Institutional Review Board (IRB) Overreach

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Institutional Review Boards (IRBs) are committees at institutions where clinical research is performed or where members of the institution perform clinical research related to their institutional jobs. Each institution has an Institutional Officer, registered with the federal government, who appoints a minimum of five people. One must be a scientist, one a non-scientist and one should represent patients. Consultants are added on an ad hoc basis as needed for expertise. The committees are overseen by the federal government and their decisions cannot be overturned by the institution they work for.

There is no question they are crucial for overseeing clinical research. Medical research has a horrific history with regard to its concerns for patients. Many patients were used as subjects for a variety of research endeavors without their consent, or even knowledge. While almost everyone is aware of Nazi experiments on humans, not all Americans are aware of the Tuskegee experiments on unwitting African Americans, prostate cancer experiments on "Bowerie bums," radiation and LSD experiments on American soldiers, and a host of other less infamous cases. Publicity describing these cases caused an outcry that culminated in the formal development of principles and structures for protecting patient safety, and the freedom to choose whether or not to participate in any research endeavor. I have had many protocols reviewed by IRBs and thus have some experience. My projects have always been mundane, carrying little more risk than routine clinical care.

Chart review studies

My concern about the overreach of IRBs began when they started to require approval for my chart review studies. These are studies in which I review my own charts to determine how useful some intervention I used in the routine treatment of patients has been, if I want to report the effect of a particular medication or other intervention for my patients. Instead of trying to recall the last few patients I saw, I might want to review all the patients I've seen with a particular condition, determine how many got a particular treatment, and see how that affected outcome in some way. The purpose of the intervention was to treat the patient, not to do research on them, but once I had some experience, I felt it incumbent to determine how useful the treatments had been. One might think that NOT reviewing the experience is tantamount to uninformed care. We all recall our last few cases, but are not so good at recalling the last 100. There is an old joke about what a doctor means when he discusses his clinical outcomes at a conference. "In my experience," means one case. "In my series," means two cases. "In case after case after case," means three cases. Yet to do a chart review with the intent of publishing the results, even though there would be no means of identifying the participants, requires IRB approval. This is not hard to get if you know how to navigate the web-based process, which requires choosing among tens of possible forms to complete, but it is time consuming, and often requires revisions when statements do not fit the required boilerplate templates.

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The IRB is often overwhelmed with large numbers of complex protocols and delays are common, although less so with chart review projects that have no risk and are often expedited. The fault lies not with the IRBs, but the federal rules by which they operate. Recently I proposed a research project in which an anonymous Monkey survey (email) would be sent to about 100 medication prescribers asking them to rank 5 choices in renaming a particular drug-induced movement disorder. I asked the IRB if this would require approval. The surprising answer was that it would, but only if I wanted to publish it. I was surprised that publication had anything

to do with it, since the role of IRBs is to protect patients. I was unsure if the fact that patients were not involved, and that all data would be from people unknown to me, hence to any reader, would allow me to bypass approval, but I hadn't thought publication would have anything to do with it. But publication, for reasons unclear to me, is central to the IRB interpretation of what research is.

One problem associated with requiring IRB approval is that it takes weeks to months to get. As a result, students, house staff and fellows who are rotating through a clinic are unable to do this sort of research, or almost any at all, other than for joining ongoing projects. In the not-too-distant past, a student/resident/fellow could come across an interesting case and decide to evaluate other patients seen in the clinic with the same problem, and start work on it as soon as other cases could be found. Now this is reserved for students or residents who return the next year and start the wheels rolling for IRB approval in the interim. It also might mean, and I'm unsure if the IRB even knows, that I might need to have approval to review charts to present my findings at a conference, even if I choose to not publish the results, if the conference publishes abstracts of the presentations. This might even be interpreted to mean that it might make it a violation for me to present my results to anyone who might choose to use these results in a publication, citing a "personal communication." Yet, it would be clearly immoral for me to refuse agreement to publish the results of a study that might have clinical importance for some patients. Would it be more ethical to be quoted as saying that I reviewed the results and know whether an intervention was useful and what its safety issues are, but am not allowed to state the results until the project is reviewed and approved?

Yet we can't fault the IRB for doing its job. Several years ago, all research was halted at a prominent institution after a federal government review deemed its oversight insufficient.

One prominent IRB critic has published articles estimating the number of deaths caused by IRB-induced delays or interference with proposed studies that ultimately led to better care, but not in time for some patients to benefit from it. This physician and ethicist, like all physicians who have used IRBs, is a strong supporter of them. They serve an important function. Physicians and medical professionals have patient care as their mission. These are ethically driven professions, but the unethical among us are as unethical, or worse, than any others. Past behavior has taught us that we need oversight.

The problem now is the transformation that has taken place from its true mission of IRB as protector of patients to protectors of hospitals and government institutions. It is not too late, and probably not too difficult, to change. ❖

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