UNC SCHOOL OF MEDICINE	Standard Operating Procedure		
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301.1: Performing the Responsibilities of the Principal Investigator

PURPOSE

This SOP describes the responsibilities and requirements of School of Medicine (SOM) principal investigators (PIs) conducting human subjects research.

SCOPE

This procedure applies to all SOM PIs conducting human subjects research.

BACKGROUND

By agreeing to serve as the PI, the investigator assumes the overall responsibility for the conduct of research involving human subjects either for the study as a whole or as a participating study site. General PI responsibilities include 1) protecting the rights, safety, and welfare of the participants under the PI's care, 2) personally conducting and supervising the research, 3) ensuring that informed consent is obtained as approved by the IRB, and 4) ensuring compliance with the investigator agreement, IRB approved investigational plan/protocol, and all federal, state and UNC-CH requirements regarding the obligations of investigators. The PI may delegate study-related tasks to qualified individuals, but they cannot delegate the primary responsibility for oversight of the research or supervision of study-related tasks performed by study team members.

The responsibilities of PIs in the conduct of clinical research are directly or indirectly described in:

- U.S. Department of Health and Human Services (HHS) Common Rule at 45 CFR 46[1]
- Food and Drug Administration (FDA) at 21 CFR 11,[8] 50,[9] 54,[11] 56,[12] 312,[13, 14] 812[22, 23]
- FDA Form 1572 (Statement of the Investigator)[7]
- FDA and HHS OHRP (Office of Human Research Protections) guidance
- International Council for Harmonisation (ICH) E6 Guideline for Good Clinical Practice (GCP)[39]
- The applicable provisions of UNC-CH Federalwide Assurance (FWA) and Institutional policies and standards.[53 (Section 2.2)]

The PI is accountable for any regulatory violations that result from the failure to perform these responsibilities.

Note that this SOP describes the PI's responsibilities of the investigator only. Additional responsibilities apply for sponsor-investigators who initiates and conducts an FDA-regulated investigation.

PROCEDURE

1. **Obtain and/or develop study protocol and documents**
   a. If creating the study protocol, ensure that it is ethically and scientifically sound.

b. If a protocol has already been developed by an external sponsor, obtain a copy of the protocol upon execution of a Confidential Disclosure Agreement (CDA).
c. Establish a master file of essential documents to assist in the management of the study, and to ensure study validity and data integrity. [39(GCP 6, 8)]
    i. Use a system for archiving that provide for document identification, version history, search, and retrieval.

2. **Conduct an internal feasibility assessment**
    a. Prior to initiating a study, conduct a feasibility assessment to identify strengths and weaknesses of the proposed plan and determine whether the project plan is practical.
3. **Demonstrate and document qualifications and training**[39(GCP 4.1, 4.2)]
    a. PI:
        i. Maintain an up-to-date curriculum vitae, licensure and certifications. In addition, an NIH biosketch is required if the study is federally funded.
        ii. Develop and maintain a thorough understanding of the regulatory and study specific requirements.
        iii. Create and maintain a PI profile in the SOM Personnel Profile and Training System.
        iv. Complete PI training required by UNC-CH, [58] SOM, the study sponsor, and all applicable regulatory authorities.
            1. File training documentation (e.g., certificates of completion, training log,[47] sponsor training documentation form, etc.) in the regulatory binder.
    b. Study Team:
        i. Verify and maintain documentation that all study personnel (which may include personnel not employed by UNC-CH SOM) complete training required by UNC-CH, SOM, the study sponsor, and all applicable regulatory authorities.
        ii. Provide access to training for all study team members based on their delegated responsibilities.
    c. Routinely review qualifications and training documentation to ensure that it is current, complete, and aligns with delegated responsibilities.
4. **Delegate study-related tasks**
    a. Establish processes for delegating responsibility.
    b. Delegate study-related tasks to study team members as appropriate based on protocol requirements and verified education, training, and experience; the overall responsibility for the study conduct may not be delegated.[18, 26, 32]
    c. Document and maintain delegation in writing (i.e., paper or approved electronic system) in the form of a delegation of authority (DOA) log[45] that indicates the names of the qualified individuals to whom significant study-related duties have been delegated, describes the delegated tasks, and documents the specific time periods (start and end dates) of involvement in the study.[39(GCP 4.1.5)]
5. **Protect the safety, rights, and welfare of participants through initial and ongoing review by an Institutional Review Board (IRB)**[3, 39(GCP 4.4), 41, 48]
    a. Seek IRB approval from the designated IRB for the study protocol and all applicable documents prior to initiation of any study procedures (including identification of potential participants).
        i. Notify the sponsor of IRB approval, as applicable.

   b. If using an external IRB (i.e., commercial IRB, other institutional IRB): [49]
      i. Prior to submitting a new study application to the external IRB, submit a rely-on application to the UNC IRB.
      ii. Ensure ongoing compliance with UNC-CH IRB post-approval requirements for ceded review, also outlined in the IRB Rely-on letter.
   c. Update the IRB with any changes to the study protocol or procedures prior to implementation. Ensure applicable study documents are approved prior to use (e.g., surveys, recruitment materials).
   d. Report information, deviations, or other safety events that meet the reviewing IRB's requirements for promptly reportable information.[52 (Table 1)]
   e. Complete IRB renewal or administrative review applications annually or more frequently as per the IRB's continuing review requirements.
   f. Notify the IRB of premature study termination or suspension.
   g. Notify the IRB of study completion.[48 (Section 2.8)]
   h. File all applicable IRB documentation into the study regulatory binder.
   i. When conducting study activities (e.g., recruiting participants) at external organizations, obtain all applicable required permissions prior to initiation.
6. **Comply with UNC-CH requirements specific to the research**
   a. Complete and submit a conflict of interest disclosure form for all studies annually when prompted by the online system (RAMSeS and/or IRBIS).
   b. Obtain applicable ancillary reviews in accordance with UNC-CH policies (e.g., Scientific review committee (SRC), Protocol Review Committee (PRC), Radiation Safety Sub-committee (RSSC), Biosafety Committee, etc.)
   c. Facilitate and ensure applicable agreements are prepared and executed by an authorized signatory official, such as the Clinical Trials Agreement (CTA), Data Use Agreement (DUA), Business Associate Agreement (BAA), Memorandum of Understanding (MOU), etc.
7. **Oversee and supervise the study**[7, 32, 39(GCP 4.2.5)]
   a. Develop and implement procedures for PI oversight and supervision. This may include routine meetings with study team members to review study progress, regular review of study procedures, routine evaluation of performance on delegated tasks, concerns raised by research participants, study team members or third parties, etc.[32]
   b. Monitor study progress and protocol adherence by periodically reviewing study records. Supervise resolution any findings as necessary.
   c. Ensure regular, timely, effective, and well-documented communication with relevant parties (e.g., participants, study team, IRB, Sponsor, etc.)
8. **Ensure eligibility and informed consent of participants**
   a. Ensure adherence to the participant eligibility enrollment criteria; verify and document participant eligibility.
   b. Ensure that legally effective informed consent and HIPAA authorization (as applicable) are obtained prospectively and documented in accordance with all applicable regulations unless a waiver has been approved by the reviewing IRB.[5, 6, 7, 10, 39(GCP 4.8), 41, 51, 54]
   c. Ensure that required (and any applicable additional) elements of informed consent[43, 55] are included in the informed consent form unless the IRB approves either an alteration of consent or a waiver of the requirement for written documentation of informed consent.

d. Inform participants of significant new findings that may impact participants or their willingness to continue study participation in a timely, accurate, and understandable manner.
e. Verify and document participants' willingness to continue participation in the study at reasonable intervals, dependent on the nature of the study.
f. Should any participants choose to withdraw their consent from the study, make reasonable effort to ascertain and document reasons for the withdrawal.

9. **Ensure protocol compliance**[39(GCP 4.5), 32]
   a. Conduct the study in accordance with the IRB-approved protocol.
   b. Ensure that any prospective planned changes to the protocol are submitted and approved by the reviewing IRB and the sponsor, if applicable, prior to implementation, unless where necessary to eliminate an immediate hazard(s) to participants.
      i. If a change is necessary to eliminate an immediate hazard to participants, report the change, the reasons for the change, and the proposed protocol amendment (as applicable) to the reviewing IRB and sponsor as soon as possible. [52]
      ii. For a planned, temporary change to the protocol submit the change per the reviewing IRB requirements prior to implementation. [48 (Section 2.7.3)]
   c. Document all deviations (i.e., any unplanned excursions from the protocol that is not intended as a permanent change) in a deviation log[46] or other tool.
   d. Report deviations to the IRB and the sponsor as applicable per their prompt reporting requirements.[52 (Table 1)]
   e. Review deviations for trends to ascertain whether re-training or a protocol amendment may be needed.
10. **Monitor participant safety**[7, 15, 39(GCP 4.11), 52]
   a. Prior to study initiation, prepare for adverse event (AE) review
      i. Review all applicable documents (e.g., protocol, investigator's brochure, Data and Safety Monitoring Plan (DSMP)) to understand safety requirements and procedures for the study.
      ii. Ensure that there are adequate procedures for promptly identifying, investigating, treating, classifying, and reporting AEs throughout the life cycle of the study.
      iii. Ensure that the evaluation of adverse events or clinical decisions or care pertaining to the study is done by a qualified clinician[39(GCP 4.3.1, 4.3.2)]
      iv. Ensure that procedures are in place for informing participants when care is needed for intercurrent illnesses of which the PI becomes aware.[39(GCP 4.3.2)]
      v. Ensure that members of the study team are aware of the safety requirements and procedures for the study.
   b. Ensure that AEs are identified and treated
      i. Assess for AEs as specified in the protocol. AEs may be identified through a variety of means, including, but not limited to: Test and procedure results, physical exams, observations by clinical research personnel, progress notes and reports in the medical record, reports by the participant, their family or caregivers, or medical care providers.
      ii. Intervene, as necessary, in accordance with the protocol (e.g., dose reductions, dose hold or specific treatment) and UNC Health standards of care and/or assist participant in seeking necessary medical care, as applicable. If determined that the blind should be broken to ensure the safety of the participant, consult with the sponsor prior to breaking the blind.

iii. Perform clinical assessments and/or laboratory assessments as necessary (frequency to be determined by the PI or designee, unless dictated by the protocol) until the AE has stabilized or resolved.
i. Follow AEs until resolution or stabilization in accordance with the protocol.

c. Ensure that AEs are investigated and documented
   i. Review all documentation related to the AE (e.g., hospital progress notes, patient diary, laboratory reports, and diagnostics reports).
   ii. Determine seriousness, unexpectedness, causality, and severity of an AE. [15, 24, 31, 37, 42]
   iii. Ensure that information regarding the AE is recorded promptly, as required by the protocol. [44]
d. Ensure that AEs are reported to the applicable parties, that may include:
   i. A safety oversight body in accordance with the DSMP.
   ii. The reviewing IRB per that IRB's prompt reporting requirements. [52 (Table 1)]
   iii. The sponsor as specified in the protocol or other related study documents. [20, 29, 31, 37]

11. **Maintain accurate and complete study documentation** [7, 27, 39(GCP 4.9), 50]
    a. Ensure that essential documents are filed as they are generated or received. [39(GCP 1.23, 8)]
    b. Ensure that all source documents are attributable, legible, contemporaneous, original, accurate, and complete (ALCOA-C).
    c. Ensure that data reported on CRFs are consistent with the source documents.
    d. Routinely check data accuracy and completeness.
12. **Manage and protect study data**
    a. Store, transmit, retain, and dispose of data and records in accordance with the IRB approved protocol, UNC-CH policies, HIPAA requirements and other applicable regulations. [4, 19, 27, 41, 50 (Section 2.8), 53 (section 2.3), 56, 57]
    b. Ensure that provisions are adequate to maintain confidentiality of identifiable private information during all data transactions for the life of the study. [56]
13. **Manage applicable test articles** [39(GCP 4.6)]
    a. Ensure that records of product delivery, inventory, use, and return/other disposition are maintained. Records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the test article and study participants.
    b. Ensure that the test article is stored as specified by the sponsor and in accordance with applicable regulatory requirement(s).
    c. Use UNC-CH investigational drug services (IDS) for investigational drug studies.
    d. Ensure that the test article is used only in accordance with the approved protocol.
    e. Ensure that each participant understands the correct use of the test article and conduct appropriate accountability assessments as needed.
    f. Reconcile the test article received from the sponsor.
14. **Facilitate monitoring activities, audits and inspections** [17, 21, 28, 34, 39(GCP 1.6, 1.38, 5.18)]
    a. Ensure that relevant parties are notified of visits and are available, as applicable:
       i. For sponsor monitoring visits or audits: Study personnel, CRAU/department, IDS, and other applicable clinical care/ancillary personnel or departments.
       ii. For FDA, OHRP, or other external agency inspections or audits: Study personnel, CRAU/department, sponsor, reviewing IRB, UNC-CH IRB when ceding review to external IRB, UNC Clinical Trials Quality Assurance (CTQA) program, IDS.

b. Ensure that any required documents (e.g., regulatory documents, participant records, investigational accountability records, as applicable) are complete, organized, and available for review.
c. Ensure that adequate space is available to conduct the visit, audit, or inspection.
d. Review applicable regulatory inspection procedures.[30, 35, 36]
e. Be available to answer questions and to meet with the monitor or inspector to review and discuss findings.
f. Ensure that all findings are addressed and responded to in a timely manner.

15. **Prepare and submit required reports**
    a. Ensure accurate, complete, and timely reports including:
        i. Any reports to the UNC-CH IRB, the reviewing IRB if other than UNC-CH, per that IRB's SOPs (e.g., promptly reportable information, renewals, modifications, etc.)
        ii. Any reports required by sponsors or funding agencies (e.g., progress reports, safety reports). [20, 29]

DEFINITIONS, ABBREVIATIONS, ACRONYMS

- **Adverse event (AE):** Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. OHRP, FDA, and ICH have similar definitions of AE.[15, 31, 37, 39 (GCP 1.2), 42]
- **Ancillary review:** Additional signs-offs or approvals pertaining to the specific research required by institutional or funding entity policy(ies) or by regulation, statute, or law. For example, UNC requires that the UNC Radiation Safety Committee (RSC) review all studies using any form of radiation. Ancillary reviews vary in whether they may occur before, during, or after IRB review, but most must be completed before initiating of the research/site activation.
- **Business Associate Agreement (BAA):** A required legal document that defines the relationship, roles and responsibilities of a business associate and a HIPAA covered entity for safeguarding Protected Health Information (PHI) in compliance with the HIPAA Privacy Rule. All BAAs accompany some other type of underlying agreement. Typically, the accompanying agreement defines the terms of the relationship between parties, but sometimes, these underlying agreements can be as simple as a purchase order. Both the business associate and the HIPAA covered entity are directly liable for HIPAA violations and impermissible disclosures of PHI. The terms within a BAA determine how the parties choose to contract for that liability.[38]
- **Causality (relatedness, attribution):** The likelihood and extent that the procedures of the research/intervention being studied contributed to the development of an adverse event. The FDA and OHRP use the *reasonable possibility* standard in the assessment of causality. Reasonable possibility means that there is evidence to suggest that there is a causal relationship between the investigational product or procedures of the study and the adverse event. [15, 31, 37, 42]
- **Clinical Trials Agreement (CTA):** A legally binding contract between the sponsor of the trial and the institution that conducts the trial that governs the allocation of funds, risks, obligations, and responsibility in conducting the trial. All CTAs must be submitted for institutional review. Study teams are not permitted to sign CTAs.

- **Confidential Disclosure Agreement (CDA):** Also referred to as Nondisclosure Agreement (NDA), a Confidential Disclosure Agreement is a legal agreement between a minimum of two parties which outlines information the parties wish to share with one another for certain evaluation purposes but wish to restrict from wider use and dissemination. All CDAs must be submitted for institutional review and signature. Investigators are not permitted to sign CDAs.
- **Data and Safety Monitoring Plan (DSMP):** A quality assurance plan that establishes the overall framework for ensuring the safety of participants and the validity and integrity of the data. The DSMP should specify the following: 1) A brief description of the study design, 2) potential risks and benefits for participating in the study, 3) procedures for data review and reportable events, 4) roles and responsibilities of study staff and monitoring entity (body), 5) content and format of the data and safety monitoring report, and 6) data management, quality control and quality assurance. A DSMP is commensurate with the risks involved with the research study and may include a Data Monitoring Committee (DMC), DSMB or DSMC.[40]
- **Data Use Agreements (DUA):** A contract that governs the exchange of specific data between two parties. DUA's establish who is permitted to use and receive a unique data set, along with the allowable uses and disclosures of the data by the recipient. A DUA also assigns appropriate responsibility to the researcher and recipient for using the data. All DUAs must be submitted for institutional review. Study teams are not permitted to execute DUAs.
- **Essential documents:** Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. These documents serve to demonstrate the compliance of the PI, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements. Examples include, but are not limited to, source documents, monitoring reports, IRB approval letters, Form FDA 1572, financial disclosure statements, and training documentation.[39(GCP 1.23, 8)]
- **FDA Form 1572 (Statement of Investigator):** An agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.[7, 33]
- **Feasibility assessment:** An assessment of the scientific, clinical, ethical, regulatory, operational, and financial feasibility of a proposed research study to ascertain the likelihood of completing the project successfully.
- **Good Clinical Practice (GCP):** International ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.[39(GCP 1.24)]
- **Identifiable private information:** Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.[2]
- **Informed Consent:** The ongoing process by which a participant voluntarily confirms their willingness to participate in a study, after having been informed of all aspects of the study that are relevant to the participants' decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form. [39(GCP 1.28)]
- **Informed Consent Form (ICF):** A written form with the required elements of informed consent approved by the IRB that when signed by the participant (or the participant's

LAR/parent/guardian) documents the participants informed and voluntary consent to participate in the study.

- **Investigator Agreement:** An agreement between the sponsor of an investigational device and the investigator to provide certain information to the sponsor and assurance that s/he will conduct the investigation in accordance with the investigational plan and applicable FDA regulations.
- **Legally effective informed consent:** Informed consent obtained from the participant or the participant's Legally Authorized Representative (LAR) and documented in a manner that is consistent with federal human subjects regulations and with applicable laws of the jurisdiction in which the research is conducted. In general terms, the regulations stipulate that informed consent is sought only under circumstances that provide the prospective participant or LAR sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence. The information provided should be in language that is understandable to the participant or the LAR and that is not serving to exculpate (exculpatory language). It is important to note that the informed consent requirements in the regulations are not intended to preempt any applicable federal, state, or local laws that require additional information to be disclosed for consent to be legally effective.
- **Memorandum of Understanding (MOU):** A general commitment to establish a partnership and explore opportunities for collaboration; non-binding and does not commit any funds or resources.
- **Principal Investigator (PI):** An individual responsible for the conduct of research involving human subjects, either for the study as a whole or for an individual site.
- **Serious adverse event (SAE):** An AE that result in any of the following outcomes: (1) death, (2) is life-threatening, (3) requires inpatient hospitalization or prolongation of existing hospitalization, (4) results in persistent or significant disability/incapacity, (5) is a congenital anomaly/birth defect, or (6) based upon appropriate medical judgment, may jeopardize the participant's health and may require medical or surgical intervention to avoid any of the forementioned outcomes. Serious adverse event is defined by OHRP, FDA and ICH with slight differences. [15, 31, 37, 39 (GCP 1.60), 42]
- **Severity:** The intensity of an adverse event as expressed in grades by intensity of signs or symptoms or by effect on activities of daily living. Generally, the protocol or investigational plan will list the specific guidelines for determining severity.
- **Source documents:** Original documents, data, and records involved in the clinical trial (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, participants' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, participant files, and records kept at the pharmacy, at the laboratories and at medico-technical departments).[39(GCP 1.52)]
- **Sponsor-Investigator:** An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.[39(GCP 1.54)]

- **Test Article:** Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulations.
- **Unexpected adverse event or adverse reaction:** An adverse event or adverse reaction that is not consistent with the known information/characteristics of the test article. Unexpected adverse event or adverse reaction is defined by OHRP, FDA and ICH with slight differences. [15, 31, 37, 39 (GCP 1.60), 42]

ASSOCIATED POLICIES, REGULATIONS, GUIDELINES

1. Common Rule, 2018 Requirements: 45 CFR 46
2. Common Rule, 2018 Requirements: 45 CFR46.102, Definitions
3. Common Rule, 2018 Requirements: 45 CFR 46.108, IRB Functions and Operations
4. Common Rule, 2018 Requirements: 45 CFR 46.115, IRB Records
5. Common Rule, 2018 Requirements: 45 CFR 46.116, General Requirements for Informed Consent
6. Common Rule, 2018 Requirements: 45 CFR 46.117, Documentation of Informed Consent
7. FDA FORM 1572: Statement of Investigator
8. FDA: 21 CFR 11, Electronic Records, Electronic Signatures
9. FDA: 21 CFR 50, Protection of Human Subjects
10. FDA: 21 CFR 50, Subpart B – Informed Consent of Human Subjects
11. FDA: 21 CFR 54, Financial Disclosure by Clinical Investigators
12. FDA: 21 CFR 56, Institutional Review Boards
13. FDA: 21 CFR 312, Investigational New Drug Application
14. FDA: 21 CFR 312, Subpart D – Responsibilities of Sponsors and Investigators
15. FDA: 21 CFR 312.32, IND Safety Reporting
16. FDA: 21 CFR 312.53, Selecting Investigators and Monitors
17. FDA: 21 CFR 312.56, Review of Ongoing Investigations
18. FDA: 21 CFR 312.60, General Responsibilities of Investigators
19. FDA: 21 CFR 312.62, Investigator Recordkeeping and Record Retention
20. FDA: 21 CFR 312.64, Investigator Reports
21. FDA: 21 CFR 312.68, Inspection of Investigator's Records and Reports
22. FDA: 21 CFR 812, Investigational Device Exemptions
23. FDA: 21 CFR 812, Subpart E – Responsibilities of Investigators
24. FDA: 21 CFR 812.3, Definitions
25. FDA: 21 CFR 812.43, Selecting Investigators and Monitors
26. FDA 21 CFR 812.100, General Responsibilities of Investigators
27. FDA: 21 CFR 812.140, Records
28. FDA: 21 CFR 812.145, Inspections
29. FDA: 21 CFR 812.150, Reports
30. FDA: Compliance Program Guidance Manual (CPGM)
31. FDA: Guidance for Industry and Investigators, Safety Reporting Requirements for INDs and BA/BE Studies
32. FDA: Guidance for Industry, Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects

33. FDA: Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors, Frequently Asked Questions – Statement of Investigator (Form FDA 1572)
34. FDA: Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors; Inspections of Clinical Investigators
35. FDA: Inspection Observations
36. FDA: Investigations Operations Manual
37. FDA: Investigator Responsibilities—Safety Reporting for Investigational Drugs and Devices, DRAFT Guidance for Industry
38. HIPAA: Summary of the HIPAA Privacy Rule
39. ICH Harmonized Guideline: Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2)
40. NIH National Institute of Aging (NIA): Glossary of Clinical Research Terms
41. OHRP: Investigator Responsibilities FAQs
42. OHRP: Unanticipated Problems Involving Risks & Adverse Events Guidance

UNC-CH Policies, Standards, and Guidelines:

43. CRSO: Guidance, Required Elements of Informed Consent
44. OCT CTQA: Adverse Event Log
45. OCT CTQA: Delegation of Responsibility Log
46. OCT CTQA: Deviations Log
47. OCT CTQA: Training Log
48. OHRE SOP 701: IRB Review Process
49. OHRE SOP 901: Multicenter Research and Reliance Process
50. OHRE SOP 1001: Documentation and Records
51. OHRE SOP 1101: Obtaining Informed Consent from Research Subjects
52. OHRE SOP 1401: Promptly Reportable Information
53. OHRE SOP 1501: Investigator Responsibilities
54. SOM SOP 501: Obtaining and Documenting Informed Consent from Adult Research Participants
55. SOM SOP 702: Developing the Informed Consent Form
56. UNC-CH ITS: Transmission of Sensitive Information Standard
57. UNC General Records Retention and Disposition Schedule
58. UNC Research: Principal Investigator Training

Revision history		
Version	**Effective Date**	**Description**
#.#	Date SOP is in effect	First approved version