

## Speaker Abstracts

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#### Controlled infection studies: ethical issues and LMICs

**Introduction:** Although controlled infection studies (CIS) fall within the scope of current research ethics guidance, morally significant differences between CIS and other forms of biomedical research, and the implications of conducting CIS in LMIC contexts, require careful consideration. Key values informing such considerations include respect, fairness, and minimisation of research risks and burdens.

**Issues:** CIS take place within a landscape of commitments to global health justice which recognise the need to address disproportionate burdens of disease and ensure no one is left behind. However, CIS are also an often counter-intuitive, unfamiliar and worrisome research design, taking place against a background of sustained vaccine hesitancy and inconsistent trust in health research. Where CIS appear to offer significant scientific and social value in addressing burdens of infectious disease in LMICs, questions arise about the nature and extent of key stakeholders' obligations relating to: (a) engaging with stakeholders from research councils, health departments, regulatory agencies, ethics committees, communities, and insurers, (b) ensuring that there is a social mandate for such research and that the design and conduct of research has been appropriately informed by engagement activities (c) building capacity to conduct effective, safe and well-governed CIS, (d) appropriate responses to fragile health and sanitation systems which impact risk management and infection control during CIS, (e) addressing tensions between promoting inclusive approaches and ensuring that participants are appropriately protected, and (f) promoting fair collaboration and sharing.

**Conclusion:** Where CIS are justified in LMICs, such research must be conducted safely, acceptably and appropriately. This requires careful consideration of not just appropriate means of addressing ethical issues arising during the design and conduct of individual CIS, but also of the development of national and international governance frameworks for the appropriate oversight of research.

