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1. Purpose

This procedure describes how CHH IRB proceeds and manages the termination of a research study. Protocols are usually terminated at the recommendation of the CHH IRB, Data Safety Monitoring Board (DSMB), Scientific Director, sponsor or other authorized bodies when subject enrollment and subject follow-up are discontinued before the scheduled end of the study.

2. Scope

This SOP applies to any study approved by CHH IRB that is being recommended for termination before its scheduled completion.

3. Responsibility

It is the responsibility of the CHH IRB Chairperson to terminate any study that the CHH IRB has previously approved when the safety or benefit of the study participants is doubtful or at risk. The Secretariat is responsible for management of the termination process.

4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I	Receive recommendation for study termination	Investigator and CHH IRB Secretariat
II	Review and Discuss the Termination Package	CHH IRB Secretariat and Chairperson
III	Notification to the Principal Investigator	CHH IRB Secretariat
IV	Store the Protocol Documents	CHH IRB Secretariat
V	Inactivate the Protocol Document	CHH IRB Secretariat

5. Detailed Instructions

5.1 Receive recommendation for study termination.

- Staff secretary receives recommendation and comments from DSMB, CHH IRB members, Sponsor or other authorized bodies for study protocol termination.
- Inform the principal investigator or the study office to prepare and submit a protocol termination package.
- Receive the study protocol termination package prepared and submitted by the principal investigator or the study office.
- Verify the contents of the package to include but not limited to the ff:
  - Request for Termination Memorandum
    (HRP-IRB-023, see ANNEX 1 of this SOP)
    - The request for termination memorandum should contain a brief written summary of the protocol, its results, and accrual data.
  - Original Continuing Review Application Form
    (HRP-IRB-018, see ANNEX 2)
    - Termination is indicated under "Decision/Comments".
    - Completeness of the information, including accrual data since the time of the last continuing review.
    - Presence of the required signatures (Principal Investigator).
- Initial and date the package upon receipt.

5.2 Review and discuss the Termination Package.

- Notify the Chairperson regarding the recommendation for study protocol termination.
- Send a copy of the termination package to the Chairperson preferably within one working day upon receipt.
- The Chairperson reviews the results, reasons and accrual data.
- The Chairperson calls for an emergency meeting to discuss about the recommendation.
- The Chairperson signs and dates the Continuing Review Application Form in acknowledgment and approval of the termination.
- The Chairperson returns the form back to the Secretariat preferably/preferably within 14 working days of receipt of the package.
- The Secretariat reviews, signs, and dates the Continuing Review Application Form indicating that the termination process is complete.

5.3 Notification to the Principal Investigator.

- Make a copy of the completed Continuing Review Application Form
- Send the copy to the principal investigator for their records within 14 working days from receipt.

5.4 Store the protocol documents.

- Keep the original version of the request memorandum for termination and the original version of the Continuing Review Application Form in the Protocol file.
- Send the file to archive.
- Store the protocol documents indefinitely.

5.5 Inactivate the protocol documents.

- Place the study protocol into the **inactive** protocol folder

6. ANNEX

ANNEX 1

CHONG HUA HOSPITAL
Healing with Passion. Caring with Compassion.

STUDY TERMINATION MEMORANDUM

Form HRP-IRB-023

DATE:			
PROTOCOL NUMBER:		ASSIGNED No.: ☐☐☐ / ☐☐☐☐-☐☐	
PROTOCOL TITLE:			
PRINCIPAL INVESTIGATOR:			
PHONE :		E-MAIL:	
INSTITUTE:			
SPONSOR:			
CHH IRB APPROVAL DATE:		DATE OF LAST REPORT:	
STARTING DATE:		TERMINATION DATE:	
NO. OF PARTICIPANTS:		NO. ENROLLED:	
SUMMARY OF RESULTS			
ACCRUAL DATA:			
P.I SIGNATURE:		DATE:	

STUDY TERMINATION MEMORANDUM

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ANNEX 2:

ANNEX 2

CHONG HUA HOSPITAL
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CONTINUING REVIEW APPLICATION FORM

Form HRP-IRB-018

DATE FILED:

PROTOCOL No.: ASSIGNED No.: ☐☐☐ / ☐☐☐☐-☐☐

PROTOCOL TITLE:

PRINCIPAL INVESTIGATOR:

1. ACTION REQUESTED:
   - ☐ Renew - New participant accrual to continue
   - ☐ Renew - Enrolled participant follow up only
   - ☐ Terminate - Protocol discontinued

2. AMENDMENTS SINCE THE LAST REVIEW?
   - ☐ NO
   - ☐ YES (Describe briefly in attached narrative)

3. PROTOCOL PARTICIPANTS SUMMARY:
   - _____ Accrual ceiling set by IRB
   - _____ New participants accrued since last review
   - _____ Total participants accrued since protocol began

4. ACCRUAL EXCLUSIONS
   - ☐ NONE
   - ☐ MALE
   - ☐ FEMALE
   - ☐ OTHER (specify):_____

5. IMPAIRED PARTICIPANTS
   - ☐ None
   - ☐ Physically
   - ☐ Cognitively
   - ☐ Both

6. HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW?
   - ☐ NO
   - ☐ YES (Explain changes in attached narrative)

7. HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW?
   - ☐ NO
   - ☐ YES (Explain changes in attached narrative)

8. CHANGE IN PRINCIPAL INVESTIGATOR?
   - ☐ NONE
   - ☐ DELETE:_____
   - ☐ ADD: _____

9. IS THERE NEW INFORMATION FROM SIMILAR RESEARCH THAT MIGHT AFFECT THE RISK/BENEFIT RATIO OF THE HUMAN SUBJECTS INVOLVED IN THIS PROTOCOL?
   - ☐ NO
   - ☐ YES (Discuss in the attached narrative)

10. HAVE ANY UNEXPECTED COMPLICATIONS OR ADVERSE EVENTS BEEN NOTED SINCE LAST REVIEW?
    - ☐ NO
    - ☐ YES (Discuss in the attached narrative)

11. HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY SINCE THE LAST IRB APPROVAL?
    - ☐ NO
    - ☐ YES (Discuss in the attached narrative)

12. HAVE ANY PARTICIPATING INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW?
    - ☐ NO
    - ☐ YES (Identify all changes in the attached narrative)

13. HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR DELETED SINCE THE LAST REVIEW?
    - ☐ NO
    - ☐ YES (Identify all changes and provide an explanation of changes in the attached narrative)

14. HAVE ANY INVESTIGATORS DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A SOURCE RELATED TO THIS PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST?
    - ☐ NO
    - ☐ YES (Append a statement of disclosure)

ANNEX 2

CHONG HUA HOSPITAL
Healing with Passion. Caring with Compassion.

CONTINUING REVIEW
APPLICATION FORM

Form HRP-IRB-018

ANNEX 2

CHONG HUA HOSPITAL
Healing with Passion. Caring with Compassion.

CONTINUING REVIEW APPLICATION FORM

Form HRP-IRB-018

SIGNED

_____ Date: _____
Principal Investigator

IRB Comment/Decision:

- ☐ Needs Clarification
- ☐ Approval
- ☐ Disapproval

SIGNED

_____ Date: _____
Chairperson, *CHONG HUA HOSPITAL IRB*

7. References

❖ World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

❖ International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

❖ Associated SOP: SOP/012/02.

❖ National Ethical Guidelines for Health Research 2011 PNHRS