THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

NRP

Biomedical Behavioral Translational Social

Network for Research Professionals

NRP APRIL 2025 Education Session

Just a few Housekeeping items:

- This presentation will be recorded and available on the NRP website
- Please keep your lines muted during speaker presentation
- You may enter your questions into the chat or come off mute if you have a question

CTQA Risk-Based Audit Plan and Self-Assessment Review

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Objectives

Identify	• Identify high risk areas to be audited by CTQA as part of the Risk-Based Audit Plan
List	• List potential benefits of using the available Self-Assessments
Locate and leverage	• Locate and leverage current Self-Assessment Series

What is a Risk-Based Audit Plan?

An Audit Plan that prioritizes areas of research posing the highest risks:

Participant Safety

Data Integrity

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What is Reviewed Under the Risk-Based Audit Plan?

- Informed Consent Forms
- Reconsent Requirements
- Informed Consent Process Documentation
- Participant Eligibility Criteria and Documentation
- Protocol Adherence
- Safety Reporting
- Data Integrity

• Informed Consent/Reconsent

- Review of all initial consent forms approved by the IRB for:
  - Required elements
  - Correct versions at the time of consent
  - Completed questions (e.g., check box for agreement to be contacted for future research)
  - Appropriate signatures and dates
- Review of reconsent requirements approved by the IRB:
  - Review IRBIS for IRB approved reconsent plan
  - Determine which participants required reconsent
  - Review for the same criteria as the initial consent form
- Informed Consent Process Documentation

Participant Eligibility

- Review current protocol eligibility at the time the participant enrolled into the study
- Ensure source documentation to support each criterion is in the participant records (either the medical record or participant binder)
- If source documentation cannot be provided, ensure that relevant criteria are documented as confirmed with the participant or investigator
- Ensure that the PI documents their review of all inclusion/exclusion criteria and the participant eligibility.

Protocol Adherence

Review	Review	Ensure	Assess	Review
Review of all screening procedures	Review of all visits to determine if all procedures are completed adhere to the required timeline, including any windows	Ensure Serious Adverse Events (SAEs) and Adverse Events (AEs) are recorded, along with deviations to the protocol	Assess SAEs and protocol deviations for IRB reporting requirements	Review investigational product accountability, including dispensation records, coordinator documentation of participant compliance and any other investigational product requirements.

Safety Reporting

- Once we determine that there is a requirement to submit safety concerns:
  - Review of IRB requirements for reporting (External IRB vs. UNC IRB)
  - Include the requirement in the audit report
  - Follow-up with the study team to ensure that the Promptly Reportable Information (PRI) has been submitted appropriately

Data Integrity

- Spot-check primary (and possibly secondary) endpoints against the source documentation and electronic data capture (EDC) systems
- Evaluate the timeline for data entry, as a delay may impact participant safety

What is the Study Team Responsible For?

- At the time of Risk-Based Audit notification, you will be asked to:
  - Set-up an initial meeting with relevant staff to go through the audit process and provide any information pertinent to the audit
  - Reserve space for the auditor(s) (private space if possible)
  - Confirm the number of participants enrolled in order for CTQA to determine how many participants we will review
  - Complete the Clinical Trial Regulatory Document Self-Assessment and provide the document at the beginning of the audit for review
  - Provide the participant records for those participants identified to be reviewed
  - Ensure a knowledgeable research team member is available either in person or via Teams for questions that arise.

Self-Assessments

A deliberate and planned review of study documents and processes by the research team to ensure protocol adherence and compliance with policies and regulations.

Improved Compliance

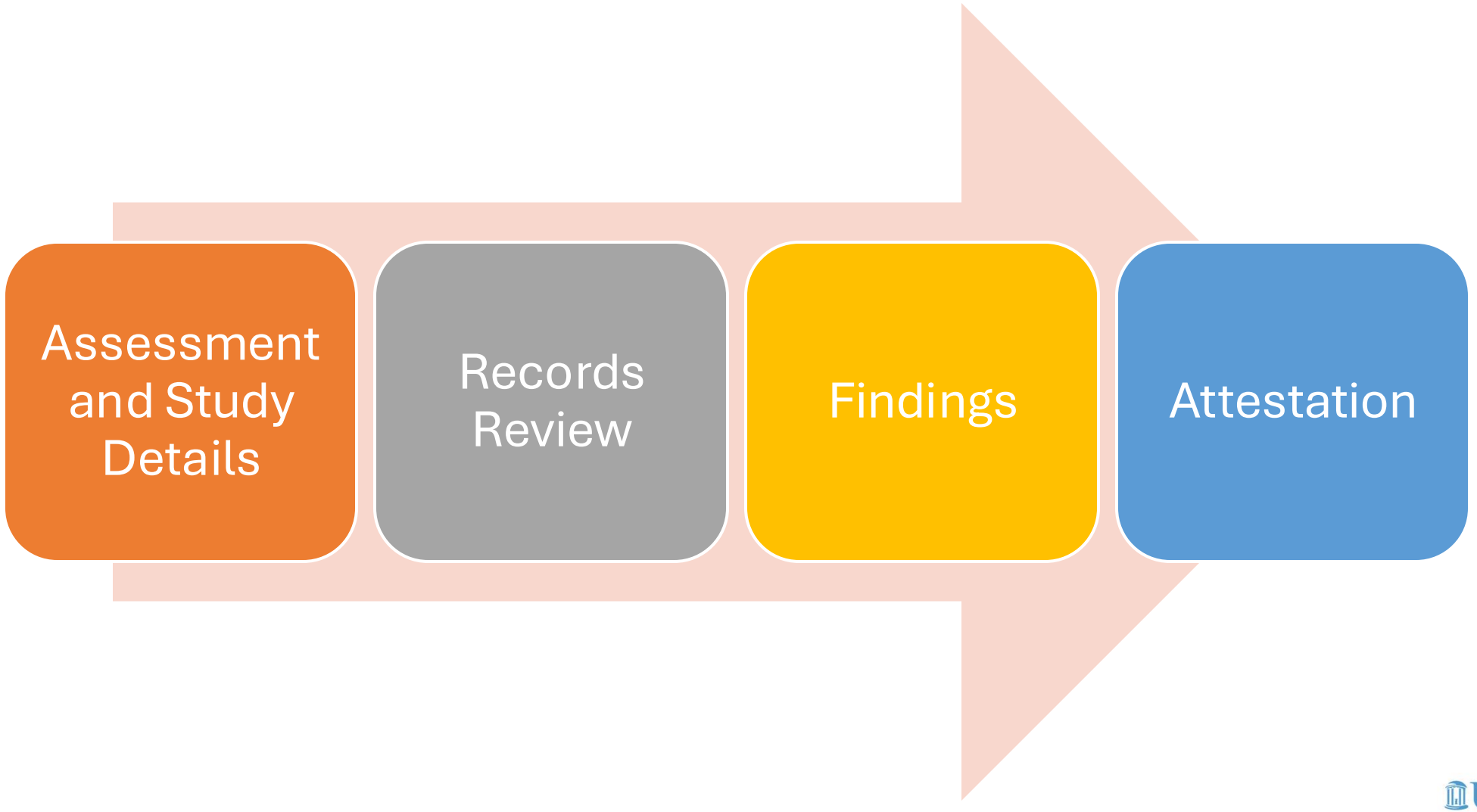
Early Detection of Issues

Enhanced Quality Control

Increased Efficiency

Better Preparedness

Common Structure



Best Practices in Self-Assessment

- **Regular Assessments:** Schedule consistently to ensure ongoing compliance.
- **Thorough Documentation:** Record findings and actions to maintain clear records.
- **Tailored Process**: Customize to study complexity and risk level.
- **Team Engagement:** Involve all team members to promote a culture of compliance.
- **Standardized Tools:** Use checklists and standardized tools for consistency and to streamline reviews.
- **Plan Updates:** Reflect protocol and regulation changes to keep the process effective.

Self-Assessment Series

Informed Consent Self-Assessment

Participant Eligibility Self-Assessment

Qualifications and Delegation Documentation Self-Assessment

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Newest Self-Assessments

Clinical Trial Regulatory Document Self-Assessment

Data Integrity Self-Assessment

Thank you!

For ongoing support and questions, please email us:

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Evaluation

Please complete the post-session evaluation, link is in the chat or scan the QR code.

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