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1. Purpose

This standard operating procedure is designed to describe how the Secretariat of the Institutional Ethics Committee / Institutional Review Board (CHH IRB) manages protocol submissions to the CHH IRB.

2. Scope

Protocol submissions include:

- Submission for Initial Review
- Resubmission of Protocols with Corrections
- Protocol Amendment
- Continuing Review of Approved Protocols
- Protocol Termination

3. Responsibility

It is the responsibility of the CHH IRB Secretariat to receive, record, distribute for review and get the submission packages approved by the CHH IRB, and to prepare them for pickup by the study coordinator

4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I	Receive submitted Package	CHH IRB Secretariat
II	Check for completeness of submitted package	CHH IRB Secretariat
III	Process submitted package	CHH IRB Secretariat
IV	Store the received package	CHH IRB Secretariat

5. Detailed instructions

5.1 Receive submitted package

5.1.1 Initial Review Application

- Go to 5.2.

5.1.2 Resubmission of Protocols with Corrections

- Retrieve the previous receipt form from the Secretariat's records.
- Go to step 5.2.1.2

5.1.3 Protocol Amendment

- Retrieve the previous receipt form from the Secretariat's records.
- Go to step 5.2.1.3

5.1.4 Continuing Review of Approved Protocols

- Retrieve the previous receipt form from the Secretariat's records.
- Go to step 5.2.1.4

5.1.5 Protocol Termination

- Retrieve the previous receipt form from the Secretariat's records.
- Go to step 5.2.1.5

5.2 Check for completeness of submitted package

5.2.1 Get relevant forms:

5.2.1-1 Initial Review Application

- a checklist for Contents of a Submitted Package, (see ANNEX 1_HRP-IRB-008)
- a checklist for IRB Application Information Sheet, (see ANNEX 2_HRP-IRB-009)
- an IRB Application Form and Questionnaire, (see ANNEX 3_HRP-IRB-010)
- a Document Receipt Form (see ANNEX 4_HRP-IRB-011); and
- Go to step 5.2.2

5.2.1-2 Resubmission of Protocols with corrections

- a review of resubmitted protocol form, HRP-IRB-016, (see ANNEX 5)
- a checklist for Contents of a Submitted Package, (see ANNEX 1, HRP-IRB-008)
- a Document Receipt Form (see ANNEX 4, HRP-IRB-011); and
- Go to step 5.2.2

5.2.1-3 Protocol Amendments

- a checklist for Contents of a Submitted Package, (see ANNEX 1, HRP-IRB-008)
- a Document Receipt Form (see ANNEX 4, HRP-IRB-011); and
- Go to step 5.2.2

5.2.1-4 Annual Continuing Reviews of Approved Protocols

- a checklist for contents of a submitted package, form HRP-IRB-008 (see ANNEX 1),
- a document receipt form, HRP-IRB-011, (see ANNEX 4) and
- a review of resubmitted protocol form, HRP-IRB-016, (see ANNEX 5)
- Go to step 5.2.2

5.2.1-5 Protocol Termination

- a checklist for contents of a submitted package form, HRP-IRB-008 (see ANNEX 1),
- a document receipt form, HRP-IRB-011 (see ANNEX 4)
- a review of resubmitted protocol form, HRP-IRB-016, (see ANNEX 5)
- Go to step 5.2.2

5.2.2 Fill in the forms:

- Give the Document Receipt Form HRP-IRB-011 (ANNEX 4) and the form HRP-IRB-010 (ANNEX 3) to the applicants to fill up the relevant information.

5.2.3 Verify Contents of Submitted Package

- Use the checklist for contents of a submitted package, form HRP-IRB-008, (ANNEX 1).
- Check the applicable documents to ensure that all required forms and materials are contained within the submitted package.
- Verify contents of the protocol submitted package to include:
  - Original Application Form for Initial Review
  - Summary Sheet or Memorandum of the study Protocol
  - Study Protocol and Protocol-Related Documents
  - Check completeness of necessary information in the Application Form for Initial Review.
  - Check the Summary Sheet or Memorandum of the study protocol for inclusion of the followings:
    - Title of the Protocol
    - Principal Investigator
    - Sponsor
    - Abstract
    - Type of Protocol (screening, survey, clinical trial and phase)
    - Objectives
    - Anticipated Outcome
    - Inclusion/Exclusion Criteria
    - Withdrawal or discontinuation Criteria
    - Modes of Treatment Studied
    - Methodology (synopsis of study design)
    - Analysis (methods)
    - Activity plan / Timeline
    - IND Number (if applicable)
    - Schedule and Duration of Treatment
    - Efficacy or Evaluation Criteria (Response/Outcome)
    - Safety Parameters Criteria (Toxicity)

- Check the submitted **Protocol and Related Documents** for the following contents:
  - Subjects' information sheets
  - Informed Consent Form
  - Case Record Form (CRF)
  - Study budget and budget justification
  - Agreement of the study
  - Curriculum Vitae (CV) of investigators
  - GCP training certificate the past 3 years
  - Investigators' Brochure
- See if changes made to the documents be underlined or highlighted.

5.2.4 Return incomplete submission package to the PI with notification of missing items/documents

5.3 Process submitted package

- Get the Form HRP-IRB-011 (see ANNEX 4) and HRP-IRB-010 (see ANNEX 3) back from the applicants.
- Verify for completeness of information and package.
- Stamp the receiving date on the letter and the first page of the documents.
- Initial the receiver's name on the receiving documents.
- Create a Protocol Specific File
  - Record the name and the number of the submitted protocol
  - Record the receiving date and the name of the receiver
- Make a photocopy of the completed Form HRP-IRB-011.
- Return the original copy of the HRP-IRB-011 to the applicants for their records.
- Attach the filled checklist (HRP-IRB-008) with the copy of the form HRP-IRB-011 with a staple.
- Keep the copy of the submitted documents with original signatures in the "Submission" file.

5.4 Store the received packages

- Bind the packages together appropriately.
- Store the dated and initial original protocol packages on the CHH IRB submission shelf for review in FIFO sequence.

6. ANNEX 1:

HRP-IRB-008: Contents of a Submitted Package

ANNEX 1

崇華醫院
Chong Hua Hospital
Fuente Osmeña, Cebu City
Tel# +63(32) 255-8000; Fax# +63(32) 253-5639

CONTENTS OF A SUBMITTED PACKAGE

Form HRP-IRB-008

Protocol Number: _____

☐ **Initial Review Submitted Package**

- ☐ Protocol Summary Sheet or Memorandum
- ☐ Original Initial Review Application Form
- ☐ Protocol and Protocol-Related Documents
  - ☐ Information for subjects
  - ☐ Case Report Forms (CRF)
  - ☐ Investigator's CV
  - ☐ Investigator's Brochure
  - ☐ Informed Consent Form
  - ☐ Study budget
  - ☐ PI GCP certification
  - ☐ others_____

☐ **Resubmission for Re-review Submitted Package**

- ☐ Resubmission or "Correction" Memorandum
- ☐ Revised Protocol Summary Sheet (if submitted initially)
- ☐ Original Initial Review Application Form
- ☐ Protocol and Protocol-Related Documents
  - ☐ Information for subjects
  - ☐ Case Report Forms (CRF)
  - ☐ Investigator's Brochure
  - ☐ Informed Consent Form
  - ☐ Study budget
  - ☐ others_____

Note: Changes made to the protocol and protocol-related documents should be clearly marked either with the underlining or highlighting feature of the document or the software package used to prepare the documents.

☐ **Protocol Amendment Submitted Package**

- ☐ Request for Amendment Memorandum
- ☐ Original Amendment Submission Form
- ☐ Protocol and Protocol-Related Documents

Note: Changes made to the protocol and protocol-related documents should be clearly marked either with the underlining or highlighting feature of the software package used to prepare the document.

☐ **Annual Continuing Review Package**

- ☐ Request for Annual Continuing Review Memorandum
- ☐ Original Continuing Review Application Form
- ☐ Current Informed Consent Document (last approved by the IEC/IRB)

☐ **Protocol Termination Package**

- ☐ Request for Termination Memorandum

☐ **Original Continuing Review Application Form** (Termination Submissions are contained on this form).

☐ **COMPLETE PACKAGE FOR SUBMISSION**

N B. THE SUBMISSION WILL NOT BE PROCESSED IF THE PACKAGE IS INCOMPLETE

CONTENTS OF A SUBMITTED PACKAGE — Page 1 of 1

ANNEX 2:

HRP-IRB-009: IRB Application Information Sheet (page 1 of 2)

ANNEX 2

崇 華 醫 院
Chong Hua Hospital
Fuente Osmeña, Cebu City
Tel# +63(32) 255-8000; Fax# +63(32) 253-5639

IRB APPLICATION INFORMATION SHEET

Form HRP-IRB-009

FOR SPONSOR-INITIATED PROTOCOLS

The Principal Investigator initiates the process of ethics review by submitting an application letter to the IRB office. The letter should be attached to the document package which should include the following:

- ❑ Nine (7) copies of **Research Protocol** or its amendments.
- ❑ Nine (7) copies of **Investigators' Brochure** if applicable
- ❑ Nine (7) copies **Informed Consent Forms and Consent forms (if applicable)** and their translations to Cebuano or dialect spoken or understood by research participants
- ❑ Nine (7) copies of **additional information sheet** *(any information not included in the above documents)* in English and Cebuano or dialect spoken and understood by research participants
- ❑ Investigators' **Curriculum Vitae** (latest updated, signed and dated).
- ❑ Recent **PRC License**
- ❑ A copy of the latest **GCP certification** of the Principal Investigator (at least for the past 2 years) or schedule of planned GCP training.
- ❑ A copy of PI's **declaration of no Conflict of Interest**.
- ❑ A completed and duly signed **IRB APPLICATION FORM**
- ❑ Duly signed **letter of consent** approved by the COO/Medical Director for the proposal to conduct clinical trials in Chong Hua Hospital.
- ❑ A **review fee** of 50,000 Php and **institutional fee** of 50,000 Php **(to be collected only after the approval and if space is available at Research Facility Unit of Chong Hua Hospital)** in two separate checks (for New Protocol) or 10,000 Php (for Protocol Amendment) is required to be submitted together with the application letter and the required documents stated above.

IRB APPLICATION INFORMATION SHEET Page 1 of 2

HRP-IRB-009: IRB Application Information Sheet (page 2 of 2)

ANNEX 2

崇華醫院
Chong Hua Hospital
Fuente Osmeña, Cebu City
Tel# +63(32) 255-8000; Fax# +63(32) 253-5639

IRB APPLICATION INFORMATION SHEET

Form HRP-IRB-009

- The investigator initiates the process of review by submitting an application form to the IRB office.
- The application letter should be accompanied by a duly signed letter of consent approved by the COO/Medical Director to conduct clinical trials in Chong Hua Hospital.
- A review fee shall be paid together with the application letter.
- IRB staff will screen the application and may request additional information or revisions if it is incomplete or contains inconsistencies.
- If the application is complete the IRB will assign an IRB Reference Number to your research submission. All communication from and to the principal investigator henceforth will use this IRB reference number for tracking purposes.
- The investigator or his designate may be invited to provide information on any aspect of the trial, but are not allowed to participate in the deliberation of the IRB or in the vote opinion of the IRB.
- Once the application meets all criteria for approval, the IRB will issue an approval letter not later than 4 weeks upon receipt of complete requirements.
- If the protocol fails to meet the criteria for approval, clarification to include more information or revisions will be requested. Should significant changes be needed, the revised protocol will require a new review.
- Unfavorable board decisions may be appealed not later than 2 weeks from receipt of the written decision.
- The sponsor/ investigator should provide the list of laboratory/ other procedures to be done in the site.

*** Please keep this copy for your guidance ***

IRB APPLICATION INFORMATION SHEET Page 2 of 2

ANNEX 3:

HRP-IRB-010: IRB Application Form and Questionnaire (page 1 of 3)

ANNEX 3

崇華醫院
Chong Hua Hospital
Fuente Osmeña, Cebu City
Tel# +63(32) 255-8000; Fax# +63(32) 253-5639

IRB APPLICATION FORM AND QUESTIONNAIRE

Form HRP-IRB-010

NAME OF ORGANIZATION/INSTITUTION: _____ REFERRENCE NO: _____

TITLE OF RESEARCH:	
Anticipated start date	
Anticipated end date	
Principal Investigator: (Must be a member of the consultant staff of Chong Hua Hospital)	
Specific Role in this project:	
Sub – Investigator: (Must be a member of the consultant staff of Chong Hua Hospital)	
Specific Role in this project:	
Has this protocol been disapproved by another IRB/IEC or hospital? YES ____ NO _____ If YES from which IRB/IEC or HOSPITAL?	

INVESTIGATOR'S ASSURANCE
THE SIGNATURES BELOW SIGNIFY THAT:
• The information and documents provided is/are accurate, current and valid
• The principal investigator has the ultimate responsibility for the protection of rights, welfare and safety of the subjects
• The principal investigator has the ultimate responsibility for the ethical conduct of the research
• Each individual listed as investigator has received the required training on Good Clinical Practice
• Each investigator and member of the team has the necessary experience on how to conduct a research on human subjects and shall abide by the regulations of Chong Hua Hospital in its conduct
• The principal investigator has the ultimate responsibility for the prompt management of any adverse reactions or suspected adverse reactions attendant to the conduct of the study.
• No research or part of it will commence before the IRB has given its approval
• The research will be conducted according to the protocol or its amendments duly approved by the Chong Hua Hospital IRB.

Principal Investigator:	[Printed Name and Signature]	Date
Sub – Investigator:	[Printed Name and Signature]	Date
Received by:	[Printed Name and Signature]	Date Received Time Received

IRB APPLICATION FORM AND QUESTIONNAIRE Page 1 of 3

HRP-IRB-010: IRB Application Form and Questionnaire (page 2 of 3)

ANNEX 3

崇華醫院
Chong Hua Hospital
Fuente Osmeña, Cebu City
Tel# +63(32) 255-8000; Fax# +63(32) 253-5639

IRB APPLICATION FORM AND QUESTIONNAIRE

Form HRP-IRB-010

SECTION I: INVOLVEMENT OF HUMAN SUBJECTS

1. Does the study involve human subjects? __ Yes __ No

*If the answer is **No**, you may not submit the study for IRB review*

SECTION II: PROJECT FUNDING

1. Is the project funded? __ Yes __ No

If the project is funded, kindly specify the funding source.

_____

_____

SECTION III: CONFLICT OF INTEREST (only required for funded research)

1. Is there any real, potential or apparent conflict of interest on the part of Investigator or any of the study team? __ Yes __ No

If Yes, please declare and explain.

N.B. NON DISCLOSURE OF ANY CONFLICT OF INTEREST MAY AFFECT IRB APPROVAL.

_____

_____

SECTION IV: TYPE OF RESEARCH STUDY

STUDY TYPE: (Mark "✓" whichever apply to the study)

☐ Survey	☐ Social	☐ Medical	☐ Community Based	☐ Individual Based
☐ Screening	☐ Observational	☐ Epidemiology	☐ Intervention Study	
☐ Clinical Trial:	☐ Phase I	☐ Phase II	☐ Phase III	☐ Phase IV
☐ Genetic Study	☐ Retrospective	☐ Prospective	☐ Others_____	
☐ Single Center	☐ Multicenter	☐ Others_____		

HRP-IRB-010: IRB Application Form and Questionnaire (page 3 of 3)

ANNEX 3

崇華醫院
Chong Hua Hospital
Fuente Osmeña, Cebu City
Tel# +63(32) 255-8000; Fax# +63(32) 253-5639

IRB APPLICATION FORM AND QUESTIONNAIRE

Form HRP-IRB-010

SECTION V: Study Population

1. Does the study involve healthy volunteers? __ Yes __ No
2. Does the study involve patients with disease? __ Yes __ No
3. Does the study involve a vulnerable population? __ Yes __ No

   If Yes, please identify.

   _____

4. Will the study exclude a particular group of individuals __ Yes __ No

   If Yes, please identify.

   _____

SECTION VI: Characteristics of Study Population (Mark "✓" whichever apply to the study)

Age Range ⇨	☐ 0 -17 yrs	☐ 18 - 44 yrs	☐ 45 - 65 yrs	☐ ≥ 66 yrs
Pediatric ⇨	☐ None	☐ < 1 yr	☐ 1-3 yrs	☐ 4 -14 yrs
Impaired ⇨	☐ None	☐ Physically	☐ Cognitively	☐ Mentally

SECTION VII: Drugs/Devices, Genetic Testing, Radiation and Biological Samples

Does the study involve the use of any of the following?

1. An FDA approved drug or medical device __ Yes __ No
2. Unapproved indication for an FDA approved drug __ Yes __ No
3. An investigational medical device __ Yes __ No
4. A non-medical device __ Yes __ No
5. A proprietary product __ Yes __ No
6. A biological agent __ Yes __ No
7. A genetic testing __ Yes __ No
8. Radiation exposure __ Yes __ No

ANNEX 4:

HRP-IRB-011: Document Receipt Form

崇華醫院
Chong Hua Hospital
Fuente Osmeña, Cebu City
Tel# +63(32) 255-8000; Fax# +63(32) 253-5639

ANNEX 4
DOCUMENT RECEIPT FORM
Form HRP-IRB-011

Received Number: ☐☐☐-☐☐☐☐-☐☐		
Protocol Number:	**Sponsor** (if applicable):	**Submission Date:**
Type of Submission:	☐ Initial Review ☐ Resubmission for re-review ☐ Protocol Amendments	☐ Continuing Review of Approved Protocols ☐ Protocol Termination
Protocol Title:		
Principal Investigator:		
Sub-Investigator:		
Telephone number/s:		
Fax:		
E-mail:		**Preferred Contact:** ☐ Phone ☐ Fax ☐ E-mail
Institutional affiliation:	☐ Active Staff ☐ Visiting Staff	
Department affiliated:		
Delivery route:	☐ Post ☐ E-submission ☐ in Person	
Documents submitted:	☐ Complete ☐ Incomplete, will submit on……..	
Documents to be submitted later :	☐ information for subjects ☐ informed consent form ☐ case report forms (CRF) ☐ study budget ☐ investigator's brochure ☐ others_____	Check what documents are received later on. ☐ information for subjects ☐ informed consent form ☐ case report forms (CRF) ☐ study budget ☐ investigator's brochure ☐ others_____
FOR IRB ONLY		
Received by: _____ [Name and Signature]		**Date received:**
Name of Primary Reviewer/s: _____		
Type of Review Scheduled:	☐ Expedited	☐ Full Board
Designating Officer: _____ Chair/IEC/IRB		**Date Signed:**

Note: Please keep the duplicate copy of the form and submit the original with the package upon submission.

DOCUMENT RECEIPT FORM Page 1 of 1

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ANNEX 5:

HRP-IRB-016: Review of Resubmitted Protocol

ANNEX 5

崇華醫院
Chong Hua Hospital
Fuente Osmeña, Cebu City
Tel# +63(32) 255-8000; Fax# +63(32) 253-5639

REVIEW OF RESUBMITTED PROTOCOL

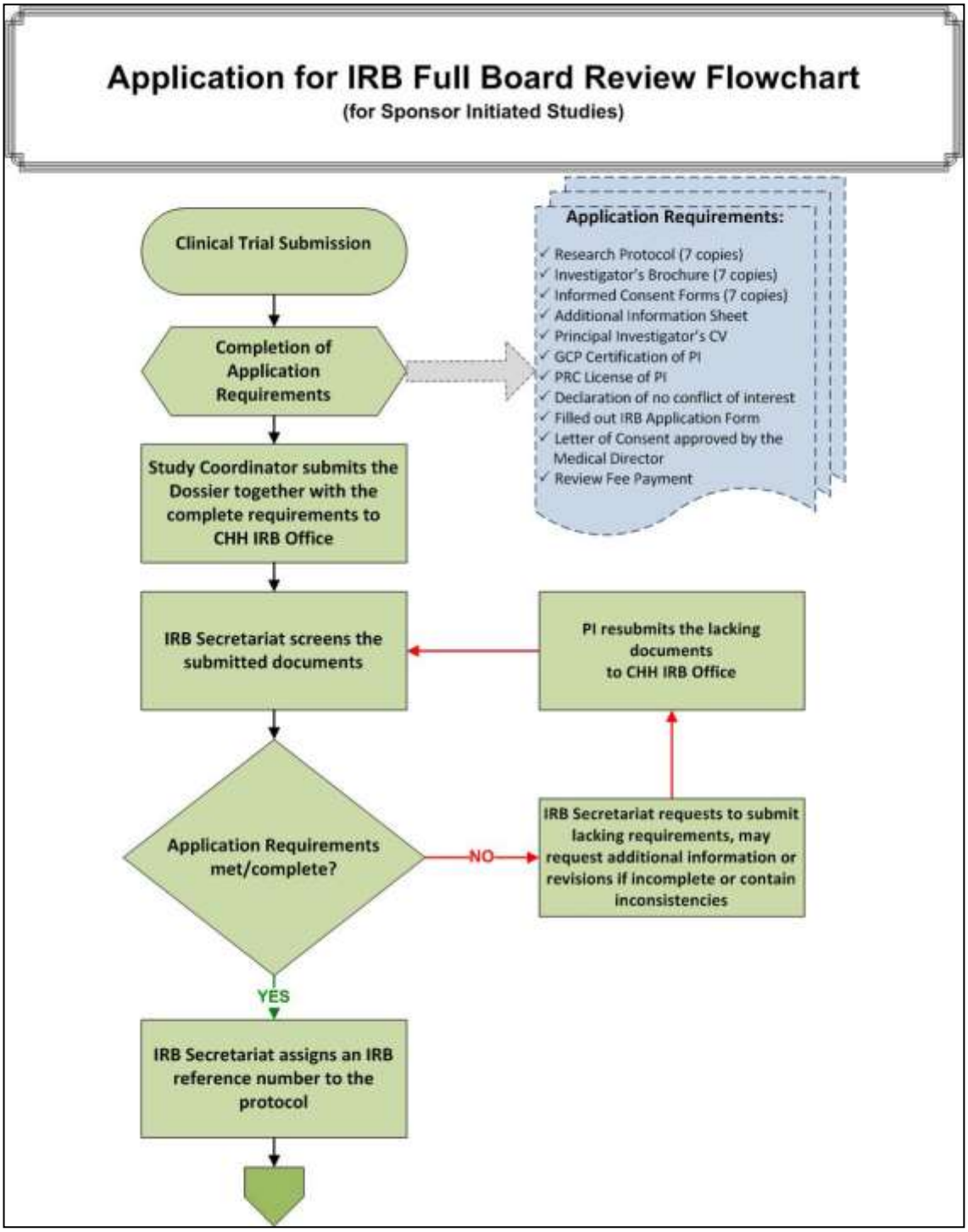
Form HRP-IRB-016

Protocol No.:	Application No.: ☐☐☐-☐☐☐☐-☐☐
Protocol Title:	
Total Participants :	☐ 2nd Review ☐ 3rd Review ☐ 4th Review
Principal Investigator:	Tel.:
Initial Review Date:	Last Review Date:
CHH IRB Decision recorded in the meeting minute :	☐ Approved with minor changes or recommendations ☐ Major changes or recommendation need to be reconsidered
Opinion of the reviewer: ✧ Revision or Modification according to the recommendation ✧ What needs to be further revised :	☐ Yes ☐ No: Explain: _____ _____
SIGNATURE/S: _____ Protocol Reviewer	Date: _____
APPROVAL: _____ Chairperson, CHH IRB	Date: _____
COMPLETION: _____ Secretary, CHH IRB	Date: _____

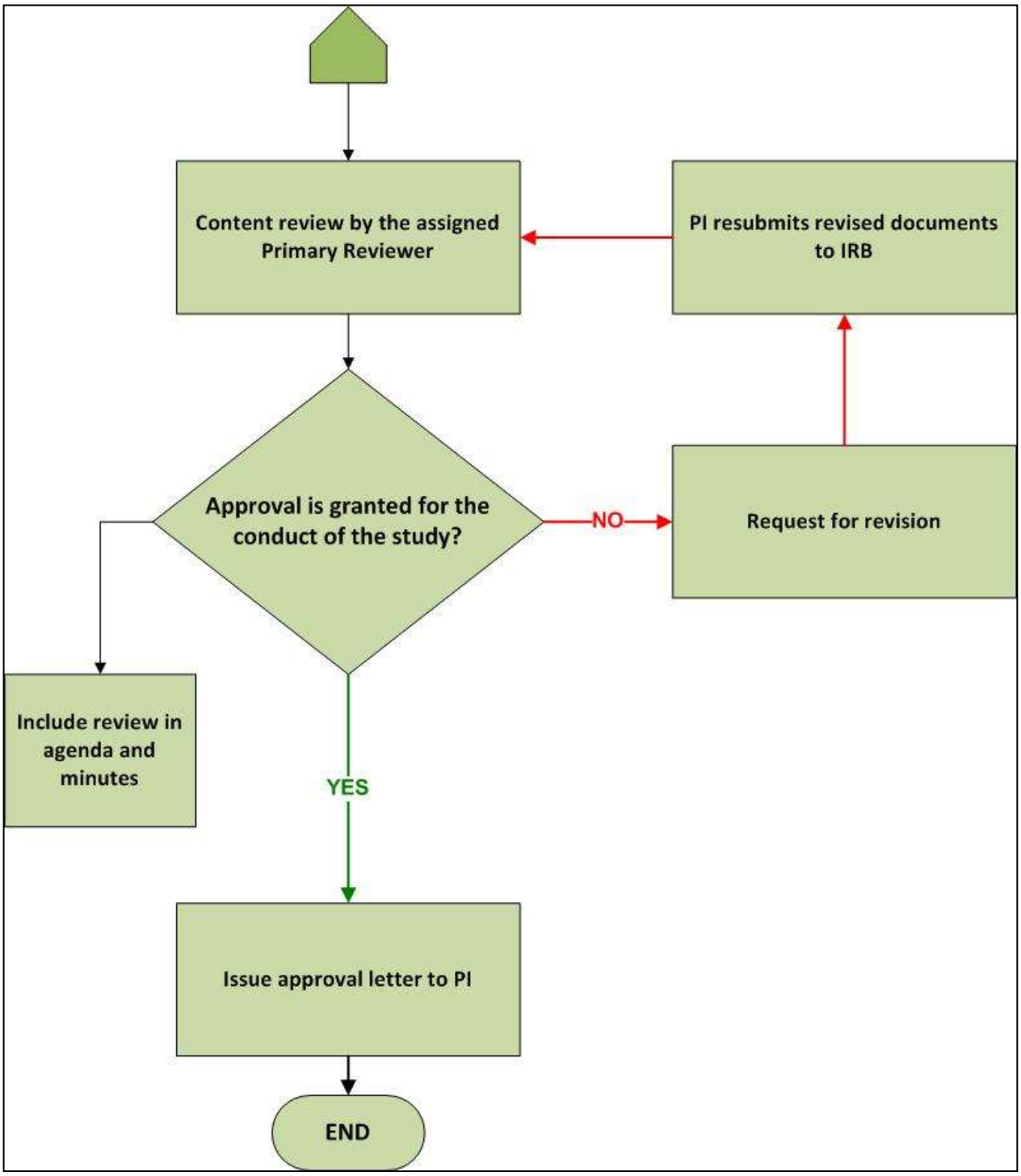
REVIEW OF RESUBMITTED PROTOCOL

Page 1 of 1

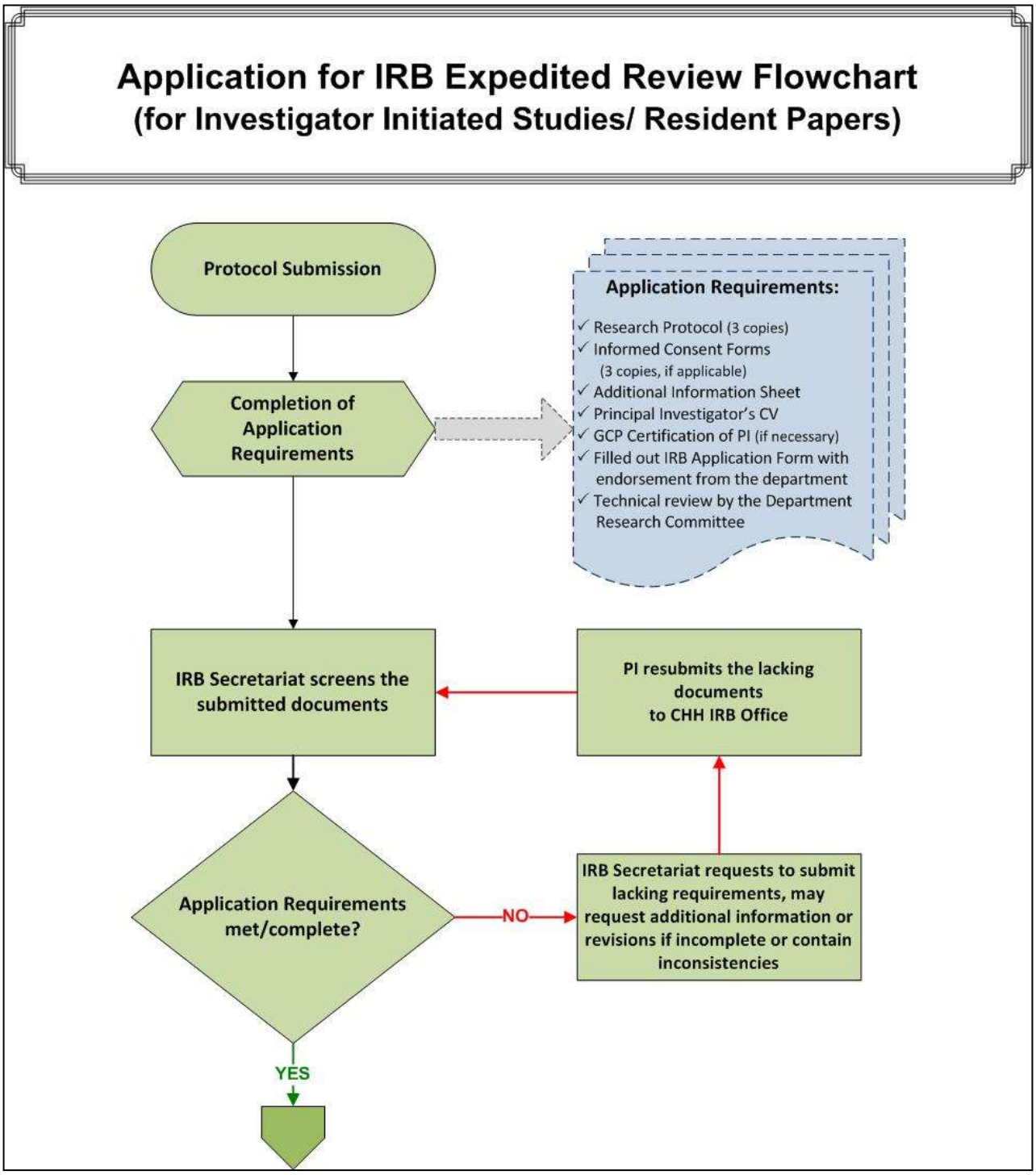
ANNEX 6: Flowchart for Full Board Review **(page 1)**



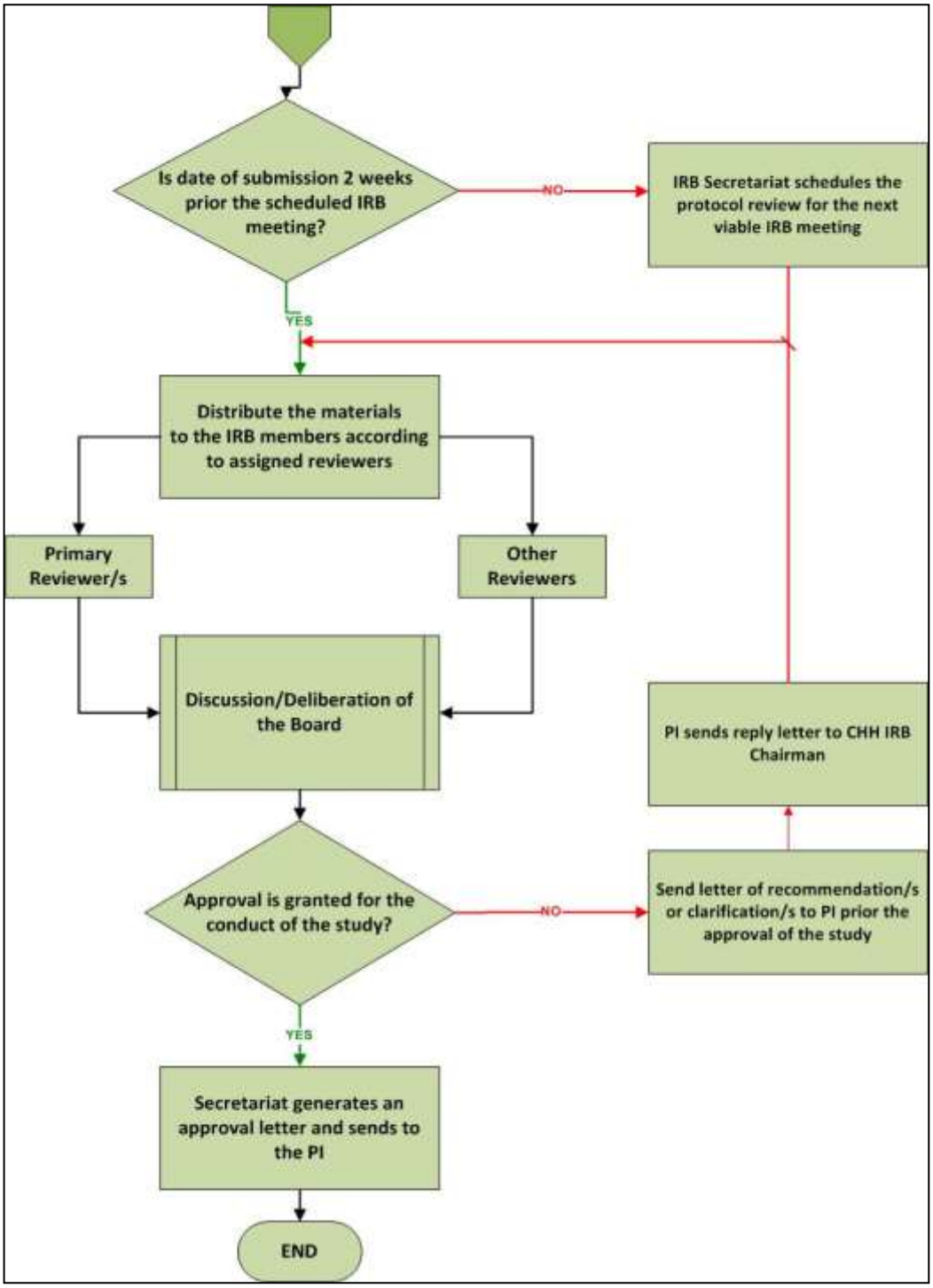
ANNEX 6: Flowchart for Full Board Review **(page 2)**



ANNEX 7: Flowchart for Expedited Review (page 1)



ANNEX 7: Flowchart for Expedited Review (page 2)



7. Reference

- 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 SOPs: SOP/007/02, 008 and 010.
- National Ethical Guidelines for Health Research 2011 PNHRS