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The Canadian Model: A Potential Solution to Institutional Review Board Overreach

James Nichols

Abstract

Over the past four decades, Institutional Review Boards have evolved into somewhat unwieldy beasts. The once-modest safety control has grown into thousands of independently operating ethical review boards called Institutional Review Boards (IRBs). While the power of these boards has grown, there is little legislation that controls or even guides these boards in their attempt to protect human research subjects. As a result, scholars are being forced to edit seemingly harmless research after, during, or even before it has begun. Despite the current system, the concerns of academic freedom of research and human safety are not opposing forces, but can coexist in a manner that promotes intuitive and promising research without sacrificing human integrity and protection. All it would take to realize this balance is minor legislative adaptations mirroring the recent changes in review boards adopted in Canada.

Evolution of IRBs

In 1974, Congress passed the National Research Act in response to prominent biomedical research abuses, such as the Tuskegee Experiment.¹ The act spawned a committee that would develop the *Belmont Report* and ultimately the creation of IRBs as a vehicle to accomplish human-subject protection during scholarly research.² Nearly five thousand IRBs have been created by universities and hospitals to screen human-based research proposals.³

The power of these IRBs does not come from the universities or hospitals that created them but from title 45, part 46 of the *Code of Federal Regulations*.⁴ As it stands, the legislative requirements are scarce, and what is present lacks guidance. For example, while IRBs are mandated to have a diverse board, no set requirement is given.⁵ In fact, the only absolute mandate is that one member must have a primary concern with scientific issues, and at least one member must have a primary concern with nonscientific areas.⁶ This requirement gives no further detail on what qualifies as *scientific* or *nonscientific*, nor does it require that the member with scientific expertise have knowledge of the scientific research type in question.⁷

It is this vague nature of the federal regulations that has become the main criticism of IRBs. The most basic and widely accepted regulatory scheme utilized by IRBs is the Common Rule, which determines what constitutes research on human subjects and what constitutes unjustifiable harm to human subjects.⁸ Due to the vague language of this test, all research involving human subjects—survey collections, interviews, and even reexaminations of previously collected data—require IRB approval.⁹

The rule to determine whether the research will be approved turns on whether the IRB believes the “risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.”¹⁰ The issue with this rule is that it gives no standard for the board to judge proposals on. As a result, many institutions and governmental departments have released reports and guidelines to supplement the lacking regulations; however, many such institutions teach members to incorporate morals and societal stigmas into their judgment on whether research should be approved.¹¹ The result is an intangible balancing test for research proposals because each local IRB will approach the Common Rule differently, depending on the location, age, morals, and personal bias of the composing members of the local organizational IRB.¹² Thus, every study one IRB rejects or alters is likely to have approved it as is by another.

Additionally, the constitutional restraint that IRB approval is only needed for publicly funded research has been substantially eroded. The creation and governmental backing of IRBs has made them the conventional method for ensuring human-subject safety, which leaves an institution open to liability if it does not seek an IRB’s approval for all research—even privately funded research.¹³ On top of this, many journals are refusing to publish research that did not have IRB approval, regardless of the funding source.¹⁴ Thus, IRB approval has become a near mandate for all research, despite the lack of federal guidance.

Effect on Academic Research

It is impossible to determine the exact effect IRBs have on research. Yet studies have found that upwards of 80 percent of proposals are not approved as submitted, and a number of IRBs have suspended or completely rejected a research proposal.¹⁵ This would suggest that possibly hundreds, if not thousands, of research proposals are altered, completely abandoned, or rejected each year. Due to the subjective nature of the IRBs' Common Rule test, it is highly probable that unique research topics or research containing unconventional methodology are disproportionately rejected or altered.¹⁶ This raises the concern that IRB overview is resulting in homogenous research, be it in methodology or topic.¹⁷

While scholars are still free to pose unconventional or unpopular research topics and methodology to their IRBs without penalty (aside from being told to alter their proposals), many researchers avoid doing so because getting IRB approval is a lengthy process. Standard reviews by a local institutional IRB can take weeks, and more complex research proposals can take a number of months to review.¹⁸ In fact, a several-month wait is typical.¹⁹ This time delay, coupled with additional time to fulfill the likely edits, can be the coup de grâce for time-sensitive topics, such as political insights, or for students who are restrained to quarter or semester systems. Concerns about time, coupled with a lack of a formal appeal system, forces some scholars to adapt their proposals to comply with societal and academic standards, even when their original area of interest would have posed no threat to human subjects.²⁰

In many respects, it appears that IRBs, to better shield their governing organization from liability, have abandoned their original intent of protecting human subjects. This can be seen in the case of Joshua Inwood, who had to remove from his research quotations given by politicians about an incident involving the Ku Klux Klan, but who was not asked to remove any quotations from lay citizens, even when the content was similar.²¹

There are hundreds of examples that show IRBs making decisions that would lead any scholar to be concerned. They have censored research on the basis of liability; blocked research on the basis of grammar; refused to allow any deviation, no matter how slight, from the original proposal; and made outrageous demands.²² Yet there exists very little case law against IRBs in the educational setting. The majority of cases stem from biomedical research and, thus, hospital IRBs.²³ While these cases may be influencing how biomedical research is conducted and the IRB process within that realm, they do very little to benefit the scholars dealing with higher education IRBs. In fact, the few challenges made by scholars against their universities' IRB holdings have not resulted in judicial opinions.²⁴

Upon examination, this lack of case law makes sense. After all, the goals behind IRBs appeal to a moral sentiment that many people do not wish to attack. Furthermore, the majority of edits requested by IRBs require only altering the study to the board's liking. The size of the change makes no difference because it puts the scholar in the same dichotomous position. The scholar can resist and challenge the IRB and his or her institution, which takes time and money and could result in losing face. Or the scholar can comply, which results in a publishable piece of work and is efficient and saves face.

The result is an Orwellian atmosphere in which scholars, out of necessity, must tailor their research to IRBs that have no legislative guidance or cohesive test, leaving such scholars to be blessed or doomed, depending on the IRB they happen to report to. Due to these increased concerns and a lack of case law, a number of approaches that aim to fix the shortcomings of IRBs have taken shape.

Current Approaches

The flaws in the IRB review process have led to a debate among three leading groups about how best to reform IRBs. The first group argues that IRBs are unconstitutional because they are, functionally, mandated censor boards.²⁵ While this argument has sound legal conclusions, it will likely never lead to change because judicial review of IRBs rarely happens, even in district courts. Furthermore, even if this approach is successful, it would lead to the dissolution of IRBs, and it does not pose a plausible replacement.²⁶

The second approach is legislative overhaul of IRBs. In fact, in 2011 the Department of Health and Human Services and the Office of Science and Technology Policy each put forth proposals on how to reduce the faults in the IRB structure.²⁷ These proposals contain reasonable steps to lessen the burden on scholars, such as a new type of classification for low-risk research. Unfortunately, there has been no movement by regulators to adopt such proposals.²⁸ One likely reason is that the proposals lack widespread support because many people fear that legislative overhaul, absent scholarly input, could result in more harm than good.

The third approach advocates for independent reform of IRBs. These scholars in this group are working to change the IRBs they personally report to. While this has had limited success, it will not result in widespread reform.²⁹ As it stands, this approach is only widening the split between IRBs because each new reform in one IRB will further differentiate it from the thousands of IRBs, despite the fact that these boards purportedly have the same end goals and rules.

All three approaches have failed to result in comprehensive reform. However, a solution that has already seen large success could garner enough support to create effective legislative change. The best solution would be to mirror the change Canada made to its review process in 2010.

A Joint Approach

The Canadian Way

The early history of ethical research reform in Canada mirrors that of the United States in many ways. In fact, Canada's early attempts to control human-based research resulted in guidelines released in 1978 by the Medical Research Council of Canada and the Social Sciences and Humanities Research Council.³⁰ These guidelines were directly based on the *Belmont Report* written just two years earlier in the United States.³¹ Much in line with this, Canada later imposed a system for human-based research that was comparable to the United States' system of the late 1990s.³² This resulted in "howls of protests from researchers" over a fear that increased homogeneity would undermine social-scientific research.³³ At this point, Canadian regulators broke free from the shadow of the United States and began a complete reform of their ethical review process, which culminated in the *Tri-Council Policy Statement 2* (TCPS2). This policy statement was a product of three years of hearings and consultations with, and drafts from, a large portion of the Canadian research community.³⁴ After this document was created, it was approved by Canada's Natural Sciences and Engineering Research Council (NSERC), Social Sciences and Humanities Research Council (SSHRC), and the Canadian Institutes for Health Research (CIHR).³⁵

One distinction between the TCPS2 and the IRB legislation is that the TCPS2 was designed by the drafters to be a living document that is constantly evolving with the help of scholars.³⁶ Perhaps the most distinct aspect of the TCPS2 is that the document expressly accepts that academic freedom is a guiding principle in the ethical review of research.³⁷

The TCPS2 sets forth the approach that Research Ethics Boards (REBs) must use in the evaluation of research proposals involving human subjects.³⁸ In this respect, REBs mirror IRBs. While REBs and IRBs have the same end goal, the TCPS2 has given these boards more guidance about how to evaluate research and has also solved many issues plaguing IRBs. The TCSP2 has accomplished this goal by including more than two hundred pages of straightforward requirements about, and examples of, issues that have been plaguing review boards across the world.³⁹

First, the TCPS2 has set forth more stringent requirements on who can serve as a member of a local REB. Whereas IRB membership requirements push for diversity, REBs mandate diversity by gender.⁴⁰ Whereas IRBs require that one member be an expert in the scientific community as a whole, REBs mandate that two members be experts with knowledge in the relevant field.⁴¹ Furthermore, REBs are required to have one member dedicated solely to focusing on ethics and another member with legal expertise.⁴²

Second, the TCPS2 has set forth a number of exceptions in which certain types of research are not required to get REB approval. These exceptions are laid out in straightforward requirements and include examples.⁴³ The kinds of research covered by these exceptions include observations of people in public places, secondary usage of anonymous information, and course-based research for undergraduate students.⁴⁴

Third, the TCPS2 has an entire chapter dedicated to the evaluation of qualitative research.⁴⁵ As noted above, the bulk of case law and the historical reasons behind the creation of ethical review boards stem from biomedical research.⁴⁶ Yet IRBs within the United States have expanded to the point where qualitative research studies, such as surveys or interviews, qualify for the same level of stringent review as biomedical research.⁴⁷ The TCPS2 has abandoned requiring that biomedical and qualitative research undergo the same level of scrutiny, and as a result qualitative research is put under less scrutiny.⁴⁸ Once again, the TCPS2 gives REBs ample research for and guidance on adequately and consistently evaluating such proposals.⁴⁹ Furthermore, over three chapters the TCPS2 sets out a higher level of scrutiny for biomedical research.⁵⁰ In effect, the TCPS2 has placed a higher level of focus on biomedical research and turned the focus away from qualitative research, which is in line with the intent and history of ethical review boards.

IRBs and REBs do not diverge in every way. Both have stringent rules for getting informed consent from participants and for ensuring the confidentiality of participants.⁵¹ Once again, however, the TCPS2 sets forth the requirements in more depth, giving REBs a unified approach, whereas IRBs are often forced to find their own way.

Unfortunately, REBs, like IRBs, do not have a formal appeal process.⁵² Instead, scholars are entitled to have their proposals reconsidered by the REB that rejected the proposal.⁵³ If the scholar is not satisfied, his only recourse is to appeal using mechanisms the governing institution (such as a university) has put in place.⁵⁴ It should be noted that the TCPS2 promotes the notion that each institution should implement an appellate system, but does not require one.⁵⁵ The TCPS2 notes that “it is not the role of the three federal research Agencies that are responsible for this Policy to consider any appeals of REB decisions.”⁵⁶ The TCPS2 states that any appellate system put in place by a university has the authority to overrule its REB’s decision.⁵⁷

While the TCPS2 does not resolve every issue that may arise during an ethical review of proposed research, it is a step in the right direction. Furthermore, the ability of this document and of Canadian REBs to evolve in the face of change is being seen in relation to community-based research in Canada.⁵⁸ A body of scholarly literature in Canada that noted the oppressive attitude of REBs toward community-based research began to grow in early 2000.⁵⁹ However, a study completed in 2012 noted that modern REBs have a “complex understanding of CBPR and conducting research in communities.”⁶⁰ Furthermore, community-based research is now specifically noted in the TCPS2 as receiving less stringent review because it qualifies as qualitative research.⁶¹

Why Copy Canada?

Implementing a document comparable to the TCPS2 in the United States could appease the three major groups pushing for IRB reform. Proponents of full dissipation could see this as a push in the right direction. The TCPS2 sets forth clear limitations that would help rein in the expanding authority of IRBs.⁶² Proponents of local reform would get not only the reform many are pushing for but also a protocol that gives the organizing institution the authority to appeal.⁶³ Thus, these reformers (if still pushing for local institutional IRB change) would have the ability to do so on a micro level. Proponents of legislative reform could follow this approach because it empowers academic freedom through a tested document.

Of course, no document could resolve all potential issues. A number of IRB oversteps, examples of which can be found in this article’s endnotes, could have been easily avoided under the guidance of the TCPS2.

Review of Methodology

This example involves the scholars Elizabeth Loftus and Melvin Guyer who faced reprimands and delays when dealing with their IRB during a journalistic investigation that debunked recalled-memory techniques.⁶⁴ Under the TCPS2, research is exempt from REB review if “the information is publicly accessible and there is no reasonable expectation of privacy.”⁶⁵ It is likely that the investigative journalism techniques of these scholars would have qualified for exemption. The scholars had gathered previously published data, and the interviewee had no reasonable expectation of privacy, having been discussed in the original author’s publication on the author’s current speaking tour.

Cost of IRBs

This example reveals that one study required the authors to spend eighteen months and 17 percent of their budget getting approval from IRBs across multiple jurisdictions.⁶⁶ Each minor alteration at one IRB resulted in a new hearing at the other IRBs.⁶⁷ This issue would likely have not existed under the TCPS2.⁶⁸ The TCPS2 has a chapter dedicated to multijurisdictional research that can help simplify the process and minimize collateral bureaucracy.⁶⁹ For example, the TCPS2 formally allows REBs to accept the holding (approval of the research) of other REBs without needing a full review.⁷⁰

Board Member Expertise

This example involves an IRB mandating that a study include information that could have put the scholars in danger because the study was being conducted in Iraq during a time of conflict.⁷¹ Ultimately the scholars had to hire their own expert to persuade their IRB that the study was ethical even without including the name of the university in the consent forms.⁷² This issue would have likely been resolved more efficiently under the TCPS2. The TCPS2 allows for the alteration of required consent if the risk is minimal and it would otherwise jeopardize the research.⁷³ Furthermore, this issue was only resolved by the scholars bringing in an expert ethics consultant.⁷⁴ Under the TCPS2, each REB must have provisions allowing them to call in experts in fields in which they lack expertise or knowledge.⁷⁵ As a result, scholars are not forced to spend their research funding on such experts.

Alteration of Proposals

This example involves the scholar Jin Lee, who had data withheld from her study because she altered its compensation scheme.⁷⁶ She compensated one group of participants less than she had specified in her original proposal because their participation was not as substantial as expected. But she did not get this alteration approved by the IRB, and the data produced was not allowed to be used in her study.⁷⁷ It's unlikely that this issue would have occurred under the TCPS2. The TCPS2 allows scholars to make minor deviations in proposed research without seeking prior approval.⁷⁸ This is to allow research to carry on when changes are made that do not increase risk or pose ethical dilemmas⁷⁹ Such an allowance could also aid scholars who conduct interviews or informal conversations.

Academic Merit

This example involves a prominent university IRB chairperson who stated that she rejects proposals that she deems to be a waste of time.⁸⁰ This means the IRB judged the worth of a study—not the potential harm to human subjects. For example, if a scholar wanted to research the validity of a new diet, he or she could get shot down by an IRB that believed it was simply a fad diet and that studying it would be a waste of time. This is unlikely to occur under the TCPS2, which states that it is acceptable to have a study whose minimal risks are no greater than what occurs in everyday life.⁸¹ Thus, the IRB's concern about wasting a participant's time is unlikely to be a valid reason to reject or alter a study.

Academic Freedom Argument

All of the examples above are easily resolved using the text in the TCPS2. It is important to note that scholars are not limited to the text of the TCPS2 because the TCPS2 has incorporated academic freedom into the guiding principles that all REBs must follow.⁸² The TCPS2 states, “Researchers must have academic freedom,” which it defines as the “freedom of inquiry, the right to disseminate the results of that inquiry, freedom to challenge conventional thought . . . and freedom from institutional censorship.”⁸³ Of course, academic freedom does not trump the right of subjects to be free from harm. A study meant to induce stress on war veterans with post-traumatic stress disorder could not go unchecked under the guise of academic freedom. That is because the TCPS2 does not make academic freedom of research an absolute or a test, but instead made it a guiding principle that runs parallel to professional standards of care in protecting subjects.⁸⁴ In short, the inclusion of academic freedom prevents REBs from looking to the *why* behind the proposal. Instead it requires them to look at how the study will be conducted and on whom.

Conclusion

It is clear that scholars do not want to forget recent history because no one wishes to repeat it. After all, the creation of IRBs comes from one of the noblest undertakings of mankind—protecting those who cannot protect themselves. However, a lack of substantive legislation has resulted in a fragmented approach by the five thousand IRBs that have spread from the field of biomedical research into all human-based research. The power given to IRBs was vastly unrestricted and has gone unchecked. More focus is given to following set norms, so that the sponsoring institution can save face, minimize liability, and prevent offense, than to reducing the risk to subjects. Nothing can be more at odds with the search for truth than these new concerns. Every academic venture into uncharted knowledge will embarrass some and enrage others. Seasoned scholars

can avoid IRB traps, but the harm, though indirect, still exists because the IRB process can result in homogenous research. Fortunately, these concerns can be resolved by following the TCPS2 used by Canada. This document is moderate enough to ensure widespread support by the majority of scholars. This unified approach means that legislative overhaul, following the TCPS2 example, is much more likely to occur than the current fragmented approach.

James Nichols is in his final year of law school at the University of Texas School of Law. He is slated to be a litigator for a major tech company after graduation. He has also published scholarly articles on topics ranging from hostage negotiation protocols in the Journal of Applied Security Research to the impact of virtual assets on divorce proceedings in the Texas Bar Section Report.

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