

## Investigator Responsibilities

From the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) (See Investigator Responsibilities FAQs: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html>)

### Who are “investigators”?

The HHS regulations at 45 CFR part 46 use the term “investigator” to refer to an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB. For the purposes of the HHS regulations, OHRP interprets an “investigator” to be any individual who is involved in conducting human subjects research studies. Such involvement would 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.

Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others. Some research studies are conducted by more than one investigator, and usually one investigator is designated the “principal investigator” with overall responsibilities for the study. In every human subjects research study, investigators have certain responsibilities regarding the ethical treatment of human subjects.

### What are investigators’ responsibilities during the conduct of an approved research study?

Investigators play a crucial role in protecting the rights and welfare of human subjects and are responsible for carrying out sound ethical research consistent with research plans approved by an IRB. Along with meeting the specific requirements of a particular research study, investigators are responsible for ongoing requirements in the conduct of approved research that include, in summary:

- obtaining and documenting informed consent of subjects or subjects’ legally authorized representatives prior to the subjects’ participation in the research, unless these requirements have been waived by the IRB (45 CFR 46.116; 45 CFR 46.117);
- obtaining prior approval from the IRB for any modifications of the previously approved research, including modifications to the informed consent process and document, except those necessary to eliminate apparent immediate hazards to subjects (45 CFR 46.108(a)(3)(iii)); and

- ensuring that progress reports and requests for continuing review and approval are submitted to the IRB in accordance with the policies, procedures, and actions of the IRB as referenced in the institution's OHRP-approved Federalwide assurance (45 CFR 46.109(f)(1)(i) and (iii), 45 CFR 46.108(a)(3)(i), 45 CFR 46.109(e), 45 CFR 46.115(a)(3)). In certain circumstances, investigators also would be responsible for meeting the following additional regulatory requirements:
  - providing to the IRB prompt reports of any unanticipated problems involving risks to subjects or others (45 CFR 46.108(a)(4)(i));
  - providing to the IRB prompt reports of serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB (45 CFR 46.108(a)(4)(i)); and
  - keeping certain records as required by the HHS regulations for at least three years after completion of the study (45 CFR 46.115(b)).

## **What are investigators' responsibilities once a study is completed?**

If all research-related interventions or interactions with human subjects have been completed, and all data collection and analysis of identifiable private information described in the IRB-approved research plan have been finished, then the human subjects research study has been completed. When a human subjects research study has been completed, the investigators no longer are required to obtain continuing review and approval of that study by the IRB. The investigators should follow any applicable institutional policies and procedures for notifying the IRB of the study's completion.

Once a study has been completed, investigators may keep the data they collected, including identifiable private data, if consistent with the IRB-approved research plan. Investigators should continue to honor any confidentiality protections of the data.

Investigators also should honor any other commitments that were agreed to as part of the approved research, for example, providing information about the study results to research subjects, or honoring commitments for compensation to research subjects for research participation.

## **What records should investigators keep, and for how long?**

The HHS protection of human subjects regulations require institutions to retain records of IRB activities and certain other records frequently held by investigators for at least three years after completion of the research (45 CFR 46.115(b)). In addition, other regulations may apply and require retention of these records for a longer period of time. Documentation of the informed consent of the subjects - either the signed informed consent form or the short form and the written research summary - are records related to conducted research that are typically held by investigators and must be retained for at least three years after completion of the research, unless the IRB waived the requirement for informed consent or the requirement for documentation of informed consent (45 CFR 46.117).

If investigators have been designated to retain certain records (e.g., informed consent documents signed by subjects) on behalf of the institution as required by the HHS regulations at 45 CFR 46.115(b), they must retain the records in some form. Such records may be preserved in hardcopy, electronic or other media form and must be accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner (45 CFR 46.115(b)). Retention of multiple copies of each record is not required. Investigators should follow the institution's policies and procedures for retaining records. If investigators who have been designated to retain records on behalf of the institution leave that institution, the investigators and the institution should identify the successor responsible for maintaining those institutional records, either at the original institution or wherever the records are relocated, for the period of time required under HHS regulations at 45 CFR 46.115(b).

Other regulations or policies may apply to the retention of records, including study data.