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

2025 AAHRPP Webinar Series

A 2025 “HRPP Innovations” Webinar:

Innovative Practices by AAHRPP-Accredited Organizations: Researcher Education Programs

July 29, 2025; 1:00 pm – 2:30 pm ET

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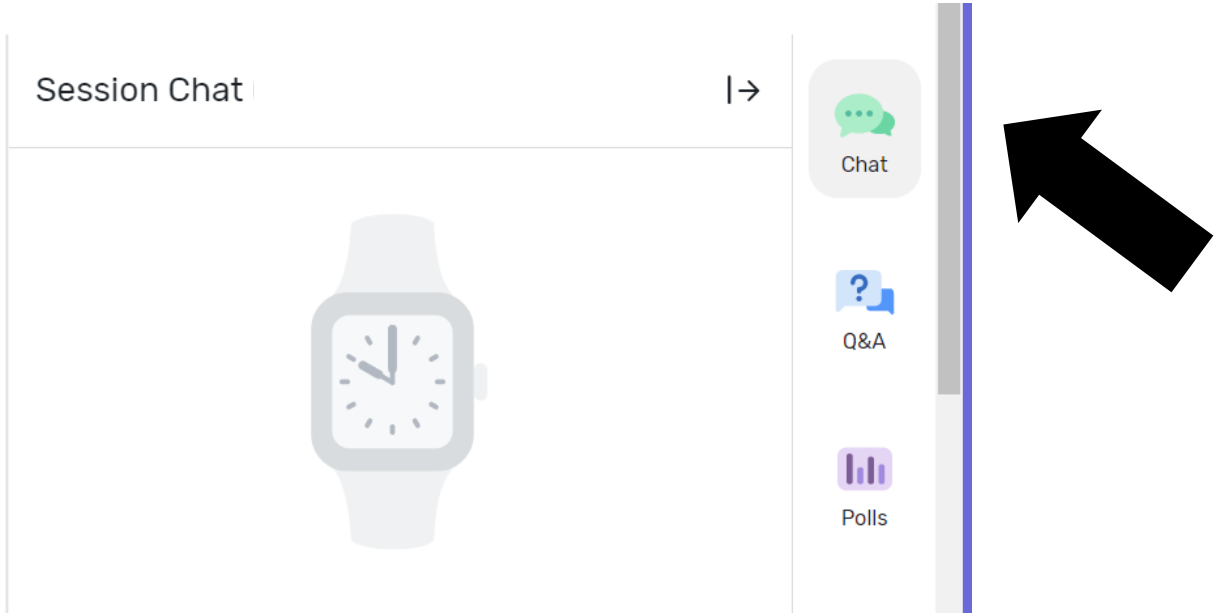
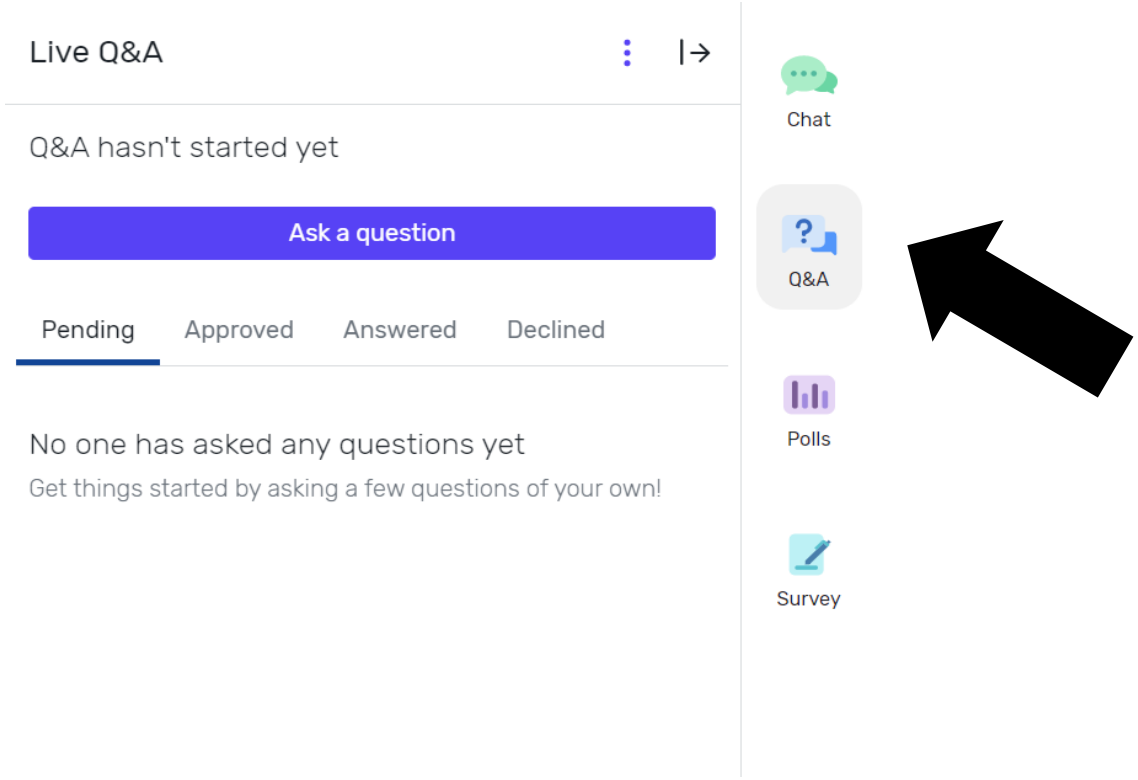
To chat with your colleagues before and after the session, or if you have technical questions, use the “Chat” icon



Questions

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



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Upcoming Webinars

Ask... AAHRPP®

Save these dates for the remaining 2025 "Ask AAHRPP" webinars:

- August 12, 2025,
- October 14, 2025
- December 9, 2025

Save these dates for the remaining 2025 “HRPP Innovations" webinars:

- October 1, 2025
- November 18, 2025

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

Maureen Tierney

Creighton University School of Medicine

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

Leslie Howes

Harvard T.H. Chan School of Public Health

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Association for the Accreditation
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Jennifer Pacheco

Baystate Health

AAHRPP

Association for the Accreditation
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Nichelle Cobb

AAHRPP

Developing Clinical Research Projects at the Creighton University School of Medicine

Maureen R. Tierney, MD, MSc., FIDSA
Ryan W. Walters, PhD
Department of Clinical Research and Public Health
RyanWalters@creighton.edu
MaureenTierney@Creighton.edu

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Disclosure Statement

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

What we present to our departments and divisions

- Will go through some of this quickly as local info
- Gives you an idea of how we help and support
- Varies a bit on audience
- Developed independently of but with the approval of Creighton University IRB director

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Learning Objectives

- Introduce research-related contacts
- Introduce the investigator-initiated research process
- Identify the required CITI training courses
- Identify InfoEd requirements
- Learn the steps to initiating investigator-initiated research
- Introduce the study proposal form and data collection sheet
- Introduce the IRB process

RyanWalters@creighton.edu

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  - Office of Research
  - Department of Clinical Research & Public Health
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  - Investigator-initiated research process
  - Study proposal form
  - Data collection sheet
- Part 3: Institutional Review Board
  - Overview
  - Stages of IRB submission

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Developing Clinical Research Projects

Part 1 of 3:
Research Contacts

Ryan W. Walters, PhD
RyanWalters@creighton.edu

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Office of Research

- Associate Dean for Research
  - Laura Hansen, PhD
- Associate Dean for Clinical Research and Public Health
  - Maureen Tierney, MD, MS, FIDSA
- Director of Research Programs
  - Brianna Conyers, BS, MHA, ACRP-CP

- Location
  - Creighton Campus, Criss II, Room 315
- Responsibilities
  - Disseminate research communications
  - Identify and promote basic science-clinical research collaborations
  - Elevate student research satisfaction
  - Work with medical student research chairs
  - Maintain SOM Student Research Resources site in Blueline

SOMResearch@creighton.edu

Department of Clinical Research & Public Health

- Chair
  - Maureen Tierney, MD, MS, FIDSA
- Informatics
  - Anne O'Keefe, MD, MPH (Director, VC)
  - Shilpa Thangirala (informatician; 7/1/25)
- Statistics and Analytics
  - Ryan Walters, PhD (Director, VC)
  - Alex Hall, MS (statistician)
  - Dannie Dilsaver, MS (statistician)
  - Paul Kang, MS (statistician; Phoenix)
- Location
  - CUMC Bergan Mercy, Education Building, Suite 502
- Responsibilities
  - Question development
  - Hypothesis development
  - Study feasibility
  - Data acquisition
  - Study design
  - Statistical analyses

ResearchAcademic@creighton.edu

Clinical Research Offices

- Medical Director
  - Maureen Tierney, MD, MS, FIDSA
- Creighton Clinical Research Office
  - Sandy Byers, MSN, RN, CCRC (Director)
  - Caroline Nubel, MHCM, BPS (regulatory, grants)
  - Julie Stubby, BSN, RN (regulatory, coordinator)
  - Rebecca Losh, BS (regulatory)
- CHI Health Clinical Research Office
  - Molly Davis, MS (Director, regulatory)
  - Mel Romsa (regulatory, coordinator)
- Location
  - CUMC Bergan Mercy, MOB 1, Suite 228
- Responsibilities
  - IRB submission
  - Study management
  - Coordinator support
  - Financial services
  - Grant preparation

ResearchAcademic@creighton.edu

Clinical Research SharePoint Site

- A one-stop shop for all things clinical research
  - Defined roles and responsibilities
  - Contact information and titles of all faculty and staff
  - Guide to conducting clinical research
  - Information about national- and state-level data sources
  - Grant information
  - Resources that include the RIG schedule and study proposal forms
  - Frequently asked questions

- The site is incredibly flexible and updated constantly
  - If you have questions or are not finding what you need, let us know!

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Developing Clinical Research Projects

Part 2 of 3:
Investigator-initiated Clinical Research Process

Ryan W. Walters, PhD
RyanWalters@creighton.edu

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Mandatory Research Preliminaries

Fact
A project will **never** start if **anyone** involved has not completed these two requirements.

1. Complete your CITI training
   - Group 1: Biomedical Research
   - Health Information Privacy and Security (HIPS)
   - Responsible Conduct of Research (RCR)

2. Log into InfoEd using your NetID and password
   - Upload your signed and dated biosketch (aka, CV or resume)
   - Upload your professional license (if applicable)

- Completed CITI training at a different institution?
  - Affiliate your CITI account with Creighton University

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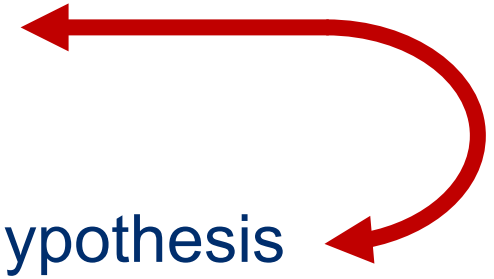
Investigator-initiated Clinical Research: Process

1. Complete all mandatory research preliminaries

2. Identify clinical and research mentor
   - Might not be the same person



3. Develop the research question and hypothesis
   - PICO(T) criteria: patient, intervention, comparison, outcome, (time)

4. Identify a data source and ensure data availability
   - CHI data contact: Shilpa Thangirala (starting 7/1/25)
   - State or national database contact: Ryan Walters

5. Design the study to answer your question
   - Consult with Statistics and Analytics

RyanWalters@creighton.edu

Investigator-initiated Clinical Research: Process

6. Develop the study proposal form
   - If using CHI data, you will also need a data collection sheet

7. Email proposal (and data collection sheet) to ResearchAcademic@creighton.edu
   - Initiates an iterative process between you, regulatory, informatics, statistics/analytics
   - All required documents will be submitted to IRB on your behalf!

8. Obtain IRB approval and obtain those data

9. (if needed) The Statistics and Analytics team will analyze them data
   - You will be sent a brief set results initiating the discussion of how you want to proceed

10. Develop and submit an abstract and manuscript

Study Proposal Form

- Completion is required for every database project

- IRB has no preferred format or content headings
  - Investigators, literature review, methods, analysis plan, risks
  - *Study Proposal Form - Chart Review and Database Studies*
  - *Study Proposal Form - Surveys and Interviews*
  - *Study Proposal Form - Prospective Study* (being updated with input from Creighton's IRB)

- Successful completion is an iterative process
  - Clinical mentor, Statistics and Analytics, Creighton's Clinical Research Office
  - All versions must always be viewed and approved by the primary clinical mentor

- Do not use AI chatbots or virtual assistants as you are responsible for all mistakes

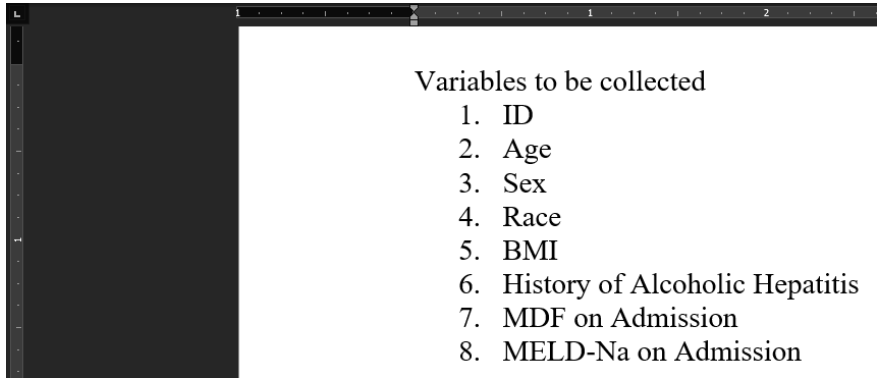
RyanWalters@creighton.edu

Data Collection Sheet

- Required for every project using CHI patient data

- A separate document submitted alongside the study proposal form
  - List every variable to be collected
  - IRB is looking for protected health information

	A	B	C	D	E	F	G	H
1	ID	Age	Sex	Race	BMI	History of Alcoholic Hepatitis	MDF on Admission	MELD-Na on Admission
2								
3								



- You can only collect data for variables listed and approved
  - Need to add variables after IRB and Data Governance approvals?
  - Submit an IRB modification: ResearchAcademic@creighton.edu

Types of Projects

- Database-National, topic specific
- Data Registries in development (local versus CSH)
- Patient Data-deidentified
- Patients Data with PHI
- Survey
  - Students-EPC
  - Residents-GME
- Interventional-Greater than Minimal Risk
  - Investigator initiated
  - Industry (CHI)

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Developing Clinical Research Projects

Part 3 of 3:
Institutional Review Board

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RyanWalters@creighton.edu

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Institutional Review Board (IRB)

- Charged to review research to assure protection of human subjects

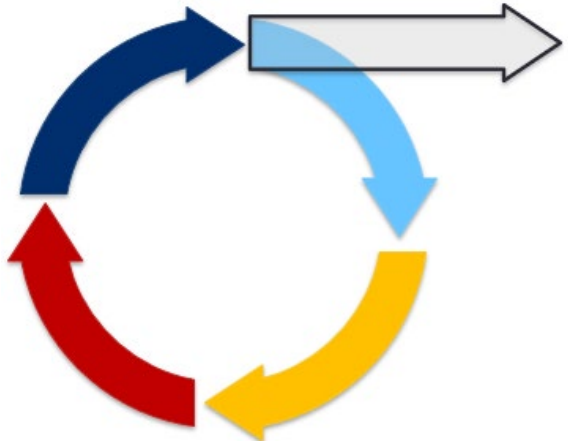
- IRB review categories
  - Exempt: no more than minimal risk without sensitive information (e.g., chart review without PHI)
  - Expedited: no more than minimal risk with sensitive information (e.g., chart review with PHI)
  - Full board: non-trivial risk (e.g., prospective RCT)
  - Not human-subjects research: concerned only with standard of care (e.g., QI, national database)

- IRB approval is required for all clinical research projects
  - Required submission document(s) dictated by proposed data source
  - CHI data: Study Proposal Form and Data Collection Sheet
  - State or national data: Study Proposal Form

- Creighton's IRB system is InfoEd Global
  - Let professionals submit to IRB for you: ResearchAcademic@creighton.edu

Stages of IRB Submission

- The pre-IRB proposal review is iterative
  - Review completed by clinical mentor
  - Review completed by Creighton's Clinical Research Office
  - Review completed by Informatics (if using CHI data)
  - Review completed by Statistics and Analytics
  - Review completed by clinical mentor (yep, again)



- Proposal submitted to IRB by Creighton's Clinical Research Office
  1. Email sent to PI for approval (PI must approve first)
  2. Then, email sent to each co-investigator for approval (projects get stuck!)
  3. Then, and only then, will IRB review for approval

ResearchAcademic@creighton.edu

Research Trainings

- Research Roadshow at Grand Rounds, Departmental Meetings
- GME Research Training 8 hours
- Investigator Bootcamp 8 hours
- RIGs Research Interest Groups monthly 1-2 hrs
- GRS electives for students 7-2 hr sessions
- EBM lectures

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Research Interest Groups

- Goal to support development of research projects
- Create research teams including students
- Students, residents and faculty encouraged to attend
- One statistician and one regulatory PM attend
- Faculty or fellow run but faculty supported
- Clinical vetting first
- Practical vetting including statistical feasibility
- Follow-up on going projects
- RIG calendar published

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Contact us

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Vice Chair of Clinical Research–Omaha
Director of Statistics and Analytics
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Innovative Practices by AAHRPP-Accredited Organizations: Researcher Education Programs

Leslie M. Howes, MPH, CIP
Director, Office of Regulatory Affairs and Research Compliance
Harvard T.H. Chan School of Public Health

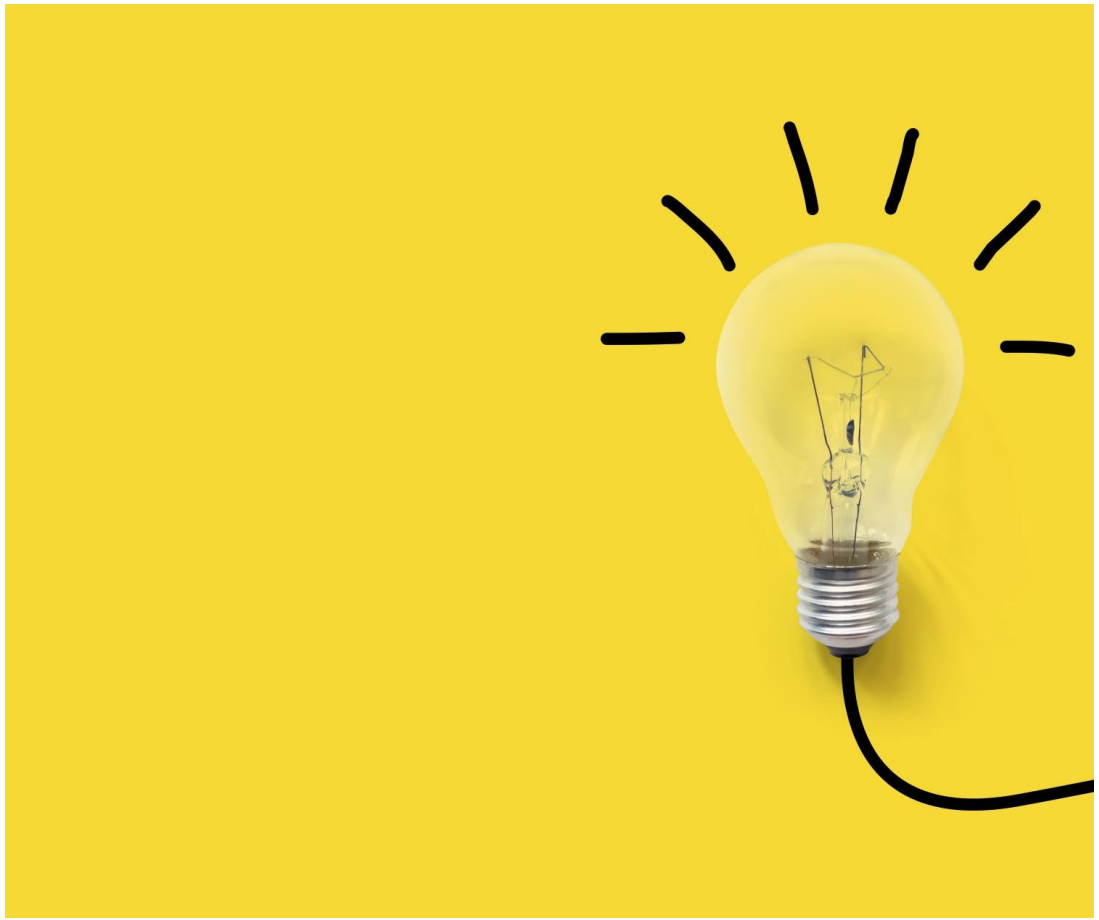
Disclosure Statement

I have a relevant personal/professional/financial relationship with respect to this educational activity:

I am an AAHRPP Peer Reviewer.

Overview

- Introduce HLC HRPP
  - Quality Improvement Program
- QIP's PASS Program
  - Process
  - Examples
  - Metrics
  - Refinements
  - Lessons Learned
- AAHRPP Element I.5.B
- Q&A



Harvard Longwood Campus
Human Research Protection Program

Harvard Longwood Campus HRPP

Shared service center across the Harvard Longwood Campus (HLC)

Two IRBs

1. Harvard Faculty of Medicine IRB (Harvard Medical School and School of Dental Medicine)
2. Harvard T.H. Chan School of Public Health IRB

Diverse portfolio

(1200 active protocols)

- SBER and biomedical
- international research
- vulnerable populations
- FDA regulatory research

AAHRPP-accredited since 2010

HLC Quality Improvement Program

Established 2009

Compliance

- IRB Minutes evaluation
- Investigator self-assessment
- Study review
- For-cause audit

Human Research Support

- IRB submission assistance
- Consultation
- Study staff orientation
- Management tools

Education

- QIP Ed Series
- Requested in-service
- Fulfilling ORARC education initiatives

Post-Approval Support Service (PASS) Program

Informed by HRPP metrics

Adaptable; customizable study support

Maximizes QIP functions: compliance, support service, and education

Selection criteria: new-to-Harvard PI or non-faculty member driving non-exempt human research

Benefits

- Investigator(s) gain knowledge and familiarity about regulatory and IRB requirements
- Study documentation is better organized; research files are audit-ready
- Investigator(s) receive direct experience with QIP services/tools and become future users
- IRB compliance evaluated

PASS in Action

IRB review occurs concurrently

IRB final approval may not occur prior to this point

QIP conducts IRB file audit concurrent to study start-up

Identification

PI submits new initial application

- IRB identifies whether PASS-eligible
- IRB notifies QIP staff
- IRB notifies PI and study contact

PASS Plan Established

QIP meets with PI/study team

- Typically 15-20 min. via Zoom; QIP receives study overview
- QIP documents study-specific PASS plan
- Plan details, timelines may evolve

Execution of Plan

QIP meets with PI/study team

- Established time points
  - start-up; mid-point; end-point
- Regulatory/study documentation review
- Consultation/education

QIP prepares a report for PI

PASS Closure

QIP completes PASS plan

- QIP communicates to PI/study contact
- QIP remains available to PI, study staff, as needed

PASS Plan Archives

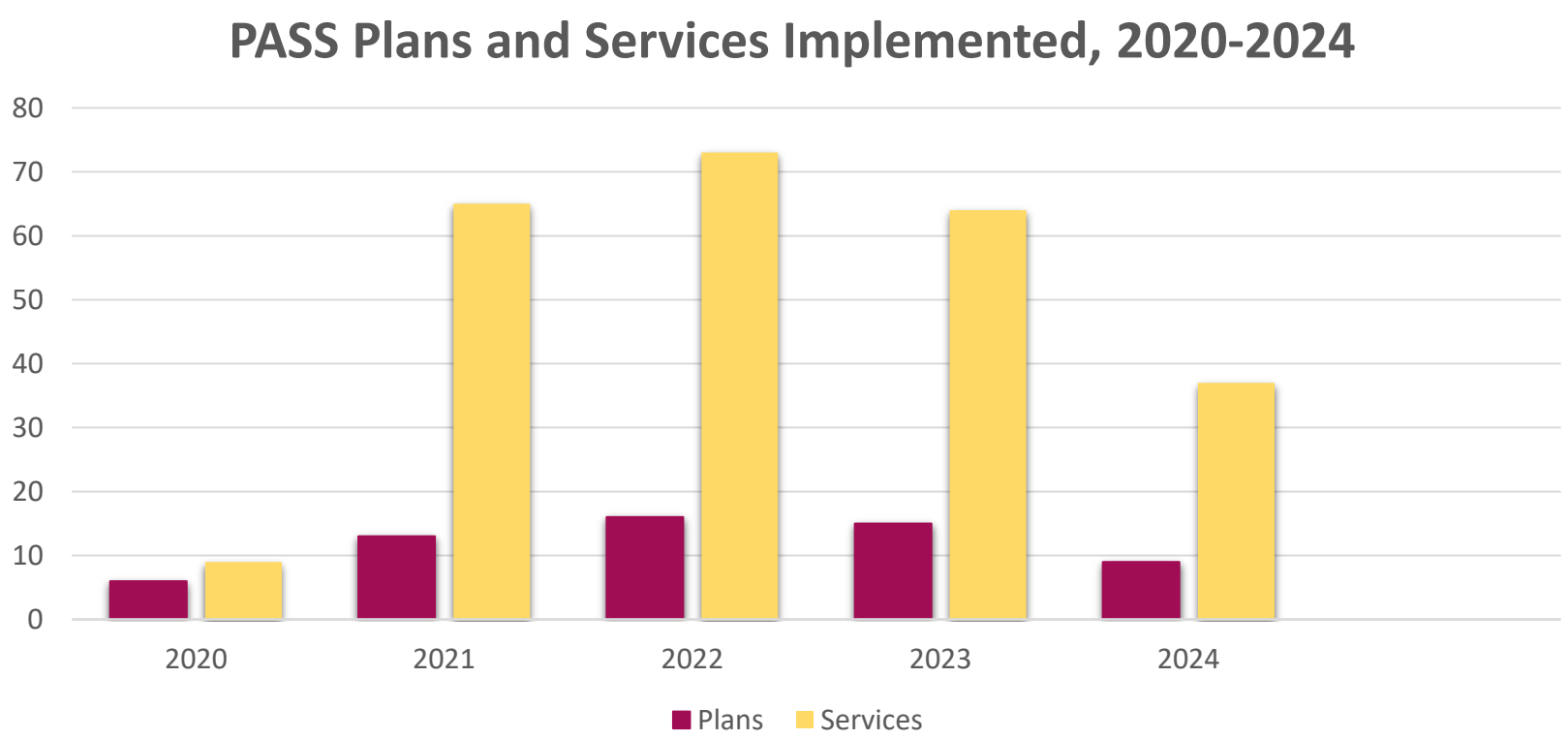
Example 1

- **Start-up orientation & Regulatory binder training**
- **Mid-point check-in**
  - Discussion
  - Regulatory Binder
  - Participant Files
- **QIP compliance check**
  - Discussion
  - Document Review
    - Regulatory Binder
    - Participant Files

Example 2

- **Start-up orientation**
- **QIP compliance check**
  - Investigator Self-Assessment (min. 10 participants enrolled)
    - Regulatory Documentation
    - Participant Files

PASS Program Metrics



PASS Program Refinements

2020
PASS Program debuts

2021
No changes made

2022
No changes made

2023
Established appropriate endpoints

2024
Established PASS-specific criteria for Investigator Self-Assessment

2025
Refined eligibility criteria to focus on student-driven non-exempt human research

Lessons Learned

- Ensure accurate and timely identification of eligible studies
  - QIP provides regular review of eligibility requirements, monitors accurate identification
  - Alternative: QA/QI staff perform this task
- Establish boundaries
  - Respond to available data
  - Be discerning and let the study drive service(s)
  - Set plan endpoints
- Don’t be afraid to give a try

AAHRPP Element I.5.B

The organization conducts audits or surveys or uses other methods to assess the quality, efficiency, and effectiveness of the Human Research Protection Program. The organization identifies strengths and weaknesses of the Human Research Protection Program and makes improvements, when necessary, to increase the quality, efficiency, and effectiveness of the program.

AAHRPP report excerpt

"…identified through their assessment of programs the need for assistance for new researchers in areas of study implementation, education, and support during their first research experience. The Harvard Longwood Campus HRPP has implemented a **Post-Approval Support Service (PASS) for this purpose**."

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2025 AAHRPP Webinar Series

Implementation of Post IRB Approval Education - Targeting Novice Investigators and Research Staff

Jennifer Pacheco, MPH, CHRC, CIM, CIP
Director of Healthcare Research Compliance & HRPP/IRB
Chief Research Compliance Officer & Research Integrity Officer

Disclosure Statement

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

Looking to Accomplish?

Internally:

- Novice research staff and investigators demonstrating a lack of understanding for responsibilities and regulatory expectations.

Externally:

- AAHRPP Element I.1.E - The organization must have an education program that improves the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.
- Stronger audit outcomes with FDA/Regulators

Baystate Health is…

- A non-profit integrated healthcare system serving Western Massachusetts
- four acute-care hospitals with over 1,000 licensed beds
- A multi-specialty group, Baystate Medical Practices, with over 700 physicians across 40 locations.
- It operates the region's only Level I trauma center.

The system manages a research portfolio of approximately $20 million in grants, additional pharma and biotech contracts for approximately 350-400 active studies.

IRB staff of 4, Education/Compliance team of 3 and 1 Director.

Program Overview

Who: Baystate Health utilized 3 FTE to create a program. This was only a portion of their time.

- 2 Education and Compliance Specialist
- HRPP Director

What: A Post IRB Approval Education Program to provide once monthly comprehensive education.

Why: Stronger foundation, open communication and improved audit outcome.

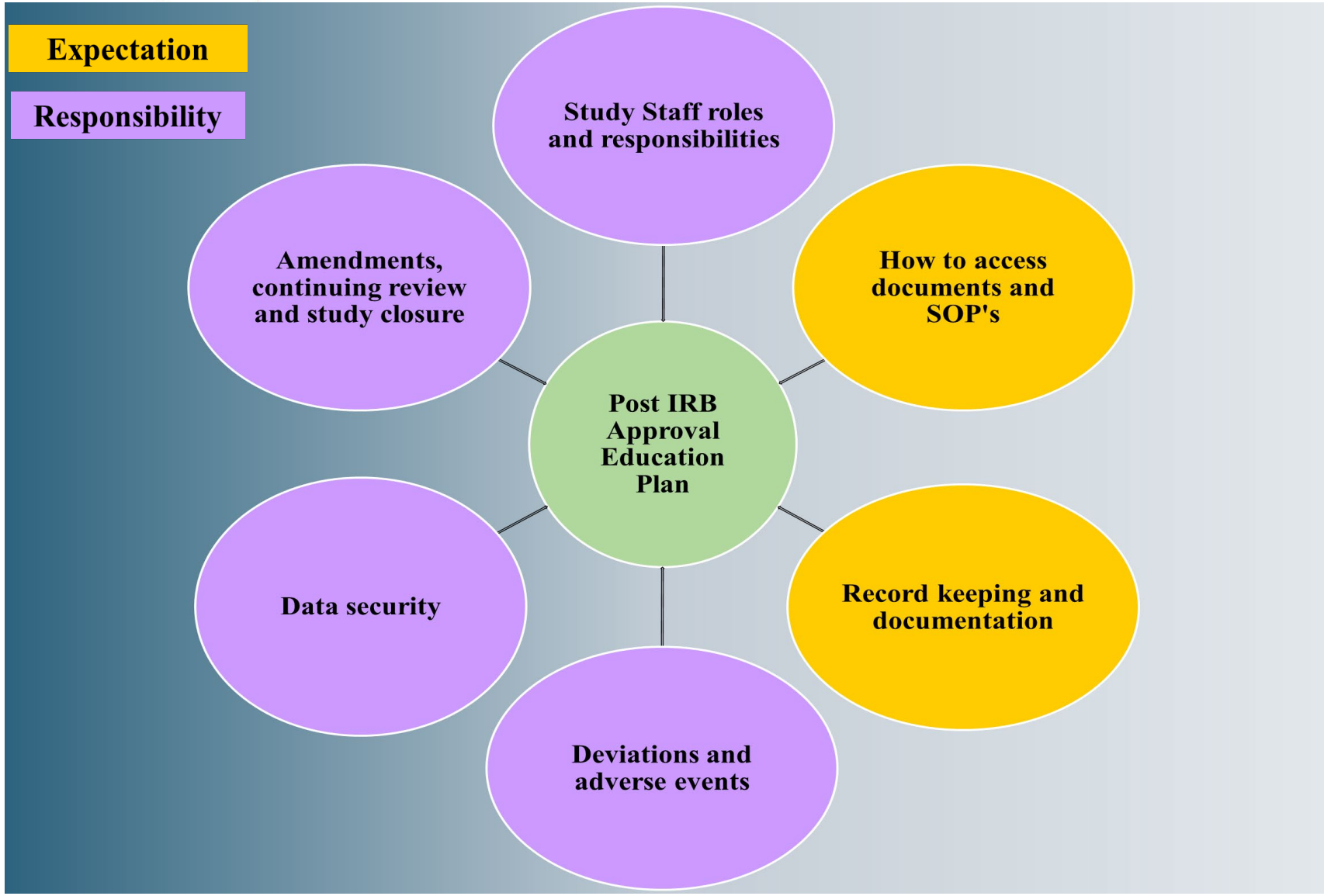
How: The HRPP staff reviewed the IRB meeting minutes each month to identify potential participants.

Program Description

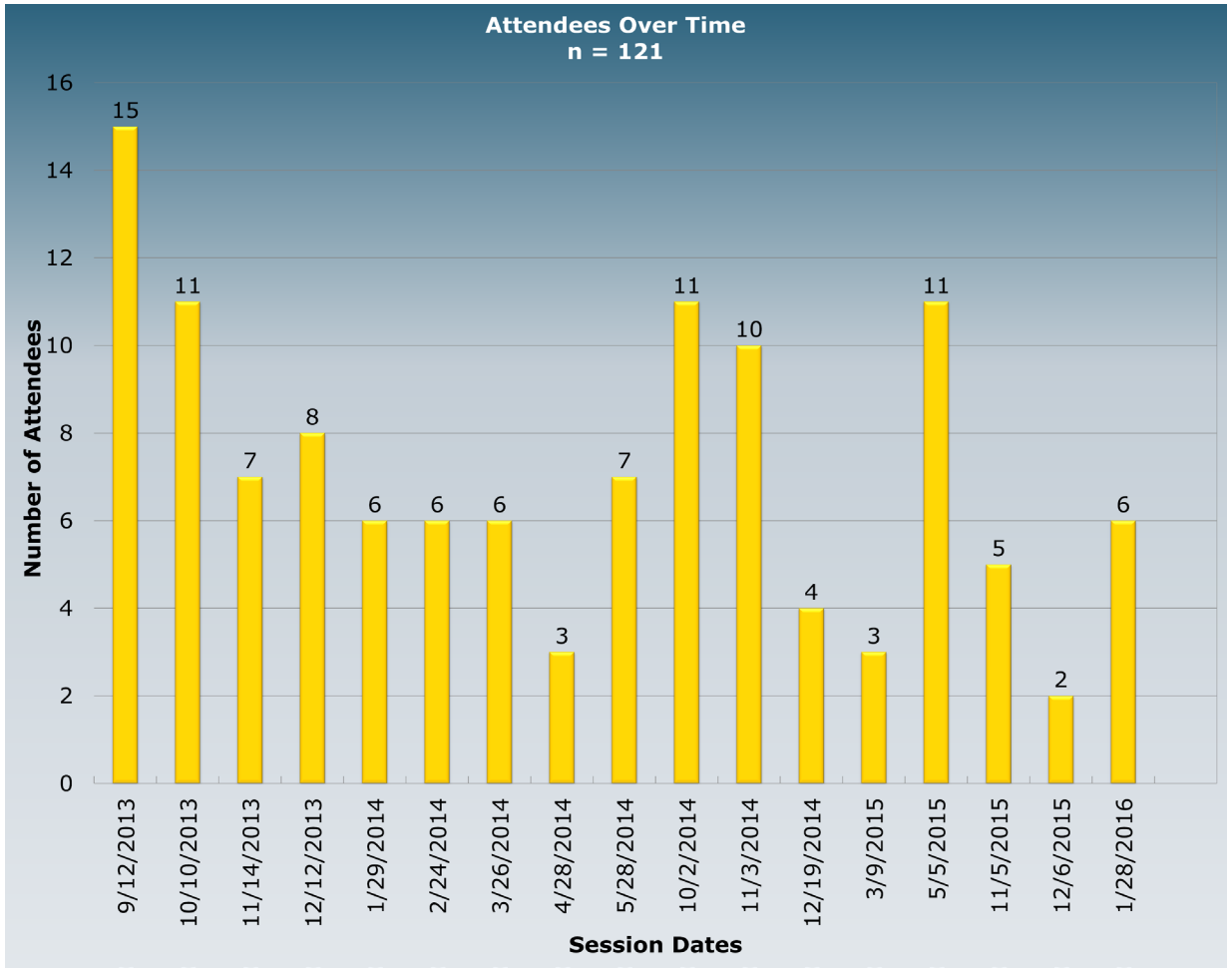
- The hour-long sessions were offered 4-8 times per year avoiding summer months when submission volumes were lower.
- Individualized invitations, which include information about the program, were emailed to each candidate and their mentor as applicable.
- Education packets were created for learners containing regulatory and policy information and templates.
- The goal with the packets was to providing a beginner framework for record keeping and documentation compliance, while reinforcing the education.

Types of Education Delivered

- Regulatory binder templates and set up; including template logs (I.e. Enrollment, DOA, Temperature, SAE…)
- Consent methods and process note templates
- Use of Interpreters and unbiased witnesses
- Misconduct Case Study – How to spot misconduct among your team.
- Visual aids


Expectation
Responsibility
Post IRB Approval Education Plan
Study Staff roles and responsibilities
How to access documents and SOP's
Record keeping and documentation
Deviations and adverse events
Data security
Amendments, continuing review and study closure

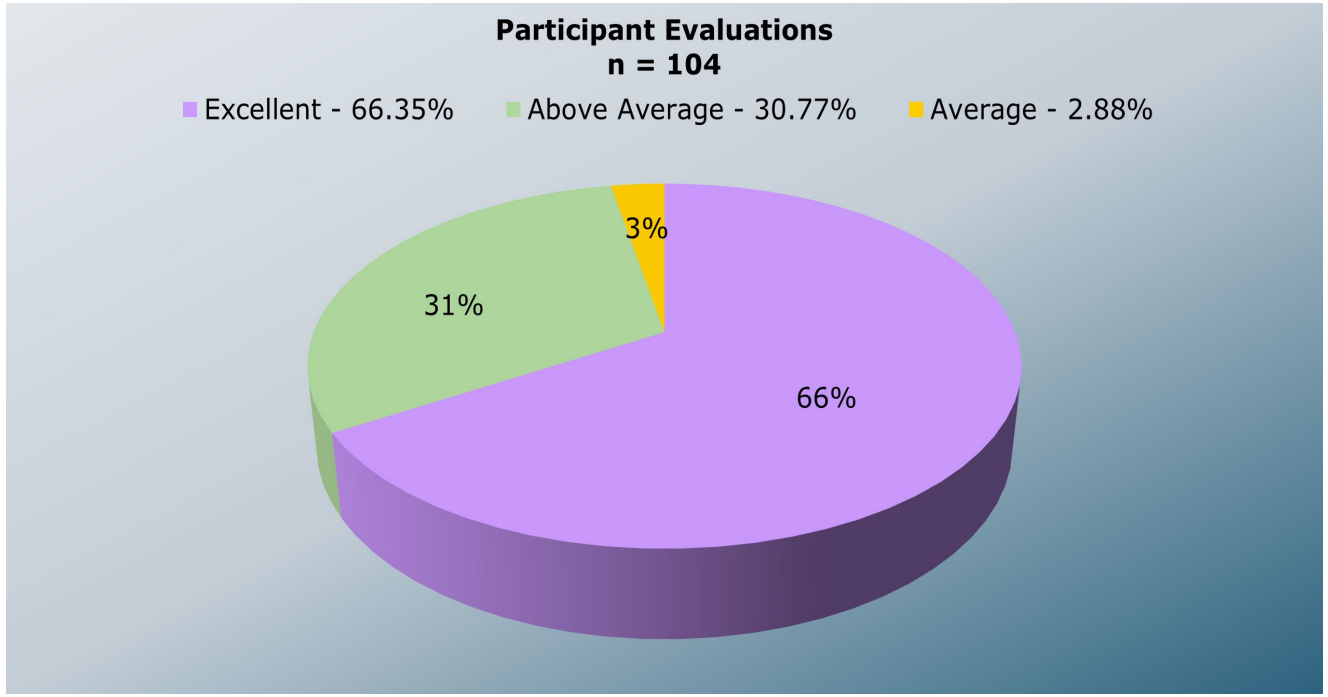
Target Population & Attendance



- Novice investigators
- Residents
- Fellows
- New research staff

Evaluation

- 97.12% of participants rated the program excellent or above average.
- Preliminary documentation demonstrates an increased compliance rate of approximately 50%. Specific, improvements were noted in record keeping and documentation.



"I plan to…"

- "Change my practice as a PI by drawing on what I learned."
- "Create a regulatory binder for any study"
- "Comply with IRB procedures, documentation, consenting"

HRPP Takeaways:

- Introduced the research community to HRPP resources early!
- Fostered greater communication and collaboration between the HRPP and study staff
- Encouraging a sense of community among participants.
- Allowed for targeted training related to specific topics while developing greater efficiency for the HRPP staff in conducting audit outcome meetings.
- Many participants made request for additional education in a targeted area
- Sampling demonstrated a 50% Improvement for internal audit outcomes

Thank You!

Questions?