

19 Investigator Responsibilities

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.

19.1 Investigators

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

Principal Investigators (PI)

At the University of Virginia only faculty or staff members with University of Virginia appointments may serve as the PI or as the faculty sponsor on a research project involving human subjects. The only exception is that students are allowed to serve as the PI on non-medical research if sponsored by a faculty advisor.

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 sub-investigators.

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.

19.2 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 Virginia and the policies of University of Virginia;
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. When following ICH-GCP (E6) guidelines :
 - a. During and following a subject's participation in a clinical trial, the researcher ensures that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the clinical trial.
 - b. The researcher follows the clinical trial's randomization procedures, if any, and ensures that the code is broken only in accordance with the protocol. If the clinical trial is blinded, the researcher promptly documents and explains to the Sponsor any premature unblinding.
 - c. A qualified physician (or dentist, when appropriate) who is a researcher for the clinical trial, is responsible for all clinical trial-related medical (or dental) decisions.

- d. Researchers inform subjects in an active study when medical care is needed for other illnesses of which the researchers become aware.
 - e. Although a subject is not obliged to give his or her reasons for withdrawing prematurely from a clinical trial, the researcher makes a reasonable effort to ascertain the reason, while fully respecting the subject's rights.
27. Seek IRB assistance when in doubt about whether proposed research requires IRB review;
 28. Retain records for the time period and in the manner required by applicable regulations, contractual agreements, and organizational policies.
 29. The researcher reports all serious adverse events (SAEs) to the sponsor except for those SAEs that the protocol or other document (e.g., investigator's brochure) identifies as not needing immediate reporting. The researcher follows regulatory requirements related to the reporting of unexpected serious adverse drug reactions to the regulatory authority and the IRB.
 30. The researcher reports adverse events or laboratory abnormalities identified in the protocol as critical to safety evaluations to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.
 31. For reported deaths, the researcher supplies the sponsor and the IRB with any additional requested information (e.g., autopsy reports and terminal medical reports).
 32. The researcher provides written reports to the sponsor, the IRB, and, where applicable, the organization on any changes significantly affecting the conduct of the clinical trial or increasing the risk to subjects.
 33. If the researcher terminates or suspends a clinical trial without prior agreement of the sponsor, the researcher informs the organization, sponsor, and the IRB.
 34. If the IRB terminates or suspends approval of the clinical trial, the researcher promptly notifies the sponsor.
 35. Upon completion of the clinical trial, the researcher informs the organization; the IRB with a summary of the trial's outcome; and the regulatory authority with any reports required.

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

19.3 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.

19.3.1 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)

19.3.2 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

19.3.3 Record Retention

Investigator records must be retained in accordance with regulatory, organizational and sponsor or grantor requirements, but no less than three (3) 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. *(Note that organizational policies on ownership of research data also must be followed.)*

19.4 Investigator Concerns

Investigators who have concerns or suggestions regarding University of Virginia '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 IRB Director will be available to address investigators' questions, concerns and suggestions.

In addition to these SOPs, which are made available on the University of Virginia website for investigators, investigators are also made aware of the process for expressing their concerns via a link on the University of Virginia website for concerns or complaints.

