Registered with the Ministry of Justice of the Russian Federation dated June 5, 2013, No. 28686

MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

ORDER
dated February 8, 2013, No. 58n

ON APPROVAL OF THE REGULATIONS ON THE ETHICS BOARD IN CIRCULATION OF MEDICAL PRODUCTS

Pursuant to Section 26, Rules of State Registration of Medical Products, as approved by the Resolution of the Russian Federation Government dated December 27, 2012, No. 1416 (Collection of Laws of the Russian Federation, 2013, No. 1, Article 14), I order:

1. To approve the attached Regulations on the Ethics Board in Circulation of Medical Products.

2. Organizational and technical support to operations of the Ethics Board in Circulation of Medical Products shall be vested with the Department for Drug Procurement and Regulation of Medical Product Circulation.

Minister
V.I. SKVORTSOVA

Approved by
Order dated February 8, 2013, No. 58n,
of the Ministry of Health
of the Russian Federation

REGULATIONS ON THE ETHICS BOARD
IN CIRCULATION OF MEDICAL PRODUCTS

I. General Provisions

1. The Ethics Board in Circulation of Medical Products is a standing body established by the Ministry of Health of the Russian Federation (hereinafter the 'Ministry') for the ethical examination of the possibility to conduct clinical trials of medical products with participation of a human as a subject (hereinafter the 'Ethical Examination').

2. The Ethics Board in Circulation of Medical Products shall be intended to protect life, health and rights of the patients participating in clinical trials of a medical product.

3. In its operations, the Ethics Board in Circulation of Medical Products shall be governed by the Constitution of the Russian Federation, federal laws, decrees and orders of the President of the Russian Federation, resolutions and orders of the Government of the Russian Federation, orders of the Ministry, provisions of international law and these Regulations.

4. The fundamental principles of operations of the Ethics Board in Circulation of Medical Products shall be independence, publicity, fairness, compliance with human / national's rights and freedoms, rights of legal entities, neutrality, competence, experts' responsibility for holding and quality of the ethical examination.

5. The Ethics Board in Circulation of Medical Products shall be tasked with:-

1) ethical examination of documents related to clinical trials of medical products;

2) issue of opinions on ethical substantiation of the feasibility or unfeasibility of clinical trials of medical products with participation of a human as a subject.

6. The Ethics Board in Circulation of Medical Products shall be entitled, according to the objectives imposed on it, to:

1) obtain documents required for the ethical expert examination;

2) request any missing materials as required for the ethical expert examination from the applicant.

II. Composition of the Ethics Board in Circulation of Medical Products

7. The composition of the Ethics Board in Circulation of Medical Products shall be approved by the Ministry Order.

8. The Ethics Board in Circulation of Medical Products shall comprise representatives of medical, scientific, higher professional education institutions as well as representatives of NGOs, religious organizations and mass media (hereinafter the 'experts').

Representatives of medical organizations shall not account for more than a half of total experts on the Ethics Board in Circulation of Medical Products.

9. The composition of the Ethics Board in Circulation of Medical Products shall be revised when necessary but at most once a year.

Any changes and additions to the Ethics Board in Circulation of Medical Products composition shall be approved by the Ministry Order.

10. The Ethics Board in Circulation of Medical Products shall include the Chairman, its deputies and members of the Ethics Board in Circulation of Medical Products.

11. The Chairman of the Ethics Board in Circulation of Medical Products shall be appointed by the Minister of Health of the Russian Federation out of the experts of the Ethics Board in Circulation of Medical Products with higher medical education, a degree of Candidate of Medical Science or M.D. and experienced in holding clinical trials of medical products and in settlement of issues related to the ethical aspects of clinical trials of medical products.

12. The Chairman of the Ethics Board in Circulation of Medical Products shall have two deputies appointed by the Minister of Health of the Russian Federation.

13. The Chairman of the Ethics Board in Circulation of Medical Products shall carry out general management, determine the focus areas of the Ethics Board in Circulation of Medical Products, arrange for its work, allocate duties among experts of the Ethics Board in Circulation of Medical Products, and exercise control over the ethical examination.

In the absence of the Chairman of the Ethics Board in Circulation of Medical Products his/her duties shall be performed by one of his/her deputies with higher medical education.

14. Experts of the Ethics Board in Circulation of Medical Products shall not be dependent on medical product manufacturers and other persons interested in the outcome of the ethical expert examination.

15. Expert groups may be set up within the Ethics Board in Circulation of Medical Products.

III. Requirements to Qualifications and Experience in Expert Examination of Scientific, Medical and Ethical Aspects of Clinical Trials of Medical Products

16. The following requirements to qualification and experience in expert examination of scientific, medical and ethical aspects of clinical trials of medical products shall be established for the Ethics Board in Circulation of Medical Products experts:-

1) for persons with higher medical education:

(a) higher professional education;

(b) post-graduate and/or additional professional education, professional certificate;

(c) experience in clinical trials of medical products and settlement of disputes related to ethical aspects of clinical trials of medical products;

2) for other persons:

(a) higher professional education;

(c) experience and knowledge in ethical and legal aspects of human and national's rights and freedoms.

IV. Proceedings of the Ethics Board in Circulation of Medical Products

17. Meetings of the Ethics Board in Circulation of Medical Products shall be held by the Chairman

or, on its assignment, the Deputy Chairman at least twice a month and shall be documented in the Minutes to be signed by the Chairman of the Ethics Board in Circulation of Medical Products or his/her deputy as well as all members attending the meeting.

Materials to the ordinary meetings of the Ethics Board in Circulation of Medical Products shall be sent to the Ethics Board in Circulation of Medical Products experts by the Department of the Ministry responsible for the organizational and technical support of the Ethics Board in Circulation of Medical Products at least three business days prior to the date appointed for the meeting.

18. A meeting of the Ethics Board in Circulation of Medical Products shall be deemed competent if at least two thirds of its members are present.

The Ethics Board in Circulation of Medical Products experts shall take part in its operation personally; delegation of powers shall not be allowed.

19. The Ethics Board in Circulation of Medical Products experts that participate in the scheduled clinical trial of a medical product shall not be involved in the ethical expert examination.

20. A resolution of the Ethics Board in Circulation of Medical Products shall be adopted on a show of hands by simple majority of votes of the experts attending the meeting.

In case of a tie vote, the resolution for which the Chairman of the meeting of the Ethics Board in Circulation of Medical Products votes, shall be deemed adopted.

21. Following the Ethics Board in Circulation of Medical Products meeting, an opinion on ethical substantiation of feasibility or unfeasibility of clinical trials of medical products shall be issued in the form contained in the Appendix hereto, signed by the Chairman or its deputy. One copy thereof shall be delivered to the applicant or sent to the applicant by registered mail with receipt confirmation, and the second copy shall be kept by the Ministry Department responsible for organizational and technical support to the Ethics Board in Circulation of Medical Products.

22. The Ethics Board in Circulation of Medical Products expert who disagrees with the decision made shall be entitled to define his/her special opinion in writing, which shall be attached to the appropriate opinion of the Ethics Board in Circulation of Medical Products and make its integral part.

23. The information on the Ethics Board composition and its operating plans shall be posted as a message in the appropriate section on the Ministry’s website and updated regularly.

The information on the Ethics Board current operations shall be posted as a message in the appropriate section on the Ministry’s website in the Internet information and telecommunications network within Three business days from holding of the Ethics Board in Circulation of Medical Products meeting.

Appendix to the Regulations on
the Ethics Board in Circulation
of Medical Products
as approved by Order dated
February 8, 2013, No. 58n,
of the Ministry of Health
of the Russian Federation

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Ministry of Health of the Russian Federation

ETHICS BOARD

Ethics Board meeting date: _____, 20__

OPINION
on Ethical Substantiation of
the Clinical Trials of a Medical Product

No. _____ dated _____, 20__

1. Medical product name (indicating the accessories required to apply the medical product according to its intended purpose)
_____
2. Medical product manufacturer _____
(full and (if any)
_____
abbreviated name, legal form of incorporation of the legal entity, its registered address)
3. Applicant: _____
4. Resolution: _____
(to provide information on the ethical substantiation of clinical trials
_____
of the medical product, with reasons for the decision in case of
_____
unfeasibility of clinical trials of the medical product)
_____

Chairman of the Board _____
(full name) (signature)

Experts _____
(full name) (signature)