AAHRPP 2022 Webinar Series:

March 2022 Webinar:
The HRPP Office of the Future

March 1, 2022 – 1:00pm – 2:30pm ET

Eric Allen, University of South Florida
Kelley O’Donoghue, University of Rochester
Rebecca Rousselle, Emory University
New Format for 2022

- **Attendee Hub**
  - Livestreaming Webinars
  - Networking/Community
  - Chat/Discussions
  - Icons on Home Page

- **All 2022 Webinar Sessions**
  - Three Webinars:
    - March, July, November
  - One Attendee Hub

- **Resources**
  - Slide Presentation
  - Documents/Resources from Speakers

- **On-Demand Video**
  - Webinar Recordings on Hub
  - Available for a Year After the Webinar
Polls Feature

Please complete the Polls on your screen now and throughout the webinar.
Chat Feature

To chat with your colleagues before and after the session, or if you have technical questions, use the “Chat” icon.
Questions

To ask questions about the topic for the presenters, please use the “Q&A” icon:
Join Us!!

2022 AAHRPP Annual Conference

in Denver, Colorado
May 24-26, 2022

Register [HERE](https://aahrpp.org) or visit [aahrpp.org](https://aahrpp.org)

2022 AAHRPP Educational Webinar
Presenter Introductions
Kelley O’Donoghue
Associate Vice President for Human Subject Protection
University of Rochester
Rebecca Rousselle
Assistant Vice President, Human Research Protection Program
Emory University
Eric Allen
Associate Director for Research Integrity and Compliance
University of South Florida
HRPP Office of the Future

Rebecca Rousselle, CIP
Assistant VP for the HRPP
Emory University
Peer into my crystal ball...
What's in the Cards?

Capacity
- pandemic/emergency research
- sufficient staff, ethics and tech expertise
- security, online systems

Remote Work
- culture, communication and integration
- tools, motivation, performance management

Research Ethics
- A.I., genomics, big data, virtual space
Building Capacity: People

- Turnover, sick leave, emergent research
- Complexity of reviews
- Single IRB review
Building Capacity: Tech

- Online systems for remote work
- Security review
  - Clarity avoids slowdowns
- eConsent platform(s) BUT...
- Part 11 compliance (not necessarily where you expect it!)
The future is remote

- Engagement survey findings
- Sources of resistance
- What changed?

- Onboarding

- Teams example

- Remote IRB meetings
Resistance and Change

- Concern from leadership that hybrid/remote would not be as satisfying or effective as thought
- Wanted time to pilot, gather data
- ...
- *the working world changed*

- Still gathering data, but swiftly provided remote option for as many staff as possible
RTW Survey and Culture Change

- 72%: “less than 1” is the ideal number of days in office to be effective
- 63%: portion of day working alone*
- 27%: portion of day working with others via phone/tech*
- Home environment rated more effective across all types of work activities
- People come to work for “amenities”
- 85%: people who would rather share a workspace than have to come into office

* self-reported, may be inaccurate
Integrating & Training New Staff

- Daily readings and one-on-one training sessions
- Staff meeting intros
- Zoom lunchtime
- “Open (Zoom/Teams) door” chats
- “Pods” of go-to colleagues
- Social Committee “events” (virtual or in-person)
  - Thank goodness for extroverts
New staff training: example
### New staff training: example (excerpt)

<table>
<thead>
<tr>
<th>Day</th>
<th>Module/Action Item</th>
<th>Date</th>
<th>Go-To Staff Member</th>
<th>Go-To Staff Responsibilities</th>
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<tbody>
<tr>
<td>-14</td>
<td>Pre-Hire Prep</td>
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<td>Done</td>
<td>1) Ensure all Pre-Hire Prep responsibilities are accomplished.</td>
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<td>1</td>
<td>Getting to know the office</td>
<td>3/2/2022</td>
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<td>1) Review Module 01</td>
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<td>2) Provide a clear explanation of the historical foundation of research ethics.</td>
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<td>3) Ensure a substantive understanding of the Belmont Report and its principles.</td>
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<td>5) Give the New-Staff Member an authentic feeling that their work is meaningful and important to both individuals and, much more broadly, society.</td>
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<td>5) Review of where to find Emory IRB SOPs and other important links</td>
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<td>2</td>
<td>Historical and Administrative</td>
<td>3/2/2022</td>
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<td>1) Review Module 04. Meeting with designated analyst about materials read and checklist used at H:\irb_shared\General\Admin SOPs\Checklists, Forms, and Templates.</td>
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<td>2) Also, new staff will go over a new EXPEDITED minimal risk study in eIRB with the designated analyst (do not assign). In order to review a minimal risk study together in eIRB, print out relevant materials (lay summary, protocol, consents, etc.) and allow new-staff to read materials before you review so they aren’t just watching you read.</td>
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<td>b) Present Expedited review designation categories clearly.</td>
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<td>c) Provide understanding of when F(8) designations are used (after Full-Board).</td>
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<td>d) Show the new-staff an example of an F5 and an F7 (most common) Expedited study protocol in eIRB.</td>
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<td>e) Provide understanding of review process (designated review, letter writing, stamped consents, set expiration, etc.) for Expedited and other minimal risk studies.</td>
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<td>Expedited Review</td>
<td>3/3/2022</td>
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Ongoing integration:

“Teams” Example

Also have a similar Team for “IRB Leadership”

Note: not the place for very sensitive information. The internet is forever...
What motivates?

• Minimize micromanaging
• Involvement in sub-committees
• Social committee
• Speaking and connecting more with researchers
  • *More now than pre-pandemic!*
• Periodic in-person gatherings
• Venting channel (redacted of course!)
What motivates us?

“I have found that at low energy times, having someone to body double really helps. So while we may be working from home by ourselves having someone on a call or video also working with us can help.”

“I am able to build my comfort zone to facilitate my optimal work space. I don’t like closed windows, air conditioning, or shoes! When I work from home, my windows are open, the birds are singing, I can see trees and greenery out the window, I'm not freezing from the air conditioning, and I am not wearing shoes! Those are all things that help me be in my at-home-work-zone.”

“I feel very interconnected in my work not only with my colleagues at IRB but also with the ORA and wider organization. I want to get my work done well and quickly because it is clear how our work connects within the wider organization and other colleagues’ work.”
Managing Performance

Again: Minimize micromanaging

- “Some companies have key loggers/mouse trackers/etc. to constantly monitor employees, which I think would be bad for my morale.”

Teams on green unless posted as OOTO

- We have a Teams channel for OOTO updates, to set expectations for each other

Turnaround Reports

- Lobby now for better reporting!
- Doesn’t have to be directly from the system vendor
- Biweekly(ish) meetings with direct reports to review inbox
IRB Members: Remote Meetings

• **Issue**: positive experience for new members?
  - **Potential solution**: create time for spontaneous questions, bonding

• Hard to force people to share their cameras

• (Also, “IRB’ing while driving”)
Virtual Connection & Communication

• Beyond the IRB office – whole HRPP
• Bi-monthly or quarterly “joint compliance” meetings
• Senior staff meetings for research administration – include broader leadership teams from each office
• “Coffee and Conversation” with all of research administration
  • Time for Q&A
  • Researcher speakers
• Social Justice Committee

Your ideas?
Emergency/Public Health Crisis Research: Emory’s “Rapid Response” Protocol

• Qualifying Criteria:
  • High Priority; Requiring emergency approval for survival
  • Public Health Emergency
  • Bioterrorist Attack
  • Significant outbreak of an Infectious Disease
  • Other significant or Catastrophic Event

• Requested by:
  • NIH or other Federal Funded Network Study
  • Centers for Disease Control and Prevention (CDC)
  • IND or IDE
Emergency/Public Health Crisis Research: Emory’s “Rapid Response” Protocol

Each department completes departmental approval.

If applicable, external/single IRB is notified of urgency.

Clinical Research Navigator team facilitates the pre-award approval process through all research administrative offices to completion.

Each office assigns one person to complete the approval and other tasks in real time, working in parallel with other offices.

Clinical Research Navigator notifies the investigator when study approvals are complete.
“Top 9 List”

• A.I. and Big Data transparency
• Consent waivers for research of public health importance
• International and Tribal regulations (e.g. privacy)
• Genomic data sharing and identifiability
• Gene editing and chimeras
• Ex-vivo brain tissue/organoids
• Research in the metaverse
• Distrust in science and scientists “truth”
• Diversity and inclusion in all spheres (e.g. AI)
The HRPP Office of the Future

Eric Allen, MLS, CIP, CPIA, University of South Florida
Objectives

• New IRB structure
• Modified IRB review process(s)
  • eConsent
• New definition of confidentiality & anonymity
• IO & upper-level administration notifications
• Recruitment & retention of IRB staff
• Data transfer processes
  • Embracing technology and ingenuity
New IRB Structure
Committee Membership

- Diversity, Equity, Inclusion and Justice (DEIJ)
- Global community member
- Information technology member
- Philosopher/ethics member
Technology Insight

1. Additional technology member

2. IT checklist guide
   • Acceptable passwords
     • Characters & length
     • Phrases
     • Two factor authentication
     • Digital certificates
     • Logon devices
     • Out of band authentication
   • Firewalls
   • Encryption
   • Institutional device usage
Technology Insight (stats)

• Avg. time from initial compromise to data extraction is minutes to a few days.
• 70%-80% are in system for months prior to detection
• Discovery of a breach by internal resources only happens 10% of the time
Technology Insight (continued)

1. Virtual QA/QI
2. Cyber insurance
   1. Sponsor requirement in 2040?
   2. Research participant expectation in 2040?
3. PI cyber insurance
4. Trusona – multi-factor security that uses driver license data verification service (US only)
Modified Review Process
Technology Adoption Life Cycle

- **Visionaries**: Get ahead!
- **Techies**: Try it!
- **Innovators**
- **Early Adopters**
- **Early Majority**
- **Late Majority**
- **Laggards**

**Pragmatists**: Stick with the herd!

**Conservatives**: Hold on!

**Skeptics**: No way!

Pragmatists cast the deciding vote
New Risks (Risk Benefit Analysis)

1. Assessment of AI & virtual reality platforms
2. Minimizing/notification of digital fingerprint
3. Platform/technology (terms & conditions)
   1. Alt. web browsers
4. Elimination of confidentiality & anonymity
5. eConsent
6. Digital violence
Compensation

- Digital currency
Recruitment & Retention of IRB/HRPP staff
Recruitment

1. Best alternative offer
   1. Location/physical perks can’t replace culture!

2. New HR approaches/practices
   1. Virtual hiring processes
   2. Greater emphases on internal hiring
   3. DEI&J social focus impacting employment decisions
   4. Recruiters expanding their skill sets
   5. Modified job descriptions
Retention

1. Mental health checks
   1. Home is not always better........
2. Building relationships with your people NOT YOUR EMPLOYEES
3. Nontraditional expenses
Data Transfer
Data Transfer Policy

• Storing data
• Transferring data
• Access to data
  • Role based access with terms
  • Leaving the institution
• Updating data security measures
Quantum Computing

1. Growth of cloud computing
2. AI supported credentialing
3. AI supported scientific merit assessment
4. AI supported risk assessments
5. AI supported hologram creation & interaction
My Prototype 2040 IRB
• IRB IT sub committee
• IRB inclusive of 50% diversity (DEIJ)
• IRB finance sub committee
• AI Credentialing
• AI supported scientific evaluations
• Virtual QA/QI (PI verification of variables)
• Continuously evolving job descriptions
• Flexible budgets to adjust to current trends
• Annual federal regulatory updates w/ biannual major updates
• Participation in international IRB audits
IO and Upper Administration Discussions

1. Compressive summary
2. Liability, Requirements and Financial Incentive
3. Comfort zone
Take Home Points

• Resources
  • IO discussions
• Technology support
• Running a 2040 HRPP
Questions?
Thank you!