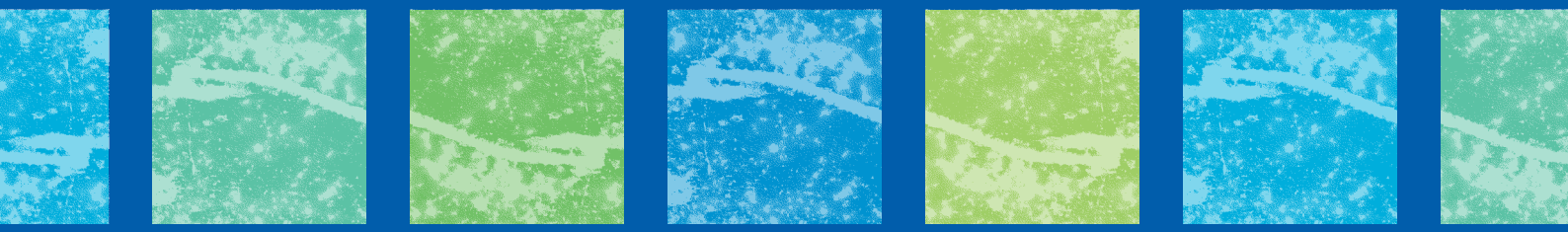
WHO/HSE/GIP/ITP/10.1

Research Ethics in International Epidemic Response

WHO Technical Consultation

Geneva, Switzerland
10–11 June 2009

MEETING REPORT



World Health Organization

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Rapporteurs

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Executive summary

- Most of the ethical issues related to research in public health emergency situations are the same as those already addressed in general ethics guidelines governing biomedical research. Differences during an emergency include such things as changes in perceptions of risks, benefits and trust which must be taken into account in the ethics review process; a heightened need for attention to organizational values like accountability and transparency; and the fact that, as a practical matter, there may not be sufficient time for standard ethics review processes which in many countries can sometimes take months.
- Despite these differences, even in an infectious disease emergency or other crisis situation, the principles and values embodied in international and national ethics guidelines, as well as human rights instruments, must be upheld.
- In many countries, most research with human participants must undergo prospective ethical review by a research ethics committee (REC), while activities characterized as public health or clinical practice are not subject to this requirement. However, distinguishing between research and practice is complicated by the fact that there is a significant area of overlap in these activities in terms of methodology, systematization of investigation, and the outcome of producing generalizable knowledge.
- Despite the conceptual problems of distinguishing between research and non-research, the distinction is deeply ingrained in many countries' regulatory structures and is unlikely to be changed any time soon. However, this does not mean that all research must undergo full REC review, nor does it mean that activities that fall outside local or international definitions of research should escape ethics review entirely.
- The ultimate goal for public policy should be to ensure that most, if not all, emergency public health activities are subject to some form of ethical oversight, whether or not those activities are formally characterized as research. The specific nature of the oversight should be commensurate with the activity's objectives, methods, risks and benefits, as well as the extent to which the activity involves vulnerable groups.
- To achieve this goal, it is crucial to streamline the ethics review process and to establish appropriate, flexible mechanisms and procedures for ethical oversight not limited to traditional REC systems.
- While some crucial emergency health research should still undergo full REC review because of significant risks to individuals or populations under study, a "fast-track" review approach should also be adopted. However, review should not be expedient to the point of dropping or narrowing ethical principles.
- Options for promoting fast-track review of emergency research include adjusting the balance between in-person and electronic communications by REC members; the use of pre-emergency repositories of study protocols or protocol parts which could be submitted to RECs for ethical pre-screening; the creation of special emergency research RECs, perhaps on a national or regional level; and, where there is no other feasible option, greater reliance on retrospective rather than prospective ethics review, with safeguards to address non-compliant or sub-standard research ethics conduct.
- Public health activities that are classified as practice may raise important ethical issues. Stakeholders should formulate plans to ensure that such activities receive appropriate and timely ethical review. One option to consider, at least in some

situations, is review by special committees with appropriate expertise and experience to examine procedures and methods specific to a public health practice. For activities that do not warrant committee review, or in countries that choose not to institute a committee review structure, public health practitioners can be equipped with tools to help them assess whether their planned activities comport with principles of public health ethics. Training modules for research ethics committees and public health professionals should be created to support this goal.

- There is a critical need for capacity building in the ethical review of public health research and practice. Researchers, public health agencies and other stakeholders should work together to develop short courses, degree programmes and other training modalities. Funding agencies should direct appropriate support to these efforts.

Background

Pandemic influenza preparedness and response raises many ethical questions. Upon request by Member States, in December 2007 WHO published a global guidance document entitled *Ethical considerations in developing a public health response to pandemic influenza* (*1*). This guidance document addressed the following issues:

- priority setting and equitable access to therapeutic and prophylactic measures;
- isolation, quarantine, border control and social-distancing measures;
- the role and obligations of health-care workers during an outbreak of pandemic influenza;
- developing a multilateral response to an outbreak of pandemic influenza.

Since the publication of this document, it has become apparent that there is a need for additional guidance on a subject that was not addressed in the previous work, namely the ethical issues that arise while doing research in infectious disease outbreaks. Notably, in a workshop in Uganda in 2008, several ministries of health representatives identified the lack of guidance in this area as a gap in the previous WHO document. The importance of filling this gap has been highlighted by the recent emergence of influenza A (H1N1).

In response to the request for additional guidance, WHO's Global Influenza Programme and the Ethics and Health team jointly convened a technical consultation on "Research Ethics in International Epidemic Response". This meeting brought together experts of international organizations, government agencies and ministries, professional medical associations, academic and research institutions, as well as staff of various WHO departments and regional offices to:

- identify and elucidate the ethical issues related to clinical and public health research and related activities during infectious disease outbreaks;
- provide WHO with urgently needed guidance in this area, with specific focus on the question of whether and how prospective ethical review should take place for these activities;
- provide practical guidance to public health practitioners and researchers in the field.

The discussion occurred in the context of the current influenza A (H1N1) event, which was declared a "pandemic" on 11 June 2009, the second day of the meeting. It was noted during the meeting, however, that the suggestions and approaches developed by the group could be extended to other infectious disease emergencies as well.

Existing ethical guidance and relevance to epidemic response

1. Participant presentations and discussions covered a broad range of ethical issues related to international response to epidemics, including: the standard of care as applied in different local and multinational research contexts; the appropriate use of placebo-controlled trials; exploitation and protection of vulnerable groups, including quarantined or isolated individuals and migrant populations; fair and equitable benefit-sharing and distribution, especially between sponsor and host countries (which typically means developed and developing countries respectively); just prioritization of public health responses; evaluation of anticipated risks and benefits; maintenance of confidentiality and privacy of personal data and information; safeguards for biobanks and intellectual property; and respect for autonomy and informed consent.

2. As a starting point of the discussion, the group agreed that, even in an infectious disease emergency or other crisis situation, the principles and values embodied in international and national ethics guidelines must be upheld.

3. Participants agreed that most of the ethical issues related to research in emergency situations are not unique to emergencies. Rather, the same issues are already addressed in general international and national ethics guidelines governing human subject research. These include questions of informed consent, risk–benefit assessment, confidentiality, community engagement, etc. Members noted, however, that many existing research ethics guidelines emphasize issues related to clinical studies, with less attention to public health research. In general, the field of research ethics would benefit from greater attention to the ethics of public health activities.

4. The group noted that ethical issues in an emergency differ from other situations in several ways.

   - Emergency situations affect perceptions of risks, benefits and trust, and these changed perceptions, especially in the patient-provider relationship, must be taken into account in the ethics review process.

   - There is a heightened need for attention to organizational values like accountability and transparency.

   - The timely generation of knowledge is a practical matter of importance. The normal processes used to ensure the scientific and ethical validity of such efforts may not react fast enough; for example, there may not be sufficient time for standard ethics review processes, which in many countries can sometimes take months.

Distinguishing public health practice from research: implications

5. Participants noted that defining the boundary between public health-oriented research and practice remains a critical challenge in public health ethics. The purpose in distinguishing the two activities goes beyond semantic concerns because of the different ways in which public health research and practice are regulated in many countries. Public health biomedical investigations that are characterized as research with human subjects will require prospective independent review by a research ethics committee (REC), unless they meet certain criteria for exemption. In general, such public health research is tightly regulated with strict requirements for protocol approval. This involves scrutinizing the competency of the investigators, the scientific merit and soundness of the study design, and other procedures such as informed consent and declaration of conflicts of interests. On the other hand, public health practices, which include population surveillance measures, disease control and prevention, and program development and evaluation, do not typically undergo prospective ethics review. They therefore do not fall within the remit of RECs, although they are subject to public health laws and regulations. In some cases, retrospective reviews of these activities may be conducted by politically authorized agencies.

6. Given that there are important procedural implications for classifying a public health activity as research or practice, it is important to clarify the definition of research. However, this is complicated by the fact that there is a significant area of overlap between public health research and practice in terms of methodology, systematization of investigation, and the outcome of generalizable knowledge. For example, public health practice, like research, can employ case-control or cohort study designs and can result in publications of generalizable findings. Moreover, public health practice and research often raise similar ethical issues, including the fact that individuals may be exposed to risks not for their own benefit but for the interests of society as a whole.

7. A possible way to resolve the conceptual problem of distinguishing between research and practice in public health is to use the "primary intent" criterion provided by the United States Centers for Disease Control and Prevention (CDC). According to the CDC *Guidelines for defining public health research and public health non-research* (*2*), the primary intent or design of research is to "generate or contribute to generalizable knowledge", whereas the primary intent or design of non-research is to "prevent or control disease or injury and improve health, or to improve a public health program or service". Under this approach, so long as the primary intent of a public health activity or response is not to generate or contribute to generalizable knowledge, it should be categorized as "non-research", even if generalizable knowledge is produced as an outcome or secondary utility of the activity or response.

8. Participants were not comfortable, however, with relying on the "primary intent" criterion as the appropriate standard for determining whether an activity constitutes research and therefore requires prospective ethics review. Three main objections were raised.

   - The approach may encourage investigators to characterize their project as "non-research" so as to circumvent the prospective ethics review process, especially when the REC system is perceived to be overly bureaucratic and cumbersome.

- The criterion fails to take into account borderline or "grey area" public health activities and response. Of particular note are those that have "dual utility" in the sense of being designed to respond to an immediate crisis while producing generalizable knowledge for future use. An example is the collection of biological specimens and data during a novel disease outbreak. The purpose of this activity is not only to develop interventions to respond to the immediate situation, but also to produce generalizable knowledge that can be applied to outbreaks in the future, whether through the development of public health strategies or the creation of commercial products.

- The distinction between research and practice in public health does not correlate with the extent to which an activity either carries risks for individuals and communities or otherwise raises ethical issues that would benefit from a prospective review process. The distinction also has no bearing on the ultimate question of whether a particular public health response is scientifically and ethically justifiable.

9. The group agreed that, regardless of whether public health investigations and interventions are categorized as research or practice – the boundary between which is not always clear, it is essential to ensure that they be conducted in accordance with generally recognized ethical principles and values. As various participants pointed out, if it is agreed that the ultimate goal is to safeguard the interests and rights of individuals and communities under study, then articulating a strict distinction between public health research and practice is of less importance than coming up with innovative and flexible review mechanisms and procedures that enable ethical and time-sensitive responses in outbreak situations. The group therefore agreed that the scope and limits of prospective ethics review should not depend primarily on whether an activity is technically classified as "research" or "practice".

10. In view of this conclusion, there was broad consensus among the meeting participants that most, if not all, emergency public health activities should undergo some form of ethical oversight. The specific nature of the oversight should be commensurate with the activity's objectives, methods, risks and benefits, as well as the extent to which the activity involves especially vulnerable groups. Participants emphasized the need to streamline the ethics review process and to establish appropriate, flexible mechanisms and procedures for ethical oversight not limited to traditional REC systems. This is particularly important for activities with the potential to produce enormous public health benefits with only minimal risks, as is the case for many interventions carried out in the context of an epidemic response.

11. Participants recognized that because the distinction between research and non-research is deeply ingrained in regulatory structures, especially in high-income countries, the concept is unlikely to change any time soon. Thus, they agreed that activities which fall within the standard definition of research will have to undergo some type of REC review. This does not mean, however, that all research must undergo full REC review, nor that activities which do not constitute research should escape ethics review entirely, whether by RECs or by other such mechanisms.

12. In order to support this approach, the review system needs to be streamlined and flexible yet ethically sensitive, and adequate review procedures should be developed. Provided that a "fast-track" oversight system can be established, this approach has the advantage of creating less incentive for investigators to mislabel their activity to avoid ethical scrutiny. Improved efficiency and proportionality in ethical oversight should be welcomed by investigators.

Practical options of ethics oversight to facilitate research in epidemics

13. Participants pointed out the merit of an organized oversight system for emergency public health research and practice that could distinguish crucial tasks from non-crucial ones. Non-crucial tasks that do not qualify for exempted or expedited review could be reserved for review after the emergency, particularly when there is potential for the oversight system to be overloaded. While some crucial emergency public health research should still undergo full REC review because of significant risks to individuals or populations under study, a fast-track review approach should generally be adopted. As participants emphasized, however, review should not be expedient to the point of dropping or narrowing ethical principles.

14. In view of the fact that there is no global "one-size-fits-all" fast-track review approach that matches the needs, capacity and research cultures of countries responding to public health emergencies, participants proposed a menu of options.

    - Determine different procedures that can speed up full REC review, such as increased face-to-face meetings between REC members, or increased reliance on e-mail communication, depending on which method is more efficient in the particular environment.

    - Create a pre-emergency repository of study protocols or protocol parts, perhaps relying on a "Wikipedia-style" model which stores and articulates "best practices" in research design. Best practices may include pre-agreements on benefit sharing, which can have significant impact on international collaborative public health research. Investigators could be encouraged to submit these protocols or protocol parts to RECs for comments, and to share the comments with other investigators who are considering similar types of investigations. The value of such a model is that it would facilitate the development of protocols or protocol parts that have already been pre-screened for ethical issues by numerous RECs. When an emergency arises, RECs could then quickly assess the potential ethical shortfalls of submitted protocols that borrow or adapt from the repository, thus allowing quick turn-around in review and approval. However, it was noted that the model may be unrealistic if investigators are reluctant to share protocols or protocol parts because of intellectual property and authorship credit issues.

    - Even without sharing their protocols as part of a repository, investigators could submit protocols or protocol parts to their own RECs in advance of an emergency. While this option would not have all the advantages of the protocol repository system, it would still give the investigators the benefit of a REC "pre-screening".

    - "Rolling" or contemporaneous review for protocols or parts of protocols could help speed the process. For example, portions of a trial could be approved while other elements are modified in real time as the trial is launched, with continuing supervision and periodic re-approval by the ethics board. This would allow flexibility in refining dosing regimens and would prevent rigid protocols from being repeatedly abandoned as new information emerges.

    - Special review or advisory committees or boards could deal with emergency research with tight timelines. Some countries might consider developing centralized national or regional committees for this purpose, or delegating oversight responsibility to an international organization.

    - Retrospective review could be combined with an accountability infrastructure for non-compli-

ant or substandard research ethics conduct. It is important to recognize, however, that an inherent drawback to retrospective review is that, by the time the review is conducted, unethical activities may have already occurred. It might be appropriate, therefore, to limit the use of retrospective review to researchers with specified training or credentials in research ethics.

The development of a prospective, proportional ethics review or advisory system for public health practice is not antithetical to the goals of public health and the duty of public health practitioners to engage in quality studies of ethical and scientific rigor. It was agreed that it is important to consider how to identify public health activities defined as practice that raise significant ethical issues, and to delineate appropriate mechanisms for providing an ethical assessment of procedures and measures specific to public health practice. One option to consider is oversight by special committees with appropriate expertise and experience to review procedures and methods specific to a public health practice. Some participants suggested that ethicists should be a part of epidemic response planning and that it might be appropriate to include them as part of epidemic response teams.

15. Participants underscored the importance of professional ethics for public health practitioners. Several members suggested that public health professionals should be required to adhere to a code of ethical conduct. For activities that do not warrant committee review, or in countries that choose not to institute a committee review structure for activities not formally classified as research, public health practitioners could be equipped with tools to help them assess whether their planned activities comport with ethical principles.

    The group noted the importance of raising the awareness and training of public health professionals and researchers and urged the development of relevant training modules.

16. Participants agreed that ethics oversight – be it for public health research or practice, conducted in emergency or non-emergency situations, or for fast-track or regular time – can better protect individual and community interests and welfare, and promote trust and solidarity in two ways: by engaging with the potentially affected communities and by receiving the input of relevant stakeholders, especially representatives of vulnerable groups. It is particularly important to ensure that communities understand that there is often no direct or immediate benefit to participants in studies conducted as part of epidemic response efforts. Community engagement for public health purposes is, however, a complex process. It sometimes involves consultation or negotiation with organizations that have beliefs and aims that are inconsistent with the values of most public health practitioners, such as groups that do not support the concept of gender equity. With regard to the study participation of vulnerable groups, it was noted that concepts and perceptions about vulnerability may be subject to change in public health emergencies. It was also noted that some individuals or groups may not appreciate being characterized as "vulnerable". The fact that individuals or groups are vulnerable does not mean that they should be excluded from study participation in emergency situations, particularly when such individuals or groups can potentially benefit the most from public health interventions. Rather, special care needs to be taken to protect the vulnerable while including them in interventions and research.

17. The participants concluded that the need for a fast-track prospective oversight procedure or mechanism is not unique to public health emergencies. The discussions brought into sharp focus the necessity to reassess and reform current oversight systems, given endemic issues of bureaucracy and undue delay. To strengthen oversight systems and reduce their burdens, building the capacity for ethics review and training of individuals involved in public health research and emergency response is a critical long-term solution – perhaps leading to "ethics certification". It is also important, particularly for international research collaborations, to create a platform for harmonizing important procedures and terminology that have an impact on oversight procedures. This should include terms like "emergency", "fast-track review", "anonymization", and "non-identifiable" in the context of biobanks.

References

1. *Ethical considerations in developing a public health response to pandemic influenza*. Geneva, World Health Organization, 2007 (http://www.who.int/csr/resources/ publications/WHO_CDS_EPR_GIP_2007_2c.pdf).
2. *Guidelines for defining public health research and public health non-research*. Atlanta, GA, United States Centers for Disease Control and Prevention, 1999 (http://www.cdc.gov/od/science/regs/hrpp/researchdefinition.htm).

Annex I. Agenda

Research Ethics in International Epidemic Response

WHO Headquarters, Salle M.205, Geneva, Switzerland

10–11 June 2009

WEDNESDAY, 10 JUNE 2009	
Morning session ■ Chair: Jeremy Farrar (Vietnam)	
8:30–9:00	**Registration**
9:00	**Welcome and introductory remarks**
	Sylvie Briand, WHO/Acting Director, Global Influenza Programme
	Objectives of the meeting
	Hande Harmanci, WHO/Global Influenza Programme
	Marie-Charlotte Bouësseau, WHO/Ethics, Equity, Trade and Human Rights
9:15	**Experiences from the field**
	Philippe Calain (MSF) [20 min.]
	Comments from: Ghaiath Hussein (MoH Sudan), Dionisio Herrera (TEPHINET), Cathy Roth (WHO) [5 min. each]
10:00	Discussion
10:30	REFRESHMENT BREAK
11:00	**Existing guidance documents: relevant points and gaps**
	CDC/CIOMS: James Thomas (University of North Carolina) [20 min.]
	Declaration of Helsinki: Julian Sheather (WMA/BMA) [5 min.]
	UNAIDS/WHO HIV vaccine research: Kayitesi Kayitenkore (UNAIDS) [5 min.]
	Council of Europe: Ingo Härtel (MoH Germany) [5 min.]
11:45	Discussion
12:30	LUNCH BREAK
Afternoon session ■ Chair: Xiaomei Zhai (Chinese Academy of Medical Sciences)	
14:00	**Research vs. surveillance and other public health practices: Definitions and respective ethical and procedural implications**
	Alex London (Carnegie Mellon University) [20 min.]
	Mark White (CDC) [10 min.]
14:30	Discussion

15:30	**REFRESHMENT BREAK**
16:00	**Special considerations for vulnerable groups**
	Isolation/quarantine: Jerome Singh (University of KwaZulu-Natal) [15 min.]
	Patients unable to consent: Anant Bhan (New Delhi) [15 min.]
	Migrants: Anita Davies (IOM) [15 min.]
16:45	Discussion
17:30	Adjourn
18:00	**Reception** at the "Red Ribbon Café", UNAIDS Building

THURSDAY, 11 JUNE 2009

Morning session ■ Chair: Ross Upshur (University of Toronto)

8:30	Synthesis of Day 1 (Carl Coleman, Seton Hall Law School/Voo Teck Chuan, National University Singapore)
9:00	**Issues related to biobanks and intellectual property**
	Collecting samples for biobanks: Diagnostic & Biosafety Group (WHO) [15 min.]
	Bernice Elger (University of Geneva) [15 min.]
	Anne Huvos (WHO) [15 min.]
9:45	Discussion
10.30	**REFRESHMENT BREAK**
11:00	**Risk-benefit analysis**
	Xiaomei Zhai (Chinese Academy of Medical Sciences) [15 min.]
	Marc Guerrier (Espace éthique) [15 min.]
	Samia Hurst (University of Geneva) [15 min.]
11:30	Discussion
12.30	**LUNCH BREAK**

Afternoon session ■ Chair: Jerome Singh (University of KwaZulu-Natal)

14:00	**Procedural issues regarding ethics review**
	Ross Upshur (University of Toronto) [20 min.]
	Joseph Ochieng (Makerere University) [15 min.]
14:45	Discussion
15:30	**REFRESHMENT BREAK**
16:00	**Synthesis of the meeting** (Carl Coleman)
16.30	Final discussion
17:30	**Conclusion of meeting**

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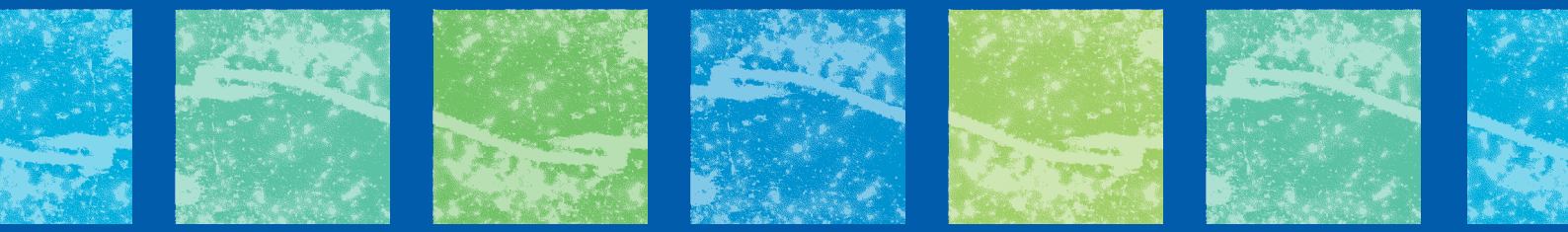

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