# 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

Jung Lee, BS

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: ~~20~~ 18 | HR: 75 | BP: 135/90 | Weight: 250 (kg) |

## Medical/Surgical History

| Condition | Dx 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? |
|---|---|---|---|---|
| Eloquis | Post-Knee Replacement | JUN/2018 | DEC/2018 | N |
| Aleve | Arthritis | MAY/2018 | N/A | Y |
| Metformin | Diabetes | NOV/2012 | N/A | Y |

# University of Shark Town

Demographics, Basic Vitals, and Medical History Form

| DEMOGRAPHICS | | | |
|---|---|---|---|
| Gender: MALE | | Age (years): 65 | |
| Race: ASIAN | | Ethnicity: NON-HISPANIC | |
| | | | |
| **VITALS** | | | |
| RR: ~~19~~ 18 | HR: 75 | BP: 135/90 | Weight: 250 (kg) |

## Medical/Surgical History

| Condition | Dx 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? |
|---|---|---|---|---|
| Eloquis | Post-Knee Replacement | JUN/2018 | DEC/2018 | N |
| Aleve | Arthritis | MAY/2018 | N/A | Y |
| Metformin | Diabetes | NOV/2012 | N/A | Y |

# University of Shark Town

Demographics, Basic Vitals, and Medical History Form

| DEMOGRAPHICS | | | |
|---|---|---|---|
| Gender: MALE | | Age (years): 65 | |
| Race: ASIAN | | Ethnicity: NON-HISPANIC | |
| | | | |
| VITALS | | | |
| RR: ~~30~~ 18 | HR: 75 | BP: 135/90 | Weight: 250 (kg) |

## Medical/Surgical History

| Condition | Dx 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? |
|---|---|---|---|---|
| Eloquis | Post-Knee Replacement | JUN/2018 | DEC/2018 | N |
| Aleve | Arthritis | MAY/2018 | N/A | Y |
| Metformin | Diabetes | NOV/2012 | N/A | Y |

**University of Shark Town**

Demographics, Basic Vitals, and Medical History Form

| DEMOGRAPHICS | | | |
|---|---|---|---|
| Gender: MALE | | Age (years): 65 | |
| Race: ASIAN | | Ethnicity: NON-HISPANIC | |
| | | | |
| VITALS | | | |
| RR: ~~20~~ 18 | HR: 75 | BP: 135/90 | Weight: 250 (kg) |

## Medical/Surgical History

| Condition | Dx 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? |
|---|---|---|---|---|
| Eloquis | Post-Knee Replacement | JUN/2018 | DEC/2018 | N |
| Aleve | Arthritis | MAY/2018 | N/A | Y |
| Metformin | Diabetes | NOV/2012 | N/A | Y |

# University of Shark Town

Demographics, Basic Vitals, and Medical History Form

| DEMOGRAPHICS | | | |
|---|---|---|---|
| Gender: MALE | | Age (years): 65 | |
| Race: ASIAN | | Ethnicity: NON-HISPANIC | |
| | | | |
| VITALS | | | |
| RR: ~~20~~ 18 | HR: 75 | BP: 135/90 | Weight: 250 (kg) |

## Medical/Surgical History

| Condition | Dx 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? |
|---|---|---|---|---|
| Eloquis | Post-Knee Replacement | JUN/2018 | DEC/2018 | N |
| Aleve | Arthritis | MAY/2018 | N/A | Y |
| Metformin | Diabetes | NOV/2012 | N/A | Y |

# University of Shark Town

Demographics, Basic Vitals, and Medical History Form

| DEMOGRAPHICS | | | |
|---|---|---|---|
| Gender: MALE | | Age (years): 65 | |
| Race: ASIAN | | Ethnicity: NON-HISPANIC | |
| | | | |
| VITALS | | | |
| RR: ~~30~~ 18 | HR: 75 | BP: 135/90 | Weight: 250 (kg) |

## Medical/Surgical History

| Condition | Dx 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? |
|---|---|---|---|---|
| Eloquis | Post-Knee Replacement | JUN/2018 | DEC/2018 | N |
| Aleve | Arthritis | MAY/2018 | N/A | Y |
| Metformin | Diabetes | NOV/2012 | N/A | Y |

# University of Shark Town

Demographics, Basic Vitals, and Medical History Form

| DEMOGRAPHICS | | | |
|---|---|---|---|
| Gender: MALE | | Age (years): 65 | |
| Race: ASIAN | | Ethnicity: NON-HISPANIC | |
| | | | |
| VITALS | | | |
| RR: ~~30~~ 18 | HR: 75 | BP: 135/90 | Weight: 250 (kg) |

## Medical/Surgical History

| Condition | Dx 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? |
|---|---|---|---|---|
| Eloquis | Post-Knee Replacement | JUN/2018 | DEC/2018 | N |
| Aleve | Arthritis | MAY/2018 | N/A | Y |
| Metformin | Diabetes | NOV/2012 | N/A | Y |

# University of Shark Town

Demographics, Basic Vitals, and Medical History Form

| DEMOGRAPHICS | | | |
|---|---|---|---|
| Gender: MALE | | Age (years): 65 | |
| Race: ASIAN | | Ethnicity: NON-HISPANIC | |
| | | | |
| VITALS | | | |
| RR: ~~30~~ 18 | HR: 75 | BP: 135/90 | Weight: 250 (kg) |

## Medical/Surgical History

| Condition | Dx 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? |
|---|---|---|---|---|
| Eloquis | Post-Knee Replacement | JUN/2018 | DEC/2018 | N |
| Aleve | Arthritis | MAY/2018 | N/A | Y |
| Metformin | Diabetes | NOV/2012 | N/A | Y |

# What is Quality Assurance?

## How do we Create a Culture of QA?

# Quality Assurance

Quality Assurance (QA)

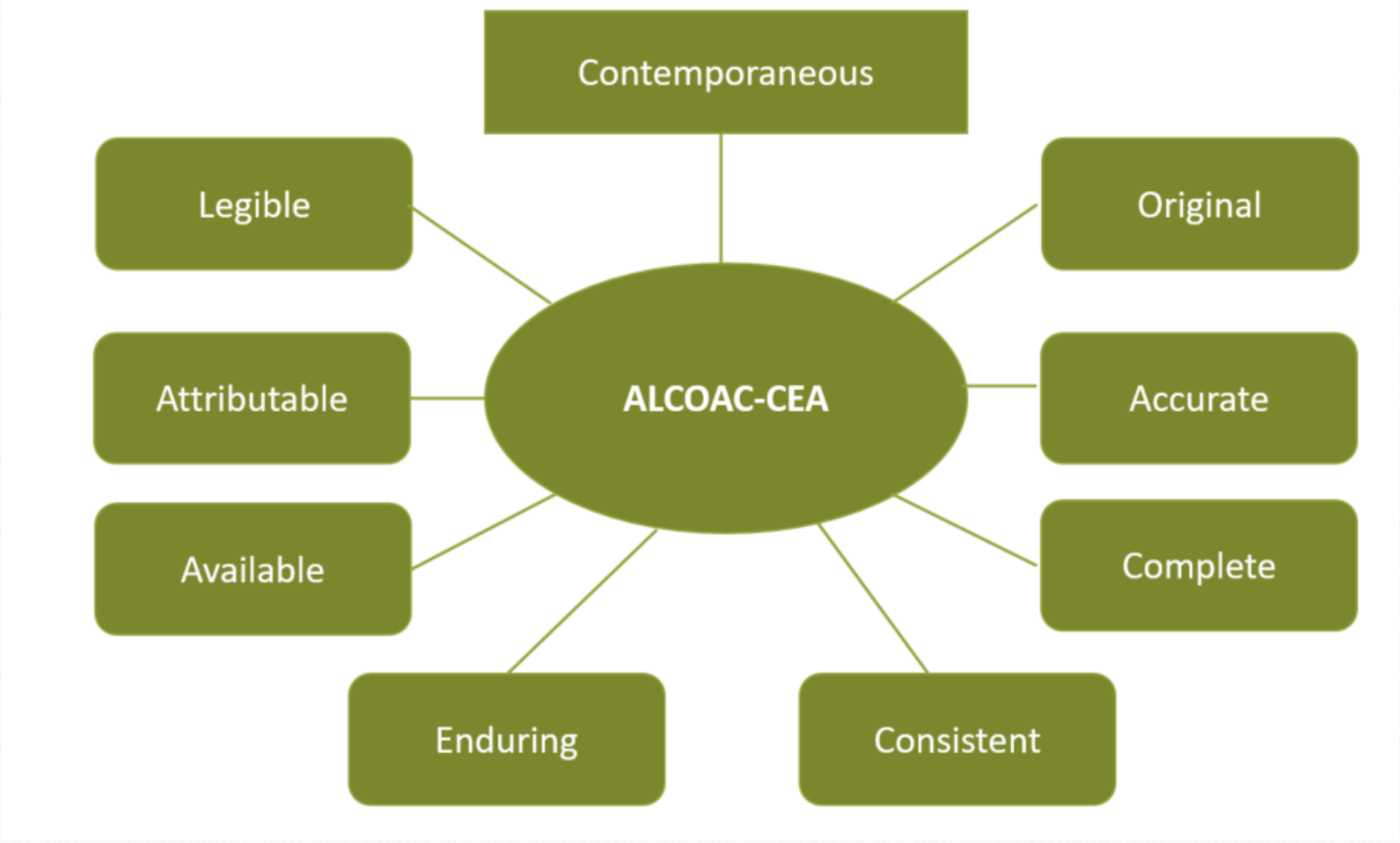
All those **planned** and **systematic actions** that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement(s).

Monitoring Plan

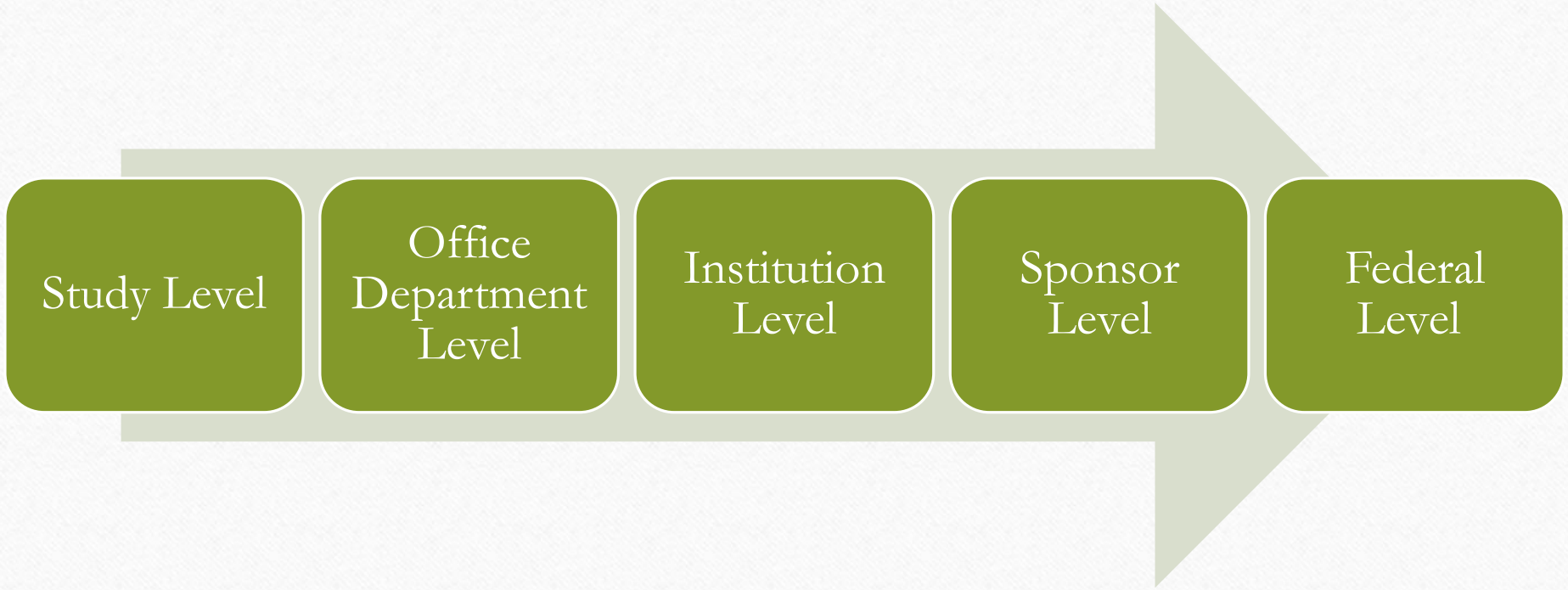
A **document** that describes the strategy, methods, responsibilities, and requirements for monitoring the trial.

-ICH GCP

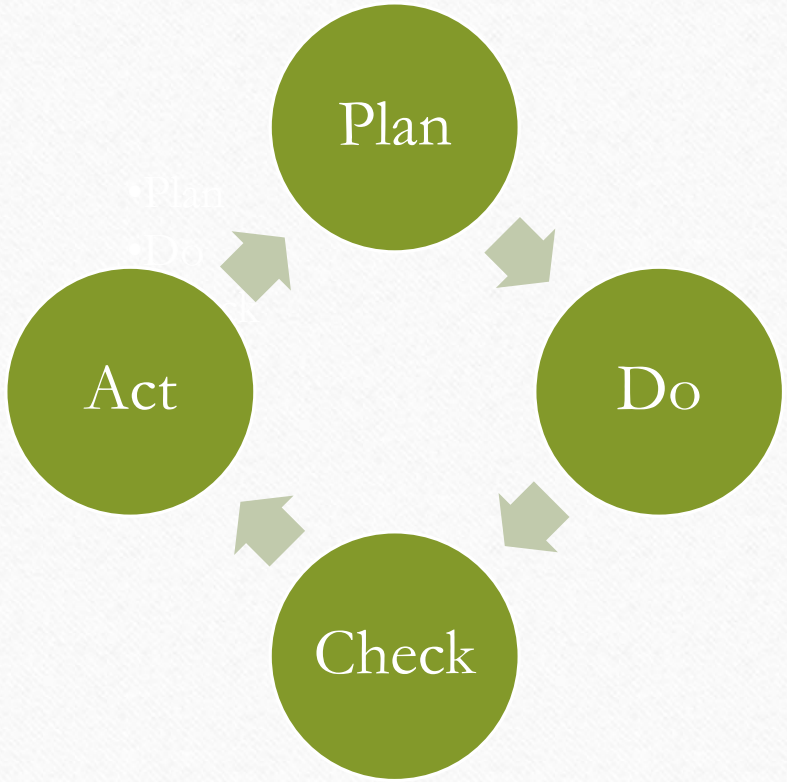
# Data Integrity



# Where can Quality Assurance be Applied?



# Continuous Improvement



# Common QA Findings

And How to Address Them

# Common QA Findings

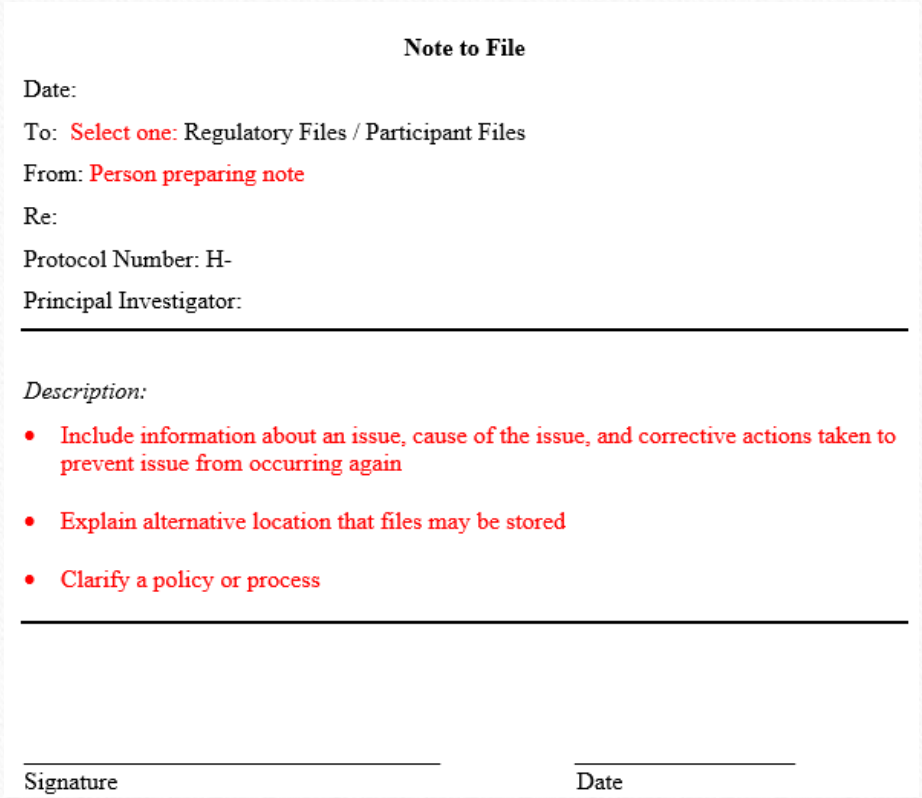
1. Informed Consent
   - Use of incorrect/unapproved versions
   - No documentation that a copy of signed ICF was given to the participant
2. Screening/Eligibility
   - Lack of source document to support eligibility
   - Enrollment of ineligible participants

# 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

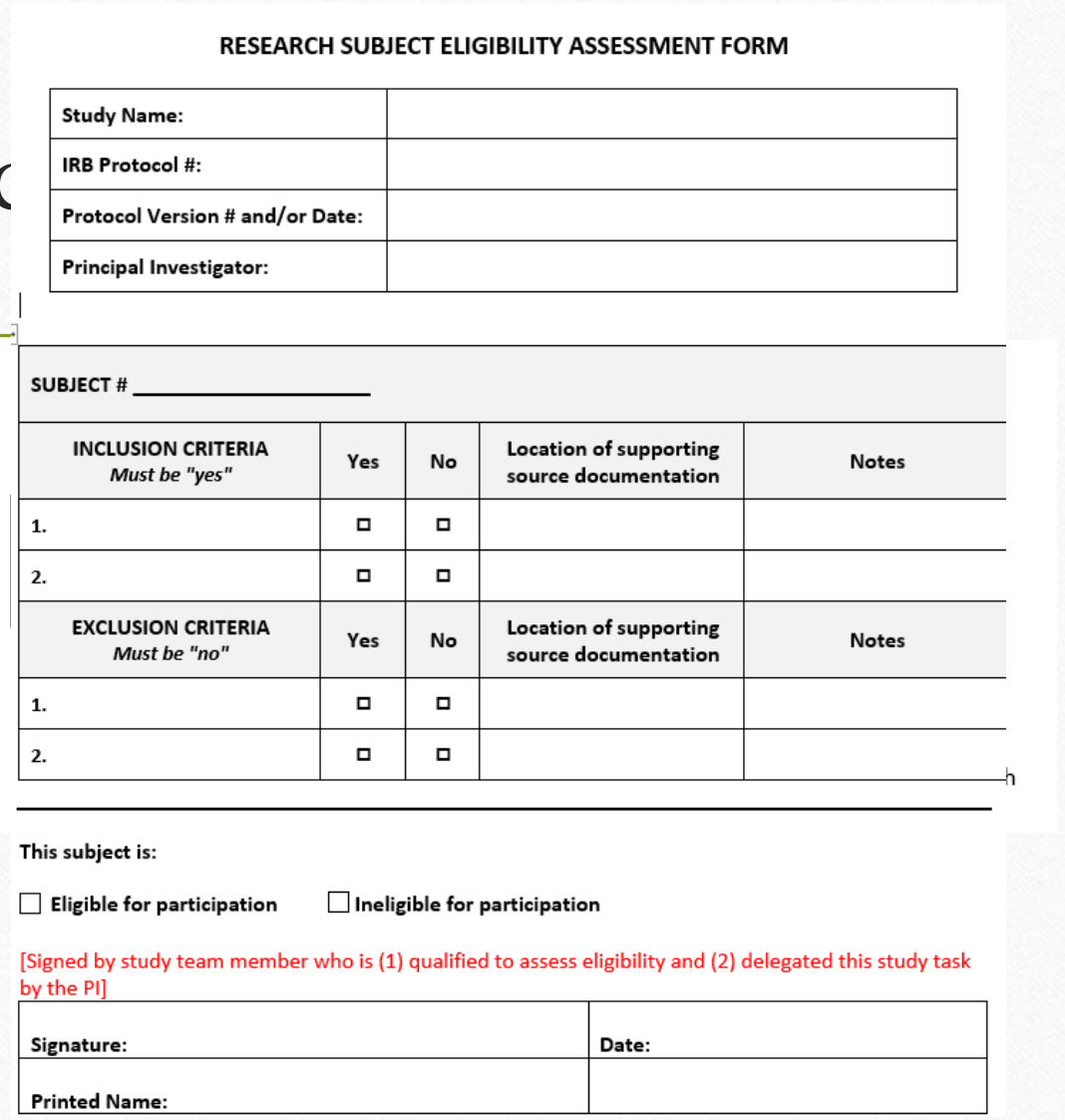
---

Signature

Date

# How to address finc

- 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** *Must be "yes"* | **Yes** | **No** | **Location of supporting source documentation** | **Notes** |
|---|---|---|---|---|
| 1. | ☐ | ☐ | | |
| 2. | ☐ | ☐ | | |
| **EXCLUSION CRITERIA** *Must be "no"* | **Yes** | **No** | **Location of supporting source documentation** | **Notes** |
| 1. | ☐ | ☐ | | |
| 2. | ☐ | ☐ | | |

**This subject is:**

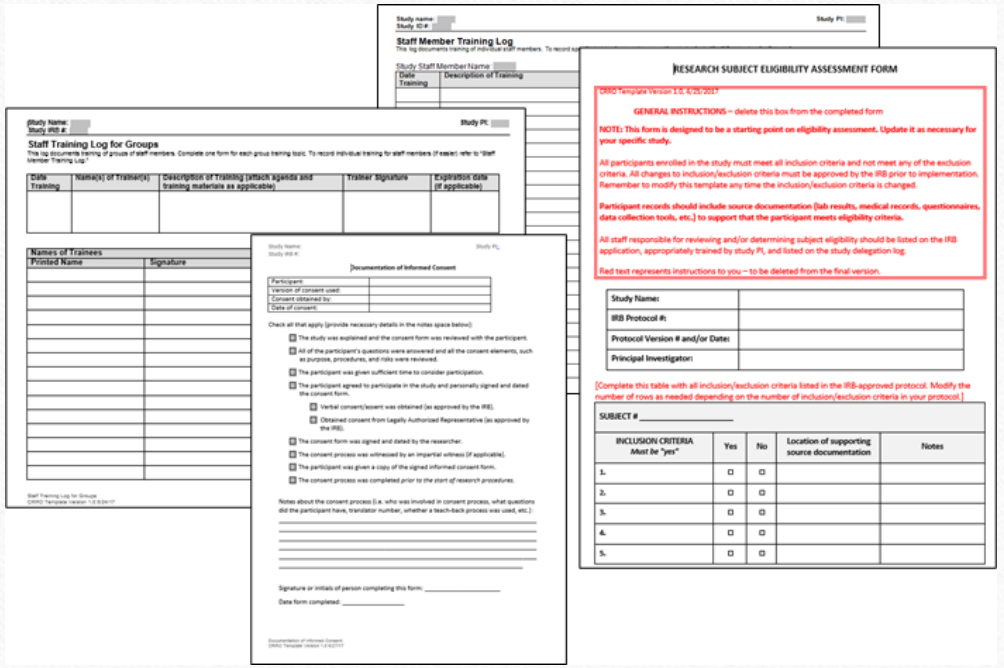
☐ **Eligible for participation** ☐ **Ineligible for participation**

[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

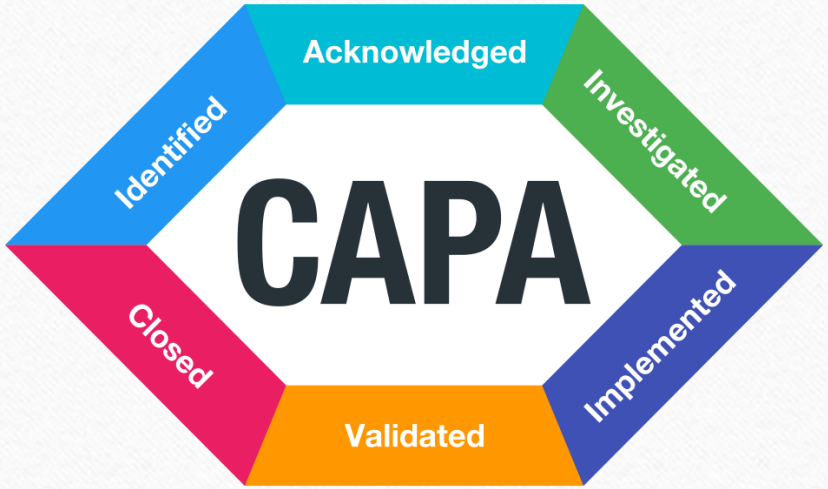
- Use documentation templates
  - Delegation logs
  - Training logs
  - AE assessment logs
- Don't reinvent the wheel! Utilize the templates that are available to you:
  - **BUMC/BMC:** https://www.bumc.bu.edu/crro/tools/
  - **UVM:** https://commons.med.uvm.edu/dean/comclntril/SitePages/Regulatory%20Documents%20and%20Resources.aspx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



# 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/crro/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/crro/training-education/past-seminars/

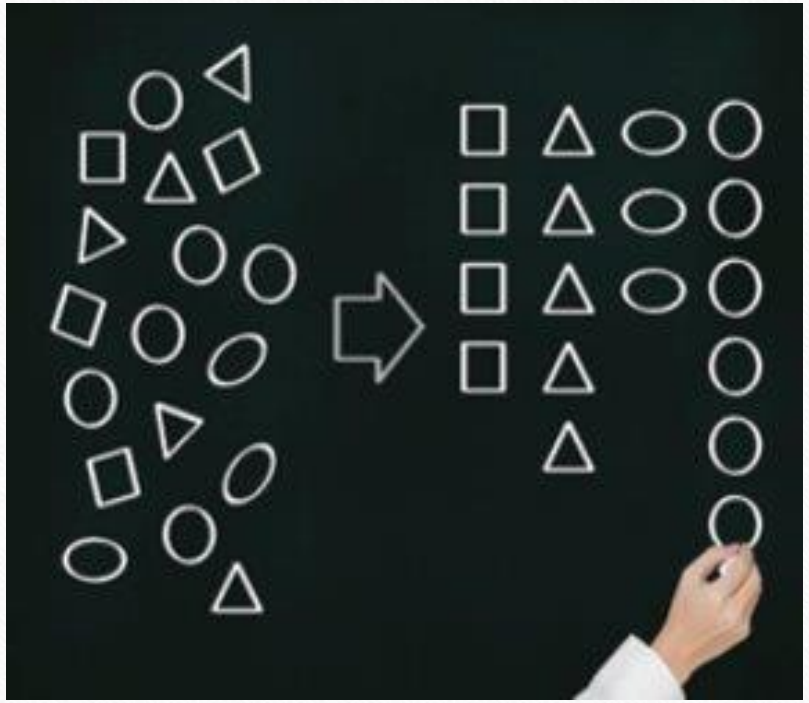
# Standard Operating Procedures

# 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 | Scope | Responsibilty | Procedure | Contingencies (Corrective Actions) |
|---|---|---|---|---|
| • Explain the objective the SOP is intended to achieve. | • State the range of activities the SOP applies to, as well as any limitations or exceptions. | • State the areas responsible for performing and complying with SOP. | • Use simple steps to explain procedures. | • 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

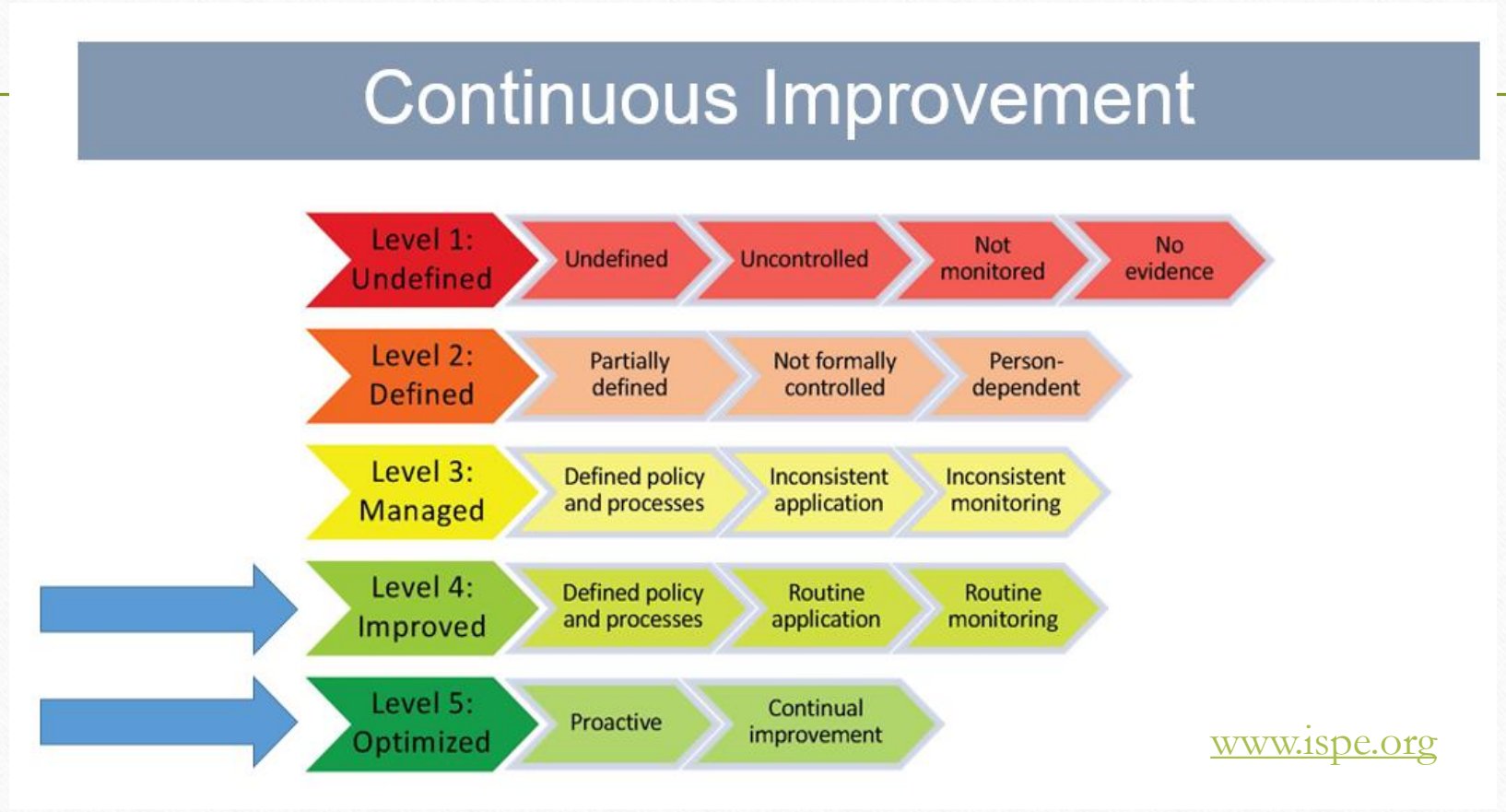
**From start to finish!**

**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



# 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?