THE MINISTRY OF HEALTH-	**SOCIALIST REPUBLIC OF VIETNAMIndependence - Freedom – Happiness**
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No. 43/2024/TT-BYT	*Hanoi, December 12, 2024*

CIRCULAR

STIPULATING THE ESTABLISHMENT, ORGANIZATION AND OPERATION OF THE ETHICS COUNCIL IN BIOMEDICAL RESEARCH

Pursuant to the Law on Pharmacy dated 06/04/2016;
Pursuant to the Law on Medical Examination and Treatment dated January 09, 2023;
Pursuant to the Government's Decree No. 96/2023/ND-CP dated December 30, 2023 detailing a number of articles of the Law on Medical Examination and Treatment;
Pursuant to the Government's Decree No. 95/2022/ND-CP dated November 15, 2022 regulating the functions, tasks, powers and organizational structure of the Ministry of Health;
At the request of the Director of the Department of Science, Technology and Training;
The Minister of Health promulgates the Circular regulating the establishment, organization and operation of the Ethics Council in biomedical research.

Chapter I

GENERAL REGULATIONS

Article 1. Scope of Regulation

This Circular provides for the establishment, organization and operation of the National Biomedical Research Ethics Council and the grassroots Biomedical Research Ethics Council (hereinafter referred to as the Ethics Council).

Article 2. Explanation of terminology

1. *Conflict of interest means a* situation in which the personal interests of a researcher or member of the Ethics Council or an independent consultant are at risk of conflict with the obligations and responsibilities of the researcher or member of the Ethics Council or an independent consultant, which may affect the objectivity of the research or the appraisal of the research.
2. *Study site* means a place where research is actually conducted and is a place under the control of the facility receiving the clinical trial.
3. *Minimal risk* means a risk in which the probability and degree of harm or discomfort or other adverse physical, mental or social effects expected in the study are not greater than the level that can be recognized in daily life or in the performance of routine examinations or tests.

Chapter II

ESTABLISHMENT OF THE ETHICS COUNCIL

Article 3. Establishment of the National Ethics Council

1. The national ethics council shall be established under the decision of the Minister of Health.
2. The Minister of Health shall decide on the appointment, supplementation, replacement, resignation or dismissal of members of the national ethics council.
3. The national ethics council shall have a term of office of 05 years; members of the National Ethics Council for the next term shall inherit the previous term and have the participation of at least 20% of new members.
4. The national ethics council shall have its own seal and account to perform its functions, tasks and powers.

Article 4. Establishment of the Grassroots Ethics Council

1. Grassroots-level ethics councils shall be established under decisions of the heads of organizations.
2. The head of the organization that establishes the grassroots-level Ethics Council shall decide on the appointment, supplementation, replacement, resignation or dismissal of members of the grassroots-level Ethics Council.
3. The grassroots-level Ethics Council shall have a term of office of 05 years; members of the Ethics Council at the grassroots level for the next term shall inherit the previous term and have the participation of at least 20% of new members.
4. For organizations that do not establish grassroots-level ethics councils, the consideration and appraisal of biomedical studies on human subjects shall be conducted by grassroots-level ethics councils in accordance with the research domains.

Chapter III

FUNCTIONS, TASKS AND POWERS OF THE ETHICS COUNCIL

Article 5. Functions of the Ethics Council

The Ethics Council has the function of reviewing the ethics and science of biomedical research on human subjects as a basis for advising competent agencies in approving, inspecting, evaluating and accepting research.

Article 6. Duties of the Ethics Council

1. The grassroots-level ethics council shall have the following tasks:
a) Appraise the following documents for drug clinical trials, medical device clinical trials, new clinical trials and new techniques and methods in medical examination and treatment before sending them to the National Ethics Council:
- Dossier, research outline, capacity of the researcher and of the research site.
- A dossier of request for change of the research outline, periodic appraisal of the research, and irregular appraisal of the research.
- Report on research results.
b) Appraise the following documents for the bioequivalence trial of drugs for approval by the person in charge of the facility receiving the bioequivalence test of the drug: dossier, research outline, capacity of the researcher and of the research site; dossier of request for change of research outline, periodic appraisal of research, irregular appraisal of research; report on research results.
c) Monitoring and supervising the research in compliance with the outline and regulations on ethics in research; evaluate the recording, reporting and handling of adverse events occurring in the study.
d) Archive, manage and keep confidential the operation dossiers of the Ethics Council in accordance with law.
2. The national ethics council shall have the following tasks:
a) Appraisal of dossiers, research outlines, capacity of researchers and research sites before conducting research.
b) Appraisal of research in the course of implementation at the receiving establishments, including: appraisal of changes to the research outline, periodic appraisal of research, irregular appraisal of research.
c) Appraisal of reports on research results of the testing establishments.
d) Monitor and supervise the research in compliance with the outline and regulations on ethics in research at the testing establishments; evaluate the recording, reporting and handling of adverse events occurring in research at the testing facilities.

dd) Archive, manage and keep confidential the operation dossiers of the Ethics Council in accordance with law.

Article 7. Powers of the Ethics Board

1. Approval or disapproval:

a) Research dossier, outline, amendments and supplements to the research outline, report on research results;

b) Exemption from obtaining the copy of the study information supply and the volunteer participation form in case it is necessary to keep absolute confidentiality for the research participant or the research participant or the legal representative cannot be obtained on the basis of fully considering the interests, risks of research to research participants and measures to protect the rights and safety of research participants;

c) The use of documents in the form of electronic documents in accordance with relevant laws.

2. Invite independent consultants to provide professional opinions to the Ethics Council.

3. Request principal researchers, organizations in charge of research, and research sponsors to report data, research results, dossiers related to research and amend and supplement the research outline to ensure the safety of research participants.

4. Propose competent agencies to stop the research when detecting that the research does not comply with the principles of good clinical research practices or violates the research outline.

Article 8. Responsibilities of the Ethics Council

1. To ensure the maximum limit of adverse impacts on the health of research participants.

2. Periodic appraisal shall be conducted at least once a year for clinical trial studies.

3. Monitoring, supervising, appraisal unexpectedly, considering adverse events occurring in the study or violating the research outline of the studies in order to ensure the rights, health and safety of the research participants, accuracy, reliability, integrity and objectivity, the science of data and research results.

4. The Chairperson of the Council shall promulgate the Regulation on operation of the Ethics Council, which stipulates the order and procedures for appraisal of the study according to the full process and the simplified process; approving and publicly announcing the standard practice procedures of the Ethics Council in order to achieve consensus in the establishment and training of members of the Council and the performance of specific tasks and tasks of the Council.

5. Publicize ethical guidelines in biomedical research used by the Ethics Council.

6. Confidentiality of research-related information.

Chapter IV

ORGANIZATION OF THE ETHICS COUNCIL

Article 9. Organization of the National Ethics Council

1. The national ethics council is composed of the Chairperson of the Council, at least 03 Vice Chairpersons of the Council, members of the Council, alternate members (if any), professional subcommittees and the Office of the Council.

2. The number of Vice Chairpersons, members of the Council, alternate members, professional secretaries, administrative secretaries, the number of professional subcommittees of the national ethics council and the number of deputy chiefs and officials of the Office of the national ethics council are specified in the Council's operation regulations.

3. The Department of Science, Technology and Training is a standing member of the national ethics council.

4. The National Ethics Council shall have an assisting agency as the Office of the National Ethics Council located at the Department of Science, Technology and Training under the Ministry of Health.
5. The Office of the National Ethics Council is composed of the Chief of Staff, Deputy Chief of Staff, Chief Accountant working on a part-time basis and officials of the Office of the Council.

Article 10. Organization of the grassroots ethics council

1. The grassroots ethics council shall consist of the Chairperson of the Council, at least 01 Vice Chairperson, members of the Council, alternate members (if any), standing divisions of the Council and professional subcommittees in case of necessity.
2. The number of Vice Chairpersons of the Council, members of the Council, alternate members (if any), professional secretaries, administrative secretaries and the number of professional subcommittees of the grassroots Ethics Council shall be specified in the Council's operation regulations.
3. The head of the organization that establishes the grassroots-level Ethics Council shall assign a unit to act as a standing member of the grassroots-level Ethics Council.

Article 11. Membership structure of the Ethics Council

1. The Ethics Council must have at least 05 members, ensuring the principle of gender, including:
a) Members who have expertise in the health sector and are independent of the organization that establishes the Ethics Council;
b) Members being clinicians;
c) Members have experience in reviewing legal documents;
d) Members not belonging to the health sector;
dd) Members under 50 years old and members aged 50 years or older.
2. Alternate members of the Ethics Council:
a) The composition of the Ethics Council may include alternate members;
b) Alternate members must meet the same standards and responsibilities as members of the Ethics Council;
c) In case the meeting of the Ethics Council's appraisal of the research dossier does not ensure the number and structure of members as prescribed, the Council's leader may invite alternate members to participate in the appraisal of the research dossier and vote as members of the Council.
3. The Ethics Council must not include the head of the organization that establishes the Council.
4. Members of the national ethics council must not include civil servants of the Ministry of Health.

Article 12. Criteria of the Chairman, Vice Chairman and members of the Ethics Council

1. Criteria of the Chairman and Vice Chairman of the National Ethics Council:
a) Having a doctoral degree or higher in the health sector;
b) Having at least 15 years of working experience related to the field of popular research assessed by the Ethics Council;
c) Having prestige and ability to administer, synthesize and agree on opinions to reach consensus of members of the Council;
d) Have an understanding of the principles of good clinical research practice and standard practice procedures of the Ethics Council;
dd) A person who is not appointed as the Chairperson of the Ethics Council for more than 02 consecutive terms.

2. Criteria of the Chairman and Vice Chairman of the Ethics Council at the grassroots level:
a) Having a university degree or higher in the health sector;
b) Having at least 10 years of working experience related to the field of popular research assessed by the Ethics Council;
c) Satisfying the criteria specified at Points c, d and dd, Clause 1 of this Article.
3. Criteria of members of the Ethics Council:
a) Members with expertise in the health sector and members with experience in reviewing legal dossiers must have a university degree or higher;
b) Non-professional members in the health sector must have a college degree or higher;
c) Have an understanding of the principles of good clinical research practice and the standard practice procedures of the Ethics Council.

Article 13. Criteria for professional secretaries and administrative secretaries of the Ethics Council

1. Criteria for professional secretaries:
a) Being an honest and objective person;
b) Having a university degree or higher in the health sector;
c) Have an understanding of the principles of good clinical research practice and standard practice procedures of the Ethics Council;
d) Members of the Ethics Council may concurrently act as professional secretaries of the Ethics Council.
2. Criteria of an administrative secretary:
a) Being an honest and objective person;
b) Having a college degree or higher;
c) Have an understanding of the standard practice procedures of the Ethics Council.

Article 14. Appointment, supplementation, replacement, resignation and dismissal of the Chairman, Vice Chairman and members of the Ethics Council

1. Appointment at the beginning of the term:
a) Based on the criteria and membership structure of the Ethics Council, the head of the unit assigned to act as a standing member of the Council shall reach agreement with the Chairman of the Council for the current term (if any) on the appointment of personnel of the Council's members;
b) The dossier of appointment of members of the Ethics Council must contain sufficient evidence to meet the criteria specified in Article 12 of this Circular and be kept at the Council;
c) For personnel under the management of other organizations, the organization that establishes the Ethics Council shall consult in writing with the organization managing the person expected to be appointed as a member of the Council. For independent experts, it is necessary to have the written consent of that person;
d) On the basis of the written proposal of the head of the unit assigned to act as the standing member of the Council, the head of the organization establishing the Ethics Council shall decide on the appointment of members of the Council;
dd) The term of office of members and alternate members shall be according to the term of office of the Ethics Council.
2. Supplementation and replacement:
When there is a need to supplement or replace members of the Ethics Council, the head of the unit assigned to act as a standing member of the Council shall reach agreement with the Chairman of the Council on personnel plans to supplement or replace members of the Council in

accordance with the regulations on criteria, dossiers and duration of being members of the Council as prescribed in Clause 1 of this Article.
3. Resignation:
a) A member of the Ethics Council may resign when he or she feels that he or she is not qualified to fulfill the tasks of the Council member or has a personal desire to resign;
b) Members who wish to resign must notify their resignation aspirations to the Chairperson of the Council and the head of the unit assigned to act as the Council's standing member;
c) The head of the unit assigned to act as the standing member of the Council shall report to the head of the organization establishing the Ethics Council for consideration and decision to accept or reject the resignation of the Council members.
4. Dismissal:
a) In case a member of the Ethics Council fails to meet the criteria for membership of the Council, the head of the unit assigned to act as a standing member of the Council shall reach agreement with the Chairperson of the Council on the dismissal of such member;
b) On the basis of the written proposal of the head of the unit assigned to act as the standing member of the Council, the head of the organization establishing the Ethics Council shall decide on the dismissal or non-dismissal of the members of the Council.

Article 15. Independent consultant to the Ethics Council

In case of necessity, the leader of the Ethics Council may invite an independent consultant to appraise the dossier and attend the meeting of the Council.
1. An independent consultant must be a person who has no conflict of interest with the research being evaluated.
2. Independent consultants may attend meetings of the Ethics Council to exchange and discuss research but do not have the right to vote. Where an independent consultant is unable to attend the meeting, his or her written comments must be reviewed by the Ethics Committee and recorded in the minutes.
3. Independent consultants shall be responsible for keeping information and documents related to research accessible.

Chapter V

ACTIVITIES OF THE ETHICS COUNCIL

Article 16. Principles of operation of the Ethics Council

1. The activities of the Ethics Council are non-profit activities.
2. When considering, commenting, guiding and approving biomedical research related to humans, members of the Ethics Council must fully apply the ethical principles prescribed in this Circular, the Council's operation regulations, the Council's standard practice procedures and relevant laws.
3. The Ethics Council shall work on the principles of collectivity, democracy and independence when appraisal and decision-making.
4. A meeting to review research related to a vulnerable group of people must be attended by a representative of this group of people or an expert with experience working with this group of people.
5. The appraisal according to the full process must be attended by at least 05 members of the Ethics Council, including at least one member with appropriate expertise in the health sector, one member without expertise in the health sector, one independent member, etc having members of both sexes; for the Ethics Council with a professional subcommittee, the meeting must be attended by at least two members of the appropriate professional subcommittee to attend the

meeting and vote; The study is only approved when there are less than 02 disapproval votes out of the total number of valid votes. In case it is difficult to reach a consensus in the appraisal meeting, the Chairperson of the Ethics Council has the right to decide on the immediate vote or request the principal researcher to complete the research dossier for the Council to consider and vote at the next meeting of the Council.
6. The simplified due diligence process shall only apply to minimum-risk research, completed dossiers based on previous appraisal results, research dossiers that have been appraised and approved by other grassroots-level ethics councils, dossiers of changes to the research outline, etc dossiers of periodic reports, irregular reports on research, documents updated in the course of research, reports on adverse events occurring in research, reports on violations of the research outline; The study is only approved when the members assigned to appraise all evaluate and approve. In case there is an appraisal member who does not approve, the Chairman of the Ethics Council has the right to decide on the appraisal according to the full process.
7. Members of the Ethics Council are not allowed to conduct research appraisal and his/her or his/her spouse, natural father, adoptive father, natural mother, adoptive mother, natural child, adopted child, brother, sister-in-law, brother-in-law, brother-in-law, sister-in-law or sister-in-law of the member and of the member's wife (or husband) have a conflict of interest; must not participate in the implementation of research that such member has evaluated when approving the Ethics Council.

Article 17. Guidelines for submitting research documents to the Ethics Committee

The Ethics Council shall issue a guiding document on the requirement to submit research dossiers for appraisal. The guidance includes the following contents:
1. Name and address of the secretary, employee or member of the Ethics Council receiving the dossier or the address of the website receiving the dossier online (if any);
2. A list of all written documents in the dossier;
3. Specifications of documents;
4. The language of the documents in the dossier;
5. The number of copies to be submitted;
6. The deadline for filing the application compared to the date of appraisal;
7. Method of notification of invalid dossiers;
8. The time period for submitting additional dossiers (if necessary);
9. The expected time for notification of appraisal results;
10. Specifications of forms to be submitted according to the Council's regulations (if any);
11. Fees for appraisal of research dossiers (if any).

Article 18. Contents of the Ethics Council to be appraised

1. Contents of appraisal for pre-implementation research:
a) Design the study and conduct the collection of research data;
b) Results of pre-clinical and clinical research (if applicable);
c) Potential risks and benefits of the study or of the research product (if applicable); impact of the study on the community in which the research participants are involved;
d) Selection of research populations and advertising information to be used in the selection of potential research participants; the process of providing information and obtaining a copy of the research information supply and a volunteer form to participate in the research; financial benefits and financial costs related to the study participants;

dd) Protect the privacy and confidentiality of information of research participants; The process of monitoring, evaluating and handling adverse events (for research with intervention on research participants);
e) Capacity of the researcher and the research location.
2. Contents of appraisal for ongoing research:
a) Compliance with the approved research outline;
b) Protect the rights, health and safety of research participants;
c) Record, handle and report adverse events or serious adverse events occurring in the study (if any);
d) Violations of the research outline and the remedy and prevention of violations (if any);
dd) Contents of amendments and supplements to the research outline and relevant documents (if any).
3. Contents of appraisal of research result reports:
a) The observance of the research outline in the course of implementation;
b) The integrity, accuracy and reliability of the research data;
c) The scientificity and accuracy of the report on research results.

Article 19. Notification of appraisal results of the Ethics Council

Within 05 working days from the date of appraisal of the research dossier, the Ethics Council shall send a written notice of the appraisal result to the testing institution and the principal researcher, specifically as follows:
1. In case the research outline is approved by the Ethics Council: notify according to the form of the Certificate of approval for the research outline in Appendix I issued together with this Circular.
2. In case of amendment or supplementation of the research outline approved by the Ethics Council: notify according to the form of the Certificate of approval for amendment and supplementation of the research outline in Appendix II issued together with this Circular.
3. In case the report on research results is approved by the Ethics Council: the notification shall be made according to the form of the Certificate of report on research results in Appendix III issued together with this Circular.
4. In case the research outline or amendment or supplementation of the research outline or report on research results is conditionally approved by the Ethics Council: the notification shall be made according to the form of Notice of conditional approval in Appendix IV issued together with this Circular.
5. In case the research outline or amendment or supplementation of the research outline or report on research results is not approved by the Ethics Council: notify according to the form of Notice of disapproval in Appendix V issued together with this Circular.
6. The head of the organization establishing the grassroots ethics council shall be responsible for prescribing the method of certification of the organization in the written notification of the appraisal result of the council.

Article 20. Monitoring and supervising research

1. The Ethics Council shall monitor and supervise research through direct supervision at the place where the research is carried out or through the review of progress reports, research results, periodic appraisal and irregular appraisal of research.
2. Contents of monitoring and supervision: compliance with the process and criteria for recruitment of research participants, the protection of the rights, safety and health of research

participants, the collection of biological samples, information and research data from research participants.

Article 21. Ethics Council Document Archives

1. All documents and notices of the Ethics Council must be clearly dated, dossiered and archived in accordance with the standard practice procedures of the Ethics Council and the provisions of law on archiving.

2. Records may be archived in paper or electronic copies.

3. Documents of the Ethics Council that need to be archived include:

a) Documents on the establishment of the Council;

b) Standard practice procedures of the Council;

c) Documents issued by the Ethics Council;

d) The annual summary report on the Council's operations;

dd) Scientific curriculum vitae of the members of the Council;

e) Invitations and working agendas of meetings of the Council;

g) Comments, research evaluation sheets, minutes of the Council's meeting;

h) The Council's written notification of appraisal results;

i) Legal documents used by the Council;

k) Guiding documents on research ethics used by the Council;

l) Research dossiers evaluated by the Council;

m) Other relevant documents as prescribed by law.

Chapter VI

IMPLEMENTATION PROVISIONS

Article 22. Enforcement effect

1. This Circular takes effect from February 01, 2025.

2. Circular No. 04/TT-BYT dated March 05, 2020 of the Minister of Health regulating the establishment, functions, tasks and powers of the Ethics Council in biomedical research shall cease to be effective from the effective date of this Circular.

Article 23. Organization of implementation

1. The Department of Science, Technology and Training, Ministry of Health

a) Assume the prime responsibility for, and coordinate with relevant units in, disseminating and guiding the implementation of this Circular;

b) Update the list of the Ethics Council that has been announced on the website of the Department of Science, Technology and Training within 15 days from the date of receipt of the notice of establishment of the Ethics Council;

c) Assume the prime responsibility for, and coordinate with relevant units in, periodically or irregularly inspecting the satisfaction of the requirements specified in this Circular for the Ethics Council;

d) In case the inspection finds that the Ethics Council does not meet the requirements specified in this Circular, the Department of Science, Technology and Training shall withdraw the name of the Ethics Council from the updated list on the website of the Department of Science, Technology and Training;

dd) Suspension or propose competent agencies to suspend the operation of the Ethics Council in case of detecting that the Council violates the provisions of this Circular, affecting the protection of the rights, safety and health of research participants.

2. Departments of Health of provinces and centrally-run cities, health ministries and sectors

a) Disseminate and guide the implementation of this Circular;

b) Periodically or irregularly inspect the satisfaction of the requirements specified in this Circular for the Ethics Council of the unit under its management;
c) Propose the Ministry of Health (the Department of Science, Technology and Training) to withdraw the name of the Ethics Council from the updated list on the website of the Department of Science, Technology and Training in case it detects that the Ethics Council of the unit under its management violates the provisions of this Circular, affecting the protection of rights and rights. safety and health of study participants.
3. Organization of the establishment of the Ethics Council
a) Ensuring conditions on human resources, infrastructure and equipment for the operation of the Council and the Council's Office or its standing divisions;
b) Allocate and ensure sufficient funding for the operation of the Council and the Council's Office or its standing divisions from the state budget and other lawful funding sources as prescribed by law;
c) Annual assessment of compliance with the provisions of law, regulations on organization and operation and standard practice procedures of the Ethics Council;
d) Notify the Department of Science, Technology and Training, Ministry of Health of the establishment and consolidation of the Ethics Council according to the form in Appendix VI issued together with this Circular and update information on the website of the establishment or consolidation of the Council.
4. The grassroots-level ethics council for appraisal of biomedical studies on human subjects may apply them in accordance with practice based on the guidance in this Circular.
In the course of implementation, if any problems arise or difficulties arise, agencies, organizations and individuals shall promptly report them to the Ministry of Health (through the Department of Science, Technology and Training) for guidance and settlement./.

KT. MINISTER
DEPUTY MINISTER

NGUYEN TRI THUC

Recipients:
- Social Committee of the National Assembly;- Government Office (KGVX Department, Official Gazette, Government E-Commerce Portal);- Ministers (for reporting);- Deputy Ministers of Health;- Ministry of Justice (VBQPPL Inspection Department);- Ministries, ministerial-level agencies, agencies attached to the Government;- People's Councils, People's Committees of provinces and centrally-run cities;- Units affiliated to, under the Ministry of Health;- Health Ministries and Branches;- Departments of Health of provinces and centrally-run cities;- Vietnam Medical Association;- Vietnam Pharmacological Association;- Central Committee of the Vietnam Oriental Medicine Association;- Ministry of Health's e-commerce portal;- Save: VT, K2DT, PC.

APPENDIX I

(Promulgated together with Circular No. 43/2024/TT-BYT)

NAME OF THE GOVERNING BODY **OF THE ETHICS COUNCIL IN BIOMEDICAL RESEARCH-------** Number:/	**SOCIALIST REPUBLIC OF VIETNAMIndependence - Freedom - Happiness-------** **--------** *....., date 20...*

CERTIFICATES

Approval of the research outline

Pursuant to Decision No. .... day.... of... on the establishment of the Ethics Council in Biomedical Research...[1];

Pursuant to Decision No. .... day.... of... on the promulgation of the Regulation on organization and operation of the Ethics Council in biomedical research...[1];

Pursuant to Record No. .... day.... of the Council on Ethics in Biomedical Research...[1] on the appraisal of the research outline,

Ethics Council in Biomedical Research .....[1]:

1. Scientific and ethical approval of research:

1.1. Research code:

1.2. Name of the study:

1.3. Research stage:

1.4. Principal Researcher:

1.5. Organizations presiding over:

1.6. Main coordinating agencies:

1.7. Sponsors:

1.8. Research location:

1.9. Participants in the study:

1.10. Expected number of participants in the study:

1.11. Research time:

2. Permission to use the following materials in the above-mentioned study:

STT	Document	Version	Day
1			
2			

3. Date of approval:

4. The date of the next periodic report:

5. Recommendations of the Ethics Committee for the study (if any):

6. Principal researchers shall have the following responsibilities:

1. Comply with the approved research outline and relevant documents, principles of Good Clinical Practice, and the provisions of the law on research ethics.

2. Report to the Ethics Committee in Biomedical Research...[1] Serious Adverse Events (SAE) and Suspected Unexpected Serious Adverse Reactions (SUSARs) in accordance with applicable guidelines and regulations.

3. Report to the Ethics Council in Biomedical Research...[1] Review and approve changes, deviations or modifications to the research outline and the consent form for participation in the

study, documents that provide information to the study participants before applying them in the study, unless it is clearly necessary to make changes to eliminate direct risks to the study participants.
4. Annual research progress report to the Ethics Council in Biomedical Research...[1] on or before the previous year's appraisal date.
5. Report on the progress of conducting extraordinary research at the request of the Ethics Council in biomedical research....[1]
6. To promptly notify the suspension of the study or the completion of the study before the expected deadline for completion and the reason for the early completion.
7. Prepare for the possibility of going to the research site inspection of the Ethics Committee in Biomedical Research....

PRESIDENT

Recipient:
- The organization in charge of the research (to know);- The principal researcher (to be implemented);- The scientific research management unit (to know);- The donor (to coordinate the implementation);- Save: VT.

APPENDIX II

(Promulgated together with Circular No. 43/2024/TT-BYT)

NAME OF THE GOVERNING BODY **OF THE ETHICS COUNCIL IN BIOMEDICAL RESEARCH-------**	**SOCIALIST REPUBLIC OF VIETNAMIndependence - Freedom - Happiness-------**
Number:/	*....., date 20...*

CERTIFICATES

Approval of changes to the research outline

Pursuant to Decision No. .... day.... of... on the establishment of the Ethics Council in Biomedical Research...[1];
Pursuant to Decision No. .... day.... of... on the promulgation of the Regulation on organization and operation of the Ethics Council in biomedical research...[1];
Pursuant to Decision No. .... day.... of... on the approval of the "....." research outline;
Pursuant to Record No. .... day.... of the Ethics Council in Biomedical Research...[1] on the appraisal of changes to the research outline,

Ethics Committee in Biomedical Research....[1]:

1. Approval of changes to the research outline for research:
1.1. Research code:
1.2. Name of the study:
1.3. Principal Researcher:
1.4. Organizations presiding over:
1.5. Sponsors:
2. To approve the following major changes to the research outline: .....
3. To permit the use of the following amendments and supplements in the above-mentioned research:

STT	Document	Version	Day

1			

4. Effective date of approval:
5. The next periodic report date:
6. The principal researcher shall comply with the research outline and the above-mentioned amended and supplemented documents from the effective date of this approval.

PRESIDENT

Recipient:
- The organization in charge of the research (to know);- The principal researcher (to be implemented);- The scientific research management unit (to know);- The donor (to coordinate the implementation);- Save: VT.

APPENDIX III

(Promulgated together with Circular No. 43/2024/TT-BYT)

NAME OF THE GOVERNING BODY
OF THE ETHICS COUNCIL IN BIOMEDICAL RESEARCH----

SOCIALIST REPUBLIC OF VIETNAMIndependence - Freedom - Happiness-------

Number:/

....., date 20...

CERTIFICATES
Research Results Report

Pursuant to Decision No. .... day.... of... on the establishment of the Ethics Council in Biomedical Research...[1];
Pursuant to Decision No. .... day.... of... on the promulgation of the Regulation on the organization and operation of the Ethics Council in biomedical research ...[1];
Pursuant to Decision No. ..... day..... of..... on the approval of the ..... research outline;
Pursuant to Record No. .... day.... of the Council on Ethics in Biomedical Research...[1] on the appraisal of the report on research results and the completed dossier (if any),

The Ethics Council in Biomedical Research...[1]Certification of the report of research results as follows:

1. Research code (if any):
2. Research name:
3. Research stage (if any):
4. Principal Researcher:
5. Organizations presiding over:
6. Principal coordinating agencies:
7. Sponsors:
8. Research Location:
9. Duration of study:
10. Name of product/technique/research method (if applicable):
11. Dosage and regimen of using products/techniques/methods in research (if applicable):
12. Conclusions of the Ethics Council on the study:
13. Date of Approval:

PRESIDENT

Recipient:
- The organization in charge of the research (to know);- The principal researcher (to be implemented);- The scientific research management unit (to know);- The donor (to coordinate the implementation);- Save: VT.

APPENDIX IV

(Promulgated together with Circular No. 43/2024/TT-BYT)

NAME OF THE GOVERNING BODY **OF THE ETHICS COUNCIL IN BIOMEDICAL RESEARCH-------**	**SOCIALIST REPUBLIC OF VIETNAMIndependence - Freedom - Happiness--------**
Number:/	*....., date 20...*

CONDITIONAL CONSENT NOTICE

To: - Organization in charge of the study1
- Principal Researcher2

On ....., the Ethics Council in Biomedical Research .....[3] (Ethics Council) conducted a pre-implementation research dossier appraisal meeting/ongoing research report/research result report.

1. General information about the study

1.1. Name of the study:
1.2. Organizations presiding over:
1.3. Principal Researcher:
1.4. Sponsors:
1.5. Research location:

2. Ethics Council's opinion on the research

2.1. Requirements of the Ethics Council:
2.2. Recommendations of the Ethics Council (if any):

Request the organization in charge of the study and the Principal Researcher to complete the dossier and send it to the ... the completed dossier on the Standing Committee of the Ethics Council in the period of... date, from the date of receipt of this official letter (electronic files of the dossier sent to the email address .....) for the Ethics Council to consider/re-evaluate.

The dossier sent to the Standing Committee of the Ethics Council includes:
- A written explanation of the reception of opinions of the Ethics Council;
- Completed documents;
- Other relevant documents.

Please notify the host organization and the main researcher to know and implement./.

PRESIDENT

Recipient:
- As above;- Scientific research management unit (to know);
- Sponsor (to coordinate implementation);- Save: VT.

APPENDIX V

(Promulgated together with Circular No. 43/2024/TT-BYT)

NAME OF THE GOVERNING BODY **OF THE ETHICS COUNCIL IN BIOMEDICAL RESEARCH-------** Number:/	**SOCIALIST REPUBLIC OF VIETNAMIndependence - Freedom - Happiness----------** *....., date 20...*

NOTICE OF DISAPPROVAL

To: - Organization in charge of the study1
- Principal Researcher2

On ....., the Ethics Committee in Biomedical Research .....[3] (Ethics Council) conducted a pre-implementation research dossier appraisal meeting/ongoing research report/research result report.

1. General information about the study

1.1. Name of the study:
1.2. Organizations presiding over:
1.3. Principal Researcher:
1.4. Sponsors:
1.5. Research location:

2. Ethics Council's opinion on the research

2.1. The Ethics Council does not approve the research dossier before implementation/ongoing research report/research result report.
2.2. Reasons for non-approval: ....
Please inform the research organization and the main researcher./.

PRESIDENT

Recipient:
- As above;- Scientific research management unit (to know);- Donor (to coordinate implementation);- Save: VT.

APPENDIX VI

(Promulgated together with Circular No. 43/2024/TT-BYT)

NAME OF THE GOVERNING BODY **ORGANIZING THE ESTABLISHMENT OF THE ETHICS COUNCIL----------** Number:/ Announcement of the establishment of the Ethics Council in Biomedical Research	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness----------** *Hanoi, May 20...*

To: Department of Science, Technology and Training, Ministry of Health

[Name of organization establishing the Ethics Council] hereby notifies the Department of Science, Technology and Training, Ministry of Health of the establishment of the Ethics Council

in grassroots biomedical research of [Name of Organization establishing the Ethics Council], specifically as follows:
1. Decision on the establishment of the Council No. ....., dated .....
2. Name of the Council:
3. The Chairperson of the Council:
Full name:
Phone: Email:
4. Professional/administrative secretary of the Council:
Full name:
Phone: Email:
5. Office of the Council:
Address:
Phone: Email:
Documents enclosed with official dispatches
1. To decide on the establishment of the Council.
2. The Council's operation regulations.
3. The list and scientific curriculum vitae of the members of the Council.
4. The list and copies of the Council's standard operating procedures.
We would like to request the Department of Science, Technology and Training to update on the Department's website as prescribed.
Thank you very much./.

UNIT HEAD

Recipient:
- As above;- Managing agency (for reporting);- Save: VT.

NAME OF THE ORGANIZATION ESTABLISHING THE ETHICS COUNCIL
LIST OF ETHICS COMMITTEE MEMBERS IN BIOMEDICAL RESEARCH
(According to the Decision on the establishment of the Council No. ....., dated .....)

STT	Full name	Gender	Year of birth	Qualifications and specialties	Independence

Total has ..... members of the Council.

....., May 202.....
UNIT HEAD

NAME OF THE ORGANIZATION ESTABLISHING THE ETHICS COUNCIL

DIRECTORY OF ETHICS COUNCIL'S STANDARD PRACTICE PROCEDURES FOR BIOMEDICAL RESEARCH

STT	Process Name	Ampersand	Version	Date of Issue

Total has ..... Standard Practice Procedures.

....., date 202....

UNIT HEAD