UiO S Global He

The aim of this free 8-week online training is to provide relevant knowledge, necessary skills, and procedures for evaluating and conducting biomedical and health related research in different contexts. It also provide the necessary tools for ethical deliberation. In addition, the aim is to promote ethical attitudes required for a better understanding of the main ethical challenges within medical and health-related research ethics and research integrity, and to sensitize participants in regard to the relation between global ethical problems in research, your own context, and cultural reality.

Course description

Why research ethics?

Centre for Medical Ethics University of Oslo

Research ethics and research integrity are highly relevant issues for global health care and global justice, not the least in low- and middle- income countries. The risk of unethical practices or exploitative procedures should be evaluated by independent research ethics committees and be avoided by local researchers as well as researchers from the affluent north.

This training provides the basic tools for members of research ethics committees and health care professionals in charge of evaluating or conducting biomedical and health related research in different contexts.

Today we are living a particularly complex period after a global pandemic that has profoundly impacted the life and health of our communities. It requires urgently quality research; both clinical research and vaccine research. This emergency occurred in a global context characterized by an exponential growth in biomedical research in low- and middle-income countries. This increase is due to varied reasons such as lower costs for the pharmaceutical industry, more flexible or non-existent regulations and little training of research ethics committees.

In this way, it is urgent to train those who will have the key role in the process of ethical evaluation of health research or will conduct it, as well as those who will participate in the design of local or national regulations in the field. This course will offer a research ethics and human rights framework concerned with the defense of the dignity, safety, and well-being of research participants.

We strongly believe that the aim of medical and health-related research should be the alleviation of suffering, the restoration of health and the promotion of human wellbeing. The means that

are carried out to achieve these objectives must always be respectful of the human rights of the people who participate.

During these eight weeks we hope to be able to provide you with the knowledge and skills necessary to face these challenging tasks and carry out a clear and effective transformative intervention in the ambience in which each of you operate. That will be our responsibility, although the most challenging task will come; i.e to apply the knowledge in your own contexts.

Important dates

Announcement	May 12, 2023
Application deadline (no participation fee)	August 4, 2023
Notification of selected applicants	August 18, 2023
Deadline to accept	August 25, 2023
Course start date	September 6, 2023
Course end date	November 3, 2023
Close	November 11, 2023

Workload:

Weeks 1-7: 6 hours per week (42 hours in total)

Week 8 (final week): 18 hours for elaboration of the final project

Total hours: 60

Who is it for:

- Members of research ethics committees (including community members)
- Young researchers in the field of health-related research and biomedical research
- Teachers of bioethics, ethics of science and research ethics
- Representatives of patient participants in biomedical research projects and members of Patient NGOs
- Employees of regulatory agencies in charge of health research evaluation or research registration

Participation fee:

No participation fee!

Learning objectives

General learning objectives

- provide the conceptual basis and promote the necessary skills for a good evaluation of health research projects, with particular attention to the wellbeing, security and respect for dignity of the participants
- promote a good understanding of the ethical challengess related to research ethics from a critical perspective
- provide relevant knowledge and specific skills for evaluating and conducting health research projects
- promote and sensitize related moral attitudes

Specific learning objectives

- familiarity with central events and factors that led to the development of medical and health care research ethics
- know the core ethical principles and norms guiding medical and health related research
- know the main international guidelines and declarations pertaining to medical and health related research
- be able to interpret and apply these principles in local research contexts
- know the responsibility of a researcher when involving human subjects
- be attentive to how to include vulnerable groups in research
- understand ways to protect human participants during the implementation of a study
- familiarity with the pitfalls of scientific misconduct and ways to avoid such conduct
- know what is needed to gain approval from a research ethics committee
- know the working procedures of a well-functioning research ethics committee when reviewing research protocols.
- familiarity with the methods and procedures of a well-functioning research ethics committee involved in policymaking
- familiarity with methods and procedures of a well-functioning research ethics committee involved in promoting public awareness and debate

Attitudinal objectives

• stimulate the development of attitudes of inquiry, dialogue, and critical reflection, as well as tolerance, respect for cultural differences, plurality of ideas and of moralities

Structure and contents

The course will have four modules:

Module 0 is an introduction to the tools of the virtual education modality.

Module I of this training provides an introduction into the history and development of medical and health-related research ethics, its core principles, and the application of these principles in poor and low-income countries. It discusses controversies pertaining to the maintenance of universal ethical standards in such settings, respect for human rights, justice, exploitation and how to provide safeguards for patients and informants.

Module II addresses challenges pertaining to establishing well-functioning research ethics committees, the working procedures of such committees, as well as their role in policymaking and in promoting public debate.

Module III includes the final project elaboration and evaluation. Participants must elaborate a final project within one of the following areas:

- Ethics teaching,
- capacity building, or
- normative frameworks for their institutions or field of work.

The training takes place in our e-learning platform, and it is a purely virtual experience, providing large flexibility to participants – when it comes to when and how to conduct their training. During the eight weeks there are only two synchronous sessions where participants are required to attend live, while the live lecture every Monday will be recorded, thus synchronous participation is not strictly required.

Educative Modality

The didactic approach as well as the technical support (virtual education methodology) are related to the objectives of the course.

Virtual education (e-learning) represents an educative methodology that has transformed the whole way in which schools and universities are following the process of teaching and learning. This is not only about including new technologies but a new logic in the way in which the educative process is understood and organized. In fact, virtual education is a new approach, a new way to be and know, that requires open-mindedness from participants as well as from teachers. Virtual education is interactive, dynamic, autonomous, and flexible in several ways, not only because it is mediated by technology, but because the teaching and learning process is understood in a double way; from teachers to participants and from participants to teachers.

What is different?

We will work from a *pedagogy of problematization*. In this education-action model, the teachinglearning process cannot be separated from the reality in which the ethical problems are identified and to which it is returned with a proposed intervention or solution. In this way, respect for cultural diversity and inter- trans-cultural approaches are fundamental. This breaks with the traditional model of an asymmetric education from "top down" and promotes a horizontal and strongly dialogical interaction that expresses a true space of exchange between values, cultural traditions, historical processes, and different forms of knowledge.

In this way our educative proposal will consider the complexity of times and the real situation of life and global health, which is crossed by social, economic, political, environmental, historical, and cultural determinants. This perspective is rooted in the human rights approach and considers gender perspective as a cross-cutting issue.

Evaluation

What do you need to do to have the course approved?

- Participate at least once in each forum of deliberation (the quality of your intervention will be considered by the facilitator).
- Participate in at least one of the plenary sessions and upload your self-evaluation form.
- Download the 7 cases with the assignments and solve them (self evaluation)
- Present and have the final project approved

Final project

The final evaluation will be done through the elaboration of a final group project (no more than 4 participants in each group).

The final project is not a monographic work, but a proposal of practical intervention for developing activities oriented to solve a real problem within the context of the participants. It has to be developed within one of the following fields:

- Ethics teaching in research ethics or bioethics, (courses, trainings, etc.)
- Capacity building (ethics or bioethics committees, advisory committees, institutional committees, ethics institutions, etc.)

• Normative frameworks (any regulation or normative framework, at different levels; hospitals, universities, educative institutions, NGO, etc, (eg. A normative framework for implementing informed consent in biomedical research for REC or for researchers)

Evaluation of the final project

- Quality of the diagnosis of situation and justification of the proposal
- Coherence and relevance of the proposal
- Understanding and interpretation of the theoretical framework and its application
- Possibilities to be realized
- Evaluation criteria applied to the project

Virtual classroom and technical requirements

The virtual classroom is organized in different sections, with detailed information about the course (presentation, program, schedule, modality, presentation of the work team, technical requirements, etc.).

Forums: Three foras: *a Forum of deliberation* (one per week), *a Forum of consultation*, and third, *a Social or play time forum* to strengthen the social ties of the group.

The Forum of deliberation is the core of the pedagogical model, which starts by triggering questions, and continues with the facilitator moderating the comments, interactions and opinions of the participants.

Lectures: Each week will have two lectures; both recorded so participants can watch the video at any moment. Some weeks the first lecture will be synchronous, so as to allow participants to make questions after the lecture.

Plenary sessions: Two plenary sessions will take place after Module 1 and Module 2. They are related to the assignments included in the two modules and aim at creating a deliberative space. A final plenary presentation follows the group discussions in the plenary sessions. These sessions are the only synchronous events.

General library: Includes mandatory readings and optional materials: papers, journals, declaration and guidelines, and other relevant resources.

Media Tech: Accompanies the entire proposal with a careful selection of different media resources. This includes videos on specific topics, (not included in the program), podcasts, and other resources.

Art Gallery: A space to use artistic resources to stimulate reflection and promote ethical awareness.

Messaging, news and chat service: These are other means of communication that will be used.

Technical requirements

Browser:

- Chrome
- Internet Explorer 8
- Firefox 3.5 or later

The browser must have enabled the execution of dynamic content on the educational platform pages (Javascript, Java, ActiveX, Flash), as well as the opening of pop-up windows (-popups-).

Media player:

- VideoLAN VLC Media Player 0.8 or later
- Windows Media Player 9.0 or later
- Adobe Reader 9
- Adobe Flash Player 8 or higher

Hardware:

- Microprocessor, RAM and hard disk adequate for the acceptable performance of the operating system and installed software.
- Audio card for the reproduction of multimedia contents with audio, with speakers or headphones.
- Monitor and video card with 1024x768 or higher.

Connectivity:

Broadband Internet connection.

Application form

Who will accompany you in this course?

Academic coordinator:

Professor Jan Helge Solbakk

Facilitators:

- Professor Jan Helge Solbakk
- Professor Rose Bernabe
- MA Susana M. Vidal

Coordinator of the virtual modality and pedagogic approach:

• MA Susana M. Vidal

Technical coordinator of the virtual modality and Webmaster:

Candelaria Arrieta

Design, Sound and video producer:

Augustin Druetta

Administrative support:

Candelaria Arrieta

Collaborations

This Research Ethics Training is coordinated by <u>Centre for Medical Ethics</u> and the <u>Centre for</u> <u>Global Health</u>, Institute of Health and Society, University of Oslo.

Questions? Please contact administrative coordinator Candelaria Arrieta