OHSRP TOWN HALL

JONATHAN M GREEN, MD MBA

DIRECTOR: OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

- 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

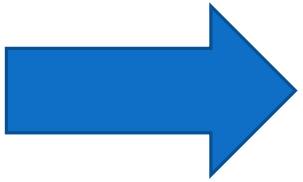
ICH-GCP

Single IRB mandate

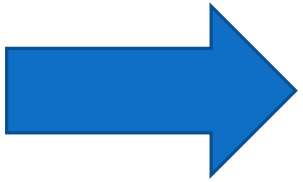
"Our research shows that heredity and environment are both very significant, but that neither is as important as government regulation"

Past, present and future

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



1 IRB
1 Central administrative office
1 way of doing things



Compliance
Efficiency
Consistency
Independence

Steps

Revise HRPP policies

Stand up centralized administrative office

Reorganize IRBs under OD

Office of IRB Operations (IRBO)

Director: Tiffany Gommel

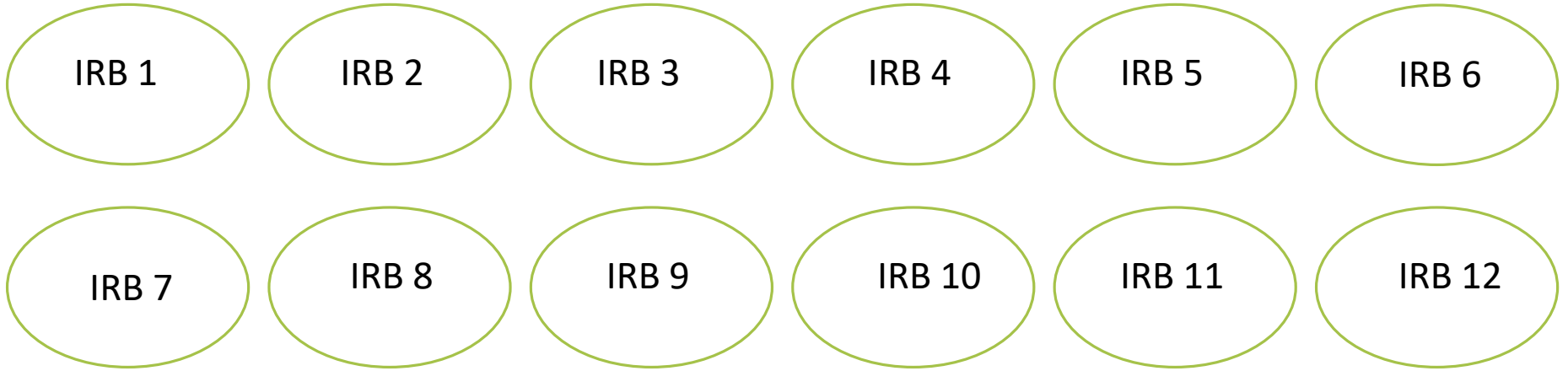
Functions

- 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

IRB Restructuring

Committee reorganization

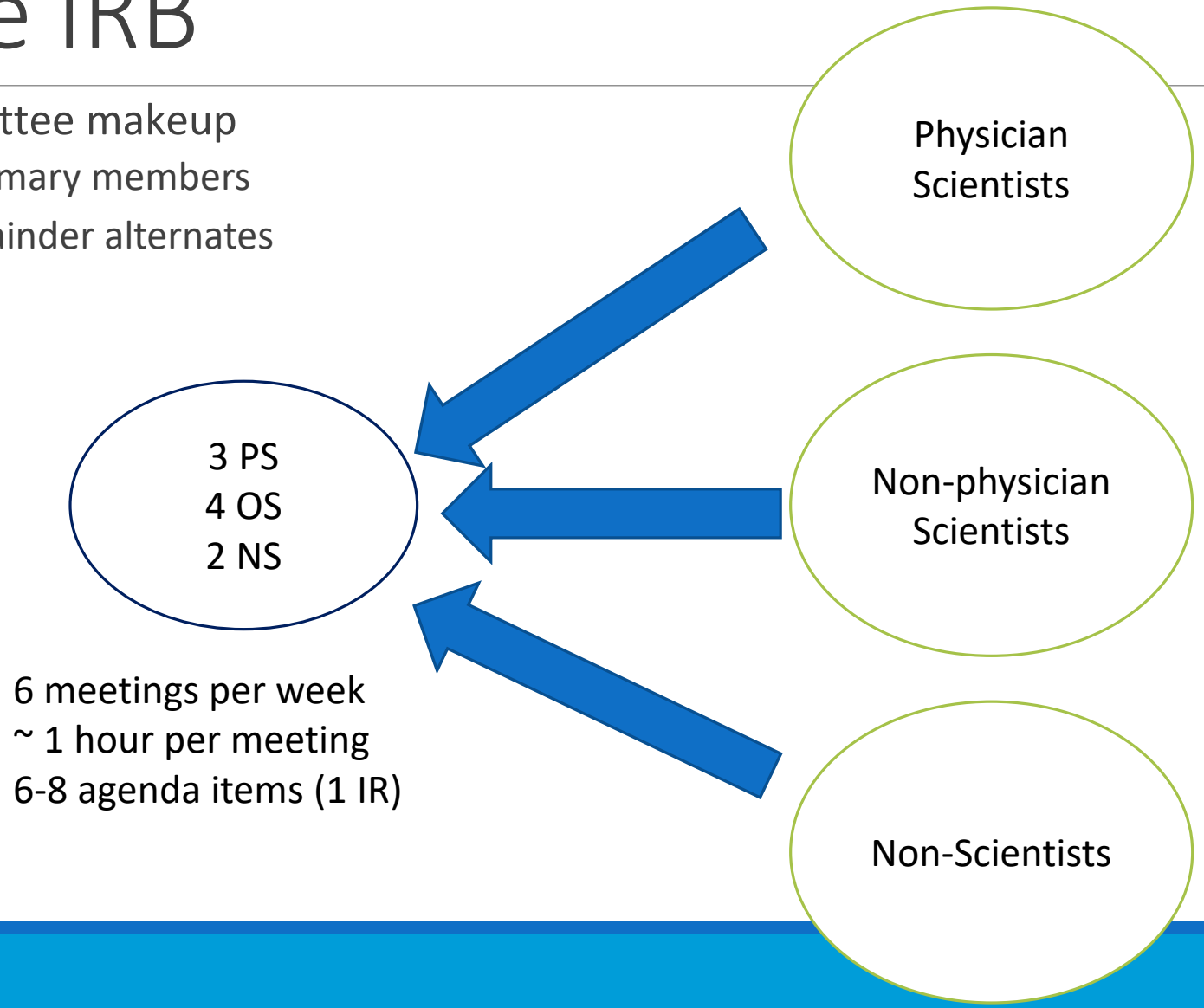


15-20 members/committee
Meet monthly for 2-6 hours
??? agenda items

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

Office of Policy

Manager: Heather Bridge

Continual evaluation and development of policy

- Functionality
- Compliance
- Address new regulatory and ethical challenges

Policy Revisions

Simplify

Keep focus on policy not operations

Compliance with revised Common Rule

Progress to date

- 8 of ~ 33 policy cleared
- 3 active

Office of Compliance and Training

Manager: Peg Sanders

Triage reportable events

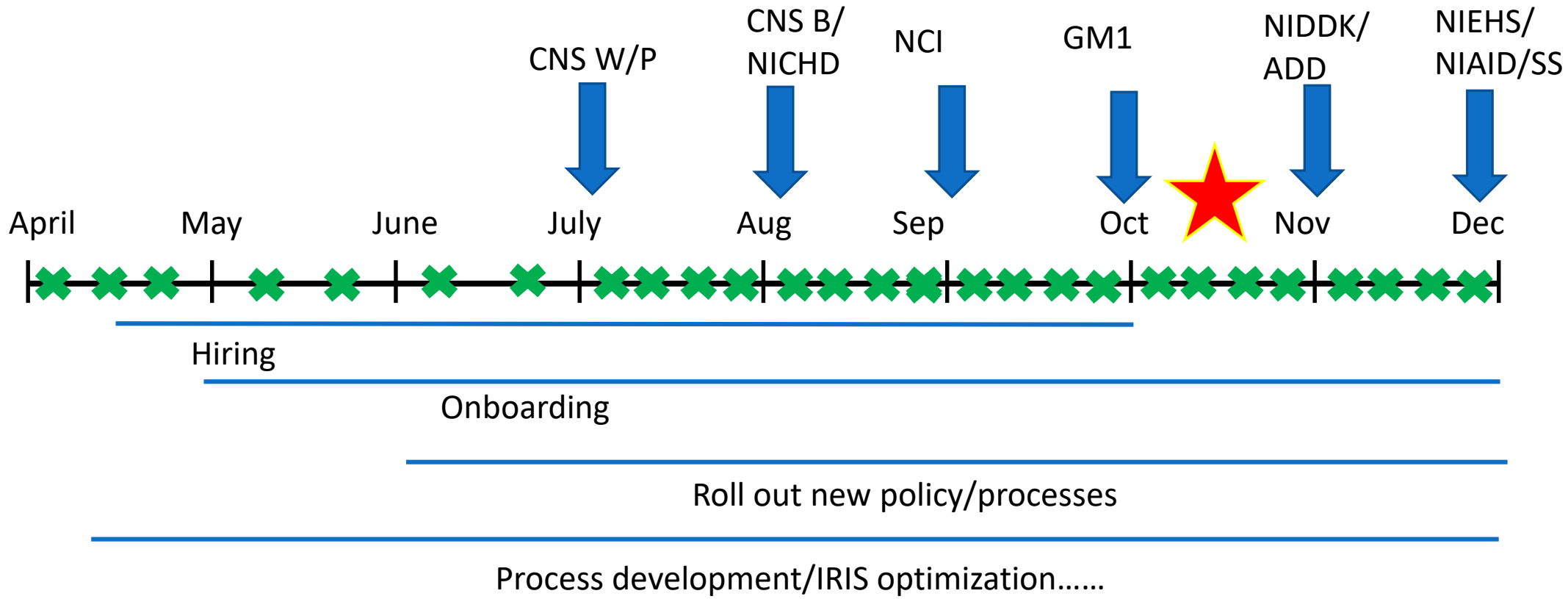
Manage non-compliance investigations

Support Research Compliance Review Committee

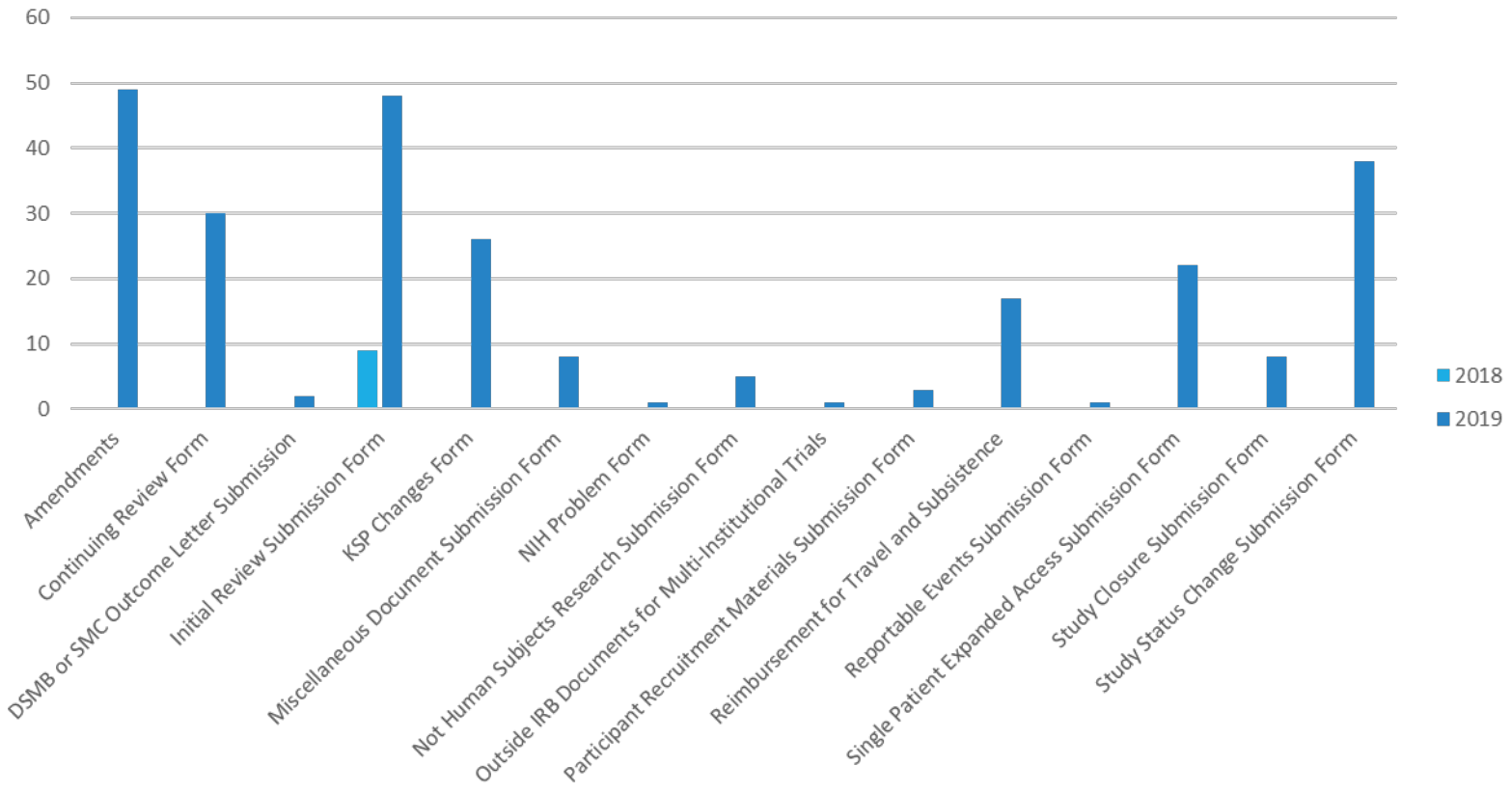
Create and implement educational programs for investigators and IRB members

Research Compliance Review Committee

Timeline

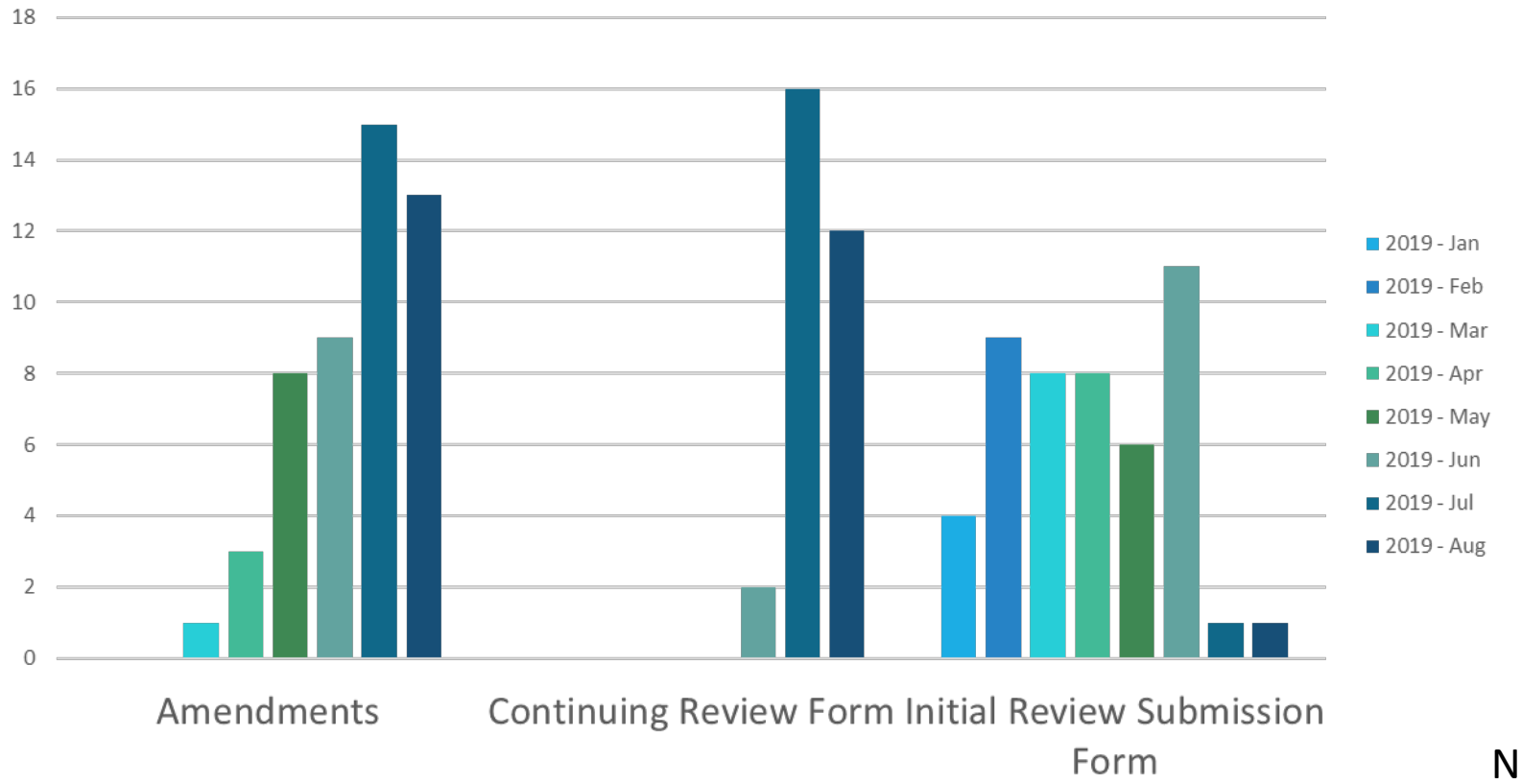

CNS W/P
CNS B/
NICHD
NCI
GM1
NIDDK/
ADD
NIEHS/
NIAID/SS
April
May
June
July
Aug
Sep
Oct
Nov
Dec
Hiring
Onboarding
Roll out new policy/processes
Process development/IRIS optimization……

Total submissions to IRB through end 8/2019



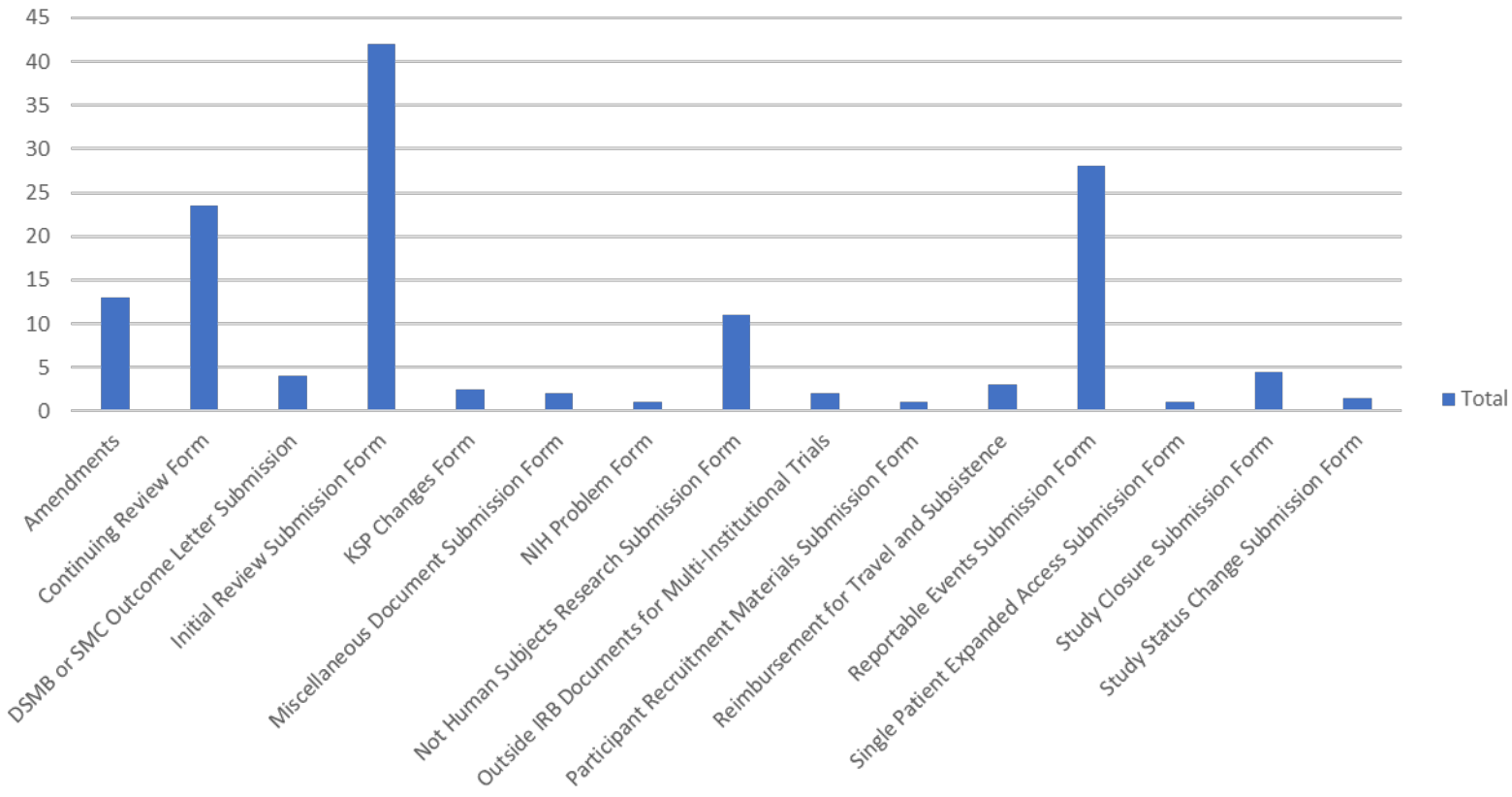
Total = 268

Submissions of IRs, Amendments, CRs (through end 8/2019)

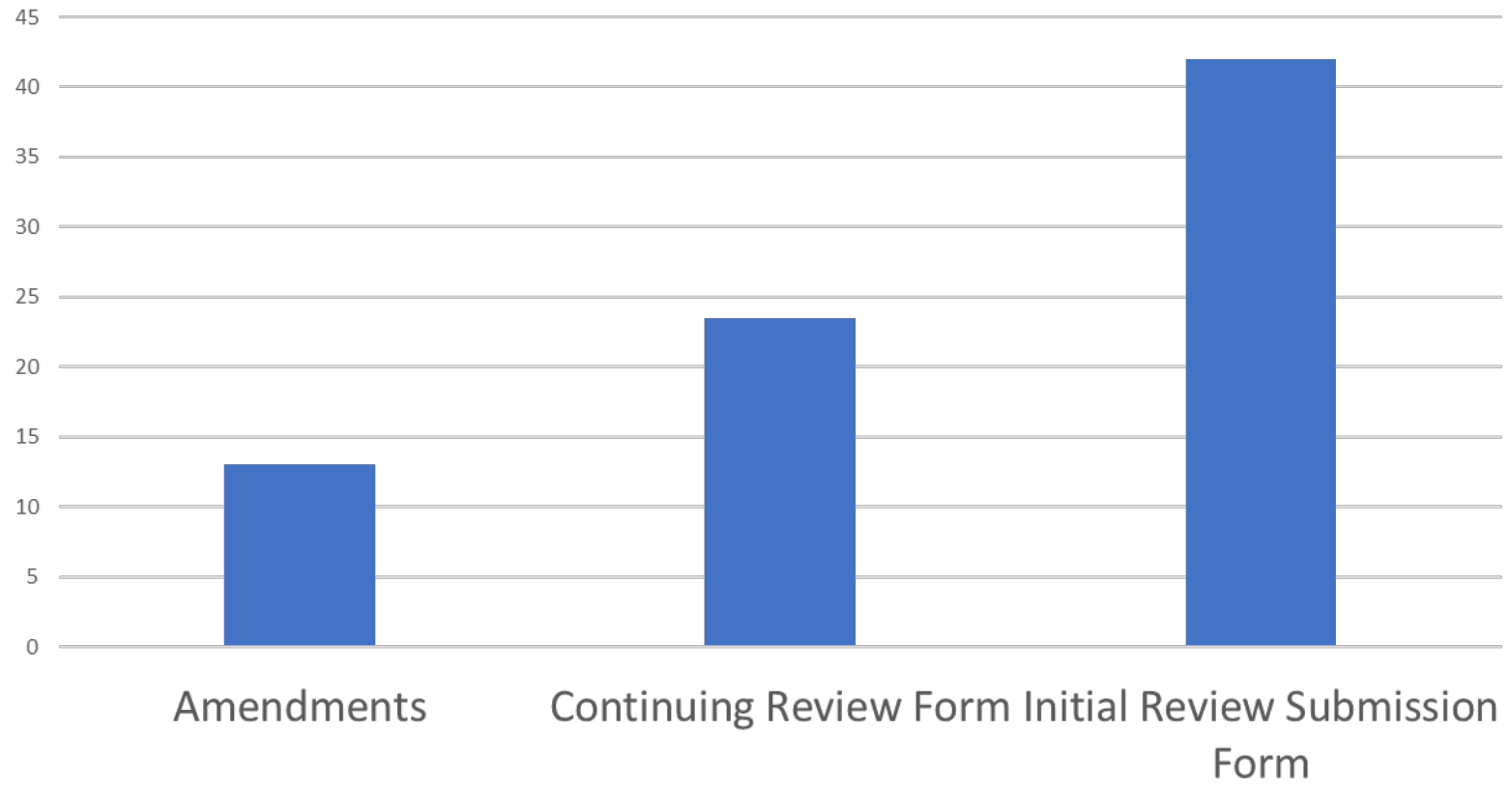


N=136

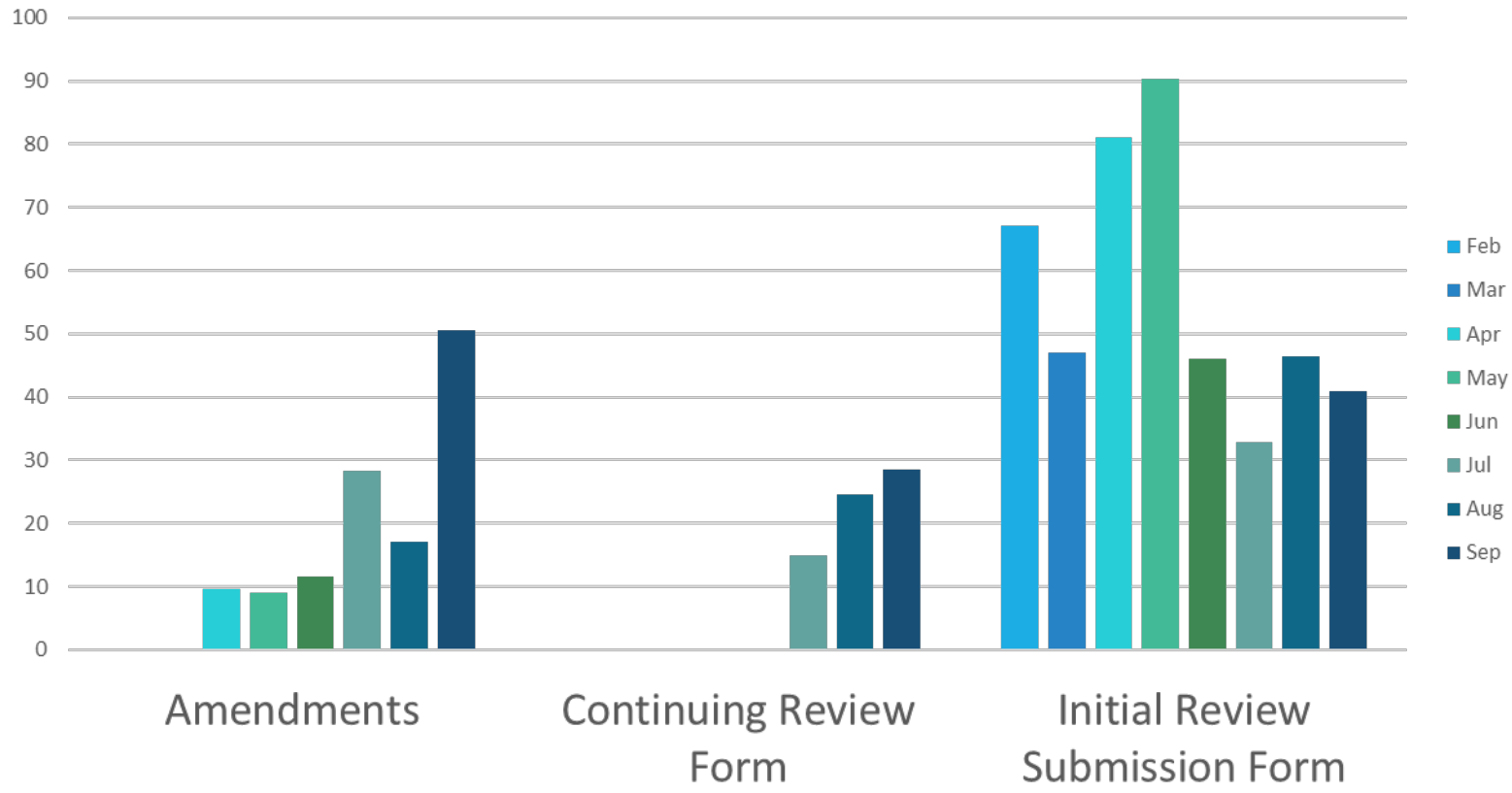
Median time to approval, all forms (ytd)



Median time to approval (ytd)



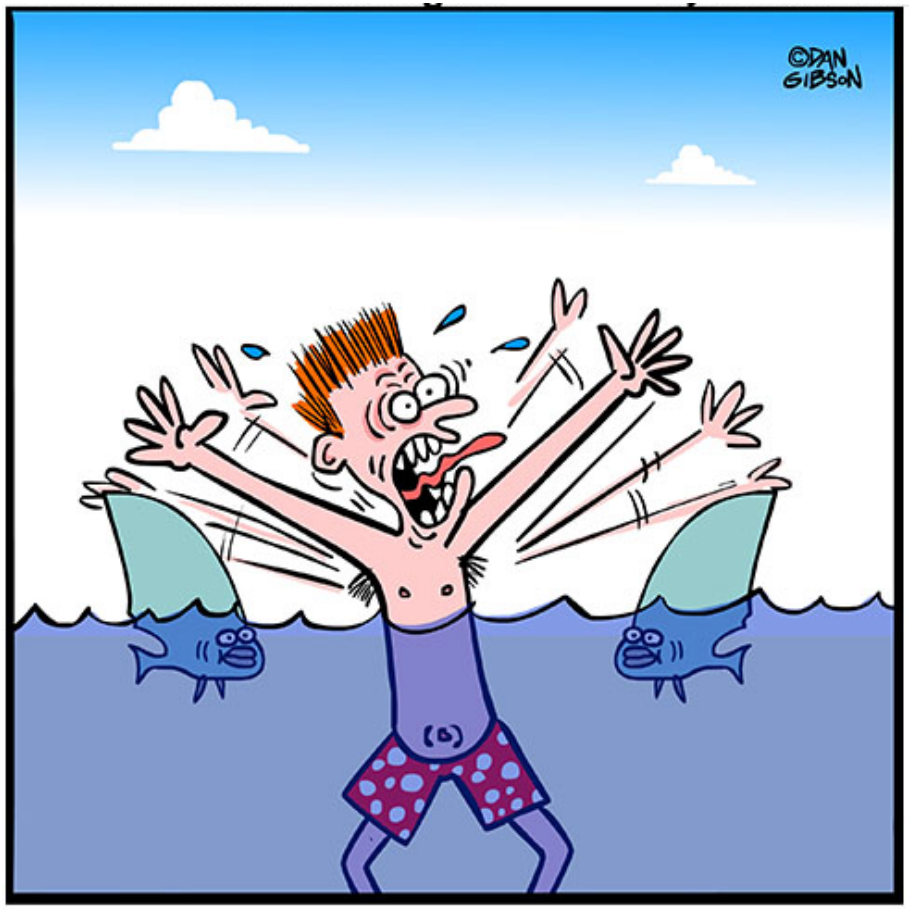
Median time to approval (ytd)



How are we doing?

Are we where we want to be?

Will we get there?



The next time you're feeling worried or stressed always remember... Your problems are never as bad as they appear to be.

What problems are we encountering

Staffing

Space

iRIS not optimal for IRBO workflows

Wide variation in protocols, expectations from each IC and IRB

Deficiencies in investigational device determinations

Problems with documentation for expedited reviews

Whats left?

- 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…..


42
12
RAIDERS
FRANTZ


SATISFIED CUSTOMERS

Save the date

September 18, 2019 2-4pm**:** WIRB Commercial IRB, FAES Classroom #4 B1C205

October 1, 2019 1-3pm**:** Advarra Commercial IRB from 1-3pm FAES, Classroom #6, B1C208

October 8, 2019, 2PM: OHSRP Education series*, Regulatory considerations in pediatric research* in Lipsett auditorium

November 4, 2019, Noon**:** OHSRP Education series*, Investigational Device Research* Lipsett auditorium