







The current report presents findings from a project undertaken in collaboration with the Covid-19 Clinical Research Coalition Ethics Working Group with funding from the WHO Health Ethics & Governance Unit. An environmental scan of the literature reviewed key ethical, legal and policy implications of an international system of ethics review and approval, termed mutual recognition, in which the decisions of a qualified research ethics committee (REC) are accepted by another REC based on shared procedural standards. The report additionally identifies barriers to, and opportunities for implementing ethics review mutual recognition during public health emergencies in low-and middle-income countries from the perspectives of Covid-19 Clinical Research Coalition members and their affiliates through a series of consultative activities. The global scale of pandemics necessarily demands a global approach to research and collaboration. As the Covid-19 pandemic ravages on, it has intensified the need for timely, rigorous, and accessible scientific evidence that can help researchers improve diagnosis, develop effective therapies and guide pandemic management. Researchers worldwide can accelerate gathering this evidence by working together. Covid-19 vaccine trials and other investigational research that involve human participants must undergo research ethics committee (REC) approval before they can begin. The process for obtaining ethics approval, however, differs considerably from country to country which can complicate collaboration. An institution-by-institution approach to ethics review and approval required in most countries often also applies to studies that will be carried out across multiple sites. Procedural inefficiencies associated with this approach delays important research, is costly to researchers and may not better protect participants.

To address this problem, policy scholars have advocated for a solution, **ethics review mutual recognition** wherein the decisions of a REC in one country are accepted by another REC in reviewing a collaborative research study on the basis that both RECs adopt equivalent procedures. Successful implementation of ethics review mutual recognition depends on **(i)** determining that the procedures which two or more RECs use to review research involving humans are equivalent and **(ii)** establishing reciprocal agreements among participating RECs in a multisite study. Originally proposed to facilitate international research in the field of genomics, ethics review mutual recognition has yet to be explored for use during public health emergencies in many countries.

The report describes how throughout the pandemic, various approaches to centralize multisite reviews were used to accelerate the review of Covid-19 related protocols while maintaining high standards of review quality. Standards, policies and recommendations used to guide accelerated reviews came directly from international conventions and related guidelines. This suggests broad consensus on the shared roles, responsibilities and structures of RECs during public health crises to successfully meet condition **(i)**. The barriers to implementing ethics review mutual recognition, rather, relate to meeting condition **(ii)**, establishing reciprocity. There is a general misunderstanding of the authority local RECs have on final review decisions, the different regulatory environments within which RECs currently operate and inequities in collaborations between researchers in well- resourced versus under-resourced countries. Factors influencing whether, and how to pursue ethics review mutual recognition differed by region. The report concludes that recommendations for how to implement ethics review mutual recognition are premature at this time. Improving trust among RECs is an incremental, yet essential step towards harmonizing REC policy and ensuring that research protections everywhere are equitable. Informants identified several ways the WHO could facilitate this trust and which are summarized in the box above.

Timely, quality and effective REC review and continuing oversight are necessary to maximize scientific benefits while ensuring the rights, dignities and welfare of individuals are universally respected. RECs play critical gatekeeping and balancing roles in this regard. This report opens the door to further inquiry into how institutions, individual countries, and regions innovate REC systems to be collaboration friendly and rigorous during times of public health crises and beyond.

Trust-building action items

-  RECs learn better when they are connected to networks.
-  Make prior REC decisions available.
-  Develop and maintain a registry of RECs.
-  Reciprocal agreements between RECs should be bilateral.
-  Clearly delineate review responsibilities.
-  Evaluate existing mutual recognition models.