Ethics Committee

Faculty of Tropical Medicine, Mahidol University

STANDARD OPERATING PROCEDURES

Edition 2018

(version 2)

Standard Operating Procedure Edition 2018 (Version 2)
Faculty of Tropical Medicine, Mahidol University

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	Quality System Documentation	
	Document No.: FTM ECS-001-08	**Effective Date:** 07 March 2018

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Quality System Documentation

CHANGE HISTORY		
Revision	Description of Change	Effective Date
00	Initial release	28 June 2007
01	The 2008 annual review of the document leads to the following changes: 1. In section 4.2, indicate that SOP Developing Working Group is later on replaced by EC Members and as a consequence, the term "EC Members" is used afterward while "the Secretary of the SOP Developing Group" is replaced by "Staff Secretary"; 2. Add responsibilities of EC Members who, later on, conduct an annual review of the quality system documents and may initiate new SOPs, Forms, or WPDs as needed.	01 July 2008
02	Entering the SIDCER/FERCIT Recognition Programme of World Health Organization (WHO), suggestions of the surveyors lead to the following changes: 1. Nomenclature changed – 'EC Secretary' is replaced with 'Staff Secretary'; 2. Section 5.0 has been divided into 2 subsections namely 'References' and 'Associated documents'; Heading of section 7.1 has been changed to "Items recommended for SOP".	24 September 2008
	There was no revision in the year 2009.	
03	As a result of the SOP annual review (16 Feb 2010), the following changes have been made 1. Chairperson's name was changed to Prof. Srisin Khusmith and Prof. Krisana Pengsaa in Section Author's Signatures, throughout the 2010 annual revision. 2. In section 3.2, the Policy was changed from "Final version of the quality system documents must be reviewed and approved by the Faculty of Tropical Medicine Executive Board and signed off by the Dean of the Faculty" to "Final version of the quality system documents must be approved by the Dean of the Faculty" throughout the 2010 annual revision. 3. Revise Dean of the Faculty of Tropical Medicine's responsibility in section 4.1, to give final approval to FTM EC quality system document.	22 April 2010

Quality System Documentation

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	4. Nomenclature changed-"Staff Secretary" was replaced by "Assistant Secretary" 5. Delete a sentence "it does not require approval by the Faculty Executive Board" in section 7.1 6. Change the decision for approval of the final version of the document from the Faculty Executive Board Meeting to the Dean in section 7.4.5, and correct the running number from 7.4.8 to 7.4.6 and from 7.4.9 to 7.4.7, in section 7.4 7. Revise the revision of an existing document, in section 7.5 8. Change the decision for approval to retire an existing document from the document system from the Faculty Executive Board Meeting to the Dean FTM in section 7.6.3	
04	According to SIDCER/FERCAP recognition in 2011, the following change has been made Add the SOPs Template in Appendix, page 8 of 8.	22 December 2011
05	The 2014 annual review of the document leads to the following change: 1. Change "Research Proposal/Protocol Submission Form" to "Research Proposal Submission Form" in section 7.2.2.	01 May 2014
06	The review for multicenter study is added, so the submission number needs to be assigned in section 7.4 Submission Number Assignment.	19 May 2015
07	The resolutions of the EC Retreat and SOP training 2016 lead to the following changes: 1. Remove Controlled Document "Any document which has a unique FTM EC number, a revision level, a red stamp CONTROLLED DOCUMENT and is controlled by Member and Secretary" in section 6.0. 2. Remove page number (Page…of…) in section 7.1.10. 3. Remove statement "All copies of documents are issued as "Controlled Copy, Do Not Duplicate" and "Internal Use Only" and replace it with "Identify page number" in section 7.1.11.	03 November 2016

Quality System Documentation

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	4. Remove identification statement "Internal Use Only" on the form from section 7.2.2 of 7.2 Items recommended for Form. Combine form "Applicable of Continuing review" with form "Extension Request" to "Progress Report Form/ Certificate of Ethical Approval Extension Request Form" 5. Revise process of document archival in section 7.8 by removing the stamping of "CONTROLLED COPY" on the master hardcopy, and adding "the Member and Secretary shall sign her name and date on all pages" to the master hardcopy. 6. Delete section 7.10 Document request "EC SOPs and WPDs are intended for internal use only. Distributing these kinds of documents to the public is prohibited. If a photocopy of the document is needed for FTM EC business, the request should be made to EC Chairperson who will grant permission. Upon EC Chairperson's permission, Member and Secretary can then make a copy of the document for the requester" 7. Remove "*Controlled copy-Do not Duplicate*" and "*Internal Use Only*" from Footer.	
08	The resolution of the EC Retreat and SOPs Training 2017 leads to the following change: 1. Revise statement in section 7.4 from "Research project belonging to FTM staff/ student or which is conducted in an area where FTM is responsible submitted directly to FTM EC is assigned 0NN" to "Research projects belonging to FTM staff/ student or which is conducted in an area where FTM is responsible with Investigators(s) affiliated with FTM submitted directly to FTM EC are assigned 0NN"	07 March 2018

Quality System Documentation

SIGNATURES		
Author	I, on behalf of the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, indicate that this SOP has been authored according to applicable business requirements for quality system documentation.	
	Name: Assoc. Prof. Jaranit Kaewkungwal	Signature:
	Title: Chairperson, Ethics Committee of the Faculty of Tropical Medicine, Mahidol University	Date: 05 MAR 2018
Approver	I indicate that I have reviewed this SOP, and find it meets all applicable business requirements and that it reflects the procedure described. I approve it for use.	
	Name: Assoc. Prof. Pratap Singhasivanon	Signature:
	Title: Dean, Faculty of Tropical Medicine, Mahidol University	Date: 06 MAR 2018

1.0 Purpose

To describe the processes utilized in the preparation, numbering, review, approval and maintenance of the documents developed by the Ethics Committee (EC) of the Faculty of Tropical Medicine (FTM), Mahidol University.

2.0 Scope

This SOP applies to documents utilized in conjunction with the activities of the FTM EC. These quality system documents included, but not limited to, Standard Operating Procedures (SOPs), Forms, Work Practice Documents (WPDs), etc.

3.0 Policy

3.1 Quality system documents are processed, reviewed, approved and issued prior to use according to the practices described in this SOP.

3.2 Final version of the quality system documents must be approved by the Dean of the Faculty.

3.3 The rationale for each document and its subsequent revision is to be clearly documented and all obsolete documents shall be archived.

3.4 The methods, practices and quality control procedures as outlined in this SOP must be observed by all EC members.

4.0 RESPONSIBILITIES

4.1 Dean of the Faculty of Tropical Medicine

4.1.1 Give final approval to FTM EC quality system documents.

4.2 *Ad hoc* SOP Developing Working Group[1] of the Ethics Committee of the Faculty of Tropical Medicine

4.2.1 Develop, review, and prepare drafts of FTM EC quality system documents.

4.3 EC Members

4.3.1 Conduct an annual review of currently in use FTM EC's SOPs/Forms/WPDs and revise them as needed.

4.3.2 Develop, review and prepare drafts of FTM EC quality system documents, if necessary.

[1] The SOP Developing Working Group is later on replaced by EC Members.

4.4 Member and Secretary

4.4.1 Implement and maintain the quality system documentation.

4.4.2 Number sequential SOPs, Forms, and Work Practice Documents.

4.4.3 Maintain the document number assignment log and update document list.

4.4.4 Archive all approved master documents, including the version currently in effect and any obsolete versions.

4.4.5 Notify the EC of the annual review date(s).

5.0 References & Associated Documents

5.1 References

5.1.1 ICH Guidelines for Good Clinical Practice E6

5.1.2 Clive CM. Handbook of SOPs for Good Clinical Practice. 2nd ed. Boca Raton: Taylor & Francis; 2004.

5.2 Associated documents

5.2.1 SOP Template

5.2.2 FTM ECF-001-RR (Document Number Assignment Log)

5.2.3 FTM ECF-002-RR (Document Revision Control)

6.0 Definitions

Electronic Copy	Any type of document (i.e., text, drawing, graphic) which is stored in magnetic or optical media, i.e., diskette, tape, CD-ROM.
Form	A quality record generated from a SOP or WPD.
Hard Copy	Any type of document (i.e., text, drawing, graphic) which exists on paper.
Quality System Document	Any document developed in compliance with FTM EC's SOP on Quality System Documentation. It is subject to develop, review and drafting by SOP Developing Working Group or EC Members. Its final approval is granted by the Dean of FTM. The document is subject to an annual review.
Standard Operating Procedure (SOP)	A formal quality system document that describes what is to be done to accomplish a designated task.
Work Practice Document (WPD)	A product/process-specific procedure.

7.0 Procedures

7.1 Items recommended for SOP

In addition to the cover page which describes the document number, title, effective date, change history and required signatures, an SOP should comprise the following items:

7.1.1	Title:	Brief and informative.
7.1.2	Purpose:	A concise and accurate summary of what the document is to accomplish.
7.1.3	Scope:	Description of the appropriate application of the document.
7.1.4	Policy:	Overview and goal of the procedure (Optional).
7.1.5	Responsibilities:	Responsibility for implementing, approving, and revising the document.
7.1.6	References:	List of other documents that are referred to or relevant to the procedure, or other relevant documents that may be utilized by personnel to acquire additional insight of the procedure.
7.1.7	Definitions:	Definitions of terms which are essential to the proper understanding and execution of the procedure. If no terms need to be defined, mark this section as "Not Applicable".
7.1.8	Procedures:	Description of the activities to be performed.
7.1.9	Appendices:	Examples of related documents, i.e., forms or templates.
7.1.10	Header:	Identify the document title, the document number, effective date.
7.1.11	Footer:	Identify page number.
7.1.12	Change history:	Identify the current revision number of the document, a description of any changes and the date that the new or revised document became effective.
7.1.13	Signatures:	Identify the document author and the one who approves it for release (individual statement, printed name, position, signature and date required).

A work practice document (WPD) may adopt this format of SOP. Difference is that a WPD is developed for EC Office use only

7.2 Items recommended for Form

7.2.1 Cover page: Form's cover page is similar to that of the SOP. It comprises header, footer, change history and signatures.

7.2.2 Form is designed according to its usage. However, its title, document number and page number have to be included on the Form. If the Form is to be used by the Investigator (e.g., Research Proposal Submission Form, Progress Report Form/ Certificate of Ethical Approval Extension Request Form etc.), such statement can be omitted.

7.3 Document numbering

Document number follows the following convention:

FTM ECX-NNN-RR

Where	FTM	refers to the Faculty of Tropical Medicine
	EC-	refers to the Ethics Committee
	X-	denotes the type of document (S for SOP, F for Form, and W for Work Practice Document)
	NNN-	indicates the sequence number for a particular type of the document
	RR-	indicates the version/revision number of the document

Therefore, ***FTM ECS-001-00*** may be interpreted as an initial version of an SOP of the Ethics Committee of the Faculty of Tropical Medicine of which number is 001 in the series.

7.4 Submission Number Assignment

A Submission Number will be assigned to each research project submitted for ethical review at the Ethics Committee of the Faculty of Tropical Medicine, as follows:

TMEC YY- NNN

Where	TM	refers to the Faculty of Tropical Medicine
	EC	refers to the Ethics Committee
	YY-	the calendar year when the project was submitted
	* NNN	indicates the sequence number for a particular type of the research project.

* Research project belonging to FTM staff/ student or which is conducted in an area where FTM is responsible with Investigators(s) affiliated with FTM submitted directly to FTM EC is assigned 0NN.

Multicenter research projects approved by Central Research Ethics Committee (CREC) submitted to FTM EC is assigned 8NN.

Multicenter research projects under Memorandum of Understanding (MOU) of Mahidol University submitted to FTM EC is assigned 9NN.

7.5 Initiating a new document

7.5.1 EC members can initiate a new document if deemed necessary.

7.5.2 A draft document shall be prepared by using FTM EC SOP Template (for SOP and WPD; if initiating a Form, follow procedure 7.2 above) with the document number assigned by Member and Secretary (Refer to the Document Number Assignment Log or FTM ECF-001-RR).

7.5.3 A meeting among EC members shall be set up to develop and discuss the draft document.

7.5.4 Comments from the meeting shall be compiled and the Member and Secretary is responsible for preparing the final version of the document.

7.5.5 After obtaining the final version of the document, the Member and Secretary shall submit it to the Dean for approval.

7.5.6 Document approval date (issue date) is the date the Approver signs the master hard copy whereas the effective date is the next day after the document has been approved. In cases that training is necessary, the effective date can be put further, but it should not be greater than one (1) month after the approval date.

7.5.7 Member and Secretary shall notify EC members of the document initiation and update the document listing.

7.6 Revising an existing document

7.6.1 When an existing document requires a change, either per an annual review or when deemed necessary, there should be a call for Ad hoc SOP developing working group.

7.6.2 The meeting shall discuss and justify the reason(s) to change. Comments from the meeting shall be compiled and the Member and Secretary is responsible for preparing the revised version of the document. When preparing the revised version, he/she shall pay attention to the revision number of the document which is changed accordingly (Refer to the Document Revision Control or FTM ECF-002-RR). Change history is also documented in the cover page of the document.

7.6.3 The revised version shall be reviewed by EC members and submitted to the Dean FTM for approval.

7.6.4 Document approval date (issue date) is the date the Approver signs the master hard copy whereas the effective date is the next day after the document has been approved. In cases that the revision leads to a substantial change and training is necessary, the effective date can be put further, but it should not be greater than one (1) month after the approval date.

7.7 Retiring an existing document from the documentation system

7.7.1 Same review and approval process as stated above is applied to the retirement of an existing document.

7.7.2 EC members shall document their justification of motivation for retiring the document.

7.7.3 Approval to retire an existing document from the document system is granted by the Dean FTM.

7.7.4 After the permission to retire the document is granted, the Member and Secretary shall stamp "RETIRED" on the master document and inform EC members of the retirement. He/ She shall also update the document listing.

7.8 Document archival

7.8.1 Hard copy archival

7.8.1.1 Upon obtaining all required signatures on the master hard copy, the Member and Secretary shall sign her name and date on all pages.

7.8.1.2 In case of revising an existing document, Member and Secretary shall stamp "RETIRED" on the previous version to indicate that it is replaced by a new one and no longer in use.

7.8.1.3 In case of retiring an existing document, Member and Secretary shall collect the approval statement/signature, then stamp "RETIRED" on the master hard copy.

7.8.2 Electronic copy of the document

7.8.2.1 Only Member and Secretary is allowed to archive electronic copies of the quality system documents in order to avoid the duplication of electronic document archival in EC.

7.8.2.2 In addition to the .doc or .xls formats being archived for revisions, Member and Secretary shall also archive the documents in .pdf format after obtaining all required signature.

7.9 Annual review of quality system document

7.9.1 Document contents shall be reviewed on an annual basis to verify that they reflect the current methodology.

7.9.2 Approximately two months prior to the document's anniversary date, Member and Secretary shall notify the EC members of the annual review.

7.9.3 Annual review can result in "NO CHANGE" or "CHANGE".

7.9.4 If the document undergoes "ANNUAL REVIEW WITH NO CHANGE", the document number remains the same (i.e., it will not be re-issued) but its change history has to be updated to indicate that the annual review has taken place and resulted in "no change". In this case, the cover pages of the document (change history and signatures) have to be rewritten.

7.9.5 If the document undergoes "ANNUAL REVIEW WITH CHANGE", the procedures 7.5.1 – 7.5.5 are applied.

Photocopied documents should be destroyed after use. EC Forms can be made available for use.

8 Appendix

8.1 SOPs Template

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2.0	SCOPE
3.0	POLICY
4.0	RESPONSIBILITIES
5.0	REFERENCES & ASSOCIATED DOCUMENTS
6.0	DEFINITIONS
7.0	PROCEDURES
8.0	APPENDIX

	Ethics Committee: Constitution, Composition, Responsibilities, Term of Membership, and Training	
	Document No.: FTM ECS-002-09	**Effective Date:** 07 March 2018

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Ethics Committee: Constitution, Composition, Responsibilities, Term of Membership, and Training

CHANGE HISTORY		
Revision	Description of Change	Effective Date
00	Initial release	28 June 2007
01	The 2008 annual review of the document leads to the following changes: 1. Revise EC Chairperson's responsibilities in section 4.1 by adding "Appoint SAE Subcommittee" and deleting #4.1.6; 2. Revise EC Members' responsibility especially those assigned as Primary Reviewers (see #4.2.2); 3. Add responsibilities of EC Member and Secretary; 4. Add responsibilities of SAE Subcommittee; 5. Revise responsibilities of Staff Secretary 6. Revise responsibilities of EC Administrative Staff or Secretary Assistant; 7. In section 7.2, some clarifications are made, i.e., adding "lawyer" as an example of 'non-scientific background' group and adding composition and characteristics of SAE Subcommittee; 8. In section 7.6, revise the termination of membership; In section 7.7, revise the training requirement for newly appointed EC member.	01 July 2008
02	Entering the SIDCER/FERCIT Recognition Programme of World Health Organization (WHO), suggestions of the surveyors lead to the following changes: 1. Nomenclatures changed – 'Secretariat' is replaced by 'Member and Secretary' and 'EC Secretary' with 'Member and Secretary'; 2. In section 4.0, add responsibilities of EC Vice Chairperson; 3. Subheading of section 4.7 has been changed from "Faculty Executive Board Member" to "Faculty Executive Board";	24 September 2008

Ethics Committee: Constitution, Composition, Responsibilities, Term of Membership, and Training

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	4. Section 5.0 has been divided to 2 subsections namely 'References' and 'Associated documents', more references are added in section 5.1; 5. In section 7.2, number of EC members has been changed from "no fewer than five (5) members" to "no fewer than seven (7) members"; 6. Also in section 7.2, state clearly that one EC member will be appointed as EC Vice Chairperson and another one as EC Member and Secretary; Add new section on "Establishment of EC Office" before the section on Alternate EC Members.	
	There was no revision in year 2009.	
03	As a result of the SOP annual review (16 Feb 2010), the following changes have been made 1. Chairperson's name was changed to Prof. Srisin Khusmith and Prof. Krisana Pengsaa, throughout the 2010 annual revision. 2. "Human participants" was replaced by "Human" in section 2.0 and section 3.0 3. Revise EC Chairperson's responsibility in section 4.1 4. Add responsibility of Consultant, as section 4.2 5. Add informed assent for review of EC Members' responsibilities and replace "favorable opinion" by "opinion" in section 4.3 6. Delete responsibility of EC Vice Chairperson 7. Add exempt review for Member and Secretary to determine which submitted research protocols are subject to exemption, expedition, or full board review, in section 4.4.1 8. Delete EC Administrative Staff or Assistant Secretary's responsibilities and Faculty Executive Board's responsibility	22 April 2010

Ethics Committee: Constitution, Composition, Responsibilities, Term of Membership, and Training

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	9. "Dean of FTM" was replaced by "Dean FTM", indicating the procedure for the appointment of EC Members in section 7.1 10. "Dean FTM shall appoint EC Chairperson" was changed to "Dean FTM shall appoint EC Chairpersons" 11. Revise the last paragraph of the composition of the EC 12. "Secretary Assistant" was replaced by "Assistant Secretary", "Degree" was replace by "Qualification" in number 2 in section 7.5 13. Frequency of Training in ethics or requirements in human subjects; research has been changed from "2 hours annually" to "annually", in section 7.8	
04	For the appropriate practice of the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University the following change is instituted: 1. "The Chairperson will be appointed for a term of two (2) and may not serve more than two (2) consecutive terms" was changed to "The Chairperson will be appointed for a term of two (2) and may serve more than two (2) consecutive terms" in section 7.7 Term of Membership	27 August 2012
05	The 2014 annual review of the document leads to the following change: 1. Change "research proposal/protocol" to "research proposal" in sections 4.7.1 and 4.7.2.	01 May 2014
06	The resolution of the EC Retreat 2014 leads to the following change: 1. Add a responsibility of Member and Secretary "4.7.6 In the case of an expedited review, the Member and Secretary will comment directly on the cover letter of revised proposal/documents and continuing review to Primary Reviewers"	03 October 2014

Ethics Committee: Constitution, Composition, Responsibilities, Term of Membership, and Training

CHANGE HISTORY		
Revision	Description of Change	Effective Date
07	As decided at the SIDCER/FERCAP-NECAST recognition and SOPs training in EC Retreat in 2015, the following changes have been made 1. Removed "consultant" from Section 4.0 Responsibilities. 2. Specified the persons responsible for review SAE in Section 4.1.2 and 4.8. 3. Added "Preparation for meeting agenda and meeting minutes" to the responsibilities of Member and Secretary in Section 4.6.5, and revised the responsibility of Assistant Secretary to "Distribute meeting agenda and meeting minutes to the EC" in Section 4.8.1. 4. Added responsibilities of Administrative Staff to Section 4.9. 5. Revised form FTM ECF-004-RR from "Confidentiality Agreement" to "Confidentiality and Conflict of Interest Agreement" in Section 7.1 Appointment of EC Members. 6. Added role of FTM EC in each panel that reviews different type of research, added a requirement to have at least 3 physicians for Panel 1and at least 1 physician for Panel 2, and added qualifications of expert members to Section 4.4 and 7.2. Added qualification of expert member to Section 4.5 and 7.2, FTM ECS-002-07. 7. Revised term "Alternate EC Members" to "Alternate/Expert Member (optional)" in Section 7.4. 8. Added requirement for signing Confidentiality and Conflict of Interest Agreement to Section 7.6 Conflict of Interest. 9. Added term of membership of EC member to Section 7.7 . 10. Add "including SOP training" to Section 7.8 Training EC Members.	16 October 2015

Ethics Committee: Constitution, Composition, Responsibilities, Term of Membership, and Training

CHANGE HISTORY		
Revision	Description of Change	Effective Date
08	The resolution of the EC Retreat and SOP training 2016 leads to the following changes: 1. Change policy in section 3.0 from "The EC assists researchers in protecting the rights and welfare of human subjects by conducting initial and ongoing review activities of research where FTM staff members/ students are either Principal Investigators and/ or research is conducted within FTM facilities" to "The EC assists researchers protect the rights and welfare of human subjects by conducting initial and ongoing review activities of research with the following criteria: 1) Research where FTM staff members/ students are the Principal Investigator conducting their research within or outside FTM facilities. Where the research is conducted outside FTM facilities, the Principal Investigator must also submit the research to the local EC for consideration; or 2) Conduct the research in FTM facilities with Investigator(s) affiliated with FTM 2. According to the Faculty of Tropical Medicine Order no. 00378/2016 dated 20 October 2016, the 2 Panels of the Ethics Committee of the Faculty of Tropical Medicine have been merged into one panel. Therefore we remove "The FTM EC has 2 Panels. Panel 1 reviews clinical trials and clinical research, while Panel 2 reviews non-clinical research including biomedical science both laboratory and field, social science, epidemiological research" and "Panel 1 should have at least three physicians, while Panel 2 should have at least one physician" from section 7.2 Composition of the EC.	03 November 2016

Ethics Committee: Constitution, Composition, Responsibilities, Term of Membership, and Training

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	3. Revise criteria of Conflict of Interest of EC Member from "1. He/she is the Investigator, Sub-investigator, or Study Coordinator for a study. 2. He/she has a significant financial interest in the research activity under consideration or the results of the study. 3. He/she has a conflict of loyalty (e.g., promoting the work of subordinates or supervisors). 4. The EC's decision may have an impact on the EC member's research" to "1. He/she is Principal Investigator (PI), Co-Principal Investigator, Investigator receiving funding from the study as listed in the study budget. 2. He/she is in a supervisory role over the PI of the study. 3. He/she has a significant financial interest in the results of the research activity under consideration. 4. He/she has conflict of loyalty (e.g., promoting the work of subordinates or supervisors). 5. He/she is a family member of PI. 6. The EC's decision may have an impact on my research" 4. Change term of membership in section 7.7 from "The Chairperson and EC Members will be appointed for a term of two (2) years and may serve more than two (2) consecutive terms" to "The Chairperson and EC Members will be appointed by the Dean of the Faculty of Tropical Medicine, Mahidol University". 5. Remove "*Controlled copy-Do not Duplicate*" and "*Internal Use Only*" from Footer.	
09	The resolution of the EC Retreat and SOPs Training 2017 leads to the following changes: 1. Revise Responsibility of Chairperson in section 4.1.2 from "Review SAE or appoint EC member(s) who are Primary Reviewer(s) of each protocol as SAE Reviewer" to "Assign EC member(s) to be Primary Reviewer(s) for each protocol, and also assign SAE Subcommittee member(s) to review AEs, SAEs, SUSAR reports for each protocol"	07 March 2018

Ethics Committee: Constitution, Composition, Responsibilities, Term of Membership, and Training

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	2. Change "SAE Reviewer" to "SAE Subcommittee" and revise their responsibility from "Review and present SAE reports to EC Chairperson or to Primary reviewer of each protocol…" to "Review and present SAE, AE, SUSAR reports to EC Chairperson or to Primary Reviewer for each protocol…" in section 4.7 3. Separate Form "Confidentiality and Conflict of Interest Agreement (FTM ECF-004-RR)" to Form "Confidentiality Agreement (FTM ECF-030-RR)" and Form "Conflict of Interest Statement (FTM ECF-031-RR)" as stated in section 5.2, 7.1 and 7.6 4. Add Form "SOP Compliance Form (FTM ECF-032-RR)" as an associated document to section 5.2.4 5. Change official appointment Ethics Committee from FTM Dean to President of Mahidol University "Dean FTM shall nominate EC Chairperson, who will propose prospective EC members of whom one will be EC Member and Secretary. FTM will submit the proposed list of Committee members to the President of Mahidol University for official appointment" in section 7.1 6. Add a condition for ending the term of EC membership "not attending monthly scheduled EC meetings constantly or not providing results of review several times" to section 7.7	

Ethics Committee: Constitution, Composition, Responsibilities, Term of Membership, and Training

SIGNATURES		
Author	I, on behalf of the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, indicate that this SOP has been authored according to applicable business requirements for quality system documentation.	
	Name: Assoc. Prof. Jaranit Kaewkungwal	Signature:
	Title: Chairperson, Ethics Committee of the Faculty of Tropical Medicine, Mahidol University	Date: 05 MAR 2018
Approver	I indicate that I have reviewed this SOP, and find it meets all applicable business requirements and that it reflects the procedure described. I approve it for use.	
	Name: Assoc. Prof. Pratap Singhasivanon	Signature:
	Title: Dean, Faculty of Tropical Medicine, Mahidol University	Date: 06 MAR 2018

	Ethics Committee: Constitution, Composition, Responsibilities, Term of Membership, and Training	
	Document No.: FTM ECS-002-09	**Effective Date:** 07 March 2018

1.0 PURPOSE

To describe the processes and procedures for forming and managing a duly-constituted Ethics Committee (EC) within the Faculty of Tropical Medicine (FTM), Mahidol University.

2.0 SCOPE

This SOP will apply to all research activity involving human regardless of the source of any supporting funds.

3.0 POLICY

The EC assists researchers protect the rights and welfare of human subjects by conducting initial and ongoing review activities of research with the following criteria:

3.1 Research where FTM staff members/ students are Principal Investigator conducting their research within or outside FTM facilities. Where the research is conducted outside FTM facilities, the Principal Investigator must also submit the research to the local EC for consideration; or

3.2 Conduct the research in FTM facilities with Investigator(s) affiliated with FTM

The EC shall meet or exceed the requirements of the Declaration of Helsinki and ICH GCP Guideline.

4.0 RESPONSIBILITIES

4.1 EC Chairperson

4.1.1 Nominate EC candidates to the Dean FTM for approval.

4.1.2 Assign EC member(s) as Primary Reviewer(s) for each protocol, and also assign SAE Subcommittee member(s) to review AEs, SAEs, SUSAR reports for each protocol.

4.1.3 Conduct meetings in an efficient and fair manner, and according to standard parliamentary procedures.

4.1.4 Follow the agenda created for each meeting.

4.1.5 Set a tone of openness to encourage dialogue in the meeting.

4.1.6 Respect the diverse backgrounds, perspectives, and sources of expertise of all EC members, especially for the contributions of the non-scientists, and the ability to foster such respect among the EC members.

4.1.7 Invest adequate time, interest, and commitment to provide guidance and expertise to EC members and Investigators.

4.1.8 Assure that the EC receives appropriate and sufficient administrative support, meeting space, and other necessary resources to function efficiently, and will report to the Dean FTM.

4.2 EC Vice-Chairpersons

4.2.1 To conduct meetings in an efficient and fair manner according to the standard parliamentary procedures in the absence of Chairperson.

4.2.2 To act for the Chairperson in situations where the Chairperson has a conflict of interest or is absent, including responsibilities such signing letters and Certificate of Ethics Approval and assigning primary reviewers for research projects.

4.3 EC Members

4.3.1 Review and approve/provide opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent/informed assent of the trial subjects.

4.3.2 EC members assigned as Primary Reviewers shall conduct an in-depth review of the research proposal and present the protocol, informed consent/informed assent, and other study-related materials to the full EC at the convened meeting.

4.4 Alternate/ Expert Members (optional)

4.4.1 Alternate/ Expert Members must have qualifications and expertise in the particular field of the studies. Their responsibilities are to review and provide opinions on the topic of their expertise in relation to the protocol in question as need by the Chairperson.

4.5 Lay Members

4.5.1 Lay Members are EC members who are from non-medical sciences or biomedical sciences. Their responsibilities are to review and provide opinions on the protocol in question, especially in regards to the Participant Information Sheet and Informed Consent Form in order to protect the rights of research study participants.

4.6 Member and Secretary

4.6.1 In addition to the responsibilities listed in 4.3.1, EC Member appointed as EC Member and Secretary shall determine whether the submitted research proposal is subject to an exempt, expedited review or regular full EC review.

4.6.2 Propose primary reviewers for each research proposal to EC Chairperson.

4.6.3 Compile reviewers' comments sent to EC Office before convened EC meeting and present to other EC members on the full board review.

4.6.4 At the EC meeting, summarize reviewers' comments and EC decision, and then draft the notification of the result of the review.

4.6.5 Prepare the meeting agenda and the EC meeting minutes.

4.6.6 Conduct a preliminary review of AE/SAE reports to determine whether such reports need an immediate response and then report to EC Chairperson for further action.

4.6.7 In the case of an expedited review, the Member and Secretary will comment directly on the cover letter of revised proposal/documents and continuing review to Primary Reviewers.

4.7 SAE Subcommittee

4.7.1 Review and present SAE, AE, SUSAR reports to the EC Chairperson or to Primary reviewer of each protocol, as appointed by Chairperson as well as its recommendations at a convened EC meeting. In case of SUSARs/SAEs where immediate responses are needed, the SAE Subcommittee shall make a recommendation to the EC Chairperson for further action.

4.8 Assistant Secretary

4.8.1 Distribute the meeting agenda and the EC meeting minutes to the EC.

4.8.2 Review the submitted proposal package for its completeness employing PI checklist.

4.8.3 Maintain the following records:

1) EC membership roster,
2) Curriculum vitae of each EC member,
3) Training records of each EC member,
4) Documentation of training sessions attended by EC members, including signed attendance sheets and a copy of the handouts and slides
5) Documentation of resignation/termination,
6) EC meeting minutes,
7) Correspondence with the Investigators,
8) Materials provided to EC members for review,
9) Documentation of exempt, expedited review and approval.

4.9 Administrative Staff

4.9.1 Check the completeness of the submitted documents and assign a Submission Number.

4.9.2 Maintain the Submission Number and Certificate of Ethical Approval Number in the Assignment Log.

4.9.3 Follow the progress of approved projects, such as Extension of Certificate of Ethical Approval, Notification of Study closure, Progress report.

4.9.4 Filing the research documents of each project considered by FTM EC.

4.9.5 Update the Information in FTM EC's web page, and in FTM EC's database.

4.9.6 Manage the FTM EC training and activity.

5.0 REFERENCES & ASSOCIATED DOCUMENTS

5.1 References

5.1.1 ICH Guidelines for Good Clinical Practice E6 section 3.2 – Composition, Functions, and Operations

5.1.2 ICH Guidelines for Good Clinical Practice E6 section 3.3 – Procedures

5.1.3 World Medical Association Declaration of Helsinki: Ethical principles for Medical Research Involving Human Subject initiated in 1964 and subsequent amendments.

5.1.4 The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. 1979.

5.1.5 WHO. Operational Guidelines for Ethics Committees That Review Biomedical Research. 2000.

5.1.6 The Medical Council's Regulation on Research Studies and Experiments on Human Subjects, B.E. 2525.

5.1.7 The Medical Council's Regulation on the Preservation of the Ethics of Medical Profession, B.E. 2545.

5.1.8 The Medical Council's Announcement No. 21/2545 on the Standards of Services Involving Reproduction Technology (No. 2).

5.1.9 Clive CM. Handbook of SOPs for Good Clinical Practice. 2nd ed. Boca Raton: Taylor & Francis; 2004.

5.2 Associated documents

5.2.1 FTM ECF-003-RR: Ethics Committee Membership Roster
5.2.2 FTM ECF-030-RR: Confidentiality Agreement
5.2.3 FTM ECF-031-RR: Conflict of Interest Statement
5.2.4 FTM ECF-032-RR: SOP Compliance Form

6.0 DEFINITIONS

Confidentiality	Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.
Good clinical practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and the rights, integrity, and confidentiality of trial subjects are protected.
Independent Ethics Committee (IEC)	An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical/scientific professionals and non-scientific members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.
Investigator	A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
Subinvestigator	Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).
Subject/Trial subject	An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.
Vulnerable subjects	Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing

students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

7.0 PROCEDURES

7.1 Appointment of EC Members

Primary and alternate EC members may be recruited from the faculty staff and from the local community by either recommendation by current EC members, administrative staff, institutional management, or by public recruitment efforts. The Dean of the FTM shall nominate the EC Chairperson who will propose prospective EC members, of whom one will be EC Member and Secretary. FTM will submit the list of proposed Committee members to the President of Mahidol University for official appointment. Each member must submit a curriculum vitae to the EC Chairperson for review and approval. Appointed EC members will sign a Confidentiality Agreement (FTM ECF-030-RR) and Conflict of Interest Statement (FTM ECF-031-RR) prior to the first EC meeting.

In appointing EC members, the EC Chairperson will consider the diversity of the members' backgrounds, including race, gender, cultural backgrounds, and sensitivity to community attitudes and the candidate's professional competence necessary to review the research. Consideration will also be given to the inclusion of one or more individuals who are knowledgeable about vulnerable populations.

7.2 Composition of the EC

The EC will be composed of no fewer than seven (7) members sufficiently qualified to carry out the EC's purpose.

The EC may not consist entirely of members of a single profession and will include member qualified in a scientific discipline (e.g., physicians and Ph.D. level physical and biological scientists, nurses, pharmacists, or other biomedical health professionals) and include at least one lay member with an unambiguously nonscientific background (e.g., lawyer, clergy and ethicists), and at least one member whose specialty is related to the protocol.

The non-scientific member should not be vulnerable to intimidation by the professionals on the EC and his/her services should be fully recognized by other EC members.

The EC will include at least one member who is not otherwise affiliated with FTM and who is not part of the immediate family of a person who is affiliated with FTM.

Every non-discriminatory effort will be made to ensure the EC is not composed entirely of men or women, so long as no selection is made to the EC on the basis of gender alone.

When research involving a vulnerable population is being reviewed, at least one member of the EC should have the appropriate background and experience in working with these prospective research participants.

One individual can satisfy more than one of the membership requirements for the EC.

The EC may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that of the EC. These individuals may contribute to the discussion, but not act as a voting member.

7.3 Establishment of EC Office

EC Office comprises EC Member and Secretary, and at least one Assistant Secretary. EC Member and Secretary is a voting member whereas the others are not. However, all office staff must have knowledge on human ethics and/or Good Clinical Practice (GCP). Training requirements are further described in section 7.8.

7.4 Alternate/Expert Members (optional)

Ad hoc substitutes are not permissible as members of the EC. Alternate/ Expert members will be invited and will function in the same manner as primary EC members. The EC membership roster (FTM ECF-003-RR) will identify the primary member(s) for whom each alternate or expert member may substitute. To ensure an appropriate quorum is maintained, the alternate's qualifications will be comparable to the primary member being replaced. The EC minutes will be documented when an alternate member replaces a primary member. When alternates substitute for a primary member, the alternate member will receive and review the same material that the primary members receive.

7.5 Membership Roster

A current membership roster (FTM ECF-003-RR) will be maintained by the EC Administrative Staff or Assistant Secretary. This list should include the following:

1) Name
2) Qualification
3) Area of expertise

4) Relationship between the member and FTM (e.g., full-time employee, stakeholder, unpaid consultant)
5) Indication of experiences (such as board certifications and licenses, etc.) sufficient to describe each member's anticipated contributions to the deliberations.

Any changes in the EC membership will be documented and reported to each Investigator upon request.

All EC members are required to provide his/her signature to EC administrative staff.

7.6 Conflict of Interest

EC Member will be considered to have a conflict of interest when:

1. He/she is Principal Investigator (PI), Co-Principal Investigator, Investigator receiving funding from the study as listed in the study budget
2. He/she is in a supervisory role over the PI of the study
3. He/she has a significant financial interest in the results of the research activity under consideration.
4. He/she has conflict of loyalty (e.g., promoting the work of subordinates or supervisors)
5. He/she is a family member of PI.
6. The EC's decision may have an impact on my research

All EC Members will be required to sign the Confidentiality Agreement (FTM ECF-030-RR) and Conflict of Interest Statement (FTM ECF-031-RR) every time that they are appointed. The EC will not have any member participate in the vote for the initial or continuing review of a project for which he/she has a conflict of interest; however, to provide information requested by the EC, the individual may contribute to the discussion. Meeting minutes should reflect that the EC member who had a conflict of interest abstained from the vote.

7.7 Term of Membership

The Chairperson and EC Members will be appointed by the Dean of the Faculty of Tropical Medicine, Mahidol University

Term of membership ends due to the following conditions:

(1) death,

(2) resignation with written notification,

(3) not attending monthly scheduled EC meetings constantly, or not providing results of review several times,

(4) convicted criminal offense,

(5) behaviors unbefitting and possibly detrimental to the EC, e.g., obscure the conflict of interest.

Documentation of the termination will be recorded in the meeting minutes of the next duly constituted EC meeting and the EC Membership Roster will be revised.

7.8 Training EC Members

The EC administrative staff will provide each new board member with the following materials:

1) ICH Guidelines for Good Clinical Practices
2) Declaration of Helsinki
3) Belmont Report
4) FTM EC's Standard Operating Procedures

Signed documentation of the receipt of the training materials should be obtained for each new member and filed with the new member's curriculum vitae as part of the training record.

All EC members must have annually of training in ethics or regulatory requirements in human subjects' research, including SOP training. A newly appointed member must complete an orientation in human subjects' protection and EC procedures within six months after his/her appointment.

The EC Chairperson and administrative staff will arrange for special training or in-service sessions for all EC members and alternates at least once each year. Documentation of training materials will be maintained by the Member and Secretary.

	Research Proposal Management	
	Document No.: FTM ECS-003-14	**Effective Date:** 15 November 2018

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CHANGE HISTORY		
Revision	Description of Change	Effective Date
00	Initial release	28 June 2007
01	1. In Section 4.2, add an item stating that EC Member Secretary cosigns the Certificate of Ethical Approval given to the approved research proposal/protocol. 2. In Section 4.4, add an item stating that Staff Secretary keeps track of the Submission Number and Certificate of Ethical Approval Number. 3. In Section 5.0, add two more Forms as Items 5.16 and 5.17. 4. In Section 7.2, after determining the completeness of the submitted research proposal/protocol, Staff Secretary will assign EC Submission Number to the document. 5. In Section 7.2, the process of assigning EC Submission Number is added. 6. In Section 7.4, a description of the Certificate of Ethical Approval is added. It mainly explains the composition of the Certificate and determines the person responsible for signing the certificate.	01 October 2007
02	1. Section 7.4 describing the format of CEA number has been changed due to the initial release of a work practice, FTM ECW-001-00: Certificate of Ethical Approval Number Assignment. 2. The mentioned work practice has been added to the list of associated documents (Section 5.0).	02 January 2008
03	1. Revise EC Member Secretary's responsibilities in section 4.2; 2. Revise Staff Secretary's responsibilities in section 4.4; 3. Specify timeline for submission of research proposal/protocol in section 7.1; 4. In section 7.2, indicate that two primary reviewers are assigned for each protocol when it is subject to full board review and summarizing EC's discussion is a responsibility of EC Member Secretary; 5. In section 7.3, add CRF as another document subject to EC approval;	01 July 2008

Research Proposal Management

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	6. In section 7.4, change notification to PI from 7 days to 5 working days, approved documents are stamped expiry date included and PI can request EC to review its decision on disapproved project; 7. In section 7.5, indicate that frequency of continuing review is determined upon EC approval; 8. In section 7.8, there will be no study termination acknowledgement, but EC may give recommendation if necessary; 9. In section 7.9, clarify archival period as 3 years after study completion; 10. Add a flowchart of EC review process as Appendix in section 8.0.	
04	Entering the SIDCER/FERCIT Recognition Programme of World Health Organization (WHO), suggestions of the surveyors lead to the following changes: 1. Nomenclatures changed – 'Secretariat' is replaced by 'Member Secretary' and 'EC Secretary' with 'Staff Secretary'; 2. Section 5.0 has been divided to 2 subsections namely 'References' and 'Associated documents', more references are added in section 5.1; 3. Add more references in section 5.0; 4. Mention Assent Form in section 7.1; 5. In section 7.3, add more attention on vulnerable subjects when reviewing the research proposal/ protocol for EC approval; 6. Procedures of continuing review of the projects approved before 17 August 2007 or before the effective date of the present set of SOPs is added as the last paragraph of section 7.5; 7. In section 7.6, specify that minor revision refers to the reducing in the amount of blood and/or frequency of blood withdrawal; 8. In section 7.7, add EC's action when a research project is suspended; 9. In section 7.8, add EC's action when the investigators notify EC of the study closure.	24 September 2008

Research Proposal Management

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	10. An asterisk (*) is added after 'Major revision' in the diagram of Appendix 8.1 indicating a repetition of a full board review.	
	There was no revision in the year 2009.	
05	As a result of the SOP annual review (16 Feb 2010), the following changes have been made 1. Chairperson's name was changed to Prof. Srisin Khusmith and Prof. Krisana Pengsaa, throughout the 2010 annual revision. 2. "EC Member Secretary" was replaced by "EC Member and Secretary" 3. Nomenclature changed-"Staff Secretary" was replaced by "Assistant Secretary" 4. FTM ECF-005-RR was replaced by FTM ECF-019-00, FTM ECF-006-RR was replaced by FTM ECF-006-002 in section 5.1 5. Revise Associated documents in section 5.2 6. Add fast-track review in Procedures of Research proposal/protocol submission for an initial review in section 7.1 7. Revise Ethical Review Process in section 8.	22 April 2010
06	As a result of SOP revision on 21 April 2011 1. FTM ECF-019-00 was replaced by FTM ECF-019-01, FTM ECF-006-02 was replaced by FTM ECF-006-03 in section 5.1 2. Website of EC's meeting schedule "http://www.tm. mahidol.ac.th/research/EC/human/meeting.doc" was changes to "http://www.tm.mahidol.ac.th/ research /ethic/ human/meeting.pdf" in section 7.1 3. Separate age groups "7 years old to less than 13 years" for using Informed Assent Form, age 13-17 years for using Informed Consent form, which has co-signed by their parents, and "relatives" was changed to "legal guardian" for permission patients be enrolled in the study, when they are unconscious in section 7.3 (4)	03 May 2011

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CHANGE HISTORY		
Revision	Description of Change	Effective Date
	4. Duration of notification to the Investigator was changed to seven working day in section 7.4 5. Reviewer's Assessment Form FTM ECF-007-03 was replaced by FTM ECF-024-00, for Continuing Review in section 7.5 6. Add amount of submission fee for amended protocol more than two times in section 7.6 7. Duration of archiving original copy of materials was changed to three (3) years after study completion in section 7.9	
07	According to SIDCER/FERCAP recognition in 2011, the following changes have been made 1. Add the criteria for full board review in section 7.2 2. Add "after approval" after "valid for 1 year" for clearly clarification about approved duration of Certificate of Ethical Approval, in section 7.4, page 11 of 40 3. Add information of submission for progress report in section 7.7 4. Add more details of disposal of reviewed research proposal/protocol in section 7.9 5. Add the protocol submission flowchart for EC staff in Appendix 8.1 6. Add the post-review flow chart in Appendix 8.3 7. Add the cover letter for protocol submission (Thai) in Appendix 8.4.1 and English version in Appendix 8.4.2 8. Add the notification of receipt protocol, protocol reference code and EC meeting date (Thai) in Appendix 8.4.3 and English version in Appendix 8.4.4 9. Add the letter of requesting expert member to review protocol (Thai only) in Appendix 8.4.5 10. Add the notification of result of initial review (Thai) in Appendix 8.4.6 and English version in Appendix 8.4.7 11. Add the communication letter for the 1st approval (Thai) in Appendix 8.4.8 and English version in Appendix 8.4.9 12. Add the communication letter for protocol amendment (Thai) in Appendix 8.4.10 and English version in Appendix 8.4.11	22 December 2011

Research Proposal Management

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	13. Add the communication letter for extension (Thai) in Appendix 8.4.12 and English version in Appendix 8.4.13 14. Add the communication letter for SAE, SUSAR, protocol deviation, protocol violation (Thai) in Appendix 8.4.14 and English version in Appendix 8.4.15 15. Add the communication letter for study closure and other report (Thai) in Appendix 8.4.16 and English version in Appendix 8.4.17	
08	The 2014 annual review of the document leads to the following changes: 1. Change the title of the form from "Research Proposal/Protocol Management" to "Research Proposal Management." 2. Change "research proposal/protocols" to "research proposal" in sections 1.0, 2.0, 4.1.1, 4.1.2, 4.1.5, 4.1.6, 4.2.1, 4.2.3, 4.2.4, 4.4.1, 4.4.3, 4.6.1, 5.1.12, 5.1.13, 5.2.6, 6.0, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.9, 8.1 and 8.2. 3. Change "protocol" to "research proposal" in sections 3.3, 6.0, 7.2, 7.3, 7.4, 7.5, 7.6, 8.4.1-8.4.5, 8.4.10 and 8.4.11. 4. Use "RR" instead of the version/revision number of the document in sections 5.1.12, 5.1.13, 5.2.1-5.2.12, 7.1, 7.2, 7.4, 7.5, 7.6, 7.7 and 7.8. 5. Change the EC's web page for submission timeline from "http://www.tm.mahidol.ac.th/research/Ethics/human/meeting.pdf" to "http://www.tm.mahidol.ac.th/research/client/Ethics.php", and change "full proposal/ protocol" to "full protocol" in section 7.1. 6. The duration of notification was revised from "The EC will provide the Investigator with written notification, within seven (7) working days" to "The EC will provide the Investigator with written notification, within seven (7) working days after convened meeting for full board review and within fifteen (15) working days for expedited review after submission" for clear understanding in section 7.4.	01 May 2014

Research Proposal Management

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	7. The submission fee making amendments more than twice was changed from "2,000 Baht" to "5,000 Baht in the case of the project being funded by private- or foreign institution/company, and 2,500 Baht for submission fee in the case the project funded by government institution", and change the criteria for requesting a PI to submit amendments as a new research proposal from "amended more than five times" to "amended in major revision (such as changing the information in synopsis, change or add main objective/ major issues ext.)" in section 7.6. 8. Change item "Submission of progress report" to "Submission of annual progress report", and change the duration of submission from "6 months after approval" to "annually after approval together with request for CEA extension" in section 7.7 and section 8.3, and remove the notification to PI in case of failure to submit progress report "The Investigator must submit a progress report within 30 days. Failure to do so will result in withdrawal of the approval." from the section 7.7. 9. Update the logo of Mahidol, EC webpage, Telephone number and revise information in the communication letters in Appendix 8.4.	
09	The resolution of the EC Retreat 2014 leads to the following changes: 1. Add required documents for first submission to section 7.1 Research proposal submission for an initial review. 2. Add sending an email to PI and Co-PI(s)/ Advisor and Co-Advisor(s) to confirm participation in the study to section 7.2. 3. Add a criterion "participants who cannot read and write by themselves must sign via thumbprint in the ICF. An independent witness must also sign the ICF" to the section 7.3 (4) Criteria for EC Approval of the Research Proposal.	03 October 2014

Research Proposal Management

CHANGE HISTORY		
Revision	Description of Change	Effective Date
10	The following changes have been made: 1. After three (3) years, the Assistant Secretary will scan only the Certificate of Ethical Approval of the first approval instead of all research documents in section 7.9. 2. Added the step to request PI(s) and Co-PI(s) to confirm participation in the research study submitted to FTM EC by E-Mail to section 4.4, Responsibility of Assistant Secretary, to Appendix 8.1 Research proposal Submission Flowchart for EC Staff, and to Appendix 8.2 EC Initial Review Flow chart. 3. Changed the number of copies of research documents submitted to EC from 14 copies to 12 copies in Appendix 8.2 EC Initial Review Flow chart.	19 May 2015
11	According to SIDCER/FERCAP-NECAST recognition and SOPs training in EC Retreat in 2015, the following changes have been made 1. Use “terminate” instead of “prematurely withdraw” in Section 3.4. 2. Change “EC Member and Secretary” to “Member and Secretary” in Section 4.2, 7.2 and 7.4 to correspond with FTM ECS-002-RR: Ethics Committee. 3. Add responsibilities of Primary Reviewer in Section 4.4. 4. Add reference of risk (45 CFR 46.102 (h) (i)) and definition of benefit (The Belmont Report) to Section 5.1. 5. Change “Deferment” to “Deferral”, and use “Approval with Conditions and/or Suggestions” instead of “Approval after Amendment(s) or Approval after Clarifications” and revise definition in Section 6.0. 6. Revise the information in Section 7.2 EC Initial Review Procedures as follows: - Change “EC Administrative Staff or Secretary Assistant” to “Administrative Staff”, add responsibilities of Administrative Staff to Section 4.6 and change the responsibility of Assistant Secretary about checking the completeness of submitted research documents and assigning the Submission Number in Section to Administrative Staff. - Revise “The Primary Reviewer(s) will present research proposal at a regular or special meeting of the EC” to “The Primary Reviewer(s) will present summary of the research proposal before comments at a regular or special meeting of the EC”	16 October 2015

Research Proposal Management

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	- Revise motion concern from "approval, conditional approval, deferred, denied" to "approval, approval with conditions and or suggestions, deferral, disapproval" - Add a criterion for full board review "4. Studies involving highly vulnerable population, eg. HIV-infected persons, comatose patients, patients under critical care" - All EC Members are required to review PIS and ICF - not only Primary Reviewers and non-scientist EC members. - Revise the expedited review process from "When both reviewers' decisions are in positive agreement, EC Chairperson will notify the Investigator; if otherwise, the research proposal will require full EC review" To "When both reviewers' decisions are in positive agreement, the Certificate of Ethical Approval will be issued. If the decisions are in disagreement, EC Chairperson will discuss with primary reviewers to meet common opinion, then notify the Principal Investigator whether it should go to the full board or ask Principal Investigator to revise research proposal" and add more detail of re-review after approval with conditions. 7. Request Investigator send progress report using Progress Report Form/Certificate of Ethical Approval Extension Request Form (FTM ECF-008-RR) instead of continuing report (FTM ECF-009-RR) as stated in Section 7.5 Continuing Review. 8. Add the appeal process to Section 7.4 Notification to the Investigator and to Section 8.2 EC Initial Review Flow Chart. 9. Change form "Certificate of Ethical Approval Extension Request Form" to "Progress Report Form/ Certificate of Ethical Approval Extension Request Form (FTM ECF-008-RR)" and add requirement that Investigator extend the certificate in Section 7.4 Notification to the Investigator.	

Research Proposal Management

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	10. Revise submission of progress report in Section 7.7 by removing "annual", changing the form for submitting the progress report from "Continuing Review Continuing Report Form (FTM ECF-009-RR)" to "Progress Report Form/ Certificate of Ethical Approval Extension Request Form (FTM ECF-008-RR)", add presenting the progress report by Primary reviewer(s) at the convened meeting and revision of the procedure for failed submission of progress report from suspension of project to not extending the Certificate of Ethical Approval. 11. Revise the item "Notification of the study Termination" to "Notification of the study Termination/Study closure" and revise the review procedure in Section 7.8 and 8.3 Post-Review Flow Chart. 12. Change the Section 7.9 "Disposal of reviewed research proposal" to "Management of Study Files" that includes both management of study file and confidentiality of study records. 13. Revise EC Initial Review Flowchart and add timeline to Section 8.2.	
12	The resolution of the EC Retreat and SOP training 2016 leads to the following changes: 1. Add the guideline for study closure of NIH to section 6.0 Definition and to section 7.8 Notification of the Study Termination/ Study Closure. 2. Revise "legally authorized representative" to "legally authorized representative or guardian" in sub-item 4, section 7.3 Criteria for EC Approval of the Research Proposal. 3. Revise submission deadline from "day 15 of the month" to "between 1st- 15th of the month" and "after 15th of the month" in section 7.1 Research proposal submission for an initial review.	03 November 2016

Research Proposal Management

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	4. The EC Initial Review Procedures in section 7.2 have been revised, as follows: - Revise "Member and Secretary will determine whether the submitted research proposal is subject to an expedited review" to "Member and Secretary will determine whether the submitted research proposal is subject to full board, expedited or exemption review". - Add procedure for exemption review. - Revise full board review from "the Assistant Secretary will distribute the appropriate materials to each of the EC members at least seven (7) days before the scheduled meeting to allow thorough review of each research proposal. The EC Chairperson will assign two primary reviewers for each research proposal. All EC members are required to review the materials of every research proposal and will complete a Reviewer's Assessment Form for Initial Review (FTM ECF-007-RR)…" **to** "the Chairperson will appoint three (3) primary reviewers and one (1) Lay member for each research proposal. The Assistant Secretary will distribute hard copies of the proposal plus any other necessary materials, for example the Participant Information Sheet, Informed Consent Form, etc. to the assigned reviewers and lay member. The Assistant Secretary will send the same files, as PDFs, by email to all members of the review panel at least seven (7) days before the scheduled EC meeting. The assigned EC members are required to in-depth review the materials of the assigned research proposal and will complete a Reviewer's Assessment Form for Initial Review (FTM ECF-007-RR)…" - Add duration of sending comments on the research proposal from assigned reviewers "three (3) days before the scheduled EC meeting"	

Research Proposal Management

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	- Add "EC members who are not assigned reviewer of the review panel will read research proposal and be ready to submit their comments at the scheduled EC meeting but do not need to submit comments in advance" - Change "The Primary Reviewer(s) will present a summary of the research proposal before comments at a regular or special meeting of the EC" **to** "The Primary Reviewer(s) will present a summary of the research proposal to all EC members attending the full board meeting before comments at a regular or special meeting of the EC" 5. Add approval of the Full Protocol to section 7.3 Criteria for EC Approval of the Research Proposal. 6. The Notification to the Investigator in section 7.4 have been revised, as follows: - Add review procedure for research proposal approved with minor revision "The Chairperson will nominate two (2) Primary reviewers to review the revised research proposal" - Change copy of documents resubmitted for full board review from "If research proposal is approved with conditions of major revision, 12 copies of the research proposal will be required" to "If research proposal is approved with conditions of major revision, five (5) copies of the research proposal will be required" 7. Change full board for continuing review from "the Assistant Secretary will distribute the materials to all EC members at least seven (7) days in advance of the meeting" **to** "the Assistant Secretary will distribute the materials to the previously assigned three (3) Primary reviewers and one (1) Lay member of each research proposal at least seven (7) days in advance of the meeting" in section 7.5.	

Research Proposal Management

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	8. Change duration of maintain the filing from "three (3) years after study completion" to "one (1) year after study completion" in section 7.9 Management of Study Files. 9. Revise flowcharts in section 8.1 Research Proposal Submission Flowchart for EC Staff, section 8.2 (1) Initial Review Flowchart (Full board review) and section 8.2 (2) Initial Review Flowchart (Exemption review & Expedited review). 10. Remove "*Controlled copy-Do not Duplicate*" and "*Internal Use Only*" from Footer.	
13	The resolution of the EC Retreat and SOPs Training 2017 and the consensus of the EC in the EC Meeting on 1 February 2018 lead to the following changes: 1. Separate Research Proposal Submission Form (FTM ECF-019-RR) to 3 forms as follows: 1) Research Proposal Submission Form for a study involving specimen collection (FTM ECF-033-RR) 2) Research Proposal Submission Form for a study NOT involving specimen collection (FTM ECF-034-RR) 3) Research Proposal Submission Form for a retrospective study and/or no-direct contact with human subjects (FTM ECF-035-RR) Thus, this form has been revised in section 5.2, 7.1 and 7.2. 2. Revise responsibility of Member and Secretary in section 4.2.1 from "Screen the research proposal submitted for an initial review and determine whether it is subject to an expedited review or a full EC review" to "Screen the research proposal submitted for an initial review and determine whether it is subject to an exemption review or expedited review or a full EC review"	07 March 2018

Research Proposal Management

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	3. Move forms "Research Proposal Submission Form" and "Research proposal Checklist for Principal investigator" stated in section 5.1 Reference to section 5.2 Associated documents 4. Separate Research Proposal Checklist for Principal Investigator (FTM ECF-006-RR) to 3 forms to correspond with the Research Proposal Submission Form as follows: 1) Research Proposal Submission Checklist for Principal Investigator (for a study involving specimen collection) (FTM ECF-033/1-RR) 2) Research Proposal Submission Checklist for Principal Investigator (for a study NOT involving specimen collection) (FTM ECF-034/1-RR) 3) Research Proposal Submission Checklist for Principal Investigator (for a retrospective study and/or no-direct contact with human subjects) (FTM ECF-035/1-RR) Thus, this form has been revised in section 5.2 and 7.1 5. Revise the study package from "Letter of permission from authorized person of the implementing institution (if the study is to be conducted outside FTM)" to "Letter of permission from authorized person of the implementing institution (if available; signature of authorized person in Appendix B3 of the Research Proposal Submission Form is acceptable)" in section 7.1 6. Change the convention of the EC Submission Number from "TMEC YY-SSS" to "TMEC YY-NNN" in section 7.2 7. Revise sub-item 3 of the criteria for full board review in section 7.2 from "Studies involving elements, procedures or interventions that require additional provisions or safeguards, as stated by federal regulations and guidance" to "Studies involving elements, procedures or interventions that require additional provisions or safeguards, as stated by national regulations and guidance"	

Research Proposal Management

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	8. Since the new version of Reviewer's Assessment Form for Initial Review (FTM ECF-007-10) includes assessing Participant Information Sheet and the Informed Consent Form, thus the form FTM ECF-015-RR: The Participant Information Sheet and the Informed Consent Form Assessment Checklist were retired and removed from section 7.2 9. Revise "This is particularly important for Lay members." to "Assessing the Participant Information Sheet and Informed Consent Form is particularly important for lay members" in section 7.2 10. Add additional fee for request the full protocol approval "10,000 Baht per one language version" to section 7.3 11. Revise the section 7.4 Notification to the Investigator, as follows: - Revise co-signing the Certificate from "The Certificate is cosigned by EC Chairperson and EC Member and Secretary" to "The Certificate is cosigned by the EC Chairperson or EC Vice-Chairperson and EC Member and Secretary, or is cosigned by the EC Chairperson and EC Vice-Chairperson" - Revise "review the revision" from "The Chairperson will nominate two (2) Primary reviewers to review the revised research proposal" to "The Chairperson will nominate two (2) Primary Reviewers to review the revised research proposal; or the EC Chairperson or at least one Primary Reviewer will consider it" - "Resubmission shall be done within six (6) months after the Investigator receives the notification from FTM EC" has been changed to "Resubmission shall be done within six (6) months after the notification from FTM EC to the Investigator"	

Research Proposal Management

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	- Remove the duplicated information from the process of resubmission "When PI resubmit the protocol, EC Chairperson or at least one Primary Reviewer will consider it. If they approve the research proposal, the Certificate of Ethical Approval will be issued. If it need to be clarified/ revised again, 3 copies of the revised research proposal are required for consideration" 12. Add submission fee for the 3rd Certificate of Ethical Approval (and subsequent) 5,000 Baht for the project funded by private or foreign institute/ company to section 7.5 13. Revise condition of the submission fee for the 3rd Amendment from "If a research proposal and/or other research documents (except Investigator Brochure) are amended more than twice, the Investigator need pay…" to "If a research proposal and/or other research documents (except Investigator Brochure) undergo major amendment (full board review is required) more than twice, the Investigator will be required to pay…" in section 7.6 14. Revise criteria of Study Closure in section 7.8 from "Investigator should notify the EC when all research-related interventions or interactions with human subjects have been completed, and all data collection and analysis has been finished, then the human subjects research study has been completed" to "Investigator should notify the EC when all research-related interventions or interactions with human subjects have been completed. All data collection and/or analysis has been finished." 15. Revise post-review flowchart in section 8.3: - Change the duration for reporting the protocol deviation from "within 5 working days of the event notification to the PI" to "in 1 month of the event notification to the PI"	

Research Proposal Management

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	- Add "SAE subcommittee" who reviews the AE/ SAE/ SUSAR reports to the flowchart 16. Adjust wording in communication letters in section 8.4	
14	As resolved at the EC Retreat and SOP Training 2018 make the following changes: 1. Revise the title of the Research Proposal Submission Form and Research Proposal Submission Checklist for Principal Investigator in section 5.2 and section 7.1, as follows: - FTM ECF-033-RR and FTM ECF-033/1-RR: "for a study involving specimen collection" has been revised to "for a study involving human subject enrollment WITH specimen collection" - FTM ECF-034-RR and FTM ECF-034/1-RR: "for a study NOT involving specimen collection" has been revised to "for a study involving human subject enrollment WITHOUT specimen collection" - FTM ECF-035-RR and FTM ECF-035/1-RR: "for a retrospective study and/or no-direct contact with human subjects" has been revised to "for a study WITHOUT human subject enrollment" 2. In section 7.2, revise the EC Initial Review Procedures: from, "The Investigator may be invited to attend a portion of the meeting, so that EC members have the opportunity to question him/her about the research proposal": to, "The Principal Investigator and/or an Accountable Investigator affiliated with the Faculty of Tropical Medicine will be invited to attend a portion of the meeting, so that EC members have the opportunity to question him/her about the research proposal. If they cannot attend the Full Board meeting, the project will be postponed for consideration the following month."	15 November 2018

Research Proposal Management

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	3. Section 7.3: add obtaining informed consent with vulnerable subjects who are mothers aged < 18 years "(b) for mothers and/or their children aged < 18 years, their legal guardian or Head of Community/ Community Affairs Board must co-sign; this depends on the culture of each study area." 4. Section 7.8: add the process that ensues after the EC terminates or suspends ethical approval, according to ICH-GCP Guidelines. 5. Adjust wording in communication letters in section 8.4.3 and section 8.4.4 Notification for Submission Number and Ethics Committee Meeting Date.	

Research Proposal Management

SIGNATURES		
Author	I, on behalf of the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, indicate that this SOP has been authored according to applicable business requirements for quality system documentation.	
	Name: Assoc. Prof. Jaranit Kaewkungwal	Signature:
	Title: Chairperson, Ethics Committee of the Faculty of Tropical Medicine, Mahidol University	Date: 12 NOV 2018
Approver	I indicate that I have reviewed this SOP, and find it meets all applicable business requirements and that it reflects the procedure described. I approve it for use.	
	Name: Assoc. Prof. Pratap Singhasivanon	Signature:
	Title: Dean, Faculty of Tropical Medicine, Mahidol University	Date: 14 NOV 2018

	Research Proposal Management	
	Document No.: FTM ECS-003-14	**Effective Date:** 15 November 2018

1.0 Purpose

To describe the processes for the initial and continuing review of research proposal submitted to the Ethics Committee (EC) of the Faculty of Tropical Medicine (FTM), Mahidol University.

2.0 Scope

This Standard Operating Procedure (SOP) will apply to all research proposal submitted to the Ethics Committee (EC) of the Faculty of Tropical Medicine (FTM), Mahidol University.

3.0 Policy

3.1 The Ethics Committee of the Faculty of Tropical Medicine is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human participants involved in a trial by conducting initial and continuing review of research activities involving FTM staff members/students.

3.2 No research participants should be admitted to a trial before FTM EC issues its written approval to the trial.

3.3 No deviations from, changes of, the research proposal should be initiated without prior written EC approval, except when necessary to eliminate immediate hazards to the research participants or when the change(s) involves only logistical or administrative aspects of the trial or exemption is granted by the Sponsor.

3.4 The Ethics Committee of the Faculty of Tropical Medicine may terminate approval of the research study if there is an evidence that the Investigator violates the protection of the rights, safety and well-being of human participants involved in a trial.

4.0 RESPONSIBILITIES

4.1 EC Chairperson

4.1.1 Assign appropriate primary reviewer(s) to conduct a review on a submitted research proposal,

4.1.2 Assign appropriate EC members to conduct a continuing review on the approved research proposal,

4.1.3 Uphold EC judgments that may not always be popular with Investigators,

4.1.4 Invest adequate time, interest, and commitment to provide guidance and expertise to EC members and Investigators,

4.1.5 Inform, in writing, the Investigator of the result of EC consideration on the submitted research proposal,

4.1.6 Sign the Certificate of Ethical Approval given to the approved research proposal.

4.2 Member and Secretary

4.2.1 Screen the research proposal submitted for an initial review and determine whether it is subject to a review exemption or expedited review or a full EC review,

4.2.2 Review and approve/provide favorable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects,

4.2.3 Summarize EC's discussions and record its decisions, including but not limited to the final disposition of each research proposal,

4.2.4 Sign the Certificate of Ethical Approval given the approved research proposal.

4.3 EC Members

4.3.1 Review and approve/provide favorable opinion on, the research proposal, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects,

4.3.2 Assigned EC members shall conduct continuing review of research covered by the FTM EC at intervals appropriate to the degree of risk, but not less than once per year.

4.4 Primary Reviewers

4.4.1 Review and provide opinion on submitted research proposal. Primary reviewers are assigned by EC Chairperson in the process of initial review, resubmission, continuing review, and study termination/closure.

4.4.2 Present summary of the research proposal as initial review at the EC meeting.

4.4.3 Make a motion concerning the research documents.

4.5 Assistant Secretary

4.5.1 Conduct a preliminary review on the completeness of the submitted research proposal and communicate with PI if the submission package is incomplete,

4.5.2 Notify PI to stand by during the EC meeting,

4.5.3 Send E-Mail to PI(s) and Co-PI(s) to confirm participation in the research study submitted to FTM EC,

4.5.4 Distribute a copy of the research proposal, informed consent, and other study-related materials to the full EC at the convened meeting,

4.5.5 Keep track of the Submission Number and Certificate of Ethical Approval Number,

4.5.6 Keep track of the continuing review,

4.5.7 Maintain the following records:

1) EC meeting minutes,
2) Correspondence with the Investigators,
3) Materials provided to EC members for review,
4) Documentation of expedited review and approval (if applicable),
5) Submission and CEA Assignment Logs,
6) CVs and training records of EC members,
7) EC Roster,
8) SOPs, Forms and Work Practice Document,

4.5.8 Serve as content master of FTM EC's web page.

4.6 Administrative Staff

4.6.1 Check the completeness of the submitted documents and assign a Submission Number.

4.6.2 Maintain the Submission Number and Certificate of Ethical Approval Number in the Assignment Log.

4.6.3 Follow the progress of approved projects, such as the Extension of Certificate of Ethical Approval, Notification of Study closure, Progress report.

4.6.4 File research documents of each project considered by FTM EC.

4.6.5 Update the Information on FTM EC's web page, and in FTM EC's database.

4.6.6 Manage the FTM EC training and activities.

4.7 The Investigator

4.7.1 Submit an Application for Continuing Review Form and necessary documents to the EC that initially reviewed the research proposal in a timely manner.

5.0 References & Associated Documents

5.1 References

5.1.1 21 CFR 56.109 – IRB Review of Research

5.1.2 21 CFR 56.111 – Criteria for IRB Approval of Research

5.1.3 45 CFR 46.102 (h) (i) – Regulatory Definition of Minimal Risk

5.1.4 The Belmont Report – Definition of Benefit

5.1.5 ICH Guidelines for Good Clinical Practice (E6) section 3.1 – Responsibilities

5.1.6 World Medical Association Declaration of Helsinki: Ethical principles for Medical Research Involving Human Subject initiated in 1964 and subsequent amendments.

5.1.7 The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. 1979.

5.1.8 WHO. Operational Guidelines for Ethics Committees That Review Biomedical Research. 2000.

5.1.9 The Medical Council's Regulation on Research Studies and Experiments on Human Subjects, B.E. 2525.

5.1.10 The Medical Council's Regulation on the Preservation of the Ethics of Medical Profession, B.E. 2545.

5.1.11 The Medical Council's Announcement No. 21/2545 on the Standards of Services Involving Reproduction Technology (No. 2).

5.1.12 Clive CM.Handbook of SOPs for Good Clinical Practice. 2nd ed. Boca Raton: Taylor & Francis; 2004.

5.1.13 Amdur R, Banbert E. editors. Institutional Review Board Management and Function. Sudbury, MA: Jones and Bartlett Publishers; 2002.

5.2 Associated documents

5.2.1 FTM ECS-001- RR: Quality System Documentation

5.2.2 FTM ECF-007- RR: Reviewer's Assessment Form for Initial Review

5.2.3 FTM ECF-008-RR: Progress Report Form/ Certificate of Ethical Approval Extension Request Form

5.2.4 FTM ECF-010- RR: Notification of Study Closure Form

5.2.5 FTM ECF-013- RR: Certificate of Ethical Approval Form

5.2.6 FTM ECF-017- RR: EC Submission Number Assignment Log

5.2.7 FTM ECF-018- RR: Certificate of Ethical Approval Number Assignment Log

5.2.8 FTM ECF-023- RR: Request for Protocol Amendment Form

5.2.9 FTM ECF-025- RR: Request for Fast-track Review Form

5.2.10 FTM ECF-033-RR: Research Proposal Submission Form for a study involving human subject enrollment WITH specimen collection

5.2.11 FTM ECF-034-RR: Research Proposal Submission Form for a study involving human subject enrollment WITHOUT specimen collection

5.2.12 FTM ECF-035-RR: Research Proposal Submission Form for a study WITHOUT human subject enrollment

5.2.13 FTM ECF-033/1-RR: Research Proposal Submission Checklist for Principal Investigator (for a study involving human subject enrollment WITH specimen collection)

5.2.14 FTM ECF-034/1-RR: Research Proposal Submission Checklist for Principal Investigator (for a study involving human subject enrollment WITHOUT specimen collection)

5.2.15 FTM ECF-035/1-RR: Research Proposal Submission Checklist for Principal Investigator (for a study WITHOUT human subject enrollment)

5.2.16 FTM ECW-001- RR: Certificate of Ethical Approval Number Assignment

6.0 Definitions

Approval	The affirmative decision of the Ethics Committee (EC) that the submitted research proposal has been reviewed, and may be conducted at the institution site within the constraints set forth by the EC, the institution, Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
Approval with Conditions and/or Suggestions	Affirmative decision given to the research proposal which is subject to the incorporation of the revisions and or clarifications indicated by Ethics Committee's recommendations.
Case Report Form (CRF)	A printed, optical, or electronic document designed to record all of the research proposal required information to be reported to the sponsor on each trial participant.
Deferral	The research proposal is not recommended for approval as submitted but can be re-assessed after revision.
Disapproval	The research proposal is not recommended for the reasons specified by the Ethics Committee.
Good Clinical Practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and the rights, integrity, and confidentiality of trial subjects are protected.
Independent Ethics Committee (IEC)	An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical/scientific professionals and non-scientific members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on, the trial research proposal, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

Informed Consent	A process by which a research participant confirms his/her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the research participant's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.
Investigational Product	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved used.
Investigator	A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
Investigator's Brochure	A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects.
Multicenter Trial	A clinical trial conducted according to a single research proposal but at more than one site, and, therefore, carried out by more than one investigator.
Nonclinical Study	Biomedical studies not performed on human subjects.
Subinvestigator	Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).
Minimal Risk	The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
Opinion (in relation to the Ethics Committee)	The judgment and/or the advice provided by the Ethics Committee.
Research proposal	A document that describes the objective(s), design, methodology, statistical consideration, and organization of a trial. The research proposal usually also gives the background and rationale for the trial, but these could be provided in other research proposal referenced documents.
Protocol Amendment	A written description of a change(s) to or formal clarification of a research proposal.
Subject/Trial Subject	An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

Vulnerable Subjects	Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.
Well-being (of the trial participants)	The physical and mental integrity of the participants in a clinical trial.
Study closure	When all research-related interventions or interactions with human subjects have been completed, and all data collection and analysis has been finished, then the human subjects research study has been completed. When a human subjects research study has been completed, the investigators no longer are required to obtain continuing review and approval of that study by the EC.

7.0 Procedures

7.1 Research proposal submission for an initial review

For the initial review of research proposal, the Investigators shall submit a study package to EC Office within the timeline. Research proposals submitted between 1st and 15th of the month will be reviewed in the 1st week of the following month. Research proposals submitted after the 15th will be reviewed in the 3rd week of the following month. The timeline is specified on EC's web page at http://www.tm.mahidol.ac.th/research/client/EC_Human.php, to ensure a full board review at the next convened EC meeting. If the Principal Investigator would like to request fast-track review because have unavoidable reasons or an urgent situation, Principal Investigator can request fast-track review in a special EC Meeting. This fast-track procedure requires 2 times of the normal submission fee. Each study package will include the following:

- Cover letter from Principal Investigator's Department or Unit
- Receipt of Submission Fee (Exempt for FTM student's projects and projects funded by FTM Research Fund)
- Research Proposal Submission Form for a study involving human subject enrollment WITH specimen collection (FTM ECF-033-RR)
- Research Proposal Submission Form for a study involving human subject enrollment WITHOUT specimen collection (FTM ECF-034-RR)
- Research Proposal Submission Form for a study WITHOUT human subject enrollment (FTM ECF-035-RR)

- Research Proposal Submission Checklist for Principal Investigator (for a study involving human subject enrollment WITH specimen collection) (FTM ECF-033/1-RR)
- Research Proposal Submission Checklist for Principal Investigator (for a study involving human subject enrollment WITHOUT specimen collection) (FTM ECF-034/1-RR)
- Research Proposal Submission Checklist for Principal Investigator (for a study WITHOUT human subject enrollment) (FTM ECF-035/1-RR)
- The most recent version of the full protocol or main protocol
- Thesis proposal (for student only)
- Copy of GR 33 or GR 37 (for student only)
- The current Investigator's Brochure or Package Insert (if applicable)
- Participant Information Sheet and Informed Consent Form/ Informed Assent Form (for participants aged 7 years to less than 13 years) – in Thai
- CRF (if applicable)
- Questionnaire, Advertisements and/or study recruitment materials (if applicable)
- Letter of permission from authorized person to use stored specimen (for study using stored specimens)
- Letter of permission from authorized person of the implementing institution (if available; signature of authorized person in Appendix B3 of the Research Proposal Submission Form is acceptable)
- Material Transfer Agreement (if applicable)
- Medical license (upon EC request)
- A copy of the Investigator's curriculum vitae
- Copy of Certificate of GCP Training, or Human and Subject Protection Training of PI and all Co-Investigators/ Thesis Committee Members
- A CD or A diskette of all documents

7.2 EC Initial Review Procedures

Upon receiving the research proposal, Administrative Staff will check for the completeness of the documents following the Research Proposal Checklist for Principal Investigator (FTM ECF-033/1-RR, FTM ECF-034/1-RR, FTM ECF-035/1-RR) inserted in the submitted package. If all items required are present, Administrative Staff will assign the EC submission number to the submitted research proposal. The convention of the EC Submission Number is TMEC YY-NNN, where TM refers to the Faculty of Tropical Medicine, EC refers to the Ethics Committee, YY refers to the year of submission and NNN denotes the sequential submission number. EC Submission Number is maintained via EC Submission Number Assignment Log (FTM ECF-017-RR).

After assigning the EC Submission Number, the Assistant Secretary will send an email to all listed as PI and Co-Investigator(s)/ Advisor and Co-advisor(s) on the submitted research proposal to confirm their participation in the study. Those, except the PI, who do not submit an inked signature on the hard copy of the

research proposal, need to reply to this email within seven (7) days, otherwise the submitted proposal will not be considered by the EC.

Member and Secretary will determine whether the submitted research proposal is subject to full board, expedited or exemption review.

If the research proposal is subject to exempt review, the Member and Secretary will present it to the Chairperson to consider. The Chairperson will make decision in accordance with the Exemption Review criteria. After the research proposal is approved, the Assistant Secretary will issue the Documentary Proof of Exemption Review.

In case of expedited review, the EC Chairperson will assign two EC members to review the research proposal. When both reviewers' decisions are in positive agreement, the Certificate of Ethical Approval will be issued. If the decisions are in disagreement, the EC Chairperson will discuss with primary reviewers to reach an agreement, then notify the Principal Investigator whether it should go to the full board, or ask Principal Investigator to revise research proposal.

The criteria for full board review are as follows:

1. Studies that cannot be reviewed and approved at an Exempt or Expedited review.
2. Studies determined by the EC Chairperson as involving more than minimal risk.
3. Studies involving elements, procedures or interventions that require additional provisions or safeguards, as stated by national regulations and guidance.
4. Studies involving highly vulnerable population, eg. HIV-infected persons, comatose patients, patients under critical care.

For full EC review, the Chairperson will appoint three (3) primary reviewers and one (1) Lay member for each research proposal. The Assistant Secretary will distribute hard copies of the proposal plus any other necessary materials, for example the Participant Information Sheet, Informed Consent Form, etc. to the assigned reviewers and lay member. The Assistant Secretary will send the same files, as PDFs, by email to all members of the review panel at least seven (7) days before the scheduled EC meeting. The assigned EC members are required to review in-depth the materials of the assigned research proposal, the contents of the Participant Information Sheet and the Informed Consent Form and will complete a Reviewer's Assessment Form for Initial Review (FTM ECF-007-RR) and send their comments on the research proposal three (3) days before the scheduled EC meeting. Assessing the Participant Information Sheet and Informed Consent Form is particularly important for lay members. EC members who are not assigned reviewer of the review panel will read research proposal and be ready to submit their comments at the scheduled EC meeting but do not need to submit comments in advance.

The Primary Reviewer(s) will present a summary of the research proposal to all EC members attending the full board meeting before comments at a regular or special meeting of the EC. The Principal Investigator and/or an Accountable Investigator affiliated with the Faculty of Tropical Medicine will be invited to attend a portion of the meeting, so that EC members have the opportunity to question him/her about the research proposal. If they cannot attend the Full Board meeting, the project will be postponed for consideration the following month. After the research has been presented, the EC Chairperson will call for a discussion on the research proposal, consent form, advertisements, and other materials.

The Primary Reviewer(s) will make a motion concerning the research proposal, consent form, and advertisements (i.e., approval, approval with conditions and or suggestions, deferral, disapproval). After discussion among the EC members, the assigned EC members who had read the proposal and those EC members attending the full board meeting will decide to approve or disapprove the research proposal by consensus.

If consensus cannot be reached, voting system will be used. No member of the EC with a conflict of interest is allowed to vote on the research proposal. Criteria for approval is receiving majority vote of at least 75% of the presenting voting members.

If the EC approves a research proposal with conditions, it must be specified, by majority vote of the members present, whether the changes will require full EC approval or may be approved by the EC Chairperson or Primary Reviewer on behalf of the EC.

A summary of the EC's discussions and a record of its decisions, including but not limited to the final disposition of each research proposal, will be made by the Member and Secretary.

7.3 Criteria for EC Approval of the Research Proposal

Documents to be approved by EC are Research proposal, Full Protocol (additional fee is required for 10,000 Baht per one language version), Participant Information Sheet, Informed Consent Form, and instruments (CRF, questionnaire, advertisement, etc.).

The EC may approve research proposal only after it has determined that all of the following requirements are satisfied:

1) Risks to research participants are minimized by using procedures that are consistent with sound research design, and that do not unnecessarily expose research participants to risk. Whenever appropriate, investigators should employ procedures that are being performed on research participants for diagnostic or treatment purposes.
2) Risks to research participants are reasonable relative to:
   a. anticipated benefits, if any, to research participants, and

b. the importance of the knowledge that may reasonably be expected to result.

3) The selection of research participants is equitable. In making this assessment, the EC must take into account the purposes of the research and the setting in which it will be conducted. The EC must be particularly attentive to the special problems that may arise when research involves vulnerable populations, such as children, pregnant women, prisoners, mentally disabled persons, or economically or educationally disadvantaged persons. If any of the research participants is likely to be susceptible to undue influence or coercion, the EC may require additional safeguards in the study to protect such research participants.

4) Informed consent will be sought from each prospective research participant, or the research participant's legally authorized representative or guardian, generally by means of a written consent document.

   The EC will carefully review these documents to assure that they contain the required elements of informed consent and that they are understandable to a layperson.

   Special attention will be given to vulnerable subjects. Examples are (a) Informed Assent Forms are required when enrolling participants aged 7 years to less than 13 years; even though participants aged 13-17 years may make the decision by themselves, their legally authorized representative or guardian have to co-sign the informed consent form; (b) for the mother and/or their children aged less than 18 years, their legal guardian or Head of Community/ Community Affairs Board must co-sign; this depends on the culture of each study area; (c) in the case that the investigators enroll psychotic patients or patients who are unconscious/ comatose or not in the condition of making decision themselves to the study with the permission of their legally authorized representative or guardian and with witnesses, an endorsement of the participant is needed when he/she is recovered; (d) the participants who cannot read and write by themselves must sign via thumbprint in the ICF. An independent witness must also sign the ICF; (e) research conducted in non-Thai participants requires a certified correct translated informed consent form (ICF).

5) The research plan makes adequate provisions for ensuring the safety of research participants.

6) There are adequate provisions to protect the privacy of research participants and to maintain the confidentiality of data.

7) The investigator is appropriately qualified and has the facilities to ensure all aspects of the research will be conducted with regard for the safety and well-being of the research participants.

When some or all of the research participants are likely to be vulnerable to coercion, the EC should add additional safeguards in the review of the research to ensure the rights and welfare of these research participants are protected.

7.4 Notification to the Investigator

The EC will provide the Investigator with written notification, within seven (7) working days after convened meeting for full board review and within fifteen (15) working days for expedited review after submission, of its decision to approve, approve with condition and or suggestions, defer, or disapprove the research proposal.

If the research proposal is approved, a Certificate of Ethical Approval (FTM ECF-013-RR) will be issued along with the letter of notification. The Certificate will include the title of the project, PI's name and affiliation as well as its Submission Number. The Certificate's number is assigned according to FTM ECW-001-RR: Certificate of Ethical Approval Number Assignment work practice. Relevant information, i.e., Research Proposal Version Number, Participant Information Sheet Version Number, Informed Consent Form Version Number, and CRF/Questionnaire/Advertisement Version Number, are also included. The Certificate Number is assigned by Member and Secretary and will be maintained through by the Certificate of Ethical Approval Number Assignment Log (FTM ECF-018-RR). Approved documents will be stamped with FTM EC's seal with expiry date.

The Certificate is co-signed by the EC Chairperson or EC Vice-Chairperson and EC Member and Secretary or is co-signed by EC Chairperson and EC Vice-Chairperson and valid for one (1) year only after date of approval and Investigator must extend the certificate using Progress Report Form/Certificate of Ethical Approval Extension Request Form (FTM ECF-008-RR) two (2) months prior to the expiry date if the study is not finished. Administrative Staff will follow up the submission of extension by notifying the Investigator by E-mail twice before the deadline. If Investigator fails to submit an extension, the EC will not extend the Certificate of Ethical Approval. An official notification letter will be provided to Investigator.

If the research proposal is approved with conditions of minor revision, the EC Member and Secretary shall compile the comments from EC members and inform the Investigator to revise the research proposal accordingly and request PI to resubmit three (3) copies of the research proposal to EC for consideration. The Chairperson will nominate two (2) Primary reviewers to review the revised research proposal; or EC Chairperson or at least one Primary Reviewer will consider it.

If research proposal is approved with conditions of major revision, five (5) copies of the research proposal will be required and will be considered in full board review. Resubmission shall be done within six (6) months after the notification from FTM EC to the Investigator. Failure to resubmit the research proposal within its timeline will lead to the cancellation of the research proposal.

If the research proposal is disapproved, the reasons for such disapproval will be documented and the Investigator will be informed by a written notification. The Investigator may appeal the EC's decision within 30 days of receiving this

notification. The Investigator may choose to submit a new proposal based on the suggested changes, or if Investigator wishes to request the EC to revise their decision, Investigator has to write a clarification letter with a justification to the EC Chairperson. This will be considered in full board review.

The decisions of the EC will be included in the files maintained by the Assistant Secretary.

7.5 Continuing Review

Upon EC approval, the frequency of continuing review will be determined. Continuing review can be conducted either by full EC or an expedited review process. The process is predetermined after the initial approval of the research proposal. The Assistant Secretary is responsible for tracking when continuing review is due for each study.

The EC will conduct continuing reviews of research at intervals appropriate to the degree of risk, but not less than once a year, in order to reassure themselves, investigators, research participants, and the public that appropriate measures are being taken to protect the rights and welfare of research participants.

The Principal Investigator is responsible for timely submission of a progress report using Progress Report Form/Certificate of Ethical Approval Extension Request Form (FTM ECF-008-RR) to the EC. The Investigator should submit the necessary documentation to the Assistant Secretary in enough advance time so that completion of continuing review can be accomplished by the due date.

For continuing review, the Investigator shall submit the following documents to the Assistant Secretary:

1) A copy of the Certificate of Ethical Approval previously given to the approved research proposal,
2) A copy of the currently approved research proposal and consent document,
3) A completed Progress Report Form/Certificate of Ethical Approval Extension Request Form (FTM ECF-008-RR)
4) A copy of receipt of Submission fee for the 3rd Certificate of Ethical Approval Extension (and subsequent)

If a research proposal is extended 3 times (and subsequent), the Investigator must pay 5,000 Baht submission fee where a project is funded by a private or foreign institution/company; however, this fee is waived where a project is funded by a government institution.

If full EC continuing review is required, the Assistant Secretary will distribute the materials to previously assigned three (3) Primary reviewers and one (1) Lay member of each research proposal at least seven (7) days in advance of the meeting. The review will take place at a convened meeting of the EC and must be approved by a format similar to the initial review. Criteria for approving the

continuation of research are the same as with the initial review. If the EC gives conditional approval to the continuing review, these conditions must be met before approval for continuation being granted.

For an expedited continuing review, the Assistant Secretary will distribute the materials to the Primary Reviewer(s) assigned by the EC Chairperson. The Primary Reviewer(s) will give recommendation to the EC Chairperson who will inform full EC at its convened meeting.

When the continuing review is completed, the EC Member and Secretary will provide the Investigator with written notification of EC's decision concerning the continuation of the research. If approval is granted, a Certificate of Ethical Approval will be issued to the Investigator. If it is disapproved, the reasons for such disapproval will be documented and the Investigator will be notified. The Investigator will also be notified of the duration of the EC's approval, which will never exceed one year. The decisions of the EC will be included in the files maintained by the Assistant Secretary.

For the projects approved before 17 August 2007 or prior to the effective date of the present set of SOPs, the continuing review is applied when the Certificate of Ethical Approval Extension Request (FTM ECF-008-RR) is filed. The continuing review shall undergo a full board review in the same manner of an initial review and the Form FTM ECF-024-RR (Reviewer's Assessment Form for Continuing Review) is used. Processes after the continuing review follows those described above.

7.6 Amendments/Revisions of an approved research proposal

Research proposals previously approved by FTM EC may undergo subsequent amendments/revisions. Revisions are usually classified into three (3) types: informational revisions (e.g., changes in telephone numbers, addition or deletion of associates or staff, reduction of the number of research participants, or deletion of questions in the questionnaire), minor revisions (reducing the amount of blood and/or frequency of blood withdrawal, revising the format of the consent form, changing of contact person and/or telephone number on the consent form), and major revisions (those changes that can be identified as more than minimal risks to the research participants).

The request for such a revision can be filed by using FTM ECF-023-RR (Request for Protocol Amendment Form). The Investigator is responsible for providing clearly articulated information, with an easily understood description and justification, to assist the EC conduct a timely review and approval. This will permit the Investigator to continue enrolling research participants after the revisions have been approved.

If a research proposal and/or other research documents (except Investigator Brochure) undergo a major amendment (full board review is required) more than twice, the Investigator is required to pay 5,000 Baht submission fee where a project is funded by a private or foreign institution/company. The Investigator is required to pay 2,500 Baht submission fee where a project is funded by a

government institution. If it undergoes a major revision (such as changing the information in the synopsis, change or addition to the main objective/ major issues etc.), the Investigator is required to submit it as a new research proposal.

Informational and minor revisions will undergo an expedited review process, where the decision is made by either the EC Chairperson or the Primary Reviewer(s). Major revisions will require a full EC review.

7.7 Submission of Progress Report

Investigators are required to submit progress reports after approval as stipulated by EC requirements related to the identified risk, using Progress Report Form/ Certificate of Ethical Approval Extension Request Form (FTM ECF-008-RR).
The progress report will be presented by the Primary reviewer(s) at the convened meeting. Administrative Staff will follow up submission of progress report by notifying Investigator by E-mail twice before the deadline. If Investigator fails to submit a progress report, the EC will not extend the Certificate of Ethical Approval. Official notification letter will be provided to Investigators.

7.8 Notification of the Study Termination/ Study Closure

Investigator should notify the EC when all research-related interventions or interactions with human subjects have been completed. All data collection and/or analysis has been finished. When a human subjects research study has been completed, the investigators no longer are required to obtain continuing review and approval of that study by the EC. Investigator shall inform EC of the study termination or final/closure report using the Notification of Study Closure Form (FTM ECF-010-RR). The EC Chairperson or at least one Primary Reviewer will review the report. Member and Secretary shall notify the EC members of the study termination or final/closure report at the next convened meeting, and if necessary a recommendation will be given. An official notification will be given to PI.
If the EC terminates or suspends its approval/ favorable opinion of a trial, the investigator should inform the institution where applicable and the investigator/ institution should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension.

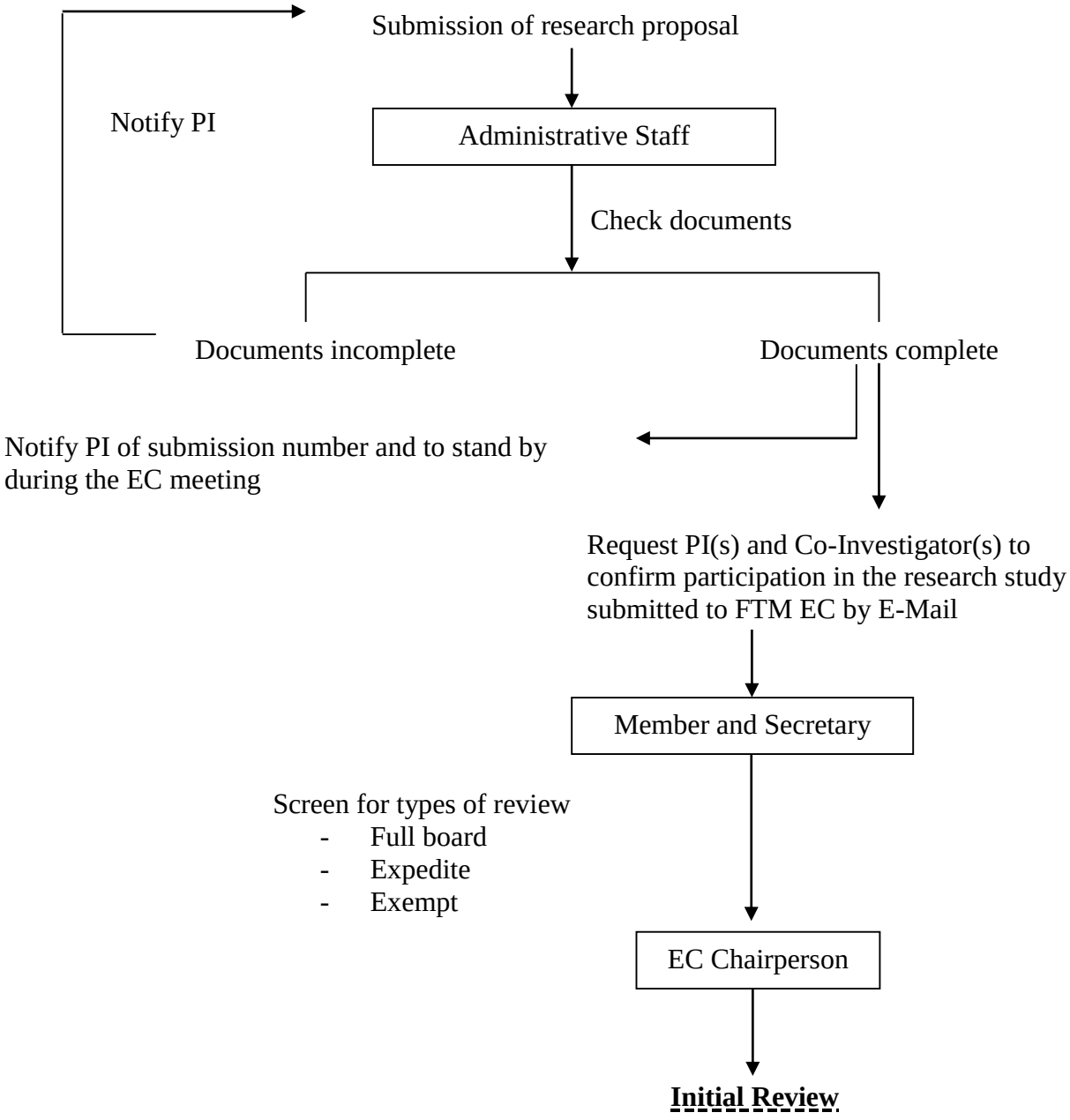
7.9 Management of Study Files

All submitted research proposals and documents will be maintained in the lockable cabinet at the office of Ethics Committee for consideration and preparation for the EC meeting. This can be accessed by Member and Secretary, Assistant Secretaries and Administrative Staff only. After EC meetings, the EC members must return the reviewed material photocopies to the Assistant Secretary immediately. All photocopied materials will be disposed with shredder except the original copy which will be filed with the colored sticker indicating the status of project (yellow=pending/ green=approved/ 2 red=disapproved/ yellow with red= aborted by EC or PI/ Green with red= Terminate by PI or Close by EC) and fill the research information including result of review in FTM EC database with using username and password before log in the EC database that Member and

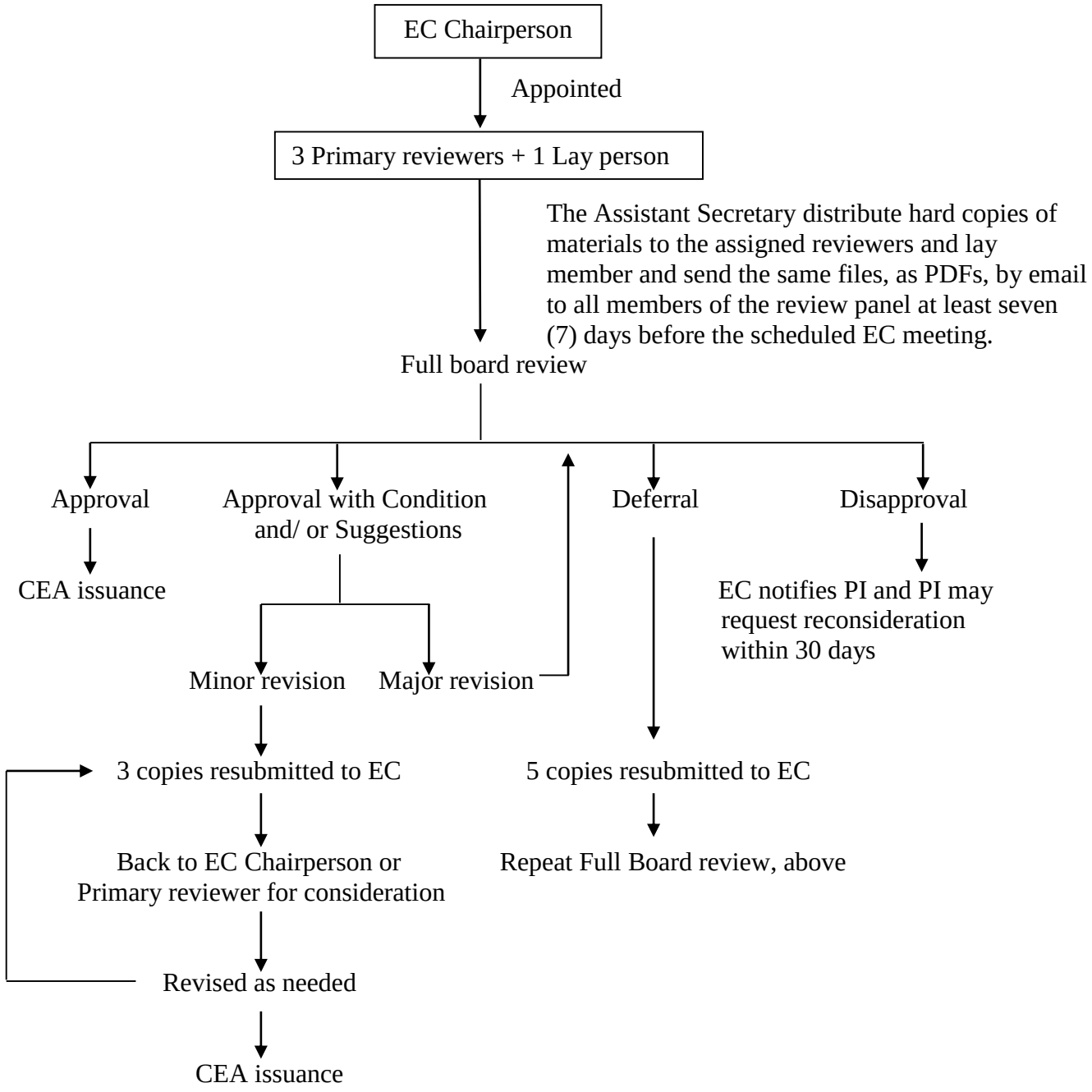
Secretary, Assistant Secretaries and Administrative Staff have this only. The filing will be kept for one (1) year after study completion. After this period, the Administrative Staff will scan the Certificate of Ethical Approval (CEA) of the first approval, or for not approved projects the result notification letter (communication letter) will be scanned instead, and saved on an EC external hard disk and on an Office of Research Services. Documents will then be shredded.

8.0 Appendix

8.1 Research Proposal Submission Flowchart for EC Staff



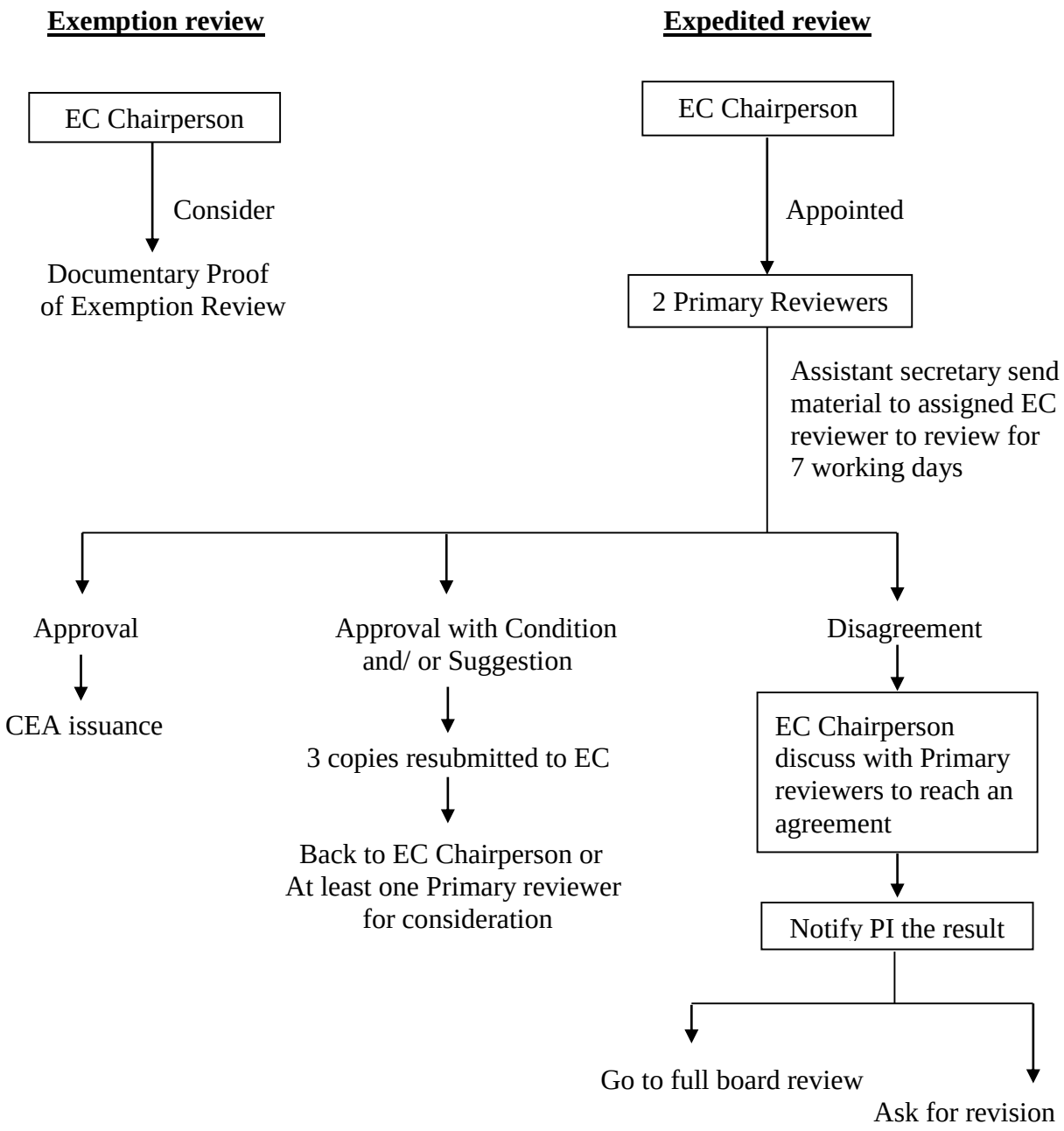
8.2 (1) EC Initial Review Flowchart (Full board review)



Remark: Timeline from date of submission to date of review is about 30 days

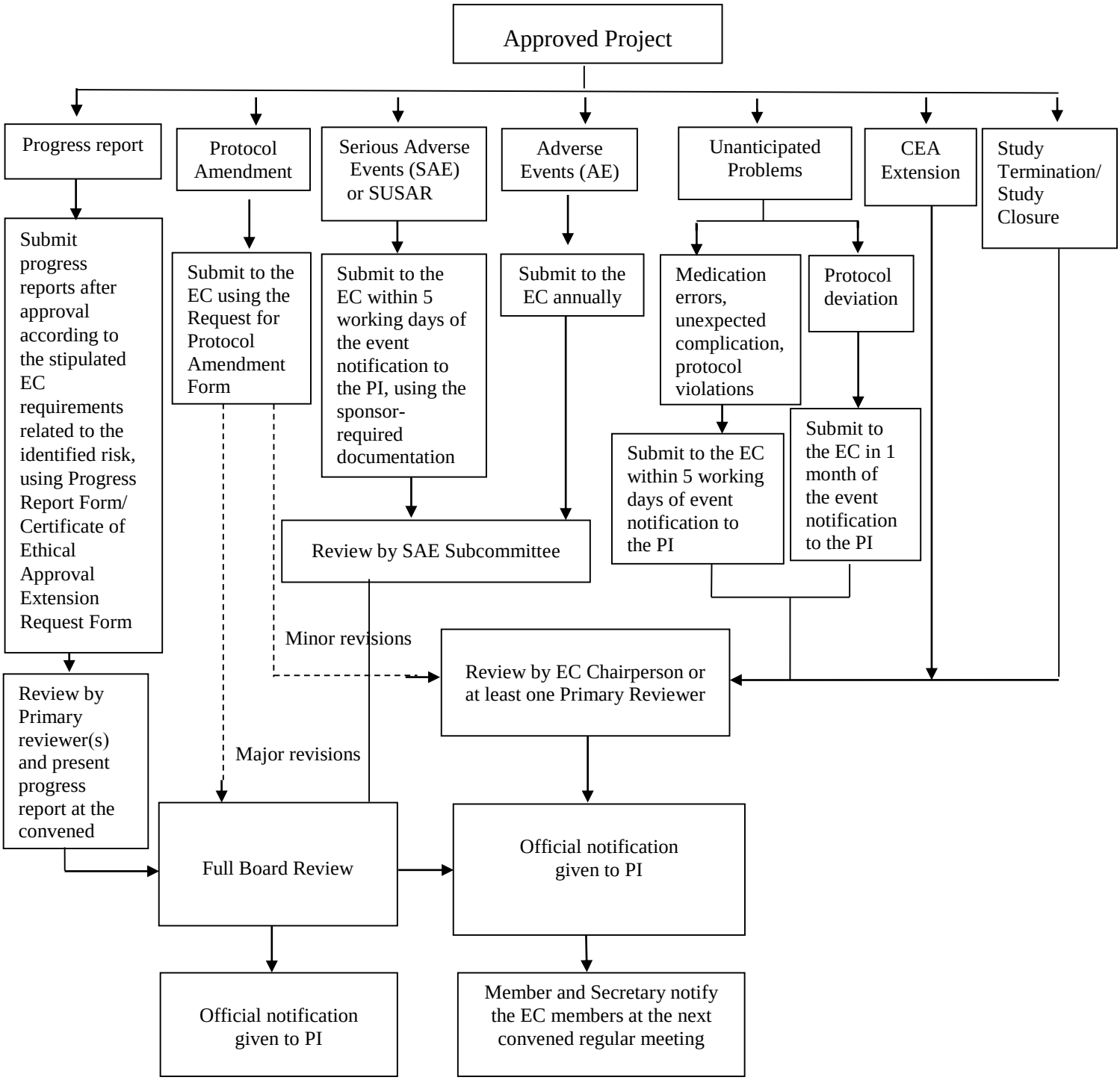
Timeline from date of review to date of notification is 7 workings days

8.2 (2) EC Initial Review Flowchart (Exemption review & Expedited review)



Remark: Timeline from date of submission to date of notification for expedited review is 15 workings days

8.3 Post-Review Flowchart



8.4 Communication letters

8.4.1 Cover letter for research proposal submission (Thai)

(ชื่อภาควิชา/หน่วยงาน) .....

โทร. ..... โทรสาร .....

ที่ ศธ.....

วันที่ ..... เดือน ..... พ.ศ. .....

เรื่อง ขอส่งเอกสารโครงการวิจัยเพื่อขอรับการรับรองจากคณะกรรมการจริยธรรมการวิจัยในคน คณะเวชศาสตร์เขตร้อน

เรียน ประธานคณะกรรมการจริยธรรมการวิจัยในคน คณะเวชศาสตร์เขตร้อน

ข้าพเจ้า ☐.....สังกัดภาควิชา/หน่วยงาน.....

☐.....นักศึกษาหลักสูตร..... รหัสนักศึกษา.....

ชื่ออาจารย์ที่ปรึกษา..... ภาควิชา.....

สอบผ่านโครงร่างการวิจัย (Proposal Examination) แล้วเมื่อวันที่ .....

มีความประสงค์ขอส่งเอกสารโครงการวิจัยเรื่อง "....." เพื่อขอรับการพิจารณารับรองจากคณะกรรมการจริยธรรมการวิจัยในคน คณะเวชศาสตร์เขตร้อน

(กรณีเป็นโครงการย่อยของโครงการวิจัยอื่น ให้เพิ่มข้อความดังนี้)

อนึ่ง โครงการดังกล่าวเป็นโครงการย่อยของโครงการวิจัยเรื่อง "....." มีหัวหน้าโครงการวิจัยชื่อ ..... สังกัดภาควิชา/หน่วยงาน..... หมายเลขเอกสารรับรอง..... ซึ่งได้รับการรับรองจริยธรรมการวิจัยในคนจาก..... แล้ว (โปรดแนบสำเนาเอกสารรับรอง)

เอกสารโครงการวิจัย มีดังนี้ (โปรดระบุเอกสารพร้อมจำนวนเอกสารที่ส่ง)

1) Research Proposal Submission Form จำนวน ..... ชุด
2) Research Proposal/Protocol Submission Checklist for Principal Investigator จำนวน 1 ชุด
3) เอกสารชี้แจงผู้เข้าร่วมการวิจัย (Participant Information Sheet) และหนังสือแสดงเจตนายินยอมเข้าร่วมการวิจัยฯ (Informed Consent Form)/(Informed Assent Form) จำนวน ..... ชุด (ถ้ามี)
4) Full Research Protocol จำนวน ..... ชุด (ถ้ามี)
5) Thesis Proposal จำนวน ..... ชุด (สำหรับนักศึกษา)
6) ผลการสอบโครงร่างวิทยานิพนธ์/สารนิพนธ์ (บท 33) หรือ ผลการแก้ไขการสอบโครงร่างวิทยานิพนธ์/สารนิพนธ์ (บท 37) จำนวน ..... ชุด (สำหรับนักศึกษา)
7) เอกสารอื่นๆ (โปรดระบุรายละเอียดทุกเอกสารที่ส่งมา)
8) ประวัติย่อ (CV) ของผู้วิจัยหลักและผู้วิจัยร่วม(หรืออาจารย์ที่ปรึกษา) พร้อมทั้งสำเนาเกียรติบัตรการเข้าอบรม GCP และ/หรือ จริยธรรมการวิจัยในคน จำนวน 1 ชุด
9) สำเนาใบเสร็จรับเงินค่าธรรมเนียมการพิจารณาโครงการวิจัย จำนวน 1 ชุด (ยกเว้นโครงการวิจัยของนักศึกษาคณะเวชศาสตร์เขตร้อน และผู้ได้รับทุนส่งเสริมการวิจัยจากเงินรายได้คณะเวชศาสตร์เขตร้อน)
10) แผ่นซีดีบรรจุไฟล์เอกสารที่ส่งทั้งหมด จำนวน 1 แผ่น

จึงเรียนมาเพื่อโปรดพิจารณา

ลงชื่อ.....

(หัวหน้าโครงการวิจัย)

ลงชื่อ.....

(ชื่ออาจารย์ที่ปรึกษา) (กรณีเป็นโครงการของนักศึกษา)

ลงชื่อ.....

(หัวหน้าภาควิชา/หัวหน้าหน่วย)

8.4.2 Cover letter for research proposal submission (English)

MAHIDOL UNIVERSITY
Since 1888

Department / Affiliation: _____

Tel.: _____ Fax: _____

Reference letter No: _____

Date / Month / Year: _____

Subject: **Submission of research proposal for consideration by the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University**

Dear Chairperson of the Ethics Committee of the Faculty of Tropical Medicine,

My name is _____, [Dept. / Affiliation] _____. I would like to submit the research proposal entitled "_____" for consideration by the Ethics Committee of the Faculty of Tropical Medicine. *[For staff]*

My name is _____, my student ID number is _____, my program is _____, [Dept. / Affiliation] _____. I passed the Proposal Examination on _____. I would like to submit the research proposal entitled "_____" for consideration by the Ethics Committee of the Faculty of Tropical Medicine. *[For students]*

[If this research is part of a sub-study project, please complete the following]
This research is a sub-study of research entitled "_____". The Principal Investigator is _____, [Dept. / Affiliation] _____. The Certificate of Ethical Approval number is _____, which received ethical clearance from [Ethics Committee's Institute] _____. *[Please attach a copy of the Certificate of Ethical Approval]*

For your consideration, please find enclosed the following:
(1) Research Proposal Submission Form – _____ copies.
(2) Research Proposal / Protocol Submission Checklist for Principal Investigator – 1 copy
(3) Participant Information Sheet _____ copies, Informed Consent Form _____ copies, Informed Consent Form _____ copies [If applicable]
(4) Full Research Proposal _____ copies. [If applicable]
(5) Thesis Proposal _____ copies. [For student projects]
(6) Evaluation of the thesis / thematic paper proposal Examination Form (GR33), or result of a revision of the thesis / thematic paper proposal Examination Form (GR37) _____ copies.
(7) Other documents [Please specify]
(8) Curriculum Vitae and copy of Certificate of GCP Training, or Human and Subject Protection Training of Principal Investigator(s) and Co-Investigator(s) (or thesis committee member) and – 1 copy
(9) Copy of Payment Receipt of Ethics Review Fee – 1 copy [Except TropMed students and anyone receiving funds from the TropMed Research Committee]
(10) One CD containing copies of all attached documents

Yours sincerely,

Signature: _____
(Principal Investigator)

Signature: _____
(Thesis / Thematic Advisor)
[In the case of TropMed student projects]

Signature: _____
(Affiliation / Department Head)

8.4.3 Notification for submission number and Ethics Committee meeting date (Thai)

สำนักงานคณะกรรมการจริยธรรมการวิจัยในคน
สำนักงานบริการการวิจัย คณะเวชศาสตร์เขตร้อน
โทร 1349 ต่อ 16/ โทรสาร 0 2306 9126

ที่ ศธ 0517.1116/ จธ.
วันที่
เรื่อง แจ้งรหัสโครงการและวันประชุม

เรียน ระบุชื่อผู้วิจัยหลัก

สำนักงานคณะกรรมการจริยธรรมการวิจัยในคน คณะเวชศาสตร์เขตร้อน ได้รับโครงการวิจัยเรื่อง "....." จำนวน.....ชุด ซึ่งได้ส่งเข้ามาเพื่อขอรับการพิจารณารับรองเมื่อวันที่..... นั้น

ขอแจ้งให้ทราบว่ารหัสโครงการของท่านคือ TMEC..... **และกรุณาอ้างอิงรหัสโครงการนี้ทุกครั้งที่ติดต่อกับหน่วยงานเพื่อความสะดวกในการดำเนินการ** โครงการนี้ได้ถูกบรรจุลงในระเบียบวาระการประชุมของการประชุมคณะกรรมการจริยธรรมการวิจัยในคน ประจำเดือน.....พ.ศ. .....(ครั้งที่...) วันที่.....

คณะกรรมการฯ ขอเชิญผู้วิจัยหลักและ/หรือผู้รับผิดชอบโครงการวิจัยซึ่งเป็นบุคลากรของคณะเวชศาสตร์เขตร้อน มาชี้แจงและให้ข้อมูลโครงการวิจัยในวันที่.....ระหว่างเวลา..... ณ ห้องประชุม.....อาคาร..... หากไม่มีผู้ใดสามารถเข้าชี้แจงโครงการวิจัยได้ คณะกรรมการฯ จะเลื่อนการพิจารณาโครงการวิจัยของท่านไปในวันที่.....(หรือจนกว่าจะสามารถเข้าชี้แจงโครงการได้)

จึงเรียนมาเพื่อโปรดทราบและกรุณาส่งคืนแบบฟอร์มตอบกลับการเข้าชี้แจงโครงการวิจัย **ภายในวันที่**..... ที่สำนักงานคณะกรรมการจริยธรรมการวิจัยในคน ชั้น 4 อาคารเฉลิมพระเกียรติฉลองสิริราชสมบัติครบ 60 ปี คณะเวชศาสตร์เขตร้อน หรือทางโทรสาร 0 2306 9126 จะขอบคุณยิ่ง

จึงเรียนมาเพื่อโปรดทราบ

(นางพรพิมล อดัมส์)
กรรมการและเลขานุการ
คณะกรรมการจริยธรรมการวิจัยในคน
คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล

แบบฟอร์มตอบกลับการเข้าชี้แจงโครงการวิจัย

ที่ขอคำรับรองจากคณะกรรมการจริยธรรมการวิจัยในคน คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล

ชื่อโครงการวิจัย .....

.....

รหัสโครงการ .....

ชื่อหัวหน้าโครงการวิจัย (Principal Investigator) .....

สังกัด .....

หมายเลขโทรศัพท์ที่สะดวกในการติดต่อ .....

ชื่อผู้รับผิดชอบโครงการวิจัย (Accountable Investigator) .....

สังกัด .....

หมายเลขโทรศัพท์ที่สะดวกในการติดต่อ .....

การเข้ามาชี้แจงและให้ข้อมูลโครงการวิจัยใน**วันที่**..... **ระหว่างเวลา**.....

ณ ห้องประชุม..... อาคาร.....

☐ มาให้ข้อมูลได้ (โปรดทำเครื่องหมาย ⊗ สำหรับผู้มาให้ข้อมูล):

- ❍ ผู้วิจัยหลัก/ผู้รับผิดชอบโครงการ (กรณีเป็นท่านเดียวกัน)
- ❍ ผู้รับผิดชอบโครงการเท่านั้น
- ❍ ผู้วิจัยหลักและผู้รับผิดชอบโครงการ

☐ ไม่สามารถมาให้ข้อมูลได้ เนื่องจาก.....

ขอให้เลื่อนการพิจารณาโครงการวิจัยไปในวันที่	ผู้มาให้ข้อมูลได้ (โปรดทำเครื่องหมาย ⊗ สำหรับผู้มาให้ข้อมูล)
❑ .....(EC กำหนด)	❍ ผู้วิจัยหลัก/ผู้รับผิดชอบโครงการ (กรณีเป็นท่านเดียวกัน)
❑ .....(EC กำหนด)	❍ ผู้รับผิดชอบโครงการเท่านั้น
	❍ ผู้วิจัยหลักและผู้รับผิดชอบโครงการ

กรุณาส่งคืนแบบฟอร์มตอบกลับการประชุมที่ สำนักงานคณะกรรมการจริยธรรมการวิจัยในคน
สำนักงานบริการการวิจัย ชั้น 4 อาคารเฉลิมพระเกียรติฉลองสิริราชสมบัติครบ 60 ปี
คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล
โทรศัพท์ 0 2354 9100-4 ต่อ 1349 กด 16 โทรสาร 0 2306 9126

ภายในวันที่.....

8.4.4 Notification for submission number and Ethics Committee meeting date (English)

MAHIDOL UNIVERSITY
Since 1888

No. TM–ORS……/….Year…….
……..Date…….

……..PI Name……
……..PI's Affiliation…….

Subject: Notification for Submission Number and Ethics Committee Meeting Date

Dear ……..PI Name……,

We hereby acknowledge receipt of …copies of your research proposal entitled "……", submitted for ethical review on ……..

Your Protocol Submission Number is **TMEC….. Please refer to this number at any time when you correspond with the Ethics Committee.** Your protocol is scheduled for review in **the EC Meeting on ……..(date)……**

The Ethics Committee invites the Principal Investigator and/or the Accountable Investigator affiliated with the Faculty of Tropical Medicine to attend an EC meeting in order to describe and clarify relevant details of the research project **on ……..(date)…….. from ……(time)…., in Meeting Room ……, …..Floor, His Majesty the King's 60 Years Accession to the Throne Building,** Faculty of Tropical Medicine, Mahidol University. If no one is able to attend the meeting, your project will be postponed for consideration on.....(until the Principal Investigator and/or the Accountable Investigator can attend to provide clarification at the meeting).

Please complete the attached EC Meeting Attendance Advice form and return it to the EC Office **by……(date)……..**; 4th Floor, His Majesty the King's 60 Years Accession to the Throne Building or by fax to +66 (0) 2306 9126.

Yours sincerely,

Mrs. Pornpimon Adams
Member and Secretary, Ethics Committee
Faculty of Tropical Medicine, Mahidol University

Ethics Committee
Faculty of Tropical Medicine, Mahidol University
Office of Research Services
Phone: 66 (0) 2354 9100 ext. 1349 press 16, Fax: 66 (0) 2306 9126

Committee Meeting Attendance Advice

Project Title: ……..……
Protocol Number: ……

Principal Investigator Name: ……
Affiliation: ……
Contact Number ……

Accountable Investigator Name: ……
Affiliation: ……
Contact Number ……..

Attendance is required to clarify the research project and provide additional information on ……(date and time of EC Meeting), in Meeting Room ….., …..Floor, at His Majesty the King's 60 Years Accession to the Throne Building, Faculty of Tropical Medicine, Mahidol University.

☐ Can attend to provide clarification and additional information (Please check ⊗ for the Attendee),
- ❍ Principal Investigator/Accountable Investigator (If the same person)
- ❍ Accountable Investigator only
- ❍ Principal Investigator and Accountable Investigator

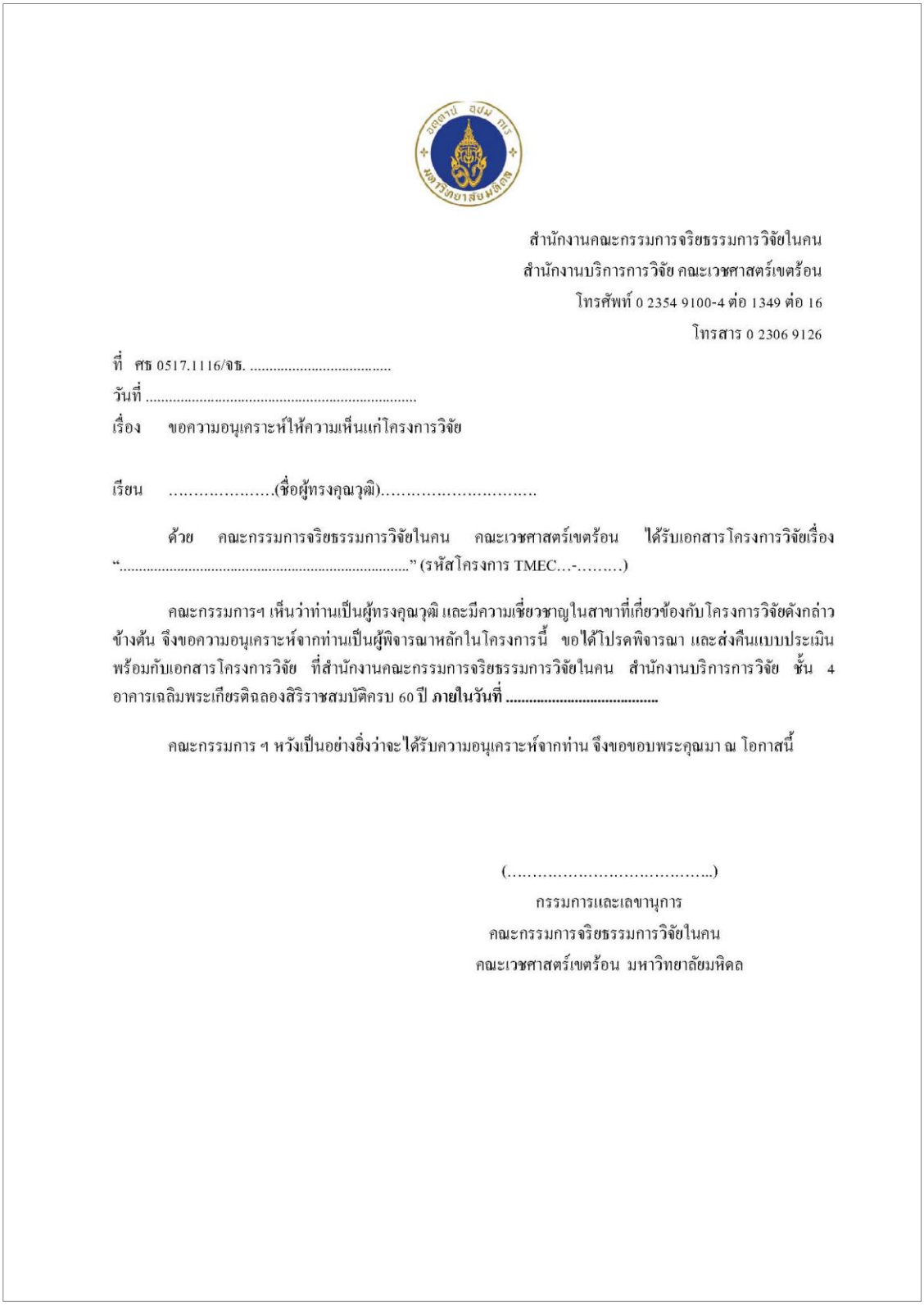
☐ Cannot attend because……..…….,

Postpone consideration of the research project on	Attendee (Please check ⊗ for the Attendee)
☐……(specified by EC)	❍ Accountable Investigator/Principal Investigator (If the same person)
	❍ Accountable Investigator only
☐……(specified by EC)	❍ Principal Investigator and Accountable Investigator

Please return form to:
Ethics Committee, Faculty of Tropical Medicine, Mahidol University
c/o Office of Research Services
4th Floor, The 60th Anniversary of His Majesty the King's Accession to the Throne Building
Faculty of Tropical Medicine, Mahidol University
420/6 Ratchawithi Road, Ratchathewi, Bangkok 10400, Thailand
Phone: 66 (0) 2354 9100-4 ext. 1349 press 16 Fax: 66 (0) 2306 9126

Due by……(date)……..

8.4.5 Letter of requesting Expert Member to review research proposal (Thai only)



สำนักงานคณะกรรมการจริยธรรมการวิจัยในคน
สำนักงานบริการการวิจัย คณะเวชศาสตร์เขตร้อน
โทรศัพท์ 0 2354 9100-4 ต่อ 1349 ต่อ 16
โทรสาร 0 2306 9126

ที่ ศธ 0517.1116/จธ. .....
วันที่ .....
เรื่อง ขอความอนุเคราะห์ให้ความเห็นแก่โครงการวิจัย

เรียน .....(ชื่อผู้ทรงคุณวุฒิ).....

ด้วย คณะกรรมการจริยธรรมการวิจัยในคน คณะเวชศาสตร์เขตร้อน ได้รับเอกสารโครงการวิจัยเรื่อง ".....” (รหัสโครงการ TMEC...-.....)

คณะกรรมการฯ เห็นว่าท่านเป็นผู้ทรงคุณวุฒิ และมีความเชี่ยวชาญในสาขาที่เกี่ยวข้องกับโครงการวิจัยดังกล่าวข้างต้น จึงขอความอนุเคราะห์จากท่านเป็นผู้พิจารณาหลักในโครงการนี้ ขอได้โปรดพิจารณา และส่งคืนแบบประเมินพร้อมกับเอกสารโครงการวิจัย ที่สำนักงานคณะกรรมการจริยธรรมการวิจัยในคน สำนักงานบริการการวิจัย ชั้น 4 อาคารเฉลิมพระเกียรติฉลองสิริราชสมบัติครบ 60 ปี **ภายในวันที่ .....**

คณะกรรมการ ฯ หวังเป็นอย่างยิ่งว่าจะได้รับความอนุเคราะห์จากท่าน จึงขอขอบพระคุณมา ณ โอกาสนี้

(.....)
กรรมการและเลขานุการ
คณะกรรมการจริยธรรมการวิจัยในคน
คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล

โดยหนังสือฉบับนี้ข้าพเจ้า.....(ชื่อผู้ทรงคุณวุฒิ).....สังกัด.....
ขอรับรองว่าได้รับเอกสารโครงการวิจัยเรื่อง "..... (Project Title).....”
จากคณะกรรมการจริยธรรมการวิจัยในคน คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล ไว้เรียบร้อยแล้ว

.....
(ชื่อผู้ทรงคุณวุฒิ)

วันที่ .....

8.4.6 Notification of result of initial review (Thai)

สำนักงานคณะกรรมการจริยธรรมการวิจัยในคน
สำนักงานบริการการวิจัย คณะเวชศาสตร์เขตร้อน
โทรศัพท์ 0 2354 9100-4 ต่อ 1349 ต่อ 16
โทรสาร 0 2306 9126

ที่ ศธ 0517.1116/ จธ. .....
วันที่ .....
เรื่อง แจ้งผลการพิจารณา ครั้งที่.....

เรียน .....(ชื่อหัวหน้าโครงการ).....

อ้างถึงหนังสือที่.....ลงวันที่.....ท่านส่งโครงการวิจัยเรื่อง "....." (รหัสโครงการ TMEC.....-.....) มาเพื่อให้คณะกรรมการจริยธรรมการวิจัยในคน คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล พิจารณา นั้น

ในการประชุมคณะกรรมการจริยธรรมการวิจัยในคน ประจำเดือน..... พ.ศ. ..... ครั้งที่..... วันที่ .....คณะกรรมการฯ ได้พิจารณาโครงการดังกล่าวแล้ว มีมติ..... โดยขอให้ท่านแก้ไขเอกสารโครงการวิจัยตามรายละเอียดตามเอกสารที่แนบท้าย ทั้งนี้กรุณาทวนและตอบคำถาม/ข้อเสนอแนะทีละข้อพร้อมทั้งระบุว่าท่านได้แก้ไขไว้ที่หน้าใดและขีดเส้นใต้หรือ highlight ส่วนที่ได้แก้ไข

จึงเรียนมาเพื่อโปรดพิจารณาทำการชี้แจงไว้ในหนังสือนำส่งพร้อมทั้งแก้ไขเอกสารโครงการ แล้วส่งเอกสารฉบับแก้ไขที่ระบุเวอร์ชั่นและวันที่ที่แก้ไขที่ Footer จำนวน ..... ชุด ภายใน 6 เดือนนับจากวันที่แจ้งผลการพิจารณา ที่สำนักงานคณะกรรมการจริยธรรมการวิจัยในคน ชั้น 4 อาคารเฉลิมพระเกียรติฉลองสิริราชสมบัติครบ 60 ปี คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล

(.....)
ประธานคณะกรรมการจริยธรรมการวิจัยในคน
คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล

หมายเหตุ

1. ผู้วิจัยต้องเปลี่ยน Version ของเอกสารที่แก้ไขใหม่ พร้อมลงวันที่กำกับ หัวหน้าโครงการและผู้ร่วมโครงการทุกคนจะต้องลงนามในเอกสารฉบับที่แก้ไขใหม่
2. ผู้วิจัยจะเริ่มดำเนินการวิจัยที่เกี่ยวข้องกับอาสาสมัครได้ก็ต่อเมื่อ ผู้วิจัยได้รับหนังสืออนุมัติให้ดำเนินการอย่างเป็นทางการแล้วเท่านั้น

8.4.7 Notification of result of initial review (English)

MAHIDOL UNIVERSITY
Since 1888

No. TM-ORS ..…/ ….…Year……

……..…Date……..…

……..……PI's name……
……..PI's affiliation……..
……...

Result Notification for Research Proposal Entitled "……..……"
(Submission Number :……)

Dear ……(PI name)..……,

Please refer to letter number..... dated..... You submitted the research proposal entitled "……" (Submission Number.: ……) for ethical consideration.

The Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, considered your research proposal at the meeting held on…….……. The Ethics Committee consensus is ……..…….. Details are provided in the attached sheet(s).

Please respond to the questions/ recommendations item by item, and indicate on which page of the research proposal or document you have made the relevant changes in the cover letter. Please also underline or highlight these changes and assign the version date at the footer.

Please return …….. copies of your revised proposal/ other documents within 6 months after notify the result of review to the EC Office, 4th Floor, the 60th Anniversary of His Majesty the King's Accession to the Throne Building, for further consideration.

Yours sincerely,

…….. ……
(Chairperson's name)
Chairperson, Ethics Committee
Faculty of Tropical Medicine, Mahidol University

Remarks:

1. The PI must change version of the revised proposal and specify the date at the footer. Signatures of all PI and Co-PI must be included in the proposal again. The Ethics Committee will consider your proposal when these requirements are satisfied.
2. The PI can conduct the project only after receipt of the Certificate of Ethical Approval.

Ethics Committee
Office of Research Services, Faculty of Tropical Medicine, Mahidol University
420/6 Ratchawithi Rd., Ratchathewi, Bangkok 10400, Thailand
Phone: 66 (0) 2354 9100-4 ext. 1349 ext. 16 Fax: 66 (0) 2306 9126

8.4.8 Communication letter for the 1st approval (Thai)

สำนักงานคณะกรรมการจริยธรรมการวิจัยในคน
สำนักงานบริการการวิจัย คณะเวชศาสตร์เขตร้อน
โทรศัพท์ 0 2354 9100-4 ต่อ 1349 ต่อ 16
โทรสาร 0 2306 9126

ที่ ศธ 0517.1116/จธ.....
วันที่ .....
เรื่อง อนุมัติโครงการและส่งเอกสารรับรองโครงการ พร้อมแนวทางปฏิบัติสำหรับโครงการวิจัยที่ได้รับการรับรอง (รหัสโครงการ TMEC.....-.....)

เรียน .....(ชื่อหัวหน้าโครงการ).....

อ้างถึงหนังสือที่.....ลงวันที่.....ท่านได้ส่งเอกสารฉบับแก้ไขตามมติของคณะกรรมการฯ ครั้งที่..... ของโครงการวิจัย เรื่อง ".....ชื่อโครงการภาษาไทย .....(....ชื่อโครงการภาษาอังกฤษ.....)" (รหัสโครงการ TMEC .....-.....) มาเพื่อให้คณะกรรมการจริยธรรมการวิจัยในคน คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล พิจารณา นั้น

คณะกรรมการจริยธรรมการวิจัยในคน ได้พิจารณาเอกสารโครงการฉบับแก้ไขแล้ว ให้ความเห็นชอบและอนุมัติให้ออกเอกสารรับรอง และรับทราบเอกสารโครงการ

รับรองเอกสาร ดังนี้

1. ..... Version ....., date.....
2. ..... Version ....., date.....

รับทราบเอกสาร ดังนี้

1. ..... Version ....., date.....
2. ..... Version ....., date.....

หลังจากที่โครงการได้รับการรับรอง ผู้วิจัยจะต้องส่งรายงานความก้าวหน้าและต่ออายุเอกสารรับรองทุก 1 ปี (หนังสือรับรองมีระยะเวลา 1 ปี) โดยใช้แบบฟอร์ม Progress Report Form/ Certificate of Ethical Approval Extension Request Form (FTM ECF-008-RR) ทั้งนี้โปรดดำเนินการขอต่ออายุ 2 เดือนก่อนวันหมดอายุ หากโครงการวิจัยดำเนินการแล้วเสร็จสิ้น ขอให้ท่านทำหนังสือแจ้งคณะกรรมการโดยใช้แบบฟอร์ม FTM ECF-010-RR (Notification of Study Closure) ซึ่งท่านสามารถ download แบบฟอร์มดังกล่าวได้ที่ http://www.tm.mahidol.ac.th/research/client/EC_Human.php หรือสอบถามมายังสำนักงานคณะกรรมการจริยธรรมการวิจัยในคน สำนัก งานบริการการวิจัย ชั้น 4 อาคารเฉลิมพระเกียรติฉลองสิริราชสมบัติครบ 60 ปี

(.....)
ประธานคณะกรรมการจริยธรรมการวิจัยในคน
คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล

ข้อปฏิบัติหลังจากได้รับการรับรอง

จากคณะกรรมการจริยธรรมการวิจัยในคน คณะเวชศาสตร์เขตร้อน

1. เอกสารรับรองโครงการวิจัย (Certificate of Ethical Approval - CEA) ที่ออกให้แก่โครงการวิจัยมีกำหนดระยะเวลาครอบคลุมโครงการวิจัย 1 ปี หลังจากวันที่ได้รับอนุมัติ

   ในกรณีที่ผู้วิจัยต้องการต่ออายุเอกสารโครงการวิจัย ขอให้ผู้วิจัยกรอกแบบฟอร์ม Progress Report Form/ Certificate of Ethical Approval Extension Request Form (FTM ECF-008-RR) นำส่งก่อนวันที่เอกสารรับรองโครงการจะหมดอายุ 2 เดือน

   หากต่ออายุเอกสารโดยไม่มีการแก้ไขรายละเอียดโครงการ ขอให้ส่งสำเนาเอกสารที่ประทับตราอนุมัติในคราวก่อน (เฉพาะเอกสารที่ประสงค์จะต่ออายุในคราวนี้) มาเพื่อประทับตราต่ออายุซ้ำ

2. กรณีโครงการวิจัยที่ได้รับอนุมัติเป็นการวิจัยทางคลินิกที่อาจเกิดเหตุการณ์ไม่พึงประสงค์ชนิดร้ายแรง (Serious Adverse Event/ SUSARs) และเหตุการณ์ไม่พึงประสงค์ที่ไม่คาดคิดและส่งผลร้ายแรง (Unanticipated problems) ทั้งที่คาดเดาได้และที่ไม่คาดคิด ขอให้ผู้วิจัยรายงานต่อคณะกรรมการฯ เป็นลายลักษณ์อักษรภายใน 5 วันทำการหลังจากผู้วิจัยรับทราบการเกิดเหตุการณ์ ในกรณีที่เหตุการณ์ไม่พึงประสงค์ชนิดร้ายแรงนั้นเกิดขึ้นกับอาสาสมัครต่างประเทศ (CIOMS) ให้รายงานต่อคณะกรรมการฯ ภายใน 1 เดือน หลังจากผู้วิจัยรับทราบการเกิดเหตุการณ์ โดยใช้แบบฟอร์ม SAE Report Form (FTM ECF-014-RR) หรือ CIOMS Form หรือแบบฟอร์มของผู้สนับสนุนการวิจัย

3. กรณีเกิดเหตุการณ์ไม่พึงประสงค์ (Adverse Event) ขอให้ผู้วิจัยรวบรวมและรายงานต่อคณะกรรมการฯ เป็นลายลักษณ์อักษรปีละ 1 ครั้ง โดยใช้แบบฟอร์มของผู้วิจัยเองหรือของผู้สนับสนุนการวิจัย

4. หากมีการปฏิบัติที่เบี่ยงเบนจากที่ระบุไว้ในโครงการวิจัย ในกรณีของ Protocol violation ขอให้ผู้วิจัยรายงานต่อคณะกรรมการฯ เป็นลายลักษณ์อักษรภายใน 5 วันทำการหลังจากผู้วิจัยรับทราบการเกิดเหตุการณ์ โดยใช้แบบฟอร์มของผู้วิจัยหรือของผู้สนับสนุนการวิจัย ในกรณีของ Protocol deviation ให้รายงานภายใน 1 เดือน

5. หากผู้วิจัยมีความประสงค์จะปรับปรุงแก้ไขเอกสารของโครงการ (แบบเสนอโครงการ, เอกสารชี้แจงข้อมูลอาสาสมัคร,หนังสือแสดงเจตนาเข้าร่วมโครงการวิจัย และเอกสารประชาสัมพันธ์ให้เข้าร่วมโครงการ/แบบสอบถาม ขอให้ผู้วิจัยกรอกแบบฟอร์ม Request for Protocol Amendment Form (FTM ECF-023-RR) และนำส่งพร้อมเอกสารฉบับแก้ไขปรับปรุง ซึ่งระบุเวอร์ชั่น/วันที่ ไว้ที่ Footer ของเอกสารทุกหน้า พร้อมลายเซ็นจริงของผู้วิจัยหลักและผู้วิจัยร่วม

6. เมื่อการวิจัยสิ้นสุดลง ขอให้ผู้วิจัยกรอกแบบฟอร์ม Notification of Study Closure (FTM ECF-010-RR) ส่งพร้อมรายงานฉบับสมบูรณ์ และ CD 1 แผ่น ที่สำนักงานคณะกรรมการจริยธรรมการวิจัยในคน

<u>หมายเหตุ</u> ทุกรายการเอกสารที่ส่งให้คณะกรรมการพิจารณา ขอให้ส่งจำนวน 3 ชุด หากมีความจำเป็นต้องส่งเข้าพิจารณาใน Full board เจ้าหน้าที่ประจำสำนักงานคณะกรรมการฯ จะติดต่อขอให้จัดทำเอกสารเพิ่มเติมในภายหลัง

****

8.4.9 Communication letter for the 1st approval (English)

MAHIDOL UNIVERSITY
Since 1888

No. TM-ORS ……/ …… Year……..

……Date……..

……PI's name……..

……..PI's affiliation……..

……..

Result Notification and Certificate of Ethical Approval for the Research Proposal Entitled "……" (Submission No. TMEC……-……)

Dear ……(PI name)……,

Please refer to letter number.....dated..... You submitted the revised research proposal entitled "……" (Submission Number.: ……-……) for ethical consideration.

The Ethics Committee has considered and approved your revised research proposal and research documents

The approval documents are as follows:

1. …… Version ……, date……
2. …… Version ……, date……

The acknowledged documents are as follows:

1. …… Version ……, date……
2. …… Version ……, date……

Please note that the CEA expires in one year from the date of approval. The Principal Investigator must submit progress reports annually after approval, and report according to the EC requirements related to the risk involved. If you wish to extend the CEA, please file the Progress Report Form/ Certificate of Ethical Approval Extension Request Form (FTM ECF-008-RR) two months prior to its expiry date. You are also required to notify the Ethics Committee of your study closure using form FTM ECF-010-RR (Notification of Study Closure).

Yours sincerely,

……
(Chairperson's name)
Chairperson, Ethics Committee
Faculty of Tropical Medicine, Mahidol University

Ethics Committee
Office of Research Services, Faculty of Tropical Medicine, Mahidol University
420/6 Ratchawithi Rd., Ratchathewi, Bangkok 10400, Thailand
Phone: 66 (0) 2354 9100-4 ext. 1349 ext.16 Fax: 66 (0) 2306 9126

Post-approval Requirements

Ethics Committee, Faculty of Tropical Medicine, Mahidol University

1. The Certificate of Ethical Approval (CEA) for each research study is valid for 1 year only, from the date of approval.

   PI must extend the certificate using Progress Report Form/ Certificate of Ethical Approval Extension Request Form (FTM ECF-008-RR) 2 months prior to the expiry date. (Relevant documents are required, e.g., Research Proposal, Participant Information Sheet, Informed Consent Form/ Inform Assent Form, Case Record Form).

2. PI must submit progress reports after approval according to the stipulated EC requirements related to the identified risk that specified in the cover letter, using Progress Report Form/ Certificate of Ethical Approval Extension Request Form (FTM ECF-008-RR).

3. Where a serious adverse event (SAE) occurs during an approved clinical study, the PI must notify the EC within 5 working days of the event notification to PI. (including suspected unexpected serious adverse reactions (SUSARs)), while in case of the SAEs occurring in different countries of a multicenter project, the PI must notify the EC in one month of the event notification to PI with a written report using SAE Report Form (FTM ECF-014-RR).

   All Adverse Events (AE) related and not related to the study are required to notify the EC Committee in 1 year of the event notification to PI.

4. For the unanticipated problems and unscheduled mandatory (e.g., medication errors, unexpected complications, protocol violations) must be reported in written within 5 working days of the event notification to PI. For protocol deviation must be reported in 1 month. (3 copies of the SAE/ SUSARs/ AE/ Unanticipated problems and unscheduled report are required).

5. If the PI wishes to amend any research document (i.e., Research Proposal, Participant Information Sheet, Informed Consent Form/ Informed Assent Form, Leaflet or Questionnaire), the Request for Protocol Amendment Form (FTM ECF-023-RR) should be filed, with the amended documents attached, and with the specified version and date shown in the footer of each document. The signatures of the PI (and any Co-PI) must be inscribed in the research proposal in ink, and 3 copies of the documentation sent to the EC. If a full board review is necessary, an EC officer will advise the PI of any additional documentation requirements.

6. If the PI wishes to notify the Ethics Committee of study closure, the Notification of Study Closure form (FTM ECF-010-RR) should be filed (3 copies of the notification letter; 3 copies of the report, are required).

Remark: 3 copies of the documentation sent to the EC. If a full board review is necessary, an EC officer will advise the PI of any additional documentation requirements.

8.4.10 Communication letter for research proposal amendment (Thai)

สำนักงานคณะกรรมการจริยธรรมการวิจัยในคน
สำนักงานบริการการวิจัย คณะเวชศาสตร์เขตร้อน
โทรศัพท์ 0 2354 9100-4 ต่อ 1349 ต่อ 16
โทรสาร 0 2306 9126

ที่ ศธ 0517.1116/จธ. .....
วันที่ .....
เรื่อง ส่งเอกสารรับรองฉบับปรับเปลี่ยนโครงร่างวิจัย (Amendment)
เรียน .....(ชื่อหัวหน้าโครงการ).....

อ้างถึงหนังสือที่..... ลงวันที่..... ตามที่ท่านได้ขอปรับเปลี่ยนรายละเอียดโครงการวิจัยเรื่อง ".....ชื่อภาษาไทย.....(.....ชื่อภาษาอังกฤษ.....)" (รหัสโครงการ TMEC.....-.....) เพื่อขอรับการรับรองจากคณะกรรมการจริยธรรมการวิจัยในคน คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล นั้น

คณะกรรมการฯ ได้พิจารณาเอกสารดังกล่าวแล้ว ให้ความเห็นชอบและอนุมัติให้ออกเอกสารรับรอง และรับทราบเอกสารโครงการ

<u>รับรองเอกสาร ดังนี้</u>

1. ..... Version ……..……, date……
2. ..... Version ……..…, date……

<u>รับทราบเอกสารดังนี้</u>

1. ..... Version……..., date……...
2. ..... Version ……..…, date……

โดยเอกสารรับรองจะหมดอายุพร้อมกับ Certificate of Ethical Approval (CEA) ที่ท่านรับไปก่อนหน้านี้แล้ว คือในวันที่.....

จึงเรียนมาเพื่อโปรดทราบ

(.....)
ประธานคณะกรรมการจริยธรรมการวิจัยในคน
คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล

8.4.11 Communication letter for research proposal amendment (English)

MAHIDOL UNIVERSITY
Since 1888

No. TM-ORS ……/……Year…….

……..……Date……..……

……..……PI's name……..
……..PI's affiliation……..
……

Certificate of Ethical Approval for Amendment for the Research Proposal Entitled "……" (Submission No.: TMEC….-……)

Dear ……(PI name)……,

Please refer to letter number……dated…… The Ethics Committee, Faculty of Tropical Medicine, Mahidol University has reviewed and approved your amendment for the research proposal entitled "……" (Submission No.: TMEC….-……) for ethical consideration.

The Ethics Committee has considered and approved your amendment, as follows:

The approval documents:

1. …… Version ……, date……
2. …… Version ……, date……

The acknowledged documents:

1. …… Version ……, date……
2. …… Version ……, date……

Attached please find the Certificate of Ethical Approval for your amendment.

Yours sincerely,

……..
(Chairperson's name)
Chairperson, Ethics Committee
Faculty of Tropical Medicine, Mahidol University

Ethics Committee
Office of Research Services, Faculty of Tropical Medicine, Mahidol University
420/6 Ratchawithi Rd., Ratchathewi, Bangkok 10400, Thailand
Phone: 66 (0) 2354 9100-4 ext. 1349 ext. 16 Fax: 66 (0) 2306 9126

8.4.12 Communication letter for extension (Thai)

สำนักงานคณะกรรมการจริยธรรมการวิจัยในคน
สำนักงานบริการการวิจัย คณะเวชศาสตร์เขตร้อน
โทรศัพท์ 0 2354 9100-4 ต่อ 1349 ต่อ 16
โทรสาร 0 2306 9126

ที่ ศธ 0517.1116/จธ.....
วันที่ .....
เรื่อง ส่งเอกสารรับรองโครงการวิจัยฉบับต่ออายุ

เรียน .....(ชื่อหัวหน้าโครงการ).....

อ้างถึงหนังสือที่ .....ลงวันที่..... ท่านขอต่ออายุเอกสารรับรองโครงการวิจัย เรื่อง ".....ชื่อภาษาไทย.....(.....ชื่อภาษาอังกฤษ.....)" (รหัสโครงการ TMEC .....-.....) มาเพื่อให้คณะกรรมการจริยธรรมการวิจัยในคน คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล พิจารณานั้น

ในการประชุมคณะกรรมการจริยธรรมการวิจัยในคน ประจำเดือน.....พ.ศ. ..... ครั้งที่..... เมื่อ..... คณะกรรมการฯ ได้รับทราบการขอต่ออายุเอกสารรับรองของท่านแล้ว ซึ่งที่ประชุมเห็นชอบให้ออกเอกสารรับรองฉบับต่ออายุได้ ดังที่แนบมาพร้อมบันทึกนี้ อนึ่ง เอกสารรับรองมีผลครอบคลุมเป็นระยะเวลา 1 ปี หากท่านประสงค์จะต่ออายุหนังสือรับรอง โปรดดำเนินการขอต่ออายุ 2 เดือน ก่อนวันหมดอายุ โดยใช้แบบฟอร์ม FTM ECF-008-RR (Progress Report Form/ Certificate of Ethical Approval Extension Request Form) ในกรณีที่โครงการวิจัยดำเนินการแล้วเสร็จสิ้น ขอให้ท่านทำหนังสือแจ้งคณะกรรมการฯ โดยใช้แบบฟอร์ม FTM ECF-010-RR (Notification of Study Closure) ซึ่งท่านสามารถ download แบบฟอร์มดังกล่าวได้ที่ http://www.tm.mahidol.ac.th/research/client/EC_Human.php หรือสอบถามที่สำนักงานคณะกรรมการจริยธรรมการวิจัยในคน สำนักงานบริการการวิจัย ชั้น 4 อาคารเฉลิมพระเกียรติฉลองสิริราชสมบัติครบ 60 ปี โทร 1349 ต่อ 16 หรือ 9126

จึงเรียนมาเพื่อโปรดทราบ

(.....)
ประธานคณะกรรมการจริยธรรมการวิจัยในคน
คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล

8.4.13 Communication letter for extension (English)

MAHIDOL UNIVERSITY
Since 1888

No. TM-ORS……/……Year……

……Date……

……PI's name……..
……..PI's affiliation……..
……

Extension of Certificate of Ethical Approval for the research proposal entitled "……..."

(Submission No: TMEC .....-.....)

Dear ……(PI name)……,

The Ethics Committee considered and approved your extension for the research proposal entitled "……" at a meeting held on ……

Attached please find a Certificate of Ethical Approval No. MUTM …… given to the project, and stamped EC documents. Please also note that the CEA expires on a specified date and it is suggested that you file the Progress Report Form/ Certificate of Ethical Approval Extension Request Form (FTM ECF-008-RR) two (2) months prior to the expiry date. It is also required that you notify the Ethics Committee of your study closure, using form FTM ECF-010-RR (Notification of Study Closure) and 3 copies of the report, if you complete the study.

Yours sincerely,

……
(Chairperson's name)
Chairperson, Ethics Committee
Faculty of Tropical Medicine, Mahidol University

Ethics Committee
Office of Research Services, Faculty of Tropical Medicine, Mahidol University
420/6 Ratchawithi Rd., Ratchathewi, Bangkok 10400, Thailand
Phone: 66 (0) 2354 9100-4 ext. 1349 ext. 16 Fax: 66 (0) 2306 9126

8.4.14 Communication letter for SAE, SUSAR, protocol deviation, protocol violation (Thai)

8.4.14 (1) Clarification

สำนักงานคณะกรรมการจริยธรรมการวิจัยในคน
สำนักงานบริการการวิจัย คณะเวชศาสตร์เขตร้อน
โทรศัพท์ 0 2354 9100-4 ต่อ 1349 ต่อ 16
โทรสาร 0 2306 9126

ที่ ศธ 0517.1116/ จธ. .....
วันที่ .....
เรื่อง โปรดชี้แจงรายงานเหตุการณ์ไม่พึงประสงค์ชนิดร้ายแรง (SAE) / เหตุการณ์รุนแรงที่ไม่อาจคาดการณ์ได้ล่วงหน้า (SUSARs) / รายงานเหตุการณ์ที่เบี่ยงเบนจากโครงการวิจัย (Protocol violation)..... ของโครงการวิจัย TMEC.....-.....

เรียน .....(ชื่อหัวหน้าโครงการ).....

อ้างถึงหนังสือที่ ..... ลงวันที่ ..... โครงการวิจัยเรื่อง "..... ชื่อภาษาไทย..... (.....ชื่อภาษาอังกฤษ.....)" (รหัสโครงการ TMEC .....-.....) ได้ส่งรายงานเหตุการณ์ไม่พึงประสงค์ชนิดร้ายแรง (SAE)/ เหตุการณ์รุนแรงที่ไม่อาจคาดการณ์ได้ล่วงหน้า (SUSARs) / รายงานเหตุการณ์ที่เบี่ยงเบนจากโครงการวิจัย (Protocol violation)/ รายงานเหตุการณ์ที่เบี่ยงเบนจากโครงการวิจัย (Protocol deviation) ของอาสาสมัครหมายเลข..... มาเพื่อให้คณะกรรมการจริยธรรมการวิจัยในคน คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล พิจารณานั้น

คณะกรรมการฯ ได้พิจารณาแล้ว มีข้อเสนอแนะ และคำถามดังนี้

1.....

2. .....

3. .....

จึงเรียนมาเพื่อโปรดทำการชี้แจง แล้วส่งมาที่สำนักงานคณะกรรมการจริยธรรมการวิจัยในคน ชั้น 4 อาคารเฉลิมพระเกียรติฉลองสิริราชสมบัติครบ 60 ปี คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล

(.....)
ประธานคณะกรรมการจริยธรรมการวิจัยในคน
คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล

8.4.14 (2) Acknowledgement

สำนักงานคณะกรรมการจริยธรรมการวิจัยในคน
สำนักงานบริการการวิจัย คณะเวชศาสตร์เขตร้อน
โทรศัพท์ 0 2354 9100-4 ต่อ 1349 ต่อ 16
โทรสาร 0 2306 9126

ที่ ศธ 0517.1116/ จธ. .....
วันที่ .....
เรื่อง รับทราบรายงาน.....

เรียน .....(ชื่อหัวหน้าโครงการ).....

อ้างถึงหนังสือที่ ..... ลงวันที่ ..... โครงการวิจัยเรื่อง ".....
ชื่อเรื่องภาษาไทย..... (.....ชื่อเรื่องภาษาอังกฤษ.....)" (รหัสโครงการ TMEC .....-.....)
ได้ส่งรายงานเหตุการณ์ไม่พึงประสงค์ชนิดร้ายแรง (SAE)/ เหตุการณ์รุนแรงที่ไม่อาจคาดการณ์ได้ล่วงหน้า (SUSARs) / รายงานเหตุการณ์ที่เบี่ยงเบนจากโครงการวิจัย (Protocol violation)/ รายงานเหตุการณ์ที่เบี่ยงเบนจากโครงการวิจัย (Protocol deviation) ของอาสาสมัครหมายเลข..... มาเพื่อให้คณะกรรมการจริยธรรมการวิจัยในคน คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล พิจารณานั้น

คณะกรรมการฯ ได้พิจารณา และรับทราบรายงานดังกล่าวแล้ว

จึงเรียนมาเพื่อโปรดทราบ

(.....)
กรรมการและเลขานุการ
คณะกรรมการจริยธรรมการวิจัยในคน
คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล

8.4.15 Communication letter for SAE, SUSAR, protocol deviation, protocol violation (English)

8.4.15 (1) Clarification

MAHIDOL UNIVERSITY
Since 1888

No. TM-ORS……/…… Year…….

……..……Date…….

……..…….PI's name……..
……..PI's affiliation……..
……

Result Notification of the Serious Adverse Events report / SUSARs / Protocol violation / Protocol deviation for the Research Proposal entitled "……..……." (Submission No.: TMEC ……-…….)

Dear …….(PI name)……,

The Ethics Committee, Faculty of Tropical Medicine suggests you to clarify the Serious Adverse Events report / SUSARs / Protocol violation / Protocol deviation, participant code…….. for the research proposal entitled "……..……"

The recommendation are as follows:
1…….
2…….
3…….

Yours sincerely,

…….
(Chairperson's name)
Chairperson, Ethics Committee
Faculty of Tropical Medicine, Mahidol University

Ethics Committee
Office of Research Services, Faculty of Tropical Medicine, Mahidol University
420/6 Ratchawithi Rd., Ratchathewi, Bangkok 10400, Thailand
Phone: 66 (0) 2354 9100-4 ext. 1349 ext. 16 Fax: 66 (0) 2306 9126

8.4.15 (2) Acknowledgement

MAHIDOL UNIVERSITY
Since 1888

No. TM-ORS……/ …… Year……

……..Date……..

……..PI's name……..
……..PI's affiliation……..
……

Acknowledging Receipt of Serious Adverse Events Report / SUSARs / Protocol Violation/ Protocol Deviation for the Research Proposal Entitled "……" (Submission No.: TMEC ……-……)

Dear ……(PI name)……,

The Ethics Committee, Faculty of Tropical Medicine suggests you to clarify the Serious Adverse Events Report / SUSARs / Protocol Violation / Protocol Deviation, participant code…… for the project entitled "……".

Yours sincerely,

(……)
Member and Secretary, Ethics Committee
Faculty of Tropical Medicine, Mahidol University

Ethics Committee
Office of Research Services, Faculty of Tropical Medicine, Mahidol University
420/6 Ratchawithi Rd., Ratchathewi, Bangkok 10400, Thailand
Phone: 66 (0) 2354 9100-4 ext. 1349 ext. 16 Fax: 66 (0) 2306 9126

8.4.16 Communication letter for study closure and other report (Thai)

สำนักงานคณะกรรมการจริยธรรมการวิจัยในคน
สำนักงานบริการการวิจัย คณะเวชศาสตร์เขตร้อน
โทรศัพท์ 0 2354 9100-4 ต่อ 1349 ต่อ 16
โทรสาร 0 2306 9126

ที่ ศธ 0517.1116/จธ. ……..
วันที่ ……..
เรื่อง ตอบรับทราบการแจ้งปิดโครงการ/ รายงานอื่นๆ

เรียน .....ชื่อหัวหน้าโครงการ.....

อ้างถึงหนังสือที่ ..... ลงวันที่ ..... โครงการวิจัยเรื่อง "....ชื่อเรื่องภาษาไทย..... (.....ชื่อเรื่องภาษาอังกฤษ.....)" (รหัสโครงการ TMEC.....-.....) ได้ส่งรายงานแจ้งปิดโครงการ/ รายงาน..... มาเพื่อให้คณะกรรมการจริยธรรมการวิจัยในคน คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล พิจารณา นั้น

คณะกรรมการฯ ได้พิจารณาและรับทราบรายงานดังกล่าวแล้ว

จึงเรียนมาเพื่อโปรดทราบ

(.....)
กรรมการและเลขานุการ
คณะกรรมการจริยธรรมการวิจัยในคน
คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล

8.4.17 Communication letter for study closure and other report (English)

MAHIDOL UNIVERSITY
Since 1888

No. TM-ORS ……/…… Year……

……..Date……..

……PI's name……..
……..PI's affiliation……..
……

Acknowledging Receipt of Study Closure/ Report of ……for the Research Proposal Entitled "……..……"(Submission No.: TMEC ……-……)

Dear ……(PI name)……,

The Ethics Committee, Faculty of Tropical Medicine, hereby acknowledges receipt of study closure /report……for the research proposal entitled "……".

Yours sincerely,

(……)
Member and Secretary, Ethics Committee
Faculty of Tropical Medicine, Mahidol University

Ethics Committee
Office of Research Services, Faculty of Tropical Medicine, Mahidol University
420/6 Ratchawithi Rd., Ratchathewi, Bangkok 10400, Thailand
Phone: 66 (0) 2354 9100-4 ext. 1349 ext. 16 Fax: 66 (0) 2306 9126

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Ethics Committee Meeting

CHANGE HISTORY		
Revision	Description of Change	Effective Date
00	Initial release	28 June 2007
01	The 2008 annual review leads to the following changes: 1. Revise the responsibilities of EC Chairperson, e.g., by deleting #4.1.5; 2. Revise EC member's responsibilities; 3. Revise the responsibilities of Member Secretary; 4. Revise the responsibilities of Staff Secretary; 5. In section 7.1, notification of regular EC meeting has been changed from 'not less than 7 days' to 'not less than 5 working days'; 6. In section 7.2, notification of EC special meeting has been changed from 'not less than 3 days' to 'not less than 3 working days'; 7. In section 7.3/Paragraph 2, clarification has been made by stating that 'no decision will be made until the quorum is restored'; 8. In section 7.4, include specific timeline for protocol submission, revise timeline for protocol distribution and delete the process of protocol revision/CEA extension/continuing review request; 9. Section 7.5 has been revised: (1) clinical investigator and ancillary staff may be called to EC meeting but are not allowed to stay during EC discussion, (2) delete 'experts will not be allowed to vote on the research proposal/protocol', (3) delete 'opinion from absent members may not be counted as vote'; 10. In section 7.6, (1) revise Paragraph 2 so that 'EC members with conflict of interest will abstain from deliberation and discussion…', (2) clarify process after the protocol is approved with clarification/ amendment, (3) clarify role of Member Secretary	01 July 2008

Ethics Committee Meeting

CHANGE HISTORY		
Revision	Description of Change	Effective Date
02	Entering the SIDCER/FERCIT Recognition Program of World Health Organization (WHO), suggestions of the surveyors lead to the following changes: 1. Nomenclatures changed – 'Secretariat' is replaced by 'Member Secretary' and 'EC Secretary' with 'Staff Secretary'; 2. Add more references in section 5.0; 3. Identify and classify "special meetings" in section 7.2; 4. Change number of voting members need in a quorum in section 7.3.	24 September 2008
	There was no revision in year 2009.	
03	As a result of the SOP annual review (16 Feb 2010), the following changes have been made 1. Chairperson's name was changed to Prof. Srisin Khusmith and Prof. Krisana Pengsaa, throughout the 2010 annual revision. 2. Add one more category in "either special EC Meeting or general Meeting": (3) "Fast-track review" request by the investigator" section 7.2 3. The presence of voting members who constitute a quorum at least 7, changed to two thirds of the committee members, in section 7.3 4. Revise Preparation for EC meetings in section 7.4 5. Indicate case of consensus and voting in section 7.6	22 April 2010
04	Due to changing of website format, the following documents have been re-uploaded 1. Website of EC's meeting schedule "http://www.tm. mahidol.ac.th/research/EC/human/meeting.doc" was changes to "http://www.tm.mahidol.ac.th/ research /ethic/ human/meeting.pdf" in section 7.4 2. FTM ECF-019-00 was replaced by FTM ECF-019-01, FTM ECF-006-02 was replaced by FTM ECF-006-03, FTM ECF-007-03 was replaced by FTM ECF-007-04, FTM ECF-021-01 was replaced by FTM ECF-021-02, FTM ECF-022-00 was replaced by FTM ECF-022-01 in section 7.4	03 May 2011

Ethics Committee Meeting

CHANGE HISTORY		
Revision	Description of Change	Effective Date
05	According to SIDCER/FERCAP recognition in 2011, the following change has been made 1. Add duration of notification for fast-track "The results of the review will be sent to the PI within 7 (seven) working days" in section 7.2 (3), page 4 of 7.	22 December 2011
06	The 2014 annual review of the document leads to the following changes: 1. Change "research proposal/protocol" to "research proposal" in sections 3.0, 4.2.2, 6.0, 7.2, 7.4 and 7.7. 2. Change "Protocol" to "research proposal" in section 6.0. 3. Change the quorum for conduct of the meeting from "at least two third of eligible voting members" to "at least half of eligible voting members" in section 7.3. 4. Use "RR" instead of the version/revision number of the document, and change "full proposal/protocol" to "full protocol" in section 7.4. 5. Change "proposal/protocol" to "research proposal" in section 7.6.	01 May 2014
07	According to SIDCER/FERCAP-NECAST recognition and SOPs training in EC Retreat in 2015, the following changes have been made 1. Add responsibility of Primary Reviewers in Section 4.3. 2. Add responsibility of Assistant Secretary "Distribute meeting agenda and meeting minutes to the EC" in Section 4.5.1. 3. Change "Deferment" to "Deferral", and use "Approval with Conditions and/or Suggestions" instead of "Approval after Amendment(s) or Approval after Clarifications" and revise definition in Section 6.0.	16 October 2015

Ethics Committee Meeting

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	4. Add the presence of at least one non-institutional/ affiliated member to constitute a quorum and a requirement that the Primary reviewer attend the meeting and presents a summary of the research study to Section 7.3. 5. Add Section 7.4 Preparation for Meeting Agenda and Minutes. 6. Revise the procedure in Section 7.5 Preparation for EC Meeting by removing submission package to remove redundancy in FTM ECS-003-RR, and included providing invitation letter, meeting agenda and previous minute to EC. 7. Revise the responsibility of EC Vice-Chairperson in Section 7.6 that acts for the EC Chairperson whenever the EC Chairperson has Conflict of Interest or could not attend the EC Meeting to correspond with responsibilities mentioned in FTM ECS 002-RR: Ethics Committee. 8. Decision in Section 7.6 Consensus and voting is revised as follows; "Unconditional approval" is revised to "Approval" "Condition approval" is revised to "Approval with conditions and or suggestions" "Deferred" is revised to "Deferral" "Disapproved" is revised to "Disapproval".	
08	The resolution of the EC Retreat and SOP training 2016 leads to the following changes: 1. Change "Written notice of the regular meeting will be given to each EC member not less than five (5) working days before the meeting" **<u>to</u>** "Written notice of the regular meeting will be given to EC members in each review week not less than five (5) working days before the meeting" in section 7.1	03 November 2016

Ethics Committee Meeting

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	2. Change Special meeting in section 7.2, as follows: - revise "Written notice of special meetings, including the time, place, and purpose, will be given to each member not less than three (3) working days before the special meeting" **<u>to</u>** "Written notice of special meetings, including the time, place, and purpose, will be given to EC members in each review week not less than three (3) working days before the special meeting" - remove unscheduled meeting for review thematic paper of students in Master of Clinical Tropical Medicine (M.C.T.M., M.C.T.M.(T.P.)) - revise submission deadline for fast-track review. 3. Change preparation for EC meeting in section 7.5 as follows: - Revise "the Assistant Secretary will distribute the appropriate materials to each EC member at least seven (7) working days before the scheduled meeting to allow thorough review of each proposal. The EC Chairperson will assign two primary reviewers for each proposal. All EC members will complete a Reviewer's Assessment Form for Initial Review..." **<u>to</u>** "the Assistant Secretary will distribute the appropriate materials to the assigned three (3) primary reviewers and one (1) lay member at least seven (7) working days before the scheduled meeting to allow thorough review of each proposal. The assigned EC members will complete a Reviewer's Assessment Form for Initial Review…" - Change "Invitation letter, meeting agenda and previous meeting minutes will be provided to EC members" **<u>to</u>** "Invitation letter, meeting agenda and previous meeting minutes will be provided to EC members in each review week"	

Ethics Committee Meeting

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	4. Change "Minutes of the meetings will be signed by the EC Chairperson" **to** "Minutes of the meetings will be signed by the EC Chairperson or Vice-Chairperson, Member and Secretary and Assistant Secretary" in section 7.7. 5. Remove "*Controlled copy-Do not Duplicate*" and "*Internal Use Only*" from Footer.	
09	The resolution of the EC Retreat and SOPs Training 2017 leads to the following changes: 1. Since assessing Participant Information Sheet, Informed Consent Form and Informed Assent Form will utilize form FTM ECF-007-RR (Reviewer's Assessment Form for Initial Review), remove form FTM ECF-015-RR (Participant Information Sheet, Informed Consent Form and Informed Assent Form Checklist)" from the statement "The assigned EC members will complete a Reviewer's Assessment Form for Initial Review (FTM ECF-007-RR) together with Participant Information Sheet, Informed Consent Form and Informed Assent Form Checklist (FTM ECF-015-RR)" in section 7.5 2. Revise statement "(1) Risks to the research participants are minimized" to "(1) Risks to the research participants are minimal" in section 7.6 3. Revise statement "Clinical Investigators or ancillary staff may be called to attend EC meetings to answer questions…" to "Principal Investigator(s) or ancillary staff may be called to attend EC meetings to answer questions…" in section 7.6	07 March 2018

Ethics Committee Meeting

SIGNATURES		
Author	I, on behalf of the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, indicate that this SOP has been authored according to applicable business requirements for quality system documentation.	
	Name: Assoc. Prof. Jaranit Kaewkungwal	Signature:
	Title: Chairperson, Ethics Committee of the Faculty of Tropical Medicine, Mahidol University	Date: 05 MAR 2018
Approver	I indicate that I have reviewed this SOP, and find it meets all applicable business requirements and that it reflects the procedure described. I approve it for use.	
	Name: Assoc. Prof. Pratap Singhasivanon	Signature:
	Title: Dean, Faculty of Tropical Medicine, Mahidol University	Date: 06 MAR 2018

	Ethics Committee Meeting	
	Document No.: FTM ECS-004-09	**Effective Date:** 07 March 2018

1.0 PURPOSE

To describe the processes and procedures for the conduct of the meetings of Ethics Committee (EC) of the Faculty of Tropical Medicine (FTM), Mahidol University.

2.0 SCOPE

This SOP will apply to all FTM EC meetings.

3.0 POLICY

Except when an expedited or exempt review procedure is used, the FTM EC will review proposed research proposal at convened meetings at which a quorum and appropriate expertise is present. The EC will meet monthly, or at some other frequency determined by the EC Chairperson.

4.0 RESPONSIBILITIES

4.1 EC Chairperson

4.1.1 Conduct meetings in an efficient and fair manner, and according to standard parliamentary procedures,

4.1.2 Follow the agenda created for each meeting,

4.1.3 Set a tone of openness to encourage dialogue in the meeting,

4.1.4 Invest adequate time, interest, and commitment to provide guidance and expertise to EC members and Investigators,

4.1.5 Assure that the EC receives appropriate and sufficient administrative support, meeting space, and other necessary resources to function efficiently, and will report deficiencies in this support to the Dean of FTM for correction.

4.2 EC Members

4.2.1 Review and approve/provide favorable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects,

4.2.2 EC members assigned as Primary Reviewers shall present the research proposal as well as their assessment report at the meeting.

4.3 Primary Reviewers

4.3.1 Mainly review and provide opinions on submitted research proposal. Primary Reviewers are assigned by the EC Chairperson in the process of initial review, resubmission, continuing review, and study termination/closure.

4.3.2 Present summary of the research proposal as initial review at the EC meeting.

4.3.3 Make a motion concerning the research documents.

4.4 Member and Secretary

4.4.1 Compile and summarize reviewers' comments,

4.4.2 Prepare meeting agenda and minutes of the meeting.

4.5 Assistant Secretary

4.5.1 Distribute meeting agenda and meeting minutes to the EC.

4.5.2 Assist Member and Secretary in taking notes and in charge of technical facility,

4.5.3 Maintain the EC meeting minutes.

5.0 REFERENCES & ASSOCIATED DOCUMENTS

5.1 FTM ECS-002-RR: Ethics Committee: Constitution, Composition, Responsibilities, Term of Membership, and Training

5.2 ICH Guidelines for Good Clinical Practice E6 section 3.2 – Composition, Functions, and Operations

5.3 ICH Guidelines for Good Clinical Practice E6 section 3.3 – Procedures

5.4 Clive CM. Handbook of SOPs for Good Clinical Practice. 2nd ed. Boca Raton: Taylor & Francis; 2004.

5.5 World Medical Association Declaration of Helsinki: Ethical principles for Medical Research Involving Human Subject initiated in 1964 and subsequent amendments.

5.6 The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. 1979.

5.7 WHO. Operational Guidelines for Ethics Committees That Review Biomedical Research. 2000.

5.8 The Medical Council's Regulation on Research Studies and Experiments on Human Subjects, B.E. 2525.

5.9 The Medical Council's Regulation on the Preservation of the Ethics of Medical Profession, B.E. 2545.

5.10 The Medical Council's Announcement No. 21/2545 on the Standards of Services Involving Reproduction Technology (No. 2).

6.0 DEFINITIONS

Approval	The affirmative decision of the Ethics Committee (EC) that the submitted research proposal has been reviewed, and may be conducted at the institution site within the constraints set forth by the EC, the institution, Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
Approval with Conditions and/or Suggestions	Affirmative decision given to the research proposal which is subject to the incorporation of the revisions and or clarifications indicated by the Ethics Committee's recommendations.
Case Report Form (CRF)	A printed, optical, or electronic document designed to record all of the research proposal required information to be reported to the sponsor on each trial participant.
Confidentiality	Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.
Deferral	The research proposal is not recommended for approval as submitted but can be re-assessed after revision.
Disapproval	The research proposal is not recommended for the reasons specified by the Ethics Committee.
Investigator	A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
Subinvestigator	Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).
Subject/Trial subject	An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

7.0 PROCEDURES

7.1 Regular meetings

The FTM EC will hold regular meetings on a monthly basis and the venue of the meeting will be determined by the Assistant Secretary. Written notice of the regular meeting will be given to EC members in each review week not less than five (5) working days before the meeting.

7.2 Special meeting

The Chairperson may call a special meeting of the EC when he/ she determines it to be necessary. Written notice of special meetings, including the time, place, and purpose, will be given to EC members in each review week not less than three (3) working days before the special meeting.

These special meetings are classified into two categories

(1) Fast-track review- this is when the investigator have unavoidable reasons or an urgent situation, Principal Investigator can request fast-track review by fill the Request for Fast-track Review Form (FTM ECF-025-RR) and submit the research proposal and related research documents. Research proposals submitted between date 16th and 22th of the month will be reviewed in the 1st week of the following month. Research proposals submitted between date 1st and 7th of the month will be reviewed in the 3rd week of the following month. However the decision for accept or not accept requesting fast-track review depends on EC Chairperson. This fast-track procedure requires 2 times of the normal submission fee. The results of the review will be sent to the PI within seven (7) working days after EC Meeting.

(2) Urgent meeting – this is when a discussion on death of research participants, SAE and/or SUSARS is needed.

7.3 Quorum

A quorum will be necessary for the conduct of a meeting. The presence of at least seven (7) eligible voting members will constitute a quorum when considering attendance, except that the majority should include at least one member whose primary concern is the non-scientific area and at least one non-institutional/ affiliated member. Moreover, at least one Primary reviewer of each study that will be considered in the meeting is required to attend and present a summary of the study during the meeting. Advisory members and members with a conflict of interest may not be counted as present for the purpose of determining a quorum.

Should the quorum fail during the meeting (e.g., those with conflicts being excused, early departures, absence of the non-scientist), no decision will be made until the quorum is restored. Any action taken without a quorum present will be considered invalid.

7.4 Preparation of Meeting Agenda and Meeting Minutes

The Assistant Secretary will obtain all research proposals and reports submitted to the EC for consideration/ acknowledgement; including report from EC Chairperson and Member and Secretary. All of these will be recorded in the agenda following the meeting agenda form (FTM ECF-028-RR) used in the next

scheduled EC meeting by Member and Secretary. The Assistant Secretary will distribute the meeting agenda together with invitation letter to the EC at least five (5) working days before EC meeting.

For the meeting minutes, The Member and Secretary will record all issues discussed in the EC meeting according to the meeting agenda, including a list of names of EC who attended/ did not attend the meeting, who have conflict of interest, final decisions, recommendations, and opening and closing time of the EC Meeting in the meeting minute form (FTM ECF-029-RR). It will also be distributed by the Assistant Secretary to EC for review and approval in the next EC meeting at least five (5) working days before the meeting.

7.5 Preparation for EC meetings

When the Investigator submit the research proposal, the Assistant Secretary will distribute the appropriate materials to assigned three (3) primary reviewers and one (1) Lay member at least seven (7) working days before the scheduled meeting to allow thorough review of each proposal. The assigned EC members will complete a Reviewer's Assessment Form for Initial Review (FTM ECF-007-RR). Invitation letter, meeting agenda and previous meeting minutes will be provided to EC members in each review week.

7.6 Conduct of the meeting

EC Chairperson declares opening the meeting when a quorum is constituted. EC members shall declare COI, if any.

The EC Chairperson is responsible for leading the meeting, conducting business so that each proposal is fairly and completely reviewed, seeing that the EC reaches a decision on the disposition of each proposal, and communicating these decisions to the individuals who submitted the proposals.

Should the EC Chairperson has conflict of interest and/ or could not attend the EC meeting, the EC Vice-Chairperson will act for the Chairperson. If EC Vice-Chairperson cannot attend the meeting, the quorum will choose one of the EC members to chair the meeting. He/ she shall take full responsibility as the EC Chairperson for that particular quorum.

At the EC meeting, each proposal will be presented by a Primary Reviewer in sufficient detail to assure adequate consideration. The presentation must include, but is not limited to, the following points:

(1) Risks to the research participants are minimal.

(2) Risks to the research participants are reasonable in relationship to the anticipated benefits.

(3) Selection of the research participants is equitable.

(4) Informed consent will be obtained from the research participant or legally authorized representative or guardian.

(5) The research proposal ensures research participant's safety through the monitoring of the data.

(6) The research proposal ensures the research participant's privacy and confidentiality of the data, if applicable.

The presentation will be followed by discussion among the attending EC members until a consensus can be reached. Principal Investigator(s) or ancillary staff may be called to attend EC meetings to answer questions and to provide additional information on the research proposal, but they should be absent from the room during the discussion. Meeting minutes will reflect whether or not this requirement has been met. The EC may also request a review/ opinion from one or more qualified outside experts.

Opinions of absent members that are transmitted by mail, telephone, fax, or e-mail may be considered by the attending EC members.

7.7 Consensus and voting

EC decision making will be done by consensus. If it could not be reached, voting will take place if necessary.

Any EC member with a conflicting interest in a proposal will abstain from deliberations and discussion on that research proposal, except to provide information as requested by the EC. Such abstentions will be recorded in the minutes.

By consensus/ majority vote of the members present, the EC may reach one of the following decisions regarding each proposal/protocol:

(1) Approval - approved as presented,

(2) Approval with Conditions and/or Suggestions – approved, subject to specific clarification/revision,

(3) Deferral - no decision can be made yet, pending evaluation of additional requested information,

(4) Disapproval - the board has decided that they cannot ethically approve the research.

If the EC approves a research proposal, subject to clarification/revision, it must specify whether the changes will require full board or primary reviewers.

A summary of the EC's discussions and a record of its decisions, including but not limited to the final disposition of each research proposal, will be made by the Member and Secretary. In case of voting, the meeting minutes will reflect the number of "Yes," "No," and "Abstain" votes. Copies of the meeting minutes

will be submitted to the members of the EC for review and approval at the next meeting. Minutes of the meetings will be signed by the EC Chairperson or Vice-Chairperson, Member and Secretary and Assistant Secretary.

7.8 Confidentiality of the review process

During the initial or continuing review of the research proposal, material provided to assigned EC members will be considered confidential and the assigned EC members will assure the confidentiality of the information provided to them.

	Review of Unscheduled Mandatory Reports	
	Document No.: FTM ECS-005-09	**Effective Date:** 07 March 2018

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Review of Unscheduled Mandatory Reports

CHANGE HISTORY		
Revision	Description of Change	Effective Date
00	Initial release	28 June 2007
01	The 2008 annual review leads to the following changes; 1. Add and revise the responsibilities of SAE Subcommittee, EC members and Member Secretary; 2. Add definition of the terms 'causality assessment' categorized as not related, doubtful, possible, probable and very likely and the term 'Suspected Unexpected Serious Adverse Reactions (SUSARs); 3. In section 7.2, clarify that SAEs is subject to report to EC within 5 days of the death/event notification to PI; 4. In section 7.3, add a sentence 'This must be accomplished in writing within five (5) days of the event notification to PI.'; 5. Add section 7.4, 'Action taken by EC'.	01 July 2008
02	Entering the SIDCER/FERCIT Recognition Programme of World Health Organization (WHO), suggestions of the surveyors lead to the following changes: 1. Nomenclatures changed – 'Secretariat' is replaced by 'Member Secretary' and 'EC Secretary' with 'Staff Secretary'; 2. Add more references in section 5.0; 3. Add roles and responsibilities of SAE Subcommittee in section 7.2	24 September 2008
	There was no revision in the year 2009.	
03	As a result of the SOP annual review (16 Feb 2010), the following changes have been made 1. Chairperson's name was changed to Prof. Srisin Khusmith and Prof. Krisana Pengsaa, throughout the 2010 annual revision. 2. "Member Secretary" was replaced by "Member and Secretary"	22 April 2010
04	As a result of SOP revision on 21 April 2011 1. Use wording "SAE" instead of description "adverse experiences that are considered serious ***and*** unexpected ***and*** related to the investigational product" in section 7.2	03 May 2011

Review of Unscheduled Mandatory Reports

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	2. Duration of notification SAE event to EC was changed to 5 working day in section 7.2, and major unanticipated problem in section 7.3	
05	The 2014 annual review of the document leads to the following change: 1. Change "research proposal/protocol" to "research proposal" in section 7.1. 2. Add "In case of the SAEs occurring in different countries of a multicenter project, the Investigator can report to the FTM EC within one month of the event notification to PI" to section 7.2.	01 May 2014
06	The resolution of the EC Retreat 2014 leads to the following change: 1. Add the section 7.3 Review of Adverse Events.	03 October 2014
07	According to SIDCER/FERCAP-NECAST recognition and SOPs training in EC Retreat in 2015, the following change has been made 1. Change "SAE Subcommittee" to "SAE Reviewer" and specify the persons responsible for reviewing SAE in Section 4.1.2, 4.2.1, 7.2 and Section 7.5. 2. Add the responsibility of Member and Secretary: "Pass the unscheduled mandatory reports, AE and SAEs report to the EC Chairperson for further action" to Section 4.4. Revise: "Review unscheduled mandatory reports except SAEs and report to EC" to "Notify the unscheduled mandatory reports and SAEs to EC at the convened Meeting". 3. Revise the process in Section 7.1 Submission from "The Assistant Secretary will review the submission for completeness and will pass the documents to the EC Chairperson for further action." to "The Administrative Staff will check the completeness of the document. The Member and Secretary will pass the documents to EC Chairperson for further action" 4. Add the person responsible for reviewing the Adverse Events report, the Unanticipated problems and unscheduled mandatory reports, and review the decision process to Section 7.2, 7.3 and Section 7.4.	16 October 2015

Review of Unscheduled Mandatory Reports

CHANGE HISTORY		
Revision	Description of Change	Effective Date
08	1. Remove "*Controlled copy-Do not Duplicate*" and "*Internal Use Only*" from Footer. 2. Add duration for notification of protocol deviation to section 7.4 Review of Unanticipated Problems and Unscheduled mandatory reports.	03 November 2016
09	The resolution of the EC Retreat and SOPs Training 2017 leads to the following changes: 1. Revise responsibility of EC Chairperson in section 4.1.2 from "Review SAE or appoint Primary Reviewers of each protocol as SAE reviewer" to "Appoint two (2) SAE Subcommittee members to review the SAE report" 2. Change "SAE Reviewer" to "SAE Subcommittee" in section 4.2, section 7.2 and section 7.5 3. Revise responsibility of SAE Subcommittee in section 4.2.1 from "Review SAE reports submitted to EC by EC Chairperson or Primary Reviewers" to "Review SAE reports submitted to EC" 4. Change responsibility for review AE in section 7.3 from "EC Chairperson or the Primary reviewers will review these reports" to "SAE Subcommittee will review these reports"	07 March 2018

Review of Unscheduled Mandatory Reports

SIGNATURES		
Author	I, on behalf of the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, indicate that this SOP has been authored according to applicable business requirements for quality system documentation.	
	Name: Assoc. Prof. Jaranit Kaewkungwal	Signature:
	Title: Chairperson, Ethics Committee of the Faculty of Tropical Medicine Mahidol University	Date: 05 MAR 2018
Approver	I indicate that I have reviewed this SOP, and find it meets all applicable business requirements and that it reflects the procedure described. I approve it for use.	
	Name: Assoc. Prof. Pratap Singhasivanon	Signature:
	Title: Dean, Faculty of Tropical Medicine, Mahidol University	Date: 06 MAR 2018

	Review of Unscheduled Mandatory Reports	
	Document No.: FTM ECS-005-09	**Effective Date:** 07 March 2018

1.0 PURPOSE

To describe the procedures for reviewing unscheduled reports submitted to the Ethics Committee (EC) of the Faculty of Tropical Medicine (FTM), Mahidol University.

2.0 SCOPE

This SOP will apply to all serious adverse events (including deaths), unanticipated problems and unscheduled mandatory reports submitted to the FTM EC for review.

3.0 POLICY

3.1 All serious adverse events (SAEs) should be reported immediately to the sponsor and FTM EC, except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports. The immediate reports should identify research participants by unique code number assigned to the research participants rather by their names, personal identification numbers and/or addresses. The Investigator should also comply with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions to the authority(ies) and FTM EC.

3.2 Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.

3.3 For reported deaths, the Investigator should supply the sponsor and FTM EC with any additional requested information (e.g., autopsy reports and terminal medical reports).

4.0 RESPONSIBILITIES

4.1 EC Chairperson

4.1.1 Preliminary review the submitted unscheduled mandatory report and determine further actions.

4.1.2 Appoint two (2) SAE Subcommittee members to review the SAE report

4.2 SAE Subcommittee

4.2.1 Review SAE reports submitted to EC.

4.2.2 Determine the relevancy of PI's causality assessment and report its suggestion/recommendation to EC.

4.3 EC Members

4.3.1 Acknowledge SAEs and/or give additional suggestion/ recommendation.

4.4 Member and Secretary

4.4.1 Pass the unscheduled mandatory reports, AE and SAEs report to the EC Chairperson for further action.

4.4.2 Notify the unscheduled mandatory reports, AE and SAEs to the EC at the convened Meeting.

4.5 The Investigator

4.5.1 Submit unscheduled mandatory report, including serious adverse events and unanticipated problems, to FTM EC,

4.5.2 Provide FTM EC with additional information regarding those unscheduled mandatory reports.

5.0 REFERENCES & ASSOCIATED DOCUMENTS

5.1 ICH Guidelines for Good Clinical Practice (E6) section 3.3 – Procedures

5.2 ICH Guidelines for Good Clinical Practice (E6) section 4.11 – Safety Reporting

5.3 World Medical Association Declaration of Helsinki: Ethical principles for Medical Research Involving Human Subject initiated in 1964 and subsequent amendments.

5.4 The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. 1979.

5.5 WHO. Operational Guidelines for Ethics Committees That Review Biomedical Research. 2000.

5.6 The Medical Council's Regulation on Research Studies and Experiments on Human Subjects, B.E. 2525.

5.7 The Medical Council's Regulation on the Preservation of the Ethics of Medical Profession, B.E. 2545.

5.8 The Medical Council's Announcement No. 21/2545 on the Standards of Services Involving Reproduction Technology (No. 2).

5.9 Clive CM. Handbook of SOPs for Good Clinical Practice. 2nd ed. Boca Raton: Taylor & Francis; 2004.

5.10 FTM ECF-014-RR: SAE Report Form

6.0 DEFINITIONS

Adverse Event (AE)	Any untoward occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.
Causality assessment	***Not related:*** An adverse event that is not related to the use of the study drug. ***Doubtful:*** An adverse event for which an alternative explanation is more likely, e.g., concomitant drug(s), concomitant disease(s), or the relationship in time suggests that a causal relationship is unlikely. ***Possible:*** An adverse event that might be due to the use of the drug. An alternative explanation, e.g., concomitant drug(s), concomitant disease(s), is inconclusive. The relationship in time is reasonable; therefore the causal relationship cannot be excluded. ***Probable:*** An adverse event that might be due to the use of study drug. The relationship in time is suggestive (e.g., confirmed by dechallenge). An alternative explanation is less likely, e.g., concomitant drug(s), concomitant disease(s). ***Very likely:*** An adverse event that is listed as a possible adverse reaction and cannot be reasonably explained by an alternative explanation, e.g., concomitant drug(s), concomitant disease(s). The relationship in time is very suggestive (e.g., it is confirmed by dechallenge and rechallenge).
Independent Ethics Committee (IEC)	An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical/scientific professionals and non-scientific members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the

	methods and material to be used in obtaining and documenting informed consent of the trial subjects.
Investigational Product	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved used.
Investigator	A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
Investigator's Brochure	A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects.
Minimal Risk	The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR)	Any untoward medical occurrence that at any dose: • Results in death • Is life-threatening • Requires inpatient hospitalization or prolongation of existing hospitalization • Result in persistent or significant disability/ incapacity, OR • Is a congenital anomaly/birth defect
Subject/Trial Subject	An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.
Suspected Unexpected Serious Adverse Reactions (SUSARs)	If an adverse event arises during a study in the patient/subject, then this concerns a SUSAR if the following three conditions are met: (1) the event must be serious, that is to say, the event (regardless of the dose): - is lethal, and/or - threatens the life of the subject, and/or - makes hospital admission or an extension of the admission necessary, and/or

- cause persistent or significant invalidity or work disability, and/or
- expresses itself in a congenital anomaly or malformation.

(2) there must be a certain degree of probability that the event is a harmful, and an undesirable, reaction to the medicinal product under investigation, regardless of the administered dose (in other words, there is an adverse reaction).

(3) the adverse reaction must be unexpected, that is to say, the nature and severity of the adverse reaction are not in agreement with the product information as recorded in the Summary of Product Characteristics (SPC) or in the Investigator's Brochure.

7.0 PROCEDURES

7.1 Submission

During any period in which the approved research proposal is being conducted, the Investigator will submit the following information to the FTM EC:

(1) Serious Adverse Events or SUSARs;
(2) Adverse Events
(3) Unanticipated problems and unscheduled mandatory reports, such as protocol deviation/violation, changes in risk to the research participants, new information affecting the conduct of the trial

The Administrative Staff will check the completeness of the document. The Member and Secretary will pass the documents to EC Chairperson for further action.

7.2 Review of Serious Adverse Events

The FTM EC will require that Investigators report all deaths that occur while the research participant is participating in a research study to the EC Chairperson. This must be accomplished in writing within five (5) working days of the death notification to PI.

The FTM EC will require that Investigators report all SAE while the research participant is participating in a research study to the EC Chairperson. This must be accomplished in writing within five (5) working days of the event notification to PI. In case of the SAEs occurring in different countries of a multicenter project, the Investigator can report to the FTM EC in one (1) month of the event notification to PI.

SAE reports shall be forwarded to SAE Subcommittee who will review the reports and determine the relevancy of PI's causality assessment. If there are no or only

minor recommendations from SAE Subcommittee, the official notification will be given to the Investigator and Member and Secretary will report it to EC at the following convened meeting.

Unless the EC Chairperson or SAE Subcommittee believes an urgent meeting should be convened to discuss the death and/or unexpected adverse event related to investigational product, EC members will review the written report at the next regular meeting and notify the Investigator.

Investigators will submit the serious adverse event to the EC using the sponsor-required documentation. If such documentation is not available, the Investigator may use the SAE Report Form (FTM ECF-014-RR).

Investigators will submit all safety information to the EC using the sponsor-required documentation.

7.3 Review of Adverse Events

The EC will require that Investigators report all Adverse Events related and not related to the study to the EC Chairperson. This must be accomplished in writing in one (1) year of the event notification to PI. SAE Subcommittee will review these reports. If there are no or only minor recommendations, the official notification will be sent to Investigator and Member and Secretary will report it to EC at the convened meeting.

7.4 Review of Unanticipated Problems and Unscheduled mandatory reports

The EC will require that Investigators report all major unanticipated problems and unscheduled mandatory reports that occur while the research participant is participating in a research study to the EC Chairperson (e.g., medication errors, unexpected complications, protocol violations). This must be accomplished in writing within five (5) working days of the event notification to PI. For protocol deviations, it must be accomplished in writing within one (1) month of the event notification to PI.

EC Chairperson or the Primary Reviewers will review the report. If there are no or only minor recommendations, the official notification will be sent to the Investigator and Member and Secretary will report it to EC at the following convened meeting.

Unless the EC Chairpersons believes a special meeting should be convened to discuss the problem, EC members will review the written report at the next regular meeting, then give the notification to the Investigator.

7.5 Action taken by EC

Upon the report of Member and Secretary and/or SAE Subcommittee at the EC meeting, EC may take action to the unscheduled mandatory reports by either:

- Acknowledgement with no further action

- Opinion/more information action for safety measures
- Opinion action for the revising ICF and reconsenting the research participants
- Certificate of Ethical Approval (CEA) suspension/withdrawal

Site monitoring may be conducted if necessary.

	Review of the Informed Consent	
	Document No.: FTM ECS-006-06	**Effective Date:** 07 March 2018

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Review of the Informed Consent

CHANGE HISTORY		
Revision	Description of Change	Effective Date
00	Initial release	28 June 2007
01	The 2008 annual review leads to the following changes: 1. In section 4.3, add a specific role of EC members with non-scientific background; 2. In section 5.0, correct the document number for Research Participant Information and Consent Form List; 3. In section 7.2, clarify responsibilities of primary reviewers, EC members with non-scientific background and other EC members in regard to review of the participant information sheet and informed consent form; 4. Add section 7.5, Verbal informed consent.	01 July 2008
02	Entering the SIDCER/ FERCIT Recognition Program of World Health Organization (WHO), suggestions of the surveyors lead to the following changes: 1. Nomenclatures changed – "Secretariat" is replaced by "Member Secretary" and "EC Secretary" is replaced by "Staff Secretary"; 2. Section 5.0 has been divided into 2 subsection, namely References and Associated documents, more references are also added in section 5.1; 3. Definition of "Vulnerable subjects" is added in section 6.0; 4. Clarify "Informed Consent" in section 7.4 as "Written Informed Consent".	24 September 2008
	There was no revision in the year 2009.	
03	As a result of the SOP annual review (16 Feb 2010), the following changes have been made 1. Chairperson's name was changed to Prof. Srisin Khusmith and Prof. Krisana Pengsaa, throughout the 2010 annual revision. 2. Nomenclatures-"Staff Secretary" was replaced by "Assistant Secretary"	22 April 2010

Review of the Informed Consent

CHANGE HISTORY		
Revision	Description of Change	Effective Date
04	The 2014 annual review of the document leads to the following changes: 1. Change "research proposal/protocol" to "research proposal" in sections 7.1 and 7.4. 2. Change "Protocol" to "research proposal" in sections 7.1 and 7.7. 3. Use "RR" instead of the version/revision number of the document in section 7.2.	01 May 2014
05	The resolution of the EC Retreat and SOP training 2016 leads to the following changes: 1. Change "legally authorized representative" **to** "legally authorized representative or guardian" in section Policy sub item 3.5, 3.6 and in section 6.0 Definition. 2. Change "Designed Primary Reviewer(s)" **to** "Designed Reviewer(s)" in section 4.2. 3. Change name of form FTM ECF-015-RR from "Research Participant Information and Consent Form Checklist" **to** "Participant Information Sheet and Informed Consent Form Assessment Checklist" in section 4.2.1, section 4.3.2 and section 5.2.1. 4. Add definition of Guardian to section 6.0. 5. Revise EC Review of the Informed Consent Document in section 7.2 as follows: - Change "The Assistant Secretary will distribute the appropriate materials to each of the EC member…before scheduled meeting" **to** "The Assistant Secretary will distribute the appropriate materials to the assigned three (3) primary reviewers and one (1) lay member... before the scheduled meeting" - Change "The Primary Reviewers and non-scientific EC members will complete a Research Participant Information and Consent Form Checklist (FTM ECF-015-RR)" **to** "Participant Information Sheet and Informed Consent Form Assessment Checklist (FTM ECF-015-RR)" - Remove the statement "but all EC members are requested to review the ICF materials for all studies"	03 November 2016

Review of the Informed Consent

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	6. Change "EC member will review each informed consent document…" **to** "Assigned EC member will review each informed consent document…" in section 7.3. 7. Change duration of record retention from "three (3) years from the date of the completion of the study" **to** "one (1) year from the date of the completion of the study" in section 7.7. 8. Remove "*Controlled copy-Do not Duplicate*" and "*Internal Use Only*" from Footer.	
06	The resolution of the EC Retreat and SOPs Training 2017 and the consensus of EC in the EC Meeting on 15 February 2018 lead to the following changes: 1. Change responsibilities of the EC Chairperson in section 4.1.1 from "Designate two Primary Reviewers for the submitted informed consent" to "Designate Primary Reviewers for the submitted informed consent" 2. Change document for assessment for informed consent from "the Participant Information Sheet and informed Consent Form Assessment Checklist (FTM ECF-015-RR)" to "Reviewer's Assessment Form for initial Review (FTM ECF-007-RR)" in section 4.2.1, 4.3.2, 5.2.1, 7.2 3. Change responsibility of Assistant Secretary from "Distribute copies of submitted informed consent to designed primary reviewer and EC members" to "Distribute copies of submitted informed consent to designated primary reviewer" in section 4.4.1. 4. Add "Online consent" and "Anonymous survey' to the circumstances for Waiver of Written Informed Consent in section 7.4. 5. Revise verbal informed consent in section 7.5 as follows: - Change the criteria for verbal consent in section 7.5 from "anonymous questionnaire and survey" to "where revealing the participant identity will have negative consequences for them, such as sex workers, IDU, illegal migrants, etc. However, the process of verbal consent should be documented and witnessed by a trusted person nominated by the participant"	07 March 2018

Review of the Informed Consent

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	- Add the statement for the study conducted in the Health Care Service in Thailand that verbal consent must not against the National Health Act 2007 section 9 that specified in Thai "ในกรณีที่ผู้ประกอบวิชาชีพด้านสาธารณสุขประสงค์จะใช้ผู้รับบริการเป็นส่วนหนึ่งของการทดลองในงานวิจัย ผู้ประกอบการวิชาชีพด้านสาธารณสุขต้องแจ้งให้ผู้รับบริการทราบล่วงหน้าและต้องได้รับความยินยอมเป็นหนังสือจากผู้รับบริการก่อนจึงจะดำเนินการได้ความยินยอมดังกล่าวผู้รับบริการจะเพิกถอนเสียเมื่อใดก็ได้"	

Review of the Informed Consent

SIGNATURES		
Author	I, on behalf of the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, indicate that this SOP has been authored according to applicable business requirements for quality system documentation.	
	Name: Assoc. Prof. Jaranit Kaewkungwal	Signature:
	Title: Chairperson, Ethics Committee of the Faculty of Tropical Medicine, Mahidol University	Date: 05 MAR 2018
Approver	I indicate that I have reviewed this SOP, and find it meets all applicable business requirements and that it reflects the procedure described. I approve it for use.	
	Name: Assoc. Prof. Pratap Singhasivanon	Signature:
	Title: Dean, Faculty of Tropical Medicine, Mahidol University	Date: 06 MAR 2018

	Review of the Informed Consent	
	Document No.: FTM ECS-006-06	**Effective Date:** 07 March 2018

1.0 PURPOSE

To describe the processes for the review of informed consent documents submitted to the Ethics Committee (EC) of the Faculty of Tropical Medicine (FTM), Mahidol University.

2.0 SCOPE

This SOP will apply to all informed consent documents that accompany research proposal/protocol submitted to FTM EC for review.

3.0 POLICY

3.1 In obtaining and documenting informed consent, the Investigator should comply with the applicable regulatory requirement(s), and should adhere to the ethical principles that have their origin in the Declaration of Helsinki.

3.2 Prior to the beginning of the trial, the Investigator should have the FTM EC's written approval on the written informed consent form and any other written information to be provided to the research participants.

3.3 The written informed consent form and any other written information to be provided to the research participants should be revised whenever important new information becomes available that may relevant to the research participant's consent. These revised materials should receive FTM EC's approval in advance of use.

3.4 Neither the Investigator, nor the trial staff, should coerce or unduly influence a research participant to participate or continue to participate in a trial.

3.5 None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the research participant or his/her legally authorized representative or guardian to waive or appear to waive any legal rights, or that releases or appears to release the Investigator, the institution, the sponsor, or their agents from liability for negligence.

3.6 The language used in the oral or written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the research participant or his/her legally authorized representative or guardian and the impartial witness, where applicable.

4.0 RESPONSIBILITIES

4.1 EC Chairperson
- 4.1.1 Designate Primary Reviewers for the submitted inform consent
- 4.1.2 Sign on the written notification to the Investigator regarding EC's decision on the submitted informed consent material

4.2 Designated Reviewer(s)
- 4.2.1 Complete the Reviewer's Assessment Form for Initial Review
- 4.2.2 Review and assess the submitted inform consent document

4.3 EC Members
- 4.3.1 Review and give favorable opinion on the submitted inform consent document
- 4.3.2 EC members with non-scientific background shall focus on the research participant and informed consent form and complete the Reviewer's Assessment Form for Initial Review

4.4 Assistant Secretary
- 4.4.1 Distribute copies of submitted informed consent to designated primary reviewer
- 4.4.2 If approved, stamp the FTM EC's seal on the informed consent documents
- 4.4.3 File the approved informed consent documents and maintain the record as stated in this SOP

4.5 The Investigator
- 4.5.1 Submit informed consent documents to FTM EC for review
- 4.5.2 Submit the revised informed consent documents to FTM EC for approval prior to use

5.0 REFERENCES & ASSOCIATED DOCUMENTS

5.1 References

- 5.1.1 ICH Guidelines for Good Clinical Practice (E6) section 1.28 – Informed Consent
- 5.1.2 ICH Guidelines for Good Clinical Practice (E6) section 1.37 – Legally Authorized Representative or Guardian
- 5.1.3 ICH Guidelines for Good Clinical Practice (E6) section 4.8 – Informed Consent of Trial Subjects
- 5.1.4 21 CFR 50.25 – Elements of Consent
- 5.1.5 45 CFR 46.116 – General Requirements for Informed Consent
- 5.1.6 45 CFR 46.117 – Documentation of Informed Consent

5.1.7 World Medical Association Declaration of Helsinki: Ethical principles for Medical Research Involving Human Subject initiated in 1964 and subsequent amendments.

5.1.8 The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. 1979.

5.1.9 WHO. Operational Guidelines for Ethics Committees That Review Biomedical Research. 2000.

5.1.10 The Medical Council's Regulation on Research Studies and Experiments on Human Subjects, B.E. 2525.

5.1.11 The Medical Council's Regulation on the Preservation of the Ethics of Medical Profession, B.E. 2545.

5.1.12 The Medical Council's Announcement No. 21/2545 on the Standards of Services Involving Reproduction Technology (No.2).

5.1.13 Clive CM. Handbook of SOPs for Good Clinical Practice. 2nd ed. Boca Raton: Taylor & Francis; 2004.

5.2 Associated documents

5.2.1 FTM ECF-007-RR: Reviewer's Assessment Form for Initial Review

6.0 DEFINITIONS

Good Clinical Practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and the rights, integrity, and confidentiality of the research participants are protected.
Impartial witness	A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the research participant or his/her legally authorized representative or guardian cannot read, and who reads the informed consent form and any other written information supplied to the research participant.
Informed Consent	A process by which a research participant voluntarily confirms his/her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the research participant's decision to

	participate. Informed consent is documented by means of a written, signed, and dated informed consent form.
Legally Acceptable Representative	An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective research participant, to his/her participation in the clinical trial.
Guardian	A legal guardian or proxy guardian can be of three (3) types: 1. Parents (father and mother are alive). 2. Person set up by the court for taking care of the child (in cases where there are no parents or parental access has been revoked). 3. If the child is adopted. The recipient shall be designated as being legally representative.
Vulnerable Subjects	Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

7.0 PROCEDURES

7.1 Submission for Review

As part of the study packet for the initial review of research proposal, Investigators will submit a draft Informed Consent Form to the Assistant Secretary.

Valid informed consent requires:

(1) Disclosure of relevant information to prospective research participants about the research;

(2) Comprehension of the information; and

(3) Voluntary agreement, free of coercion and undue influence, to research participation.

Changes to the consent form that result from research proposal amendments will be handled in the same manner as the original document.

7.2 EC Review of the Informed Consent Document

The Assistant Secretary will distribute the appropriate materials to assigned three (3) Primary Reviewers and one (1) lay member at least seven (7) days before the scheduled meeting to allow thorough review of each research proposal. The Primary Reviewers assigned to review the research proposal will also review the accompanying consent. The assigned EC members will complete a Reviewer's Assessment Form for Initial Review (FTM ECF-007-RR).

7.3 Elements for Written Informed Consent Documents

Assigned EC members will review each informed consent document to ensure that it meets the following basic elements of consent:

(1) A statement that the study involves research;

(2) An explanation of the purpose of the research and the expected duration of participation;

(3) A description of the procedures to be followed and identification of any procedures that are experimental;

(4) A description of any foreseeable risks or discomforts to the research participant, an estimate of their likelihood, and a description of what steps will be taken to prevent or minimize them;

(5) A description of any benefits to the research participant or to others that may reasonably be expected from the research. Monetary compensation is not a benefit. If compensation is to be provided to research participant, the amount should be stated in the consent document;

(6) A disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the research participant;

(7) A statement describing to what extent records will be kept confidential, including a description of who may have access to research records;

(8) For research involving more than minimal risk, an explanation and description of any compensation and any medical treatments, where further information could be obtained, and contact person when experiencing the adverse event will be given to the research participants.

(9) An explanation of whom to contact for answers to pertinent questions about the research and the research participant's rights (including FTM EC Member and Secretary and telephone number); and

(10) A statement that participation is voluntary and that refusal to participate or discontinuing participation at any time will involve no penalty or loss of benefits to which the research participant is otherwise entitled.

EC Reviewers will ensure that, when appropriate, the following additional elements will be included in the consent form:

(1) If the research participant is or may become pregnant, a statement that the particular treatment or procedure may involve risks, which are currently unforeseeable, to the research participant or to the embryo or fetus;

(2) A description of circumstances in which the participation may be terminated by the investigator without the research participant's consent;

(3) Any costs that may result from participation in the research;

(4) What will happen if the research participant decides to withdraw from the research and how withdrawal will be handled;

(5) A statement that the Investigator will notify research participants of any significant new findings developed during the course of the study that may affect them and influence their willingness to continue participation;

(6) The approximate number of research participants involved in the study;

(7) When appropriate, a statement concerning an investigator's potential financial or other conflict of interest in the conduct of the study.

7.4 Waiver of Written Informed Consent

EC will waive the requirement to obtain written informed consent for the following circumstances.

- Use of unidentifiable left over/ preserved specimens
- Review of medical records
- Online consent
- Anonymous survey

However, permission documentation from the Director/ Designated authorized person of the institution must accompany the research proposal submitted to the EC.

7.5 Verbal Informed Consent

Verbal consent may be used when revealing the identity of the participant will have negative consequences for them, such as sex workers, IDU, illegal migrants, etc. However, the process of verbal consent should be documented and witnessed by a trusted person nominated by the participant. Study conducted in the Health Care Service in Thailand verbal consent must not against the National Health Act 2007 section 9 that specified in Thai "ในกรณีที่ผู้ประกอบวิชาชีพด้านสาธารณสุขประสงค์จะใช้ผู้รับบริการเป็นส่วนหนึ่งของการทดลองในงานวิจัย ผู้ประกอบการวิชาชีพด้านสาธารณสุขต้องแจ้งให้ผู้รับบริการทราบล่วงหน้า และต้องได้รับความยินยอมเป็นหนังสือจากผู้รับบริการก่อนจึงจะดำเนินการได้ ความยินยอมดังกล่าว ผู้รับบริการจะเพิกถอนเสียเมื่อใดก็ได้" Investigators are required to submit EC the information sheet for verbal consent. With this practice, a copy of information sheet must be given to research participants.

7.6 Notification to the Investigator

The FTM EC will provide the Investigator with written notification of its decision to approve, disapprove, defer, or modify the informed consent document. If modifications are required, the description of those modifications will also be documented. The informed consent form will not be considered fully approved until the required modifications are incorporated into the document.

All EC-approved informed consent documents will be stamped with FTM EC seal. Only stamped copies of these documents will be used to obtain the consent of research participants.

7.7 Record Retention

The Assistant Secretary will file a copy of the approved informed consent for each study. If there are revisions to the consent form that are the result of a research proposal amendment, these revised, approved consents will also be filed. All records will be retained for one (1) year from the date of the completion of the study.

	Expedited and Exempt Review of Research Proposal	
	Document No.: FTM ECS-007-10	**Effective Date:** 15 November 2018

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Expedited and Exempt Review of Research Proposal

CHANGE HISTORY		
Revision	Description of Change	Effective Date
00	Initial release	28 June 2007
01	The 2008 annual review leads to the following changes: 1. On Page 5 of 6, when mentioning the criteria when expedited review cannot be applied, add the following statement for a clarification "Except research proposal/protocol of multi-center study approved by the Joint Research Ethics Committees (JREC), the expedited review procedure may *not* be used:…"; 2. In section 7.2, clarify the point that Certificate of Ethical Approval will be issued only when 2 assigned expedited reviewers have positive agreement.	01 July 2008
02	Entering the SIDCER/FERCIT Recognition Programme of World Health Organization (WHO), suggestions of the surveyors lead to the following changes: 1. Add more references in section 5.0; 2. In section 7.2, state clearly that Certificate of Ethical Approval could be issued if both primary reviewers' decisions are in positive agreement.	01 May 2014
	There was no Revision in year 2009.	
03	As a result of the SOP annual review (16 Feb 2010), the following changes have been made 1. Chairperson's name was changed to Prof. Srisin Khusmith and Prof. Krisana Pengsaa, throughout the 2010 annual revision. 2. "EC Secretariat" was replaced by "Member and Secretary" in section 4.2 3. "EC Secretary" was replaced by "Assistant Secretary" in section 4.4 4. Revise Criteria for an Expedited Review of research proposal/protocol in section 7.1 5. Add Criteria for an exempt review as section 7.2 6. Correct the running numbers from 7.2 to 7.3	22 April 2010

Expedited and Exempt Review of Research Proposal

CHANGE HISTORY		
Revision	Description of Change	Effective Date
04	Add more details in this Form 1. FTM ECF-007-RR: "Reviewer's Assessment Form" was changed to "Reviewer's Assessment Form for Initial Review", in section 5.0 and section 7.3 2. Add FTM ECF-026-RR:Request for Exemption Form in section 5.0	03 May 2011
05	The 2014 annual review of the document leads to the following changes: 1. Change the title of the form from "Expedited and Exempt Review of Research Proposal/ Protocol" to "Expedited and Exempt Review of Research Proposal." 2. Change "research proposal/protocol" to "research proposal" in sections 2.0, 4.1.5, 4.6.1, 5.12, 5.13, 6.0, 7.1, 7.2 and 7.3. 3. Change "Protocol" to "research proposal" in section 6.0. 4. Add a definition for 'leftover specimen' to section 6.0. 5. Add the permitted duration for storing stored or left-over specimens to section 7.1. 6. Use "RR" instead of the version/revision number of the document in section 7.3.	01 May 2014
06	Updated information to correspond with the review for Multicenter research project has led to the following changes: 1. Updated name of institute and revised information from "Non clinical trial research proposal of multi-center study approved by the Joint Research Ethics Committees (JREC) of which FTM EC is a member" to "Research proposal of multi-center study approved by the Central Research Ethics Committee (CREC) of which FTM EC is a member (See FTM ECS-009-RR)" in section 7.1, Categories of research which may be considered for expedited review. 2. Removed the conditions of multicenter study from section 7.1.	19 May 2015

Expedited and Exempt Review of Research Proposal

CHANGE HISTORY		
Revision	Description of Change	Effective Date
07	According to SIDCER/FERCAP-NECAST recognition and SOPs training in EC Retreat in 2015, the following change has been made: 1. Change "Deferment" to "Deferral", and use "Approval with Conditions and/or Suggestions" instead of "Approval after Amendment(s) or Approval after Clarifications" and revise definition in Section 6.0.	16 October 2015
08	The resolution of the EC Retreat and SOP training 2016 leads to the following changes: 1. Change the policy in section 3.0 was changed from "The Ethics Committee of the Faculty of Tropical Medicine is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human by conducting initial and continuing review of research activities involving FTM staff members/students." to "The Ethics Committee of the Faculty of Tropical Medicine is an independent body whose responsibility is to ensure in protecting the rights and welfare of human subjects by conducting initial and ongoing review activities of research having criteria as following: 1) Research where FTM staff members/ students are Principal Investigator conducting their research within or outside FTM facilities. Where the research is conducted outside FTM facilities, the Principal Investigator must also submit the research to the local EC for consideration; or 2) Conduct the research in FTM facilities with Investigator(s) affiliated with FTM 2. Revise categories of research which may be considered for expedited review in section 7.1 as follows: - Revise "Individual or group behavior, surveys, interviews, oral histories" to "Low risk non-participatory observation, surveys, interviews, oral histories" in sub item 7.	03 November 2016

Expedited and Exempt Review of Research Proposal

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	- Change "Research involving the collection or study of existing data, documents, medical records, stored, or anonymous leftover specimens…" to "Research involving the collection or study of existing data, documents, medical records, stored, or identifiable leftover specimens…" in sub item 8. - Add "project conducted outside Thailand by FTM staff/ student and has been approved by the local EC" to sub item 9. - Add sub item 10. Continuing review of research previously approved by FTM EC. 3. Add category of research which may be considered for exemption "anonymous leftover specimens, data/ de-identified/ no identifiers maintained such as online survey" to sub item 4 of section 7.2. 4. EC Review Procedure in section 7.3 have been revised as follows: - Revise "If all items required are present, the Member and Secretary will determine whether the submitted research proposal is subject to an expedited review" to "If all items required are present, the Member and Secretary will determine whether the submitted research proposal is subject to an expedited or exemption review" - Add duration of EC review for expedited review "for seven (7) working days" in section 7.3 EC Review Procedures. - Change the decision of expedited review from "When both reviewers' decisions are in positive agreement, EC Chairperson can issue a Certificate of Ethical Approval (CEA)... If otherwise, the research proposal will require full EC review" to "When both reviewers' decisions are in positive agreement, EC Chairperson can issue a Certificate of Ethical Approval (CEA)… If the decisions are in disagreement, the EC Chairperson will discuss with primary reviewers to reach an agreement, then notify the Principal Investigator whether it should go to the full board, or ask Principal Investigator to revise research proposal." - Add procedure for exemption review. 5. Remove "*Controlled copy-Do not Duplicate*" and "*Internal Use Only*" from Footer.	

Expedited and Exempt Review of Research Proposal

CHANGE HISTORY		
Revision	Description of Change	Effective Date
09	The resolution of the EC Retreat and SOPs Training 2017 leads to the following changes: 1. Revise responsibility of Member and Secretary in section 4.2.1 from "…determine whether it is subject to an expedited review or a full EC review" to "… determine whether it is subject to an exempt review, an expedited review or a full EC review" 2. Change "EC Primary Reviewer" to "Primary Reviewers" in section 4.3 3. Change "trial subjects" to "research subjects" in section 4.2.2, 4.3.1 4. Revise the responsibility of the Investigator in section 4.6.1 from "Submit an Application for Continuing Review Form and necessary documents to the EC that initially reviewed the research proposal in a timely manner" to "Submit a research proposal and necessary documents to the EC that initially reviewed, in a timely manner" 5. Separate Research Proposal Checklist for Principal Investigator (FTM ECF-006-RR) to 3 forms as follows: 1. Research Proposal Submission Checklist for Principal Investigator (for a study involving specimen collection) (FTM ECF-033/1-RR) 2. Research Proposal Submission Checklist for Principal Investigator (for a study NOT involving specimen collection) (FTM ECF-034/1-RR) 3. Research Proposal Submission Checklist for Principal Investigator (for a retrospective study and/or no-direct contact with human subjects) (FTM ECF-035/1-RR) Thus, this form has been revised in section 5.0 and 7.3 6. Change the number of the category for expedited review from 9 to 10 in section 7.1 7. Add "Research proposal of multi-center study under Memorandum of Understanding of Mahidol University has been considered by lead EC (Where the FTM EC is a local EC)" to the 9th category in section 7.1	07 March 2018

Expedited and Exempt Review of Research Proposal

CHANGE HISTORY		
Revision	Description of Change	Effective Date
	8. Revise statement "The Member and Secretary will track all research proposal approved by expedited review, and will inform the full EC at the next convened meeting. Research proposal subject to an expedited review and reviewers' decision will be recorded in EC minutes" to "The Member and Secretary will track all research proposals approved by exempt review and expedited review, and will inform the full EC at the next convened meeting. Research proposals subject to exempt review and expedited review. and reviewers' decisions, will be recorded in EC minutes." in section 7.3	
10	As resolved at the EC Retreat and SOP Training 2018 make the following change: 1. Revise the title of the Research Proposal Submission Checklist for Principal Investigator in section 5.0 References & Associated documents, as follows: - FTM ECF-033/1-RR: "for a study involving specimen collection" has been revised to "for a study involving human subject enrollment WITH specimen collection" - FTM ECF-034/1-RR: "for a study NOT involving specimen collection" has been revised to "for a study involving human subject enrollment WITHOUT specimen collection" - FTM ECF-035/1-RR: "for a retrospective study and/or no-direct contact with human subjects" has been revised to "for a study WITHOUT human subject enrollment"	15 November 2018

Expedited and Exempt Review of Research Proposal

SIGNATURES		
Author	I, on behalf of the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, indicate that this SOP has been authored according to applicable business requirements for quality system documentation.	
	Name: Assoc. Prof. Jaranit Kaewkungwal	Signature:
	Title: Chairperson, Ethics Committee of the Faculty of Tropical Medicine, Mahidol University	Date: 12 NOV 2018
Approver	I indicate that I have reviewed this SOP, and find it meets all applicable business requirements and that it reflects the procedure described. I approve it for use.	
	Name: Assoc. Prof. Pratap Singhasivanon	Signature:
	Title: Dean, Faculty of Tropical Medicine, Mahidol University	Date: 14 NOV 2018

	Expedited and Exempt Review of Research Proposal	
	Document No.: FTM ECS-007-10	**Effective Date:** 15 November 2018

1.0 PURPOSE

To describe the criteria for expedited review of research proposal/protocol submitted to the Ethics Committee (EC) of the Faculty of Tropical Medicine (FTM), Mahidol University.

2.0 SCOPE

This Standard Operating Procedure (SOP) will apply to all research proposal submitted to FTM EC for approval.

3.0 POLICY

3.1 The Ethics Committee of the Faculty of Tropical Medicine is an independent body whose responsibility is to ensure in protecting the rights and welfare of human subjects by conducting initial and ongoing review activities of research having criteria as following:

1) Research where FTM staff members/ students are Principal Investigator conducting their research within or outside FTM facilities. Where the research is conducted outside FTM facilities, the Principal Investigator must also submit the research to the local EC for consideration; or
2) Conduct the research in FTM facilities with Investigator(s) affiliated with FTM

3.2 No research participants should be admitted to a trial before FTM EC issues its written approval to the trial.

3.3 Research proposal/protocol submitted to FTM EC for an initial review may undergo expedited review only when it meets the criteria stated in this SOP; otherwise it shall require full EC review.

4.0 RESPONSIBILITIES

4.1 EC Chairperson

4.1.1 Assign appropriate two primary reviewers to conduct an expedited review on a submitted research proposal

4.1.2 Uphold EC judgments that may not always be popular with Investigators

4.1.3 Invest adequate time, interest, and commitment to provide guidance and expertise to EC members and Investigators

4.1.4 Inform, in writing, the Investigator of the result of EC consideration on the submitted research proposal/protocol

4.1.5 Sign on the certificate given to the approved research proposal

4.2 Member and Secretary

4.2.1 Screen the research proposal submitted for an initial review and determine whether it is subject to exempt review or an expedited review or a full EC review

4.2.2 Review and approve/ provide favorable opinion on, the research proposal, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the research subjects

4.2.3 Conduct continuing review of research covered by the FTM EC at intervals appropriate to the degree of risk, but not less than once per year

4.3 Primary Reviewers

4.3.1 Review and approve/ provide favorable opinion on, the research proposal, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the research subjects

4.3.2 Conduct continuing review of research covered by the FTM EC at intervals appropriate to the degree of risk, but not less than once per year

4.4 Assistant Secretary

4.4.1 Conduct a preliminary review on the completeness of the submitted research proposal

4.4.2 Distribute a copy of the research proposal, informed consent, and other study-related materials to the full EC at the convened meeting

4.4.3 Make a summary of the EC's discussions and record its decisions, including but not limited to the final disposition of each research proposal

4.4.4 Keep track of the continuing review

4.4.5 Maintain the following records:

1) EC meeting minutes
2) Correspondence with the Investigators
3) Materials provided to EC members for review
4) Documentation of expedited review and approval (if applicable)

4.5 EC Administrative Staff or Assistant Secretary

4.5.1 Assist Assistant Secretary in distributing materials to be reviewed and maintaining the records

4.6 The Investigator

4.6.1 Submit a research proposal and necessary documents to the EC that initially reviewed, in a timely manner

5.0 REFERENCES & ASSOCIATED DOCUMENTS

5.1 FTM ECS-001-RR: Quality System Documentation

5.2 21 CFR 56.109 – IRB Review of Research

5.3 21 CFR 56.111 – Criteria for IRB Approval of Research

5.4 ICH Guidelines for Good Clinical Practice (E6) section 3.1 – Responsibilities

5.5 World Medical Association Declaration of Helsinki: Ethical principles for Medical Research Involving Human Subject initiated in 1964 and subsequent amendments

5.6 The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. 1979

5.7 WHO. Operational Guidelines for Ethics Committees That Review Biomedical Research. 2000

5.8 The Medical Council's Regulation on Research Studies and Experiments on Human Subjects, B.E. 2525

5.9 The Medical Council's Regulation on the Preservation of the Ethics of Medical Profession, B.E. 2545

5.10 The Medical Council's Announcement No. 21/2545 on the Standards of Services Involving Reproduction Technology (No. 2)

5.11 Clive CM. Handbook of SOPs for Good Clinical Practice. 2nd ed. Boca Raton: Taylor & Francis; 2004

5.12 FTM ECS-003-RR: Research Proposal Management

5.13 FTM ECF-007-RR: Reviewer's Assessment Form for Initial Review

5.14 FTM ECF-026-RR: Request for Exemption Form

5.15 FTM ECF-033/1-RR: Research Proposal Submission Checklist for Principal Investigator (for a study involving human subject enrollment WITH specimen collection)

5.16 FTM ECF-034/1-RR: Research Proposal Submission Checklist for Principal Investigator (for a study involving human subject enrollment WITHOUT specimen collection)

5.17 FTM ECF-035/1-RR: Research Proposal Submission Checklist for Principal Investigator (for a study WITHOUT human subject enrollment)

6.0 DEFINITIONS

Approval	The affirmative decision of the Ethics Committee (EC) that the submitted research proposal has been reviewed, and may be conducted at the institution site within the constraints set forth by the EC, the institution, Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
Approval with Conditions and/or Suggestions	Affirmative decision given to the research proposal which is subject to the incorporation of the revisions and or clarifications indicated by Ethics Committee's recommendations.
Deferral	The research proposal is not recommended for approval as submitted but can be re-assessed after revision.
Disapproval	The research proposal is not recommended for the reasons specified by the Ethics Committee.
Independent Ethics Committee (IEC)	An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical/scientific professionals and non-scientific members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.
Investigator	A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
Investigator's Brochure	A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects.
Nonclinical Study	Biomedical studies not performed on human subjects.
Minimal Risk	The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.
Leftover Specimen	Remaining portion of a specimen obtained for clinical purpose that is no longer needed for its original purpose and that would otherwise be discarded.

Opinion (in relation to the Ethics Committee)	The judgment and/or the advice provided by the Ethics Committee.
Research proposal	A document that describes the objective(s), design, methodology, statistical consideration, and organization of a trial. The research proposal usually also gives the background and rationale for the trial, but these could be provided in other research proposal referenced documents.

7.0 PROCEDURES

7.1 Criteria for an Expedited Review of Research Proposal

Expedited review allows certain kinds of research to be reviewed and approved without convening a meeting of the EC. The EC will review certain categories of research through an expedited procedure only.

Expedited review applies to research with the following characteristics

1. Minimal risk
2. May include identifiers (direct or indirect)
3. Topics that are not sensitive OR may include some mildly sensitive topics, but where confidentiality is secure
4. Populations may include regulated vulnerable populations & others with adequate protection
5. Consider a formal informed consent process OR justify a waiver of consent
6. Requires continuing IRB review, at least annually
7. Fits one of the 10 expedited categories, shown below

Categories of research which may be considered for expedited review include the following:

1. Clinical studies: IND (Investigating New Drug)/ IDE not required
2. Blood sample collection (routine methods–small amounts)
3. Prospective collection of biological samples—noninvasive means
4. Data collected though noninvasive means (routinely practiced in clinical settings)
5. Materials (data, documents, specimens, etc.) have been collected or will be collected for non-research purposes
6. Collection of voice, video or digital data for research purposes
7. Low risk non-participatory observation, surveys, interviews, oral histories
8. Research involving the collection or study of existing data, documents, medical records, stored, or identifiable leftover specimens, if these sources are available through authorized permission, or if the information is recorded by the investigator in such a manner that research participants cannot be identified directly or through identifiers linked to the research participants

Leftover- or stored specimen can be stored as quality of specimen is available, but not more than ten (10) years

9. Research proposal of multi-center study approved by the Central Research Ethics Committee (CREC) of which FTM EC is a member (See FTM ECS-009-RR), Research proposal for a multi-center study under a Memorandum of Understanding of Mahidol University has been considered by lead EC (where the FTM EC is the local EC), and project conducted outside Thailand by FTM staff/ student and has been approved by the local EC
10. Continuing review of research previously approved by FTM EC as follows:
    a) where the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
    b) where no subjects have been enrolled and no additional risks have been identified; or
    c) where the remaining research activities are limited to data analysis

7.2 Criteria for an Exempt Review of Research Proposal

An exempt review applies to research that involves

1. Minimal risk
2. Does not include identifiers, with some exceptions
3. Topic generally not sensitive
4. Non-vulnerable populations
5. Exempt from formal informed consent requirement, but subjects deserve to know about the research
6. Exempt from continuing IRB review
7. Fits one of 6 exempt categories below

Categories of research which may be considered for exemption include the following:

1. Typical educational practices
2. Educational tests, and surveys
3. Research with elected public officials, appointed public officials, candidate for public office
4. Existing data, documents, pathological specimens (if publicly available or rendered unidentifiable) and anonymous leftover specimens, data/ de-identified/ no identifiers maintained such as online survey
5. Evaluation of public benefit service programs
6. Taste and food quality evaluation and consumer acceptance studies

7.3 EC Review Procedures

Upon receiving the research proposal, Administrative Staff will check for the completeness of the documents following the Research Proposal Checklist for Principal Investigator (FTM ECF-033/1-RR, FTM ECF-034/1-RR, FTM ECF-035/1-RR) inserted in the submitted packet.

If all items required are present, the Member and Secretary will determine whether the submitted research proposal is subject to an expedited or exemption review.

In case of expedited review, the EC Chairperson will assign two EC members to review the research proposal using a Reviewer's Assessment Form for Initial Review (FTM ECF-007-RR) for seven (7) working days. When both reviewers' decisions are in positive agreement, EC Chairperson can issue a Certificate of Ethical Approval (CEA) and will notify the Investigator within fifteen (15) working days. If the decisions are in disagreement, the EC Chairperson will discuss with primary reviewers to reach an agreement, then notify the Principal Investigator whether it should go to the full board, or ask Principal Investigator to revise research proposal.

If the research proposal is subject to exempt review, the Member and Secretary will present it to the Chairperson to consider. The Chairperson will make decision in accordance with the exemption review criteria. After the research proposal is approved, the Assistant Secretary will issue the Documentary Proof of Exemption Review.

The Member and Secretary will track all research proposal approved by exempt review and expedited review, and will inform the full EC at the next convened meeting. Research proposal subject to exempt review and an expedited review and reviewers' decision will be recorded in EC minutes.

	Monitoring of Approved Research Project/ Noncompliance/ Addressing subject inquiries and complaints	
	Document No.: FTM ECS-008-05	**Effective Date:** 07 March 2018

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Monitoring of Approved Research Project/ Noncompliance/ Addressing subject inquiries and complaints

CHANGE HISTORY		
Revision	Description of Change	Effective Date
00	Initial release	01 July 2008
	There was no revision in the year 2009.	
01	As a result of the SOP annual review (16 Feb 2010), the following change has been made 1. Chairperson's name was changed to Prof. Srisin Khusmith and Prof. Krisana Pengsaa, throughout the 2010 annual revision.	22 April 2010
02	According to SIDCER/FERCAP recognition in 2011, the following changes have been made 1. The title of this form "Monitoring of Approved Research Project" was revised to "Monitoring of Approved Research Project/Noncompliance/ Addressing subject inquiries and complaints" 2. Add more detail of purpose in section 1.0 for covering about the noncompliance, addressing subject inquiries and complaints. 3. Add "complaint" in section 2.0 scope and section 4.1.1 responsibility of EC chairperson. 4. Add definition of complaint in section 6.0 5. Add title and details of addressing subject inquiries and complaints in section 7.4 page 3-4 of 4.	22 December 2011
03	The 2014 annual review of the document leads to the following change: 1. Change "Protocol" to "research proposal" in sections 1.0, 3.0 and 6.0.	01 May 2014
04	Remove "*Controlled Copy - Do Not Duplicate*" and "*Internal Use Only*" from Footer.	03 November 2016
05	The resolution of the EC Retreat and SOPs Training 2017 leads to the following changes: 1. Add "AE" to the 2nd bullet "Reports" in section 2.0 2. Use "Member and Secretary" instead of "EC Secretary" in section 7.3.3	07 March 2018

Monitoring of Approved Research Project/ Noncompliance/ Addressing subject inquiries and complaints

SIGNATURES		
Author	I, on behalf of the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, indicate that this SOP has been authored according to applicable business requirements for quality system documentation.	
	Name: Assoc. Prof. Jaranit Kaewkungwal	Signature:
	Title: Chairperson, Ethics Committee of the Faculty of Tropical Medicine, Mahidol University	Date: 05 MAR 2018
Approver	I indicate that I have reviewed this SOP, and find it meets all applicable business requirements and that it reflects the procedure described. I approve it for use.	
	Name: Assoc. Prof. Pratap Singhasivanon	Signature:
	Title: Dean, Faculty of Tropical Medicine, Mahidol University	Date: 06 MAR 2018

	Monitoring of Approved Research Project/ Noncompliance/ Addressing subject inquiries and complaints	
	Document No.: FTM ECS-008-05	**Effective Date:** 07 March 2018

1.0 PURPOSE

To take action and maintain records for any of the following deviation or non-compliance:

- Investigators/Institutes that do not follow procedures in approved research proposals
- Failure to comply with national/international guidelines for the conduct of human research
- Failure to respond to the requests of the Ethics Committee of the Faculty of Tropical Medicine (FTM EC)
- A participant or family member has logged a written or verbal complaint related to the research
- Research publication has been written by investigators at the Faculty of Tropical Medicine, Mahidol University, for which there is no approved research proposal

2.0 SCOPE

This SOP will apply to research projects with the following characteristics:

- Protocol violation/deviation
- Reports of remarkable AEs/SAEs/SUSARs
- Non-compliance or suspicious non-compliance
- Frequently fail to submit required documents
- EC's judgement
- Complaint

3.0 POLICY

The EC shall protect the rights and welfare of human participants and ensure that the research projects approved by FTM EC are conducted according to national and international standards such as Declaration of Helsinki, ICH GCP Guideline and the procedures set forth in the research proposals.

4.0 RESPONSIBILITIES

4.1 EC Chairperson

4.1.1 Designate EC members responsible for collecting and recording non-compliance list/ complaint

4.1.2 Inform the Investigator of the site visit

4.1.3 Provide advice to the designated EC members responsible for the site monitoring

4.2 Designated EC members responsible for site monitoring
- 4.2.1 Plan the monitoring by preparing the checklist, review necessary documents (for examples, SAE and unexpected events reports) and scoping the site visit
- 4.2.2 Conduct a site visit
- 4.2.3 Report the observation to EC
- 4.2.4 Follow up the site monitoring

4.3 Member and Secretary
- 4.3.1 Provide necessary documents as needed
- 4.3.2 Arrange the site visit by coordinating EC and study site
- 4.3.3 Keep records

5.0 REFERENCES & ASSOCIATED DOCUMENTS

5.1 Clive CM. Handbook of SOPs for Good Clinical Practice. 2nd ed. Boca Raton: Taylor & Francis; 2004.

5.2 ICH Guidelines for Good Clinical Practice (E6)

6.0 DEFINITIONS

Compliance	Adherence to all the trial-related requirements, Good Clinical Practice (GCP) requirements, and the applicable regulatory requirements.
Complaint	Expression of dissatisfaction of a participant or family member about the impact of the research study.
Good Clinical Practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and the rights, integrity, and confidentiality of the research participants are protected.
Monitoring	The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the research proposal, Standard Operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
Study site	The location(s) where trial-related activities are conducted.

7.0 PROCEDURES

7.1 Before the visit

7.1.1 EC notifies PI and coordinates a time for site visit

7.1.2 Make appropriate arrangement

7.1.3 Designated EC members review study files

7.1.4 Designated EC members may copy some parts of the files for comparison with the site files

7.1.5 Prepare a checklist to be used during the site visit

7.2 During the visit

7.2.1 Observe facilities whether they are appropriate

7.2.2 Review documentations, such as Informed Consent Form (ICF)

7.2.3 Observe processes, such as informed consent process, patient care, management

7.2.4 Interview involving parties, for examples, participants, investigators, site staff

7.2.5 Debrief and comments

7.2.6 Get immediate feedback

7.3 After the visit

7.3.1 Designated EC members shall prepare a report for a full board review

7.3.2 Send a copy of an official report to the Investigator/Site

7.3.3 Member and Secretary shall keep a record in the correct files

7.4 Addressing subject inquiries and complaints

7.4.1 Once the report of noncompliance, complaint, deviation, and eligibility exceptions are received, the EC will treat each report in a prompt, professional, and fair manner.

7.4.2 Appropriate investigation and response to complaint or report of noncompliance, should be relative to its level of seriousness. According to Title 45 CFR 46.103 (b)(5) (i) any unanticipated problems involving risks to subjects or others, as well as any serious or continuing noncompliance with this policy or the requirements or determinations of the EC, and (ii) any suspension or termination of EC approval.

7.4.3 According to Title 45 CFR 46.113, the EC shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the EC's requirements, or has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the EC's action, and shall be reported promptly to the Investigator, appropriate institutional officials, and the Department or Agency head.

7.4.4 When suspension or termination is not necessary, the issue will be resolved among the EC Chairperson, and the PI, PI's Department head. All communication will be documented.

7.4.5 When suspension or termination is necessary, the notice of suspension effective immediately, will be sent to the PI, Co-PIs, Department head, grants and contracts Department. The notification includes the requirement to halt further participant enrollment. All communication will be documented.

	Review of Multicenter Research Project	
	Document No.: FTM ECS-009-02	**Effective Date:** 07 March 2018

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Review of Multicenter Research Project

CHANGE HISTORY		
Revision	Description of Change	Effective Date
00	Initial release	19 May 2015
01	Remove "*Controlled Copy - Do Not Duplicate*" and "*Internal Use Only*" from Footer.	03 November 2016
02	The resolution of the EC Retreat and SOPs Training 2017 leads to the following changes: 1. Use "Member and Secretary" instead of "EC Secretary" in section 7.1.1 and 7.1.2 2. Add review process for local issue to section 7.1.1 in Phase I 3. Add "Notify Principal Investigator and CREC" after diagram "CEA issuance" in section 7.1.2	07 March 2018

Review of Multicenter Research Project

SIGNATURES		
Author	I, on behalf of the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, indicate that this SOP has been authored according to applicable business requirements for quality system documentation.	
	Name: Assoc. Prof. Jaranit Kaewkungwal	Signature:
	Title: Chairperson, Ethics Committee of the Faculty of Tropical Medicine, Mahidol University	Date: 05 MAR 2018
Approver	I indicate that I have reviewed this SOP, and find it meets all applicable business requirements and that it reflects the procedure described. I approve it for use.	
	Name: Assoc. Prof. Pratap Singhasivanon	Signature:
	Title: Dean, Faculty of Tropical Medicine, Mahidol University	Date: 06 MAR 2018

	Review of Multicenter Research Project	
	Document No.: FTM ECS-009-02	**Effective Date:** 07 March 2018

1.0 Purpose

To describe the processes for the initial and continuing reviews of multicenter research projects submitted to the Ethics Committee (EC) of the Faculty of Tropical Medicine (FTM), Mahidol University.

2.0 Scope

This Standard Operating Procedure (SOP) will apply to all multicenter research projects previously approved by the Ethics Committee for multicenter study, such as but not limited to CREC, and later on being submitted to the Ethics Committee (EC) of the Faculty of Tropical Medicine (FTM), Mahidol University, for a review.

3.0 Policy

3.1 The Ethics Committee of the Faculty of Tropical Medicine is an independent body whose responsibility is to ensure the protection of the rights, safety, and well-being of human participants involved in a trial by conducting initial and continuing review of research activities involving FTM staff members/ students.

3.2 The Ethics Committee of the Faculty of Tropical Medicine will consider the multicenter research project compliance with Memorandum of Understanding (MOU) for instant CREC, Mahidol University.

3.3 The Faculty of Tropical Medicine will conduct an expedited review for multicenter research projects previously approved by CREC, and for multicenter research projects under the Memorandum of Understanding (MOU) of Mahidol University.

4.0 RESPONSIBILITIES

4.1 EC Chairperson

4.1.1 Review or assign EC members to review the submitted research documents and submission form.

4.1.2 Sign the Certificate of Ethical Approval given the approved research project

4.2 Member and Secretary

4.2.1 Inform the FTM EC Chairperson to consider the research project.

4.2.2 Sign the Certificate of Ethical Approval given to the approved research project.

4.3 EC Members

4.3.1 Review and approve/provide favorable opinion on submitted research documents and submission forms.

4.4 Assistant Secretary

4.4.1 Send research documents, submission form and assessment to the assigned EC member to review.

4.4.2 Document the result of review and send it to the CREC, Lead EC or Principal Investigator.

4.5 The Principal Investigator

4.5.1 Submit the research documents to the CREC or Local and Lead EC for consideration and revise the document following recommendation of EC.

5.0 References & Associated Documents

5.1 References

5.1.1 Central Research Ethics Committee (CREC)'s MOU

5.2.2 Mahidol University's MOU

5.2 Associated documents

5.2.1 Submission package

5.2.2 Certificate of Ethical Approval

6.0 Definitions

Multicenter research project	A research project conducted according to a single research proposal but at more than one site, and, therefore, carried out by more than one investigator.
Central Research Ethics Committee (CREC)	An institute under the support from the Foundation of Human Research Promotion in Thailand (HRPT) to solve the slow progress, repetitive and inconvenient for multi-center clinical researches.
Memorandum of Understanding (MOU)	A bilateral or multilateral agreement between two or more parties. It expresses a convergence of will between the parties, indicating an intended common line of action.
Local EC	The Ethics Committee of faculty/institution affiliated with the Investigator.
Lead EC	The Ethics Committee that is selected as primary Committee for first review of the multicenter research project, and issues the documents and Certificate of Ethical Approval.

7.0 Review Procedures

7.1 Multicenter research project approved by Central Research Ethics Committee (CREC)

7.1.1 Review procedure of multicenter research project previously approved by Central Research Ethics Committee (CREC)

The Central Research Ethics Committee (CREC) will only consider multicenter research projects, either clinical or health related social studies, project sponsored by a government agency, the research projects of institutes that do not have EC, and projects of institutes which have signed the Memorandum of Understanding.

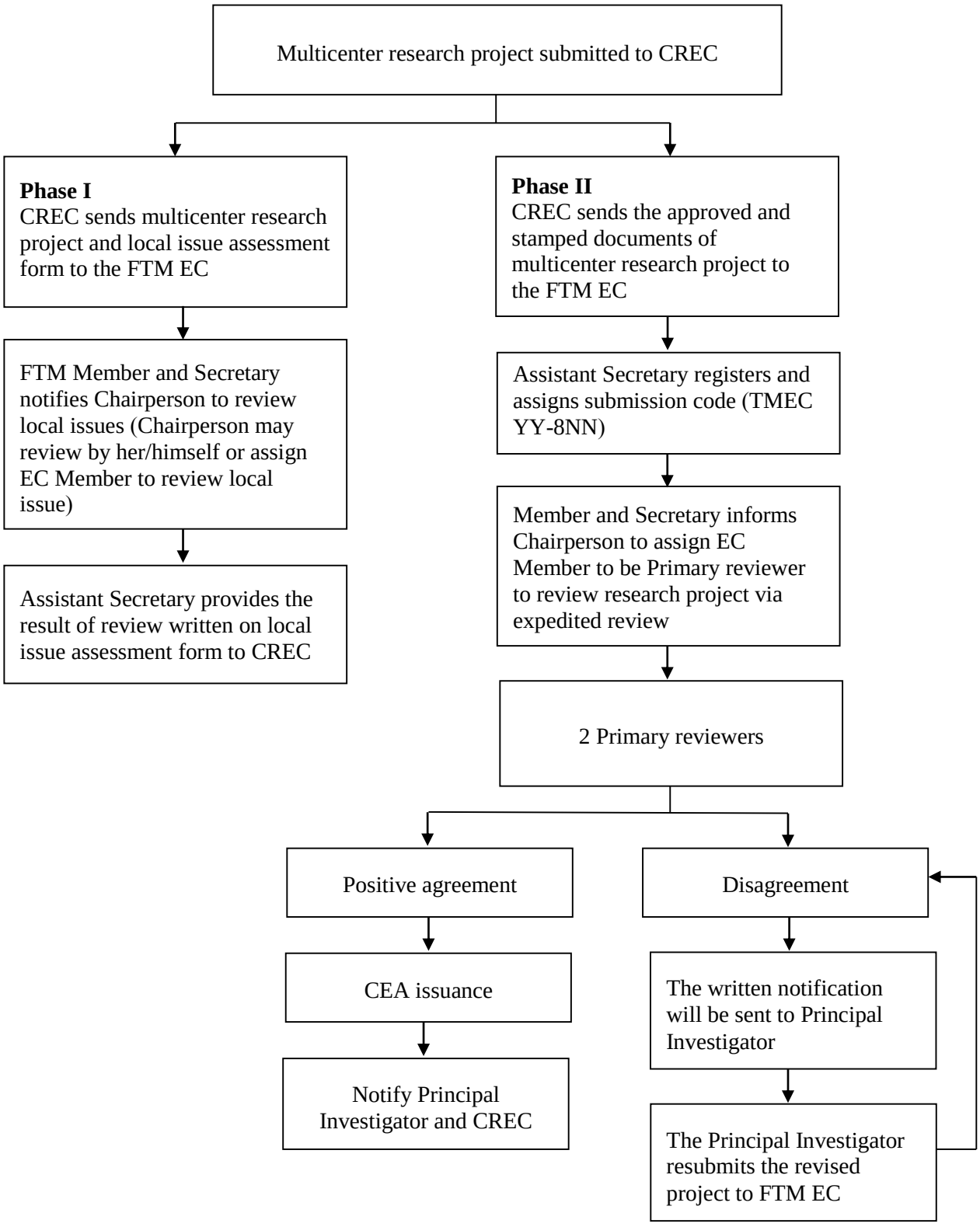
Step I

The CREC will send multicenter research projects involving FTM staff to the Ethics Committee, Faculty of Tropical Medicine (FTM EC) to consider local issues, by using the Local Issue Assessment Form (AP 03). The FTM Member and Secretary notifies the FTM EC Chairperson to review local issues. The Chairperson may review by her/himself or assign an EC member to review the local issue. The Assistant Secretary provides the result of the review on the Local Issue Assessment Form to CREC.

Step II

When the multicenter research project is approved by CREC, the CREC sends the approved and stamped documents to the FTM EC, the Assistant Secretary will register and assign submission code TMEC YY-8NN. The FTM EC will conduct an expedited review. The result of such review will be sent to the Principal Investigator with a written notification. If a clarification or revision is required, the Principal Investigator will have to resubmit the revised project to FTM EC within the timeline. After the project is approved, the Certificate of Ethical Approval will be issued and CREC will be notified. The project can be conducted after FTM EC approval. Continuing reviews are required following the SOP of FTM EC.

7.1.2 Review flowchart of multicenter research project approved by Central Research Ethics Committee (CREC)



7.2 Multicenter research project under Memorandum of Understanding (MOU) of Mahidol University

7.2.1 Review procedure of multicenter research project which co-considered with other EC(s)

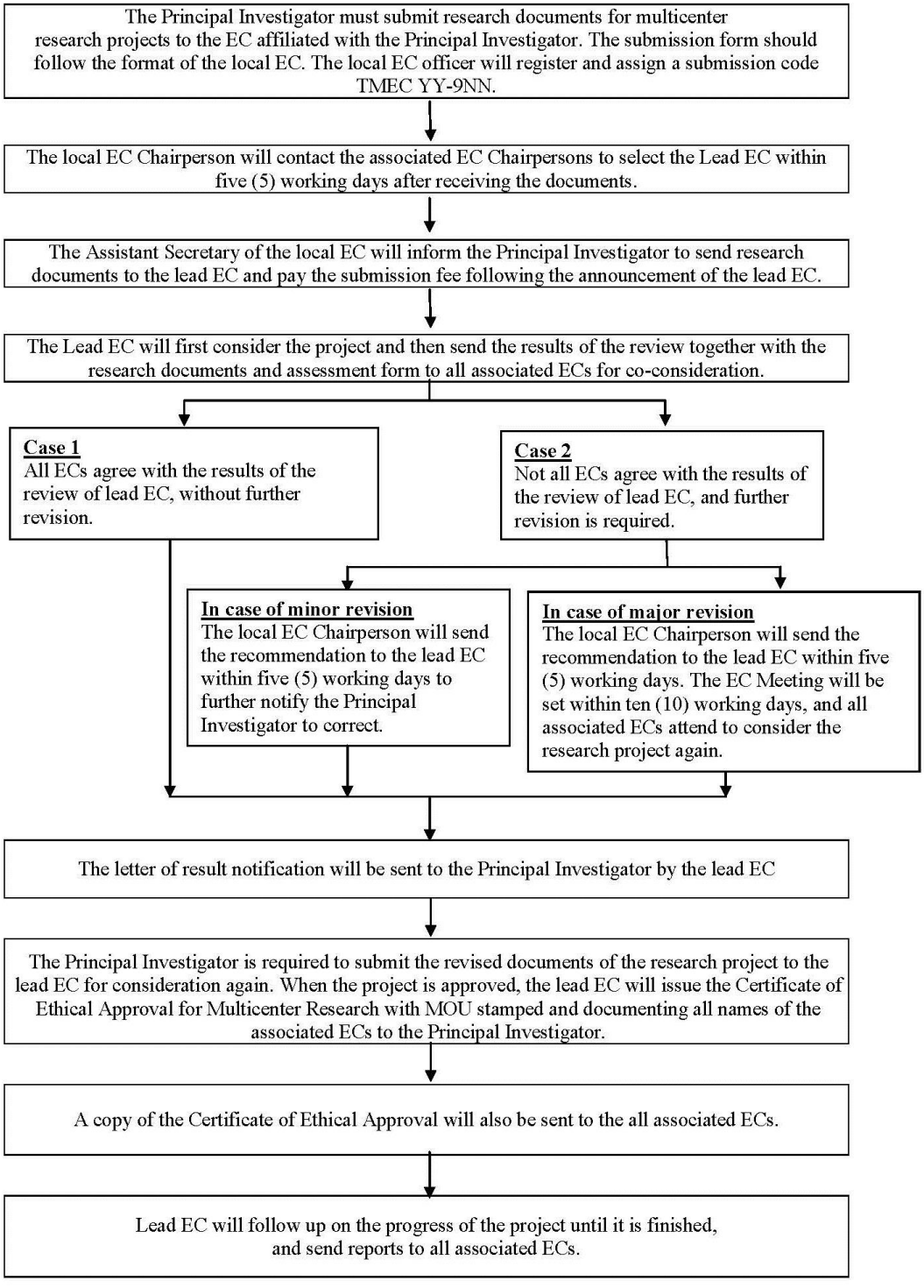
The Ethics Committees belonging to Faculties at Mahidol University sign a Memorandum of Understanding for co-consideration for multicenter projects conducted at more than 1 study site within Mahidol University only.

The Principal Investigator must submit research documents of multicenter research projects to the EC affiliated with the Principal Investigator. The submission form should be followed format of local EC. The Assistant Secretary of local EC will register and assign submission code (For the FTM EC will assign submission code TMEC YY-9NN). The local EC Chairperson will contact the associated EC Chairpersons to select the Lead EC within five (5) working days after receiving the documents. Then the Assistant Secretary of the local EC will inform the Principal Investigator to send research documents to the lead EC and pay the submission fee following the announcement of lead EC. The Lead EC will first consider the project and then send the results of the review together with the research documents and assessment form to all associated ECs for co-consideration. The letter of result notification will be sent to the Principal Investigator by the lead EC. When the project is approved, the lead EC will issue the Certificate of Ethical Approval for Multicenter Research with MOU stamped and documenting all names of the ECs that approved the project to the Principal Investigator. A copy of the Certificate of Approval will also be sent to the other ECs.

For continuing review, the Principal Investigator should send protocol amendments using the format of multicenter to the lead EC for consideration. Reporting SAE the investigator of the study site occurring SAE should send the report using the format of the multicenter to the local EC, and inform Principal Investigator to send the report to the lead EC for consideration. For extension and study closure, the Principal Investigator sends report to the lead EC for consideration.

7.2.2 Review flowchart of multicenter research project which co-considered with other EC(s)

Initial Review



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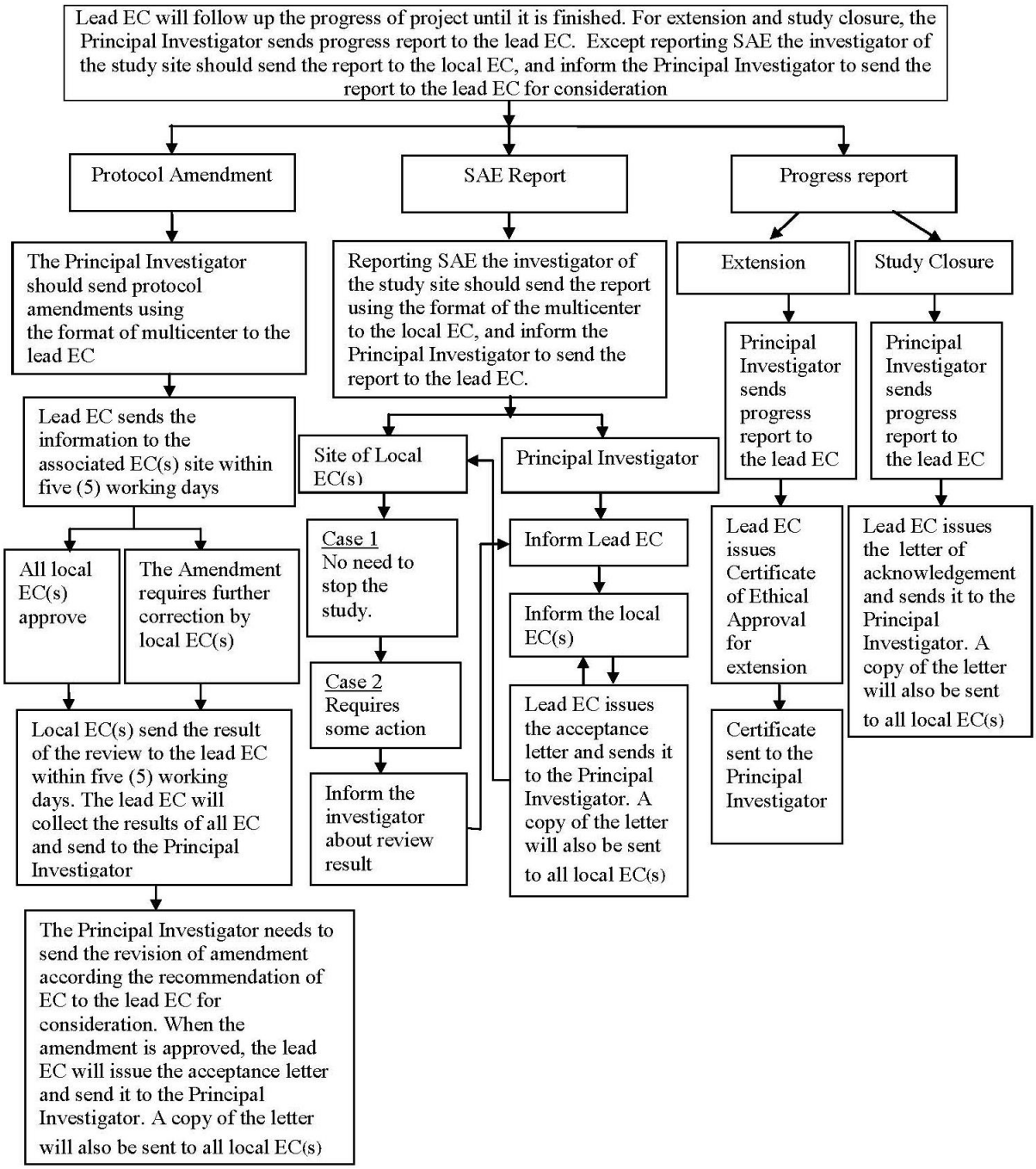
Continuing review