Chapter 3.4 Ethics in Research

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Further reading

1. Nuffield Council on Bioethics. The ethics of research related to healthcare in developing countries. 2002. https://www.nuffieldbioethics.org/wp-content/uploads/2014/07/Ethics-of-research-related-to-healthcare-in-developing-countries-I.pdf (accessed 22 February 2022).

   Summary of this document: Developing countries urgently need research to help to address the enormous burden of disease that they carry. This reading presents relevant tools for guiding ethical practices in research conducted in developing countries.

   In this longform report, the authors examine ethical issues raised when research related to healthcare is carried out in developing countries and funded by sponsors from developed countries. It begins by outlining the social, economic, and cultural dimensions of healthcare and their relation to ethics. The report presents an ethical framework for others to use to assist those involved in the development of national guidance for the ethical review of research. The report concludes with a series of recommendations for researcher, funding agency, and decision-maker on issues of consent, standards of care, ethical review, and what should be done once the research is completed.

2. Nuffield Council on Bioethics. The ethics of research related to healthcare in developing countries, follow-up discussion paper. 2005. http://nuffieldbioethics.org/wp-content/uploads/2014/07/HRRDC_Follow-up_Discussion_Paper.pdf (accessed 22 February 2022).

   Summary of this document: Developing countries urgently need research to help to address the enormous burden of disease that they carry. This reading is based on a follow-up workshop on the ethics of research related to healthcare in developing countries, held in Cape Town in February 2004.

   In this longform discussion paper, the authors outline discussions held as part of the Nuffield council on Bioethics workshop. It discusses existing guidance on ethical health research alongside workshop discussion topics, including consent, standards of care, what happens after the research is over, and ethical review. The authors conclude that many existing standards are not immediately suitable for guiding field research, but researchers must still attempt to align their research objectives to respect local needs and cultural contexts.

3. Nuffield Council on Bioethics. Research in global health emergencies: ethical issues; 2020. https://www.nuffieldbioethics.org/publications/research-in-global-health-emergencies (accessed 22 February 2022).

   Summary of this document: This reading is one of the most up-to-date and relevant tools for guiding ethical practices in research during health emergencies, particularly in challenging humanitarian contexts.

In this longform report, the authors discuss unique ethical issues which arise in disaster and emergency research settings. It includes scenarios such as infectious disease outbreaks, natural and human-made disasters, and emerging risks from conflicts and migration. The report covers important concepts in bioethics, ethical compass development to inform higher level policy approaches, and key considerations for study design. Its conclusions and recommendations are further targeted towards funders and research sponsors, as their decision-making can have large-scale and direct impact on the practice of health emergency research.

4. Parker M, Bull S. Sharing Public Health Research Data: Toward the Development of Ethical Data-Sharing Practice in Low- and Middle-Income Settings. Journals of Empirical Research on Human Research Ethics. 2015: 10(3): 217-24.

   Summary of this document: This reading explores the collaborative nature of global health research in informing the development of models of good, ethical data-sharing practice.

   In this short article, the authors report on qualitative research conducted in five low- and middle-income countries exploring the experiences of key research stakeholders and their views about what constitutes good data-sharing practice. The countries included are India, Kenya, South Africa, Thailand, and Vietnam. The article reviews the process for creating an ethical approach to health research data sharing in low- and middle-income countries (LMICs). The authors conclude that stakeholder- and consensus-driven discussions are well-suited for the development of ethical data-sharing practices.

5. World Health Organization. Ethical standards for research during public health emergencies: Distilling existing guidance to support COVID-19 R&D; 2020. https://www.who.int/publications/i/item/WHO-RFH-20.1 (Accessed 22 February 2022).

   Summary of this document: This reading is intended to provide a brief distillation of key ethical standards and considerations that are viewed as being most relevant to supporting the World Health Organization and Global Research Collaboration for Infectious Disease Preparedness Research Roadmap for COVID-19.

   In this policy brief, the authors provide guidance on health emergency research ethics, specifically targeted towards COVID-19 researchers. The brief includes a list of key ethical guidance documents for research during health emergencies. Additionally, the authors emphasize that research during emergencies must not disrupt recovery efforts. The authors present a question-and-answer section for researchers to consult, including requirements for independent ethical review, informed consent, and data sharing. The authors conclude that while some ethical procedures can be adapted, researchers remain obligated to uphold core international ethical standards.

6. World Health Organization. Guidance for managing ethical issues in infectious disease outbreaks; 2016. https://apps.who.int/iris/bitstream/handle/10665/250580/9789241549837-eng.pdf?sequence=1 (Accessed 22 February 2022)

   Summary of this document: Global infectious diseases raise many ethical issues that require new guidance. This reading is one of the most up-to-date and relevant tools for guiding ethical practices in research during health emergencies.

In this guidance document, the WHO uses the 2014-2016 Ebola outbreak as a starting point for discussing ethical issues in infectious disease outbreaks. The document aims to complement existing guidance on ethics in public health. It begins by outlining the ethical principles that should guide communication planning and implementation at every level from frontline workers to policymakers. It then provides 14 specific guidance points on conducting ethical and safe outbreak response interventions. The authors conclude that this guidance, in conjunction with general guidance documents, can provide important ethical insights to researchers operating in unusual public health events. This document is available in Simplified and Traditional Chinese, Faroese, and Persian.

7. World Health Organization. Ethics in epidemics, emergencies and disasters: Research, surveillance and patient care; 2015. https://apps.who.int/iris/bitstream/handle/10665/196326/9789241549349_eng.pdf;jsessionid=67B5B83637727A0DBA5F53AB58325B2F?sequence=1 (Accessed 22 February 2022).

    Summary of this document: Epidemics, emergencies, and disasters raise many ethical issues for the people involved including responders, researchers, public health specialists and policymakers. This reading presents relevant tools for guiding ethical practices in research during health emergencies, particularly in challenging humanitarian contexts.

    In this WHO training manual, the authors provide instruction on ethical principles that align with the WHO's *Research ethics in international epidemic response*. The aim of this training manual is to give participants a certain proficiency in ethical reasoning and awareness of the main ethical dilemmas that can arise in emergencies. The first part of the manual discusses research and surveillance, while the second part covers patient care and health care workers' duties during disasters and emergencies. The manual covers seven core competencies and 26 learning objectives through individual modules. The authors conclude that researchers, healthcare workers, and policy-makers alike could benefit from ethical guidance in Health EDRM. Each section also contains further readings for non-expert consultation.

8. World Health Organization. Guidance for research ethics committees for rapid review of research during public health emergencies; 2020. https://www.who.int/publications/i/item/9789240006218 (Accessed 22 February 2022).

    Summary of this document: This reading is one of the most up-to-date and relevant tools for guiding research ethics committees for rapid review of research during public health emergencies.

    In this WHO guidance document, the authors provide guidance for ethics committees for changes to existing standard operating procedures to facilitate time-sensitive ethics review. The document advises that to expedite reviews, many processes will be occurring simultaneously rather than sequentially. The guidance contains 20 recommendations for additions or changes to existing ethics committee standard operating procedures, many seeking to reduce approval timelines by eliminating unnecessary synchronous steps. The authors conclude that rigorous ethical standards need to be upheld even in health emergencies, so it is advisable for committees to have pre-established plans to deploy in the event of a health emergency.