

Research Ethics Network in CEE | Newsletter #1



Dear Fellows, Alumni, Faculty, and
Friends,

Happy Holidays and Best Wishes for
2013.

Eugenjus Getenas
Sean Philpott
Martin Strosberg

Dear Colleagues,

This is the first newsletter of our Network. Its purpose is to distribute information on CEE Advanced Certificate Program news, fellows' and alumni recent accomplishments, including publications, career developments and research projects, as well as Research Ethics events, funding opportunities, and any other issues related to Network activities and Research Ethics in CEE more generally.

I'd like to distribute new issues every half a year, depending on how much is going on. Therefore I'd like to invite you to share information on your recent accomplishments and any other news that could be interesting and/or useful to Network members. I am sure that there's much more happening than I am aware of. You are kindly invited to join this effort to maintain and strengthen links between Network members and build a sense of community.

Your feedback regarding the newsletter will also be appreciated. Please say what you like, what you don't and what you might like to see added. I will try to make adjustments, where possible, based on your suggestions.

Sincerely,

Vilius Dranseika
Network Coordinator,

Fellow/Alumni News



'Failures in Clinical Trials in the European Union: Lessons from the Polish Experience' by Program alumnus Marcin Waligora was recently published in *Science and Engineering Ethics* as OnlineFirst. It is a useful addition to a series of in-depth country overviews recently published by other Program fellows.

Abstract:

When discussing the safety of research subjects, including their exploitation and vulnerability as well as failures in clinical research, recent commentators have focused mostly on countries with low or middle-income economies. High-income countries are seen as relatively safe and well-regulated. This article presents irregularities in clinical trials in an EU member

state, Poland, which were revealed by the Supreme Audit Office of Poland (the NIK). Despite adopting many European Union regulations, including European Commission directives concerning Good Clinical Practice, these irregularities occurred. Causes as well as potential solutions to make clinical trials more ethical and safer are discussed.

And here's a link to a blog post about Marcin's paper by Amal Matar (whom we had a chance to meet in Prague).

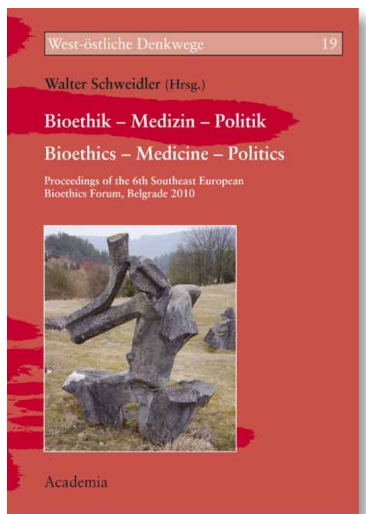
Analysis and critical review of the development of bioethics in Belarus by Yuliya A. Vishneuskaya is another recent addition to the literature on the region. The paper is published in *Medicine, Health Care and Philosophy*.

Abstract:

The main trends of the bioethics development in Belarus have been analyzed on the basis of the materials collected by the Ethics Documentation Center (ISEU, Minsk, Belarus). A critical review of the most important publications in the field since 2000 suggests that development of bioethics in Belarus has occurred in two parallel directions distantly connected to each other: a theoretical direction and a practical one. [...].



A paper by Marija Todorovska was published in a volume of conference proceedings:



Marija Todorovska, “Public Health Issues and Perspectives – Between Science, Politics and Bioethics”, Walter Schweidler (Ed.): *Bioethics - Medicine - Politics. Proceedings of the 6th Southeast European Bioethics Forum*, Belgrade 2010, Academia, Sankt Augustin, 2012, pp 31-44.

[More information](#)

Recent collection *Human Medical Research. Ethical, Legal and Socio-Cultural Aspects* includes two chapters by Program alumni. Research Involving Human Subjects and Human Biological Material from a European Patent Law Perspective. Autonomy, Commodification, Patentability by Tomasz Zimny and Rethinking the Ethics of Human Biomedical Non-Interventional Research by Kristi Lõuk.



And some news on career development. Cohort 3 alumna Alma Linkeviciute is starting PhD in Foundations Of the Life Sciences And Their Ethical Consequences with University of Milan and European School of Molecular Medicine in Italy.

Research on structure and functioning of RECs

During past several years program fellows and alumni have published several studies on structure and functioning of ethical review systems in countries of the region. This is a very important development since quality information on the region was almost unavailable just a few years ago and in many respects it is still very scarce now. The series of papers began with a paper by Vents Silis (2010) on the situation in Latvia and two collaborative studies (both papers were authored by Gefenas, Dranseika, Cekanaukaite, Hug, Mezinska, Peicius, Silis, Soosaar, and Strosberg) on all three of the Baltic States (Gefenas et al. 2010 and Dranseika et al. 2011). Shortly, Andrei Famenka (2011) published a study on Belarus and Marcin Waligora (2012) - on Poland. Currently new studies are underway on Moldova and Georgia.

We'd like to encourage Network members to join this effort. Some countries are still not covered at all and even where some publications already exist there's usually space for more detailed and nuanced analysis.

Ethics Teacher Training Course in Vilnius

In November 2012 a number of Program alumni and fellows from Russia, Belarus, Latvia, and Lithuania have attended a course in Vilnius.

Organized by the Bioethics Programme at UNESCO Headquarters in Paris, in partnership with the Vilnius University, this Ethics Teacher Training Course offered an opportunity for participants from all over the world, but especially from Lithuania and other countries in the region, to engage in one-week long training designed to enhance their teaching capacities in ethics.



The course also included a presentation of our Program.

[Additional information.](#)

Regulatory changes

European Network of Research Ethics Committees (EUREC) recently formulated an opinion on the new proposal for a European regulation on clinical trials. The new regulation is expected to replace current Clinical Trials Directive (2001/20/EC).

This new development may change the whole model of ethical review in Europe as it introduces a new authorisation procedure for clinical trials that leaves it to each Member State to define the organisational setup and internal competences for assessing clinical trial authorisations. Concerns are that this new Regulation will lessen the role of RECs. As indicated in the opinion:

'EUREC believes that the choice of the Commission to undo the positive steps established through the current Directive by omitting the clear position of Research Ethics Committees (RECs) in the process is not acceptable.'

You can find more comments on the nature of the proposal in a brief note by Marcin Waligora [A European consistency for functioning of RECs? We just lost our chance forthcoming in JME.](#)

Translation of study materials

One of the aims of the Program is to contribute to the development of publicly available Research Ethics study and teaching materials in national languages of the CEE countries. An effort was initiated to translate materials developed by the Program as well as the [European Textbook on Ethics in Research](#) into several languages: Russian, Romanian, Moldovan, Georgian, Lithuanian, Serbian, and Croatian.

Some of the translated materials are already available for download. You can find them on the

Program's website. Others will follow shortly.

In addition to translation of study materials, new online courses are being constructed and taught by the Program fellows. Goran Mijaljica is leading the effort to offer a course in four countries of Croatia, Serbia, Bosnia and Herzegovina, and Montenegro. Rodica Gramma and Adriana Paladi have constructed and taught an online course in Moldova. Yuliya A. Vishneuskaya and Andrei Famenka are getting ready to teach a course in Belarus. These courses are also expected to be made publicly available for download.

If you have any study materials in your national language and you are in a position to share them and make them publicly available, please let me know.

Presentations from Prague

During our Network Meeting in Prague presentations were made by just about everyone in the Network. For the time being presentation files are available for download from [this online folder](#) (accessible only to those in possession of this link).

The folder also includes a zip archive of all the presentation files (Archive.zip, 50 MB).

Photos from Prague



Meeting participants



Bottom row: Eugenijus Gefenas, Vilius Dranseika, Sholpan Primbetova.

Middle row: Barbara Sina, Andres Soosaar, Rodica Gramma, Leyla Akhmadeeva, Martin Strosberg.

Top row: Vents Silis, Tomasz Zimny, Daniela Cutas, Marija Todorovska, Weronika Chanska, Joanna Rozynska, Signe Mezinska, Roman Belyaletdinov, Aleksei Trubetckov, Svitrigaile Grinceviciene.



Elena Grebenshchikova and Barbara Sina



Filip Krepelka



Marcin Waligora, Marty Strosberg, and Joanna Rozynska



Jelena Dobricic



Renata Veselska and Marty Strosberg



Joanna Rozynska, Ketevan Shermadini, Stetana Moisa, and Marina Topuridze



On a boat in Frague



Leyla Akhmadeeva's mother, Leyla Akhmadeeva, Henry Silverman, Amal Matar, Alexei Trubetckov, Roman Belyaletdinov, Elena Grebenshchikova, Andrei Famenka



Joanna Rozynska, Tomasz Zimny, Vilius Dranseika, Vents Silis, Katarina Zejic



Prague gardens



Katarina Zejjic, Ksenia Eritsyan, Jelena Dobricic, Sholpan Frimbetova



At the brewery

Do you have photos with more/other participants? You're invited to share them.

Network website?

Another thing we've been discussing during our Network meeting in July was the idea to have an interactive website of our Network.

Perhaps, something akin to the one hosted by [The Middle East Research Ethics Training Initiative \(MERETI\)](#), which is another Fogarty International Program.

We'd like to ask you to go to the [MERETI site](#), take a tour, and let us know how useful it would be and how likely you would ever use it.

Please, complete the following anonymous survey. Once you have familiarized yourself with the MERETI website, the survey should not take more than five or seven minutes. We would appreciate to have your responses as soon as possible but no later than the 1st of January 2013. Thank you!

[Click here to take survey.](#)

I hope you have enjoyed this update. Please send your news to:

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