

Opinion

Theoretical Shortcomings of Institutional Review Boards and Possible Solutions

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Introduction

An Institutional Review Board (IRB) is an organized group formally designated to review and monitor research involving human subjects.¹ IRB has the authority to approve, require modifications in, or disapprove a research project. IRB performs careful inspection over the conduction of research projects involving human subjects to ensure they are scientific, ethical, and regulatory. IRBs were developed after scandals with research abuse earlier in the twentieth century. Originally, IRBs were committees at academic institutions and medical facilities to monitor research studies involving human subjects, primarily to avoid ethical problems.¹ There is no doubt that IRBs have provided major ethical improvement in performance of research activities and respect for the research participants, however, there are still important unmet needs where IRBs could be modified to meet them. The objective of this paper is to scrutinize some of the unmet needs of the IRB.

IRB inconsistency

Inconsistency is one of the important shortcomings of an IRB and is partly due to differences in IRB members. In the US, according to Campbell et al., 73% of IRB members were male and 81% were white (non-Hispanic). Of these researchers, 71% were clinical researchers and the remainder, basic researchers.² Extent of this variability may depend on the cultural diversity in the specific society for which an IRB serves. On the other hand, diversity is necessary to respect justice and the rights of minority groups as well as vulnerable populations. The optimal balance between these two extents is highly dependent on multiple factors including social values and financial resources and might be tricky to attain.

Inconsistency between different IRBs is another issue that can be due to lack of a unique systematic approach in evaluating an application used by IRBs. The approach of different IRBs to a sample proposal ranged from ignoring some evident ethical rules to complicating the process with exaggeration of the application of these rules.^{3,4} Having a unified checklist for IRBs could reduce the inconsistency in IRB approach. This can particularly be significant in multi-center studies, which need IRB approval from all

participant institutes. In the study by Green et al., submitting one application to 43 IRBs resulted from waiver to outright rejection. One IRB granted a multisided study exemption, for which it did not qualify; 12 asked at renewal for names of responding physicians, which would have increased risk and violated the terms under which human subjects had consented to participate; and one abridged individual autonomy by deciding that physicians could not make the informed choice to participate.³

In addition, it seems that most IRB members are trained in typical health research methodology and might not be sufficiently familiar with atypical research proposals such as qualitative or social research, in order to assess them efficiently. Having a central or regional IRB with members who are experts in the field of qualitative research may help improve this. A central IRB is able to decide independent of the institute or municipality it serves. Furthermore, a central IRB can have several specific subgroups with each specialized in one topic. These subgroups can deal with more specific and atypical issues than a normal IRB. Central IRB may remove the need of submitting to several IRBs in case of multi-center studies. This may also reduce the total budget dedicated to IRBs. A central IRB could not be simply considered a perfect solution and its pitfalls including ignoring regional cultural boundaries and work overload should not be overlooked.

IRB and conflict of interest

IRBs may have two major types of conflict of interest: conflict of interest of individual members and of the IRB as an organization. Of review board members in the US, 47% have been serving as industry consultants.² IRB's decision might be influenced toward facilitating approval of proposals received from their own institute or municipality compared to proposals submitted externally. Furthermore, for various reasons, IRB members might be favorably biased toward the researchers from their own institute than those from another institute. This is even more an issue when the applicant is part of the IRB. One might argue that members are more stringent with fellow members to ensure integrity among the group and because a member "ought to know better". Even though this is true, it can induce further IRB inconsistency as discussed earlier. The author believes that many IRBs need improvement in their rules and execution.

Furthermore, IRBs are influenced by various stakeholders in the institution or the area they are serving. The institution itself is one of these stakeholders. Society may also have such a role. Although the main role of IRB is acting in the best interest of research subjects, IRB members might have the fear of losing money from external sources for their institute if try to act in the

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best interest of research subjects in the current competitive field of research fundraising. They may also consider empowering their institute or municipality in the competition to do more research and achieve a higher rank. In addition, attractiveness of a new invention or discovery may blind the eyes of IRB members in a way that ignore ethical conflicts in a proposal.

IRB gender distribution

There is no rule to equally distribute IRB members based on their gender. Some IRBs have tried to decrease the biased decision by choosing at least one female member. The main challenge again would be that one member does not affect the decision of the five-member committee. This is especially important when talking about researches involving sensitive topics.

IRB nonscientific member

Most of the IRBs have a non-scientific member. The logic for this is to protect the rights and opinions of the general population. However, whether this member can adequately comment on specific ethical issues and have its predicted role is highly debatable. Sengupta et al. have studied exclusively non-scientist members of IRBs with open-ended questions and showed that 94% reported that their main contribution was to simplify the informed consents.⁵ IRBs should develop ways to better integrate these members.

IRB final decision

Each IRB can have its own rule on how to achieve a final decision. Either the votes of all members are necessary or a sufficient majority is arguable. In order to avoid any controversy, the IRB should try to reach a complete agreement on its decision. Any negative vote may mean an unsolved ethical problem that could have been avoided.

IRB expenses

In a US study, total estimated costs for operating high-volume and low-volume IRBs were \$770674 and \$76626, respectively. The average cost per action, a measure of economic efficiency, was lower for high-volume IRBs (\$277 per action) than it was for low-volume IRBs (\$799 per action).⁶ Having some large IRBs or even one central IRB promises a lower total budget dedicated to the same level of activity or higher level of activity with the same budget for IRBs.

IRB regional distribution

Regional distribution of IRBs is not fair enough to be sure that every researcher has easy access to an IRB and each research participant has received enough attention regarding ethical issues. This is particularly true in the developing world. In some areas of the world, there are a few IRBs serving the entire country and consequently, these are not equally accessible for all researchers countrywide. Therefore, research participants may not have equal respect based on their geographical distribution. However, this is likely to be due to a lack of budget, human resources or pro-IRB policy rather than a shortcoming of the IRB itself.

IRB definition of minimal risk

This is one of the major issues possibly discussed under IRB inconsistency but in the author's opinion, it has enough impor-

tance for a separate discussion. There is no unique definition of minimal risk research. Underestimating a proposal as minimal risk research may affect the life, health or privacy of participants or end in unauthorized release or sharing information on patients' health records.

IRB work overload

IRBs have always complained about the number of research proposals they encounter. This overload could cause bias in the evaluation of research projects and may lead an IRB to act in a way that is not in the best interest of research subjects.

Conclusion

Although IRBs are the essential part of research systems and have added significantly to the application of research ethics by respecting research participants and their rights, there are challenges on the shortcomings of IRBs. In this article the author has argued that there are still unmet needs for improvement in the practice and context of IRBs. Establishing a central IRB might resolve some of these problems but it has its own disadvantages. Although this central IRB may reduce the inconsistency in IRB decisions, there is no guarantee that the other shortcomings of the IRB, which have been discussed in this paper, would not happen in a central system. Accepting a central IRB by local institutes is another debatable issue. The National Cancer Institute of the United States has started a trial of Central Institutional Review Board from 2001 but they are still far from establishing an applicable and acceptable system. It should be kept in mind that any changes in an IRB system should be dealt with cautiously and with consensus from experts. As discussed, most ethical issues have controversial or even paradoxical aspects deserving an intellectual approach, with the involvement of all stakeholders. Otherwise, these changes do not improve the current situation but also would aggravate it.

Disclosure

The author declares no conflict of interests.

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