

OHRP Investigator Responsibility Frequently Asked Questions

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Question 1: Do the human research regulations apply to non-U.S. institutions?
Answer: Yes, whenever non-U.S. institutions are engaged in non-exempt HHS-supported or –conducted human subjects research, the regulations apply. Please see: <http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm#sectionb> .

Question 2: Who are “investigators”?
Answer: 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.

Question 3: Must investigators obtain IRB approval before involving human subjects in nonexempt research?

Answer: Yes. Investigators are responsible for obtaining IRB approval before beginning any nonexempt human subjects research ([45 CFR 46.109\(a\) and \(d\)](#)). Investigators are responsible for providing the IRB with sufficient information and related materials about the research (e.g., grant applications, research protocols, sample consent documents) so that the IRB can fulfill its regulatory obligations, including making the required determinations under [45 CFR 46.111](#) and, if applicable, [subparts B, C and D](#). Investigators should follow institutional policies and procedures for IRB review that are required by HHS regulations at [45 CFR 46.103\(b\)\(4\)](#) and referenced in the institution’s OHRP-approved Federalwide assurance.

Question 4: What are investigators’ responsibilities during the conduct of an approved research study?

Answer: 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 46.103\(b\)\(4\)](#)); 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 46.103\(b\)\(4\)](#), [45 CFR 46.109\(e\)](#), [45 CFR 46.115\(a\)\(1\)](#)).

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 46.103\(b\)\(5\)](#));
- providing to the IRB prompt reports of serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB ([45 CFR 46.103\(b\)\(5\)](#)); and
- keeping certain records as required by the HHS regulations for at least three years after completion of the study ([45 CFR 46.115\(b\)](#)).

You may wish to view the answers to the following related questions:

[Are investigators responsible for obtaining and documenting informed consent?](#)

[What should investigators do if they want to revise an IRB-approved research study?](#)

[Are investigators responsible for obtaining continuing review of research?](#)

Question 5: Are investigators responsible for obtaining and documenting informed consent?

Answer: Yes. Investigators are responsible for obtaining and documenting the informed consent of research subjects or their legally authorized representatives, unless the IRB approves a waiver of informed consent, or a waiver of documentation of informed consent, respectively ([45 CFR 46.116](#), [45 CFR 46.117](#)). Investigators must give a copy of the informed consent document to each research subject (or the subject's legally authorized representative), and keep the signed original or a copy of it for their records ([45 CFR 46.117\(a\)](#); [45 CFR 46.115\(b\)](#)).

When the documentation requirement is waived, the IRB may require investigators to provide subjects with a written statement regarding the research ([45 CFR 46.117\(c\)](#)). (For information about parental permission and assent, see the [FAQs related to subpart D of 45 CFR part 46](#).)>

Question 6: What should investigators do if they want to revise an IRB-approved research study?

Answer: If investigators wish to modify an ongoing IRB-approved research study, they must submit a request to the IRB and receive IRB approval before implementing the proposed modification, unless the change is designed to eliminate an apparent immediate hazard to subjects ([45 CFR 46.103\(b\)\(4\)](#)). If the investigators change the research in order to eliminate apparent immediate hazards to subjects without prior IRB approval, they should report those changes promptly to the IRB. The HHS protection of human subjects regulations allow for expedited review and approval of requests for minor changes in previously approved studies ([45 CFR 46.110\(b\)\(2\)](#)).

Question 7: What should investigators do when considering changes to an exempt study that could make it nonexempt?

Answer: Investigators should consult with the appropriate institutional authority whenever questions arise about whether planned changes to an exempt study might make that study nonexempt human subjects research. OHRP recommends that institutions have policies in place that designate the individual or entity authorized to determine whether human subjects research qualifies for exemption under HHS regulations at [45 CFR 46.101\(b\)](#). OHRP recommends that investigators not be given the authority to make an independent determination that human subjects research is exempt. The person(s) authorized to make the determination should be knowledgeable about the human subject protection regulations. In addition, the institution should ensure the appropriate communication of such a policy to all investigators.

Question 8: Are investigators responsible for obtaining continuing review of research?

Answer: Yes. Investigators are responsible for fulfilling requirements associated with continuing review in time for the IRB to carry out review prior to the expiration date of the current IRB approval. Continuing review of research and approval of research studies is required so long as the research study is ongoing, that is, until research-related interactions and interventions with human subjects or the obtaining and analysis of identifiable private information described in the IRB-approved research plan have been completed. Investigators are responsible for submitting sufficient materials and information for the IRB to meet its regulatory obligations, and should follow the institutional policies and procedures for continuing IRB review of research that are required by HHS regulations at 45 CFR 46.103(b)(4) and referenced in the institution's OHRP-approved Federalwide assurance. OHRP guidance regarding continuing review is available at <http://www.hhs.gov/ohrp/humansubjects/guidance/contrev2002.htm>.

Question 9: What should investigators do if IRB approval expires?

Answer: If IRB approval of a specific study expires before continuing review and approval occur, investigators must stop all research activities involving human subjects related to that study ([45 CFR 46.103\(b\)](#)), except where they judge that it is in the best interests of already enrolled subjects to continue to participate. When investigators make this judgment, they must promptly notify the IRB ([45 CFR 46.103\(b\)\(5\)](#)). When the IRB reviews the investigator's decision, it may decide whether it is in the best interests of already enrolled subjects to continue to participate in the research by considering the best interests of subjects either one at a time or as a group. If an IRB determines that it is not in the best interests of already enrolled subjects to continue to participate, investigators must stop all human subjects research activities, including intervening or interacting with subjects, or obtaining or analyzing identifiable private information about human subjects ([45 CFR 46.103\(b\)](#)). Investigators may resume the human subjects research activity once continuing review and approval by the IRB has occurred.

Question 10: What are investigators' responsibilities once a study is completed?

Answer: 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.

Question 11: What records should investigators keep, and for how long?

Answer: 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.

Question 12: Must investigators obtain training in the protection of human subjects?

Answer: The HHS regulations for the protection of human subjects ([45 CFR part 46](#)) do

not require investigators to obtain training in the protection of human subjects in research. However, an institution holding an OHRP-approved Federalwide Assurance (FWA) is responsible for ensuring that its investigators conducting HHS-conducted or -supported human subjects research understand and act in accordance with the requirements of the HHS regulations for the protection of human subjects. Therefore, as stated in the [Terms of the FWA](#), OHRP strongly recommends that institutions and their designated IRBs establish training and oversight mechanisms (appropriate to the nature and volume of their research) to ensure that investigators maintain continuing knowledge of, and comply with, the following:

- relevant ethical principles;
- relevant federal regulations;
- written IRB procedures;
- OHRP guidance;
- other applicable guidance;
- state and local laws; and
- institutional policies for the protection of human subjects.

Furthermore, OHRP recommends that investigators complete appropriate institutional educational training before conducting human subjects research.

In some cases, other federal requirements regarding training for investigators must be met, such as the National Institute of Health's (NIH) requirement for the training of key personnel in NIH-sponsored or -conducted human subjects research.