Human subject protections in clinical research: Monitoring compliance with the Common Rule

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Much of the clinical research being done in the United States and around the world involves human subjects. In the U.S., the federal agencies that fund such research help to ensure that human subjects are protected from abuse, and the Office for Human Research Protections (OHRP) within the Office of the Assistant Secretary for Health, Department of Health and Human Services (HHS) has responsibility for providing guidance and ensuring compliance with HHS regulations for protecting human subjects. The regulations, referred to as the Federal Policy for the Protection of Human Subjects, or the Common Rule, are codified at 45 CFR part 46. After Congress and others raised questions about OHRP's independence, Congress requested that the Office of Inspector General (OIG) review OHRP procedures and make recommendations to strengthen protections for human subjects and ensure OHRP's independence. Questions regarding OHRP's independence were partly in response to the controversy that arose when National Institutes of Health (NIH) officials lobbied HHS and OHRP to reverse OHRP's findings and corrective action request regarding a recent NIH-funded study. In its report dated July 2017, the OIG concluded that OHRP appears to maintain its independence from the HHS agencies that fund the research and the institutions that conduct the research while carrying out its compliance activities. However, the OIG also identified several factors that may limit or appear to limit OHRP's ability to operate independently.

OHRP has procedures in place to evaluate compliance with HHS regulations for protecting human subjects and discretion in how it implements those procedures. To determine the extent to which OHRP independently initiates, conducts and makes determinations about compliance with HHS regulations for protecting human subjects, the OIG analyzed data on OHRP's compliance activities from 2000 through 2015, administered surveys, performed interviews and reviewed documents from eight compliance evaluations. Overall, the OIG found that OHRP appears to independently carry out its compliance activities for protecting human subjects. However, the OIG noted that varying interpretations of OHRP's role, including OHRP's placement within HHS and the way OHRP's budget is set, may limit OHRP's ability to operate independently. In addition, the OIG found that OHRP's practice of not publicly reporting most of its compliance activities may give the appearance of limited oversight and independence.

The OIG report recommends that HHS address factors that may limit OHRP's ability to operate independently by taking steps to:

- Issue guidance that clarifies OHRP's role
- Evaluate OHRP's position within HHS
- Evaluate the sufficiency of OHRP's resources
- Consider ways to elevate the prominence of its budget, such as including OHRP's budget as a line item in the president's budget

The OIG report also recommends that HHS consider seeking statutory authority for OHRP's independence and that OHRP post information on its website that describes its approach to oversight and provides data regarding its compliance activities.

Human subject protection in clinical research is critical to ensuring the safety of those who volunteer to participate in research studies as well as ensuring that the public can have confidence in the research being conducted. OHRP's ability to independently

review compliance with the Common Rule's protections for human subjects is an important part of the checks and balances in place to protect human subjects involved in clinical research studies.

Hospitals and other facilities that conduct clinical research involving human subjects should ensure that they are conducting such research in accordance with the Common Rule. The Common Rule was updated in January 2017—the first substantial revision to the Common Rule since it was published in 1991. The updated Common Rule includes new requirements for informed consent and new categories of research exempt from IRB review. It also includes a requirement for the use of a single IRB in research conducted by multiple institutions. Facilities conducting clinical research involving human subjects should be aware of these updates to the Common Rule. The updated Common Rule can be accessed here and is effective January 18, 2018.

Authors