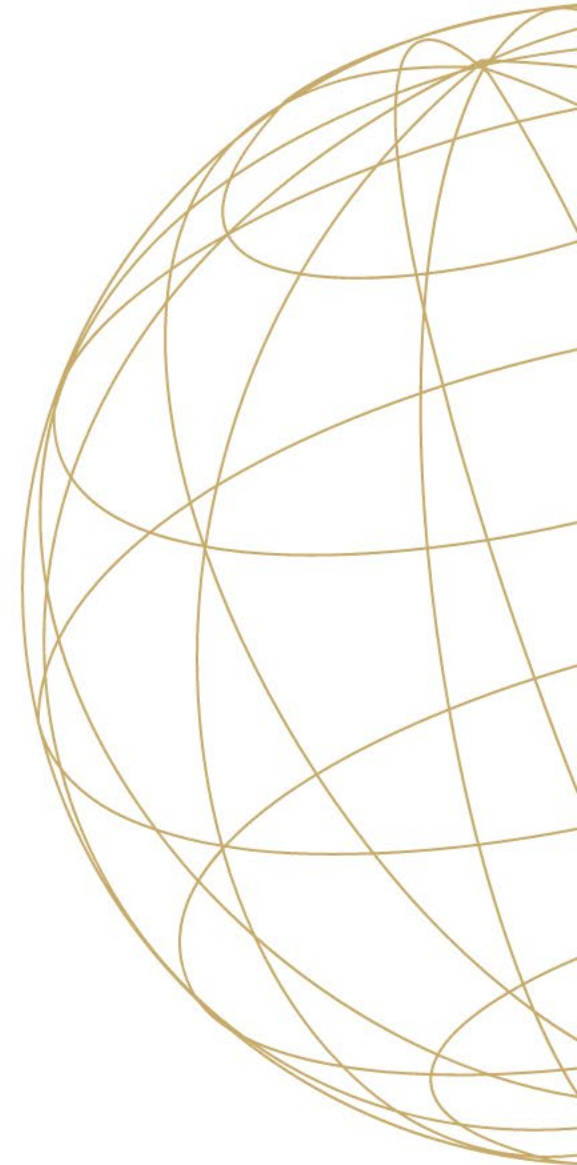


AAHRPP 2022 Webinar Series:

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

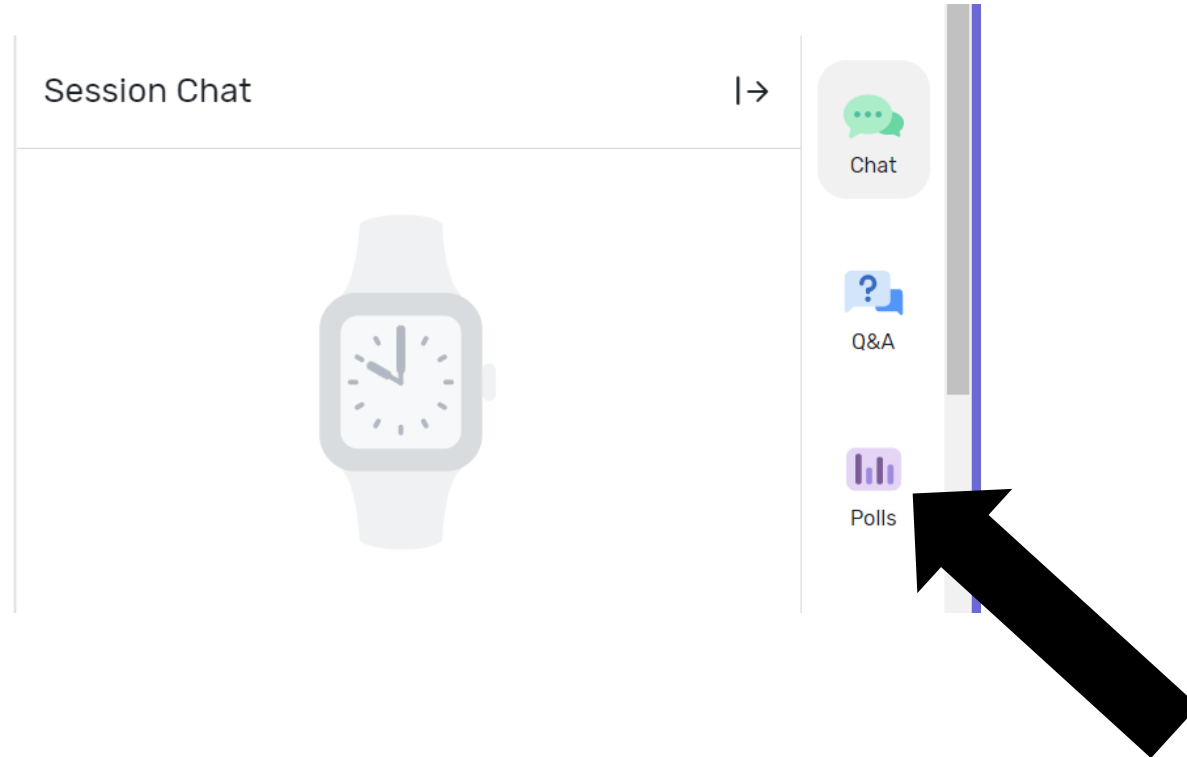


On-Demand Video

Webinar Recordings on
Hub
Available for a Year
After the Webinar

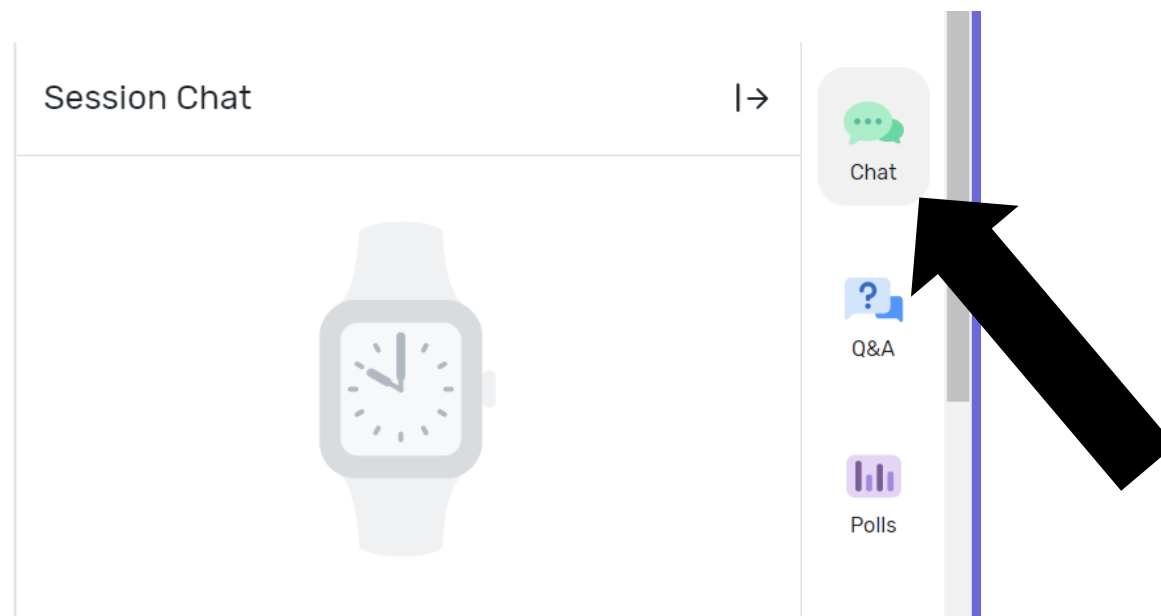
Polls Feature

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



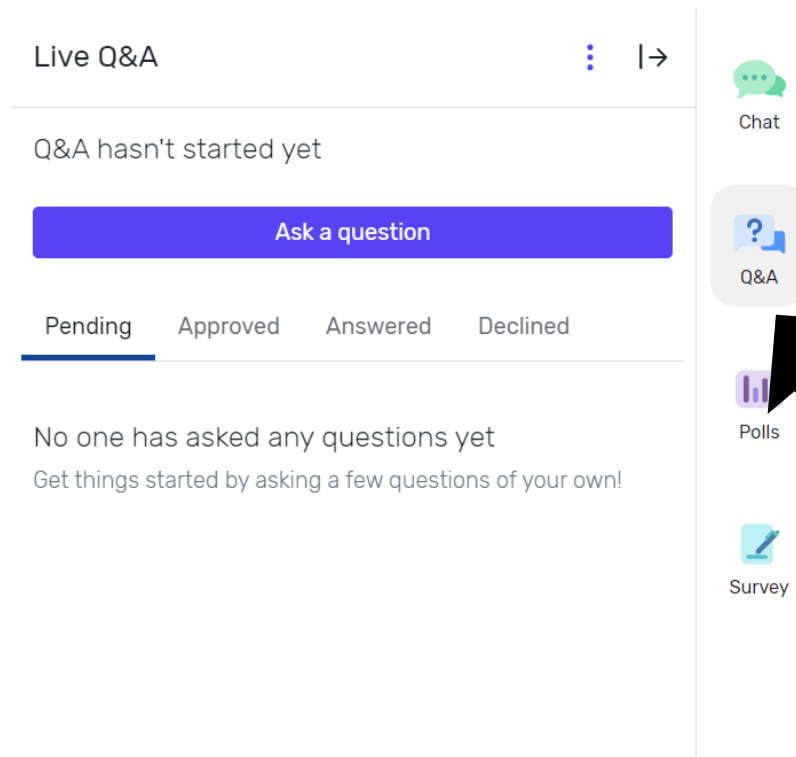
Chat Feature

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:



Live Q&A

Q&A hasn't started yet

[Ask a question](#)

Pending Approved Answered Declined

No one has asked any questions yet
Get things started by asking a few questions of your own!

Chat

Q&A

Polls

Survey



Join Us!!

2022 AAHRPP Annual Conference

in Denver, Colorado
May 24-26, 2022

Register [HERE](#)
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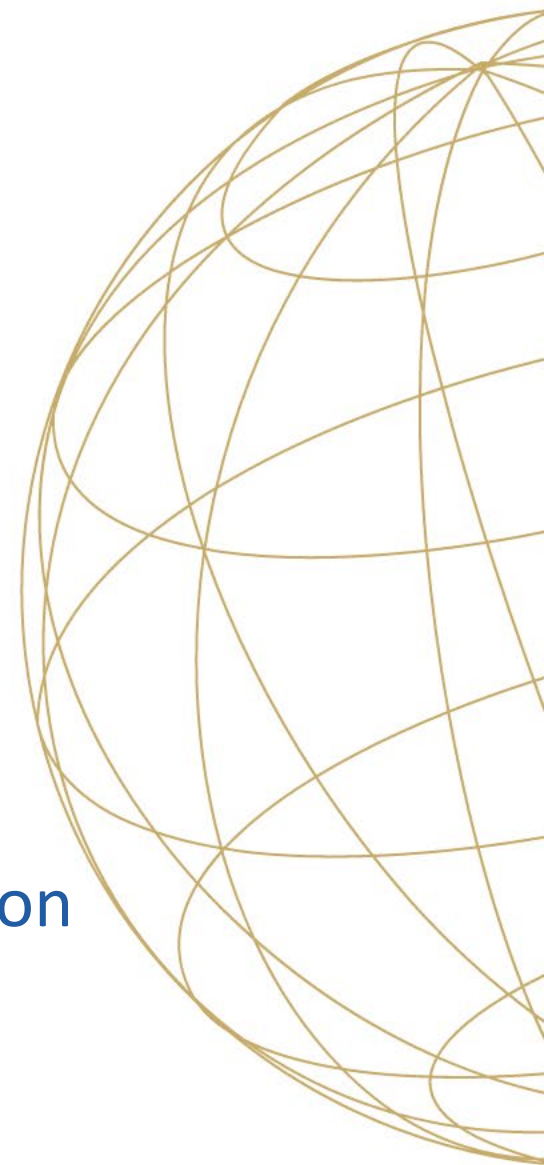
Presenter Introductions





Kelley O'Donoghue

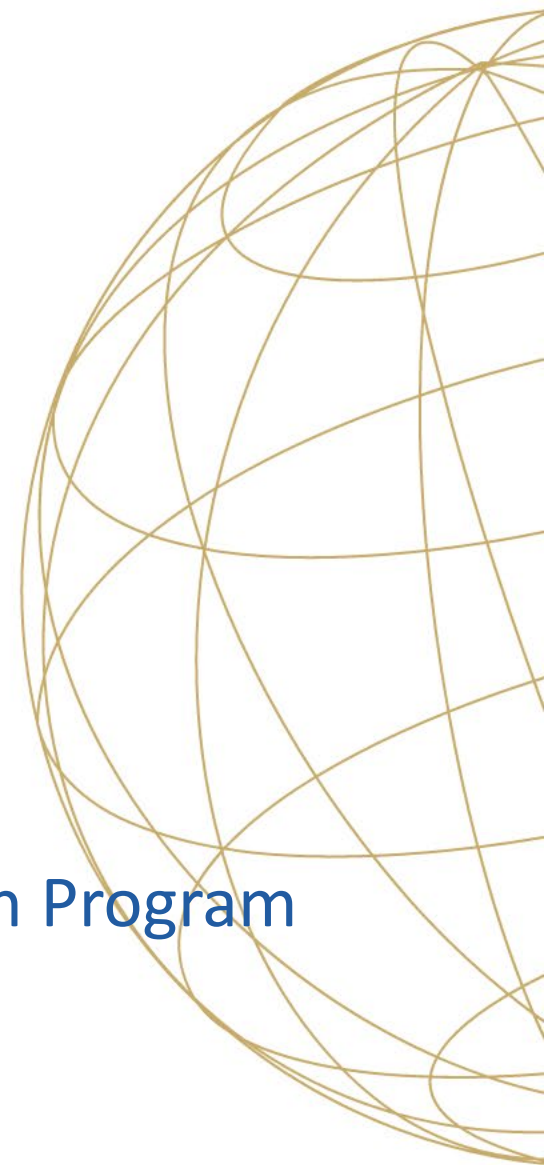
Associate Vice President for Human Subject Protection
University of Rochester





Rebecca Rousselle

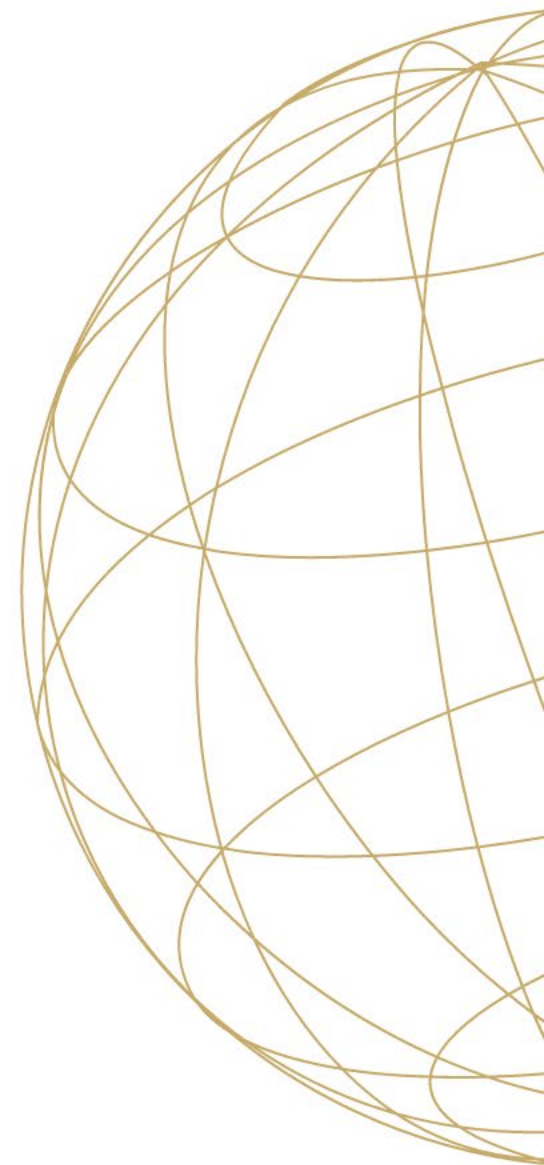
Assistant Vice President, Human Research Protection Program
Emory University





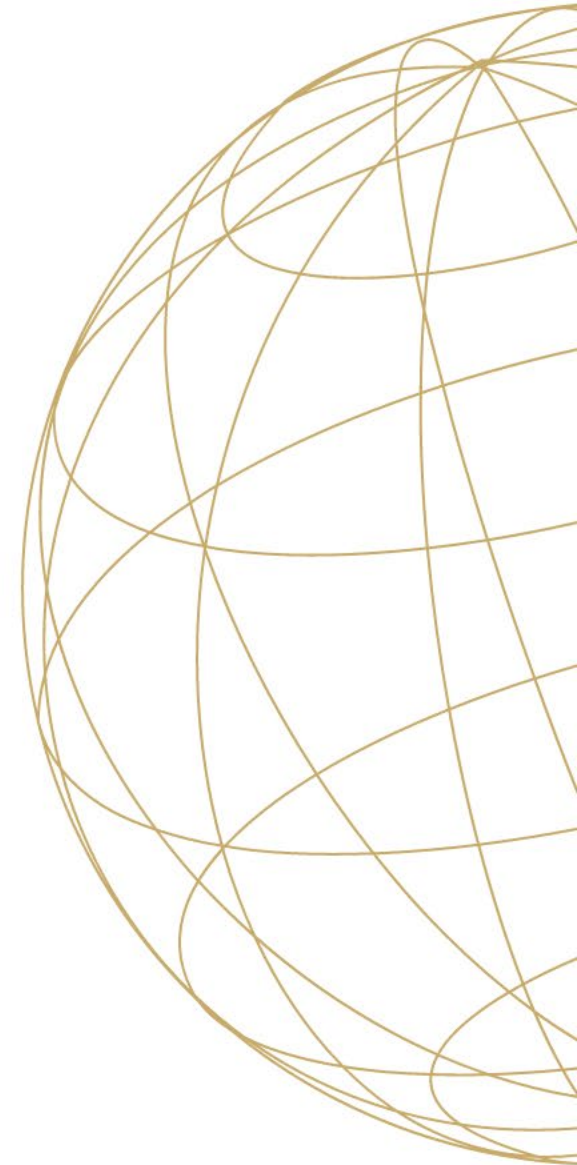
Eric Allen

Associate Director for Research Integrity and Compliance
University of South Florida



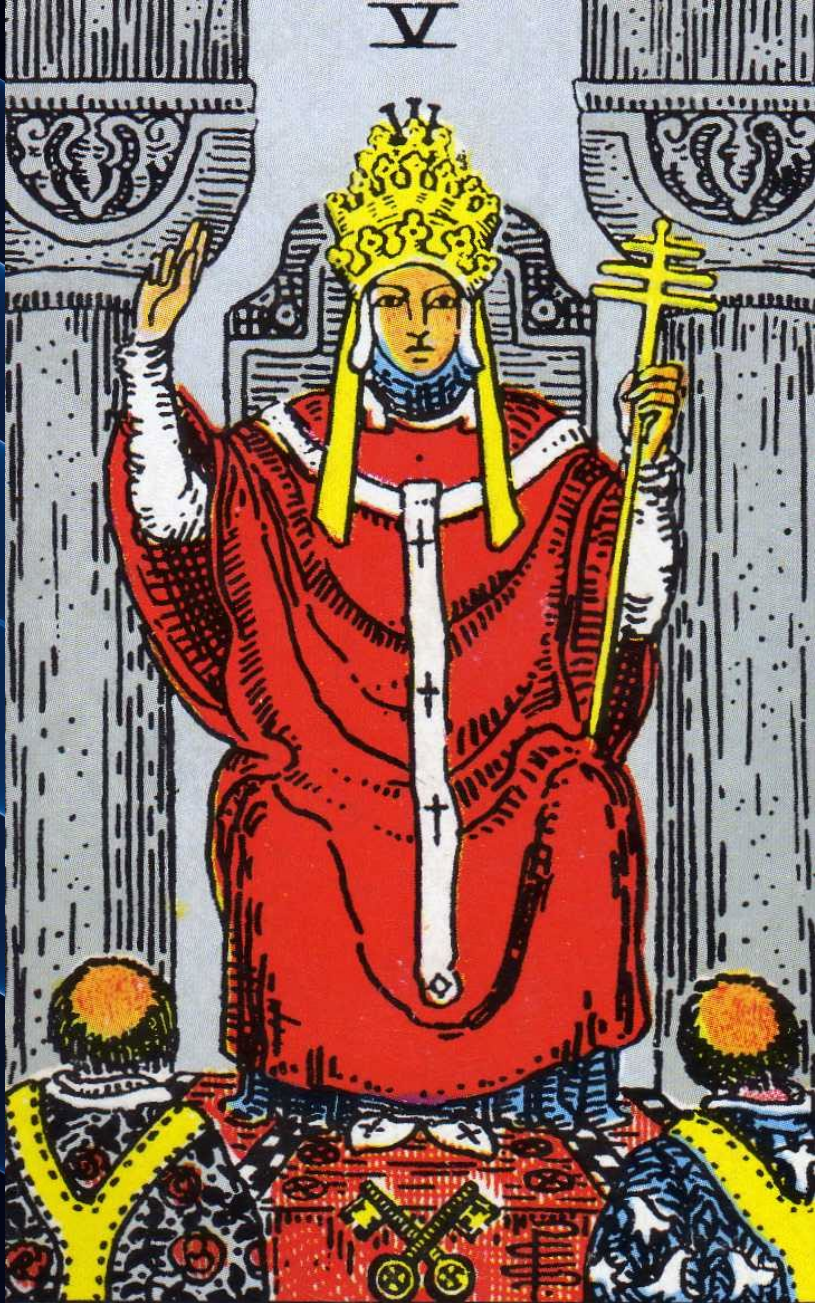
HRPP Office of the Future

Rebecca Rousselle, CIP
Assistant VP for the HRPP
Emory University



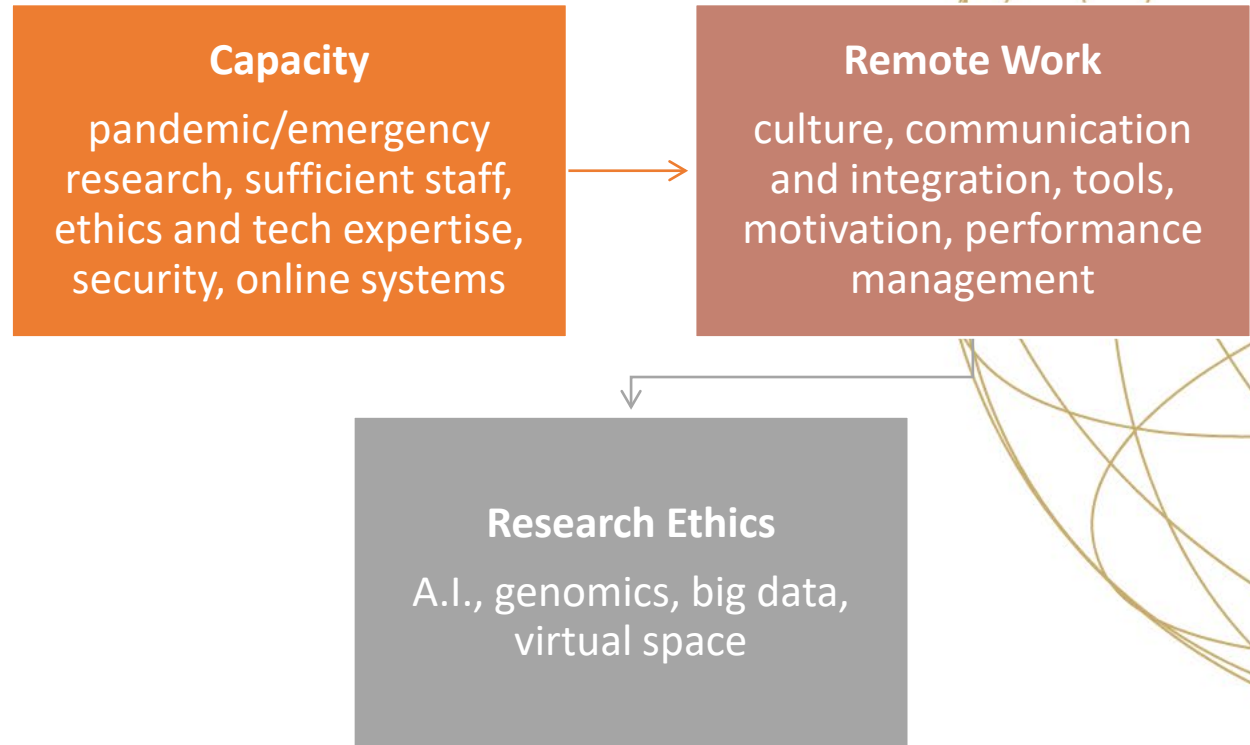
Peer into my crystal ball...





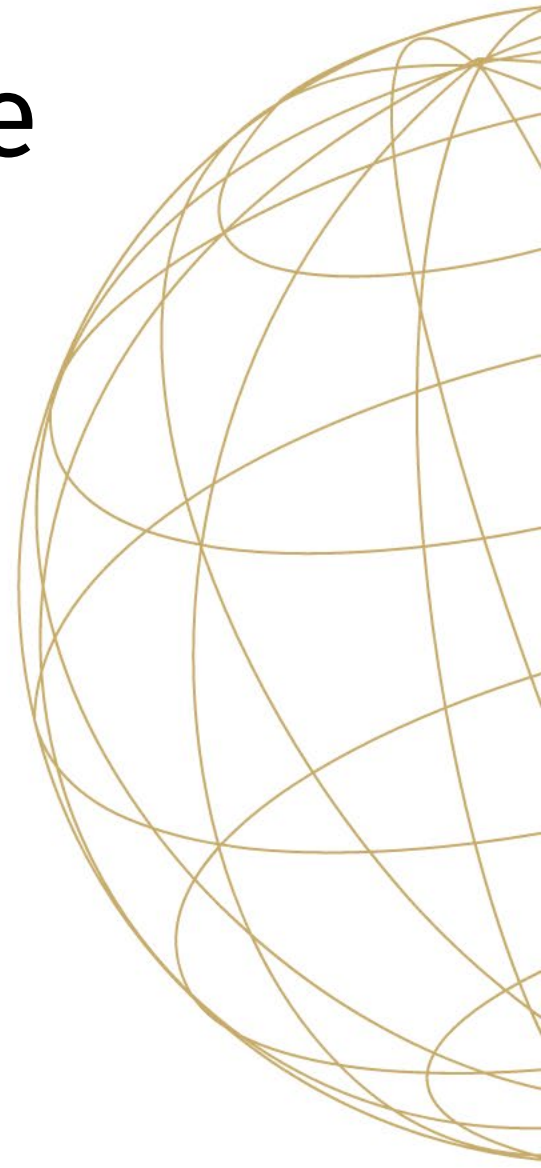
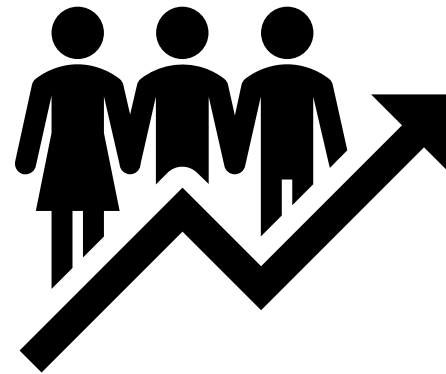
THE HIEROPHANT.

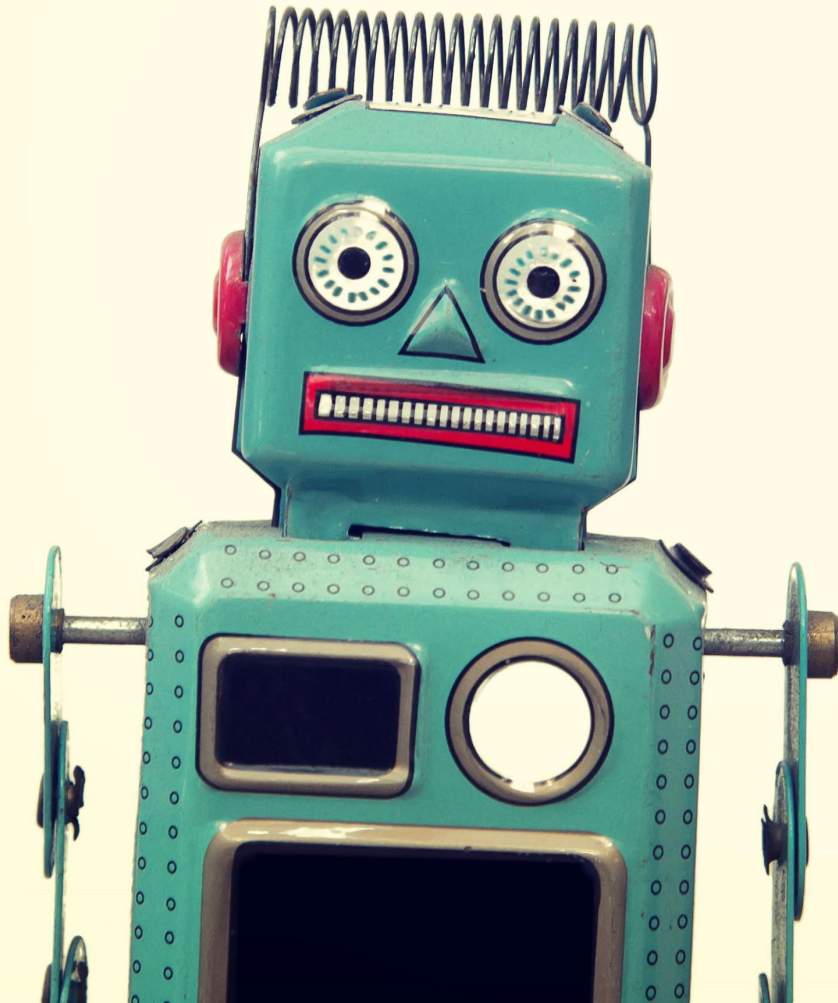
What's in the Cards?



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*

Emory's culture shift

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

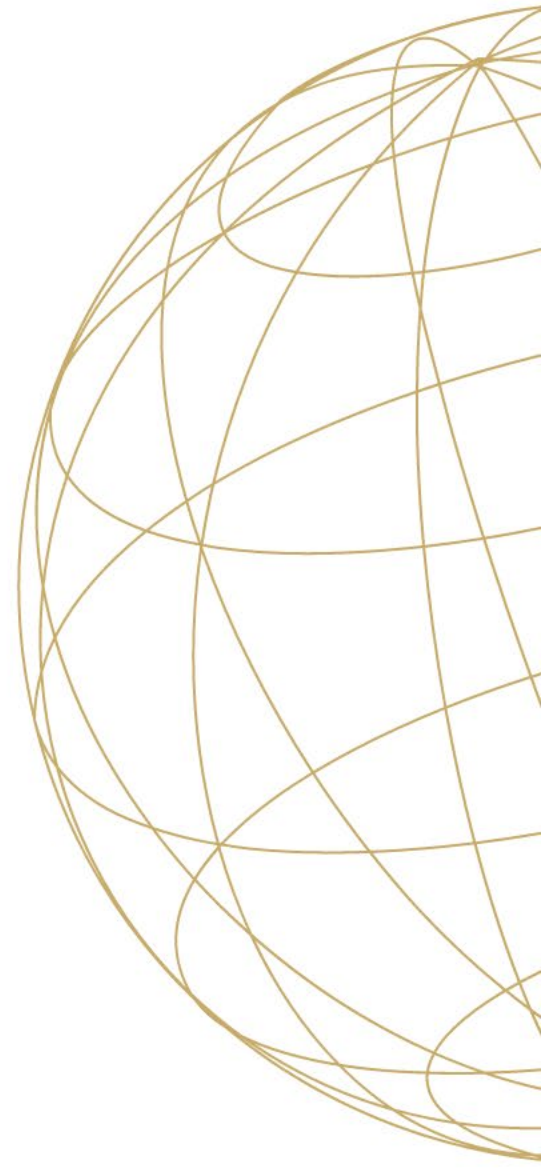
Onboarding

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”

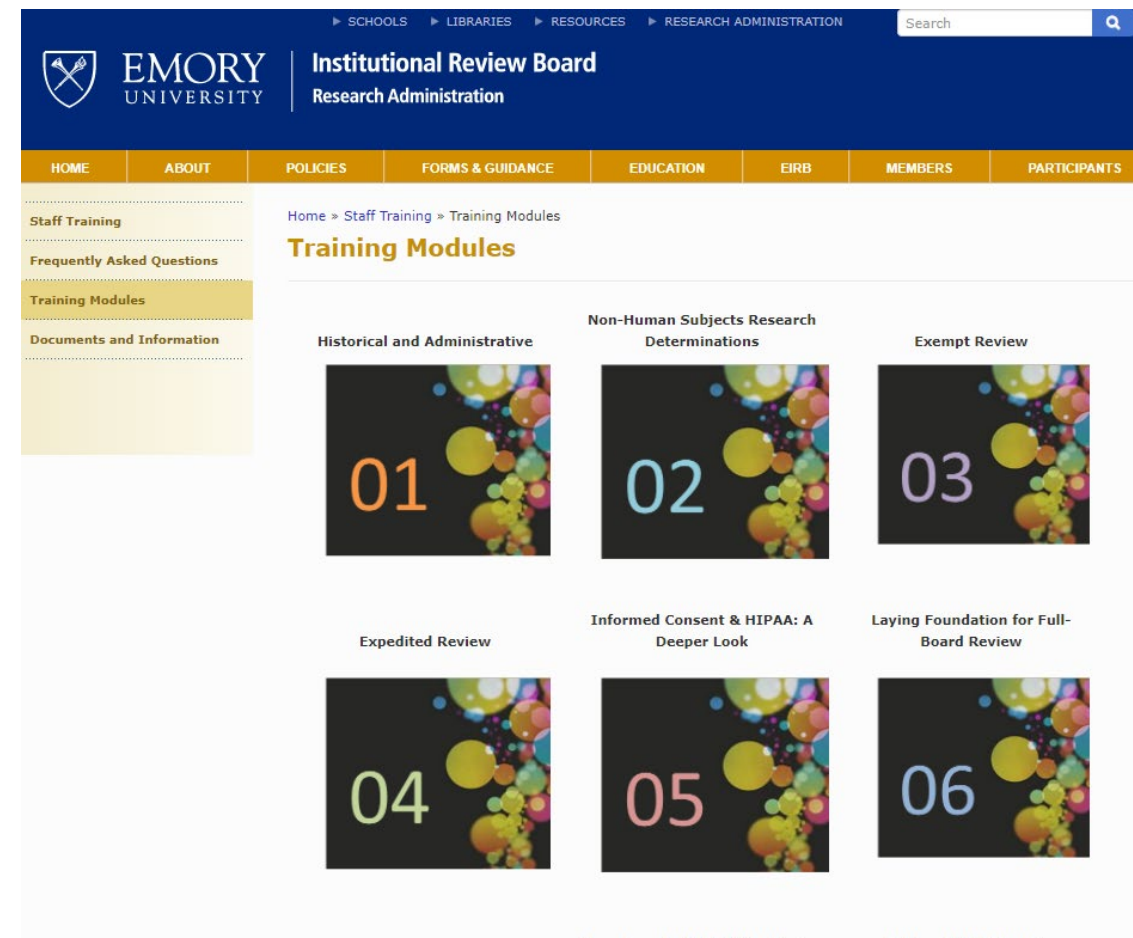
85%: people who would rather share a workspace than have to come into office

* 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



The screenshot shows the Emory University Institutional Review Board Research Administration website. The top navigation bar includes links for SCHOOLS, LIBRARIES, RESOURCES, and RESEARCH ADMINISTRATION, along with a search bar. The main header identifies the site as EMORY UNIVERSITY Institutional Review Board Research Administration. A secondary navigation bar lists HOME, ABOUT, POLICIES, FORMS & GUIDANCE, EDUCATION, EIRB, MEMBERS, and PARTICIPANTS. On the left, a sidebar menu highlights Staff Training, Frequently Asked Questions, Training Modules (selected), and Documents and Information. The main content area shows the breadcrumb path Home > Staff Training > Training Modules and the title Training Modules. It displays six training modules in a grid:

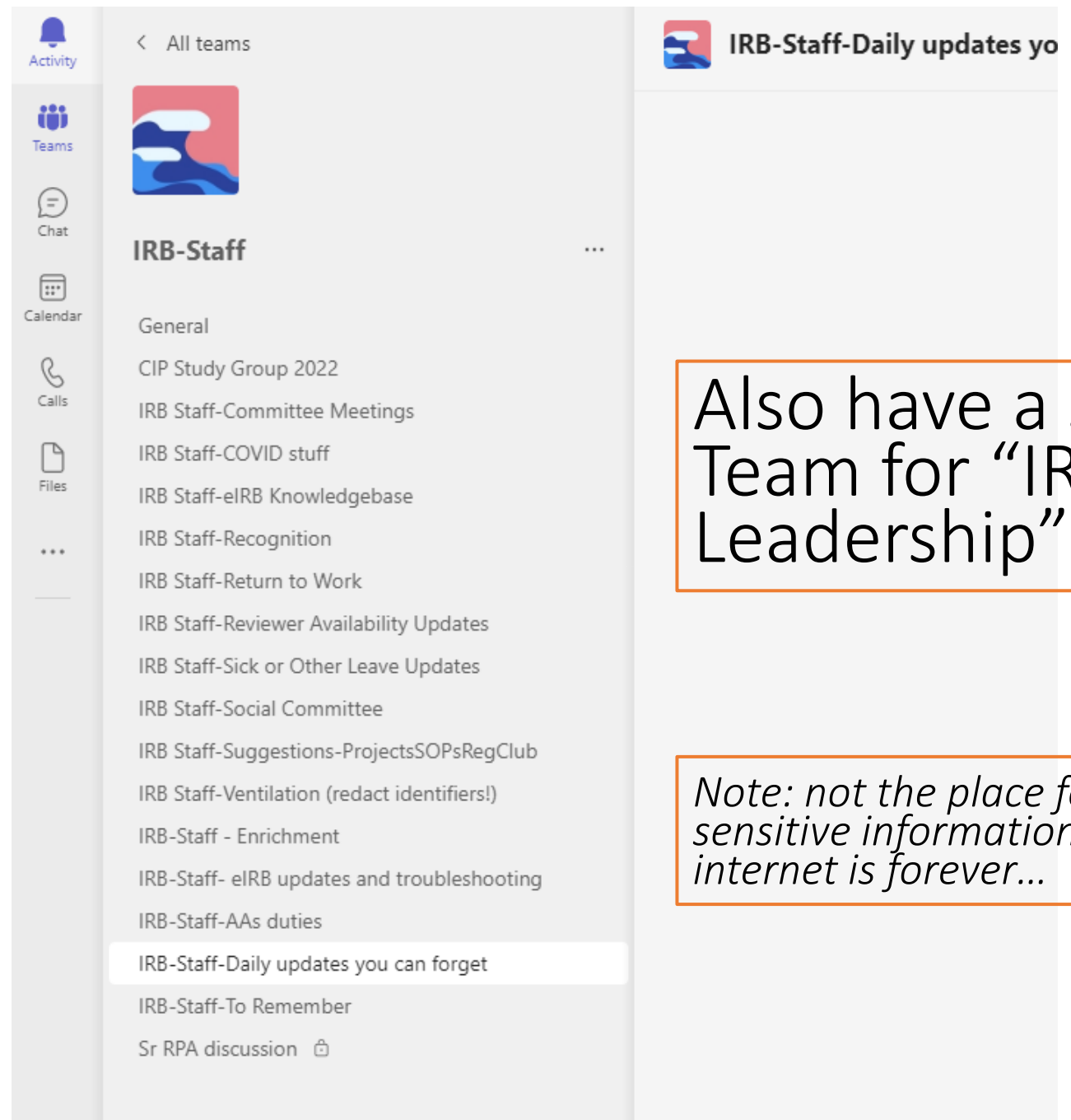
Historical and Administrative	Non-Human Subjects Research Determinations	Exempt Review
01	02	03
Expedited Review	Informed Consent & HIPAA: A Deeper Look	Laying Foundation for Full-Board Review
04	05	06

New staff training: example (excerpt)

Day	Module/Action Item	Date	Go-To Staff Member	Go-To Staff Responsibilities
-14	Pre-Hire Prep		Done	1) Ensure all Pre-Hire Prep responsibilities are accomplished.
1	Getting to know the office	3/2/2022		1) Get computer, access to phone, and parking. 2) Provide a clear picture of what the IRB's role is in relation to Research Administration as a whole. 3) Take care of administrative house-keeping including the response to emails and comments in eIRB, listserv, etc, access to Teams, Skype, H drive, CITI. 4) Review the staff training page at https://staging.web.emory.edu/irb/staff_training/index.html
2	Historical and Administrative	3/2/2022		1) Review Module 01 2) Provide a clear explanation of the historical foundation of research ethics. 3) Ensure a substantive understanding of the Belmont Report and its principles. 5) Give the New-Staff Member an authentic feeling that their work is meaningful and important to both individuals and, much more broadly, society. 5) Review of where to find Emory IRB SOPs and other important links
3	Expedited Review	3/3/2022		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. 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. 3) The goals of today are: a) Ensure new-staff understands difference between Exempt and Expedited. b) Present Expedited review designation categories clearly. c) Provide understanding of when F(8) designations are used (after Full-Board). d) Show the new-staff an example of an F5 and an F7 (most common) Expedited study protocol in eIRB. e) Provide understanding of review process (designated review, letter writing, stamped consents, set expiration, etc.) for Expedited and other minimal risk studies.

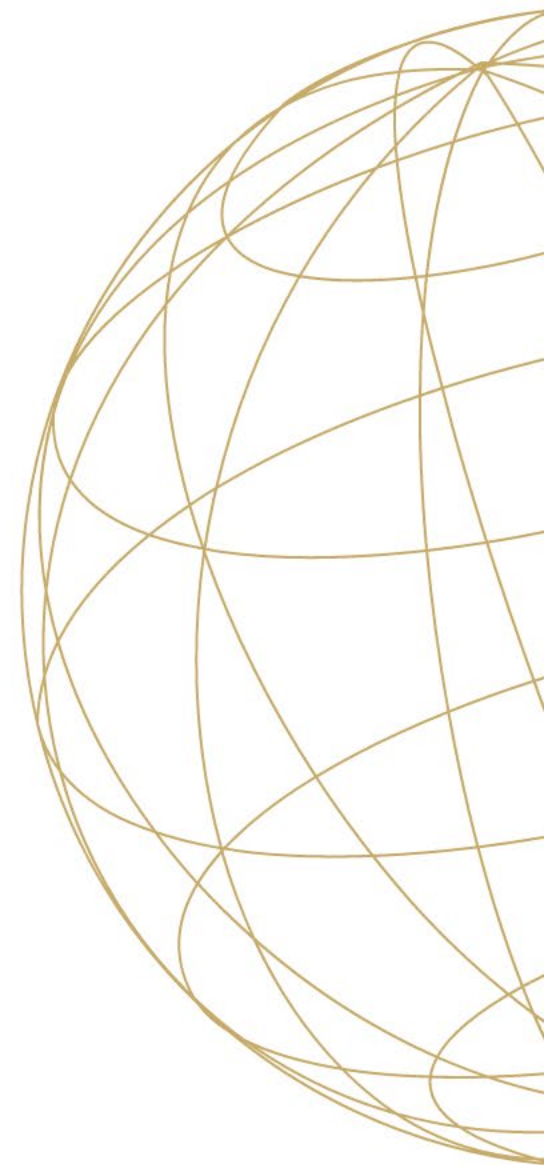
Ongoing integration:

“Teams” Example



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



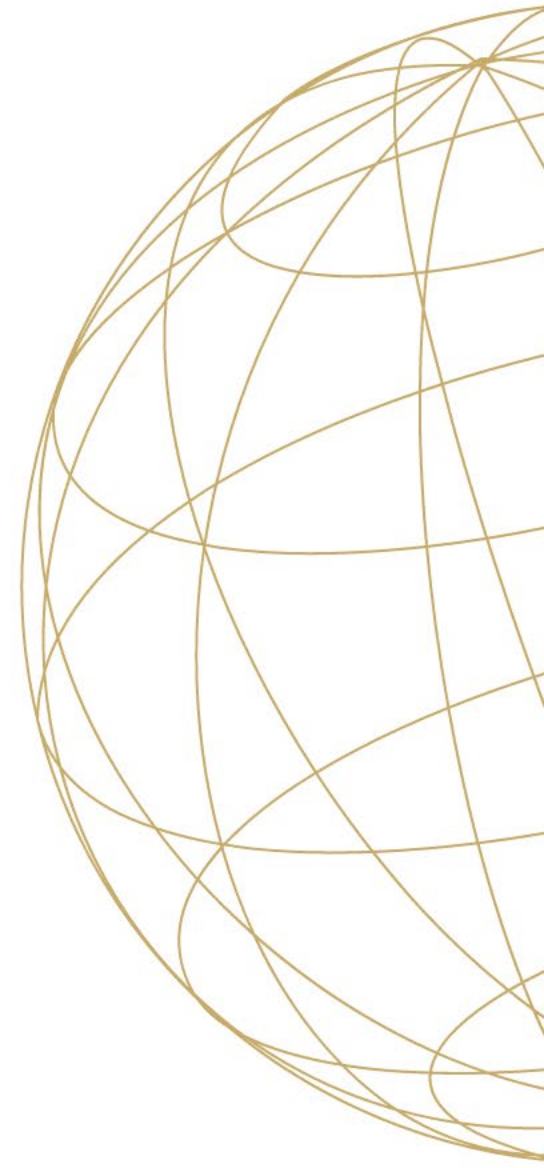
- **Issue:** positive experience for new members?
 - **Potential solution:** create time for spontaneous questions, bonding
- Hard to force people to share their cameras
- (Also, “IRB’ing while driving”)



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.

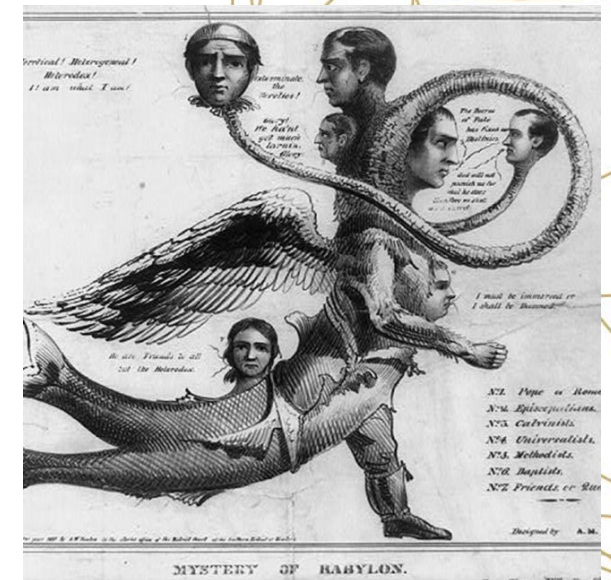
Each office assigns one person to complete the approval and other tasks in real time, working in parallel with other offices.

Clinical Research Navigator notifies the investigator when study approvals are complete.



“Top 9 List”

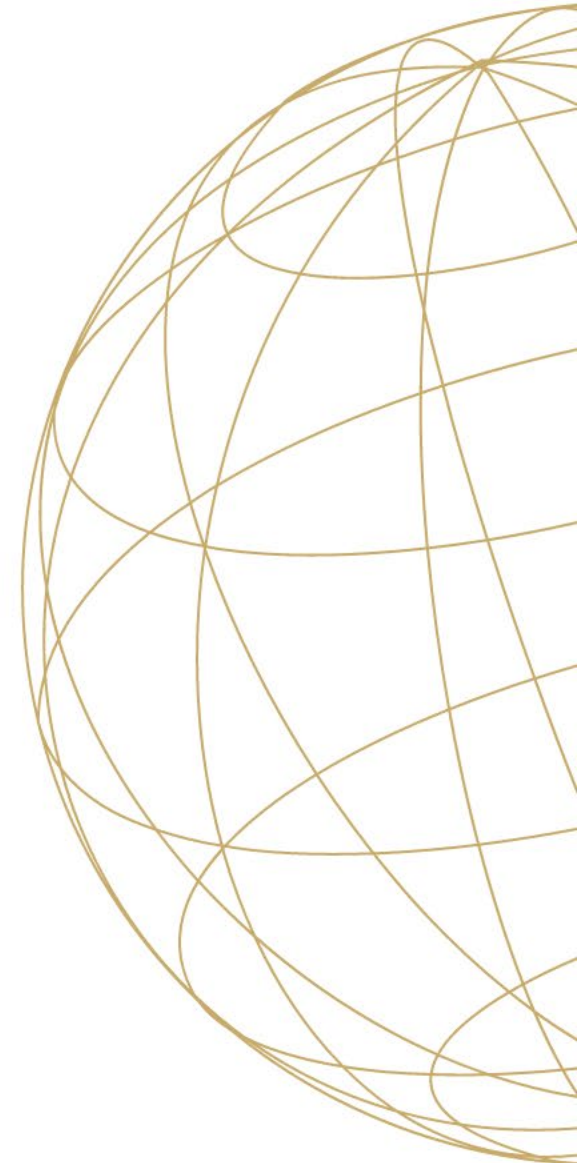
- A.I. and Big Data transparency
- Consent waivers for research of public health importance
- International and Tribal regulations (e.g. privacy)
- Genomic data sharing and identifiability
- Gene editing and chimeras
- Ex-vivo brain tissue/organoids
- Research in the metaverse
- Distrust in science and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



LIBRARY OF CONGRESS

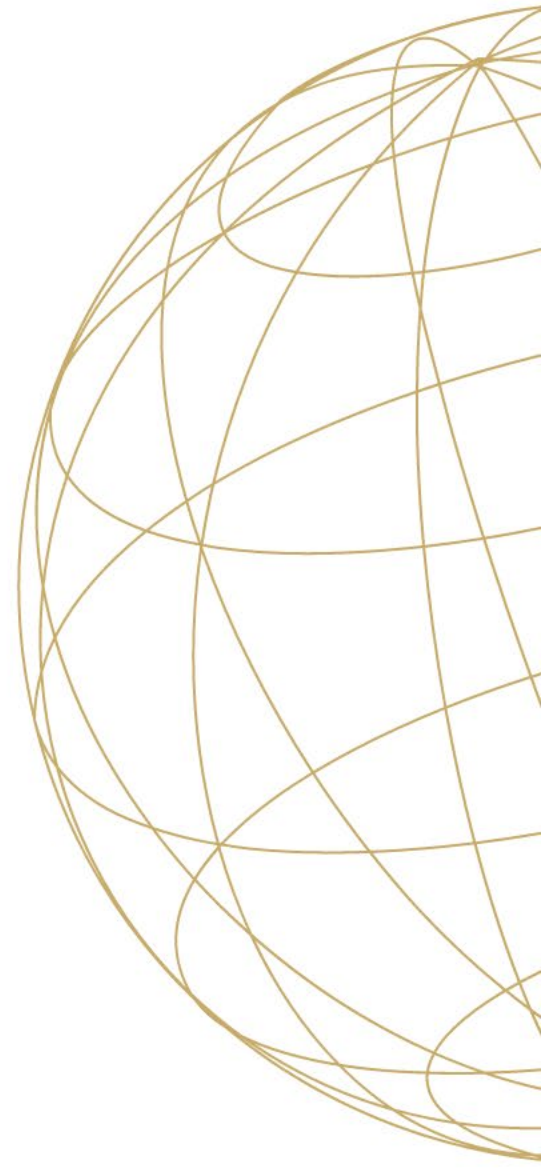
The HRPP Office of the Future

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



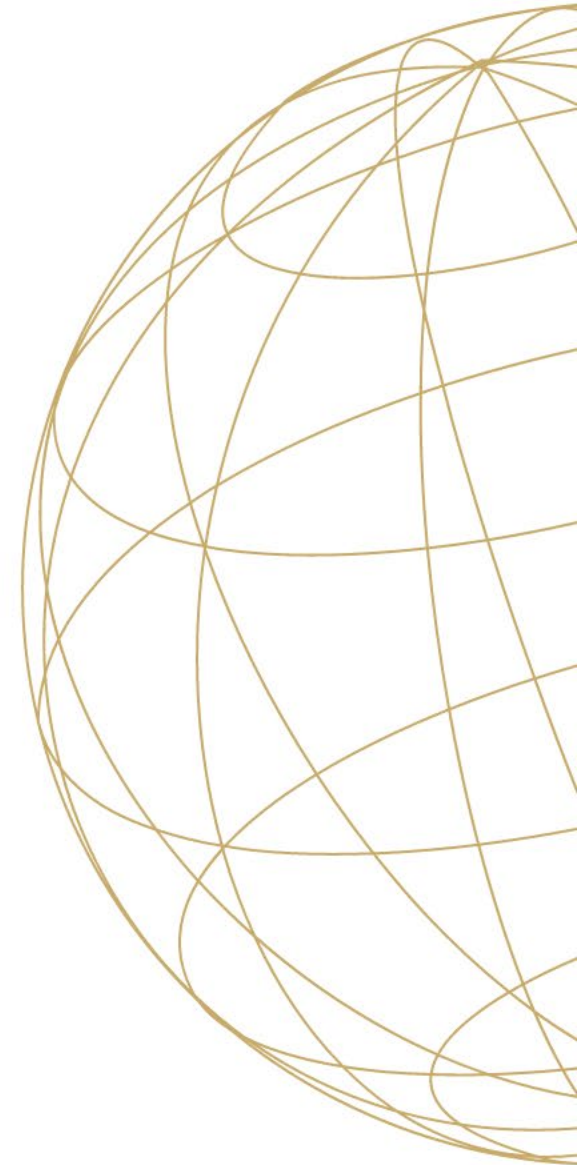


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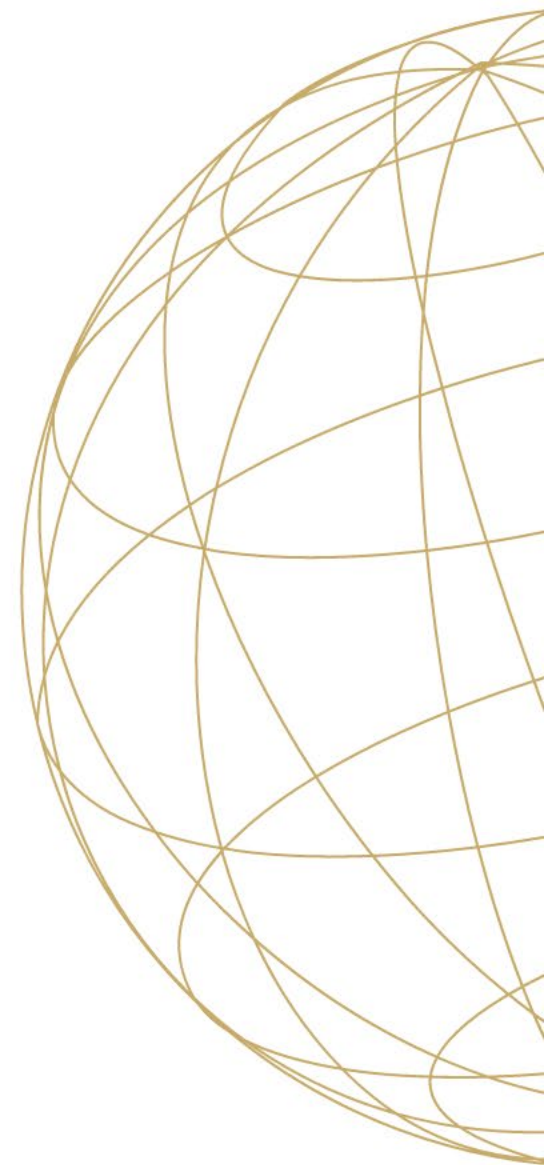
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New IRB Structure



Committee Membership

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



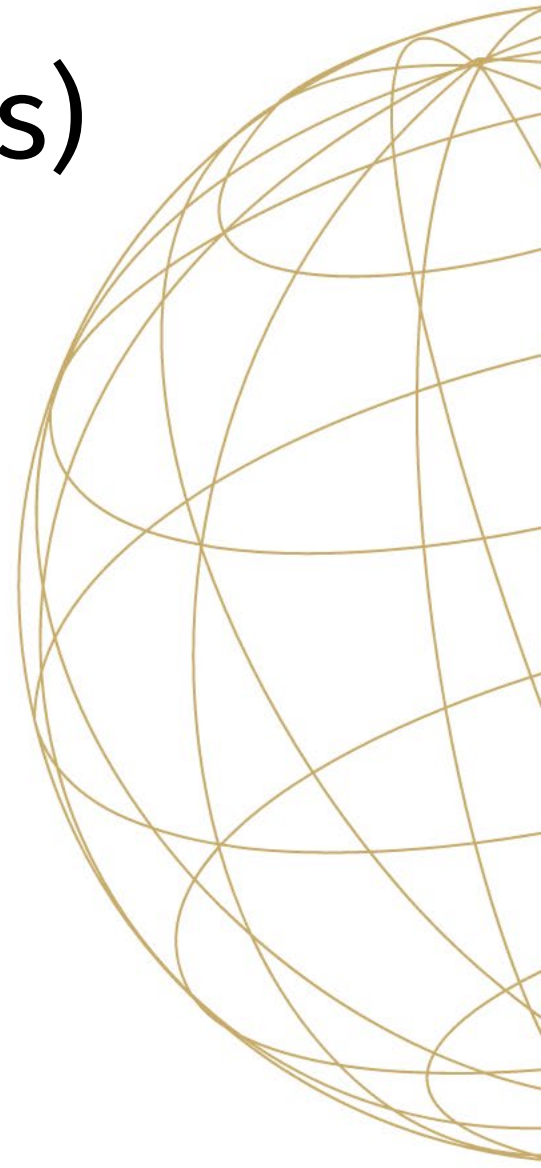
Technology Insight



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)



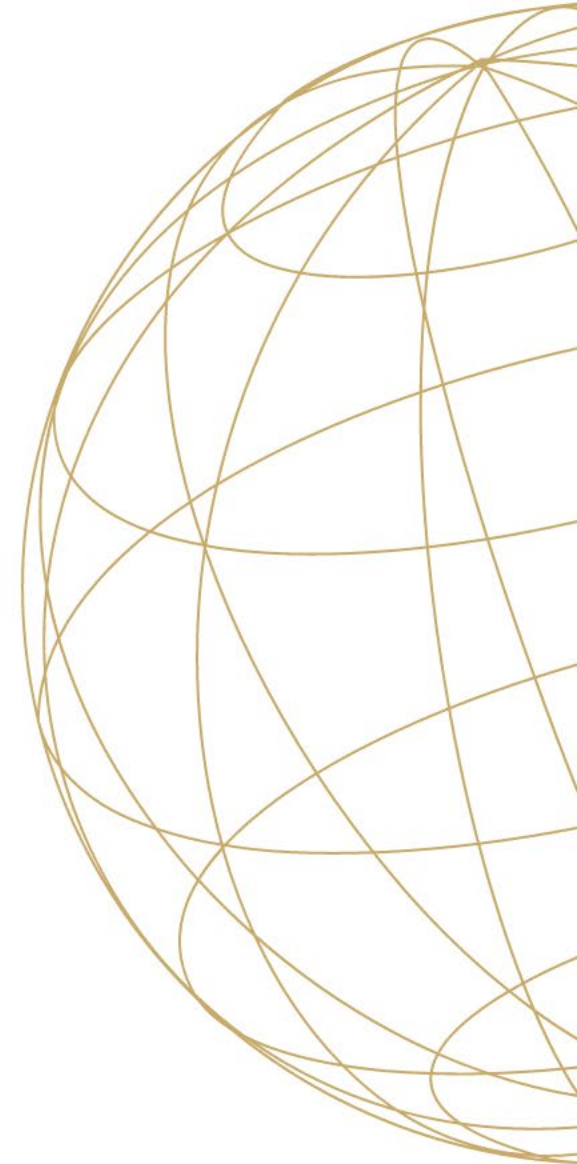
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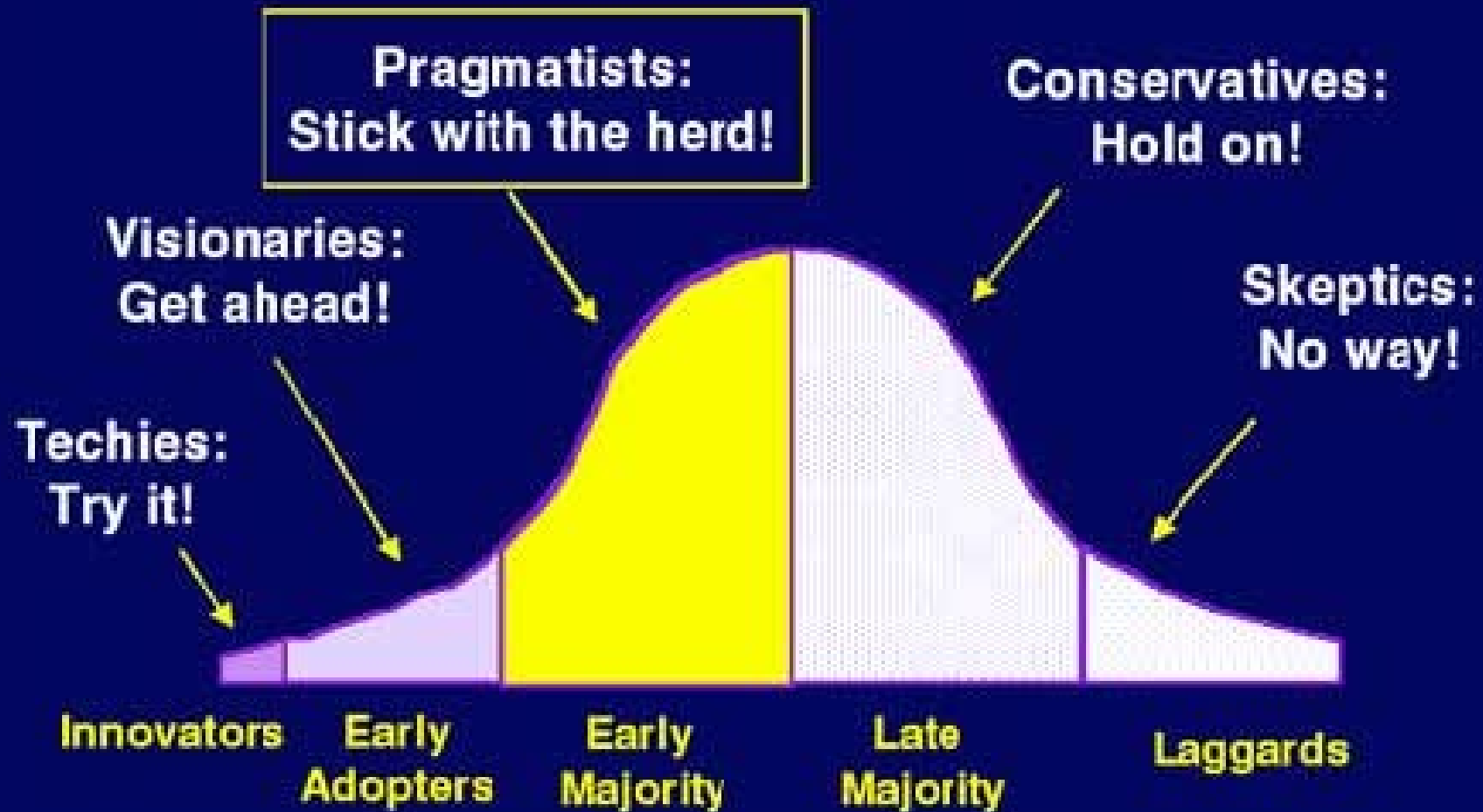
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Modified Review Process



Technology Adoption Life Cycle



Pragmatists cast the deciding vote

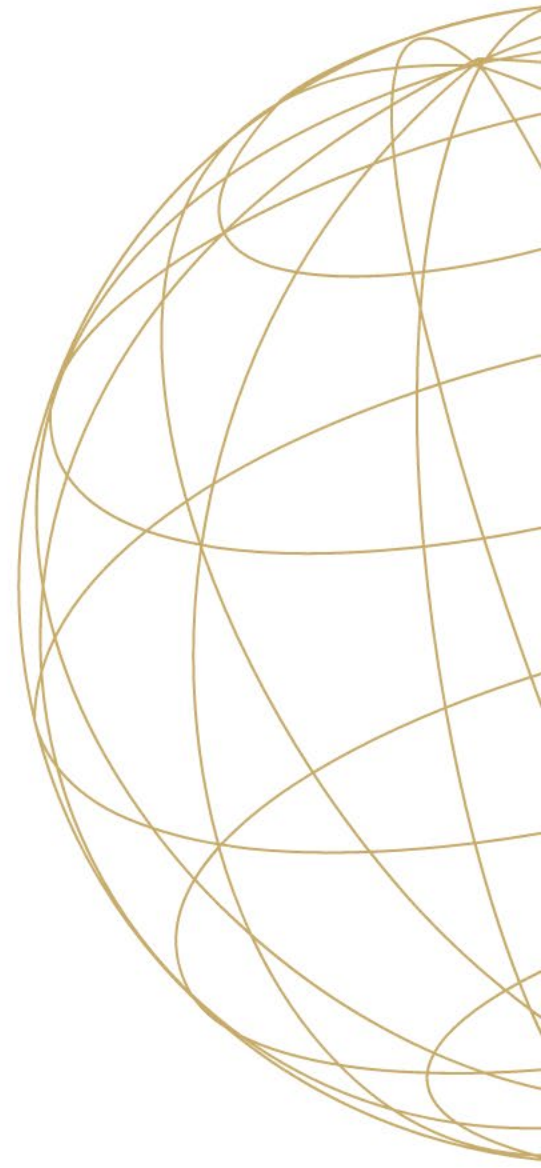
New Risks (Risk Benefit Analysis)

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



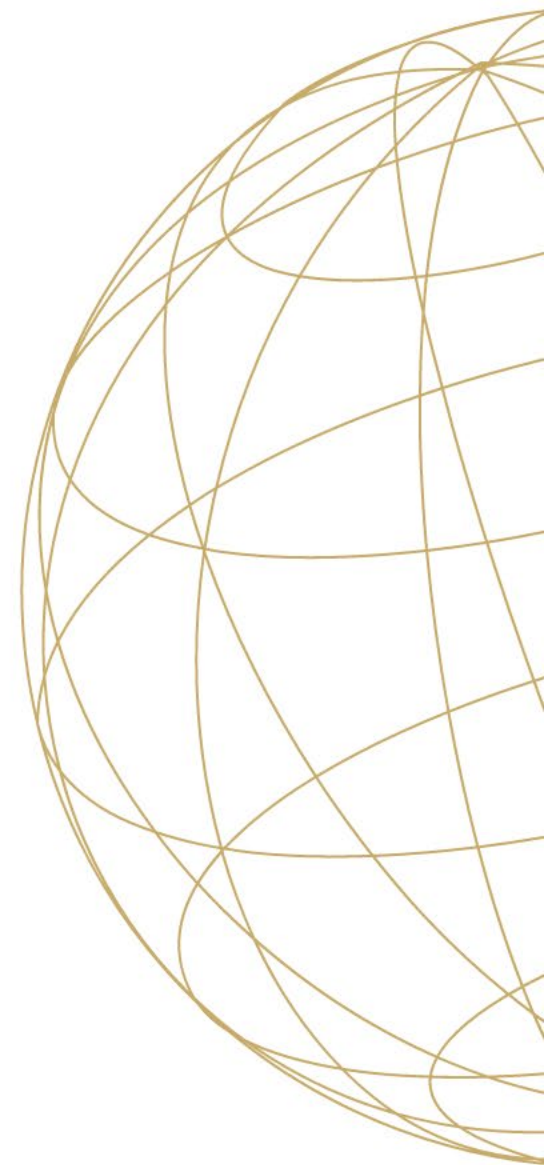
Recruitment

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

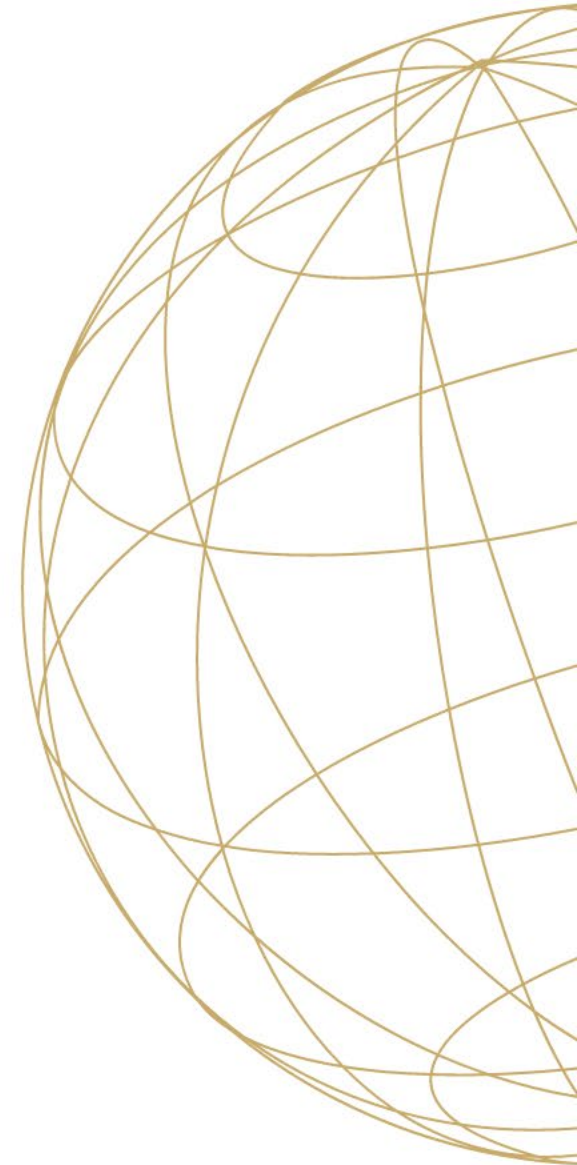


Retention

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

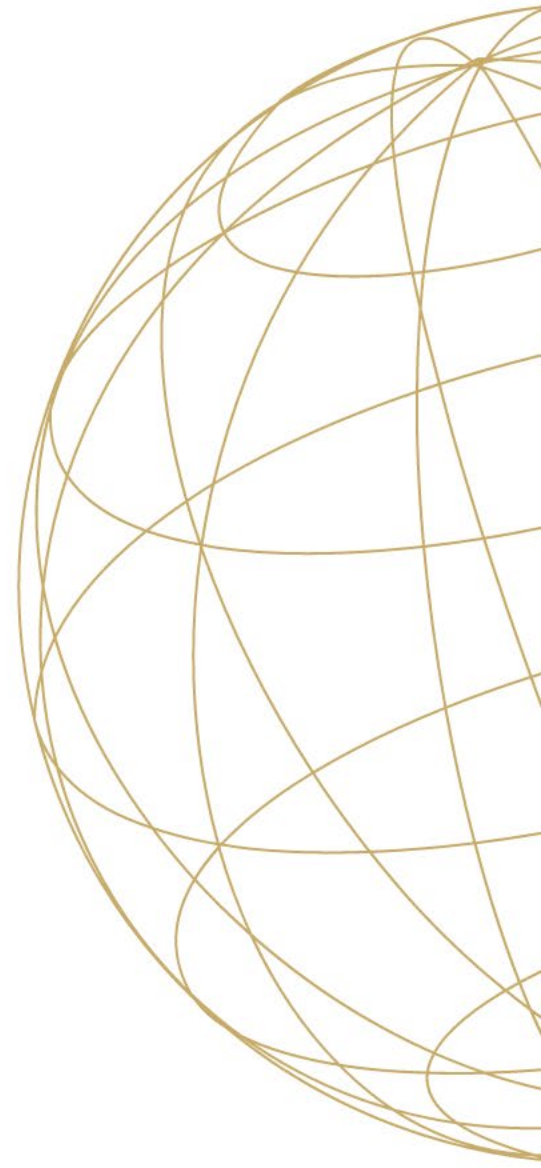


Data Transfer



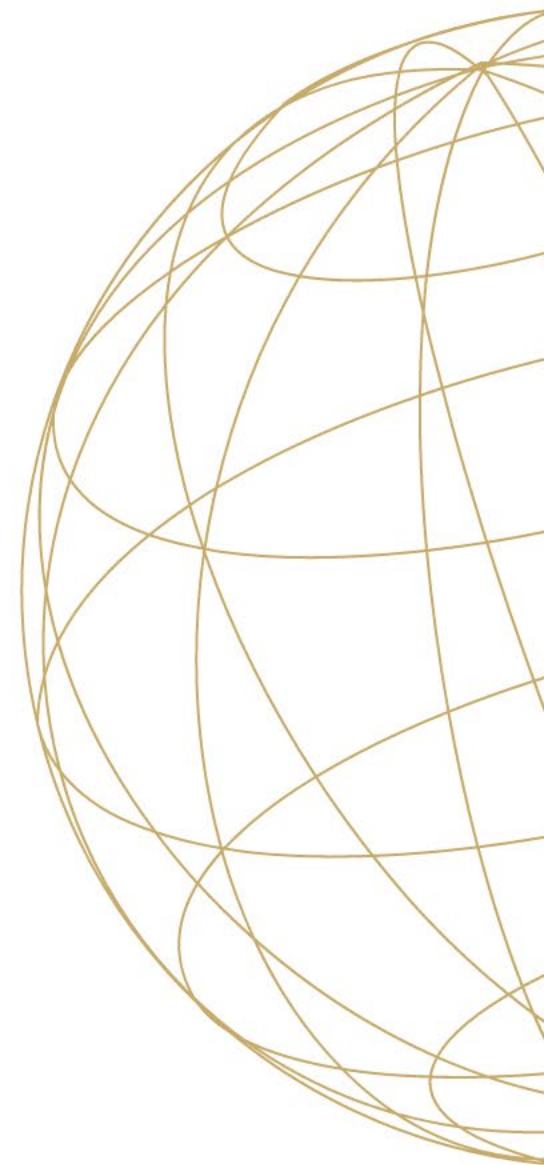
Data Transfer Policy

- 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



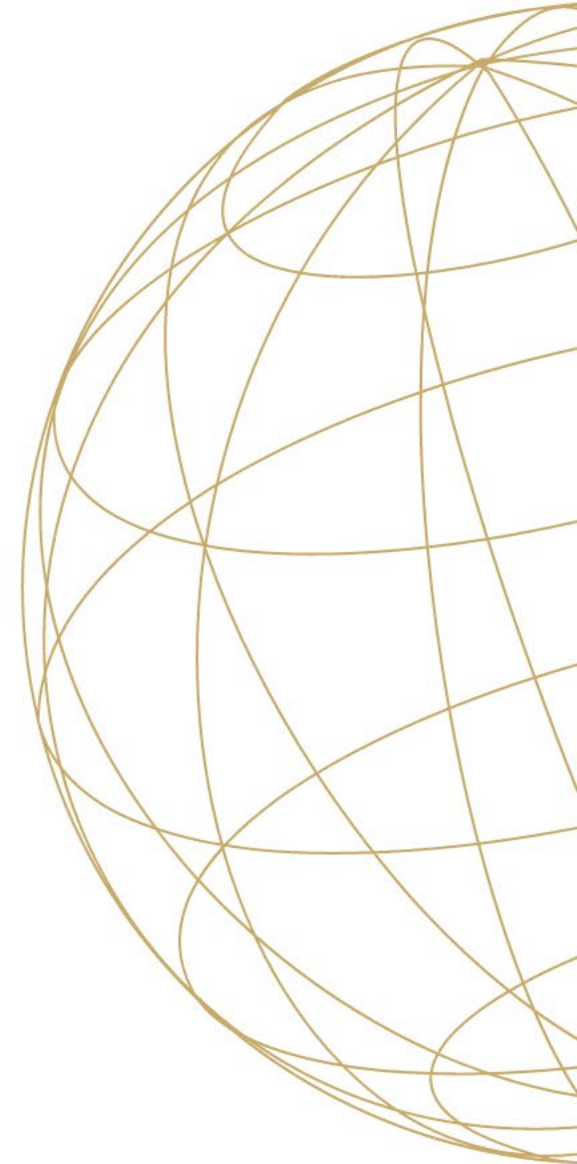


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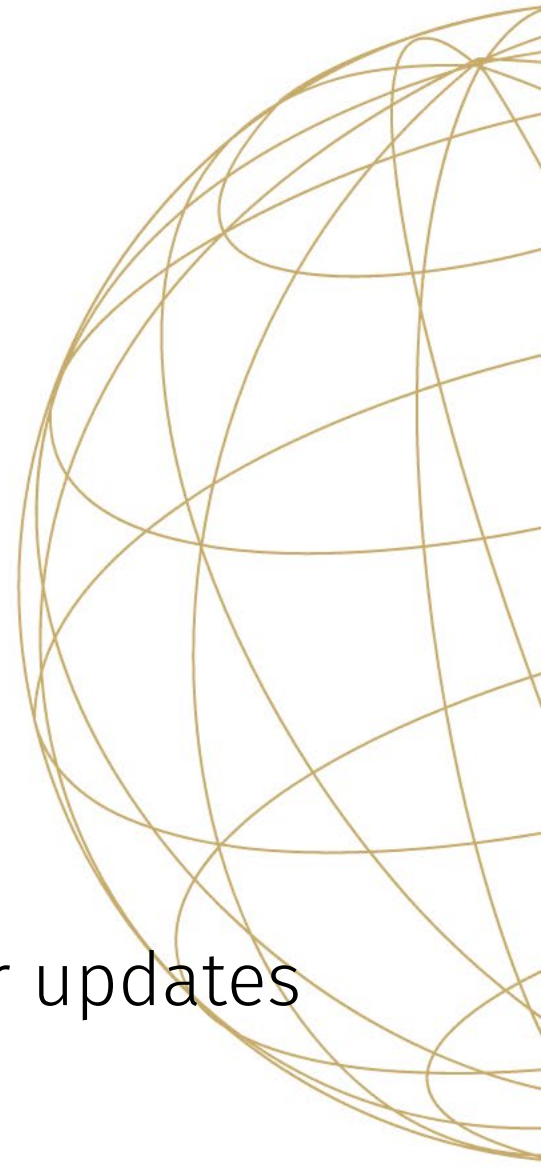
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My Prototype 2040 IRB

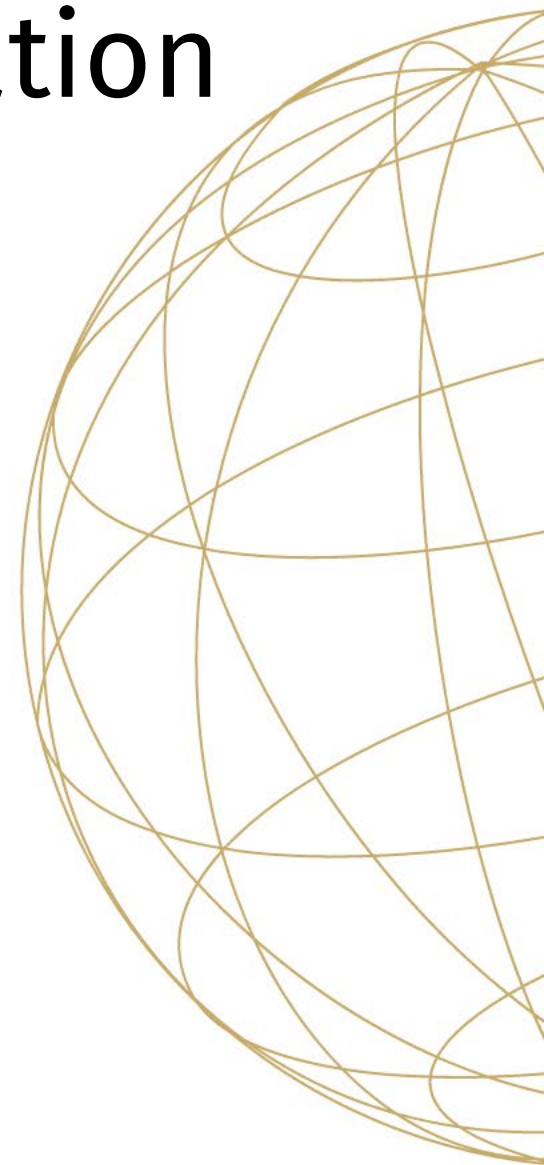


- IRB IT sub committee
- IRB inclusive of 50% diversity (DEIJ)
- IRB finance sub committee
- AI Credentialing
- AI supported scientific evaluations
- Virtual QA/QI (PI verification of variables)
- Continuously evolving job descriptions
- Flexible budgets to adjust to current trends
- Annual federal regulatory updates w/ biannual major updates
- Participation in international IRB audits



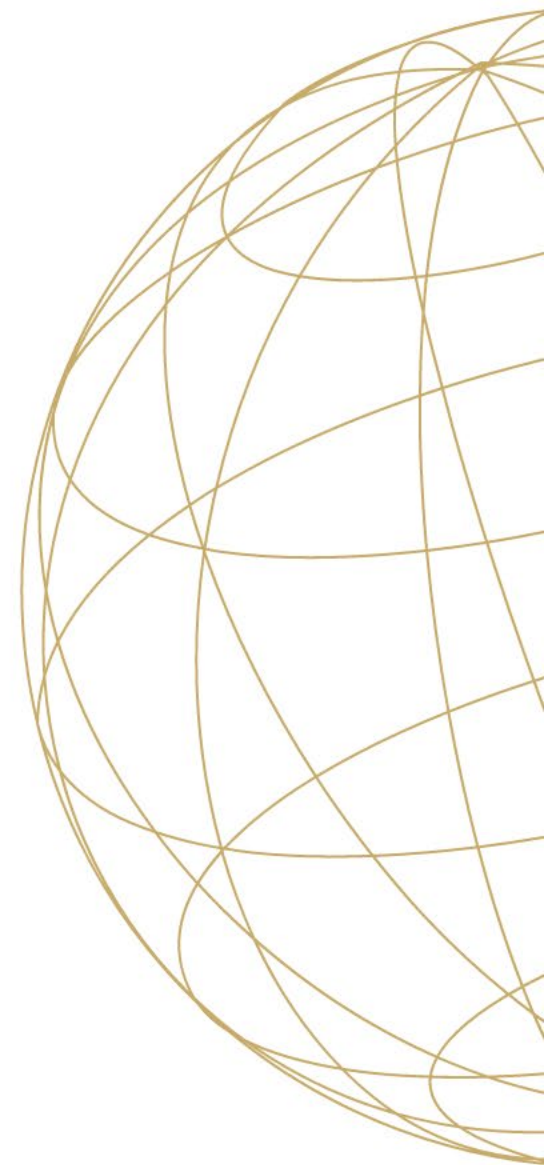
IO and Upper Administration Discussions

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



Take Home Points

- Resources
 - 10 discussions
- Technology support
- Running a 2040 HRPP



Questions?



Thank you!

