Audit Readiness Without the Panic: A Guide to Audit Success

June 16, 2026

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Audit Readiness - FDA/Sponsor Audit

Michelle Chidester, BA, CCRC
Assistant Director of Regulatory and Quality, WVU

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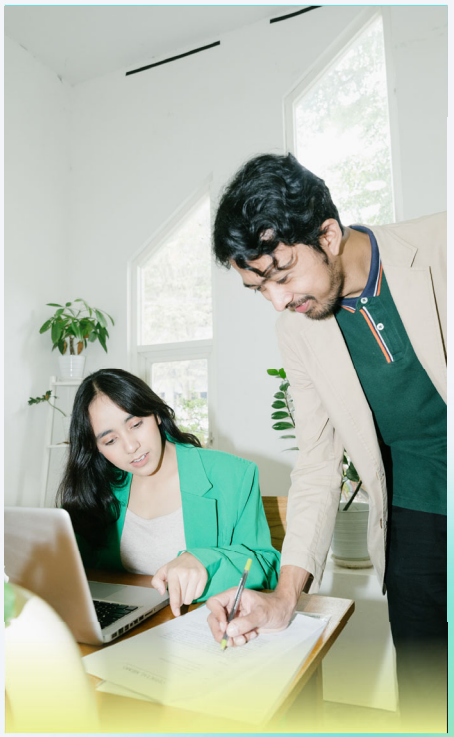
Objectives

- Apply best practices to ensure readiness for regulatory review by auditors and understand the roles of auditors in ensuring clinical trial quality.
- Recognize what data auditors evaluate, including subject protection, protocol adherence, and regulatory compliance.
- Implement practices that support continuous inspection readiness by identifying how to maintain documentation, processes, and oversight practices that minimize audit risk.
- Identify frequent issues such as incomplete documentation, workflow inconsistencies, and training deficiencies.



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How many of you have participated in a Sponsor Audit and/or FDA Inspection?

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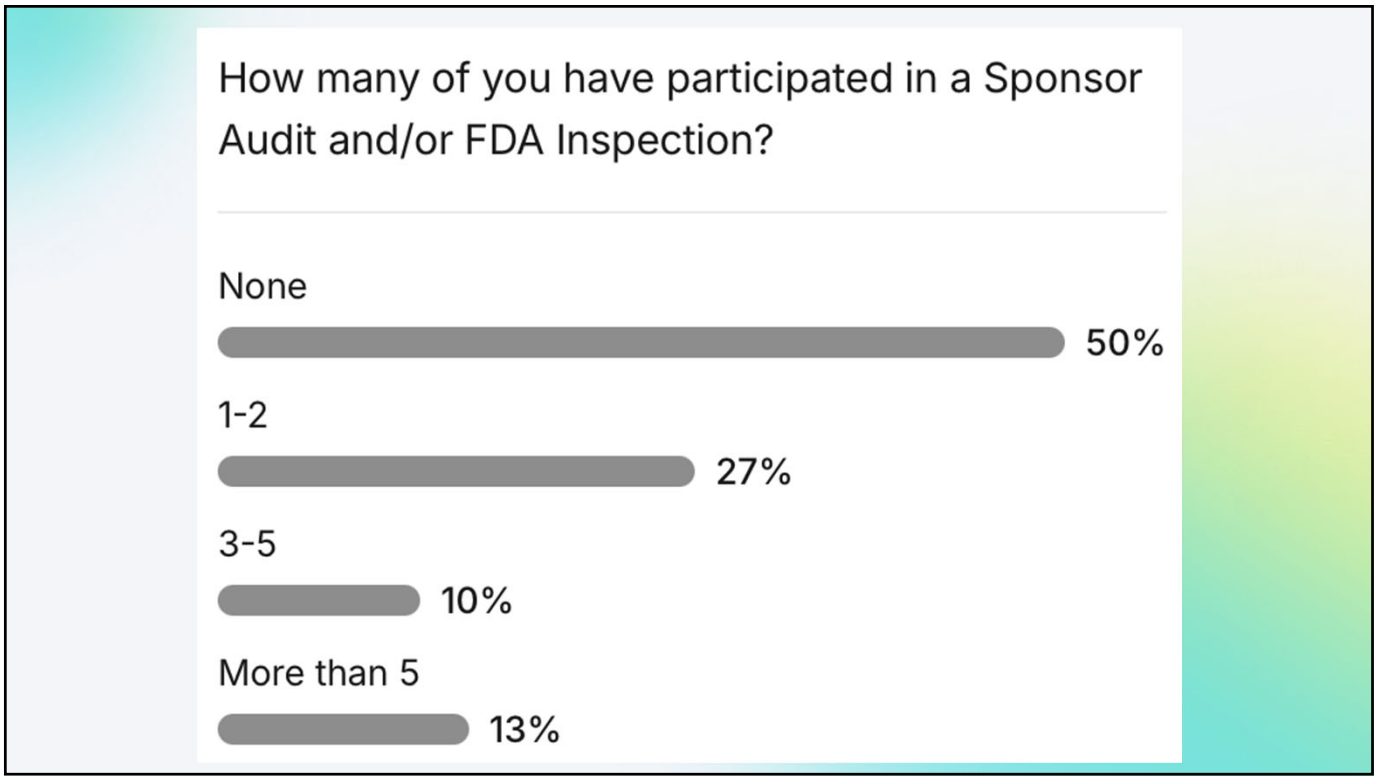

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Why Audit Readiness Matters

Ensures data integrity

Protects subject safety

Supports regulatory submissions

Strengthens site credibility

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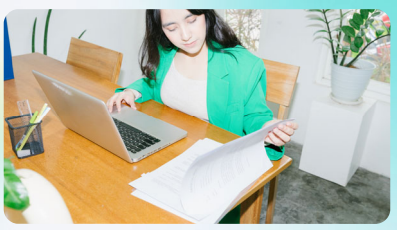
What is an Audit?

E6 (R3) Good Clinical Practice Guidance defines as an " independent review to evaluate whether the processes put in place to manage and conduct the trial are appropriate to ensure compliance with the protocol, GCP and regulatory requirements”

Independent review

Verification of compliance



Assessment of data credibility

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What is an Inspection?

The definition according to the E6 (R3) Good Clinical Practice Guidance is “The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical trial and that may be accessed at the investigator site, at the sponsor’s and/or service provider’s (including CRO’s) facilities.”

Key Points:

- May occur on-site or remotely
- Focuses on compliance and subject protection

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When will a spo
conduct an aud

- Pre-New Drug Application or pre-approval readiness
- Preparing for FDA inspection
- Suspicion of misconduct

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Why the FDA May Inspect

- Routine surveillance
- Pre-approval inspection
- “For-cause” inspection

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What Auditors Evaluate

- Subject protection
- Protocol adherence
- Regulatory compliance
- Data accuracy and completeness
- Documentation practices
- Delegation and training
- IP accountability

Key Documents Auditors/Inspectors Review

- Informed consent forms
- Source documents/Case Report Forms
- SOPs
- Delegation logs
- Training Records
- Protocol deviations
- Safety reporting documentation
- IP accountability logs

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Tips

- Designate an audit lead.
- Provide an overview of the protocol to the auditor. Include a list of personnel at the site and their role. Can provide a brief slide deck that overviews eligibility criteria, AE reporting, etc. (Sponsor may be able to help with this if Regulatory Agency Inspection).
- Provide documentation as requested by the auditor to the audit lead or designate in a timely manner.
- For Regulatory Agency audits, interview or meet with the auditor only if the audit lead or designate is present.
- Answer all questions truthfully to the best of your ability. Don't volunteer information.
- Answer only question asked and only questions relevant to your Job Description/study involvement. If you do not know the answer, say so and defer to another employee, if applicable, or provide an answer at a later time during the audit.

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Tips

- Be professional at all times (i.e. NO chewing gum, NO inappropriate conversation, NO interrupting or arguing with the inspector). Assure that appearance is clean and professional at all times.
- Keep confidential information filed away and office areas neat.
- Do not use your personal cell phone during interactions with the auditor, they should be muted or placed on vibration mode.
- Do not provide any gifts to the auditors; as such action may be interpreted as coercive. Do not offer refreshments or lunch.
- Do not provide documentation directly to the auditor(s) without prior permission from the audit lead or designate.
- Make a list of all documentation that the auditor/inspector is reviewing and copies in the order provided if possible.

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Audit Readiness - What happens during an Internal Compliance Audit?

Melinda Moore, CCRC – Research Compliance Auditor, MUSC

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Compliance Audit

A compliance audit is intended to be a constructive, service oriented process conducted for several positive reasons….

To **ensure full compliance** with the laws, policies, and standards governing human subjects research

To **identify potential problem areas**

To **educate** on standards and expectations of research practices and promote Good Clinical Practices

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Compliance Audit

Ultimate goal = to help improve the quality of human subjects research.

Think of us as a part of the team

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Scheduling

Studies to be audited are selected a few weeks in advance of the audit

An e-mail is sent to the PI and study coordinator with a proposed date

The email includes a copy of an audit checklist for study team members to review prior to the audit

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Audit Checklist

The audit process is guided by a checklist that lists the specific items to be reviewed.

Informed Consent Findings		Yes	No	N/A	Policy Reference	Reviewer Comments
1.	Were original Informed Consent Documents (ICD) found for each study subject?	☐	☐	☐	MUSC HRPP 6.1.B: *Informed Consent to Participate in Research Policy and Procedures*	
2.	Was the appropriate Institutional Review Board (IRB) watermark used on ICD and Health Insurance Portability and Accountability Act (HIPAA) authorizations?	☐	☐	☐	MUSC HRPP 6.1.III.H: *Informed Consent to Participate in Research Policy and Procedures*	
3.	Are all consents complete with full signatures, images and dates by appropriate parties and where applicable appropriate initialing? *(Note: the word images refer to e-consent technology)*	☐	☐	☐	MUSC HRPP 6.1.B.4: *Informed Consent to Participate in Research Policy and Procedures*	
4.	Was the IRB approved consenting method used for all subjects? (e.g., in-person, by mail, verbal, e-consent, etc.)	☐	☐	☐	MUSC HRPP 6.1.Q: *Informed Consent to Participate in Research Policy and Procedures* MUSC HRPP 1.5 *State Laws Affecting Human Subjects Research* (Legal Representative Definition)	
5.	Was documentation provided to verify that the subject consented and that consent took place prior to the subject starting study procedures and/or screening activity, as applicable?	☐	☐	☐	MUSC HRPP 6.1.B.1: *Informed Consent to Participate in Research Policy and Procedures*	
6.	If applicable, was assent given?	☐	☐	☐	MUSC HRPP 6.1.C: *Informed Consent to Participate in Research Policy and Procedures*	
7.	If applicable, did the legally authorized representative sign and date the ICD/HIPAA authorization?	☐	☐	☐	MUSC HRPP 6.1.I.C, 6.1.I.C, MUSC HRPP 6.3.F: *Informed Consent to Participate in Research Policy and Procedures*	
8.	If applicable, was an IRB approved translation, either by a translator or translation of the ICD/HIPAA authorization provided to non-English speaking subjects?	☐	☐	☐	MUSC HRPP 7.5: *Research Involving Non-English Speaking Subjects Policy and Procedures* MUSC HRPP 6.1.K, MUSC HRPP 6.3.E: *Informed Consent to Participate in Research Policy and Procedures*	
9.	Was the HIPAA authorization properly signed and dated?	☐	☐	☐	MUSC HRPP 4.13.D: *Privacy and Confidentiality*	
10.	Was consent obtained by an IRB approved study team member?	☐	☐	☐	MUSC HRPP 6.1.B.3: *Informed Consent to Participate in Research Policy and Procedures*	
11.	Were subject payments made as outlined in the ICD?	☐	☐	☐	MUSC HRPP 7.3: *Payment for Participation Policy and Procedures*	

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Audit Checklist

What is the audit checklist based on?

- IRB Human Research Protection Program https://research.musc.edu/about/research-integrity/institutional-review-board/policies-procedures
- Federal & State laws and regulations https://www.hhs.gov/ohrp/
- FDA Good Clinical Practices https://www.fda.gov/about-fda/center-drug evaluation-and-research-cder/good clinical-practice

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Audits

Ok, but why is *MY* study being audited?

Compliance has adopted a risk based approach for audit studies selection. More effort is spent on new PI's, investigator initiated, vulnerable populations, and high enrolling studies

A small percentage of audits (5-10%) are 'for cause,' (typically generated by a subject, staff or sponsor concern)

Administrative request (ex. failure to submit for continuing renewal)

Exempt studies (ex. Making sure data collection is correct)

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Audit Documents

What exactly will be audited?

Review of all **Informed Consent Documents and HIPAA authorizations** to verify subjects have been properly consented

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Audit Documents

What exactly will be audited?

Review of the **Regulatory Binder** for essential documents

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Audit Documents

What exactly will be audited?

Review of **Individual Subject Data Records** for protocol adherence, safety and confidentiality

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Audit Documents

What exactly will be audited?

Verification of **data storage and security**

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Audit Documents

What exactly will be audited?

Overall **site operations**

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Primary Audit Components

What are the Primary Audit Components?

Informed Consent and HIPAA Authorizations

Regulatory Binder

Review of Individual Subject Data Records for protocol adherence, safety and confidentiality

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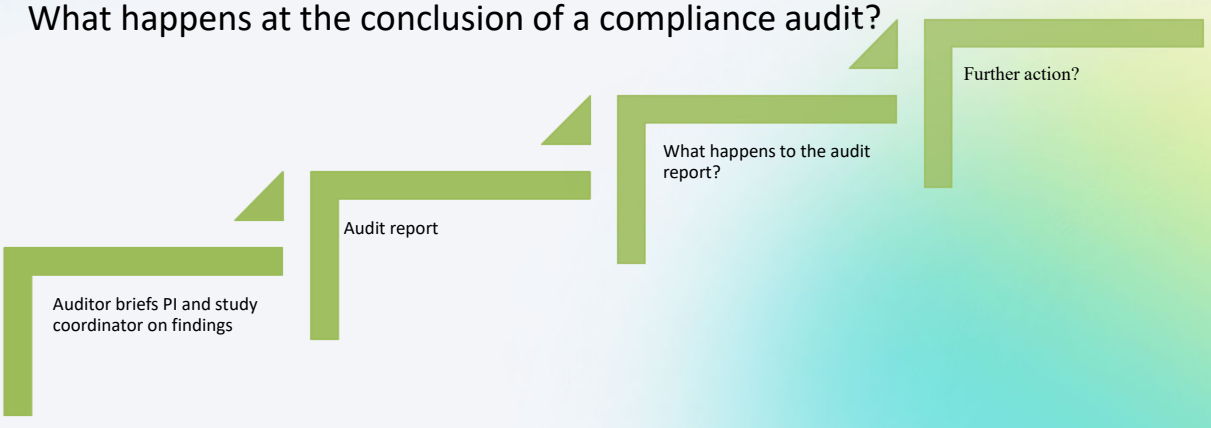
Human Research Audits

What happens at the conclusion of a compliance audit?



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Audit Readiness - Leveraging Self-Assessments

Hallie Altwies - Human Research Quality Manager, BUMC/BMC

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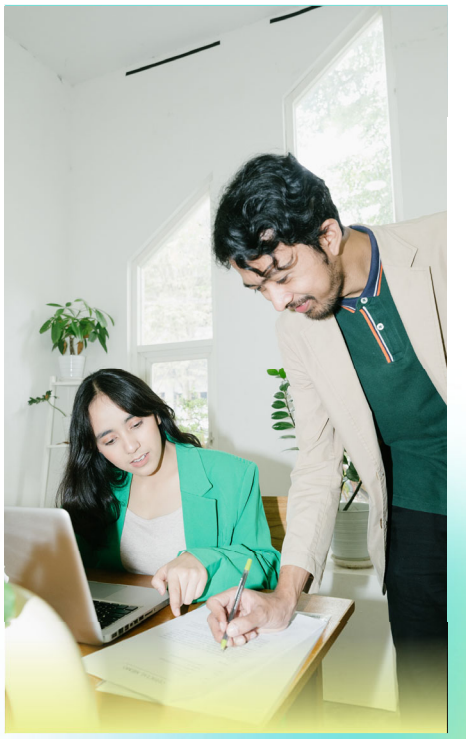
Topic We'll be Covering

What is a self-assessment?

How do you conduct a self-assessment?

What is the outcome of a self-assessment?

Tools, Resources, and Links



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Have you ever taken part in a self-assessment conducted on your study?

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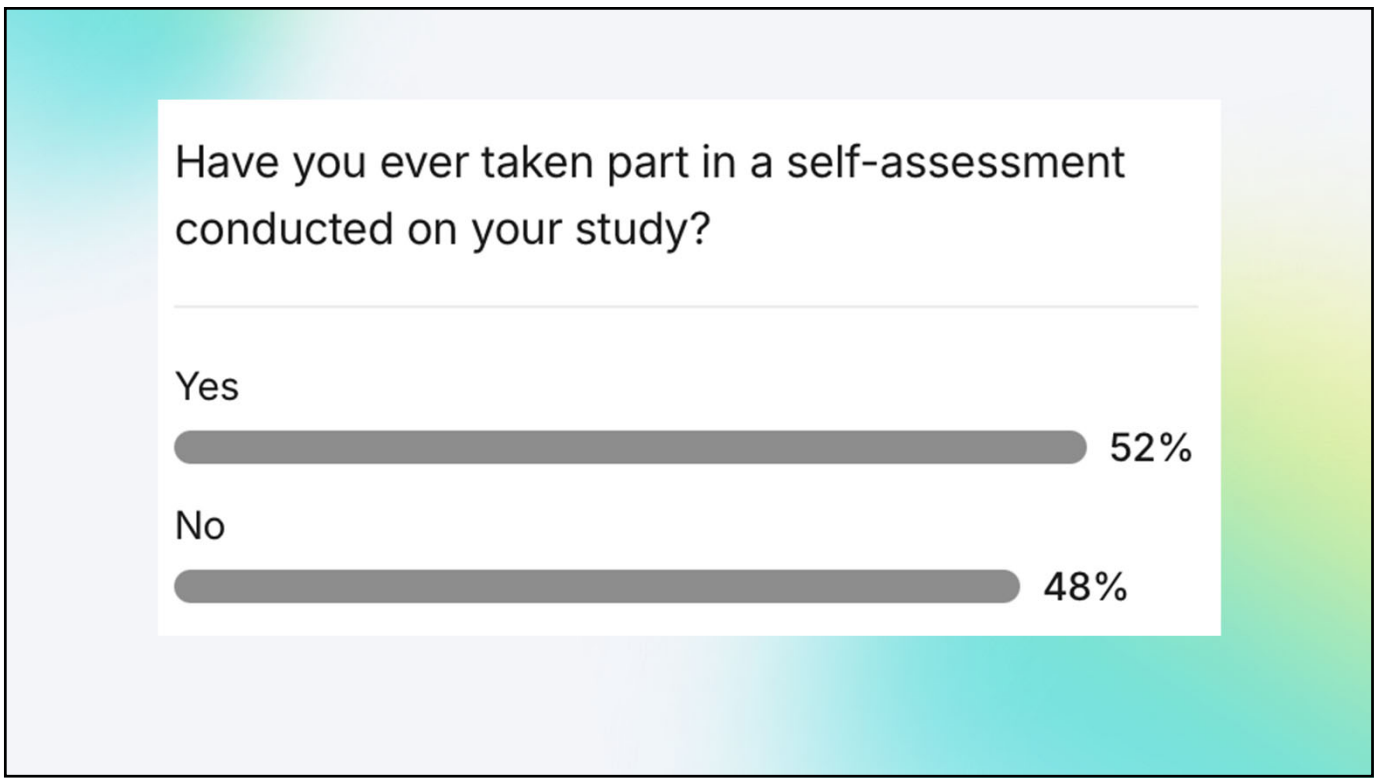

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What is a self-assessment?

A research team's deliberate and planned review of their own study documents and processes to verify protocol adherence and compliance to policy and regulations

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Why should we conduct self-assessments?

- Supports participants **safety** and **protection of rights**
- Increases data **integrity** and **reliability**
- Ensures study staff are following the **procedures outlined in protocol**
- Useful for **preparing** for quality assurance visits from monitors or auditors

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More to know on self-assessments

- The **goal**: incorporating proactive quality control checks that continually assess the quality of research conduct
- Recommended for any research team even if the study receives ongoing oversight by outside monitors
- Can be implemented at specified time points during the study; i.e. after X months of study life, or X patients are enrolled and/or receiving study intervention

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What are the stages of a self-assessment?

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Planning → Conducting → Correcting

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What happens during the PLANNING stage?

- Extent and nature of self-assessment review should be specific to YOUR study
  - Consider risk, complexity of overall study + specific aspects, study procedures, enrollment pace, previous issues encountered, etc.
- What should be reviewed?
  - Subject ICFs, Subject Eligibility, Protocol Adherence

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Planning stage example

- Background:
  - A Post-Approval, prospective registry to evaluate long-term outcomes of a commercially available pacemaker with new battery pack
  - FDA regulated (IDE exempt)
  - Greater than Minimal Risk
  - PI-initiated (investigator led registry)
  - Target recruitment N = 100

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Planning stage example

- Perform self-assessment after first 5 patients are enrolled (initial quality check) then proceed by reviewing biannually (or adjust to more frequent assessments if enrollment rate increases)
- Examine all signed ICFs since last review
- Examine random selection of participants (e.g. 3 subjects) eligibility criterion and study visit adherence per protocol standards
- Adapt self-assessment plan based on most recent review findings
- Maintain record of self-assessment procedures and outcomes

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How to CONDUCT a self-assessment?

- Note: Assess what is feasible for your study team based on staffing and workload (partial assessment is better than none at all!)
- Reference the policies and regulations that are relevant to your study
- Use self-assessment tools provided by your institution
- Document your self-assessment; keep record of what you reviewed, how you reviewed it, and what you found as the "auditor"

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How to CONDUCT a self-assessment?

- What's important to check?
  - Are your research operations doing what your protocol is directing you to do?
  - Are you able to document that you've adhered to protocol and relevant policies/regulation standards?

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A quick (but important!) note on documentation

- Think to yourself: If I were not study staff, would I be able to look at our documentation and clearly understand what is being indicated?
  - If the answer is no, it's a good idea to supplement additional documentation!

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How to CORRECT your procedures after a self-assessment?

- What did you find during your self-assessment?
  - What can you fix internally?
  - Does anything need to be reported?
    - If yes, when does this need to be reported and how to do it?

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Reporting your findings - who/what/when?

- Reporting depends on . . .
  - IRB approved protocol requirements
  - Institutional and IRB of record policies
    - Defines the time frame for reporting and what constitutes deviation severity
    - If PHI issues, reference Privacy Officer guidelines
  - Sponsor, lead site, and/or funder policies
  - If the PI is a sponsor-investigator who holds the IND or IDE, then FDA reporting may be required
- Major deviations and Unanticipated Problems (UPs) reporting entails CAPA development

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Outcomes of self-assessments

- Recognize and applaud yourself for the things your research team has done well!
- Discover areas for improvement and address the gap
- Participants are better protected and their rights preserved
- Audits and reviews will go more smoothly - save yourself a headache!

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Audit Readiness - Common Audit Findings

Coralee Tye, PhD – IRB Regulatory Analyst, UVM

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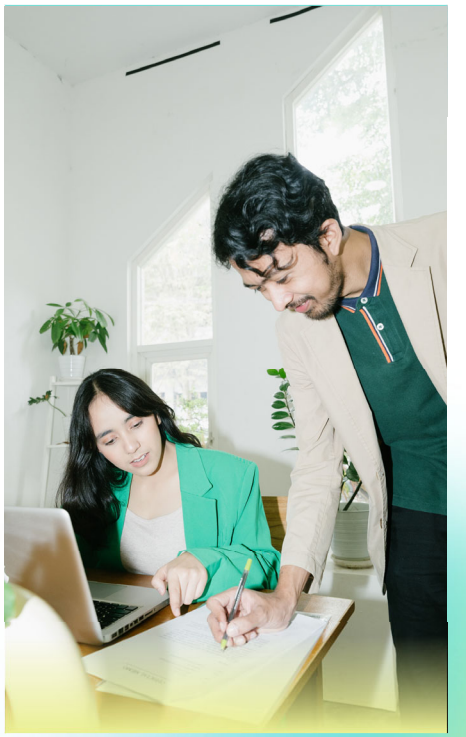
Topic We'll be Covering

Identify common audit findings, including incomplete documentation, protocol inconsistencies, and training gaps.

Present a fictional Case Study of a for-cause FDA Audit

Give a more comprehensive list of common findings



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Case Study Background

Study type: Phase II, single-site, industry-sponsored drug trial
Indication: Chronic inflammatory condition
Principal Investigator (PI): Academic clinician managing multiple concurrent trials
Regulatory oversight: FDA-regulated clinical investigation (IND in effect)
Study team: PI, one full-time study coordinator, one part-time research nurse
Study Status: study is on-going. Has enrolled 16 of 58 planned participants.

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FDA Inspection Trigger For Cause Inspection

- Late reporting of a **serious adverse event (SAE)**
- Repeated **protocol deviations** identified during quarterly sponsor monitoring with late reporting to the FDA
- **Data inconsistencies** identified during sponsor monitoring

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FDA Key findings

The FDA issued a **Form 483** citing failure to provide adequate oversight of the clinical investigation in violation of **21 CFR 312.60**.

1. Failure to adequately supervise the study team
   The PI delegated critical trial responsibilities without maintaining **ongoing supervision**
   The study coordinator independently made **subject eligibility determinations**
   There was **no documentation** demonstrating PI review of:
   - Eligibility assessments
   - Case report forms (CRFs)
   - Adverse event evaluations

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FDA Key findings

2. PROTOCOL DEVIATIONS NOT PREVENTED OR CORRECTED
   - MULTIPLE SUBJECTS WERE ENROLLED DESPITE NOT MEETING INCLUSION/EXCLUSION CRITERIA
   - PROTOCOL DEVIATIONS WERE:
     - NOT IDENTIFIED IN A TIMELY MANNER
     - NOT REPORTED TO THE IRB
     - NOT EVALUATED FOR POTENTIAL IMPACT ON SUBJECT SAFETY
   - PROTOCOL DEVIATIONS IDENTIFIED DURING SPONSOR MONITORING CONTINUED

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FDA Key findings

3. Inadequate Safety Oversight
   SAEs were assessed by study staff without PI involvement
   SAE reporting to the sponsor and IRB was delayed
   There was no evidence that the PI evaluated whether events met expedited reporting requirements
4. Incomplete and Inaccurate Records
   Discrepancies between source documents and CRFs
   Missing PI signatures and dates
   No documentation confirming PI review or approval of study data

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What are some things the PI could have done to prevent a for-cause FDA Inspection?

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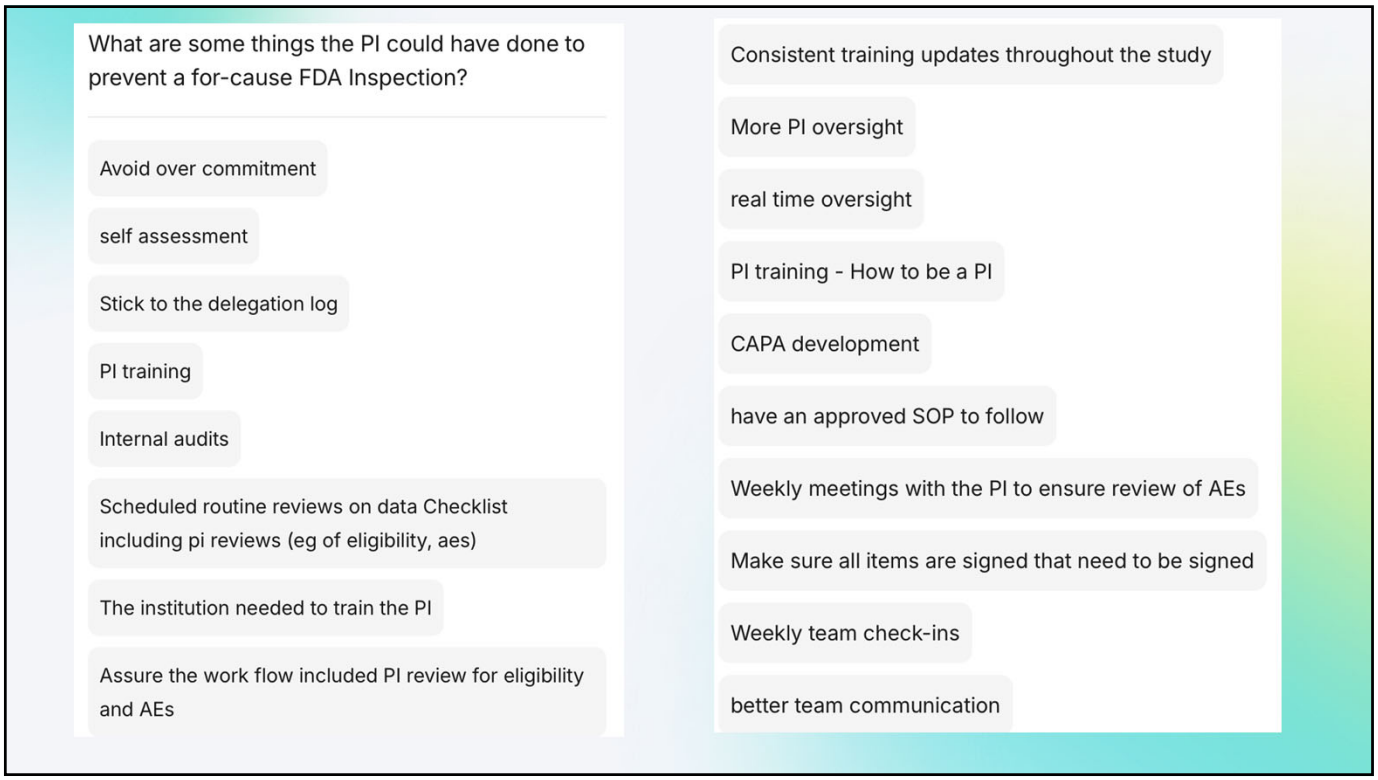
What are some things the PI could have done to prevent a for-cause FDA Inspection?
Avoid over commitment
self assessment
Stick to the delegation log
PI training
Internal audits
Scheduled routine reviews on data Checklist including pi reviews (eg of eligibility, aes)
The institution needed to train the PI
Assure the work flow included PI review for eligibility and AEs
Consistent training updates throughout the study
More PI oversight
real time oversight
PI training - How to be a PI
CAPA development
have an approved SOP to follow
Weekly meetings with the PI to ensure review of AEs
Make sure all items are signed that need to be signed
Weekly team check-ins
better team communication

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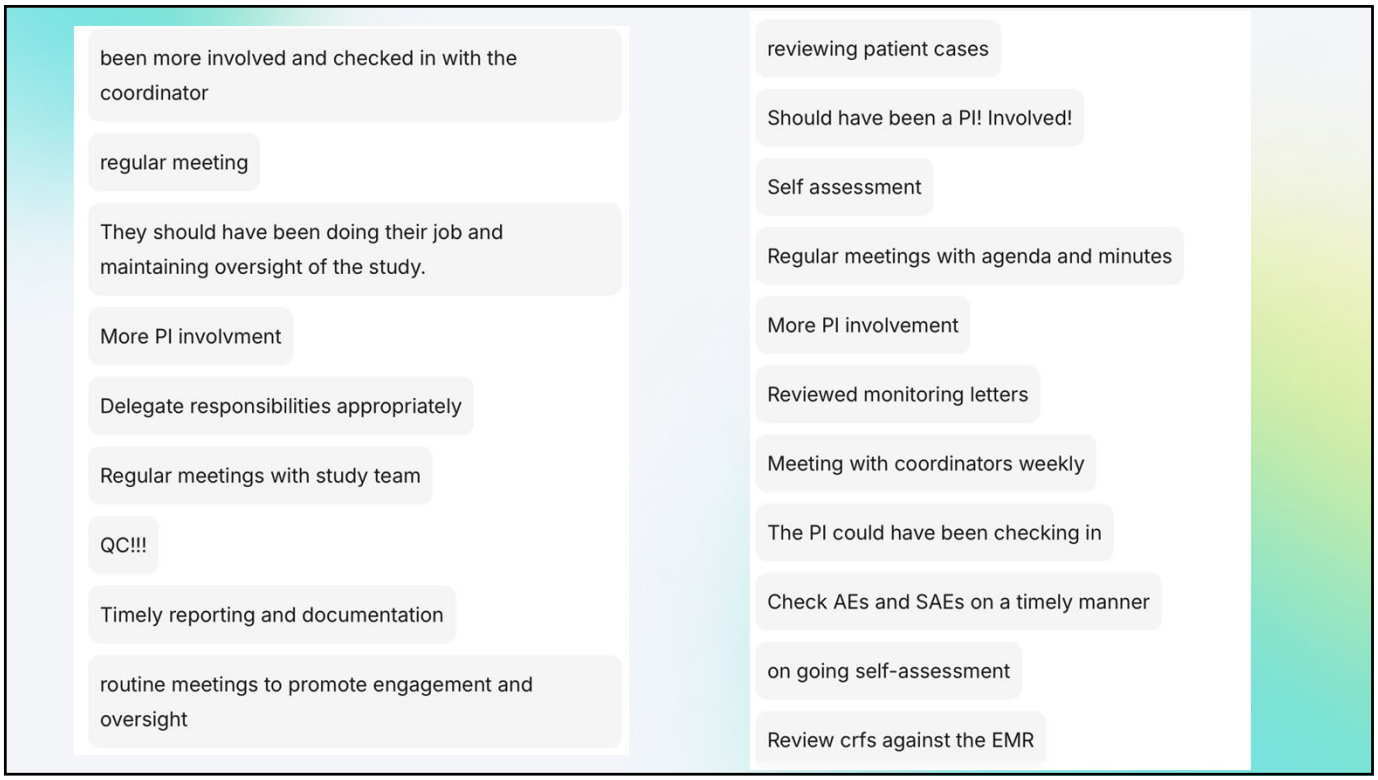
been more involved and checked in with the coordinator
regular meeting
They should have been doing their job and maintaining oversight of the study.
More PI involvment
Delegate responsibilities appropriately
Regular meetings with study team
QC!!!
Timely reporting and documentation
routine meetings to promote engagement and oversight
reviewing patient cases
Should have been a PI! Involved!
Self assessment
Regular meetings with agenda and minutes
More PI involvement
Reviewed monitoring letters
Meeting with coordinators weekly
The PI could have been checking in
Check AEs and SAEs on a timely manner
on going self-assessment
Review crfs against the EMR

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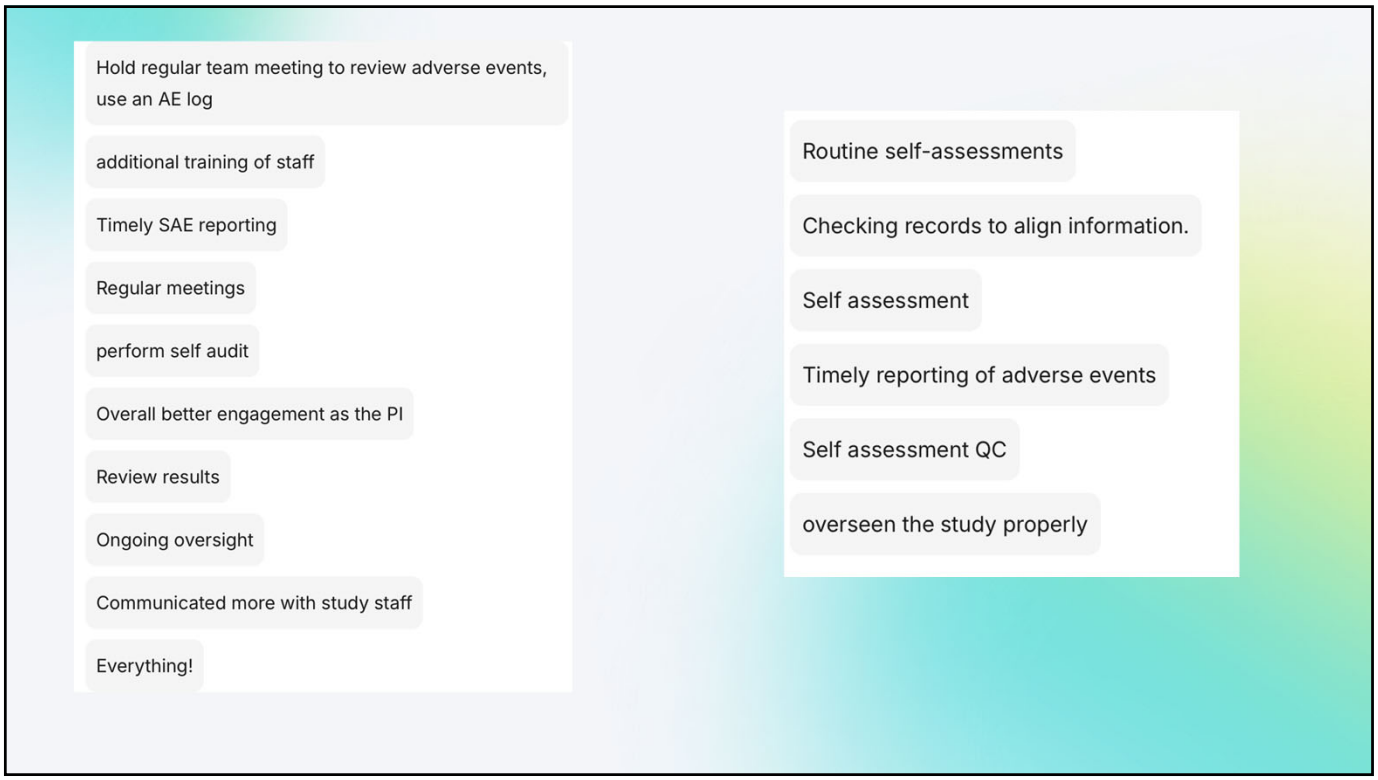

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What could have been done prior to an FDA audit trigger?

- Internal and/or Self auditing
- Previous sponsor monitoring audit findings applied to all aspects of the study
- Internal monitoring at beginning or add once issues are recognized
- Eligibility checklists
- Study team could have met to re-review all processes a few months once patients were enrolled to ensure compliance
- Ensure everyone was trained to recognize when documents were incomplete and who to escalate to
- Regular check in meetings with agenda and minutes
  - Review procedures and process improvements

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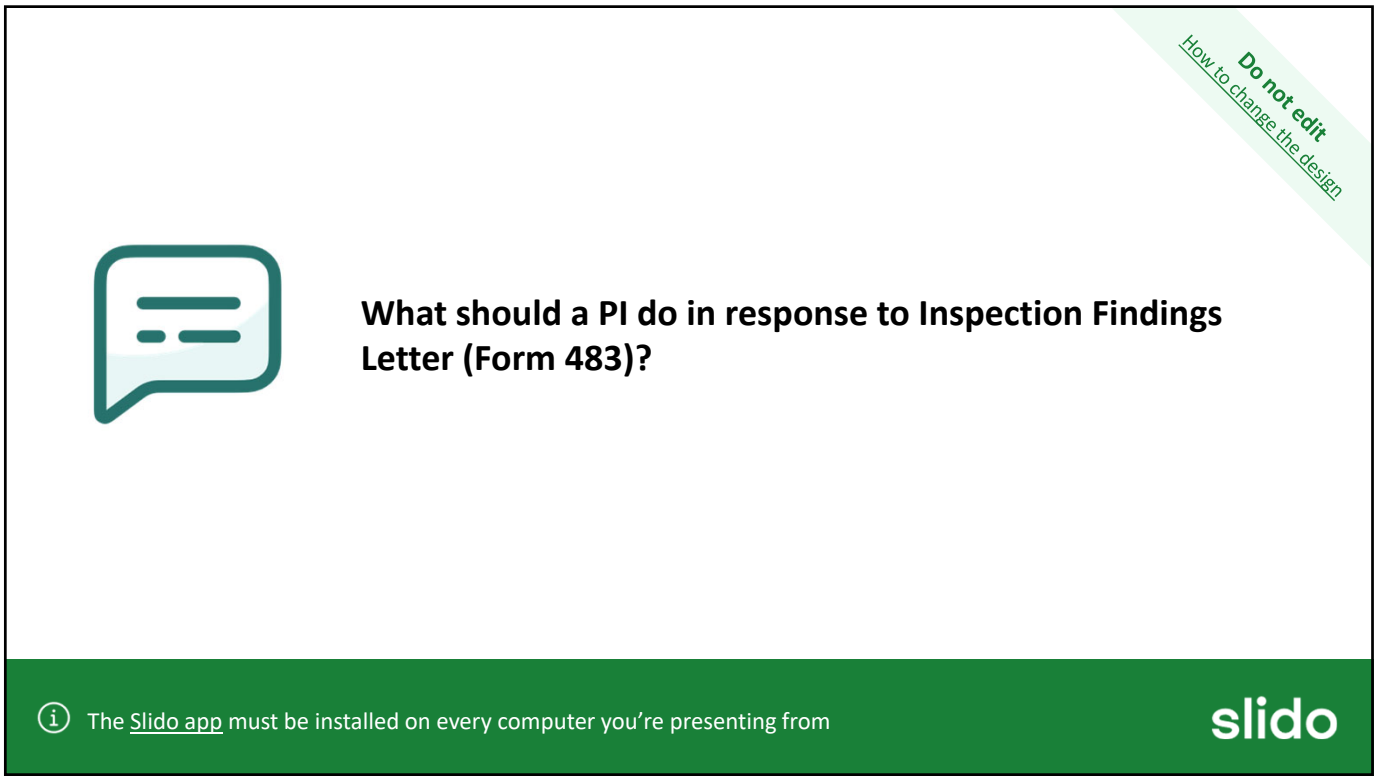
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What should a PI do in response to Inspection Findings Letter (Form 483)?
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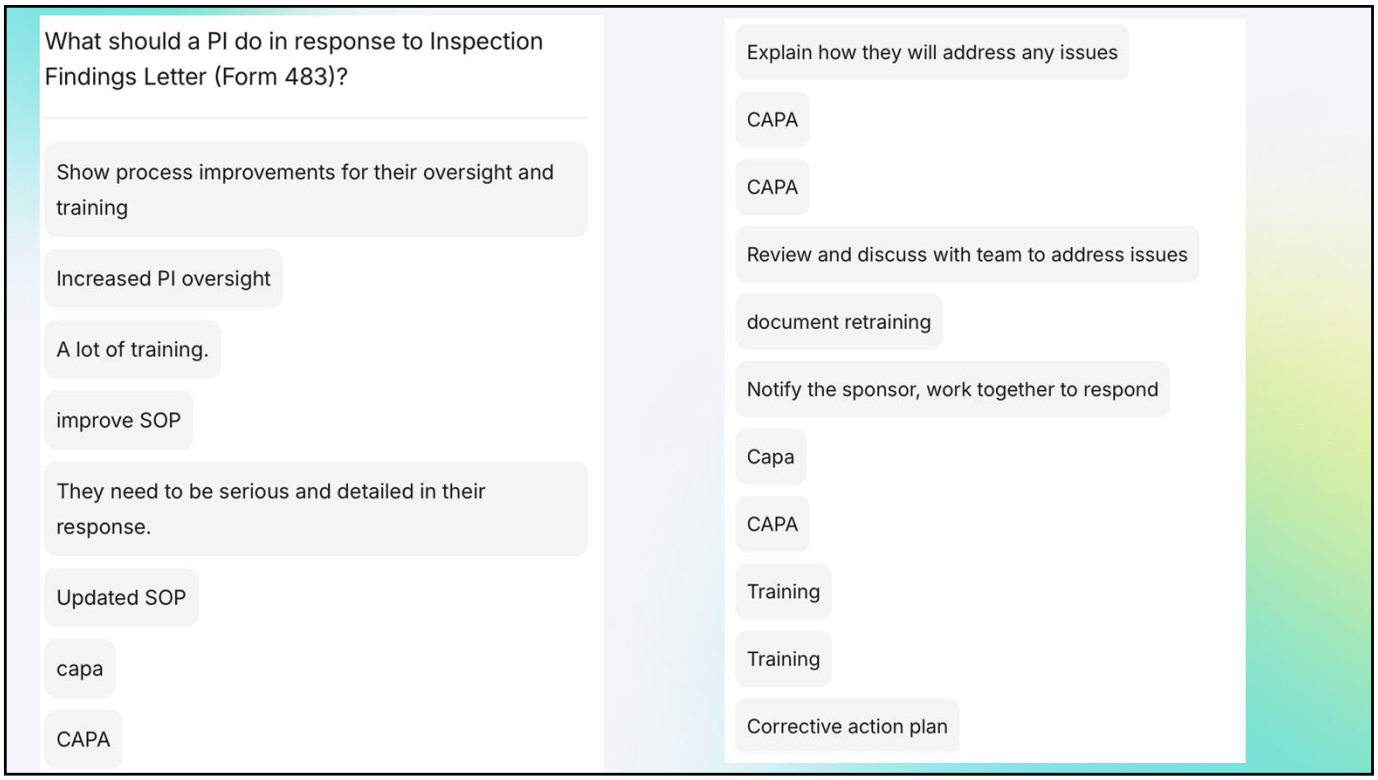
What should a PI do in response to Inspection Findings Letter (Form 483)?
Show process improvements for their oversight and training
Increased PI oversight
A lot of training.
improve SOP
They need to be serious and detailed in their response.
Updated SOP
capa
CAPA
Explain how they will address any issues
CAPA
CAPA
Review and discuss with team to address issues
document retraining
Notify the sponsor, work together to respond
Capa
CAPA
Training
Training
Corrective action plan

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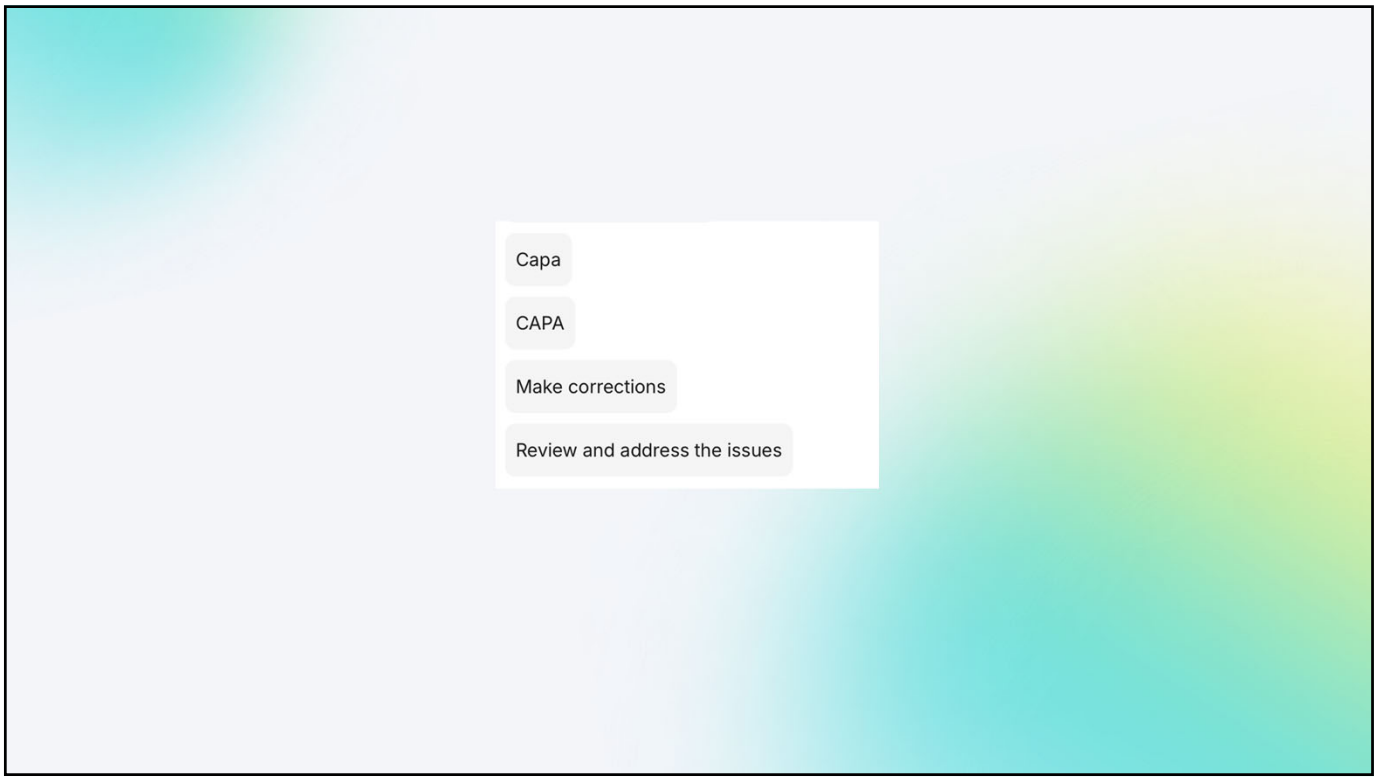

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Response to Form 483

- A comprehensive Corrective and Preventive Action (CAPA) plan
- Documentation of:
  - Revised delegation and supervision procedures
  - Routine PI review of safety data and study records
- Evidence of GCP retraining for the PI and all study personnel
- A preventive plan to ensure compliance across future clinical investigations
- Add staff such as co-PI to assist with oversight and/or data coordinator
- Documentation of frequent meetings with the PI to include an agenda and meeting

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More examples of common audit findings

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What do you think are some common consent findings?

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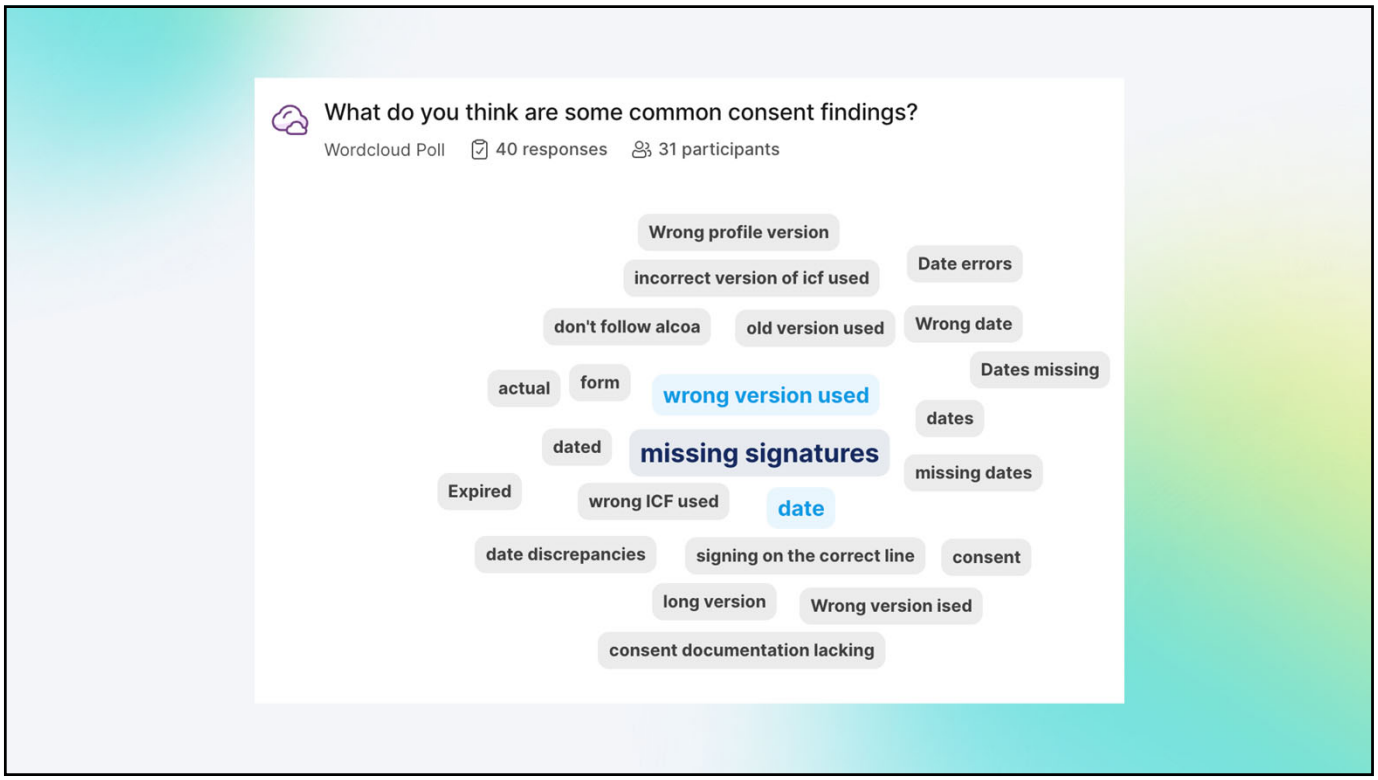

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Common Consent Findings

- The wrong version of the consent form was used
- Not using the IRB stamped consent form
- Participant consent was obtained via a non-IRB approved method (ie: use of e-consent, an LAR or witness without approval)
- Not maintaining original, fully executed consent
- Enrollment of non-English speakers without IRB approval or without translated consent.
- Person obtaining consent not approved on the IRB Study Team

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Common Consent Findings

- Pre-signing and dating of consent forms by PI/designee
- The consent form was not signed or dated by the study participant and/or PI/designee
- Additional consent form checkboxes are not completed, or initials are missing
- Consent process documentation not completed or completed days/months after consent
- The consent was signed by PI, but the consent process was documented by designee
- Lack of notes on consent process explaining different consent circumstance –ie: use of a witness, delayed countersignature etc.

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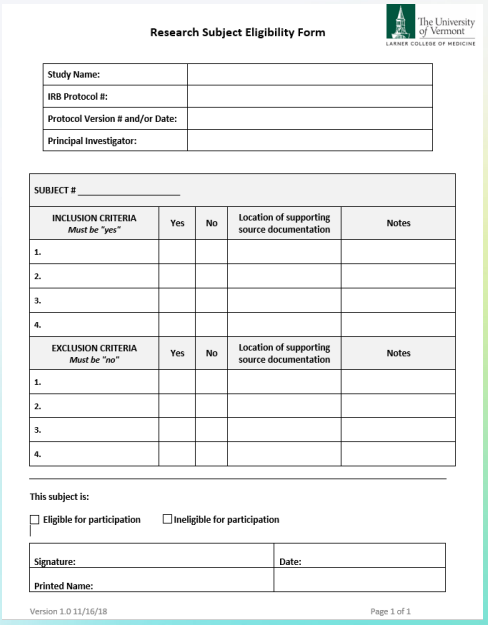
Common Eligibility Findings

- Inclusion/exclusion criteria not documented (no corresponding source documents)
- Eligibility checklist not attributable
- KP does not have required training to determine eligibility and/or was not designated the task on DOA log
- Study participant ineligible for the study
- Approved eligibility was too vague and criteria are not met
- Lack of Screening/Enrollment Log, including screen fails



Research Subject Eligibility Form

The University of Vermont Larner College of Medicine

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.				
3.				
4.				
EXCLUSION CRITERIA *Must be "no"*	**Yes**	**No**	**Location of supporting source documentation**	**Notes**
1.				
2.				
3.				
4.				

This subject is:

☐ Eligible for participation ☐ Ineligible for participation

Signature:	Date:
Printed Name:	

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Common Protocol Findings

- Removing procedures without modifying protocol and getting IRB approval
- Use of questionnaires without approval
- Incomplete records/case report forms
- Any deviation from the approved protocol is a protocol deviation and should be appropriately recorded and reported to the IRB (if applicable)
- Study team not kept up-to-date

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Common Data Storage & Security Findings

- Data is not stored in an IRB approved location
- Data is not stored according to approved plan- fully identifiable dataset and not coded, or stored on an unapproved portable device
- Data shared with external collaborators without a DUA
- Usernames & passwords not stored securely - An inspector found a sticky note on a piece of sponsor issued research equipment with a username and password
- Original documentation not retained (e.g., documents shredded after scanning)

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Common Regulatory & Institutional Policy Findings

- Missing or incomplete Deviation Log; ie: meets Reporting Req not completed
- Lack of documentation of trainings on protocol and data management plan
- Lack of minutes of safety/DSMB meetings
- Missing CVs (signed and dated), and Licenses
- Missing communications and approvals from External IRB or Lead Site
- Research flag in EPIC not activated/deactivated
- Expired CITI trainings

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Do you have additional example findings you would like to share?

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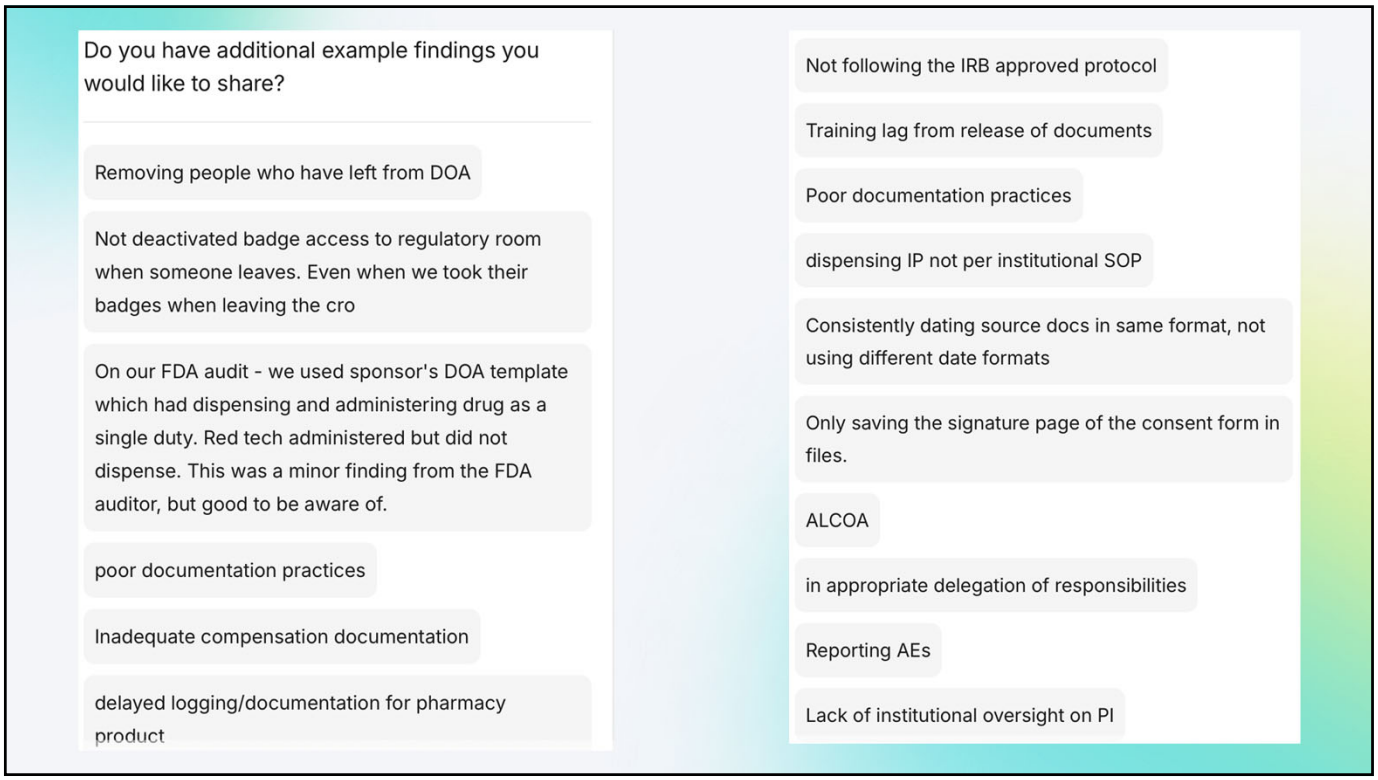

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Tools, Resources, and Links

- Previous Training and Education
  - RPN Workshops
    - September 2024
    - November 2022
    - June 2019
  - Clinical Research Seminars
    - April 2018
- Self-Assessment Tools
  - Many helpful tools provided on BUMC/BMC CRRO Tools Website

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Reporting Policies and Resources

UVM
- RNI Reporting
- Quality Assurance Program

WVU
- Standard Operating Procedures
- Site Audit and Close Out Visits

UF
- HRP Policy 112 Reportable Events
- Deviation Reporting – Event Reporting – Adverse Events, Unanticipated Problems Involving Risks to Subjects of Others, Protocol Deviations, and Other Problems

BUMC/BMC
- HRPP Policy 6.6.5.2 Major Deviations
- HRPP Policy 7.4.5 Submission of Reportable Events and New Information
- IRB Templates

MUSC
- Policy IRB HRPP 10.1 Human Research Audit
- Policy 4.14 Protocol Deviation
- Protocol Deviation Report Form

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