Do IRBs Protect Human Research Participants?

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Institutional review boards (IRBs) are the core of the well-established US system for the protection of human research participants. Institutional review boards were initially created to provide independent review of research conducted by researchers at their own institutions, impartial assessment of the ethical acceptability of proposed research, and a check on investigators’ interests. Subsequently, advances in knowledge, technology, and resources have changed the face of research. Pharmaceutical industry research spending exceeds the National Institutes of Health (NIH) budget, which increased from approximately $1 billion in 1970 to $30 billion in 2010. Multisite research, expansion into international and community settings, novel scientific opportunities, freezers of stored samples, expanded categories of researchers, and entities including contract research organizations, data and safety monitoring committees, clinical trial coordinating centers, and commercial IRBs have transformed the clinical research enterprise.

Concurrently, the number of, investment in, and responsibilities of IRBs have increased. Most research institutions, health care facilities, and research universities have at least 1 IRB; and more than 200 programs have been accredited by the Association for the Accreditation of Human Research Protection Programs. Most clinical and social science research undergoes IRB review, often by multiple IRBs. In addition to compliance with human subjects regulations, IRBs are often responsible for review of scientific merit, conflicts of interest, and compliance with privacy regulations.

Although considerable time and resources are devoted to IRBs, there exists much dissatisfaction and concern about the expansive mission and bureaucracy of IRBs. Institutional review boards are described as dysfunctional, in crisis, and “...more concerned with protecting the institution than research participants.” Researchers, institutions, and some IRB members complain about burden and “mission creep”—the excessive paperwork, inflexible interpretation of regulatory requirements, attention to inconsequential details, and expanding obligations of IRBs that seem to have little to do with protection of research participants.

Excessive or “hyper” regulation is seen as seriously affecting or stifling research productivity without adding meaningful protections for participants. According to Bledsoe et al., “IRBs have disrupted student careers, set back tenure clocks, and blunted the essence of many intellectual traditions. Facing demands that spiral to the level of sheer impracticality, faculty and students...face a stark choice: to conduct innovative research in their fields or to meet the requirements of their IRB.”

Over decades, scores of studies have concluded that IRBs are inconsistent in their judgments and variably apply a standard set of regulations. Practices and decisions vary from IRB to IRB, including determinations about whether full or expedited review is needed, whether risk is minimal or greater, and the appropriateness of methods of recruitment and consent, often without justification for the variation. Despite these worrisome data and persistent concerns, remarkably little is known about how well IRB review protects human research participants. Notwithstanding repeated calls for assessment of the effectiveness of IRBs, studies of how effective IRBs are at protecting human research participants and ensuring the ethical conduct of research are conspicuously absent from the literature. To date, no published study of which I am aware has evaluated the effectiveness of IRBs in protecting research participants and few have investigated the nature, quality, or thoroughness of IRB deliberations. As Hyman noted, “The available evidence indicates that there are substantial direct and indirect costs associated with IRB oversight of research. IRBs also operate inconsistently and inefficiently, and focus their attention on paperwork and bureaucratic compliance. Despite their prevalence, there is no empirical evidence that IRB oversight has any benefit whatsoever—let alone benefit that exceeds the cost.”

Without evaluative data, it is unclear to what extent IRBs achieve their goal of enhancing participant protection and whether they unnecessarily impede or create barriers to valuable and ethically appropriate clinical research. This lack of data is complicated by the reality of no agreed-on metrics or outcome measures for evaluating IRB effectiveness. Although available data suggest a need for more efficiency and less variation in IRB review, neither efficiency nor con...
consistency directly gauges effectiveness in protecting research participants. Protection from unnecessary or excessive risk of harm is an important measure of IRB effectiveness, yet no systematic collection of data on research risks, no system for aggregating risks across studies, and no reliable denominator of annual research participants exist. Even if aggregate risk data were easily available, it may be difficult to quantify the specific contribution of IRB review to reducing risk because protection of research participants is not limited to the IRB.

Serious efforts are needed to address these concerns and provide evidence of IRB effectiveness. Regulatory guidance should help clarify the appropriate scope, responsibilities, and specific goals of IRBs. Accrediting bodies should expand their focus beyond structure and process to evaluate outcomes and effectiveness. Innovation and creativity are needed to develop useful metrics to understand and measure research participant protection and IRB effectiveness. Reliable systematic data on research risk is crucial. Proposals suggest exploring and applying conceptions of quality assessment from other fields to IRB review, evaluating IRB deliberations, justifications for decisions, risk-benefit determinations, and the process and comprehension of informed consent. Understanding expectations of prospective research participants and their communities may be useful in defining appropriate metrics. Data on satisfaction of investigators and other IRB users and the knowledge, workload, interactions, and costs of IRBs continue to be important but are unsatisfactory as measures of effectiveness. The clinical research ethics group of the NIH-funded Clinical and Translational Science Awards Consortium has begun delineating measures of IRB quality to investigate how well IRBs protect the rights and welfare of research participants while promoting ethical research. These important efforts should be supported and encouraged to determine how effective IRBs are at achieving their goals and whether they are worth the substantial investment of time and resources.

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REFERENCES