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Institutional review boards: the cost to academic medical centers

Stephen B Hanauer

Earlier this year, Sugarman and colleagues reported the results of a 2002 survey of 121 US medical schools regarding the costs incurred by institutional review boards (IRBs).[1] For the 63 institutions that responded, the education and experience of the IRB staff; the composition of the IRB; the cost of equipment, supplies, travel and space; and the estimated time spent on 'activities' (e.g. review and approval of protocols, monitoring compliance, etc.) were documented (activities were converted to costs based on standardized figures). The authors concluded that the median amount spent by academic medical centers (AMCs) on IRBs is ~$750,000 per year (range $400,000–$1.15 million, according to the volume of reviews performed).

Although their cost estimates included staff and IRB salary, Sugarman *et al.* did not investigate several important and practical areas of the cost of IRBs to AMCs and how they impact on clinical research. It has been estimated that in 1998 there were over 60,000 ongoing clinical trials in the US and that 70% of the funding for these trials came from industry ($3.3 billion). Since then, the number of clinical trials in the US has surely increased; at the University of Chicago there are now more than 2,000 ongoing trials. In addition, there has been a significant shift in who carries out clinical trials, from AMCs to contract research organizations (CROs). CROs can potentially use central IRBs and benefit from efficiencies of size and cost compared with AMCs.

The true costs of IRBs in AMCs have to still to be elucidated, along with how they are inhibiting AMCs from competing with CROs to carry out clinical research, increasing the overall cost of clinical research (and pharmaceutical development), and impacting on the productivity of faculty.

Clinical research performed at AMCs is, inherently, more expensive because of institutional overhead expenses, but it is also less efficient because of the need for each AMC's IRB to evaluate and monitor protocols. Most AMCs charge for IRB submission, which, in multicenter trials, becomes duplicative for the sponsor (be it the NIH or industry). Individual patient charges are also higher because of institutional overheads and the need to account for faculty as principal and coinvestigators at each site. For multicenter clinical trials performed at AMCs, the redundant cost of IRB submissions to each individual institution can significantly impact upon the overall cost of trials as well as on operational efficiency and monitoring. What are also not accounted for in the report from Sugarman *et al.* are the indirect costs to AMCs of IRB operations. With the need to review and monitor hundreds (or thousands) of clinical trials at each institution, the numbers of faculty assigned to IRB committee work and their time commitment are expanding. Many high-volume AMCs have expanded their number of IRBs to accommodate the number of clinical trial submissions (e.g. there are now three IRBs at the University of Chicago), with more frequent committee meetings.

It is time that AMCs in the US collaborate to improve the efficiency and operation of clinical research by ending the redundancy currently required by individual institutions

A simple solution to this problem would be the development and acceptance of a single, cooperative academic IRB, supported mutually by AMCs. Such a concept has been considered by the National Cancer Institute and could be developed by the NIH—the safety and financial benefits of streamlining clinical research would easily offset the initial and ongoing running costs. It is time that AMCs in the US collaborate to improve the efficiency and operation of clinical research by ending the redundancy currently required by individual institutions.

Supplementary information, in the form of a reference list, is available on the *Nature Clinical Practice Gastroenterology & Hepatology* website.

SB Hanauer is Editor-in-Chief of Nature Clinical Practice Gastroenterology & Hepatology.

Competing interests
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