SOM SOP 301.1

Performing the Responsibilities of the Principal Investigator

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Session Outline

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Attesting in PaTS

SOP Overview

Questions

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Attesting in PaTS

Profile and Training System

Who is Required to Attest in PaTS?

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All personnel who select the responsibility of “serve as Principal Investigator” or “serve as Sponsor/Investigator” are required to attest to the SOP in PaTS

If you did not select the responsibility, you can still view and attest to the SOP.

When Is the Attestation Due?

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30 Days from Issue Date

April 3, 2023

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How to Attest

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SOP Overview

Performing the Responsibilities of the Principal Investigator

SOP Sections

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- Obtain and/or Develop the Study Protocol and Associated Documents
- Conduct an Internal Feasibility Assessment
- Demonstrate and Document Qualifications and Training & Delegate Study-Related Tasks
- Ensure Initial and Ongoing Approval by an Institutional Review Board (IRB)
- Ensure Completion of Ancillary Reviews
- Ensure Applicable Agreements are Prepared and Executed by an Authorized Signatory Official
- Exercise Appropriate Oversight of the Overall Finances of the Project

SOP Sections

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- Oversee and Supervise the Study
- Ensure Eligibility and Informed Consent of Participants
- Ensure Protocol Compliance & Monitor for Safety
- Maintain Accurate and Complete Study Documentation & Manage and Protect Study Data
- Manage Applicable Test Articles
- Facilitate Monitoring Activities, Audits, and Inspections
- Prepare and Submit Reports

SOP Sections

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Obtain and/or Develop the Study Protocol and Associated Documents

- If creating the protocol, ensure it is scientifically sound
- If obtaining the protocol, ensure a CDA has been executed prior

SOP Sections

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Conduct an Internal Feasibility Assessment

- Determine if the study is operationally and financially feasible.

SOP Sections

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Demonstrate and Document Qualifications and Training & Delegate Study-Related Tasks

- Maintain your training materials (e.g., CV, licensure) and understand all regulations and requirements that pertain to the study
- Ensure study staff are trained
- Delegate tasks based on experience, training, licensure, etc.
- Keep record of both training and delegation

SOP Sections

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Ensure Initial and Ongoing Approval by an Institutional Review Board (IRB)

- Make sure that you obtain IRB approval:
  - Initial
  - Modifications
  - Promptly Reportable Information
  - Renewals/Administrative Reviews
  - Study Termination/Suspension/Completion

SOP Sections

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Ensure Completion of Ancillary Reviews

- Can Include:
  - Conflict of Interest
  - Scientific Review Committee
  - Data Safety Monitoring Boards
  - Radiation Safety
  - UNC Health Collaboration

SOP Sections

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Ensure Applicable Agreements are Prepared and Executed by an Authorized Signatory Official

- Don’t sign any agreement on behalf of the University

SOP Sections

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Exercise Appropriate Oversight of the Overall Finances of the Project

- Ensure sponsors are being invoiced appropriately and on time
- Ensure that a Billing Coverage Analysis is completed at study start-up as necessary

SOP Sections

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Oversee and Supervise the Study

- Communicate with your team
- Document communication as necessary
- Review study records

SOP Sections

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Ensure Eligibility and Informed Consent of Participants

- Verify and document participant eligibility
- Obtain informed consent using IRB approved methods
- Inform participants of significant new findings

SOP Sections

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Ensure Protocol Compliance & Monitor for Safety

- Conduct the study per the protocol
- Ensure that any deviations are documented
- Follow appropriate procedures if deviations are necessary to protect the health of the participant
- Ensure study team is trained on safety/reporting requirements
- Evaluate and monitor AEs
- Ensure AEs are documented and reported appropriately

SOP Sections

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Maintain Accurate and Complete Study Documentation & Manage and Protect Study Data

- Use the ALCOA-C standard (attributable, legible, contemporaneous, original, accurate, complete).
- File study documents appropriately (including regulatory and source documents)
- Ensure data management and sharing practices align with applicable regulations

SOP Sections

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Manage Applicable Test Articles

- Ensure appropriate storage, records, and use of any test articles
- Use UNC Health Investigational Drug Services for any investigational drug products

SOP Sections

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Facilitate Monitoring Activities, Audits, and Inspections

- Notify appropriate parties of visits
- Ensure all study documentation is available for review
- Be available to meet with the monitor/auditor as necessary
- Respond to findings in a timely manner

SOP Sections

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Prepare and Submit Reports

- Ensure timely reports to any parties such as sponsors, funding agencies, IRB, or federal agencies.

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Questions


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