



Research in global health emergencies: ethical issues
Report developments

May 2021



NUFFIELD COUNCIL ON BIOETHICS

Contents

Introduction	2
Initial response to the Call for Action	3
Global workshop series	3
Impact on the UK and international COVID-19 research response	4
Translations.....	10
Use of the report in education in the UK and worldwide.....	10
Dissemination, presentations, and events.....	11
Next steps	15
Annex A: individual contributions of working group members	16
Annex B: the report's recommendations	18

Introduction

1. The Nuffield Council's report [Research in global health emergencies: ethical issues](#) was published on 28 January 2020. It has been widely distributed among key stakeholders, and by the end of April 2021 the project webpage had been visited over 4,000 times. This document notes key evidence of impact in the period since the report's publication, and highlights developments relating to or aligned with our [24 recommendations](#). It also lists where the report has been cited in academic journals and specialist press articles, and where its findings have been presented as part of a conference or event.
2. Only two days after the publication of the report, the World Health Organization (WHO) declared the novel COVID-19 outbreak to be a Public Health Emergency of International Concern (PHEIC). The advent of COVID-19 has inevitably affected our plans for dissemination which, in line with the global ethos of our work, initially included a series of international meetings and events. The report, however, has been particularly timely in influencing the research response to the COVID-19 outbreak. Since its launch, we have been working to strengthen the impact of its findings and recommendations in the context of the pandemic through a number of international activities. Highlights include:
 - Members of the working group joining / chairing national and international committees aimed at guiding the research response throughout the pandemic, including the WHO's COVID-19 working groups on [Ethics](#), [Vaccines Prioritisation](#), and [Social Science Research](#).
 - Members of the working group and executive joining the [COVID-19 Clinical Research Coalition](#), and forming the Coalition's Ethics working group.
 - The report being highlighted as a key resource for COVID-19 research ethics in guidance documents issued by international authorities, including the Pan American Health Organization (PAHO) and the WHO.

3. Alongside these, the Council has engaged with international partners to share its work across the world and understand how different aspects of the report might be relevant and useful in varied contexts and environments. A comprehensive list of our work with partners and accounts of how our work has contributed to the COVID-19 research response, to date, are provided in the sections below.

Initial response to the Call for Action

4. The launch of the report was accompanied by a [Call for Action](#) to funders, governments, and other key stakeholders for a more ethical and collaborative approach in conducting research during emergencies. A number of high-profile organisations and research institutions have responded to the Call for Action and highlighted the report in statements and news stories on their websites and social media accounts. Highly positive responses included that of Jess Camburn, CEO of [Elrha](#), who stated:

“As a leading funder of public health research and innovation in some of the most challenging humanitarian settings, Elrha fully supports this critical Call for Action. There is an urgent need for greater investment and innovation to support humanitarian and global health emergencies, but we know that such activity will engage the people and communities at times of extreme vulnerability. It’s therefore crucial that all funders champion the adoption of the highest possible ethical standards and approaches to safeguard vulnerable individuals, and advocate for fair and equitable collaborations. We applaud the Nuffield Council on Bioethics for spearheading this work.”

5. The list of [supporters](#) of our Call for Action, to date, is as follows:
 - The African Academy of Sciences;
 - Elrha;
 - Fundação Oswaldo Cruz (Fiocruz);
 - Geneva Centre for Education and Research in Humanitarian Action;
 - International Rescue Committee;
 - Liverpool School of Tropical Medicine;
 - Médecins Sans Frontières UK;
 - Medical Sciences Division of the University of Oxford;
 - The London School of Hygiene & Tropical Medicine; and
 - Wellcome;
6. Various other international organisations have promoted the report internally and online, including the [Medical Research Institute of Sri Lanka](#), the [Institute of Tropical Medicine in Antwerp](#), the [University of York](#), the [University of Warwick](#), the [Infectious Diseases Data Observatory](#), and [The Academy of Medical Sciences](#).

Global workshop series

7. Following the launch of the report, a series of [roundtable consultative meetings](#) was planned, one in each of the WHO regions, to share and discuss the report’s

findings across the world, engage with communities, and understand how different aspects of the report might be relevant in varied contexts.

8. In March 2020, the first of these meetings was held in Colombo, Sri Lanka. Participants included leading medical administrators, public health specialists, health professionals, academics, and representatives from the Ministry of Health, the National Hospital of Sri Lanka, and the WHO Country Office. The workshop facilitated the sharing of the report's findings and recommendations with relevant stakeholders and explored how different national contexts might influence culturally-appropriate applications and implementations. Following the event, a [summary note](#) of the workshop was published on the Council's website.
9. Subsequent consultative meetings had been planned in the Philippines, Brazil, and West Africa, alongside a panel discussion with UK policymakers to be hosted in the House of Lords. All these initiatives have had to be postponed due to the COVID-19 restrictions. Over the past year, however, we kept engaging with international organisations, such as the Africa Centres for Disease Control and Prevention (Africa CDC) and the Philippines National Health Research System to take these and other events forward. For instance, Katharine Wright has been invited to give a presentation at the Philippine National Health Research System annual conference, which will be held in August 2021.
10. In February 2021, a WHO-funded workshop was held in Conakry, Guinea, with the aim of exploring the relevance and value of our ethical compass and of the report's findings in the context of the Guinean research response to COVID-19 and Ebola virus disease. Participants included members of the Guinean National Health Research Ethics Committee (CNERES) and the Guinean Scientific Council for the Response to COVID-19 (CRS). The two-day event was facilitated by Elysée Nouvet, assistant professor in Global Health from the Western University, Canada; working group member Julian Sheather; and Oumou Younoussa Bah-Sow, President of the CNERES and professor of pneumonology in the Faculty of Medicine of Conakry. A report of the workshop has been published on the Council's website and is available in [English](#) and [French](#). A [blog post](#) with reflections on the meeting in Guinea was subsequently published by Julian Sheather on the BMJ Opinion website.

Impact on the UK and international COVID-19 research response

Influence on COVID-19 research guidance

11. The Council's report has been cited in publications released by other organisations providing guidance on the conduct of COVID-19-related research, including:
 - WHO guidance document: [‘A coordinated global research roadmap: 2019 novel coronavirus’](#)
 - WHO guidance document: [‘Ethical standards for research during public health emergencies: distilling existing guidance to support COVID-19 R&D’](#)

- The World Bank / CEPI background paper: [‘Funding the development and manufacturing of COVID-19 vaccines: background paper for the World Bank / CEPI financing COVID-19 vaccine development consultation on February 20, 2020’](#)
- The ICMR national ethical guidelines: [‘National Guidelines for Ethics Committees Reviewing Biomedical and Health Research During Covid-19 Pandemic’](#)
- PAHO guidance document: [‘Guidance and strategies to streamline ethics review and oversight of COVID-19- related research’](#)
- WHO guidance document: [‘Good participatory practice for COVID-19 clinical trials: a toolbox’](#)
- WHO policy brief: [‘Key criteria for the ethical acceptability of COVID-19 human challenge studies’](#)
- WHO Regional Office for Europe guidance document [‘Survey tool and guidance: rapid, simple, flexible behavioural insights on COVID-19’](#)
- NHRA Zambia guidance document: [‘Guidance on conducting research during the COVID-19 and other Epidemics in Zambia’](#)
- SAGE-EMG and DCMS research and analysis paper: [‘Science framework for opening up group events’](#)

Involvement in the Scientific Advisory Group for Emergencies

11. In April 2020, Michael Parker was invited to become a member of the [Scientific Advisory Group for Emergencies](#) (SAGE). SAGE was activated in January 2020 in response to the COVID-19 pandemic, and helps provide technical and scientific advice to support the UK Government’s response. The group is currently chaired by the Government Chief Scientific Adviser, Patrick Vallance, and co-chaired by the Chief Medical Officer, Chris Whitty, and includes experts from within government and specialists from the fields of healthcare and academia.
12. In September 2020, Patricia Kingori was invited to become a member of the [Scientific Pandemic Insights Group on Behaviour](#) (SPI-B). SPI-B provides independent behavioural science advice to SAGE to assist policy decisions related to the COVID-19 pandemic.

Impact on WHO’s Global Research Roadmap

13. In February 2020, Michael Parker, Beatriz da Costa Thomé, and Emily Chan were invited to participate in a [Global Research Forum](#) organised by the WHO and the Global Research Collaboration for Infectious Disease Preparedness (GLOPID-R) to discuss ways to accelerate research on COVID-19. The meeting was expected to produce a global research agenda for COVID-19, set priorities for selecting research projects and facilitate the development of global research platforms to improve preparedness for the next epidemic. Beatriz da Costa Thomé and Emily Chan co-chaired the ‘ethical considerations for research’ and the ‘social sciences in the outbreak response’ sessions, respectively.

14. Based on the deliberations during the meeting, the WHO published a [coordinated global research roadmap](#) for COVID-19. The document identified a number of key ethical considerations in line with some of the Council's own conclusions and recommendations, and presented our report as "a key ethical guidance document." It states:

"A January 2020 report on ethical issues related to research in global health emergencies, published by the Nuffield Council on Bioethics, represents the State of the Art on this topic."

15. Consistent with the Council's conclusions, emphasis is given to the importance of supporting local capacity strengthening in low-resource settings, fostering equitable collaborations between multiple stakeholders, and being transparent when discussing the sharing of biological samples. Importantly, guidance is also given on the process of participant selection. In line with our recommendations, the document highlights the need to avoid the *a priori* exclusion of pregnant women, children, and other groups who could be considered vulnerable.

Membership of WHO committees supporting COVID-19 research

16. In February 2020, Beatriz da Costa Thomé was invited to co-chair the [WHO Ethics and COVID-19](#) working group, established to advise on key ethical questions that WHO Member States need to address as part of their response to COVID-19. She was also invited to join [the ACT-Accelerator Ethics and Governance working group](#), a global collaboration established by the WHO to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines. Michael Parker was invited to become a member of the Ethics and COVID-19 working group.
17. In February 2020, Michael Parker was invited to become a member of the [WHO Vaccine Prioritization for COVID-19 Vaccines working group](#), which aims to prioritise vaccine candidates for future development and to provide guidance for vaccine developers.
18. In February 2020, Emily Chan was invited to co-chair the [WHO COVID-19 Social Science working group](#), established to facilitate social science research on COVID-19 and understand the consequences of epidemic-control decisions.

WHO guidance on ethical standards for research during public health emergencies

19. In March 2020, the WHO Working Group on Ethics and COVID-19, co-chaired by Beatriz da Costa Thomé, published a [guidance document](#) setting out the ethical standards for conducting research during the COVID-19 outbreak that should be adhered to by researchers, review bodies, funders, publishers, and manufacturers.
20. The brief recognises the Council's report as a "key ethical guidance document", with many of its recommendations closely aligned with the Council's own conclusions, including:

- Coordinating research and health care response and ensuring that priority is always given to health care services;
- Building fair research collaborations between international research institutions and researchers from local contexts;
- Engaging with local stakeholders during the whole research process;
- Developing creative ways to obtain informed consent in consultation with local communities;
- Informing participants about potential future use of their data and samples; and
- Ensuring that groups considered vulnerable are not excluded from research participation without a reasonable scientific justification.

The WHO toolkit on good participatory practice for COVID-19 clinical trials

21. In April 2020, the COVID-19 Ethics and Social Sciences working groups, co-chaired by Beatriz da Costa Thomé and Emily Chan, jointly published a [toolkit](#) on Good Participatory Practice for COVID-19 Clinical Trials.
22. The document, which cites the Council's report among the additional resources for good participatory practices, provides guidelines on how to engage with communities and ensure collaborative partnerships between research institutions. Among the suggestions, there are several aligned with the Council's conclusions. Some of the key points are:
 - Engaging with local communities early on to ensure that the study design is locally appropriate;
 - Adopting recruitment strategies that are sensible to power imbalances and that seek to avoid false hopes and therapeutic misconceptions;
 - Ensuring a valid, culturally appropriate and voluntary consent;
 - Ensuring that research is aligned with emergency response needs; and
 - Ensuring that information about study findings is provided to participants once the study is concluded.

COVID-19 Clinical Research Coalition

23. In April 2020, an international group of scientists, physicians, ethicists, funders, and policymakers came together to form [the COVID-19 Clinical Research Coalition](#), with the aim to accelerate COVID-19 research in resource-limited settings. The creation of this coalition, facilitated by a group of experts including Philippe Guérin, was made public with a [declaration](#) that was subsequently published in The Lancet. The values underpinning the coalition's work are closely aligned with those of the Council and draw extensively on the Council's report. In the declaration, members of the coalition commit to facilitate equitable collaborations between research institutions in low- and high-income countries, encourage the development of a global research agenda, and foster the rapid sharing of findings, data and samples to facilitate research in resource-poor settings. Members of the coalition include Katharine Wright, who signed the declaration on behalf of the Council.

24. Following the launch, Katharine Wright and Michael Parker were asked to form the [ethics working group](#) for the COVID-19 Clinical Research Coalition, with the aim of acting as a sounding board for investigators in low-resource settings facing ethical challenges arising in the development, validation, and review of COVID-19 clinical studies.
25. The group was established in May 2020 with its initial membership including Katharine Wright, Michael Parker, Paulina Tindana, and Patricia Kingori. They work closely with the WHO's Epidemic Ethics network to provide timely support on the ethical issues arising in the context of the COVID-19 pandemic.

Contribution to work for the World Bank / CEPI on financing COVID-19 vaccine development and manufacturing

26. Sanjoy Bhattacharya was asked to contribute to a [background paper](#) for the World Bank / CEPI financing of COVID-19 vaccines. In particular, he was asked to give guidance on section seven, which highlights the ethical issues that need to be considered when conducting vaccines trials in the midst of an outbreak.
27. The paper was published in March 2020, following the World Bank / CEPI vaccine development consultation in February. In line with the Council's conclusions, emphasis is placed on the importance of having a collaborative approach when conducting research and being sensitive to the needs of communities. It also makes direct reference to the Council's report and associated Call for Action, and includes a description of the ethical compass developed by the working group.

PAHO guidelines and strategies to streamline ethics review and oversight of COVID-19-related research

28. In April 2020, the Pan American Health Organization (PAHO) recommended the Council's report as a source document for the training of ethics committee members on the ethics of research with human participants during emergencies. The Council's report is mentioned in [guidance](#) published in April by PAHO, alongside other resources developed by the Council of International Organisations of Medical Sciences (CIOMS), the WHO, and the PAHO itself.
29. The document guides research ethics committees in the process of implementing rapid and rigorous ethics review of COVID-19 studies, and makes a number of recommendations in line with some of the Council's conclusions. In particular, it highlights the importance of research collaboration at all levels, community engagement, and the need for considering local contexts when designing procedures for ethics review.

GLoPID-R and UKCDR guidance on research in epidemics and pandemics

30. In July 2020, the UK Collaborative on Development Research (UKCDR) and the Global Research Collaboration for Infectious Disease Preparedness (GLoPID-R) called on research funders to commit to seven [principles](#) and coordinate efforts for supporting high-quality research during COVID-19 and future epidemics. The

two organisations also agreed that ethical considerations should be at the heart of funding decision-making, and referred funders to the Council's report for guidance.

31. The seven principles emphasise the importance of aligning global and local research priorities, promoting equitable research partnerships, and ensuring maximum impact of investments for research through the coordination of research activities. This is in line with a number of recommendations made by the Council in the report and directed to research funders, as summarised in a [statement](#) we released in response to the publication of the principles.
32. The principles were published on the UKCDR's [website](#) on 17 July 2020. Organisations who have committed to the principles include:
 - Department for Business, Energy and Industrial Strategy
 - Department of Health and Social Care
 - Foreign, Commonwealth and Development Office
 - GLoPID-R
 - Sexual Violence Research Initiative
 - UKCDR
 - Wellcome

SAGE guidance for opening-up group events in the UK

33. In March 2021, the SAGE Environmental Modelling Group (EMG) and the Department for Digital, Culture, Media and Sport (DCMS) published a [guidance document](#) aiming to inform a research programme for enabling the opening up of events and venues with minimal COVID-19 transmission risk in the UK. The document was prepared by a working group formed by members of the DCMS and of different SAGE subgroups, including Michael Parker.
34. The document draws on the Council's report in setting out ethical considerations that should be made when implementing such a research programme. In particular, it highlights the importance of involving the public and communities in decision-making processes, ensuring adherence to open science and reproducibility principles and guaranteeing a fair selection of group events for piloting.

Use of the ethical compass

35. The ethical compass developed by the working group has been influential in supporting reflection on the ethical challenges arising in the context of diverse forms of COVID-19-related research and evidence-gathering. For example, in the questions and answers section of the [COVID-19 Hygiene Hub platform](#), the ethical compass is recommended as a key source of guidance for research organisations carrying out data collection activities. Considerations based on the ethical compass have also been included in the conceptualisation of the digital contact tracing systems for COVID-19. In a [paper](#) by Michael Parker and colleagues at the [Fraser Group](#), whose [research](#) has contributed to inform the development of the UK contact tracing app for COVID-19, the authors highlighted that the compass'

three values of equal moral respect, fairness, and the importance of reducing suffering must underly any policy and practice decisions in the context of contact tracing systems.

Translations

36. When it was launched, the overview of the report was translated into Arabic, Chinese, French, Portuguese, and Spanish. Following the launch of the report, we were also contacted by Iranian researchers who kindly translated the overview into Farsi / Persian. Also after the launch, the short policy version of the report was translated into Chinese, Farsi, French, Portuguese, and Spanish. The translations, available on the Council's website, have been produced with the help of the [Collaborating Centre for Oxford University and CUHK for Disaster and Medical Humanitarian Response \(CCOUC\)](#), [The Jockey Club School of Public Health and Primary Care](#), [The Chinese University of Hong Kong](#), [The Iran University of Medical Sciences \(IUMS\)](#) and working group members Emily Chan, Beatriz da Costa Thomé, Karl Blanchet, and Philippe Guérin. All [translations](#) are available on the Council's website.

Use of the report in education in the UK and worldwide

Training course

37. Together with The Global Health Network (TGHN), the Council has developed a specialist [online training course](#). The course explores the particular ethical challenges that arise when conducting research during global health emergencies and is entirely based on the report. From the date of its launch in May 2020 until the end of April 2021, the English version of the course has been taken nearly 10,000 times.

38. The course has been translated into [French](#) by Translators without Borders, an online platform that helps non-profit organisations to share information in local languages, and by Karl Blanchet, professor of humanitarian public health at the University of Geneva and director of the Geneva Centre for Education and Research in Humanitarian action (CERAH). The French course has so far been taken over 500 times since its launch in August 2020.

39. The course has also been translated into [Spanish](#) by Ana Palmero, coordinator of the Research Ethics Program of the Directorate of Research for Health of the Ministry of Health in Argentina, and Paulina Correa, assistant professor at the Institute of Nutrition and Food Technology in Chile. The Spanish course has so far been taken nearly 5,500 times since its launch in July 2020.

40. A Portuguese course is currently under development.

Educational events

41. In March 2020, Katharine Wright recorded a [webinar](#) about the report for the [Health Research Authority](#) to be used as part of research ethics committee training in the United Kingdom.

42. In April 2020, Patricia Kingori and Michael Parker gave a lecture on global health emergencies, drawing on the report, to the NIHR Global Health Research Unit on Mucosal Pathogens at University College London.
43. In June 2020, Katharine Wright contributed to the [Institutional Research Ethics Capacity Strengthening Workshop](#) in Liberia, organised by the [National Research Ethics Board of Liberia](#) in collaboration with the Project and Partnership for Research on Vaccines and Infectious Diseases in Liberia (PREVAIL).
44. In November 2020, Katharine Wright discussed the ethical challenges associated with research in global health emergencies at a [training workshop](#) in Uganda on conducting research during outbreaks and epidemics. The workshop was co-chaired by Julian Sheather, and organised by the [African coalition for Epidemic Research, Response and Training](#) (ALERRT).
45. In January 2021, Katharine Wright ran a short course on the report for the students of the Oxford MSc in International Health and Tropical Medicine.

Dissemination, presentations, and events

46. The project webpage has been visited over 4,000 times. Copies of the report, short report, and overview have been sent to nearly 500 key stakeholders, and disseminated more widely via the Council's social media networks and news alerts service.
47. Members of the working group and executive have been invited to present the report's findings and conclusions at academic and policy-focused events, including:
 - Michael Parker presented about the report at the University of Oxford event on 'The global response to the novel coronavirus (SARS-CoV-2) outbreak' (**27 February 2020**)
 - Katharine Wright discussed the ethical challenges of conducting research in the UK during global crises at a COVID Realities webinar on 'Researching poverty ethically at a time of global crisis: lessons and challenges' organised by COVID Realities (**11 June 2020**)
 - Katharine Wright gave a presentation at the 15th World Congress of Bioethics held by the International Association of Bioethics (**18 June 2020**)
 - Katharine Wright gave a presentation on sharing data in global health emergencies as part of 'The secret life of immortal data symposium' at the 12th Annual Web Science conference organised by the University of Southampton (**7 July 2020**)
 - Heidi Larson and Beatriz da Costa Thomé presented at a webinar on 'Vaccine confidence in the context of trials' held as part of the Vaccine Confidence Project webinar series (**30 July 2020**)

- Beatriz Da Costa Thomé presented about the report at a Fiocruz webinar on 'Research in global health emergencies – ethical aspects' (**16 December 2020**)
- Katharine Wright discussed the impact of global health research as part of a podcast for the Impact Frameworks Cultural Change conference (**25 February 2021**)
- Katharine Wright discussed the 'The role of ethics committees in preparedness and response during a public health emergency: international experience' at a webinar organised by the Forum of Ethics Committees, Republic of Kazakhstan (**19 March 2021**)
- Paulina Tindana discussed the report at the annual Health Summit focused on 'Strengthening the resilience of Ghana's health system to better respond to emergencies', organised by the Ministry of Health of the Republic of Ghana (**7 May 2021**). The approach in the report was well-received, and generated a great deal of discussion.

Working group and executive contributions in academic publications and specialist press

48. Executive staff and members of the working group have published a number of articles in academic journals and specialist press drawing on the report:

- Bull S, Jamrozik E, Binik A, and Parker M (2020) [SARS-CoV-2 challenge studies: ethics and risk minimisation](#) *Journal of Medical Ethics* **Published online first**: 25 September 2020
- COVID-19 Clinical Research Coalition (2020) [Global coalition to accelerate COVID-19 clinical research in resource-limited settings](#) *The Lancet* **Published online**: 2 April 2020
- da Costa Thomé B, and Larson H (2020) [Research in the time of coronavirus: keep it ethical](#) (STAT News)
- Dawson A, Emanuel EJ, Parker M, Smith MJ, and Voo TC (2020) [Key ethical concepts and their application to COVID-19 research](#) *Public Health Ethics* **13(2)**: 127-32
- Hughes J, and Sheather J (2020) [COVID-19: 'Contagion to this world' and the demand for ethical research](#) (BMJ Blogs)
- Hughes J, Sheather J, and Wright K (2020) [COVID-19: 'Contagion to this world' and the demand for ethical research](#) *Journal of Ethics in Mental Health* **11**:1-18
- Sheather J (2020) [Coronavirus – knowledge is the antidote to fear](#) (BMJ Blogs)
- Schweitzer MC, and da Costa Thomé B (2021) [Research ethics and resource allocation in times of covid-19](#) *Revista Bioética* **29(1)**: 21-6
- Tindana PO, De Vries J, and Kamuya D (2020) [Ethical challenges in community engagement practices in research during the COVID-19 pandemic](#) *Africa AAS Open Research* **3(23)**: 23

- Wilson B, Wright K, Taylor R, and Higgs E (2021) [Beyond recruitment: good participatory practice enhances the impact of research in a pandemic](#) *Nature Medicine* **27(3)**: 369-71
- Wright K, Parker M, and Bhattacharya S, on behalf of the Nuffield Council on Bioethics Working Group (2020) [In emergencies, health research must go beyond public engagement toward a true partnership with those affected](#) *Nature medicine* **26(3)**: 308-9
- Wright K, and Sheather J (2020) [The role of solidarity in research in global health emergencies](#) *The American Journal of Bioethics* **20(5)**: 4-6
- Wright K (2020) [Ethical research in global health emergencies: making the case for a broader understanding of 'research ethics'](#) *International Health* **12(6)**: 515-7
- Wright K, and Sekalala S (2020) [Human rights and the ethical conduct of research in emergencies: expanding the role of duty-bearers](#) (Global Campus of Human Rights)

Journal and specialist press citations

49. Since its publication, the Council's report has been cited in a wide range of academic journals and specialist press articles from across the world, including:

- Asghari F and Tehrani SS (2020) [Ethical issues in responding to the covid-19 pandemic; a narrative review](#) *Advanced Journal of Emergency Medicine* **Published online first**: 28 April 2020
- Balakrishnan VS (2020) [Increasing accessibility in COVID-19 clinical trials](#) *The Lancet Microbe* **Published online**: 1 May 2020
- Beach MC, Lederman HM, Singleton M, *et al.* (2020) [Desperate times: protecting the public from research without consent or oversight during public health emergencies](#) *Annals of Internal Medicine* **173(11)**: 926-8
- Chaturvedi S, Kumar N, Tillu G, Deshpande S, and Patwardhan B (2020) [AYUSH, modern medicine and the Covid-19 pandemic](#) *Indian Journal of Medical Ethics* **Published online first**: 13 May 2020
- Chiumento A, Rutayisire T, Sarabwe E, *et al.* (2020) [Exploring the mental health and psychosocial problems of Congolese refugees living in refugee settings in Rwanda and Uganda: a rapid qualitative study](#) *Conflict and Health* **Published online**: 16 November
- Degeling C, Chen G, Gilbert GL, *et al.* (2020) [Changes in public preferences for technologically enhanced surveillance following the COVID-19 pandemic: a discrete choice experiment](#) *British Medical Journal Open* **Published online**: 18 November
- De Vries J, Burgess T, Blockman M, and Ntusi NAB (2020) [Research on COVID-19 in South Africa: Guiding principles for informed consent](#) *South African Medical Journal* **110(7)**: 635-9

- Diac I, Udriștioiu L, and Popescu CA (2020) [Ethical issues and arguments for a learning health care system in the COVID-19 pandemic](#) *Romanian Journal of Legal Medicine* **28(2)**: 101-8
- Fenton E and Chillag K (2021) [Conditions of global health crisis decision-making – an ethical analysis](#) *Bioethical Inquiry* **Published online**: 16 April
- Hamilton D and Gallagher A (2020) [How to approach ethical dilemmas in a pandemic: a respiratory nurse asks an ethics professor about issues raised by COVID-19](#) *Nursing Standard* **35(7)**: 35-6
- JD Supra (2020) [Resource for organizations conducting research in the developing world amid COVID-19 pandemic](#)
- Johnson SB (2020) [Advancing global health equity in the COVID-19 response: beyond solidarity](#) *Journal of Bioethical Inquiry* **17(4)**: 703-7
- Labuschaigne M (2020) [Ethicolegal issues relating to the South African government's response to COVID-19](#) *South African Journal of Bioethics and Law* **13(1)**: 23-8
- The Lancet Digital Health (2020) [Transparency during global health emergencies](#)
- Lanzing M (2020) [Contact tracing apps: an ethical roadmap](#) *Ethics and Information Technology* **Published online**: 29 September 2020
- Lawrence DS and Gyapong M (2020) [Spotlight on global health research](#) *International Health* **12(6)**: 507-8
- Li H, Hu M, and Liu S (2020) [The need to improve the laws and regulations relevant to the outbreak of COVID-19: what might be learned from China?](#) *Journal of Global Health* **Published online**: 7 April 2020
- Moodley K., Allwood BW, and Rossouw TM (2020) [Consent for critical care research after death from COVID-19: arguments for a waiver](#) *South African Medical Journal* **110(7)**: 629-34
- Reyes M (2020) [Research in the time of COVID-19: challenges of research ethics committees](#) *Journal of the ASEAN Federation of Endocrine Societies* **35(1)**: 29-32
- Smith MJ and Upshur RE (2020) [Learning lessons from COVID-19 requires recognizing moral failures](#) *Journal of Bioethical Inquiry* **17(4)**: 563-6
- Smith MJ, Ahmad A, Arawi T, et al. (2021) [Top five ethical lessons of COVID-19 that the world must learn](#) *Wellcome Open Research* **Published online**: 29 January
- Tanveer F, Khalil AT, Ali M, and Shinwari ZK (2020) [Ethics, pandemic and environment; looking at the future of low middle income countries](#) *International Journal for Equity in Health* **Published online**: 15 October 2020
- Tol WA, Ager A, Bizouerne C, et al. (2020) [Improving mental health and psychosocial wellbeing in humanitarian settings: reflections on research funded through R2HC](#) *Conflict and Health* **Published online**: 30 October 2020
- Wang Y, Zhou F, Zhang D, et al. (2020) [Evaluation of the efficacy and safety of intravenous remdesivir in adult patients with severe COVID-19: study](#)

[protocol for a phase 3 randomized, double-blind, placebo-controlled, multicentre trial](#) *Trials* **Published online:** 24 May 2020

- Xafis V, Schaefer GO, Labude MK, Zhu Y, and Hsu LY (2020) [The perfect moral storm: Diverse ethical considerations in the COVID-19 pandemic](#) *Asian Bioethics Review* **12(2)**: 65-83

Next steps

50. The Nuffield Council will continue to work to share the report's findings around the world and to monitor policy developments relating to this project. The working group is encouraged to consider and advise on how best to prioritise and target any future activity.

Annex A: individual contributions of working group members

This section includes personal reflections from working group members describing how their individual work has contributed to strengthened the impact of the report findings, share its recommendations across the world, and influence the way in which research is conducted in contexts of global emergencies.

Michael Parker

Following the publication of the Nuffield report on the 28 January 2020, I was invited to become a member of the World Health Organization's COVID-19 Ethics Working Group. This group has met regularly for more than a year and has had input into a wide range of policy decisions and guidance development relating to COVID research and public health interventions. In the work of the WHO Ethics Working Group, regular use has been made of the Nuffield report both in terms of paying close attention to the issues it identified as ethically important, and in the use of the values outlined in the ethical compass to frame discussion.

I was also invited to attend a World Health Organization plenary meeting in Geneva on 11 February. At this meeting, the Nuffield report was discussed in an ethics side meeting and was presented in the main WHO plenary where it was referred to as the most up to date cutting-edge thinking on global health bioethics relating to emergencies. Following this meeting, I was invited to join the WHO Working Group on Vaccine Prioritisation.

Later, in early April 2020, I was invited to participate in the UK's Scientific Advisory Group for Emergencies (SAGE). SAGE is responsible for providing government with coherent, coordinated authoritative scientific advice presenting complex or uncertain scientific evidence in non-technical language. The main SAGE group has held around 90 meetings over the course of the pandemic. In addition to being a participant on SAGE itself I have also participated in a number of the subgroups. I am also a member of the Science Board for the Department of Culture, Media, and Sport's research programme on the opening up of group events.

In May 2020, I was invited to provide ethics input into the RECOVERY Trial at design stage. I also provided ethics support around the design of the international arm of RECOVERY as it moved into South East Asia.

Finally, since March 2020 I have been a member of the DSHC Moral and Ethical Advisory Group.

Patricia Kingori

I am a member of the SPI-B Scientific Pandemic Insights Group on Behaviours, and draw substantially on the report during committee discussions.

I am a Co-Investigator of the RECAP project (Research capacity building and knowledge generation to support preparedness and response to humanitarian crises and epidemics). Since the COVID-19 pandemic and the fuel tank explosion in Lebanon in August 2020, the report's focus on equitable partnerships and capacity strengthening has been used to inform the research as part of the RECAP project.

Together with Michael Parker, I supervised a PhD student who successfully defended her thesis in November last year on data sharing in emergencies, drawing strongly on the report.

Beatriz da Costa Thomé

I've been invited to join the WHO ethics and COVID-19 working group as co-chair since its inception. When it was convened, the WG had as its main objective to provide guidance to support ethical conduct of research for the then newly arising epidemic, and the Nuffield report of course constituted a key reference document as the WG distilled existing guidance to adapt to the new emergency.

For instance, very early on ethical review boards were revisiting their SOPs for rapid ethics review, and when the group came out in support in developing relevant guidance, oftentimes the Nuffield report was mentioned and brought to the discussion as a key reference.

As the work evolved, the group started broadening its scope of work in order to also support the public health response to the pandemic from an ethics perspective. Yet again, while we discussed and elaborated guidance on the interfaces of ethics and immunity / vaccination certificates, public health and social measures (PHSM), human challenge studies, resource allocation etc., the Nuffield report was a key reference.

As co-chair, I think I've had the opportunity to more closely weigh-in on which topics the WG should elaborate guidance on, and having the Nuffield report as backbone reference, so to speak, has allowed me, I believe, to have a more fine-tuned radar for the issues that are more relevant to countries / communities as they navigate the pandemic, and in particular, try to focus on the needs of who is disproportionately affected by them. This is something that came out so strongly in the Nuffield report: how communities are unequally affected.

Additionally, I have been part of a taskforce for GPP-EP (Good participatory practices for emerging pathogens) convened as part of the WHO social science and COVID-19 working group and chaired by Lisa Schwartz. In the development of relevant guidance on community engagement in COVID-19 trials (as outputs of this group) again the Nuffield report was often referenced as it provides a great overview on how community engagement, when done properly, can be a key pillar in public health response and research during an emergency such as this one.

Annex B: the report's recommendations

Recommendation 1 (directed to the funders of WorldReport)

We recommend that the valuable WorldReport initiative, mapping research investments and partnerships, be expanded to include a much wider range of prospective research plans of relevance to global health emergencies. This would facilitate increasingly coordinated planning of research relating to emergency preparedness and response.

Recommendation 2 (directed to WHO and other stakeholders)

We recommend that WHO work with all stakeholders to expedite the development of mechanisms for supporting the integration of research into outbreak response, including standing operating procedures for agreeing research priorities in infectious disease outbreaks; and that this valuable model is also extended to research in other forms of emergency.

Recommendation 3 (directed to Heads of International Research Organizations)

We recommend that the Heads of International Research Organizations take the lead in exploring the scope and appetite for the creation of a dedicated pool of resources, established with its own governance arrangements, for funding research for emergency preparedness and response. A necessary requirement of any such funding mechanism would be the diversity of representation from research institutions around the world, particularly among affected countries, among its leadership and decision-making processes, and a strong emphasis on coordination.

Recommendation 4 (directed to funders)

We recommend that individual funding bodies should put in place innovative ways in which they can facilitate researchers in involving affected communities directly at the grant application stage – for example through the availability of small seed grants to enable initial scoping work, and sufficient flexibility to enable shifts in focus after grants have been awarded in response to community input.

Recommendation 5 (directed to funders)

Research funders should require coherent, achievable and inclusive plans for community engagement in funding proposals, while avoiding being over-prescriptive on how this might be achieved, thus allowing for activities to be guided by reality on the ground. They should include explicit reference to community engagement in budget templates, accompanied by the recognition that budgets need to allow for community activities and reimbursements, as well as staff costs.

Recommendation 6 (directed to researchers, research institutions, research ethics committees, and funders)

Study protocols should be developed with the input of local communities and local researchers before being finalised, in order to ensure that proposed procedures are acceptable to communities, as well as meeting ethical requirements. Even in multi-site trials, there will be elements that can and should be operationalised differently in different sites, in response to engagement and feedback. Ethics committees should actively encourage such involvement, and as a minimum should expect local

engagement in the development of appropriate tools for communication and consent procedures.

Recommendation 7 (directed to researchers, sponsors, and ethics committees)

Any exclusion criteria from studies should be clearly justified with reference to the risks and benefits for the group in question, in this context, rather than an automatic exclusion of ‘vulnerable groups’.

Recommendation 8 (directed to humanitarian organisations and their funders)

We recommend that humanitarian organisations explicitly build in a step of ‘ethical consideration’ when planning needs assessment, evaluations and other forms of data collection not formally classed as research.

Recommendation 9 (directed to ethics committees)

When reviewing proposed consent processes for research in emergency settings, research ethics committees should consider:

- whether the proposed consent processes are the best and most sensitive possible that can be achieved in the circumstances;
- what other requirements might be needed to ensure respect for participants as people of equal moral worth and agency; and
- whether, in all the circumstances, what is being asked of participants can be justified as fair.

Recommendation 10 (directed to ethics committees and funders)

Funders should provide a ringfenced budget to support researchers in providing meaningful feedback to their participants, and wider communities, about what their study has learned, and should audit whether this takes place. Ethics committees should similarly look for communication plans across the lifetime of the research when asked to authorise studies.

Recommendation 11 (directed to funders)

In order to ensure that people’s basic needs are being met when they are being asked to take part in research, funders should routinely expect research teams / research collaborations to include clear partnership plans with relevant service-providers, such as humanitarian organisations and national health departments, when seeking funding for research during emergencies. These arrangements should also include clear plans of action if partners prove unable, at any point, to provide the expected services.

Recommendation 12 (directed to funders)

We recommend that funders develop and implement effective and creative ways of promoting and supporting more equitable collaborations, following the principles of the Research Fairness Initiative. In addition to taking account of equity in the review of proposals, these could include taking an active role in linking potential collaborators; providing seed funding for scoping meetings between potential partners from high-income countries and low- and middle-income countries to enable more inclusive input into subsequent funding applications; including budget lines for immediately relevant capacity support of less well-resourced partners; and specific prompts within funding calls to describe how all partners have contributed to the proposed research.

Recommendation 13 (directed to research institutions)

We recommend that research institutions review their performance management systems to ensure that mentoring and supporting overseas colleagues, as part of international collaborations, is recognised and credited.

Recommendation 14 (directed to funders)

Research funders should explicitly take a long-term approach to funding capacity strengthening, and in addition to supporting capacity development through international collaborations should aim to shift to direct relationships with research institutions in low- and middle-income countries. They should also consider how to support maximum flexibility at the micro level – for example enabling project leads to approach local partners and explore mutually beneficial arrangements that strengthen local capacity.

Recommendation 15 (directed to national governments)

As a key part of national emergency preparedness, national governments should prioritise strengthening academic capacity, including in social science and bioethics, to support the development of national / regional expertise in future. They should also ensure that national ethics committees are adequately resourced and supported.

Recommendation 16 (directed to national governments)

National governments are urged to be alert to the importance of international collaboration and exchange as part of research capacity development, and to ensure that visa requirements, for example for attending meetings and training, do not in practice prevent academics, vouched for by funders and partner research institutions in the receiving country, from being able to attend such events.

Recommendation 17 (directed to funders, national and regional research leaders, national governments and all levels of the WHO)

We recommend that funders and leading research institutions should prioritise further research, in different parts of the world, on stakeholders' views as to what consent and governance mechanisms would create sustainable trust and confidence in the sharing of data and samples for future research use. This evidence should then inform the development of guidance, such as that being developed by the African Academy of Sciences. National governments and intergovernmental agencies should actively support such initiatives as an essential part of emergency planning.

Recommendation 18 (directed to research institutions holding 'legacy' or archive samples, and to the WHO)

We recommend that all research institutions currently holding substantial sample collections share this information on an inventory (to be held by a body such as the WHO or a regional Centre for Disease Control). Where the scope of the consent provided is unclear, they should commit to discussions with relevant national governments, national and regional research leaders, and community representatives such as survivor organisations, about what form fair and respectful future use of these samples might take.

Recommendation 19 (directed to funders, governments and other regulators, and WHO)

We recommend that, in the future, any international research collaborations that intend to collect and store samples prospectively for future research use, should be required to register that collection (including information, for example, about the relevant disease, the number of samples, and the location of the biorepository) in a publicly available database.

Recommendation 20 (directed to journals and research institutions)

We recommend that journals and research institutions explore innovative ways to recognise significant intellectual input into research findings short of direct involvement in writing: for example through more inclusive authorship criteria or other forms of recognising primary research contributors on a named basis. We further recommend consideration of publication policies that actively promote the inclusion of primary researchers in any later re-analysis of shared data and/or samples, and ensure that those working in low- and middle-income countries can access research findings freely.

Recommendation 21 (directed to funders)

We recommend that funders consider how they can take a more active role with respect to the future responsible *use* of data and samples, once these have been made more widely available. In addition to monitoring how their grantees meet any existing obligations to make data not only available but useable (for example through requiring compliance with the FAIR principles), this could include specific funding policies to support secondary analysis, building, for example on the model of the WorldWide Antimalarial Resistance Network study groups.

Recommendation 22 (directed to funders)

We recommend that funders explore ways in which they can require, and support, their grantees to share their research findings in accessible and timely ways with key policy stakeholders. We further recommend that they consider ways in which they could help ensure findings, including negative findings, are publicly accessible in non-academic formats, for example through the development of shared platforms.

Recommendation 23 (directed to research institutions)

We recommend that research institutions, when setting policies, both in general and for a particular emergency, should explicitly consider whether those conditions represent a 'fair offer' in the circumstances. We suggest that elements of a fair offer will include:

- being transparent about how rates of pay are set, and the basis for any differential treatment of local / international workers;
- working with other partner organisations, in particular those responsible for providing routine health services in the location where the research is planned, to understand the context and potential consequences of employers' decisions;
- aiming to provide the highest attainable standard of care and support for any person working on behalf of the institution, whose care needs arise as a result of that work;
- providing explicit justification for any differences in treatment with respect to safeguarding and safety; and

- including temporary and indirectly employed (e.g., sub-contracted) workers within these considerations.

Recommendation 24

There is a need for a flexible, well-funded platform to provide timely ethics advice and support for those involved in all aspects of research in emergencies, including those funding, planning, and carrying out research. We welcome the launch of the Public Health Emergency Ethics Preparedness and Response (PHEEPR) Network. We welcome, in particular, the planned focus on the support for ethics capacity in low-income settings, and the recognition of the central importance of such sources of ethics advice being widely dispersed around the world.