Table of Contents

1. Purpose

To describe the procedures when protocol submissions are classified for full board review

2. Scope

This SOP applies to the review and approval of study protocols or amendments with medium to high risk to study participants and major revisions in the protocol or informed consent. The submission procedures are the same as first time submission.

3. Responsibility

It is the responsibility of the Secretariat to manage the document submission, send protocol documents to the primary reviewers, refer the protocol to full board meeting for discussion and decision, communicate the review results to the Principal Investigator, keep copies of the documents in the protocol files and update the protocol entry in the IRB database.

It is the responsibility of the Chairman to assign a medical member as the primary reviewer of the methodology/scientific part of the protocol depending on the nature of the study. A non-medical member is assigned as the primary reviewer of the informed consent.

It is the responsibility of the primary reviewers to review the protocol and related documents by using the assessment forms and make a recommendation for appropriate action.

The following are types of protocols that should undergo full board review after initial submission:

- Clinical trials about investigational new drugs, biologics or device in various phases (Phase 1, 2, 3)
- Phase 4 intervention research involving drugs, biologics or device
- Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g. related to sexual preferences etc., or about sensitive issues that may cause social stigma) that may cause psychological, legal, economic and other social harm
- Protocols involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of

refusal to retaliate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent) that require additional protection from the IRB during review

- Protocols that involve collection of identifiable biological specimens for research

Criteria for Full Board Review of Resubmissions/ Amendments/ Reports

- Major revisions of the protocol and informed consent after initial review
- Amendments that involve major changes from previously approved protocol or consent form (major changes in the inclusion/ exclusion criteria, safety issues, etc.)
- Major amendments that change the risk/ benefit ratio
- Major protocol violations
- Progress/ Final reports that deviate from original approval given by the IRB
- Onsite SAEs or SUSARs that may require protocol amendment or reconsent of participants

The Secretariat is responsible for receiving, verifying and managing the contents of both the hard copies and the electronic version (if any) of the submitted protocol package. In addition, the Secretariat should create a specific protocol file, make copies of the file and then distribute the copies to the CHH IRB reviewers, together with a cover letter where the due date for returning the reviewed protocol is indicated. It is the responsibility of the assigned reviewers to thoroughly review the study protocols delivered to them, give their decision, observation and comments and put all of this in the Study Assessment Forms before returning the reviewed protocol and assessment form to the Secretariat on the due date.

4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I	**Receive the submitted documents and forwards to the Chair or Member-Secretary**	Secretariat
II	**Determine that the protocol qualifies for Full Board review**	Member-Secretary/ Chair
III	**Assign primary reviewers for Scientific issues and for Informed Consent**	Member-Secretary/ Chair
IV	**Distribution of protocols to primary reviewer and to other members**	Secretariat
V	**Review the protocol documents using the assessment forms and submit the decision/ recommendation to the Secretariat**	Primary Reviewers
VI	**Include the protocol in the meeting agenda for discussion to arrive at a decision through full board**	Secretariat/ Members
VII	**If modifications are required, revise the protocol or related document and resubmit to the IRB**	Principal Investigators

VIII	**Check and review revisions and refer to full board for decision**	Primary Reviewers
IX	**After board approval, prepare the Approval Letter to be signed by the Chair and sent to the PI**	Secretariat
X	**Keep copies of all documents in the files**	Secretariat
XI	**Update the protocol entry in the IRB database**	Secretariat

5. Detailed Instructions

5.1 Receive the protocol package

- Check the completeness of the protocol package.
- Fill in the "Document Receipt Form" (**ANNEX I, HRP-IRB-011**) upon receiving the package, indicate the date and affix reviewer's signature.
- Return the signed acknowledgment form back to the representative of the principal investigators

5.2 Determine if the protocol qualifies for full board review, select primary reviewers with appropriate qualifications (clinician with expertise related to the protocol and non-medical person to review the consent form.) An independent consultant may be invited to provide expert opinion.

- Send the protocol files together with the assessment forms to the primary reviewers/ independent consultant.
- Note the due date for submitting the results (accomplished checklists) and the protocols back to the IRB Secretariat.

5.3 Review the Protocol

a. Use the Assessment Review Form to review the protocol and the consent form and write relevant comments and or recommendations (**refer to ANNEX II**)
b. Check the CV or information about the investigators (including GCP training for clinical trials), the study sites and other protocol related documents, including advertisements.
   - Consider whether study and training background of the principal investigator/s are related to the study.
   - Look for disclosure or declaration of potential conflicts of interest.
   - Non-physician principal investigators should be advised by a physician when necessary.
   - Determine if the facilities and infrastructure at study sites can accommodate the study.
c. Check the "Assent Form" if the protocol involves children or other vulnerable groups as study participants based on PHREB guidelines. The procedure for getting the assent of vulnerable participants should be clear (the objective of the study and the procedures to be done should be explained to the child or vulnerable participant separately).

5.4 The primary reviewers are advised to note the following Review Guidelines:

- The protocol manifests scientific validity and contains all the standard sections to ensure scientific soundness.
- In assessing the degree of risk against the benefit, determine whether the risks are reasonable in relation to anticipated benefits; and/or if the risks can be minimized.
- Study participants are selected equitably especially if randomization is not to be used. Study participant's information sheet should be clear, complete and written in understandable language.
- There is voluntary, non-coercive recruitment of study participants.
- The Informed Consent is adequate, easy to understand and properly documented.
- There should be a translation of the Informed Consent document into the local dialect which should be comprehensible by the general public.
- The procedure for getting the Informed Consent is clear and unbiased.
- The persons who are responsible for getting the Informed Consent are named and they introduce themselves to the study participants.
- The research plan makes adequate provision for monitoring data collection to ensure the safety of study participants, where appropriate.
- There are adequate provisions to protect the privacy of study participants and to maintain the confidentiality of data, where appropriate.
- There is provision for compensation to study participants. There should be reasonable provision for medical/psychosocial support; treatment for study related injuries, as well as compensation for participation to cover expenses like transport and lost wages because of participation.
- There are appropriate safeguards included to protect vulnerable study participants.
- Contact persons with address and phone numbers are included in the Informed Consent.
- There is clear justification for the use of biological materials and a separate consent form for future use of biological specimens.
- There are appropriate contracts or memoranda of understanding especially in collaborative studies.

5.5 Examine community involvement and impact/ benefit of the study to the community and/ or the institution. If relevant, the reviewer looks for the following in the protocol:

- 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 in benefit to local communities
- Sharing of study results with the participants/ community

5.6 After reviewing the protocol and the documents, the reviewer recommends a decision.

- Record the decision by marking the appropriate block in the CHH IRB Decision Form: Approved, Disapproved, Resubmission or Needs Clarification.
- Include comments and reasons for disapproval.
- Check the completeness and correctness of marked items in the Assessment Report Forms. Indicate the date and affix the reviewer's signature in the CHH IRB Decision Form.
- Submit the completed forms to the Secretariat together with the protocol documents

5.7 Include the protocol in the next meeting agenda.

5.8 Conduct a full board meeting to discuss and make a decision about the protocol and related documents.

5.9 For CHH funded proposals, a member of the TRC shall sit in the full board meeting as a consultant to explain technical issues. For non-CHH funded proposals, the IRB may request for comments/ approval from other IRB-TRC to provide additional inputs as deemed necessary.

5.10 The members of the IRB attending the full board meeting arrive at a decision on the protocol for approval, minor revision, major revision for resubmission or disapproval.

5.11 If the study is approved, the CHH IRB determines the frequency of continuing review.

5.12 The Secretariat sends an action letter/approval letter, the IRB Approval Form with a list of approved documents and a copy of the Guidelines for Reporting Adverse Events to the principal investigator.
(**refer to ANNEX IV**)

5.13 The letter contains identification of the document approved with version numbers and dates, the frequency of continuing review and the responsibilities of the principal investigator throughout the course of the study.

5.14 If the CHH IRB votes not to approve the study, the Secretariat shall notify the principal investigator in writing about the decision and the reason for not approving the study.

5.15 If the principal investigator wishes to appeal the IRB decision, he/she may do so through a written request submitted to the CHH IRB.

5.16 If the CHH IRB requires modifications to any of the documents, the Secretariat prepares a letter to the Principal Investigator and identifies the necessary revisions to the documents before resubmission to the IRB.

5.17 If the protocol is approved, the Secretariat drafts the approval letter, forwards it to the Chair to sign, then sends it to the principal investigator. There should be a file/ received copy with specific date. All information regarding the date of the CHH IRB decision such as the date when decision was written and signed by the Chair, and date when it was delivered to the principal investigator, are entered in the IRB database.

5.18 All meeting deliberations and decision regarding a protocol are noted in the meeting minutes, with relevant sections filed in the specific protocol file.

5.19 The IRB database is updated to record the decision. Copies of the assessment forms are kept in the protocol files.

6. ANNEX I: Document Receipt Form

CHONG HUA HOSPITAL
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ANNEX I

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:	**Date received:**
_____ [Name and Signature]	
Name of Primary Reviewer/s: _____	
Type of Review Scheduled: ☐ Expedited ☐ Full Board	
Designating Officer:	**Date Signed:**
_____ Chair/IEC/IRB	

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

ANNEX II: Assessment Report Form (I. Methodology)

ANNEX II

CHONG HUA HOSPITAL
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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☐	

ASSESSMENT REPORT FORM
I. Methodology

Page 1 of 6

Assessment Report Form (I. Methodology)

CHONG HUA HOSPITAL
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ANNEX II

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☐

Assessment Report Form (II. Informed Consent)

ANNEX II

CHONG HUA HOSPITAL
Healing with Passion. Caring with Compassion.

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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Assessment Report Form (II. Informed Consent)

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ANNEX II

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☐	

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Assessment Report Form (III. Monitoring and Observation)

ANNEX II

CHONG HUA HOSPITAL
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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 III: CHH IRB Decision Form

ANNEX III

CHONG HUA HOSPITAL
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CHH IRB DECISION FORM

Form HRP-IRB-014 ver05

IRB REFERENCE NO.	IRB -	
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	

CHH IRB DECISION FORM Page 6 of 6

ANNEX IV: CHH IRB Approval Form

Institutional Review Board
CHONG HUA HOSPITAL
Don Mariano Cui St., corner J. Llorente St., Cebu City, Philippines 6000
☎ 255-8000 (local 7434); Email: chh_irb@chonghua.com.ph

< Date > IRB reference code: _____

_____, MD
Principal Investigator
Chong Hua Hospital

Protocol number and Study Title:

Dear Dr. _____,

Attached please find your notice of Research Protocol Approval. With this notification you are bound by the following responsibilities:

1. The research activity can now commence. Henceforth, any communications/additional documents submitted to the IRB must carry the IRB reference code assigned to the protocol.
2. To facilitate subject recruitment, the PI is encouraged to submit their recruitment poster *(as appropriate)* for posting at the CHH IRB bulletin board.
3. Principal Investigator/ Sub-Investigator should do the explaining of the research to potential subjects using the approved Informed Consent Form
4. The IRB should be informed and approval be obtained for any modification/amendments in the research protocol and/or informed consent prior to or during their implementation and it should be tabulated side by side from the old version to the new version and to include rationale of changes for ease of clarification during the Board meeting. (**N.B.** Filled out Protocol Amendment Submission Form (*Form HRP-IRB-017*) shall be required upon submission of the amended document/s).
5. If existing records to select subjects need to be reviewed, permission must be obtained from the attending physician and the Hospital for access to those records for inpatient records.
6. If the study is a clinical trial, the IRB should be informed of any SAE and SUSARS as per attached guidelines.
7. Progress reports/ Continuing Review Reports should be submitted annually one (1) month before the approval expiry on _____ together with the request for continuing review (**N.B.** Filled out Continuing Review Application Form (*Form HRP-IRB-018*) shall be required upon submission of the Continuing Review Report).
8. Withdrawal/ termination of study must be reported. Use IRB form for this purpose.
9. A site visit may be done on an agreed date during the time of the study.
10. A final report is expected at end of study. An IRB form is available for this purpose.
11. This approval is valid for 1 year and will expire _____

The Chong Hua Hospital – Institutional Review Board is organized and operates according to ICH Guidance on Good Clinical Practice (GCP) and applicable local laws and regulations.

Institutional Review Board
CHONG HUA HOSPITAL
Don Mariano Cui St., corner J. Llorente St., Cebu City, Philippines 6000
☎ 255-8000 (local 7434); Email: chh_irb@chonghua.com.ph

Sincerely,

_____
Chairman, Institutional Review Board
Chong Hua Hospital

The Chong Hua Hospital – Institutional Review Board is organized and operates according to ICH Guidance on Good Clinical Practice (GCP) and applicable local laws and regulations.

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INSTITUTIONAL REVIEW BOARD APPROVAL FORM

Form HRP-IRB-033

Name of PI: <_____>	
Title of Protocol: Protocol:	
IRB assigned number:	IRB-☐☐☐☐-☐☐
Type of IRB review conducted on the Protocol	
Date of Review:	
Version No./Version Date of Protocol Reviewed	
Date of Protocol Approval	
Version No./ Version date of the ICF reviewed	
Date of informed consent document approval	
Other documents reviewed: *(please refer to attachment for the complete list of documents approved)*	
Date of Next Continuing Review	
Names of IRB members who participated in the protocol review: ❖ ❖ ❖ ❖ ❖ ❖ ❖ ❖ ❖	
Decision of the meeting:	☐ Approved ☐ Resubmission ☐ Disapproved
Signature of IRB Chair	Date Signed
Name of IRB Chair <_____>	

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Institutional Review Board
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Don Mariano Cui St., corner J. Llorente St., Cebu City, Philippines 6000
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The following are the complete list of the documents **reviewed** and **approved** by the Board:

Document	Version No.	Version Date

Institutional Review Board
CHONG HUA HOSPITAL
Don Mariano Cui St., corner J. Llorente St., Cebu City, Philippines 6000
255-8000 (local 7434); Email: chh_irb@chonghua.com.ph

Guidelines for Reporting Adverse Events

Per requirements of the Food and Drug Administration (FDA) the following serves as a guide for the reporting of adverse events within or outside the Chong Hua Hospital System.

Definition of Terms

An **Adverse Event** (**AE**) is any undesirable experience or any adverse change in health or "side-effect" which is unintended, although not necessarily unexpected that occurs in a subject who participates in a clinical trial while the subject is receiving the treatment (study medication, application of the study device, etc.) or within a pre-specified period of time after their treatment has been completed.

A **Serious Adverse Event** (**SAE**) in human drug trials is defined as any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of ongoing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.

An **Unexpected Adverse Experience** (**UAE**) is any adverse experience associated with the use of the drug/device, the specificity or severity of which is not consistent with the current investigator brochure; or, if an investigator brochure is not required or available, the specificity or severity of which is not consistent with the risk information provided to subjects (in the Informed Consent Document) and the IRB.

A **Related adverse event** occurs when there is a reasonable possibility that the adverse event is caused by the research activity (drug/device/procedure).

The relationship of the Adverse Events to the Investigational Product, Study drug, device or procedure is left to the discretion of the Primary Investigator of the study. Likewise it is the responsibility of the Principal Investigator to decide if the event warrants a change to the protocol to minimize risks and/or the informed consent form to better inform subjects of the potential risks and procedures to minimize such risks.

On Site Adverse Events

On Site adverse event is any untoward medical occurrence in a patient or clinical investigation participant which happens under the study conducted inside CHH Research Facility Unit. An adverse event that meets any of the following criteria must be reported to the CHH IRB.

Institutional Review Board
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Reporting requirement

1. The event is Serious or Unexpected, and Related to the research activity.
2. If the event is Related, Expected or not Serious but in the opinion of the investigator the protocol and/or informed consent form requires modification. Examples: identification of a "new trend" (adverse event occurring with greater frequency than anticipated) or a change in the risk/benefit ratio.
3. All non serious adverse events regardless of the relationship to the study drug.

Timelines for reporting

1. Serious and related AEs must be reported within 24 hours after discovery.
2. Serious but unrelated AEs must be reported within 2 weeks after discovery.
3. If the event is Related, Expected or not Serious but in the opinion of the investigator the protocol and/or informed consent form requires modification. Examples: identification of a "new trend" (adverse event occurring with greater frequency than anticipated) or a change in the risk/benefit ratio the event must be reported within 2 weeks after discovery.
4. All other non serious AEs must be reported within 24 weeks after discovery.

Off Site Adverse Events

Reporting requirement

An Off Site adverse event is any untoward medical occurrence in a patient or clinical investigation participant which happens under the study conducted outside CHH Research Facility Unit. These may include sponsor provided adverse events reports. An Off Site event that meets any of the following criteria must be reported to the CHH IRB:

1. The event is Serious or Unexpected and Related to the submitted research.
2. For a study not conducted at CHH, submit only those event reports that require a change in the submitted protocol and/or informed consent form.

Timelines for reporting

1. Serious and related AEs must be reported within 2 weeks after discovery.
2. Serious but unrelated AEs may be reported within 4 weeks after discovery.
3. Events that require a protocol or informed consent form modification must be reported within 2 weeks upon receipt from the study sponsor.
4. All other non serious AEs may be reported within 48 weeks after discovery.

Institutional Review Board
CHONG HUA HOSPITAL
Don Mariano Cui St., corner J. Llorente St., Cebu City, Philippines 6000
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How to Submit an Adverse Event Form

1. For reporting of the Adverse Events/Reactions the investigator may use the **CIOMS** or any other similar form deemed appropriate by the investigator.
2. On Report form should be accomplished per event.
3. Incomplete forms will be returned to the investigator for completion.
4. Provide a brief description/summary of the adverse event.
5. Attach pertinent supporting documents (e.g., hospitalization summary) as needed.
6. The **IRB** expects regular updates from the reported Adverse Events and the resolution of the **Serious Adverse Drug Reaction/s** reported.

N.B.: There are situations where a serious or unexpected adverse event requires an immediate change to a protocol in order to eliminate apparent immediate hazards to research subjects. In these situations, the principal investigator may immediately implement a protocol change necessary to protect the welfare of the research subjects without a **CHH IRB** approved amendment. Investigators are required to notify the IRB in writing of the change, within 7 working days, and include a written description of the change and events that necessitated immediate implementation. The investigator must indicate in the report whether a change to the protocol and/or informed consent is necessary.