

**RESEARCH ETHICS TRAINING AS AN ESSENTIAL CONDITION CONTRIBUTING
TO SCIENTIFIC INTEGRITY: THE BEST INTERNATIONAL PRACTICES
AND THE PERSPECTIVES FOR DEVELOPMENT IN UKRAINE**

Dobrova V. Ye., Ratushna K. L.

National University of Pharmacy, Kharkiv, Ukraine

Department of Clinical Pharmacology and Clinical Pharmacy

pharmaxena@gmail.com

Conducting research projects require consideration of a range of important and complex aspects that need to be addressed in order to achieve defined tasks as well as obtain quality results which could be successfully recognized at the international level. One of these aspects is compliance with fundamental principles of research ethics (RE) that defines the level of academic honesty and qualification of investigators as well as strengthens the trust of society to research enterprise. The increasing need for research ethics expertise in Ukraine stems from the growth of the health research conducted by international biopharmaceutical companies, the rising number of human subjects involved and transitional processes taking place in social and economic life as well as healthcare field [1]. The evolving research and healthcare landscapes require strengthening of RE capacity that will provide a more in-depth ethical review of studies, assuring appropriate protection of study subjects and meeting the international quality and ethical standards of human research. According to the National Bioethics Advisory Commission, the introduction of training programs that encompass responsibilities of all stakeholders underlies the framework of RE oversight and provides the necessary protection of human subjects [2]. Thus, enhancing RE training becomes an essential part of national research practices advancement.

An invaluable contribution to the development of educational programs in RE has been made by NIH's Fogarty International Center which has been provided grants for trainees from low- and middle-income countries including Ukraine since 2000 [4]. Some of the trainees were selected to complete Masters of Science in Bioethics through the Bioethics Program of Clarkson University and the Icahn School of Medicine at Mount Sinai. This program covers six online courses and one intensive onsite practicum at Mount Sinai in New York City. In 2016 the first trainee from Ukraine was awarded a scholarship for completing this Program. The components of the Program aimed at developing knowledge and skills in the various domains of bioethics including public health ethics, principles and issues of biomedical ethics, RE review, organization and administration of IRBs, conducting the meetings and effective communication. Important to mention that the diversity of learning activities (discussion forums, essays, participation in mock IRB meetings, writing grant proposals and research projects, active involvement of the students, etc) significantly promoted the learning of trainees that are mostly intensively engaged in their professional field as well as encouraged them to implement acquired knowledge and skills at their institutions in the process of the study.

The onsite Practicum of the Program which took place at the Icahn School of Medicine at Mount Sinai (New York, NY) in June 2019 was intended to improve practical skills in RE through the face-to-face course. According to the learning objectives, the trainees were expected to advance their expertise in research review and oversight, to show skillfulness in management and organization as well as to enhance their experience in research, writing and bioethical training. The subjects covered by the Research Ethics Onsite Practicum reflected various facets of RE theory and practice. The faculty provided excellent lectures and discussions on such bioethical issues as involvement of vulnerable populations in research, managing conflict of interests, the problem of distinguishing

research from practice, administration of IRBs, the use of controlled substances in research, providing research subjects advocacy, biobanking ethical issues, the use of exemption from informed consent. The interactive learning activities included tours and observation of some Icahn School of Medicine facilities, role-playing exercises, engaging in discussion and intensive training of communication skills. The latter is an essential competence for any specialist involved in human research and contacting with a study participant, especially during the informed consent process. The trainees had the extraordinary opportunity to improve their interpersonal and communication skills exercising the obtaining informed consent in Morchand Center at the Icahn School of Medicine at Mount Sinai. This exercise provided a conducive learning environment where trainees could practice the interaction with a “standardized patient” and the further evaluation of encounter by the faculty. To sum up, the Research Ethics Onsite Practicum of the Bioethics Program gave invaluable experience in RE training as it combined excellent content, clear structure and effective timing assuring achievement of learning goals thus enabling trainees to translate acquired knowledge and experience to their countries and contribute to the RE capacity building [1, 4].

The initiation of the training programs in RE using the best international practices provided by the Fogarty International Bioethics Training will significantly strengthen the ethics of biomedical research in Ukraine. These programs should respond to the specific needs of human research in biomedical field as current shortcomings in conducting responsible research, research subjects advocacy and gaps of RE review in Ukraine. It is important also to institute educational opportunities that address targeted groups of professionals (investigators, policymakers, research coordinators, REC members) providing them with knowledge and skills which are relevant to the scope of their interests, responsibilities and functions performed in research enterprise [3-5]. Thus, the design of training curricula and learning activities requires a great individual and institutional commitment in order to cover the most relevant components and utilize effective pedagogical approaches. Such approaches might include distance learning, andragogy principles like the active engagement of learners to the development of content, resources and evaluation of their own learning, interactive and various practical exercises (group work, case studies, discussion forums, etc). We believe that enhancing RE training will improve the quality of human research at the national level, facilitate the cooperation of educators and professionals involved in the biomedical research field as well as encourage learners to make substantial changes building sustainable RE capacity.

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