Title:	Investigator Responsibilities		
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1 Purpose

Investigators are ultimately responsible for the conduct of research. Investigators may delegate tasks to appropriately trained and qualified members of their research team. However, investigators must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibilities.

2 Procedures

2.1 Investigators

The research team is made up of 'investigators', differentiated as follows, along with their responsibilities in the conduct of research involving human participants.

At the University of North Carolina at Chapel Hill (UNC-Chapel Hill) only faculty members with the UNC-Chapel Hill-paid appointments may serve as the Principal Investigator or as the faculty sponsor on a research project involving human subjects.

Adjunct faculty of the Organization and any investigator whose status is considered to be "in training" (e.g., students and medical residents) may not serve as a PI but may serve as a co-investigator or sub-investigator. PIs will ensure that research designed and conducted by trainees has sound research design and is appropriately supervised.

The IRB recognizes one PI for each study. The PI has ultimate responsibility for the research activities.

Studies that require expertise or skills beyond those held by the PI must either be modified or have expertise and skills supplemented by the inclusion of one or more additional qualified co/sub-investigators.

2.1.1 Trainee Investigators

Trainee investigators are students, employees in postdoctoral training programs, or fellows who have the primary research responsibility for an application submitted to the IRB. These investigators may take a leading role in the research, but do not have ultimate administrative and fiscal responsibility for the project. Trainee investigators should be privy to all correspondence sent by the IRB that pertains to a project on which a Trainee investigator is listed.

2.1.2 Sub-Investigators

A sub-investigator is any individual other than the PI who is involved in the conduct of a research study. Such involvement could include:

- Obtaining information about living individuals by intervening or interacting with them for research purposes;
- Obtaining identifiable private information about living individuals for research purposes;
- Obtaining the voluntary informed consent of individuals to be subjects in research; and
- Studying, interpreting, or analyzing identifiable private information or data for research purposes.

2.1.3 Research team members

Every member of the research team is responsible for protecting human subjects in accordance with the guidelines specified in SOP 101, reporting all noncompliance to the IRB, and for complying with all IRB findings, determinations and requirements. Team members must complete human subject research training as required by the University's "Policy on Education and Certification of Investigators Involved in Human Subjects Research."

2.2 Responsibilities

In order to satisfy the requirements of this policy, investigators who conduct research involving human subjects must:

1. Develop and conduct research that is in accordance with the ethical principles in the Belmont Report;

2. Develop a research plan that is scientifically sound and minimizes risk to the subjects;

3. Incorporate into the research plan a plan to ensure the just, fair, and equitable recruitment and selection of subjects;

4. When some or all of the subjects are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons), include additional safeguards in the study to protect the rights and welfare of these subjects;

5. Ensure that the research plan includes adequate provisions for the monitoring of subjects and data to ensure the safety of subjects;

6. Ensure that there are adequate provisions to protect the privacy interests of subjects;

7. Ensure that there are adequate provisions to protect data confidentiality and interests of subjects, including an information security plan that considers the collection, storage, maintenance, analysis, and transmission of data and other identifiable information;

8. Have sufficient resources necessary to protect human subjects, including:

   a. Access to a population that would allow recruitment of the required number of subjects.

   b. Sufficient time to conduct and complete the research.

   c. Adequate numbers of qualified staff.

   d. Adequate facilities.

   e. Necessary equipment.

   f. A plan to ensure proper supervision of the research including a plan for periods of absence or decreased availability.

   g. Availability of medical, psychological, or other support that subjects might require during or as a consequence of their participation in the research.

9. Assure that all procedures in a study are performed with the appropriate level of supervision and only by individuals who are licensed or otherwise qualified to perform such under the laws of North Carolina and the policies of the UNC-Chapel Hill.

10. Assure that all study personnel are educated in the regulatory requirements regarding the conduct of research and the ethical principles upon which they are based;

11. Assure that all persons assisting with the research are adequately trained and informed about the protocol/research plan and their specific duties and functions.

12. Promptly report any changes in, addition to, or departure of investigators or research staff to the IRB for evaluation and approval (note that investigators and staff may not begin work on the research until IRB-approved);

13. Protect the rights, safety, and welfare of participants;

14. Ensure that when private health information is used, legally effective HIPAA authorization is obtained for each subject unless the Privacy Board or IRB has approved a waiver of the requirement;

15. Ensure that the language in the consent form is consistent with that in the protocol/research plan and, when applicable, in the HIPAA authorization;

16. Obtain and document informed consent and ensure that no human subject is involved in the research prior to obtaining consent or consent/permission from their legally authorized representative, unless a waiver of the requirement has been approved by the IRB;

17. Have a procedure to receive questions, complaints, or requests for additional information from subjects and respond appropriately;

18. Ensure that all information provided to the IRB is accurate and complete so that the IRB may fulfill its responsibilities to review the research and make the required determinations;

19. Ensure that all research involving human subjects receives IRB review and approval in writing or a determination of exemption before research begins;

20. Ensure that all research involving human subjects is reviewed by other experts and organizational components and committees as applicable to the research;

21. Comply with all IRB decisions, conditions, and requirements;

22. Ensure that studies receive timely continuing IRB review and approval;

23. Report unanticipated problems, deviations, complaints, non-compliance, suspensions, terminations, and any other reportable events to the IRB;

24. Notify the IRB if information becomes available that suggests a change to the potential risks or benefits of the research

25. Obtain IRB review and approval before changes are made to the research unless a change is necessary eliminate apparent immediate hazards to the subject(s);

26. Seek HRPP or IRB assistance when in doubt about whether proposed research requires IRB review;

27. Retain records for the time period and in the manner required by applicable regulations, contractual agreements, and organizational policies.

Additional investigator responsibilities, including specific responsibilities for investigators engaged in FDA-regulated research are described elsewhere in this document.

2.3 Investigator Records

Under these policies investigators must maintain, at a minimum but not limited to, the following research records under these policies. In addition, investigators must also comply with all record-keeping sponsor requirements.

2.3.1 Study Records

- Individual subject records
- Recruitment materials
- Documentation of consent process (who, what, when and how)
- Signed consent forms
- Unanticipated Problem & Reportable Event Reports
- Subject complaint reports
- Results of all procedures conducted on the subject, including final visit (if no final visit, reason why: e.g., removal from study, withdrawal from study, death)

2.3.2 Regulatory Records

- Most recent IRB-approved protocol/research plan
- Previous versions of protocol/research plan

- All correspondence (i.e., approvals, reporting forms and responses, etc.) to and from the IRB
- All correspondence with the sponsor and others regarding the study
- Continuing review progress reports
- Modification Requests
- Investigational product accountability records, when applicable

2.3.3 Record Retention

Investigator records must be retained in accordance with regulatory, organizational and sponsor or grantor requirements, but no less than three years following the completion of the research. All records must be maintained securely with limited access. Disposal of investigator records must be done in such a manner that no identifying information can be linked to research data.

For records not included in the UNC-CH General Records Retention and Disposition Schedule, refer to Federal retention requirements

1. DHHS regulations require that, "records relating to research which is conducted shall be retained for at least 3 years after completion of the research." [45 CFR 46.115(b)]
2. For Investigational New Drug (IND) research, the FDA requires that sponsors and investigators retain "records and reports required by this part for two years after a marketing application is approved for the drug; or if an application is not approved for drug, until two years after shipment and delivery of the drug for investigational use is discontinued and the FDA so notified." [21 CFR 312.57(c)]

2.3.4 Public Records request

Some of this documentation may be subject to public access under the North Carolina Public Records Act. The Office of University Counsel should be consulted when a public records request is received.

A records retention and disposition schedule is a document used to identify and manage the records that document the activities and history of an organization. It identifies and classifies the records created, received, and used by the organization and provides instructions on how long they need to be retained for legal, fiscal, and historical purposes.

This records retention and disposition schedule is a tool for employees of The University of North Carolina at Chapel Hill to use when managing the records of the University. It lists records found in the administrative, academic, and health affairs units of the University and gives an assessment of their value by indicating if, and when, they should be destroyed or transferred to University Archives.

2.4 Recruitment Incentives

Payment arrangements among sponsors, organizations, investigators, and those referring research participants present a conflict of interest and may place participants at risk of coercion or undue influence or cause inequitable selection. Payment in exchange for referrals of prospective participants ("finder's fees") is not permitted. Similarly payments designed to accelerate recruitment that is tied to the rate or timing of enrollment ("bonus payments") are also not permitted.

2.4.1 Compensation from Sponsors

To minimize inappropriate financial incentives in study sponsorship, project support in all University projects:

- Must be based on fair market value of services performed or actual cost;
- Must be expressly stated in a contract between the University and the research sponsor;
- May not be conditioned upon a particular research result or tied to successful research outcomes; and
- May not include payments or other incentives for achieving human subject enrollment target numbers or meeting target enrollment accrual timelines or identifying eligible human research subjects.

2.5 Investigator Concerns

Investigators who have concerns or suggestions regarding the UNC-Chapel Hill's HRPP or IRB(s) should convey them to the Institutional Official or other responsible parties (e.g., supervisor, college dean, departmental Chair), when appropriate. The Institutional Official will consider the issue, and when deemed necessary, seek additional information and convene the parties involved to form a response for the investigator or make necessary procedural or policy modifications, as warranted. In addition, the Chair of the IRB or the OHRE Director will be available to address investigators' questions, concerns and suggestions.

In addition to these SOPs, which are made available on the UNC-Chapel Hill website for investigators, investigators are also made aware of the process for expressing their concerns via statement on approval letters, link on the UNC-Chapel Hill website for concerns or complaints.