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Commentary

Does Accreditation Improve the Protection of Human Research Subjects and the Quality of Institutional Review Board Reviews?

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Twenty-five years ago, the Institute of Medicine recommended voluntary, external accreditation of human research protection programs to enhance the protection of human subjects participating in research and to preserve public trust in our system of protecting human research subjects. Today, accreditation of human research protection programs as well as independent institutional review boards has been well established. It is carried out by a sole accrediting organization, the Association for the Accreditation of Human Research Protection Programs, Incorporated. However, there has been no evaluation of whether accreditation improves human research subject protections or the quality of institutional review board reviews, and whether accreditation is cost-effective. Thus, it is imperative that we find out whether accreditation has achieved its primary objective of enhancing human research subject protections and the quality of institutional review board reviews.

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Accreditation of human research protection programs (HRPPs)[1] was recommended by the Institute of Medicine (now the US National Academy of Medicine) to improve the protection of human subjects participating in research and to preserve public trust in our system of protecting human research subjects. However, 25 years later, while voluntary external accreditation of HRPPs in the US has been well established, we had no idea whether accreditation, in fact, led to improved human research subject protections.

Background

In 1999, Jesse Gelsinger, an 18-year-old, relatively healthy young man, volunteered to participate in a Phase 1 gene transfer clinical trial and died 4 days after he was given a dose of an experimental gene transfer agent through direct infusion into his right hepatic artery [1][2]. At around the same time, federally funded research programs at nine US major academic institutions, including one Department of Veterans Affairs (VA) research facility, were suspended due to persistent and serious noncompliance with federal regulations governing human

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research subject protections [3][4]. The intense public scrutiny and Congressional inquiries that followed led the Secretary of the Department of Health and Human Services (HHS) to ask the Institute of Medicine to conduct an in-depth study of how to improve the structure and function of activities related to the protection of human research participants. The Institute of Medicine recommended a systems approach toward protecting research participants, i.e., human research participant protection programs (HRPPPs)[2], and the voluntary accreditation of HRPPPs to preserve public trust [5].

As part of its recommendation of voluntary accreditation of HRPPs, the Institute of Medicine recommended that Congress should request an evaluation of the pilot accreditation program by the General Accounting Office (now Government Accountability Office) and that the Secretary of HHS should also request the Inspector General's Office to conduct a parallel evaluation. Specifically, "The HRPPP accreditation process should be evaluated not only according to whether it has improved protections for human research participants but also according to whether resources devoted to accreditation could be spent to equal or better effect on other ways to improve HRPPP oversight such as education, research monitoring, and improved feedback mechanisms. Evaluation should take into account both the costs of establishing a national accreditation system and the costs to applicant organizations. The costs to applicant organizations will include direct costs for the accreditation process and also costs for the preparation for and following up on the accreditation process." (p. 20) [5].

Early History of Accreditation (2000-2005)

The Department of Veterans Affairs is the largest integrated health care system in the US, with over 100 VA medical centers conducting research involving human subjects. In response to the Institute of Medicine's recommendation for voluntary external accreditation of HRPPPs, the VA Under Secretary for Health declared that external accreditation of VA HRPPs would be mandatory, i.e., no VA research facilities would be allowed to conduct research involving human subjects unless they were accredited by an external HRPP accrediting organization [4]. In May 2000, the VA awarded a 5-year contract to the National Commission for Quality Assurance (NCQA) to accredit VA HRPPs.

The Institute of Medicine reviewed accreditation standards developed by NCQA as well as standards developed by Public Responsibility in Medicine and Research and recommended that NCQA standards be modified for all VA and non-VA research institutions and serve as the basis for the proposed pilot HRPPP accreditation testing project [5].

The Association for the Accreditation of Human Research Protection Programs, Incorporated (AAHRPP, Inc), founded in April 2001, independently developed its own accreditation standards based on the criteria recommended by the Institute of Medicine and started to offer accreditation of HRPPs in 2002 [6].

In December 2005, AAHRPP won a 5-year contract to accredit VA HRPPs. With the loss of the VA contract, NCQA discontinued its HRPP accrediting services. As a result, AAHRPP became the sole accrediting body for HRPPs in the US.

Current Status of HRPP Accreditation (2006-2025)

As the sole HRPP accrediting body in the US since 2006, AAHRPP has been successful in the accreditation of HRPPs and institutional review boards (IRBs) of

diverse human research entities including, but not limited to, academic medical centers, hospitals, healthcare systems, dedicated research sites, contract research organizations, independent IRBs, government institutions, and research sponsors, both inside and outside of the US.

Independent IRBs, unlike traditional IRBs, are free-standing IRBs, not affiliated with any research institutions. They provide IRB review services to research institutions, investigators, and/or research sponsors on a fee-for-service basis [7]. Thus, these independent IRBs are for-profit, commercial entities. In 2016, it was estimated that independent IRBs were responsible for reviewing 70% of US clinical trials for drugs and medical devices [8].

The AAHRPP accreditation standards consist of three domains of responsibilities: *organization, IRB or ethics committee (EC)*, and *researchers and research staff.* Within each domain are standards, and for each standard, there are elements that provide more specificity for the standards. To be accredited by AAHRPP, an organization must meet all its accreditation standards and elements. The processes for an organization seeking initial AAHRPP accreditation include conducting a self-assessment of its own HRPP, developing and submitting an application, evaluation of written materials by AAHRPP, a site visit by AAHRPP to evaluate the organization's HRPP practices, and AAHRPP Council on Accreditation Review reviewing the application and making a decision whether to grant an accreditation. These processes usually take about one year to complete [6]

For accredited organizations to maintain their accreditations, organizations are required to file annual reports and event reports each year. In addition, accredited organizations renew their accreditations three years after the initial accreditation, and every five years thereafter, by going through the same procedures as described above for the initial accreditation.

The cost of AAHRPP accreditation depends on the size of the program. In 2025, the application fees for initial accreditation are $13,352.00 for programs with a total number of active protocols of 1–100, and $93,978.00 for programs with a total number of active protocols of more than 7,000. The annual fees are $5,960.00 for programs with a total number of active protocols of 1–100, and $27,790.00 for programs with a total number of active protocols of more than 7,000.

AAHRPP claims that all major U.S. independent IRBs are AAHRPP accredited. More than 60 percent of U.S. research-intensive universities and 65 percent of U.S. medical schools are either AAHRPP accredited or have begun the accreditation process [9].

As of April 24, 2025, 245 organizations were accredited by AAHRPP, Inc., of which 205 were from the U.S. and 40 were from other countries. Of the 205 accredited organizations from the U.S., 13 were independent IRBs.

AAHRPP claims the following benefits of being an AAHRPP-accredited organization:

- Earn the respect and meet the expectations of their peers,
- Play a leadership role in collaborative efforts,
- Gain a competitive edge with sponsors and other funders,
- Reduce the risk of noncompliance,
- Enhance their standing with U.S. federal agencies, and
- Benefit from a common commitment to continuous quality improvement. [6]

What is missing here is that AAHRPP did not claim that HRPP accreditation leads to improved human research subject protections and/or the quality of IRB reviews. Neither the Government Accountability Office nor the HHS Inspector General's Office ever conducted an evaluation of the effectiveness of HRPP accreditation as recommended by the Institute of Medicine.

Conclusion and recommendations

Twenty-five years after the Institute of Medicine recommended voluntary external accreditation of HRPPs to improve human research subject protections and preserve public trust, accreditation of HRPPs as well as independent IRBs has been well established. However, there has been no evaluation of whether accreditation improves human research subject protections or the quality of IRB reviews and whether accreditation is cost-effective. Thus, it is imperative that we find out whether accreditation has achieved its primary objective of enhancing human research subject protections and the quality of IRB reviews.

I recommend that the Government Accountability Office and/or the HHS Inspector General's Office carry out such an evaluation to determine whether accreditation by AAHRPP improves human research subject protections or the quality of IRB reviews by comparing the effectiveness of human research subject protections or the quality of IRB reviews before and after accreditation, or by comparing the effectiveness of human research subject protections or the quality of IRB reviews of accredited and non-accredited institutions.

Specifically, protections of human research subjects can be quantitatively measured using human research subject protection performance metrics developed by Tsan and Puglisi [10][11]. These performance metrics, which include unanticipated, serious, and research-related adverse events; not obtaining required informed consent or Health Insurance Portability and Accountability Act authorization; research conducted without required IRB reviews and approval; and continuing research activities during a lapse in required IRB continuing reviews, measure harms actually experienced by research participants. Likewise, the quality of IRB reviews can be quantitatively measured as proposed by Tsan and Van Hook [12][13], in which a quality IRB review is defined as a review that is performed by a duly constituted IRB with all necessary expertise and free of conflicts of interest for the protocol being reviewed, and the IRB has systematically assessed each of the eight Common Rule approval criteria and determined whether each criterion has been satisfied or stipulated what changes are necessary to ensure the three ethical principles of the Belmont Report are met, namely respect for persons, beneficence, and justice.

Alternatively, AAHRPP can carry out this evaluation by requiring institutions to collect data on the effectiveness of human research subject protections and the quality of IRB reviews annually, starting on the year the institution applying for the initial accreditation, i.e., the pre-accreditation year, and each year after receiving accreditation for at least 3 years. This would allow AAHRPP to determine whether there is a statistically significant trend of changes in the effectiveness of human research subject protections and the quality of IRB reviews[10][11].

If AAHRPP accreditation can be shown to improve both human research subject protections and the quality of IRB reviews, then accreditation may be used as a global strategy to enhance the protection of human subjects participating in research.

Footnotes

[1] Acronyms used: AAHRPP, Association for the Accreditation of Human Research Protection Programs; HRPP, human research protection program; HRPPP, human research participant protection program; HHS, Department of Health and Human Services; NCQA, National Commission for Quality Assurance; VA, Department of Veterans Affairs.

[2] Human research participant protection program (HRPPP) and human research protection program (HRPP) are essentially the same. HRPPP was preserved in this commentary because it was first used by the Institute of Medicine.

Statements and Declarations

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Data Availability

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Author Contribution

MFT conceived the idea, reviewed the literature, and wrote the manuscript.

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