Update from Office of Research
Subject Protection

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Director, HRPP
Agenda

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

As of 29 April 2019
How can you help?

FACILITATING ETHICAL RESEARCH
IRBs Must Support Researchers

- Participants
- Researchers
- Institution
How You Can Help

1. Look for the rest of the story.

2. Highlight and promote successes.

3. Help us make change.
Average Days to Initial Approval

<table>
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<tr>
<th></th>
<th>Exempt</th>
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<th>Expedited</th>
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<th>Full Board</th>
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<td>FY 2019</td>
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<td>68.37</td>
<td>76.06</td>
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FY 2019 data as of 30 April 2019
Percent of Time by Role for Initial Approval

<table>
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<tr>
<th>Role</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
<th>FY 2019</th>
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<tr>
<td>IRB Staff Post Review</td>
<td>33.99%</td>
<td>45.59%</td>
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<td>PI Time</td>
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<td>55.58%</td>
<td>39.89%</td>
<td>27.64%</td>
<td>28.12%</td>
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<tr>
<td>IRB Staff Post Review</td>
<td>21.15%</td>
<td>35.13%</td>
<td>39.24%</td>
<td>44.48%</td>
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<tr>
<td>PI Time</td>
<td>26.88%</td>
<td>19.28%</td>
<td>19.44%</td>
<td>18.23%</td>
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<tr>
<td>Under Review</td>
<td>49.06%</td>
<td>44.33%</td>
<td>40.46%</td>
<td>36.90%</td>
</tr>
<tr>
<td>Full Board</td>
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<tr>
<td>IRB Staff Post Review</td>
<td>20.48%</td>
<td>14.31%</td>
<td>9.05%</td>
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<tr>
<td>PI Time</td>
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% of Total Days In Role
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.