Features of the Bioethical Regulation of Human Studies in Aerospace and Maritime Medicine

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Abstract—The author considers the specific features of applying the universally accepted standards of biomedical ethics to human research in aerospace and maritime medicine. The extreme factors that act on human subjects may be a menace to their health and physical and mental well-being. Therefore, medical information that comes from human studies is important not only scientifically, but also practically as the basis for revealing and preventing the risks related to such factors and for ensuring the safety of both human subjects and members of missions who may be exposed to such impacts in the future. This makes it necessary to not only strictly adhere to the basic standards of biomedical ethics, but also adapt some of them to the priority task of ensuring human safety under extreme conditions. Among other problems, the author discusses possible ways of correcting the scope of application of bioethical principles, such as confidentiality, voluntariness, and the right to refuse from or stop taking part in an experiment.

The 40-year research and practical activity of the Institute of Biomedical Problems (IMBP) is aimed at studying and developing methods capable of ensuring the safety and effectiveness of human activity under extreme conditions.

Impacts of the kind that may be described as “the other side of the medal” in scientific and technological progress are becoming increasingly important. Unfortunately, their spectrum is very wide. The totality of anthropogenic factors, acting directly or indirectly, through environmental change or social tension, has reached a biologically significant level. Dangerous ecological disturbances, conflicts, and occupational hazards may negatively affect public health and the occupational safety and health of some population groups.

This harsh reality urges researchers to focus efforts on multifaceted studies aimed at protecting humans against the adverse side effects of industrial progress. This problem is of particular importance in aerospace and maritime medicine, dealing with environmental extremes that threaten human health and occupational activities. Similar problems exist in industry, transport, sports medicine, and military medicine.

Although the study of the effects of environmental extremes may include theoretical analysis and application of various biological and other models, experiments are the main source of reliable scientific information. Unlike clinical trials, where subjects are interested in results potentially useful to them, studies of the effects of environmental extremes are “nonclinical” and are carried out with volunteers who consciously agree to be exposed to such extremes under controlled conditions for the goal of acquiring new knowledge that would allow technological development based on real human capacities and limitations. On many occasions, being directly interested in obtaining reliable scientific information, researchers themselves volunteer to take part in such tests. Another common situation is that the volunteers are more than test subjects; they become actively involved in experimentation. The highest moral duty of researchers is to observe the bioethical standards and rules that protect the health, safety, and rights of the voluntary participants such studies.

Contemporary internationally recognized bioethical standards and rules of conducting experimental research, accepted in Russia, are based on statements formulated in codes, conventions, agreements, and methodological guides, as well as in the Constitution of the Russian Federation, the Fundamentals of the Legislation of the Russian Federation on the Protection of Citizens’ Health, and other legislative acts [1–5]. In particular, they proceed from the experience of Russian physiologists and physicians in engaged in experimental research and tests [6, 7].

After World War II, the Institute of Aerospace Medicine, Ministry of Defense of the USSR, worked out and put into effect the Regulations for Conduct of Tests, which specify the procedure for organizing and carrying out experiments, the duties and responsibilities of officials, and safety rules. The regulations required that volunteers be admitted to a study only with the sanction of a commission of medical experts; written consent for being tested should be obtained, in which the participants are informed beforehand about the test conditions, safety measures, and their right to withdraw from the test before its end. To evaluate the risk that may be caused by extreme stress factors, many researchers
used to conduct experiments on themselves (including A.P. Apollonov, V.V. Strel’tsov, O.G. Gazenko, M.I. Vakar, B.B. Egorov, V.G. Lazarev, V.G. Volovich, V.A. Smirnov, A.V. Eremin, I.I. Kas’yan, S.A. Bugrov, and V.V. Polyakov, among others).

A similar system of test organization existed at the Institute of Biomedical Problems. The system was established and controlled by the administration. Although it was not identified with bioethics until the early 1990s, it presupposed many elements of bioethics, including the protection of subjects’ rights, health, and safety. As international cooperation in space medicine expanded, it became urgent to standardize the approaches to conduction of biomedical tests and bring them into correspondence with international standards of biomedical ethics.

Following these standards, an independent Commission for Biomedical Ethics (CBME) was formed at the IMBP in 1993. It was chaired by Prof. A.M. Genin, a founder of Russian space biology and medicine and an expert in aviation and hyperbaric medicine.

In 1994, this commission was given the status of an interagency physiological section of the Russian National Committee for Bioethics (RNCB), Russian Academy of Sciences. It consisted of 25 representatives of ten organizations (physicians, biologists, philosophers, lawyers, astronauts, and clergymen). In the same year, the committee agreed upon the Regulations on the CBME with the RNCB and the Russian Aerospace Agency (RASA).

The CBME considers the programs and methodology of human and animal biomedical research projects on land or in space, making conclusions on their correspondence to the standards and rules of biomedical ethics.

The main principles of evaluating the permissibility of biomedical human research projects in aerospace and maritime medicine correspond to the internationally recognized standards; at the same time, they have some specific features and need in places more detailed elaboration.

**Human studies must be justified by their high scientific and practical importance, and it must be impossible to achieve the expected result by alternative methods.** The implementation of this principle includes the evaluation of the significance and expected usefulness of the research and the quality of its methodological elaboration. In physiology of extreme states, research projects may be considered significant if they lead to (1) detecting mechanisms whereby occupation-associated environmental extremes act on humans and developing protective measures; (2) normalizing the working environment and testing the life support systems in living quarters; (3) testing the means and methods of medical control, prevention of diseases and functional disorders, individual and collective protection, and rescue under extreme conditions; (4) evaluating human psychophysiological capacities under extreme conditions and developing the methods and means of expanding these capacities; (5) obtaining ergonomic estimates and testing the indication, signalization, and control systems of spacecraft hardware; or (6) accumulating new scientific data in the fundamental fields of physiology, biology, and medicine (adaptation, regulation, resistance, trainability, gravitational dependence, specific and nonspecific reactions, etc.), which may enrich aerospace medicine theoretically and practically.

Researchers should observe test subjects’ human rights and respect their dignity and will, ranking their interests above the corporate interests. This principle requires that consent for participation in a particular experiment be given voluntarily (without any signs of coercion) by well-informed subjects, enjoying the right to withdraw from that experiment at any stage with impunity and without giving any reason. To provide the test subjects with exhaustive information, the person in charge of the experiment must provide them with its description written in easily understandable terms (Description for Non specialists). It must include the purposes and a detailed account of test procedures, methods, the kind and degree of discomfort, the risk of complications, and the measures taken to prevent them and ensure the test subjects’ safety. In addition, the description must include instructions regarding test subjects’ behavior (physical activity, diet, medication, loading tests according to other programs, etc.). After being familiarized with the Description for Non specialists and told about all other related problems, the test subjects should give their consent for taking part in the test in writing (Informed Consent).

**Maximum safety must be guaranteed to the test subjects.** Safety means the ability to effectively withstand extreme factors, which may jeopardize human life and health, with the aid of a set of measures (technical, organizational, and medical) undertaken. Under the real impact of extreme factors, the medical strategy of safety is based on a wide variety of means and methods of medical support of the tests (crew selection and training, sanitary and hygienic facilities, collection and analysis of medical information, treatment and protective measures, psychological support, etc.). The measures aimed at ensuring safety of human participants of medical tests include bioethical evaluation of the permissibility of risks and discomfort during the tests, observation of safety requirements, medical monitoring of the test subjects’ condition and the environment, and readiness to provide medical aid in the case of adverse reactions to test factors.

The following definitions are used to evaluate the expected risk [8].

**Minimum risk** means that the probability and the degree of the expected harm and discomfort associated with the test do not exceed those occurring in everyday life or after a usual medical or psychological examination (sampling of metabolic and external secretion products; placement of transducers on the body surface...