Ethics guidance on issues raised by the novel coronavirus disease (COVID-19) pandemic

Developed by the Regional Program on Bioethics, Department of Health Systems and Services, based on:

Pan American Health Organization. **Zika Ethics Consultation: Ethics guidance on key issues raised by the outbreak**. Washington, DC: PAHO; 2016. Available from: http://iris.paho.org/xmlui/bitstream/handle/123456789/28425/PAHOKBR16002_eng.pdf

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For other topics relevant to the new coronavirus (such quarantine or isolation), consult:

- World Health Organization. **Guidance for Managing Ethical Issues in Infectious Disease Outbreaks.** Geneva: WHO; 2016. Available from: https://apps.who.int/iris/bitstream/handle/10665/250580/9789241549837-eng.pdf?sequence=1
- World Health Organization. **Ethical considerations in developing a public health response to pandemic influenza.** Geneva: WHO; 2009. Available from: https://apps.who.int/iris/bitstream/handle/10665/70006/WHO_CDS_EPR_GIP_2007.2_eng.pdf?sequence=1

For ethics guidance for surveillance:

- World Health Organization. **WHO guidelines on ethical issues in public health surveillance**. Geneva: WHO; 2016. Available from: https://apps.who.int/iris/bitstream/handle/10665/255721/9789241512657-eng.pdf?sequence=1
  (Guideline 15 focuses on emergencies).

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PAHO Pan American Health Organization World Health Organization Regional Office for the Americas

PUBLIC HEALTH

Health authorities are tasked with protecting the health of the population and responding to public health emergencies. An adequate health response to public health emergencies, such as the current WHO-declared COVID-19 pandemic, requires up-to-date information. To obtain this information, health authorities have the duty to conduct surveillance and to act without delay on the basis of information obtained. In the context of the COVID-19 pandemic, surveillance is needed to reduce some of the uncertainty that surrounds the virus and its consequences. Health authorities must ensure that the information is collected rigorously, that all relevant cases are reported, and that data are managed responsibly, always taking the benefit of the population into account. As in other cases of surveillance, during the pandemic public health authorities may need to collect personal data or samples. While informed consent may not be required for such data collection, the information must be collected in a respectful manner, safeguarding the privacy of individuals, maintaining confidentiality to the extent possible, and providing information about the data collection in a transparent manner.[1] Public health authorities also have the ethical duty to implement interventions that are already known to work.

How should public health activities that involve data collection be distinguished from research?

Not every activity that involves data collection in a systematic manner constitutes human subjects research. Research is characterized by the primary intent to produce generalizable knowledge. Health authorities engage in various forms of research, for which prior ethics approval must be obtained, and in which participation is voluntary following an informed consent process. Health authorities also conduct activities that aim primarily at the direct benefit of the population they serve, e.g. improving their health or addressing public health problems. Even if those activities involve the systematic collection or analysis of personal data, as in the case of surveillance, they do not constitute research with human subjects.[2] Therefore, they are not subject to the rules and regulations that govern human subjects research, such as prior approval of a research protocol by an ethics review committee. Nevertheless, all public health surveillance and other activities must be undertaken in an ethical manner, for example

[1] World Health Organization. WHO guidelines on ethical issues in public health surveillance. Geneva: WHO; 2017. Available from: https://apps.who.int/iris/bitstream/handle/10665/255721/9789241512657-eng.pdf?sequence=1.
[2] World Health Organization. Ethics in epidemics, emergencies and disasters: Research, surveillance and patient care. Training manual. Geneva: World Health Organization; 2015. Available from: http://apps.who.int/iris/bitstream/10665/196326/1/9789241549349_eng.pdf.

being attentive to minimizing risks for individuals and communities.[3] Appropriate ethical guidance and oversight should be sought, especially in the context of a public health emergency.

It is often difficult to distinguish between public health research and other public health initiatives and activities, particularly during a health emergency. In the Region of the Americas, making this distinction was particularly challenging during H1N1 and SARS. Various existing guidance documents and training materials can help distinguish public health research from non-research.[4] [5] [6] [7] The determination of whether an initiative constitutes human subjects research or not should be made by an appropriate third party, such as an ethics review committee. If it is determined that the initiative constitutes human subjects research, then a corresponding research protocol must be submitted for ethics review.

How should the health of the public be advanced during the pandemic?

A range of public health responses is needed. Their ethical design and implementation require the incorporation of equity, responsibility, solidarity and transparency. Equity entails efforts to ensure that the poor and disadvantaged are not disproportionately burdened. Public health interventions as part of the response should aim at reducing inequities. Public health activities aimed at controlling the pandemic should be conducted responsibly and, inter alia, build capacity to improve response to future health emergencies. Responsibility and solidarity dictate that relevant data should be promptly shared so other countries can act to reduce the harm caused by the outbreak.

[3] Pan American Health Organization Directing Council. Bioethics: Towards the integration of ethics in health. Concept paper. 28th Pan American Sanitary Conference, 64th Session of the Regional Committee. 2012 Sep 17-21. (Document CSP/28/14, Rev.1). Available from: http://new.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=18416&Itemid=&lang=en .

[4] World Health Organization. Ethics in epidemics, emergencies and disasters: Research, surveillance and patient care. Training manual. Geneva: WHO; 2015. Available from: https://apps.who.int/iris/bitstream/handle/10665/196326/9789241549349_eng.pdf?sequence=1.

[5] Cash R, Wikler D, Saxena A, Capron A, editors. Casebook on ethical issues in international health research. Geneva: WHO; 2009. Available from: http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf.

[6] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. Tri-Council policy statement: ethical conduct for research involving humans. Ottawa: Canadian Institute of Health Research; 2010. Available from: http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf.

[7] Centers for Disease Control and Prevention. 2010. CDC's Policy on distinguishing public health research and public health nonresearch. Available from: http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-publichealth-research-nonresearch.pdf. This material includes examples that can help distinguish between public health research and public health activity.

The pandemic might present us with thorny priority-setting issues. We should anticipate scenarios in which health systems are overwhelmed and cannot provide care to all persons needing it, e.g. access to ventilators or beds in intensive care units for all affected patients. Health authorities have the ethical obligation to provide a public justification of the criteria used for priority-setting decisions. Transparency about the rationale for priority-setting decisions enhances public trust, increases their acceptability, and promotes compliance with related recommendations.[8]

What do health authorities owe to the general public in terms of communication during the pandemic?

Health authorities have the duty to proactively design and implement procedures for translating complex health information into layperson language and disseminating this widely to patients and the public. They have a duty to provide the most accurate and complete information about the pandemic and its consequences that is available. Extreme care should be used in communications in order to facilitate comprehension. Health authorities should assume the burden of ensuring that messages are comprehensible as opposed to passing to the population the burden of decoding technical information, which would further increase inequity.

Health authorities also have the duty to provide the population with the general epidemiological information about the pandemic and make relevant information about the public health response publicly available. The population should be aware that data are being collected as part of surveillance efforts in order to improve public health, and that individual data are protected and will be managed confidentially and used responsibly. Providing this information in a comprehensible manner is key for public trust. This is particularly important in emergency situations, which tend to be characterized by a background of distrust and resistance to following related public health recommendations. Sensitive information that has the risk of causing stigmatization or discrimination must be communicated with the necessary precautions to minimize those risks. If stigmatization or discrimination occur, measures must be taken to mitigate them.[9]

Communication and engagement with local populations and communities also fosters public trust and helps ensure that messages are sensitive to cultural differences and respectful of diversity. Health authorities should lead by example and ensure transparency, in addition to providing truthful, accurate and unbiased information.

[8] The World Health Organization will publish more specific ethics guidance for resource allocation during COVID-19.

[9] World Health Organization. WHO guidelines on ethical issues in public health surveillance. Geneva: WHO; 2016. Available from: https://apps.who.int/iris/bitstream/handle/10665/255721/9789241512657-eng.pdf?sequence=1

Partnerships with the news media should be explored as possible means of disseminating information and countering disinformation with fact.

How should uncertainty be handled?

People are owed the truth. Public health authorities should be honest and transparent about the information that we do not have about the pandemic and its consequences. They should avoid statements of certainty when it does not exist about a particular issue, and be straightforward about the scope of uncertainty. The communication of uncertainty is important because it enables individuals to make decisions based on their own risk assessments, and avoid the harms that may result if decisions are made by taking what is uncertain as fact. Health authorities have the duty to explain that certainty may increase as more data are collected, and as more research is conducted. Recommendations may change on the basis of the new knowledge we acquire. More certainty will allow more informed policymaking and individual decision-making.

RESEARCH

Research is crucial to reduce the uncertainty about the pandemic and its consequences. We have the ethical obligation to conduct research during the outbreak in order to improve prevention and care. Research is essential firstly to understand the disease so that interventions and management practices can be devised, and then to assess the safety and efficacy of any proposed diagnostic tests, treatments, vaccines or management approaches. We should aim at conducting the most rigorous studies that are possible in the current conditions to ensure that we learn as much and as fast as we can. Conducting research can be challenging during an emergency and should not compromise the duty to provide care as outlined in this document.

Populations and communities must be continuously informed about the importance of doing research during the emergency and also afterwards, and that this requires the collection of samples and data during and after the pandemic. Community consultations prior to the initiation of related research are strongly encouraged to ensure that studies address local needs and priorities and that design of studies will be acceptable to host populations. Community consultation will thus build trust, which is vital during an emergency, and essential to the conduct of research that will provide accurate and meaningful information.

This pandemic also highlights the need for ongoing local research capacity development in order to strengthen the ability to respond in outbreaks and pandemics such as this. As stated in the 2013 World Health Report, unless low- and middle-income countries become the generators and not only the recipients of data then there will never be any

great improvements to public health.[10] From an ethical perspective, research capacity development efforts should therefore be considered a priority.

Can we fast-track ethics review during an emergency?

Human subjects research conducted during emergencies must be subject to higher, not lower, ethical safeguards. Ethics approval must be obtained for all emergency research with human participants before studies begin, and the need to accelerate research should not come at the expense of thorough ethics review. Ethics review committees, however, must fast track ethics review for emergency research while ensuring a rigorous ethics review. Mechanisms to fast-track ethics approval processes must be devised, along with strategies to integrate the work of different ethics review committees to avoid duplication. Investigators and research funders may consider seeking ethics review of standard protocols that can later be adjusted and approved in an accelerated process.[11] Involving ethicists in the development of research protocols is recommended.

Particularly during emergencies, ethics review processes should examine accountability of the researchers, institutions, and funders involved to guarantee that studies are conducted ethically. Health authorities and institutions conducting research should enhance the visibility and credibility of ethics review committees to promote trust in research.[12] Trust can be built by informing and engaging communities and local populations about the design, implementation, and probable benefits and outcomes of research, and continuously informing the public about the research that is being conducted and the various processes and requirements aimed at ensuring that it is ethical. This also facilitates consent processes that tend to be challenging during emergencies.[13]

Is consent necessary when doing research during emergencies?

Existing national and international ethical guidelines that govern research involving human participants apply to all research conducted during emergencies. Accordingly,

[10] World Health Organization. Research for universal health coverage: World health report 2013. Geneva: WHO; 2013. Available from: http://apps.who.int/iris/bitstream/10665/85761/2/9789240690837_eng.pdf?ua=1.

[11] Global Forum on Bioethics in Research (GFBR). Meeting report: Emerging epidemic infections and experimental medical treatments. Annecy, France. 3-4 November 2015. Available from: http://www.gfbr.global/wp-content/uploads/2016/03/ GFBR-2015-meeting-report-emerging-epidemic-infections-and-experimental-medical-treatments.pdf

[12] For example, enhancing and protecting their independence and providing support and arms length expertise where needed, and especially where non-traditional research methods and innovative trial design will be involved.

[13] Global Forum on Bioethics in Research (GFBR). Meeting report: Emerging epidemic infections and experimental medical treatments. Annecy, France. 3-4 November 2015. Available from: http://www.gfbr.global/wp-content/uploads/2016/03/ GFBR-2015-meeting-report-emerging-epidemic-infections-and-experimental-medical-treatments.pdf.

obtaining informed consent is necessary for research in emergencies involving human participants or their identifiable samples or information. Existing guidelines stipulate circumstances in which the requirement to obtain informed consent can be waived by a research ethics committee when: (a) it is not feasible to obtain consent, and the studies (b) have important social value and (c) pose only minimal risks to participants.[14]

Especially in the context of pandemics, and in order to catalyze much needed research, the practice of obtaining broad consent for the use of samples and data in future research (including biobanking research) should be strongly encouraged. Unlike traditional consent, which seeks participation in one specific study, broad consent applies to participation in a range of future studies that are not planned or conceptualized yet, but are likely to be designed as new information emerges. In cases of broad consent, future research involving a participant's samples or data should ordinarily be approved by an ethics review committee, and this should be explained to participants as part of the broad informed consent process. Overall, individuals should always know whether they are participating in research, receiving medical care, or participating in a public health intervention. This is vital to instilling and upholding public trust in research and health professionals.

The pandemic presents with the need to conduct research in emergency settings: With people who suffer from an acute condition, need interventions within a limited time frame, and will suffer severe consequences if they do not receive efficacious interventions. Such studies pose specific ethical challenges, including difficulties conducting adequate consent processes, for which there is ethics guidance.[15]

Can samples collected for other purposes be used for research?

Research during and after the pandemic is needed. Samples collected for purposes other than research (e.g. surveillance by the health authority, or left over clinical samples) can be used for research in some circumstances. These include when individuals provide broad consent to the use of their specimens for their future use in human subjects research, or when the public has been informed that left over clinical samples may be used for research after anonymizing them. These studies must obtain prior ethics approval.[16] If broad consent for the future use of samples was not obtained

[14] Council for International Organizations of Medical Sciences (CIOMS). International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva: CIOMS; 2016. Available at: https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

[15] Millum J, Beecroft B, Hardcastle TC, et al. Emergency care research ethics in low-income and middle-income countries. BMJ Global Health. 2019;4:e001260.

[16] Certain guidelines and regulations for human subjects research are restricted to studies involving persons or their identifiable samples. Accordingly, research with samples previously collected for other purposes can move forward without obtaining ethics approval if these samples

when the samples were collected, ethics review committees might require asking for the consent of the persons who provided the specimens in order to use them for research. Ethics review committees may also assess if a waiver of consent is appropriate.

Do we have a duty to share the results of research?

Yes. As internationally agreed after the Ebola virus outbreak, during a health emergency all involved parties have the duty to share data and research results quickly in order to guide decision-making.[17] Efforts should be made to ensure data are complete and of the highest possible quality. In the current outbreak, research is urgently needed to minimize the harms caused by the pandemic. It is ethically unacceptable to block or delay the publication of research results. Every party involved in research should contribute towards ensuring that research results are shared promptly through channels that are widely accessible (e.g. open access journals) to better inform public health responses to the pandemic. Research teams have the duty to make the results of their research publicly available without delay, and to provide public health practitioners promptly with all relevant information. Research teams also have the duty to advance further research, which implies sharing research protocols and instruments, data and samples to the extent that it is possible to do so ethically. These duties apply to all researchers, including those at governmental institutions.

The pandemic constitutes a public health emergency of global concern. Global collaboration and data sharing across national borders is therefore strongly encouraged. Global collaboration should not be restricted to data and research results. When possible, researchers and funders should incorporate designs and activities that build research capacity in low- and middle-income countries and other resource-limited settings.

are completely unidentifiable for the researchers. This is consistent with international guidelines: The Declaration of Helsinki provides ethical guidelines for “medical research involving human subjects, including research on identifiable human material and data,” and CIOMS refers to “research involving human subjects, including research with identifiable human tissue or data.”

[17] Leading international stakeholders from multiple sectors convened at a WHO consultation in September 2015, where they affirmed that timely and transparent pre-publication sharing of data and results during public health emergencies must become the global norm: http://www.who.int/medicines/ebola-treatment/blueprint_phe_data-share-results/en/. This commitment to sharing data during public health emergencies has been deemed relevant in the context of the Zika virus outbreak and endorsed by various key partners: http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/ Data-sharing/Public-health-emergencies/index.htm.

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