Guiding questions for ethics review of research involving human participants

Regional Program on Bioethics of the Pan American Health Organization (PAHO)

This tool contains questions to guide members of research ethics committees in the ethics review of research protocols with human subjects. It is not a checklist, nor does it attempt to be an exhaustive list of questions to consider during the review of a study. All ethics review should be done on a case-by-case basis and adhere to CIOMS Ethical Guidelines.

1	**Social value** Can this study lead to improvements in health or well-being? Who will benefit from the conduct and results of research? What is the potential value of the research for each of the prospective beneficiaries?	
2	**Scientific validity** Is the investigation methodologically valid and scientifically (and statistically) sound? Do the scientificand statistical design and methods satisfy generally accepted standards and achieve the objectives of the study? Will the study generate valid and reliable data that can be generalizable? Is the study feasible? Does the study design ensure participants receive the healthcare interventions they are entitled to? If not, are there methodologically compelling reasons to participate and are participants protected from serious harm?	
3	**Fair participant selection** What are the criteria to include and exclude participants? Is selection of participants based on scientificcriteria? Are research participants selected to minimize risks and maximize potential benefits? If participants are vulnerable, are there adequate safeguards to protect them? Are the risks and potential benefits of the study fairly distributed?	

4	**Favorable risk-benefit ratio** What are the physical, psychological, social, and economic risks of the study? Can the risks for participants be minimized? Can potential benefits for individuals and society be improved? Do thepotential benefits for society and individuals outweigh the risks?	
5	**Community engagement** How will communities' priorities and concerns be considered? What are the plans to engage communities in research?	
6	**Adequate informed consent** Is the information provided to potential participants accurate, clear, relevant, and complete? Are the recruitment procedures, consent process and incentives appropriate for their culture and context? Is there an appropriate plan for obtaining permission for those who can't consent for themselves? Are the participants being made aware of their right to refuse to participate and are they actually free to refuse?	
7	**Respect for participants** How will the health and well-being of participants be monitored to minimize harms? How will their confidentiality be protected? Can participants withdraw from the study without penalty? What are the plans for care after the study is completed? Will participants be given any new information (including theresults of the study)?	

Adapted from: (1) Emanuel E, Wendler D, Grady C. An ethical framework for biomedical research. In: Emanuel E et al. eds. The Oxford textbook of clinical research ethics. New York, NY: Oxford University Press; 2008: 123-135. (2) Emanuel E, Wendler D, Grady C. What makes clinical research ethical? JAMA 2000;283:2701-27711. (3) Emanuel E, Wendler D, Killen J, Grady C. What makes clinical research in developing countries ethical? The benchmarks of ethical research. JID 2004;189:930-937.