

ESTABLISHING A MASTER PROGRAM IN RESEARCH ETHICS AND METHODOLOGY IN CLUJ-NAPOCA, ROMANIA

An interview with Dr Horațiu Colosi, Associate Professor at the Iuliu Hațieganu University of Medicine and Pharmacy, Cluj-Napoca, Romania, Director and Principal Investigator of the program

Question 1: *“Next year, in 2020, a new master program will start in Cluj-Napoca, within the Iuliu Hațieganu University of Medicine and Pharmacy. What is this new program about?”*

The new program builds upon a previous master program in Medical Research Methodology, by significantly broadening its scope and curriculum to include Clinical and Research Ethics in Medicine.

The new and improved two-years curriculum has been developed together with faculty from the Icahn School of Medicine at Mount Sinai Hospitals in New York (ISMMS), as part of a research and development grant awarded by the Fogarty Foundation of the U.S. National Institutes of Health (NIH).

Throughout the project, ISMMS faculty will provide mentoring and support to assure sustainability of the program by ongoing activities to foster a collaborative community of bioethicists, researchers and healthcare professionals from Romania, Europe and the USA.

Question 2: *„What is the aim of the new master program?”*

The new training program will prepare its graduates to conduct ethically and methodologically sound research projects, to participate in the review of research projects, to participate in ethically sound clinical decision-making, to train others and to promote the development of clinical and research ethics infrastructure and policy in Romania and its surrounding region.

Question 3: *“Who can apply for this program?”*

We welcome applications from graduates of medical schools, including all specialties (e.g. general, dental and veterinary medicine, pharmacy, nursing, physiotherapy, etc.), graduates in biology, chemistry, law and philosophy, with an interest in bioethics, clinical ethics and medical research.

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Each academic year, until 2023, there will be 5 stipends that will be awarded to cover the costs of tuition fees for graduate students who are not eligible for state-budgeted places in master's degree programs (e.g. graduates of undergraduate programs with a duration of 5 or 6 years). We also encourage students from disadvantaged socioeconomic backgrounds to apply for this master program and the before mentioned stipends.

Question 4: *"Which are the main topics of the program?"*

The program will cover topics like:

- History of Medical Research
- Research Methods in Fundamental Science
- Clinical Research Methods
- Dissemination of Medical Information
- Responsible Conduct of Research
- Legal Issues in Medical Research
- Legal Issues in Medical Practice
- Basic Concepts in Research Ethics (Equipoise, Clinical Equipoise, and Placebo-Controlled Trials, Informed Consent, the Therapeutic Misconception, and Variable Consent, Confidentiality and Privacy in Clinical Research, Concepts of good clinical practice in pharmaceutical research)
- Basic Concepts in Medical Ethics (The Virtues of a Clinician, The Fiduciary Responsibility and Personal Objections of Clinicians, Concepts of good clinical practice, Respect for Autonomy and Assessing Capacity, Non-judgmental regard, Truth-telling and Informed Consent, Confidentiality, Clinical Justice (Allocation of Benefits Among Individuals and Communities))
- Ethics in International Public Health Research and Practice
- Research with Vulnerable Groups
- Advanced Topics in Clinical and Research Ethics (Reproductive ethics, Organ transplantation issues, End-of-life issues, Advanced directives for treatment and refusal, Decisions for patients without Surrogates, Vaccine Development and Research, Use of human samples and genetic data for research, Incidental Findings and Returning Study Results, Translational Comparative Effectiveness Research, Embryo and Stem Cells Research)
- Ethical Issues in Research on Animal Models
- Teaching Clinical and Research Ethics
- Applied Bioethics and Professionalism

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Question 5: *“In your opinion, why is such a program necessary in Romania?”*

A growing number of domestic and international pharmaceutical companies have been applying to conduct clinical trials in Romania while the country is in the process of reinforcing its rules for the conduct of animal and human research so as to conform more closely to European Union standards. At the same time, few individuals in Romania who serve on clinical and research review boards have formal training in clinical ethics and research ethics. Yet, it is critically important for reviewers and investigators to appreciate and respond to the developing multifaceted and subtle issues involved in both clinical practice and in the conduct of today’s biomedical research and the evolving rules for the ethical conduct of research.

Thus, Romania needs to increase its capacity of educated professionals with expertise in clinical and research ethics. This program is designed to equip scientists, health professionals, research reviewers, and academics in Romania with in-depth knowledge of ethical principles, processes, and policies related to international, clinical and public health research, and to strengthen the capacity of healthcare and medical research institutions in the region for providing research ethics education, ethics consultation, and research review at their institutions.