APPENDIX A1

	Cebu Doctors University Hospital Research Ethics Committee (CDUHREC)		
	Sample Checklist for the Assessment of the Clinical Trial Protocol and Protocol Amendment (s)	CDUHREC FORM	1
		Version No.	3
		Version Date	09 Jul 2015
		Effective Date	09 Jul 2015

STUDY PROTOCOL Number:
STUDY PROTOCOL TITLE:
PRINCIPAL INVESTIGATOR:
Date of Initial Review:
CDUHREC Reviewer: (Printed name, signature and date)

Checklist for the Assessment of the Clinical Trial Protocol and Protocol Amendment(s)

(Based on ICH-GCP Current *Step 4* version dated 10 June 1996)

The contents of a trial protocol should generally include the following topics. However, site specific information may be provided on separate protocol page(s), or addressed in a separate agreement, and some of the information listed below may be contained in other protocol referenced documents, such as an Investigator's Brochure.

Are the following included in the study protocol?

6.1 General Information

	Yes	No	Comment
1. Protocol title, protocol identifying 2. number, and date. Any amendment(s) should also bear the amendment number(s) and date(s).			

3. Name and address of the sponsor and monitor (if other than the sponsor).			
4. Name and title of the person(s) authorized to sign the protocol and the protocol amendment(s) for the sponsor.			
5. Name, title, address, and telephone number(s) of the sponsor's medical expert (or dentist when appropriate) for the trial.			
6. Name and title of the investigator(s) who is (are) responsible for conducting the trial, and the address and telephone number(s) of the trial site(s).			
7. Name, title, address, and telephone number(s) of the qualified physician (or dentist, if applicable), who is responsible for all trial-site related medical (or dental) decisions (if other than investigator).			
8. Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the trial.			

6.2 Background Information

	Yes	No	Comment
1. Name and description of the investigational product(s).			
2. A summary of findings from nonclinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial.			
3. Summary of the known and potential risks and benefits, if any,			

to human subjects.			
4. Description of and justification for the route of administration, dosage, dosage regimen, and treatment period(s).			
5. A statement that the trial will be conducted in compliance with the protocol, GCP and the applicable regulatory requirement(s).			
6. Description of the population to be studied.			
7. References to literature and data that are relevant to the trial, and that provide background for the trial.			

6.3 Trial Objectives and Purpose

	Yes	No	Comment
A detailed description of the objectives and the purpose of the trial.			

6.4 Trial Design

The scientific integrity of the trial and the credibility of the data from the trial depend substantially on the trial design. A description of the trial design, should include:

	Yes	No	Comment
1. A specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the trial.			
2. A description of the type/design of trial to be conducted (e.g. double-blind, placebo-controlled, parallel design) and a schematic diagram of trial design, procedures and stages			
3. A description of the measures taken to minimize/avoid bias, including: (a) Randomization. (b) Blinding.			

4. A description of the trial treatment(s) and the dosage and dosage regimen of the investigational product(s). Also include a description of the dosage form, packaging, and labelling of the investigational product(s).			
5. The expected duration of subject participation, and a description of the sequence and duration of all trial periods, including follow-up, if any.			
6. A description of the "stopping rules" or "discontinuation criteria" for individual subjects, parts of trial and entire trial.			
7. Accountability procedures for the investigational product(s), including the placebo(s) and comparator(s), if any.			
8. Maintenance of trial treatment randomization codes and procedures for breaking codes.			
9. The identification of any data to be recorded directly on the CRFs (i.e. no prior written or electronic record of data), and to be considered to be source data.			

6.5 Selection and Withdrawal of Subjects

	Yes	No	Comment
1. Subject inclusion criteria.			
2. Subject exclusion criteria.			
3. Subject withdrawal criteria (i.e. terminating investigational product treatment/trial treatment) and procedures specifying: a. When and how to withdraw subjects from the trial/ investigational product treatment.			

b. The type and timing of the data to be collected for withdrawn subjects. c. Whether and how subjects are to be replaced. d. The follow-up for subjects withdrawn from investigational product treatment/trial treatment.			

6.6 Treatment of Subjects

	Yes	No	Comment
1. The treatment(s) to be administered, including the name(s) of all the product(s), the dose(s), the dosing schedule(s), the route/mode(s) of administration, and the treatment period(s), including the follow-up period(s) for subjects for each investigational product treatment/trial treatment group/arm of the trial.			
2. Medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial.			
3. Procedures for monitoring subject compliance.			

6.7 Assessment of Efficacy

	Yes	No	Comment
1. Specification of the efficacy parameters.			
2. Methods and timing for assessing, recording, and analyzing of efficacy parameters.			

6.8 Assessment of Safety

	Yes	No	Comment
1. Specification of safety parameters.			
2. The methods and timing for			

assessing, recording, and analysing safety parameters.			
3. Procedures for eliciting reports of and for recording and reporting adverse event and intercurrent illnesses.			
4. The type and duration of the follow-up of subjects after adverse events.			

6.9 Statistics

	Yes	No	Comment
1. A description of the statistical methods to be employed, including timing of any planned interim analysis(ses).			
2. The number of subjects planned to be enrolled. In multicentre trials, the numbers of enrolled subjects projected for each trial site should be specified. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.			
3. The level of significance to be used.			
4. Criteria for the termination of the trial.			
5. Procedure for accounting for missing, unused, and spurious data.			
6. Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in protocol and/or in the final report, as appropriate).			
7. The selection of subjects to be included in the analyses (e.g. all randomized subjects, all dosed subjects, all eligible subjects,			

evaluable subjects).			

6.10 Direct Access to Source Data/Documents

	Yes	No	Comment
1. The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/ institution(s) will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspection(s), providing direct access to source data/documents.			

6.11 Quality Control and Quality Assurance

	Yes	No	Comment
A description of how QC and QA are monitored.			

6.12 Ethics

	Yes	No	Comment
Description of ethical considerations relating to the trial.			

6.13 Data Handling and Record Keeping

	Yes	No	Comment
A description of data handling and record keeping.			

6.14 Financing and Insurance

	Yes	No	Comment
Financing and insurance if not addressed in a separate agreement.			

6.15 Publication Policy

	Yes	No	Comment
Publication policy, if not addressed in a separate agreement.			

6.16 Supplements

	Yes	No	Comment

Notes and Comments from Reviewer:

APPENDIX A2

	Cebu Doctors University Hospital Research Ethics Committee (CDUHREC)		
	Sample Checklist for the Assessment of the Informed Consent	CDUHREC FORM	2
		Version No.	3
		Version Date	09 Jul 2015
		Effective Date	09 Jul 2015

STUDY PROTOCOL Number:
STUDY PROTOCOL TITLE:
ICF Version and Date:
Date of Initial Review:
CDUHREC Reviewer: (Printed name, signature and date)

Checklist for the Assessment of the Informed Consent Form

(Based on National Ethical Guidelines for Health Research 2011 and on ICH-GCP Current *Step 4* version dated 10 June 1996)

Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following: Are the following included in the written information provided to the subjects?

	Yes	**No**	**Comment**
1. That the trial involves research.			
2. The purpose of the trial.			
3. The trial treatment(s) and the probability for random assignment to each treatment.			
4. The trial procedures to be followed, including all invasive procedures.			
5. The subject's responsibilities.			
6. Those aspects of the trial that would be experimental.			
7. The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.			
8. The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.			
9. The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.			
10. The compensation and/or treatment available to the subject in the event of trial related injury.			
11. The anticipated prorated payment, if any, to the subject for participating in the trial.			

12. The anticipated expenses, if any, to the subject for participating in the trial.			
13. That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at anytime, without penalty or loss of benefits to which the subject is otherwise entitled.			
14. That the monitor(s), the auditor(s), the EC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.			
15. That the records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.			
16. That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.			
17. The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.			
18. The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be			

terminated.			
19. The expected duration of the subject's participation in the trial.			
20. The approximate number of subjects involved in the trial.			

	Yes	No	Comment
Is the informed consent form written in a language understandable to the participants?			

	Yes	No	Comment
Does the informed consent process ensure that it is voluntary?			

Comments and Notes of Lead Reviewer:

APPENDIX A3

	Cebu Doctors University Hospital Research Ethics Committee (CDUHREC)		
	Sample Checklist for the Assessment of the Risk/Benefit	CDUHREC FORM	3
		Version No.	3
		Version Date	09 Jul 2015
		Effective Date	09 Jul 2015

STUDY PROTOCOL Number:
Principal Investigator:
Date of Review:
CDUHREC Reviewer: (Printed name, signature and date)

Risk/Benefit Assessment

Note: This form is for use as guidance by the reviewer to consider regulatory requirements for minimizing risks to participants and balancing risks with benefits.

Section A – Conducting Risk-Benefit Assessment

1. Identify and distinguish risks associated with:
   a) Procedures performed solely for research

   b) Procedures or therapies subjects would receive even if not in research

   c) Procedures that are experimental or investigational

2. Identify the context in which research procedures are performed:
   d) Are research procedures added to conventional (standard) care?

3. Consider the subject population.
   e) Age, health status?

   f) Are they more sensitive or vulnerable to risks posed by the research?

   g) How are they identified and recruited?

   h) Should additional protection be in place to minimize risks and maximize benefits?

4. Minimal risk or greater than minimal risk?
   a) Do the risks of procedure meet the definition of minimal risk?

Section B – RISKS

Definition of minimal risk: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(h)(i)).

When evaluating the minimal risk standard, the criteria shall be applied based on the experience of a population that is considered healthy and in the prevailing environment. The standard would therefore not to be applied using, for example, the normal harm and discomfort experienced by HIV-positive women ages 15-40 in developing countries, but to women ages 15-40 in a stable and healthy environment.

Check appropriate risk category:

1. _____The research involves no more than minimal risk to subjects.

2. _____The research involves more than minimal risk to subjects.

   _____The risk(s) represents a minor increase over minimal risk, **OR**

   _____The risk(s) represents more than a minor increase over minimal risk.

3. _____ If the risk represents greater than minimal risk, please describe what measures have been taken to minimize risk to the participant. Evaluate research methods that might be less risky, if any. Consider whether any diagnostic, therapeutic, or other procedures already performed on the participant could be used to gather the data needed. Consider whether

risks have been minimized by using procedures that are consistent with sound research practices and that do not unnecessarily expose participants to risk.

4. _____If the risk represents greater than minimal risk, indicate plans for detecting research-related harm promptly, and plans for mitigating potential harms.

Section C - BENEFITS

Definition: A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.

Check appropriate benefit category:

- ❑ The research involves the prospect of direct benefit to individual participants.
- ❑ The research involves no prospect of direct benefit to individual participants, but is likely to yield generalizable knowledge about the subject's disorder or condition.

Section D – JUSTIFICATION OF STUDY RISK

The Common Rule requires that risks to participants are reasonable in relation to anticipated benefits, if any, to participants and the importance of the knowledge that may reasonably be expected to result. When research involves vulnerable populations, additional safeguards may be required.

Check appropriate

- ❑ The study population is not considered vulnerable. Based on the above criteria, risks to participants are reasonable compared to expected benefits.
- ❑ Participants belong to vulnerable populations. For children, prisoner, or pregnant women populations, submit additional checklist for the population involved. Otherwise, explain what safeguards will be implemented for the study's vulnerable population.

APPENDIX A4

	Cebu Doctors University Hospital Research Ethics Committee (CDUHREC)		
	Sample Checklist for the Scientific Evaluation of a Clinical Trial Protocol (for Lead Reviewer)	CDUHREC FORM	4
		Version No.	3
		Version Date	09 Jul 2015
		Effective Date	09 Jul 2015

STUDY PROTOCOL Number:
Principal Investigator:
Date of Review:

CDUHREC Reviewer: (Printed name, signature and date)

Scientific Evaluation of a Clinical Trial Protocol

Any protocol raising many minor concerns or a few major concerns should either be rejected or subject to revision and subsequently re-assessed. The following lists essential information needed for a proper evaluation of the scientific soundness of a clinical trial protocol:

Matters of concern	**Potential questions**	**Comments**
Third party review	Have any regulatory or scientific bodies reviewed and formally accepted the current version of the protocol? Have any other ECs reviewed the protocol?	
Protocol development	Are the names of the persons involved in the protocol development, their qualifications and responsibilities provided?	
Pre-clinical information	What is the safety and efficacy profile of the test article?	
Test article manufacturing	Is the product evidently manufactured according to GMP?	
Study objective	What is the scientific rationale behind the study?	
Clinical rationale	What is (are) the expected benefit(s) of the test article in normal clinical care?	
Study design – treatment	If placebo comparison is used rather than the best standard treatment, what is the justification?	
Study design – outcome	Is the study exploratory or confirmatory in nature? Is the primary outcome of the trial a clinical outcome or a surrogate outcome? Is the outcome the current and most valid internationally accepted outcome? Does the trial use the best possible comparison groups for its purpose?	
Study design – randomisation	Does the trial use randomisation to treatment	

	groups? If randomised, how will this be performed?	
Study design – blinding	Are the investigator, participants and the trial outcome evaluator blinded? If blinding is utilised, how is this ensured?	
Study design – sample size	Has a proper sample size calculation been made? Who calculated the sample size? What were the assumptions behind the sample size calculation?	
Participant availability	Are there enough participants available? What is the anticipated duration of patient recruitment? Are there other clinics or hospitals available to secure the anticipated sample size?	
Resources	Are enough financial and manpower resources available for completion of the trial?	

APPENDIX A5

	Cebu Doctors University Hospital Research Ethics Committee (CDUHREC)		
	Study Protocol/ICF Amendment Submission Form	CDUHREC FORM	5
		Version No.	3
		Version Date	09 Jul 2015
		Effective Date	09 Jul 2015

Study Protocol/ICF Amendment Submission Form

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *A study protocol amendment is a written description of a change(s) to or formal clarification of a protocol and/or informed consent documents. Favorable*

opinion or approval should be obtained from the CDUHREC that issued the ethical clearance or approval prior to the implementation of an amendment. Please fill out the form and submit together with your cover letter and documents.

INSTRUCTIONS TO THE CDUHREC OFFICE SECRETARY: *The original form should be forwarded to the Chair and/or lead reviewer for the type of review. For documents requiring full board review, the accomplished form should be photocopied and provided to each committee member with the documents for review.*

STUDY PROTOCOL Number:
INITIAL APPROVAL DATE:
PRINCIPAL INVESTIGATOR:
AMENDMENT SUBMISSION DATE: (to be filled out by CDUHREC Secretary)
1. **NO. OF AMENDMENT/S**:
2. **STATE NATURE OF STUDY PROTOCOL/ICF AMENDMENT** (Cite study protocol section and page where amendment is found. For amended ICF, please make sure that all amendments in the ICF have been highlighted prior to submission to CDUHREC for review. Additional sheet may be used if necessary.)
Signature of Principal Investigator: **Date of Signature:**

RECOMMENDATIONS (for CDUHREC use only)

3. **TYPE OF REVIEW**: (To be accomplished by CDUHREC Chair or deputy chair) **3.1.☐ EXPEDITED** REVIEW **3.2.☐ FULL BOARD REVIEW**
Comments from Lead Reviewer:

Risk Benefit Assessment:
Recommended Action ☐ APPROVAL ☐ MINOR MODIFICATION TO THE STUDY PROTOCOL , SUBJECT TO EXPEDITED REVIEW AT THE LEVEL OF THE PANEL CHAIR ☐ MAJOR MODIFICATION TO THE STUDY PROTOCOL, SUBJECT TO FULL PANEL REVIEW ☐ DISAPPROVAL
Lead REVIEWER Signature _____ Date: Name

APPENDIX A6

	Cebu Doctors University Hospital Research Ethics Committee (CDUHREC)		
	Checklist for Initial Submission for New	CDUHREC FORM	6
		Version No.	3
		Version Date	09 Jul 2015

	Application for Review	Effective Date	09 Jul 2015

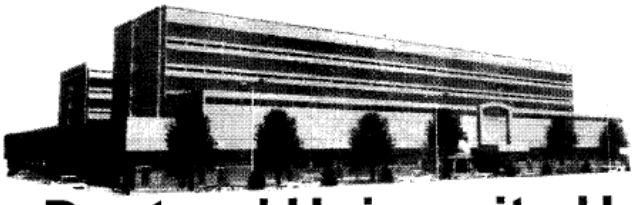
Date of Submission:		
STUDY PROTOCOL Number:		
STUDY PROTOCOL TITLE:		
PRINCIPAL INVESTIGATOR:		
Email:	**Telephone:**	**Mobile:**
STUDY SITE:		
STUDY SITE ADDRESS:		
SPONSOR:		
STUDY COORDINATOR:		
Email:	**Telephone:**	**Mobile:**
Date of Review: (To be filled up by CDUHREC secretary):		

Checklist for Initial Submission for New Application for Review

Document	Number of Copies Received	Signature CDUHREC	Comment
1. Application letter for review from the PI			
2. Signed protocol and amendments (if any)			
3. Investigator Brochure			
4. Study Information and Consent/Assent Forms (English and Cebuano Versions)			
5. Study tools (questionnaires, patient diaries, posters/ advertisements for recruitment) in English and Cebuano version			
6. Case report forms			
7. Curriculum vitae of principal investigator			
8. Information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, if any			
9. Insurance/Indemnity statement			
10. Evidence of submission to regulatory authority			
11. Certificate of GCP Training of PI			

Received By:_____ Date:_____

Printed Name and Signature



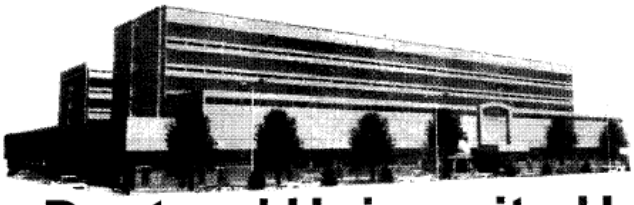
Cebu Doctors' University Hospital

CEBU DOCTORS' UNIVERSITY HOSPITAL RESEARCH ETHICS COMMITTEE

FINAL REPORT FORM

Total Number of patients screened	
Date of first patient randomized at site	
Date of last patient randomized at site	
Date of patient last visit	
No. of screen failure	
No. of patients who have completed the trial	
No. of patients discontinued	
No. of Serious adverse events	

Ground Floor, Administrative Building, Gov. M. Roa St. corner Don Jose Avila St., Cebu City 6000 Philippines
Telefax: +6332 4169341 Email: cduhrec@gmail.com



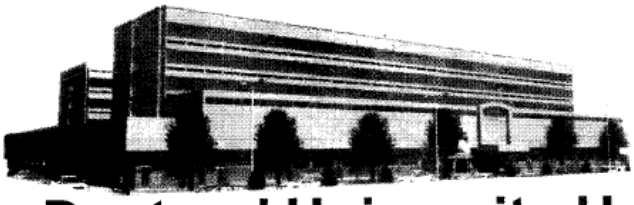
Cebu Doctors' University Hospital

CEBU DOCTORS' UNIVERSITY HOSPITAL RESEARCH ETHICS COMMITTEE

PROGRESS REPORT FORM

Total Number of patients screened	
Date of first patient randomized at site	
Date of last patient randomized at site	
No. of patients in Run-in Phase	
No. of screen failure	
No. of patients who have completed the trial	
No. of patients discontinued	
No. of Serious adverse events	

Ground Floor, Administrative Building, Gov. M. Roa St. corner Don Jose Avila St., Cebu City 6000 Philippines
Telefax: +6332 4169341 Email: cduhrec@gmail.com



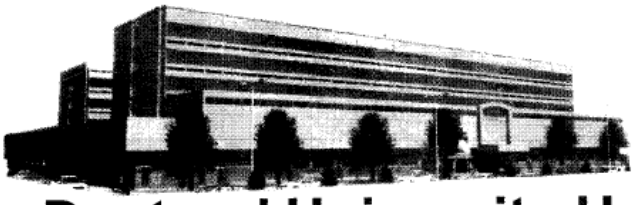
Cebu Doctors' University Hospital

CEBU DOCTORS' UNIVERSITY HOSPITAL RESEARCH ETHICS COMMITTEE

PROTOCOL DEVIATION REPORT FORM

DATE OF IMV	PATIENT/SUBJECT NO.	MINOR/MAJOR DEVIATION	ACTION TAKEN

Ground Floor, Administrative Building, Gov. M. Roa St. corner Don Jose Avila St., Cebu City 6000 Philippines
Telefax: +6332 4169341 Email: cduhrec@gmail.com



Cebu Doctors' University Hospital

CEBU DOCTORS' UNIVERSITY HOSPITAL RESEARCH ETHICS COMMITTEE

SERIOUS ADVERSE EVENTS REPORT FORM

SITE NAME/NUMBER	PATIENT/ SUBJECT NUMBER	EVENT TERM	DATE OF ONSET	DESCRIPTION	TYPE OF REPORT

Ground Floor, Administrative Building, Gov. M. Roa St. corner Don Jose Avila St., Cebu City 6000 Philippines
Telefax: +6332 4169341 Email: cduhrec@gmail.com