AAHRPP

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

2022 AAHRPP Webinar Series

Successful Tools for Educating and Evaluating HRPP Teams

Shemetra Owens, Baystate Health

Jeffrey Schmoll, Mayo Clinic

Alan Teller, Yale University

AAHRPP

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

New Format for 2022

Attendee Hub

- Livestreamed Content
- Networking
- Chat/Discussions

All 2022 Webinar Sessions

- Three Webinars: March, July, November
- One Attendee Hub

Resources

- Slide Presentation
- Documents
- Resources from Speakers

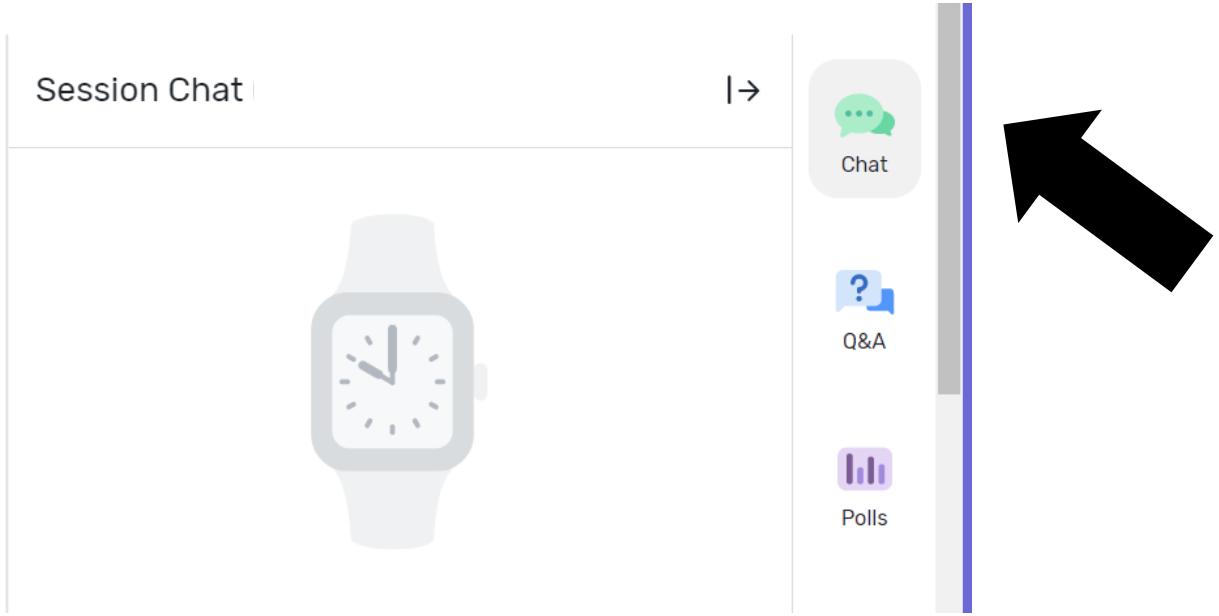
On-Demand Video

- Webinar Recordings on Hub
- Available for a Year After the Webinar

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

Chat Feature

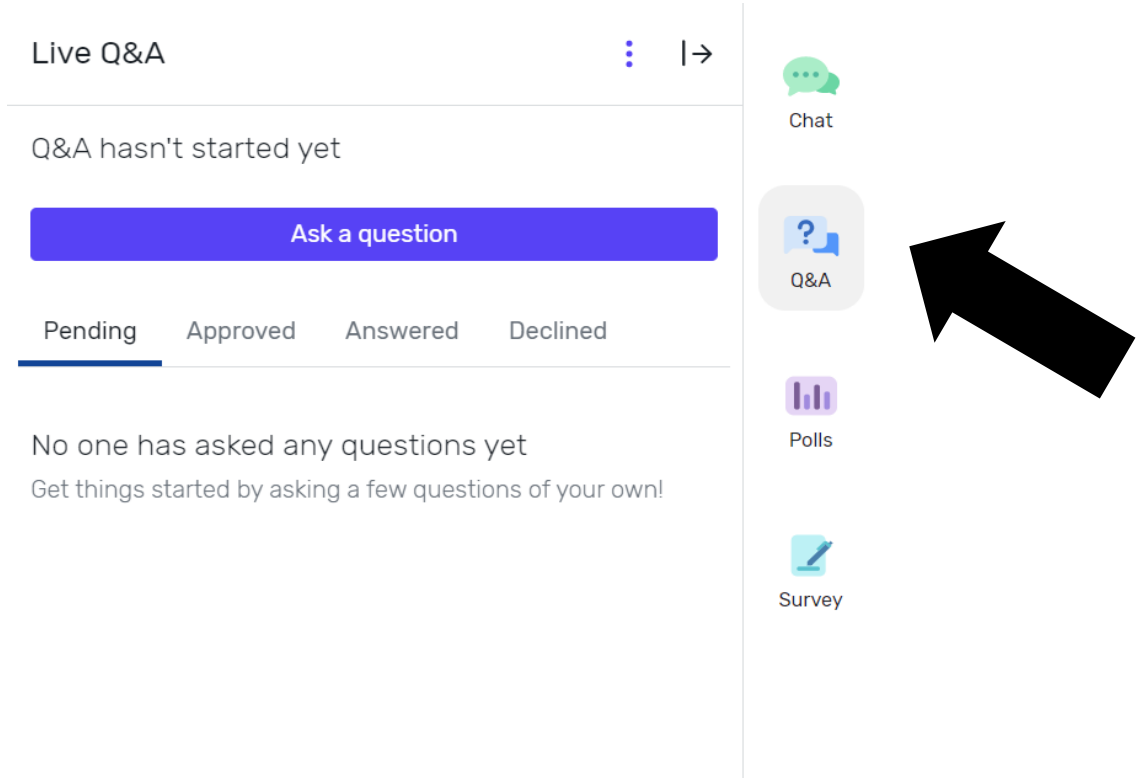
To chat with your colleagues before and after the session, or if you have technical questions, use the “Chat” icon



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

Questions

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



2023 AAHRPP Annual Conference

Save the Date

Hyatt Regency Baltimore
May 16-18, 2023

Presenter Introductions

Shemetra Owens, CIP
Director of the HRPP and the IRB
Baystate Healthcare, Inc.

Jeffrey Schmoll, MBA, FACHE
Administrator, Research Shared Services
Assistant Professor of Health Care Administration
Mayo Clinic

Alan Teller, CIP
Assistant Director, IRB
Yale University

Thank You

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

2022 AAHRPP Webinar Series

Strategies for Finding, Educating and Keeping HRPP and IRB Staff

Shemetra Owens, CIP/Baystate Health

Shemetra.Owens@baystatehealth.org

July 12, 2022

AAHRPP

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

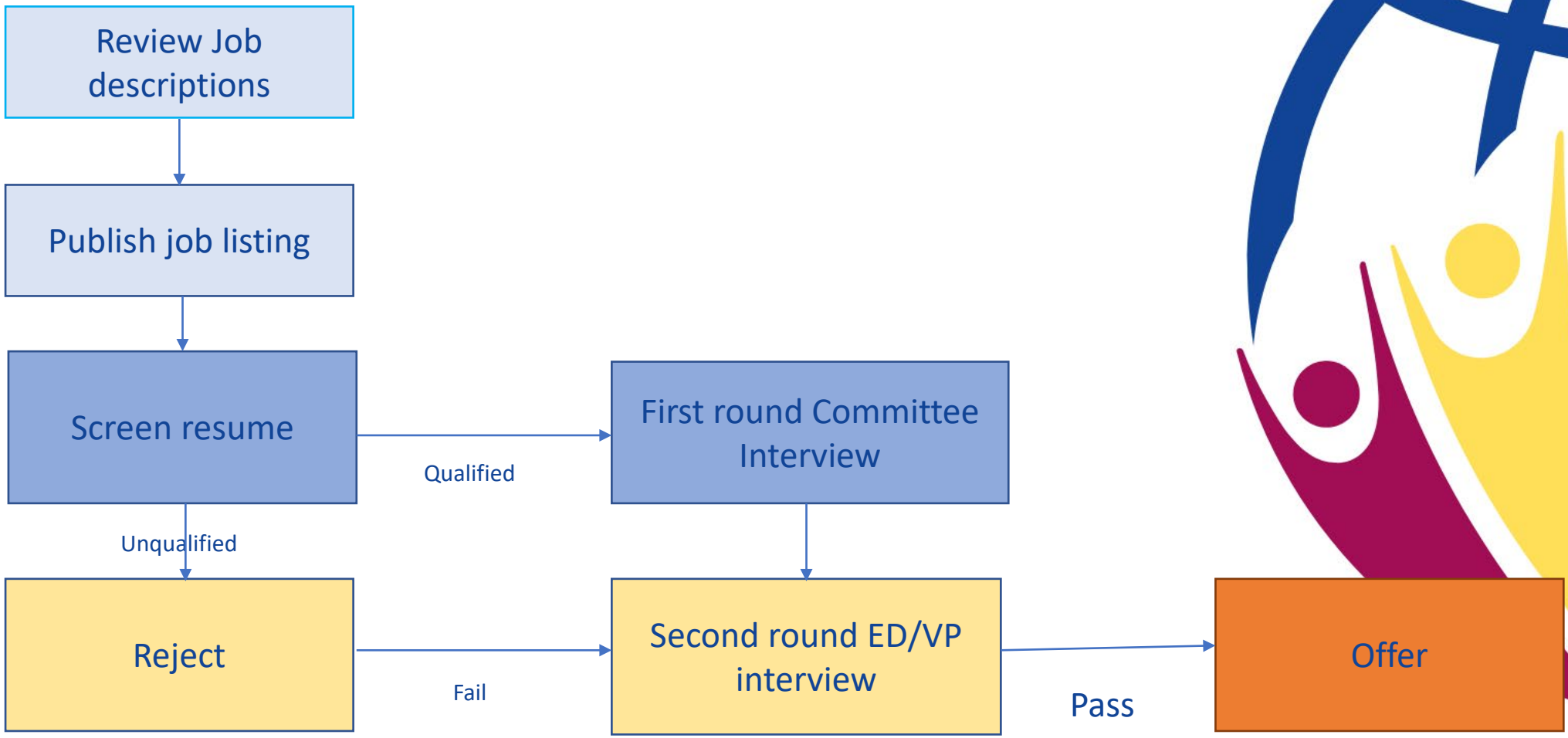
Recruitment

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

Recruitment Content

- Process
- Methods
- Recruiting in the Post-Pandemic Future
- Time to Hire
- IRB Board Members

Process


Review Job descriptions
Publish job listing
Screen resume
Unqualified
Reject
Qualified
First round Committee Interview
Second round ED/VP interview
Fail
Pass
Offer

Sample Knowledge, Skills and Abilities (KSA) Checklist for IRB Analyst Position

Strong knowledge or ability to develop a strong knowledge of Federal and State research regulations and AAHRPP guidelines			
Prior experience or ability to learn IRB process regarding review submissions for issues of ethics and regulatory compliance			
Assists in compliance activities including study reviews, external audit preparation, and policy development and revisions			
Reviews and contributes to IRB policies and procedures			
Strong computer skills and proficient in current Windows environment; experience with relational databases; word processing; electronic scheduling and mail			
Demonstrated ability to functions with minimal supervision and has significant autonomy and judgment			
Take an active role in HRPP and institutional process development and improvement			
Prior experience with issue resolution in collaboration, and implements corrective actions as appropriate			
Advise the faculty, staff, IRB Chairs, and IRB Members			
Administrative lead on special projects			
Excellent organizational skills, meticulous attention to detail			

Recruitment Methods

Internal recruitment	Employee referral, internal candidate pool, company intranet, noticeboard
External recruitment	Social network, national press, local press, recruitment agencies, job centers, online advertisement, networking, refer previous candidates

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

Recruiting in the Post-Pandemic Future

- Pre-Covid 19 Workforce Realities
- Less in-person interviews
- Calculating Time to Hire
- Telework and remote hybrid work model
- Creating jobs for candidates without college degrees
- Contract Employees and Contingent Workforce

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

Time to hire

Position	Recruiting start date	Accept date	Days to accept	Start date
IRB Analyst	8/21/21	11/17/21	97	12/13/21
IRB Analyst	12/6/21	12/28/21	21	1/13/22
IRB Reliance Analyst	12/9/21	12/30/21	21	2/7/22
		average	46.6 days	

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

Recruiting IRB Members

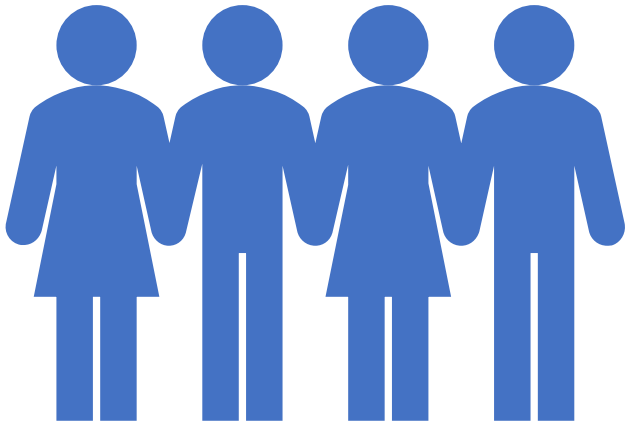
- K-awardees – pay portion of salary
- Local Advertisement
- Referral (community and prisoner representation)
- IRB Chairs, Medical Chair and Vice Chairs (portions of salary paid to department or negotiation of time commitment on unit)
- Member pay per meeting; per review

AAHRPP

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

2022 AAHRPP Webinar Series

Employee Development



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

Contents

ONBOARDING

PEER TRAINING ON KEY PERFORMANCE INDICATORS

TEAM MEMBER MEETINGS

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

Onboarding

Elsevier for training and events	Access to email	Employee information, paychecks, benefits through workday	Annual Review	Remote desktop	IRBnet access and training
Redcap	Microsoft Teams	DUO for authentication	Workplace for Facebook	Servicenow for service management	Schedule of department meetings
Phone list	HRPP Education and Compliance Manual	IRB Analyst Coordinator Manual	Review job requirements	Peer Training	Hospital Management Training (if applicable)

Orientation Binder

	Orientation Binder
	Introduction
	Department Welcome Letter
	Orientation Plan/Schedule – date, time and location of orientation event
	Copy of Job Description
	Department Reporting Relationships (organizational chart)
	Department Policies and Procedures
	Access: ID, parking, building access
	Requesting time away from work (vacation/sick, PTO, bereavement leave, leave of absence). Holiday Schedule
	Availability for work (scheduled time off, unscheduled time off, tardy, job abandonment)
	Severe Weather Policy
	Workplace attire
	Confidentiality
	Code of Conduct
	Customer Service Standards
	Computer, Network, phone and voicemail usage
	Additional Resources
	IRB Meeting Schedule
	Research Staff Meeting Schedule
	CITI Instructions
	IRBNet Registration Instructions
	New Employee Checklist
	Resource Guide New Team Members
	HRPP Competency Based Training
	HR Service Center
	Training Schedule
	PRIM&R membership
	List of Stakeholders
	IRB Management and Function Book

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

Orientation Schedule

Sample HRPP Education and Compliance Specialist Orientation Schedule:

	Orientation Schedule
	Day 1
	Human Resources Training
	Training: Begin HR, CITI, Elsevier Online Trainings
	IT: Email, computer systems, etc.
	Day 2
8:00 AM	General Orientation: E-mails, Voicemails, Policies
8:30 AM	Training: Continue HR, CITI, Elsevier Online Trainings
9:00 AM	Welcome: Meeting with Director and Team members
10:00 AM – 11:30 AM	Training: Shadow HRPP Team Member (Redcap, Florence eBinder, OnCore, Power trials, Education and Audit Functions)
11:30 AM – 12:30 PM	Lunch
12:30 PM - 3:00 PM	Training on job function: Shadow HRPP Team Member (RedCap, Florence eBinder, OnCore, Powertrials)
3:00 PM – 4:00 PM	Meeting with Director
4:00 -6:30 PM	Unscheduled time to finish online training, to read policies or IRB Management and Function book, ask questions of Director and HRPP Team members

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

Team Meeting schedule

Monday	Tuesday	Wednesday	Thursday	Friday
9AM Check- in	9AM Check-in	9AM Staff Meeting	Education & special topics	9AM "Open Door"
IRB	HRPP	IRB & HRPP	IRB & HRPP*	IRB & HRPP

*depending up workload

AAHRPP

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

Certification Support

Department pays for Certified Manager Examination (CIM) and Certified IRB Professional (CIP) Examination

IRB Management and Function (depending on book allowance)

Navigate TestPrep for Institutional Review Board: Management and Function Study Guide, Third Edition

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

Continued Education

Education & Networking Event for Clinical Research Professionals (ACRP) Conference
AAHRPP Conference
PRIM&R Conference
MAGI's Clinical Research Conference
Special Projects: Informed Consent Observation and training
Monthly research staff meetings (staff members present)
Publications: Human Research Report

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

IRB Member Training

IRB Membership

Training and Education

Human Research Protection Program
Education and Compliance

Baystate Health | ADVANCING CARE. ENHANCING LIVES.

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

IRB Member Training

- Member onboarding sessions (Research Ethics and History of the IRB, IRB systems, IRB review sheets
- Paired reviews until trained
- PRIM&R and AAHRPP Conferences
- IRB member book
- Included in education efforts: IRB Chairs present to peers, departments, surgery grand rounds, summer scholars about the IRB
    - Getting started with research at Baystate medical
    - Common pitfalls in IRB submissions
    - Top 10 mistakes in full board submission
    - Research ethics and IRB
    - Research versus clinical practice

AAHRPP

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

Employee retention

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

Content

- Join, Stay, Leave
- Turnover
- Management styles
- Timeline and Stats
- Staff Evaluation
- IRB Member

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

Join Stay Leave

Top reasons for joining	Top reasons for staying	Top reasons for leaving
Job security	Job security	Competitive pay
Career opportunities	Medical benefits	Manager
Competitive pay	Development opportunities	Job security
Development opportunities	Flexible schedule	More interesting work
Meaningful work	Competitive pay	Career opportunities

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

Turnover

Join, stay, leave model

- Evaluate your current employees
  - What constraints may impact the team?
- Take inventory of your employees' responsibilities
  - Have all the basic functions of the job been defined?
  - Process Improvement (ongoing)
  - Have specific policy objectives have defined?
- Set up cross-training initiatives
  - Have substitutes been appointed
- Offboarding process

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

Management Styles

Management Styles	
Visionary	Inspirational; builds trust; team fixated on leader's vision
Democratic	Teamwork makes the dream work; Abe Lincoln; surrounded by capable people; drawn out decision making
Coaching	Creates positive environment; increase team awareness; requires time and patience
Autocratic	Top down; efficient; team develop dependency
Laissez-faire	Trust and rely on employees; don't micromanage; passivity

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

Tips from personal style

- “as far as it depends on you”
- Personal fulfilment = happiness
- “The whole is greater than the sum of all parts” = Teamwork valued
- Allow employees to speak their minds* (respectfully)
- Listening, connection
- Provide flexibility
- Relaxation time

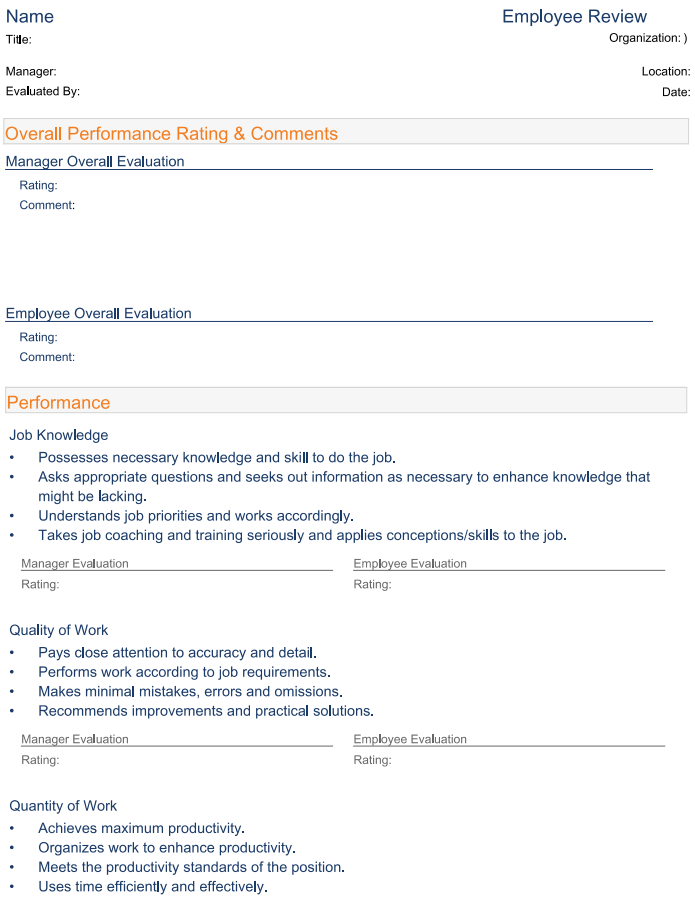
AAHRPP
Association for the Accreditation of Human Research Protection Programs, Inc.®

Missteps

- Unclear communication
- Being Kind but not direct = message
- Indirect messages causes confusion
- The skills refined in one workplace do not necessarily translate in a new environment
- Unaware of generational differences
- Unaware of bad actors

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

Staff Evaluation



Name
Title:
Manager:
Evaluated By:

Employee Review
Organization:)
Location:
Date:

Overall Performance Rating & Comments

Manager Overall Evaluation
Rating:
Comment:

Employee Overall Evaluation
Rating:
Comment:

Performance

Job Knowledge
- Possesses necessary knowledge and skill to do the job.
- Asks appropriate questions and seeks out information as necessary to enhance knowledge that might be lacking.
- Understands job priorities and works accordingly.
- Takes job coaching and training seriously and applies conceptions/skills to the job.

Manager Evaluation — Rating:
Employee Evaluation — Rating:

Quality of Work
- Pays close attention to accuracy and detail.
- Performs work according to job requirements.
- Makes minimal mistakes, errors and omissions.
- Recommends improvements and practical solutions.

Manager Evaluation — Rating:
Employee Evaluation — Rating:

Quantity of Work
- Achieves maximum productivity.
- Organizes work to enhance productivity.
- Meets the productivity standards of the position.
- Uses time efficiently and effectively.

Performance Reviews

- Current year review
- Next year goals

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

Audit of IRB staff and reviewers

Baystate Medical Center Institutional Review Board
IRB Reviewers Worksheet: New Submission

Title of Protocol or IRB Number: [redacted]
Reviewer: [redacted]

Type of Review (check one)	**Risk Level (check one)**
☐ Full Board Initial Review	☒ Greater than Minimal Risk
☒ Expedited Initial Review *	☐ Minimal Risk*
***Expedited Review** requires completion of the **Expedited Review Determination Form**	
Recommendation (check one)	**Continuing Review Frequency (check one)**
☐ Approve as submitted	☐ 12 Months
☐ Modifications Required	☐ 6 Months*
☐ Deferred for additional information or substantive modifications*	☐ Other*
☐ Disapproved*	*If continuing review frequency should be more often than annually, indicate the reason.
* For **deferral** or **disapproval**, briefly describe reason: _____	_____

* **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(i)).

Timelines and Stats

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

Number of results returned: 5

Total number of records queried: 1,238

Report execution time: 4.5 seconds

Stats & Charts | Export Data | Print Page | Edit Report

Live filters: [What Board was this assigned to?]

AAHRPP Full Board Timelines Local/Non Local IRB

REDCap ID id	IRBnet Number irbnet	Principal Investigator pi	What Board was this assigned to? irb	Submission Type irb_type	Date of Baystate IRB Submission submitted	Date of Initial Board Determination board	Date of Final Determination final	External IRB Review Type wirb_board	IRB Submission to Initial Board Determination (Expedited, Full Board) dur_sub_board	IRB Submission to Final Determination dur_subfinal	Baystate IRB Board Determination Letter Published ... tted (Expedited, Full Board) dur_letter_resp	local/emergency use IRB does this belong to? irb_other	Days from Non-Local Submission to Final Approval (Non-Local) dur_nl_subfin
			Main (0)	Non-Local IRB (5)	03-22-2022		04-11-2022	Full Board (1)					
		#2 (2)		Full Board (3)	03-14-2022	04-13-2022	04-27-2022						
			#2 (2)	Full Board (3)	04-11-2022	05-11-2022	06-14-2022						
			Main (0)	Non-Local IRB (5)	03-22-2022		04-28-2022	Full Board (1)					
			#2 (2)	Full Board (3)	05-09-2022	06-07-2022	06-07-2022						

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

IRB Member Retention

Scientific Curiosity

Societal Good

Evaluation

Self assessment survey and form review by chair

Chair performance by VP of Research

Board member review counts, attendance

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

credits

- Slide 4. Recruitment/hiring Process Flowchart (https://www.zenflowchart.com/guides/recruitment-hiring-process-flowchart)
- Slide 5. The Knowledge, Skill, and Ability Requirements for Teamwork: Implications for Human Resource Management, Michael J. Stevens, Michael A. Campion First Published April 1, 1994
- Slide 6. Images (Facebook, LinkedIn) Unknown Author is licensed under CC BY-SA-NC
- Recruiting Internally and Externally, Publisher: Society for Human Resource Management (SHRM), Website 2017 – Present
- Slide 22. Khoros Publishing, https://twitter.com/mercer/status/1208945349320040449
- Slide 24. 6 management styles: how to choose the right one for you; Chia, Sam; 11/8/21 (https://www.betterup.com/blog/management-styles)
- Slide 25 – scripture reference
- Slide 25 – Aristotle quote

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

2022 AAHRPP Webinar Series

Successful Tools for Educating and Evaluating HRPP Teams @ Mayo Clinic

Tam Armbrust, IRB Education Coordinator
Melissa Kuntz, IRB Education Coordinator
Jeff Schmoll, Operations Administrator

HRPP Talent

Finding
Keeping
Developing

HRPP Talent

Finding

Developing

Keeping

HRPP Talent

Finding

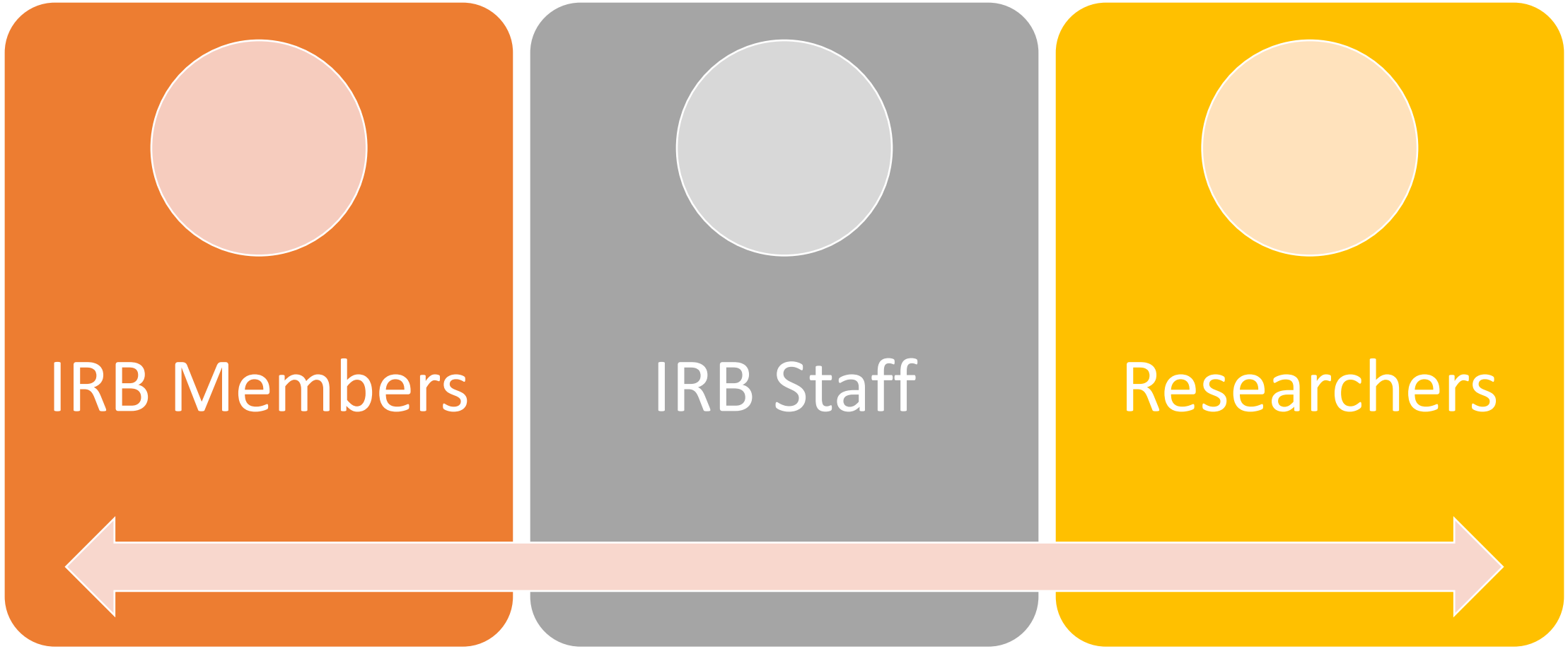
Developing

1. Yourself
2. Your Leadership Team
3. HRPP Team members

Keeping

Finding HRPP Talent

HRPP Customers



Finding HRPP Talent

- IRB Members
  - Request Recommendations Medical Division/Department Chairs
  - Request Recommendations from Nursing Leadership
  - Community Connections
- IRB Staff
  - Internal:
    - Clinical Research Coordinators
    - Research Protocol Specialists
    - Compliance
  - External:
    - National connections
    - Other medical centers

Developing HRPP Talent

Training Concept

Foundational

Day ~(0-7)

Education Team Coordinates

Functional

Day ~(5-60)

Training conducted by Education Team

Proficiency

Day ~(90-tenure)

Trainee works with experienced colleagues

- Assessment & Competency feedback

IRB Members

New Member Orientation

Education Days

Just in Time

Chair Specific Education

Quality of Reviews / Correct Determinations

Community Member

IRB Staff

New Staff Orientation

Education Days

Weekly Huddle

Just in Time

Bi-monthly Educational Meetings

Researchers

- Clinical Research Orientation
- In-person Classes
- Online Classes
- Departmental Requested Training
- IRB Super Users
- Clinical Research Newsletter
- Just in Time

Developing Yourself & Your Leaders

- Healthcare is arguably most complex and dynamic industry
- Not all aspects that have brought about success will allow success to be maintained
- Colleagues are struggling to apply their current skills and capabilities, carefully and diligently honed to succeed in the previous environment, to this new environment and are experiencing reduced professional efficacy.
- Managing exceptionally complex work requires mustering the hands and minds of employees at all levels so that improvement, innovation, and adaptation are unending.
- Organizations which will thrive in the emerging paradigms will be those who invest in developing mastery of the only non-reproducible asset any organization has, their internal environment.

AAHRPP

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

2020 – Year of Adaptation

Doing More...Sooner

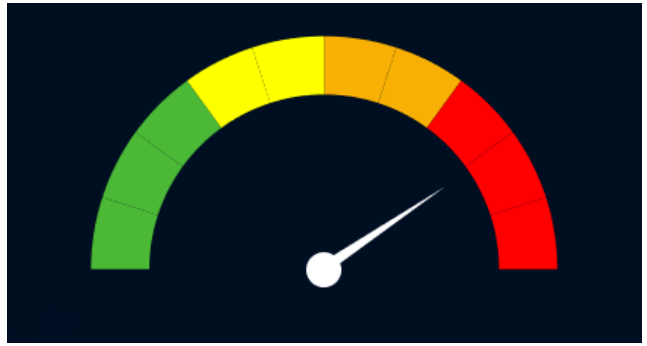
AAHRPP | Association for the Accreditation of Human Research Protection Programs, Inc.®

2020 – Year of Adaptation

What we learned:

- Capacity under constraints
- Accomplishments in previously ‘impossible’ timeframes
- Pulled future forward

What it Cost



AAHRPP

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

2021 – Year of Execution

Doing More...Faster

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

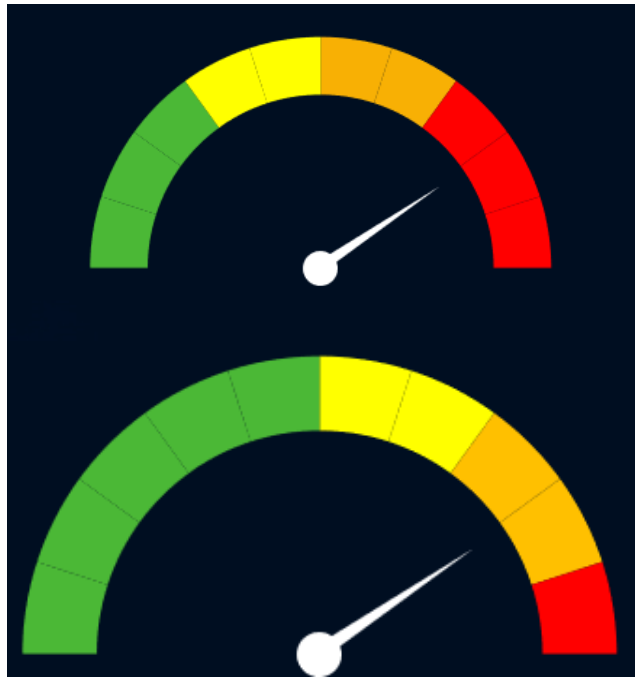
2021 Year of Execution

What we learned:

- Capacity under ‘next normal’ conditions
- Service delivery capabilities in fractions of expected time
- Implemented ‘the future’ *now*

We must ‘normalize’ our new reality and align ourselves to be dynamic, adaptive, self-improving, and self-innovating?

What it Cost?



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

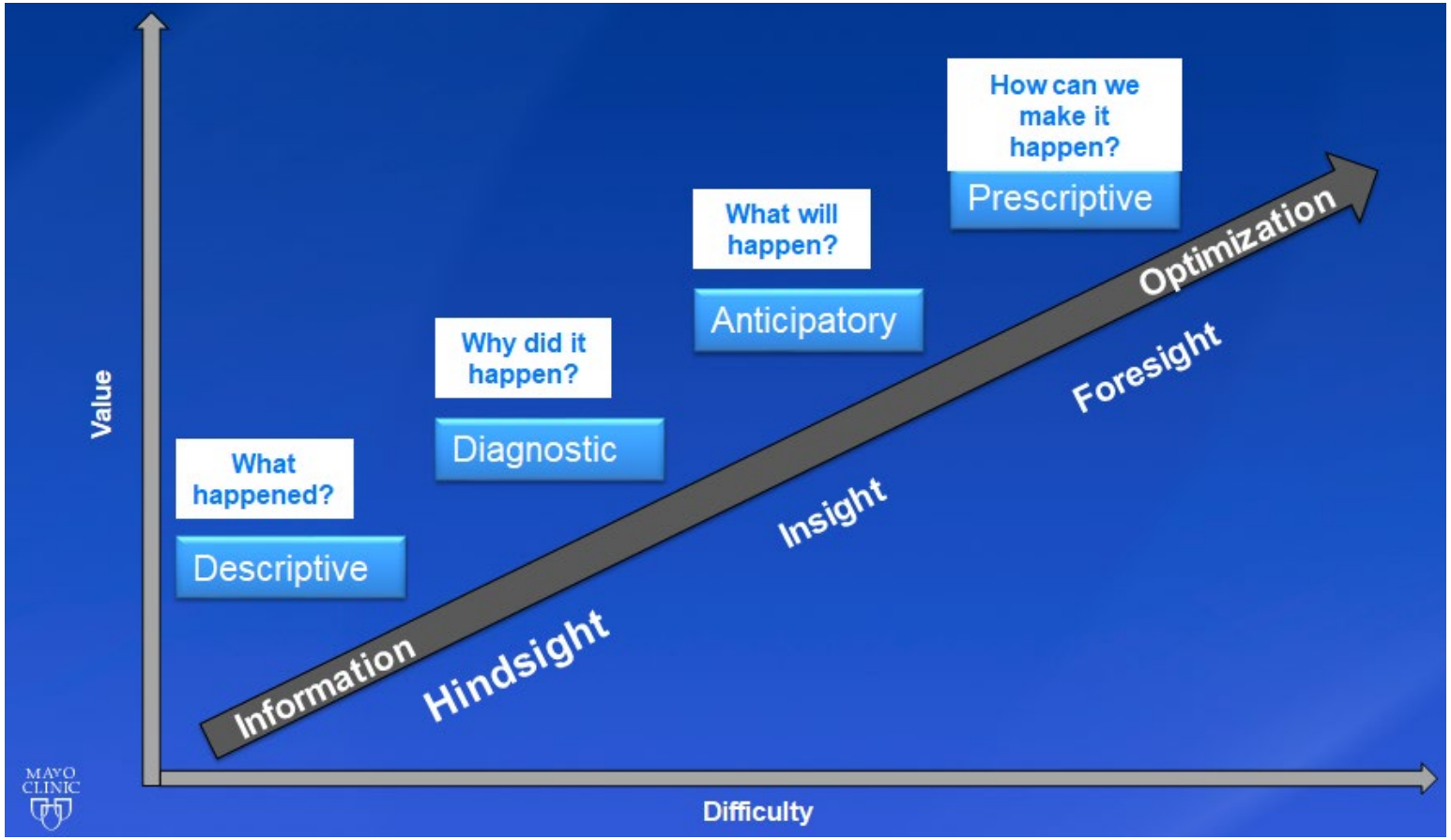
HRPP Business Agility

- 2020: Doing more…sooner
- 2021: Doing more…faster
- Beyond: Doing more…of what is better…sooner, faster

How?

- Current: Engage – Enable
- Needed: Engage – Equip – Enable – Energize

Creating the Future

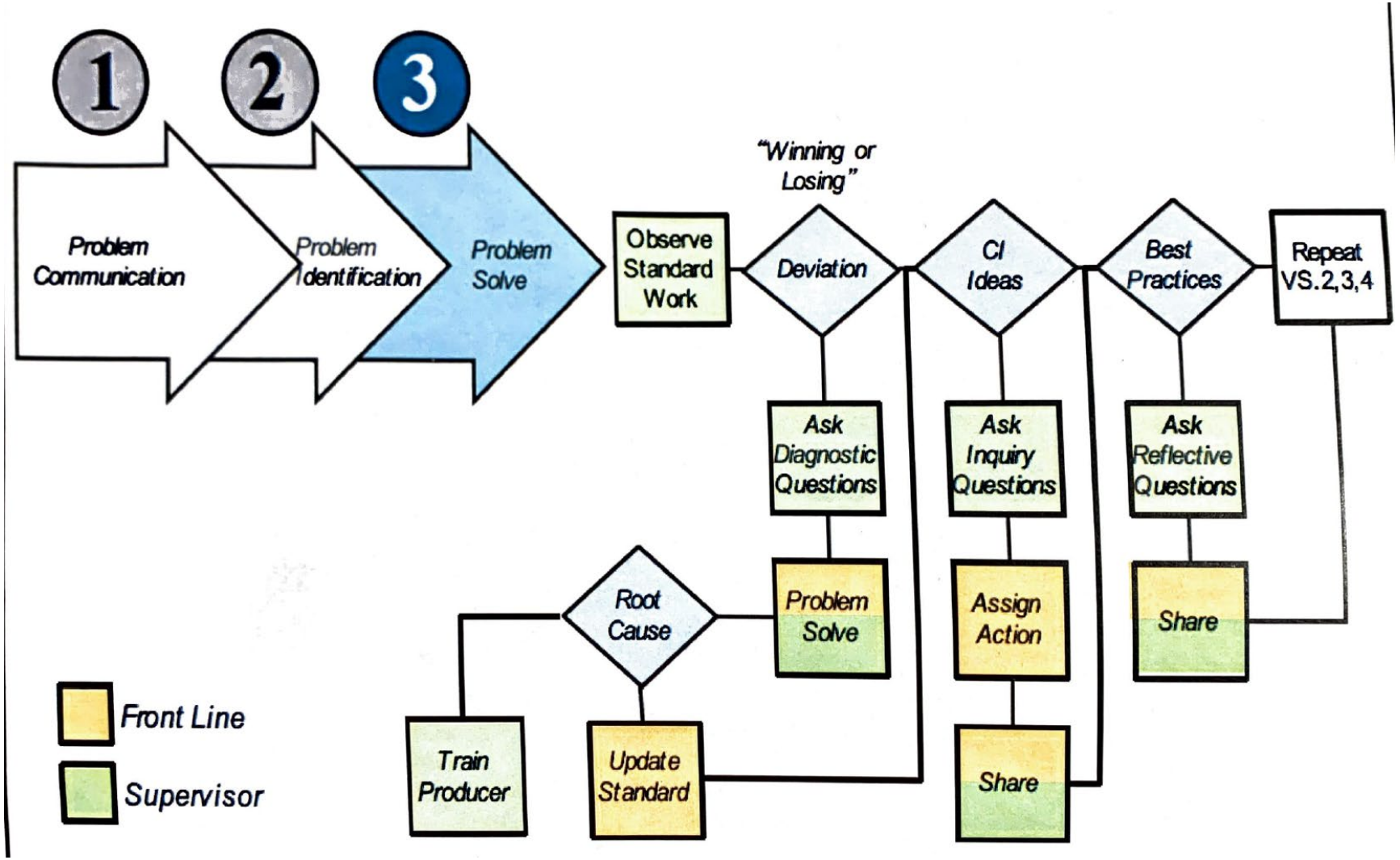


Pareto

IRB Office - Occurrence / Defect Tracking

Instructions: Please document any experiences or observations of impediments or inefficencies in your daily workflow. Record in the cell the number of occurences on a given day adding to any previous number in that cell.

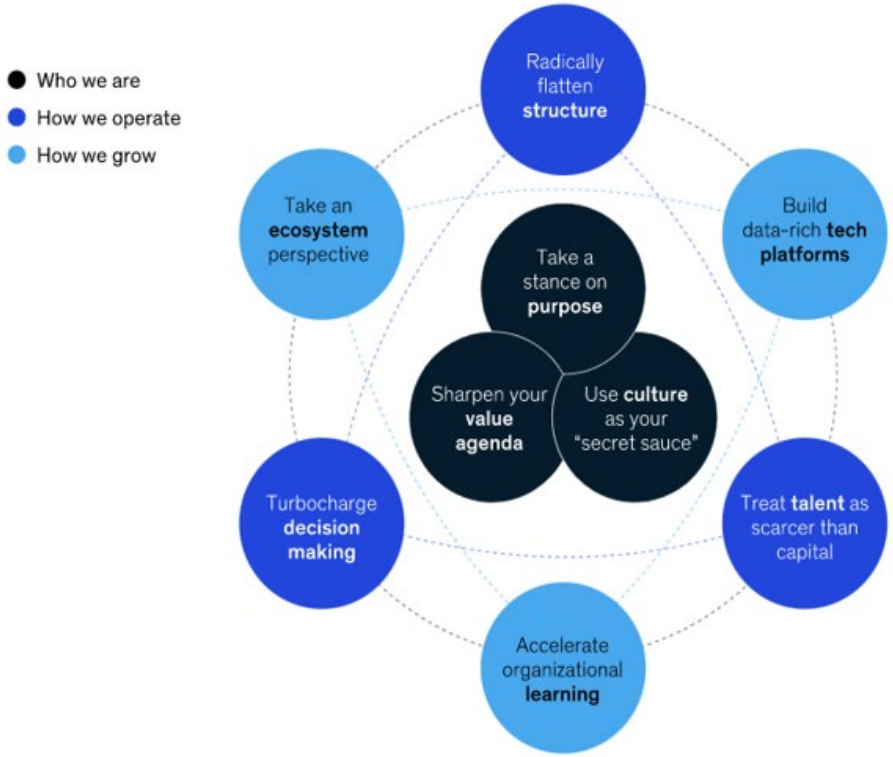
	Monday	Tuesday	Wednesday	Thursday	Friday		Monday	Tuesday	Wednesday	Thursday	Friday	Total
Occurrence / Defect Observed	**5/10/2021**	**5/11/2021**	**5/12/2021**	**5/13/2021**	**5/14/2021**		**5/17/2021**	**5/18/2021**	**5/19/2021**	**5/20/2021**	**5/21/2021**	
ie. dog ate homework	1		3		1		5			3		13
												0
												0
												0
												0
												0
												0
												0
												0
												0
												0
												0
												0
												0
												0
												0
												0
												0
												0
												0
												0
												0
												0


1
2
3
Problem Communication
Problem Identification
Problem Solve
Observe Standard Work
"Winning or Losing"
Deviation
CI Ideas
Best Practices
Repeat VS.2,3,4
Ask Diagnostic Questions
Ask Inquiry Questions
Ask Reflective Questions
Root Cause
Problem Solve
Assign Action
Share
Train Producer
Update Standard
Share
Front Line
Supervisor

Keeping HRPP Talent

Future-Proof **Traits**

- Purpose
- Value
- Culture
- Structure
- Decision-Making
- Talent
- Ecosystem
- Technology
- Learning



•4

- Structure

Radically flatten structure

- Fitter, flatter, faster
- Increased participation
- Increases speed of communications

•5

- Decision-Making

Turbocharge Decision Making

- Speed to see
- Speed to solve
- Speed to share
- Speed to learn

HRPP Management Principles

- Respect for All Persons
- Sustain Constancy of Purpose
- Think Systemically
- Focus on Process
- Embrace Scientific Thinking
- Flow and Pull Value
- Increase Speed to See Opportunities and Threats
- Swarm Opportunities and Threats When and Where they Emerge
- Solve Problems in Context at the Source
- Understand and Manage Variation
- Pursue Perfection; Catch Excellence
- Facilitate and Disseminate Learning Continuously

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

2022 AAHRPP Webinar Series

Successful Tools for Educating and Evaluating HRPP Teams

Alan Teller

Assistant Director
Yale University
Human Research Protection Program

Special Thanks:
Yale HRPP Leadership & Management Team

- Linda Coleman – Director
- Michele Antisdel – Manager
- Brandy Lagner- Manager
- Monika Lau – Assistant Director
- Amanda Liss – Manager
- Cathleen Montano – Assistant Director
- Ed Monico – Senior Advisor
- Dawn Pedevillano – Senior Manager
- Jessica Rowe – Associate Director
- Matthew Stafford – Assistant Director
- Meriam Worzella – Manager

Topics

- Recruitment and Hiring
- Onboarding
- Training
- Continuous Improvement
- Performance Evaluation

Recruitment and Hiring

- Recruitment – where do you advertise?
  - Internal – HRPP & Organization
  - External - times when it is good to bring in from outside
  - PRIM&R Job Board
  - LinkedIn
  - Professional Job Boards and List Servs
  - Networking!!!
- Review keywords in Job Description
- Other important information to include in the recruitment process

Job Description

- What are the primary responsibilities?
- Are there any secondary responsibilities?
- Who does the position report to?
- Qualifications/Requirements
  - Professional certification (CIP)?
- Flexibility in the posting to cover multiple positions?

Great time to re-review and refresh JDs that you have been recycling over the years!

Other Important Information

- Flexibility?
  - Work hours
  - Work location – remote?
- Organizational Benefits
  - Personal and Professional
    - $$$
    - “Typical” benefits (including PTO)
    - Opportunities for growth
    - Professional development
    - Career ladder opportunities

Hiring tips

- Define interview process for both sides
- Transparency
- Work ethic, loyalty, customer service
- Effective Communication
- Ability to handle your volume
- You can train on Regs, Policies and Procedures
- Ask direct questions – don’t be afraid to ask questions
- Don’t sugar coat

Onboarding – organization

- "Welcome to Yale"
  - HR Onboarding including organization-wide systems
  - Institutional Training
- HRPP Operations
    - Org Chart - staff, IRB Chairs, IOs
    - Telecomm, IT, calendars, web-video platforms, etc.
    - Meeting invitations (standing staff meetings, HRPP/IRB Meetings)
    - Electronic systems
        - Website
        - Network share drive
        - eIRB system
            - Library and help center
            - Tools – checklists, work flows, macros

Onboarding – HRPP/IRB

- Institutional Training requirements
- HRPP/IRB process
  - Institutional review
    - Intake
    - Ancillary Committees
  - Exempt/NHSR
  - Expedited review
  - Full Board
    - Agenda and minutes processes
- Policies and Procedures

Training

- CITI Program
- PRIM&R Modules
- Staff training program
  - Newsletter/list serv
  - Staff sessions
  - IRB meetings
- Webinars (AAHRPP, PRIM&R, OHRP, SMART IRB, SOCRA)
- Conferences
- Certifications
- Networking – be a part of the community!
- Professional Development
  - Lynda.com, MS Suite training, HR Courses

Development

- Time for training
- Special projects
- Opportunities to shine
  - Presentations
  - Topic expert
- Set career goals
- Reset goals
- Coaching and mentoring opportunities
  - Help staff succeed and achieve their goals

Continuous Improvement

- Give feedback in real time with concrete examples
- Meet to discuss and answer questions
- Teach/Educate
  - Focus on area for training and development
  - Not focusing on what was incorrect
  - Work towards sustained improvement

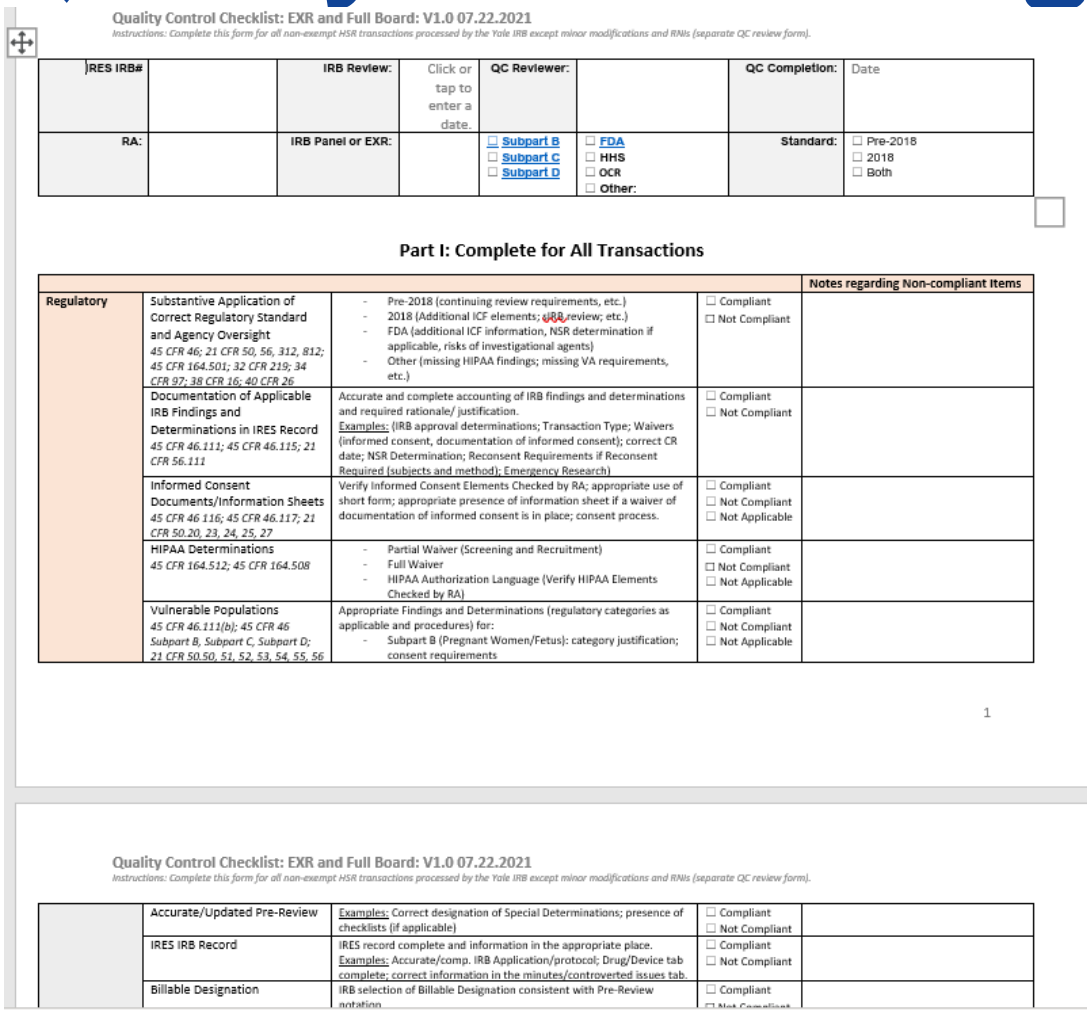
Inbox Reports

Owner	Type	State	ID	Expiration Date	Days
Karen Smith	CR	Committee Review	CR00011491	7/4/2022	4
Karen Smith	MOD	Committee Review	MOD00052236	3/22/2023	7
Karen Smith	STUDY	Committee Review	2000031973	(blank)	3

Productivity Reports

Name	CR	Initial	MOD	MODCR	Grand Total
Bob Johnson			1		1
Thu			1		1
Anna Williams			4		4
Mon			1		1
Tue			1		1
Wed			1		1
Thu			1		1
Kimberly Stevens		1	1		2
Mon		1			1
Tue			1		1
Jack Simpson	21			3	24
Mon	2				2
Tue	10				10
Wed	4			1	5
Thu	5			2	7
Grand Total	21	33	106	3	165

Quality Control Program



Quality Control Checklist: EXR and Full Board: V1.0 07.22.2021

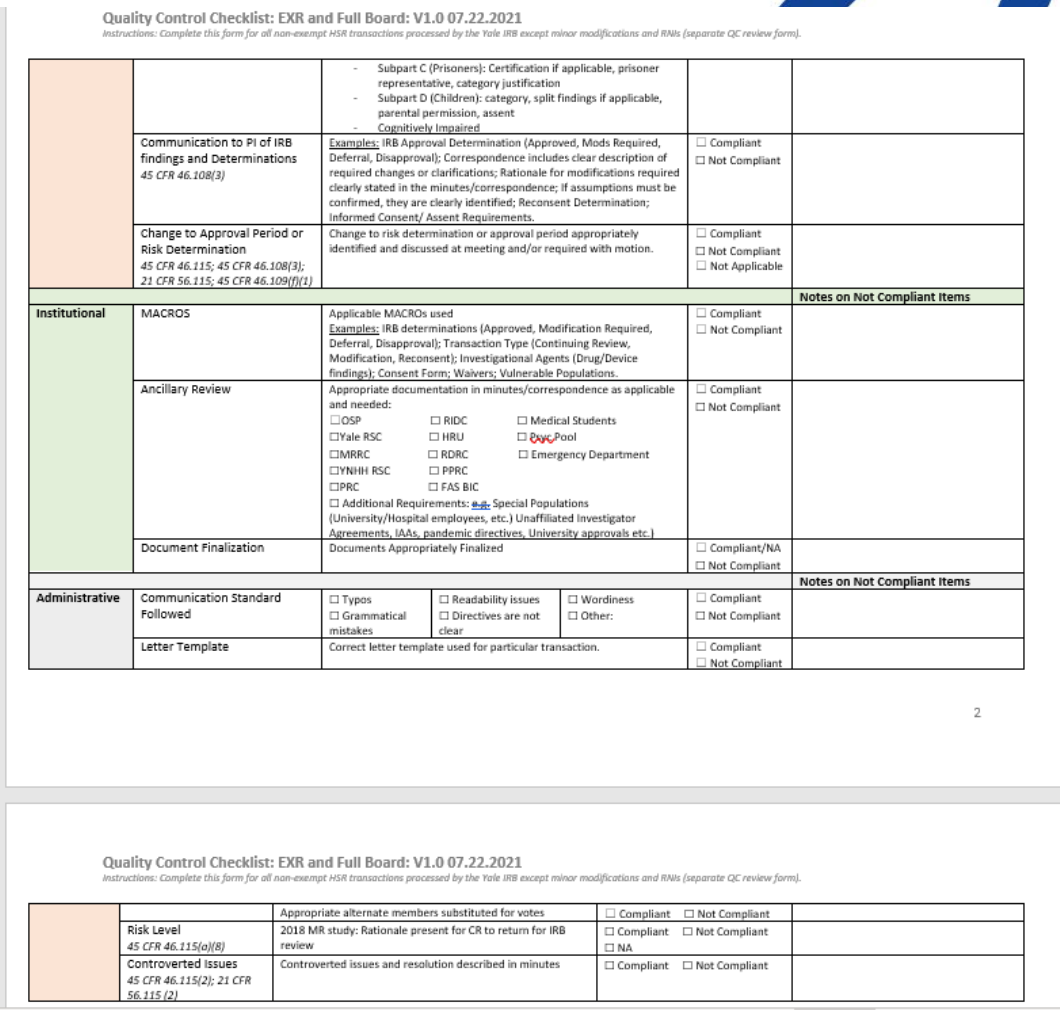
Instructions: Complete this form for all non-exempt HSR transactions processed by the Yale IRB except minor modifications and RNIs (separate QC review form).

IRES IRB#		IRB Review:	Click or tap to enter a date.	QC Reviewer:		QC Completion:	Date
RA:		IRB Panel or EXR:		☐ Subpart B ☐ Subpart C ☐ Subpart D	☐ FDA ☐ HHS ☐ OCR ☐ Other:	Standard:	☐ Pre-2018 ☐ 2018 ☐ Both

Part I: Complete for All Transactions

				Notes regarding Non-compliant Items
Regulatory	Substantive Application of Correct Regulatory Standard and Agency Oversight *45 CFR 46; 21 CFR 50, 56, 312, 812; 45 CFR 164.501; 32 CFR 219; 34 CFR 97; 38 CFR 16; 40 CFR 26*	- Pre-2018 (continuing review requirements, etc.) - 2018 (Additional ICF elements; eIRB review; etc.) - FDA (additional ICF information, NSR determination if applicable, risks of investigational agents) - Other (missing HIPAA findings; missing VA requirements, etc.)	☐ Compliant ☐ Not Compliant	
	Documentation of Applicable IRB Findings and Determinations in IRES Record *45 CFR 46.111; 45 CFR 46.115; 21 CFR 56.111*	Accurate and complete accounting of IRB findings and determinations and required rationale/ justification. Examples: (IRB approval determinations; Transaction Type; Waivers (informed consent, documentation of informed consent); correct CR date; NSR Determination; Reconsent Requirements if Reconsent Required (subjects and method); Emergency Research)	☐ Compliant ☐ Not Compliant	
	Informed Consent Documents/Information Sheets *45 CFR 46 116; 45 CFR 46.117; 21 CFR 50.20, 23, 24, 25, 27*	Verify Informed Consent Elements Checked by RA; appropriate use of short form; appropriate presence of information sheet if a waiver of documentation of informed consent is in place; consent process.	☐ Compliant ☐ Not Compliant ☐ Not Applicable	
	HIPAA Determinations *45 CFR 164.512; 45 CFR 164.508*	- Partial Waiver (Screening and Recruitment) - Full Waiver - HIPAA Authorization Language (Verify HIPAA Elements Checked by RA)	☐ Compliant ☐ Not Compliant ☐ Not Applicable	
	Vulnerable Populations *45 CFR 46.111(b); 45 CFR 46 Subpart B, Subpart C, Subpart D; 21 CFR 50.50, 51, 52, 53, 54, 55, 56*	Appropriate Findings and Determinations (regulatory categories as applicable and procedures) for: - Subpart B (Pregnant Women/Fetus): category justification; consent requirements - Subpart C (Prisoners): Certification if applicable, prisoner representative, category justification - Subpart D (Children): category, split findings if applicable, parental permission, assent - Cognitively Impaired	☐ Compliant ☐ Not Compliant ☐ Not Applicable	

1



Quality Control Checklist: EXR and Full Board: V1.0 07.22.2021

Instructions: Complete this form for all non-exempt HSR transactions processed by the Yale IRB except minor modifications and RNIs (separate QC review form).

		- Subpart C (Prisoners): Certification if applicable, prisoner representative, category justification - Subpart D (Children): category, split findings if applicable, parental permission, assent - Cognitively Impaired		
	Communication to PI of IRB findings and Determinations *45 CFR 46.108(3)*	Examples: IRB Approval Determination (Approved, Mods Required, Deferral, Disapproval); Correspondence includes clear description of required changes or clarifications; Rationale for modifications required clearly stated in the minutes/correspondence; If assumptions must be confirmed, they are clearly identified; Reconsent Determination; Informed Consent/ Assent Requirements.	☐ Compliant ☐ Not Compliant	
	Change to Approval Period or Risk Determination *45 CFR 46.115; 45 CFR 46.108(3); 21 CFR 56.115; 45 CFR 46.109(f)(1)*	Change to risk determination or approval period appropriately identified and discussed at meeting and/or required with motion.	☐ Compliant ☐ Not Compliant ☐ Not Applicable	
				Notes on Not Compliant Items
Institutional	MACROS	Applicable MACROs used Examples: IRB determinations (Approved, Modification Required, Deferral, Disapproval); Transaction Type (Continuing Review, Modification, Reconsent); Investigational Agents (Drug/Device findings); Consent Form; Waivers; Vulnerable Populations.	☐ Compliant ☐ Not Compliant	
	Ancillary Review	Appropriate documentation in minutes/correspondence as applicable and needed: ☐OSP ☐ RIDC ☐ Medical Students ☐Yale RSC ☐ HRU ☐ Pwc Pool ☐MRRC ☐ RDRC ☐ Emergency Department ☐YNHH RSC ☐ PPRC ☐PRC ☐ FAS BIC ☐ Additional Requirements: e.g. Special Populations (University/Hospital employees, etc.) Unaffiliated Investigator Agreements, IAAs, pandemic directives, University approvals etc.)	☐ Compliant ☐ Not Compliant	
	Document Finalization	Documents Appropriately Finalized	☐ Compliant/NA ☐ Not Compliant	
				Notes on Not Compliant Items
Administrative	Communication Standard Followed	☐ Typos ☐ Readability issues ☐ Wordiness ☐ Grammatical mistakes ☐ Directives are not clear ☐ Other:	☐ Compliant ☐ Not Compliant	
	Letter Template	Correct letter template used for particular transaction.	☐ Compliant ☐ Not Compliant	

2

Quality Control Checklist: EXR and Full Board: V1.0 07.22.2021

Instructions: Complete this form for all non-exempt HSR transactions processed by the Yale IRB except minor modifications and RNIs (separate QC review form).

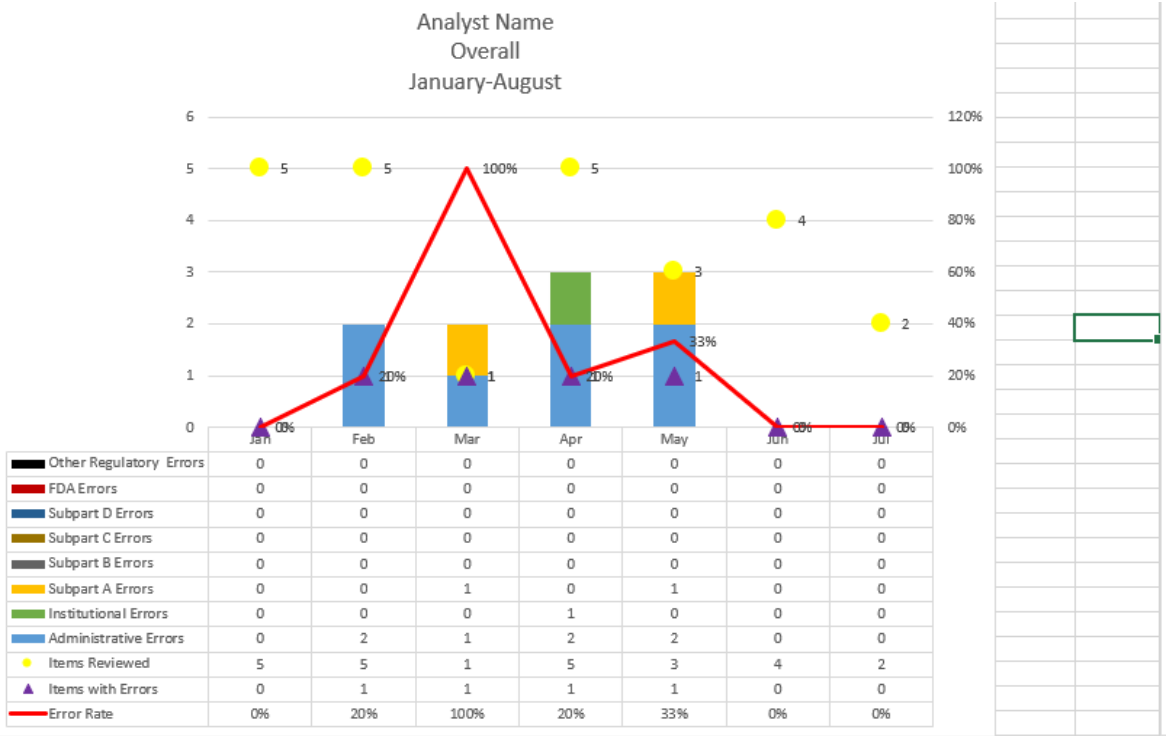
	Accurate/Updated Pre-Review	Examples: Correct designation of Special Determinations; presence of checklists (if applicable)	☐ Compliant ☐ Not Compliant
	IRES IRB Record	IRES record complete and information in the appropriate place. Examples: Accurate/comp. IRB Application/protocol; Drug/Device tab complete; correct information in the minutes/controverted issues tab.	☐ Compliant ☐ Not Compliant
	Billable Designation	IRB selection of Billable Designation consistent with Pre-Review notation	☐ Compliant

Quality Control Checklist: EXR and Full Board: V1.0 07.22.2021

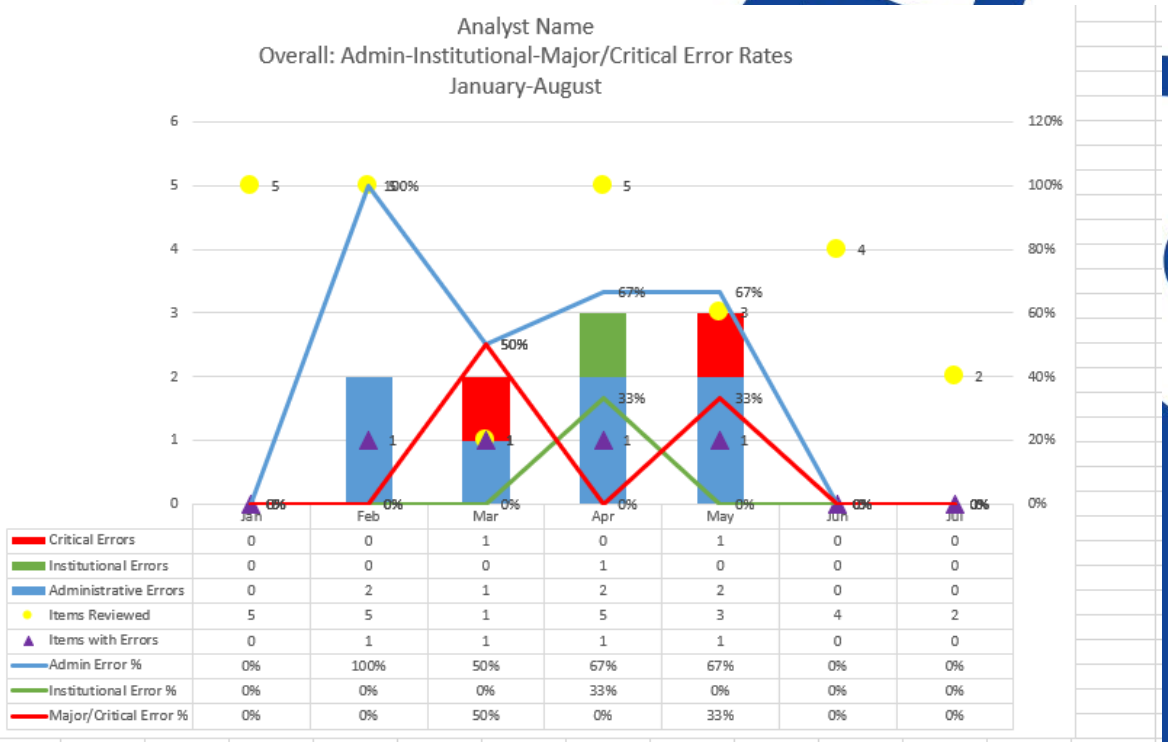
Instructions: Complete this form for all non-exempt HSR transactions processed by the Yale IRB except minor modifications and RNIs (separate QC review form).

		Appropriate alternate members substituted for votes	☐ Compliant ☐ Not Compliant	
	Risk Level *45 CFR 46.115(a)(8)*	2018 MR study: Rationale present for CR to return for IRB review	☐ Compliant ☐ Not Compliant ☐ NA	
	Controverted Issues *45 CFR 46.115(2); 21 CFR 56.115 (2)*	Controverted issues and resolution described in minutes	☐ Compliant ☐ Not Compliant	

Individualized QC Reports



	Jan	Feb	Mar	Apr	May	Jun	Jul
Other Regulatory Errors	0	0	0	0	0	0	0
FDA Errors	0	0	0	0	0	0	0
Subpart D Errors	0	0	0	0	0	0	0
Subpart C Errors	0	0	0	0	0	0	0
Subpart B Errors	0	0	0	0	0	0	0
Subpart A Errors	0	0	1	0	1	0	0
Institutional Errors	0	0	0	1	0	0	0
Administrative Errors	0	2	1	2	2	0	0
Items Reviewed	5	5	1	5	3	4	2
Items with Errors	0	1	1	1	1	0	0
Error Rate	0%	20%	100%	20%	33%	0%	0%



	Jan	Feb	Mar	Apr	May	Jun	Jul
Critical Errors	0	0	1	0	1	0	0
Institutional Errors	0	0	0	1	0	0	0
Administrative Errors	0	2	1	2	2	0	0
Items Reviewed	5	5	1	5	3	4	2
Items with Errors	0	1	1	1	1	0	0
Admin Error %	0%	100%	50%	67%	67%	0%	0%
Institutional Error %	0%	0%	0%	33%	0%	0%	0%
Major/Critical Error %	0%	0%	50%	0%	33%	0%	0%

Analyst | **Overall** | Initials | Modifications | Continuing Reviews | MODCRs

Performance Evaluation

- Frequent communication
  - Regular 1:1 meetings/discussions
  - Quarterly/Biannually
- Focus of positive and areas in need of improvement
- End of year: Summary/Recap of Performance
- Self assessment, manager assessment, people-leader assessment
- Goal setting

Self and Manager Assessment Criteria:

1. Performance of Job Responsibilities (Productivity, Innovation, Quality & Efficiency)
2. Individual &Team Project Results
3. Customer Service & Work Habits (Approachable, Responsive, Helpful, Flexible, Reliable, Accountable, Positive Attitude)
4. Teamwork and Ability to Work with Others (Team-Oriented, Professional, Respectful, Inclusive & Helpful)
5. Organizational Commitment (Ethics, Integrity, Adherence to Organizational Requirements, Drives for Results; Alignment with the Mission & Goals)

People Leader Assessment Criteria:

1. Leadership
2. Managing Conflict
3. Managing Staff
4. Managing/Implementing Change
5. Managing for Results

Take Home Messages

- Hire good people with good work ethic
- Lead the way you want to be led
  - Leadership
    - HBR: Leadership refers to an individual's ability to influence, motivate, and enable others to contribute toward organizational success
  - Management Style:
    - HBR: Management consists of controlling a group or a set of entities to accomplish a goal
  - Influence and inspiration separate leaders from managers, not power and control
- Focus on what is important
  - GYSD: Get Your Stuff Done!
- Staff Performance Development
- SUPPORT

Questions?

Thank You!