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1. Purpose

To ensure that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study participants are promoted.

2. Scope

This SOP applies to the management and review of protocol amendments submitted by the proponent of previously approved protocol.

3. Responsibility

It is the responsibility of the IRB Secretariat to manage protocol amendments. Investigators may amend the contents of protocols from time to time. Protocol amendments may be submitted for either "expedited" review by the Chairperson/members / reviewers or full IRB review.

4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I	Manage the Amendment Package	IRB Secretariat
II	Notification of CHH IRB Chairperson	IRB Secretariat
III	Determine whether Expedited or Full Review	Chairperson
IV	Expedited Review	Chairperson / Designated members
V	Full Review by the CHH IRB	IRB Secretariat / Chairperson / members
VI	Protocol Amendment Review Process	IRB Secretariat / Chairperson / members
VII	Notification to the Principal Investigator	IRB Secretariat
VIII	Storage of the Documents	IRB Secretariat

5. Detailed Instructions

5.1 Manage the Amendment Package.

- Upon receipt of the protocol amendment package, the IRB Secretariat should follow the receiving procedure in SOP on the Management of Protocol Submission and SOP on Procedure for Maintaining Confidentiality of IRB Documents. Contents of the Amendment Package should include but may not be limited to the ff.
  - **Request for Amendment Memorandum** of the Protocol by the Principal Investigator on an existing and previously approved protocol. The memorandum should:
    - State/describe the amendment
    - Provide the reason for the amendment if applicable
    - State any untoward effects with original protocol if applicable
    - State expected untoward effects because of the amendment if applicable
  - **Protocol Amendment Submission Form**
    - Check for completeness and for the presence of the required signatures (Principal Investigator or Medical Advisor of the Institute, if applicable).
      (See ANNEX 1, Form HRP-IRB-017)
  - **Protocol and Related Documents**
    - The related amendments may be summarized accordingly
    - The amended version of the protocol and related documents should be provided.
    - The changes or modifications should be underlined or highlighted.

5.2 Notification of CHH IRB Chairperson

- Upon receipt of the amendment package, the Secretariat should inform the Chairperson of the IRB verbally.
- The request for amendment memorandum and the protocol and related documents must be noted received by the Chairperson by the Secretariat.
- After review of the materials, the Chairperson will determine whether the protocol requires expedited or full review.
- The type of review will be noted on the comments portion of page 2 of the **Protocol Amendment Submission Form**

5.3 Determine whether expedited or full board review.

- Refer to SOP/006/05 for Expedited Review.
- Refer to SOP/007/05 for Full Board Review.

Protocol amendments for Full Board review include protocols which increase risk to study participants, as judged by the Chairperson, such as a change in study design, which may include but is not limited to:

- additional treatments or the deletion of treatments
- any changes in inclusion/exclusion criteria
- change in method of dosage formulation, such as, oral changed to intravenous
- significant change in the number of subjects
  - (Increase: if there are <20 subjects enrolled, change of 5 is significant; if there are >20 subjects enrolled, a change of 20% is significant –
  - Decrease: if the decrease in the number of subjects alters the fundamental characteristics of the study, it is significant)
- significant decrease or increase in dosage amount

- If the Chairperson decides the protocol requires full board approval, the Chairperson will indicate this decision on the **Protocol Amendment Submission Form**
- The Secretariat places the protocol amendment request on the agenda for the next convened meeting.
- For full board review, the following documents are distributed to each IRB member:
  - the amendment's revision documents to clearly identify each change.
  - requested changes to the consent form, if applicable
- If an amendment is received just prior to the IRB meeting, the Chairperson may decide to review the amendment in full board, even though the amendment may be expedited.

5.4 Expedited Review

- Refer to SOP expedited review procedure.

5.5 Full Review by the CHH IRB

- Refer to SOP for full Board Review.

5.6 Protocol Amendment Review Process

5.6.1 Review amended protocols

- Note recommendations for changes to the protocol and/or informed consent requested by IRB Members in the minutes as "with

modifications made by CHONG HUA HOSPITAL" and will be communicated to the clinical trial office or investigator.

- The Chairperson or designee calls for comments on the proposed amendment to:
    - Approve the protocol amendment as is with no modification of the informed consent
    - Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with follow-up by the Chairperson
    - Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with a follow-up for full board review
    - Suspend the study, until further information is obtained
    - Not suspend the study as currently approved, but request further information regarding the amendment and the effects of the amendments on the approved study
    - Not approve the amendment request, stating the reason – but allow the study to continue as previously approved
- If the IRB approves the protocol amendment, the Secretariat staff communicates this decision to the investigator.
- If the IRB does not approve the protocol amendment, the Secretariat staff immediately notifies the investigator in writing of the decision and the reason for not approving the amendment.
- If the IRB arrives at a consensus to require modifications to any of the documents, or the protocol amendment, the Secretariat sends a written request about the specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to CHONG HUA HOSPITAL Ethics Committee.
- The Chairperson completes a decision form after the IRB has reached its decision.
- Keep the forms, minutes of the meeting relevant to the discussion and the decision reached by the IRB as the official records of the amendment review process.

5.6.2 Written Communication of the Decision

The Secretariat staff notifies the Principal Investigator in writing after the IRB meeting as soon as possible, but no later than 14 working days following the review.

5.6.3 Completion of the Amendment Submission Form

- The Chairperson must sign and date the original version of this form and return this to the Secretariat no later than 5 working days after the review.
- Addition of Amendment to the Protocol Number

  The Secretariat assigns a letter to the protocol number that corresponds to the number of the amendment. For example: The third amendment to CHONG HUA HOSPITAL 015/01-03 would be formatted as: CHONG HUA HOSPITAL 015/01-03**C**
- Record the amended protocol number on the form.
- The Secretariat signs and dates the original version of the form.

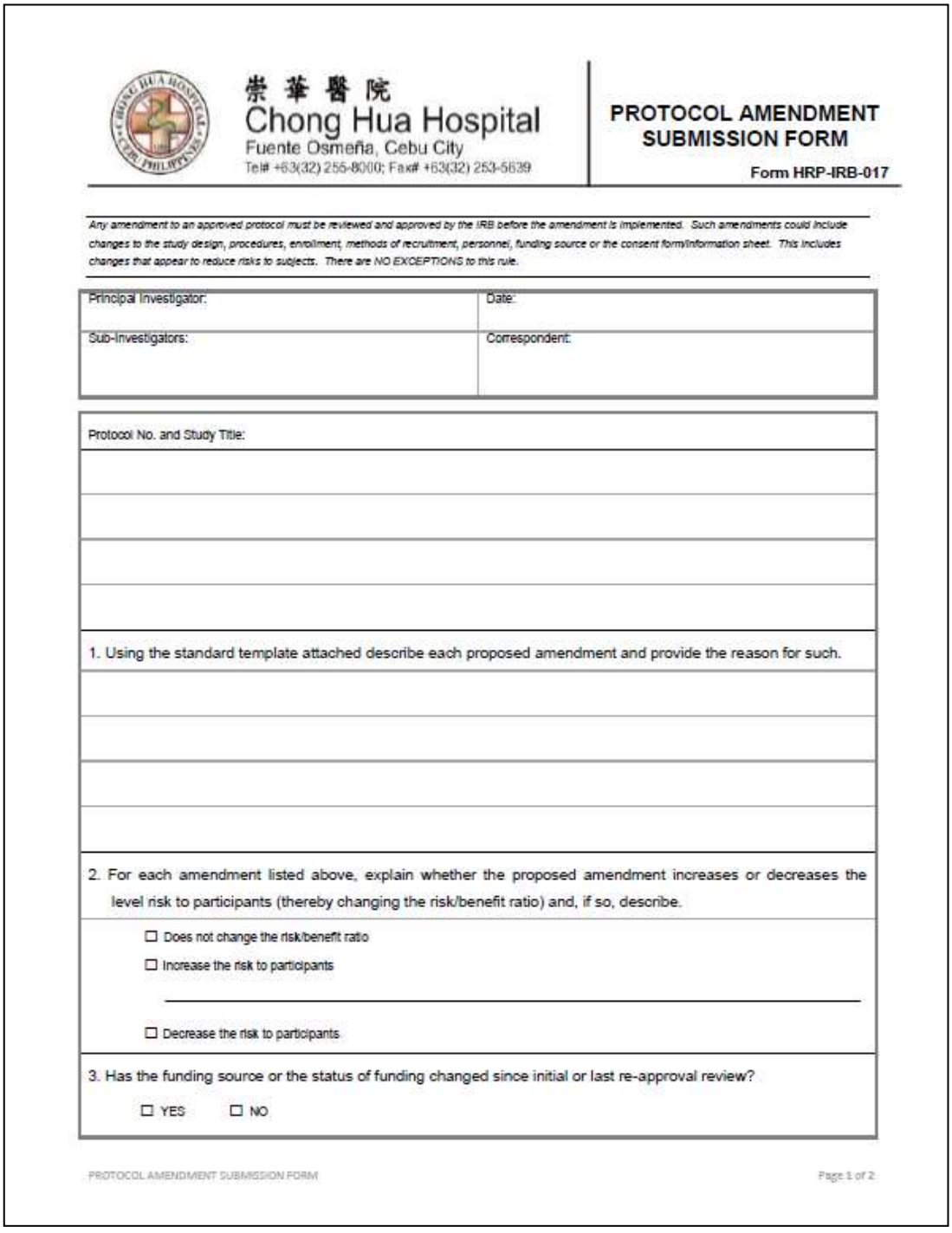
5.7 Notification to the Principal Investigator

- Send a signed and dated Amendment Submission Form to the Principal Investigator (P.I.) for their records no later than 14 working days.
- The P.I. should then provide a "clean" copy (underlining and highlighting removed) of the protocol and related documents as well as the "clean" electronic version (where applicable) to the Secretariat of the IRB.

5.8 Storage of the documents

- Place the original completed documents, the "clean" version of the protocol and related documents in the protocol file with the other documents pertaining to the amendment.

6. ANNEX



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PROTOCOL AMENDMENT SUBMISSION FORM

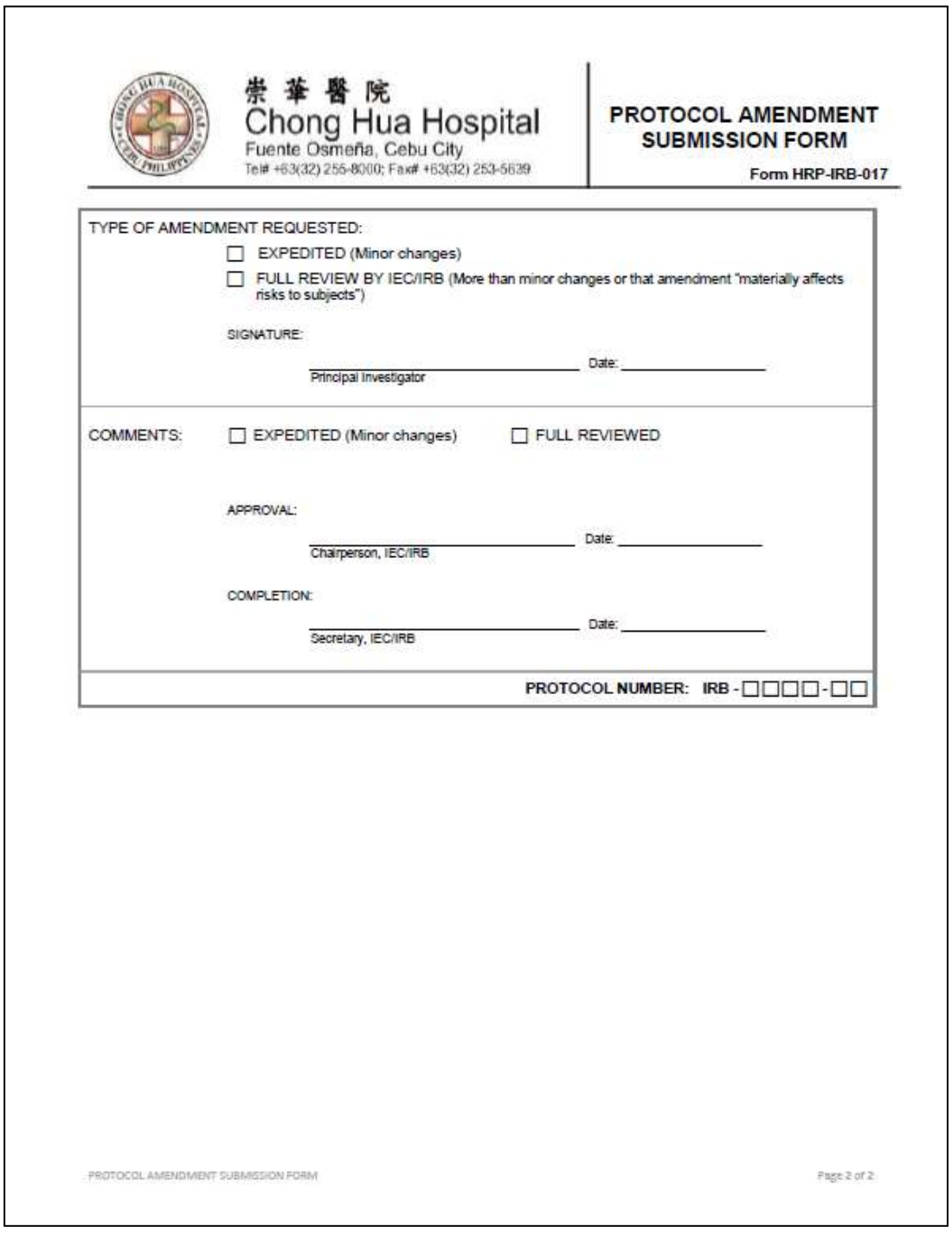
Form HRP-IRB-017

Any amendment to an approved protocol must be reviewed and approved by the IRB before the amendment is implemented. Such amendments could include changes to the study design, procedures, enrollment, methods of recruitment, personnel, funding source or the consent form/information sheet. This includes changes that appear to reduce risks to subjects. There are NO EXCEPTIONS to this rule.

Principal Investigator:	Date:
Sub-Investigators:	Correspondent:

Protocol No. and Study Title:
1. Using the standard template attached describe each proposed amendment and provide the reason for such.
2. For each amendment listed above, explain whether the proposed amendment increases or decreases the level risk to participants (thereby changing the risk/benefit ratio) and, if so, describe.
☐ Does not change the risk/benefit ratio ☐ Increase the risk to participants _____ ☐ Decrease the risk to participants
3. Has the funding source or the status of funding changed since initial or last re-approval review? ☐ YES ☐ NO

PROTOCOL AMENDMENT SUBMISSION FORM Page 1 of 2



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PROTOCOL AMENDMENT SUBMISSION FORM
Form HRP-IRB-017

TYPE OF AMENDMENT REQUESTED:

☐ EXPEDITED (Minor changes)

☐ FULL REVIEW BY IEC/IRB (More than minor changes or that amendment "materially affects risks to subjects")

SIGNATURE:

_____ Date: _____
Principal Investigator

COMMENTS: ☐ EXPEDITED (Minor changes) ☐ FULL REVIEWED

APPROVAL:

_____ Date: _____
Chairperson, IEC/IRB

COMPLETION:

_____ Date: _____
Secretary, IEC/IRB

PROTOCOL NUMBER: IRB -☐☐☐☐-☐☐

PROTOCOL AMENDMENT SUBMISSION FORM Page 2 of 2

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PROTOCOL AMENDMENT STANDARD TEMPLATE FORM
Form HRP-IRB-017

Sponsor:	Title:	Protocol No.:
Version No.:		Superseded:
Effective Date:		

Clinical Study Protocol Title:	

Section	Before Amendment	After Amendment	Rationale

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INFORMED CONSENT STANDARD TEMPLATE FORM
Form HRP-IRB-017

Sponsor:	Title:	Protocol No.:
Version No.:		Superseded:
Effective Date:		

Clinical Study Protocol Title:	

Section	Before Amendment	After Amendment	Rationale

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.
- Code of Federal Regulation (CFR), 21 §56.110, The United States of America, 1998
- Relevant SOPs: SOP/006/02, 007, 008 and 009
- National Ethical Guidelines for Health Research 2011 PNHRS