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EDITORIALS

Streamlining ethical review of data intensive research

Unfounded concerns about local liability should not delay urgent reform

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Research that crosses international borders and analyses large volumes of data from multiple sources is growing. Such data intensive research—for example, precision medicine studies driven by genomic research and DNA sequencing—creates difficult governance challenges, one of which is repetitive and inefficient ethical review. There is no clear evidence that review of the same study by multiple research ethics committees better protects participants, particularly for research analysing large aggregate datasets.

International, data intensive research may require different assessment from research that risks physical harm to participants.[1 2] However, concerns about liability mean that local ethics committees—and their administrators and institutional lawyers—tend to insist on reviewing research protocols themselves, rather than "delegating" review to another ethics committee or otherwise recognising outside reviews. These concerns are some of the main barriers to reform of the ethics review system for international research.[3] We argue that the concerns are more perception than reality.

The first concern is that mutual recognition of one another's decisions might breach a local committee's regulatory duty to review the research protocol, leading to regulatory or criminal liability of the ethics committee, institution, sponsor, or principal investigator. True, local review is sometimes specified in a study's protocol, without the possibility of delegation to other ethics committees,[4] and in such cases ceding or delegating a review could amount to a breach of duty. But many regulatory instruments governing research ethics committees (such as those in the Netherlands,[5] US,[6 7] and Canada[8]) are sufficiently open ended to allow most committees to discharge their duty of local full review. In some countries, including Australia, research ethics committees are encouraged to reduce unnecessary duplication of effort.[9]

The second concern is about negligence claims if, for example, a participant is harmed in a study that was not reviewed locally. Similar concerns may arise when local committees lack adequate information about emerging data from other sites, preventing them from deciding whether an international study should be altered at the local site. Finally, institutions may see the purpose of their local committee as primarily to protect them from legal liability rather than to protect research participants from harm, making them reluctant to weaken that protection.[10 11]

In reality, there are routine legal solutions to these concerns, including individual or master agreements formalising responsibilities and indemnity between institutions and their research ethics committees; acknowledgment of shared liability insurance among institutions; indemnity insurance; "no fault" compensation funds for injuries related to data intensive research such as psychological, social, financial, or privacy based harm; and proportionate liability arrangements among all research ethics committees in a mutual recognition framework.

Although liability is a concern for lawyers and administrators, multiple review processes are an even bigger concern for researchers, participants, and society in general. In addition to the legal solutions mentioned above, one solution could be for national authorities, working with international organisations such as the Global Alliance for Genomics and Health (http://genomicsandhealth.org/), to produce a list of "accepted equivalent processes" for ethics committee review of international, data intensive research. Any such list cannot ensure equivalence across all elements of review or address all locally sensitive problems, but it could encourage harmonisation of key processes and elements relevant to data intensive research, and perhaps eventually be expanded to other types of international biomedical research.

Authoritative recognition that ethical review from another jurisdiction is "equivalent enough" to that from the local jurisdiction would reduce concerns over both legal and regulatory liability. Adherence to the list of agreed processes would increase confidence in the adequacy of another jurisdiction's review system. An ethics review system built on mutual recognition of other committees' decisions would follow from sufficiently similar assessments of the ethics of a study, and by extension, from a mutual understanding that the research

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would be acceptable according to the standards of a community of researchers. Together, these legal arrangements and policy solutions should help dispel the myth of liability, allow overdue systemic reform of the ethics review process for data intensive research, and, ultimately, enhance biomedical progress.

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