Why Should IRBs Report Protocol Data Accurately in the IRB Registry?

By Michael Stidham

Institutional Review Boards (IRBs) are required to register with the Office for Human Research Protections (OHRP) if they will review human subjects research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP uses its IRB registry for compliance oversight activities, distribution of education materials, and fulfillment of data requests for research about IRBs (The Federal Register, 2002). Nearly 5,000 institutions currently register one or more IRBs with OHRP.

The current Office of Management and Budget (OMB)-approved IRB registration form (OMB 0990-0279) collects information about IRBs, including a membership roster and the number of protocols the IRB reviews. The IRB reports the approximate number of all active protocols and HHS-supported or -conducted protocols under the IRB's purview. For IRB registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months (OHRP, 2022).

In January 2023, the U.S. Government Accountability Office (GAO) issued a report, GAO-23-104721, INSTITUTIONAL REVIEW BOARDS: Actions Needed to Improve Federal Oversight and Examine Effectiveness (U.S. GAO, 2023). In a sample of IRB registrations, GAO found inaccuracies in institutional reporting of protocol data, and one of GAO's recommendations calls for ensuring the accuracy of protocol data in OHRP's IRB registry.

There are benefits to accurately reporting these data. The data inform OHRP's compliance efforts, which in turn can help OHRP uphold an effective and trustworthy system of human research protections. Additionally, the public can access some IRB registration information online and can request non-public IRB registration information from OHRP. In some cases, researchers have requested IRB registration data as part of efforts to study the IRB enterprise. Policymakers, institutions, and research participants can benefit from these knowledge discovery efforts, for which accurate data are important.

OHRP is currently updating the IRB registration instructions and the registry's software systems (OHRP, 2022). These changes may help institutions provide more accurate protocol data. Additionally, OHRP is working to adopt a change to the regulations at 45 CFR part 46 subpart A (the Common Rule) to no longer collect an IRB roster (The Federal Register, 2017). This requires changing the IRB registration form and software systems to remove the membership roster, which also eliminates information collections such as IRB member qualifications and gender. OHRP is prioritizing this change. For now, when institutions want to clarify information about an IRB member beyond what the form permits (e.g., due to the form's limited gender identity options), institutions can add notes in the "comments" field. The regulations at 45 CFR 46.108(a)(2) and .115(a)(5) continue to require an IRB to prepare and maintain a current list of IRB members (OHRP, 2022). Even so, eliminating the registration's roster requirement may reduce administrative burden and improve accuracy of information in the registry.

With improved tools and focused efforts from institutions that operate IRBs, OHRP aims to increase the accuracy of information in the IRB registry. Institutions can assist by reviewing all IRB details to make sure information is current each time they update or renew their IRB registration. Accurate information helps us achieve shared goals to protect the rights and welfare of human subjects in research.

Disclaimer: The opinions expressed are those of the author and do not necessarily reflect the policy of the U.S. Department of Health and Human Services.

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More information about IRB Registration, including forms, instructions, and FAQs can be found on the OHRP website at:

www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-registration/index.html

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