The Ethics Review of COVID-19 Vaccine Clinical Trials

An International Workshop on the Draft Recommendations for Ethics Committees (IECs/IRBs) When Reviewing Vaccine Clinical Trials During Public Health Emergencies

Monday, March 22, 2021, 13:00 to 15:00 UTC

For conversions to your local time: https://www.worldtimebuddy.com/

Zoom Meeting Link:

5.1.2e

The best response is one that responds proportionately to immediate threats while protecting human rights and the rule of law.
Antonio Guterres, Secretary-General, United Nations[1]

1. Introduction: How Strengthening National Ethics Review Systems and Ethics Committees Promotes Confidence in Vaccine Clinical Trials and COVID-19 Vaccines

   5.1.2e
   African Vaccine Regulatory Forum (AVAREF) & Regional Vaccine Regulatory Officer at the African Regional Office (AFRO), World Health Organization
   (5 minutes)

2. From Capacity Building to Capacity Sharing: Building Ethics and Trust into Vaccine Research

   5.1.2e COVID-19 Clinical Research Coalition, Ethics Working Group; Good Clinical Practice Alliance – Europe (GCPA) & Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Leuven, Belgium
   (10 minutes)

   Discussion: What are the main objectives the Recommendations should consider?
   (5 minutes)

3. A Critical Appreciation of the Draft Recommendations from a National and Global Perspective

   5.1.2e Specialist Ethicist in Office of the President and CEO of SA Medical Research Council; Former Director, Steve Biko Centre for Bioethics, Faculty of Health Sciences, University of the Witwatersrand; Honorary Professor, College of Human and Health Sciences, Swansea University, UK; Vice-Chair on the Ministerial Advisory Committee for COVID-19 Vaccines, South Africa ; Chairperson, Vice-Chairperson, International Bioethics Committee, UNESCO; Board Member, South

[1] United Nations. Policy Brief. *COVID-19 and Human Rights: We are all in this together.* https://www.un.org/en/un-coronavirus-communications-team/we-are-all-together-human-rights-and-covid-19-response-and

African Health Products Regulatory Authority
(10 minutes)

Discussion: How can we bring the national and local perspectives of ethics committees (IECs/IRBs) into a shared global framework during a public health emergency, as for instance now with COVID-19?
(10 minutes)

4. ## Why Vaccine Developers Need Competent Ethics Review for Vaccine Clinical Trials During COVID-19 and Other Public Health Emergencies

5.1.2e Center for Global Health, Johns Hopkins Vaccine Initiative, and Member, Institutional Review Board, Johns Hopkins Bloomberg School of Public Health, USA
(10 minutes)

Discussion: How can ethics committees (IECs/IRBs) be 'team players' during a pandemic without losing their independence or their primary objectives of protecting patients and communities, and providing assurances to society on the ethical reliability of vaccine clinical trials?
(10 minutes)

5. ## The Role, Remit, and Function of Ethics Committees in Society During a Public Health Emergency

5.1.2e COVID-19 Clinical Research Coalition, Ethics Working Group; Professor of Bioethics, Department of Science and Technology Studies (STS) University College London, United Kingdom
(10 minutes)

Discussion: What are the limits of an ethics committee's (IEC's/IRB's) mandate in vaccine clinical trials? Does that mandate change during a public health emergency?
(10 minutes)

6. ## How Improved Ethics Review Can Contribute to Equity in Research and Access to Vaccines During the Current COVID-19 Pandemic and Regarding Future Public Health Emergencies

5.1.2e Project Lead Precision Medicine, World Economic Forum
(10 minutes)

Discussion: What is the relationship between equity in vaccine clinical trials and equity in access to vaccines during a public health emergency? Do ethics committees (IECs/IRBs) really have a role to play? If yes, what is that role?
(10 minutes)

7. ## Summary of the International Workshop and Next Steps

5.1.2e, Office Director, Peking University Human Research Protection Program, Peking University Health Science Center, Beijing, China
(5 minutes)

Discussion: What steps are needed to implement these recommendations into the practice of ethics committees (IECs/IRBs) in the immediate future? in the long

term? What differences across countries and committees should we expect when implementing these recommendations?
(10 minutes)

About the Project and the Panellists

It is widely accepted that infectious disease emergencies do not overrule the need to uphold universal ethical standards. With that said, it is accepted that ethical standards can be adaptive and responsive to changing circumstances and to what is culturally appropriate.
The World Health Organization[2]

The Project

These draft Recommendations were developed with funding from the World Health Organization to support the work of the Health Ethics & Governance Unit and PHEPREN (the Public Health Emergency and Response Ethics Network, which the unit initiated) in the competitive call for proposals on 'The Ethics of Public Health Emergency Preparedness and Response' (published October 9, 2020). The project was led by the Good Clinical Practice Alliance – Europe (GCPA) with the support of the COVID-19 Clinical Research Coalition's Ethics Working Group. Input into the project was received by experts from the COVID-19 the Regulatory Working Group; CRC Maternal, Newborn & Child Health Working Group; Social Science Working Group; and the Vaccine Surveillance Working Group as well as from the PREP Group (Preparedness Planning for Clinical Research During Public Health Emergencies). Further, the project has benefited tremendously from the largest global survey of ethics committees yet undertaken, a literature review, learning conversations (interviews), case studies, and topic-specific webinars as well as from advice provided by a broad variety of experts in vaccine development, regulatory oversight, ethics review, and patient and community involvement.

The draft Recommendations were researched and written by the Project Team and the Project Advisory Board with monthly reporting to, and input from, the COVID-19 CRC EWG. Alongside expertise in international, regional, national, and local ethics review practices, the draft recommendations have additionally benefited from specific expertise in vaccine development, regulatory oversight, patient and community representatives and advocates, and specific expertise in clinical trial, regulatory science, population studies, and social science methodologies as well as quantitative and qualitative data analysis. Ethics review oversight was provided by the WHO COVID-19 Ethics Review Committee complemented by the review of specific aspects of the project by ethics committees in Brazil, Iran, Liberia, Malaysia, Nigeria, Pakistan, Russia, and Turkey.

An enormous international effort involving more than a thousand contributors over an 80-day period has gone into producing these draft Recommendations. This demonstrates the global interest and international need for values, efficiency, quality, and collaboration in the ethics review of COVID-19 vaccine clinical trials as well as for future vaccine clinical trials during public health emergencies. More importantly, it demonstrates a core principle of international ethics: We are stronger and more ethical when we reduce reliance on the authority of

[2] World Health Organization. 2020. *2019 novel Coronavirus: Global research and innovation forum: towards a research roadmap*. Page 78. https://www.who.int/blueprint/priority-diseases/key-action/Roadmap-version-FINAL-for-WEB.pdf?ua=1

centralised institutions and moved to a model of sharing decision-making that is as close to the patient, as close to the community as possible. The GCPA and the COVID-19 CRC EWG thank all those who were involved in the project and contributed to these draft recommendations.

The Objectives of This International Workshop

The COVID-19 pandemic raises our awareness of the importance of science, both in research and international cooperation. The present crisis also demonstrates the urgency of stepping up information sharing through open science. The time has come for us to commit all together,
Audrey Azoulay, UNESCO Director-General [3]

The first objective of this International Workshop is to examine the draft Recommendations and receive input from the broad international community for their further development and finalization. The principal research question addressed by this project was as follows: In the context of the current COVID-19 pandemic and other recent epidemics involving the rapid development of vaccines, what are the most pressing problems encountered by ethics committees (IECs/IRBs) and the most salient issues they have needed to address?

The specific objectives of this workshop are

- to review and critically appraise the ethical values and their potential application by IECs/IRBs when reviewing vaccine clinical trials during PHEs;
- to explore the salient ethical issues to be addressed by IECs/IRBs when reviewing vaccine clinical trials during a PHE;
- to examine specific ethics review procedures for reviewing vaccine clinical trials during a PHE;
- to outline specific training and education needs for IECs/IRBs in preparing for, and responding to, the requirement of ethics review for vaccine clinical trials during a PHE;
- to identify potential specific international considerations for IECs/IRBs when reviewing vaccine clinical trials during a PHE; and
- to set out the next steps for the finalisation and implementation of the Recommendations.

The workshop provides an opportunity for input from members of ethics committees (IECs/IRBs) as well as from members of scientists, regulatory authorities, patient and community representatives and advocates, state actors, and members of the public.

[3] The UNESCO Virtual Ministerial Dialogue on Covid-19 and Open Science, 1 April 2020. https://en.unesco.org/news/unesco-hosted-virtual-ministerial-dialogue-covid-19-and-open-science

The Panelists

The capacity of local contexts or countries to provide independent ethics review may be diminished due to the outbreak or a lack of expertise and resources. Efforts should therefore be made to support and coordinate local capacities for independent ethics review.
The World Health Organization[4]

5.1.2e

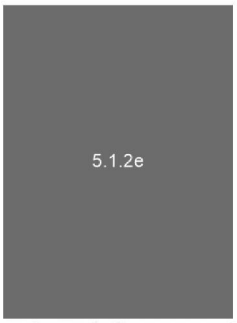
5.1.2e is a member of the African Vaccine Regulatory Forum (AVAREF) and works as the Regional Vaccine Regulatory Officer at the African Regional Office, World Health Organization. He was previously the Deputy Director General for the National Drug Regulatory Authority in Mali and Pharmaceutical Policy Advisor to the Ministry of Health in Mali. Dr. Maïga has extensive experience in public health practice, including positions as Medicines Regulatory Officer and Public Health Consultant at Public Health Canada as well as with USAID/MSH. Provide technical support and advice to the African Region member states for the regulation of vaccines. He provides technical advice and support for regulation of medical products and specifically support the National Regulatory Authorities (NRAs) and Ethics Committees (ECs) of Member States of the African Region to review and approve clinical trial applications (including COVID-19 vaccine clinical trials) and provides oversight of clinical trials. He works with NRAs and ECs of the countries within the African Vaccine Regulatory Forum (AVAREF) and the African Medicines Regulatory Harmonization (AMRH), through facilitating their meetings, supporting development of regulatory strategies, guidelines, and standards and tools as well as monitoring timelines for reviews and approvals of clinical trial applications. He additionally plans, organizes, directs, controls, and evaluates the development and administration of health care policies and national drug policies.

5.1.2e

5.1.2e is the Project Lead for this WHO-funded project. He is a member of the COVID-19 Clinical Research Coalition's Ethics Working Group. Francis is the Executive Director of the Good Clinical Practice Alliance – Europe (GCPA) in Brussels, Belgium. He is the co-founder of the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER). He coordinates the GCPA-SIDCER European Fellowship in Research Ethics (EFRE). He is a philosopher specialised in ethical, legal, and regulatory issues in health research, having taught at several European, Asian, and Middle East universities. He chaired the committee that developed the *Guidelines and Recommendations for European Ethics Committees* (1993/1995), the WHO committee that developed the *Operational Guidelines for Ethics Committees That Review Biomedical Research* (2000, translated into more than 40 languages), the WHO committee that developed the *Surveying and Evaluating Ethical Review Practices* (2002), the WHO Committee that developed the *Operational Guidelines for Data & Safety Monitoring Boards* (2005). He led the founding of the SIDCER fora: FERCAP, FLACEIS, PABIN, FECCIS, and FOCUS as well as the SIDCER Recognition Programme. He

[4] World Health Organization. 2020. *2019 novel Coronavirus: Global research and innovation forum: towards a research roadmap*. Page 79. https://www.who.int/blueprint/priority-diseases/key-action/Roadmap-version-FINAL-for-WEB.pdf?ua=1

has assisted in the development of other WHO, UNAIDS, CIOMS, WMA, European, and guidances for research ethics, ethics committees, and research integrity.



5.1.2e is a leading authority in Bioethics. She is Founder and Past Director of the Steve Biko Centre for Bioethics at the Wits Faculty of Health Sciences (2007 – 2019), Visiting Professor of Bioethics and Health Law at the Wits School of Clinical Medicine, Specialist Ethicist at the Office of the President and CEO of the South African Medical Research Council (SAMRC) and member of the Academy of Science South Africa (ASSAf). She is Honorary Professor in the College of Human and Health Sciences, Swansea University, UK; Chairperson of the National Bioethics Committee of the UNESCO National Commission, and Chairperson of the SAMRC Bioethics Advisory Panel. She is also a Vice Chairperson of the International Bioethics Committee of UNESCO. She is on the ASSAf Biosafety and Biosecurity Committee and has served on several consensus panels of the ASSAf, including the ASSAf Panel on Gene Therapies and Gene Editing ELSI. She also serves as Vice-Chair on the Ministerial Advisory Committee for COVID-19 Vaccines and member of the Ministerial Advisory Committee on Unrelated Organ Transplants. She is Editor-in-chief of the South African Journal of Bioethics and Law and Associate Editor of the South African Medical Journal. She is a mediator with international accreditation through the Centre for Effective Dispute Resolution, UK. She can be credited with entrenching bioethics and human rights as an integral aspect of health sciences in SA. Using an academic platform, Professor Dhai has taken a lead in health advocacy and activism locally and internationally and has published extensively in this field. Professor Dhai started off her career as a medical doctor, specialised as an obstetrician and gynaecologist and then moved into the disciplines of bioethics and health law.

5.1.2e MD. Division: Global Disease Epidemiology and Control, School of Medicine, Johns Hopkins University, Baltimore, Maryland, USA. My research involves the evaluation of experimental vaccines in human clinical trials. At the Center for Immunization Research, we have conducted numerous clinical trials of many different pediatric and adult candidate vaccines. These trials have included vaccines against HIV, hepatitis C, human papilloma virus, influenza, rotavirus, respiratory syncytial virus, dengue virus, and malaria. I am primarily interested in vaccines against dengue viruses and malaria have a very active dengue and malaria vaccine programs here at the Center for Immunization Research. We haven conducted numerous Phase I live attenuated dengue vaccine trials with the ultimate goal of identifying suitable monovalent vaccine viruses for inclusion in a tetravalent dengue vaccine. In addition, we have conducted many Phase I malaria vaccine trials at our clinical site in Washington DC. An important interest of mine is studying the immunopathogenesis of dengue infection and disease. We hope to better understand the viral, host, and immunologic factors causing severe dengue illness by extensively characterizing the cellular and humoral responses of volunteers to live attenuated dengue virus vaccines. In addition to our clinical studies, my laboratory is also developing an animal model of dengue using rhesus macaques.

5.1.2e

5.1.2e COVID-19 Clinical Research Coalition, Ethics Working Group; Professor of Bioethics, Department of Science and Technology Studies (STS) University College London, United Kingdom. Professor Edwards' research focus on the ethics of health research to answer practical and policy questions raised by new technologies. having trained in Psychology, in Philosophy, and in Medical Ethics and Law, concentrating her research career on research ethics. She has a track record of research and policy work related to public health crises. Based on work she initially published in AJOB 2013 on study design and ethics, and hosted an international conference with the World Health Organization in June 2014. She has been closely involved in ethics and social sciences work during epidemics of emerging and re-emerging infectious diseases ever since. Her original work has since been developed with WHO and now under the EDCTP funded PANDORA-ID NET grant to support Africa. She mentored Dr Raji Tajudeen, Director of the National Institutes for Public Health at the African CDC, through his year-long Chatham House Fellowship to develop a 'bottom-up' Afrocentric policy framework on the ethics of research during epidemics for Africa. She also leads a training programme for clinical researchers and for members of research ethics committees in the United Kingdom.

5.1.2e

5.1.2e is Lead, Shaping the Future of Health and Healthcare, at the World Economic Forum, and based in San Francisco. Her work focuses developing and testing policies to advance precision medicine approaches in emerging economies, for which she recently released a whitepaper on Genomic Data Policy Frameworks and Ethical Tensions. She also manages the Forum's Global Future Council on Synthetic Biology and is developing initiatives on health system responses to the COVID-19 pandemic. By background, 5.1.2e worked in the bio-pharmaceutical industry bringing specialty therapeutics to market and worked for the Maryland State government developing and implementing business and economic policy. She led patient strategy and digital innovation for biosimilar immunology products at MSD, brought their ground-breaking immunotherapy cancer treatment (KEYTRUDA) to market, and developed the company's first 24/7 patient support program. 5.1.2e was a Woodruff Fellow at Emory University's Goizueta Business School, where she earned her MBA. She received her BA from Cornell University. 5.1.2e was named to the inaugural class of the 40 Under 40 in Cancer.

5.1.2e

5.1.2e received her PhD degree with a particular interest in research ethics from the Department of Philosophy, Peking University. Dr. Zhang was a visiting scholar at Duke University's Health System Institutional Review Board (DUHS IRB), University of Michigan Medical School. She is the Office Director of Peking University's Human Research Protection Program, where she oversees the research ethics and research integrity training for the research community at Peking University. During the past ten years she engaged deeply in the institutional policymaking and capacity building of Peking University's Institutional Review Board. Her research interests lie in research ethics, public health ethics, and vulnerable populations protection.

Health-related research with human subjects is an essential component of the response to the COVID-19 pandemic. All research should be reviewed and approved by a research ethics committee (REC) before its initiation in order to guarantee its social and scientific value as well as its ethical conduct, including respect for participants' rights, security, and wellbeing.
The Pan American Health Organization[5]

[5] The Pan American Health Organization. *Guidance for ethics oversight of COVID-19 research in response to emerging evidence*. 2020. https://iris.paho.org/bitstream/handle/10665.2/53021/PAHOIMSHSSCOVID-19200035_eng.pdf?sequence=1&isAllowed=y