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

2022 AAHRPP Webinar Series

Innovative Practices by AAHRPP-Accredited Organizations: Tools for Quality Assurance and Compliance

Stephanie deRijke, Emory University
Pamela Johnson, Hartford Healthcare
Pam Stafford, University of Kentucky
Moderated by **Nichelle Cobb**, AAHRPP

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Format for 2022

Attendee Hub

- Livestreamed Content
- Networking
- Chat/Discussions

Webinar Sessions

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

Resources

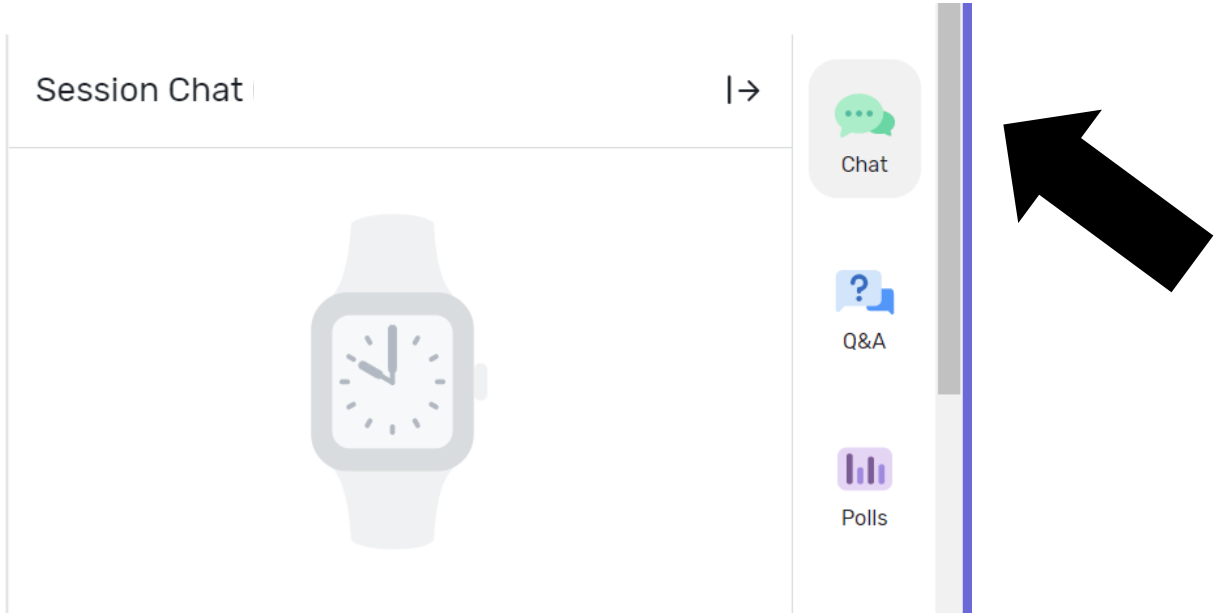
- Slide Presentation
- Documents
- Resources from Speakers

On-Demand Video

- Webinar Recordings on Hub
- Available for the Whole Year

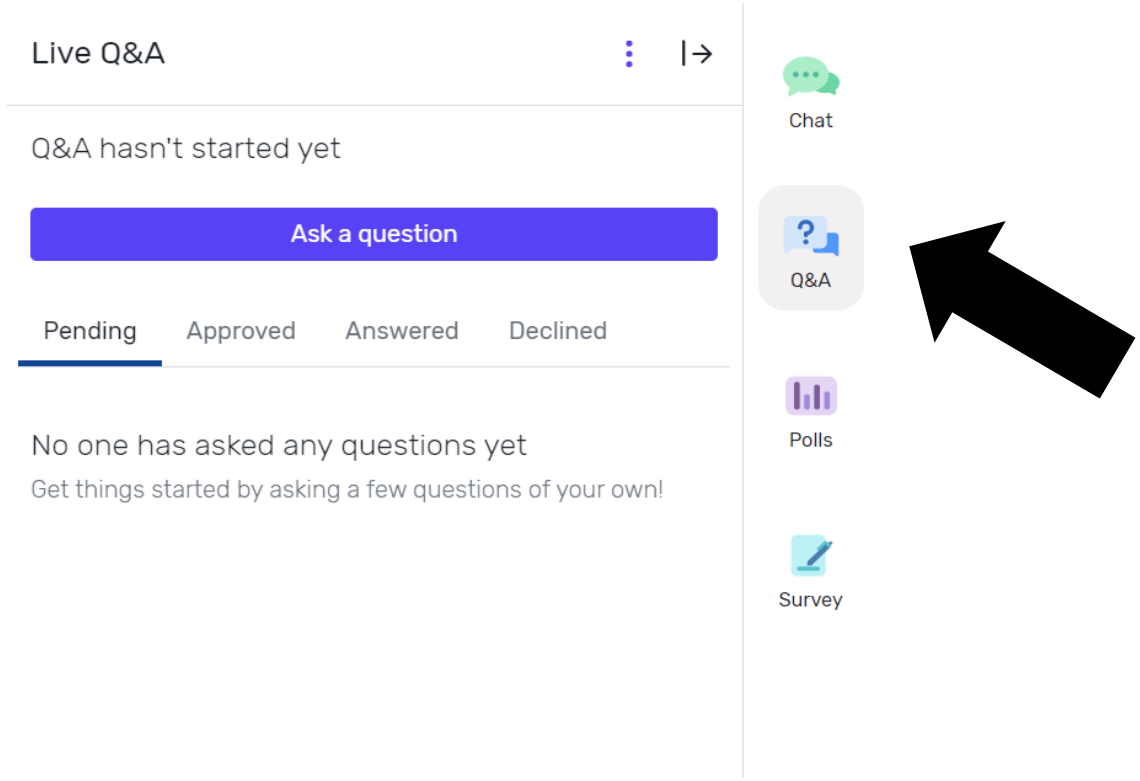
Chat Feature

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:



AAHRPP

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

2023 AAHRPP Annual Conference

Challenge and Change in Charm City

May 16-18, 2023 | Hyatt Regency Baltimore

Presenter Introductions

AAHRPP

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

Nichelle Cobb, PhD

Senior Advisor for Strategic Initiatives
AAHRPP

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

Pam Stafford, MA

Associate Director, Office of Research Integrity

University of Kentucky

AAHRPP

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

Stephanie deRijke, RN, MSN

Senior Director, Clinical Trials Audit and Compliance

Emory University

AAHRPP

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

Pamela Johnson, MPH, CCRC

Research Education & Quality Improvement Manager

Hartford HealthCare

Session Goals

- At the end of this session, participants will be able to:
  - Interpret AAHRPP Elements I.5.A, I.5.B, and I.5.D
  - Understand the importance of a quality assurance program for their HRPP to ensure compliance with applicable laws, regulations, and codes, and guidance
  - Identify innovative tools and methods for assessing HRPP compliance and quality, efficiency, and effectiveness of their HRPPs and addressing and reporting non-compliance

Areas of Distinction – What Are They?

Areas of Distinctions are activities, resources, processes, or approaches that are innovative, unique, or a potential best practice that HRPPs at other organizations may benefit from knowing about or adopting.

Awarded by the AAHRPP Council on Accreditation after a site visit, usually based on recommendations from the site visit team

Areas of Distinction Themes for This Webinar: QI and Compliance

- Focus on initiatives to
  - Measure and improve compliance with organizational policies and procedures, applicable laws, regulations, and codes, and guidance (*Element I.5.A*)
  - Measure and improve the quality, effectiveness, and efficiency of their Human Research Protection Programs (HRPPs) (*Element I.5.B*)
  - Monitor allegations and findings of non-compliance with HRPP requirements and use that information to institute targeted education and changes in practice (*Element I.5.D*)

Element I.5.A

- The organization conducts audits or surveys or uses other methods to assess compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The organization makes improvements to increase compliance, when necessary.

Guidance from the Evaluation Instrument

- An organization's quality improvement program should include measures of compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance.
- The organization's quality improvement program should include an evaluation of the HRPP to determine whether it is effective in achieving compliance.
- The organization should collect objective data through audits, surveys, or other methods and use the data to make improvements and monitor compliance on an ongoing basis.
- The number of audits or surveys, or the breadth of the audits or surveys, conducted should be determined by the organization and sufficiently robust to provide data that inform the quality improvement program.

AAHRPP expects organizations to have QI programs.

The QI program should evaluate the HRPP functions (e.g., IRB, COI Committee).

Evaluations should be systematic, ongoing, and drive improvements. Improvements should be monitored.

The QI activities should be tailored to the organization.

Required written materials

- The organization has a quality improvement plan that periodically assesses compliance of the HRPP.
  - The plan states the goal of the quality improvement plan with respect to achieving and maintaining compliance.
  - The plan defines at least one objective to achieve or maintain compliance.
  - The plan defines at least one measure of compliance.
  - The plan describes the methods to assess compliance and make improvements.

Common Types of Materials that May be Used to Meet the Element

- Compliance plans
- Audits, surveys, or data collection tools
- Surveys
- Evaluation reports

Outcomes

- The organization monitors compliance based on objective data and makes improvements, when necessary.

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.

Guidance from the Evaluation Instrument

- An organization's quality improvement program should include measures of quality, efficiency, and effectiveness to evaluate the performance of the HRPP. The organization should use results from the quality improvement program to design and implement improvements.
- The organization should collect objective data through audits, surveys, or other methods and use the data to make improvements and monitor quality, efficiency, and effectiveness on an ongoing basis.

AAHRPP expects organizations to evaluate their HRPPs for quality, efficiency, and effectiveness in addition to compliance.

Evaluations should be systematic, ongoing, and drive improvements. Improvements should be monitored.

Required written materials

- The organization has a quality improvement plan that periodically assesses the quality, efficiency, and effectiveness of the HRPP.
- The plan states the goals of the quality improvement plan with respect to achieving targeted levels of quality, efficiency, and effectiveness of the HRPP.
- The plan:
  - Defines at least one objective of quality, efficiency, or effectiveness.
  - Defines at least one measure of quality, efficiency, or effectiveness.
  - Describes the methods to assess quality, efficiency, and effectiveness and make improvements.

Common Types of Materials that May be Used to Meet the Element

- Quality improvement plan
- Audits, surveys, or other data collection tools
- Evaluation reports

Outcomes

- The organization:
  - Identifies targets for quality, efficiency, and effectiveness of the HRPP.
  - Plans improvements based on measures of quality, efficiency, and effectiveness.
  - Implements planned improvements.
  - Monitors and measures the effectiveness of improvements.

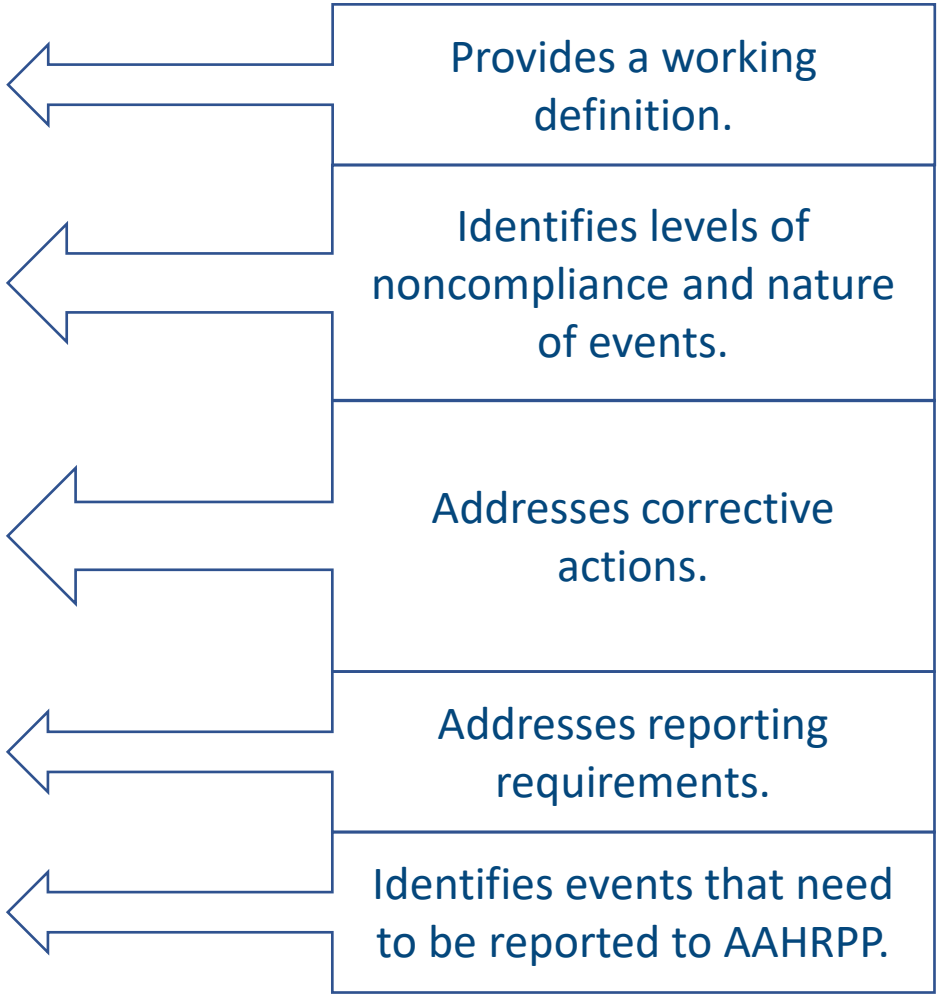
Element I.5.D.

- The organization has and follows written policies and procedures for addressing allegations and findings of non-compliance with Human Research Protection Program requirements. The organization works with the Institutional Review Board or Ethics Committee, when appropriate, to ensure that participants are protected when non-compliance occurs. Such policies and procedures include reporting these actions, when appropriate.

This element focuses on study team non-compliance and reporting non-compliance (study teams to IRBs/ECs and others + IRBs/ECs reporting to others, such as Federal agencies.

Guidance from the Evaluation Instrument

- Non-compliance refers to not following laws or regulations that govern research involving human participants, the organization's policies and procedures, or the requirements or determinations of the IRB or EC.
- Non-compliance can be relatively minor or serious.
- Non-compliance can also be a one-time event or a continuing problem.
- Policies and procedures should consider a range of corrective actions that are applicable to the spectrum of non-compliance.
- Corrective actions should be appropriate to the nature and degree of the non-compliance.
- Some laws or regulations specify reporting requirements to regulatory agencies, sponsors, or other entities that should be incorporated into the organization's policies and procedures.
- Additionally, written materials describe requirements for reporting to AAHRPP, per AAHRPP Accreditation Procedures.



Required Written materials

- Policies and procedures define:
  - Non-compliance.
  - Serious non-compliance.
  - Continuing non-compliance.
- Policies and procedures include non-compliance of researchers, staff, other employees, and of the IRB or EC.

Required Written Materials

- Policies and procedures describe the various mechanisms for informing the organization or IRB or EC of non-compliance:
  - Reporting requirements for researchers, staff, and employees.
  - Consideration of complaints and protocol deviations.
  - Results of audits.

Required Written Materials

- Policies and procedures describe:
  - The organization's process to decide whether each allegation of non-compliance has a basis in fact.
  - The organization's process to decide whether each incident of non-compliance is serious or continuing.
- Policies and procedures describe the organization's process to manage non-compliance that is neither serious nor continuing.

Required Written Materials

- Policies and procedures describe the process for management of serious or continuing non-compliance by the convened IRB or EC, including:
  - If a primary reviewer system is used, documents distributed to primary reviewers.
  - Documents distributed to all IRB or EC members.
  - Policies and procedures indicate the IRB or EC is required to consider the following range of possible actions:
    - Suspension of IRB approval the research.
    - Termination of IRB approval the research.
    - Notification of current participants when such information might relate to participants' willingness to continue to take part in the research

Required Written Materials

- Policies and procedures indicate that, in addition to the required actions, the IRB or EC optionally may consider the following possible actions:
  - Modification of the protocol.
  - Modification of the information disclosed during the consent process.
  - Providing additional information to past participants.
  - Requiring current participants to re-consent to participation.
  - Modification of the continuing review schedule.
  - Monitoring of the research.
  - Monitoring of the consent process.
  - Referral to other organizational entities.

Required Written Materials

- Policies and procedures describe the reporting of serious or continuing non-compliance, including:
  - A requirement for the report to be distributed to:
    - Specific organizational officials.
    - Other agencies when the research is overseen by those agencies.
  - The maximum time allowed between the recognition of a reportable event and fulfilling reporting requirements.

Required Written Materials

- Policies and procedures describe the reporting to AAHRPP as soon as possible but generally within 48 hours after the organization or any researcher (if the researcher is notified rather than the organization) becomes aware of:
  - Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.
  - Any litigation, arbitration, or settlements initiated related to human research protections.
  - Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP.

Additional Requirements

- Written materials also may need to address the requirements for:
  - DHHS
  - DoD
  - DOE
  - FDA
  - VA

Outcomes

- Researchers and research staff report allegations of non-compliance to the IRB or EC.
- Non-compliance is identified and managed.
- The IRB or EC or organizational official reports serious or continuing non-compliance as required.

University of Kentucky: Pam Stafford

- The Office of Research Integrity (ORI) Quality Assurance and Improvement Program provided a four-pronged approach and worked closely with the ORI Education Program on prevention and process improvement, including the following:
    1. on-site reviews;
    2. a web-based self-assessment for researchers;
    3. "wellness checks" for both biomedical and social-behavioral research, within six months of initial IRB approval, to offer assistance as needed and early detection and resolution of any areas of concern prior to the first continuing review using a risk-based approach; and
    4. a comprehensive administrative assessment of the quality of the HRPP, including IRB records, ORI files, IRB member performance, determination of expedited and exempt categories, timeliness of review, outreach activity, major vs. minor revisions, documentation of protocol-specific determinations for vulnerable populations and for waivers of consent, inclusion of elements of consent, data safety monitoring plans, and completeness of IRB minutes.
- A monthly QA Task Force (made up of members of the CCTS, Markey Cancer Center, and ORI) met to identify trends, develop plans for resolution, and coordinate their work to more efficiently use their resources. For example, after identification of a problem related to informed consent, a guidance module for researchers for re-obtaining informed consent was developed. (Elements I.5.A. and I.5.B.)

University of Kentucky

- Fully accredited since 2007
- 4 hospitals with 40+ centers/clinics, and an academic campus
- Five IRBs
  - 4 Medical
  - 1 SBER
- Office of Research Integrity (ORI)
  - Protocol management
  - IRB management
  - Education
  - Allegations of Research Misconduct
  - QA/QI

Elements I.5.A and I.5.B

PI self-assessment

- Implemented in 2004 with guidance from Dr. Delia Wolf Christiani
- Initial focus was medical clinical trial protocols
- Investigators could access and complete it on their own or the IRB could require or suggest the investigator complete it
  - Investigators rarely did so on their own
- Future plans …

On-site reviews/visits

- Directed (aka “for cause”) visits
  - Requested by the IRB
  - Report provided to the IRB
- Wellness Checks
  - Selected by ORI QA/QI team via risk-based approach
  - Medical and SBER protocols
  - Full/convened and Expedited review
  - Goal is 3-6 months post-IRB approval
  - Report not provided to the IRB unless findings warrant such

Wellness Checks

- Goals:
  - Offer assistance as needed
  - Early detection/resolution of any areas of concern
  - Facilitate cleaner annual review/renewal process (CR/AAR)
- Selection process: (*primarily risk-based approach**)
  - Greater than minimal risk with no sponsor/additional oversight
  - Investigators who struggled during the initial review process
  - Physician-led protocols without a study coordinator/support staff
  - Student investigators
  - Vulnerable participant population(s)

**Wellness Checks are also arranged for investigators who request them*

Common Findings in Wellness Checks

- Informed consent process and/or document itself
  - Not retaining complete copy of executed consent
  - Using incorrect version
  - Issues with signatures and/or dates
  - Not providing participant with a copy
- Inconsistencies in protocol materials
  - IRB-approved application in system not matching what investigator is using
- Data collection materials
  - Incomplete records (missing forms, blank forms) in study files
- Study personnel issues
  - Unapproved/unlisted personnel working on protocol
  - Personnel not authorized to obtain informed consent doing so
- Recruitment methods/materials
  - Using method or materials never submitted to/approved by the IRB
- Missing IRB-specific documentation/records in study file (e.g., approval letters)

Wellness Check Feedback Form

Quality Assurance/Quality Improvement (QA/QI) visit feedback form

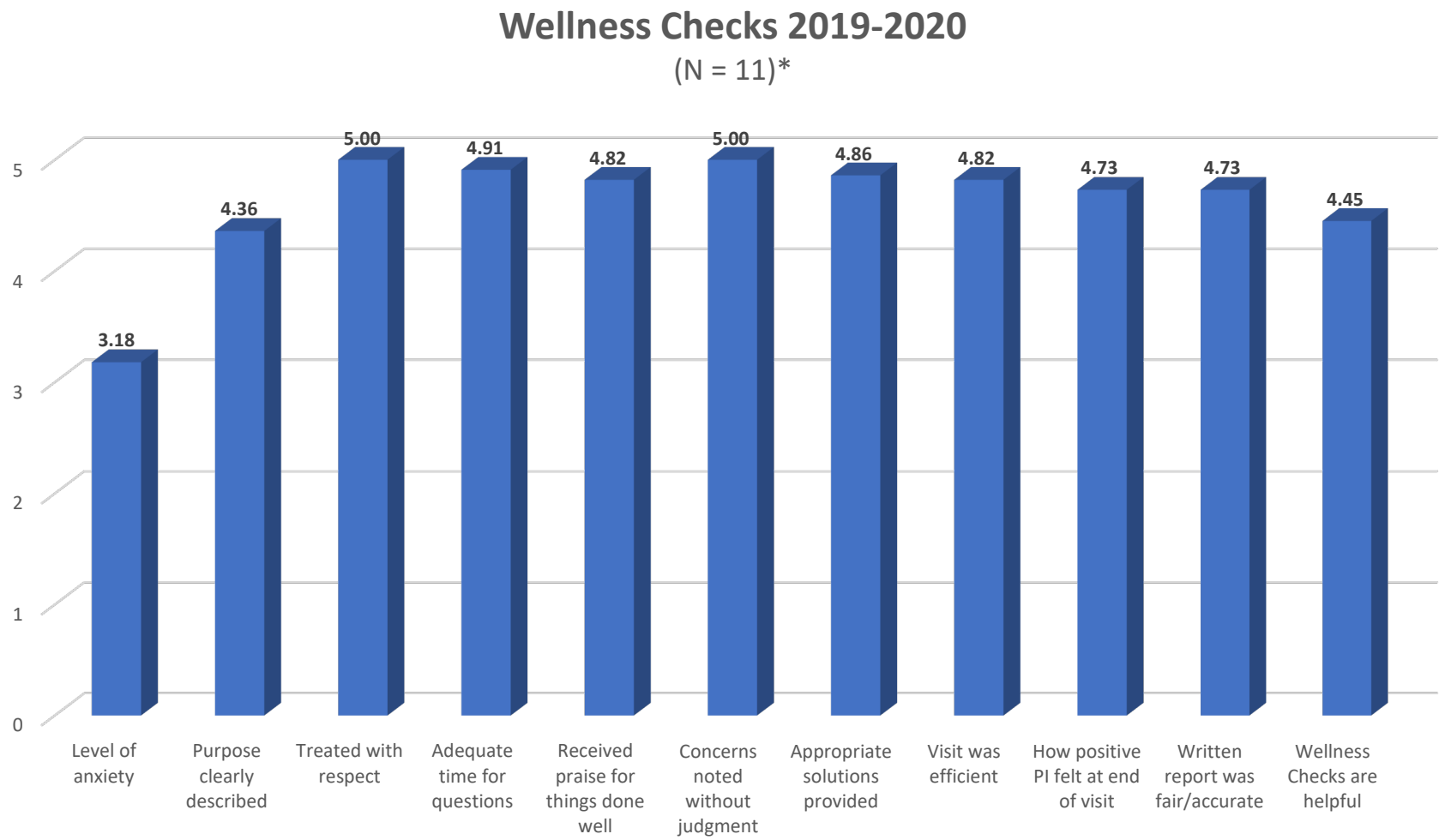
Please complete the survey below.

Thank you!

Your role in the research for which a Quality Assurance/Quality Improvement (QA/QI) visit was conducted:	◯ Principal Investigator (PI) ◯ Study Coordinator ◯ Faculty Advisor ◯ Other study personnel
I felt nervous when Quality Assurance/Quality Improvement (QA/QI) staff contacted me about scheduling a visit for my research.	◯ Strongly Disagree ◯ Disagree ◯ Undecided ◯ Agree ◯ Strongly Agree
QA/QI staff clearly described the purpose of the QA/QI visit.	◯ Strongly Disagree ◯ Disagree ◯ Undecided ◯ Agree ◯ Strongly Agree
QA/QI staff treated the researcher(s)/study personnel with respect throughout the experience.	◯ Strongly Disagree ◯ Disagree ◯ Undecided ◯ Agree ◯ Strongly Agree
QA/QI staff allowed adequate time for questions and discussion during the visit.	◯ Strongly Disagree ◯ Disagree ◯ Undecided ◯ Agree ◯ Strongly Agree
QA/QI staff provided positive comments about things that were noted to have been done well.	◯ Strongly Disagree ◯ Disagree ◯ Undecided ◯ Agree ◯ Strongly Agree
Were there any issues of concern, errors, or other problems discovered during the visit?	◯ Yes ◯ No
QA/QI staff informed the researcher(s) of the concerns/problems in a professional and non-judgmental manner.	◯ Strongly Disagree ◯ Disagree ◯ Undecided ◯ Agree ◯ Strongly Agree
QA/QI staff provided appropriate suggestions/solutions/guidance on the issue(s) during the visit and/or indicated they would seek consult and follow-up with the researcher(s).	◯ Strongly Disagree ◯ Disagree ◯ Undecided ◯ Agree ◯ Strongly Agree

The QA/QI visit was conducted in an efficient manner that was respectful of study personnel's time.	◯ Strongly Disagree ◯ Disagree ◯ Undecided ◯ Agree ◯ Strongly Agree
I felt positive at the conclusion of the QA/QI visit.	◯ Strongly Disagree ◯ Disagree ◯ Undecided ◯ Agree ◯ Strongly Agree
The written report received from QA/QI staff after the visit was fair and accurate.	◯ Strongly Disagree ◯ Disagree ◯ Undecided ◯ Agree ◯ Strongly Agree
QA/QI visits are helpful experiences for researchers and study personnel.	◯ Strongly Disagree ◯ Disagree ◯ Undecided ◯ Agree ◯ Strongly Agree
What suggestions do you have for how QA/QI visits may be improved?	_____
Is there anything else you'd like to share with us about the QA/QI visit or process? If so, please describe:	_____

Wellness Check Feedback Results



(**42% response rate*)

Feedback Results, cont.

Suggestions to improve visits:

- *"Do this early stages in the study, not after I have finished recruitment."*
- *"Make clear when first notified that the wellness check was not triggered because of something that happened … being a graduate student I was concerned it was because I had done something wrong or someone reported my study."*
- *"Make sure the visits are short and to the point. Clinicians who engage in research are doing it on their own time, despite already having a busy clinical schedule. Respect of our time is greatly appreciated. My experience was excellent! Keep up the great job!"*
- *"I think this is a necessary evil."*

Final Comment on Wellness Checks

Anything else you'd like to share with us about the visit or process?:

- *"Thanks for making what we believed would be a difficult experience, an enjoyable one. It was nice to meet you folks and I feel better knowing that you're available when we have questions or issues."*

Other Assessments and Activities

- Annual IRB member evaluation
  - Timing coincides with the fiscal year
  - Members evaluate themselves, the education and training they receive, and the Chairs
- Timeliness and completeness of IRB meeting minutes
  - QA/QI staff review on a quarterly basis and discuss with staff
- Protocol review timelines
  - Select ORI QA/QI staff have access to run reports in Tableau
- Monthly collaborative meeting of QA/QI personnel
  - UK Center for Clinical and Translational Services (CCTS)
  - UK Markey Cancer Center (MCC)
  - UK Office of Research Integrity (ORI)

Emory University: Stephanie deRijke

- The Clinical Trials Audit & Compliance (CTAC) department implemented a data collection mechanism via REDCap to record data on their quality assurance reviews and quality assurance checklists. This unique data capture mechanism allowed the CTAC to regularly report on compliance trends and use this data to inform HRPP education and compliance activities. (Element 1.5.A.)

Emory University

- Large academic medical center in Atlanta, GA
- AAHRPP accreditation in 2007
- 5,300 non-exempt active studies
- 2 IRBs (1 biomed, SHB) meet 6 times per month
- CTSA and NCI Comprehensive Cancer Center
- HRPP QA activities
  - ORA units including IRB
  - Cancer Center DSMC and internal monitoring program
  - Departmental QA reviews
  - Clinical Trials Audit and Compliance

Choosing Studies for Review

- Priority list
  - Sponsor-Investigator, investigator-initiated, DHHS-funded, no monitoring
  - Sponsored research with unfavorable monitoring reports
  - PI-requested reviews
- Investigator-initiated studies
  - Get to them early
  - Train team how to manage the study and self-assessments
- Corrective and preventive action plan implementation reviews

QA Reviews: Regulatory Binder

- IRB history
- FDA documents and DHHS grant information
- Study staff: training and delegation of authority
- Adverse events: internal and external recording and reporting
- Protocol deviations: recording and reporting
- Data and safety monitoring plans
- Investigational product accountability: receipt, storage, dispensation, and return

QA Reviews: Participants

- Informed consent
- Eligibility
- Study procedures
- Study treatment
- Adverse events
- Investigational product accountability

After the Review

- Preliminary report
- Close-out discussion with PI and study team
- Final report
- Studies with significant deficiencies
  - PI reports events to sponsor and/or IRB, per policies
  - CAPA plan implementation
  - Training by CTAC
  - CAPA implementation QA review
  - Additional QA reviews, site visits, keep in close communication

QA Review Results: Record and Trend

- Record
  - REDCap: **R**esearch **E**lectronic **D**ata **Cap**ture is a secure web application for creating and managing surveys and databases
  - Moved audit checklist into REDCap in 2013

- Trend
  - Tableau: external, customizable data analytics tool to view and understand data collected over time
  - Push REDCap data into Tableau monthly

Getting Started with REDCap

- Start with your basic checklist
- Make multiple smaller checklists that contribute to the larger checklist
  - "Build your checklist" model to populate only sections that are applicable to the study
- Create fields of interest for trending on your Main or Intake Page
- Organize questions by category

Study Title **TEST**

Arm 1: Audit Checklists

Re-enable floating table headers ?

Data Collection Instrument	Study Information	Audit 1	Audit 2	Audit 3	Audit 4	Audit 5	Audit 6	Audit 7
Study Information								
Audit Information								
Emory Investigator as Sponsor								
Regulatory Documentation								
Winship Audit								
Subject Checklist								
CAPA Audit								
Audit Summary Information								

Full Study Title * must provide value	TEST Full Title of Study
Current PI * must provide value	Dr. Jones
Department * must provide value	Medicine
Division	
IRB # * must provide value	IRB00000888
Study Supporter	☑ Federal Funds ☐ Industry ☐ Foundation ☐ Emory Internal ☐ Unknown ☐ None
Federal Funds Supporter	National Institutes of Health
NIH Institute/Center	National Institute of Arthritis and Musculoske

FDA Regulations	☐ Investigational New Drug ☐ Investigational New Drug Exempt ☑ Investigational Device Exemption ☐ Investigational Device Exemption, Non Significant Risk ☐ Phase IV ☐ Other ☐ None
Is the Emory PI acting as the Sponsor-Investigator * must provide value	◉ Yes ○ No reset
IND/IDE #:	
Is this an Emory investigator initiated trial? * must provide value	◉ Yes ○ No reset
Initial IRB Approval Date	Today M-D-Y
First Enrollment Date	Today M-D-Y
Is the study conducted in the CRN?	Yes
Where in the CIN is the study conducted?	CHOA
Is this a cancer study?	◉ Yes

AUDIT INFORMATION

Auditor * must provide value	Stephanie deRijke
PI Name * must provide value	Dr. Jones
IRB #: IRB00000888	
Type * must provide value	Not for Cause
Audit Date * must provide value	10-05-2022 Today M-D-Y
Which Checklists are Needed for this Audit?	☑ Regulatory Documentation ☑ Emory Investigator as Sponsor ☐ Winship Audit ☐ Monitoring Report ☑ Subject Audit

ATTACHMENTS

Add Attachment 1	Upload file
Add Attachment 2	Upload file
Add Attachment 3	Upload file

REDCap QA Review Checklist

- Group questions by categories
- Question answers
  - Yes, No, Not assessed, Not applicable
- Compliance assessment
  - In compliance, Noncompliance
- Comments
  - List your review findings, both positive and negative

Is this an abbreviated Subject Review?	○ Yes ◉ No reset
SUBJECT 1 INFORMED CONSENT	
1. Did the subject give written consent and/or reconsent by signing and dating the ICF? * must provide value	Yes
Individual Assessment	In Compliance
Additional Comments	Subject signed IRB-approved version 3 with IRB approval stamp of 2/22/2022. Subject signed and wrote date of 4/1/2022 at 15:35. Expand
2. Did the subject complete all fields on the ICF form and/or sign any other consent forms (e.g., tissue bank)? * must provide value	Yes / No / Not Applicable / Not Assessed
3. Was the consent the correct IRB-approved version? * must provide value	
4. Did the person obtaining informed consent have IRB approval? * must provide value	
5. Did the subject sign consent prior to research interventions? * must provide value	

Event: **Audit 1 (Arm 1: Audit Checklists)**

Study Title	TEST
Total Number of Subjects Reviewed:	3
SUBJECT 1	
SUBJECT 1 UID * must provide value	XYZ
Is this an abbreviated Subject Review?	(•) Yes ( ) No reset
Sections Reviewed	☐ Informed Consent ☐ Eligibility ☐ Treatment ☐ Adverse Events ☐ Protocol Adherence ☐ Data Management ☐ Investigational Product Accountability
ADD SUBJECT 2	☐ Add

SUMMARY OF SIGINFICANT DEFICIENCIES AND CAPAs

Are there Significant Deficiencies and/or CAPA to Summarize?

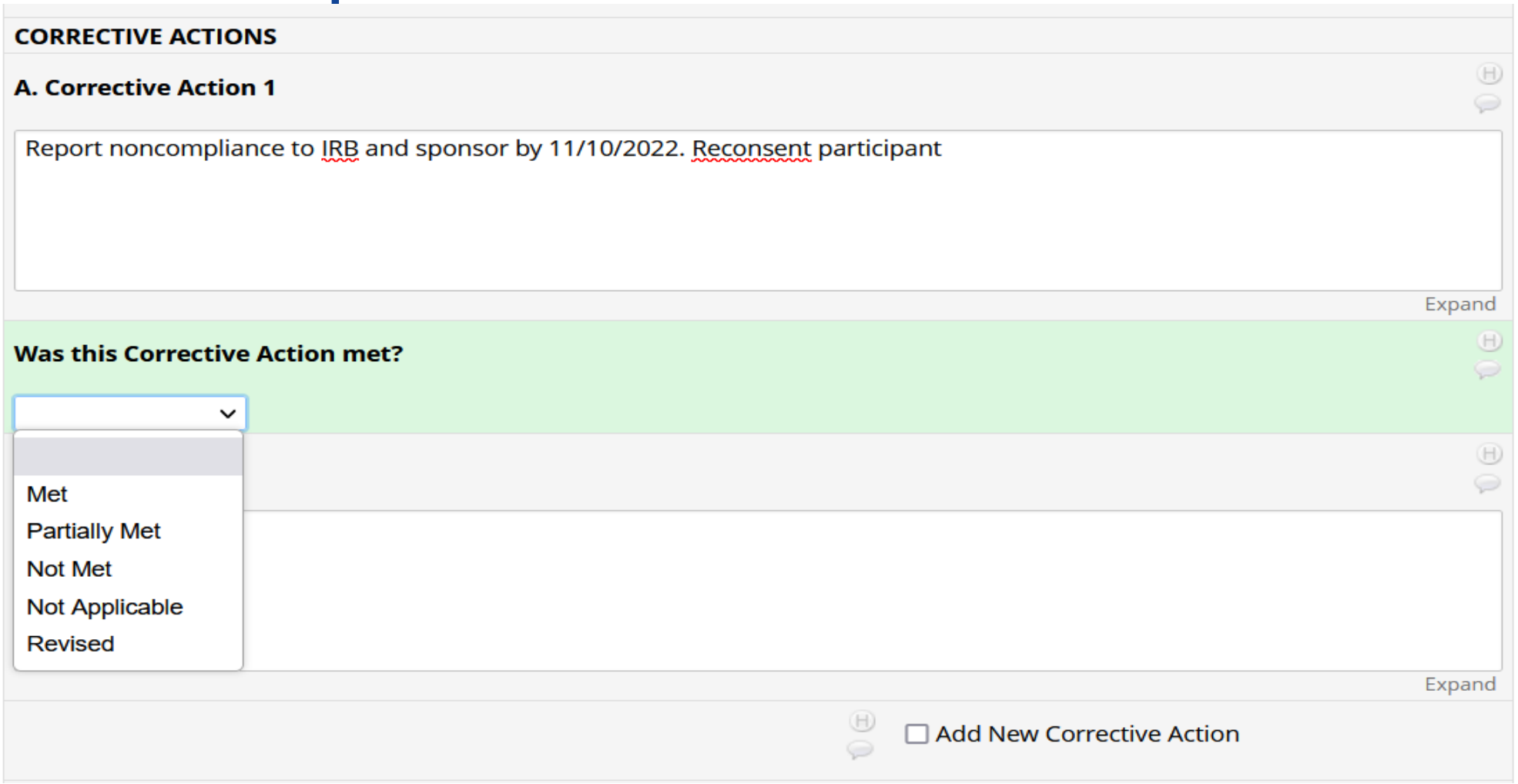
- (●) Yes
- ( ) No

reset

In which categories are there significant deficiencies?

- [ ] Adverse Event not documented
- [ ] Did not follow COI policies
- [ ] Did not follow OCR policies
- [ ] Did not follow sponsor requirements
- [ ] Inadequate documentation of IP accountability
- [ ] Inconsistencies between the protocol, ICF, and/or CRFs
- [ ] Insufficient data management
- [ ] Insufficient documentation of informed consent
- [ ] Insufficient documentation of HIPAA authorization
- [ ] Insufficient documentation of sponsor responsibilities
- [ ] Insufficient GCP documentation practices
- [ ] Insufficient regulatory documentation
- [ ] Insufficient reporting to IRB
- [ ] Insufficient source documentation
- [ ] Insufficient Training
- [ ] Noncompliance with the DSMP
- [ ] Noncompliance with departmental SOPs
- [ ] Protocol non-adherence
- [ ] Research started prior to informed consent
- [ ] Subjects were not eligible
- [ ] Study Staff without IRB approval

CAPA Implementation Reviews



REDCap Reporting

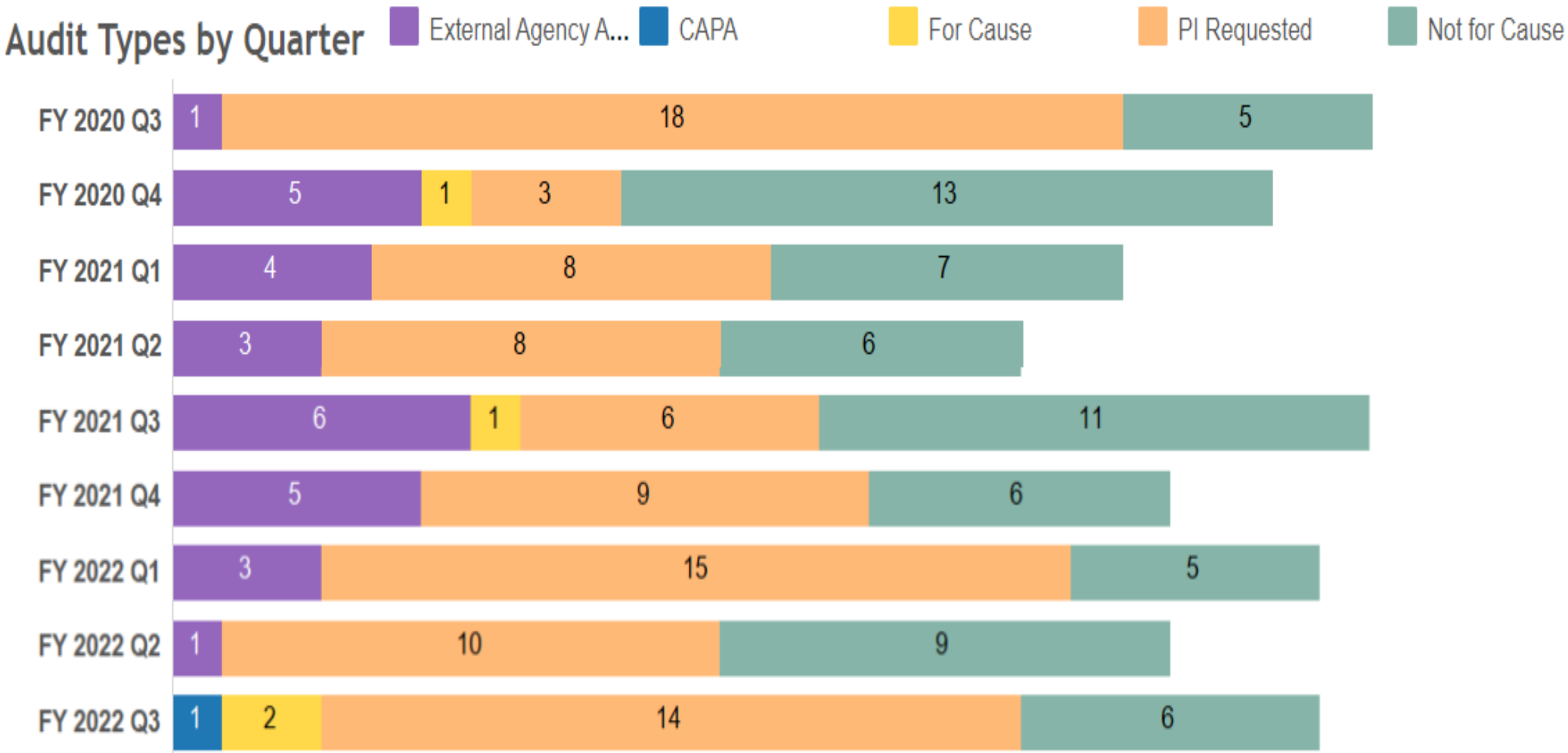
- Summary information form
- Group significant deficiencies by category
- Add flags for IRB reporting and other follow-up (e.g., training)
- Add flags for studies needing a CAPA implementation review

REDCap Reports

Getting Started with Tableau (trend)

- Wait to accrue data before you can trend
- Meet with your statisticians early in the process to make sure you are looking at the data accurately
  - Raw numbers vs percentages since most sections of the checklist will have different numbers of questions
- Can trend broadly on categories and more detailed with individual questions
- Use trends to inform institution on educational initiatives. Use caution in using trends to sound the alarm on compliance issues and pointing fingers.

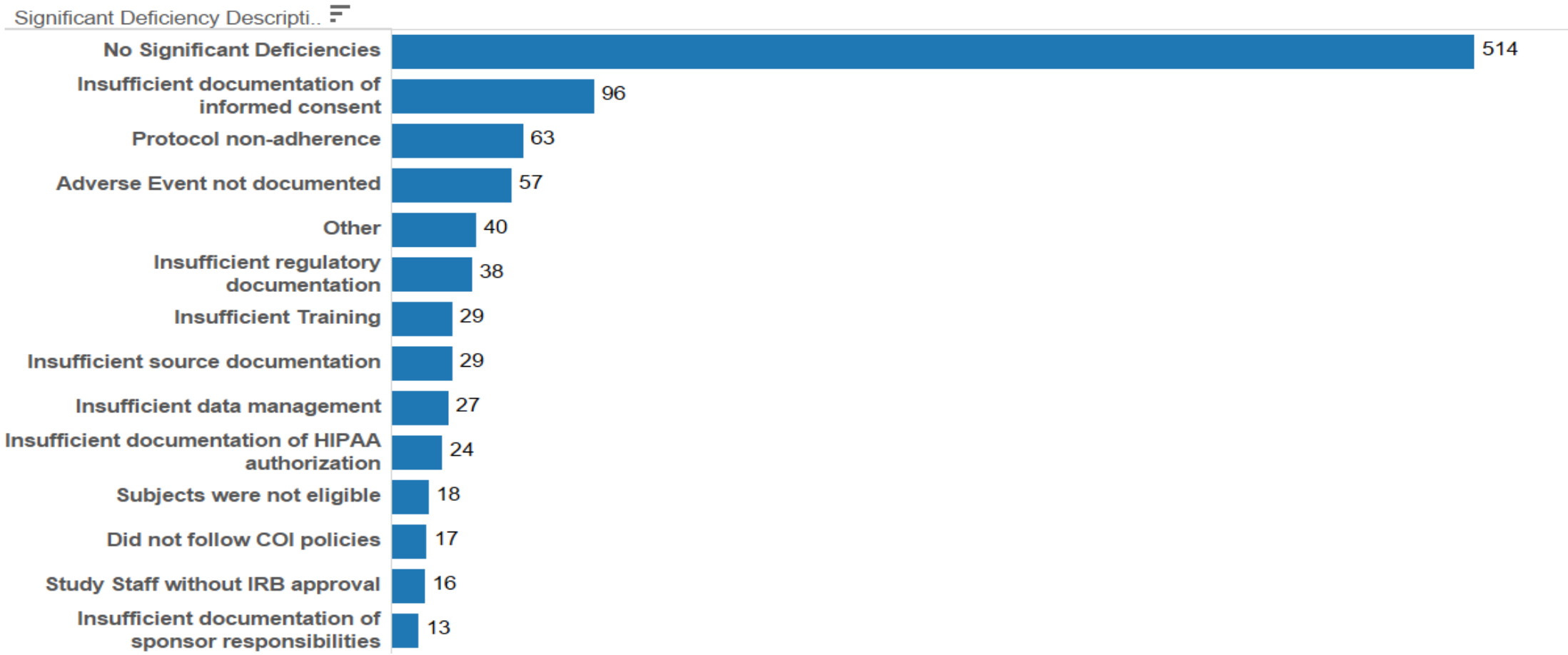
04 Audit Activity by Quarter and Type v4.0



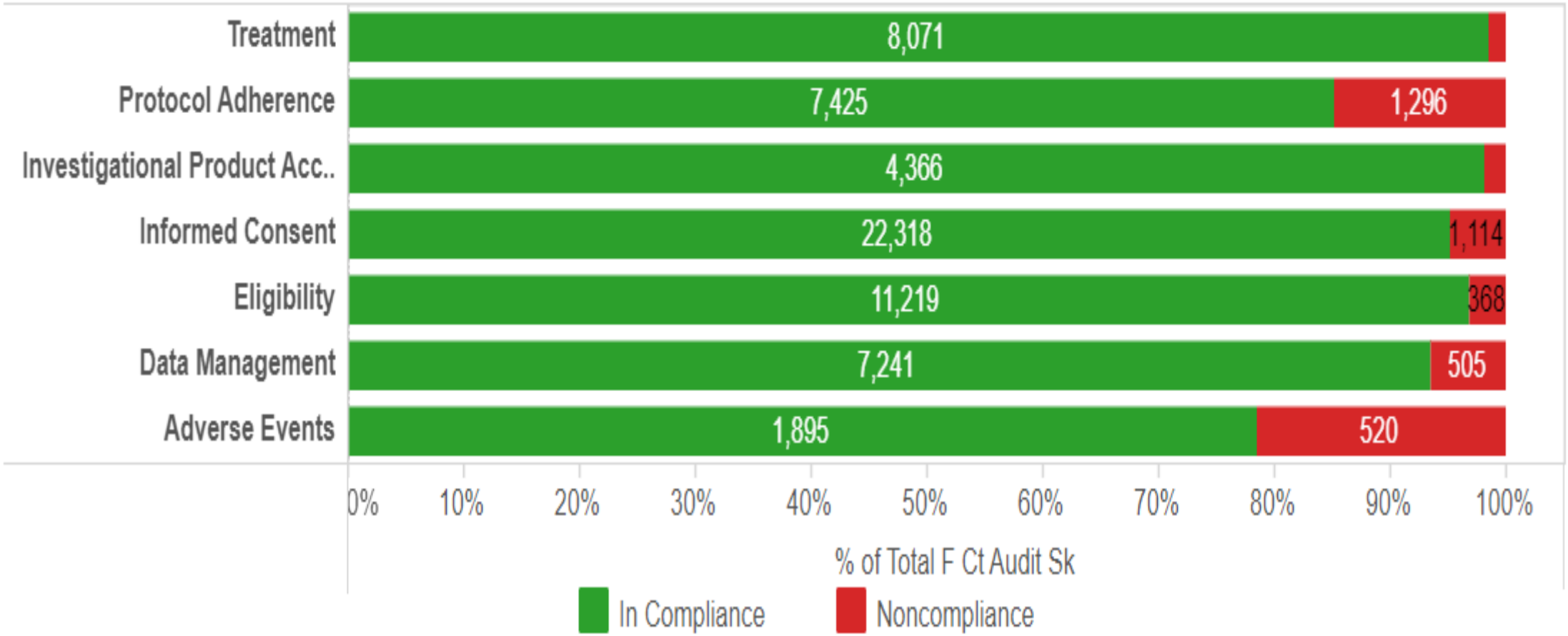
11 Audit Summary v4.0

Total Audits	Total Significant Deficiencies
797	522

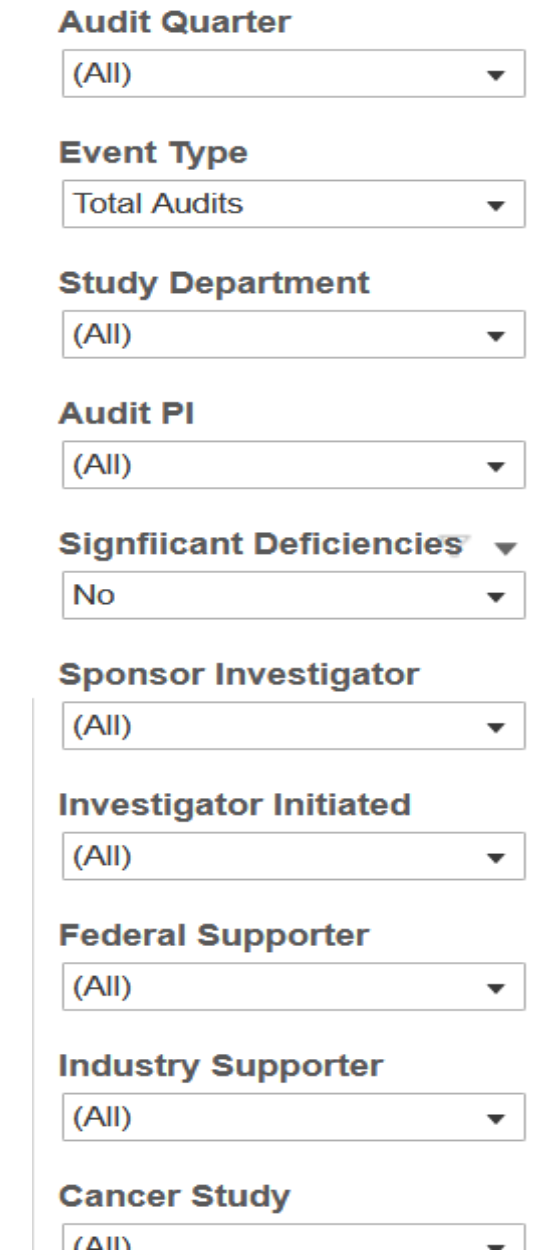
Significant Deficiencies Audit Count



Subject Checklist Compliance Ct/%

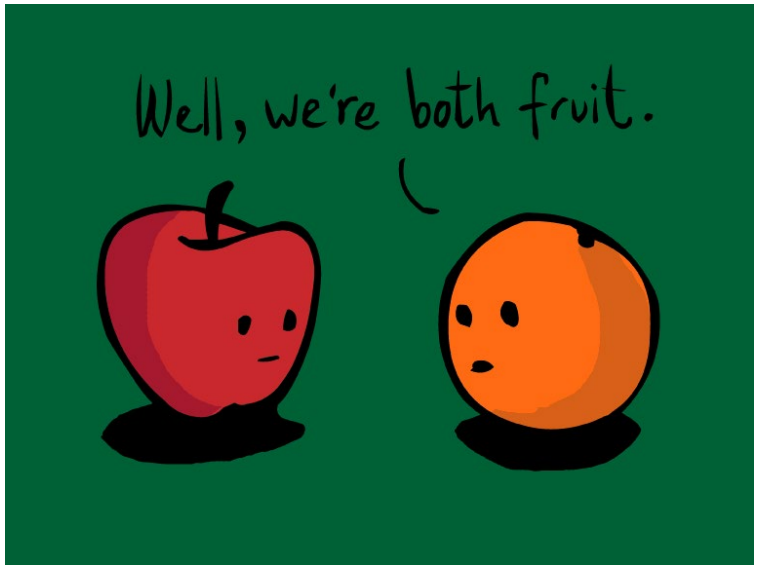


- Sort data for comparison
- Data originates from REDCap Study Information Form. Add fields of interest there.
- Show change over time
- Report departmental trends to School of Medicine Chairs



Trend Reporting: Variables

- Study duration
- Study complexity
- Study funding/resources
- Study team experience
- Investigator-initiated
- Sponsor-investigator
- Participant records pulled during review (e.g., date of enrollment)



Hartford HealthCare: Pamela Johnson

- Harford HealthCare (HHC) developed and implemented a noncompliance tracking system, which allows the HRPP to continuously monitor the frequency and types of noncompliance events that are reported by researchers or identified at audits. These metrics are utilized to institute targeted education and changes in practice. (Element 1.5.D.)

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

2022 AAHRPP Webinar Series

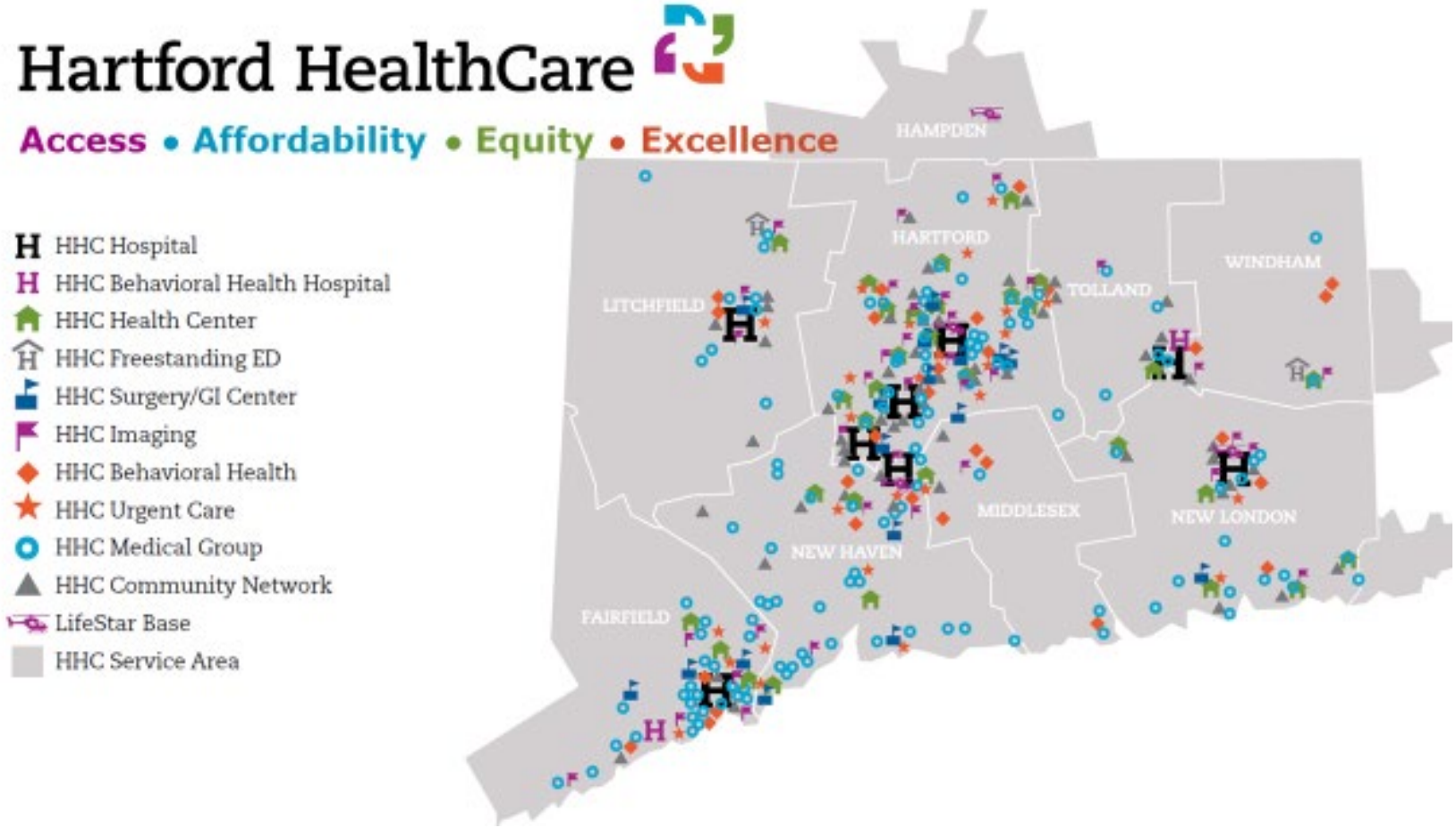
Addressing Element I.5.D. with a Non-Compliance Tracking Tool

Pamela Johnson, MPH, CCRC
Research Education & QI Program Manager, Hartford HealthCare

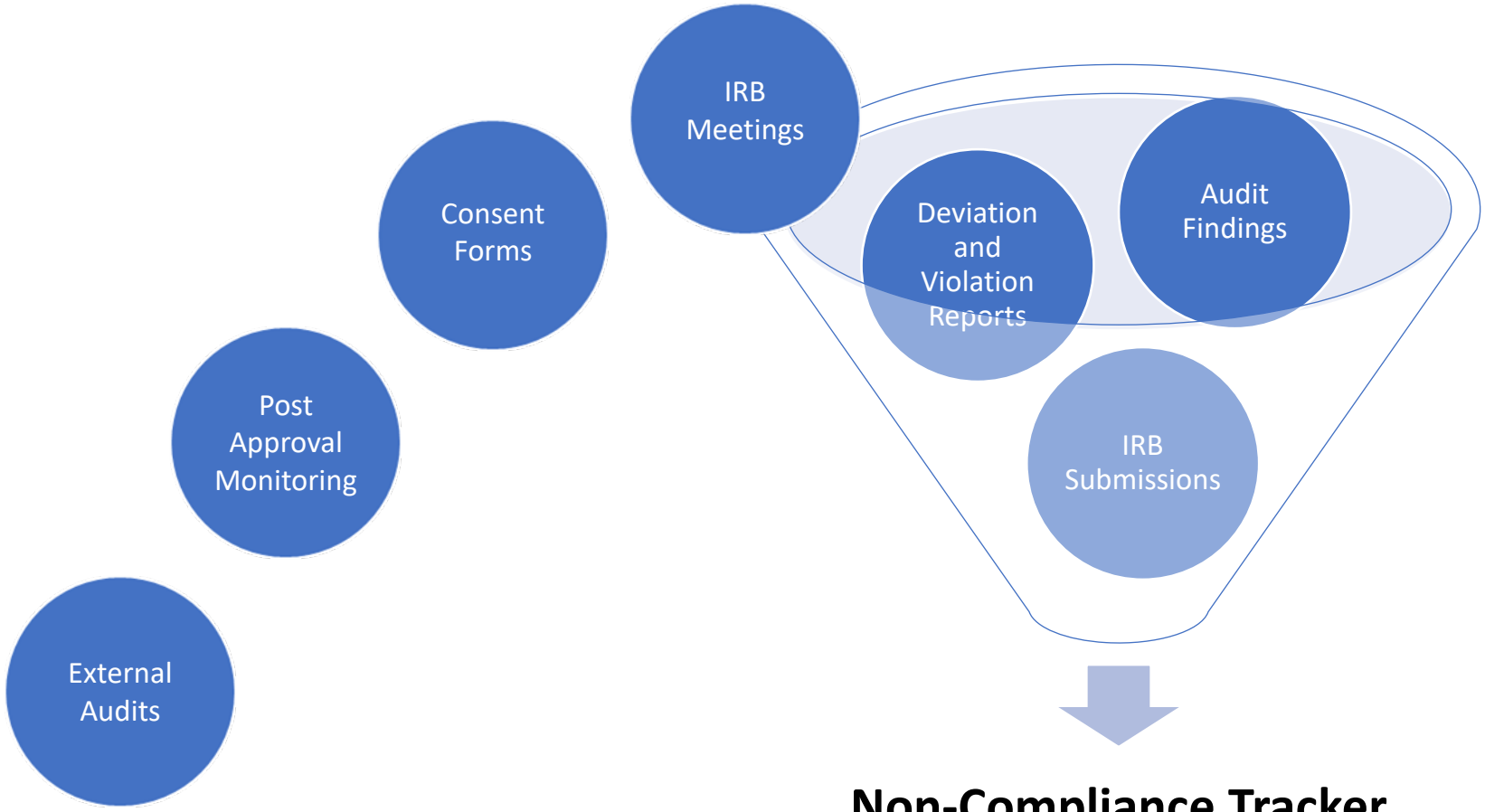
Hartford HealthCare

Our Organization

- 2nd largest employer in the state of CT
- 430+ locations with 7 Acute Care Hospitals
- 608 researchers
- 773 active studies, 156 Accepted facilitated review studies
- 2 IRB Panels



Non-Compliance has Multiple Sources



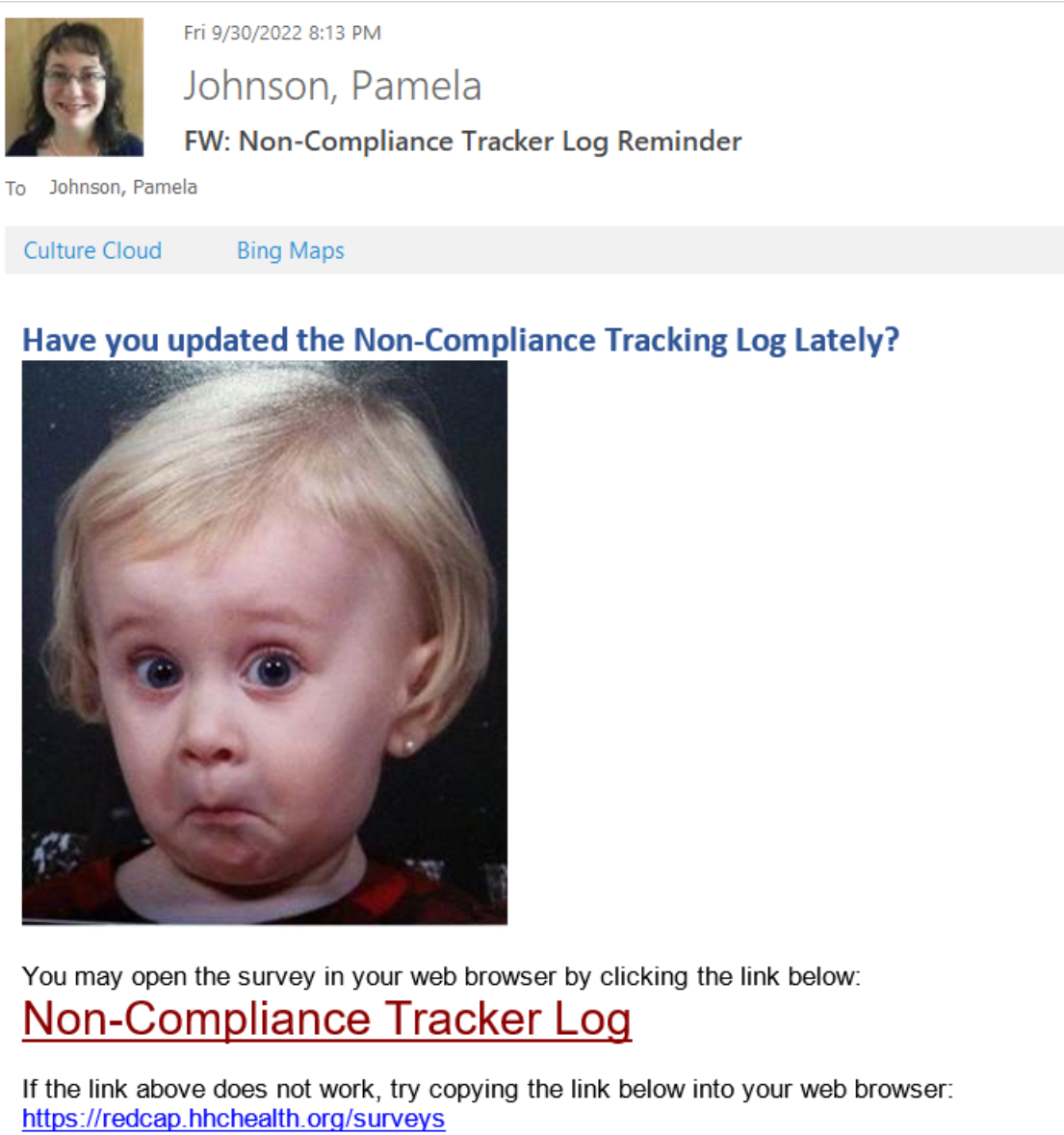
Non-Compliance Tracker

Key Tips to Consider in Development

1) Keep it simple
   - Too complex and they won't do it
   - Use drop downs and check boxes
2) Target key areas
   - Consent Non-Compliance
   - Other Non-Compliance
   - Action Requested
3) Have staff test it
   - Gather input, make adjustments and re-test
4) Have alerts in real time
   - Notifications give you a heads up on emerging trends so you can address issues promptly

Communication

- Send staff regular reminders with links
- Book mark the links (shortcuts)
- Remind staff of the importance of prompt data entry –to detect issues in real time!



Let's Try It!

Using the Data to Address Element I.5.D.

Non-Compliance broken down by:

- submission type

	Frequency	Percent
continuation	**31**	**49.2**
deviation	23	36.5
UAP	9	14.3
Total	63	100.0

- review type

	Frequency	Percent
Expedited	**40**	**64.5**
Full Board	22	35.5
*Total	62	100.0

- type of error

Error type	Freq	% of type	% of total
Protocol deviation	**26**	**41.3**	**66.7**
Other	8	12.7	20.5
AE/SAE/DSMB reporting deviation	2	3.2	5.1
Study drug/device deviation	1	1.6	2.6
Data security deviation	2	3.2	5.1
Screening or recruitment methods not approved	0	0	0.0
total	39	---	100.0

Using the Data to Address Element I.5.D.

Consent Non-Compliance broken down by;

- Type of error

Error Type	N	% of type	% of total
Signatures or dates missing/incomplete	**15**	**23.8**	**38.5**
Expired consent used	5	7.9	12.8
Wrong version of consent used	5	7.9	12.8
Consenter not study personnel or not approved to consent	3	4.8	7.7
Consent process not followed	**8**	**12.7**	**20.5**
Improper consent of non-English speaking person	1	1.6	2.6
Improper consent with LAR or Next of Kin	2	3.2	5.1
total	39	---	100.0

All Non-Compliance broken down by;

- PI
- staff involved
- processing IRB Administrator
- action taken → **NTF, Education provided, Audit Requested, UAP Requested, IO/FDA/OHRP Reporting**

Success

- ✓ Alerted to issues with REDCap e-consent during Covid that allowed for immediate mitigation efforts
  - Signature boxes not working
  - New versions overwriting previous versions
  - Date boxes in European format –made it look like patients were dating consents in the future
  - Use of e-consent without IRB approval
  - ➢ 37% of consent non-compliance was due to issues with REDCap process
- ✓ Able to track institutional trends across time to see old habits popping back up
  - Enables targeted re-education or closing of studies for continuing non-compliance
- ✓ Able to easily see volume of non-compliance in specific areas
  - Privacy and security concerns with more working from home and outside collaborators
- ✓ Able to easily track appropriate reporting

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Thank You!