



The Bioethics Program

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Union Graduate College
Mount Sinai School of Medicine

VILNIUS, LITHUANIA

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Research Ethics Network in CEE | Newsletter #7

Dear Colleagues,

Welcome to the seventh edition of our Network Newsletter!

Sincerely,
Vilnius Team

Upcoming research visits

Recently, research visit program was initiated, aimed at bringing Program alumni to Vilnius to work on topics in Research Ethics.

The following research visits are planned in early 2016 (all dealing with issues in developing research ethics infrastructure in the applicant's countries):



Andrei Famenka (Belarus). Does research ethics receive appropriate political attention in Post-Communist societies? Examining the state of political priority for research ethics in Belarus and Lithuania.

Marina Topuridze and **Ketevan Shermadini** (Georgia) Effective IRB/Rec systems and research ethics policy development strategies

Sergiy Pakharyna (Ukraine) Study of Key Management Principles of Bioethics Committees System in Lithuania



Revision of CIOMS guidelines

The Council for International Organizations of Medical Sciences (CIOMS) is conducting a substantial revision of the Ethical Guidelines for Biomedical Research Involving Human Subjects. A working group has been established and it has developed a draft of the revised guidelines. This draft is now open for comments until March 1, 2016.

You are invited to discuss selected guidelines (Guidelines 2, 3, and 8) on our Network Facebook Page.

If our discussions will result in valuable comments, we should consider submitting them to CIOMS for consideration.

Conference section

In November 2015, two program fellows—S. Rasputniak and V. Dobrova—organized and hosted a special session on ethical issues in clinical drug trials in Clinical trials of medicines in Ukraine – 2015 conference in Kiev, Ukraine (19–20 November, 2015).



New paper on Research Ethics in Belarus, Latvia, Lithuania, and Poland

Research Ethics in the Context of Transition: Gaps in Policies and Programs on the Protection of Research Participants in the Selected Countries of Central and Eastern Europe
Andrei Famenka
Science and Engineering Ethics

Abstract

This paper examines the ability of countries in Central and Eastern Europe (CEE) to ensure appropriate protection of research participants in the field of increasingly globalizing

biomedical research. By applying an analytical framework for identifying gaps in policies and programs for human subjects protection to four countries of CEE—Belarus, Latvia, Lithuania, and Poland, substantial gaps in the scope and content of relevant policies and major impediments to program performance have been revealed. In these countries, public policies on the protection of research participants lack consistency and reliable mechanisms for their implementation.

Impediments to program performance most often relate to inadequacies in the national research ethics systems with regard to organizational structure, budgetary support, supervision, and training. The level of research ethics capacity varies from country to country and depends on socio-economic and political factors of post-communist transition. The breadth and depth of the problems identified suggest that the current level of protection for research participants in CEE might be inadequate to the challenges posed by the globalization of biomedical research. In CEE countries, there is a need for strengthening research ethics capacity through modification of relevant policies and improvement of program management. The differences among the countries call for further research on identifying the best approaches for filling the gaps in the policies and programs aimed at ensuring effective protection of research participants.

REMEDY, Research Ethics in Medicine Study Group

Program alumni Marcin Waligora, Joanna Rozynska, and Vilius Dranseika have established a team of researchers dealing with the ethical aspects of conducting research with human participants. You can read more about their activities on the group's website.

As always, we hope you enjoyed this update. You are encouraged to share information on your recent publications and any other accomplishments, as well as any other news that could be interesting and/or useful to Network members. One way to do this is via our Network Facebook Page.

Please also send your news to Vilius Dranseika, vilius.dranseika@fsf.vu.lt

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