MINISTRY OF HEALTH	THE SOCIALIST REPUBLIC OF VIETNAM
	Independence – Freedom - Happiness
No: 111 /QĐ - BYT	

Hanoi, January 11, 2013

DECISION

On promulgation of Regulation on Organization and Operation of Council of Ethics in Biomedical Research at grass-root level

MINISTER OF HEALTH

Based on the Decree No.63/2012/NĐ-CP dated August 31, 2012 by the Government stipulating functions, tasks, mandate and organizational structure of the Ministry of Health;

Considering the request by the Director of Bureau of Science, Technology and Training (BSTT),

DECIDE:

Article 1. Issued in attachment to this Decision is the Regulation on Organization and Operation of the Council of Ethics in Biomedical Research at grass-root level (CEBR).

Article 2. This decision comes into force and effect from the date of signing and promulgation.

Article 3. Mandate the Director of BSTT to roll out and monitoring enforcement of this Regulation.

Article 4. Heads of Ministerial Administration Office, Ministerial Inspectorate, Directors of bureaus, directors of departments under HOH, leaders of units and organizations under MOH, leaders of relevant organizations and Chairman of the Review Board, shall enforce this Decision./.

Recipient:
- As listed in Article 4;
- Vice ministers (for information);
- General Association of Medicine of Vietnam, Vietnam Association of Pharmacy;
- MOH Website;
- Office filing: VT, TCCB; K2ĐT (02).

MINISTER OF HEALTH

(signed)

Nguyễn Thị Kim Tiến

REGULATION ON ORGANIZATION AND OPERATION OF COUNCIL OF ETHICS IN BIOMEDICAL RESEARCH AT GRASS-ROOT LEVEL

(Issued under Decision No.111/QĐ - BYT
dated January 11, 2013 by Minister of Health)

Chapter I

GENERAL PROVISIONS

Article 1. General Principles

Prior to putting into implementation, all biomedical research on human subjects in Vietnam is subject to review and evaluation for ethics in research in accordance with current provisions and guidelines of this Regulation

Article 2. Biomedical research on human subject

Biomedical research on human subject includes clinical medical trial research (new medicine, medical materials, traditional medicines, vaccine, other biological products used in illness prevention and treatment, biological utility research and biological evaluation), health equipment and facilities, research on methods of treatment, diagnosis, biological samples, epidemiological survey, social survey, psychological survey conducted on human subjects.

Article 3. Mandate of establishment and appraisal of CEBRGL

1. CEBRGL is established in units with a view to performing ethnical and scientific review and assessment on biomedical research conducted in organizations and units in accordance with laws and regulations.

2. Based on specific functions and tasks of the organization or unit conducting the research, the leader/head shall decide to establish, appoint, dismiss or substitute members of the CEBRGL.

3. Ministry of Health shall consider, evaluate and grant operating code, supervise and inspect operations of the CEBRGL in units and organizations. If appropriate, Ministry of Health reserves the right to suspend the service of CEBRGL.

Article 4. Scope and mandate of CEBRGL

1. For research or project at ministerial level, or research on international relations, clinical medical trial (new medicine, medical materials, traditional medicines, vaccine, other biological products used in illness prevention and treatment, biological utility research and biological evaluation, treatment equivalence); research on clinical trial of health equipment; research on first-time application of new technology, method on human in Vietnam, CEBR shall consider and assess ethics in research prior to submitting research documents to SEBR of MOH for consideration and evaluation (SEBR of Ministry of Health).

2. For research at grass-root level beyond the list specified in the Clause 1, ethics in research shall be reviewed and assessed by SERBGL.

3. In special cases, Ministry of Health shall mandate the tasks of reviewing and assessing ethics in biomedical research and project on human subject falling under the appraisal mandate of the CERB of MOH to qualified CERBGL.

Chapter II

ORGANIZATION OF COUNCIL OF ETHICS IN BIOMEDICAL RESEARCH AT GRASS-ROOT LEVEL

Article 5. Function, task, mandate and responsibility of Council of Ethics in Biomedical Research at Grass-root level (hereinafter referred to as Council)

1. Function:

Review, assess ethical and scientific aspect in biomedical research as basis to provide advisory opinions to the leader of organization or unit that hosts the research.

2. Task:

a) Assess research ethics in documents of biomedical research (research outline, reports and relevant papers) prior to commencing implementation.

b) Monitoring, inspecting research for its compliance with the outline and guidelines on ethics in research; assess records, reporting and resolution of problems happening during the course of research implementation;

c) Assess research results according to approved outline and current guidelines and regulations;

d) Exercise archiving and control of operating documentations of the council.

3. Mandate:

a) Approve, request for revision of the research outline prior to giving official approval or disapproval of documents of biomedical documents as basis for decision-making authority to decide on implementing the research;

b) Approve or disapprove modifications concerning research contents during the course of implementation;

c) Request to suspend research upon detecting non-compliance of good clinical practice (GCP), non compliance of research outline or the risk to research subject during the course of research conducting;

d) Inspect and supervise compliance with research outline, principles of GCP at the time of research, and data, results and documentations related to research.

4. Responsibility:

a) Protect rights, safety and health of all subjects taking part in the research and concerned communities, rights of researchers;

b) Safeguard fairness to all subjects taking part in the research (risk and benefit sharing by social class, age, gender, economic, cultural, ethnic and religious status);

c) Ensure fairness, democracy, honesty and promptness of assessment of ethics in research;

d) Ensure legality and appropriateness and confidentiality of research and documents.

Article 6. Number, composition, title and membership eligibility of the council

1. Number of member:

a) The council has at least five members and at most 11 members, among whom one shall be the member cum chief secretary of the council;

b) Secretariat shall assist the Council. Secretariat is based in the Science Research Management Office or an appropriate office decided by the Head of the Organization. Secretariat has two or three members.

c) Secretariat shall receive documents/applications and process them, prepare necessary things for the work of the council, complete letters or documents by the council and roll out tasks required by the council.

2. Council composition:

Chairman;

Deputy chairman (if appropriate);

Council members;

Council secretary.

3. Eligibility of council member:

3.1. General eligibility

Council members must be honest, having objective viewpoint, good experience and knowledge about ethics in biomedical research in order to protect rights and interests for research subjects and members.

Council secretary must be honest, having objective viewpoint and good knowledge about management of science and technology, science research and ethics in biomedical research, be trained in administration, book-keeping and managerial tasks.

Chairman, deputy chairman, members and secretary of the council must hold a certificate of good clinical practice issued by Ministry of Health or organizations accredited by Ministry of Health, and get regular training to understand and update new issues related to ethical aspects in biomedical research.

3.2. Specific eligibility

a) Chairman, deputy chairman of the council should be prestigious scientist. In order to ensure fairness and objectivity, the leader of the organization shall not act as the council chairman.

b) Council members include the following:

- Members of both genders;
- Members out of biomedical field, members in biomedical field;
- Members not related to the unit/organization that host the research;
- Member with professional qualification in law or ethics;
- Members as medical doctor
- Other members are scientists with deep knowledge in the subject issue.

Article 7. Review and assessment of ethical aspect in organizations/unit without council

For units without CEBRGL established, ethical review and assessment shall be performed by the Scientific Council of the unit. The leader of the unit shall issue a decision on amending the tasks of ethical assessment in biomedical research for the scientific council on the condition that two thirds of the members have GCP certificate issued by Ministry of Health.

For units without Ethical Council or Scientific Council established, ethical review and assessment shall be performed by CEBRGL which is mandated by the Ministry of Health to assess biomedical research on human subject in the local area.

Chapter III

OPERATION F COUNCIL OF ETHICS IN BIOMEDICAL RESEARCH AT GRASS-ROOT LEVEL

Article 8. Working Regulation of the Council

1. The council works on the basis of three to five year term and specified in the council establishment decision.

2. The council works in the principle of collectivity, democracy upon considering and making decisions. Council meetings are legally valid if having presence of at least two thirds of council members to vote and the meeting must have the minute of meeting.

3. The council chairman (or deputy chairman) shall chair meetings of the council, make conclusions for the meetings and report to the leader of the

organization/unit as basis to make decisions.

4. In necessary cases, the council may invite counselors who have no conflict of interest with the research. The counselor may attend the meeting without voting.

5. Upon assessing research documents and conclusions, the council shall attention to the following:

a) Risks and benefits for research participants;

b) Risks are minimal and appropriate compared with presumably attained outcomes;

c) Protection and care for research participants;

d) Voluntary participation of research participants/subjects

e) Fairness in selection of research participant

f) Integrity of data collected;

g) Respect for privacy and confidentiality of participants

h) Protective conditions for vulnerable subjects

i) Scientific design of research outline

j) Implementation model and feasibility of research

Article 9. Working principle of council members

1. Council members shall work in the principle of independence, objectivity, honesty and individual responsibility for their own decision made upon reviewing and assessing research issues prior to implementing them, during implementation and acceptance of research outcomes.

2. Only members free of conflict of interest with the research shall be eligible to assess and vote.

3. Before meetings on review of documents, members and experts shall study the documents, prepare comments sheets to the secretariat.

4. Members shall be subject to comply with standard procedures of practice of the council.

5. Council members reserve the right to report to the head of organization that directly manage the council to handle non-compliances against working

principles by council chairman or any council member.

Article 10. Assessment procedure of council

Units should refer to operating regulations of the Review Board of Ethics in Biomedical Research, Ministry of Health (issued under Decision No.460/QD-BYT dated February 16, 2012) to develop assessment procedure for the council of your own organization.

Article 11: Registration forms for ethical assessment in biomedical research

The registration forms for ethical assessment in biomedical research for clinical trial research can be referred in the Circular No.03/2012/TT-BYT dated February 02, 2012 by Ministry of Health. For other research, the organizations may refer current regulation on scientific and technological management.

Article 12. Financing source for council operation

Fund for council operation is guided by existing financial regulations applicable to scientific studies and research, for research, project without using state fund, researchers and donors must prepare a cost plan to cover all expenses of the council by their own account.

Article 13. Major documents subject to review, assessment by the council

a) Research outline;

b) Information sheet, voluntary participation acceptance sheet;

c) Procedures for participant selection and advertisement;

d) Information sheet for security of interest and confidentiality of participant;

e) Procedures for monitoring, assessment, resolution of problems and issues (for research on subjects);

f) Product information sheet for researchers (for clinical trial research);

g) Professional profile, qualifications and certificates of researchers

Chapter IV

IMPLEMENTATION

Article 14. Implementation provisions

This regulation shall apply to all agencies, units under Ministry of Health, department of health under provinces and centrally-run cities, sectoral health, local and foreign people upon conducting research related to human in Vietnam. Heads of above-listed organizations shall instruct and guide enforcement of this regulation.

Article 15. Implementation

For any problems and issues happening during the course of implementation, the heads of organizations shall report to Ministry of Health (Bureau of Science, Technology and Training) for consideration and amendment. Any complaints regarding ethical assessment in biomedical research from organizations and individuals to higher science and technology management agency shall be resolved in accordance with specified level and laws.

MINISTER

(signed)

Nguyễn Thị Kim Tiến