Chapter 7.4
Getting ethical approval for your research

Siu Kai Lo

Holly C.Y. Lam

Emily Y.Y. Chan

Learning objectives

To understand the following in relation to applying for ethical approval for a research study in health emergency disaster risk management (Health EDRM), with a focus on relevant WHO guidance:

- General processes involved in ethical approval of research projects.
- Types of documents that are usually needed for an ethics application.

Introduction (1)

Health EDRM research is important for investigating the effectiveness of:

- Prevention
- Preparedness
- Response
- Recovery

Research that involves human participants require ethics approval in order to ensure that the participants are **treated ethically**, **not taken advantage of**, and that the research procedure is carried out to **high ethical standards**.

Introduction (2)

- Researchers have a duty to promote and ensure respect for the participants in their research and protect their health and rights. Specific morals that need to be upheld include:
  - Respect for persons
  - Non-maleficence
  - Beneficence
  - Justice
  - Utility
- According to WHO, research involving humans should be reviewed by an ethics committee (with some exemptions), with approval obtained from a **recognized ethics committee** before it begins.

Where to request and obtain ethics approval (1)

A research ethics committee (**REC**) is responsible for:

- Ensuring the ethical safety and scientific merit of the research.
- Protecting the safety of potential research participants.
- Evaluating the potential harms and benefits for participants and the community.

Each REC may have its own standards, which is why researchers should check with the REC they intend to approach to identify the documents that will need to be submitted with their application.

Where to request and obtain ethics approval (2)

- RECs are usually based in regional or national public facilities or individual academic institutions.
- They usually consist of scientific members and non-scientific members to provide a comprehensive and quality ethical evaluation.
- Institutions might have their own committees, such as an **institutional review board (IRB)** or **University Human Research Ethics Committee (UHREC)** to allow them to evaluate research with local and familiar perspectives and to monitor the study more closely.

Example: in the United Kingdom, the Health Research Authority is responsible for the management and conduct of national-level research, including the REC process.

Research approval for studies beyond local regions

If the study will be conducted outside the researchers' local region, it is important to:

- Ensure that the proposed procedure is locally acceptable.
- Take account of local culture and tradition in the study design.
- Include input from local researchers, if possible.
- Obtain approval from both the regional authorities and the researchers' host institution.

What if no REC is available in the affected area?

Alternative actions are needed to obtain ethics approval if no REC is available in the affected region during a disaster:

Action	Limitation
Ask the relevant local authorities for agreement and obtain ethics approval from researchers' local region.	Approval might be biased to one or a small number of local authorities.
Ask the relevant local representatives or authorities to organize a review committee.	It takes time to organize a committee and the members might not have the necessary experience for review and decision.
Obtain ethics approval from an international organization (such as WHO).	Approval might not have considered local context.
Obtain approval from an established special review board.	It takes time to organize the committee and must be organized by a trusted organization.

Types of ethics review (1)

WHO uses five common types of ethics review for proposals:

- **Full committee review of proposals**: Research proposals that present more than minimal risk to human participants are reviewed by two REC members who present the proposal to the full REC, which then has a general discussion before reaching a consensus decision.
- **Expedited review of proposals**: Research procedures that present no more than a risk of minimal harm to the research participants or communities are reviewed by two REC members who are required to provide their feedback to the secretariat within 15 working days.

Types of ethics review (2)

- **Exemption from REC review:** Research procedures that present less than minimum risks to participants are exempt from review.
- **Accelerated review:** Research procedures may be submitted for accelerated review during public health emergencies.
- **Continuing review:** Ethics approvals are valid for a limited time period, so RECs review the progress of the study at periodic intervals. To renew the approval, researchers must submit the necessary documentation to the REC before their approval expires.

Definition of minimal risk

- There is no global consensus on minimal risk.
- For example, Australia, Canada, South Africa, the USA and the Council for International Organizations of Medical Sciences (CIOMS) have a standard for minimal risk which involves interpretations of 'everyday risks', 'routine examinations' and 'best interest' of the studied population.
- Researchers should check the minimal risk definition of the REC they are applying to before submitting their application for ethics approval.

Case study: *The value of an accelerated ethics review process*

- During the Ebola outbreak in 2014-2016, the WHO was responsible for reviewing and discussing ethics for various interventional and observational studies to control the outbreak.
- The WHO REC established a subcommittee to conduct accelerated reviews to facilitate this process.
- This was the first time that the accelerated review was put into practice.
- The subcommittee reviewed 24 new and 22 amended applications, with an average reviewing time of 6 working days.

Documents: the research protocol (1)

The research protocol is the core document of the ethics application. The WHO recommends that the research protocol should include the following:

- **Project summary**: rationale, objectives, methods, participants, time frame and expected outcomes.
- **General information**: protocol title, investigators, sponsors and the locations and institutions where the research will be done.
- **Rationale and background information**: current knowledge about the research topic and intervention, the need for the research to be conducted, and other basic information.

Documents: the research protocol (2)

- **Study goal and objective**: intended outcomes and aims (see also *Chapter 3.5*).
- **Study design**: type of study, target population, recruitment methods, research or diagnostic tools, duration of the study and eligibility criteria.
- **Methodology**: information about the research procedure, how the research will be conducted and how participant confidentiality will be ensured.
- **Safety consideration**: the safety of participants will be ensured.
- **Follow-up**: follow-up activities, and their duration for participants.

Documents: the research protocol (3)

- **Data management and statistical analysis:** how the data collected will be processed, stored and analysed.
- **Quality assurance:** quality control and quality assurance system for the research.
- **Expected outcome of the study**: how the study results might contribute to the advancement of knowledge.
- **Dissemination of results and publication policy:** information on the method, policy and responsible personnel and target audience.
- **Duration**: detailed timeline of the project (usually, in months).

Documents: the research protocol (4)

- **Anticipated challenges:** foreseeable problems and possible solutions.
- **Project management:** roles and responsibilities of each member of the research team.
- **Ethics:** ethical considerations and how informed consent will be obtained.
- **Conflict of interest:** any interests that the researchers have which are related to the study or its results and might be regarded as a conflict.
- **Budget and other financial support**
- **References**

Ethics application: What else to include (1)

- **Participant information leaflet:** document given to potential participants that provides information on the study.
- **Informed consent forms:** used for recruiting potential participants to the research study and obtaining their agreement before they enter the study, receive the intervention or provide data.
- **Any associated study instruments:** such as questionnaires, interview guides, focus group discussion guides or other documents related to the research (e.g. case report forms or patient diaries, if applicable).

Ethics application: What else to include (2)

- Final approval document by other scientific/technical review committees or peer reviewers, if applicable.
- Principal investigator's response to any previous review.
- Comments made by the other scientific peer review groups (if the protocol has been reviewed by another REC or other committee).
- Information about the researchers, including their CVs.

Approval process

When the application has been reviewed, the REC will make a decision regarding its status and use one of four classifications to indicate its status:

- Approved as submitted.
- Approved conditionally; requires amendments or clarifications.
- Not approved; requires additional information or rewriting.
- Rejected.

The REC might also have questions and comments about the research protocol and ask the researchers to submit a revised protocol, which answers the questions and shows any changes.

Other communications with the REC (1)

- **Progress report:** a progress report might be required by the REC on a periodic basis, usually annually.
- **Application for continuing review:** a renewal application is required if a study needs continuing review.
- **Application for amendment:** if the originally submitted documents and study protocol are amended after approval, the researchers should notify the REC about these amendments.
- **Protocol deviation:** any protocol deviation made during the research should be reported to the REC.

Other communications with the REC (2)

- **Adverse events and serious adverse events:** any adverse events or serious adverse events should be reported according to the requirements of the REC.
- **Project closure:** when the study is successfully completed or terminates early, the REC should be informed and provided with a completed set of documents .

Conclusions

- Research ethics applications and approvals are important and necessary before research involving human participants.
- There is no single, globally agreed standard or requirement that applies to all RECs.
- Researchers should always check the specific requirements of the REC they are applying to before submitting their application.

Key messages (1)

- All research studies involving human participants should be reviewed and approved by a research ethics committee, which would also decide if a study should be exempted from the full review process.
- Research should be conducted in ways that protect the safety and confidentiality of the participants, both physically and mentally and be carried out in accordance with the principles underpinning the Declaration of Helsinki.

Key messages (2)

- The type of ethics review required depends on the nature and the urgency of the study.
- Current ethics review procedures might not be fully applicable to the challenges encountered in the Health EDRM context, especially during rapid onset emergencies and disasters because of the relatively long lead time of non-emergency ethics review processes. Changes in the ethics review procedure are needed to accommodate the special needs for emergency researches.

Key messages (3)

- Ethics application requirements vary across different REC and different settings.
- Researchers should check the requirements of the REC they will submit their application to before doing so.

Further readings

Council for International Organizations of Medical Sciences and WHO. International ethical guidelines for biomedical research involving human subjects, 2002.

Document offering ethical guidelines to countries seeking to define their human research policies.

Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2), 2016.

Unified GCP standard for the European Union, Japan, and the USA, established by the ICH.

Panel on research ethics. The Tri-Council Policy Statement 2: Course on Research Ethics. Ottawa, Canada: Government of Canada.

Online resource on the Tri-Council Policy Statement (TCPS).

Wellcome Trust, Policy on research involving human participants.

Website outlining the human research policy of the Wellcome Trust.

World Medical Association Declaration of Helsinki - Ethical principles for medical research involving human subjects, 2013.

Key set of ethical principles on human research.

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Contact information

Professor Emily Ying Yang Chan
Professor and Assistant Dean, Faculty of Medicine, The Chinese University of Hong Kong
Shatin, Hong Kong SAR, China
Email: emily.chan@cuhk.edu.hk

Health EDRM Research Network Secretariat
WHO Centre for Health Development (WHO Kobe Centre)
Email: wkc_tprn@who.int