Canada's research community divided over proposed prescription to ease ethics approval woes

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Researchers have long complained that ethics approval processes for studies involving multiple institutions are time-consuming, overly complicated, and often redundant.

Historically, research ethics boards (REBs) at each participating hospital or university would conduct their own reviews of proposed studies — duplicating and sometimes conflicting with each other's processes and verdicts.

Canada's Interagency Advisory Panel on Research Ethics is proposing to dramatically simplify that process by mandating that all applications for multisite, minimal risk studies undergo an initial review by a single REB of record whose verdict and rationale would then be circulated to other participating sites for their review and approval.

During consultations on the proposal, some researchers welcomed the change as necessary and long overdue.

According to Hilary Bergsieker, chair of the University of Waterloo Human Research Ethics Board, the proposal could result in "substantial savings in time for researchers" and reduce conflicts arising from "minor local differences" in the interpretation of ethics policies.

For example, she noted that the University of Waterloo requires a notice of ethics clearance on all study recruitment materials, but the University of British Columbia strongly discourages such statements as being potentially coercive.

"For almost every single protocol involving our two institutions, we've had to address these differing interpretations, resulting in delays, although eventually mutually approved wording was reached every time."

However, the proposal has met resistance from others involved in research ethics, particularly in jurisdictions that have invested considerable time, energy, and money in developing their own streamlined ethics review processes.

Susan Marlin, president and CEO of Clinical Trials Ontario (CTO), explains that, although there is wide support for harmonizing ethics review processes across Canada, "it's about how you do it."

Marlin and others argue that the federal panel's proposal is too prescriptive about how the new review model should work and doesn't account for existing innovations.

"In Ontario… our main concern was that we didn't think what they're proposing would be as efficient as what we have in place now," Marlin says. "We would be moving backwards."

Multisite investigators registered with CTO can already apply for streamlined review via a single "REB of record." Local ethics boards have no role in the review process. After the REB of record approves the study, participating institutions submit applications to adopt that approval and flag any relevant local issues, such as potential conflicts of interest.

Canada's panel on research ethics cited CTO's model among several successful initiatives providing centralized ethics review for multisite studies. But, unlike CTO, the federal panel is still proposing to require local REBs to conduct their own review of the decisions and rationale of the REB of record.

According to the panel, "ideally, that consideration and acknowledgement would be done by a single individual at the local REB," who would have three weeks to make their own review and flag concerns.

Laurel Evans, director of research ethics at the University of British Columbia, is frustrated that the federal panel didn't consult more widely before floating proposed changes.

"The problem with this proposal is they've tried to tell us how to do it, and they have no idea how we do it," Evans says. "A single REB review would basically torpedo our whole process in BC."

In British Columbia, all applications for multisite studies are run through an online program that uses an algorithm to identify which institution's REB will serve as the REB of record. Other participating sites can choose to simply rubberstamp that board's decision, or they can have a local representative participate in the review.

According to UBC's REB, the changes proposed by the federal panel would require dismantling the province's existing harmonization system "at great cost, with no benefits."

UBC's REB also argued that the proposed changes don't account for the unique circumstances involved in research partnerships with Indigenous communities.

In a 10-page response strongly opposing the changes, the board explained that studies may involve multiple Indigenous communities, each with their own "local considerations" that would be difficult for

a single REB to address, particularly throughout the course of monitoring the research.

Meanwhile, many academic institutions have invested millions of dollars and years of work into creating online systems for ethics review that are integrated into other research and compliance functions.

Evans argues that a standalone, centralized review by an external board will not allow for such integration. "Ethics is just one piece of the whole pie."

Gordon McKay, chair of the biomedical ethics board at the University of Saskatchewan, says that delays in approvals often have more to do with sorting through the different operational requirements at participating sites than actual ethical concerns.

"Ethics often gets blamed for slowing things down, when it's really something beyond ethics — such as contract negotiations, budget review, creation of data transfer agreements, creation of material transfer agreements," McKay explains. "Those things are ancillary, but they're the responsibility of the ethics office."

According to a federal spokesperson, the panel on research ethics is not proposing to replace streamlined ethics review models or formal agreements between institutions.

While the panel's proposal acknowledges these other models and agreements, "many institutions have not established or do not participate in mechanisms for multijurisdictional ethics review. The intent of the proposed guidance is to help fill existing gaps."

The panel is still analyzing and following up on the 64 responses it received from individuals and institutions during consultations in 2021. It aims to make recommendations on reforming ethics review processes to Canada's federal research funding agencies in the fall of 2022.

Marlin would like to see the panel scrap the current proposal to create a framework that will "further encourage single REB reviews across the country that doesn't bring us backward or discourage systems that are already in place."

"Many of us are hoping that what's been put out doesn't just get tweaked and then comes [back] into play," she says.

Meanwhile, the clock is ticking on meaningful reform to simplify ethics approvals. According to Marlin, "Canada will be left behind if we don't — sometime in the near future — figure out a way to do single REB reviews across the country."

Greg Basky, Saskatoon, Sask.