Preparation of standard operating procedures and their modifications

Preparation and Revision of Standard Operating Procedures

Issue that 5.1 Effective date: 24 July 2024

replaces the previous issue 5.0 Dated October 31, 2023

Author July 24, 2024

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Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

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1. Objective To

provide guidelines for writing, reviewing, distributing and revising Standard Operating Procedures (SOPs) for the work of the Human Research Ethics Committee and its staff. Standard Operating Procedures (SOPs) are controlled documents that can be disseminated.

2. Scope

The Standard Operating Procedures (SOPs) preparation guidelines described herein should be used as a guideline for preparation.

All Standard Operating Procedures (SOPs) of the Central Committee and Office staff

3. Responsibility

3.1 The Executive Board of the Foundation for the Promotion of Human Research in Thailand appoints the Subcommittee for Drafting Standard Procedures and the Committee for Development of Standard Procedures. 3.2 The Subcommittee for Drafting Standard Procedures drafts the standard procedure based on the latest revised standard procedure of the Central Committee for Research Ethics Review. In people in Thailand (Central Research Ethics Committee: CREC) together with recommendations From the SIDCER/FERCAP Survey and evaluation report and the Central Research Ethics Committee (CREC)

3.3 The Chairman of the Foundation's Executive Board approves the standard operating procedures. 3.4 The Central Committee, Office staff, or partner institutions propose amendments to the operating procedures. standard

3.5 The Subcommittee for the Development of Standard Operating Procedures shall make improvements as proposed by the Central Committee for review and the Chairman of the Foundation's Executive Board shall approve the revised version. 3.6 Improvements to the Standard Operating Procedures may be made in accordance with the recommendations of the Quality Evaluators of the Central Committee.

4. Procedure flow chart

Order	Operation	responsible person
1	Appoint a subcommittee to draft standard operating procedures ÿ	Foundation Executive Board
2	Define standard operating procedures ÿ	Drafting Subcommittee
3	Define the outline and format ÿ	Drafting Subcommittee
4	Write standard operating procedures ÿ	Drafting Subcommittee
5	Review standard operating procedures ÿ	Partner institutions
6	Approve standard operating procedures ÿ	Chairman of the Executive Board Foundation
7	Distribute standard operating procedures ÿ	Office staff
8	Improve ÿ	Development Subcommittee Standard operating procedures
9	Approved revised version ÿ	Chairman of the Executive Board Foundation
10	Distribute revised editions ÿ	Office staff
11	Keep the original standard operating procedures and published on the website ÿ	Office staff
12	Dealing with old standard operating procedures	Office staff/Committee members Middle

5. Procedures 5.1

Appointment of the Subcommittee for Drafting Standard Operating Procedures

5.1.1 The Foundation's Executive Board appoints the Subcommittee for Drafting Standard Operating Procedures by selecting persons who have

Experience in the operation of the Research Ethics Committee and/or

Experience in writing standard operating procedures of the research ethics committee and being in a partner institution

5.1.2 The subcommittee for developing standard operating procedures is selected by the foundation's executive committee and consists of at least 5 subcommittee members. The subcommittee member is the chairperson of the research ethics committee of the partner institution or a member appointed by the chairperson.

The Foundation has assigned

5.2 Standard Procedure Listing 5.2.1 Review the list of chapters from the revised CREC Standard Procedures (CREC Version 5.0, 31 October 2023). 5.2.2 Include new chapters or use existing chapters as necessary for the operation of the CREC.

Central Committee and Office staff

5.2.3 Prepare a list of standard operating procedures and amendments (AO 01-S01) together with

List of annexed documents (AO 02-S01)

5.3 Format and layout 5.3.1 The format of the standard operating procedures is divided into 3 parts: the summary of the procedure, the standard operating procedures, the table of contents, the main topics of the standard operating procedures with details, according to the AO 03-S01 template.

5.3.2 Provide the Standard Operating Procedure (SOP) codes as CREC XX / vYW - XX as 2 digits for the chapter number, e.g. Chapter 1 uses the code 01 - v for version.

- Y is a 1-digit version number for the version of that SOP chapter, e.g. version 1 is coded 1, and W is a 1-digit number for a draft or minor revision of that SOP chapter.

5.3.3 Annex documents of each chapter of the standard procedures shall use the following codes:

5.3.3.1 Application groups of the annex

- AO XX-SYY is a document used for internal operations of the office. - AP XX-

SYY is a document for researchers/research funders. - AL XX-SYY is

a document of letters or letters used for internal communication within the office.

Or contact and coordinate with researchers and partner

institutions 5.3.3.2 XX in order in each group of appendix documents, starting

from 01 5.3.3.3 S stands for SOP; YY is the chapter of SOP that refers to the documents in

the appendix 5.3.3.4 The header on the left has the CREC logo, telephone/fax, email on the right.

Enter document code

5.3.3.5 The footer on the left side indicates the version and date.

Documents such as AL02 Version 5.0 Date 31 October 2023 on the right side, enter the number.

Page X of Page Y

5.3.3.6 In this case, when actually used, the office staff may take only the content to use accordingly.

Suitability

5.4 Writing standard operating procedures

5.4.1 Use concise and concise language. 5.4.2

Identify the version of the standard procedure. 5.4.3 Check the

correctness of the layout, language, spelling, and grammar.

5.5 Review

5.5.1 The first version of the standard operating procedures prepared by the Subcommittee will be distributed.

A copy is provided to partner institutions for review and recommendations.

5.5.2 The Chairman of the Drafting Subcommittee organizes a meeting of the Drafting Subcommittee to collect information.

Suggestions and amendments to standard operating procedures

5.6 Approval of Standard Operating Procedures (Approval)

The Chairman of the Drafting Subcommittee submits the revised Standard Operating Procedures as

recommended to the Chairman of the Foundation's Executive Board for approval.

5.7 Distribution of copies of the standard operating procedures

The Office staff distributes copies of the approved SOPs to all Central Directors and records the evidence in the SOP distribution log.

Model (AO 04-S01)

5.8 Standard Procedure Revision (Revision) 5.8.1 Office staff collect information and suggestions for improving the standard procedure from the central committee or suggestions from the quality assessment inspection committee or partner institutions. 5.8.2 The chairman of the foundation's executive committee appoints a development subcommittee from the central committee and qualified persons. 5.8.3 The development subcommittee meets to revise, amend, and add some chapters and appendices of the standard procedure as necessary and appropriate to be consistent with

The situation of the problem, major improvements covering all chapters should be done at least every 3 years.

5.8.4 The Secretary of the Central Committee may make minor corrections to the appendix documents as necessary and the Chairman of the Central Committee shall approve the revised version by changing the date at the end (footer) but not changing the version (version) until the version of the SOPs is changed by presenting the revised document at a joint meeting of the Chairman and Secretary of the Central Committee.

5.9 Approval of the revised standard operating procedures The Chairman of the Development Subcommittee proposes the revised standard operating procedures to the Chairman. The Foundation's Executive Committee for signing approval

5.10 Distribution of revised standard operating procedures shall be carried out in the same manner as for distribution of copies of the standard operating procedures in section 5.7.

5.11 Standard Procedure for Original Document Storage

5.11.1 The office staff shall keep all original copies of the standard operating procedures in a storage cabinet.

Office documents

5.11.2 Record all standard operating procedures in electronic form.

5.11.3 Publish on the Office's website.

5.12 Dealing with the replacement of old standard operating procedures

5.12.1 When a new standard operating procedure is approved, it shall be deemed to supersede the old one.

Since the date of signing by the Chairman of the Foundation's Executive Board

5.12.2 The Central Committee Office keeps old standard procedure documents that are

The original should be stamped with the word “Superseded” and the electronic file should be preserved.

The copies can be destroyed.

5.12.3 The Central Committee may destroy the old standard operating procedures or delete the files.

Electronics from computers permanently

6. Definition

Drafting Subcommittee	The Subcommittee for Drafting Standard Procedures is appointed by the Chairman. Foundation Executive Board
Development Subcommittee	The Subcommittee for the Development of Standard Operating Procedures is appointed by Chairman of the Board of Directors of the Foundation
Standard operating procedures	A detailed procedure for achieving a result in a particular matter. Consistent Operation
Controlled documents	Documents in a quality system that are controlled for revision, distribution and retrieval It is constantly being restored and updated to ensure that The content used by users is accurate.

7. Appendix

AO 01-S01	List of standard procedures and amendments List of Standard Operating Procedures (SOPs)
AO 02-S01	List of Annexes
AO 03-S01	Standard Operating Procedures Template
AO 04-S01	Record of distribution of standard operating procedures documents

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

8.3 U.S. Department of Health and Human Services. Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs. May 2018.

9. History of standard procedures

step **Proceed**	**Issue 1** **v.1.0**	**Issue 2** **v.2.0**	**Issue 3** **v.2.1**	**Issue 4** **v.3.0**
Prepared by	Drafting Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures
Reason of Improvement		For convenience Performing work of Central Committee and office staff	Edit to version The same throughout the book	
details Of the correct	Appendix Use as AF CREC all	Group usage of Appendix documents (Annex) is	- Changed from v.2.0 It is v.2.1. - Add reference documents	- Changed from v.2.1 It is v.3.0. - Add reference documents

step Proceed	Issue 1 **v.1.0**	Issue 2 **v.2.0**	Issue 3 **v.2.1**	Issue 4 **v.3.0**
		- AO XX is a document that Use in the office - AP XX is a document For researchers/ Research Funders - AL XX is a document Books or letters that Contact within the office		
Reviewed by the Central Committee	Consider research ethics In humans	Central Committee Consider the ethics of Human research	Central Committee Consider the ethics of Human research	Central Committee Consider the ethics of Human research
Review Date Appointment Date	November 21, 2012 Until 24 January 2013	Appoint date June 14, 2014 to July 3, 2014	Appoint date March 14, 2015 Until May 14, 2015	Appoint date May 16, 2017 Until 30 September 2017
Approved	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit	Prof. Dr. Thadasiblinwong
by Position	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management	Chairman of the Board Foundation	Chairman of the Board Foundation Management
Approval	January 25, 2013	July 4, 2014	Administration 28 September 2016	October 1, 2017
Date, Effective Date	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017

History of Standard Procedures (continued)

Author	Version Approval Date		Show main edits	Approved by
Edition No. 5 Subcommittee Development Method of operation standard	v.4.0	June 15 2563	- The Chairman may slightly revise the form (Annex Form) no more than twice a year without changing the version, only changing the date. - Supersede the old version to make it easier to manage the old SOPs. - Added definitions of “Controlled Documents” and “Procedures” standard" - Change the format of the history recording to be more concise. and easy to print	Prof. Dr. Thadasiblinwong Chairman of the Board Foundation Management

Producer	Version Approval Date		Show main edits	Approved by
			- Added SOPs templates - Adjust the Annex format to be easy to use so that staff can print it out for use by adjusting the new header format.	
Subcommittee Development Method of operation standard	Issue 6 v.5.0	October 31 2566	- Adjust the number of SOPs development subcommittees from Originally at least 7 people, now at least 5 people. - Added a process for handling documents in case of document corrections. Appendix - Added management of old SOPs documents	Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management
Subcommittee Development Method of operation standard	Issue 7 v.5.1	24 July 2567	- Changed from v.5.0 to v.5.1	Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management

Structure of the Central Committee for Consideration of Human Research Ethics

Constituting the Central Research Ethics Committee

Issue that 5.1 Effective date: 24 July 2024

replaces the previous issue 5.0 Dated October 31, 2023

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Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

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1. Objectives

The Central Research Ethics Committee (CREC) or abbreviated as “Central Committee”, “Committee” or “CREC” is a committee established with the objectives to consider multi-institutional research projects or other research projects that are under its scope of responsibility to be efficient and transparent, to protect the rights, safety, and well-being of volunteers participating in research, and to make the consideration of research proposals fast, not repetitive, and wasteful of resources as specified in the “Memorandum of Understanding” of partner institutions, including developing the potential of the process of considering human research ethics to be of international standards, accepted by various agencies both domestically and internationally. This standard procedure shows the acquisition, appointment, roles,

and duties of and the responsibility of Central Committee

2. Scope

The Central Committee has the scope of reviewing research projects submitted for research ethics approval and overseeing research projects that have been approved throughout the research period, covering research projects that meet one of the following criteria:

2.1 It is a pharmaceutical-sponsored multicenter clinical trial.
multi-center clinical trial)

2.2 It is a multicenter study project of researchers who plan/apply/receive funding from the government sector, such as the National Research Council of Thailand (NRCT), the Health Promotion Foundation (ThaiHealth), the Health Systems Research Institute (HSRI), professional associations, royal colleges, foundations, etc.

2.3 It is a single center, multi-sites study of researchers at partner institutions with co-researchers from each site. 2.4 A research project assigned to be considered by the Foundation's Executive Board.

3. Responsibility

3.1 The Central Committee has duties to operate within the specified scope by coordinating with the principal investigators, research funders, and research ethics committees of partner institutions to ensure the operation. Complies with Standard Operating Procedures (SOPs) and Good Clinical Practice (GCP) Guidelines

3.2 The research ethics committee of the partner institution has the duty to (a) establish standard operating procedures for (a) Coordinate with CREC in case it is a site in the research project and in related matters; (c) Provide cooperation.

Propose the names of the selection subcommittee members and the names of those who are suitable to be the central committee members upon request.

3.3 The Foundation's Executive Committee has the duty to select and appoint the Selection Subcommittee and The Central Committee in accordance with the Foundation's practices

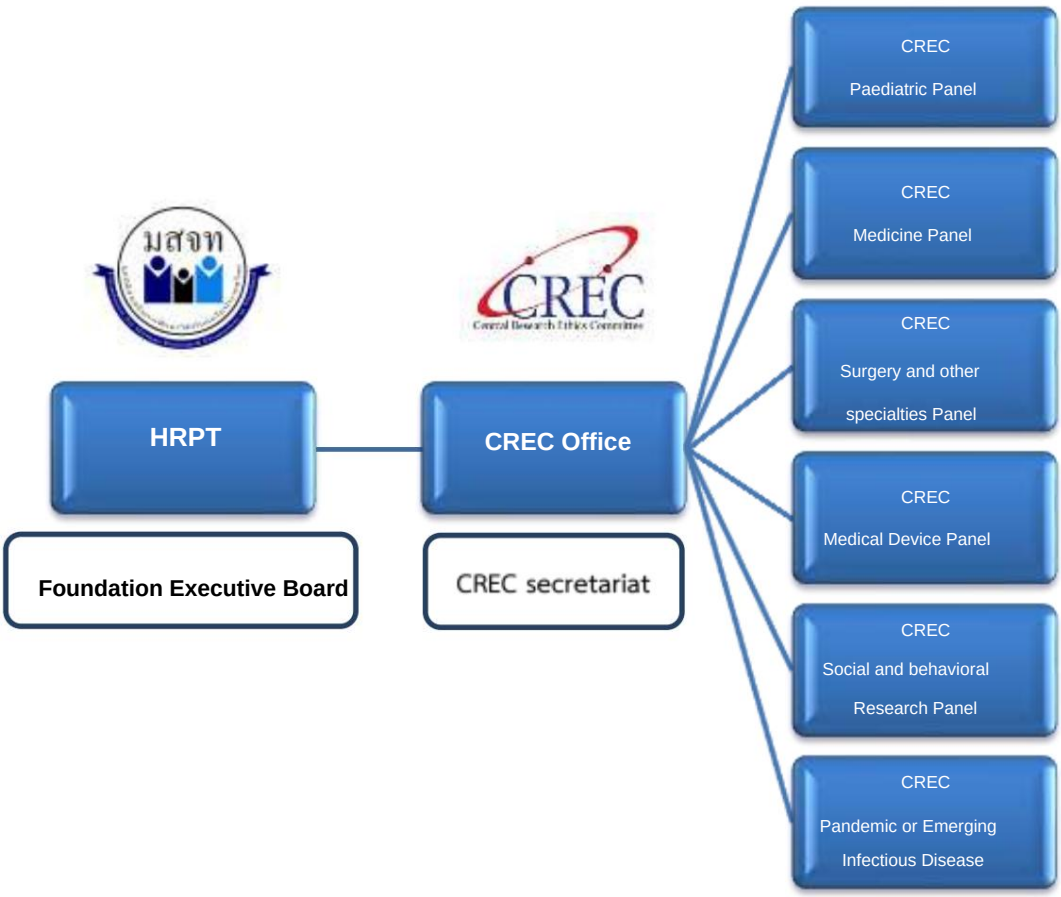
3.4 The Foundation for the Promotion of Human Research in Thailand (FHRCT) has a duty to support the work of The Central Committee shall comply with the project proposed to the National Research Council of Thailand (NRCT) in order to: The consideration of research proposals and other related works of the Central Committee Be free

4. Procedure flow chart

Sequence	Operation	responsible person
1	Appoint a subcommittee for selecting the Central Committee ÿ	Foundation Executive Board
2	Recruitment of the Central Committee ÿ	Selection Subcommittee
3	Select and appoint the Central Committee ÿ	Selection Subcommittee
4	Roles and duties of the Central Committee ÿ	Central Committee
5	Additional committee ÿ	Partner institutions
6	Resignation, dismissal from office and replacement appointment ÿ	Central Committee

Sequence	Post-appointment	responsible person
7	**actions** ÿ	Central Committee
8	Office of the Central Committee ÿ	Foundation Executive Board
9	Head of Office and Staff	NRCT/Executive Committee Foundation

Office administration chart



5. Procedure 5.1

Appointment of the selection subcommittee for the Central Committee for Consideration of Human Research Ethics

5.1.1 The Foundation shall write to partner institutions requesting them to nominate (a) a number of representatives to be on the Selection Sub-Committee and (b) a number of institute ethics committee members with appropriate qualifications to serve as the Central Committee. 5.1.2 The Foundation's Executive Board shall select 15 nominees from partner institutions to be on the Selection Sub-Committee, of which at least half shall be from the ethics committees of partner institutions that have been recognized by SIDCER FERCAP.

5.1.3 The Chairman of the Foundation's Executive Board signs the appointment of the selection subcommittee. **5.2 Selection and appointment of the Central Committee for Human Research Ethics (CREC)**

5.2.1 The Selection Subcommittee shall determine the structure and duties of the Central Committee at each meeting as follows:

5.2.1.1 The Central Committee shall consist of at least two panels: (a) a biomedical research panel and (b) a social/behavioral research panel. Each panel shall consist of a Chairperson of the Central Committee (“Chairperson”), a Vice-Chairperson of the Central Committee (“Vocational Panel”), and a Member of the Committee. (“Vice-Chairman”), Secretary of the Central Committee (“Secretary”), Assistant Secretary of the Central Committee (“Assistant Secretary”) and members of the committee. Central (“Committee”)

5.2.1.2 The Biomedical Committee shall consist of at least 7 members from both the science and non-science fields. Of these members,

have

- At least 3 people are doctors.

- At least 1 person is a pharmacist or a person with knowledge in pharmacology - At least 1 person is a layperson member - At least 1 person is a non-affiliated member

5.2.1.3 The biomedical committee may be subdivided into (1) pediatrics, (2) internal medicine, (3) other biomedicine, (4) medical device, and (5) epidemic or emerging infectious disease. At least two of the pediatricians shall be members of the committee.

- The medical team members must be at least 2 medical doctors. - The medical equipment team members must have at least 1 person with qualifications and experience in engineering related to medical devices. Health professionals who are frequently considered for medical devices, such as dentists, doctors.
At least 1 medical technologist, physical therapist, and radiological technologist

5.2.1.4 The Social Science/Behavioral Science Committee consists of the following members:
In the field of science and outside the field of science, a total of at least 7 people, of which there must be - at least 1 person who is an expert in the field of social science/behavioral science/humanity - at least 1 person who is a doctor or in a profession related to science.
Health -
At least 1 person who is a general public person, villager, community representative or Layperson member - At least one person with legal qualifications - At least one person who is not affiliated with a partner institution (non-affiliated member)

5.2.1.5 Each committee member may have more than one qualification.

5.2.1.6 The committee member should come from the ethics committee of the partner institution that has been approved. SIDCER-FERCAP certified, except layperson members, non-affiliated members and persons with qualifications and experience in engineering related to medical devices.

5.2.1.7 The committee must have a diverse and up-to-date knowledge base, at least in the following matters:

- CREC standard procedures - Good clinical practice (ICH Good Clinical Practice) (ICH GCP) - International Ethical Guidelines for Human Research Guidelines)

- Ethical issues in research that are of public interest - Regulations, rules and laws related to human research - Inspection process to ensure the quality of work performance 5.2.1.8 The committee must consist of both males and females. 5.2.1.9 The committee should consist of a diverse age group. 5.2.2 The selection subcommittee organizes a meeting to select candidates for the position of the central committee. The meeting must have at least half of the total number of subcommittees present to constitute a quorum. The subcommittees attending the meeting shall select the chairperson and secretary of the meeting. Subcommittees who are unable to attend the meeting due to other commitments may provide written comments but have no right to vote. 5.2.3 In the event that the list of candidates proposed by partner institutions exceeds the number o

To vote for each position, the secretary shall prepare a voting document and distribute it to each member of the selection subcommittee to vote. It must contain at least the following information: - Name of the nominated person - Nominated partner institution

- Panel - Voting: Agree/ Disagree/Abstain

- Names of voters: Then,

the secretary will summarize the names of those who are suitable to hold the position of the Central Committee, ranked from the highest score down, and include them according to the number of positions of the Central Committee in each group. 5.2.4 In the case that the list of names proposed by partner institutions to be the Central Committee is not complete in the required number, the selection subcommittee will propose additional names and contact them at the meeting or determine the additional selection process according to the resolution of the meeting.

5.2.5 When the list of the Central Committee members has been obtained, the Selection Subcommittee shall propose the names of each committee and determine the person who is suitable to hold the position of Chairman of each Central Committee to the Foundation's Executive Board,

taking into account the qualifications of the person who is suitable to hold the position of Chairman of the Central Committee, as follows: 5.2.5.1 Person who is or has been Chairman of the Research Ethics Committee of the institution. Certified by SIDCER-FERCAP and/or

5.2.5.2 Persons who have experience in holding the position of Chairman of the Ethics Committee of Institute not less than 3 years

5.2.6 The Foundation coordinates with the appointed Chairman of the Central Committee to propose the names of directors who are suitable to hold the positions of Vice Chairman, Secretary and Assistant Secretary or can propose additional names from qualified persons who are suitable and then submit them to the Chairman of the Foundation Executive Committee to issue a letter of appointment.

5.3 Powers and duties of the Central Committee

5.3.1 The Central Committee may approve or disapprove a research project applying for consideration, or temporarily suspend approval, or terminate approval of an approved research project if it is found to have a serious adverse effect on the rights, safety, and well-being of research participants. 5.3.2 The Chairman of the Central Committee

has the following duties: 5.3.2.1 Facilitate the meetings of

the Central Committee to ensure that they proceed smoothly and efficiently.

efficiency

5.3.2.2 Conduct meetings in accordance with the rules, regulations and guidelines specified in the standard operating

procedures. 5.3.2.3 Present and summarize the voting results at the end of the discussion of the research outline and related documents.

5.3.2.4 Follow up on the actions of the office staff to ensure that the recording of meeting resolutions and communication with researchers is correct, in writing, and signed by the chairman of the central committee or the person designated by the chairman.

The Central Committee has assigned

5.3.2.5 Assign committee members to review the research outline as proposed by the Secretary or change it as appropriate. 5.3.3 The Vice Chairman of the Central Committee has the following duties: Chair the meeting in the event that the Chairman of the Central Committee is unable to: Able to attend meetings and perform other duties as assigned by the Chairman of the Central Committee. Has the following duties: 5.3.4 Secretary of the Central Committee 5.3.4.1 Manage the operations of the Central Committee to be efficient.

Completed according to standard procedures

5.3.4.2 Consider accepting or not accepting the research project by discussing with the committee chairman.

In the middle, if there are any doubts

5.3.4.3 Propose the names of the committee members to the Chairman of the Central Committee for assignment of duties.

Be a reviewer of the research outline

5.3.4.4 Review the following items and provide comments to the Chairman of the Central Committee or the meeting for decision: - Minor research proposal amendments (CREC 09) - Continuous review of research that is eligible for urgent consideration as announced.

Central Committee (CREC 10)

- Non-local SAE/SUSAR, periodic SUSAR and IDMC letter reports

(CREC 11)

- Research Termination Report (CREC 12) - Report on premature termination of research projects/research suspension that falls under the category of

Urgent Consideration (CREC 13)

- Reports of non-compliance/deviation (CREC 14) - Complaints (CREC 15) - Research proposals that are exempt from consideration (Exemption)

(CRE 21)

5.3.4.5 Arrange a meeting of the Central Committee.

5.3.4.6 Check the accuracy of the documents prepared by the office staff.

Conducting a meeting

5.3.4.7 Meeting minutes or supervise the recording of meeting minutes by the staff.
Office

5.3.4.8 Provide advice and supervise the operations of the office to ensure efficiency. 5.3.5 The Assistant Secretary of the Central Committee has the following duties: Assist the
work of the Secretary of the Central Committee as assigned or act on behalf of the Secretary of the Central Committee in the event that the Secretary of the Central Committee is unable to perform his duties.

5.3.6 The Central Committee has the following duties:

5.3.6.1 Participate in the meeting of the Central Committee

5.3.6.2 Review, consider, discuss and vote on the results of the consideration of the research outline 5.3.6.3 Maintain the confidentiality of the research project documents, related documents and
Consider and decide at the meeting

5.3.6.4 Inform the Chairman of the Central Committee if there is a conflict of interest (conflict of interest) on any agenda of the meeting

5.4 Appointment of the Central Committee to consider human research ethics and its work schedule

5.4.1 The Foundation's Executive Board considers and approves the names and appoints the Central Committee, whose term of office is 3 years. 5.4.2 When the term is complete, proceed according to Section 5.2. 5.4.3 When the term is complete, if a new Central Committee has not been appointed, the Central Committee whose term has expired shall remain in office to continue its work until a newly appointed Central Committee member assumes the duties of a member.

Can hold office for multiple terms

5.5 Alternative member

5.5.1 The additional committee members shall be appointed by the Foundation President
by 5.5.1.1 appointing from the list of research ethics committee members from partner institutions that have been approved.

5.5.1.2 In case of necessity, may select from an institution that has been certified by SIDCER/FERCAP as an additional committee member.
SIDCER/FERCAP but not in a partner institution, the reasons for this must be stated in the meeting report.

5.5.2 Additional committee members assigned by the Chairman of the Central Committee to attend meetings in place of committee members who are unable to attend meetings and must have qualifications and experience similar to the committee member they are replacing.

5.5.3 Additional committee members assigned by the Chairman of the Central Committee to attend meetings as above shall have the same powers and duties as the Central Committee. In considering projects at the meeting, the committee members with the right to vote are the Central Committee members and the additional committee members who review

the matter. 5.5.4 Central Committee members in other groups may be invited to participate as additional committee members.

5.6 Independent consultant in considering research projects in

cases where the Central Committee does not have an expert in the field

The Committee may consider appointing an independent consultant to review the project as follows: 5.6.1

The Secretary of the Central Committee shall propose a list of experts to review and provide academic opinions related to the research project.

5.6.2 The Chairman of the Central Committee shall write to the experts to review the research project in the capacity of an independent consultant.

5.6.3 The independent consultant shall not have any conflict of interest in the research project.

5.6.4 The independent consultant shall not participate in voting in the committee meeting.

5.7 Resignation, termination from office and appointment of replacement directors

5.7.1 A member of the Central Committee who wishes to resign before the end of his/her term of office must submit a resignation letter to the Chairman of the Central Committee and receive approval from the Chairman.

Central Committee

5.7.2 In addition to vacating the position according to the term, the Central Committee member shall vacate the position when:

5.7.2.1 Death

5.7.2.2 Resignation

5.7.2.3. Has been sentenced to imprisonment by a final judgment, except for an offence committed through negligence or a minor offence. 5.7.2.4. Has become

bankrupt. 5.7.2.5. Has become

incompetent or quasi-incompetent.

5.7.2.6 There is a serious deficiency in the performance of duties or there is serious misconduct and half of the Central Committee members agree to dismiss him from his position. 5.7.2.7 The Central Committee members who must attend Central Committee meetings have attended less than half of the total number of meetings throughout the year.

5.7.3 In the event that a member of the Central Committee resigns or is removed from office before the end of his term, the Chairman The Central Committee inquires for suitable names from the Central Committee and proposes names of those with suitable qualifications for the Chairman of the Foundation's Executive Committee to appoint to replace the directors who resign or leave their positions. The persons appointed to fill vacant positions will serve in the positions for the remaining term of the directors who were previously appointed.

5.7.4 In the event that the Chairman of the Central Committee resigns, the Vice Chairman of the Central Committee shall resign. Acting as the acting director and have the meeting propose the names of the remaining members of the Central Committee to hold the position instead/or propose the names of external persons to fill the vacant position.

5.8 After appointment

5.8.1 The Office staff shall request a biography from each member of the Central Committee, Alternate Member or Independent Consultant directly or from the Office of the Ethics Committee of the partner institution. The information must be current (not more than 2 years old) and include at least the following information: **-** First and last name in both Thai and English.

- sex

- Workplace or department/affiliation **-**

Qualifications and

professions **-** Experience as an ethics committee member (specify

institution) 5.8.2 The office staff may send the AO01-S02 form to the central committee, alternate members and independent consultants who request to fill in the information. 5.8.3 After receiving the biography, the office staff prepares a list of

the central committee, alternate members and independent consultants.

consultant) and the qualifications of each committee according to form AO02-S02. (CREC membership roster)

5.8.4 The Central Committee, Alternate Members and Independent Consultants must sign the Confidentiality and Disclosure Agreement (AO 01-S03) and the Appointment Order document specifying the terms of reference. 5.8.5 The Central Committee and Alternate Members must undergo training.

SOPs prior to duty and training as deemed appropriate.

5.9 Office of the Central Committee for Human Research Ethics

5.9.1 The Foundation for the Promotion of Human Research in Thailand shall recruit and select office personnel, specify terms of reference, and appoint them.
Head of Office

5.9.2 The Office Chief has the following duties:

5.9.2.1 Inform researchers, research funders and the central committee of the regulations, ethical guidelines, procedures and standard procedures of the research. Central Committee

5.9.2.2 Supervise the website of the Central Committee to be up-to-date and accessible to the general public. 5.9.2.3

Supervise the progress of the review of research proposals and various reports after certification to be in accordance with the specified time frame, including supervising the inspection and preparation of complete documents for the Central Committee to review.

5.9.2.4 Prepare for the meeting of the Central Committee, including sending documents to the reviewing committee, setting the meeting date and supervising to ensure a

quorum. 5.9.2.5 Coordinate with the Chairman of the Central Committee in preparing for the meeting, considering the research outline by the full committee and considering urgent research projects.

5.9.2.6 Coordinate with researchers and/or research project coordinators in various related tasks, including revising the research outline, submitting research reports, making additional edits to the research outline, research progress reports, research result summary reports, etc. 5.9.2.7 Coordinate with the chairman of the central committee in preparing research reports. Meetings and annual reports of the Central Committee (including a summary Income and expenses of the Central Committee)

5.9.2.8 Supervise the collection of research project documents, post-accreditation reports, research outlines, and other related documents, including overseeing the confidentiality of the Central Committee's information.

5.9.2.9 Assist in searching for/collecting research ethics documents and training program information that is useful to the Central Committee. 5.9.2.10 Organize the Central Committee's information system regarding history, ethics training, and conflict of interest disclosure information. 5.9.3 The Office staff has the following duties: 5.9.3.1 Check research project documents and provide information to visitors. 5.9.3.2 Assist the secretary and assistant secretary of the Central Committee in management and coordination with principal investigators, research funders, and partner institutions.

5.9.3.3 Perform operations in accordance with standard operating procedures. 5.9.3.4 Perform other duties in accordance with the employment contract.

5.9.4 The office staff should have knowledge of the following: - CREC standard operating procedures - Good Clinical Practice (ICH GCP) - International Ethical Guidelines for Human Research Guidelines)

- Ethical issues of research in areas of public interest - Regulations, rules and laws related to human research - Inspection process to ensure the quality of work performance

6. Definition

“Committee” or "Central Committee"	The Central Committee on Human Research Ethics (Central The Research Ethics Committee (CREC) is a committee of individuals appointed by the Foundation with the duty to consider research ethics of multi-institutional research projects or other research projects that fall within the scope of responsibility according to the main objectives to protect the rights, safety and well-being of volunteers participating in research and to reduce duplication in Consideration
Foundation Executive Board etc.	The Board of Directors of the Foundation for the Promotion of Human Research in Thailand is a group of individuals representing partner institutions appointed by the Cooperation Meeting. Between partner institutions
Foundation	Foundation for the Promotion of Human Research in Thailand (FHRCT) Foundation for Human Research Promotion in Thailand (HRPT) was established with the objectives to 1. Promote and support human research studies to be accepted both in Country and abroad 2. Support human research studies in accordance with the laws and regulations or international regulations. 3. To be the center of coordination of agencies, organizations and Institutions conducting human research 4. Cooperate with other institutions or organizations for charity or commonwealth 5. Do not engage in any political activities whatsoever. The
Partner institutions	university, department, ministry, hospital or organization that signs the agreement Multi-Institutional Research Ethics Review Cooperation Agreement with the National Research Council of Thailand (NRCT)
Line Committee Science (Scientific	(Biomedical Group) A committee member with core expertise in the field of science, including medicine, health science, physical science, who plays a primary role in the assessment.

member/Expert member)	The scientific side of the project Research (scientific review) For example, doctors, pharmacists, physical therapists, and qualified teachers. Master's/Doctorate degree in Health Sciences, Health Professional Health A member of the medical board may be called a medical member. (Social Science/Behavioral Science Series) Committee members with knowledge and understanding Leading experts in the social sciences and humanities, who play a role Principles of scientific review of research proposals, for example, a professor with a master's/doctorate degree in the field Social Sciences/Humanities
Off-line referee Science (Non-scientific member)	Non-scientific members are members who are not experts in their field. Related to research (Biomedical Group) Board members with core expertise outside their field. Science includes medicine, health science, biological science, and physical science, which play a major role in non-therapeutic Evaluate the academic aspects of the research proposal (scientific review), for example, administrative staff/clerks, librarians, lawyers, researchers Social welfare (Social Science/Behavioral Science Series) Committee members with knowledge and understanding Expertise outside the social sciences and humanities, which has a role Non-academic evaluation principles of research proposals (scientific review) For example, doctors, pharmacists, dentists, nurses, physicists. Architects, engineers, etc.
Layperson member	Layperson is an ordinary person, a villager, who has a basic education. Not necessarily a medical or research specialist, but someone who Can reflect the views of the general public in society for opinions on the matter Related to research and health research

Non-Institutional Board Members (Non-affiliated member)	The Central Committee who attended the meeting to consider the research project and were not present Position of civil servants, employees, or workers of the institute that conducted the research/ Agencies or organizations that support research funding for the research projects under consideration Meeting or not being a member of the board of the Foundation for the Promotion of Human research in Thailand
Social science research/ Behavioral Science (Social/ behavioral research)	A study of the behavior of individuals, groups, communities, organizations or societies with the aim of obtaining facts and theories or interventions that are knowledge and alleviate health problems.
Multi-institutional Research (multicenter trial or research)	Research that is a single research project but is conducted in multiple institutions, at least two institutions, where each main institution has a principal investigator at the institution.
A single-center research project with multiple data collections (single center, multi-sites study)	The research is a single research project with a research project leader affiliated with Single institution but collects data from at least 2 institutions.

7. Appendix

AO 01-S02 CREC membership history form CV form)	
AO 02-S02 List of names and qualifications of the Central Committee (CREC membership roster)	
AO 01-S03 Confidentiality Agreement and Disclosure of Conflicts of Interest	

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

8.3 World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013; 310 (20):2191-4.

8.4 International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva. Council for International Organizations of Medical Sciences (CIOMS); 2016.

8.5 Announcement of the Food and Drug Administration on the criteria, methods and conditions for acceptance Human Research Ethics Committee for the Consideration of Clinical Research Projects on Drugs, announced on 8 August 2013, Government Gazette, Volume 130, Special Issue 135, 14 October 2013. 2013, pages 12-15.

9. History of Standard Procedures,

Step No. 1 **Carry out**	**v.1.0**	**Issue 2** **v.2.0**	**Issue 3** **v.2.1**	**Issue 4** **v.3.0**
Prepared by	Subcommittee for Drafting Standard Procedures	Subcommittee for Development of Standard Operating	Subcommittee for the Development of Standard Operating Procedures,	The Subcommittee for the Development of Standard Operating Procedures has
Reason for improvement		Procedures - To clarify the objectives Scope and Responsible for Central Committee Including partner institutions	revised according to recommendations Of SIDCER/FERCAP (14 March 2015) To provide clarity on the independent operations of Central Committee	revised the guidelines based on recommendations from Partner institutions
details Of the correction	- objective - Scope: Method of operation This standard applies to Operation of Central Committee - responsibility	- Objectives: Increase details - Scope: Specify the characteristics of the research project to be submitted for consideration and increase supervision of the research project after certification. - Responsibilities: Specify the responsibilities of Central Committee Partner institutions and M.S.T. - Added a set of biological committee members Medicine, have a doctor At least 3 people	- Increased responsibility of the Foundation for the Promotion of Human Research in Thailand (FHRCT) - Add reference documents	- Edit number Selection Subcommittee - Adjust the properties of Central Committee To be more specific - add the duties of the deputy Chairman of the Board Central and Head Office - Amend the procedure for appointing the central committee to replace the committee members resign - Adjust the definition of social/behavioral research - Add reference documents
Reviewed by the Central Committee Consider the ethics of Human		Central Committee Consider the ethics of Human	Central Committee Consider the ethics of Human research,	Central Committee Consider the ethics of Human research,
research, **review date,** appointment	date 21 November 2012 to 24 January 2013	research, appointed on 14 June 2014 to 3 July 2014 to 14 May 2015, Assoc. Prof. Dr. Suchart	date of appointment March 14, 2015	date of appointment 16 May 2017 to 30 September 2017
Approved by	Assoc. Prof. Dr. Suchart Areemit	Areemit, Assoc. Prof. Dr. Suchart Areemit		Prof. Dr. Thada Sueblinwong

step Carry out	Issue 1 **v.1.0**	Issue 2 **v.2.0**	Issue 3 v.2.1	Issue 4 **v.3.0**
Position	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management	Chairman of the Board Foundation	Chairman of the Board Foundation Management
Approval	January 25, 2013	July 4, 2014	Administration 28 September 2016	October 1, 2017
Date, Effective Date	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017

History of Standard Operating Procedures (continued)

Producer	Version Approval Date No. 5		Show main edits	Approved by
Subcommittee Development Method of operation standard	v.4.0	June 15 2563	- Added the purpose of this SOPs chapter. - Adjust the scope of consideration for research projects CREC - Organization chart according to the sub-panel of the biology. Medical - Added sub-panel elements - Create a CREC membership roster with topics. standard - Added definitions of scientific member and non- scientific member - Adjust the definition of affiliated member from non-affiliated Partner institutions are not affiliated with any institution. Research projects under review	Prof. Dr. Thada Sueblinwong Chairman of the Board Foundation Management
Subcommittee Development Method of operation standard	Issue 6 v.5.0	October 31 2566	- Added the purpose of this SOP chapter. - Adjust the scope of consideration for research projects CREC - Organization chart according to the sub-panel of the biology. Medical - Add information on the appointment of additional directors - Define the responsibilities, qualifications, training and voting rights of additional directors - Add consultant - Add definition of non science and layperson to be clear	Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management

Producer	**Version Approval Date** No. 7	**Show major edits** - Add	**Approved by**
Subcommittee Development Method of operation standard	v.5.1	24 July 2567	layperson replacement - Add non science definition of non science and layperson to be clear - Add details of the alternative board members member)	Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management

Confidentiality Agreement and Conflict of Interest

Confidentiality Agreement and Conflict of Interest

Issue that 5.1 Effective date: 24 July 2024

replaces the previous issue 5.0 Dated October 31, 2023

Author July 24, 2024

(Colonel Assoc. Prof. Dr. Sahapol Anantanacharoen)

Chairman of the Subcommittee on Standard Procedures Development

Approver July 24, 2024

(Assoc. Prof. Dr. Kwanchanok Yimtae)

Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

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1. Objective

To enable stakeholders to read, understand, accept and sign the data confidentiality document.

Relating to the information in the research outline and to ensure that the consideration of the research outline complies with ethical principles.

Without any conflict of interest of the Central Committee for Human Research Ethics Review

2. Scope

Standard operating procedures cover confidentiality agreements for information and documents related to:

The operations and conflicts of interest of the Central Committee

3. Responsibility

The Foundation's Executive Committee, the Central Committee, the Office staff and all relevant persons

You must read, understand, accept and sign the confidentiality agreement before starting work and accept and

Comply with the guidelines specified in the Standard Operating Procedures to manage conflicts of interest of the Board of Directors.

The Foundation and the Central Committee, Office staff and those involved in the consideration of the research outline

4. Procedure flow chart

Sequence	Operation	responsible person
1	Read the confidentiality agreement/ Conflict of Interest ÿ	Foundation Executive Board Central Committee Office staff and Stakeholders
2	Recognizing the importance of maintaining confidentiality Information/Conflict of Interest ÿ	Foundation Executive Board Central Committee Office staff and Stakeholders
3	Sign the confidentiality agreement/ Conflict of Interest ÿ	Foundation Executive Board Central Committee Office staff and Stakeholders

5. Procedure 5.1

Reading the confidentiality agreement/conflict of interest

The Foundation's Executive Committee, Central Committee, Office staff and related persons must receive a confidentiality agreement and read and understand it before starting work/accessing information.

5.2 Awareness of the importance of maintaining confidentiality of information/conflict of interest

The Foundation's Executive Board, the Central Committee, office staff and relevant parties must be aware of the importance of considering research proposals in which any Central Committee member has a conflict of interest, such as in his or her capacity as a researcher on the same subject or in connection with a research funder. That Central Committee member must disclose such conflict of interest.
Research projects may provide comments to the Central Committee, but must not participate in voting.

The research outline shall include the preservation of confidentiality regarding the information in the research outline, discussions, the results of the Central Committee meeting's voting, and other relevant information.

5.3 Signing of the Data Confidentiality Agreement / Conflict of Interest

The Foundation's Executive Committee, Central Committee, Additional Committees, Office Staff and related persons must sign and specify the date of signing in the Confidentiality Agreement before performing work/or accessing information in the Office. This Agreement shall be kept at the Office.

6. Definition

Confidentiality of information	The obligation to keep information confidential, unless permitted to be disclosed by the owner of the information/person related to the information or in some cases by the relevant officers. Failure to disclose information related to information in research projects, deliberations of the Central Committee meetings, and other relevant information.
Conflict of Interest	Situations in which a person, such as a Central Committee member or an Office officer, has a great deal of personal interest that may induce dishonest performance of duties, causing deviation from the main objectives or duties. Such interest may

	In the form of money, position or profession Conflicts of interest arise when - Personal interests that differ from those specified in the framework of duties - The action or decision is questionable to independent observers. - Conflict depends on the situation and not on specific characteristics or actions. Personally specific - Any potential conflicts of interest must be disclosed and managed accordingly. Regulations of the Central Committee or partner institutions

7. Appendix

AO01-S03	Confidentiality Agreement and Disclosure of Information Conflict of Interest for the Central Board of Directors and Office Staff
AO 02-S03	Confidentiality Agreement and Disclosure of Information Conflicts of Interest for Consultants, Guests, Observers or Visitors

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

9. History of standard operating procedures

step **Carry out**	**Issue 1** **v.1.0**	**Issue 2** **v.2.0**	**Issue 3** **v.2.1**	**Issue 4** **v.3.0**
Prepared by	Drafting Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures
Reason of Improvement		For convenience Performing work of Central Committee and office staff	Make it into one version The whole book	The same
details Of the correction		Adjust the agreement book Keep the secret of Information and disclosure Conflict of Interest Keep it short and concise. And it is divided into 2 forms.	- Changed from v.2.0 It is v.2.1. - Add reference documents	- Changed from v.2.1 to in 3.0 - Add reference documents
Reviewed by the Central Committee	Consider the ethics of Human research	Central Committee Consider the ethics of Human research	Central Committee Consider the ethics of Human research	Central Committee Consider the ethics of Human research
Review Date Appointment Date	21 November 2012 Until 24 January 2013	Appoint date June 14, 2014 to July 3, 2014	Appoint date March 14, 2015 Until May 14, 2015	Appoint date May 16, 2017 Until 30 September 2017
Approved	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit	Prof. Dr. Thada Sueblinwong
by Position	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management	Chairman of the Board Foundation	Chairman of the Board Foundation Management
Approval	January 25, 2013	July 4, 2014	Administration 28 September 2016	October 1, 2017
Date, Effective Date	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017

History of Standard Operating Procedures (continued)

Creator	Version	Approval Date	Show main edits	Approved
Subcommittee on Development Method of operation standard	Edition No. 5 v.4.0	June 15 2563	Added definition of data confidentiality new Adjust the content and language of the confidentiality agreement (AO 01, 02)	**by** Prof. Dr. Thada Sueblinwong Chairman of the Board Foundation
Subcommittee on Development Method of operation standard	Issue 6 v.5.0	October 31 2566	Add English form (AO 01, 02) and cut out the witness part	Management, Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation
Subcommittee on Development Method of operation standard	Issue 7 v.5.1	24 July 2567	Changed from v.5.0 to v.5.1	Management, Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management

Management of research proposals submitted for initial consideration

Management of Initial Protocol Submission

Issue that 5.1 Effective date: 24 July 2024

replaces the previous issue 5.0 Dated October 31, 2023

Author July 24, 2024

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Chairman of the Subcommittee on Standard Procedures Development

Approver July 24, 2024

(Assoc. Prof. Dr. Kwanchanok Yimtae)

Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

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1. **Objective:** To

serve as a guideline for the committee and office staff in managing research projects.

Submitted for the committee's first consideration

2. Scope

Standard operating procedures cover the management of research proposals and related documents submitted for initial consideration, from the receipt of research project documents to pre-consideration review at the meeting. Committee

3. Responsibility

The various steps of managing a research project submitted for consideration are the responsibility of: follows: Office staff and the Central Committee 3.1 The responsibility is divided as

Office staff receive research project documents, check their completeness and correctness, and assign codes. Research Project, send a letter to notify the receipt of documents and project code, separate the types of research projects.

Write a letter to inform the research results and store research project documents and record data in electronic format.

3.2 The Secretary of the Central Committee determines the method of considering research projects and the Central Committee is responsible for reviewing the

research outline. 3.3 The Central Committee reviews the research outline and returns the review results to the Office within the specified time.

Set

3.4 The Chairman of the Central Committee conducts the committee meeting and signs the notification document. Review and certification

4. Step chart

Sequence	Operation	responsible person
1	Verify completeness and accept documents ÿ	Office staff
2	Sort research projects by type ÿ	Office staff
3	Select review channels and select reviewers ÿ	Each set of secretaries
4	Specify research project code ÿ	Office staff
5	Request for documents assessing the readiness of the institution ÿ	Office staff
6	Submit research project documents to the primary reviewer ÿ	Office staff
7	Review the research project ÿ	Principal Review Committee
8	Receive the review results from the reviewing committee. Submit to Secretary and Chairman ÿ	Office staff
9	Notification of consideration results ÿ	Office staff
10	Research Project Archiving	Office staff

5. Procedures

5.1 Checking the completeness and acceptance of documents

5.1.1 The principal investigator or research project coordinator shall submit the research project documents to the Office staff by filling in the information in the system and attaching the electronic file to the CREC online submission system to request the first ethical review in the case that

If necessary, the office may request a document file as appropriate, according to the number requested by the office on a case-by-case basis, and fill in the information in the system along with attaching the file. Electronic entry into CREC's on-line submission system

5.1.2 The office staff shall check the completeness of the research project documents within the date of receipt. Documents according to the checklist form (AO 01-S04) (or AO 02-S04 in the case of other institute ethics committees that have been cancelled and have a document transfer agreement)

5.1.2.1 If the research outline documents are complete, the office officer

(1) Record the receipt of documents in the document receiving system, indicating the date the documents were received and the date the documents were complete on the first page of the delivery letter cover page. document

(2) The online submission system will accept documents through the system to Researchers and research project coordinators (3) determine the date of the meeting according to the schedule announced in advance on the website.

5.1.2.2 If the documents are incomplete, the office staff will contact the principal researcher/research project coordinator to request the required documents in order to prepare complete documents.

5.2 Classification of research outlines

5.2.1 The office staff separates the research proposals into categories, namely (1) biomedical research projects in pediatrics, (2) biomedical research projects in internal medicine, (3) biomedical research projects in medical equipment, (4) biomedical research projects in surgery, and others, (5) biomedical research projects in epidemics or emerging infectious diseases, and (6) social/behavioral science research projects, and forward them to the secretaries of each committee for action.

5.2.2 In the case of overlapping research projects and uncertainty about which group to consider, consult with the secretary of one of the groups concerned, with the following basic principles: - Research projects that are specifically related to children will be considered in the Pediatrics group, but if they are related to adults and children aged 15 years and over, they may be considered in the Internal Medicine group. Consideration will be made on a case-by-case basis

- Research projects involving both medical devices and drugs should take into account primary Outcome of the research outline, such as:

o The study of drug-eluting stents has the main objective of dilating blood vessels and should be considered in the medical kit, but invite the committee that is a physician or Pharmacists participate in the consideration

o The study of the effect of using a new insulin injection pen has the main objective of studying the mechanism of action of the drug, so it should be considered in the internal medicine set. However, the research outline must include details of the characteristics and use of the syringe pen for consideration.

5.3 Selection of the research project review channels and reviewers 5.3.1 The research project proposal office staff and the committee's membership roster Set to be considered (AL 02-S02) to the Secretary

5.3.2 The secretary shall assign the research to be submitted through the expedited review channel (CREC 06), to be considered at the meeting (CREC 05), or exempted from consideration (CREC 21). 5.3.3 In the case of expedited review, the secretary shall select at least 2 committee members to review according to the guidelines in CREC 06. These members may be all scientific members or 1 layperson member. In cases where layperson members are required, the secretary shall select layperson members depending on the nature of the research project and propose the names to the chairman for assignment. 5.3.4 In the case of consideration at the meeting, the secretary shall select 3 central committee members as primary reviewers (2 scientific members, 1 layperson).

layperson member) and coordinate in attending the meeting as pre-determined on website

5.3.4.1 In the event that the Central Committee is unable to attend the meeting or does not have expertise In line with the research topic, select from the additional committee.

5.3.4.2 Consideration in the meeting of the directors who have the right to vote are the main directors and The review committee can invite committee members from other committees that are related. Experts can participate in the consideration and have the right to vote (in the case of being an observer) The meeting can provide comments on the project when the chairman asks for comments, but (Cannot vote)

5.3.5 In the case that the project falls under exemption, the secretary shall review the research project and provide opinions. To the Chairman, according to CREC 21

note: The entire process is completed within 5 working days after receiving the documents. completely

5.4 Research project code determination

Research projects that have been verified to have complete documentation must be coded within 1 day.

The project consists of the following sequence and types of research projects:

5.4.1 Research project ranking system 5.4.1.1 Use 3 digits for the research outline number, starting at number CREC001

5.4.1.2 The research outline for the year 2014 is written as /57 after the research outline number. The first research project of 2014 was CREC001/57.

5.4.2 Research funding source system/number of research institutes/type of research (Table 1)

Table 1. Research project document coding assignment

	By funding source
BP	Pharmaceutical company research projects
BR	Research projects funded by government agencies, foundations, or others.
BT	Research projects funded by other sources

By research type	
SBR Social and Behavioral Science Research Project	
PED Biomedical Research Project, Pediatrics Branch	
MED Biomedical Research Project, Department of Internal Medicine	
MDV Medical devices research project Biomedical research project	
BIO	Other fields Biomedical research project
EID	in the field of epidemics or emerging infectious diseases

example

- CREC005/65 BP-PED1 means the 5th biomedical research proposal of the year 2022 from a multi-center pharmaceutical company, which is the 1st project in the field of Pediatrics. - CREC 007/65 BR-BIO5 means the 7th biomedical research proposal of the year 2022 funded by a central government agency, which is the 5th project in other biomedical fields. - CREC 020/55 BR-SBR12 means the 20th social and behavioral science research proposal of the year 2022 funded by a government agency, which is the 12th project in the field of Social and Behavioral Science.

5.5 Procedure for requesting documents to assess the readiness of the institution (local issues) that conducts research in Proposed Project

5.5.1 In case the research institute is a partner institute, the office officer shall send a letter with documents assessing the readiness of the institute (local issues) (AP 01-S04) to the coordinator of the institute in the form of paper or electronically and/or according to the requirements of each institute for the institute to complete the information and return it to the office electronically. The institute must send the local issues to the Central Committee Office within 10 working days or 1 day before the meeting with the agenda to consider the project. 5.5.2 In case the research institute participating in the multi-institutional research project is not a partner institute, it must have the potential certification from the Foundation Executive Committee (CREC 20) and have an agreement to accept the Central Committee to consider the research ethics to consider the signed research proposal (AP 01-S20) before issuing the research certificate.

5.6 Submission of research project documents to the primary

reviewer 5.6.1 The assigned reviewer will receive an email notifying them of their assignment to review the research project.

The research draft from the CREC automated system along with the username and password to read the project online. However, if the reviewers request the research project file, the office will send it on a case-by-case basis. The project must be sent to the reviewers at least 5 working days before the meeting.

5.6.2 Reviewers will be able to enter their evaluation comments in the CREC online system or complete the evaluation form as follows:

5.6.2.1 Scientific members include:

(1) The form for reviewing and presenting the research proposal at the meeting for biomedical research (AO 01-S05) or social science/

Behavioral Science (AO 02-S05)

(2) Review and submission of consent documents

(AO 03-S05)

5.6.2.2 The committee members are ordinary people, villagers, community representatives, or volunteer representatives (layperson members), including:

(1) Review and submission form for consent documents

(AO 03-S05)

(2) Guidelines for reviewing and presenting information disclosure documents to volunteers in human genetics research projects (AO 04-S05)

(3) Guidelines for the secondary research review of personally identifiable personal data or biological material (AO 05-S05)

5.7 Meeting invitation

The office staff organizes the meeting by

5.7.1 sending a meeting invitation letter (AL01-S04) together with the meeting agenda (AO 01-S16) to All directors at least 3 working days before the meeting date

5.7.2 Provide username and password to all committee members to access the research project and committee comments in the CREC online system.

5.8 Receiving the results of the research project review from the committee

5.8.1 The office staff checks the results of the research proposal review entered in the system or receives a copy of the completed review form from the main reviewer and other reviewers (if any). 5.8.2 The staff

records the review results/comments in the meeting minutes form.

(AO 02-S16) and prepared to bring it in for further amendments at the meeting.

5.9 Notification of the results of the consideration to the principal investigator or research project coordinator and the institute/partner institute 5.9.1 Notification of the results document

5.9.1.1 When the decision result is

Approved (1) The office officer stamps a rubber stamp/electronic seal with the name CREC and the date of approval (the date the full committee voted to approve) on the document as follows:

- Research outline and certified documents, stamped, first page

Of documents

- Informed consent form (participant information sheet and consent form) and documents for volunteers, stamped on every page (2) Office staff prepare a letter to present to the

chairman for signature.

- In case of certification by the meeting: Notification of decision and list of the participating committee members (membership roster) (AL 03-S16), certificate in Thai (AL 04-S04) and English.

(AL 05-S04) separated by research institute

- In case of expedited certification: Notification of decision (AL06-04), certificate in Thai (AL 07-S04) and English.

(AL 08-S04) separated by research institute

- Attach the cooperation guidelines (AL 01-S18) with the certification letter sent to the Research Ethics Committee of each institution.

of

5.9.1.2 When the decision is to **revise and approve,** the office officer prepares a letter informing the consideration result (AL09-S04) which includes the consideration result, the consideration date, and the recommendations of the committee, signed by the committee chairman, and sends the explanatory table, adjusts the new research proposal and related documents (AP 03-S04). 5.9.1.3 When the consideration result of the research proposal is **to revise and submit for reconsideration** or **revise for consideration (in the case of urgent consideration),** the office officer prepares a letter informing the consideration result (AL 10-S04) which includes the consideration result, the consideration date, and Recommendations of the Committee, signed by the Chairman of the Committee

5.9.1.4 When the decision is **not accepted** The Office staff shall prepare a letter notifying the consideration result (AL 11-S04) which shall consist of the consideration result, consideration date, reasons for disapproval, and shall contain the statement “You may appeal the consideration result of the Committee by stating your intention and reasons for disapproval to the Committee Chair in writing within 90 calendar days from the date you receive the notice of consideration result”, signed by the Committee Chair.

5.9.1.5 In the event that the research proposal is exempted (exemption), a letter notifying the consideration result shall be sent along with a certificate of exemption in Thai. (AL 12-S04) and Thai version (Al 13-S04)

5.9.2 Method of notification of results

The office staff will inform the results via electronic system to the principal investigator or research project coordinator and the research institute.

5.9.3 Notification period The office officer will send the notification documents within 5 working days after the Meeting/ After the secretary summarizes and the chairman signs

5.9.4 Determination of the date of issuance of the research proposal certificate

5.9.4.1 The first research proposal considered

(1) Consideration by expedited method o

In case of certification: The date on which the reviewing committee members approve shall be the date of approval for all

members. (2) Consideration at the meeting

o In case of approval at the meeting: Use the meeting date as the approval date. o

In case of approval after amendment: Use the date on which the reviewing committee approves as the date of complete approval by all

members. **5.9.4.2 For the part about additional amendments to the research outline that are slightly revised and considered by the secretary or committee member assigned by the secretary, use** the date on which the secretary or committee member assigned by the secretary decides to approve as the date guarantee

5.9.4.3 Renewal of certificate shall use the criteria according to SOPs, Chapter CREC 10 (1). If

the requested documents are received within 1 month before expiration, the renewal date shall be from the expiration date of the certificate (in the case of attending a meeting) or the date on which the chairman signs the acknowledgement (in the case of urgent consideration).

(2) If the application document is received more than 1 month before its expiration date, the certification date shall be the date on which the meeting acknowledges it (in the case of attending the meeting) or the date on which the chairman signs the acknowledgement (in the case of urgent consideration).

5.10 Issuance of a certificate in the event that the institution sends local issues after the 5.10.1 Committee meeting. The office proposes that the chairman signs the certificate, stating the effective date as the same day as the chairman signs. The expiration date is the same as the certificate issued to other institutions previously.

5.10.2 Resulting in accordance with Section 5.9.2

5.11 Implementation of research projects revised and submitted by researchers. See SOPs in Chapter CREC 08.

5.12 Research project storage

5.12.1 At the end of the meeting, the office staff will collect the research project and related documents in electronic file format in the system.

5.12.2 Office staff collect research projects and related documents into files/files.

Electronic research outline

5.12.3 Office staff collects certificates and notifications of consideration results in files/

Electronic files of research outlines separated by document type

5.12.4 The office staff shall collect evidence of data transmission via electronic systems and

Other contacts with the researcher are kept in the research outline file/electronic file.

5.12.5 The office staff shall record the research project data in the database system.

Office

5.13 Management of consideration of research proposals in urgent and important cases

In an unusual situation such as an epidemic or disaster, it is necessary to shorten the time period.

Managing each step as much as possible by the office staff coordinating with the secretary and the person

Closely coordinate research and notify the committee in advance to be available to review the proposal.

Expected research submissions

6. Definition

- do not have -

7. Appendix

AL

AL 01-S04	Invitation letter to the
AL 02-S04	meeting, list of the central committee members who review the research outline
AL 03-S04	Notification of results and list of the Central Committee members
AL 04-S04	Thai language certificate
AL 05-S04	Certificate of Approval, COA
AL 06-S04	Notification of certification by expedited review method
AL 07-S04	Thai language certificate (expedited approval)

AL 08-S04	Certificate of Approval, COA (expedited approval)
AL 09-S04	Notification of amendment for certification
AL 10-S04	Notification of amendment for reconsideration
AL 11-S04	Notification letter, not certified

TO THE

AO 01-S04	Research Proposal Completeness Check Form
AO 02-S04	Completeness check form for research proposals transferred from IHRP

AP

AP 01-S04	Institutional readiness assessment documents (local issues) from the institution Conduct research
AP 02-S04	Institutional readiness assessment documents (local issues) from the institution Conduct clinical trial phase I, II research
AP 03-S04	Table explaining the revision of the research outline
AP 04-S04	Proposal form for ethical consideration of human research for Biomedical Research Project
AP 05-S04	Proposal form for ethical consideration of human research for Social/Behavioral Science Research Project
AP 06-S04	Form of Conflict of Interest

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011

9. History of Standard Procedures,

Step No. 1 **Carry out**	**v.1.0**	**Issue 2** **v.2.0**	**Issue 3** **v.2.1**	**Issue 4** **v.3.0**
Prepared by	Subcommittee on Drafting Procedures standard	Subcommittee for Development of Procedures Standards	Subcommittee for Development of Standard Operating Procedures	Subcommittee for Development of Standard Operating Procedures
Reason for improvement		for convenience Performing work of Central Committee and office staff	- According to the suggestion of SIDCER-FERCAP - To facilitate the operation of Central Committee and office staff	The same
details Of the correction		- Adjust the researcher's documents Submit to the committee Middle - Adjusted the method of providing codes Research Outline - Specify details of the notification method. The research results are clear.	- Adjustment of Section 5.10 Consider the outline Research at the Full board meeting by adding Consider the outline Research in case of documents Some institutions are incomplete. Central Committee Only institutions that have will be considered for certification. Complete documents - Add reference documents	- Changed from v.2.1 to in 3.0 - Add more details Sending a response form Proceed according to Standard operating procedures (AL11) - Add reference documents
Reviewed by the Central Committee	Consider the ethics of Human research	Central Committee Consider the ethics of Human research,	Central Committee Consider research ethics In	Central Committee Consider the ethics of Human research,
Review Date Appointment Date	21 November 2012 to 24 January 2013	date of appointment June 14, 2014 to July 3, 2014 to May 14, 2015 Assoc. Prof. Dr. Suchart Areemit Assoc.	person, appointed date March 14, 2015	date of appointment 16 May 2017 to 30 September 2017
Approved	Prof. Dr. Suchart Areemit Assoc.	Prof. Dr. Suchart Areemit		Prof. Dr. Thada Sueblinwong
by Position	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management

step Carry out	Issue 1 **v.1.0**	Issue 2 **v.2.0**	Issue 3 **v.2.1**	Issue 4 **v.3.0**
Approval	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017
Date, Effective Date	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017

History of Standard Operating Procedures (continued)

Creator	Version Approval Date		Show main edits	Approved by
Subcommittee Develop procedures standard	Edition No. 5 v.4.0	June 15 2563	*From the inspection* - Added Local issue documents for phase I & II study - Added date stamp to complete documents - Change ICF reviewers to non-committees physician - Adjust the time period for officials to submit the outline Research revised to certify the Central Committee from 1 working day to 3 working days. - Cut off the case where the central committee does not send. Additional suggestions in due time are considered That I agree - Added an appendix table explaining the revised framework. New research draft *From the Development Subcommittee* - Move some appendices to other chapters. - Arrange the steps concisely. - Modify or add forms - Request for MOU will be made only when there is Change the chairman of the ethics committee Institutional or executive research institution - Adjust the operating procedures to be consistent With the online submission system of CREC - Increase management of research projects in case of disease Epidemics or disasters that require Urgent	Prof. Dr. Thada Sueblinwong Chairman of the Board Foundation Management

Producer	Version Approval Date No.	Show main edits	Approved by
Subcommittee for Development of Procedures standard	6 October 31 v.5.0 2566	- *Modify the text and operations according to actual practices* - Add an evaluation form according to SIDCER Template	Prof. Dr. Kwanchanok Yimtae chairman Executive Board Prof. Dr.
Subcommittee for Development of Procedures standard	Issue 7 v.5.1 24 July 2567	- Changed from v.5.0 to v.5.1 - Added layperson instead non science	Kwanchanok Yimtae Foundation Chairman of the Board Foundation Management

Review of new research proposals by the full committee
(Full Board Initial Review)

Issue that 5.1 Effective date: 24 July 2024

replaces the previous issue 5.0 Dated October 31, 2023

Author July 24, 2024

(Colonel Assoc. Prof. Dr. Sahapol Anantanacharoen)

Chairman of the Subcommittee on Standard Procedures Development

Approver July 24, 2024

(Assoc. Prof. Dr. Kwanchanok Yimtae)

Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

list of contents

1. Objective : To

serve as a guideline for the Central Committee to consider newly submitted research projects and make decisions at the meeting.

meet

2. Scope

Standard operating procedures cover the review process for all newly submitted research projects for acceptance.

Consideration at the Central Committee meeting

3. Responsibility

3.1 The assigned reviewer shall present a summary of the review results and comments.

3.2 The chairman conducts the meeting in order.

3.3 The committee discusses the results of the research proposal consideration, votes on risk types and frequencies.

of continuous research review

4. Procedure flow chart

Sequence	Operation	responsible person
1	Receive research project documents ÿ	Principal Reviewer
2	Review the research outline ÿ	Principal Reviewer
3	Present and consider the research outline ÿ	Principal Reviewer
4	Judgment ÿ	Board member/Chairman
5	Vote to Decide ÿ	Central Committee
6	Assign a review committee	chairman

5. Procedures

5.1 Receipt of research project documents

5.1.1 The committee member assigned by the Chair to be the primary reviewer receives documents or logs into the online system to view electronic files used in the research project review and checks for accuracy. Complete including:

5.1.1.1 The submission letter specifies the list of documents.

5.1.1.2 The documents specified in the submission letter,

5.1.1.3 the research outline evaluation form, correspond to the set of fields of study being considered.

(1) Scientific member has received AO 01-S05 or AO 02-S05 or AO 02-S07 in conjunction with AO 03-S05 and/or AO 05-S05

(2) Layperson member has received AO 03-S05 and AO 05-S05 (in case of collecting remaining specimens for study or in case of specimens Send for genetic testing)

5.1.2 If incomplete, contact the Central Committee Office for additional information.

5.2 Review of research proposal

5.2.1 The Central Committee reviews the research outline and posts the results in the online system or form. Complete assessment

5.2.2 In case of filling in the assessment form, send the electronic file of assessment results to the office. Central Committee before the meeting

5.3 Presentation and consideration of the research proposal

5.3.1 Check the quorum. Before considering the research project, a quorum must be present (CREC 16). The central committee members who have a stake in or conflict of interest with the research project must leave the meeting, except when the chairman sees fit to invite them to provide details on certain issues, and must leave the meeting when a decision is made.

5.3.2 The meeting may have observers from partner institutions attend, but they must not have any conflict of interest with the project and must not have voting rights. They may only express their opinions when asked by the chair of the meeting. 5.3.3 The Central Committee, the scientific member who has been assigned

Assign the first person to present a brief research proposal, along with the analysis and conclusion, and comments on scientific, risk/benefit, autonomy and vulnerability, justice, expertise, and conflicts of interest of the researcher, in accordance with the previously submitted evaluation results in order.

5.3.4 The second assigned scientific member presents additional information and further analysis.

5.3.5 The assigned layperson member analyzes and comments on the participant data documents and all relevant consent forms. 5.3.6 The meeting member thoroughly discusses and provides additional comments. 5.3.7 The chair summarizes the important scientific and ethical issues and informs the meeting committee in sequence.

3. Present the results

5.4 Consideration of the Central Committee Meeting The Central Committee will consider and decide on research projects based on the following framework:

- Research generates scientific/social value
- Risks to subjects are minimized and reasonable in relation to anticipated benefits
- Selection of subject is equitable
- Vulnerable subjects have additional protection
- Adequate protection of privacy and confidentiality
- Investigator(s) are qualified by education training and experience
- Informed consent will be sought from each prospective subject or legally acceptable representative. Waiver or alteration of informed consent is justified.
- Subjects are sufficiently informed, comprehended and voluntary enter the research
- Involvement of local community culture or tradition is justified
- Research complies to Thai laws and regulations

5.5 Voting

Only the Principal and Reviewing Committee members have the right to vote.

5.5.1 The Chair of the meeting shall request each Committee member to vote independently to decide on the approval of the research proposal as follows:

(1) Approve

(2) Revise for approval (3)

Revise and resubmit for reconsideration (4)

Do not

approve 5.5.2 The chairman discusses the types of risks of the research proposal in the meeting and proposes one of the following:

(1) The risk is not greater than the minimal risk (minimal risk).

(2) The risk is greater than the minimal risk but may have benefits for the investor.

(3) The risk is

greater than the risk and does not directly benefit the volunteer, but there is

a possibility of gaining knowledge about the disease or condition the volunteer has. (4) The risk and

benefit do not meet all three criteria, but there may be an opportunity to

understand or prevent or alleviate a serious problem affecting the

volunteer's health and well-being. If no

objection is raised, the meeting is deemed to have approved that item. If there is another opinion that may not be conclusive, a

vote is taken. 5.5.3 The chairperson discusses the frequency of the continuation review in cases where the board resolution is “Approve” or “Revise to approve”, taking into account the risk level (e.g. 1 year for risk category 1 or 2, 6 months for category 3 or 4) and proposes one of the following:

(1) 3 months

(2) 6 months

(3) 1

year (4) Other (specify)

If the proposal is submitted and no one objects, it is considered that the meeting has voted in agreement with that item. However, if there are other opinions that may not be conclusive, a vote is used. 5.5.4 In the event that the meeting resolves to have the frequency of continuous reviews be less than 1 year, the chairman must request a resolution from the meeting on whether to issue a certificate for 1 year or to cover only the period specified in the frequency of continuous reviews.

5.6 Assignment of Review Committee Members

5.6.1 In case the meeting resolution is to amend for approval, the meeting chairman shall specify the names of the assigned committee members to review the revised project and submit it to the chairman for approval, and then inform the next meeting. 5.6.2 In case the meeting resolution is to amend and submit for reconsideration, at least 2 committee members shall review the revised project and submit it for consideration at the next meeting. 5.6.3 In case the meeting resolution is to disapprove and the researcher appeals the decision, the chairman shall consider the appeal and submit it for consideration at the next meeting.

6. Definition

Decision: A resolution in which a majority of the directors agree, more than half of the number of directors in the meeting (majority vote) and a quorum is present, in one of the following matters:	(1) Approval (2) Modifications required prior to approval to its approval) (3) Revise, amend and submit for reconsideration (Revisions and resubmission) (4) Disapproval **Note:** In the case where the research project under consideration has unclear risk identification or the risks and benefits that may occur to the volunteers in participating in the research cannot be assessed, it should be brought up for consideration at the meeting again.

7. Appendix

AO 01.1-S05 Research proposal review and presentation form at the meeting for research	Biomedical
AO 01.2-S05 Research proposal review and presentation form at the meeting for research	Biomedical (for children)
AO 02-S05	A form for reviewing and presenting research proposals at a research conference Social Sciences/Behavioral Sciences
AO 01-S07	Medical Device Research Project Review Form
AO 03-S05	Informed Consent Review and Presentation Form
AO 04-S05	Guidelines for secondary research reviews on personally identifiable information or biological material Individuals can
AO 05-S05	Issues to be Addresses in storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

8.3 45 CFR 46 (US Code of Federal Regulations. Title 45 Public Welfare Department of Health and Human Services Part 46 Protection Of Human Subjects)

9. History of standard operating procedures

Procedure No. 1	Issue 2	Issue 3	Issue 4
	CREC 05 / v.1.0	CREC 05 / v.2.0	CREC 05 / v.2.1	CREC 05 / v 3.0
Prepared by	Drafting Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures
Reason of amend		- For convenience in The work of the faculty The Central Committee and Office staff	Modified according to the advice of SIDCER (14 Mar 2015)	The same
Details of the correct		- Added additional topics Consider of Full Board - Specify the vote using Voting Form(AO 10)	- Edit the flow chart to be correct. With content - Added consideration of the matter Local issues - Corrected the text in the voting. - Add reference documents	- Changed from v.2.1 to in 3.0 - Add reference documents
Reviewed by	Central Committee Consider research ethics In humans	Central Committee Consider the ethics of Human research	Central Committee Consider research ethics In humans	Central Committee Consider the ethics of Human research
Review Date	Appointed from 21 November 2012 to 24 January 2013	Appointed from 14 June 2014 to 3 July 2014	Appoint date March 14, 2015 Until May 14, 2015	Appoint date May 16, 2017 Until 30 September 2017
Approved	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit	Prof. Dr. Thada Sueblinwong
by Position	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management
Approval	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017
Date, Effective Date	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017

History of Standard Operating Procedure

(Continued) Author	Version	Approval Date	Show main edits	Approved
Subcommittee Development Method of operation standard	Version 5 v.4.0	June 15 2563	- Added delivery of documents used for review Research projects using shared electronic files too - Establish the framework for consideration in making decisions According to international research ethics criteria - Only vote on the decision results. As for the type of risk and frequency of continuous review, the chairman will discuss with the meeting and then make a decision. Consensus model - Assign the chairman to assign a committee to review the revised project and send it back. - Move some forms from CREC 04 CREC 05 added storage list form of biospecimens for future use - Add text for	**by** Prof. Dr. Thada Sueblinwong Chairman of the Board Foundation Management
Subcommittee Development Method of operation standard	Issue 6 v.5.0	October 31 2566	clarity in voting - SIDCER: Added assessment form based on SIDCER Template	Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation
Subcommittee Development Method of operation standard	Issue 7 v.5.1	24 July 2567	- Changed from v.5.0 to v.5.1 - Added layperson instead non science	Management, Prof. Dr. Kwanchanok Yimtae Chairman of the Executive Board Foundation

Urgent Research Project Consideration

Expedited Review

Issue that 5.1 Effective date: 24 July 2024

replaces the previous issue 5.0 Dated October 31, 2023

Author July 24, 2024

(Colonel Assoc. Prof. Dr. Sahapol Anantanacharoen)

Chairman of the Subcommittee on Standard Procedures Development

Approver July 24, 2024

(Assoc. Prof. Dr. Kwanchanok Yimtae)

Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

list of contents

1. Objective: To

provide guidelines for reviewing and judging new research projects that are submitted for expedited consideration.

(Expedited Review)

2. Scope

Standard operating procedures cover the consideration of first-time research proposals that will be considered.

Urgent form by the committee assigned by the chairman of the central committee, notification at the central committee meeting, and notification of the results of the consideration to the principal investigator or research project coordinator and partner institutions.

3. Responsibility

3.1 Committee for reviewing and judging research projects or research reports

3.2 The office staff collects a list of research projects or research reports that have been certified by the following methods:

Urgently inform the Central Committee meeting according to each set.

3.3 The office officer shall forward the decision to the principal investigator or research project coordinator and

Partner institutions

4. Procedure flow chart

Sequence	Operation	responsible person
1	Receive research project documents ÿ	director
2	Quick Review ÿ	director
3	Summary of the decision ÿ	secretary
4	Notification of decision ÿ	Office staff
5	Announce the list of approved research projects to the meeting.	Office staff

5. Procedure

5.1 Receiving research project documents 5.1.1 The committee assigned by the chairman receives research project documents via the online system. namely

5.1.1.1 A submission letter specifying the following documents: 5.1.1.2 Documents as specified in the submission letter 5.1.1.3 Two sets of research project evaluation forms (1) Set 1: Urgent research project evaluation forms that correspond to the research field (AO 01-S06 or AO 02-S06) for committee members in the science field

(2) Set 2 Evaluation Form for Consent Request Documents (AO 03- S05) for both scientific members and layperson members. 5.1.1.4 If incomplete, contact the committee office for additional information.

5.2 Urgent research project review

5.2.1 The committee reviews the research project by completing the evaluation form in full.

5.2.2 Send the completed evaluation form to the office within 10 working days from the date of receipt. document

5.3 Summary of the decision

5.3.1 The secretary summarizes the decision of the reviewing committee and the recommendations to the chairman. The decision of any one of the central judges may be

(1) Approval

(2) Amendment for approval (3)

Consideration in the Central Committee meeting

5.3.2 In the event that any of the central committee members see fit to bring it into consideration in the committee meeting because it is not approved or the research context causes the risk to exceed the minor risk level.

(over minimal risk) The secretary shall include it in the agenda of the board meeting.

5.4 Notification of decision results

5.4.1 After receiving the complete decision from all reviewers, the decision shall be informed to the principal investigator or research project coordinator and the research institution according to CREC 04 within 5 working days after the secretary summarizes the decision. 5.4.2 The certification shall only be for sites that have submitted the approved local issues (AP 01-S04). If a certificate has been issued and other institutions submit additional local issues, the office may issue additional certificates, but the approval date shall be the date the chairman signs, while the expiration date shall be the same as the previously issued certificate. 5.4.3 The office officer shall inform the result by sending electronic documents via the system Electronic to the principal investigator or research project coordinator and research institute.

5.5 Notification of the list of research projects/research reports that have been approved to the committee meeting.

Prepare **monthly** research project reports/research reports that have been approved by expedited review , consisting of the following information:

5.5.1 CREC Project Code

5.5.2 Project Name

5.5.3 Name of Research Project Leader 5.5.4 Name of Research Sponsor 5.5.5 Date of Chairman's Signature

6. Definition

Minor risk (Minimal risk)	The risk is not greater than that which occurs in the daily life of healthy volunteers or at annual health check-ups. The
Consideration of type Urgent (expedited review)	decision to approve the study is made without a meeting, but is reviewed by the committee chair or two committee members designated by the chair. This method is used to review research projects and report on research progress where the risk does not exceed low risk.

7. Appendix

AO 01-S06	Rapid Biomedical Research Project Assessment Form
AO 02-S06	Rapid Assessment of Social Science/Behavioral Science Research Projects
AO 03-S05	Informed Consent Review and Submission Form Informed Consent Review Form
AP 01-S04	Local Issue Assessment of the Institute

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

8.3 Department of Health and Human Services. Food and Drug Administration. Protection of Human Subjects: Categories of Research that may be Review by the Institutional Review Board (IRB) through an Expedited Review Procedure. Federal Register/Vol.63, No. 216/Monday, November 9, 1998, p.60353.

9. History of Standard Procedures,

Step No. 1 **Carry out**	**CREC 08 / v.1.0**	**Issue 2** **CREC 06 / v.2.0**	**Issue 3** **CREC 06 / v.2.1**	**Issue 4** **CREC 06 / v 3.0**
Prepared by	Subcommittee for Drafting Standard Procedures	Subcommittee for Development of Procedures Standards	Subcommittee for Development of Standard Operating Procedures	Subcommittee for Development of Standard Operating Procedures
Reason for improvement		for convenience The work of the faculty Board of Directors and Office staff	Modified as per recommendations Of SIDCER (14 Mar. 58)	
details Of the correction	- Selection criteria The research outline will Urgent consideration	Adjust the section - Protocol Amendment that contains additional amendments Only a small amount and there is little risk to Volunteer - report Progress of Research with criteria Specific and low risk Volunteer	- Add details Select the board of directors review - Add reference documents	- Remove 5.1.1 Outline of the research that has been reviewed. Considered by the committee And have an opinion "Revised for certification" (approve after correction) - Add reference documents
Reviewed by	Central Committee Consider the ethics of Human research,	Central Committee Consider the ethics of Human research,	Central Committee Consider the ethics of Human research,	Central Committee Consider research ethics In
Review Date	date of appointment 21 November 2012 to 24 January 2013	date of appointment June 14, 2014 to July 3, 2014 Assoc. Prof. Dr.	date of appointment March 14, 2015 Until May 14, 2015, Assoc.	person, appointed date 16 May 2017 to 30 September 2017
Approved by	Suchart Areemit Assoc. Prof. Dr. Suchart Areemit Friend		Prof. Dr. Suchart Areemit, Assoc. Prof. Dr. Thada Sueblinwong	

Position	Chairman of the Board Foundation Management	chairman Executive Board Foundation	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management
Approval	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017
Date, Effective Date	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017

History of Standard Operating Procedures (continued)

Author	Edition No. Approval Date	Show main edits	Approved by
Subcommittee develop Method of operation standard **Edition** No. 5	v.4.0 June 15 2563	- Number of Expedited Reviewers Review edited from 1 to 1-2 people. - Added assessment - Prepare separate criteria for announcement Instead of writing in SOP - Cut out research on cadavers. - Added expedited review definition - Add local issues to consideration Issue a certificate	Prof. Dr. Thada Sueblinwong Chairman of the Board Foundation Management
Subcommittee develop Method of operation standard	Issue 6 v.5.0 October 31 2566	- Added work procedures to enable Consistent with operations and Update information to current - Adjust the processing time	Prof. Dr. Kwanchanok Yimtae Chairman of the Executive Board Foundation
Subcommittee develop Method of operation standard	Issue 7 v.5.1 July 24 2567	- Changed from v.5.0 to v.5.1 - Added layperson replacement non science - Added complete appendix documents.	Prof. Dr. Kwanchanok Yimtae Chairman of the Executive Board Foundation

Consideration of research proposals that are medical devices

Review of Medical Device Study

Issue that 5.1 Effective date: 24 July 2024

replaces the previous issue 5.0 Dated October 31, 2023

Author July 24, 2024

(Colonel Assoc. Prof. Dr. Sahapol Anantanacharoen)

Chairman of the Subcommittee on Standard Procedures Development

Approver July 24, 2024

(Assoc. Prof. Dr. Kwanchanok Yimtae)

Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

list of contents

1. Objective

To determine the method of review, consideration and decision of research projects on medical devices that are submitted for approval

Approved by the Central Committee for Consideration of Human Research Ethics

2. Scope

Standard operating procedures cover the application and review of research projects on instruments.

Physicians who conduct human research, including mobile medical applications that are under the control of

Food and Drug Administration and Software as Medical Device (SaMD)

3. Responsibility

3.1 Office staff receives research outline documents, determines research outline codes, and prepares documents for

Consider writing a letter announcing the research results and storing research outline documents and electronic data.

3.2 The secretary selects the committee members who are responsible for reviewing the research outline and submitting it to the chairman for assignment.

3.3 The committee reviews the research outline and returns the review results to the office within the specified time.

3.4 The reviewer presents a summary of the review results and comments.

3.5 The meeting considered the research outline, voted to determine the certification period and the frequency of report submission.

Research progress

4. Procedure flow chart

Sequence	Operation	responsible person
1	Receive research project documents ÿ	director
2	Review the research outline ÿ	director
3	Present and consider the research outline ÿ	Principal Reviewer
4	Vote to Decide ÿ	Committee
5	Assign a review committee ÿ	chairman

Sequence	Operation	responsible person
6	Notification of consideration results ÿ	Office staff
7	Archive research project documents	Office staff

5. Procedures

5.1 Receive research project documents

5.1.1 The committee assigned by the chairman to be the main reviewer receives the research project documents.
Through the online system and check the completeness, including:

5.1.1.1 Delivery letter, specifying the following

documents: 5.1.1.2 Documents as specified in the

delivery letter 5.1.1.3 Research outline evaluation form

(1) Scientific member received AO 01-S07, AP01-S07.

(2) Layperson member received AO 03-S05.

5.1.1.4 If it is incomplete, please contact the office for additional information.

5.2 Review of research proposal

5.2.1 The primary reviewer reviews the research proposal and enters the review results into the system.
Online or complete the assessment form.

5.2.2 In case of using an assessment form, send an electronic copy of the completed assessment form to

Office before the meeting)

5.2.3 The framework for consideration is as follows:

5.2.3.1 In reviewing the medical device research project, the committee

It is important to note that the review framework may differ from drug trial to trial.

Clinics such as the trial phase, evaluation methods

5.2.3.2 The committee must first consider whether the study of the medical device will cause

What level of risk is it? Does it correspond to the risk level claimed by the

manufacturer? 5.2.3.3 The committee must consider the nature of the potential hazards arising from the use of the medical device.

This is based on consideration of all risks that may result from the use of that medical device, not risks when compared to other devices or procedures. If the medical device to be studied is used in conjunction with a method or procedure that has risks, the committee must take the risks of the method or procedure into consideration together with the risks of the device, including risks arising from errors of the device itself. 5.2.3.4

Assessment of the risks of medical devices based on the announcement of the Office Food and Drug Administration and US FDA Guidelines

5.2.3.5 The classification of medical devices according to risk level has control measures according to the announcement of the Ministry of Public Health that manufacturers or importers (1) must obtain permission for: - Medical devices for in vitro diagnostics (IVD) Category 4 or - Medical devices that are not medical devices for in vitro diagnostics (non-IVD) Category 4.

(2) The following details must be reported:

- IVD type 2 or 3
- Non-IVD type 2 or 3

(3) Must be notified:

- IVD Type 1 or
- Non-IVD Medical devices that are not diagnostic devices for in vitro diagnostics, Category 1

IVD classification according to risk level takes into account factors affecting the risk level, such as the intended use and indication of the medical device as determined by the product owner, the expertise of the user of the medical device, the importance and impact of the information obtained from the medical device on the person. and public health

Non-IVD risk classification is based on factors affecting risk, such as degree of invasiveness, residence time, application type, biological effect, and investigative medical device. It is classified into (1) significant risk medical device (SR) and (2) no significant risk medical device (NSR).

5.3 Presentation and consideration of the research proposal

5.3.1 Any committee member who is a researcher, co-researcher, consultant, or has a conflict of interest with the research project must leave the meeting while the research project is being considered.

5.3.2 The first assigned scientific member presents a brief research outline, analysis results and summary of comments based on the previously completed evaluation form. 5.3.3 The second assigned scientific member presents additional comments and additional analysis results. 5.3.4 The third assigned layperson member presents the analysis results and summary of comments on the data documents for research participants.

Letter of Consent

5.3.5 The chairman summarizes each section in sequence and gives the meeting committee an opportunity to discuss thoroughly and provide additional opinions.

5.4 Voting

5.4.1 The Chairman summarizes and asks the meeting members to vote freely as follows:

(1) Certification

(2) Revised for approval (3)

Revised and submitted for reconsideration (4)

Not approved

5.4.2 The chairman discussed the following types of risks of medical devices in the meeting:

5.4.2.1 Medical devices for *in vitro* diagnostics

medical device (IVD)) o

Type 1 Medical

devices that pose low risk to individuals and public health.
(Class A Low Individual Risk and Low Public Health Risk)

o Class 2 Medical

devices with moderate individual risk and/or low public health risk (Class B.
Moderate Individual Risk and/or Low
Public Health Risk)

o Class 3

Medical devices that pose a moderate risk to individuals or a moderate risk to public health (Class C. High Individual Risk and/or Moderate Public Health Risk) o

Type 4 Medical

devices that pose a high risk to individuals and public health.
(Class D. High Individual Risk and High Public Health Risk)

5.4.2.2 Medical devices under research study that are not medical devices for external diagnosis

Non-in vitro diagnostic medical device (Non-in *vitro* diagnostic medical device) is classified

according to risk as follows: o Category 1 is low

risk o Category 2 is low-moderate risk o Category 3 is moderate-high risk o

Category 4 is high risk

If the proposal is submitted and no one objects, it is considered that the meeting has voted in favor of that proposal.

However, if there are other opinions that may not be conclusive, a vote is taken.

5.4.3 The chairman discussed at the meeting the frequency of continuous review in the case of a board resolution. It is “certified” or “amended to be certified” as follows:

(1) 3 months

(2) 6 months

(3) 1 year

(4) Other (specify) If the proposal is submitted and no one objects, it is considered that the meeting has voted to approve that item. However, if there are other opinions that may not be conclusive, a vote is used.

5.4.4 The meeting may have observers from partner institutions attend, who have no voting rights and may only comment when asked by the Chair.

5.5 Assignment of Review Committee Members

5.5.1 In case the meeting resolution is to amend for approval, the meeting chairman shall specify the names of at least 2 committee members to review the revised project and submit it to the chairman for approval, and then inform the next meeting. 5.5.2 In case the meeting resolution is to amend and submit for reconsideration, at least 2 committee members shall review the revised project and submit it for consideration at the next meeting. 5.5.3 In case the meeting resolution is to disapprove and the researcher appeals the decision, the chairman shall consider the appeal and submit it for consideration at the next meeting.

5.6 Notification of decision results

Watch CREC 04

5.7 Research project document storage

Watch CREC 04

6. Definition

Clinical research studies (clinical investigation)	Systematic human research that requires a large number of volunteers One or more people to assess safety or performance Medical Devices
Clinical research medical devices (investigational medical device)	Medical devices that have been tested or are undergoing clinical testing to assess the safety or performance of the medical device.
Clinical data	Safety and performance information of medical devices from Clinical use includes (1) clinical research studies of medical devices, and (2) clinical trials or other published study reports. Scientific journal of medical devices similar to the device The doctor (equivalent device) (3) Reports on published or unpublished clinical experience using the medical device or medical device that Similar to medical devices
Clinical research study plan (clinical investigation plan)	A document that includes background, purpose, design and Methods of analysis, research methodology, monitoring, implementation and collection Record of clinical research study data (1)
Medical equipment (medical device) Section 4 [Equipment Act Medical Act 2008, as amended By the Medical Devices Act (No. 2) 2019]	instruments, equipment, machinery, objects inserted into the body, liquids used. Examine, in or outside the laboratory, any product, software or other material intended specifically for a particular use by the manufacturer or owner of the product. Any of the following with humans or animals, whether used alone, together or in combination with anything else: (a) Diagnose, prevent, monitor, treat, relieve or cure diseases. (b) Diagnose, monitor, treat, relieve or cure injuries. (c) inspect, replace, correct, modify, support, trade or sustain the physical aspect; Anatomy or physiological processes of the body (ÿ) sustain or save a life

	(c) Birth control or assisted reproduction (c) Assist or compensate for disability or handicap. (c) Provide information from examination of the specimens sent from the body in order to Medical or diagnostic purposes (c) Destroy or sterilize medical equipment. (2) Accessories for use with medical devices according to (1). (3) Tools, equipment, machinery, products or other objects that the Minister Declared as a medical device The outcome in accordance with the purpose of what is mentioned in (1) which occurs in The human or animal body must not be primarily driven by pharmacological, immunological, or metabolic processes that produce energy,
Risk	meaning that the sum of the probabilities of the potential for harm to occur And the severity of that danger
Medical devices with risks Significantly (significant risk medical device, SR)	The following clinical research medical devices (1) are intended for implantation in the body and are likely to cause harm; Serious risk to the health, safety and well-being of Volunteer (2) Used to support or save human lives and has a tendency to cause Serious risks to health, safety and well-being Of volunteers (3) It is very important in diagnosis, prevention, treatment, relief or (4) Any other medical device that is likely to pose a serious risk to the health, safety and well-being of the volunteers. Volunteer health, safety and well-being

Medical devices that are not Significant risk (Nonsignificant risk medical device, NSR)	Medical devices used in clinical research studies that do not meet the definition of devices Physicians at significant risk
Medical equipment for In vitro diagnostics (In vitro diagnostics) Vitro Diagnostic (IVD) medical devices)	Reagent, reagent product, calibrator, instrument, apparatus or equipment, analytical Substances to be considered M (control material) system or any other object, (kit, whether used alone, in combination or in conjunction with Other medical devices intended by the product owner for examination of specimens From the human body, including blood and organ donations to provide information (1) Physiological or pathological condition or congenital disability. (2) Consider the safety and tissue compatibility of the affected person. Opportunity to receive organs or (3) Monitor the treatment, including the containers for storing the items for examination.

7. Appendix

AO 01-S07	Medical Device Research Project Review Form
AP 01-S07	Investigator's Brochure for Medical Device Study
AO 03-S05	Review and submission of consent documents by informed consent Informed Consent Review Form Information

8. Reference documents

8.1 US FDA. Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors Significant Risk and Nonsignificant Risk Medical Device Studies. January 2006.

8.2 ASEAN Medical device directive, 2015

8.3 US DHHS. Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff. Document issued on February 9, 2015.

8.4 IMDRF Software as a Medical Device (SaMD) Working Group Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations. Date: 18 September 2014

8.5 Medical Device Act B.E. 2008

8.6 Medical Device Act (No. 2) B.E. 2562 8.7 Ministry of Public Health Announcement on the Classification of Medical Devices According to Risk Level B.E. 2562 Gazette, Volume 136, Page 53, December 18, 2019

8.8 ISO 14155 (2020): Clinical Investigation of Medical Devices for human subjects- Good clinical practice

8.9 ISO 20916 (2019): Clinical Performance Studies using specimens from human subjects- good study practice

9. History of standard operating procedures

step Carry out	Issue 1 CREC 21 / v.1.0	Issue 2 CREC 07 / v.2.0	Issue 3 CREC 07 / v.2.1	Issue 4 CREC 07 / v 3.0
Prepared by	Drafting Subcommittee Method of operation standard	Development Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures
Reason of amend		For convenience The work of the faculty The Central Committee and Office staff	Edit to version The same throughout the book	The same
details Of the correction		Management procedures Manage research proposals and reviews at the venue Board meeting Full set, reference from CREC 04 / v.2.0 and CREC 05 / v.2.0	- Changed from v.2.0 to v.2.1 - Add reference documents	- Add reference documents
Reviewed by	Central Committee Consider ethics Human research	Central Committee Consider the ethics of Human research	Central Committee Consider the ethics of Human research	Central Committee Consider the ethics of Human research
Review Date	Appoint date 21 November 2012 to 24 January 2013	Appoint date June 14, 2014 to July 3, 2014	Appoint date March 14, 2015 Until May 14, 2015	Appoint date May 16, 2017 Until 30 September 2017
Approved	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit,	Assoc. Prof. Dr. Thada Sueblinwong
by Position	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management	Chairman of the Board Foundation	Chairman of the Board Foundation Management
Approval	January 25, 2013	July 4, 2014	Administration 28 September 2016	October 1, 2017
Date, Effective Date	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017

History of Standard Operating Procedures

Date	(continued) Version Approval	Show main edits	Approved
Development Subcommittee Method of operation standard	**Creator** Version 5 15 v.4.0	June 2020 Major revision to be in line with FDA guidelines.	**by** Prof. Dr. Thada Sueblinwong Chairman of the Board Foundation
Development Subcommittee Method of operation standard	Issue 6 v.5.0	October 31, 2023 - Change the definition of terms to be consistent with Medical Devices Act No. 2 and the announcement of the Ministry of Public Health - Categorize research tools by Ministry of Public Health	Management, Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management
Development Subcommittee Method of operation standard	Issue 7 v.5.1	Announcement 24 July 2024 - Changed from v.5.0 to v.5.1 - Added layperson instead. non science	Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management

Consideration of research projects submitted after revision

Review of Resubmitted Protocol

Issue that 5.1 Effective date: 24 July 2024

replaces the previous issue 5.0 Dated October 31, 2023

Author July 24, 2024

(Colonel Assoc. Prof. Dr. Sahapol Anantanacharoen)

Chairman of the Subcommittee on Standard Procedures Development

Approver July 24, 2024

(Assoc. Prof. Dr. Kwanchanok Yimtae)

Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

list of contents

1. Objective

To serve as a guideline for managing the re-review of research projects that are sent back for consideration after

Clarification/correction according to the recommendations of the committee meeting

2. Scope

This standard procedure applies to research projects that have been previously considered and approved by the Committee and It is resolved to (1) amend for approval or (2) amend and submit for reconsideration.

3. Responsibility

3.1 The office officer has a duty to check the completeness of the documents for clarification and research projects/

Related documents that the researcher has edited and added

3.2 The Secretary has the duty to summarize the opinions of the committee and (a) submit them to the Chairman for decision or (b) bring them into consideration at the meeting.

4. Procedure flow chart

Sequence	Operation	responsible person
1	Receive and verify the completeness of research project documents. Amendments ÿ	officer
2	Send to the central committee as designated by the chairman of the meeting. ÿ	officer
3	Review and consider the revised project according to the meeting resolution. ÿ	director
4	decide ÿ	Chairman/Board of Directors
5	Notification of decision ÿ	officer
6	Archive research project documents	officer

5. Details of implementation

5.1 Receive and re-check the completeness of the research project documents that have been sent back.

The officer checks the document files that have been sent for consideration as follows:

5.1.1 A detailed meeting minutes indicating the sections requested for amendment. 5.1.2 A record of amendments (AP 03-S04) 5.1.3 A revised version of the research project, such as the research proposal (protocol), participant data documents, advertisements, etc. 5.1.4 The revised sections should appear in underlined or highlighted format and in a clean version.

Note: Submit to the reviewer within 3 working days after the documents are complete.

5.2 Sending for review and consideration

5.2.1 Assignment of Reviewing Committee

Members (1) If the previous decision was “Revised for approval”, the committee member assigned by the chairman shall review and consider the matter and submit it to the chairman for approval.

(2) If the previous decision was “Revised and considered again”, the committee member assigned by the chairman shall review and consider the matter and submit it to the meeting for approval.

Vote to Decide

5.2.2 The office officer sends documents to the reviewing committee, including a letter announcing the results of the previous review, research project documents that have been revised and improved (1) in the case where the decision is “Revised for approval”, attach a table showing the revisions and improvements (AP 03-S04);

(2) in the case where the decision is “Revised and resubmitted for reconsideration”, attach a document, a table showing the revisions and improvements (AP 03-S04), and a research outline evaluation form that corresponds to the set of fields of study being considered.

(a) Scientific member has received AO 01-S05 or AO 02-S05 or AO 02-S07 together with AO 03-S05 and/or AO 05-S05

(b) Layperson member received AO 03-S05 and AO 05-S05.

5.3 Review

5.3.1 In the case of revisions for certification, the assigned reviewing committee member shall provide comments on the attached evaluation form and return an electronic copy of the evaluation form to the office within 5 days.

Do

5.3.2 In case of revision and re-consideration, the reviewing committee provides comments on the evaluation form and prepares to present it at the meeting (CREC 05).

5.4 Judgment

Complies with CREC 05 in case of attending the Full Board Review meeting and CREC 06 in case of research with risks not exceeding minor risks Expedited Review.

5.5 Notification of decision results

Complies with CREC 04

5.6 Research project document storage

5.6.1 Keep a copy of the notification of consideration results in a file/electronic file in the database system.

Research Project

5.6.2 Keep the approved research projects together with the first submitted research projects. 5.6.3

Keep the files/electronic files in the database system.

6. Definition

Minor risk (Minimal risk)	The risk is not greater than that which occurs in the daily life of healthy volunteers or at annual health check-ups. The
Consideration of type Urgent (expedited review)	decision to approve the study is made without a meeting, but is reviewed by the committee chair or two committee members designated by the chair. This method is used to review research projects and report on research progress where the risk does not exceed low risk.

7. Appendix

AP03 S04	Table explaining the revision of the research outline and related documents according to the resolution of Central Committee on Human Research Ethics
AO 01.1-S05	A form for reviewing and presenting research proposals at the conference for Biomedical research
AO 01.2-S05	A form for reviewing and presenting research proposals at the conference for Biomedical research (for children)
AO 02-S05	A form for reviewing and presenting research proposals at the conference for Social Science/Behavioral Science Research
AO 01-S07	Medical Device Research Project Review Form
AO 03-S05	Informed Consent Review and Presentation Form
AO 04-S05	Guidelines for secondary research reviews on identified personal or biological data Individuals can
AO 05-S05	Issues to be Addresses in storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

8.3 Department of Health and Human Services. Food and Drug Administration. Protection of Human Subjects: Categories of Research that may be Review by the Institutional Review Board (IRB) through an Expedited Review Procedure. Federal Register/Vol.63, No. 216/Monday, November 9, 1998, p.60353.

9. History of Standard Procedures No. Approval

	Date	**Author**	**Show main edits**	**Approved by**
Subcommittee for Development of Procedures standard	v.1.0	No. 1 15 June 2020		Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation
Subcommittee for Development of Procedures standard	Issue 2 v.5.0	October 31, 2023	- Added operating steps to be consistent with Perform and update data to be current - Add evaluation form in Appendix topics - Changed from v.1.0 to v.5.0 to be consistent with other chapters for ease of use.	Management, Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management
Subcommittee for Development of Procedures standard	Issue 3 v.5.1	July 24, 2024	- Changed from v.5.0 to v.5.1 - Added information in section 6. Definitions - Added information in section 7. Appendix - Added evaluation form based on suggestions SIDCER	Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management

Consideration of additional amendments to the research outline

Review of Protocol Amendment

Issue that 5.1 Effective date: 24 July 2024

replaces the previous issue 5.0 Dated October 31, 2023

Author July 24, 2024

(Colonel Assoc. Prof. Dr. Sahapol Anantanacharoen)

Chairman of the Subcommittee on Standard Procedures Development

Approver July 24, 2024

(Assoc. Prof. Dr. Kwanchanok Yimtae)

Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

list of contents

1. Objective

To serve as a guideline for reviewing protocol amendments that have already been approved by the Committee, in order to ensure that human subjects are protected.

Rights and safety throughout participation in research projects

2. Scope

Standard operating procedures cover review of amendments to the research proposal and other relevant documents.

It has been approved by the previous committee and the researcher has submitted it to the committee for consideration and approval before.

Proceed as amended

The Central Committee will consider amendments to the research protocol that must be carried out at all sites (protocol-wide amendment). However, if the amendments are site-specific,

You can submit a request for certification to the Research Ethics Committee of that institution and then notify the results of the consideration.

The Central Committee is aware of or has suggestions.

3. Responsibility

The Secretary of the Central Committee and the Office staff are responsible for management in order to ensure that:

Review the research proposal with additional amendments, which may include an expedited review or

Reviewed at the Central Committee meeting

4. Procedure flow chart

Sequence	Operation	responsible person
1	Receive additional editing of the research outline ÿ	Office staff
2	Select the consideration channel and the central committee that reviews ÿ	Secretary of the Board
3	Review and Consider ÿ	Reviewing Committee
4	Consider and decide ÿ	Chairman/Board of Directors

Sequence	Operation	responsible person
5	Notification of decision ÿ	Office staff Secretary and Chairman
6	Actions when researchers submit additional amendments to the manuscript Research revised for certification ÿ	Office staff
7	Actions when researchers submit additional amendments to the project outline Revised and re-considered research ÿ	Office staff
8	Document storage ÿ	Office staff

5. Procedure 5.1

Acceptance of additional research proposal amendments

5.1.1 Office staff check the completeness of documents.

A. Record of submission of additional amendments to the research outline from the researcher/research coordinator.

B. Research Proposal Amendment Report Form (AP 01-S09) and other documents as follows:

Delivery Note

If the documents are complete:

- Record the receipt of documents in the receipt book/document receipt system, specifying the date the document was received.

and the date the documents are complete on the first page of the cover page of the document delivery letter

- The online submission system will accept documents through the system to researchers.

Research Project Coordinator

If the documents are incomplete

- Office staff contact the research project coordinator to request additional documents.

- Submit documents in order to the Secretary of the Central Committee/Committee members

Assigned within 3 working days

5.1.2 Request for additional research locations

5.1.2.1 In the case of a site under a partner institution, when the principal investigator sends a report of the amendment by adding a partner institution, CREC will inquire with the institutional ethics committee to assess the Local Issue (AP 01-S04) and use the results.

Consideration for certification

5.1.2.2 In the case of a site outside of a partner institution, the Foundation shall conduct a potential assessment according to CREC 20

5.1.2.3 The addition of a co-research location must be announced at the meeting to request a resolution to acknowledge or have.

Additional suggestions

5.2 Selection of the Central Committee, Reviewers and Reviewing

Channels 5.2.1 The Secretary selects the reviewing channel.

5.2.1.1 Enter the expedited reviewing channel if it is a minor amendment.

(minor change or non-substantial change)

- The Secretary/Assigned Committee member is the person who reviews and considers Present the review results to the Chairman.

5.2.1.2 Enter the consideration channel in the meeting if it is an additional amendment.

(major change or substantial change)

- The Secretary or the assigned committee member selects suitable committee members to conduct the review, no more than 3 persons, and presents them to the Chairman for assignment to review and consider.

5.2.2 The Office staff prepares documents and sends them to the assigned Central Committee member within 3 working days in the form of (1) documents or (2) CD or DVD with complete document information and an access code, 1 disk or (3) via electronic system, in accordance with the Office's regulations. 5.2.2.1 Documents sent to the Central Committee consist of:

a. Research proposal amendment report form (AP 01-S09) b. Research proposal version before amendment c. Amended research proposal (if any) d. Report of the meeting that first considered the research proposal

5.2.2.2 In the case of adding sites, additional documents from the above are required, as follows: a. A letter from the research project leader with a statement or attached documents that (a) state the reasons for the necessity of adding sites, (b) the total number of volunteers planned and the number of volunteers currently enrolled in the project, (c) concerns about volunteer safety (if any), and (d) the number of volunteers who withdrew from the research.

B. Local issue assessment form (AP 01-S04) C. Consent request document/consent letter used with the site

5.3 Reviewing and considering the amendments to the research outline

5.3.1 The Secretary or the Central Committee member assigned by the Chairman reviews the amendments to the research outline, records comments and suggestions in the amendment assessment form.

Research proposal The consideration framework covers

a. Reasons and necessity for requesting a change in the research proposal b. Research methodology that is being requested for change c. Risk and benefit assessment, changes from the original after the change d. Fairness to all volunteer groups, changes from the original after the change correct

1. The necessity of informing of amendments to the research proposal

Volunteers who have completed the research or are currently participating in the research

If informed consent is required, it must be specified whether the researcher will re-consent all research subjects or only obtain consent from new research subjects and those currently participating in the study.
from new and active research subjects)

5.3.2 The Secretary or the Central Committee member who reviews the review shall send the review results back to the Office via electronic system in accordance with the Office's regulations. 5.3.2.1 Expedited consideration: The Secretary or the Central Committee member

Return to the Office within 5 working days after receiving the revised research outline. 5.3.2.2 Consideration

at the Central Committee meeting The Central Committee returns to the Office within 5 working days after receiving the revised research outline.

Research outline and pre-meeting of the Central Committee

5.4 Judgment

5.4.1 In the case of urgent consideration (expedited) 5.4.1.1

The Secretary of the Central Committee shall present the results of the review together with opinions to the Chairman of the Central Committee for decision. The decision may be

(1) **Approve** means that the researcher can conduct the research according to the amended research outline. (2)

Minor **revision** prior to Approval means that the researcher must make changes to the research outline according to

Recommendations from the Central Committee and returned to the Committee

The Central Government will consider before granting certification.

(3) **It is deemed appropriate to bring it to the** full committee meeting (Major revision and Full Board Review is required) meaning the risk to the research participants exceeds the minor risk. 5.4.1.2 In the case where the decision is

for consideration at the meeting, the secretary shall include it in the meeting agenda. 5.4.2 In the case where

amendments to the research proposal are brought to the meeting, 5.4.2.1

The central committee member who reviewed the proposal presents the review

results at the meeting. 5.4.2.2 The chairman of the meeting presents the decision results in order and shall

The Central Committee votes

(1) Approve means that the researcher can conduct the research according to the amended research outline. (2)

Minor revision prior to approval means that the researcher must make changes to the research outline according to the recommendations of the central committee and send it back.

The Central Committee reviews before certification.

(3) Revise and revise (Major revision and Full Board Review is required) means that the researcher must change or add content or research outline documents.

According to the recommendations of the Central Committee and brought for reconsideration in the Central Committee meeting (4) Disapprove means that the researcher is not permitted to make changes to the research proposal as newly proposed, but can continue the research according to the original research proposal that was previously approved.

5.4.2.3 The decision is based on a majority vote. In the event of an equal number of votes, the Chairman of the Central Committee shall cast one additional vote as the deciding vote.

broken

5.4.2.4 The secretary records the votes for, against, abstained and the number of the Central Committee members present in the meeting room when the vote is cast.

5.5 Notification of decision results

5.5.1 When the decision is approved, the official of the Office 5.5.1.1 shall stamp the name of the Central Committee and the date of approval on the document (new version requesting approval, if any) as follows:

(1) Research outline and certified documents, stamped on every page. Of documents

(2) Information sheet and consent form, stamped on every page.

5.5.1.2 Prepare a letter notifying the results of the consideration based on the consideration form. First Research Project (see CREC 04)

5.5.1.3 The certification period shall be based on the last research project certification expiration date.

5.5.1.4 In the case of adding a site, issue a certificate of adding a research institute, specifying the progress reporting period and the certification end date.

According to 5.5.1.3

5.5.2 When the decision result is to amend for approval, amend and re-consider.

Or not certified,

the office officer prepares a letter informing the results of the consideration, which includes the results of the consideration, the date of consideration, and the recommendations of the central committee, signed by Chairman of the Central Committee

In case the decision is not approved, the office officer will prepare a letter informing the consideration result (AL 11-S04) which includes the consideration result, consideration date, reason for not approving and must include the statement “You may appeal the consideration result of the committee by stating your intention and reason for disputing to the committee chair in writing within 90 days from the date you receive the notice of consideration result” signed by the committee chair, referring to the initial research project consideration form (CREC 04).

5.5.3 Method of notification of decision results The office officer will inform the results by sending the results of the consideration of the certified document amendments, stamped with the name CREC and the date of certification, via the electronic system to the principal investigator or coordinator.

Research projects and research institutes

5.5.4 Time period for notification of decision results 5.5.4.1 In case of using the expedited consideration method, the office officer sends a document informing the results as specified above within 5 working days after receiving the results of the consideration from the reviewing committee and summarizing the decision results. 5.5.4.2 In case of consideration at the meeting of the Central Committee, the office officer sends a document informing the results as specified above within 5 working days after the meeting.

5.6 Procedures when researchers submit additional amendments to the revised research proposal for approval

5.6.1 The office officer shall forward the documents as specified in Section 5.3 to the same reviewing committee member.

Within 3 working days after receiving complete documents

5.6.2 The Central Committee reviews the researchers' revisions, records comments and suggestions in the research proposal revision evaluation form, and sends the review results back to the Office via electronic system in accordance with the Office's requirements within 5 working days after receiving the documents.

5.6.3 The office officer sends a letter informing the decision result to the chairman.

The Central Committee shall sign within 5 working days from the date of receiving the review results from Central Committee

5.7 Procedures when researchers submit additional amendments to the revised research proposal and submit them for reconsideration: Procedures shall begin from Section 5.1 in accordance with the consideration channels.

5.8 Document storage

5.8.1 Office staff collects research proposal amendments into the database. 5.8.2 Office staff collects certification letters and letters of consideration results according to type.

5.8.3 Office staff collect evidence of

electronic data transmission and other contacts with researchers in the database. 5.8.4 Office staff record research outline data in the Office database.

6. Definition

Additional amendments to the framework Research draft	Descriptive writing of changes from the original research outline (protocol amendment) An
Additional amendments a little	amendment to a research protocol that exposes volunteers to additional risks that do not exceed the risks or affect the scientific value. For example 1) Modification of management system such as coordinator name Research Project 2) Modification of the Investigator brochure that does not increase the risk to volunteers. 3) Minor changes such as corrections to spelling, date, edition, format of the research outline.

	4) Editing the public relations text inviting volunteers to join Research Project 5) Any amendments to the research project that do not include recruiting new volunteers. To study and perform activities or procedures related to The research with volunteers has ended, only follow-up remains. Volunteer 6) No volunteers were recruited into the study. 7) No changes or additions to the research procedure were made that did not increase the risk to Volunteer or the risk is not more than a small risk or if it is more than a small risk, it is an action for The purpose of general medical treatment is not to perform procedures for: research 8) The research project has ended, only the remaining Data analysis 9) Modification or addition of data analysis methods 10) The additional amendment report has been reviewed by Ethics Committee accepted by the Central Committee for
More amendments	amendments to the research protocol that result in risks to volunteers Adding more than a small risk or affecting scientific value

7. Appendix

AO 01-S09	Evaluation form for research proposal amendments
AO 02-S09	Example of more/less additional editing
AP 01-S09	Research Proposal Amendment Form
AL 11-S04	Letter of notification of the research proposal review results when the review result is not approved
AP 01-S04	Institutional readiness assessment documents (local issues) from the institution Conduct research

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011

9. History of Standard Procedures,

Step No. 1 **Carry out**	**CREC 10 / v.1.0**	**Issue 2** **CREC 09 / v.2.0**	**Issue 3** **CREC 09 / v.2.1**	**Issue 4** **CREC 09 / v 3.0**
Prepared by	Subcommittee for Drafting Standard Procedures	Subcommittee for developing standard operating procedures	Subcommittee for the Development of Standard Operating Procedures,	Subcommittee for Development of Standard Operating Procedures
Reason for improvement		to facilitate operations The Central Committee and Office staff	revised according to recommendations Of SIDCER (14 Mar. 58)	The same
details Of the correction		- Specify the time period for each step clearly - Specify the details of How to report research results clear - Cut off item 5.5.2 Institute The parties shall issue a letter Certification or response letter Please notify us within 2 working days	Add reference documents	- Adjust reference documents
Reviewed by the Central Committee Consider the ethics of Human		Central Committee Consider research ethics In	Central Committee Consider the ethics of Human research,	Central Committee Consider the ethics of Human research,
Research **Review Date** Appointment Date	21 November 2012 to 24 January 2013	person, appointed date June 14, 2014 to July 3, 2014 Assoc. Prof. Dr.	date of appointment March 14, 2015 Until May 14, 2015, Assoc.	date of appointment 16 May 2017 to 30 September 2017
Approved by	Assoc. Prof. Dr. Suchart Areemit	Suchart Areemit	Prof. Dr. Suchart Areemit, Assoc.	Prof. Dr. Thada Sueblinwong

step Carry out	Issue 1 CREC 10 / v.1.0	Issue 2 CREC 09 / v.2.0	Issue 3 CREC 09 / v.2.1	Issue 4 CREC 09 / v 3.0
Position	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management	Chairman of the Board Foundation	Chairman of the Board Foundation Management
Approval	January 25, 2013	July 4, 2014	Administration 28 September 2016	October 1, 2017
Date, Effective Date	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017

History of Standard Operating Procedures (continued)

Producer	Version	Approval Date	Show main edits	Approved by
Subcommittee Development Method of operation standard	Issue No. 5 v.4.0	June 15 2563	- Reorder the steps - Add consideration for requesting additional site - Added more editing examples Or less in the appendix	Prof. Dr. Thada Sueblinwong Chairman of the Board Foundation Management
Subcommittee Development Method of operation standard	Issue 6 v.5.0	October 31, 2023 - Adjust the work process to Consistent with operations and Update information to current - Improve the type of decision accordingly SIDCER Suggestions - Added complete evaluation criteria Explain additional evaluation criteria to Clarity		Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management
Subcommittee Development Method of operation standard	Issue 7 v.5.1	July 24 2567	- Changed from v.5.0 to v.5.1 - Added recording of voting scores Section 5.4.2.4 shall be consistent with the Meeting minutes {vote for, vote against, abstain Pronounced (abstained)} - Add information to section 7. Appendix completely - Correct the document code.	Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management

Review of progress reports and renewal of research certification

Progress report and Renewal of IRB Approval

Issue that 5.1 Effective date: 24 July 2024

replaces the previous issue 5.0 Dated October 31, 2023

Author July 24, 2024

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Chairman of the Subcommittee on Standard Procedures Development

Approver July 24, 2024

(Assoc. Prof. Dr. Kwanchanok Yimtae)

Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

list of contents

1. Objective 1.1

To provide guidelines for reviewing the progress reports of research projects that have been approved.

Research and request for renewal of certification from the board

1.2 To protect the rights and well-being of volunteers participating in research projects on an ongoing basis.

2. Scope

Standard operating procedures cover review of research progress reports and renewal of research.

Certify the research proposal that has been approved by the research ethics committee.

3. Responsibility

3.1 The Central Committee shall determine the frequency of research progress reports appropriate to the level of research risk. 3.2 The principal investigator

shall submit research progress reports to the Committee on a regular basis as determined by the Central Committee.

3.3 The Office staff is responsible for notifying the principal investigator/research project coordinator to submit the research progress report before the certificate expires, as well as preparing the meeting minutes, sending the consideration result letter or research project certificate to the principal investigator/research project coordinator, and keeping the data in the Office database. 3.4 The secretary or the committee

member assigned by the chairman is responsible for reviewing the research progress report and summarizing the opinions to the Central Committee meeting for consideration of renewal or change of research project certification.

4. Procedure flow chart

Sequence	Operation	responsible person
1	Notify the principal investigator/research project coordinator Submit progress reports and renew project certification. ÿ	Office staff
2	Receive reports and check their completeness ÿ	Office staff
3	Consider the review/progress report format and request for project certification renewal ÿ	Secretary or Received Board Members assign
4	Set the frequency of progress reporting ÿ	Committee
5	Project certification renewal ÿ	Committee
6	Meeting minutes ÿ	Office staff
7	Notification of consideration results ÿ	Office staff
8	Collection of research progress reports	Office staff

5. Procedures

5.1 Notification to submit research progress reports

5.1.1 The office/office officer's automatic system will notify the principal researcher or the person Coordinate the project before the certificate expires 2 months, 1 month and the expiration date. In case of system failure, the office staff will enter the research project database every first week. of the month to check if any research projects will expire in 2 months.

5.1.2 The principal investigator/research project coordinator shall submit a research progress report or Enter information and attach electronic documents through the office's online system.

(e-submission) by

5.1.2.1 Research projects that have been approved by the meeting committee (Full Board Review) and research projects that have been approved by expedited review must use the research progress report form (AP 01-S10) and/or request for renewal of certification.

Research Outline

5.1.2.2 Attach a copy of the information sheet and the most recent consent form.

Stamped with the certification stamp of the Central Committee and signed by Volunteer This case includes re-consent.

5.1.2.3 Attach a summary table of the status report of all sites in Thailand.

(AP 02-S10)

5.2 Receiving research progress reports

5.2.1 The office officer shall examine the progress report documents, which include (a)

Delivery Letter (B) Documents according to Section 5.1.2

5.2.2 Record the date of receipt in the database system and check the expiration date of the certification framework.

Latest research

5.2.3 Office staff submit research progress reports with evaluation forms attached.

(AO 01-S10) to the Secretary or assigned committee member within 3 working days for

Consider the review format

5.3 Review of research project progress reports and decision-making

5.3.1 The Secretary/Assigned Reviewer submits the evaluation results into the online system.

The office or send a copy of the evaluation form (AO 01-S10) to the office before the meeting.

5.3.2 In the event that the progress report is subject to urgent consideration as announced by the committee

The Secretary/Review Committee member who is assigned is the one who reviews the matter.

Report progress and provide comments to the Chairman for decision.

5.3.3 In the event that the progress report does not meet the urgent consideration criteria as announced by the committee

The Secretary/Assigned Review Committee presents the results of the review.

5.3.4 The chairman of the meeting makes a decision by a majority vote. 5.3.5 The chairman discusses the risk types (see CREC 05) in the meeting and makes a decision on the risk type. If no one objects, the risk type decided is considered the resolution of the meeting.

5.3.6 Only the main directors and reviewing directors have the right to vote.

5.4 Determination of the frequency of submission of research progress reports 5.4.1 Research projects that the meeting has approved or requested additional information must specify the frequency of submission of progress reports. The chairman discusses the matter in the meeting and proposes the frequency of progress reports. If no one objects to the proposal, it is considered that the meeting approves that point. However, if there are other opinions that may not be conclusive, a majority vote is used to decide. 5.4.2 Research projects that have been approved by the expedited method must specify the frequency of submission of reports Progress once a year

5.5 Renewal of certification at the meeting

5.5.1 In case the researcher submits a progress report and requests for a renewal of research project certification, with complete documents within 30 days before the certification expiration date, the committee will renew the certification starting from the last research certification expiration date. 5.5.2 In case the researcher submits a progress report and requests for a renewal of research project certification more than 30 days before the certification expiration date, the committee will renew the certification on the meeting date that the resolution is continuously approved for the research project that has been approved at the meeting and renew it on the date the chairman signs for the research project that has been approved by the expedited method.

5.5.3 In the event that the principal investigator/research project coordinator does not submit a research progress report until after the research certification expiration date, the office officer shall prepare a letter for the president to sign to inform the researcher of the suspension of research certification and

Recommendations/conditions in case researchers want to renew the research project certification (by proceeding in accordance with the resolution of the chairman of the central committee of each group) 5.5.4 In case the principal investigator/research project coordinator submits a research progress report after the research certification expiration date, the committee will consider the information according to the conditions informed to the researchers. In case the committee resolves to suspend the research project certification by renewing it on the meeting date that approves the continuation of research for research projects that have been approved at the meeting and renewing it on the date the chairman signs for research projects that have been approved by the expedited method. The expiration date will start counting from the latest research certification expiration date (not counting continuously from the new certification date). During the certification break, researchers cannot recruit new volunteers to participate in the research and cannot conduct any research unless the committee considers that the research is necessary for the benefit of the volunteers who are still in the research or the research termination will increase the risk to the volunteers. In this case, the researcher should follow up and take care of the volunteers as appropriate. The committee should specify whether the exception is for a specific volunteer or all volunteers in the research project.

5.6 Meeting minutes The office staff records the discussion results, votes, and summarizes the consideration results.

Research project certification period and frequency of submission of research progress reports

5.6.1 The consideration of temporary suspension or termination of certification will be made by a resolution of the full committee meeting when it is considered that: - The researcher has not complied with the requirements specified by the central committee; - The researcher has not consistently complied with the guidelines for good research practice (ICH-GCP); - The conduct of the research project places more risk on the volunteers than the benefits. receive

- It has been reported that the Food and Drug Administration has temporarily suspended or terminated the research. Research

5.6.2 In the event of a request for extension of research project certification, when considering certification or certification after receiving additional information, the committee meeting will summarize the certification period.

Research projects and the frequency of submitting research progress reports. However, the period for renewing research project certification and the frequency of submitting research progress reports may differ from the previous time.

5.7 Notification of the results of the consideration to researchers and partner institutions 5.7.1 The office officer drafts a letter of notification of the results of the consideration or a certificate to the principal researcher/research project coordinator and partner institutions, which includes:

a. The results of the consideration of the research progress report and the date of consideration **b.** In the case where the decision is "approved", specify the approval date from the beginning until the end of the research proposal approval **c.** In the case where the decision is "request for information", specify the additional information required by the principal investigator/coordinator.

Research projects must be carried out

d. In the case where the decision is “recommend further action”, please specify the recommendation that you would like the principal investigator/coordinator to make.

Research projects must be carried out

5. In the event that there is an opinion that the project certification should not be renewed, it shall be brought for consideration in the Central Committee meeting.

5.7.2 The Secretary checks the accuracy of the information and language before sending the letter or certificate for the signature of the Central Committee Chairman (AL 02-S10 or AL 03-S10). or AL 04-S10 or AL 05-S10 or AL 06-S10)

5.7.3 Method of notification of results

The office staff will inform the results via electronic system to the principal investigator/research project coordinator and the institutional research ethics committee.

5.7.4 The period for notification of results depends on the method of considering the research progress report.

5.7.4.1 Progress report of research projects previously approved by urgent review. The office staff will send a document informing the results within 5 working days after the date of receiving the evaluation results documents from the reviewing committee. 5.7.4.2 Progress report of research projects brought to the meeting for consideration. The office staff will send a document informing the results within 5 working days after the meeting.

5.8 Collection of research progress reports

5.8.1 Office staff collects research progress reports and committee evaluation forms.

and a copy of the letter stating the results of the consideration or the certificate signed by the chairman, included with

All documents of the research project

5.8.2 Office staff shall enter information into the Office database system, unless the online system

Automatically saved in full.

6. Definition

Suspension of certification temporary (suspension of prior approval)	The decision to temporarily suspend the approval of all activities or Some, such as suspending enrollment in research, wait Internal audit results or suspension of all research activities, leaving only health care Research participants whose research projects have been suspended are still considered ongoing and Progress must be reported to the Board until the suspension is lifted or The research project was withdrawn. Suspension of approval occurs when the Board finds serious or continuing noncompliance or unanticipated problems. The decision is made at the meeting. The Committee, unless the Chairman deems that delaying the meeting will endanger the participants. Research
End of certification (termination of prior approval)	The decision to permanently withdraw certification occurs in cases where the Board finds serious or continuing noncompliance or unanticipated problems judgment Done at the Central Committee meeting

7. Appendix

TO 01-S10	Notification letter for submission of progress reports/request for project extension
TO 02-S10	Urgent notification of progress report and project renewal
TO 03-S10	Progress Report and Project Extension Notification Form for Public Consideration meet
TO 04-S10	Letter of notification of progress report and project extension upon consideration of results That is, request for additional information.

TO 05-S10	Letter of notification of progress report and project extension upon consideration of results It is a temporary suspension of certification (suspension)
TO 06-S10	of the progress report certification notification and project extension when the results of the consideration are known. That is, termination of certification.
AO 01-S10	Research progress report assessment form
AP 01-S10	Research progress report form
AP 02-S10	Summary table of status reports of all sites in Thailand (both those that have applied for certification) CREC and Local EC)

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

8.3 Office of Human Research Protection, Department of Health and Human Service. Guidance on IRB Continuing Review of Research. November 10, 2010.

8.4 Guidance for IRBs, Clinical Investigators, and Sponsors. IRB Continuing Review after Clinical Investigation Approval, February 2012.

8.5 45 CFR 46 (US Code of Federal Regulations. Title 45 Public Welfare Department of Health and Human Services Part 46 Protection of Human Subjects).

9. History of standard operating procedures

step Carry out	Issue 1 CREC 11 / v.1.0	Issue 2 CREC 10 / v.2.0	Issue 3 CREC 10 / v.2.1	Issue 4 CREC 10 / v 3.0
Prepared by	Drafting Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures
Reason of Improvement		For convenience The work of the faculty The Central Committee and Office staff	Modified as per recommendations Of SIDCER (14 Mar. 58)	The same

step **Carry out**	**Issue 1** **CREC 11 / v.1.0**	**Issue 2** **CREC 10 / v.2.0**	**Issue 3** **CREC 10 / v.2.1**	**Issue 4** **CREC 10 / v 3.0**
details **Of the** **correct**		Set guidelines Review the report Research progress that It is considered in the place Board meeting Full set or consider Urgent - Set guidelines Request for renewal of certification Research Outline - Set time frame Consideration of the report The progress of Rapid research And clear	- Added flow chart fixes Verification Completeness of the report and responsible persons - Added date setting The certification period must not be Start before expiration date More than 1 month - Fix sending copies Documents showing Consent Latest version at Certified - Corrected the text in the voting. - Add reference documents	Adjust reference documents
Reviewed by the Central Committee	Consider the ethics of Human research	Central Committee Consider the ethics of Human research	Central Committee Consider the ethics of Human research	Central Committee Consider the ethics of Human research
Review Date Appointment Date	21 November 2012 to 24 January 2013	Appoint date June 14, 2014 to July 3, 2014	Appoint date March 14, 2015 Until May 14, 2015	Appoint date 16 May 2017 to 30 September 2017
Approved	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit	Prof. Dr. Thada Sueblinwong
by Position	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management	Chairman of the Board Foundation	Chairman of the Committee Foundation Executive Board
Approval	January 25, 2013	July 4, 2014	Administration 28 September 2016	October 1, 2017
date, Effective date: 25 January 2013		July 4, 2014	September 28, 2016	October 1, 2017

History of revisions to standard operating procedures (continued)

date	Version	Approval	Show main edits	Approved
Subcommittee **Creator** 15 June Development Method of operation standard	Issue No. 5 v.4.0	2563	- Adjust the responsible person to be consistent - Fix the issue of copies of the intent document Signed consent of volunteers - Set the renewal date if the report is submitted before the expiration date is more than 30 days - Change the counting of the renewal date to the meeting date (if the report is not submitted within 30 days before Expired) - The date for sending the results to researchers has been changed from 5 days to within 3 working days.	**by** Prof. Dr. Thada Sueblinwong Chairman of the Board Foundation Management
Subcommittee Development Method of operation standard	Issue 6 v.5.0	31 October 2023 - Revised the chapter title for appropriateness - Revised the work procedures to be consistent with the work and updated the information to be current - Improved the type of decision according to SIDCER's suggestions		Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management
Subcommittee Development Method of operation standard	Issue 7 v.5.1	July 24 2567	- Changed from v.5.0 to v.5.1 - Improved the detail steps Operate according to the suggestions of The Central Committee shall be consistent With the operating guidelines - add information in section 6. Definitions - add information in section 7. Appendix	Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management

Review of adverse event reports
Review of Adverse Event Report

Issue that 5.1 Effective date: 24 July 2024

replaces the previous issue 5.0 Dated October 31, 2023

Author July 24, 2024

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Chairman of the Subcommittee on Standard Procedures Development

Approver July 24, 2024

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Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

list of contents

1. Objective: To

provide guidelines for considering adverse events occurring in research projects that have been approved by Central Committee

2. Scope

Standard operating procedures include consideration of adverse events reported by investigators, sponsors or contract research organizations (CROs), or by reports from the institutional ethics committees where the adverse event occurred, and reports from independent data monitoring boards (IDMC, DSMB, DMC)

3. Responsibility

3.1 The principal investigator at each institution (site PI) is responsible for reporting serious or unexpected adverse events (SAEs/SUSARs) or unexpected problems (local unanticipated problems) to the local IRB/REC and sponsor within a specified timeframe. 3.2 The local IRB/REC is responsible for reviewing reports of adverse events at the institution in accordance with the institutional standard operating procedures and reporting the results of the review to the Central Committee only for trials that are (a) subject to a site visit, (b) suspension of approval, and (c) termination of approval within 10 working days from the date of such resolution.

3.3 Research sponsors (sponsors) or contract research organizations (CROs) (company research projects)

3.3.1 Report serious or unexpected adverse events

(SAEs) occurring in volunteers at the research institution (local SAE/SUSAR) or unexpected events (local unanticipated problems) occurring in volunteers at the research institution that the sponsor has assessed as likely or definitely related to the investigational drug and may increase the risk to the volunteer or new issues that may adversely affect the safety of the volunteer must be reported in the form of a follow-up report with a summary report pointing out the important issues to the Central Committee after the results of the evaluation of the relationship with

3.3.2 Report serious or unexpected adverse events that occur outside the institution {Institution Others in Thailand and abroad (if any)} (non-local SAE and periodic SUSAR report) that are reported at least every 6 months to the Central Committee.

Line Listing Form with Summary Report showing key points

3.3.3 Report from the Independent Data Monitoring Board (DSMB) or medical team and Other types of reports are submitted to the Central Committee.

Note: (1) For reports or adverse events that may increase the risk to volunteers or reveal new issues that may compromise the safety of volunteers or may Affecting the research operation, the research sponsor must report to the Central Committee as soon as possible, within 15 calendar days. (2) Other types of reports must be reported annually or on a Period or as requested in the form of a summary report pointing out key issues

3.4 The Secretary or the Central Committee or the assigned committee members are responsible for reviewing the report. Consider, decide and present the report to the Central Committee meeting.

3.5 Office staff are responsible for receiving reports according to the specified criteria and checking for completeness and taking action. Submit a report to the Central Committee, notify the results of the consideration and collect documents.

4. Procedure flow chart

Sequence	Operation	responsible person
1	Receive adverse event reports ÿ	Office staff
2	Review the report ÿ	Secretary of the Central Committee or the assigned committee
3	Consider and decide ÿ	Central Committee
4	Report results ÿ	Office staff
5	Document storage	Office staff

5. Procedure 5.1.

Receiving reports of adverse events

5.1.1 The office staff shall receive reports of adverse events that meet the following criteria:

5.1.1.1 Report from research sponsors/contract research organizations that meet the criteria

Next

(a) Report any serious or unexpected adverse events that occur with

Volunteers in the research institution (local SAE/SUSAR) or non-research events (local unanticipated problems) that occurred with volunteers in

The research institution that the research funder has assessed as likely related or definitely related to the investigational drug and

This may increase risk to volunteers or reveal new issues that could have adverse effects.

For the safety of volunteers, any new and significant information must be reported in the form

Monitoring report with summary report highlighting key issues

(b) Report any serious or unexpected adverse events that occur outside

Institutions (other institutions in Thailand and abroad (if any)) (non-local SAE and periodic SUSAR report) that have reported periodically at least

Every 6 months in a line listing format with a summary report.

Point out important points

(c) Reports from the Independent Data Monitoring Board (DSMB) or medical team and other types of reports in the form of summary reports.

Key Points

5.1.1.2 Report from the local institutional ethics committee (IRB/REC)

It is a report of a serious or unexpected adverse event (local SAE/SUSAR) or The case that is not Think (local unanticipated Problems) that occur with volunteers in the supervising institutions have a decision result.

(a) subject to a site visit, (b) suspension of approval, and (c) termination of approval.

Serious Adverse Event Report Form

Institution (or AP Form 01-S11) with a letter of notification of decision from

Institutional Research Ethics Committee

5.1.2 The office staff presents the report to the secretary or the assigned committee member or the pharmacist/or the assigned pharmacology knowledgeable person to review the report and present it to the meeting. **Note:** The time period for reviewing the report and the completeness of the documents is not the total time. More than 3 working days

5.1.3 Send documents to reviewers or allow reviewers to access electronic documents in The online system contains the following documents: a. Reports received from the research sponsor/institutional ethics committee; b. Adverse event assessment form or other documents as requested by the reviewer, such as; c. The latest approved research protocol; d. The latest informed consent document; e. The latest research progress report (if any); f. The latest Investigator's brochure.

5.2 Review of the report has the following guidelines:

1) What is the relationship between the serious adverse event and the research procedure or the investigational drug? For example, - definitely related - probably related. 2) A serious adverse event is an unexpected event that poses a risk to the

What kind of unexpected danger is this?

- unexpected (in terms of nature, severity, or frequency); and
- related or possibly related to participation in the research; and
- subjects or others are placed at a greater risk of harm than was recognized.

3) The outcome of the adverse event to the volunteers; 4) Considerations and actions of the researcher and/or the research funder, such as:

- Improving research projects (e.g. safety monitoring, updates to inclusion/exclusion criteria or withdrawal criteria)

- Adding information to the volunteer information document
- Request for new consent

5) The reviewer shall record one of the following comments in the evaluation form (AO 01-S11):

(1) Acknowledged without any further action required, or

(2) Request for information

(3) Recommendations for further action (recommend further action) (specify...)

(4) For consideration at the Central Committee meeting (need full board review)

{(4) In the event that the reviewer considers that the reported adverse events may increase If there is a risk to the volunteer or it may affect the safety of the volunteer or it may affect the research, the research team should be advised or should have Consideration for conducting an inspection or suspending certification}

Note: The reviewing committee shall submit the review results to the Office within 5 working days or Before the meeting of the Central Committee (in the case of being brought for consideration in the meeting)

5.3 Decision-making at the Central Committee Meeting 5.3.1

The Secretary or Reviewing Committee presents the review results at the meeting. 5.3.2

The Chairman opens the discussion and presents the decision results in the following order:

(1) Acknowledged without any further action required.

(2) Request for information

(3) Recommendations for further action as follows (select):

- Recommend a visit to supervise the research (recommendation for site visit)
- Suspension of approval - Termination of approval
- Other (specify)

5.3.3 In the case where the decision is a request for additional information or recommendations Further action (recommend further action) What might be the recommendation?

One of the following, or in addition to these

- Should improve the research project (update protocol, eg, safety monitoring, updates to inclusion/exclusion criteria or withdrawal criteria)

- Additional information should be provided to research participants/volunteers (provide new safety information to research participants)

- The information document for research participants/volunteers should be improved and requested. Re-consent (update ICF and re-consent)

- In case of temporary suspension of certification, please specify the period of suspension of certification and the conditions in Such withdrawal of certification suspension

- In case of termination of certification, please state the reasons and the period within which an appeal can be made. Central Committee

Note: In the case of reports of serious adverse events or unexpected events (local SAE/SUSAR) or unexpected events (local unanticipated problems) occurring with volunteers at research institutions in Thailand that meet the criteria of the Central Committee, where the reviewers believe that there should be recommendations for the research team, the meeting decides whether the event should be notified to other partner institutions or not (by concealing the name of the institution where the event occurred).

5.3.4 The Chairman shall cast a vote. The decision shall be made by a majority vote. If the number of votes is equal, the Chairman shall cast one additional vote as the deciding vote.

5.4 Notification of consideration results

5.4.1 The office staff shall prepare a letter announcing the decision (AL 01-S11) dated at the meeting or on the date of the reviewing committee's consideration, signed by the chairman of the central committee, within 5 working days after the meeting or after receiving the decision from the reviewing committee.

5.4.2 The result shall be notified to the ethics committee of the institution or the research sponsor/organization that received the decision. Conduct research under contract via electronic system

5.5 Document storage

5.5.1 The office staff shall collect reports and assessment forms into electronic files. Research Project

5.5.2 Office staff shall keep evidence of electronic data transmission and other contacts with researchers, research project coordinators, and partner institutions in the electronic files of the research project.

5.5.3 Office staff shall record operational data in the Office database.

6. Definition

Unexpected events (unanticipated problems)	An event, experience, or outcome that meets all of the following criteria: 1. Unexpected (in terms of symptoms, severity, or frequency) It is known in accordance with (a) the research procedures described in the relevant documents. With research proposals, such as research proposals approved by IRB and Documents expressing consent and as known from (b) the nature of Population currently being studied 2. Involved or may be involved in the research process Volunteering may be a method involved in research procedures. 3. It is believed that it increases physical, mental, economic or social risk. More than ever known
Adverse events (Adverse Event, AE)	Refers to any adverse medical event that occurs in a patient. or volunteers participating in the research, including any unusual signs (e.g., abnormal physical examination or laboratory results), symptoms, clinical events, or illnesses that occur while the volunteer is participating. During the research participation, regardless of whether the event was related to Whether or not the volunteers participate in the research. Adverse events are It highlights the clinical, physical and psychological harms that are most commonly found in biomedical research, although they can occasionally occur in Context of social science and behavioral science research
Adverse Event Type Serious Adverse Events, SAEs)	Refers to any adverse medical event that occurs when taken. Medicine or use of medical devices or diagnostic or treatment procedures And then make - Died - It is life-threatening. - Need to be hospitalized or stay in the hospital longer - Permanent and significant disability/disability occurs - Congenital disabilities/abnormalities

Suspected incident Adverse Event Type Vicious, violent and unexpected (Suspected Unexpected Serious Adverse Reactions, SUSARs)	A serious adverse event that was previously unknown or unexpected, both in terms of the study method and the study population, and was not previously specified in the study. Research Project or Researcher's Manual

7. Appendix

AP 01-S11	Report of serious or unexpected adverse events occurring in the institution
AO 01-S11	Assessment of safety/serious or non-serious adverse event reports Expected (institutional and non-institutional)
TO 01-S11	Notification of adverse event review results

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

8.3 FERCIT. Guidelines for reporting adverse events from the seminar. "Achieving Guidance in Clinical Trial Safety Information among Stakeholder" June 2011

9. History of standard operating procedures

step Carry out	Issue 1 CREC 11 / v.1.0	Issue 2 CREC 10 / v.2.0	Issue 3 CREC 10 / v.2.1	Issue 4 CREC 10 / v 3.0
Prepared by	Drafting Subcommittee Method of operation standard	Development Subcommittee Standard operating procedures	Subcommittee Develop procedures standard	Development Subcommittee Standard operating procedures
Reason of Improvement		For convenience Performing the work of	Modify according to Advice of SIDCER	To be suitable for Working with partner institutions

step **Carry out**	**Issue 1** **CREC 11 / v.1.0**	**Issue 2** **CREC 10 / v.2.0**	**Issue 3** **CREC 10 / v.2.1**	**Issue 4** **CREC 10 / v 3.0**
		Central Committee and office staff 1. Procedure	(14 Mar. 2015)	
details **Of the correction**	1. Method of practice 2. Appendix documents - Added assessment Adverse Event Report Type serious	- Identify the person who reports adverse events to the committee. The middle is clear - add the results of the consideration in the meeting, which is acknowledgement and conduct inspection visits - Fix the method of reporting results Consider specifying the method and persons to be notified. clear - Set the framework Review period and notification of results Fast and clear 2. Fix AP 06_1, AP 06_2, TO 14_1, TO 14_2, AL 05	- Edit sequence number 1 flow chart - Add reference documents	Separate into 2 approaches is 1) Reporting of serious adverse events In partner institutions or institutions with a committee Research ethics and 2) Report serious adverse events in institutions that do not have Ethics Committee, Research or when received Request - Adjust the comments of The Central Committee review - Adjust the voting in the meeting Central Committee - Adjust reference documents - Adjust AP 06_1 add part Of Local EC
Reviewed by the Central Committee	Consider the ethics of Human research	Central Committee Consider the ethics of Human research,	Central Committee Consider the ethics of Human research,	Central Committee Consider research ethics In
Review Date Appointment Date	21 November 2012 to 24 January 2013	date of appointment June 14, 2014 to July 3, 2014 Assoc. Prof. Dr.	date of appointment March 14, 2015 Until May 14, 2015, Assoc.	person, appointed date 16 May 2017 to 30 September 2017
Approved by	Suchart Areemit Assoc. Prof.	Dr. Suchart Areemit	Prof. Dr. Suchart Areemit,	Assoc. Prof. Dr. Thada Sueblinwong

step **Carry out**	**Issue 1** **CREC 11 / v.1.0**	**Issue 2** **CREC 10 / v.2.0**	**Issue 3** **CREC 10 / v.2.1**	**Issue 4** **CREC 10 / v 3.0**
Position	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management
Approval	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017
Date, Effective Date	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017

History of Standard Operating Procedures (continued)

Creator	**Version**	**Approval Date**	**Show main edits**	**Approved by**
Subcommittee Development Method of operation standard	Edition No. 5 v.4.0	June 15 2563	- Separate into 2 approaches: 1) Reporting of adverse events Severe type in partner institutions or institutions that have Research Ethics Committee and 2) Report on adverse events type Serious in institutions without a committee Research ethics or upon request - Adjust the opinions of the central reviewers. - Adjust the voting in the board meeting Middle - Adjust reference documents - Adjust AP 06_1, add Local EC section.	Prof. Dr. Thada Sueblinwong Chairman of the Board Foundation Management
Subcommittee Development Method of operation standard	Issue 6 v.5.0	October 31 2566	- Added text for clarity Operation - Improve the type of decision accordingly SIDCER Suggestions	Prof. Dr. Kwanchanok Yimtae Chairman of the Executive Board Foundation
Subcommittee Development Method of operation standard	Issue 7 v.5.1	24 July 2567	- Changed from v.5.0 to v.5.1 - Added details for eligible reports Consider for clarity in implementation	Prof. Dr. Kwanchanok Yimtae Chairman of the Executive Board Foundation

Consideration of the research end-of-term report

Review of Close-out Study

Issue that 5.1 Effective date: 24 July 2024

replaces the previous issue 5.0 Dated October 31, 2023

Author July 24, 2024

(Colonel Assoc. Prof. Dr. Sahapol Anantanacharoen)

Chairman of the Subcommittee on Standard Procedures Development

Approver July 24, 2024

(Assoc. Prof. Dr. Kwanchanok Yimtae)

Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

list of contents

1. Objective

To serve as a guideline for reviewing the research termination report of the research project that has been approved.

Research from the committee reviewed by the full committee meeting

2. Scope

Standard operating procedures cover review of the end-of-study report, which is a requirement for researchers.

The research project coordinator or project director must submit the research project to the Central Committee when the research project is completed (completion of a trial). The research completion report must be submitted to the meeting in all cases, regardless of whether it has been approved.

In any format, the meeting may make additional decisions based on the information in that report.

3. Responsibility

3.1 The principal investigator or research project coordinator is responsible for reporting the completion of the research to the committee.

3.2 The Office staff is responsible for notifying the principal investigator of the expiration date of the certification.

Receive reports and check their completeness, notify the results of the consideration, and store documents.

3.3 The Secretary or assigned committee member has the duty to review the research completion report and submit it to Chairman of the Central Committee

3.4 The Chairman of the Central Committee has the duty to consider and decide on the research conclusion report.

4. Procedure flow chart

Sequence	Operation	responsible person
1	Remind to submit the research end report ÿ	Office staff
2	Receive the research completion report document ÿ	Office staff Secretary
3	Review and Consider ÿ	Secretary or Assigned committee
4	Consider the decision at the full committee meeting. ÿ	Committee
5	Notification of decision ÿ	Office staff

Sequence	Operation	responsible person
6	Document storage	Office staff

5. Procedure 5.1

Notification of researchers to submit research completion reports

The Office Officer shall send a reminder letter to the principal investigator or research project coordinator at least 60 days before the expiration date of the certificate, as detailed in the Procedures.

Standards for considering research progress reports (CREC 10)

5.2 Receipt of research completion report documents

5.2.1 The office staff receives the research completion report and checks its completeness and signs it.

Received in database system

5.2.2 The office staff shall submit the research completion report to the secretary within 3 working days in the form of

(1) a document or (2) research project information and related documents via

The electronic system consists of the following documents:

- Research Ending Report Form (AP01-S12)
- End of research evaluation form (AO 01-S12)
- The most recent approved research proposal (if requested by the reviewer)
- Latest research proposal certification (if requested by the reviewer)

5.3 Review of the research end report 5.3.1 The

secretary or the committee assigned by the secretary shall review the report by considering:

The following points

- Is the number of volunteers participating in the research project as planned?
- The researcher's operations are in accordance with the research framework approved by the committee.

Or not

- Are there any complaints about the research or the researchers during the research?
- What are the conclusions of the preliminary study?

- Benefits and impacts on volunteers, including actions related to volunteers after the end of the research.
- Problems and obstacles of research

5.3.2 The Secretary or the reviewing committee member shall send the review results according to the research end evaluation form (AO 01-S12) back to the office via the electronic system in accordance with the office's requirements within 5 working days after receiving the report or before Central Committee Meeting

5.4 Judgment

5.4.1 The Secretary or the reviewing committee shall present the consideration of the research completion report to Chairman

5.4.2 The Chairman shall decide on one of the following:

(1) approve (2) request for information (3) recommend further action (specify...)

5.5 Notification of consideration results

5.5.1 The office staff shall send the results of the consideration in a written form notifying the results of the consideration of the research end report (AL 01-S12) signed by the chairperson within 5 working days after the chairperson's decision via the electronic system to the principal investigator or research project coordinator and Research Ethics Committee of the Research Institute

5.5.2 The research end report acknowledgment letter must include: - The date of the acknowledgment committee meeting -
The Office's research project document retention period is 3 years from the date the committee acknowledges the end of the research project.

5.6 Storage of research completion report documents

5.6.1 The office staff collects the research completion report and evaluation form into a file. Electronics of research projects

5.6.2 The office staff shall keep evidence of electronic data transmission and other contacts with the principal investigator, research project coordinator, and partner institutions in the research project electronic file.

5.6.3 Office staff record the operation data in the office database.

5.7 Reporting to the meeting: The office officer shall report the termination of the research project decided by the chairman in the agenda item "Consideration of the research termination report", which shall include at least the following details:

- Name of the research project.
- CREC project code and/or the research project proposer's name - Principal investigator's name - Research project sponsor - Certification date and certification termination date - Method of consideration (except/urgent/in the meeting) - Date the office received the termination report. If there is a research summary, it must be sent in electronic form to the committee. consider

6. Definition

End of research report (close study report)	Closing report of all research activities according to the research outline at the institute where the research is being conducted when the research is complete according to the plan in the outline. Research draft It has the same meaning as the final report in ICH GCP.

7. Appendix

AL 01-S12	Letter of notification of the decision on the research end report,
AO 01-S12	research end report evaluation form,
AP 01-S12	research end report form

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

9. History of Standard Procedures,

Step No. 1 **Carry out**	**CREC 11 / v.1.0**	**Issue 2** **CREC 10 / v.2.0**	**Issue 3** **CREC 10 / v.2.1**	**Issue 4** **CREC 10 / v 3.0**
Prepared by	Subcommittee for Drafting Standard Procedures	Subcommittee for developing standard operating	The Subcommittee for the Development of Standard Operating Procedures has	Subcommittee for Development of Standard Operating Procedures
Reason for improvement		procedures to facilitate operations Central Committee and office staff 1. Procedures	revised the standard to be a single version throughout.	remains the same.
details Of the correction	Procedure - The method for sending documents to the committee is not specified. Middle Reviewer - Review guidelines (1) Number of volunteers Participate in The research project is going on As planned (2) Operation of The main researcher is in accordance with the research outline. Central Committee Is it certified or not? (3) What is the conclusion of the initial study results?	- Specify the method of submitting the report, research results summary and research outline. To the Central Committee Reviewer - Add guidelines Review the benefits and the impact on volunteers, including related actions Later volunteers ~~End of research~~ - Set time frame The process of Operate quickly And clear	- Changed from v.2.0 v.2.1 - Added reference documents	- Added definition of summary report Research results - Adjust reference documents

step Carry out	Issue 1 CREC 11 / v.1.0	Issue 2 CREC 10 / v.2.0	Issue 3 CREC 10 / v.2.1	Issue 4 CREC 10 / v 3.0
	(4) Problems and obstacles Of research	- Specify the results of the consideration In the meeting, Clear and no need to post Resolution - Specify the notification method. The results of the consideration Clearly state both the method and the person who must notify. 2. Fix AP 07, AO 15, AL 07		
Reviewed by the Central Committee	Consider the ethics of Human research	Central Committee Consider the ethics of Human research	Central Committee Consider the ethics of Human research	Central Committee Consider the ethics of Human research
Review Date Appointment Date	21 November 2012 to 24 January 2013	Appoint date June 14, 2014 to July 3, 2014	Appoint date March 14, 2015 Until May 14, 2015	Appoint date May 16, 2017 Until 30 September 2017
Approved	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit	Prof. Dr. Thada Sueblinwong
by Position	Chairman of the Board Foundation Management	Chairman of the Board Management Foundation	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management
Approval	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017
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History of Standard Operating Procedures (continued)

Producer	Version	Approval	Show main edits	Approved by
Subcommittee Development Method of operation standard	Issue No. 5 v.4.0	**date** June 15 2563	- Change the chapter name from final report to close study report. - Adjust the review process - Adjust the definition of “End of Period Report” research"	Prof. Dr. Thada Sueblinwong Chairman of the Board Foundation Management

Producer	Version	Approval Date	Show main edits	Approved by
Subcommittee on Development Method of operation standard	Issue 6 v.5.0	October 31 2566	- The research conclusion report does not need to be considered in the meeting. But use the urgent method by The secretary or the committee member assigned by the secretary shall consider and propose to the chairman for consideration. decide - Add details of the procedures in the case of an exempted research project. Or receive it by express method	Prof. Dr. Kwanchanok Yimtae Chairman of the Executive Board Foundation
Subcommittee Development Method of operation standard	Issue 7 v.5.1	July 24 2567	- Changed from v.5.0 to v.5.1 - Correct the document code - Improve the type of decision according to SIDCER's suggestions	Prof. Dr. Kwanchanok Yimtae Chairman of the Executive Board Foundation

Consideration of reports on premature termination/suspension of research projects

Review of Premature Termination/Suspension of a Trial

Issue that 5.1 Date of July 24, 2024

replaces the previous issue 5.0 use: Dated October 31, 2023

Author July 24, 2024

(Colonel Assoc. Prof. Dr. Sahapol Anantanacharoen)

Chairman of the Subcommittee on Standard Procedures Development

Approver July 24, 2024

(Assoc. Prof. Dr. Kwanchanok Yimtae)

Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

list of contents

1. Objective

To serve as a guideline for the Central Committee in reviewing the report on the premature termination of research projects/

Temporary suspension of research

2. Scope

Standard operating procedures cover research projects that have received research outline approval from the committee.

Central but the Central Committee or the Data and Safety Oversight Committee or the funders

Researchers have resolved to terminate the research project before the deadline or temporarily suspend the research.

3. Responsibility

3.1 The principal investigator or research project coordinator has the duty to report to the Central Committee when there is

Terminate the research project before the deadline or temporarily suspend the research, along with a written explanation by

Details of the reasons for discontinuing or suspending research

3.2 The Central Committee has the duty to review the report on premature termination/suspension of research projects.

It also has the power to terminate or withdraw approval of a research project before the due date (withdraw approval) when

there is information indicating or suspecting that the continuation of the research project may cause problems in

Regarding the safety or benefits of volunteers participating in research projects

3.3 The person in charge of the research institute has the authority to terminate the research project before the deadline or suspend the research according to the advice of

Data Safety Oversight Board or Research Funder or Central Committee

or the Institute's Research Ethics Committee

4. Procedure flow chart

Order	Operation	responsible person
1	Receive report documents ÿ	Office staff
2	Review and evaluate research project termination reports Pre-scheduled/research suspension ÿ	Secretary or Central Committee
3	Considered at the Central Committee meeting ÿ	Central Committee

Order	Operation	responsible person
4	Notification of consideration results ÿ	Office staff
5	Document storage	Office staff

5. Procedures 5.1

Receiving documents reporting the termination of

a research project 5.1.1 The office staff receives documents reporting the premature termination of a trial or the temporary suspension of a trial from

The principal investigator or research project coordinator, according to the AP 01-S13 form and submit to Secretary

5.1.2 The Secretary or the assigned committee member shall review the report.

5.1.3 The office staff shall collect all documents of the research project and submit them to the secretary or assigned committee member within 3 working days in the form of (1) documents or (2) research project information and related documents via the electronic system.

Consisting of the following documents

- Report on premature termination of research projects/suspension of research (AP 01-S13)
- Evaluation form for the report on premature termination of research projects/research suspension (AO 01-S13)
- The most recent approved research proposal (if requested by the reviewer)
- Latest research proposal certification (if requested by the reviewer)

5.2 Review of premature research termination/suspension reports

5.2.1 The Secretary or assigned committee member shall review the research project termination report first.

Research suspension/suspension has the following review principles:

- Reasons for premature termination of research project/research suspension
- Appropriate treatment or monitoring of volunteers after the termination of the research project.

Pre-scheduled/research suspension

- Plans for informing volunteers

5.2.2 The Secretary or the assigned committee member records the opinion in the evaluation form of the report on the premature termination of the research project/ suspension of research (AO 01-S13) in one of the following ways: (1) approve (2) request for additional information (3) recommend further action (recommend further action) (specify...)

(4) bring to the consideration of the Central Committee meeting (need full board review)

5.2.3 The Secretary or the assigned committee member sends the evaluation form of the report on the premature termination of the research project/suspension of research (AO 01-S13) in one of the following ways: (1) approve (approve) (2) request for additional information (request for information) (3) recommend further action (recommend further action) (specify...) (4) bring to the consideration of the Central Committee meeting (need full board review)

Pre-scheduled research projects/research suspension (AO 01-S13) return to the office via Electronic system in accordance with the Office's regulations within 5 working days after receiving the report or before the Central Committee meeting.

5.3 Consideration in the Central Committee meeting 5.3.1 The Secretary or the assigned committee member presents the summary of the consideration of the report on premature termination of the research project/research suspension in the Central Committee meeting.

5.3.2 The chairman discusses at the Central Committee meeting and summarizes the decision as one of the following: As follows

(1) approve (2) request for information (3) recommend further action (specify...) If no one objects, the matter shall be considered a resolution of the meeting.

5.4 Notification of consideration results

5.4.1 The office staff sends a letter informing of the consideration results (AL 01-S13) dated at the Central Committee meeting or the date of the reviewing committee's consideration, signed by the Central Committee Chair, within 5 working days after the meeting or after receiving the consideration results from the reviewing committee via the electronic system to the principal investigator or research project coordinator and the Research Ethics Committee. research institute

5.4.2 The book must consist of:

- Date of the review committee meeting or date of the reviewing committee's consideration

- The Office's research project documents are kept for 3 years from the date.

The Central Committee acknowledged the premature termination of the research project.

5.5 Document storage

5.5.1 The Office's research project documents are kept for 3 years from the date of the committee.

The Central Committee acknowledges the premature termination of the research project/research suspension.

5.5.2 The office staff shall collect reports on premature termination of research projects/research suspensions and Evaluation form entered into electronic file of research project

5.5.3 Office staff collect evidence of data transmission via electronic media and

Contact the principal investigator, research project coordinator and partner institutions at Electronics of research projects

5.5.4 Office staff record the operation data in the office database.

6. Definition

Premature cessation of research (premature termination of a trial)	It means the termination of the research project by - stopping the recruitment of research participants (Enrollment) before the number is reached - or stopping the follow-up of research participants (Follow-up) before the number of times specified in the research project is reached.
Temporary suspension of research suspension of a trial	It has a similar meaning to premature termination of research, but it is It is temporary and will resume after the problem is solved. However, if the researcher wants to continue, they must submit an application for approval. In the form of protocol amendment

7. Appendix

AL 01-S13	Notification of consideration of research termination results before the deadline
AO 01-S13	Evaluation form for early termination of research projects
AP 01-S13	Report on premature termination of research project

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

9. History of Standard Procedures,

Step No. 1 **Proceed**	**CREC 11 / v.1.0**	**Issue 2** **CREC 10 / v.2.0**	**Issue 3** **CREC 10 / v.2.1**	**Issue 4** **CREC 10 / v 3.0**
Prepared by	Subcommittee for Drafting Standard Procedures	Subcommittee for developing standard operating	The Subcommittee for the Development of Standard Operating Procedures has	Subcommittee for Development of Standard Operating Procedures
Reason for improvement		procedures to facilitate implementation Work of the Central Committee and office staff	revised the standard to be a single version throughout.	The same
details Of the correction	Original CREC 15 1. Method of practice - Report review Termination of the research project before the deadline by Secretary, Chairman or Central Committee - Not specified Duration of review - Notification of results Consideration Resulting in Researchers and partner institutions	1. Modify the procedure - Researchers must inform the Central Committee as soon as possible. From the date of notification - Review of the report Termination of the research project before the deadline by the Secretary Central Committee Or the Central Committee - Set a time frame In each phase of Operate quickly and clear - Notification of consideration results Resulting in the principal investigator and coordinator of the research project or institution associate	- Changed from v.2.0 v.2.1 - Added reference documents	- Adjust the comments of Reviewed by Central Committee - Adjusted notification results Including pdf file document - Adjust reference documents

step **Proceed**	**Issue 1** **CREC 11 / v.1.0**	**Issue 2** **CREC 10 / v.2.0**	**Issue 3** **CREC 10 / v.2.1**	**Issue 4** **CREC 10 / v 3.0**
		2. Fix AP 08, AO 16. AL. 08		
Reviewed by the Central Committee Consider the ethics of Human research		Central Committee Consider research ethics In humans	Central Committee Consider the ethics of Human research	Central Committee Consider the ethics of Human research
Review Date Appointment Date	21 November 2012 to 24 January 2013	Appoint date June 14, 2014 to July 3, 2014	Appoint date March 14, 2015 Until May 14, 2015	Appoint date May 16, 2017 Until 30 September 2017
Approved by Position	Assoc. Prof. Dr. Suchart Areemit Areemit Chairman of the Committee Foundation Management	Assoc. Prof. Dr. Suchart Chairman of the Board Foundation Management	Assoc. Prof. Dr. Suchart Areemit, Chairman of the Board Foundation	Assoc. Prof. Dr. Thada Sueblinwong Chairman of the Board Foundation Management
Approval	January 25, 2013	July 4, 2014	Administration 28 September 2016	October 1, 2017
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History of Standard Procedures (continued)

Date:	**Version**	**Approval**	**Show main edits,** adjust	**Approved by**
Subcommittee **Author:** 15 June Development Method of operation standard	Issue No. 5 v.4.0	2563	the order of the steps	Prof. Dr. Thada Sueblinwong Chairman of the Executive Board Foundation
Subcommittee Development Method of operation standard	Issue 6 v.5.0	October 31 2566	Add document storage in the form Electronic files	Prof. Dr. Kwanchanok Yimtae Chairman of the Executive Board Foundation
Subcommittee Development Method of operation standard	Issue 7 v.5.1	July 24 2567	- Changed from v.5.0 to v.5.1 - Correct the document code. - Improved type of decision based on SIDCER recommendations. - Add information in section 6. Definitions	Prof. Dr. Kwanchanok Yimtae Chairman of the Executive Board Foundation

Non-compliance, deviation

Non-Compliance/Protocol Deviation/Protocol Violation

Issue that 5.1 Effective date: 24 July 2024

replaces the previous issue 5.0 Dated October 31, 2023

Author July 24, 2024

(Colonel Assoc. Prof. Dr. Sahapol Anantanacharoen)

Chairman of the Subcommittee on Standard Procedures Development

Approver July 24, 2024

(Assoc. Prof. Dr. Kwanchanok Yimtae)

Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

list of contents

1. Objective: To

provide guidelines for action when researchers do not comply with the requirements of the Central Committee or do not comply with the steps specified in the research outline approved by the Central Committee or have actions that are contrary to the ethics of human research.

2. Scope

Standard operating procedures cover research projects involving humans that have received research proposal approval from Central Committee

3. Responsibility

3.1 The principal investigator at the research institution (site PI) is responsible for submitting a report of non-compliance to the Research Ethics Committee of that institution (or the Central Committee in cases where the affiliated unit does not have a Research Ethics Committee) and the research project coordinator (Research Coordinator) or the research funder (Sponsor/CRO).

3.2 The Institute's Research Ethics Committee (or the Central Committee in cases where the affiliated agency does not have a Research Ethics Committee) is responsible for reviewing, considering and making decisions according to its own standard procedures and then sending the results of its consideration of reports of serious non-compliance/deviations to the Central Committee.

3.3 The Secretary or the assigned Central Committee member has the duty to review the report and present it at the Central Committee meeting. 3.4 The Central

Committee has the duty to make decisions and inform the relevant persons of the results.

4. Procedure flow chart

Order	Operation	Responsible
1	Receive the report of non-compliance/deviation ÿ Review	**person:** Office staff
2	the report of non-compliance/ deviation ÿ	Secretary or assigned committee member

Order	Operation	responsible person
3	Considered at the Central Committee meeting ÿ	Central Committee
4	Notification of decision ÿ	Office staff
5	Document storage	Office staff

5. Procedure 5.1

Receiving reports of non-compliance/deviation

5.1.1 The officer receives the following reports:

5.1.1.1 Report on non-compliance/deviation (AP 01-S14) (in case
At partner institutions, there is no institutional research ethics committee.)

5.1.1.2 Report on non-compliance/deviation with a decision result
site visit/ suspension/ termination of approval from the committee
Institutional Research Ethics (in cases where **partner institutions have committees)**
Institutional Research Ethics Code)

5.1.2 Prepare documents and submit them to the secretary or assigned committee member within 3 days.

The actions are as follows:

- Report of non-compliance/deviation AP 01-S14 or notification letter
Decision from the Institute's Research Ethics Committee
- Assessment form (AO 01-S14)

Or other documents as requested by the reviewing committee, such as:

- Latest approved research proposal
- Research protocol amendment
report - Serious adverse event report -
Research progress report -
History of noncompliance reports - Latest
research protocol certification letter
- First meeting report

5.1.3 The Secretary includes the meeting agenda.

5.2 Review of non-compliance/deviation reports

5.2.1 The Secretary or the assigned committee member is the reviewer. 5.2.2

The review uses the AO 01-S14 assessment form with the following review principles:

A. The severity of the event is assessed from

(1) the risk or harm caused to the volunteer, (2) the

damage to the research data, (3) the

event occurred due to force majeure or the volunteer's lack of understanding

of the steps used in the research, or due to ignorance of good research

practices, negligence or intent on the part of the researcher, (4)

the event occurred because the researcher intentionally or neglected to perform.

According to research ethics or medical professional ethics or

5.2.3 The reviewer records

their opinion on the evaluation form of the

non-compliance report/

Deviation (AO 01-S14) Any of the following:

(1) Acknowledged, no further action required (2) Request for information

(3) Recommend further action as follows

(specify...) {In the case of a minor non-compliance/deviation, does not increase risk or harm to the volunteer/scientific value, is not intentional, careless or negligent on the part of the research team, does not violate ethics or medical standards, and has appropriate preventive measures for recurrence} (4) Submit to the Central Committee meeting (need full board review) {In the case that the reviewer considers that the major non-compliance/deviation may increase risk to the volunteer/scientific value or is recurring, or is intentional, careless or negligent on the part of the research team, or is contrary to ethics or medical standards, and recommendations should be given to the research team, or consideration should be given to conducting an inspection or suspending the certification}

5.3 Consideration at the Central Committee meeting

5.3.1 The Secretary or the assigned reviewer presents the evaluation results to the Central Committee meeting. The Chairman opens the discussion. 5.3.2 The Chairman makes a decision as one of the following:

A. In the case of a report of non-compliance/deviation from researchers in partner institutions that do not have an institutional research ethics committee, a vote shall be made using:

The majority vote (1)

no further action required (2) request for information (3) recommend

further action as follows: - Recommend a research

supervision visit.

(recommendation for site visit)

- Temporary suspension of approval (suspension of

approval) - Termination of approval (termination

of approval)

- Other (specify) B. In the case of a report of the decision of the Research Ethics Committee

The Institute Chairman shall discuss with the meeting and decide on one of the following points:

(1) Acknowledged (without taking any further action)

required)

(2) Request for information (3) Recommend further

action as follows: - Recommend a research supervision visit.

(recommendation for site visit)

- Recommendation for temporary suspension of approval - Recommendation

for termination of approval - Other suggestions (specify) If no one

objects, that suggestion shall be

considered a resolution of the meeting. **Note:** The meeting shall

decide whether the incident should be informed to other partner institutions of the incident

(by concealing the name of the institution where the incident occurred).

5.4 Notification of decision results

5.4.1 In the case of a report from a partner institution that does not have an institutional ethics committee, the office staff must write a letter announcing the decision (AL 01-S14) using the resolution in section 5.3.2(a), submit it to the chairman of the central committee for signature (after reviewing by the secretary), and send it to the researcher or research project coordinator and the relevant partner institution after the meeting or after receiving the consideration results from the reviewing committee within 5 working days. 5.4.2 In the case of a report from a partner institution that has an institutional ethics committee,

The Office has sent a letter informing the decision (AL 01-S14) but uses the resolution according to Section 5.3.2(c) as a proposal.

The Chairman of the Central Committee signs (after review by the Secretary) and sends it to the Institute Ethics Committee after the meeting or after receiving the results of the review from the Review Committee within 5 working days.

5.5 Document storage 5.5.1

Office staff collects letters notifying the results of consideration of non-compliance reports.

Requirements in the electronic file of the research project

5.5.2 Office staff record the operation data in the office database.

6. Definition

Non-compliance with the requirements (Non-compliance)	Non-compliance with International Good Clinical Practice Guidelines Conference on Harmonization (ICH) Good Clinical Practice or ICH GCP or not following the requirements of the Central Committee or not following the research standards, research conduct
Deviation from outline Research (Protocol deviation)	that deviates from the steps specified in the research protocol and causes damage to the volunteers or the research results data, may be a large deviation or a small deviation (the words deviation and violation may be used interchangeably or differently depending on the standard procedures or regulations of the research).) Research
Non-compliance/ Serious deviation	misconduct that may cause significant damage to the rights, safety and well-being of the volunteers or the credibility of the researcher. Research results

Non-compliance/ minor deviation	Faulty research practices that cause insignificant damage to the rights, safety and well-being of human subjects or the credibility of the researcher. Research results

7. Appendix

AL 01-S14	Notification of the results of the consideration of the report of non-compliance with the
AO 01-S14	requirements, the assessment form of the report of non-compliance with
AP 01-S14	the requirements, the report form of non-compliance with the requirements

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

8.3 Guideline for the notification of serious breaches of 3 Regulation (EU) No 536/2014 or the clinical trial protocol. Draft. 31 January 2017 EMA/430909/2016.

9. History of Standard Procedures,

Step No. 1 **Proceed**	**CREC 13 / v.1.0**	**Issue 2** **CREC 14 / v.2.0**	**Issue 3** **CREC 14 / v.2.1**	**Issue 4** **CREC 14 / v 3.0**
Prepared by	Subcommittee for Drafting Standard Procedures	Subcommittee for Development of Procedures Standards	Subcommittee for Development of Standard Operating Procedures	Subcommittee for Development of Standard Operating Procedures
Reason for improvement		for convenience Performing work of Central Committee and officials Office	Adjust to be the same version for the whole book.	

step Proceed	Issue 1 CREC 13 / v.1.0	Issue 2 CREC 14 / v.2.0	Issue 3 CREC 14 / v.2.1	Issue 4 CREC 14 / v 3.0
details **Of the** **correct**	1. Procedure - Researchers submit a report of non-compliance to the committee. Institutional Ethics associate - Committee Institutional Ethics The partners review, report and deliver results. Central Committee - Central Committee Consider the report from Committee Institutional Ethics The parties and the votes have been cast. Report back the results. Partner institutions and Research Funders 2. AF Annex Document 13/01, FROM 13/02 And AF 13/03	1. Procedure - The principal investigator or research funder submits a report of non- Comply with the requirements Central Committee - Secretary or Central Committee Is a reviewer of the report Comply with the requirements and Presented at the full board meeting Set for consideration Resolution - Set the framework Duration of each step To operate Fast and clear - Office staff Notification of consideration results To the principal researcher or coordinate Research projects and Partner institutions 2. Edit AP documents 09,AO 17 and AL 09	- Separate into 2 The approach is 1) Report events in partner institutions or institutions that have committees Research ethics and 2) Report events in institutions that do not have Committee Research ethics or upon request - Adjust the comments of The Central Committee review - Adjust the voting in the meeting Board meeting Middle - Adjust reference documents	- Adjust the comments of Reviewed by the committee Middle - Adjust the type of results consider - Adjusted the notification of results including pdf file document - edit reference document

step Proceed	Issue 1 CREC 13 / v.1.0	Issue 2 CREC 14 / v.2.0	Issue 3 CREC 14 / v.2.1	Issue 4 CREC 14 / v 3.0
Reviewed by the Central Committee Consider the ethics of Human research	Central Committee Consider the ethics of Human research	Central Committee Consider the ethics of Human research	Central Committee Consider the ethics of Human research	
Review Date Appointment Date November 21, 2012 Until 24 January 2013	Appoint date June 14, 2014 to July 3, 2014	Appoint date March 14, 2015 Until May 14, 2015	Appoint date May 16, 2017 Until 30 September 2017	
Approved	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit	Prof. Dr. Thada Sueblinwong
by Position	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management	Chairman of the Board Foundation	Chairman of the Board Foundation Management
Approval	January 25, 2013	July 4, 2014	Administration 28 September 2016	October 1, 2017
Date, Effective Date	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017

History of Standard Procedures (continued)

Date:	Version	Approval	Show main edits	Approved by
Subcommittee **Author:** 15 June Development Method of operation standard	Issue No. 5 v.4.0	2563	- Divide the steps into Research projects of institutions without local RECs and partner institutions that do local REC - Optimize the text - Added EMA reference documents Regarding serious breaches, which have Definitions and examples are available. With protocol evaluation deviation/ noncompliance	Prof. Dr. Thada Sueblinwong Chairman of the Board Foundation Management
Subcommittee Development Method of operation standard	Issue 6 v.5.0	October 31 2566	- Add details to make it more interesting Clear in action and increase Storing documents in file format electronics - Improve the type of decision accordingly SIDCER Suggestions	Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management

Producer	Version	Approval Date	Show main edits	Approved
Subcommittee Development Method of operation standard	Issue 7 v.5.1	24 July 2567	- Changed from v.5.0 to v.5.1 - Correct the document code - Improve the type of decision according to SIDCER's suggestion in Consistent in each category consider	**by** Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management

Preparing meeting agendas, minutes and meeting procedures
Preparation of Meeting Agenda, Minutes and Meeting Procedures

Issue that 5.1 Effective date: 24 July 2024

replaces the previous issue 5.0 Dated October 31, 2023

Author July 24, 2024

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Chairman of the Subcommittee on Standard Procedures Development

Approver July 24, 2024

(Assoc. Prof. Dr. Kwanchanok Yimtae)

Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

list of contents

1. Objective 1.1

To serve as a guideline for preparing the agenda and conducting the meeting.
Central Committee

1.2 To serve as a guideline for preparing minutes of the Central Committee.

2. Scope

The standard operating procedures cover all administrative steps related to the board meeting, which are divided into three parts: preparing the agenda, conducting the meeting and taking minutes. In some situations, the chairman may

legally require the meeting to be held via electronic media.

3. Responsibility

3.1 The Office staff is responsible for coordinating with invited committee members, preparing the meeting agenda, preparing all necessary documents for the meeting, collecting suggestions from committee members, preparing draft meeting minutes, printing and storing meeting minutes. 3.2 The secretary is responsible

for organizing the meeting quorum, preparing the presentation of the meeting minutes, checking the quality and accuracy of the meeting minutes, and presenting them for approval at the next meeting. 3.3

The committee members are responsible for reviewing the research proposal or various reports and sending the review results back to the Office, discussing ethical issues, casting votes, and checking the recording of data during the meeting.

3.4 The chairman has the duty to conduct and control the meeting and to sign the minutes.
meet

4. Procedure flow chart

Sequence	Operation	responsibility
1	**Meeting Preparation** - Coordinate, prepare agenda and documents - Organize the meeting, prepare the report presentation ÿ	Office staff Secretary
2	**Meeting** Conduct and control the meeting - Discussion and voting - Record meeting minutes ÿ	Chairman Central Committee Office staff
3	**Meeting minutes** - Prepare meeting minutes - Check meeting minutes - Sign and approve meeting minutes - Keep meeting minutes	Office staff Secretary Chairman Office staff

5. Procedures 5.1

Meeting preparation 5.1.1

Preparation of the meeting agenda

5.1.2 Other preparations prior to the Central Committee meeting 5.1.2.1

The Office staff contacts the committee members to confirm their

attendance at the meeting 7 working days prior to the meeting date. 5.1.2.2 The Office staff

prints the meeting invitation

letter (AL01-S04) containing the meeting agenda and related documents (see details in the

standard procedures for each chapter). The secretary checks the accuracy and

signs to certify the meeting agenda before sending it to the committee members. In

the event that a committee member is unable to attend the meeting, the secretary may invite

Additional and replacement directors

5.1.2.3 The office staff sends the meeting invitation letter, meeting agenda, schedule, research proposal review committee (AO 02-S04), and documents to be considered at the meeting to the committee via electronic system according to the Office's regulations approximately 3-5 working days before the meeting. 5.1.2.4 The office staff prepares documents to be presented at the meeting and prepares a draft meeting report (AO 02-S16) as an electronic file for presentation and amendments at the meeting.

5.1.2.5 The office staff prepares the venue, audiovisual equipment, etc. before the meeting.

5.1.2.6 In the case of a remote meeting, the staff will send the meeting link at least 1 working day before the meeting. During the meeting, the committee members must turn on their cameras and use their real names to participate in the meeting. No third party is allowed to listen in. No audio or video recording of the meeting is allowed (except in the case of a host)

5.2 Meetings

5.2.1 Quorum 5.2.1.1 Quorum

The Biomedical Committee shall conduct a meeting when there is a quorum as follows:

The number of participants (Central Committee/Additional Committee) in the meeting must not be less than half of the number of the Central Committee, and must include both men and women. Of this number, at least one-third of the Central Committee members must be present. - At least 3 people must be doctors. - At least 1 person must be a layperson member. - At least 1 person must be a natural person, villager, community representative, or volunteer representative. member)

However, a director may have more than one qualification.

5.2.1.2 Quorum The Behavioral Science Committee will conduct the meeting.

The meeting can be held when there is a quorum as follows: The number of participants (central committee members/auxiliary committee members) in the meeting must not be less than half of the number of the central committee members, and there must be both men and women. Of this number, at least one must be a member of the central committee. Number 1 in 3

- At least 1 person who is an expert in the field of social science/behavioral science/ Humanities - at least one person who is a physician or in a scientific profession. health
- At least 1 person who is a general public person, villager, or community representative Or a layperson member - at least 1 person who is an outsider or member of the general public who is not affiliated with the institution conducting the research (Non-affiliated member). However, one committee member may have more than 1 qualification.

* In the case of research where a government agency specifies in its regulations or announcements that it must have a specific number and composition of committee members, it must comply with those regulations or announcements.

** In the case of research related to medical devices, there should be experts in fields related to that medical device, such as engineers or health professionals such as dentists, medical technologists, etc.
At least 1 physical therapist and radiological technologist

5.2.2 Meeting Procedures 5.2.2.1

The attending committee members sign the meeting attendance record document. meet

5.2.2.2 In the case where there are researchers or observers, they must introduce themselves to the meeting and must sign a confidentiality agreement before entering the meeting.

5.2.2.3 The chairman checks that the quorum is present before opening the meeting.

5.2.2.4 The chairman asks if any directors have conflicts of interest with the meeting outline. Research and other matters to be considered. The committee members who are researchers, co-researchers, consultants, and those with conflicts of interest that may affect the consideration must inform the meeting and leave the meeting during the consideration of the research outline or such matter. When the committee member leaves, the chairman must check that the quorum is still present. The officer records the time of departure and re-entering of the meeting.

5.2.2.5 Consider approving the meeting agenda. 5.2.2.6 The chairman conducts the meeting as specified in the meeting agenda, except when necessary, the meeting agenda may be switched. In the event that the meeting cannot be conducted, the deputy chairman will conduct the meeting instead.

5.2.2.7 Presentation and consideration of research proposals or reports (see details in each chapter of the Standard Procedures). 5.2.2.8 After the discussion, summarize and ask the meeting committee to vote freely by a show of hands for the following items: (1) Approval of the initial research proposal (CREC05, CREC07); (2) Approval of the research proposal amendment (CREC 09); (3) Continuing approval (CREC 10); (4) Adjudication of adverse event reports (CREC 11); (5) Adjudication of non-compliance/deviation reports occurring in the institution without an institutional research ethics committee (CREC 14).

(6) Inspection (CREC 19) 5.2.2.9 The Committee shall consider the majority vote as the result. decide

5.2.2.10 The secretary shall record the number of votes for, against, abstained and the total number of directors present at the meeting. In the event of a tie, the chairman of the meeting shall cast one additional vote as the deciding vote.

5.2.2.11 The following items shall be discussed by the chairman of the meeting and decided upon. If no one objects, the chairman shall ask the meeting whether anyone has any other opinion. If no one has any other opinion, it shall be deemed that the meeting has voted in favor of the matter (consensus). However, if there is any other opinion and there may be no conclusion, a voting method shall be used: (1) Type of research risk (CREC 05, CREC 09, CREC 10); (2) Frequency of continuation reviews (CREC 05, CREC 09, CREC 10); (3) Report on completion of research (CREC 12); (4) Type of medical device (CREC 07); (5) Report on premature termination of research/suspension of research (CREC 13); (6) Report on the decision on non-compliance/deviation

Institutional Research Ethics Committee (CREC 14)

(7) Report on the results of response to complaints from the committee.

Institutional Research Ethics Code (CREC 15)

5.2.2.12 The Office staff shall record the discussion and voting results in the draft.

Meeting Report

Note: In the case of a Hybrid meeting, both the online and onsite meeting committees will vote using the voting method used in the office meeting.

5.3 Meeting Report 5.3.1

The office staff prints the meeting report (AO 02-S16). 5.3.2 The secretary checks the quality and accuracy of the meeting report before presenting it.

Signed

5.3.3 The secretary presents at the next meeting to request approval of the meeting minutes from

Secretariat Committee

5.3.4 The office staff shall keep the meeting agenda and meeting minutes in the meeting minutes file. The meeting minutes are considered confidential documents and have limited access to the information.

5.4 Extraordinary meeting 5.4.1 An extraordinary meeting will be held in one of the following cases: 5.4.1.1 There is an unexpected event that requires urgent measures to protect the rights, safety and well-being of the research participant. 5.4.1.2 There is an event that causes serious harm or threatens the life of the research participant.

research

5.4.1.3 Matters that require urgent measures to stop, suppress or alleviate the occurrence of diseases and health threats that have serious impacts. 5.4.1.4 Matters that require a meeting before the scheduled meeting in order to consider the research project in time according to the schedule and the situation that occurs at that time. 5.4.1.5 There are complaints or reports of serious non-compliance. 5.4.1.6 Other matters that should be called for a special meeting. 5.4.2 Special meeting quorum and practices Special meetings must consist of the same quorum as regular committee meetings, but the procedures and time frame must be concise. and timely by reducing unnecessary steps. The details must be recorded regarding the reasons and necessity.

6. Definition

Agenda	A document recording the plans, agendas and sequence of matters to be presented or considered at a full committee
Meeting report,	meeting. A document recording various things done at a central
special meeting (Extra-ordinary meeting)	committee meeting, a committee meeting outside of the regular scheduled meeting. in advance
The occurrence of diseases and health threats that have a severe impact	A disease or health threat event meets at least two of the four criteria: (a) causes a severe impact; (b) is an unusual or unprecedented event.

	(c) There is a possibility of it spreading to other areas; (d) The movement of people or goods must be restricted, e.g. due to infectious diseases, chemicals, natural disasters, injuries or accidents.

7. Appendix

AL 01-S16	Notice
AO01-S16	Agenda
AO 02-S16	Meeting minutes template
AL 01-S04	Meeting invitation letter
AO 02-S04	Schedule of the Research Proposal Review Committee

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

8.3 US DHHS. Minutes of Institutional Review Board (IRB) Meetings Guidance for Institutions and IRBs. September 2017.

8.4 Royal Decree on Electronic Meetings B.E. 2563, Government Gazette, Volume 137, Episode 30, 19 April 2020, Page 20.

9. History of Standard Procedures,

Step No. 1 **Carry out**	**CREC 14 / v.1.0**	**Issue 2** **CREC 15 / v.2.0**	**Issue 3** **CREC 15 / v.2.1**	**Issue 4** **CREC 15 / v 3.0**
Prepared by	Subcommittee on Drafting Procedures standard	Subcommittee for Development of Standard Operating Procedures	Subcommittee for Development of Standard Operating Procedures	Subcommittee for Development of Standard Operating Procedures
Reason for improvement		For convenience Performing work of Central Committee And office staff 1. Cut the	Modified as per recommendations Of SIDCER (14 Mar. 2015)	To make it easier to understand
details Of the correction		overlapping parts. Method of operation Other standards such as: Selection of directors Central review of the framework Research Draft Presentation and Signing Resolution of the meeting 2. Cut the agenda format by moving it to AO. 19 and report Meeting moved to AO 21 3. Fix AL 10, AO 19, TO 20, TO 21	Add reference documents	- Adjust the words in the sentence. Quorum made easy - add voting for Consideration of the report Adverse events and non-adverse events reported Comply with the requirements - Add reference documents
Reviewed by the Central Committee	Consider the ethics of Human research	Central Committee Consider the ethics of Human research	Central Committee Consider the ethics of Human research	Central Committee Consider the ethics of Human research
Review Date Appointment	21 November 2012 to 24 January 2013	appoint June 14, 2014 to July 3, 2014 May 2015 Assoc. Prof. Dr. Suchart Areemit	appoint March 14, 2015 to 14	appoint 16 May 2017 to 30 September 2017
Approved by	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit		Prof. Dr. Thada Sueblinwong

step Carry out	Issue 1 CREC 14 / v.1.0	Issue 2 CREC 15 / v.2.0	Issue 3 CREC 15 / v.2.1	Issue 4 CREC 15 / v 3.0
Position	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management	Chairman of the Board Foundation	Chairman of the Board Foundation Management
Approval	January 25, 2013	July 4, 2014	Administration 28 September 2016	October 1, 2017
Date, Effective Date	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017

History of Standard Operating Procedures (continued)

Date	Version	Approval	Show main edits	Approved by
Subcommittee Development Method of operation standard	Issue No. 5 **Creator** 15 June v.4.0	2563	- Added the signing of the meeting agenda by Secretary (as advised by SIDCER) - Clearly divide the judgments into which cases use which method Vote by raising your hand. Which case is it? consensus - Add extra-meeting in case of Disaster or epidemic - Adjust the meeting agenda template Compliant with the online system of Office - Adjusted the meeting report template for media More meaning according to the recommendations of US DHHS	Prof. Dr. Thada Sueblinwong Chairman of the Board Foundation Management
Subcommittee Development Method of operation standard	Issue 6 v.5.0	October 31 2566	- Edit the chapter title for appropriateness. - Modify the procedures for convenience Clear in operations - Added requirements for conducting meetings Online as per suggestion SIDCER	Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management
Subcommittee Development Method of operation standard	Issue 7 v.5.1	July 24 2567	- Changed from v.5.0 to v.5.1 - Correct the document code. - Added layperson replacement non science	Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management

Producer	Version	Approval Date	Show main edits	Approved by
			- Adjust the number of quorums according to the suggestions. Of the Central Committee - Modify the chapter title according to the suggestions of SIDCER	

Research project document management

Management of Study Files

Issue that 5.1 Date of July 24, 2024

replaces the previous issue 5.0 use: Dated October 31, 2023

Author July 24, 2024

(Colonel Assoc. Prof. Dr. Sahapol Anantanacharoen)

Chairman of the Subcommittee on Standard Procedures Development

Approver July 24, 2024

(Assoc. Prof. Dr. Kwanchanok Yimtae)

Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

list of contents

1. Objective

To serve as a guideline for collecting, storing, searching and destroying documents related to research projects that have been received.

Considered by the Central Committee for convenience in searching and to maintain confidentiality.

information

2. Scope

Standard operating procedures cover the management of documents related to research projects that have been considered by

Central Committee Both ongoing and completed research projects

3. Responsibility

3.1 Office staff have duties to collect, store, search and destroy documents related to

Research projects considered by the Central Committee

3.2 The Secretary of the Central Committee is responsible for supervising the management of documents related to the research project.

Considered by the Central Committee to comply with standard operating procedures

4. Procedure flow chart

Sequence	Operation	responsible person
1	Collect and store documents related to the original research project. Enter files/electronic files according to the document type in the system. Database ÿ	Office staff
2	Arrange documents into categories according to the index. ÿ	Office staff
3	Store the research outline files/electronic files in the system. Database and limited access to the data ÿ	Office staff
4	Record the data related to the research project in the database and in Backup system ÿ	Office staff
5	Group research outlines and store them according to the specified time period. ÿ	Office staff

Sequence	Operation	responsible person
6	Select inactive research project documents that are due for storage To proceed with requesting approval to delete data	Office staff

5. Procedures

5.1 Document collection and storage

5.1.1 Office staff collect and store documents related to the research project as follows:

Types of documents in electronic databases and restricted access

5.1.2 Office staff record information related to the research project in the database, which has:

Confidentiality system, limited access to data and has a backup system.

Keep in a safe place every month.

5.1.3 Grouping of research outlines and determination of document retention period are as follows:

5.1.3.1 A research proposal that has been approved and is currently being conducted by the researcher is called an ongoing research proposal or Active file.

5.1.3.2 The research outline has been approved and the research has been completed. The researcher sends Research Summary Report (Close Study report) Research Project Termination Report

Premature termination is grouped into two groups: Inactive research or Inactive file 5.1.3.3 Research proposals that have been approved but the researcher has not submitted a progress report or any reports for a period of 1 year, the office staff will contact.

The researcher or the parent organization to clarify the status of the research, if the status Research is finished or there is no explanation. It is brought to The Secretary will the Central Committee meeting for consideration. It is organized into groups. Inactive research or Inactive file

Note: If the status of the research is In Progress, the officer

The office will notify researchers to submit research progress reports.

and renew the research outline certification

5.1.3.4 The research protocol that has been approved but has a safety report or report of deviation or non-compliance with the approved research protocol or report of non-compliance with the principles of good clinical research practice and the Central Committee has considered and resolved to "suspend the approval of the research protocol. "Provisional Research (suspension of protocol approval)" and if the Central Committee does not lift the temporary suspension of approval within 1 year, the Secretary of the Central Committee will bring it to the full committee meeting to vote that the research proposal will be grouped into a research proposal group that does not have Operation or Inactive file

5.1.3.5 A research protocol that has been approved but has a safety report or report of deviation or non-compliance with the approved research protocol or report of non-compliance with the principles of good clinical research practice and the Central Committee has considered and voted to "withdraw the research protocol approval". After 1 year, if there is no change in the resolution, the Secretary will bring it to the full committee meeting for a vote so that the research protocol will be grouped into a research protocol that has no Operation or Inactive file

5.1.3.6 Research proposals that are considered "not accepted" after 1 year, if there is no change of resolution, the Secretary will bring it to the full committee meeting to vote that the research proposal will be grouped as an inactive research proposal or Inactive file.

5.1.3.7 Research proposals submitted for consideration at the Central Committee meeting or urgently considered, the Central Committee has resolved to amend for approval or amend for reconsideration, but the researcher does not submit a new research proposal for consideration within 6 months from the date of sending the letter announcing the results of the consideration to the researcher, the secretary will bring it to the full Committee meeting for a vote so that the research proposal will be organized into a group of research proposals that have not been approved. Inactive or Inactive file

Note: In case the researcher submits a new research proposal after 6 months from the date of sending the letter notifying the consideration result to the researcher, the consideration of the new research proposal will be carried out in the same way as the research proposal was submitted for the first consideration.

5.1.4 The inactive research project documents (inactive file) will be kept separately from the active research project drafts (active file) and kept for at least 3 years before.

Consider destroying documents

5.1.5 Research proposals that the researcher requests to withdraw before the Central Committee meeting will be deleted from the system.

5.2 Searching and copying documents

5.2.1 Search for documents related to research projects for the Central Committee to consider.

5.2.1.1 The office staff is responsible for searching for documents for the central committee to consider the research project.

5.2.1.2 The office staff returns the documents to their original place in the research project outline file. 5.2.2 Request to search documents related to the research project by the researcher or others

5.2.2.1 In the case where the researcher wishes to request to search and/or make copies of their own research project documents, the researcher must submit the Request to Search/Make Copy of Research Project Documents Report Form (AO 01-S17) to the Office Head for the staff to proceed.

The office searches for documents and/or makes copies of documents.

5.2.2.2 In the event that others wish to search and/or make copies of research project documents, a confirmation letter or permission letter from the researcher must be provided and a report requesting to search/ make copies of research project documents (AO 01-S17) must be submitted to request approval from the Chairman of the Central Committee or the Secretary to allow the search of documents. 5.2.2.3 Office staff are responsible for searching documents, making copies, and recording evidence in Record of request for search/copy of documents (AO 02-S17)

5.2.2.4 The office staff returns the documents to their original place in the research outline file, recording the name of the returner, the name of the document collector, and the date the documents were collected in the form. Record of request for search/copy of documents (AO 02-S17)

5.3 Document destruction

5.3.1 The office staff shall prepare a list of inactive research projects (inactive file).

Stored for 3 years or more

5.3.2 The office staff shall prepare a list of research project documents to be destroyed and the request report form.

Destroy research project documents (AO 03-S17) for submission to the Secretary.

5.3.3 The Secretary presents to the Central Committee meeting for approval to destroy.

Research project documents

5.3.4 When the Central Committee meeting votes to destroy the research project documents, the Chairman

The Central Committee signed to approve the report requesting the destruction of research project documents.

(AO 03-S17)

5.3.5 The office staff shall destroy the research project documents within the office.

Document shredder

5.3.6 The office staff collects the research project document destruction request report form (AO 03-S17).

In the Office of Document Destruction Files

5.4 Operations regarding electronic documents stored online

5.4.1 Research project documents and committee documents must be kept in accordance with regulations.

As determined by the Ministry of Digital Economy and Society (MDES)

5.4.2 Access to documents after the meeting has concluded must be approved by the chairman or

Secretary The office must record the name of the requesting committee member and specify the time of visit.

by providing username and password

5.4.3 The committee member downloading documents for storage is the committee member's responsibility.

Keep confidentiality in accordance with the signed confidentiality agreement.

6. Definition of terms

Ongoing research outline Active file	Research outline that is currently being conducted as specified in the research outline Research certified by the Central Committee
Non-implemented research outline Inactive file	The research project has been completed or the project has been terminated or the Central Committee has terminated any action on the research project.

7. Appendix

AO 01-S17	Request for a search report form, copy of research project documents
AO 02-S17	Search request record form
AO 03-S17	Report form requesting the destruction of research project documents

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

9. History of standard operating procedures

step **Carry out**	Issue 1 **CREC 09 / v.1.0**	Issue 2 **CREC 05 / v.2.0**	Issue 3 **CREC 05 / v.2.1**	Issue 4 **CREC 05 / v 3.0**
Prepared by	Drafting Subcommittee Standard operating procedures	Subcommittee Develop procedures standard	Development Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures
Reason of **Improvement**		For convenience Performing work of Central Committee and office staff	Modified as per recommendations Of SIDCER (14 Mar 2015)	To make it easier to understand
details **Of the correction**		Edit AO 20, AO 21, TO 22	- Added 5.1.7 Outline Research that the researcher requests to withdraw Withdraw before Meeting of Central Committee Will be returned to the researcher. All - Add reference documents	- Adjust the words in the sentence. quorum To make it easier to understand - Added voting for Consideration of the report Adverse events And the report does not Comply with the requirements - Add reference documents
Reviewed by the Central Committee	Consider the ethics of Human research	Central Committee Consider the ethics of Human research	Development Subcommittee Standard operating procedures	Central Committee Consider the ethics of Human research
Review Date Appointment Date	21 November 2012 to 24 January 2013	Appoint date June 14, 2014 to July 3, 2014	Appoint date March 14, 2015 Until May 14, 2015	Appoint date May 16, 2017 Until 30 September 2017
Approved	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit	Prof. Dr. Thada Sueblinwong
by Position	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management	Chairman of the Board Foundation	Chairman of the Board Foundation Management
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Date, Effective Date	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017

Standard Operating Procedure History

Date	Version	(continued) Approval	Show main edits	Approved
Subcommittee on Development Method of operation standard	Issue No. 5 v.4.0	15 June 2563	- Adjust format	**by** Prof. Dr. Thada Sueblinwong Chairman of the Executive Board Prof. Dr.
Subcommittee on Development Method of operation standard	Issue 6 v.5.0	October 31 2566	- Modify the work procedures to be consistent with the work procedures - Modify by adding text according to the guidelines Practice with digital/electronic documents according to SIDCER Suggestions	Kwanchanok Yimtae Foundation Chairman of the Executive Board Foundation
Subcommittee on Development Method of operation standard	Issue 7 v.5.1	July 24 2567	- Changed from v.5.0 to v.5.1	Prof. Dr. Kwanchanok Yimtae Chairman of the Executive Board Foundation

Collaboration between the Central Committee

and the Institute's Ethics Committee

Co-operation between CREC and Local Institutional Review Board

Issue that 5.1 Effective date: 24 July 2024

replaces the previous issue 5.0 Dated October 31, 2023

Author July 24, 2024

(Colonel Assoc. Prof. Dr. Sahapol Anantanacharoen)

Chairman of the Subcommittee on Standard Procedures Development

Approver July 24, 2024

(Assoc. Prof. Dr. Kwanchanok Yimtae)

Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

list of contents

1. Objective

To serve as a guideline for the management and consideration of research projects and various report documents. Involved with the Institute's Ethics Committee

2. Scope

The standard procedure covers the initial review of the research proposal and the post-research report. guarantee

3. Responsibility

3.1 The office staff has a duty to coordinate with the Institute's Ethics Committee on matters of:

Review the research proposal and review various reports after the research proposal is approved. Of the Central Committee

3.2 The Institute's Research Ethics Committee shall cooperate and act in accordance with Standard procedures of the Central Committee in considering research proposals and Consider various reports after the approval of the research outline by the Central Committee.

3.3 The Central Committee shall issue an announcement of guidelines in accordance with the standard procedures of this chapter.

4. Procedure flow chart

Order	Operation	responsible person
1	Cooperation in implementing standard operating procedures ÿ	Office staff Central Committee
2	Initial research proposal review ÿ	Office staff Central Committee
3	Research implementation after research proposal approval ÿ	Office staff Central Committee
4	Storage of research outlines	Office staff

5. Procedures 5.1

Cooperation in implementing the standard operating procedures

5.1.1 When a standard operating procedure of the Central Committee is created or revised, the Office Officer shall inform the ethics committee of the partner institution of the significant revisions. 5.1.2

The ethics committee of the partner institution shall revise the standard operating procedures. Consistent

5.1.3 The partner institution shall submit a new version of the Agreement (AL 01-S20) to the Central Committee every time. When there is a change of president or head of the organization

5.2 Initial consideration of the research outline

5.2.1 The Institutional Ethics Committee has a duty to forward the results of the local issue assessment to the Central Committee as soon as possible before the first research project consideration meeting. **(Note:** The Institutional Ethics Committee can observe the meeting and present the local issue assessment data in the consideration meeting.) 5.2.2 In the case where the result of the consideration is approval, the Institutional Ethics Co

A certificate of approval (CoA) or a letter of acknowledgement for researchers at the institution, by specifying the date of approval/certification as the date of approval from the institution's ethics committee, and the end date of certification as the same date specified in the CoA from the central committee *(except in cases where the institution's ethics committee does not issue a new CoA, the approval date and the end date of certification can be the same as those specified in the CoA from the central committee).*

5.2.3 In the event that the institution sends local issues late, the Central Committee will issue a certificate immediately upon receipt of the local issues, but the approval date will be the date signed by the Chairman of the Central Committee. Name

5.2.4 In the event that the result of the consideration is not certified, the office officer sends a copy of the notification letter.

Consideration of the research outline of the Central Committee to the Ethics Committee

The institution has a copy of the document and a PDF file, which includes the reasons and suggestions.

Of the Central Committee

5.3 Consideration after approval of the research proposal

5.3.1 Report on amendments to the research proposal

5.3.1.1 Site-specific amendments shall be submitted by the researcher at that institution.

Request certification from the ethics committee of your own institution.

The Institutional Ethics Committee shall proceed in accordance with the procedures as follows:

The institute's standards and notify the Central Committee of the results of the consideration.

The Central Committee will issue a letter of acknowledgement effective from the date of

acknowledgement of the approval/consent of the Institute's Ethics Committee. In this case,

The Institute does not have an institutional ethics committee. The central committee

will be considered. **Note:**

Site-specific amendments mean amendments only at that institution without affecting documents

of other institutions, such as: - Adding or changing researchers at the institution

- Adding/

reducing the number of volunteers at the institution (n)

without affecting the number of volunteers nationwide (N) - Changing specific information, such

Total of items as changing the name and address of

the research ethics committee at the institution or contact information of the researcher in a

site-specific document that the central committee has previously approved. ** Amendments

that do not fall under site-specific amendments.

1) In case of a change in the research project leader, please submit it to the Central

Committee because the qualifications of the researcher who has changed must be

considered to see if they are

appropriate or not. 2) In case of a change that affects the overall research project or an

addition that affects the research process or has an effect on the research.

Volunteer decision to participate in research, such as adding invitation documents Invite volunteers

5.3.1.2 General amendments (trial-wide) shall be submitted by the research project coordinator. Approval from the Central Committee and the Central Committee shall inform the Ethics Committee of the decision. In the case that the Central Committee approves the amendment of the research project, the office staff shall send the decision to the Ethics Committee of the Institute, specifying the date of approval.

The Institutional Ethics Committee issues a certificate of amendment to the research project. The date of approval/certification is the date of approval by the Institutional Ethics Committee *(except in cases where*

The Institute Ethics Committee has not issued a new certificate or has not reconsidered it.

The certification date may be the same as the date given by the Central Committee.

Certification)

5.3.2 Progress report and request for extension of research project certification

5.3.2.1 The Central Committee shall consider the continuation approval of the research project. 5.3.2.2 In the case where the Central Committee approves the continuation, the office officer shall send the certificate and other relevant documents to the Ethics Committee of the institution, specifying the approval date and expiration date in the CoA. 5.3.2.3 The Ethics Committee of the institution shall issue a certificate of continuation or an acknowledgement letter to the researchers in the institution, specifying the approval date and expiration date as the date specified in the CoA from the Central Committee.

5.3.2.4 The Ethics Committee of the institution may not approve the continuation of the research project, in which case the Central Committee shall be notified with reasons. **5.3.3 Report of adverse events** 5.3.3.1 The Ethics Committee of the institution shall consider serious or unexpected adverse events. that occur in the institution (local SAE/SUSAR) that may be related to the drug or research device, according to the standard operating procedures of the institution, and report the results of the consideration only for research that (a) has been inspected, (b) has had its certification suspended, and (c) has had its certification terminated to the Central Committ

Notified within 10 working days from the date of the Ethics Committee

The institute has made such a resolution.

5.3.3.2 The sponsor of the study is responsible for submitting reports of serious adverse events or unexpected adverse events that occur outside the institution that are reported as Periodic (non-local SAE and periodic SUSAR report) or letter

Report the results of the consideration from IDMC (DSMB) or medical team to the

The Central Committee The Central Committee has considered the report.

Inform the results of the consideration to the Institute's Ethics Committee.

According to the reporting period

In the case of a report that is significant and has an impact on scientific value or Safety of volunteers The Central Committee will report to

The Institutional Ethics Committee shall be informed within 5 working days. **5.3.4**

Report of non-compliance/deviation

The Institutional Ethics Committee shall consider the procedures according to the procedure. The standards of the institution and the results of the consideration, especially in cases where a site visit is required or a temporary suspension of approval is required or a termination of approval is required, must be reported to the Central Committee within 10 working days.

Since the date the Institute Ethics Committee made such resolution

5.3.5 Consideration of complaints from volunteers or other persons 5.3.5.1

The Institute's Ethics Committee shall consider and notify the results.

To inform the Central Committee of the decision (in cases where it has an impact on the project) (Overview)

5.3.5.2 In cases where the institution conducting the research does not have a research ethics committee

The institution shall be assigned to the parent institution (other committees assigned by the executives) as follows:

The judges will consider and inform the Central Committee of the decision (in the case of Impact on the overall project)

5.3.5.3 In the event that the institution conducting the research does not have an institutional ethics committee and a complaint is filed with the Central Committee, the Central Committee is the

The judges will inform the relevant parties of the decision.

5.3.6 Report on research completion/premature termination of research projects or research suspension temporary

5.3.6.1 If it is the completion of research or the termination/suspension of research in a single location, the Ethics Committee of the Institution shall consider and notify the decision. The Central Committee is aware

5.3.6.2 If it is a termination/suspension, the Central Committee shall consider and inform the Ethics Committee of the decision. **5.3.7 Visiting the research site**

5.3.7.1 The Institutional Ethics Committee shall visit research sites in the Institute in accordance with its standard operating procedures, but may request the Central Committee to join the visit and inform the Central Committee of its decision.

know

5.3.7.2 The Central Committee shall be the inspector of research sites in institutions that do not have an institutional ethics committee in cases where the Central Committee is the certifier of the research proposal. **Note:** The

notification of the consideration results from the Central Committee to the relevant persons shall be made by the Central Committee.

Process within 5 working days for notification of consideration results from

The Institute's Ethics Committee has submitted the matter to the Central Committee for action.

Within 10 working days

5.4 Research outline storage The

office staff will store documents related to the research outline, including the documents of

Coordination with the institutional ethics committee to enter the research outline file according to

Standard operating procedures of the institute

6. Definition

do not have

7. Appendix

AL 01-S18	Guidelines for collaborative work between the Central Committee on Human Research Ethics and the Institutional Research Ethics Committee
AP 01-S18	Example of a certificate issued by a local IRB/REC
AL 01-S20	Collaboration Agreement

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

8.3 International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva. Council for International Organizations of Medical Sciences (CIOMS); 2016.

8.4 US DHHS. Guidance for Industry Using a Centralized IRB Review Process in Multicenter Clinical Trials March 2006

9. History of standard procedures

step Proceed	Issue 1 CREC 09 / v.1.0	Issue 2 CREC 05 / v.2.0	Issue 3 CREC 05 / v.2.1	Issue 4 CREC 05 / v 3.0
Prepared by	Drafting Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures	Subcommittee Develop procedures standard	Development Subcommittee Standard operating procedures
Reason of Improvement				To provide coordination With the committee Institutional Ethics in Consideration of the outline Research and Reports Various effective
details **Of the correction**	do not have	do not have	do not have	Add an entire chapter
Reviewed by the Central Committee	Consider research ethics In humans	Central Committee Consider research ethics In humans	Subcommittee Develop procedures standard	Central Committee Consider the ethics of Human research
Review Date Appointment Date	21 November 2012 to 24 January 2013	Appoint date June 14, 2014 to July 3, 2014	Appoint date March 14, 2015 Until May 14 2558	Appoint date May 16, 2017 Until 30 September 2017
Approved by	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Aree Friend	Prof. Dr. Thada Sueblinwong
Position	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management	chairman Executive Board	Chairman of the Board Foundation Management
Approval	January 25, 2013	July 4, 2014	Foundation 28 September 2016	October 1, 2017
Date, Effective Date	January 25, 2013	July 4, 2014	September 28, 2016	October 1, 2017

Standard Operating Procedure History (continued)

Date	Version	Approval	Show main edits	Approved
Subcommittee on Development Method of operation standard **Creator** 15 June	Issue No. 5 v.4.0	2563	- Revised the content to be clearer and easier to follow, defining the roles and responsibilities between CREC and local IRB in certain considerations. - Prepared a guideline statement to be attached to the CoA for the local IRB/REC.	**by** Prof. Dr. Thada Sueblinwong Chairman of the Board Foundation Management
Subcommittee Development Method of operation standard	Issue 6 v.5.0	October 31 2566	- The types of the description have been revised and expanded. Amendment Site Specific Report - Additional information on certification of documents is provided to guide Local IRB/REC Practices -	Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management
Subcommittee Development Method of operation standard	Issue 7 v.5.1	July 24 2567	Changed from v.5.0 to v.5.1 - Added documents in Section 7. Appendix. completely	Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management

Supervision visits for research

Site Monitoring Visit

Issue that 5.1 Effective date: 24 July 2024

replaces the previous issue 5.0 Dated October 31, 2023

Author July 24, 2024

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Chairman of the Subcommittee on Standard Procedures Development

Approver July 24, 2024

(Assoc. Prof. Dr. Kwanchanok Yimtae)

Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

list of contents

1. Objective: To

serve as a guideline for inspection visits to supervise research to ensure compliance with the research outline that has been approved. Certified by the Central Committee and in accordance with international ethical principles.

2. Scope

The standard operating procedures apply to (a) visits to research institutes that have received research protocol approval from the Central Committee but do not have a research ethics committee at the institute, and (b) visits in conjunction with the research ethics committee of the institute when the visit is for cause.

3. Responsibility

3.1 The Foundation for the Promotion of Human Research in Thailand has the duty to appoint a visiting team. 3.2 The visiting team has the duty to conduct visits to research institutes selected by

The Central Committee and submit the inspection results to the Central Committee.

3.3 The Chairman of the Central Committee has the duty to select the Central Committee members to join the inspection visit.

Partner institutions upon request

3.3 Office staff are responsible for coordinating between the Central Committee and the inspection working group.

Visit and research and have the duty to collect the visit report documents.

4. Procedure flow chart

Order	Operation	responsible person
1	Select the research institute to be	Central Committee
2	visited ÿ Appoint the visiting team ÿ	Chairman of the Foundation
3	Prepare for the visit ÿ	Inspection Team
4	Conduct the visit ÿ	Inspection Team
5	Report the visit ÿ	Inspection Team Central Committee

Order	Operation	responsible person
6	Consider and decide ÿ	Central Committee
7	Report results ÿ	Office staff
8	Document storage	Office staff

5. Procedures

5.1 Selection of research institutions to be inspected 5.1.1 The

Central Committee meeting resolved to inspect research sites in the following institutions:

There is no institutional research ethics committee for the following reasons: - There are

reports of serious adverse events at the institution that may have resulted in the volunteers being disinherited.

Death or life-threatening event of volunteer

- There are reports of deviations or non-compliance with the approved research protocol.

from the Central Committee and may have an impact on volunteers, institutions and/or society.

- I have a complaint.

Others as the meeting deems appropriate

5.1.2 The Chairman of the Central Committee shall make a record informing the Foundation of the research institutes that should be inspected.

Visit and the necessity of the visit by informing the institute at least 10 working days in advance.

5.1.3 In the event of a request from a partner institution, the President shall assign one of the committee members who has:

Qualifications as requested by the Institute's Research Ethics Committee

Participate in the inspection of the institute

5.2 Appointment of the inspection subcommittee

5.2.1 The Foundation for the Promotion of Human Research in Thailand has appointed a visiting team to conduct

visits to research institutes selected by the Central Committee.

At least 3 people from the Central Committee that considers the project, of which at least 1

person must be a scientific member (in the case of a clinical trial of

drugs/medical device should be a doctor)

- At least 1 person is a layperson member. 5.2.2 The

working group selects each other to hold the position of chairman and secretary of the working group.

5.2.3 The office staff sends a copy of the appointment order to all members of the working group.

5.3 Preparation for the

inspection visit 5.3.1 The office staff coordinates with the researchers and the working group to schedule a visit as soon as possible. 5.3.2 The office staff prepares a copy of the Central Committee meeting report.

Reasons for the Visit to Subcommittee 5.3.3 The

Visit Working Group reviews the possible causes of problems of researchers and research institutions and requests the necessary documents for the visit from the office staff as

Central Committee follows:

- Local SAE/SUSAR report, Deviation/noncompliance report/ Progress report
- The latest research proposal and/or the latest research amendment - The latest consent form - The latest Investigator's brochure - The main investigator's (site PI) biography - Other documents as required for the visit

5.3.4 The office staff shall deliver the documents to be used in the evaluation of the visit to

5.3.5 The chairman of the

subcommittee shall set the inspection plan according to the document AO 01-S19 and send it to the office staff. In the case of interviews, it shall be stated in the letter. 5.3.6 The office

staff shall send the schedule to both the researcher and the research institute within 1 day.

5.4 Inspection Procedure 5.4.1

The inspection team signs a confidentiality agreement prepared by the research institute. 5.4.2

The inspection team inspects according to the schedule and plan. 5.4.3

Each inspection subcommittee records their observations in the inspection report form.

(AO 02-S19)

5.4.4 The inspection team summarizes the inspection results.

5.4.5 Present the preliminary visit results verbally and give the researcher an opportunity to ask questions or provide additional information. 5.4.6 In the case of a joint visit with a partner institution, proceed according to the procedures. Standards of partner institutions

5.5 Reporting the inspection results to the Central Committee 5.5.1 The Secretary of the inspection team summarizes the inspection report of the Sub-Committee in Form AO 03-S19 and then informs the working team to make corrections and improvements within 7 working days after the inspection.

5.5.2 The chairman of the inspection committee signs the inspection report and sends it to the office. Central Committee

5.5.3 In the case of a joint visit with a partner institution, request the results of the visit from the partner institution.

5.6 Consideration of the decision of the Central Committee

5.6.1 The office staff prepares a visit report for the secretary of the central committee. Before the Central Committee meeting 5.6.2 The Secretary presents the inspection results to the Central Committee meeting for consideration and to summarize the decision, which may be one of the following:

(1) Acknowledge

(2) Acknowledge and order another inspection within a certain period (3) Temporarily suspend approval (suspension of approval) (4) Termination of approval

5.6.3 In the case of a joint inspection with a partner institution, the chairman discusses with the meeting to decide on one of the following:

(1) Acknowledged

(2) Acknowledge and request additional information.

5.7 Notification of results

5.7.1 The Chairman of the Central Committee shall notify the decision of the Central Committee meeting to the Research Institute in document form and/or electronically within 5 working days after the meeting (see the notification form in CREC 04) and the Foundation.

5.7.2 In case of temporary suspension of certification or termination of certification, notify the Food and Drug Administration (in the case of drug or medical device research) and/or the research funder.

5.8 Document storage

5.8.1 The office staff shall keep the inspection report form and the notification letter of the consideration results in the file of the inspection subcommittee and keep 1 copy in the research project file.

5.8.2 The office staff records the results of the Central Committee's consideration in the database.

6. Definition

Inspection Team	The working group appointed by the Central Committee to be representatives for visiting research institutes.

7. Appendix

AO 01-S19	Visit Schedule Form Visit
AO 02-S19	Report Form Visit Report
AO 03-S19	Summary Form

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

9. History of standard procedures

step Proceed	Issue 1 CREC 19 / v.1.0	Issue 2 CREC 17 / v.2.0	Issue 3 CREC 17 / v.2.1	Issue 4 CREC 17 / v 3.0
Prepared by	Drafting Subcommittee Method of operation standard	Development Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures	Development Subcommittee Standard operating procedures
Reason of amend				To provide supervision Research Institute is going Efficiently
details Of the correction	do not have	do not have	do not have	Add a visit Single institution first Consider approving the outline Research
Reviewed by	Central Committee Consider the ethics of Human research	Central Committee Consider the ethics of Human research	Subcommittee Develop procedures standard	Central Committee Consider the ethics of Human research
Review Date	Appoint date 21 November 2012 to 24 January 2013	Appoint date June 14, 2014 to July 3, 2014	Appoint date March 14, 2015 Until May 14, 2015	Appoint date May 16, 2017 Until 30 September 2017
Approved	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit	Assoc. Prof. Dr. Suchart Areemit,	Assoc. Prof. Dr. Thada Sueblinwong
by Position	Chairman of the Board Foundation Management	Chairman of the Board Foundation Management	Chairman of the Board Foundation	Chairman of the Board Foundation Management
Approval	January 25, 2013	July 4, 2014	Administration 28 September 2016	October 1, 2017
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History of Standard Operating Procedure

(continued) Author	Version	Approval Date	Show main edits	Approved
Subcommittee Development Method of operation standard	Issue No. 5 v.4.0	June 15 2563	- Separate site monitoring from institutional potential assessment because it is a human factor. Different reasons and committees - used for research projects that are endorsed by CREC but not local IRB because monitoring of research projects has a local IRB as the responsibility Local IRBs and CRECs will send referees. The center joins in case of request	by Prof. Dr. Thada Sueblinwong Chairman of the Board Foundation Management
Subcommittee Development Method of operation standard	Issue 6 v.5.0	October 31 2566		Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation
Subcommittee Development Method of operation standard	Issue 7 v.5.1	24 July 2567	- Changed from v.5.0 to v.5.1 - Added layperson instead non science	Management, Prof. Dr. Kwanchanok Yimtae Chairman of the Executive Board Foundation

Screening to assess the potential of human research at the institute

Site Evaluation Visit

Issue that 5.1 Date of July 24, 2024

replaces the previous issue 5.0 use: Dated October 31, 2023

Author July 24, 2024

(Colonel Assoc. Prof. Dr. Sahapol Anantanacharoen)

Chairman of the Subcommittee on Standard Procedures Development

Approver July 24, 2024

(Assoc. Prof. Dr. Kwanchanok Yimtae)

Chairman of the Board of Directors of the Foundation for the Promotion of Human Research in Thailand

list of contents

1. Objective: To

serve as a guideline for assessing the potential of research institutes outside the partner institutions that intend to be sites.

One of the multicenter clinical trials

2. Scope

Standard operating procedures cover the assessment of research sites submitted for consideration.

Research outline from the Central Committee

3. Responsibility

3.1 The Foundation for the Promotion of Human Research in Thailand has a duty to appoint a working group to assess the potential of human research studies of agencies, organizations and institutions outside the partner institutions to certify their ability. Participate as a research site in a multicenter clinical trial and the Central Committee can proceed with the consideration of the research project as requested.

3.2 Office staff are responsible for coordinating between the Central Committee, the Subcommittee for Potential Assessment, and researchers. They are also responsible for collecting documents and reports of potential assessment.

4. Procedure flow chart

Sequence	Operation	Responsible
1	ÿ Determine the list of research institutes to be assessed for their	**person:** Foundation
2	potential ÿ Appoint a working group to assess their potential ÿ	Chairman of the Foundation
3	Prepare for potential assessment ÿ	Evaluation Working Group Potential
4	Conduct a potential assessment ÿ	Evaluation Working Group Potential
5	Potential Assessment Report ÿ	Evaluation Working Group Potential
6	Consider and decide ÿ	Central Committee

Sequence	Operation	Responsible
7	Report results ÿ	**person:** Office staff
8	Document storage	Office staff

5. Procedure 5.1

Qualifications of the research institute to conduct the potential assessment

Non-affiliated institutions must have an institutional ethics committee or rely on the results of the

Considered by one of the ethics committees

5.2 Appointment of a working group to evaluate the potential of human research studies

5.2.1 The Foundation's Executive Board appoints a working group to assess the potential of human research studies to conduct an assessment of the potential of research institutions selected by the Central Committee.

5.2.2 The working group consists of at least 3 Central Committee members, one of whom must:

Be a doctor

5.2.3 The appointed person has no conflict of interest with the research institute/researcher who is being evaluated. 5.2.4 The Foundation's Executive Board shall inform the Chairman of the Central Committee of the names of the working group.

5.3 Preparation for the potential assessment

5.3.1 Office staff coordinate with researchers and the working group to schedule an assessment date as soon as possible. 5.3.2 Office staff prepare documents for the working group as follows:

- Basic information form of the research institute (AP 01-S20) - Order to appoint the research ethics committee of the institute being evaluated - Announcement of the Food and Drug Administration on the criteria, methods, and conditions for accepting the human research ethics committee that considers the clinical research project on drugs.

- Standard procedures of the Research Ethics Committee of the Institution - Research projects submitted for consideration (if any)

- Biography of the Principal Researcher (site PI)

5.3.3 The chairman of the working group determines the plan for assessing the potential according to the documents.
AO 01-S20 and send to the office staff. In case of an interview, please state in the letter.
too

Note: The office staff will forward to the researcher/research institute at least before the evaluation.
10 working days

5.4 Conducting a potential assessment

5.4.1 The working group signs a confidentiality agreement prepared by the research institute.

5.4.2 The working group inspects according to the schedule and plan.

5.4.3 The working group conducts a potential assessment covering various aspects.

A. Researchers and research
assistants - have research qualifications and
experience - have knowledge, understanding and follow the research procedures specified in
Rigorous research outline
- The amount of research work in the project is not excessive when considering the number of
researchers and
co-researchers. B. The
institution conducting the research - Has a policy to protect rights, safety and well-being by
appointing a research ethics committee at the institution.
- There is support for research resources. - The
location is suitable and conducive to research.

C. Institutional Research Ethics Committee
- Contains ingredients as announced by the Food and Drug Administration.
- There are standard operating
procedures for products used in
research. - There are guidelines for the supervision of products used in research as specified in the project.
Research draft

5. Document and information storage system for data confidentiality - There are
guidelines for storing documents and data of volunteers participating in the research project
appropriately and limiting those who can access the data.

5.4.4 Each member of the working group records their observations in the evaluation form (AO 02-S20).

5.4.5 The working group summarizes the results of the potential assessment.

5.4.6 Presents the results of the preliminary potential assessment verbally and gives the researcher an opportunity to ask questions or provide additional information.

5.5 Reporting the results of the potential assessment to the Foundation

5.5.1 The Secretary of the Working Group summarizes the potential assessment report (AO 02-A20) and informs the Working Group to make corrections and improvements within 7 working days after the assessment. Potential

5.5.2 The chairman of the working group signs the report on the potential assessment results and sends it to Office of the Central Committee to present to the Foundation within 2 working days.

5.6 Foundation's Consideration 5.6.1

Foundation office staff prepare a potential assessment report for the secretary.

Foundation Executive Committee Before the meeting,

the Foundation Chairman may invite the Working Committee Chairman to provide information at the meeting. 5.6.2 The Secretary presents the results of the potential assessment at the Foundation Board meeting for consideration and presents the decision, which may be one of the following:

(1) Accept as a research site for multicenter clinical trials only in Phase III. clinical trial

(2) Accept as a research site for multicenter clinical trials only in Phase II. and III clinical trial

(3) Accept to be a research site of multicenter clinical trials in all phases of clinical trial

(4) The research institute must improve its potential before accepting it as a research site for a multicenter clinical trial (indicate the areas that need improvement).

5.6.3 The Foundation President presents the results of each decision and has the Foundation Board members vote by showing their hands. The decision is based on a majority vote. In the event of an equal number of votes, the President shall have a casting vote.

5.7 Notification of results

5.7.1 The Secretary of the Foundation's Executive Committee shall inform the researchers of the results of the consideration and decision.

Research institutions in hard copy and/or electronic format within 5 working days after the meeting, along with sending the Institutional Review Board (IRB) Authorization Agreement (AL 01-S20) to the head of the institution and the chairman of the ethics committee.

Signature of the Institute

5.7.2 The Secretary of the Foundation's Executive Committee sends a copy of the MOU to the Central Committee.

know

5.8 Document storage

5.8.1 The Foundation Office staff collects the potential assessment report forms and books.

Report the results of the consideration and AL 01-S20 in the file of the Evaluation Working Group.

5.8.2 The Central Committee Office staff shall store the AL 01-S20 file in the system.

Database

6. Definition of terms

Conflict of Interest (of the assessor)	The assessor is an advisor or a member of the committee of the institution being assessed, or is an advisor or co-investigator of the research project of the assessed researcher, or is a father, mother, or child of the assessed researcher.

7. Appendix

AL 01-S20	Acceptance Agreement Form
AO 01-S20	Potential Assessment Schedule
AO 02-S20	Research Institute/Research Site Potential Assessment Form
AP 01-S20	Basic information form of research institute/research site

8. Reference documents

8.1 ICH Harmonised Guideline. Integrated addendum to ICH E6(R1): Guidance for Good Clinical Practice E6(R2), 2016.

8.2 WHO. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

8.3 Attachment A: Consideration of Local Context with Respect to Increasing Use of Single IRB Review. January 10, 2013, SACHRP Letter to the HHS Secretary. January 10, 2013.

8.4 US DHHS. Guidance for IRBs, Clinical Investigators, and Sponsors IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed August 2013.

8.5 OHRP's Compliance Oversight Procedures for Evaluating Institutions Date: October 14, 2009.

9. History of standard operating procedures

Author No. Approval Date			Show main edits	Approved by
Subcommittee Development Method of operation standard	Issue No. 1 v.1.0	June 15 2563	Rewrite the entire chapter	Prof. Dr. Thada Sueblinwong Chairman of the Board Foundation Management
Subcommittee Development Method of operation standard	Issue No. 2 v.5.0	October 31 2566	- Edit chapter title - Correct the word "Subcommittee for Inspection" Assessing the potential" is a "working group" Evaluate potential" - Section 3. Responsibility, adjust for the sake of clear - Section 5. Procedures for extending the time of operation Resulting in greater operational flexibility	Prof. Dr. Kwanchanok Yimtae Chairman of the Board Foundation Management
Subcommittee Development Method of operation standard	Issue No. 7 v.5.1	24 July 2567	- Changed from v.5.0 to v.5.1 - Correct the item number.	Prof. Dr. Kwanchanok Yimtae Chairman of the Executive Board Foundation

Research Ethics Certification Exemption

(Exemption from Ethical Review)

Date of Effectiveness October 31, 2023

Replaces the previous edition 1 Dated June 15, 2020

Creator [signature] Date October 31, 2023

(Colonel R.Pol. Anantanacharoen)

Chairman of the Subcommittee on Standards Procedure Development

Approver October 31, 2023

(Dr. Khanchanok Yimtae)

Chairman of the Board of Directors of the Foundation for Human Research in Thailand

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CREC Central Research Ethics Committee	Central Committee on Human Research Ethics **Central Research Ethics Committee; CREC**	**CREC 21 / v. 5.0**
	Research Ethics Certification Exemption	**Start using on October 31, 2023**
	Exemption from Ethical Review	3 **uncles of** 6 uncles

1. Objective: To

provide guidelines for the implementation of research projects that are eligible for ethical research certification exemption.

2. Scope

Standard operating procedures cover the decision-making of research projects that are submitted for the first time and are eligible.

Except for the certification of research ethics by the Central Committee for Consideration of Research Ethics in Humans

Announcement of the Board of Directors

3. Responsibility

3.1 The office officer presents the research outline to the secretary for review in accordance with the criteria.

Announcement

3.2 The Chairman signs the document confirming the cancellation.

3.3 The Office of the Researcher shall report the decision to the researcher or the research project coordinator and

Partner institutions

4. Procedure flow chart

Sequence	Operation	responsible person
1	Accepting research projects ÿ	secretary
2	Police with the criteria ÿ	secretary
3	Decision Result ÿ	chairman
4	Notification of decision ÿ	Officer of the Office
5	Report the names of research projects that have been proposed to the meeting.	Officer of the Office

5. Procedure

5.1 Acceptance of research project documents

5.1.1 The office staff receives the research project documents or views the documents through the database system. Online and comprehensive, including:

5.1.1.1 Documents specified in the document 5.1.1.2

Documents as specified in the document 5.1.1.3 If additional documents are required, please contact the Office of the Coordinating Committee.

Researcher

5.2 Examination against exemption criteria (Exemption Determination) 5.2.1 The Secretary shall examine the Board's announcement and use the following framework. Comprising of checkpoints

– The risk is at a low level and – The research participants' data to be recorded does not directly identify any individual (non-identifiable private information) ÿÿÿ

– The research design is observational study and there is no staged, fake situations or intervention.

5.2.2 Which of the following is the subject of the Nakham?

5.2.2.1 The proposal shall be excluded from consideration by the committee by specifying the items in the announcement that are consistent with the research project characteristics.

5.2.2.2 Not yet finalized but must be considered by the committee by expedited method. (Expedited)

5.2.2.3 Not required to be waived but must be considered by the full committee. 5.2.3 In the event that the secretary has a conflict of interest or is named as a researcher/advisor in a research project, another committee member must be assigned to act as a reviewer and advisor on his/her behalf.

5.3 Exemption decision The chairman makes one of the following decisions:

5.3.1 Except from consideration by the committee

5.3.2 Do not waive and submit to the committee for consideration by expedited method.

5.3.3 Do not waive and submit to the full committee for consideration.

5.4 Notification of decision results

5.4.1 The Office Officer shall inform the decision to the researcher or the research project coordinator and the research institution according to CREC 04 within 5 working days after the meeting/after the Secretary and the Chairman signs. 5.4.2 The approval of the waiver shall only be for sites with local issues (AP 01-S04) that have been approved. If after the certification letter is issued and a partner institution submits additional local issues, the Office may issue additional certification letters, but the approval shall be on the date the Chairman signs at that time, which shall expire the same as the certification letter issued earlier. 5.4.3 The Office Officer shall inform the result by the following methods: 5.4.3.1 Send the electronic document via the electronic system to the researcher.

Or the research project director

5.4.3.2 Submit the original document (if any) to the researcher or coordinator.

Research Project

5.5 Notification of the names of research projects/research reports that have been considered to the committee meeting.

List of research projects/research reports that have been exempted from ethical approval.

Monthly research and notification to the meeting, consisting of the following information:

5.5.1 CREC Project

5.5.2 Project name

5.5.3 Research project title 5.5.4 Name of research sponsor 5.5.5 Exemption criteria as announced 5.5.6 Date of the chairman's signature certifying the exemption

6. Definition

do not have

7. Appendix

AP 01-S04	Institute Local Issue Assessment Form
AL 13-S04	Certificate of Exemption

8. References

8.1 Electronic Code of Federal Regulation. Title 45 Public Welfare Part 46 Protection of Human Subjects §46.104 Exempt research.

8.2 Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans,* December 2018. Chapter 2.

9. History of standard operating procedures

Producer:	Issue No.	Date of approval	Red theft correction
Development Subcommittee Standard operating procedures	1.0	June 15, 2020	
Development Subcommittee Standard operating procedures	5.0	October *31 , 2023*	Edit the threat to make it clearer. And in line with the practice