



2024 Annual State-of-the-IRB Townhall

October 16, 2024

Northwestern University

COLLEGES AND SCHOOLS



Weinberg College of Arts
and Sciences



School of
Communication



School of Education and
Social Policy



McCormick School of
Engineering and Applied
Science



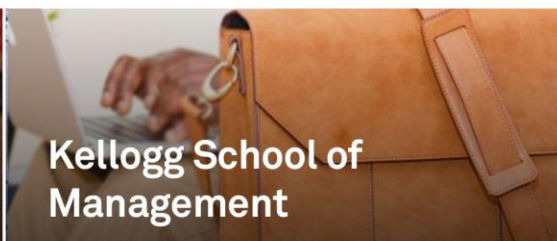
Medill School of
Journalism, Media,
Integrated Marketing
Communications



The Graduate School



Pritzker School of Law



Kellogg School of
Management



Feinberg School of
Medicine



Bienen School of Music



School of Professional
Studies



Northwestern in Qatar

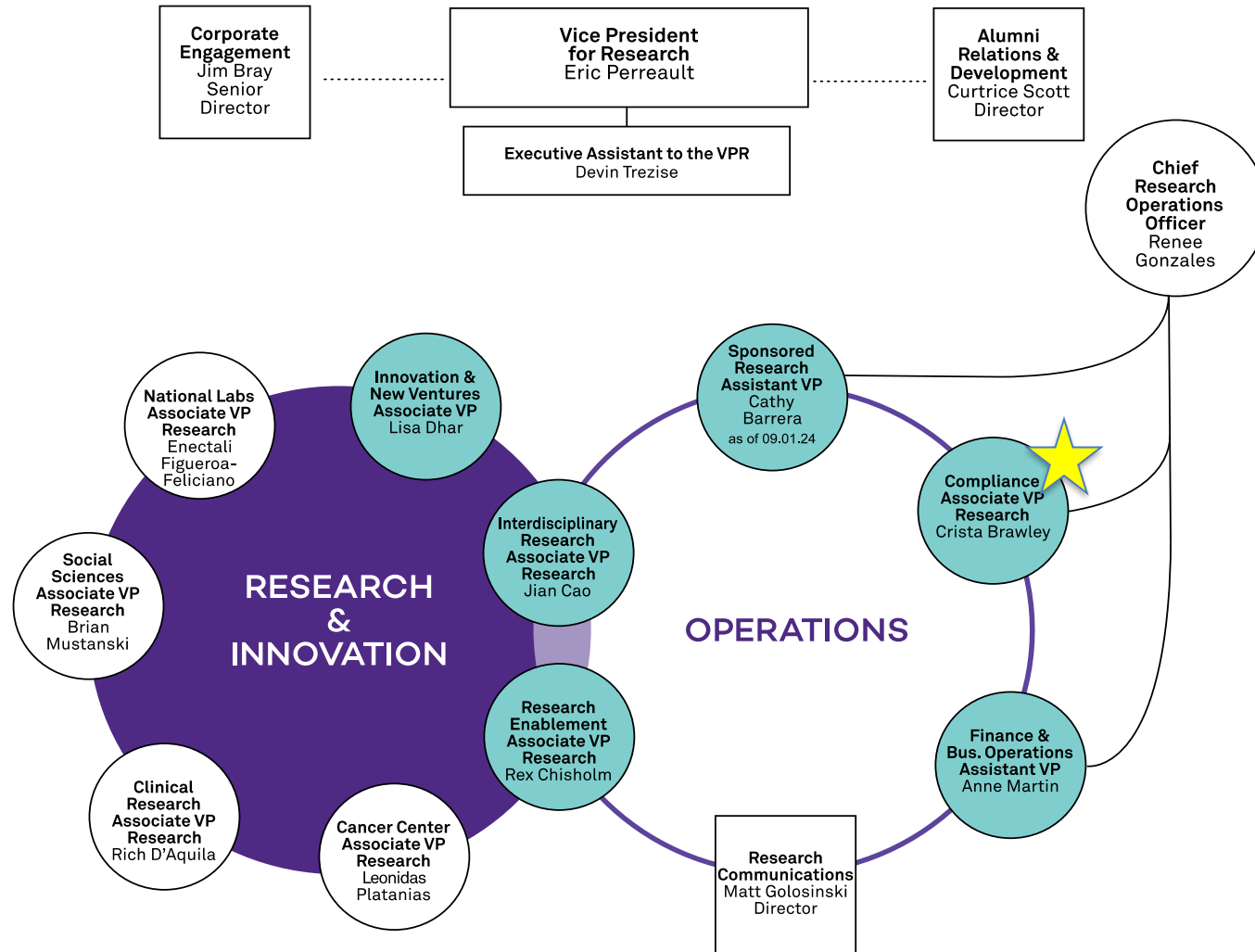
University Research Centers and Institutes

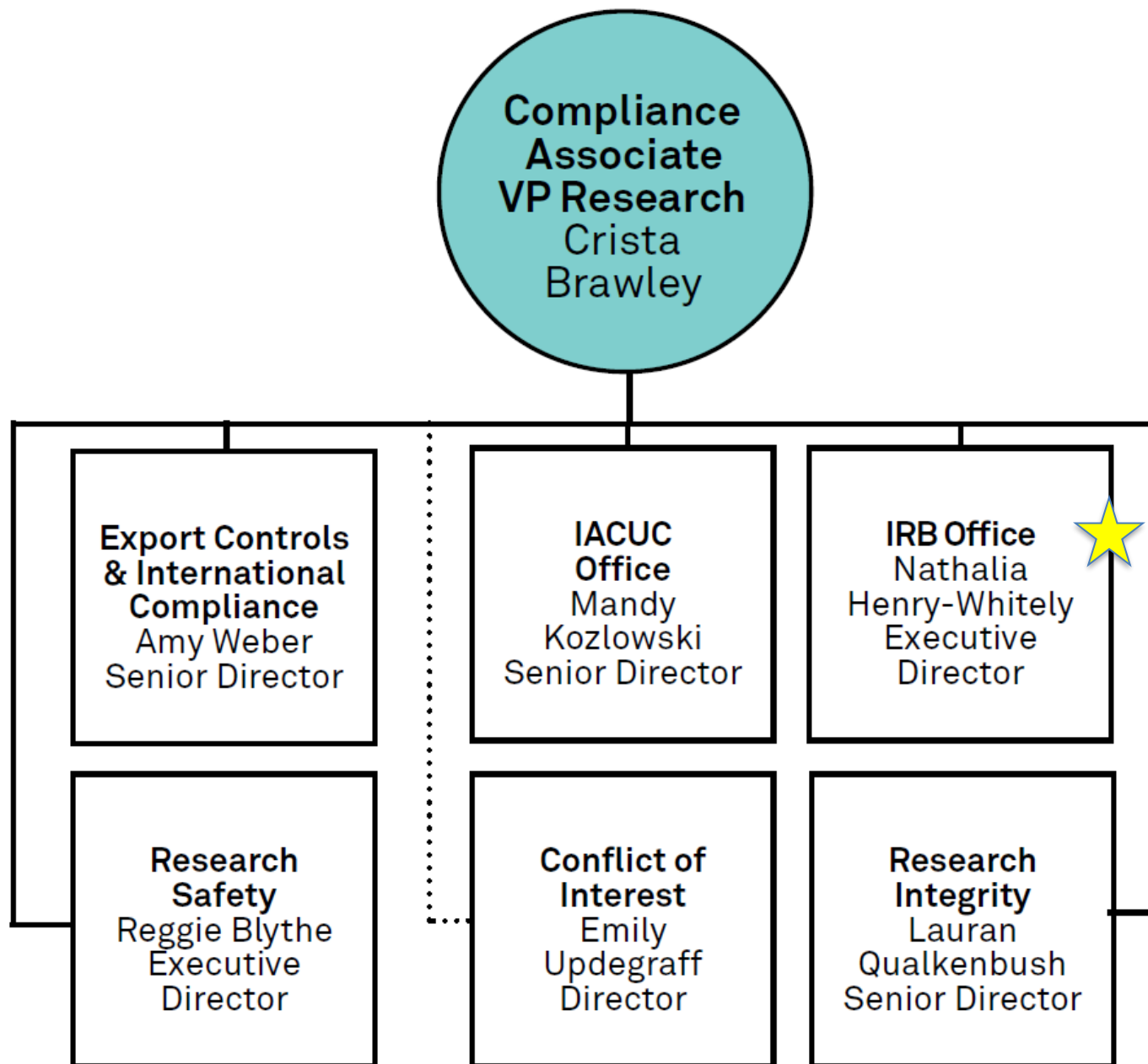


Louis A. Simpson and Kimberly K. Querrey
Biomedical Research Center

- Northwestern Buffett Institute for Global Affairs
- Center for Bio-Inspired Energy Science
- Querrey Simpson Institute for Bioelectronics
- Center for Synthetic Biology
- Simpson Querrey Center for Neurogenetics
- Center for Regenerative Nanomedicine (CRN)
- Center for Reproductive Science (CRS)
- Center for Scientific Studies in the Arts
- Chemistry of Life Processes Institute (CLP)
- Institute for Policy Research (IPR)
- Paula M. Trienens Institute for Sustainability and Energy
- International Institute for Nanotechnology (IIN)
- Louis A. Simpson and Kimberly K. Querrey Biomedical Research Center
- Materials Research Center (MRC)
- Northwestern Institute on Complex Systems (NICO)
- Northwestern University Clinical and Translational Sciences (NUCATS)
- Northwestern/Argonne Institute of Science and Engineering (NAISE)
- Robert H. Lurie Comprehensive Cancer Center

Office for Research Organization Chart 2024

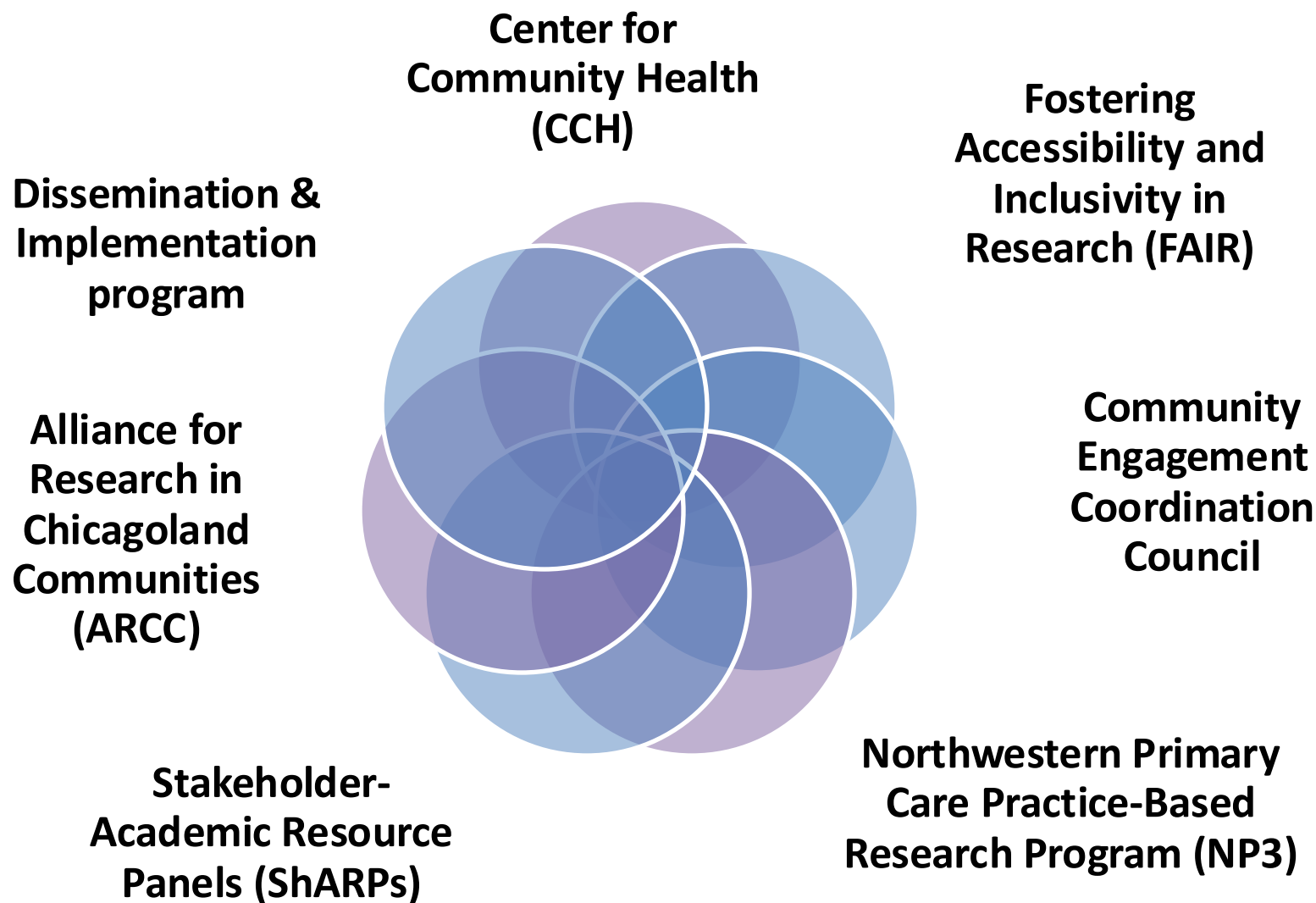




THE HUMAN RESEARCH PROTECTION PROGRAM



Community Engagement Efforts/Initiatives/Programs



HRPP Strategic Initiatives



Infrastructure, Staff Knowledge & Expertise



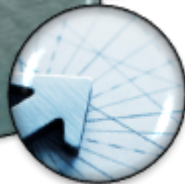
Technology, Process Improvement and Efficiency



Communication, Customer Service and Education



Quality, Compliance Oversight and Support



Local and National Leadership



FY 2024 Highlighted Accomplishments

- **Accreditation of Human Research Protection Programs (AAHRPP) Re-accreditation submissions and site visit**
- **IRB Office Infrastructure & Staffing/Retention/Education & Training**
- **NU-Qatar On-Site Research Community Education, Training and Engagement**
- **HRPP Education: Navigating Human Research, Ethics and Regulatory Review (new) and CITI Training (updated)**

IRB OFFICE ELEVATOR PITCH

Our Purpose



Protects the rights and welfare of participants in human research.

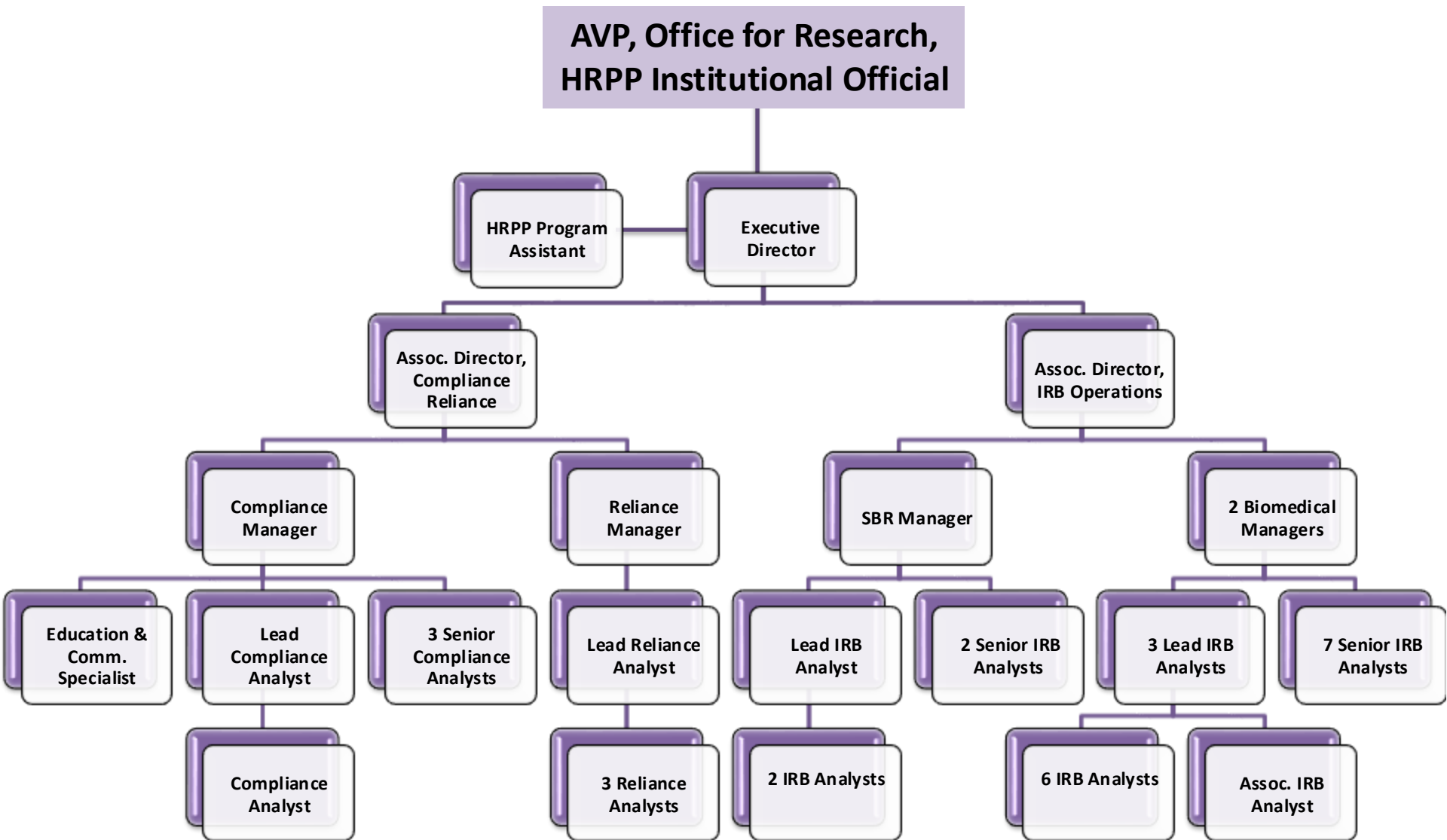


Administratively supports the IRB which is responsible for approving research protocols, informed consent documents and other study related materials before a study can begin.

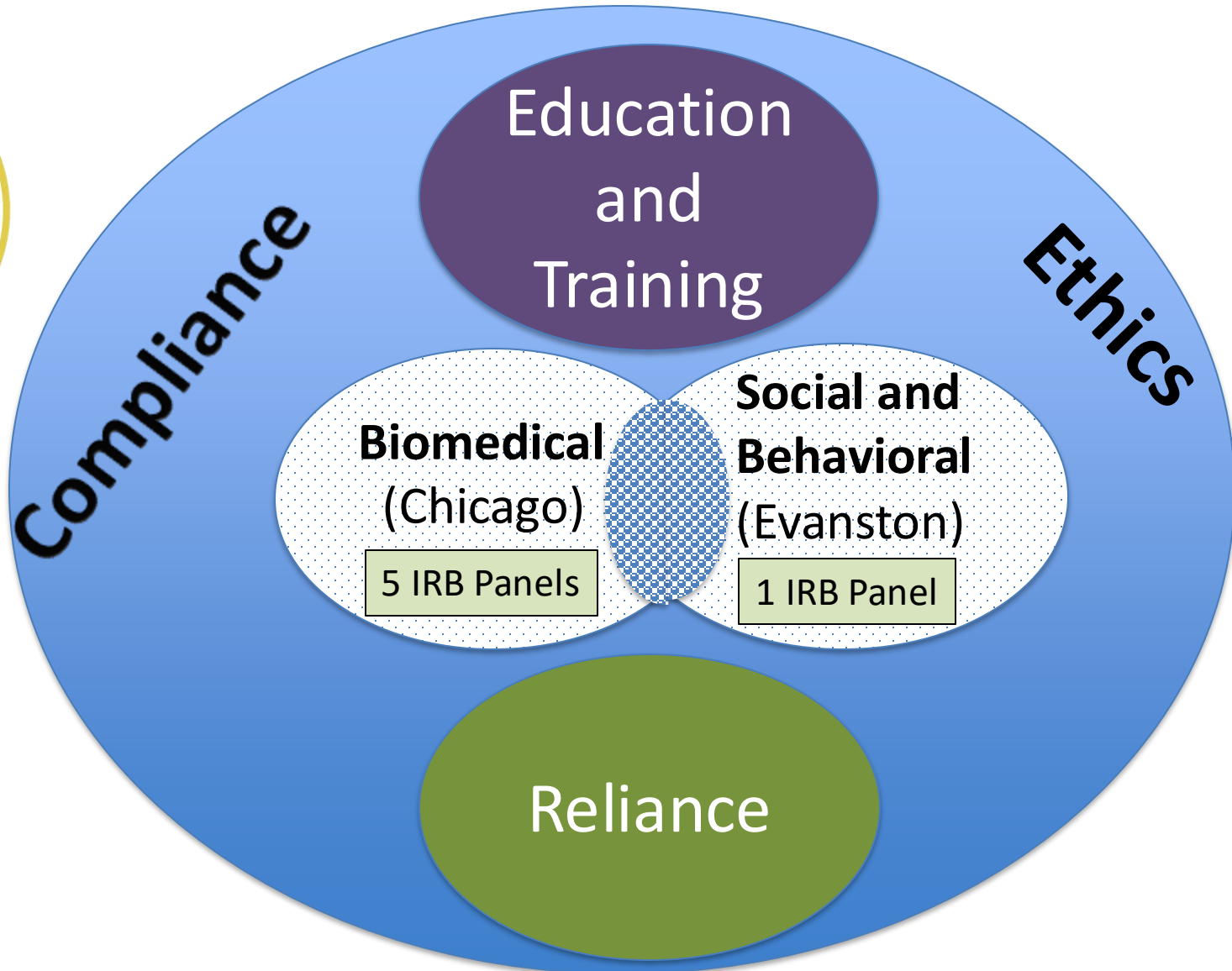


Provides guidance, education and relevant compliance tools, and equips the University's research community to conduct ethical human research that minimizes risk to participants and maximizes benefit.

IRB OFFICE ORG CHART



Regulatory/Functional Framework



FY2024 IRB Office Key Metrics

MEDIAN TAT (Days)

TYPE	PANEL	EXP.
NEW	70	39
CR	24	15
MOD/ CR	29	18
MOD	47	18

Active Studies

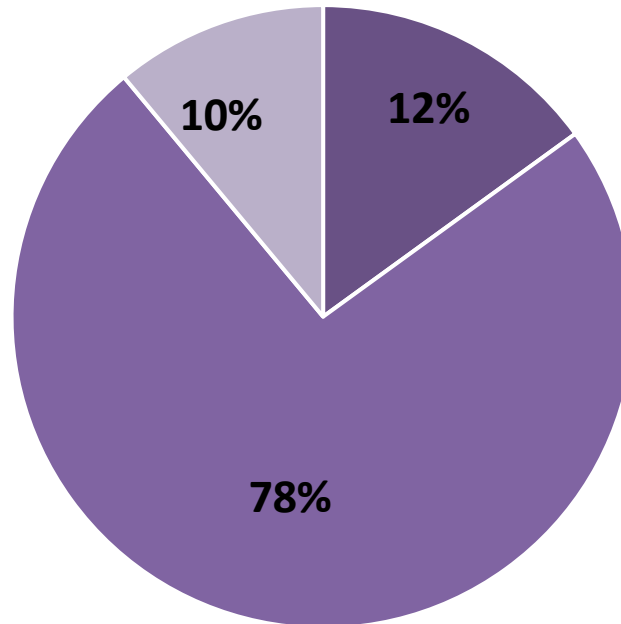
8,992

64%

Biomedical

36%

Social
Behavioral



Funding Sources:

- *Federal: 22%
- *Industry: 11%
- *Other External: 26%
- *Internal: 50%

Total Submissions:

15,669

■ Convened ■ Expedited ■ Exempt

1630

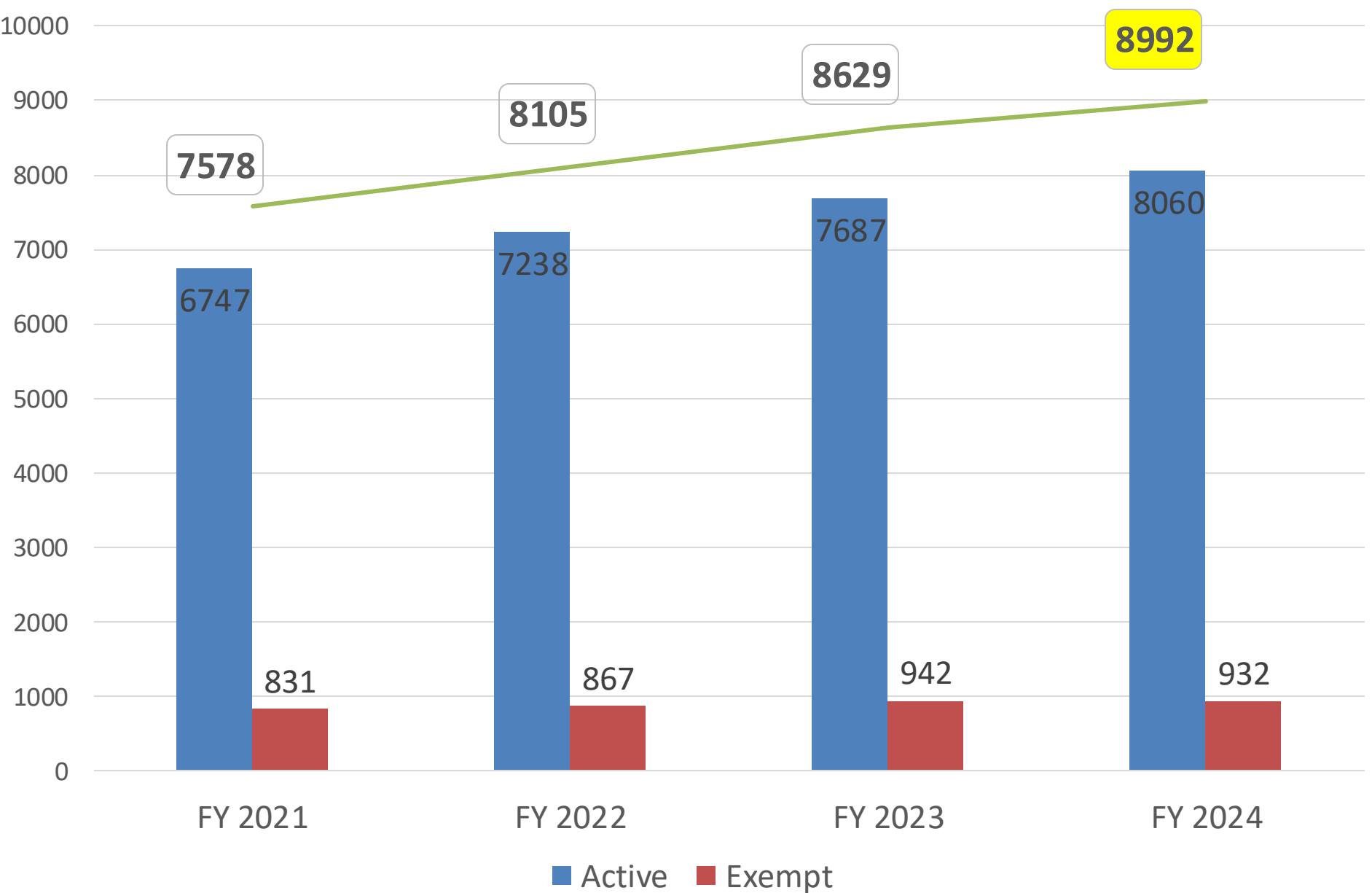
Principal
Investigators

10,277

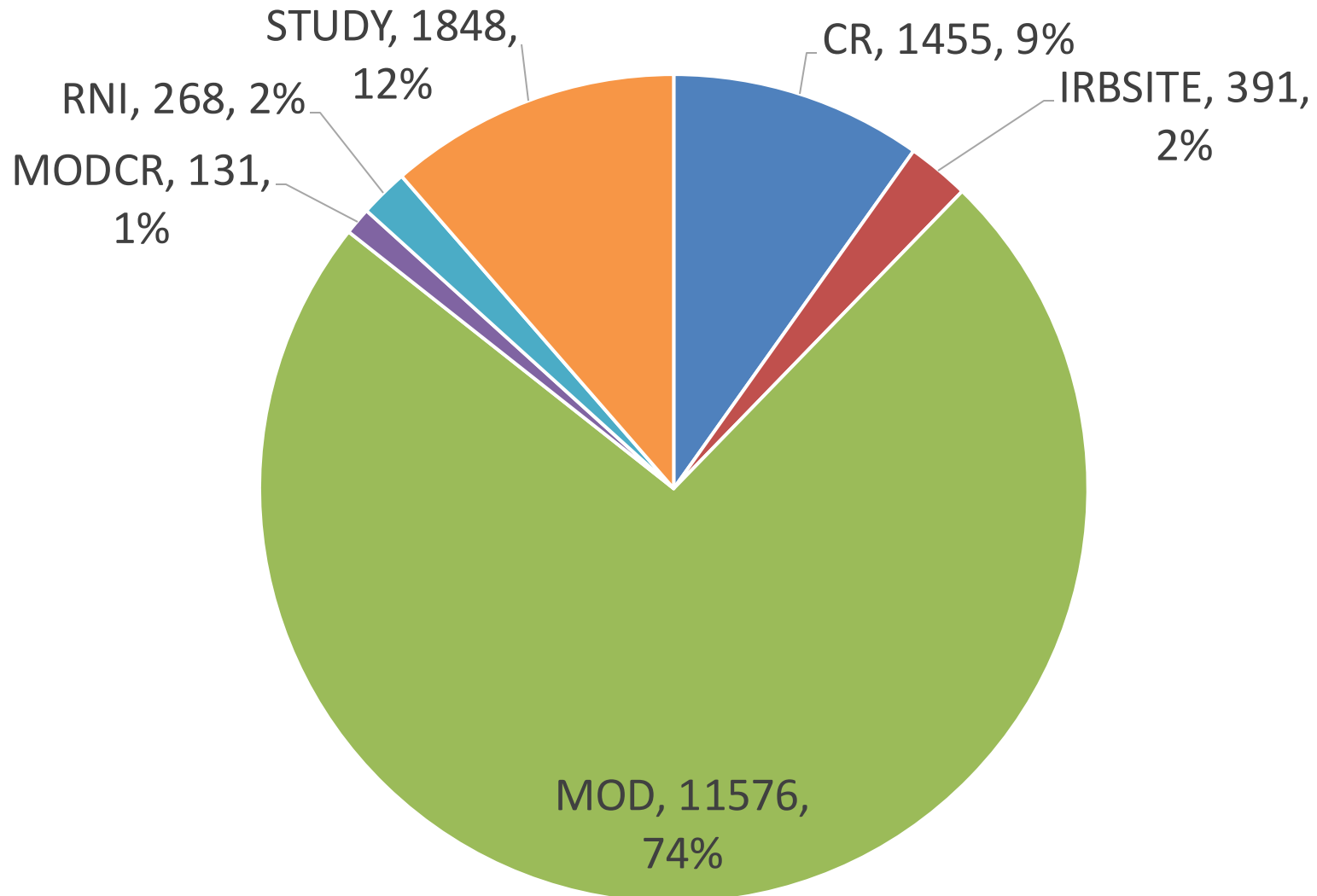
Research Staff

110 Convened IRB Meetings

Active & Exempt Studies by Fiscal Year



IRB Submission Types FY2024



Reliance and Single IRB

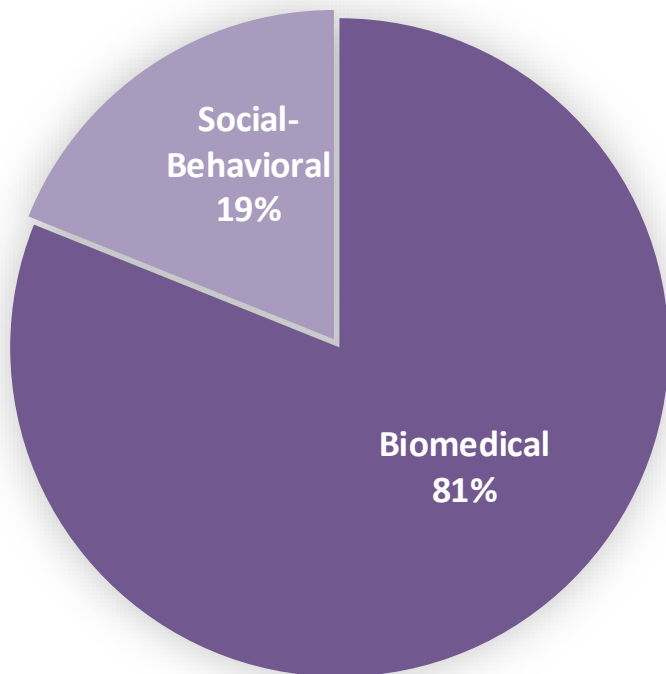
230

FY24 Total Letters of Support

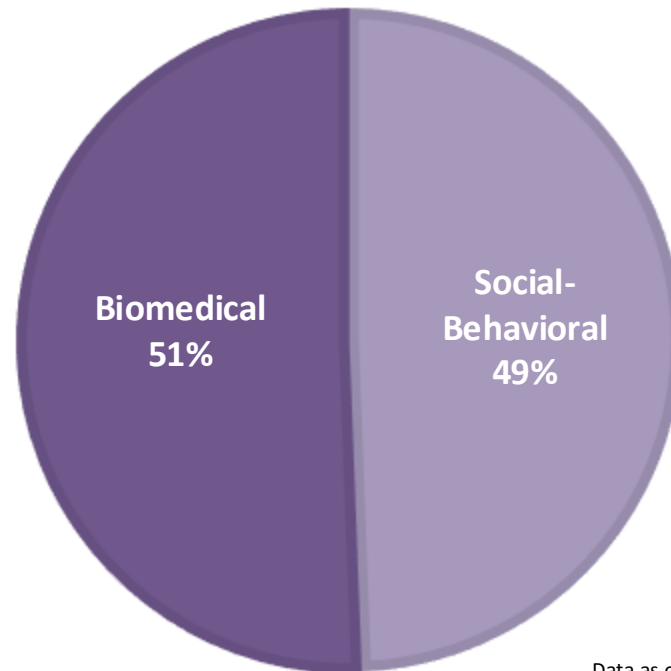
135

**Letters of Support w/
Northwestern as sIRB**

**EXTERNAL IRBs
TOTAL = 1200**



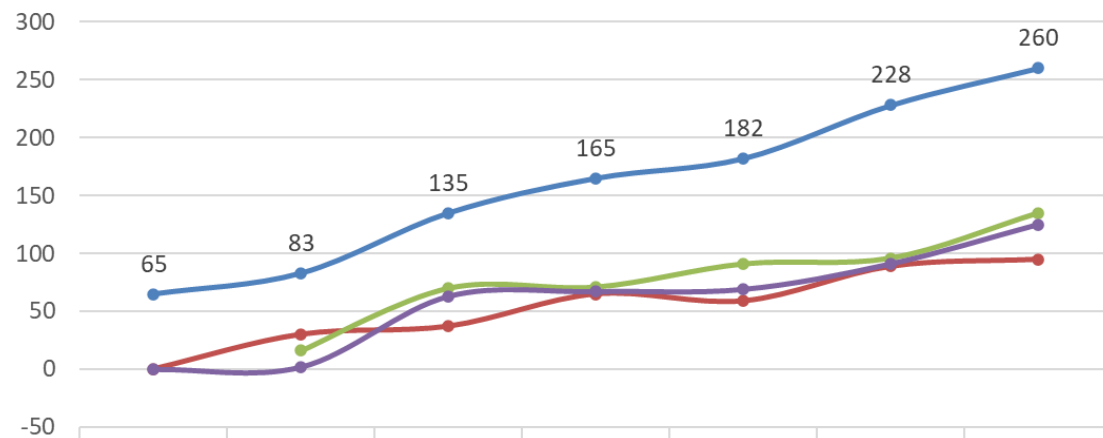
**NU: IRB OF RECORD
TOTAL = 334**



Data as of 10/2/24 reports

Reliance and Single IRB

Single IRB Growth (FY18 – FY24)



	FY2018	FY2019	FY2020	FY2021	FY2022	FY2023	FY2024
Number of Single IRB Consultation Requests	65	83	135	165	182	228	260
Letters in Support of the Northwestern IRB Ceding to sIRB	0	30	37	65	59	89	95
Letters in Support of the Northwestern IRB Serving as sIRB		16	70	71	91	96	135
Number of Quotes for IRB Fees	0	2	63	67	69	91	125

Post-Approval Compliance Activities

1

- Directed Reviews (For-Cause Audits)

33

- Compliance Reviews and Other Investigations

37

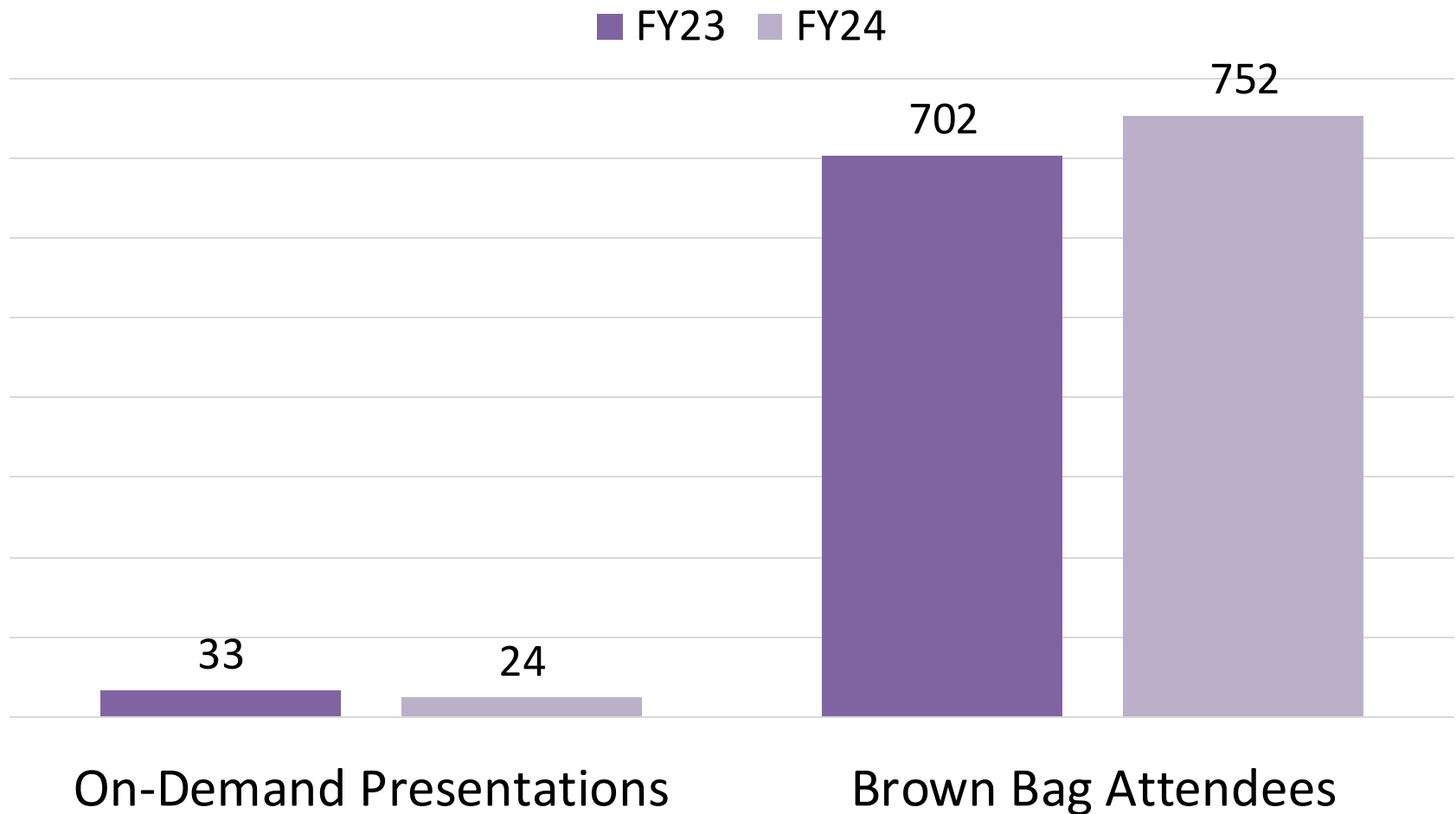
- External / Institutional Reports Sent

204*

- PI Assessments / Post-Approval Monitoring

*assessments completed during FY24

Research Community Educational Programming



(NEW!) eIRB+ Compliance Workspace

The transition of compliance activities into eIRB+


Compliance eSolution Project Overview


- In FY21, the Compliance team began collaborating with Research IT (RIT) to explore creating an electronic solution (eSolution) for IRB Compliance services
 - ✓ **Phase 0:** System feasibility and design, workflow development, and internal activities implementation; eIRB+ chosen as the ideal electronic platform
 - **Phase I:** Building post-approval monitoring (PAM) and auditing (Directed Review) processes in eIRB+; near completion
 - **Phase II:** Develop external reporting, participant complaints, and incidental disclosures processes in eIRB+; preliminary project scoped
 - **Phase III:** Develop other Compliance activity processes in eIRB+; not started

Current PAM Process

- Manually driven
 - Email communication
 - Word documents and PDFs
 - Spreadsheets
- Prone to human error and inconsistencies
- Inefficient workflows
- Limited data analysis capabilities


Post-Approval Monitoring Checklists


[HRP-443 - CHECKLIST Observation of the Consent Process](#) 


[HRP-427 - CHECKLIST Post Approval Monitoring: Drug or Device Clinical Trial](#) 

[HRP-428 - CHECKLIST Post Approval Monitoring: Participant File](#) 

[HRP-430 - CHECKLIST Post Approval Monitoring: Human Research](#) 


[HRP-433 - CHECKLIST Post Approval Monitoring: Studies Without an Expiration Date](#) 

[HRP-1401 - CHECKLIST Post Approval Monitoring: Recruitment Activities](#) 

[HRP-1405 - CHECKLIST Post Approval Monitoring: Registry, Data Review, and/or Specimen Collection](#) 

[HRP-1406 - CHECKLIST Post Approval Monitoring: Studies Under External IRB Review](#) 

[HRP-1407 - CHECKLIST Post Approval Monitoring: Site File](#) 

[HRP-1409 - CHECKLIST Post Approval Monitoring: Humanitarian Use Device](#) 

<https://irb.northwestern.edu/resources-guidance/checklists-worksheets/#pamc1>

(NEW!) eIRB+ Compliance Workspace: PAM Process



The IRB Office Compliance Team will conduct post-approval monitoring with research teams in the IRB's electronic submission system, eIRB+.



Study teams will fill out our existing post-approval monitoring checklists electronically in the eIRB+ Compliance Workspace, and then submit responses to Compliance observations and follow-up requests within the workspace.

Advantages and Improvements

- Smart logic electronic forms
- Streamlined workflows
- Automated, real-time documentation and tracking
- Accessibility and transparency of status and communications
- Reduced human error
- Improved accountability and consistency
- Enhanced data analysis and metrics reporting
- Compliance activity and monitored study will be visually linked



A woman with blonde hair, wearing a dark blazer over a light blue shirt, is seated at a wooden desk. She is holding a silver pen and writing in a white notebook. To her right is a black laptop. The background is slightly blurred, showing a window with wooden frames.

Upcoming IRB Office November Brown
Bag

Wednesday, November 13, 2024

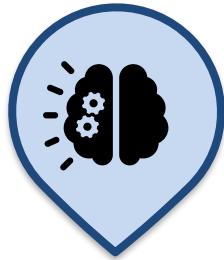
12:00 pm - 1:00 pm

Streamlining Compliance: The New eIRB+ Compliance Workspace

25

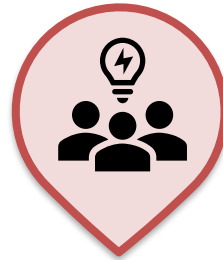
HRPP Workforce Culture and Health

Psychological Safety



Community
Trust
Respect

Empowerment



Fairness
Creativity
Accountability

Autonomy



Independence
Flexibility
Ownership

Office for Research Values

In the
Office for
Research, we:

UNDERSTAND EMPATHY

We treat each other with compassion, dignity, and respect through listening to learn, not to confirm our views.

MODEL ACCOUNTABILITY

We keep our commitments, actively participate, and take ownership of our successes and failures.

ENSURE FAIRNESS

We build transparent and equitable processes, and embrace high ethical standards.

EMBRACE COMMUNITY

We build and nurture relationships between people and enable connections to grow, learn, and excel.

VALUE CREATIVITY

We take responsible risks and encourage autonomy to find innovative solutions and continuous improvement.

