From the Ground Up:
Implementing QA at the Site Level

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Disclosure to Webinar Participants

- To participate in the CEU course, participants must have:
  - Already enrolled to the Quality Assurance Webinar March 6, 2026 - From the Ground Up: Implementing QA at the Site Level course in ExpertusOne.
  - Joined the webinar via their individual login. If you are attending as a group in a conference room, only the person that logged into the ExpertusOne system can obtain CEUs for participation in the live webinar.
- To receive 1.0 CEU contact hour the participant must:
  - **Attend the entire educational activity and then complete and submit the post activity-evaluation via the Survey Monkey link that will be provided via WebEx chat message at the end of the webinar.**
  - CEU certificates for webinar participation will be batch-issued, approximately 1 week after the webinar, to all attendees who attended the entire webinar and completed the post-activity evaluation.

    Note: For site staff who were unable to attend the entire webinar: 1 hour CEU will also be offered via review of the webinar recording and completion of the post-course evaluation within a forthcoming: From the Ground Up: Implementing QA at the Site Level course posted in the CTSU CLASS learning management system. When available in CLASS, the link to the post-meeting enduring course will be accessible from: SWOG Quality Assurance Live Webinar Series | SWOG and the online CTSU CLASS catalog. The Disclosure for Enduring Course Participants will be posted under the "Resources" tab of the forthcoming course in CLASS.
- There are no relevant financial relationships with ineligible companies for those with the ability to control content of this activity.
- This nursing continuing professional development activity was approved by the Maryland Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.
- **Maryland Nurses Association Approval Code**: **IAA25-56**
- The expiration date of this activity is **March 5, 2028**.

What type of QA activities are done at your site?

1. Thorough review at the time of an audit.
2. Ongoing source checks of data entered in RAVE
3. Proactive reviews of research activities
4. Use of ongoing metrics
5. Ongoing education and training

A. 1
B. 1 , 2 & 3
C. 2 & 3
D. 3 & 4
E. 1 – 5
F. Other

Do you have a Quality Assurance (QA) program or QA specialist at your site?

A. No

B. We have added this within the last year

C. Yes, have had this greater than a year

D. Is this required?

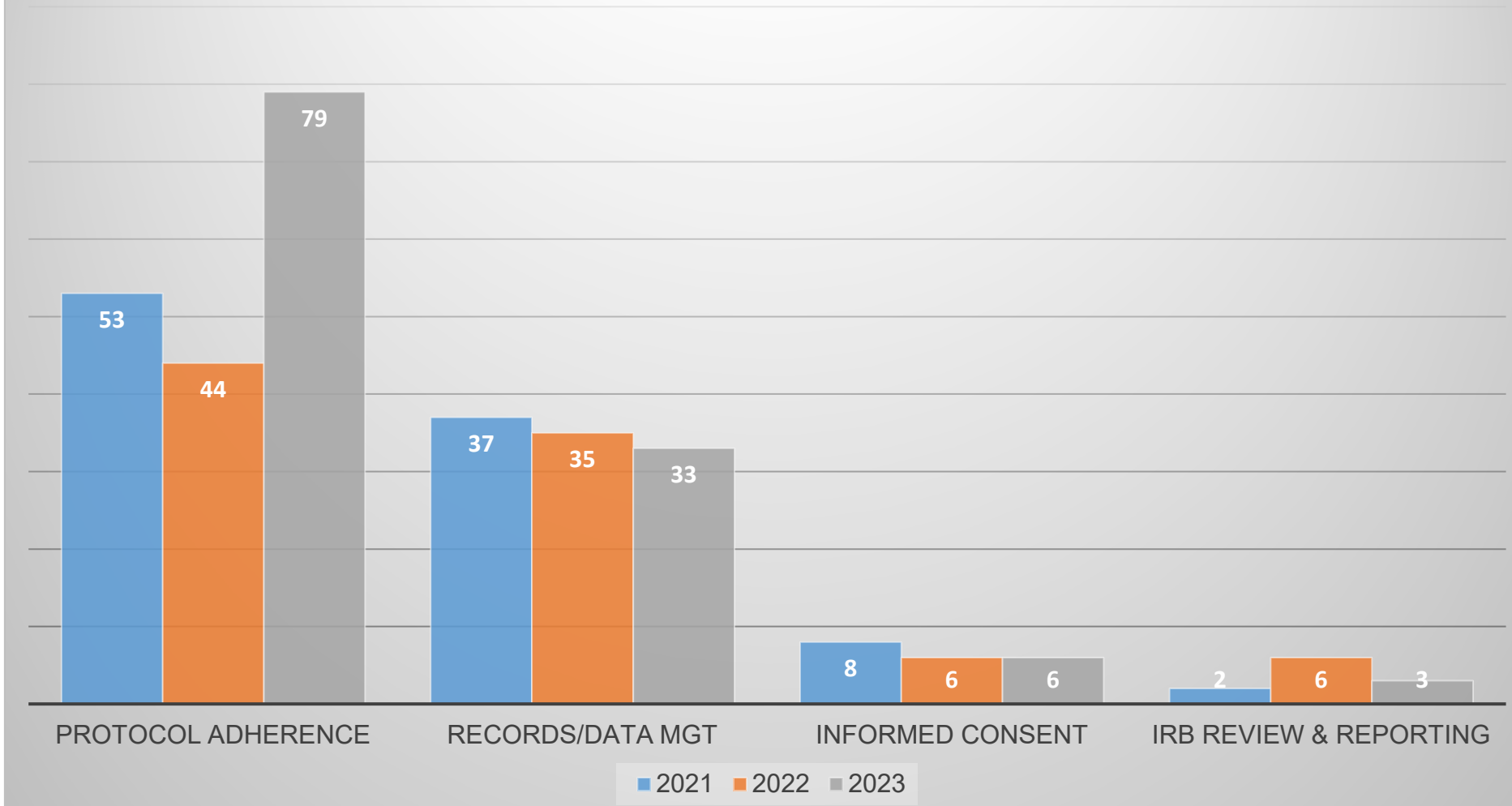
Why conduct QA activities?

PATIENT PROTECTION

DATA INTEGRITY

REGULATORY COMPLIANCE

Clinical Investigator Deficiencies
Post inspection Correspondence Issued



https://www.fda.gov/media/170390/download

Quality Definitions

- Quality:
  The degree to which a set of inherent properties of a product system or process fulfills requirements.

- Quality Assurance:
  All the planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented and reported in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirement.

Quality Management

ISO, 2015; APC, 2024
Goldfarb, 2018; B, 2024

From the Ground Up:

"Components of a Robust QA Program"

By Stephanie Scala, MA, CCRP

Manager, Research Quality Assurance Program

Beth Israel Lahey Health
Lahey Hospital & Medical Center | Research Administration

About Our RQAP- **Perspective**

Lahey Hospital & Medical Center Research Quality Assurance Program (RQAP)

- Part of **Research Administration** (HRPP-IRB, OSR, RQAP)

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Lahey Hospital & Medical Center | Research Administration

- Provides **QA oversight of all member organizations** under our FWA (7 sites/institutions and over 300 clinical trials at any given time)
- Team of **3 FT quality professionals-** 1 Manager, 1 Sr Quality Analyst, 1 QA
  - Extensive experience in research coordination and regulations
  - SoCRA/ACRP certification
- We focus on our **research support staff** (now centralized in a CRC) - they are our most captive audience

Goals of an RQAP

Typical QA Goals

Specific goals of a robust QA program should:

- Ensure comprehensive training, protocol adherence, and regulatory compliance
- Protect human subjects and maintain study integrity
- Promote ethical conduct and accurate data collection
- Support understanding of institutional policies and SOPs
- Identify issues early and implement corrective/preventive action, and
- Maintain communication, transparency, and recognition of both compliance and high performance

https://www.clker.com/clipart-599711.html

In short: A robust QA program systematically strengthens compliance, safety, and research quality.

Drivers of Quality Research

***What* Factors Contribute to the Overall Quality of Research?**

- ❑ Education & Knowledge
- ❑ Experience & Skill Proficiency
- ❑ Practice Expectations & Direction
- ❑ Clear & Accessible Tools & Policies
- ❑ Appropriate Supports & Resources
- ❑ Workload

https://www.wannapik.com/

- ❑ Perceived Benefit(s)
- ❑ Work Climate & Culture
- ❑ Effective Leadership & Program
- ❑ Ongoing Communication
- ❑ Accountability
- ❑ Others…

Getting Started- Where to Begin

So Where Does One Begin?

1. Define the Research Profile

- Determine the **volume** of ongoing research at your organization-*how much you'll oversee and assure.*
- Identify the **types** of research conducted (e.g., industry-sponsored, investigator-initiated, federally-funded, non-HSR, etc.)- *what you'll oversee and assure.*

2. Define Your Mission, Vision and Goals

- Specify what you aim to **achieve** and outline your **plan to accomplish it.**
- Assess **strengths, gaps** and **areas of concern** and consider **driving factors** (Slide 13).
- Establish your QA's **purpose and its relationship** *to the organization, leadership, researchers, study patients, IRBs, sponsors, and other stakeholders.*

Getting Started- Determine QA Activities

3. Identify and Determine QA Activities

Address key risk areas: protocol adherence, records/data, informed consent, and IRB compliance (Slide 6- Investigator Deficiencies) while considering all driving factors (Slide 13).

To strengthen compliance & quality:

- Use a **preventive, educational approach** (vs. reactive)
- Foster **collaboration, trust, and transparency** (we're a team)
- Define **core QA activities** (aligned with your mission and goals): training, monitoring, auditing, communication, corrective action, and
- Establish a formal **QA policy** outlining scope, roles and processes

Getting Started- Relationships & Communication

4. Build Strong Relationships and Maintain Consistent Communication

Establish a **routine**, **structured method for sharing important research updates** (e.g., policy changes, process reminders, tips, learning opportunities).

- A well-defined communication plan helps ensure messages are ***received*** and **acted upon**.
- Use a designated **point of contact** (communicator), define the **intended audience** and maintain a consistent **communication format** (email, newsletter) on a **predictable schedule** (every Monday), rather than sending ad-hoc messages.

When new staff join, send a **welcome email** and follow up with a brief **15-minute introduction** to build rapport and set expectations; establish office hours.

QA Activities

"QA Activities"

I. Educating

II. Monitoring

III. Auditing

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I. QA **Educational** Activities

Create and Maintain a Comprehensive Educational Training Program

Education and training are essential for preventing noncompliance, supporting protocol adherence, protecting human subjects, building staff competency and improving research outcomes.

1. Determine Types of Educational Activities

- **Institutional-Level Training:** Define core content (internal expectations), required learners, delivery methods (in-person, virtual, on-demand), training requirements and frequency.
  - Engage frontline staff and key stakeholders to ensure training content is relevant and well-received.
- **Leverage Existing Resources:** Utilize established education such as CITI, FDA materials and other available resources.
- **Offer Ongoing Education:** Provide continuing education through research presentations (L&L), free webinars, newsletters and recurring learning opportunities.
- **Conduct Readiness Assessments:** Meet with study teams after IRB approval to confirm preparedness and identify key risk areas- standardize this review using a template.

2. Create and Promote Available Resources

- Identify and/or create key policies, SOPs, and guidance essential for study conduct.
- Store resources in a **centralized, easily accessible location** and regularly remind staff of their availability.

II. QA **Monitoring** Activities- Review of Monitor Visit Reports

Routinely preform core Monitoring Activities to ensure ongoing human subject protection and protocol compliance.

1. **Collect & Review Monitor Visit Reports:**

   QA review of monitoring follow-up reports helps to:

   - Identify findings and gain insight into site operations (**leverage what others have already audited**).
   - Detect **trends in noncompliance** across departments, or the broader research community.
   - Support research staff in **resolving findings**, and
   - Ensure monitors are not making **inappropriate requests**.

   Track and Assess Trends:

   - Perform an overall assessment (receipt timing, findings-missing/ expired docs, etc.) of each report using a standardized **template**.
   - **Log findings & assessments** in a **tracking system** to highlight studies requiring increased oversight.

QA **Monitoring** Activities- Review of ICFs

2. Review Executed Informed Consents

Each consent should be evaluated to confirm:

- The **correct**, **current IRB-approved** ICF version and **mode** were used
- The consent discussion was conducted by an **IRB-approved investigator** or authorized study team member, in accordance with organizational policy
- The **ICF is complete**, including all required signatures, printed names, dates, times and any additional required sections (checkboxes, initials)
- Informed consent was obtained ***before*** any research procedures were initiated
- For **reconsents**, the process followed **IRB directives** (appropriate timing, method, and intended population), and
- **Communicate findings** to the study team with appropriate guidance or re-education as needed

Track and Assess Trends:

- Log all noncompliance in a **tracking system**.
- Look for **trends** over time to **identify recurring issues** and **support early intervention**.

QA **Monitoring** Activities- Review of Minor Deviations

3. Collect and Review Deviation Reports

Minor deviations are common, but **repeated minor issues can escalate into major noncompliance** if not addressed.

- **Establish a process** for prompt reporting of minor deviations to QA (e.g., within 21 days of awareness) to support rapid response to noncompliance, early correction and identification of emerging trends.
- Create and require completion of a **minor deviation report form** that captures essential information (*who, what, when, where, why, how and impact*) **from study teams** similar to what's required for IRB review of major deviations, and
- Define **trigger criteria** (impact, avoidability, attribution) that signal when further QA intervention is needed.

Track and Assess Trends:

- Log all deviations in a **tracking system** (study, deviation type, attribution, avoidability, impact, CAPA).
- Track submitted reports for deviation **trends, repeated noncompliance** or **noted improvements**.

III. QA **Auditing** Activities- Planning and Selection

Perform routine and for-cause Auditing as this is a key function of any robust QA program.

- Standardized templates and tools support consistency.

1. **Annual Audit Work Plan**
   - Develop an **annual audit plan** to identify which studies to audit and adjust priorities as needed.
   - If *resources are limited,* focus audits on highest-risk areas: **ICF, eligibility, safety endpoints, AEs, dose mods, primary endpoint data**.

2. **Audit Indicators Assessment Tool**
   - Establish a **protocol review activity** and an "**Audit Indicator Assessment Tool**" to determine which studies to audit, and why.
     - Incorporate **key risk indicators (KRIs)** to guide study selection (new investigator, unmonitored, etc.).

QA **Auditing** Activities- Auditing Consistently

Audit Tools & Templates

3. Audit Templates

Create comprehensive **audit tools ("Audit Templates")** that guide auditors of what to review and how to conduct the audit.

- Develop **focused** templates: Regulatory, Patient Files and other areas (DARFs, IRB, Financial)
- Create **study-type specific templates** (e.g., drug, device, drug/device, non-interventional) aligned with your research portfolio; include space to capture findings and provide an overall assessment.

4. Auditing Tracking Log

Maintain a log listing each study, its KRIs, and the planned audit type and frequency and audit status to track progress and prioritize work.

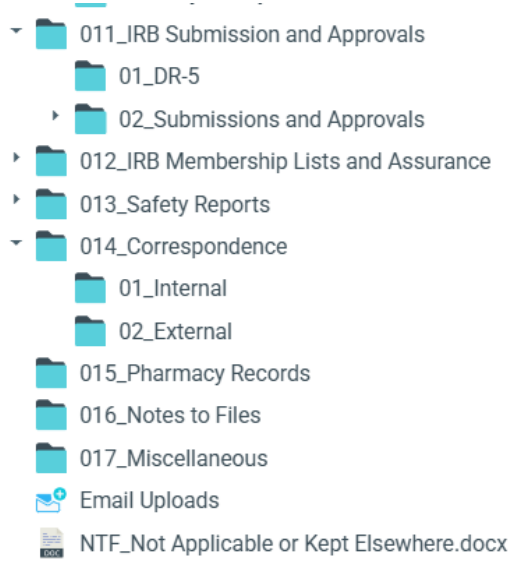
QA **Auditing** Activities- Reporting, Corrective Actions and CAPA Plans

5. **Audit Findings Report Template**: Use a **standardized report** to document findings and share with the study team:
   - each identified noncompliance,
   - the related regulation, policy, or ICH-GCP reference,
   - required corrective actions, and
   - an overall audit assessment ranging from “excellent” to “requires a CAPA plan.”
6. **Annotated Templates:** Create *annotated* versions of finding reports with **common findings,** and **corresponding CAPAs** to streamline audits & standardize guidance.
7. **Audit Response Tool:** Provide research staff with am **Audit Response Tool** template **to report their corrective actions** and submit supporting evidence.
8. **CAPA template**: Use a CAPA template for significant issues; include root-cause analysis and follow **SMART** criteria (specific, measurable, achievable, relevant/realistic, time-bound).

Establish A **Regulatory Record** Framework

Develop an organizational framework for regulatory files.

- **Centralize and standardize** how **essential records** must be **organized and maintained.**
  - Promotes regulatory compliance and **high-quality recordkeeping** across all research staff.
- Audit these files using the **regulatory audit template- address** and **track findings**.



Continuous QA

Continuous QA and QI

A single QA activity often spans multiple QA domains, risk areas & outcomes.

- **Each action can achieve several objectives** simultaneously (ensuring patient safety while maintaining regulatory compliance).
- Together these activities create a **continuous quality improvement loop**.
  - They help teams understand research requirements
  - Enable early issue detection
  - Support rapid correction, and
  - Prevent future noncompliance- ultimately driving high-quality research

How QA Activities Help Minimize Investigator Deficiencies

Deficiency Addressed	QA Mitigating Activity	Result
Protocol Adherence	❑ Training & education ❑ Readiness assessments ❑ MVR review ❑ Routine audits ❑ Deviation review	➢ Fewer protocol deviations ➢ Improved protocol compliance/ patient safety ➢ Earlier detection of systemic issues ➢ Strengthened workflows ➢ Improved study activation readiness
Records & Data Management	❑ Training & education ❑ eReg structure & maintenance ❑ eReg & routine audits ❑ MVR review	➢ Improved record keeping ➢ Improved inspection readiness ➢ Complete & compliant regulatory files ➢ Earlier detection of data/documentation errors
Informed Consent (ICF)	❑ Training & education ❑ ICF review ❑ Deviation review	➢ Reduced consent errors ➢ Fewer deviations ➢ Improved overall compliance ➢ Earlier issue detection ➢ Enhanced protection of patient rights, welfare
IRB Review & Reporting	❑ Training & education ❑ eReg structure ❑ eReg, IRB & routine audits ❑ MVR review	➢ Reduced IRB-related errors ➢ Improved inspection readiness ➢ Better record keeping ➢ Accurate, timely IRB submissions ➢ Improved IRB communication & oversight

https://www.flaticon.com/free-icon/ eliminate_5290035

UPMC Hillman Cancer Center

Mary Horak, MS, CCRP

Director, Clinical Research Services

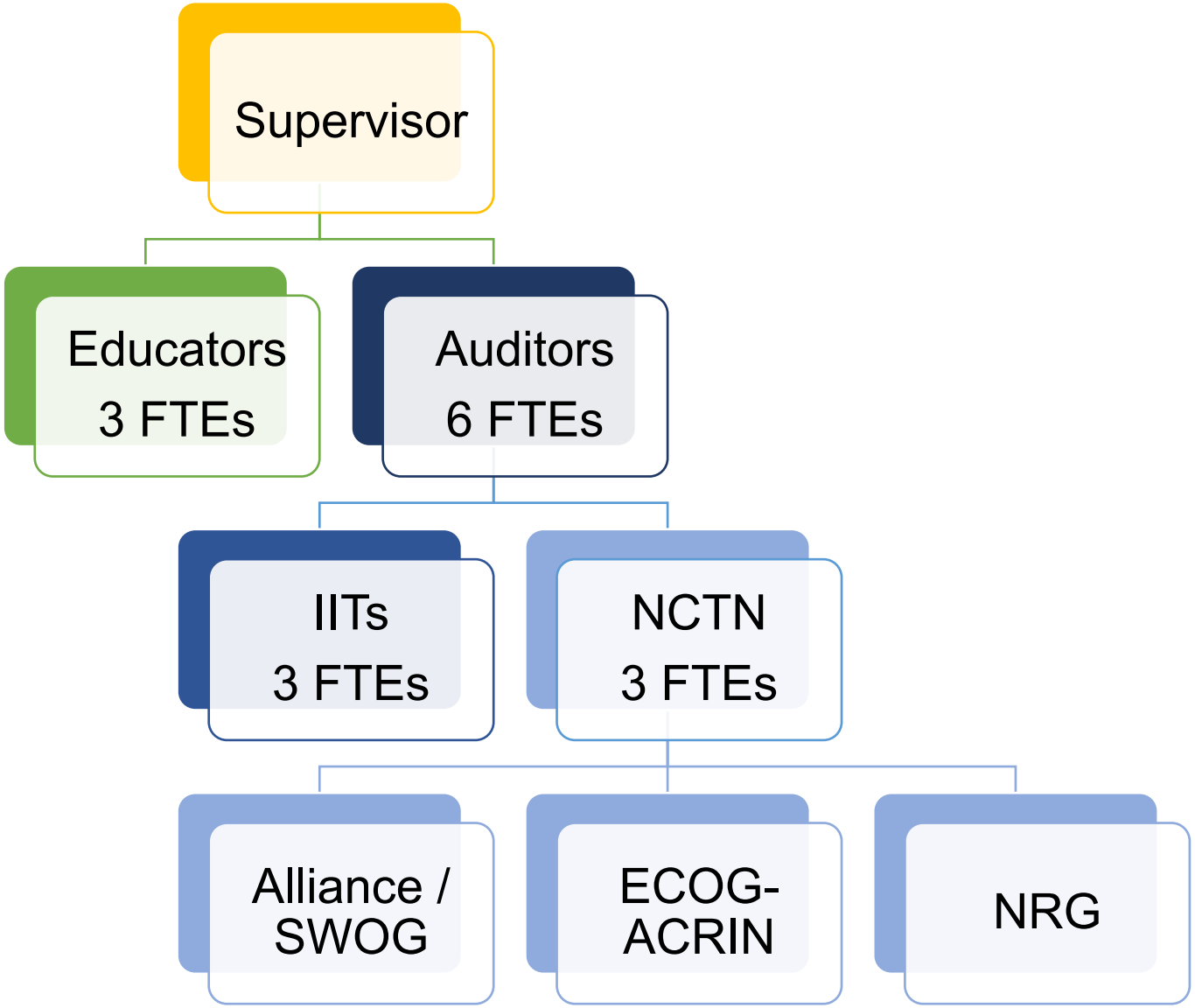
About Us… UPMC Hillman Cancer Center

- NCI Designated Comprehensive Cancer Center
- LAPS institution
- Member of Alliance, ECOG-ACRIN, NRG, SWOG, and ETCTN
- UPMC Children’s Hospital is a member of COG

About Us… CRS Quality, Education, and Compliance Team

- An ancillary service of the Clinical Research Services (CRS) department
- Provides QA oversight of all CRS staff (235 FTEs) and non-industry trials
  - 44 integrated component network sites and over 500 clinical trials at any given time
- Team of 10 FT quality professionals – 1 Supervisor, 3 Educators, and 6 Auditors
- Extensive experience in research coordination, regulations, and data entry
  - SOCRA/ACRP certification required for the Senior level role
- QA efforts focus on structured onboarding, ongoing education and resources, and internal monitoring with feedback

QA/QC Team Staffing Model



I. QA **Educational** Activities

- **Create and Maintain a Comprehensive Educational Training Program**
  - New hire onboarding is a two-step process comprised of QA Orientation (research foundation and theory) and Mentorship (hands-on training)
  - Ongoing educational opportunities and trainings are managed through QA team office hours and various educational series

I. QA **Educational** Activities

QA Orientation

- New staff training includes up to a fourteen-day orientation period with the QA Educator team who teach basic research principles prior to the new hire training with a mentor in an assigned disease center
  - Each day of the fourteen-day orientation period includes one-on-one training regarding specific components of the research process
- Companion *Skills Labs* are completed by the new hires for the topics reviewed with the QA Educator team
  - The Skills Labs are formatted as either a quiz or are a task-based exercise related to the material and topics reviewed

I. QA **Educational** Activities

QA Mentorship

- Once the initial fourteen-day orientation is completed, the new staff train directly with an assigned mentor in their disease center

- Bi-weekly *Touch Base* meetings are held once the twelve-week mentorship begins to review experiences and set goals for the next two weeks of training

I. QA **Educational** Activities

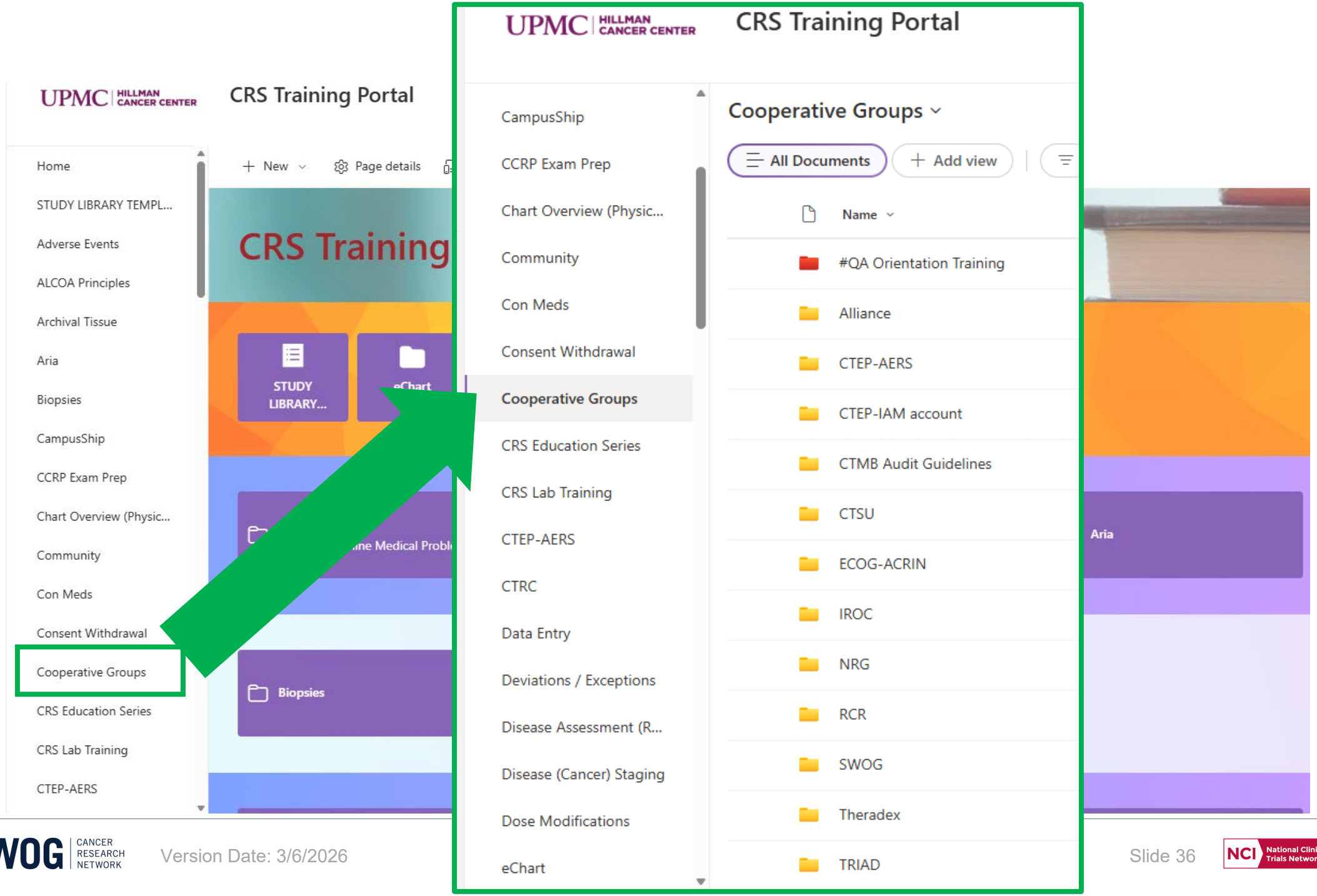
Determine Types of Educational Activities

- **Institutional-Level Training:** Institutional annual mandatory modules, CITI modules, Foundations to Practice Oncology Series, Antineoplastic Therapy & Immunotherapy Course, Biological Substance Shipping training
- **Leverage Existing Resources:** Links to the internal Infonet, CTEP-AERS, NCI PMB, AJCC Staging manuals
- **Offer Ongoing Education:** Daily QA Office Hours, CRS Educational Series, Refresher Series, Safety Training, Eligibility Training, Data Entry Training, All Staff Meetings, Ad Hoc trainings

I. QA **Educational** Activities

Create and Promote Available Resources

- SOPs and essential documents are stored in eReg, with standardized study templates for ease of navigation
- Store resources in a centralized, easily accessible location and regularly remind staff of their availability
    - Departmental resources are hosted on Microsoft SharePoint sites
        - CRS Central – central location to navigate to departmental resources
        - CRS Training Portal – education portal managed by the QA team
        - Regulatory Hub – education and process portal for the regulatory team


UPMC HILLMAN CANCER CENTER
CRS Training Portal
Home
STUDY LIBRARY TEMPL...
Adverse Events
ALCOA Principles
Archival Tissue
Aria
Biopsies
CampusShip
CCRP Exam Prep
Chart Overview (Physic...
Community
Con Meds
Consent Withdrawal
Cooperative Groups
CRS Education Series
CRS Lab Training
CTEP-AERS
New
Page details
CRS Training
STUDY LIBRARY...
eChart
Biopsies
Aria
UPMC HILLMAN CANCER CENTER
CRS Training Portal
CampusShip
CCRP Exam Prep
Chart Overview (Physic...
Community
Con Meds
Consent Withdrawal
Cooperative Groups
CRS Education Series
CRS Lab Training
CTEP-AERS
CTRC
Data Entry
Deviations / Exceptions
Disease Assessment (R...
Disease (Cancer) Staging
Dose Modifications
eChart
Cooperative Groups
All Documents
Add view
Name
#QA Orientation Training
Alliance
CTEP-AERS
CTEP-IAM account
CTMB Audit Guidelines
CTSU
ECOG-ACRIN
IROC
NRG
RCR
SWOG
Theradex
TRIAD

I. QA **Educational** Activities

Tools used by the Educator team

- **Orientation Tracker** – an Excel spreadsheet used to track start date, QA mentor, disease center mentor, dates of CITI completion, external trainings, etc.
- **QA Orientation Guide** – documents completion of QA Orientation tasks
- **Mentorship Skills Checklist** – a role specific document which outlines tasks and skills to be reviewed with the disease center mentor
- **Email templates** – used for consistent communication, Touch Base Meeting summaries, alerting staff of upcoming trainings / outlining tasks

II. QA **Monitoring**

Routinely preform core Monitoring Activities to ensure ongoing human subject protection and protocol compliance.

- The QA Auditors oversee ‘real time monitoring’ for Investigator Initiated Trials (IITs) and NCTN trials
- The six-person team is split so that three staff are dedicated to IITs and three staff are dedicated to NCTN trials
  - The NCTN team tracks subject registrations via OPEN, which drives monitoring activities
  - The IIT team arranges quarterly monitoring visits for each applicable IIT

II. QA **Monitoring**

Routinely preform core Monitoring Activities to ensure ongoing human subject protection and protocol compliance.

- The teams strive for risk-based monitoring, reviewing 100% of consents and at a minimum 30% of cases for source data verification
- Upon notification of an upcoming NCTN audit, the IIT auditors may shift focus to assist with NCTN audit preparations

II. QA **Monitoring**

Tools used by the Auditor team

- **REDCap Tracker** – tracking of subject cases, specific source documents, data, and miscellaneous information reviewed during a specific monitoring visit
- **Monitoring Checklist** – ensures consistency throughout the team and within each subject chart
- **Data Clarification Forms (DCFs)** – generated with the monitoring findings and queries; sent via email to the applicable staff for review and updates

III. QA **Auditing**

- Upon notification of an upcoming audit, a subject registration list is exported from OPEN and filtered for enrollments since the prior audit
  - List is compared for those subjects already monitored through the Real Time Monitoring process
- Pre-audit priority is given to the integrated component sites with few registrations or those subject cases with high risk (i.e., staff turnover, known SAEs or protocol deviations, FDA registration trials)

III. QA **Auditing**

- The QA Auditor team meets to determine a pre-audit strategy and timeline based upon the known NCTN case selection metrics:

Case Selection Metrics	
1	A minimum of **4** protocols representing studies conducted at the institution must be selected, when applicable.
2	Emphasis is given to: IND, registration, high accrual, prevention/cancer control, multi-modality trials and advanced imaging studies.
3	10% of patient cases accrued must be selected from each participating institution (see the NCTN org chart). CTMB requires that the auditing group round up (for example, if 12 eligible cases=2 selected for audit): •10% of treatment cases where the auditing Group is the protocol lead or credited with the enrollment; **PLUS** •10% of patient cases from protocols with advanced imaging studies/imaging studies embedded in treatment protocols; **PLUS** •10% of patient cases enrolled onto DCP cancer control/prevention trials; **PLUS** •1 patient case from **every registration trial** selected for audit for every site being audited.
4	At least 1 unannounced case is reviewed during the audit (limited review of informed consent, eligibility, GDQ). The unannounced case selection will be released ***1 business day prior*** to the audit. Note: For audits that are conducted off site/remotely, the unannounced audit case requirement has been removed.

Table Reference: Preparing for an ECOG-ACRIN Audit, ECOG-ACRIN Audit Program; Fall 2023 Group Meeting

III. QA **Auditing**

- NCI Guidelines for Auditing Clinical Trials for the NCI National Clinical Trials Network (NCTN) Program Including NCI Community Oncology Research Program (NCORP) AND NCORP Research Bases

  https://dctd.cancer.gov/research/ctep-trials/for-sites/nctn-auditing.pdf

- List of FDA registration trials: https://www.ctsu.org/RegLicTrialsReport.aspx

- Internal Audit Checklist – ensures applicable stakeholders are notified and consistent communication

Continuous QA

- CRS QA Educators and Auditors operate as an integrated QA/QI program, using monitoring results, audit findings, and eligibility reviews to identify knowledge gaps and risk areas
- Education topics for the CRS Refresher Series and CRS Educational Series are data-driven, informed by audit trends, internal monitoring outcomes, Office Hours questions, and combined QA team discussions
- Continuous feedback from multiple sources, including new hire touch bases, manager requests, and real-time staff inquiries, ensures education is responsive, targeted, and timely
- The closed-loop approach supports continuous quality improvement, aligning education, monitoring, and remediation to reinforce protocol compliance and high-quality data practices

Essentia Health NCORP

Tammie Mlodozyniec BS, CCRP

Clinical Research Manager and NCORP Administrator

Essentia Health

Team-

Essentia Health Community Cancer Research Program-NCORP (EHCCRP)

- EHCCRP team along with Essentia compliance team
- Oversees all oncology research activities at Essentia and non-Essentia sites (29 sites 300+ clinical trials at any given time)
- Team consists of **18 FTE research professionals- 1 Adminstrator-1 Medical Director**
- Our **focus** is as follows:
  - #1-Patient safety-do no harm
  - #2-Team
  - #3-EHCCRP-program

Essentia Health

EHCCRP Goals

- Set team up for SUCCESS!! (6 month onboard training & ongoing education)
- Team has resources to do their job!
- Protect human subjects
- Promote ethical conduct and accurate data collection
- Support understanding of EHCCRP SOPs
- Identify issue(s), review with team at weekly huddle, and implement corrective/preventive action
- Open communication, transparency, and recognition of both compliance and high performance
- Ask questions-never assume!!

Essentia Health

Onboarding

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Essentia Health Community Cancer Research Program (EHCCRP)
Oncology Clinical Trials

Clinical Research Orientation/Training

Name: _____

Hire Date: _____

Position: _____

	Trainer	Date Discussed/ Demonstrated	Trainer's Initials	Date Performed	Manager's Initials
Research Program Organization	Tammie				
NCI Organization (NCORP)	Tammie				
Research Bases	Tammie				
ECOG	Tammie				
NRG	Tammie				
Alliance	Tammie				
SWOG	Tammie				
Wake Forest	Tammie				
MNCCTN	Tammie				
Pharmaceutical Trials	Tammie				
Consortium Trials (AFT/ACCRU)	Tammie				
Investigator Initiated	Tammie				
CREDIT	Alaina				
Patients (Pre-Study/On Study)	Alaina				
Protocols	Alaina				
Documents	Alaina				
Patient Check-offs	Alaina				
OCT Calendar	Alaina				
Reports	Alaina				
Billing 101	Tammie				
OPEN Funding Dates	Taylor				
Highlighted Test Schedules	Tammie/Alaina				
Funding Sheets	Alaina				
MCA	Tammie/Alaina				
Study Start Up	Tammie/Michael				
Feasibility	Tammie/Michael				
Cancer Research Committee	Tammie/Michael				
IRB process	Tammie/Michael				
Consent creation	Tammie/Michael				
HIPAA	Tammie/Michael				
Credentialing/Ancillary Depts.	Tammie/Michael				
Binder Layout (Forms)	Tammie/Michael				
Study Maintenance	Tammie/Michael				
Amendments/Updates	Tammie/Michael				
Mailings	Michael/Taylor				
Patient Notifications	Michael				
Unanticipated Problem/Event	Michael				
Deviations/Violations	Michael				
Where to find study documents	Michael				
CTSU Reg Sub Portal	Michael/Taylor				
MD Research Paperwork	Michael				

	Trainer	Date Discussed/ Demonstrated	Trainer's Initials	Date Performed	Manager's Initials
Protocols	Michael				
Layout	Michael				
Differences	Michael				
Informed Consent	Sarah				
Process	Sarah				
Methods	Sarah				
Age Specific Concerns	Sarah				
Reproductive Risks	Sarah				
Documentation	Sarah				
Patient Chart / Data					
Research Chart Layout	Taylor				
On-Study Forms	Taylor				
Off Study checklist	Taylor				
Follow-Up Forms	Taylor				
Data Submission timeline	Taylor				
RAVE training	Taylor				
Source Documentation Portal	Taylor				
Test Schedule	Taylor				
Location on Web Site	Taylor				
Patient Tally Book	Taylor				
Prepping Charts	Taylor				
Processing Charts	Taylor				
Patient Transfer Sheet	Taylor				
EPIC					
Prior Authorization	Taylor				
Imaging Prior Authorization	Taylor				
Problem List	Taylor				
Episodes	Taylor				
Lab Order Preference	Taylor				
Putting in Orders	Taylor				
MyHealth Recruitment	Alaina/Tammie				
Out of Office InBasket	Taylor				
Level of Service	Sarah				
RSH Record (Linking)	Alaina/Tammie				
Point of Care Scanning	Alaina/Tammie				
Laboratory Specimens	Taylor				
Obtaining	Taylor				
Shipping	Taylor				
Kit / Supply Ordering	Taylor				
Pathology Specimens	Taylor				
Obtaining	Taylor				
Shipping	Taylor				
Specimen Tracking Systems	Taylor				
ECOG	Taylor				
SWOG	Taylor				
Alliance/BioMS	Taylor				
Radiology	Taylor				
PACS	Taylor				
Requesting	Taylor				

	Trainer	Date Discussed/ Demonstrated	Trainer's Initials	Date Performed	Manager's Initials
Shipping/Uploading	Taylor				
Protocol Specific Central Review	Taylor				
RECIST/RANO training	Taylor				
Adverse Event Assessments					
Protocol Location	Taylor/Sarah				
AE Assessment Form	Sarah				
Routine Reporting	Taylor				
CTEP-AERs	Taylor				
Investigational Drug	Marsha				
Handling Policy	Marsha				
Ordering	Marsha				
Storage	Marsha				
Delivery	Marsha				
Drug Log	Marsha				
Returning	Marsha				
Patient Screening	Taylor				
Screening Sheet	Taylor				
Procedure	Taylor				
Eligibility Criteria	Taylor				
Staging Procedure	Taylor				
Communication with MD	Taylor				
GCA	Taylor				
Patient Management					
Pre-Study RN process	Sarah				
Treatment Plan (Beacon)	Sarah				
Treatment Chart Guts	Sarah				
Oral Treatment process	Sarah				
Dose Determination	Sarah				
Dose Modification	Sarah				
Communication with Care Team	Sarah				
Documentation	Sarah				
RN Orders & Considerations	Sarah				
Licenses/Certifications					
Chemo/Bio – RN only	Sarah				
State Licensing – RN only	Sarah				
BLS	Sarah/Taylor				
Audits					
Preparation	Tammie/Sarah/Taylor				
Procedure	Tammie				
Repercussions/Responses	Tammie				
Resources					
Oncology/Staging Books	Taylor/Sarah				
CancerHelp website	Taylor/Sarah				
CTCAE Coding	Taylor/Sarah				
Resource Center	Taylor/Sarah				
Office Coordination					
Stockroom Supply Process	Taylor				
Standard Operating Procedures	Tammie/Alaina				

	Trainer	Date Discussed/ Demonstrated	Trainer's Initials	Date Performed	Manager's Initials
Education Opportunities					
Research Base Meetings	Tammie				
Staff Meetings	Tammie				
Team Meetings	Tammie				
Equipment					
Computers	Tammie				
Computer Network (T-Ranch)	Taylor				
Printer/Fax/Copier	Taylor				
Phones	Taylor				
1:1 Overviews					
	Tammie				
	Michael				
	Alaina W.				
	Marsha				
	Erika				
	Carly				
	Darcie				
	Sarah				
	Karin				
	Alex				
	Madison				
	Catey				
	Lindsey				
	Sydney				
	Kendal				
	Barb				
	Taylor				
	Olivia				
	Betsy				
	Andrea				

I accept responsibility for performing the above within the established guidelines/timeframes.

Signature: _____ Date: _____

Briefings

Template	Study Briefing

SPECIAL NOTATIONS	REQUIREMENT DETAILS	REQUIREMENT COMPLETED Y/N
LAB REQUIREMENTS	Archival Tissue, Urine Protein, EDTA Whole Blood, Streck cfDNA, Streck RNA tube	**Streck RNA and cfDNA tubes provided, EDTA instintutional supplies**
QUESTIONNAIRES	FACT GA, PRO-CTCAE	
TISSUE SUBMISSION	Archival Tissue, FFPE	**No kits**
RT REQUIREMENTS		
RADIOLOGY REQUIREMENTS	N/A	**N/A**
TRAINING REQUIREMENTS	N/A	
FUNDING	Sendout, Veinipuncture (if not drawn alongside SoC labs. Nivolumab provided	
AE ASSESSMENTS	Standard plus start/stop dates	

Template	Study Briefing

PHI DISCLOSURE	Standard PHI	Follow Essentia Health Policy EHA3032
MISC.	Opening in Brainerd, Fargo, Duluth, and Ashland, as well as some satellite locations.	
OUTREACH	Complete review for the following: • Lab – Keep Lindsey in the loop • Radiology – Standard • Radiation –N/A • Treatment – On pharmacy sheet	

STUDY BRIEFING ATTENDANCE SIGN-OFF

By signing this debriefing, I attest that I have reviewed all required training modules, protocol, and/or any special requirements listed above for my study role. I agree to follow GCPs and instructions provided in the protocol in the conduct of this study. This briefing was completed prior to any study procedures, and I was given the opportunity to ask questions.

NOTE: The study briefing does not replace the teams (CRC/CRA) responsibility for reading the protocol in its entirety. It is the responsibility of each team (CRC/CRA) to brief/train any staff member who is covering this study in their absence.

PRINT NAME	SIGNATURE	TITLE	DATE
Barbara Morris		RN	

EHCCRP Goals

Essentia Health

EHCCRP Internal Audits-*staying on top of it*

- Research chart review
  - consent review/eligibility criteria/documentation/Beacon/pill diaries/QOLs
- RAVE
- Schedule Events
  - Protocol test schedule/CREDT (CTMS)
- RECIST
- AE/AERS
- PHI double checks

Essentia Health

Team Weekly Huddle-Transparency

- Review of weekly deviations (opportunity to learn)
- Review of research bases data reports (IPEC, CTSU, SWOG, etc.,)
- Review of internal audits and outside audits
- Review of internal process vs. SOP
- Review audits with Essentia Research Compliance team
- Meeting minutes to leadership (Director/PI)

Essentia Health

Stephanie Scala: stephanie.a.scala@lahey.org

Mary Horak: mhorak@upmc.edu

Tammie Mlodozyniec: tammie.mlodozyniec@essentiahealth.org

Prior QA Webinars Accessible for Review

Previous Webinars and Upcoming Webinar Information is posted at:
SWOG Quality Assurance Live Webinar Series | SWOG

All enduring courses are posted via CTSU CLASS

CEU Courses:

- **Navigating Adverse Events: What's New in CTCAE v6** (1 contact hour)
- **Biospecimen Collection and Submission** (1 contact hour)
- **Cytogenetics** (1 contact hour)
- **Serious Adverse Event Reporting & Updates** (1 contact hour)
- **Workload Prioritization in Clinical Trials** (1.5 contact hours)
- **Disease Assessment in Solid Tumors** (1 contact hour)

CEU Courses Expiring Soon:

- **Best Practices for Informed Consent**
  1 contact hour; CEU Expiration: 3/15/26.
  Last Day to Enroll to CLASS course: 3/14/26;
  Last day to Complete for CEU credit: 3/15/26
- **Research Protocol Deviations vs Deficiencies**
  1 contact hour; CEU Expiration: 6/11/26.
  Last Day to Enroll to CLASS course: 6/10/26;
  Last day to Complete for CEU credit: 6/11/26

Non-CEU Courses posted in CLASS:

- **Adverse Event Reporting**
- **SWOG Audits: Preparing for Success and Audit Process**
- **How to Develop a CAPA Plan**

Thank you