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## ЕЩЕ РАЗ – О СТАТУСЕ ЭТИЧЕСКИХ КОМИТЕТОВ

**Н. Н. Седова**

*заместитель Главного редактора журнала «Биоэтика»*

*доктор философских наук, доктор юридических наук, профессор заслуженный деятель науки РФ, заведующий кафедрой философии, биоэтики и права ФГБОУ ВО «Волгоградский государственный медицинский университет» Минздрава России, Руководитель Отдела этической, правовой и социологической экспертизы в медицине ГБУ «Волгоградский медицинский научный центр», nns18@yandex.ru*

В связи с активным внедрением в медицину новых биотехнологий, остро стоит вопрос об этических рисках их применения. Поиски ответов на него входят в предметное поле биоэтики. Эта наука должна взять на себя не только оценочные и объяснительные, но и прогностические функции. Реализовать их могут специально организованные социальные субъекты этического регулирования – этические комитеты. Но их статус в России не легитимизирован, единой системы таких комитетов, организованной по сетевому или иерархическому принципу, нет. Необходимо предпринять теоретические и практические усилия для определения и закрепления статуса этических комитетов и активного использования их рекомендаций.

**Ключевые слова:** биотехнологии, этические комитеты, юридические документы, кодексы, этический прогноз.

## ONCE AGAIN – ON ETHICAL COMMITTEES STATUS

**N. N. Sedova**

*Chief Editor Deputy of «Bioethics» journal, Doctor in Philosophy, Doctor in Law, Professor, Honored Scholar of RF, Head of Philosophy, Bioethics and Law Department of FSBEI HE «The Volgograd State medical university» of the Ministry of Health of Russia, Head of the Department of Ethical, Legal and Sociological Examination in Medicine of SBI «Volgograd Medical Research Center», nns18@yandex.ru*

Due to new biotechnologies being actively integrated in medicine, their application is becoming an issue of ethical risks. The field of bioethics searches for answers to these questions. This science must perform assessing, explanatory and prognostic functions. These are only special social bodies of ethics regulation – ethics committees – who are able to fulfill these tasks. Though, their status in Russia has not been legitimized yet, there is no single system of such committees organized to the principle of a network or hierarchy. It is important to take theoretical and practical efforts to define and establish the status of ethics committees and actively implement their recommendations.

**Key words:** biotechnologies, ethics committees, legal documents, codes, ethical prognosis.

It is well-known that there are problems of minor importance in bioethics. Nevertheless, social demands form a certain hierarchy of ethical risks that make the society worry and bioethics must respond to them. At present, new biotechnologies that are first of all implemented in medicine refer to such risks. Implementation of new biotechnologies requires: Prognosis of social consequences Special measures of social control over the rights of test subjects and obligations of investigators performing clinical researches [1].

There are no universal mechanisms to accomplish these requirements, so far. Legal regulations are only fragmentary. It is only in early 2019 when a document appeared that prescribes permissive and restrictive procedures of researches into a genome. According to the Order of President of the Russian Federation of November 28, 2018 № 680 «On development of genetic technologies in the Russian Federation» the Decree of the Government of RF of April 22, 2019 № 479 «On approval of the Federal scientific and technical program of genetic technologies development

for 2019–2027» was passed. In this program the main attention was paid to safety while developing and applying these technologies. Page 12 of the documents reads: «The most important task is to provide safety on application of the results of biotechnological researches. A control system over activities of the companies who are involved in such researches, as well as assessment of risks on application of genetic technologies is a necessity» [2]. It is evident that in order to provide such control, it is necessary to rely on the corresponding legal documents. Though, they do not exist. Moreover, the program does not contain any clarifications who and how this supposed control can be exercised.

At the same time, the rules of ethical examination as a control mechanism were established in clinical researches long ago. The mechanism of ethical examination and its subjects (independent ethical committees) is described both in the above mentioned two laws, and in the National standard of RF GOST R ISO 14155 – 2014 «Clinical researches. Appropriate clinical practice». As for the Program,

it is only in p. X «Possible risks» the wording «ethical reasons» is mentioned (?). Not a single word was said more about the ethics of researches into genome. Ethical risks of application of examination results are ignored, but is it possible to demand development of any legal regulations without definite ethical norms? This would contradict the order of law development. Consequently, it is necessary to legitimize the mechanism of ethical examination, spreading the standards described in federal laws № 61-ФЗ of 2010 and № 80-ФЗ of 2016 as well the national standard RF GOST R ISO 14155 of 2014 to all tests and implementation of new biotechnologies. It goes about independent ethical committees who are the main subjects of ethical examination of development and implementation of new biotechnologies. As in all above-mentioned laws the items about ethical committees are identical, we can speak of the same model. What are its advantages and disadvantages?

**Advantages.** The regulation on the independent ethical committee exactly follows international requirements. There are many documents of this kind at the international level and they do not differ much. We can refer to the Guide for Research Bioethics Committees. The Guide was published by United Nations Educational, Scientific and Cultural organization (UNESCO) (Department of Science and Technology Ethics) in 2005 in Paris. We published it in our journal [3]. As our local ethics committees were set up in collaboration with international companies (pharmaceutical ones in the first line), they were formalized in compliance with the requirements of all members of this collaboration. Following international standards allowed to broaden the communication research field in medicine. Besides, it made it possible to improve the quality of researches and minimize risks for a test subject.

**Disadvantages.** Single rules to establish the committees do not exist. Usually, they are established to the order of the head of the department or organization where researches are done. Quite often they exist only for the period of the research and if a new contract is not concluded, they are dissolved. Besides, such approach does not allow to create a single database of these committees in spite of numerous attempts. At present, there are pages of ethics committees on the web sites of medical universities and research institutes but the content differs because of the lack of uniformity.

One more disadvantage is the absence of education system for the ethics committees members. The problem is that due to obligatory rotation new members join the committee regularly. Highly probable that there must be an adequate model of information sharing with them that unfortunately does not exist so far.

Rules for setting-up, functions and SOPs for ethics committees in medicine were developed long ago and

are aimed at researches in pharmacology. Nowadays, the scope of ethics examination application must be much wider, as technologies to convert living and non-living materials require a new level of assessment [4]. So, research into genome is associated with an assessment *vector*. It is important to make conclusions from the future data that do not exist yet. In such cases decision is made on basis of a large data array from the past. As for new biotechnologies, they do not have the past data array. For this reason a prognostic function of the ethics examination becomes vitally important.

To overcome these difficulties is possible if the status of independent ethics committees is legally secured. It may be formalized by changing the Federal law № 323-ФЗ of 2011, adding an article about ethics committees. It may also make sense to develop a Code of Ethics in medicine which could include moral standards in all fields of medical activities – from the primary medical aid to new biotechnologies. In the future, generalizing the experience of the existing laws application in medicine and health care that have a differentiated character, it may be reasonable to develop and approve a legal document – the Code for human rights protection as a biological species, where moral norms would be presented as obligatory and reinforce in the public conscience. It corresponds to the conformity of ethics and laws development and are equitable to the interests of all members of the society.

We hope that our readers will express their opinion on the status of ethics committees in up-to-date Russia and send their suggestions how to strengthen it in medical practice to the editorial office

#### ЛИТЕРАТУРА

1. Седова Н.Н., Навроцкий Б.А., Волчанский М.Е. Технологии «улучшения человека» в социологическом измерении. – Волгоград: Изд-во ВолГМУ. – 2017. – 198 с.
2. Постановление Правительства РФ от 22 апреля 2019 г. № 479 «Об утверждении Федеральной научно-технической программы развития генетических технологий на 2019–2027 годы» [Электронный ресурс]. – Режим доступа: [https://www.sbras.ru/files/news/docs/geneticheskie\\_tehnologii\\_poekt\\_postanov.pdf](https://www.sbras.ru/files/news/docs/geneticheskie_tehnologii_poekt_postanov.pdf). – Доступ 16.07.2019
3. Руководство № 1 ЮНЕСКО по созданию комитетов по этике // Биоэтика. – 2008. – № 1. – С. 27–34.
4. Ковальчук М.В. Конвергенция наук и технологий – прорыв в будущее // Российские нанотехнологии. – 2011. – Т. 6. – № 1–2. – С. 14.

#### REFERENCES

1. Sedova N.N., Navrotsky B.A., Volchansky M.Ye. Technologies of «human improvement» in sociological measurement. – Volgograd, VolGMU, 2017. – 198 p.
2. Decree of RF Government of April 22 № 479 «On approval of the Federal scientific and technical program of genetic technologies development for years 2019–2027» // [https://www.sbras.ru/files/news/docs/geneticheskie\\_tehnologii\\_poekt\\_postanov.pdf](https://www.sbras.ru/files/news/docs/geneticheskie_tehnologii_poekt_postanov.pdf). Access 16.07.2019
3. Guide № 1 UNESCO for research ethics committees // Bioethics. – 2008. – № 1. – P. 27–24.