Science and ethics review: the thrill is gone

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If we work with animals, patients or human volunteers, we are required to carry out experiments and studies in an ethically acceptable way. To ensure compliance with laws and regulations, we usually subject our planned studies to ethical review, by an independent institutional review board (IRB) or ethics committee. The reviewers consider the relevant science and, if it respects regulations and ethical norms, such as the protection of human subjects, privacy, informed consent, protection of laboratory animals and the extent of potential suffering inflicted on animals, or biosafety, the research is permitted. As taxpayers' money is often used, and as it is possible that ethical review documentation could become legal evidence in court, review boards demand high standards, and rightly so. Their work is an important regulatory measure in research. But, as with many other things, ethical review can do more harm than good when it gets out of control.

The problems lie in the IRBs mandate of providing independent review, which potentially gives them almost dictatorial powers to judge applications. In my experience, most IRBs try to reach consensus about whether to accept or reject a proposal and therefore seldom, if ever, need to vote. There is a hidden danger with this consensus approach: I have witnessed several times how one or a few strong, dominant personalities or opinionated committee members can sway the IRB or bias the decision. We all have experience with such a dominance phenomenon, whether it is a school bully, a member of a sports club, a boss or a politician. IRBs need to be aware of this danger—they should not abrogate responsibility to strong personalities, but respect the principles of democracy.

Another risk is that necessary and potentially beneficial studies are rejected either out of ignorance or because some IRB members take extreme positions. Of course IRBs cannot include experts in all research fields.

Usually, the applicant is the expert and IRB members query him or her about the state of progress or the accepted standards in the field. IRBs should therefore not be paternalistic, and should value the knowledge and expertise of the applicant during the review if the scientist already has extensive practical experience with animal models or human subjects. Similarly, theoretical worst-case scenarios or assuming ideal situations are not helpful either if years of experience show that this is not the case in reality.

Another risk is that applicants become bogged down in the review of their proposed work instead of actually doing the experiments. Unnecessary queries from IRBs easily become the order of the day if IRB members want to show due diligence or get lost in minor details. This causes unnecessary delays before approval and requires considerable time input from the applicant. Overzealous ethical review is not prudent, as the public pays for most academic research and loses benefits when it is delayed. Moreover, undue delays might also risk wrecking an interesting and innovative project and the careers of the scientists involved.

IRBs might also be tasked to investigate allegations of misconduct, which are often made public by whistle-blowers. As with IRBs, whistle-blowing has its good and its bad side. Clearly we need to know about fraud in science, but the system can be abused by vindictive people who seek to stop or delay someone else's work through accusations of professional misconduct or breaching of ethical standards. In my experience, it is the wrongfully accused who suffer most from delays in their research and a damaged reputation, whereas the accuser faces no consequences. In such cases, a lack of a rigorous response to a false accuser is simply unacceptable. Using ethics as a weapon for petty revenge or sabotage should have consequences as harsh as those for misconduct.

Some funding agencies demand annual renewal of IRB approval for all projects they support. It is surely reasonable to do annual—or even more frequent—review for clinical trials, but this is absolutely foolish for basic research. This consumes a huge amount of time and money, and places an unnecessary administrative burden on the personnel involved, both for researchers who have to write reports and submit extension applications, as well as IRB members.

Many funding agencies and others invest much of their scarce funding into the process of ethical review, but the consumers, that is the taxpayers, do not get their money's worth out of it. The original rationale for IRBs was to protect human research subjects and animals, but overloading the usually voluntary IRB members probably makes them miss genuine ethical violations. The recent trend to expand reviews benefits, in my opinion, only IRB interest groups that, as with a national civil service, are almost never pruned despite unfettered growth. More rules require more work, which demands more personnel to monitor and so on. This is not in the interest of publicly funded research and for the vast majority of researchers; the thrill has gone out of their work. It is time to concentrate on what is important.

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CONFLICT OF INTEREST

The author declares that he has no conflict of interest.

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