

The Background

The Institutional Review Board (IRB) is a committee established to review and approve research involving human subjects. The primary purpose of the IRB is to protect the rights and welfare of the human subjects.

Federal law requires that researchers get approval from an Institutional Review Board (IRB) before conducting any research that involves human subjects. The law applies only to research that is funded or regulated by the federal government but even most privately funded institutions, professional associations, and industry journals rely on some type of IRB approval process.

An IRB is a standing committee established by the “institution” sponsoring the research. Thus, every major university, government agency and private corporation that engages in human subject research will have its own IRB. Each institution’s IRB reviews all research proposals involving human subjects in order to ensure that the “protocol,” or procedures of the research, adequately protects the subjects.

The Board is required to have at least five members, both men and women from varied professions with at least one member who is not a scientist, one who is, and one person who is not affiliated with the institution at all. They should have diverse backgrounds with some experience in the types of research being reviewed and be sensitive to community attitudes and vulnerable populations.

IRBs are quite powerful. They have the authority to approve research, reject it, require modifications and/or ongoing monitoring and to terminate research already in progress. Typically, any decision by an IRB is accompanied by a justification or a list of reasons why the Board decided as it did. Researchers use this feedback to modify or create new research proposals.

When Quality Improvement Activities are Exempt from IRB

The United States Department of Health and Human Services (HHS) determines that Quality Improvement activities, such as the ACS NSQIP do not satisfy the definition of “research” under (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.

The obvious clinical and practical uses for such performance measurements and reporting could include, for example, reducing surgical complications. Other utilizations for QI data could be to enable insurance companies to make higher performing sites preferred providers, or to allow other third parties to create incentives rewarding better performance.

Furthermore, the HHS allows the analysis of data that are not individually identifiable, such as the Participant Use Datafile (PUF). As long as the PUF is stripped of individual patient identifiers, sites may use the information for research purposes without having to apply the HHS protection of human subject’s regulations.

The PUF does 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 regulation.

