Update from Office of Research Subject Protection

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Agenda

1. Current Challenges at the IRB
2. Facilitating Ethical Research
3. IRB Data

What's new at the IRB?

CURRENT CHALLENGES AT THE IRB

Current Challenges

- 2018 Common Rule Implementation
  - Except FDA-regulated and DoJ-funded
- Converting studies – HIGH volume.
  - to new SmartForm
  - to new regulations
- Lack of guidance from Federal Authorities

Changes in ORSP

- New Phone Tree
- Redesigned SmartForm
- Hiring Education Coordinator

Changes on Hiatus

AAHRPP re-accreditation submission in process

- Self-evaluation due June 15th
- HRPP should not implement substantial changes during the re-accreditation process
  - Cannot implement changes between final submission and site visit

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Changes under Consideration

- Timing of Comments for Committee Review
- Personnel Amendments
- Fast-Pass
- IRB Membership

Other Undertakings

- Defining Exempt Category 3: Benign Behavioral Intervention
- Refining External IRB Review Process
- IRB Satisfaction Survey – Happening Now!

Current Workload

Committee Review

- 75 Active Submissions
  - 36 Amendments
  - 4 Closures
  - 16 Continuations
  - 16 Initial Reviews
  - 3 Reports
- 21 Pending PI Action
- Median Time in State: 12 Days

Single Reviewer

- 287 Active Submissions
  - 92 Amendments
  - 21 Closures
  - 57 Continuations
  - 113 Initial Reviews
  - 3 Reports
- 81 Pending PI Action
- Median Time in State: 12 Days

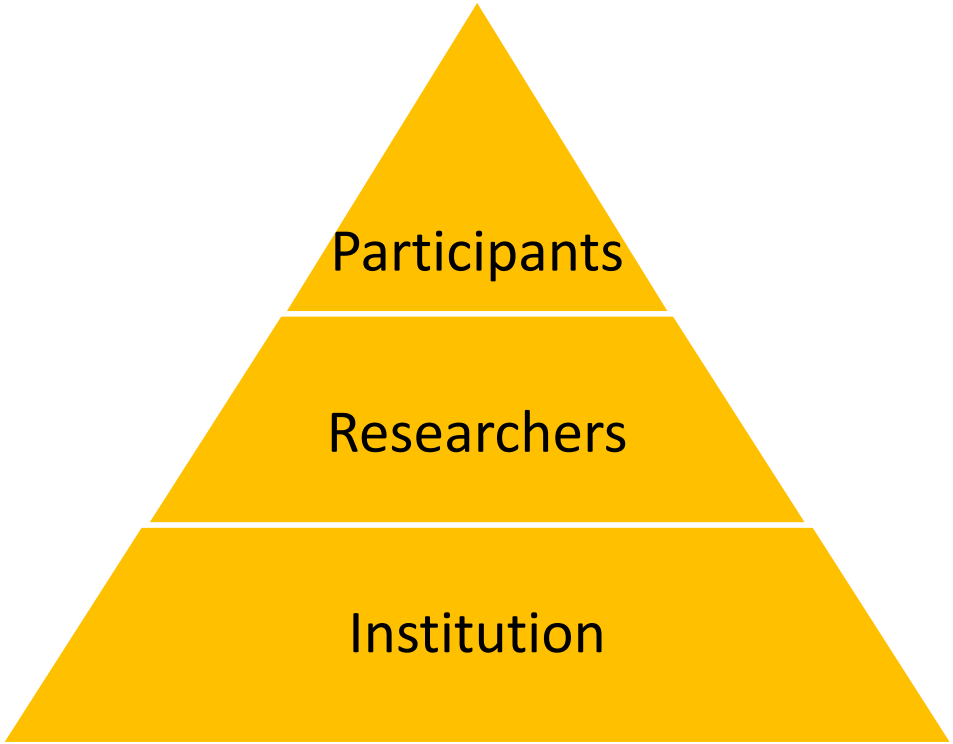
External IRB Review

- 27 Active Submissions
  - 14 Amendments
  - 13 Initial Reviews
    - 2 Pending PI Action
    - 3 In Review by External IRB
- Median Time in State: 10 Days

How can you help?

FACILITATING ETHICAL RESEARCH

IRBs Must Support Researchers

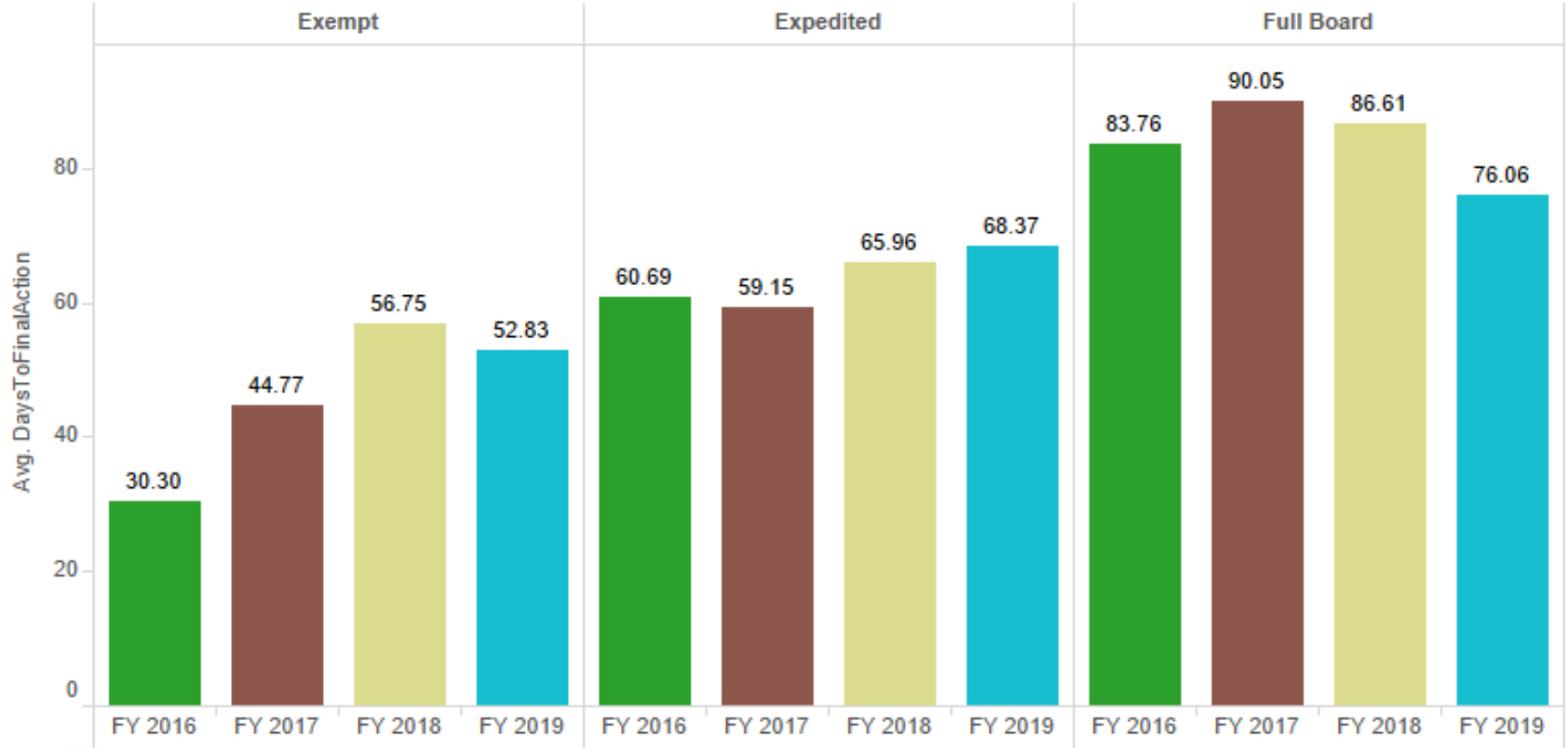


How You Can Help

1. Look for the rest of the story.
2. Highlight and promote successes.
3. Help us make change.

DATA

Average Days to Initial Approval



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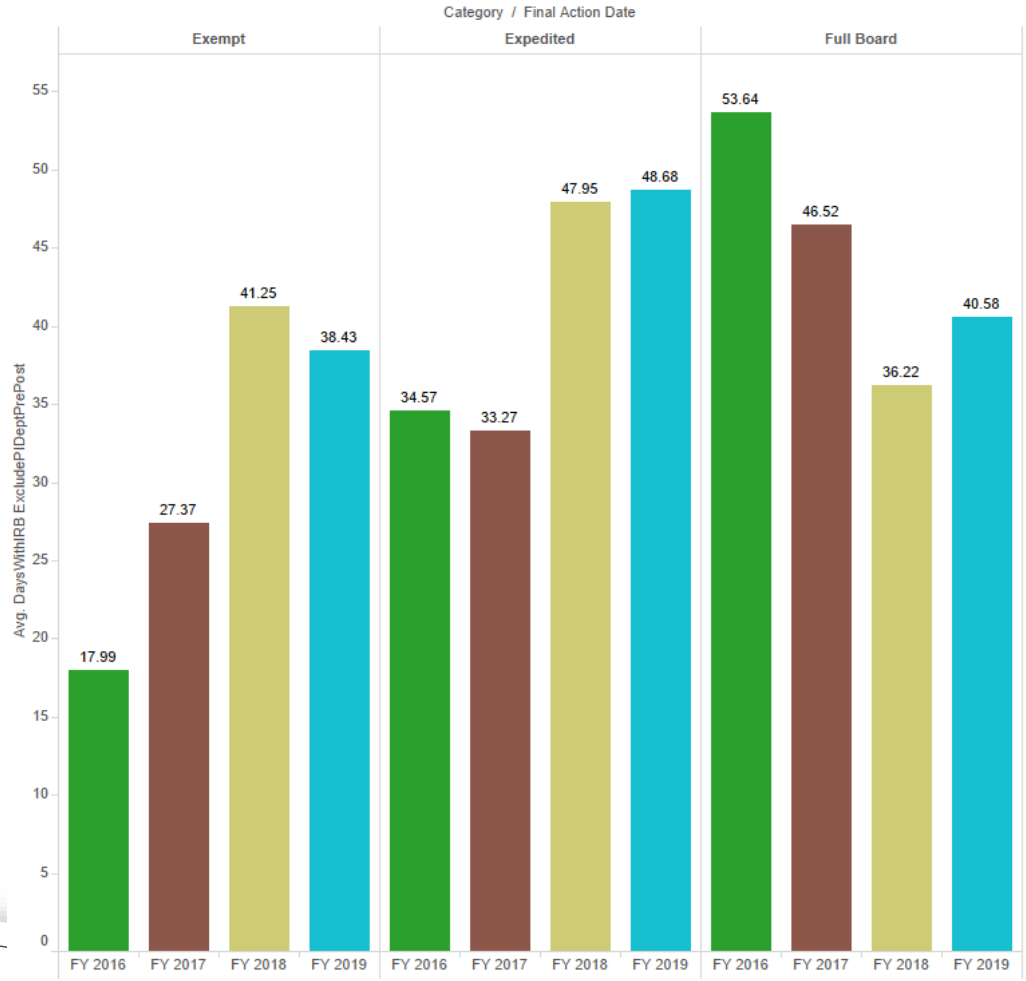
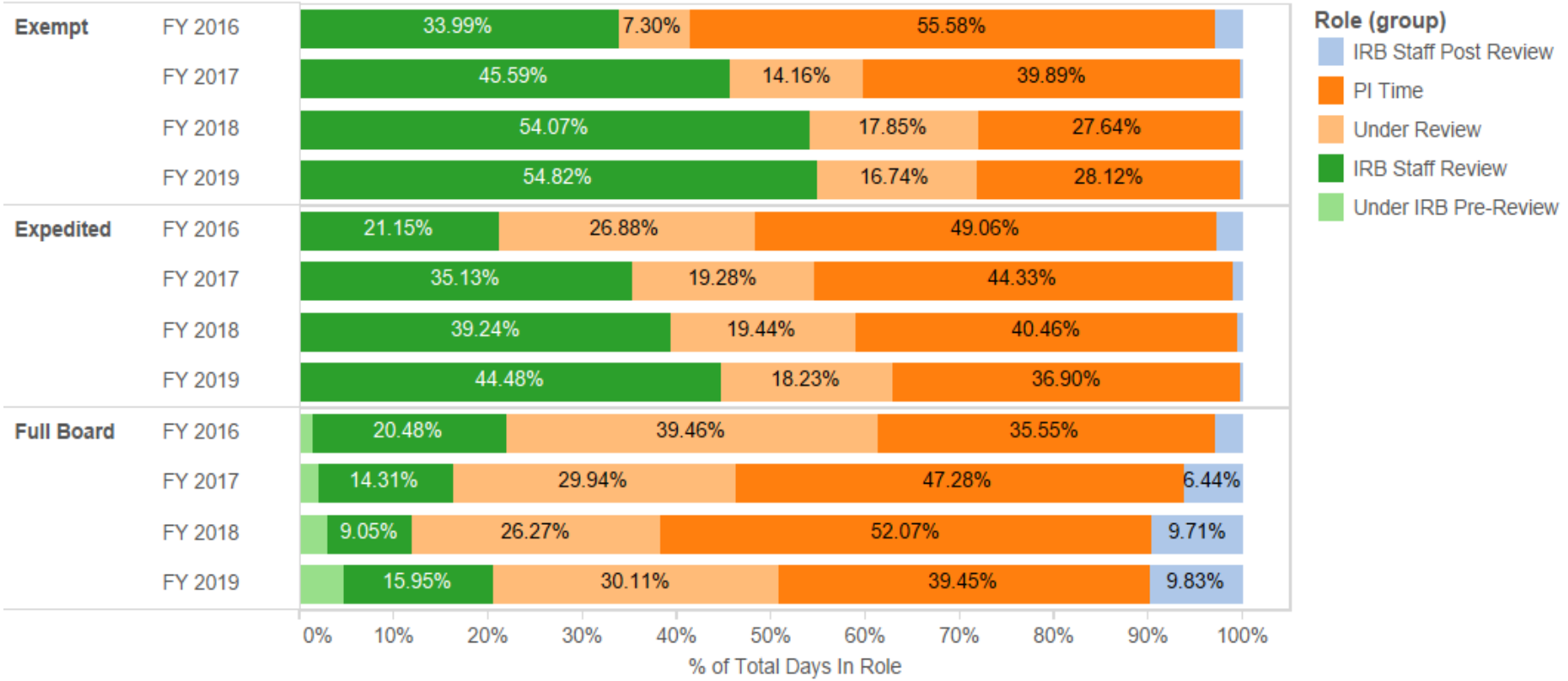
FY 2019 data as of 30 April 2019

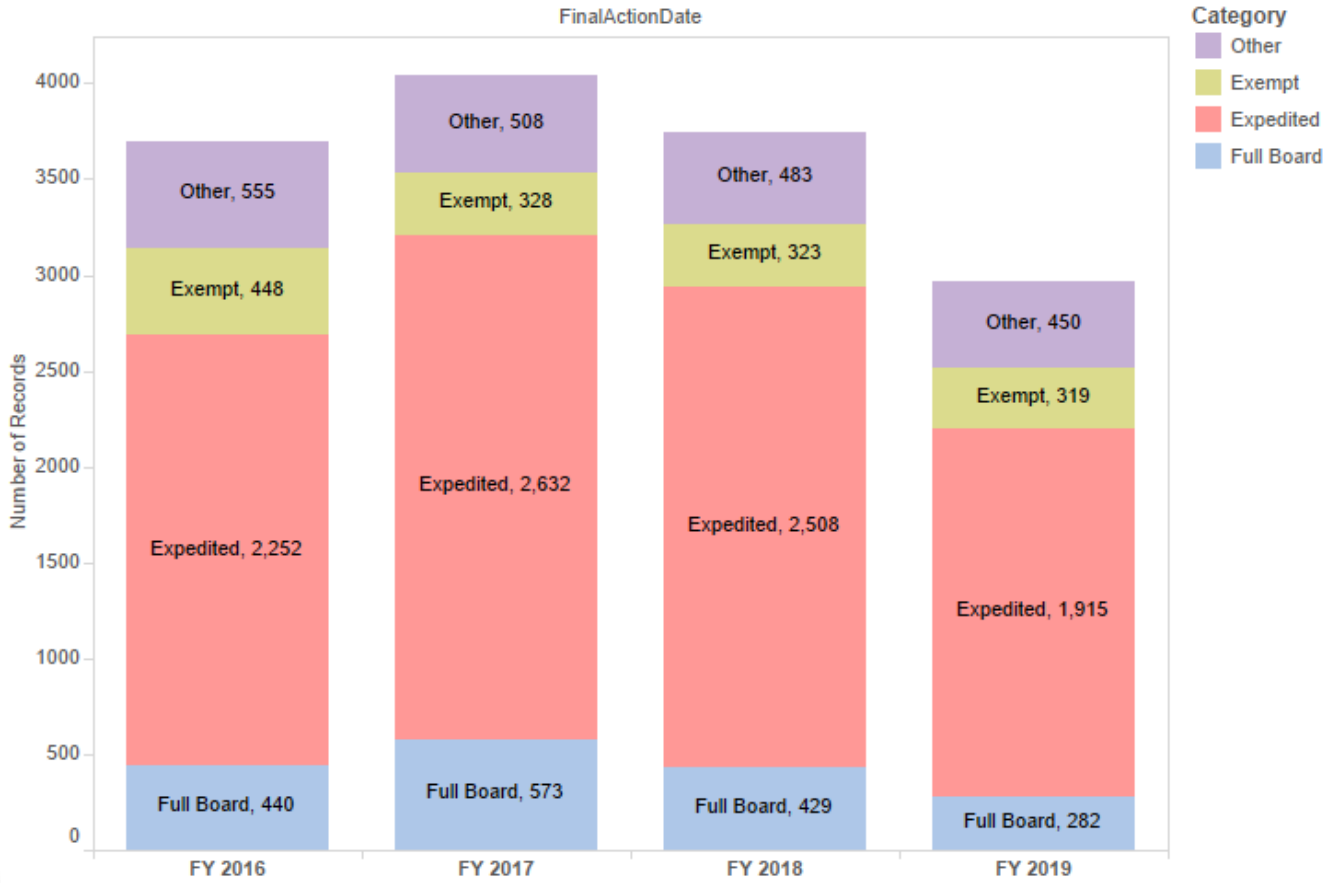
Avg Days To Approval_Less PI



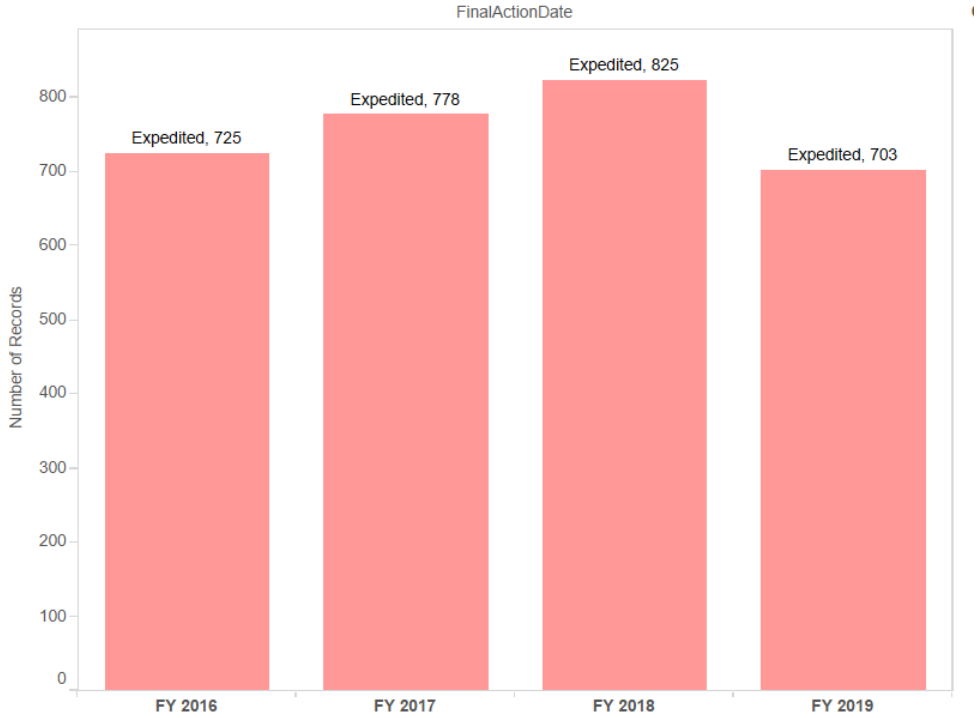
Percent of Time by Role for Initial Approval



IRB Submissions Over Time



Expedited Continuing Review



Number of submissions (Initial, Amend, Continuing, and Report) by year of Final Action Date. Excludes data from InfoEd.

2018 Common Rule does not require continuing review for Minimal Risk Research.

After 2019, these reviews should be gone, reducing the Single Reviewer workload by roughly 1/3.