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1. Purpose

This SOP describes how the CHH IRB members use the assessment forms when reviewing the study protocols initially submitted for approval. The Study Assessment Form (HRP-IRB-013 ver05) is designed to standardize the review process and to facilitate reporting, recommendation and comments given to each individual protocol.

2. Scope

This SOP applies to the review and assessment of all protocols submitted for initial review and approval from the CHH IRB. The specific questions in the Assessment Form must be adequately addressed in the protocol itself and/or protocol-related documents under review.

Relevant points made during discussion and deliberation about a specific protocol should be recorded on the form.

The decision reached by the committee and the reasons for its decision is recorded on the Study Application Assessment Form.

3. Responsibility

It is the responsibility of the reviewers to fill the assessment form along with decision and comments they might have after reviewing each study protocol. The CHH IRB Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision. The Chair of the CHH IRB must sign and date to approve the decision in the form.

4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I	Summarize protocol in the Study Assessment Form	CHH IRB Secretariat
II	Review the Study Protocol	CHH IRB Members / Reviewers
III	Examine the qualification of Investigators and of study sites	CHH IRB Members / Reviewers
IV	Review study participation	CHH IRB Members / Reviewers
V	Examine community involvement and impact	CHH IRB Members / Reviewers
VI	The reviewer/s makes a decision	CHH IRB Members / Reviewers
VII	Gather the Assessment Reports	CHH IRB Secretariat
VIII	Record the CHH IRB Decision	CHH IRB Secretariat

5. Detailed Instructions

5.1 Summarize protocol in the Study Assessment Form

5.1.1 General Protocol Information

- Record general information about the protocol in the form such as:
  - Title of the protocol
  - Protocol number and date
  - Principal Investigators, license & contact number
  - Co-investigators & contact number (if applicable)
  - Sponsor & contact number
  - Type of Study
  - Duration of the study
  - Status of the protocol – Initial Review/ Resubmission/ Amendment
  - Review status – Full Board / Expedited
  - Primary Reviewer's name
  - Study Design and Objectives of the Study

5.2 Review the study protocol

- Need for human participants of the study
- Objectives of the study
- Review of literature
- Sample size
- Methodology and Data Management
- Inclusion/Exclusion criteria
- Control arms (placebo, if any)
- Withdrawal or Discontinuation criteria

5.3 Examine the qualification of investigators and of study sites

- Review CV of the PI
- Check for presence of current (within the past 3 years) GCP certificate of training
- Consider whether study and training background of the participating investigators relate to the study.
- Non-physician principal investigators (PI) should be advised by a physician when necessary.
- Examine disclosure or declaration of potential conflicts of interest
- Can facilities and infrastructure at study sites accommodate the study?

5.4 Review study participation

- Voluntary, non-coercive recruitment/participation
- Procedures for obtaining informed consent
- Contents of the patient information sheet
- Contents and language of the informed consent document
- Translation of the informed consent document in the local
- Language used – plain and easy to understand by general public
- Contact persons with address and phone numbers
- Privacy and confidentiality
- Risks – physical / mental / social
- Benefits – to participants and to others
- Compensation – Reasonable / unreasonable
- Involvement of vulnerable participants
- Provisions for medical/psychosocial support
- Treatment for study related injuries
- Use of biological materials

5.5 Examine community involvement and impact (if applicable)

- Community consultation
- Involvement of local researchers and institutions in the protocol design, analysis and publication of the results
- Contribution to development of local capacity for research and treatment
- Benefit to local communities
- Availability of study results

5.6 The reviewer/s makes a decision

- Get the Assessment Report Form (HRP-IRB-013 ver05, see ANNEX 1-3)
- Record the decision by marking in the desired block any of the following: "*Approved, Needs Clarification, Resubmission and Disapproved."*
- Include comments, suggestion and reason for disapproval.
- Check the completeness and correctness of the assessment form.
- Sign and date the CHH IRB Decision form (HRP-IRB-014 ver05, see ANNEX 4)
- Give or send the complete forms to the CHH IRB Secretariat.

5.7 Gather the assessment reports

- CHH IRB Secretariat collects the assessment forms and the review result from each reviewer.
- Organize the forms in order.

- Summarize the comments, suggestions, and opinions of each study in the meeting agenda.
- Follow SOP on Preparation of meeting agenda and minutes.

5.8 Record the CHH IRB decision

- Get the CHH IRB's decision form (HRP-IRB-014 ver05), see ANNEX 4.
- Complete the information. (by the Secretariat)
- List participating members and their votes.
- Summarize the guidance, advice and decision reached by the CHH IRB members.
- Sign and date the document. (by the Chairperson of the CHH) Make a copy of the completed decision form.
- Keep the original copy in the file labeled "CHH IRB's decision".
- Keep the copy of the decision form with the study protocol
- Return the file and the protocol to the appropriate shelves.

6. ANNEX 1:

ANNEX 1

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ASSESSMENT REPORT FORM
I. Methodology
Form HRP-IRB-013 ver05

IRB REFERENCE NO. I R B -

PRINCIPAL INVESTIGATOR	SPONSOR	DATE OF REVIEW

PROTOCOL NO. & TITLE

QUESTIONS			Comments/Remarks
1) Is adequate information given for the background of the study?	Y☐	N☐	
2) Is the study significant and relevant for the population studied?	Y☐	N☐	
3) Is the scientific rationale of the study sound?	Y☐	N☐	
4) Are the objectives clear, specific and measurable?	Y☐	N☐	
5) Is the study design appropriate for the objectives?	A☐	I☐	
• Are the control arms appropriate? (for clinical trials)	A☐	I☐	
6) Is the setting of the study clearly identified?	Y☐	N☐	
• Are the facilities and infrastructure of the participating sites adequate?	Y☐	N☐	
• Is the duration of the study specified?	Y☐	N☐	
7) Is the approximate number of subjects involved in the trial specified?	Y☐	N☐	
• Are the inclusion criteria appropriate?	A☐	I☐	
• Is the proposed subject population appropriate for the nature of the research?	A☐	I☐	
• Has the IRB taken into account any special vulnerability among prospective subjects that might be relevant to evaluating the risk of participation?	Y☐	N☐	
• Are the exclusion criteria appropriate?	A☐	I☐	
• Are there any groups of people who might be more susceptible to the risks presented by the study and who therefore ought to be excluded from the research?	Y☐	N☐	
8) Are the procedures to be done in the study clearly described and understandable?	Y☐	N☐	
• Are blood/tissue samples sent abroad?	Y☐	N☐	
9) Are research data recorded and maintained with strict confidentiality?	Y☐	N☐	
10) Considering the degree of risk, is the plan for monitoring the research appropriate and adequate in terms of timeliness and thoroughness?	A☐	I☐	

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ASSESSMENT REPORT FORM
I. Methodology
Form HRP-IRB-013 ver05

	QUESTIONS		REMARKS
11)	If the principal investigator is other than full-time on the project, is the oversight and monitoring time sufficient?	Y☐ N☐	
12)	Is the mechanism for providing information to the IRB in the event that unexpected results are discovered appropriate?	A☐ I☐	
13)	If the research involves the evaluation of a therapeutic procedure, have the risks and benefits of the research interventions been evaluated separately from those of the therapeutic interventions?	Y☐ N☐	
14)	Has due care been used to minimize risks and maximize the likelihood of benefits?	Y☐ N☐	
15)	Are there adequate provisions for a continuing reassessment of the balance between risks and benefits?	Y☐ N☐	
16)	Does the institution have a data and safety monitoring board?	Y☐ N☐	
	a. If so, should it be asked to monitor the project under review?	Y☐ N☐	
	b. If the institution does not have a data and safety monitoring board, should the IRB request or recommend that one be appointed, either by the institution or the sponsor, for this project?	Y☐ N☐	

ANNEX 2:

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ANNEX 2

ASSESSMENT REPORT FORM

II. Informed Consent

Form HRP-IRB-013 ver05

IRB REFERENCE NO. I R B - - -

PRINCIPAL INVESTIGATOR	SPONSOR	DATE OF REVIEW

☐ Applicable ☐ Not Applicable

PROTOCOL NO. & TITLE

QUESTIONS			Comments/Remarks
1) Is the purpose of the trial clearly stated?	Y☐	N☐	
2) Is there an explanation to the subjects why they were included in the study?	Y☐	N☐	
3) Are there provisions ensuring that the subject's participation in the trial is voluntary?	Y☐	N☐	
4) Is the subject well-informed of his/her responsibilities? *(This includes providing health information including symptoms or any changes made in her regimen.)*	Y☐	N☐	
5) Is the language and presentation of the information to be conveyed appropriate to the subject population? *(Consider the level of complexity and the need for translation into a language other than English.)*	A☐	I☐	
6) For clinical trials, are the trial treatment(s) and the probability for random assignment to each treatment arm explained?	Y☐	N☐	
7) Is the expected duration of the subject's participation in the trial specified?	Y☐	N☐	
8) Is detailed explanation of the procedures or tests that are new or not widely used or combinations/doses of drugs never tested before provided to the subject?	Y☐	N☐	
9) Are the proposed explanations of the research appropriate and adequate to provide the subject an accurate assessment of its risks and anticipated benefits?	A☐	I☐	
10) Are the risks to the study participants disclosed?	Y☐	N☐	
11) Are the potential adverse events disclosed?	Y☐	N☐	
12) Are the possible benefits to the participants discussed?	Y☐	N☐	
13) Are there lists of alternative procedure(s) or course(s) of treatment that may be available to the subject and their important potential benefits and risks?	Y☐	N☐	
14) Is there a compensation and/or treatment available to the subject in the event of trial-related injury?	Y☐	N☐	
Is there a person to contact in the event of trial-related injury?	Y☐	N☐	
15) Is there a person to contact for further information regarding the trial and the rights of the trial subjects?	Y☐	N☐	
16) Do other groups of potential subjects have a greater need to receive any of the anticipated benefits?	Y☐	N☐	
17) Whether they finish the study or not, are the subjects compensated on a per visit basis for trial related expenses?	Y☐	N☐	

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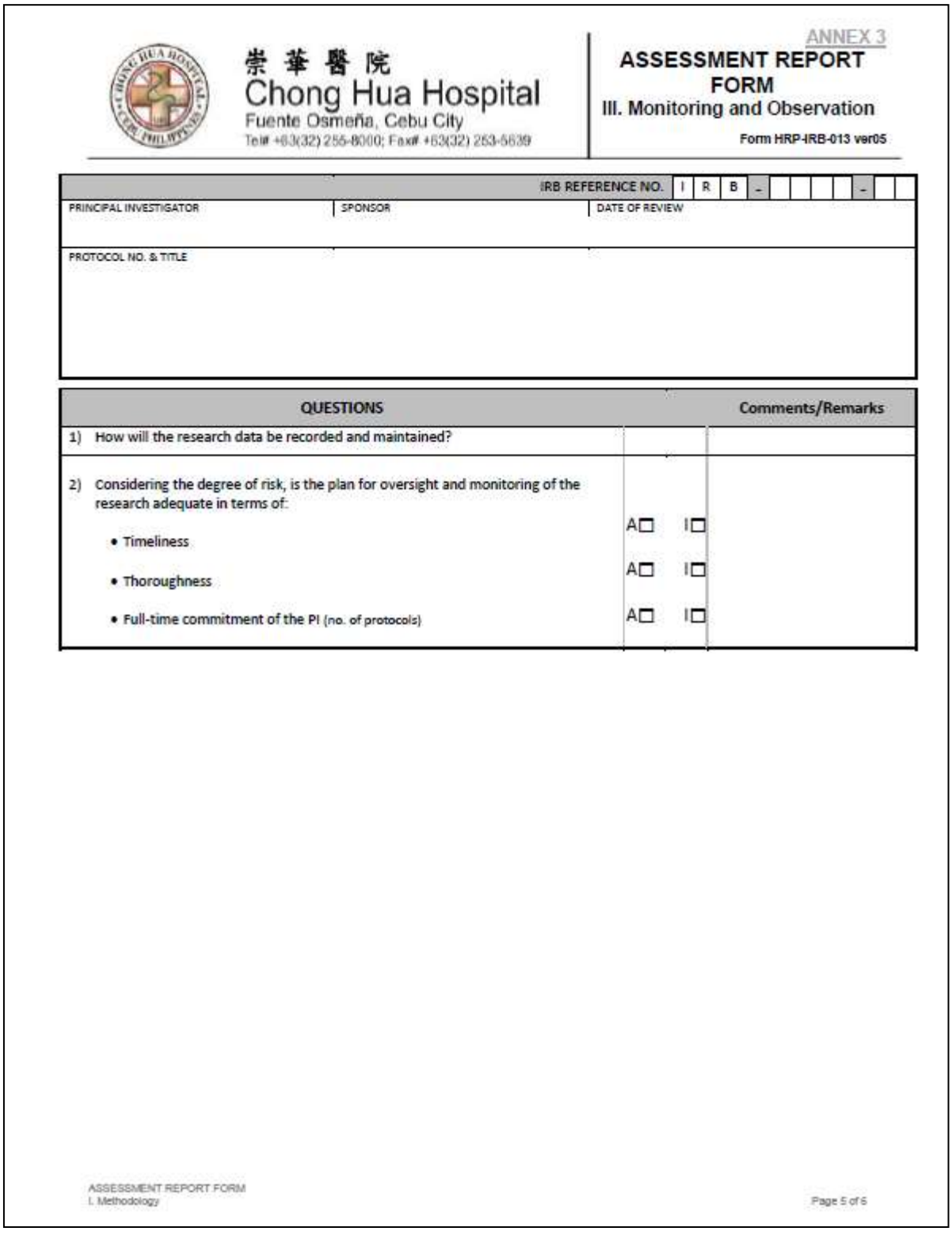
ANNEX 2

ASSESSMENT REPORT FORM
II. Informed Consent

Form HRP-IRB-013 ver05

QUESTIONS			Comments/Remarks
18) Will the subject or the subject's legally acceptable representative (LAR) be informed, in a timely manner, of any new available information which may be relevant to the subject's willingness to continue his/her participation?	Y☐	N☐	
19) Is the subject informed of his right to refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled?	Y☐	N☐	
20) Is the subject informed of any foreseeable events and or reasons which may cause his/her participation in the trial to be terminated?	Y☐	N☐	
21) In the event of any information that will affect the willingness of the subject to participate, is re-consenting necessary or provided for?	Y☐	N☐	
22) Are the withdrawal criteria made known to the subject?	Y☐	N☐	
23) If a waiver of some or all of the consent requirements is requested, does the importance of the research justify such a waiver?	Y☐	N☐	
24) Are there provisions for medical / psychosocial support if applicable?	Y☐	N☐	
25) Does the research involve observation or intrusion in situations where the subjects have a reasonable expectation of privacy?	Y☐	N☐	
Would reasonable people be offended by such an intrusion? Can the research be redesigned to avoid the intrusion?	Y☐	N☐	
If privacy is to be invaded, does the importance of the research objective justify the intrusion?	Y☐	N☐	
What if anything, will the subject be told later?	Y☐	N☐	
26) Is there a mechanism for providing information to the IRB in the event that unexpected results are discovered? *(Unexpected results may raise the possibility of unanticipated risks to subjects)*	Y☐	N☐	
27) Is there a provision allowing consent from the subject for other monitors/ auditors/ IRB/IEC access to the subject's original medical record for verification purposes?	Y☐	N☐	
28) Are the records identifying the subject kept confidential and to the extent permitted by the applicable laws and/or regulations, not made available in public?	Y☐	N☐	
Should the trial be published, will the subject's identity remain confidential?	Y☐	N☐	

ANNEX 3:



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ANNEX 3

ASSESSMENT REPORT FORM
III. Monitoring and Observation

Form HRP-IRB-013 ver05

IRB REFERENCE NO.	I	R	B	-					-		

PRINCIPAL INVESTIGATOR	SPONSOR	DATE OF REVIEW

PROTOCOL NO. & TITLE

QUESTIONS			Comments/Remarks
1) How will the research data be recorded and maintained?			
2) Considering the degree of risk, is the plan for oversight and monitoring of the research adequate in terms of:			
• Timeliness	A☐	I☐	
• Thoroughness	A☐	I☐	
• Full-time commitment of the PI (no. of protocols)	A☐	I☐	

ASSESSMENT REPORT FORM
I. Methodology

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ANNEX 4:

ANNEX 4

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CHH IRB DECISION FORM

Form HRP-IRB-014 ver05

IRB REFERENCE NO.	I R B -		-	
PRINCIPAL INVESTIGATOR	SPONSOR	DATE OF REVIEW		
PROTOCOL NO. & TITLE				

Is the project acceptable according to the following:	YES	NO
I. Methodology	☐	☐
II. Informed Consent Form	☐	☐
III. Monitoring and Observation	☐	☐
IV. Continuous Monitoring Date:		

DECISION OF THE BOARD

☐ APPROVED ☐ NEEDS CLARIFICATION ☐ RESUBMISSION ☐ DISAPPROVED

1)
2)
3)
4)
5)

IRB MEMBERS	SIGNATURE
1) Atty. Dean G. Decal	
2) Dr. Manuel Emerson S. Donaldo	
3) Dr. Elaine L. Gallardo	
4) Dr. Cheryl K. Bullo	
5) Romel V. Cabazor, PTRP, MA	
6) Rev. Fr. Benedicto P. Tao	
7) Dr. Omid Etemadi	

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.
- Ethical Guidelines for Biomedical research on Human Subjects, 2000.
- Associated SOP: SOP/019/02