Investigator Responsibilities FAQs

Do the human research regulations apply to non-U.S. institutions?

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/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html#sectionb.

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.

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

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).

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 46.103(b)(4)); and