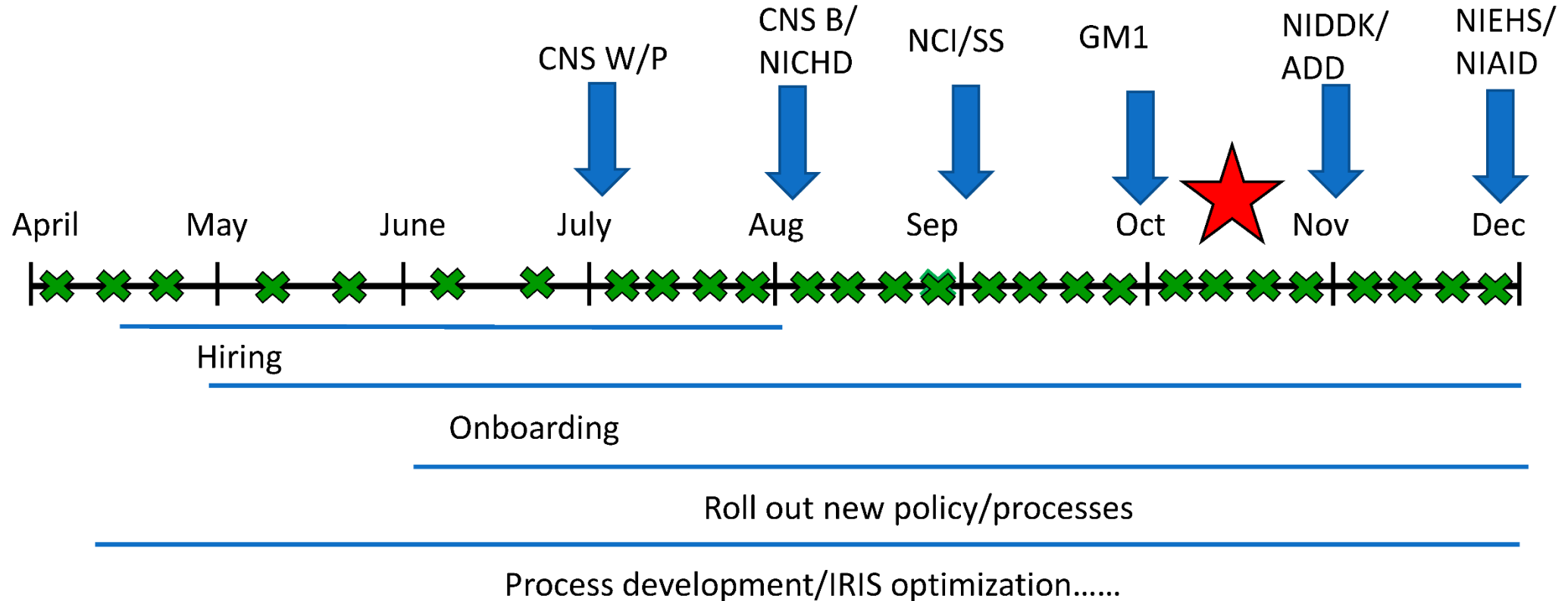
Registered with OHSRP 12/2018
Reviewing all new protocols since
January 21, 2019
Rolling in IC IRBs beginning
7/1/2019



Compliance and training

Manager and 1 staff
Revised relevant policies
Hiring in progress
RCRC established

Where are we headed.....



Whats left?

THINGS TO DO: ◀◀◀◀◀◀ ▶▶▶▶▶▶

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Build capacity of IRBO
Assimilate existing IRBs
Optimize iRIS
Finish policy updates
sIRB processes
Office of Compliance and Training
Optimize processes for investigators
Communicate, communicate, communicate
Everything else.....



NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

