

Ethics Committees: Some Experiences Around the World

Research Ethics in Russia

BORIS YUDIN*

During last Soviet decades medical ethics in the USSR was developing mainly in forms of medical deontology; problems of research ethics had attracted little if any attention. For instance, two-volume edition *Deontology in medicine*,¹ which can be considered as the most comprehensive summary of the Soviet deontology, includes only scarce remarks on problems of experiments with humans. It does contain chapter "Deontology in experimental medicine" (Vol. 1, p. 295-318); this chapter, however, deals only with animal experimentation. At the same time, there was no any public interest in ethical issues of human experimentation.

It is worth to note in this connection that one hundred years ago, in 1901, Russian physician and novelist V. Veresaev (1867-1945) published the first edition of his "Physician's Notes".² Among others issues he discussed the hottest problems of ethics of research on humans; many of his remarks keep their meaning up to now. Within few weeks "Physician's Notes" had generated rather sharp worldwide as well as All-Russian debate on medical ethics in general and ethics of human experimentations particularly. One of characteristic traits of the debate was extensive participation of the general public.

According to prevailing – at least proclaimed – ethical norms of the Soviet morality, well-being, health and even life of an individual could easily be sacrificed for the sake of common good or scientific progress. It is well known that more or less similar situation for many decades was characteristic for other countries as well, but in the Soviet Union such attitudes were in action much longer. Besides, strongly paternalistic style of physician-patient (as well as researcher-participant) interrelations made non-obligatory not only receiving consent on the part of research subjects, but even informing them about their participation in research.

Ministry of Healthcare of the USSR or corresponding Ministries in the Soviet Republics were the only authorities empowered to regulate research on humans. They assessed scientific merits as well as ethical soundness of research projects. By the way, as early as in 1936, People's Commissariat of Healthcare of the RSFSR (than Ministry of healthcare of the Russian Federative republic) had issued an

* Institute of Human Studies, Russian Academy of Sciences, Moscow; Board of Directors of the IAB.

order regarding protection of research subjects³; regrettably, it was known to medical professionals, let alone about general public. Generally speaking, up to the end of 80-th rather traditional way of dealing with human experimentation was in action in the USSR.

Profound changes had started in 90-th, after the fall of the Soviet regime. For the first time research on humans tended to become object of not only inner departmental regulation, but federal legislation as well. According to the new Russian Constitution adopted in 1993, "nobody can be subjected to medical, scientific and other experiments without his (her) voluntary consent" (Art. 21). Similar norms concerning mentally ill persons were included in the Federal law on psychiatry (1992).

The most important Russian law related to healthcare – "Foundations of legislation of the Russian Federation on the Protection of the Citizens' Health" (1993) – introduced many new norms with regard to research on humans. The law gave protection to research subjects: it forbids research with participation of persons deprived of liberty (Art. 29). Article 43 of the law framed basic condition of informed written consent for recruitment into the research. It suggest that a future participant must be informed about goals, methods, possible risks, side effects, duration and anticipated results of the research and that participant has right to withdraw his (her) consent at any time.

The article allows research on minors before 15 only for treatment of diseases directly threatening to their lives and with written consent of their legal representatives. This norm seems too restrictive and really does not observed. As it is evident now, it was rather difficult to implant into the Russian soil many novelties borrowed from Western sources and included in these laws. Very often excellent norms were and are only a kind of declarations lacking real mechanisms of implementing them in everyday practice.

In this relation the Federal Law "On Medical Drugs", which was adopted in 1998, seems more realistic. It makes obligatory review by an ethics committee of any project directed at testing of new drugs. Regrettably, the law says nothing about composition of research ethics committees, possibilities for researchers to appeal against their decisions, auditing their activities and so on.

It must be said that present Russian legislation in dealing with biomedical research has many gaps and contradictions. For instance, now there are no laws related to testing of new medical devices and technologies; a lot need to be done at legislative level to protect personal data of participants.

One of the important developments in the last decade is much more visible public interest and active involvement of non-professionals in problems of biomedical research. In 1992 under the aegis of the Russian Academy of Sciences Russian National Committee on Bioethics (RNCB) was formed. RNCB is a non-governmental and non-commercial organisation. In its activities biological and medical scientists take part together with jurists, philosophers and theologians. In 1994 RNCB for the first time in Russia held interdisciplinary conference on ethical and legal problems of biomedical research.⁴

Russian Orthodox Church – the most numerous religious confession in Russia – in last years also demonstrates growing interest in bioethical issues. In 2000 it

issued extensive document, which presents its views on different issues of social life. Special chapter of it is devoted to biomedical problems.⁵ It poses position of the Church regarding such problems, as research in human genetics and human cloning, preimplantation diagnostics, foetal therapy and so on.

One of the recent developments is rapidly widening involvement of mass media in discussion on research ethics. Now bioethical topics attract much more public attention than it was ten years ago; they are constantly presented in mass media. Rather often authors deal with problems of biomedical research. Some years ago the main point of concern was possibilities of importing into the country “dirty research”, which due to ethical restrictions could not be carried in Western countries. Especially notorious scandal, for instance, took place in 1996, after TV programs concerning ethically dubious experiments in which foetal tissues were used for treating such diseases as parkinsonism etc. These experiments were carried in one of the Russian research centres with participation of an American physician, whose license for medical practice, as it was reported, had been cancelled in the USA.⁶

One of the most popular themes of current discussions is multi-centre multinational research. For Russian researchers such projects very often are the only source of getting rather essential – in comparison with their usual earnings – financial support. This generates some concerns about their scientific integrity and validity of gained results. Another point of concern is whether multinational trails tackle with health problems relevant for the Russian population.

It must be said, however, that in multinational trails generally accepted norms and requirements of research ethics usually are fulfilled much stricter than in projects carried out without foreign partners. Participation in such projects allows Russian researchers to get acquaintance and rich experience in dealing with these norms and requirements in their everyday practice.

References

¹ *Deontology in Medicine*, in two volumes, ed. by B.V. Pterovsky, Moscow, Meditzina, 1988 (in Russian).

² V. Veresaev, “Physician’s Notes”, in Mir Bojii, *Cod’s World*, 1901, 1-5 (in Russian).

³ Olga Kubar, “Research Involving Human Subjects: ethics and law in early 20th century Russia”, *Bulletin of Medical Ethics*, 172, October 2001, p.16.

⁴ See *Ethical and Legal Problems of Clinical Trials and Scientific Experiments on Human and Animal Subjects*, Moscow, 1994 (in Russian).

⁵ *Fundamentals of Social Conception of the Russian Orthodox Church*, Moscow, 2001 (in Russian), pp. 90-103.

⁶ See Pavel Tichtchenko and Boris Yudin, “The Moral Status of Fetuses in Russia”, *Cambridge Quarterly of Healthcare Ethics*, Vol.6, 1, p.31-38.