AAHRPP
Association for the Accreditation of Human Research Protection Programs, Inc.®

2026 AAHRPP Webinar Series

Why HRPPs Matter

Debra Dykhuis, CIP

University of Minnesota

Rachel Karlnoski PhD, CHRC

Tampa General Hospital

Scott J Lipkin, DPM

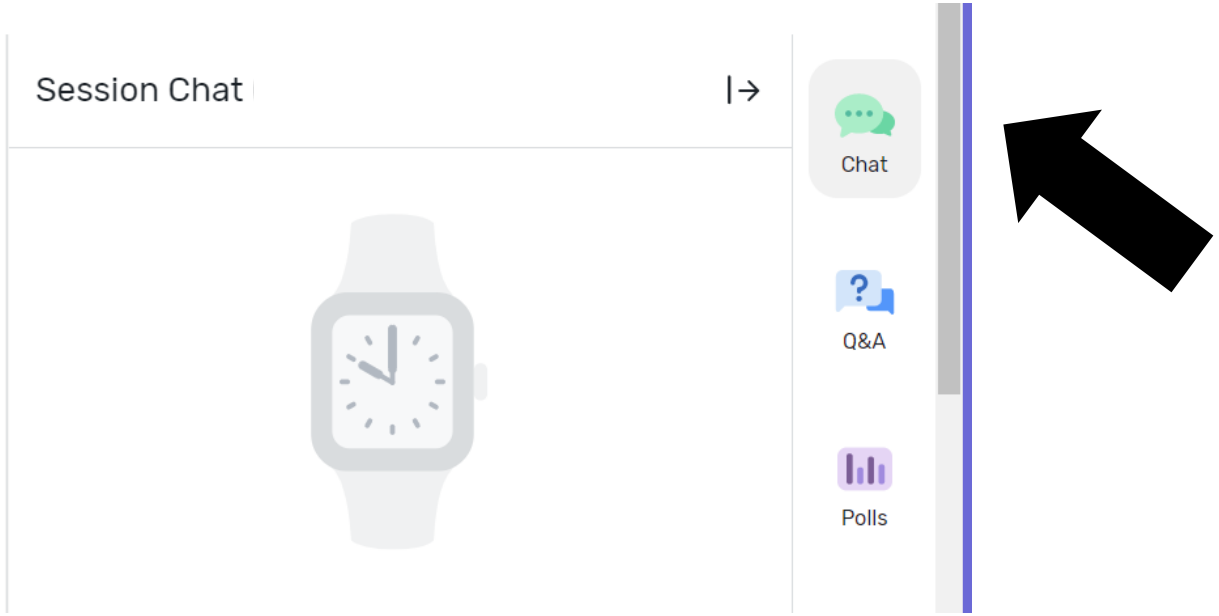
Baptist Health South Florida

Moderated by: **Robert Hood, PhD**, AAHRPP

February 17, 2026

Chat Feature

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



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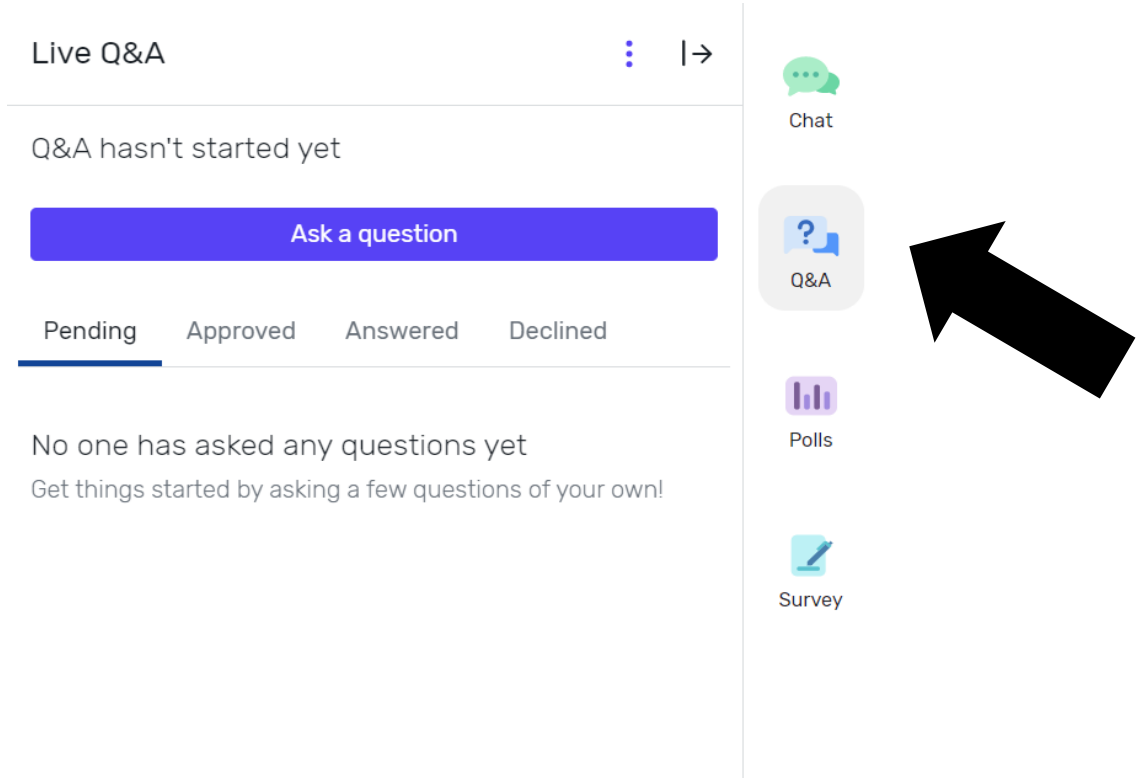
Questions

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



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Upcoming Webinars

Ask... AAHRPP®

Save the following dates for the 2026 "Ask AAHRPP" webinar series:

- **April 14, 2026**, 3:00 pm ET: Evaluation of Written Materials: The Step 1 Application Review
- **June 9, 2026**, 3:00 pm ET: Evauation of Practice: Preparing for the Site Visit
- **August 11, 2026**, 3:00 pm ET: Responding to the Draft Site Visit Report
- **October 13, 2026**, 3:00 pm ET: Understanding the Council on Accreditation Review
- **Tuesday, December 8**, 2026, 3:00pm ET: Responding to Council Review and Maintaining Accreditation

Visit Webinars (aahrpp.org) for more information and registration links

Upcoming Webinars

Save the following dates for the 2026 "HRPP Innovations" webinar series:

- **July 14, 2026**: 1:00 pm – 2:30 pm ET
- **November 10, 2026**: 1:00 pm – 2:30 pm ET

Topics to be determined

Visit Webinars (aahrpp.org) for more information and registration links

Visit AAHRPP's Annual Conference page for more information

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Presenter Introductions

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Debra Dykhuis, CIP

University of Minnesota

Rachel Karlnoski, PhD, CHRC

USF Health and Tampa General Hospital

AAHRPP
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Scott Lipkin, DPM, CIP

Baptist Health South Florida

AAHRPP
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Robert Hood, PhD

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Why HRPPs Matter

February 17, 2026

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Disclosure Statement

I have relevant personal/professional/financial relationship(s) with respect to this educational activity with the following organization(s):

AAHRPP, Inc

Robert Hood, PhD

Director of Accreditation and Global Outreach

AAHRPP, Inc

History → IRB → HRPP

Following Regulations?... Problems Discovered

The Washington Post

U.S. Halts Human Research at Duke

By Rick Weiss
Washington Post Staff Writer
Wednesday, May 12, 1999; Page A1

The U.S. government has temporarily shut down federally funded research on humans at Duke University Medical Center, one of the nation's largest and most prestigious medical research facilities, after federal investigators determined that the university could not ensure the safety of participants.

UIC Suspended From Doing Most Human Research...Some Test Subjects Not Fully Informed

August 28, 1999|By Jeremy Manier, Tribune Staff Writer.

The federal government on Friday suspended virtually all research on humans at the University of Illinois at Chicago, marking the second time in a year that regulators have imposed severe sanctions on a local medical institution.

History of "Human Research Protection Programs (HRPP)"

- Institute of Medicine (IOM) Report (2001): *Preserving Public Trust: Accreditation and Human Research Protection Programs*
- IOM Report (2002): *Responsible Research: A Systems Approach to Protecting Research Participants*
  - Response to the mounting concerns and government "shutdowns" of the late 1990's
  - Concept of a "shared responsibility"
  - Series of recommendations focusing on improving ethics review of protocols, enhancing safety monitoring, and developing a standard of quality improvement in HRPPs
  - Awareness and accountability at highest levels

HRPPs

- Go beyond the ethical review of human participants research (IRB/EC review)
- Include all of the activities that contribute to research participant safety and research integrity
- Are a communication system that works together to protect research participants

Is an HRPP a Fancy Name for an IRB/EC?

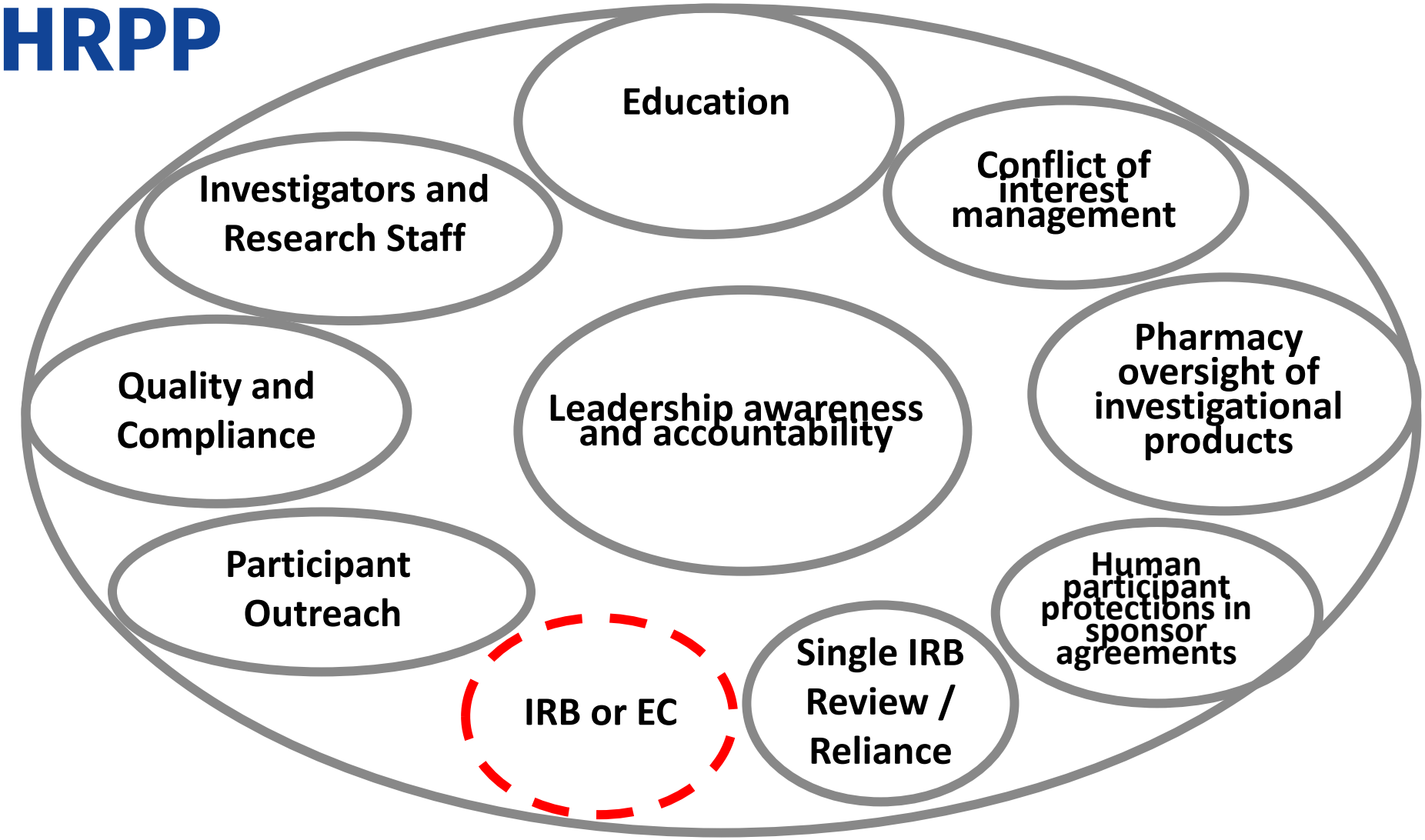
- **No**
  - It's an infrastructure that goes beyond protocol review
  - It highlights all activities that contribute to research participant safety and research integrity
  - It's a communication system that works together to fill the gaps that put participants at risk

- ***It's a real paradigm shift in approach***

Should "IRB Professionals" become "HRPP professionals"?

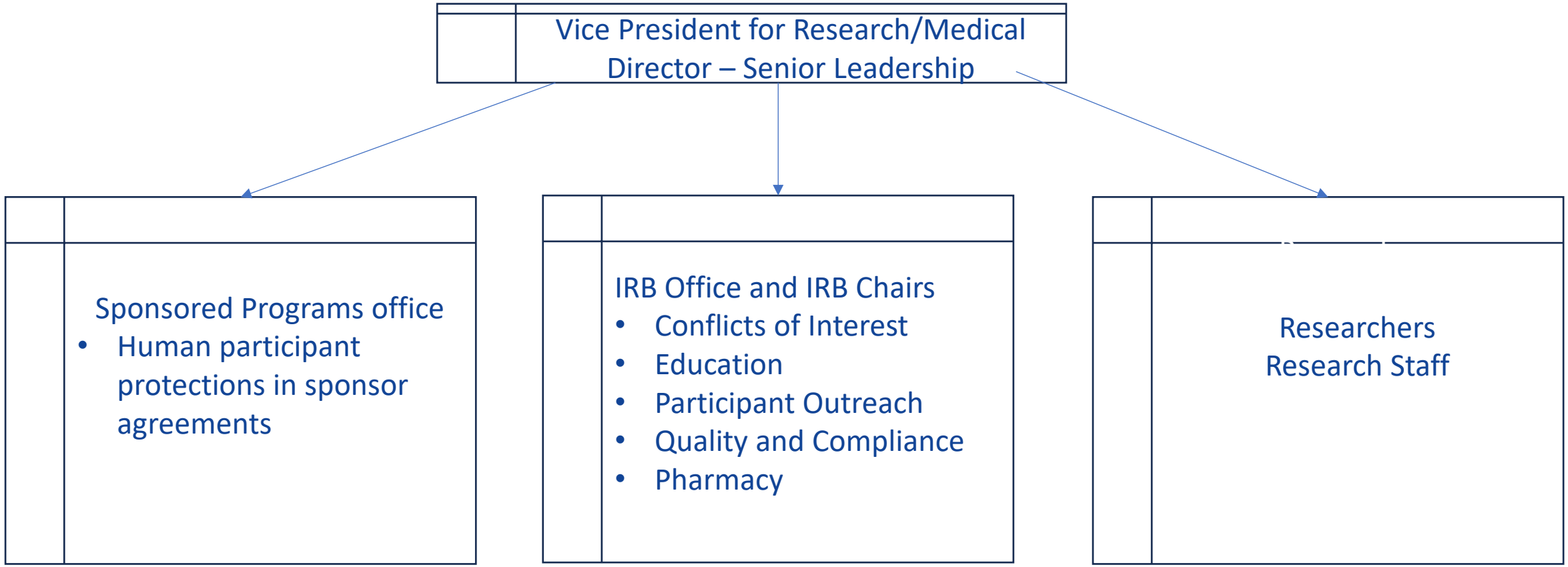
- **Yes**
  - Organizations increasingly rely on external IRBS, some even close internal IRBs/ECs
  - Organizations – through HRPP professionals - must still ensure:
    - Conflicts of interest are managed (researcher and organizational)
    - Researchers and research staff are knowledgeable
    - Investigational products are stored and handled appropriately
    - And more…
- ***It's a real paradigm shift in approach***

HRPP


Education
Investigators and Research Staff
Conflict of interest management
Quality and Compliance
Leadership awareness and accountability
Pharmacy oversight of investigational products
Participant Outreach
Human participant protections in sponsor agreements
IRB or EC
Single IRB Review / Reliance

"Centralized" HRPP

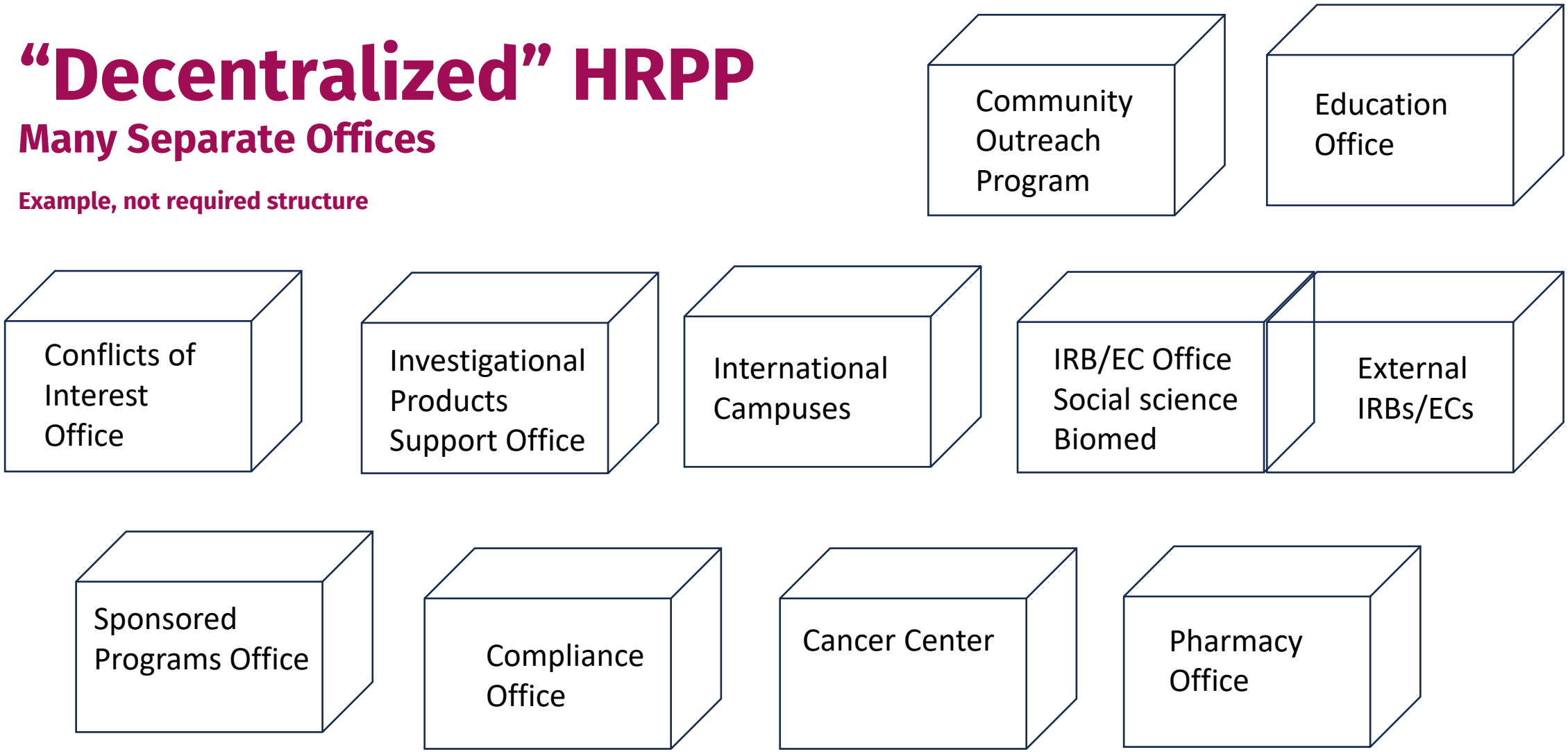
*** Example, not required structure**



"Decentralized" HRPP

Many Separate Offices

Example, not required structure



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Current factors driving paradigm shift from IRBs to HRPPs

- Changing research environment
  - IOM Reports: Rise of global clinical trials at thousands of research sites
- Changing regulatory environment
  - US: Creation of independent IRBs/ECs -> widespread Single IRB Review
  - US FDA: Proposed rule requiring single IRB review
  - Japan, Korea, other countries: also creating infrastructure for single IRB review
  - US: Removal of requirement for continuing review for some minimal risk research – shift from IRB oversight to oversight by the organization
- Healthcare consolidation – move from individual hospitals to integrated health systems
  - Replacing many IRBs/ECs at individual hospitals with fewer IRBs/ECs
  - Organizational responsibilities remain, even if local IRBs/ECs go away

Why HRPPs matter more than ever

- Organizations retain responsibilities for oversight of research, even if they do not have IRBs/ECs
  - Management of conflicts of interest
  - Oversight of investigational products (control of drugs and devices)
  - Responding to questions, concerns and complaints from research participants
  - Quality and compliance
  - Emergency preparedness
  - Education of researchers and research staff

Why HRPP professionals matter more than ever

- Without IRBs/ECs HRPP professionals may have fewer resources, less visibility, but are still responsible for:
  - Management of conflicts of interest
  - Oversight of investigational products (control of drugs and devices)
  - Responding to questions, concerns and complaints from research participants
  - Quality and compliance
  - Emergency preparedness
  - Education of researchers and research staff
- Without IRBs/ECS, staff take on additional leadership roles:
  - Improving communication, breaking down organizational silos, making the case to leadership to maintain an HRPP

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Overview and Role of the HRPP at the University of Minnesota

Debra Dykhuis/Executive Director/University of Minnesota

Disclosure Statement

I have no relevant personal/professional/financial relationship(s) with respect to this educational activity

Who We Are By the Numbers

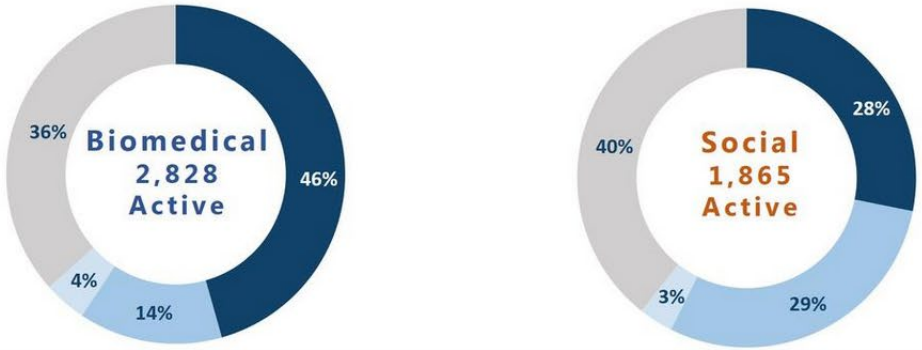
Campuses	*5*
Research and development expenditures	*1.32 billion*
Students	*70,000*
Faculty and staff	*28,000*
AAHRPP accredited (since 2004)	*22 years*
Number of IRB Staff	*16*
Number of IRB Panels	*10 8 Biomedical – 2 Social Behavioral*
Number of IRB Members	*68*
Average number of submission per month	*1,254*
Number of HRPP Office Operations and Reporting staff	*5*
Number of HRPP Office Quality Assurance staff	*6*

Active IRB Studies & Exempt Determinations Made in the Last 12-Months

ACTIVE IRB STUDIES BY RESEARCH TYPE (excluding exempt studies)

BIOMEDICAL	SOCIAL /BEHAVIORAL
2,828 (60%)	1,865 (40%)

ACTIVE IRB STUDIES BY FUNDING CATEGORY* (excluding exempt studies)



Active IRB Studies Biomedical + Social
4,693

Exempt Determinations Jul. 1, 2024 – Jun. 31, 2025
890

% of All Active Studies with Sponsored Project Funding**
40%

* Funding category is based on the funding selection made by the investigator in ETHOS

University of Minnesota's HRPP Mission

Protecting research participants is **the responsibility of everyone** within an organization and is not limited to the Institutional Review Board (IRB).

The mission of the Human Research Protection Program committee is to collaborate in the **development, coordination, and evaluation** of the university's Human Research Protection Program with the goal to ensure the protection of research participants, uphold ethical standards of research, and improve our practices at every step.

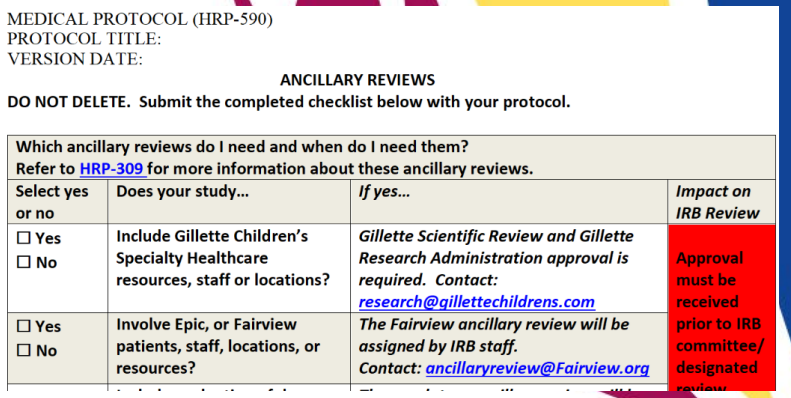
Understanding & Supporting Shared Oversight

Researchers & staff
Conflict of Interest Committee
Privacy Office
Office of General Counsel
Vulnerable Populations Advisor
Sponsored Projects
Institutional Review Board
Department of Audits
Office of Institutional Compliance
Biosafety
Cancer Protocol Review
Education and Outreach

And more. And growing!

How Mission Translates to Practice

- HRPP Meetings
- Ancillary Reviews
- Regularly scheduled meetings with key groups
- Education opportunities for analysts
- Transparency
- Building connections and bridges



MEDICAL PROTOCOL (HRP-590)
PROTOCOL TITLE:
VERSION DATE:

ANCILLARY REVIEWS

DO NOT DELETE. Submit the completed checklist below with your protocol.

Which ancillary reviews do I need and when do I need them? Refer to HRP-309 for more information about these ancillary reviews.			
Select yes or no	**Does your study…**	***If yes…***	***Impact on IRB Review***
☐ Yes ☐ No	Include Gillette Children's Specialty Healthcare resources, staff or locations?	*Gillette Scientific Review and Gillette Research Administration approval is required. Contact: research@gillettechildrens.com*	Approval must be received prior to IRB committee/ designated
☐ Yes ☐ No	Involve Epic, or Fairview patients, staff, locations, or resources?	*The Fairview ancillary review will be assigned by IRB staff. Contact: ancillaryreview@Fairview.org*	

Thank You!

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Why HRPPs Matter: Institutional Ownership in a Single IRB World

Rachel Karlnoski PhD, CHRC
Executive Director, Office of Clinical Research
Tampa General Hospital

Disclosure Statement

I have no relevant personal/professional/financial relationship(s) with respect to this educational activity

Tampa General Hospital: Who We Are

Tampa General Hospital at a Glance

- **Structure:** Not-for-profit academic health system partnered with USF Health Morsani College of Medicine for over 50 years.
- **System Scale:** 1,354 total licensed beds across the system.
- **Education:** Primary teaching hospital for ~700 residents/fellows annually
- **Transplants:** 908 (Nation's #1 transplant center).

Our Research Environment

Research at TGH

- **Active Trials:** Approximately 690 funded active clinical trials.
- **Scope:** Mix of interventional, observational, and biorepository studies.
- **Personnel:** 143 active investigators and ~14,000 enrolled participants.
- **Quality Standards:** Maintains AAHRPP accreditation alongside Magnet designation and recognition as one of the World's Best Hospitals

Why HRPPs Matter in a Single IRB World

The Core Reality

- **IRBs** review protocols.
- **HRPPs** protect participants.
- **Institutional Accountability**: While the IRB review may be external, the responsibility for training, monitoring, and compliance remains local.

Domain I: Organizational Responsibilities

Institutional Ownership at TGH

- **Centralized Oversight**: A dedicated Office of Research Compliance managing all human research activities.
- **Quality Review Program**: Conducting routine, for-cause, and pre-audit reviews to provide oversight that external IRBs cannot perform.
- **Financial Integrity**: Integrated research billing and financial review programs.
- **Reporting Pathways**: Multiple channels (hotline, email) for reporting concerns or scientific misconduct.

Domain III: Research Personnel & Participant Protection

Supporting the Clinical Research Workforce

- **Role-Based Education**: Targeted guidance for investigators and staff at various developmental stages.
- **Collaboration over Enforcement**: Positioning HRPP compliance as a support mechanism for study teams.
- **Real-time Feedback**: Sharing monitoring findings immediately with teams to prevent recurrence and improve safety.

Unique Features of Our HRPP Model

The TGH Advantage

- **No Internal IRB:** Strategic reliance on AAHRPP-accredited, external/single IRB models for a high-volume system
- **Centralized Excellence:** All HRPP functions are intentionally consolidated to ensure consistency across multiple hospital sites (TGH North, TGH Rehabilitation, TGH Behavioral Health)
- **Academic Integration**: Strong partnership with USF Health while maintaining separate, specialized governance.

Thank You!

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Why HRPPs Matter

Scott J Lipkin, DPM, CIP

Vice President for Research, Baptist Health South Florida

Chief Research Officer, Miami Cancer Institute

Disclosure Statement

Scott Lipkin: I have relevant personal/professional/financial relationship(s) with respect to this educational activity with the following organization(s):

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Board of Directors

Baptist Health

- Largest healthcare organization in the Southeast Florida region
- 12 hospitals
- 200+ outpatient centers, urgent care facilities and physician practices
- Four counties: Monroe, Miami-Dade, Broward and Palm Beach
- Institutes for cancer, cardiac and vascular, orthopedics/sports medicine, and neuroscience care
- 27,000+ employees
- 4,000 affiliated physicians

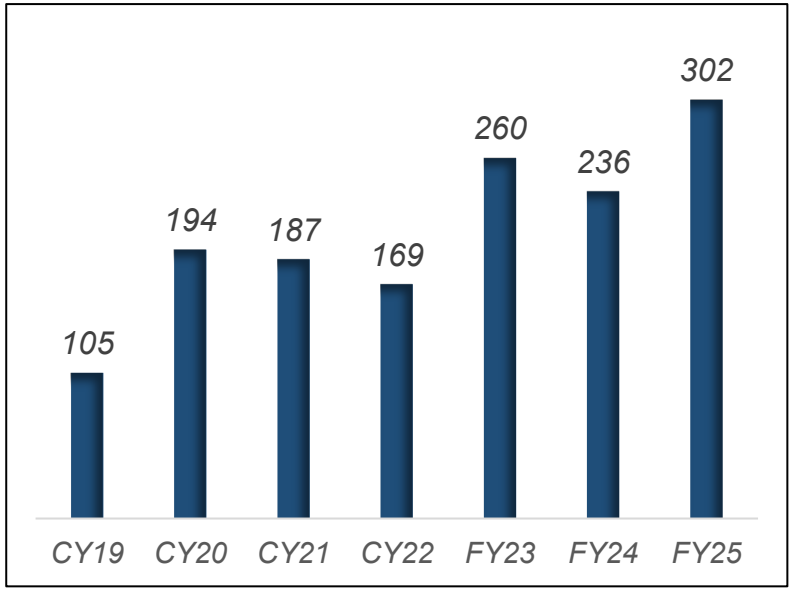
The Miami Cancer Institute of Baptist Health South Florida

- Opened January 2017
- Hybrid community-academic model
- 119 physicians (110 employees of BH/MCI)
- Ranked #6 by the 2023-2024 US News and World Report Cancer Centers in Florida
- Ranked as the 2nd largest Cancer Center in Florida (S. FL Business Journal, 2026)
- Apex accredited proton therapy program
- Advanced radiation oncology therapies including gamma knife, MR Linac, and brachytherapy
- Fact accredited blood and marrow stem cell transplant program
- CAR T-cell therapy
- CAP accredited biorepository

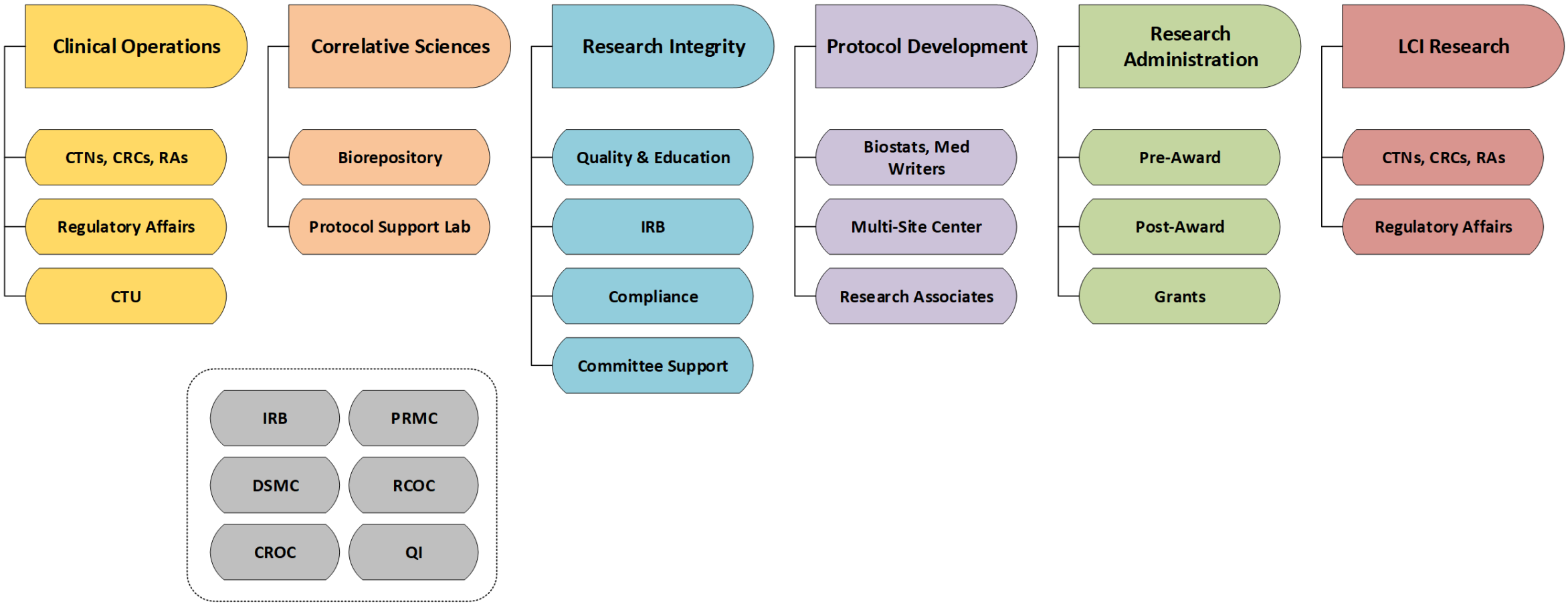
380 Active Human Research Studies

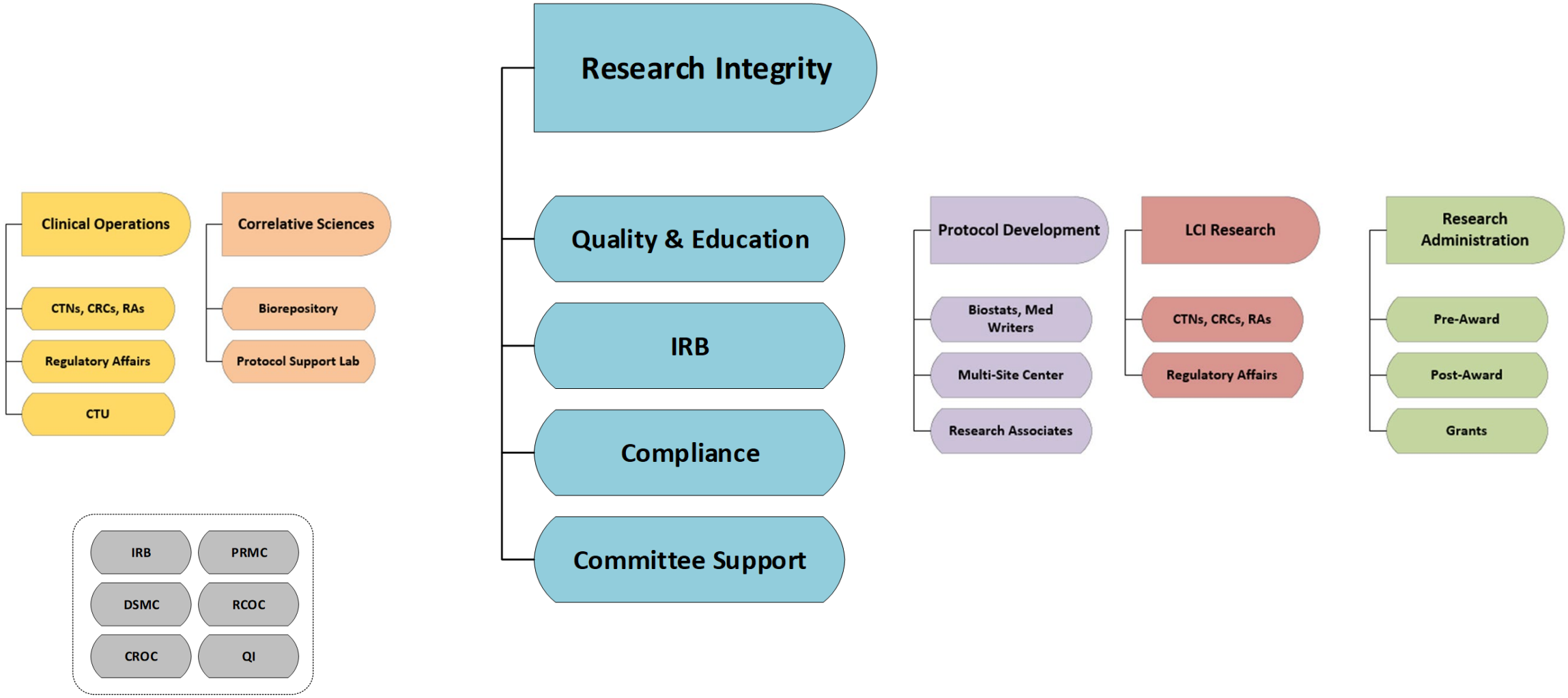
- 186 Therapeutic Clinical Trials
- 55 Non-Therapeutic Studies
- 139 Retrospective Studies

Accruals to Tx Clinical Trials



- Non-Therapeutic Accruals: 325
- Biorepository Accruals: 1725


Clinical Operations
CTNs, CRCs, RAs
Regulatory Affairs
CTU
Correlative Sciences
Biorepository
Protocol Support Lab
Research Integrity
Quality & Education
IRB
Compliance
Committee Support
Protocol Development
Biostats, Med Writers
Multi-Site Center
Research Associates
Research Administration
Pre-Award
Post-Award
Grants
LCI Research
CTNs, CRCs, RAs
Regulatory Affairs
IRB
PRMC
DSMC
RCOC
CROC
QI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Post-Award
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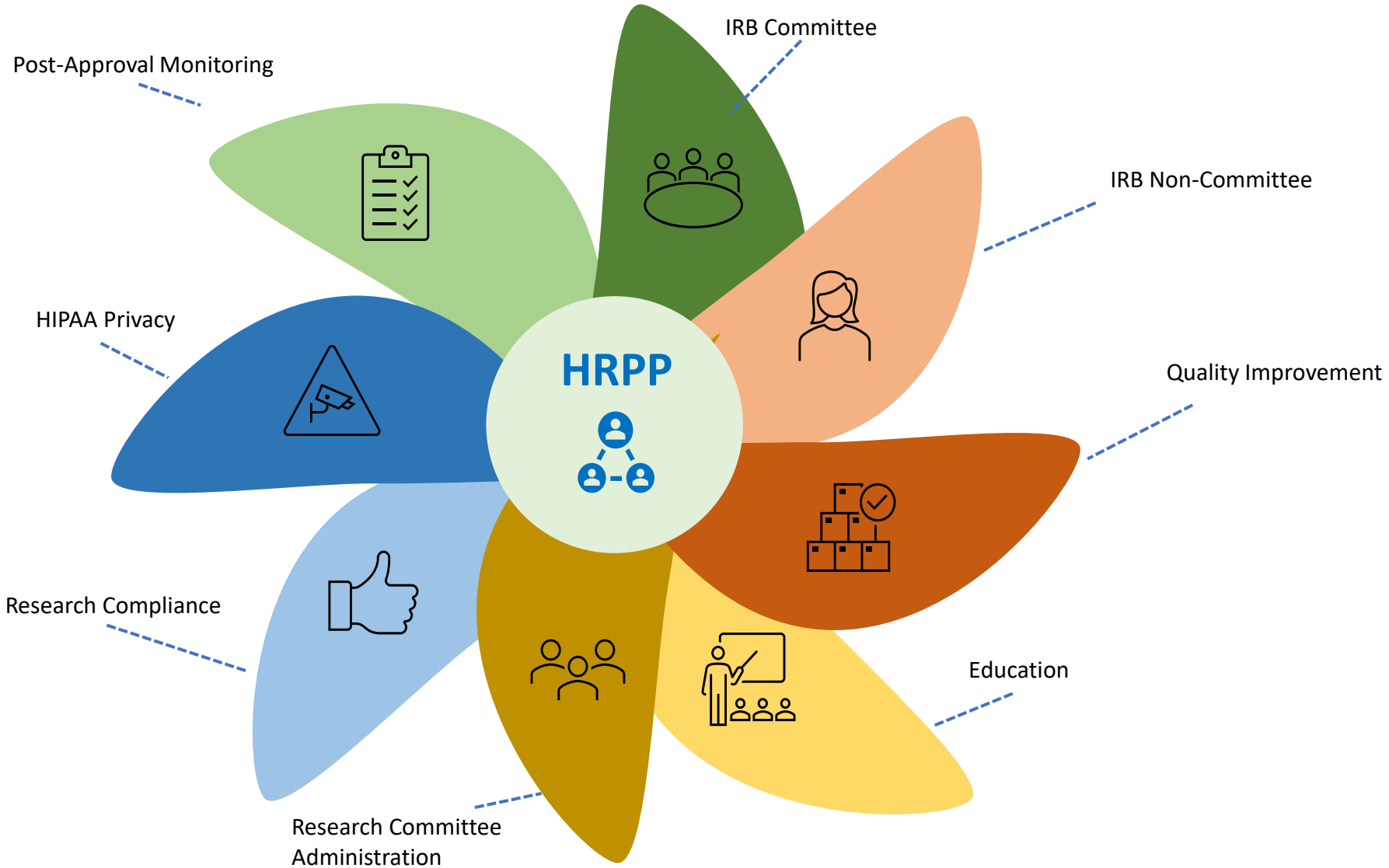
PRMC
DSMC
RCOC
CROC
QI


HRPP
IRB Committee
IRB Non-Committee
Quality Improvement
Education
Research Committee Administration
Research Compliance
HIPAA Privacy
Post-Approval Monitoring

Thank You!

Questions?