

Deliberation and decisions in the IRB process

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Abstract

Institutional review boards (IRBs) regularly vote to resolve conflict. This article argues that voting minimizes protections for human subjects and violates moral order. Rather than vote, IRBs should be mediating disputes, which respects the moral difference and integrity of IRB members.

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It is my honor and pleasure to be a participant in this *Festschrift* honoring Victor W. Sidel, MD. Vic Sidel was my mentor, guide, benefactor, editor, co-author, and friend for many years in the Department of Social Medicine and in the world of protecting human subjects. He has shown the way for generations of medical students and the occasional lawyer. He has set a standard of excellence in moral leadership.

I can think of no better way to honor his achievement than to continue a discussion that we engaged in for years, whose goal, ending the process of voting on contentious matters in the Montefiore Medical Center Institutional Review Board (IRB), eluded us. However, given my own work in mediation,¹ with which some of you are familiar, and given new voices in the discussion, I plan to expand my dissent, which I regularly offered in the Montefiore IRB, with hoped-for future agreement that voting is not a useful tool for promoting and protecting the interests and rights of human subjects.

The intellectual architecture of the regulations governing research with human subjects² appears to anticipate the full range of ethical dilemmas that IRBs might face in attempting to review protocols

within the specific regulatory standards and guided by a set of moral principles. The regulations stipulate, among other things, membership in the IRB, categories of protocols receiving more or less intensive review, processes for notification of investigators, special protections for vulnerable populations, and even the specific logic of review for research involving specific populations, i.e., prisoners and children who exhibit compromised or developing abilities to provide legally and ethically adequate informed consent.¹ Surprisingly, the regulations are silent on any process to be used to resolve disputes over any particular protocol. As a result, most IRBs use some system of majority vote, an approach that, I would argue, is not suited to the resolution of complex moral matters. Nor is voting, by extension, helpful to the identification and protection of the rights and interests of potential human subjects, which should be the sole focus of IRB deliberation. I suggest, in these brief remarks, that voting may actually distort deliberation when an IRB addresses ethically complex issues.

A word about the gold standard for voting before moving on: first, to an argument about moral complexity and, second, to an examination of two cases illustrating the dangers of the voting process. According to Wikipedia (as of March 28, 2012):

Robert's Rules of Order is the short title of a book containing rules of order intended to be adopted as a parliamentary authority for use by a deliberative assembly written by Brig. Gen. Henry Martyn Robert. The first edition of the book, whose full title was Pocket Manual of Rules of Order for Deliberative Assemblies, was published in February 1876 by then U.S. Army Colonel Henry Martyn Robert (1837–1923) with the short title Robert's Rules of Order placed on its cover. The procedures prescribed by the book were loosely modeled after those used in the United States House of Representatives, with

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*such adaptations as Robert saw fit for use in ordinary societies.*³

Interestingly, Robert's notion was that deliberative bodies should decide, as part of their organizing process, whether to adopt these rules to govern deliberations. (Note that the U.S. House of Representatives is no longer seen as that ideal deliberative body whose process should be duplicated for the benefit of humankind.) What Robert's Rules do is: keep order, move the agenda, and facilitate domination by the majority. None of these supposed virtues is sympathetic to the exploration of moral complexity.

In a 2011 article, Autumn M. Fiester defines an "aporetic case" as "a case in which the moral permissibility (or correctness) of opposing positions can both be justified on moral grounds (that is, using moral reasons)—as opposed to grounds of pure self-interest."⁴ Feister argues that in aporetic cases, voting is not a morally supportable structure and that only a consensus process should be used to resolve differences.

Feister goes on to argue that a dispute among members of a clinical ethics committee (or by extension an IRB) on the proper resolution of a case indicates not just disagreement but a state of moral uncertainty or perplexity. Where such disagreement exists, not on a verifiable issue—Did this investigator meet a deadline?—but on a matter that is ethically significant, then what is at stake is a "clash between moral considerations, values, or principles, or significant disagreement about which moral consideration ought to trump the others in the case."⁴

Feister, who opposes voting in these circumstances, concludes that:

Mediation, as a process, honors the validity of both sides in a dispute. It works towards consensus about outcome, even when consensus about principles or values is not possible. This approach provides a built-in safeguard against choosing between incommensurable values because it takes no stand on which moral principles or claims ought to trump in a disputed case. It does not claim moral authority when there is none to be had. It does not prioritize one set of values over another in the absence of any access

*to the moral knowledge or expertise needed to anchor such claims. And mediation levels the playing field in an arena with clear power and status differentials that can artificially (and illegitimately) grant priority to the values of the powerful. Because it includes the voices of all affected by the outcome, it legitimizes and safeguards the moral claims of all of the participants.*⁴

These observations apply similarly to clashes of moral judgment among IRB members.

Consider two cases that illustrate disagreement: the first is an actual case and the second is a hypothetical. The first involved the approval of synthetic growth hormone to replace human growth hormone to avoid the spread of Creutzfeldt-Jakob disease; the second involved the creation of scars on the skin of African American subjects in order to test various interventions to lessen the scarring.

In the first case, the molecular structure of the synthetic hormone was identical to that of the human growth hormone, but of chemical and not human origin. The study protocol required all children enrolled in the protocol to receive weekly injections for two years, one year with and one year without the active agent. Although the synthetic material was already available for clinical use, it was hugely expensive and often not reimbursed by insurance companies. In this case, there was a vote and, over vociferous objection, the protocol was approved by the IRB.

Consider some of the arguments offered for enrolling children in trials of synthetic growth hormone: without FDA approval, insurance companies would not cover treatment; poor children enrolled in the study would receive state-of-the-art care that would be beyond their families' means; the process would make growth hormone available to greater numbers of children who needed it; and the burden of placebo injections was outweighed by the benefit of treatment. (Although it is generally inappropriate to assert that there will be a benefit from a research intervention, in this case, given the identical molecular structure, the intervention could appropriately be described as treatment.) The counter arguments noted the abuse of poor children whose lives would be adversely affected for one year by the pla-

cebo injections; the fact that no parent who could afford the treatment would ever accept placement of her child in the protocol; and the clear class bias of the study. The vote disposed of the matter, but did nothing to reconcile the opposing moral claims or claimants.

The hypothetical, which I created for a law school class, hypothesized a protocol that sought to identify remedies for scarring in the African American population. The danger in the protocol was that scars created to test interventions might not be remediable. In the course of a classroom discussion, it became clear that there was a huge difference of opinion about the approvability of the study. Those in favor argued that it targeted a problem about which little was known and for which few treatments were clinically efficacious. Advocates for rejection of the study cited the Tuskegee syphilis study^{5,6} and the Retin A prison experiments⁷ as dispositive. A consensus process sharpened the issues and adjourned the discussion until members of the affected community could be invited to participate.

Voting, especially under Robert's Rules: limits discussion; declares certain lines of reasoning out of order; permits those disgruntled, uncomfortable, or just plain bored to push toward a vote; and, "moves the agenda" of a long and possibly tedious meeting. What these rules and voting procedures do not do is: encourage discussion of underlying moral principles; help level the playing field distorted by power differentials between investigators and human subjects; surface individual biases against populations affected by the proposed research; and permit and facilitate intellectual "horse trading" that might modify a protocol to minimize moral hazard.

In contrast, a consensus process: assumes that all will offer reasons for their espousal of one or another position and attempt to convince others to accept their logic; supports open discussion, leading to the minimization of differences; and seeks a common moral and intellectual ground that identifies an outcome not as morally superior but as morally possible.

Most IRB proposals are neither so complex nor so contentious as the ones referenced here. However, mediating disputes rather than outvoting the objectors respects moral difference and the integrity of IRB members.

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