Introduction of Ethic Research Committee

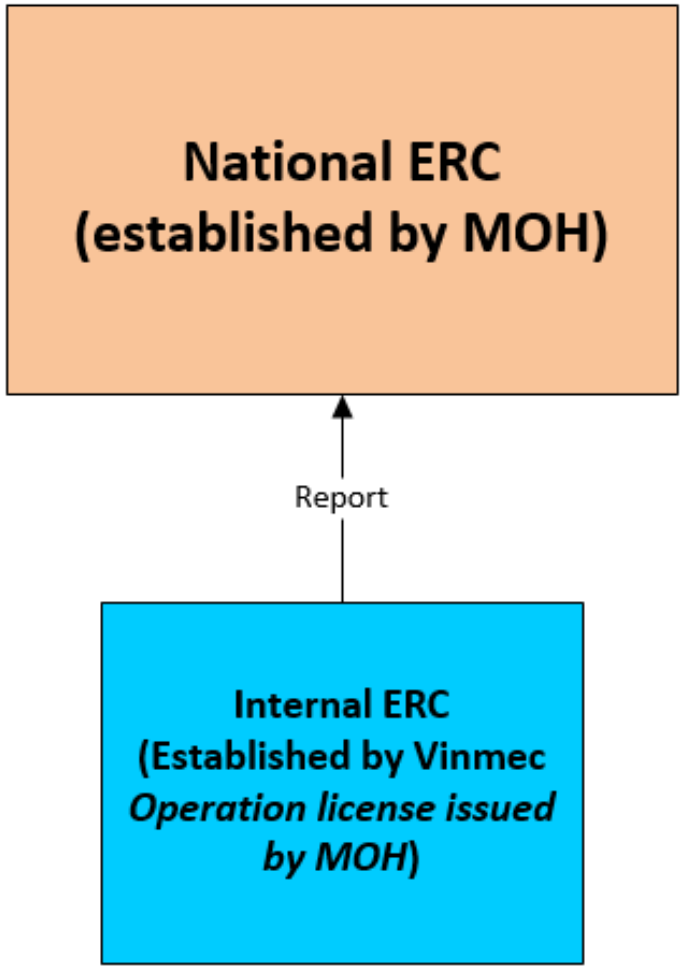
Prof. PhD. MD. Do Tat Cuong – Chairman of Vinmec's ERC

VINMEC
HEALTHCARE SYSTEM
Great connection - Great care

1. Definition of Ethic Research Committee (ERC):

The Ethic Research Committee is an *independent organization* (can be classified by levels: base, region, country or region) including members in the *medical and non-medical majors*; has a role to *protect rights, safety and subject's health into the study*.

I. Introduction of Ethic Research Committee



2. Functions and tasks of ERC:

- Advising the head of the entity establishing the ERC about considering and reviewing ethical and scientific aspects of research involving human participants to form a basis for approving, conducting and completing the research.

- Undertake ethical and scientific review of research studies involving human participants that is presided over by the entity establishing the internal ERC before submitting research documentation for review by the national ERC.

- ERC' operations must follow the regulations of **Circular No. 4/TT-BYT dated March 05, 2020** on establishment, functions, tasks and rights of Research Ethics Committees

I. Introduction of Ethic Research Committee

3. Composition of ERC members:

At least 5 members	Age	Gender
• 1 Chair • 1 – 2 Deputy Chair • Other members	• under the age of 40 • aged from 40 to under 50 • aged 50 or older	• Male • Female • Each gender take up at least 20% of total number of ERC members

3. Composition of ERC members:

Composition

- members that have a degree in the health sector related to common research assessed by the ERC, including 01 person with no connection to the entity establishing the ERC;
- members that are clinical doctors;
- members that have expertise in legal matters and/or ethics;
- lay members that do not have expertise in the health sector.

GCP

- All members must have the certificate of training in **Good Clinical Practice and ERC's SOPs** issued by the Ministry of Health or organizations recognized by the Ministry of Health, and be recurrently trained.

VINMEC
HEALTHCARE SYSTEM

BỘ Y TẾ
MINISTRY OF HEALTH

CERTIFICATE OF ATTENDANCE

is hereby awarded to

LÊ CỰ LINH

Vinmec International Hospital Joint Stock Company

for attending

The Good Clinical Practice and Ethics Training

Hanoi, 9th June, 2017

DR. NGUYEN NGO QUANG
Deputy Director, Administration of Science, Technology & Training
Ministry of Health, Vietnam

Sample of MOH's certified GCP training

Studies that required to review at internal ERC:

- Biomedical research with human subjects includes clinical trials of drugs (modern medicines, medicinal herbs, traditional medicines, vaccines and other biologicals for prevention and control), medical treatment, study of bioavailability and assessment of bioequivalence), medical equipment;
- Research on treatment methods, diagnostics, biological samples, epidemiological investigations, sociology and psychology were conducted with human subjects.

II. Review Process

Studies that required to review at national ERC:

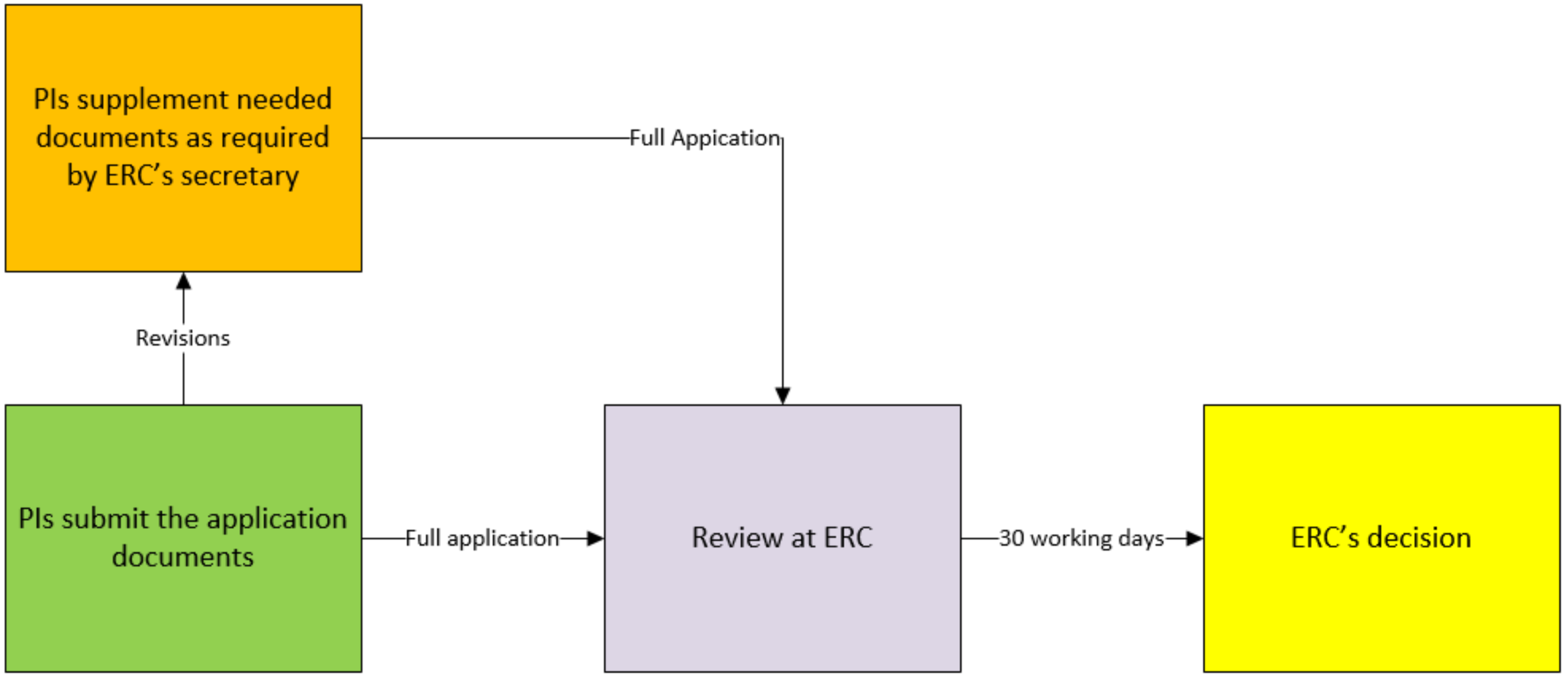
- Clinical trials of medicinal products, equipment and other products that have not yet been licensed for sale in Vietnam;
- Multicenter trials;
- Research on clinical trial of new techniques and methods in humans in Vietnam;
- Ministerial and national scientific research involving human subjects in healthcare field in Vietnam;
- International cooperation research where biological samples of research subjects are sent abroad or research results that are representative of Vietnamese people
- Other biomedical research at the request of the Ministry of Health, organizations and individuals that preside over research.

II. Review Process

Contents that ERC need to review:

- Research design and conduct of the research;
- Risks and potential benefits;
- Selection of research population, and recruitment and protection of research participants;
- Financial benefits and financial costs;
- Protection of research participants' privacy and confidentiality;
- Informed consent process;
- Effects of research on communities from which participants will be drawn;
- Capacity of researchers and research sites.

II. Review Process



III. Documents required for review

Notes:

- ***Language for documents submitted to internal ERC:***

- English and Vietnamese
- Particularly, the following documents will need to be prepared in Vietnamese: Application form; Informed Consent Form; A project summary; A description of the ethical considerations involved in the research

- ***Language for documents submitted to national ERC:***

- All documents must be prepared in Vietnamese

III. Documents required for review

1. Review for the first time (new studies)

General Documents	Signed and dated application form, including signatures of listed co-applicants and institutional officials where relevant.
	The protocol for the research project (with date and version number), together with supporting documents and annexes (if any)
	A project summary or synopsis in non-technical language.
	A description (which may be included in the protocol) of the ethical considerations involved in the research; a description of measures that will be taken to ensure the protection of participants' privacy and the confidentiality of data; a statement describing any remuneration or other goods or services to be provided to research participants; a description of arrangements for insurance coverage for research participants (if applicable).
	An adequate summary of all safety, pharmacological, pharmaceutical, and toxicological data available on the research product (applicable to research involving an experimental product).
	All data collection forms to be used in the research project, with date and version number.
	All forms, documents, advertisements to be used in recruitment of potential participants.

VINMEC
HEALTHCARE SYSTEM

III. Documents required for review

1. Review for the first time (new studies)

Informed Consent Form (ICF) and related documents	Informed consent form(s) (with date and version number) for the research subjects (if research subjects are aged 18 or older and have full legal capacity to provide informed consent).
	Informed consent form(s) (with date and version number) for the research subjects and their parents or legal guardians (if research subjects are aged from 16 to under 18).
	Informed consent form(s) (with date and version number) for the research subjects and their parents or legal guardians (if research subjects are aged under 16).
	Assent form(s) (with date and version number) for the research subjects who are not competent to give legally valid informed consent, including children aged from 12 to under 16, person having insufficient legal capacity or cognitively impaired persons.
	A detailed description of the recruitment and ICF collection process.

III. Documents required for review

1. Review for the first time (new studies)

Other documents	The procedure for monitoring, assessing and handling adverse events (applicable to research intervening in research subjects).
	All previous decisions (including the reasons for previous negative decisions and modification(s) to the proposal made on that account) by other ERCs or regulatory authorities for the proposed research.
	Written permission for conduct of the research after obtaining the approval of the competent authority, which is granted by the organization managing research sites (if the research is conducted outside the entity establishing the ERC).
	Scientific Review Board's written approval

III. Documents required for review

1. Review for the first time (new studies)

PI's documents	A statement that the PI(s) agree to comply with ethical principles set out in relevant guidelines.
	Current curricula vitae and relevant certificates of the PI(s).
	Good Clinical Practice and ERC's SOPs issued by the Ministry of Health (*incase the study is clinical trial*)
	Other relevant documents

III. Documents required for review

2. Review during research progress (on-going studies)

Follow-up review of ongoing research report	Summary of the research protocol.
	A complete research protocol, including the modifications previously approved
	Research progress reports
	Report on number of subjects that are selected, complete or withdraw from participation in the research or whose track is lost
	Reports on adverse events and issues involving risks of harm to the participants, and cases of withdrawal from participation
	Summary of relevant information, especially information about safety
	Current ICF
	Independent audit reports of the researcher and the sponsor
	Notification from the PI or sponsor with regard to suspension/premature termination or completion of the research.

III. Documents required for review

2. Review during research progress (on-going studies)

Modifications to the research protocol	A report on modifications
	Modified documents
	Scientific Review Board's written approval
	Other relevant documents

III. Documents required for review

2. Review during research progress (on-going studies)

Report on adverse events occurring in the context of the research	A report on adverse events occurring in the context of the research
	Other relevant documents (if any).

III. Documents required for review

2. Review during research progress (on-going studies)

Report on violations against the research protocol	A report on violations against the research protocol
	Other relevant documents (if any).

III. Documents required for review

3. Review when complete the study

Review of the research result report	Signed and dated application form, including signatures of listed co-applicants and institutional officials where relevant
	A research result report (with date and version number), together with supporting documents and annexes (if any).
	Study products (if any).
	Other relevant documents.

IV. Full and expedited review

1. Expedited review in following cases:

- It contains minimal risks
- It has been reviewed by the ERC before
- It has been reviewed and approved by another ERC at the same level
- The periodic research report has been approved
- The application for amendments to the approved research protocol has been approved
- The report on adverse events occurring in the context of the approved research has been approved
- The report on violations against the approved research protocol has been approved.

2. Full review in following cases:

- It is ineligible to be reviewed through an expedited procedure
- It has been reviewed through an expedited review but the reviewer requests a full review

V. Follow-up and irregular reviews of research

Follow-up reviews of research	At least once a year on or before the day the research protocol is approved by the ERC
	A decision resulting from a follow up review should indicate either that the original decision is still valid or that there has been a modification, suspension, or withdrawal of the ERC's original decision.

V. Follow-up and irregular reviews of research

Irregular reviews of research	Any protocol amendment likely to affect the rights, safety, and/or well-being of the research participants or the conduct of the study
	Adverse events (AE) or Serious unexpected Adverse events (SATE related to the conduct of the study or study product.
	Any event or new information that might affect the potential benefits or risks of harm involved in the study.
	Decisions made by a sponsor or regulatory authority to suspend a study in whole or in part.

VI. Contact

When submitted a research project (included new and on-going), the PI(s) should send the application documents to these following persons:

1. Mr. Vu Xuan Huyen - Vinmec's Research Management Office:

- Email: v.huyenvx@vinmec.com
- Tel: (+84) 983 651 563/ (+84) 968 208 682

2. Ms. Pham Quynh Hoa – ERC's Secretary:

- Email: v.hoapq@Vinmec.com
- Tel: (+84) 88 64 28990/ (+84) 83 212 0090


Q&A

VINMEC
HEALTHCARE SYSTEM

XIN CẢM ƠN!