

Register with PolLEV

- Go to <https://pollev.com/allisontrain080>
- Text **ALLISONTRAIN080** to **22333** once to join

**This poll only allows the first 50 participants to respond.*

If you are having trouble getting into PolLEV,
please Zoom-Chat Allison Trainor directly for assistance.

Creating a Culture of Quality Assurance

Erica Ellington, CRA, CHRC, CHPC, CCEP

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Jennifer Holmes, CCRP

Allison Trainor, MPH, CCRC

Conflict of Interest

None of the presenters have any financial or personal conflict of interest to report in relation to this presentation.

Objectives

- Define the purpose of Quality Assurance
- Describe best practices in the context of Data Integrity and Quality Assurance
- Demonstrate a Quality Assurance Process, Review, and Response for continuous improvement
- Apply Quality Assurance processes to create a supportive QA culture for your study team

First...We want to hear from you!

- Go to <https://pollev.com/allisontrain080>
- Text **ALLISONTRAIN080** to 22333 once to join

University of Shark Town

Demographics, Basic Vitals, and Medical History Form

DEMOGRAPHICS

Gender: MALE	Age (years): 65		
Race: ASIAN	Ethnicity: NON-HISPANIC		
VITALS			
RR: 18	HR: 75	BP: 135/90	Weight: 250 (kg)

Medical/Surgical History

Condition	<u>Dx</u> or Surgery Date (mmm/yyyy)	Ongoing (Y or N)	Date Stopped (mmm/yyyy)
Hypertension		Y	N/A
Basal Cell Carcinoma	OCT/2019	Y	DEC/2019
Arthritis	MAY/2015	Y	N/A
Type II Diabetes Mellitus	JAN/2013	Y	N/A

Prior and Concomitant Medications

Medication Name	Indication	Date Started	Date Stopped	Ongoing?
<u>Eloquis</u>	Post-Knee Replacement	JUN/2018	DEC/2018	N
Aleve	Arthritis	MAY/2018	N/A	Y
Metformin	Diabetes	NOV/2012	N/A	Y

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What is Quality Assurance?

How do we Create a Culture of QA?

Quality Assurance

Quality Assurance (QA)

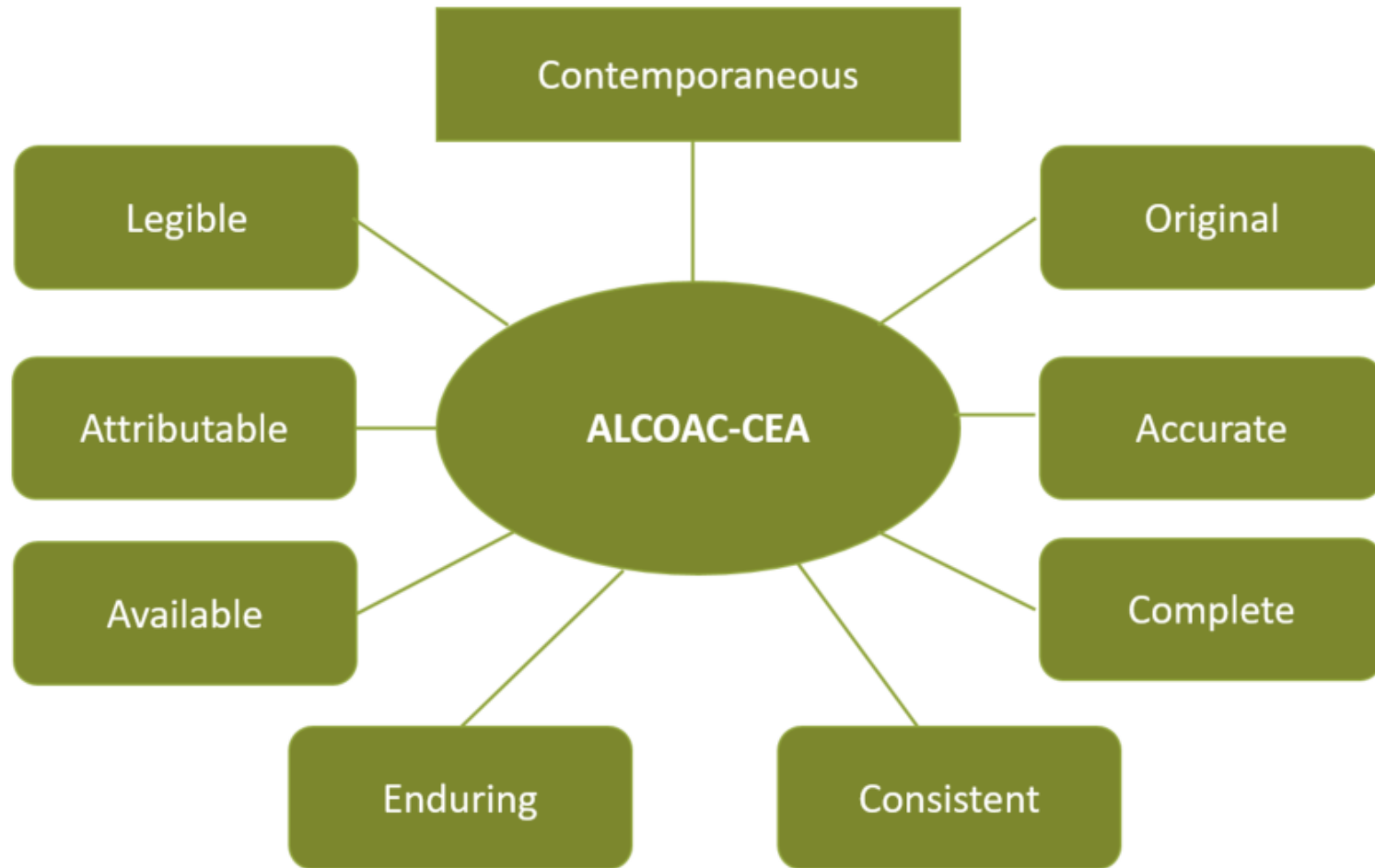
All those **planned** and **systematic actions** that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement(s).

Monitoring Plan

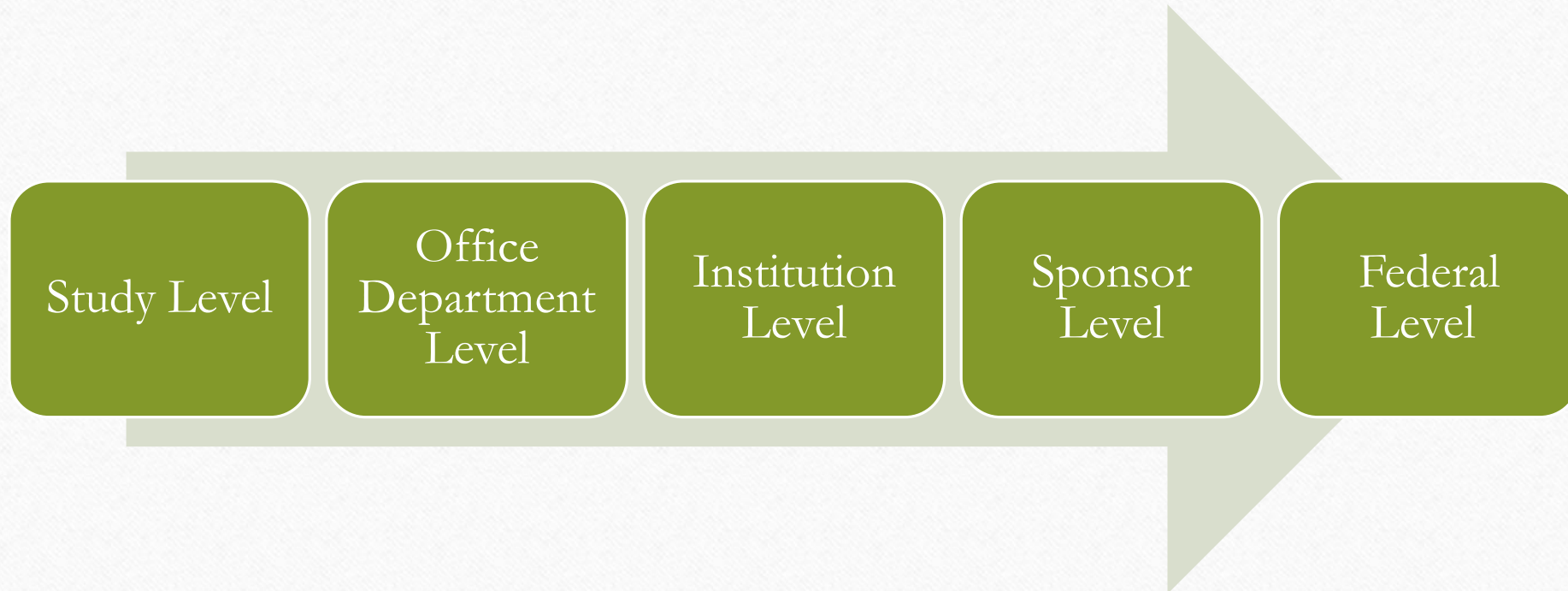
A **document** that describes the strategy, methods, responsibilities, and requirements for monitoring the trial.

-ICH GCP

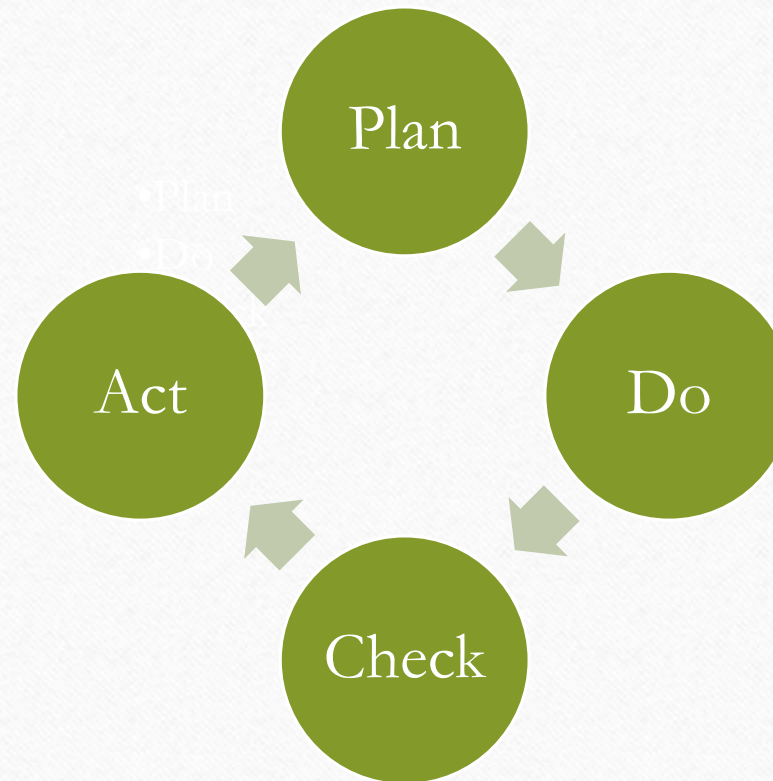
Data Integrity



Where can Quality Assurance be Applied?



Continuous Improvement



Common QA Findings

And How to Address Them

Common QA Findings

1. Informed Consent

- Use of incorrect/unapproved versions
- No documentation that a copy of signed ICF was given to the participant

2. Screening/Eligibility

- Lack of source document to support eligibility
- Enrollment of ineligible participants

Common QA Findings

3. Adverse Events:

- No documentation of who made the AE assessment and when
- Reporting to all appropriate entities and time frame of reporting

4. Missing essential documents

- Delegation log, training log, CVs and Licenses

How to address findings/Useful tools

- Creating a NTF
 - Explain the reason for the error/omission/discrepancy or process/policy it aims to address
 - Signed and dated by the staff who prepared it
 - Include any corrective action and/or follow-up action taken
 - File with the binder/file to which it applies

Note to File

Date:

To: **Select one:** Regulatory Files / Participant Files

From: **Person preparing note**

Re:

Protocol Number: H-

Principal Investigator:

Description:

- **Include information about an issue, cause of the issue, and corrective actions taken to prevent issue from occurring again**
 - **Explain alternative location that files may be stored**
 - **Clarify a policy or process**
-

Signature

Date

How to address financial

- Use checklists
 - Informed Consent Documentation
 - Study Visits
 - Eligibility checklist**

RESEARCH SUBJECT ELIGIBILITY ASSESSMENT FORM

Study Name:	
IRB Protocol #:	
Protocol Version # and/or Date:	
Principal Investigator:	

SUBJECT # _____

INCLUSION CRITERIA <i>Must be "yes"</i>	Yes	No	Location of supporting source documentation	Notes
1.	<input type="checkbox"/>	<input type="checkbox"/>		
2.	<input type="checkbox"/>	<input type="checkbox"/>		
EXCLUSION CRITERIA <i>Must be "no"</i>	Yes	No	Location of supporting source documentation	Notes
1.	<input type="checkbox"/>	<input type="checkbox"/>		
2.	<input type="checkbox"/>	<input type="checkbox"/>		

This subject is:

☐ Eligible for participation ☐ Ineligible for participation

[Signed by study team member who is (1) qualified to assess eligibility and (2) delegated this study task by the PI]

Signature:	Date:
Printed Name:	

How to address findings/Useful tools

- Use documentation templates
 - Delegation logs
 - Training logs
 - AE assessment logs
- Don't reinvent the wheel! Utilize the templates that are available to you:
 - **BUMC/BMC:** <https://www.bumc.bu.edu/crrro/tools/>
 - **UVM:** <https://commons.med.uvm.edu/dean/comclntril/SitePages/Regulatory%20Documents%20and%20Resources.aspx>
 - **MUSC:** <https://horseshoe.musc.edu/everyone/compliance/univ-compliance/research/human-subject-audits/checklists>
 - **UF:**

The image displays three research documentation templates. The first is a 'Staff Member Training Log' with columns for Date, Name(s) of Trainee(s), Description of Training (topics, agenda, and training materials as applicable), Trainer Signature, and Expiration Date (if applicable). The second is a 'RESEARCH SUBJECT ELIGIBILITY ASSESSMENT FORM' with a red-bordered box containing general instructions and a table for inclusion/exclusion criteria. The third is a 'Documentation of Informed Consent' form with sections for Participant Information, Consent, and a table for documentation of the consent process.

Staff Member Training Log

Study Name: _____ Study PI: _____

Staff Member Training Log
This log documents training of individual staff members. To record individual training for staff members (if asked), refer to "Staff Member Training Log".

Date Training	Name(s) of Trainee(s)	Description of Training (topics, agenda, and training materials as applicable)	Trainer Signature	Expiration Date (if applicable)

RESEARCH SUBJECT ELIGIBILITY ASSESSMENT FORM

CRRO Template Version 1.0, 6/25/2017

GENERAL INSTRUCTIONS – delete this box from the completed form

NOTE: This form is designed to be a starting point on eligibility assessment. Update it as necessary for your specific study.

All participants enrolled in the study must meet all inclusion criteria and not meet any of the exclusion criteria. All changes to inclusion/exclusion criteria must be approved by the IRB prior to implementation. Remember to modify this template any time the inclusion/exclusion criteria is changed.

Participant records should include source documentation (lab results, medical records, questionnaires, data collection tools, etc.) to support that the participant meets eligibility criteria.

All staff responsible for reviewing and/or determining subject eligibility should be listed on the IRB application, appropriately trained by study PI, and listed on the study delegation log.

Red text represents instructions to you – to be deleted from the final version.

Study Name: _____

IRB Protocol #: _____

Protocol Version # and/or Date: _____

Principal Investigator: _____

[Complete this table with all inclusion/exclusion criteria listed in the IRB-approved protocol. Modify the number of rows as needed depending on the number of inclusion/exclusion criteria in your protocol.]

SUBJECT #	INCLUSION CRITERIA Must be "yes"	Yes	No	Location of supporting source documentation	Notes
1.		<input type="checkbox"/>	<input type="checkbox"/>		
2.		<input type="checkbox"/>	<input type="checkbox"/>		
3.		<input type="checkbox"/>	<input type="checkbox"/>		
4.		<input type="checkbox"/>	<input type="checkbox"/>		
5.		<input type="checkbox"/>	<input type="checkbox"/>		

Documentation of Informed Consent

Study Name: _____ Study PI: _____

Participant: _____

Version of consent used: _____

Consent obtained by: _____

Date of consent: _____

Check all that apply (provide necessary details in the notes space below):

- ☐ The study was explained and the consent form was reviewed with the participant.
- ☐ All of the participant's questions were answered and all the consent elements, such as purpose, procedures, and risks were reviewed.
- ☐ The participant was given sufficient time to consider participation.
- ☐ The participant agreed to participate in the study and personally signed and dated the consent form.
- ☐ Verbal consent/assent was obtained (as approved by the IRB).
- ☐ Obtained consent from Legally Authorized Representative (as approved by the IRB).
- ☐ The consent form was signed and dated by the researcher.
- ☐ The consent process was witnessed by an impartial witness (if applicable).
- ☐ The participant was given a copy of the signed informed consent form.
- ☐ The consent process was completed prior to the start of research procedures.

Notes about the consent process (i.e., who was involved in consent process, what questions did the participant have, translator number, whether a teach-back process was used, etc.):

Signature or initials of person completing this form: _____

Date form completed: _____

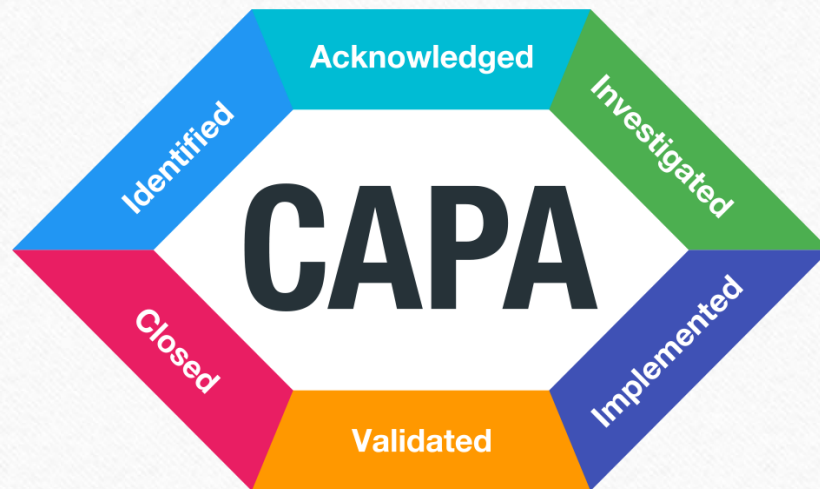
Documentation of Informed Consent
CRRO Template Version 1.0, 6/25/2017

How to address findings/Useful tools

- Train/re-train staff on study process and/or protocol
 - And document it!
- Create an SOP to help with specific processes/procedures



Elements of a Good CAPA



- June 18, 2019; Developing Effective Corrective and Preventative Action Plans (CAPAs); Mary-Tara Roth (BU): <https://www.bumc.bu.edu/crrro/research-professional-network/resources-programs/past-rpn-workshops/>
- April 11, 2018 Clinical Research Seminar: How to develop a Corrective and Preventative Action Plan (CAPA) that even the FDA will love: <https://www.bumc.bu.edu/crrro/training-education/past-seminars/>

Standard Operating Procedures

Standard Operating Procedures – Why?

Standard Operating Procedures (SOPs) are uniformly written procedures, with detailed instructions to record routine operations, processes and practices followed within a business organization.

SOPs facilitate a culture of Quality Assurance...

Standard Operating Procedures – Organization



**Why...? When a process is
written down,
you are more likely to follow it!**

Elements of an SOP

Purpose

- Explain the objective the SOP is intended to achieve.

Scope

- State the range of activities the SOP applies to, as well as any limitations or exceptions.

Responsibility

- State the areas responsible for performing and complying with SOP.

Procedure

- Use simple steps to explain procedures.

Contingencies (Corrective Actions)

- State what happens if the SOP cannot be followed and requires contingencies.

<https://hub.ucsf.edu/sops>

RPN April 24, 2019, SOP Development Jessica Howard (BU) and Kimberly Parker (BMC)

Common SOPs

- GCP Training
- Authority and Delegations of Responsibilities of Research Staff
- Subject Screening and Recruitment
- Informed Consent Process and Documentation
- Eligibility Confirmation
- Source Documentation
- Data Management
- Protocol Deviations
- Adverse Events and Serious Adverse Events Reporting
- Confidentiality of Information
- Drug/Device Storage, Accountability and Management
- Monitoring Visits

Sample User Standard Operating Procedure Status:

Original Date:

Revision Date:

Version: Revised by:

Approved By: Approval Date:

DRAFT

Standard Operating Procedures: Delegation of Responsibility

The Principal Investigator is responsible for:

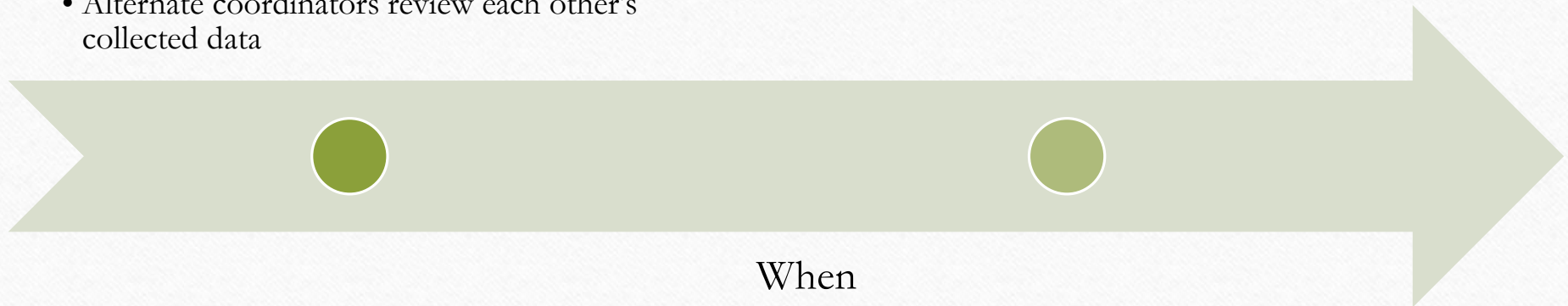
- 1.Designating all Co-Investigators and other research personnel on the initial review application submitted to the IRB.
- 2.Ensuring that co-investigators have read and understood the protocol and their specific role in the research, and all other study-related materials (e.g., the investigator brochure, if applicable).
- 3.Assigning specific tasks and responsibilities for each member of the study team; and communicating and providing training for these roles and responsibilities to each member.
- 4.Authorizing all members of the study team, who are included in the initial application or later added to the protocol, to perform specific study related tasks but only after receiving approval from the IRB.
- 5.Maintaining a study responsibility delegation table on which all study team members are named, their respective duties/tasks are outlined, and each member's entry is signed and dated to indicate the team member's willingness to perform his/her designated tasks. Use the specified table found in Section II.B.1 in this manual.

https://www.hopkinsmedicine.org/institutional_review_board/about/compliance_monitoring/researchers_tool_kit/standard_operating_procedure.pdf and <https://hub.ucsf.edu/sops>

Quality Assurance SOP

How

- Checklists
- Document QA plan was followed
- Alternate coordinators review each other's collected data



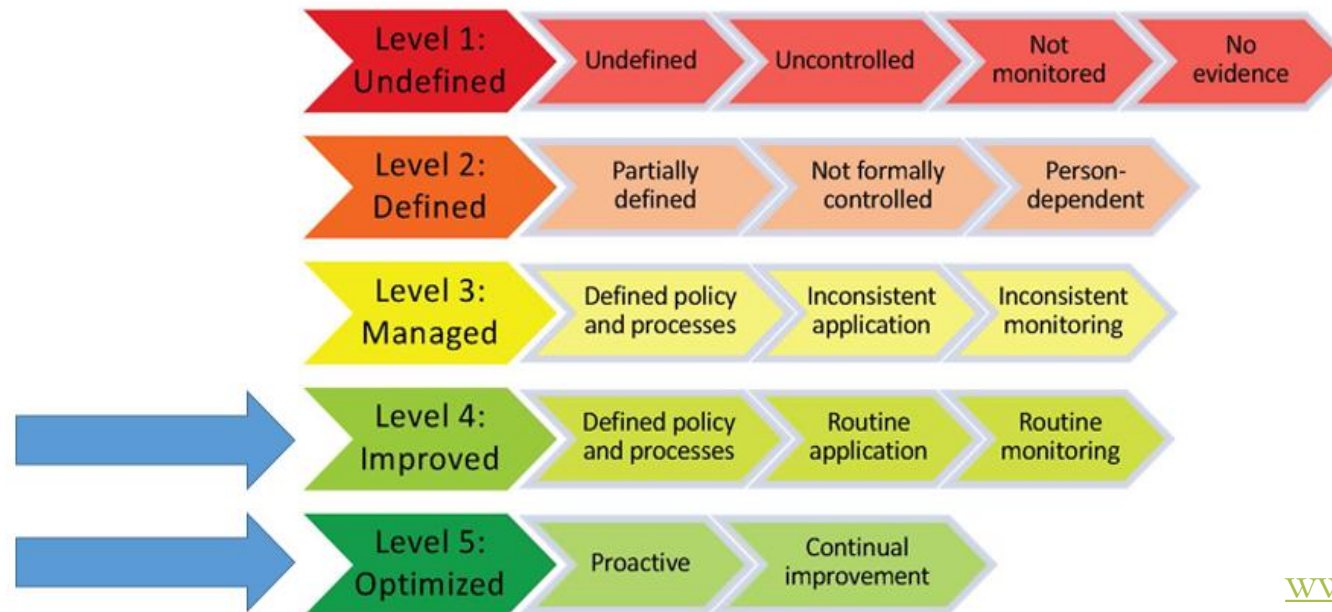
From start to finish!
Early Detection and Prevention

When

- First three subjects on study – review consent
- Every five subjects on study – review current research chart
- After first subject completed – Audit entire chart

SOP – Continuous Improvement

Continuous Improvement



SOPs - Proactive versus Reactive

Standard Operating Procedures allow sites to be proactive instead of reactive.



Practice Time!

- Breakout room
- Review the case study (5 minutes)
- Discussion (20 minutes)
 - What are some findings that your small group found?
 - What are the TOP 3 findings that your group would like to share?
 - How would you addressing each of these TOP 3 findings?
- Assign a spokesperson for your group

Key Takeaways

- **Culture of QA** – you have control!
- **Build a personalized Quality Assurance Monitoring Program** – what does this look like on your team? How can this improve *your* processes?
- **Quality Assurance and Audit Preparation Resources** – available technology, QA plan specific to each study

UVM Quality Assurance Monitoring Program

The Larner College of Medicine, in conjunction with the UVM Research Protections Office (RPO), Quality Assurance Monitoring Program.

Purpose: to be proactive in ensuring our institution is compliant with local and federal research requirements and regulations

Selection: currently selecting active research studies that are more than minimal risk (IRB Full Committee Review) that are not actively monitored

Contact Us:

Research.Navigator@med.uvm.edu

Given Building C423

802-656-9404

Medical University of South Carolina

- The MUSC University Compliance Office conducts audits on research projects involving human participants.
- Audits are a tool to assist the Medical University in achieving compliance with applicable federal regulations and laws and MUSC policy and procedures during the conduct of research involving human participants.
- This mechanism of post-review monitoring also serves as a vehicle for
 - continuing education,
 - increased operational awareness, and
 - quality improvement.

MUSC University Compliance Office
Univ-compliance@musc.edu

Boston University Medical Campus & Boston Medical Center

- The Office of Human Research Affairs conduct routine QA reviews to help investigators and study staff perform IRB-approved research in compliance with the applicable regulations, policies, and guidance in order to protect the safety of participants or the reliability or validity of study data.
- Investigators can request a QA review or the HRPP selects QA reviews to be done. Recently-approved studies are prioritized for selection according to their potential for risk to subject safety or data integrity, based on having one or more of the following characteristics:
 - Greater than minimal risk
 - Investigator-initiated
 - Interventional clinical trials
 - First time Principal Investigators
 - Studies where the Principal Investigator holds the IND or IDE
 - Studies having a conflict of interest management
- For more information please visit: QA reviews FAQ page <https://www.bumc.bu.edu/ohra/audits-for-research-oversight/quality-assurance-reviews-faqs/>

UNIVERSITY of FLORIDA

Institutional Review Board, Quality Assurance Program

What is the UF Quality Assurance (QA) Program?

- Part of the UF IRB Program to assist the University of Florida and the researchers in performing human subjects research within the framework of State and Federal regulations, institutional policies, and good clinical practice through on-going monitoring of UF IRB approved studies.

What services do we provide?

- On-site Reviews
 - Random/not-for-cause monitoring
 - For-Cause Audit
 - Investigator Requested Review
- Consultations
 - Regulatory Binder/Subject chart review
 - General study Q&A (best-practice implementation strategies)
 - Assistance with preparation for an external audit
 - Small Group QI In-Service

How do I request QA Program Services?

Nicole Corwine	ncorwine@ufl.edu	273-9606
Allison Trainor	awickham@ufl.edu	273-9602

Questions?

