



# The Rutgers Office for Research

Human Research Protection Program  
(HRPP) & IRB

10.25.2024

Hila Berger, MPH, CHC, CIP  
AVP, Research Regulatory Affairs

Dr. Swapnali Chaudhari MBBS, MS, CRC/CRA  
IRB Director





RUTGERS UNIVERSITY  
Office for Research

[research.rutgers.edu](https://research.rutgers.edu)

## Our Vision

The Rutgers Office for Research seeks to be the most innovative and trusted research office among all research universities, empowering faculty, students, and staff, to achieve excellence.

## Our Mission

Rutgers' Office for Research supports the research, scholarship, and creative endeavors of **ALL** Rutgers faculty.



RUTGERS UNIVERSITY  
Office of the Executive Vice  
President for Academic Affairs



RUTGERS UNIVERSITY  
Office for Research

[research.rutgers.edu](https://research.rutgers.edu)

## Our Values

### RESPECT

*We are transparent and collaborative, treat everyone with dignity and respect, and give every person a voice and opportunity to succeed.*

### SIMPLICITY

*Our services must be as easy to understand and use as possible.*

### COLLABORATION

*We partner and convene to achieve shared goals for the common good.*

### EXCELLENCE

*We strive to be effective, efficient, and innovative in all we do.*



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President for Academic Affairs

# Research Administration



**José M. Román**  
Vice President,  
Research  
Administration

122 FTEs

## UNIVERSITY-WIDE APPLICATIONS

RAPSS  
eCERT  
eIRB  
eCOI+  
Pivot  
InfoReady

## Research & Sponsored Programs (Pre-Award)

- Guides faculty through proposal review, submission, and award setup including subawards
- Provides educational programs for faculty and staff
- Policy development and training

## Research Financial Services (Post-Award)

- Performs central financial accounting and reporting for sponsored research
- Provides post-award administration support for sponsored programs and other restricted funds
- Coordinates effort certification processes

## Research Regulatory Affairs

- Assists research faculty, administrators and staff comply with local, state and national laws and regulations
- Promotes the responsible conduct of research through education, training and certification

## Research Contract Services

- Reviews, drafts and negotiates all research-related material transfer agreements, data use agreements, nondisclosure agreements (NDAs, CDAs), and all research contracts

**3,500+**  
Award  
Submissions  
Annually

**8,000+**  
Active Awards  
Managed

**6,800+**  
IRB Reviews  
Annually

**2,000+**  
Contracts  
Executed  
Annually

# OfR's Key Research Compliance Functions



**Hila Berger**

Assistant Vice President,  
Research Regulatory Affairs

## Human Research Protection Program

25 FTEs

IRB

Quality Assurance & Evaluation

Reliance and Collaborations

DRAFT/Pre-review and Exempt Review

Education and Outreach

Clinical Trials Compliance

## Export Compliance

4 FTEs

Export Controls Compliance

VSA & Travel Compliance

MTA Compliance

Foreign Influence Compliance

## Research Integrity

2 FTEs

Responsible Conduct of Research  
Training

Conflict of Interest Compliance

Research Misconduct Investigations

# HRPP Functional Roles and Responsibilities

## Quality Assurance and Evaluation (QA&E)

- Roles & Responsibilities
  - AAHRPP annual and reaccreditation [with all other areas]
  - Quality and Assessments of all HRPP components
  - Audit Program (For-Cause, Routine, Programmatic)
  - Study Complaints and Concerns (HRP-024 form)
  - Clinical Trials Compliance Team
    - CTG compliance and monitoring
    - CTG related training with researchers



## IRB Team

- Role & Responsibilities
  - IRB Submissions and Reviews
  - Routing
  - IRB inbox
  - Full Board Meetings
  - EIRB system
  - Paper Conversion (2024)
  - Monthly meetings with the School Dean or the Representative
  - Regulatory guidance and personalized eIRB support



# HRPP Functional Roles and Responsibilities

## Reliance Team

- Roles & Responsibilities
  - IRB Submissions
  - Reliance Agreements
  - SMART IRB
  - RWJBH and external entity support



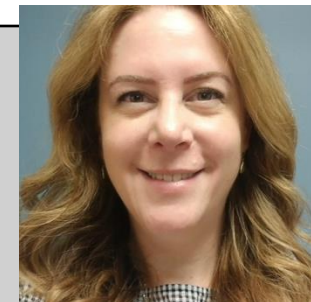
## DRAFT Services/Exempt/Pre-Review Team

- Roles & Responsibilities
  - Exempt workflow and Reviews
  - Open Office Hours
  - DRAFT reviews
  - Interactive Tools
  - Newsletter
  - Orientation of new IRBAs
  - Coaching and ongoing training IRBAs



# HRPP Functional Roles and Responsibilities

## Education, Membership, Training and Outreach

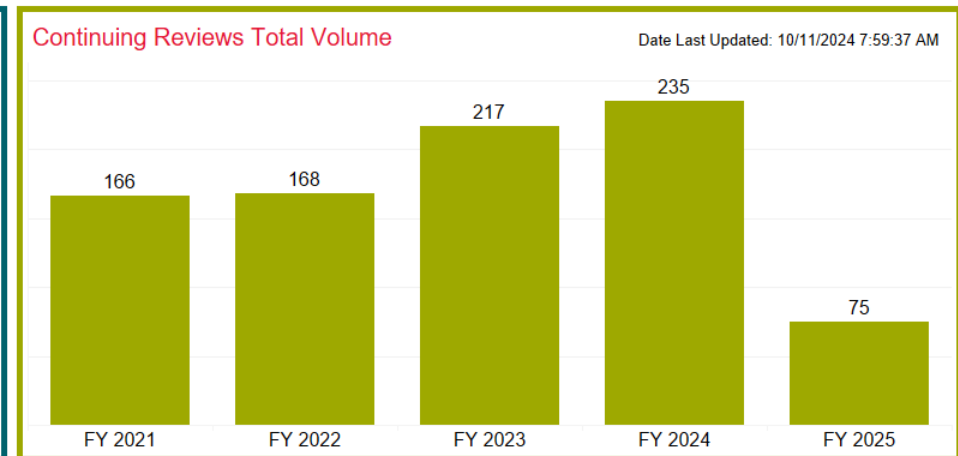
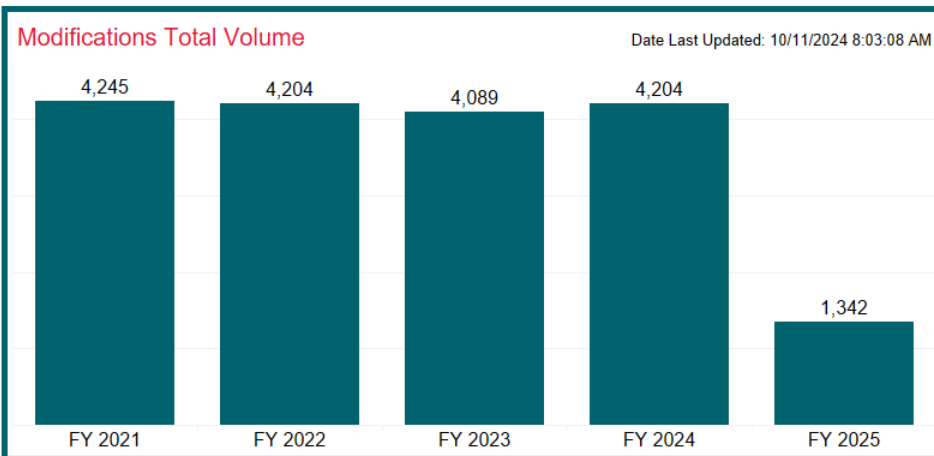
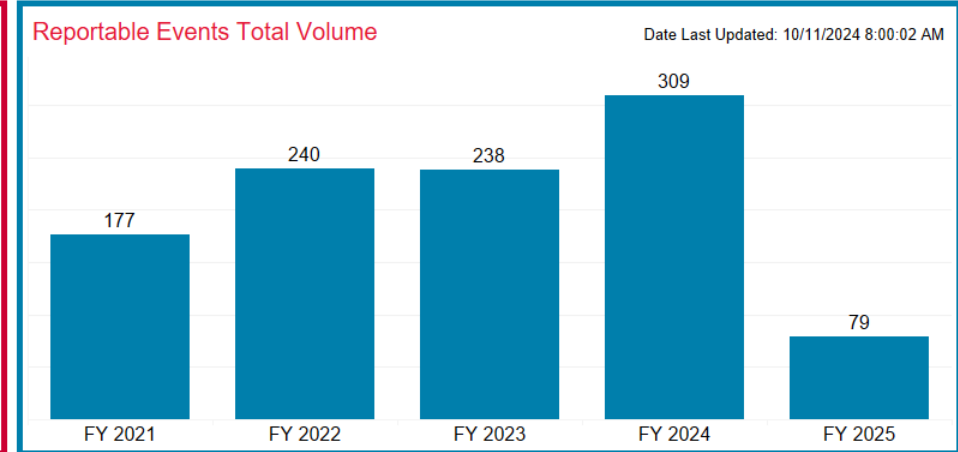
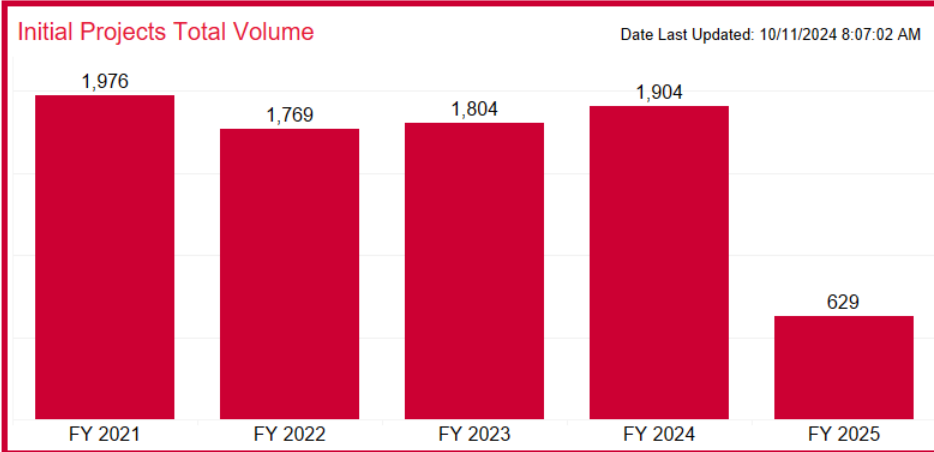


- Roles & Responsibilities
  - IRB Committee Membership Management and Orientation of new IRB members
  - Ongoing Training of Committee Members
  - Education strategy for all of HRPP
  - OHRP Registration
  - EIRB+ training

# IRB/HRPP Support of ALL Rutgers Research



## Reliance Total Volume Previous Five Fiscal Years by Submitted Date



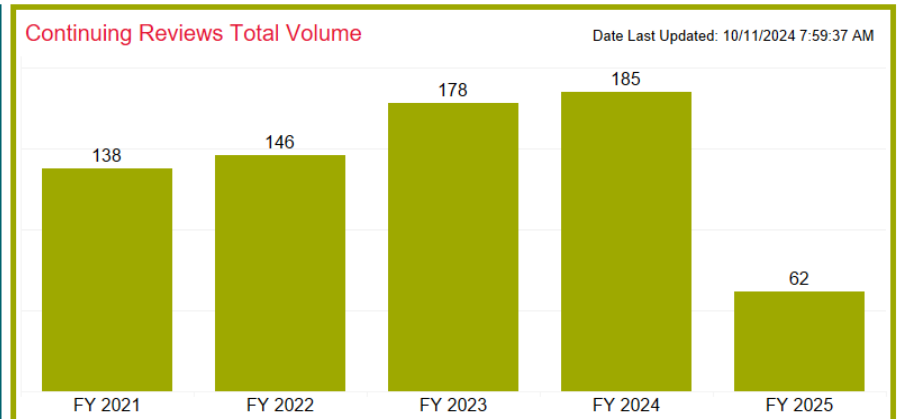
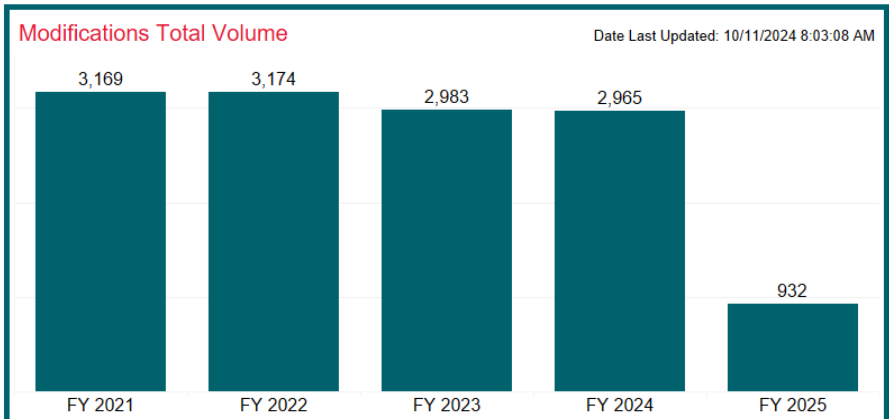
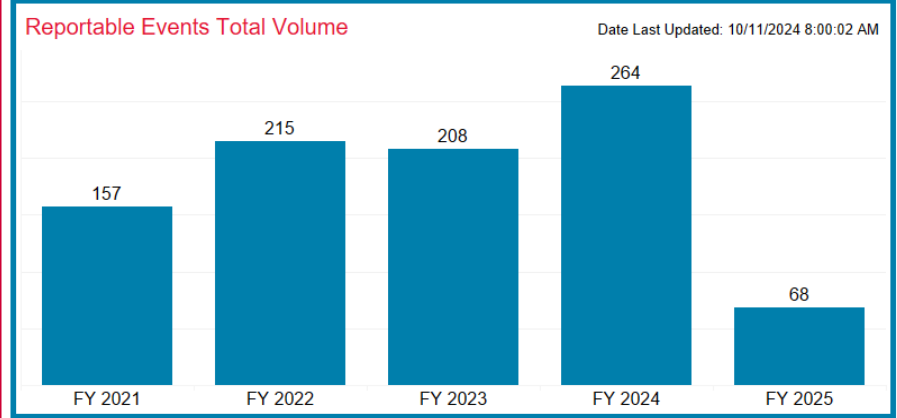
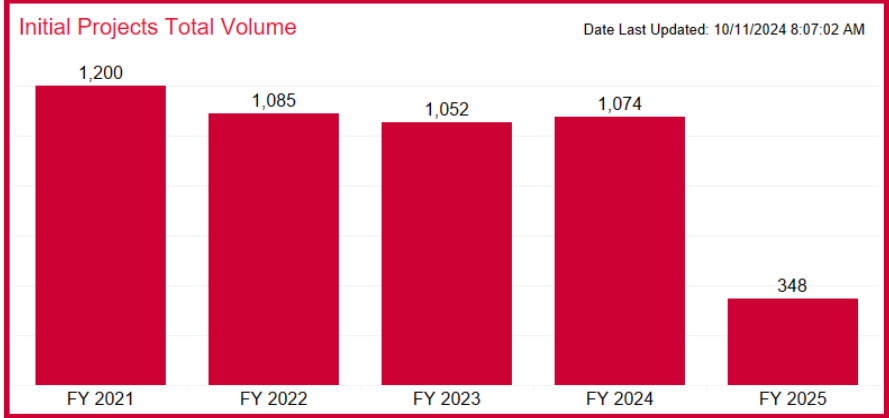
Chancellor Unit: (All) | School: (All) | Department: (All) | Is a Clinical Trial?: (All) | Fund Type: (All) | Sponsors: (All) | RWJBH: All Studies

# IRB/HRPP Support of Rutgers Health



RUTGERS UNIVERSITY  
Office for Research

## Reliance Total Volume Previous Five Fiscal Years by Submitted Date



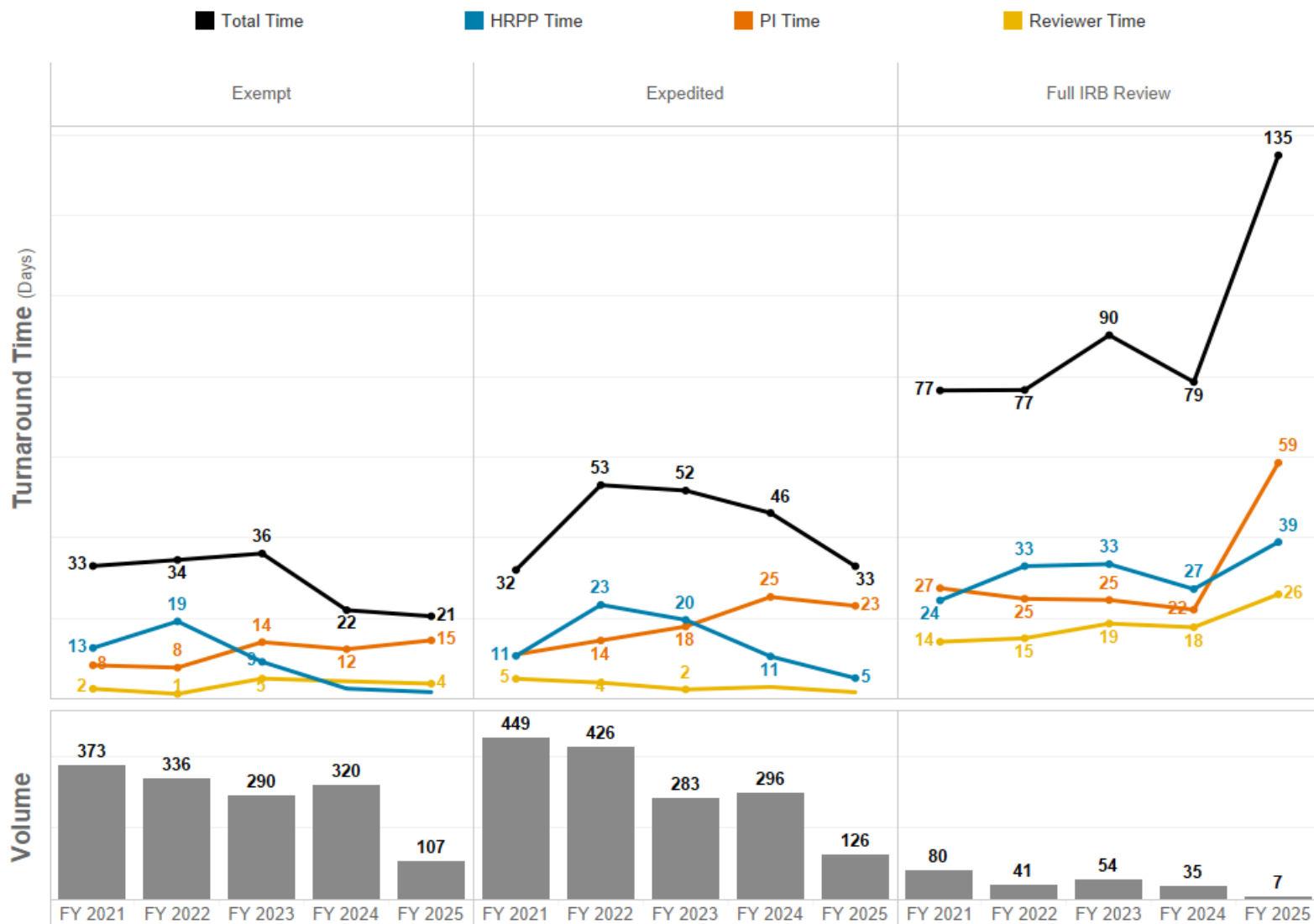
Chancellor Unit: RBHS | School: (All) | Department: (All) | Is a Clinical Trial? (All) | Fund Type: (All) | Sponsors: (All) | RWJBH: All Studies

# Initial Study Review Time – Rutgers Health

FY24 Median Exempt Review – 22 days  
 FY24 Median Expedited Review - 46 days  
 FY24 Median Full Board Review - 79 days

## Median Initial Study Turnaround Time in Calendar Days by Fiscal Year

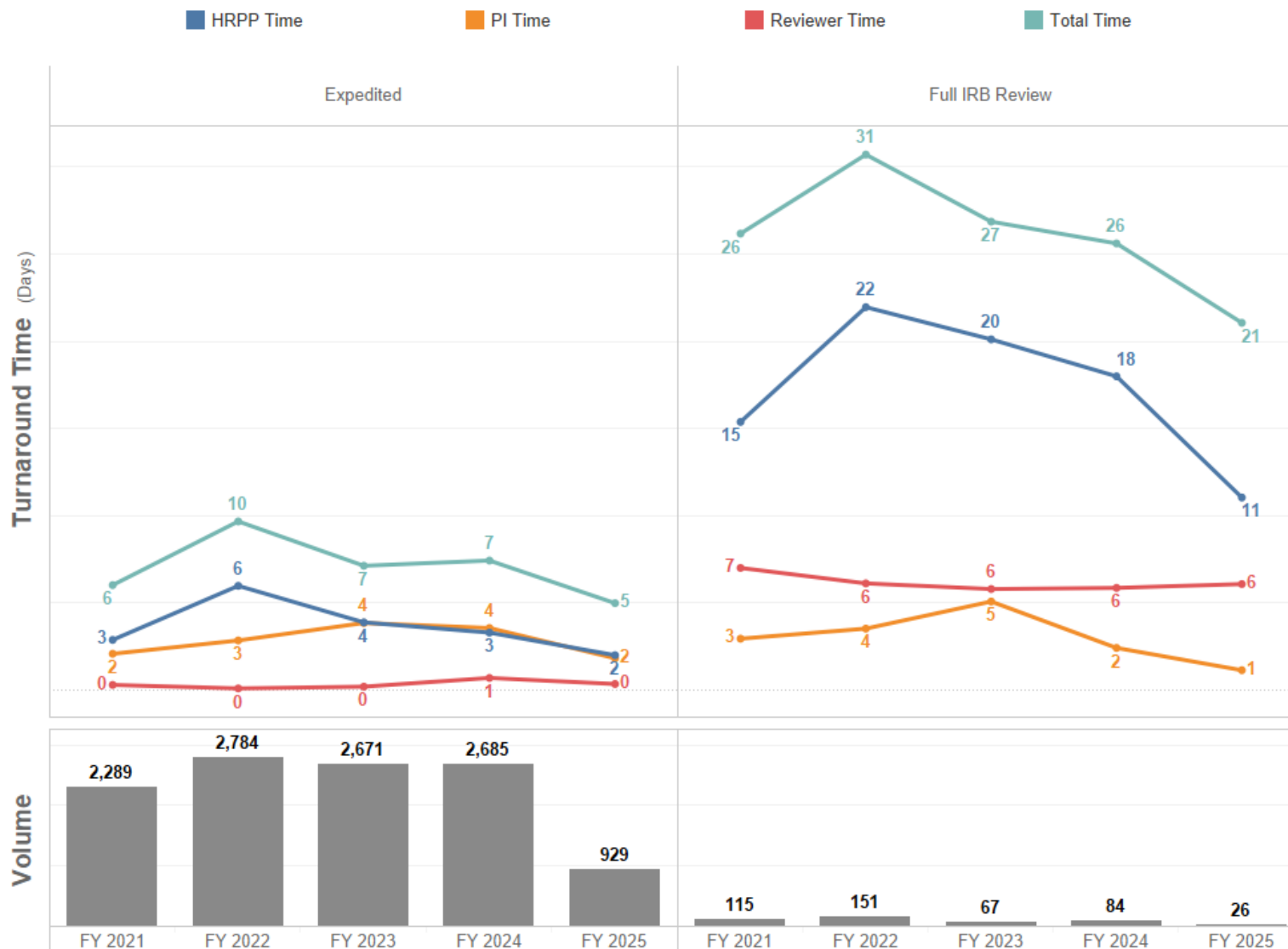
Chancellor Unit: RBHS



# Modifications Review Time – Rutgers Health

FY24 Median Expedited Review - 7 days  
 FY24 Median Full Board Review - 26 days

Median Modification Turnaround Time in Calendar Days by Fiscal Year  
 Chancellor Unit: RBHS



# HRPP Updates

- Launch eIRB+
- Virtual Open Office Hours
- Interactive Tools
- Training

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Office for Research | eIRB+TEST

» Home

**eIRB+ Support**

IRB Submission Help:  
IRBOffice@research.rutgers.edu

IT Tech Support:  
eirb@research.rutgers.edu

Virtual Office Hours  
Tuesdays, 1:00pm – 1:30pm  
Thursdays, 10:00am – 10:30am

**eIRB+**

This is an electronic gateway for the submission, review, approval, and tracking of IRB applications.

**Helpful HRPP Tools**

Interactive IRB Tools

Open Office hours - <https://research.rutgers.edu/faculty-staff/compliance/human-research-protection/draft-services>

Interactive Tools - <https://research.rutgers.edu/faculty-staff/compliance/human-research-protection/interactive-irb-tools>

Training - <https://crs.research.rutgers.edu/>

# HRPP Newsletter

**R** | RUTGERS UNIVERSITY  
Office for Research

HRPP/IRB Newsletter  
June 2024

[Contact the IRB](#) | [Contact IRB Balance Team](#) | [Contact DRAET Services](#) | [Contact Quality Assurance and Evaluation Team](#) | [Contact For Clinical Trials.gov Support](#)

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

Rutgers University has earned full accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP). [Learn more.](#)

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 Kathryn Greene Named Co-Chair of the Rutgers Institutional Review Board

SC&I Professor of Communication Kathryn Greene has been named a chair of the Rutgers Institutional Review Board (IRB) effective April 2024 for a defined term of three years. Rutgers University Office for Research Senior Vice President for Research Michael E. Zwick appointed Greene.

[Read more.](#)

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**Rutgers Human Research Protection Program at AAHRPP**

The [Association for the Accreditation of Human Research Protection Programs, Inc. \(AAHRPP\)](#)'s annual conference provides our Rutgers Office for Research team members with the opportunity to engage with Human Research Protection Program (HRPP) colleagues from across the globe to share ideas and learn.

Our own Andrea Dragan, MPH, CIP and Angela Cartmell-McGlyn, PhD, CIP presented at the 2024 AAHRPP conference, discussing best practices and sharing their respective subject matter expertise.

Andrea presented on *Maximizing Benefits for All: Why Including Minimal Risk, SBER Research in your Audit Program Matters.*

Angela discussed growing and cultivating new HRPP professionals in the panel, *HRPP/IRB Staffing: Onboarding, Education, and Empowerment.*



Congratulations to Andrea and Angela, and thank you for representing Rutgers University and the Office for Research!



## eIRB+ System Enhancements Live!

Responding to valuable feedback from our research community, we've simplified the IRB submission process by **seamlessly integrating the protocol into the eIRB+ application.**

The updated eIRB+ system **introduces new initial submission types**, providing increased flexibility and customization to accommodate a diverse array of research projects.

Our **enhanced Consent and Waivers section** now offers comprehensive guidance through help text, making it easier to navigate and complete appropriate waiver and consent requests.

Collaboration and document management is smoother and more efficient than ever in eIRB+, with a **more intuitive new attachments** section that populates at the end of the eIRB+ application.



## Get to know the eIRB+ Dashboard

The eIRB+ Dashboard makes managing your IRB portfolio more intuitive with the addition of widgets for Upcoming Expiration Dates, links to Helpful Tools, contact information for eIRB+ Support, direct access to your eIRB+ Profile, and to access Recently Viewed Projects.

Furthermore, the eIRB+ Dashboard introduces the 'Pending Items Requiring Action' feature, which displays IRB-related items that require action and/or response by the study team.



# eIRB+ Enhancements

# Highlights

1. Brand new workspace
2. Department Approval, CITI, COI requirements
3. Accept Participation request
4. Draft Services
5. Introducing research protocol within the EIRB application
6. Extensive revisions to section #8 – Consent and Waivers
7. New revised section #10 – Attachments
8. Brand new research protocol guide for eIRB+ – HRP503+

# Types of Submissions

## Introducing 10 Initial Submission Types

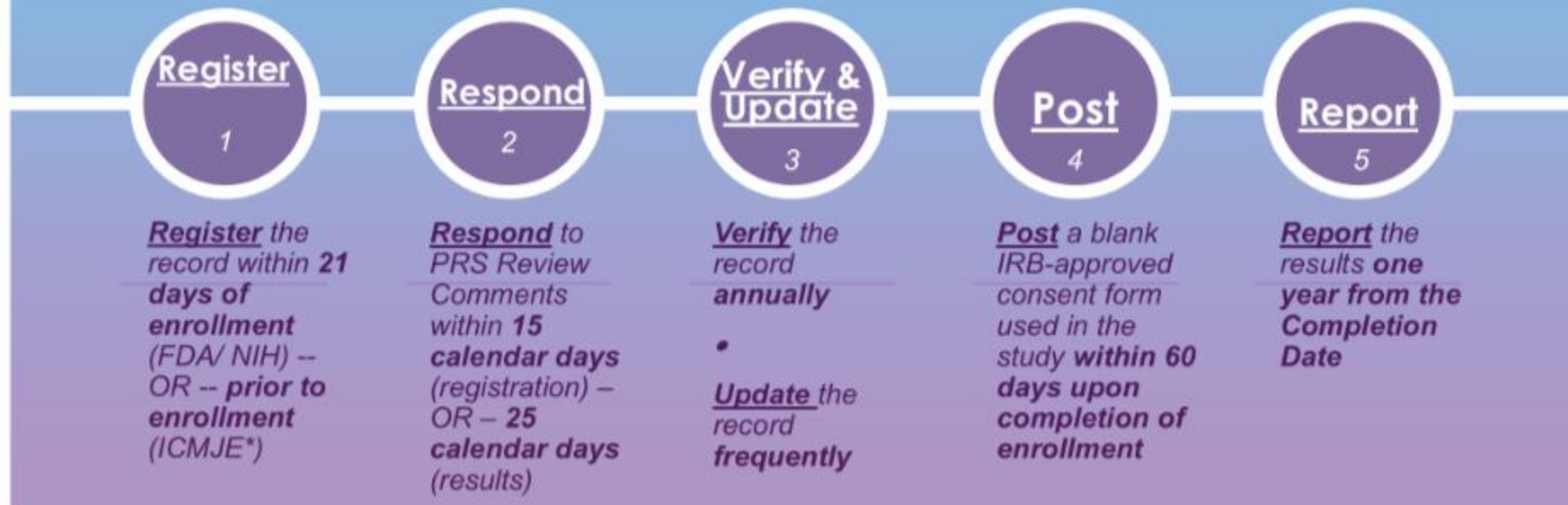
1. Research Protocol Study (GTMR) – Full Board
2. Research Protocol Study (MR) – Expedited/Exempt
3. Secondary Data Analysis Only - Exempt
4. Research (Biospecimen or Data) Bank – Full Board
5. Humanitarian Use Device – Full Board
6. Emergency Use of a Test Article – Expedited
7. Just In Time – Expedited
8. Non-Human Subject Research
9. Administrative Review – External IRB (Rutgers U is not the IRB of record)
10. Commercial IRB – WCG/Advarra

# Clinical Trials

Registration with ClinicalTrials.gov and Results

## Important Timeline

*Clinical Trials Registration and Results Reporting*



# Services

General Inquiries?

[IRBOffice@research.Rutgers.edu](mailto:IRBOffice@research.Rutgers.edu)

Document Revision And Feedback (DRAFT) Team  
Consultations & Pre-Review

[IRBDraftServices@research.rutgers.edu](mailto:IRBDraftServices@research.rutgers.edu)

Monthly HRPP IRB Bulletin

To sign up for the HRPP/IRB Newsletter, please click on this link:

<https://lp.constantcontactpages.com/sl/aFwrBpa>

Rutgers Reliance Team: Pre-Consultations & Assistance:

[IRBRelianceAdmin@research.rutgers.edu](mailto:IRBRelianceAdmin@research.rutgers.edu)

Quality Assurance & Evaluation Program (Post-Approval  
Monitoring) [qualityassurance@research.rutgers.edu](mailto:qualityassurance@research.rutgers.edu)

[Clinical Trials \(CTG\) Registration and Results Reporting](#)

[IRB Directory](#) [Human Research Protection Program Staff](#) [Human Research Protection Program Staff Staff Directory | Rutgers Research](#)

A hand holding a blue marker is writing the text 'We Are here to help' on a whiteboard. The text is written in a casual, cursive style. The whiteboard is set against a background with a black triangle in the top-left and a red triangle in the bottom-right.

We Are  
here to  
—help—



# eIRB+ Workshops

<https://crs.research.rutgers.edu/>



**eIRB+/eCOI+  
questions?**

# Questions and Open Discussion



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