



United States Department of Health & Human Services

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Office for Human Research Protections (OHRP)

OHRP Quality Improvement Activities Frequently Asked Questions

These FAQs provide guidance that represents OHRP's current thinking on these topics and should be viewed as recommendations, unless specific regulatory requirements are cited. The use of the word "must" in OHRP guidance means that something is required under HHS regulations at 45 CFR part 46. The use of the word "should" in OHRP guidance means that something is recommended or suggested, but not required. An institution may use an alternative approach if the approach satisfies the requirements of the HHS regulations at 45 CFR part 46. OHRP is available to discuss alternative approaches at 240-453-6900 or 866-447-4777.

Commonly Used Abbreviations

CFR — Code of Federal Regulations
 FDA — Food and Drug Administration
 FWA — Federalwide Assurance
 HHS — Health and Human Services
 IEC — Independent Ethics Committee
 IRB — Institutional Review Board
 OHRP — Office for Human Research Protections

- Question 1:** How does HHS view quality improvement activities in relation to the regulation for human research subject protections?
- Question 2:** Do the HHS regulations for the protection of human subjects in research (45 CFR part 46) apply to quality improvement activities conducted by one or more institutions whose purposes are limited to: (a) implementing a practice to improve the quality of patient care, and (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes?
- Question 3:** Do quality improvement activities fall under the HHS regulations for the protection of human subjects in research (45 CFR part 46) if their purposes are limited to: (a) delivering healthcare, and (b) measuring and reporting provider performance data for clinical, practical, or administrative uses?
- Question 4:** Can I analyze data that are not individually identifiable, such as medication databases stripped of individual patient identifiers, for research purposes without having to apply the HHS protection of human subjects regulations?
- Question 5:** Are there types of quality improvement efforts that are considered to be research that are subject to HHS human subjects regulations?
- Question 6:** If I plan to carry out a quality improvement project and publish the results, does the intent to publish make my quality improvement project fit the regulatory definition of *research*?
- Question 7:** Does a quality improvement project that involves research need to be reviewed by an IRB?
- Question 8:** Does IRB review of a quality improvement project that is also non-exempt human subjects research always need to be carried out at a convened IRB meeting?

Question 9: If a quality improvement project involves non-exempt research with human subjects, do I always need to obtain informed consent from all subjects (patient and/or providers) involved in the research?

Question 10: If a quality improvement project is human subjects research requiring IRB review, do I need to obtain separate IRB approval from every institution engaged in the project?

Question 1: How does HHS view quality improvement activities in relation to the regulation for human research subject protections?

Answer: Protecting human subjects during research activities is critical and has been at the forefront of HHS activities for decades. In addition, HHS is committed to taking every appropriate opportunity to measure and improve the quality of care for patients. These two important goals typically do not intersect, since most quality improvement efforts are not research subject to the HHS protection of human subjects regulations. However, in some cases quality improvement activities are designed to accomplish a research purpose as well as the purpose of improving the quality of care, and in these cases the regulations for the protection of subjects in research (45 CFR part 46) may apply. To determine whether these regulations apply to a particular quality improvement activity, the following questions should be addressed in order: (1) does the activity involve research (45 CFR 46.102(d)); (2) does the research activity involve human subjects (45 CFR 46.102(f)); (3) does the human subjects research qualify for an exemption (45 CFR 46.101(b)); and (4) is the non-exempt human subjects research conducted or supported by HHS or otherwise covered by an applicable FWA approved by OHRP. For those quality improvement activities that are subject to these regulations, the regulations provide great flexibility in how the regulated community can comply. Other laws or regulations may apply to quality improvement activities independent of whether the HHS regulations for the protection of human subjects in research apply.

Question 2: Do the HHS regulations for the protection of human subjects in research (45 CFR part 46) apply to quality improvement activities conducted by one or more institutions whose purposes are limited to: (a) implementing a practice to improve the quality of patient care, and (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes?

Answer: No. Such activities do not satisfy the definition of "research" under 45 CFR 46.102(d), which is "...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge..." Therefore the HHS regulations for the protection of human subjects do not apply to such quality improvement activities, and there is no requirement under these regulations for such activities to undergo review by an IRB, or for these activities to be conducted with provider or patient informed consent.

Examples of implementing a practice and collecting patient or provider data for non-research clinical or administrative purposes include:

- A radiology clinic uses a database to help monitor and forecast radiation dosimetry. This practice has been demonstrated to reduce over-exposure incidents in patients having multiple procedures. Patient data are collected from medical records and entered into the database. The database is later analyzed to determine if over-exposures have decreased as expected.
- A group of affiliated hospitals implements a procedure known to reduce pharmacy prescription error rates, and collects prescription information from medical charts to assess adherence to the procedure and determine whether medication error rates have decreased as expected.
- A clinic increasingly utilized by geriatric patients implements a widely accepted capacity assessment as part of routine standard of care in order to identify patients requiring special services and staff expertise. The clinic expects to audit patient charts in order to see if the assessments are performed with appropriate patients, and will implement additional in-servi

training of clinic staff regarding the use of the capacity assessment in geriatric patients if it finds that the assessments are not being administered routinely.

Question 3: Do quality improvement activities fall under the HHS regulations for the protection of human subjects in research (45 CFR part 46) if their purposes are limited to: (a) delivering healthcare, and (b) measuring and reporting provider performance data for clinical, practical, or administrative uses?

Answer: No. Such quality improvement activities do not satisfy the definition of "research" under 45 CFR 46.102(d), which is "...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge..." Therefore the HHS regulations for the protection of human subjects do not apply to such quality improvement activities, and there is no requirement under these regulations for such activities to undergo review by an IRB, or for these activities to be conducted with provider or patient informed consent.

The clinical, practical, or administrative uses for such performance measurements and reporting could include, for example, helping the public make more informed choices regarding health care providers by communicating data regarding physician-specific surgical recovery data or infection rates. Other practical or administrative uses of such data might be to enable insurance companies or health maintenance organizations to make higher performing site preferred providers, or to allow other third parties to create incentives rewarding better performance.

Question 4: Can I analyze data that are not individually identifiable, such as medication databases stripped of individual patient identifiers, for research purposes without having to apply the HHS protection of human subjects regulations?

Answer: Yes. Whether or not these activities are research, they do not involve "human subjects." The regulation defines a "human subject" as "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.... Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects." Thus, if the research project includes the analysis of data for which the investigators cannot readily ascertain the identity of the subjects and the investigators did not obtain the data through an interaction or intervention with living individuals for the purposes of the research, the analyses do not involve human subjects and do not have to comply with the HHS protection of human subjects regulations. (See *OHRP Guidance on Research Involving Coded Private Information or Biological Specimens*, October 2008; available at <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>.)

Question 5: Are there types of quality improvement efforts that are considered to be research that are subject to HHS human subjects regulations?

Answer: Yes. In certain cases, a quality improvement project may constitute non-exempt human subjects research conducted or supported by HHS or otherwise covered by an applicable FWA. For example, if a project involves introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collecting information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results, that quality improvement project may also constitute nonexempt human subjects research under the HHS regulations.

Question 6: If I plan to carry out a quality improvement project and publish the results, does the intent to publish make my quality improvement project fit the regulatory definition of *research*?

Answer: No. The intent to publish is an insufficient criterion for determining whether a quality improvement activity involves research. The regulatory definition under 45 CFR 46.102(d) is "Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of research; people seek to publish descriptions of nonresearch

activities for a variety of reasons, if they believe others may be interested in learning about those activities. Conversely, a quality improvement project may involve research even if there is no intent to publish the results.

Question 7: Does a quality improvement project that involves research need to be reviewed by an IRB?

Answer: Yes, in some cases. IRB review is needed if the research involves human subjects, is not exempt, and is conducted or supported by HHS or otherwise covered by an applicable FWA. (See exempt categories at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>.)

Question 8: Does IRB review of a quality improvement project that is also non-exempt human subjects research always need to be carried out at a convened IRB meeting?

Answer: No. If the human subjects research activity involves no more than minimal risk and fits one or more of the categories of research eligible for expedited review, the IRB chair or another member designated by the IRB chair may conduct the review. The categories of research eligible for expedited review are available at <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>.

Question 9: If a quality improvement project involves non-exempt research with human subjects, do I always need to obtain informed consent from all subjects (patient and/or providers) involved in the research?

Answer: No. The HHS regulations protecting human subjects allow an IRB to waive the requirements for obtaining informed consent of the subjects of the research when (a) the risk to the subjects is minimal, (b) subjects' rights and welfare will not be adversely affected by the waiver, (c) conducting the research without the waiver is not practicable, and (d) if appropriate, subjects are provided with additional pertinent information after their participation (45 CFR 46.116(d)). Other applicable regulations or laws may require the informed consent of individuals in such projects independent of the HHS regulations for the protection of human subjects in research.

Question 10: If a quality improvement project is human subjects research requiring IRB review, do I need to obtain separate IRB approval from every institution engaged in the project?

Answer: No, not if certain conditions are met. The HHS protection of human subjects regulations allow one IRB to review and approve research that will be conducted at multiple institutions. An institution has the option of relying upon IRB review from another institution by designating that IRB on its FWA and submitting the revised FWA to OHRP, and having an IRB Authorization Agreement with the other institution (see http://www.hhs.gov/ohrp/assurances/assurances_index.html for information on FWAs and IRB Authorization Agreements).

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