MINISTRY OF HEALTH **--------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------**
No.: 460 /QD - BYT	*Hanoi, February 16th 2012*

DECISION

On the promulgation of Regulations on organization and operation of Ethical Evaluation Committee in biomedical research of Ministry of Health, period 2012 - 2017

MINISTER OF HEALTH

Pursuant to Decree No. 188/2007/ND-CP dated 27/12/2007 of the Government stipulating functions, duties, powers, and organizational structure of Ministry of Health;

Pursuant to Decision No. 458/QD-BYT dated 16/02/2012 of Minister of Health on the establishment of Ethical Evaluation Committee in biomedical research of Ministry of Health, period 2012 - 2017;

At the request of Director of Sciences and Training Department, Director of Personnel Department.

DECIDES:

Article 1. To promulgate with this Decision the Regulations on organization and operation of Ethical Evaluation Committee in biomedical research of Ministry of Health, period 2012 – 2017.

Article 2. To assign the standing office of the Ethical Evaluation Committee in biomedical research of Ministry of Health period 2012 – 2017 to implement and inspect the implementation of this Regulation.

Article 3. This Decision becomes effective since the date of signing.

Article 4. The Chief Secretariat of the Ministry's Office, Chief Inspector of the Ministry, General Director, Directors of General Departments, Directors of Departments under Ministry of Health, Heads of relevant units under Ministry of Health, Heads of relevant units and Chairman of the Ethical Evaluation Committee shall be responsible to carry out this Decision./.

Recipients:
- As in Article 4;
- Deputy Ministers;
- Vietnam Medical Association, Vietnam Pharmaceutical Association;
- Website of Ministry of Health;
- Archived.

MINISTER

(Signed)

Nguyen Thi Kim Tien

MINISTRY OF HEALTH --------	SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness ----------
No. 460 /QD - BYT	*Hanoi, February 16th 2012*

REGULATIONS

On the organization and operation of Ethical Evaluation Committee in biomedical research of Ministry of Health, period 2012 - 2017

(Promulgated with Decision No.: 460/QD-BYT dated February 16th 2012 of Minister of Health)

Chapter I
GENERAL PROVISIONS

Article 1. This Regulation governs the organization and operation of Ethical Evaluation Committee in biomedical research of Ministry of Health, period 2012 – 2017 which was established with Minister of Health's Decision No. 458/QD-BYT dated February 16th 2012.

Subjects of governing of this Regulation include members of Ethical Evaluation Committee in biomedical research Ministry of Health period 2012 - 2017 and individuals and organizations in Ministry of Health who are related to the implementation, supervision, evaluation, and management of biomedical research on human.

Article 2. Biomedical research in this Regulation comprise of: clinical drug trial, medical equipment; treatment methods, diagnostic methods; research using biological samples; epidemiological, socio-medical and psychological research on human subjects.

Article 3. Before carrying out any research, all biomedical research on human subjects (hereinafter referred to as biomedical research) in Vietnam shall have to be examined and evaluated by Ethical Evaluation Committee in biomedical research (hereinafter referred to as Ethical Evaluation Committee) in terms of research ethical aspects and specialized scientific aspects in compliance with this Regulation and Guidelines of Good Clinical Practices promulgated with Decision No. 799/QD-BYT dated 7/3/2008 of Minister of Health and Guidance on clinical trial in Circular No. 03/2012/TT-BYT dated 02/02/2012 of Minister of Health.

Article 4. The Standing Office locating at the Ministry of Health shall assist the Ethical Evaluation Committee. The Standing Office of the Ethical Evaluation Committee shall have legal status and use the stamp and account of the Ethical

Evaluation Committee for transactions within their functions and duties. Budget for the operation of Ethical Evaluation Committee shall be from the State budget and other assistance fund in compliance with current regulations.

Chapter II
FUNCTIONS, DUTIES, POWERS, RESPONSIBILITIES AND ORGANIZATIONAL STRUCTURE OF ETHICAL EVALUATION COMMITTEE

Article 5. Functions, duties, powers, responsibilities of Ethical Evaluation Committee

1. Functions

Ethical Evaluation Committee is the advisor to the Minister of Health in terms of ethical issues in biomedical research.

2. Duties

a) To evaluate the ethical issues in biomedical research documents (research proposals, relevant reports and documents) to ensure their legality, objectivity, and honest.

b) To monitor, examine, and supervise the research in compliance with Good Clinical Practices and regulations on research ethics.

c) To evaluate the research results of the approved research proposals based on the current guidelines and regulations.

d) To train, guide, and improve the researchers for the health sector regarding research ethics and Good Clinical Practices (GCP).

3. Powers

a) To accept or not accept biomedical research documents, serving as basis for management authorities to approve the conducting of research.

b) To accept or not accept changes in research contents during implementation.

c) To propose the termination of research upon signs of incompliance of GCP or discovery of risks to the research subjects's safety which may possibly happen during the research process.

d) To request the main researchers, organizations conducting clinical trials to report on the figures, data, research results and research-related documents.

đ) To examine and supervise the compliance with Good Clinical Practices at research field and the figures, data, research results and research-related documents.

4. Responsibilities

a) To protect the safety of research subjects and the community.

b) To protect the rights of research subjects and researchers.

c) To ensure justice for all research stakeholders.

d) To ensure the scientific aspects and feasibility of the research.

Article 6. Structure, membership, number of, positions and membership requirements of Ethical Evaluation Committee.

1. Organizational structure

- Ethical Evaluation Committee comprises of Standing office, Standing subcommittee, 3 specialized subcommittees: Pharmaceuticals, Traditional medicines, Vaccines and secretary team.

- Leaders of the Ethical Evaluation Committee include Chairman and Vice Chairmen.

- The subcommittees include the Head of subcommittee and members.

- The Standing office of the Ethical Evaluation Committee has its head office at Ministry of Health (138 A Giang Vo, Ba Dinh district, Hanoi) and its standing unit in Pasteur Institute Ho Chi Minh city (167 Pasteur, Precinct 8, District 3, Ho Chi Minh city).

2. Membership, number of members:

a) Chairman, Vice Chairmen of the Ethical Evaluation Committee are scientists capable of embracing the fields related to the Committee's duties.

b) The Standing office of the Ethical Evaluation Committee comprises of the Chairman, Vice Chairmen of the Ethical Evaluation Committee and members of the Standing subcommittee. Members of the standing subcommittee has the following membership structure:

- Including members of both sexes.

- Including members representing the scientific management authorities, with good management skills and good legal knowledge.

- Including members representing rights of research subjects, who are honest, impartial, with good sense of morality and good knowledge.

- Including members who are lawyers or jurists to ensure the legality of research documents, to protect legitimate rights of research subjects as well as researchers, members of research teams.

- Including members who are scientists with in-depth knowledge of clinical, epidemiology, pharmacy, medical statistics, research approach.

c) Each specialized subcommittee comprises of 07 - 09 members who are scientists with in-depth knowledge of their specialized fields of pharmaceutical chemistry, traditional medicines, vaccines and medical biological products.

d) The Secretary team comprises of 07 - 09 members who possess good management skills and knowledge of biomedical research.

đ) Members of the subcommittees and secretary team must be provided with Ministry of Health's training program on "Good Clinical Practices".

Article 7. Functions, duties, powers of the Standing office of the Ethical Evaluation Committee

1. Functions

The Standing office of the Ethical Evaluation Committee assists the Ethical Evaluation Committee in developing planning, plans, arranging the examination, evaluation, inspection, supervision, and management of clinical trial research.

2. Duties

a) To develop long- and short-term plans on the development of Ethical Evaluation Committee's operations in compliance with international standards and Vietnamese regulations, including: examination, evaluation, inspection, supervision, and management of clinical trial research;

b) To coordinate for the development of standard procedures on examination, evaluation, inspection, supervision, and management of clinical trial research;

c) To coordinate for the implementation and to supervise the implementation of standard procedures on examination, evaluation, inspection, supervision, and management of clinical trial research;

d) To act as a focal point in working with international and domestic organizations to develop the Ethical Evaluation Committee's operations in compliance with international standards and Vietnamese regulations;

đ) To prepare documents, to record and store the minutes of regular and ad-hoc meetings of the Ethical Evaluation Committee and relevant documents;

e) To settle the payment of expenditures and prepare the final account of budget for the Ethical Evaluation Committee and Standing office of the Ethical Evaluation Committee in compliance with current financial regulations;

f) To compile 3-month, 6-month and annual reports on the performance of the Ethical Evaluation Committee.

3. Powers

a) To be entitled to select officers, civil servants, officials to work concurrently or as secondee at the Standing office of the Ethical Evaluation Committee in compliance with the current regulations to submit to the Ethical Evaluation Committee for consideration and further submit to the leaders of Ministry of Health for approval;

b) To recruit and sign contract with domestic and international consultants, contract employees to work for the Standing office of the Ethical Evaluation Committee depending on the work demand in compliance with current regulations;

c) To use public service budget for science and other sources of funding for the operations of Ethical Evaluation Committee and the Standing office of the Ethical Evaluation Committee in compliance with current regulations;

d) The Standing office of the Ethical Evaluation Committee is entitled to use the stamp and account of the Ethical Evaluation Committee for transactions within their functions and duties.

đ) The Chief Secretariat of the Ethical Evaluation Committee Standing office is the Account Holder of the Ethical Evaluation Committee.

Article 8. Structure of the Ethical Evaluation Committee Standing Office:

1. The Chief Secretariat of the Ethical Evaluation Committee Standing office is appointed and dismissed by the Chairman of the Ethical Evaluation Committee;

2. Staff of the Ethical Evaluation Committee Standing office comprises of 3 – 5 specialized officers who are experts from Department of Science and Training and other concurrent officers and secondees recruited by the Chief Secretariat of the Ethical Evaluation Committee Standing office to submit to the Ministry's leaders for approval;

3. Besides, the Ethical Evaluation Committee Standing office has other experts, officers, and staff recruited by the Chief Secretariat of the Ethical Evaluation Committee Standing office for short-term working contracts in compliance with current regulations.

Chapter III
OPERATION OF THE ETHICAL EVALUATION COMMITTÊ

Article 9. Principles for the operation of the Ethical Evaluation Committee

The Ethical Evaluation Committee shall operate as a team with the democratic principles.

The members shall work with the principles of independence, objectivity, honest and personal responsibility for their decisions when examining and evaluating research contents before implementation, changes during the implementation and evaluating research results.

Only members of the Ethical Evaluation Committee who have no conflict of interests with the research shall have the right to evaluate and vote.

Members of the subcommittees shall be responsible to provide general and specific evaluation of the documents assigned by the head of the specialized subcommittee.

Before the meetings to evaluate the documents, the members and critic experts shall study the documents, complete and send the evaluation sheets to the Standing office of the Ethical Evaluation Committee.

Members of the Ethical Evaluation Committee shall be responsible to comply with the Committee's Standard operational Practices (SOPs).

Members of the Ethical Evaluation Committee shall have the responsibilities and rights to directly report to the Minister regarding the violations of working principles by the Committee Chairman or any Committee member.

Article 10. Working methods of Ethical Evaluation Committee

Ethical Evaluation Committee's activities comprise of plenary meetings, subcommittee meetings, periodical and ad-hoc investigation and supervision activities.

Ethical Evaluation Committee 's activities are carried out in compliance with the processes and procedures provided for in the standard operational practices of the Ethical Evaluation Committee.

The Standing subcommittee shall meet monthly, the specialized subcommittees shall attend the same meeting with the standing subcommittee when there are relevant documents to be considered.

The Ethical Evaluation Committee Standing Office shall be responsible to assign the critic members, and to invite independent experts to provide criticism on the documents.

The conclusion of the evaluation meeting must be based on ballot results. The meeting's approval conclusion shall only be valid by at least 2/3 affirmative votes.

With regard to the evaluation of documents on clinical trial of medicines, vaccines (different periods), new treatment methods, clinical trial of medical equipment, such documents shall be examined and evaluated by the standing subcommittee and specialized subcommittees in accordance with the complete procedures.

With regard to the research documents on amendment and supplementation, periodic evaluation and approval, reporting of adverse events, reporting on incompliance with proposal, epidemiological and sociological surveys on human subjects, and other researches shall be examined and evaluated by the standing subcommittee in accordance with the reduced procedures and submit to the Committee Chairman for approval.

Article 11. Physical and technical conditions for Ethical Evaluation Committee:

The Ethical Evaluation Committee and its Standing office shall be provided with sufficient physical facilities to perform their duties: including offices, equipment, supervision and monitoring tools, and operating budget to satisfy the management requirements and plan implementation as provided for in this Regulation.

The Ministry's Office shall be responsible to arrange offices for the Ethical Evaluation Committee Standing office at the Ministry of Health's head office. In case it is impossible to arrange an office at the Ministry of Health's head office, the Ethical Evaluation Committee Standing office is allowed to rent an office.

The Ethical Evaluation Committee shall be provided office equipment and supplies and stationery to serve the meetings and other equipment and supplies to perform their functions and duties.

Chapter IV
IMPLEMENTATION PROVISIONS

Article 12. This Regulation shall be applicable since the date of effectiveness. Based on this Regulation, the Ethical Evaluation Committee shall consider the development of the standard operational practices (SOPs) for the Committee's specific activities.

The agencies and entities under the Ministry of Health shall carry out their research activities in compliance with this Regulation in order to organize and develop the Operating Rules of their own Ethical Evaluation Committees to ensure compliance with the fundamental principles of research ethics.

If there are any difficulties during the implementation, individual and organizations shall report to the Ministry of Health (Department of Science and Training) for consideration to amend and supplement this Regulation. All complaints on ethical evaluation in biomedical research shall be sent to the Ethical Evaluation Committee Standing Office for examination and resolution in compliance with current law./.

MINISTER

(signed)

Nguyen Thi Kim Tien