• 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)
FDAn 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

- 3 PS
- 4 OS
- 2 NS

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
Stable membership
- Experienced clinical researchers
- Experienced IRB members

Duly convened IRB

Review potential serious/continuing non-compliance for all protocols

Focus on identifying systemic problems and developing solutions

Research Compliance Review Committee
Timeline

- 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?
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

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

Things to do:

- 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.....
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