Cebu Doctors' University Hospital
Osmeña Boulevard, Cebu City, 6000 Philippines

"We Lead to Serve and We Serve so that Others May Live"

Cebu Doctors' University Hospital Research Ethics Committee

(CDUHREC)

Standard Operating Procedures
(Revised 2015)

Supersedes	SOP Version 4 (09 July 2015)	
Authored by	CDUHREC (Adapted from WHO,ICH-GCP, PNHRS, CIOMS 2009)	
Effective Date	15 Dec 2015	
Approved by	Enrico B. Gruet, M.D. Chairman, CDUHREC	15 DEC 2015
	Jose Antonio Quitevis, M.D. Chairman, Clinical Governance Board	08 JAN 2016
	Potenciano V. Larrazabal Jr., M.D. President and Chairman of the Board	07 JAN 2016
Approval Date		

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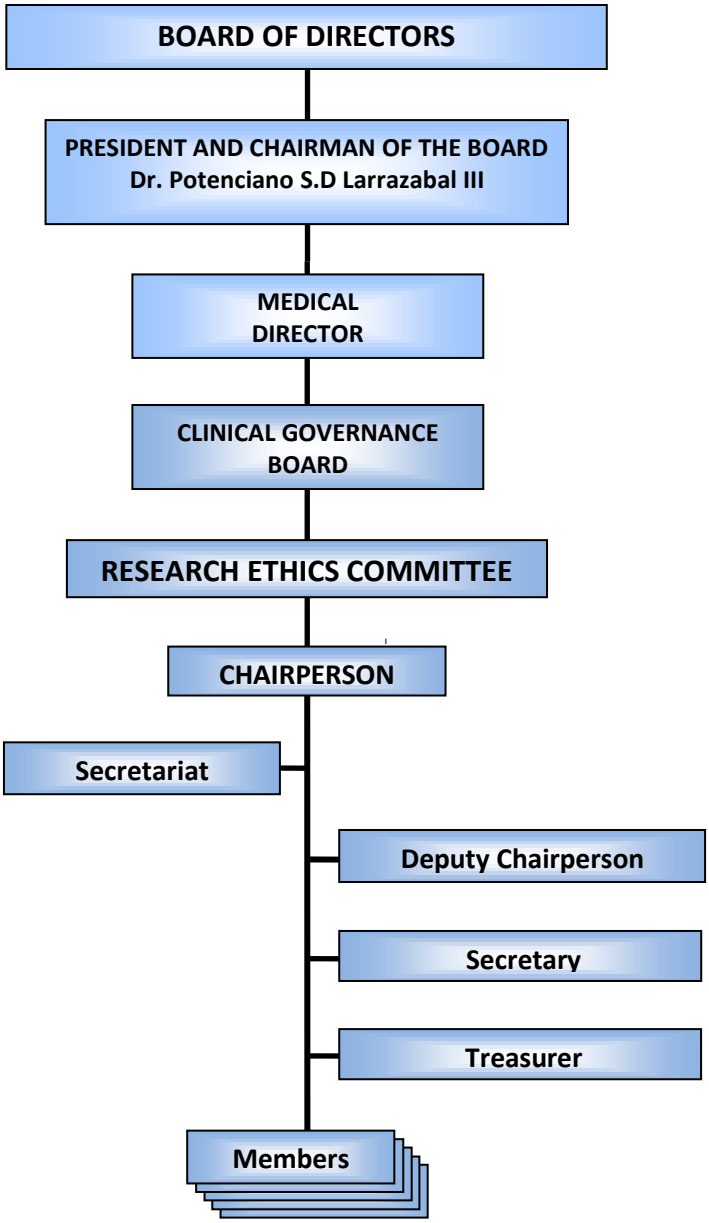
Cebu Doctors' University Hospital
Research Ethics Committee
(CDUHREC)

Organizational Chart



Cebu Doctors' University Hospital
Research Ethics Committee
(CDUHREC)

List of Members

The members of the Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC) effective immediately until 31 December 2017:

1. Dr. Enrico B. Gruet	Chair; Medical Doctor Contact no. +63 32 416 9341
2. Dr. Ma. Noemi A. Uy	Deputy Chair; Medical Doctor Contact no. +63 32 416 9341
3. Mr. Nimrod N. Quiñones	Committee Secretary, Journalist; Not affiliated with the Institution; Non-scientific member
4. Mrs. Lani B. Arcenal	Treasurer; Nurse
5. Dr. Lamberto M. Garcia, Jr.	Medical Doctor
6. Dr. Helen V. Madamba	Medical Doctor
7. Atty. Allan Orvien Geotina	Lawyer; Non-scientific member
8. Rev. Fr. Julius D. Pelarion	Priest; Non-scientific member
9. Ms. Fabiana G. Sunit	Teacher; Lay member; Not affiliated with the Institution; Non-scientific member
10. Ms. Quenie Mae Tiro	Pharmacist

CDUHREC Office Secretary: Divelyn Grace B. Paulino

Office Hours:
Mondays to Fridays 8:00am to 12:00 noon; 1:00 pm to 5:00pm
Office Address:
Ground Floor, CDUH Administrative Offices Building
Cebu Doctors' University Hospital
Gov. M. Roa St. corner Don Jose Avila St.
6000 Cebu City, Philippines
Office Telefax +63 32 416 9341
Email cduhrec@gmail.com

Cebu Doctors' University Hospital
Research Ethics Committee
(CDUHREC)

Institutional Authority, Vision, Mission and Functions

I. Institutional Authority

The CDUHREC is a part of and operates under the authority of the Cebu Doctors' University Hospital (CDUH) Clinical Governance Board. It is responsible for the review and final approval of the human subject studies that would be conducted at Cebu Doctors' University Hospital, South General Hospital, North General Hospital, Mactan Doctors' Hospital, San Carlos Doctors' Hospital and Ormoc Doctors' Hospital.

II. Vision

All research projects at CDUH involving human subjects are conducted according to the highest ethical standards.

III. Mission

To protect the psychological and physical welfare, rights, dignity and safety of participants in research, to facilitate ethical research through efficient and effective review processes, to promote ethical standards of human research and to review research in accordance with the National Ethical Guidelines for Health Research (2011), ICH-GCP, CDUH policies and local regulatory laws.

IV. Functions

1. To provide independent, competent and timely review of research projects involving human subjects with respect to their ethical acceptability;
2. To provide ethical oversight, monitoring and advice for research projects involving human subjects;
3. To prescribe the principles and procedures that govern research projects involving human subjects, human tissue and/or personal records.

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	STRUCTURE AND COMPOSITION	SOP No.	1
		Version No.	5
		Version Date	15 Dec 2015
		Effective Date	15 Dec 2015

I. Policy

The procedures conducted by CDUHREC are based on the provisions of CDUH, national and international guidelines (WHO Operational Guidelines/CIOMS Guidelines/ICH GCP and the National Ethics Guidelines)

II. Purpose

The purpose of this section is to define the composition and process of appointment of members of CDUHREC.

III. Document History

SOP No. 1 (Institutional Authority, Objective & Functions of CDUHREC) Version 1 dated 01 June 2012

SOP No. 1 (Membership) Version 4 dated 9-July-2015, formerly SOP No. 2 version 1 dated 01 June 2012, version 2 dated 01 Apr-2013 and version 3 dated 01-Feb-2014

Final as SOP No. 1 (Structure & Composition) version 5 dated 15-Dec-2015

IV. Scope

This Standard Operating Procedure applies to the membership of Cebu Doctors' University Hospital Research Ethics Committee.

V. Appointment of CDUHREC Members

1. Members are appointed as individuals rather than in a representative capacity.
2. The Chair, Deputy Chair and members are appointed by the CDUH Medical Director.
3. The conditions of their appointment include:
   a) Being compliant with the provisions of the WHO Operational Guidelines/CIOMS Guidelines/ICH GCP and the National Ethical Guidelines for Health Research (2011). Hard and soft copies of above guidelines are kept on file, accessible for use by any member.
   b) Preparing for and attending scheduled meetings; or if unavailable, providing comments
   c) Attending continuing education or training in research ethics at least every 2 years. All members are expected to attend introductory and continuing education and training (such as. Proof of training will be

kept on file. Reasonable costs associated with attendance of training and educations are met by the CDUHREC. To aide in the monitoring, a checklist will be provided and kept on file for each member on the trainings and continuing education attended and to be attended.

d) An assurance of confidentiality on undertaking their appointment (all matters which they become aware of during the course of their work in the CDUHREC will be kept confidential).

e) Declaration of any conflicts of interest, which exist at the time or which may arise during their tenure in the CDUHREC. This should be made to the Medical Director or at a CDUHREC meeting if the conflict of interest relates to a specific research project.

4. Members are appointed for a period of two years and may serve consecutive terms at the discretion of the CDUH Medical Director and Board of Directors. Members are advised when his/her term is about to expire.
5. Members may seek a leave of absence from the CDUHREC for extended periods. Steps shall be taken to fill the vacancy when necessary.
6. A member may be removed if he/she fails to attend at least fifty percent (50%) of all scheduled CDUHREC meetings in each year, barring exceptional circumstances.
7. A member may resign from the CDUHREC at any time upon giving notice in writing to the CDUHREC Chair and CDUH Medical Director. Steps shall be taken to fill the vacancy when necessary.

VI. Workflow (Appointment)

ACTIVITY	RESPONSIBILITY
Identify possible members including external experts ↓	CDUHREC Members
Invite and Confirm ↓	CDUHREC Chair
Endorsement ↓	CDUHREC Chair
Appoint ↓	Medical Director
Announce ↓	CDUHREC Chair
File CVs in the membership file	CDUHREC Office Secretary

Detailed Instructions of the Steps based on the Workflow

Step 1 – CDUHREC members will identify and recommend new members including external experts based on their qualifications and the needs of the committee. The qualifications considered are: scientific and medical expertise, for non-scientific members, those related to social, legal or cultural considerations, and gender balance

Step 2 – CDUHREC Chair will invite and confirm the availability of possible members and the external expert

Step 3- CDUHREC Chair endorses the recruited member and the external expert for appointment by the medical director

Step 4 – The Medical Director appoints the new members and the external expert based on the recommendations of the CDUHREC and endorsement of the Chair. The CDUHREC Chair will have the following responsibilities: prepares the agenda for each meeting; assigns a lead reviewer for all new study applications including a lead reviewer for the ICF; presides over the meeting; determines the kind of review that will be done, either full board or expedited; conducts expedited review together with the lead reviewer; assigns the Safety Report Reviewer and signs the Review Notification Letter. The Deputy Chair will take over the responsibilities of the Chair in his/her absence. The CDUHREC Secretary will be responsible for the keeping of record of attendance and taking the minutes of the meeting. When required, the CDUHREC may seek advice and assistance from an external expert to help review a clinical study. Such external expert shall have no conflict of interest. Such person(s) is required to provide an undertaking of confidentiality and is not entitled to vote on any matter. A standing list of external expert, as appointed by the Medical Director, is identified to provide special expertise to the EC on proposed research protocols. The external expert is required to attend the deliberation in the full board meeting. Their appointment is for a period of two years.

Step 5 - The CDUHREC Chair announces to the committee the newly appointed member(s) and the external expert during the next monthly meeting

Step 6 - The office secretary files the CV of the newly appointed member(s) and the external expert

VII. Removal of Member (Workflow)

ACTIVITY	RESPONSIBILITY
Identify none compliant member ↓	CDUHREC Secretary
Confirm and Reports ↓	CDUHREC Chair
Deliberates and Decides ↓	CDUHREC Members
Furnish and Files Decision in the membership file	CDUHREC Office Secretary

Detailed Instructions of the Steps based on the Workflow

Step 1 – CDUHREC Secretary will inform the Chair of the attendance of each member taking note of the absences.

Step 2 – CDUHREC Chair will determine whether the said member has failed to attend at least 50% of the total meetings from his date of appointment. The Chair will then report to the body of said circumstance.

Step 3 – The CDUHREC members will then deliberate on the matter afterwhich a resolution will be passed removing the said member.

Step 4 - The office secretary will furnish the affected member the resolution and files the same in the membership files

VIII. Framework

1. There shall be a minimum of seven (7) members, with both genders represented, as follows:
   1.1 a Chair;
   1.2 a Deputy Chair;
   1.3 a Secretary;
   1.4 at least one member who is a lay person, who has no affiliation with the institution or organization, and who is not currently involved in medical, scientific, or legal work;
   1.5 at least one member with knowledge of, and current experience in, the professional care, counseling or treatment of people;
   1.6 at least one member who performs a pastoral care role in the community;
   1.7 at least one member who is a lawyer;
   1.8 at least one member with knowledge of, and current experience in, the areas of research that are regularly considered by the CDUHREC.

2. To ensure the membership equips the CDUHREC to address all the relevant considerations arising from the categories of research likely to be submitted, some or all of the above categories may be represented by more than one person.

3. Additional members may be appointed to ensure the CDUHREC has the expertise required to assess the applications submitted for review. If additional members are appointed, the composition of the CDUHREC shall continue to reflect the diversity and balance of its members, including gender and the relative proportion of institutional and non-institutional members, where possible.

4. The CDUHREC Office Secretary
   1. The CDUHREC will hire a fulltime secretary.
   2. The responsibilities of the CDUHREC office secretary are as follows:
      a. Preparing and issuing the schedule of CDUHREC meetings
      b. Preparing the draft agenda (with the CDUHREC Chair) for review/approval by the committee
      c. Ensuring completeness of documents for application prior to the committee review
      d. Informing the lead reviewers as assigned by the Chair
      e. Distributing the agenda and documents for review
      f. Notifying the principal investigator of the scheduled review
      g. Preparing the venue
      h. Recording apologies for absence prior to the meeting
      i. Recording attendance
      j. Ensuring that members have declared an interest in advance of the meeting and mentioning this interest at the beginning of the discussion of that item
      k. Making a written record of the meeting
      l. Preparing the minutes of the meeting for review and approval at the following meeting

m. Notifying applicants of decisions taken at the meeting and taking other follow-up action as necessary
n. Filing and archiving records

VIII. Compensation

All members shall receive the following honorarium:

1. Five hundred pesos (Php500) for every committee meeting attended;
2. Two thousand five hundred pesos (Php2500) for every new protocol review;
3. One thousand pesos (Php1000) for every substantial/major amendment review.

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Meetings	SOP No.	2
		Version No.	5
		Version Date	15 Dec 2015
		Effective Date	15 Dec 2015

I. Policy

The procedures conducted by CDUHREC are based on the provisions of CDUH, national and international guidelines (WHO Operational Guidelines/CIOMS Guidelines/ICH GCP and the National Ethics Guidelines)

II. Purpose

The purpose of this section is to define the conduct of committee meetings of the CDUHREC.

III. Scope

This Standard Operating Procedure of CDUHREC applies to the conduct of meetings.

IV. Document History

SOP No. 2 (Membership) Version 1 dated 01 June 2012, version 2 dated 01 Apr 2013, version 3 dated 01-Feb-2014 and version 4 dated 09-July-2015

Final as SOP No.2 (Meetings) Version 5 dated 15-Dec-2015

V. Scheduled Meeting

The CDUHREC shall meet every first Thursday of the month, except when it falls on a legal or special holiday, in which case the meeting shall be held on the next business day or upon agreement among the members.

VI. Meeting (Workflow)

ACTIVITY	RESPONSIBILITY
Preparation for Review Meetings including date of meeting ↓	CDUHREC Members
Assignment of Reviewers ↓	CDUHREC Chairperson
Sends protocols, minutes and agenda ↓	CDUHREC Office Secretary
Preside the Meeting including checking the Quorum, approval of the Minutes of the previous meeting ↓	CDUHREC Chairperson

Discussion, Deliberation and Decision ↓	CDUHREC Members
Taking of the Minutes ↓	CDUHREC Secretary
Signs Decision ↓	CDUHREC Chairperson
Sends Notifications to PI	CDUHREC Office Secretary

Detailed Instructions of the Steps based on the Workflow

Step 1 – The preparation of the meeting involves the entire membership of CDUHREC

Step 2 – CDUHREC Chairperson will assign the lead reviewer for the Protocol, lead reviewer for the ICF and reviewer for the Safety Reports.

Step 3 – The CDUHREC Office Secretary sends hard copies of the Protocols including the checklists and emails the agenda and minutes to the entire membership

Step 4 – The CDUHREC Chairperson will preside the meeting after checking the quorum. Declaration of Conflict of Interest, Approval of the Minutes and Matters arising from the Minutes are all presided by the CDUHREC Chairperson

Step 5 - The Lead reviewers will initiate the discussion on the Protocols assigned to them, including the reviewers for the ICF and Safety Reports. Afterwards, the entire membership of the CDUHREC will discuss and deliberate the matter before deriving at a decision

Step 6 – The CDUHREC Secretary take notes of the matters discussed and reflects it in the Minutes

Step 7 - The CDUHREC Chairperson signs the Decision derived at by the CDUHREC members

Step 8 – The CDUHREC Office secretary sends out the Notifications to the PIs.

VII. Preparing for Review Meetings

1. Set schedule for next monthly meeting.
2. Set cut-off date for new applications. (14 calendar days)
3. Set cut-off date for replies to EC (i.e. issues that would need full board review; 7 working days).
4. Make a list of all pending protocols for follow-up (i.e. protocols with pending issues, pending approval)
5. Photocopy all submission letters for new applications and major amendments. The photocopy shall be provided to the lead reviewer.
6. Set the agenda and email agenda to all members at least 10 days prior to review.
7. Encode all protocols and submitted documents for review
8. The Chair will assign a lead reviewer for all new study application.
9. The lead reviewer will initiate and lead the discussion of the said application.
10. Prior to the meeting, the lead reviewer should accomplish all checklists for the protocol, forms, scientific evaluation and risk-benefit assessment.
11. Distribute all documents. This should be done not later than 10 days prior to review date.

    11.1. For new applications

        11.1.1. For the Lead Reviewer – Provide checklist for protocol, ICF, IB, scientific evaluation, risk-benefit assessment, and photocopy of submission letter

        11.1.2. For the Legal and Lay Members – Provide checklist for ICF

11.1.3. For all other members – Provide checklist for protocol and ICF

11.2. For major amendments

8.2.1. For the lead reviewer – Provide the study protocol/ICF amendment submission form original copy accomplished by the principal investigator

8.2.2. For all other members - Provide a photocopy of the study protocol/ICF amendment submission form accomplished by the principal investigator

11.3. Safety Reports

11.3.1. Set cut-off date for safety reports. This should be 7 days prior to review date.

11.3.2. Make the monthly safety log. Print and give to the safety reviewer for comments. Collect this log after the meeting and after the safety reviewer has made a report to the committee.

11.3.3. Email a copy of the safety log to the Chair and safety reviewer.

11.3.4. Email the safety reports 7 days prior to review date to the safety reviewer.

11.3.5. Email the safety reports to the safety reviewer.

VIII. Conduct of Meetings

1. The CDUHREC Chair prepares the agenda for each meeting at least 10 days before the scheduled date.
2. The agenda for each meeting will include:
   a) The date, time and venue of the meeting
   b) Approval of the minutes of the previous committee meeting
   c) Matters arising from the minutes of the previous meeting
   d) Declarations of interest relating to items on the agenda
   e) Applications for ethical review to be considered at the meeting, including lead reviewers
   f) Items of importance arising from new guidelines or recent publications
   g) Matters relating to the establishment or membership of the CDUHREC
   h) Matters relating to CDUHREC decisions on policy
   i) Actions by the Chair relevant to previous applications
   j) Training issues
   k) Any other matters
3. Quorum requirements and meeting attendance
   a) The quorum for CDUHREC meetings is at least 5 members are present including the non-affiliated member with both genders represented.
   b) In the absence of the Chair, the Deputy Chair may preside over the meeting. The committee cannot hold a review without either the chair or deputy chair present. In case the chair and the deputy chair have a conflict of interest for the clinical study under review, the lead reviewer shall preside over the review of the said clinical study.
   c) The CDUHREC secretary shall keep a record of attendance, indicating which members are present for the discussion of each application. The CDUHREC members are expected to attend the majority of scheduled meetings each year and are required to attend at least half of such meetings.
   d) Whenever possible, the meeting should reach decisions by consensus. If a consensus is not achievable, a formal vote should be taken. All members have the right to vote, including the Chair. The decision of the Committee should be determined by a

two-thirds majority of those members present and entitled to vote. In the event of a split decision, the Chair has the deciding vote.

e) If any member wishes to record formal dissent from the decision of the CDUHREC, this should be recorded in the minutes.

4. Declaration of interests
   a) Any member must declare any general conflicts of interest they may have in relation to an application for ethical review or any matter for consideration at CDUHREC meetings.
   b) In addition, each member must declare his/her interests at the beginning of each meeting to ensure the independence of the review. Where the Chair has a conflict of interest, that meeting shall be chaired by the Deputy Chair.
   c) The WHO Declaration of Interests for WHO Experts defines a conflict of interest as follows: "A conflict of interest means that the expert or his/her partner ("partner" includes a spouse or other person with whom he/she has a similar close personal relationship), or the administrative unit with which the expert has an employment relationship, has a financial or other interest that could unduly influence the expert's position with respect to the subject matter being considered. An apparent conflict of interest exists when an interest would not necessarily influence the expert but could result in the expert's objectivity being questioned by others. A potential conflict of interest exists with an interest which any reasonable person could be uncertain whether or not should be reported".
   d) If a CDUHREC member is the principal investigator (PI) or key investigator/collaborator in a research study, the member may take part in the discussion but he/she cannot vote and this should be reflected in the minutes of the meeting.
   e) The minutes should record all declarations of interest.

7. Confidentiality of proceedings
   a) Members do not sit on the CDUHREC in any specific representative capacity (institutions, associations, departments) and must be able to discuss freely the applications submitted to them. The CDUHREC meetings must be completely confidential. Any breaches of confidentiality by members will result in termination of their membership.

IX. Preparing for/formatting/finalizing meeting minutes

1. Minutes of the Meeting
   a) The minutes of the meeting shall contain a record of the following:
      1. The members present and absent
      2. Any interests declared and the decision of the Committee on the participation of the member concerned
      3. The submission of written comments by members
      4. A summary of the main ethical issues considered
      5. The decision of the CDUHREC on the applications
      6. In the case of an approval, any special approval conditions or additional advice to be given to the applicant
      7. In the case of a rejection, a list of reasons for the decision
      8. In the case of a conditional opinion, the additional information requested by CDUHREC and the arrangements for considering this information and issuing the final opinion of CDUHREC.

9. When a decision is held in abeyance, the issues for which further advice is required
10. When an unfavorable opinion is given on an application, the reasons for the decision must be stated
11. The outcome of any vote taken
12. Any formal dissent from the decision of CDUHREC by a named member, with reasons

b) The minutes are to be presented as the outcome of collective discussion, including written comments made by members following discussion of an application, and should not attribute particular statements to individual members, with the exception of any formal dissent.
c) The minutes of the meeting shall be approved by the committee on the next scheduled meeting.
d) Copies of the approved minutes of the meeting will be available upon request.

X. Preparing for protocol-review-related documents after the meeting

1. The CDUHREC office secretary will be responsible for the collection and filing of all applications reviewed immediately after each meeting. The committee will only keep two (2) copies of the document submitted and reviewed on file and all other copies from the members shall be collected and returned to the principal investigator.

2. The decision of the committee shall be communicated to the PI by the Chair. A written notification shall be available within 10 working days from the date of review. The written notification shall contain the following:

a. The CDUHREC decision on the new application
b. Date of the review
c. Study protocol number and title
d. The documents that were reviewed including the version numbers and document date;
e. The list of members who were present during the review and voted

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	The Review Process for New Applications	SOP No.	3
		Version No.	5
		Version Date	15 Dec 2015
		Effective Date	15 Dec 2015

I. Policy

The procedures conducted by CDUHREC are based on the provisions of CDUH, national and international guidelines (WHO Operational Guidelines/CIOMS Guidelines/ICH GCP and the National Ethics Guidelines)

II. Purpose

The purpose of this section is to define a standardized, uniform process for initiating new clinical trials and extension studies at Cebu Doctors' University Hospital (CDUH) including researches initiated by resident physicians and fellows involving CDUH patients and employees.

III. Scope

This Standard Operating Procedure of CDUHREC applies to the review process of new applications, extension studies and researches initiated by resident physicians and fellows involving CDUH patients and employees.

IV. Document History

SOP No. 3 (Meetings) Version 1 dated 01-June-2012, version 2 dated 01-Apr-2013 and version 3 dated 01-Feb-2014

Final as SOP No. 3 (The Review Process for New Application) Version 4 dated 9 July 2015 and version 5 dated 15-Dec-2015

V. The Review Process

1. All researches involving human subjects shall be recorded in the CDUHREC Registry logbook (registry number, date of application, protocol number, protocol title, therapeutic area, principal investigator, lead reviewer, date received, date of review, date of approval, study start, study close-out).

2. The CDUHREC will only perform ethical review for new applications once all required documents have been submitted.

3. The principal investigator (PI) shall be required to take note of the Guidelines on Risk Benefit Assessment, Pediatric Population and Methods of Birth Control (please see Appendix A12 for more details) and to submit the following documents (please refer to checklist for more details in Appendix A6) in this order and properly labeled. Please take note that for Investigator Initiated Studies, CDUHREC does not require any Insurance/Indemnity Statement and Evidence of Submission to Regulatory Authority if the drug to be used is already commercially available.

3.1. Application letter addressed to CDUHREC Chair, Ground Floor CDUH Administrative Offices Building, Cebu Doctors' University Hospital, Governor M. Roa Street corner Don Jose Avila Street, Cebu City.
3.2. Signed and dated protocol/ protocol synopsis and amendments (if any)
3.3. Investigator Brochure
3.4. Study Information and Informed Consent/Assent Forms (English and Cebuano Versions)
3.5. Study tools (questionnaires, patient diaries, posters/advertisements for recruitment) in English and Cebuano versions
3.6. Case report forms
3.7. Curriculum vitae of principal investigator
3.8. Information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, if any
3.9. Insurance/Indemnity statement
3.10. Evidence of submission to regulatory authority
3.11. Certificate of GCP Training of the PI

4. All documents for review should be submitted in 10 copies.

5. Deadlines for submission of documents:

5.1. New protocols - at least 2 weeks prior to the scheduled review meeting.
5.2. Amendments - at least 2 weeks prior to the scheduled review meeting.
5.3. Reply to comment letter should be received at least 1 week prior to the scheduled review meeting.

6. There shall be a maximum of 3 new protocols to be reviewed per meeting. If there are 4 or more submitted protocols, CDUHREC has the option to hold 2 meetings for the month.

7. A checklist of the initial submission shall be reviewed for completeness by the CDUHREC secretariat. Incomplete submissions shall be communicated to the PI accordingly. All documents shall be acknowledged with a stamped receipt by the CDUHREC secretariat. This checklist shall be put on file.

8. The closing date for application is no later than 14 calendar days prior to each CDUHREC meeting.

9. Distribution of papers for meetings - Documents pertaining to the new applications for review must be received by all CDUHREC members at least ten days prior to the scheduled meeting at which the application will be reviewed.

10. Study protocols and all pertinent documents shall be reviewed within 2-7 weeks upon receipt of the application.

11. The CDUHREC Chair or his/her representative shall determine the kind of review that will be done – full board or expedited. He or she will assign the reviewers for either type. The Chair shall prepare the agenda for each CDUHREC meeting for consideration and approval by the committee.

12. Extension studies - An extension study is any study using previously collected data or biological material, medical records or population study information for a new purpose or to test a new hypothesis not envisaged at the time the original consent was obtained. Extension studies shall require a full board review and approval by CDUHREC prior to its conduct.

13. Types of Review

13.1. Full board review

a. All initial applications, extension studies and major amendments shall undergo a full board review by the committee.
b. The protocol is reviewed and discussed during a committee meeting.
c. A quorum must be established during the review and before a final action on the protocol has been made.

13.2. Expedited review

a. Expedited review can be done on initial review of minimal risk protocols, minor protocol amendments, minor informed consent changes, case reports and retrospective studies with minimal risk to study subjects as determined by the Chair.
b. Expedited review refers to the number of CDUHREC members doing the actual review rather than the length of time it requires.
c. This can be done by the lead reviewer and the committee Chair only. Their decision can be communicated to the PI even before a regular committee meeting. Their decision shall be reflected in the minutes of the succeeding committee meeting.

14. The Lead Reviewer

14.1. The Chair will assign a lead reviewer for every new clinical study application.

14.2. The lead reviewer will do the following evaluation and accomplish the following checklists prior to the meeting:

a. Protocol Review
b. Informed Consent Forms (English and Cebuano version)
c. Risk-Benefit Assessment
d. Scientific Evaluation

14.3. The lead reviewer will facilitate the discussion of the assigned clinical study.

15. Clinical Study Review

15.1. The CDUHREC will assess the protocol based on the following (please refer to Appendices A1-A4)

15.1.1. Review of scientific and technical issues (including relevant policy issues and study tools to be used in the study);

15.1.2. Review of ethical issues (vulnerability of research participants, confidentiality, conflict of interest, qualifications of the proponent, use of placebo if relevant, etc.);

15.1.3. Review of the informed consent documents including, but not limited to how the informed consent of the subject will be obtained; in emergency situations, when prior consent of the subject is not possible, how the consent of the subject's legally acceptable representative will be obtained; compensation/reimbursement for expenses incurred by the study participants

15.1.4. Determination of the risk/benefit ratio and degree of risk (minimal, moderate or high).

16. Attendance of the Principal Investigator

16.1. The PI may be invited to attend the meeting at which his/her application is to be reviewed in order to respond to requests from the Committee for further information, clarification or reassurance.

16.2. When the PI is unable to attend, it is acceptable for the sub-investigator to attend instead. It is not acceptable for a representative of the sponsor to attend in place of the PI.

17. Quorum requirements and meeting attendance

17.1. The quorum for CDUHREC meetings is at least 5 members are present including the non-affiliated member with both genders represented.

17.2. In the absence of the Chair, the Deputy Chair may preside over the meeting. The committee cannot hold a review without either the Chair or Deputy Chair present.

17.3. The CDUHREC secretary shall keep a record of attendance, indicating which members were present for the discussion of each application. The CDUHREC members are expected to attend the majority of scheduled meetings each year and are required to attend at least half of such meetings.

17.4. Whenever possible the meeting should reach decisions by consensus. If a consensus is not achievable, a formal vote should be taken. All members have the right to vote including the Chair. The decision of CDUHREC should be determined by a two-thirds majority of those members present and entitled to vote.

17.5. If any member wishes to record formal dissent from the decision of the CDUHREC, this should be recorded in the minutes.

18. Declaration of interests

18.1. Any member must declare any general conflict of interest they may have in relation to an application for ethical review or any matter for consideration at CDUHREC meetings.

18.2. In addition, each member must declare his/her interests at the beginning of each meeting to ensure the independence of the review. Where the Chair has a conflict of interest, that meeting shall be chaired by the Deputy Chair. Where the Chair and Deputy Chair have a conflict of interest, then the lead reviewer shall preside over the review of the said clinical study.

18.3. The WHO Declaration of Interests for WHO Experts defines a conflict of interest as follows: "A conflict of interest means that the expert or his/her partner ("partner" includes a spouse or other person with whom he/she has a similar close personal relationship), or the administrative unit with which the expert has an employment relationship, has a financial or other interest that could unduly influence the expert's position with respect to the subject matter being considered. An apparent conflict of interest exists when an interest would not necessarily influence the expert but could result in the expert's objectivity being questioned by others. A potential conflict of interest exists with an interest which any reasonable person could be uncertain whether or not should be reported".

18.4. If a CDUHREC member is the principal investigator (PI) or key investigator/collaborator in a research study, the member may take part in the discussion but he/she cannot vote and this should be reflected in the minutes of the meeting.

18.5. The minutes should record all declarations of interest.

19. Proceedings

19.1. Members do not sit on the CDUHREC in any specific representative capacity (institutions, associations, departments) and must be able to discuss freely the applications submitted to them. The CDUHCREC meetings must be completely confidential. Any breaches of confidentiality by members will result in termination of their membership.

19.2. The CDUHREC office secretary will be responsible for the collection and filing of all applications reviewed immediately after each meeting. The committee will only keep two (2) copies of the document submitted and reviewed on file and all other copies from the members shall be collected and returned to the principal investigator.

19.3. The decision of the committee shall be communicated to the PI by the Chair. A written notification shall be available within 10 working days from the date of review. The written notification shall contain the following:

19.3.1. The CDUHREC decision on the new application

19.3.2. Date of the review

19.3.3. Study protocol number and title

19.3.4. The documents that were reviewed including the version numbers and document date

19.3.5. The list of members who were present during the review and voted

19.4. The decision on the clinical study may be any one of the following:

19.4.1. Approval - In case of approval, the committee will inform the investigator, in writing, of the requirements for approved researches that must be complied with during the conduct of the research. These include the following:

a. report of serious and/or unexpected adverse event(s) (SAEs, suspected unexpected serious adverse reactions (SUSARs)) that may occur in any of the CDUH site study participants. This must be done within 24 hours from site's initial knowledge of the event;
b. report of SAEs from other study sites or centers (i.e., CIOMS, expedited safety reports) must be submitted to CDUHREC within one (1) month from the site's receipt of the report; (refer to the CDUHREC SOP on safety reporting);
c. any changes or amendments to the approved protocol and informed consent document; these shall require another review and approval by CDUHREC;
d. any protocol violations and deviations;
e. progress report at least once a year from date of approval of the clinical study;
f. written notification to the committee within 30 days from actual date of study start and study closure or termination;
g. preparation for possible CDUHREC site visit

19.4.2. Modifications required prior to approval

In case modifications are required, CDUHREC will inform the investigator what revisions/changes are required.

19.4.3. Disapproval

In case of disapproval, CDUHREC will inform the investigator of the reason of the disapproval.

19.4.4. Held in abeyance for a subsequent meeting pending receipt of further information.

20. In case of an unfavorable decision, the investigator may write an appeal for reconsideration to the committee within fifteen (15) days from receipt of the Disapproval. The appeal will be tabled for reconsideration by the CDUHREC in the

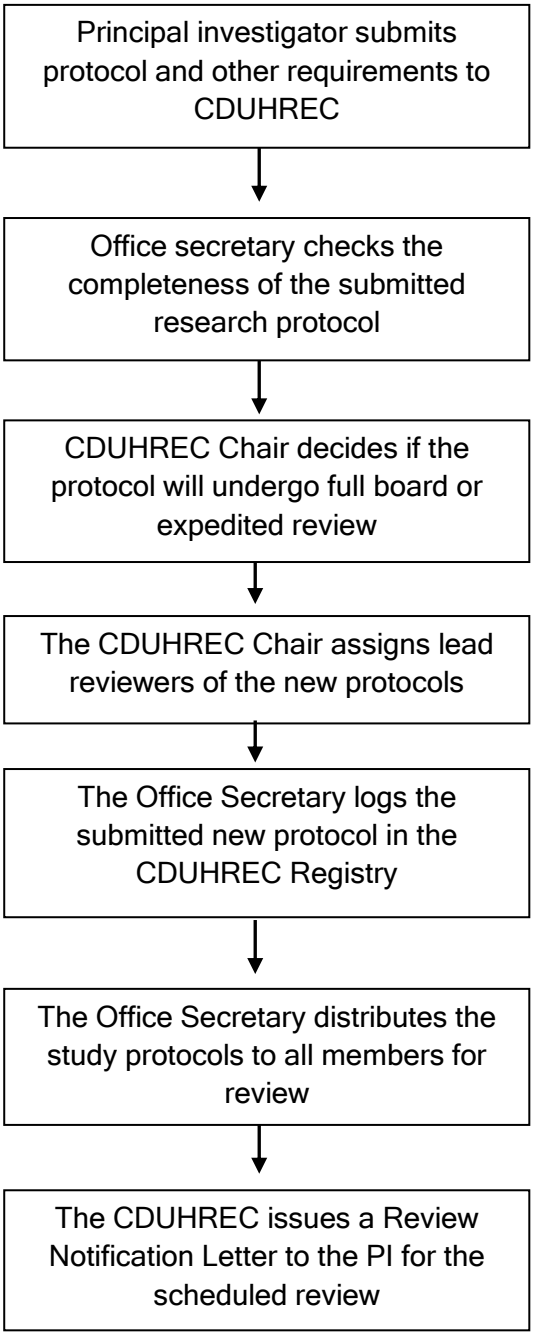
next scheduled meeting. The resolution of the Appeal will be notified to the investigator not later than 7 days from the date of the meeting.

21. Prior approval may be withdrawn by the committee for the following reasons:

21.1. Undue or significant number of serious adverse events directly or indirectly attributed to the research;

21.2. Breach of previously agreed upon conduct of the research.

VI. Flowchart



	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Post-approval Review	SOP No.	4
		Version No.	6
		Version Date	15 Dec 2015
		Effective Date	15 Dec 2015

I. Policy

The procedures conducted by CDUHREC are based on the provisions of CDUH, national and international guidelines (WHO Operational Guidelines/CIOMS Guidelines/ICH GCP and the National Ethics Guidelines)

II. Purpose

The purpose of this section is to define the continuing review process. As part of its function, the CDUHREC must monitor and continuously review a protocol that it has approved.

III. Scope

This Standard Operating Procedure of CDUHREC applies to continuing review.

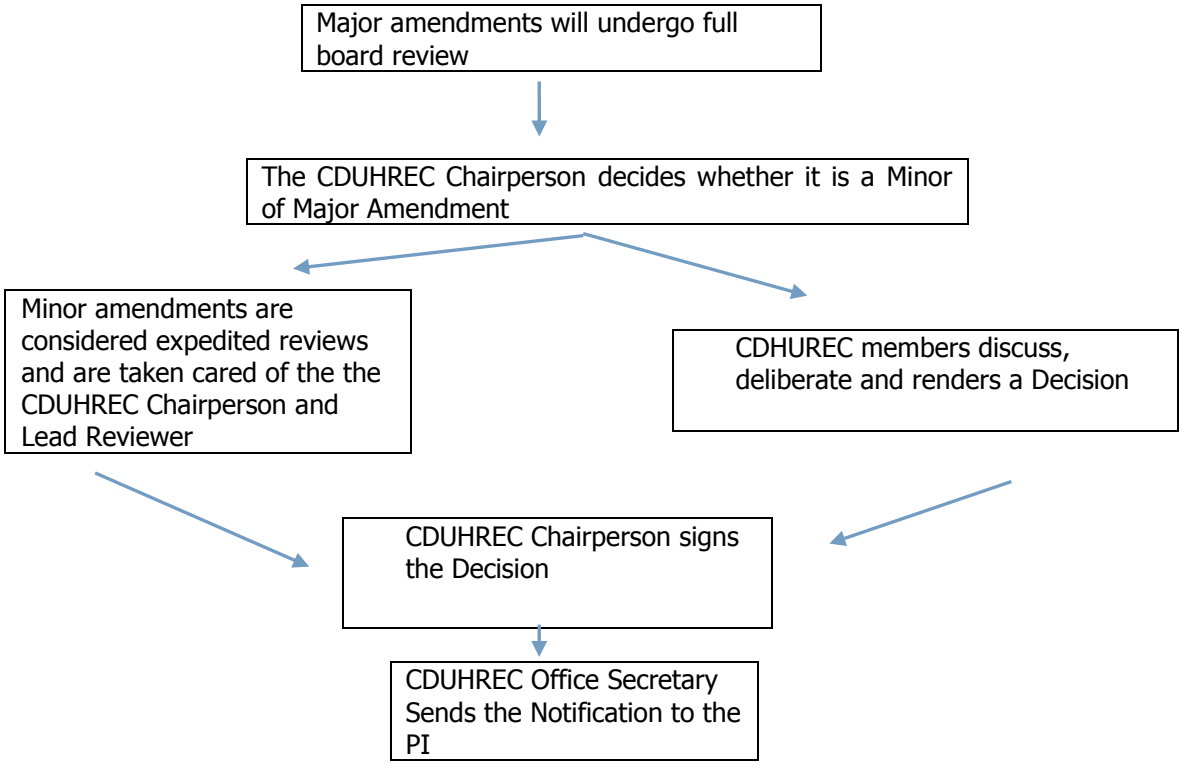
IV. Document History

SOP No. 4 (Review Process of New Application) version 1 dated 01-June-2012, version 2 dated 2-Feb-2013 and version 3 dated 01-Feb-2014

SOP No. 4 (Continuing Review) Version 5 dated 09-July-2015

Final SOP No. 4 (Post Approval Review) Version 6 dated 15-Dec-2015

V. Flowchart on Amendments



VI. Amendments

1. The sponsor/principal investigator (PI) may propose to revise the terms of the review application, the protocol or other supporting documentation after approval has been given or after the study has commenced.

2. Types of Amendments

2.1. Minor Amendments

2.1.1. Minor amendments are defined as any changes that do not involve a more than minimum risk for participants or the conduct of the trial. Examples of minor amendments are correcting typographical errors, minor clarifications of the protocol.

2.2. Major Amendments

2.2.1. Changes to the design or methodology of the study, or to background information affecting its scientific value

2.2.2. Changes to the procedures undertaken by participants

2.2.3. Any change relating to the safety or physical or psychological integrity of participants, or to the risk/benefit assessment for the study

2.2.4. Changes to study documentation such as participant information sheets, consent forms, questionnaires, letters of invitation, letters to other clinicians, information sheets for relatives or caregivers

2.2.5. Change in the use of biological samples

2.2.6. A change of sponsor(s) or sponsor's legal representative

2.2.7. Appointment of a new PI or key collaborator

2.2.8. A change to the responsibility and liability insurance coverage for the study

2.2.9. A significant change to the definition of a research site

2.2.10. A change to the definition of the end of the study

2.2.11. Any other significant change to the protocol or the terms of the original review application

2.2.12. A change in the primary purpose or objective of the research, such as introduction of additional genetic studies

2.2.13. A substantial change in research methodology

2.2.14. Introduction of new classes of investigations or other interventions (rather than simply re-scheduling or modifying those already approved)

2.2.15. Recruitment of a new type of participant (especially if these would be regarded as being from vulnerable groups)

3. The CDUHREC has the discretion to decide whether or not a proposed amendment is minor or major.

3.1. In making this judgment, consideration must be given to how the proposed changes would affect the research. Particular account should be taken of any implications of the amendment for the safety or welfare of participants and of any information that participants might require to give informed consent to continue their participation in the research as amended. Where there is any doubt about the potential implications of the amendment for participants, the amendment should be treated as major and ethically reviewed by the committee.

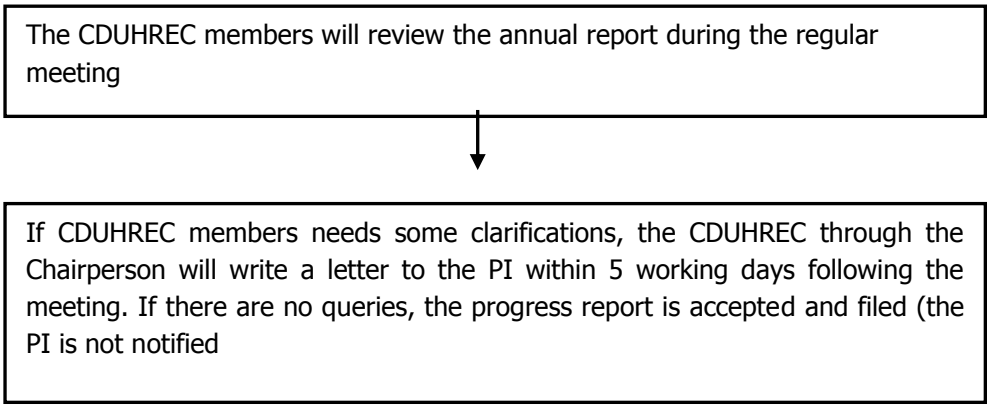
4. All major amendments shall be submitted for a full board review while minor amendments shall undergo an expedited review.

5. The principal investigator must submit a duly-accomplished Study Protocol/ICF Amendment Submission Form version date 09 Jul 2015 together with the amended protocol and/or ICF.

IV. Progress reports

1. The follow up review intervals should be determined by the nature and the events of research projects, although a progress report by the PI must be submitted to CDUHREC at least annually from date of approval.
2. The progress report shall include:
   2.1. Number of participants accrued
   2.2. Adverse events
   2.3. Progress of research including summary results of preliminary analyses, publications and abstracts
3. The committee will review the annual report during a regular monthly meeting.
   3.1. An annual risk-benefit assessment shall also be done by the committee.
4. If there are queries, comments or clarifications raised during the annual review, the Committee shall write a letter to the PI within 5 working days following the meeting. If no queries are raised, the progress report is accepted and filed (the PI is not notified).

5. Flow Chart:



V. Safety reporting

1. In clinical study, a Serious Adverse Event (SAE) is defined as an untoward occurrence that:

   1.1. Results in death
   1.2. Is life-threatening
   1.3. Requires hospitalization or prolongation of existing hospitalization
   1.4. Results in persistent or significant disability or incapacity
   1.5. Consists of a congenital anomaly or birth defect
   1.6. Is otherwise considered medically significant by the investigator

2. An on-site SAE is an SAE occurring on a study participant of the approved clinical study at CDUH.

   2.1. The CDUHREC must be notified of the SAE within 24 hours that the event was first known to the trial site staff.
   2.2. A follow-up report must be given to CDUHREC within 5 working days that the event was first known to the trial site staff.
   2.3. The on-site SAE must be a written/paper report.

2.4. The on-site SAE report shall be forwarded to the protocol lead reviewer.
2.5. The protocol lead reviewer will review the risk-benefit assessment of the protocol and will make a report during the monthly committee meetings.
2.6. The protocol lead reviewer will make the following report to the Committee and this should be reflected in the minutes of the meeting:
    2.6.1. Was the committee notified within 24 hours that the event was known to the trial site staff? (EC secretary must immediately forward notification letter to the lead reviewer upon receipt of the SAE letter from the site.)
    2.6.2. What was the event?
    2.6.3. What was the causality as assessed by the principal investigator?
    2.6.4. Did the event change the risk-benefit assessment of the study?

3. Reports of SAEs or safety reports from other study sites or centers (i.e., CIOMS Report, expedited safety reports, suspected unexpected serious adverse event (SUSAR)) shall be submitted to CDUHREC.

    3.1. Reports of SAE from other study sites or centers must be submitted to CDUHREC within one (1) month from the site's receipt of the report.
    3.2. Reports of SAE from other study sites or centers should be submitted to CDUHREC by email to cduhrecsafetyreports@gmail.com with a subject heading SAFETY REPORT FOR (state PROTOCOL Number). An electronic PDF copy of the report shall be attached to the email report.
    3.3. An email acknowledgement from CDUHREC office secretary shall be issued upon email receipt of the safety report.
    3.4. All safety reports shall then be forwarded to the Safety Report Reviewer who will make an evaluation and summary. The Safety Report Reviewer, who is medical member, shall be assigned by the Chair.
    3.5. The Safety Report Reviewer shall discuss the reports with the committee during monthly meetings. This shall be reflected in the minutes of the meeting.

VI. Protocol waivers, deviations and violations

1. All protocol deviations and violations must be reported to the committee within a reasonable time period.
2. Protocol waiver is not allowed in any clinical study.

VII. Notifications

- The PI will be notified by the CDUHREC Secretary of the CDUHREC's decision on protocol amendments, progress reports, protocol deviations/violations, and review of SAE reports.

VIII. Study Site Monitoring

- The CDUHREC will visit the study site within five (5) days from date of CDUHREC meeting at the expense of the sponsor if the prevalence of SAEs and Protocol Deviations will endanger or increase the risk of patient's safety.

- The visit will be attended by at least a quorum of the CDUHREC including the Chair and the Lead Reviewer.

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Review Fees	SOP No.	5
		Version No.	4
		Version Date	09 July 2015
		Effective Date	09 July 2015

I. Policy

The procedures conducted by CDUHREC are based on the provisions of CDUH, national and international guidelines (WHO Operational Guidelines/CIOMS Guidelines/ICH GCP and the National Ethics Guidelines)

II. Purpose

The purpose of this SOP is to define the review fees.

III. Scope

This Standard Operating Procedure of CDUHREC applies to review fees.

IV. Document History

SOP No. 5 (Continuing Review) Version 2 dated 02-Aug-2012, version 3 dated 01-Feb-2013 and version 4 dated 01-Feb-2014

New SOP No 5 (Risk Benefit Assessment) version 2 dated 09-July-2915

Final SOP No. 5 (Review Fees) version 4 dated 09-July-2015

V. Review Fees

1. CDUHREC is implementing the following review fees effective 01 Feb 2014:
    a. New application – Php40,000.00
    b. Major/Substantial Amendment – Php10,000.00
    c. Annual continuing review fee – Php5,000.00
2. All CDUHREC Review Fees shall be net of tax.
3. The principal investigator will receive a billing statement from CDUHREC.
4. The principal investigator or study sponsor will issue a check in favor of Cebu Doctors' University Hospital.
5. All review fees shall be paid directly to the CDUH cashier.
6. An official receipt reflecting the payment of the review fee shall be issued by CDUH.

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Documentation/ Archiving	SOP No.	6
		Version No.	4
		Version Date	15 Dec 2015
		Effective Date	15 Dec 2015

I. Policy

The procedures conducted by CDUHREC are based on the provisions of CDUH, national and international guidelines (WHO Operational Guidelines/CIOMS Guidelines/ICH GCP and the National Ethics Guidelines)

II. Purpose

The purpose of this section is to describe the procedure for the preparation and maintenance of records of the CDUHREC.

III. Scope

This Standard Operating Procedure of CDUHREC applies to documentation and archiving.

IV. Document History

SOP No. 6(Risk/Benefit Assessment) Version 1 dated 25-June-2012)

New SOP No. 6 (Office Secretary) Version 1 dated 09-July-2015

Final SOP No. 6 (Documentation and Archiving) Version 1 dated 15-Dec-2015

V. Documentation and Archiving

1. The following documents should be filed and archived at the CDUHREC Office:

1.1. The written standard operating procedures of CDUHREC;

1.2. Curriculum Vitae of all CDUHREC members;

1.3. Training Certificates of all CDUHREC members;

1.4. Certificate of Registration to Philippine Health Research Ethics Board (PHREB);

1.5. Annual Reports to PHREB;

1.6. Record of all income and expenses of CDUHREC including allowances and reimbursements made to the members and secretary;

1.7. Agenda of meetings;

1.8. Minutes of meetings;

1.9. Two copies of all materials submitted for review;

1.10. Correspondence by the Committee with clinical investigators or concerned parties regarding application, decision, and follow-up;

1.11. Copy of the decision and any advice or requirements sent to an applicant;

1.12. All written documentation received during the follow-up;

1.13. Notification of the study start, completion, premature suspension, or premature termination of a study;

1.14. Final summary or final report of the study;

1.15. All relevant records and communications of the Committee, including applications, membership, minutes and correspondence, which will be kept as confidential files;

1.16. All records pertaining to a clinical study, which will be retained for 15 years following completion of the clinical trial.

1.17. All active protocol files must be kept in a separate cubicle duly labeled.

1.18. All inactive protocol files must likewise be kept in a separate cubicle duly labeled.

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Writing and Revising SOPs	SOP	7
		Version No.	2
		Version Date	15 Dec 2015
		Effective Date	15 Dec 2015

I. Policy

This Standard Operating Procedure (SOP) defines the procedure for writing, reviewing, amending, and distributing SOPs of the Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC).

The SOP will detail directions to insure all activities of CDUHREC are conducted in accordance with the World Health Organization (WHO) Operational Guidelines for Ethics Committees that Review Biomedical Research, National Ethical Guidelines for Health Research, and ICH (International Conference on Harmonization) Good Clinical Practice (GCP).

The SOPs are drafted and adopted to conform to the Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP) SOP 2006. Furthermore, in order to be relevant and updated to the prescribed and/or good practices, it is mandated that the SOPs of the CDUHREC should be reviewed at least every three (3) years and revisions be made, if necessary.

II. Objectives

The SOPs governing the writing, reviewing, distributing and amending SOPs are made to provide a systematic and uniform procedure and steps in the review and amendment of SOPs.

These SOPs will also establish the proper documentation disclosing prior to, during the review and amendment process of the SOPs, including the distribution of the amended SOPs as well as the steps in archiving copies of the previous versions.

III. Scope

This SOP applies to Writing and Revising SOPs.

IV. Document History

SOP No. 7 (Secretary) Version 1 dated 01-June-2012

New SOP No. 7 (Review Fees) version 4 dated 09-July-2015

Final SOP No. 7 (Writing and Revising SOPs) Version 2 dated 15-Dec-2015

V. Responsibilities

A. Members of the CDUHREC

- Request review and/or revision of the SOPs

B. CDUHREC Chair

- Presides and supervises the SOP Writing/Review to formulate revisions/amendments of the SOPs following the same procedures, format, and coding system when drafting or editing any SOP of the CDUH
- Reviews and approves the SOPs
- Signs and dates when he/she receives the approved SOPs

C. Member Secretary and Office Secretary

- Co-ordinate activities of writing, reviewing, distributing and amending SOPs
- Maintain on file all current SOPs, both hard and soft copies.
- Maintain an up-to-date distribution list for each SOP distributed to the CDUHREC
- Distribute the SOPs including the latest revision
- Ensure that all members of the CDUHREC and involved administrative staff have access to the SOPs to ensure that they are working according to the current version of the SOPs

D. SOP Writing/Review Team members

- Review and propose revisions of SOPs
- Design the format, layout and coding system
- Assess the request(s) for SOP revision in consultation with the Chair and Office Secretary
- Draft amendments or revisions of the SOPs
- Deliberate and approve in a meeting the revised or amended SOPs prepared by the SOP Writing/Review team
- Sign and date when they receive the approved SOPs
- Maintain a file of all SOPs received
- Return all out-of-date SOPs to the Office Secretary

E. Workflow

ACTIVITY	RESPONSIBILITY
Step 1 Request for review, revision, amendment of SOPs	Chair, Deputy Chair, Secretary, Members
Step 2 Appoints the SOP Writing/Review Team	Chair
Step 3 List all relevant SOPs	SOP Writing/Review Team
Step 4 Design the format, layout, coding system	SOP Writing/Review Team
Step 5 Review and make recommendations, provide inputs	Chair, Secretary, Members
Step 6 Draft and present the new/revised SOPs for approval by the CDUHREC	SOP Writing/Review Team
Step 7 Deliberate and approve/reject revised or amended SOPs	Chair, CDUHREC Members
Step 8 Present the approved revisions of the SOPs to the Medical Director for acceptance	Chair
Step 9 Implement, distribute and file all SOPs	Office Secretary
Step 10 Manage and archive superseded SOPs	Office Secretary

F. Detailed Instructions of the Steps based on the Workflow

1. Request for review, revision, amendment of SOPs
   - The Chair and members of the CDUHREC staff may request for a review and/or revision of any SOP.

2. Appoints the SOP Writing/Review Team
   - The Chair appoints suitable individuals who have the necessary preparation, training, and thorough understanding of the ethical review process to form the SOP Writing/Review team.
   - Persons appointed may include current members of the CDUHREC or non-members.
3. List all relevant SOPs

- The SOP Writing/Review Team shall inventory all SOPs.
- They shall solicit from the members of the CDUHREC suggestions and inputs for SOPs needing review and/or amendment.
- They shall review and make an assessment of the SOPs.
- They shall propose items or list relevant SOPs for amendment.

4. Design the format, layout, coding system
   - The SOP Writing/Review Team shall formulate a suitable format, layout and/or coding system for all SOPs or of the SOPs under review, if necessary.
5. Review and make recommendations, provide input
   - The Chair, Secretary and members review the SOPs, make recommendations and provide input.
6. Draft and present the new/revised SOP for approval
   - The SOP Writing/Review Team shall study and discuss the SOPs under review pointing out its applicability and flaws, if any.
   - The team evaluates the recommendations and inputs from the members of the CDUHREC.
   - The team formulates the amendments and/or revisions of the SOPs under review.
   - The team adopts and/or incorporates recommendations of the members of the CDUHREC.
   - The team finalizes and recommends for approval the new/revised or amended SOPs to the CDUHREC members.
7. Deliberate and approve/reject revised or amended SOPs
   - Upon presentation of draft revisions of the SOPs by the SOP Writing/Review Team, CDUHREC members shall deliberate and approve or reject the revisions.
8. Present the approved revisions of the SOPs to the Medical Director for acceptance
   - The Chair presents the approved revisions of the SOPs to the Medical Director for acceptance.
9. Implement, distribute and file all SOPs
   - Upon approval and acceptance of the revisions, the Office Secretary shall apprise the members of the CDUHREC of the approved revisions of the SOPs.
   - The Office Secretary shall illustrate the changes in procedures brought about by the revised SOPs.
10. Manage and archive superseded SOPs
    - Superseded SOPs should be retained, clearly marked "Obsolete", and archived in the historical file by the Office Secretary.

APPENDIX A1

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	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)		
	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?			
Does the informed consent form describe how the informed consent will be obtained			
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)		
	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 <u>not</u> 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 Application for Review **(Sponsor Initiated Study)**	CDUHREC FORM	6
		Version No.	3
		Version Date	09 Jul 2015
		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

APPENDIX A7

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Checklist for Initial Submission for New Application for Review **(Researcher Initiated Study)**	CDUHREC FORM	7
		Version No.	3
		Version Date	09 Jul 2015
		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 (NA)			
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 (if any)			
7. Curriculum vitae of principal investigator			
8. Transmittal Letters to Hospital Medical Director and Department Chair for permission to conduct the research.			
9. Insurance/Indemnity statement (if any)			
10. Technical Committee Approval			
11. Certificate of GCP Training of PI			

Received By: _____ Date:_____
Printed Name and Signature

APPENDIX A8

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Confidentiality Agreement and Conflict of Interest Disclosure Template **(CDUHREC MEMBER)**	CDUHREC FORM	8
		Version No.	3
		Version Date	09 Jul 2015
		Effective Date	09 Jul 2015

CEBU DOCTORS' UNIVERSITY HOSPITAL RESEARCH ETHICS COMMITTEE

Confidentiality Agreement and Conflict of Interest Disclosure

Know all Men by these Presents:

In view of the appointment as member of the Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC) and hereinafter referred to as the ***Undersigned***, and whereas:

the ***Undersigned*** has been asked to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines/

the appointment of the ***Undersigned*** as a member of CDUHREC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

the fundamental duty of a member is to independently review both scientific and ethical aspects of research protocols involving human subjects/ adverse events occurring during the conduct of researches involving human subjects and make a determination and the best possible objective recommendations, based on the merits thereof under review; and

the CDUHREC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

the following terms and conditions covering **Confidentiality and Conflict of Interest** arising in the discharge of said function as a member of CDUHREC are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the CDUHREC to carry out its mandate.

Confidentiality

This Agreement thus encompasses any information deemed Confidential, Privileged, or Proprietary provided to and/ or otherwise received by the ***Undersigned*** in conjunction with and/ or in the course of the performance of his/her duties as a member of the CDUHREC.

Any written information provided to the ***Undersigned*** that is of a Confidential, Privileged, or Proprietary in nature shall be identified accordingly. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of CDUHREC.

As such, the ***Undersigned*** agrees to hold in trust and in confidence all Confidential, Privileged or Proprietary information, including trade secrets and other intellectual property Rights (hereinafter collectively referred to as the "information"). Moreover, the ***Undersigned*** agrees that the information shall be used only for contemplated purposes and none other. Neither shall the said information be disclosed to any third party.

The ***Undersigned*** further agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement. Furthermore, the ***Undersigned*** confirms that her performance of this agreement is consistent with the policies of Cebu Doctors' University Hospital (CDUH) and any contractual obligations owed to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist; however, there is concomitant faith in the ability of the CDUHREC to manage these conflict issues, if any, in such a way that the ultimate outcome of the protection of human subjects remains.

It is the policy of the CDUHREC that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the CDUHREC.

The ***Undersigned*** will immediately disclose to the CDUHREC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in recommendations and voting in respect of such proposals.

Examples of conflict of interest cases may include but it is not limited to any of the following:

□ A member is involved in a potentially competing research program.

□ Access to funding or intellectual information may provide an unfair competitive advantage.

□ A member's personal biases may interfere with his or her impartial Judgment.

Agreement on Confidentiality and Conflict of Interest

[To the Undersigned: Please sign and date this Agreement, if you agree with the terms and Conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the CDUHREC. A copy will be given to you for your records.]

In the course of my activities as a member of the CDUHREC, I will be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information, subject to applicable legislation, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third Party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the Chair not to count me toward a quorum for voting.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____

Printed Name and Signature of Member

Date:_____

APPENDIX A9

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Confidentiality Agreement and Conflict of Interest Disclosure Template **(External Expert)**	CDUHREC FORM	9
		Version No.	3
		Version Date	09 Jul 2015
		Effective Date	09 Jul 2015

Confidentiality Agreement and Conflict of Interest Disclosure

Know all Men by these Presents:

In view of the appointment of Dr. ---------- as an external expert of the Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC) and hereinafter referred to as the ***Undersigned***, and whereas:

the ***Undersigned*** has been asked to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines/

the appointment of the ***Undersigned*** as an external expert of CDUHREC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

the fundamental duty of an external expert is to independently review both scientific and ethical aspects of research protocols involving human subjects/ adverse events occurring during the conduct of researches involving human subjects and make a determination and the best possible objective recommendations, based on the merits thereof under review; and

the CDUHREC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

the following terms and conditions covering **Confidentiality and Conflict of Interest** arising in the discharge of said function of an appointed external expert of CDUHREC are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the CDUHREC to carry out its mandate.

Confidentiality

This Agreement thus encompasses any information deemed Confidential, Privileged, or Proprietary provided to and/ or otherwise received by the ***Undersigned*** in conjunction with and/ or in the course of the performance of his/her duties as an external consultant of the CDUHREC.

Any written information provided to the ***Undersigned*** that is of a Confidential, Privileged, or Proprietary in nature shall be identified accordingly. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of CDUHREC.

As such, the ***Undersigned*** agrees to hold in trust and in confidence all Confidential, Privileged or Proprietary information, including trade secrets and other intellectual property Rights (hereinafter collectively referred to as the "information"). Moreover, the ***Undersigned*** agrees that the information shall be used only for contemplated purposes and none other. Neither shall the said information be disclosed to any third party.

The ***Undersigned*** further agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement. Furthermore, the ***Undersigned*** confirms that her performance of this agreement is consistent with the policies of Cebu Doctors' University Hospital (CDUH) and any contractual obligations owed to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist; however, there is concomitant faith in the ability of the CDUHREC to manage these conflict issues, if any, in such a way that the ultimate outcome of the protection of human subjects remains.

It is the policy of the CDUHREC that no member/external expert may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the CDUHREC.

The ***Undersigned*** will immediately disclose to the CDUHREC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for r review by the Committee, and to abstain from any participation in recommendations and voting in respect of such proposals.

When an external consultant has a conflict of interest, he/she should not notify the Committee.

Examples of conflict of interest cases may include but it is not limited to any of the following:

- □ An external consultant is involved in a potentially competing research program.
- □ Access to funding or intellectual information may provide an unfair competitive advantage.
- □ An external expert's personal biases may interfere with his or her impartial Judgment.

Agreement on Confidentiality and Conflict of Interest

[To the Undersigned: Please sign and date this Agreement, if you agree with the terms and Conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the CDUHREC. A copy will be given to you for your records.]

In the course of my activities as an external expert of the CDUHREC, I will be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information, subject to applicable legislation, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third Party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the Chair not to count me toward a quorum for voting.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____
Printed Name and Signature of External Expert
Date:_____

Noted:

Enrico B. Gruet, M.D.
CDUHREC CHAIR
Date: _____

APPENDIX A10

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Appointment Letter **(TEMPLATE)**	CDUHREC FORM	10
		Version No.	4
		Version Date	03 Aug 2017
		Effective Date	03 Aug 2017

APPOINTMENT

Date: _____

Name: _____
Cebu Doctors' University Hospital
Cebu City

Dear Dr. _____,

This is to inform that you have been appointed as **Chair** of the **Cebu Doctors' University Hospital Research Ethics Committee.**

As Chair of the committee, you are empowered to:
1. Conduct committee meetings;
2. Organize the committee in terms of objectives, terms of reference, schedules, etc.;
3. Evaluate research proposals for ethical issues especially those involving human subjects.

You are requested to update the Clinical Governance Board (CGB) on the activities of the committee.

This appointment is effective _____ to _____.

Thank you very much.

Respectfully yours,

Potenciano S.D Larrazabal III, M.D.
President and Chairman of the Board
Cebu Doctors' University Hospital

cc: Hospital Administrator
Clinical Governance

APPENDIX A11

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Appointment Letter **(TEMPLATE)**	CDUHREC FORM	11
		Version No.	4
		Version Date	03 Aug 2017
		Effective Date	03 Aug 2017

APPOINTMENT

Date: _____

Name: _____
Cebu Doctors' University Hospital
Cebu City

Dear Dr. _____,

This is to inform that you have been appointed as **Deputy Chair** of the **Cebu Doctors' University Hospital Research Ethics Committee.**

Please coordinate with the appointed Chair, _____ for activities and responsibilities related to the committee.

This appointment is effective _____ to _____.

Thank you very much.

Respectfully yours,

Potenciano S.D Larrazabal III, M.D.
President and Chairman of the Board
Cebu Doctors' University Hospital

cc: Hospital Administrator
Clinical Governance Board

APPENDIX A12

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Appointment Letter **(TEMPLATE)**	CDUHREC FORM	12
		Version No.	4
		Version Date	03 Aug 2017
		Effective Date	03 Aug 2017

APPOINTMENT

Date: _____

Name: _____
Cebu Doctors' University Hospital
Cebu City

Dear Dr. _____,

This is to inform that you have been appointed as a **member** of the **Cebu Doctors' University Hospital Research Ethics Committee.**

Please coordinate with the appointed Chair, **_____** for activities and responsibilities related to the committee.

This appointment is effective _____ to _____.

Thank you very much.

Respectfully yours,

Potenciano S.D Larrazabal III, M.D.
President and Chairman of the Board
Cebu Doctors' University Hospital

cc: Hospital Administrator
Clinical Governance Board

APPENDIX A13

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Guidelines	CDUHREC FORM	13
		Version No.	2
		Version Date	08 Jan 2016
		Effective Date	08 Jan 2016

METHODS OF BIRTH CONTROL

I. Policy

1. Women in their reproductive years who will undergo investigational drug trials or procedures should be advised against getting pregnant and should be given options regarding contraception methods.
2. CDUH does not allow the use of implanted hormonal methods, intrauterine devices, intrauterine systems, and surgical sterilization as methods of contraception.

II. The CDUH acceptable forms of contraception include:

1. True abstinence (When this is in line with the preferred and usual lifestyle of the subject. [Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception.
2. Barrier methods of contraception: Condom or Occlusive cap (diaphragm or cervical/vault caps) with spermicidal foam/gel/film/cream/suppository;

RISK BENEFIT ASSESSMENT

III. Policy

The procedures conducted by CDUHREC are based on the provisions of CDUH, national and international guidelines (WHO Operational Guidelines/CIOMS Guidelines/ICH GCP and the National Ethics Guidelines)

IV. Responsibility

The CDUHREC is responsible for evaluating the potential risks and weighing the probability of the risk occurring and the magnitude of harm

that may result among clinical trial participants. The Committee must then judge whether the anticipated benefit, either of new knowledge or of improved health for the research subjects, justifies asking any person to undertake the risks. The Committee cannot approve research in which the risks are judged unreasonable in relation to the anticipated benefits.

V. Definitions

- Benefit: a valued or desired outcome; an advantage
- Risk: the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study
- A characteristic of ethical research is that:
    1. the study is designed so that the risks to subjects are minimized and;
    2. the potential benefits of the research justify the potential risks.

VI. Conducting Risk-Benefit Assessment

- The Committee's assessment of risks and anticipated benefits of each study involves a series of steps. In reviewing a research protocol, the Committee is required to:

1. Identify the risks associated with the research. In biomedical studies, it is required to identify the risks associated with the research as distinguished from the risks of therapies the subjects would receive even if not participating in research.
2. Determine that the risks to subjects will be minimized:
    a. By using procedures that are consistent with sound research design and that did not unnecessarily expose participants to risk.
    b. When appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

    This responsibility also includes evaluating the probability, magnitude, and duration of the risks involved. The Committee is required to consider the physical pain or discomfort as well as the psychological, emotional, economic, legal, or sociological harm, including invasion of privacy, loss of confidentiality, harassment, and lessening of an individual's dignity. Inconveniences such as loss of time or pay must also be evaluated. The Committee is required to consider the potential risks as well as the precautions that will be taken to avoid or minimize potential risks.

3. Identify the probable benefits to be derived from the research. The benefits of research fall into two major categories: benefits to subjects and benefits to society.

Frequently, the research subjects are undergoing treatment for an illness or abnormal condition. This kind of research often involves evaluation of a procedure that may benefit the subject by providing a better understanding of their disorder. Patients or healthy individuals may also agree to participate in research that is either not related to any illnesses they might have or that is related to their conditions but not designed to provide any diagnostic or therapeutic benefit. Such research is designed principally to increase understanding and store of knowledge about human physiology and behavior. Research that has no immediate therapeutic intent may, nonetheless, benefit society as a whole. These benefits take the form of increased knowledge, improved safety, technological advances, and better health. The Committee is required to determine that the anticipated benefits to research subjects and the knowledge researchers expect to gain are clearly identified.

4. Determine that the risks to subjects are reasonable in relation to the anticipated benefits to subjects, if any, and the importance of the knowledge that may be expected to result.
5. Determine if there are 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. In addition, determine whether there are procedures for identifying such individuals.
6. Determine if there are adequate plans to exclude subjects who are vulnerable to injury during the period of withdrawal of active and effective therapy, if that is part of the research design.
7. Ensure that potential subjects will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits.
8. Determine intervals of periodic review [at which time risks and benefits will be reassessed] and whether there should be a data and safety monitoring board.

VII. Checklist for Risk-Benefit Assessment

1. The risk-benefit assessment shall be done by the committee during the initial review and during continuing review (annual/progress report review).
2. The principal investigator (PI) shall submit to the committee a risk-benefit assessment using the Checklist for the Assessment of the Risk/Benefit Version No. 3 dated 09 Jul 2015 (Appendix A5).
3. The lead reviewer shall also complete the Checklist for the Assessment of the Risk/Benefit Version No. 3 dated 09 Jul 2015 (Appendix A5) and this shall be discussed during the committee review.

PEDIATRIC POPULATION

VIII. General Guidelines

1. Pediatric population would include persons below 18 years of age.
2. Research involving the pediatric population should follow general guidelines and SOPs of CDUHREC and this would include National Ethical Guidelines for Health Research 2011.
3. A child or minor may only participate in a research after his/her parent or legal representative has given permission. In default of parents or judicially declared guardians, this order of authority shall be followed:
    a. grandparents;
    b. oldest sibling over 21 years of age, unless unfit or disqualified;
    c. actual custodian over 21 years of age, unless unfit or disqualified.
4. Where the parents are both of minor age or themselves incapacitated to enter contracts giving consent to their children's participation in research, the guidelines on medical treatment of such children may be followed, where the parents as well as a legally capacitated third party both give consent (e.g.. the child's grandparents, physician, or the hospital administrator, as in emergency cases).
5. The child should express assent to participate in the research study in oral and written form.
6. The child's assent should be obtained without coercion.
7. A child's refusal to participate or continue in the research study should be respected.
8. If the child is 7 to 13 years old, he/she will sign an Assent Form which is different from the informed consent form which would be signed by the parents or guardians.
9. The assent form should be reviewed and approved by CDUHREC prior to utilization.
10. If a child is at least 14 years old, he/she can sign on the same informed consent documents signed by his/her parents. Both parent and child must sign.
11. If a child is less than 7 years old, no assent is needed but a sign of dissent on the part of the child must be respected and documented.
12. At any age, any signs of dissent must be observed, and such children who dissent must not be recruited to the study except when they will directly benefit from the research, and the parents consent.
13. Information on the study to which the child's participation is sought and terms such as "research," "study design," "procedures," "adverse effect," "voluntary" should be explained in a manner and language the child understands for purposes of assent and dissent.

APPENDIX A14

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Curriculum Vitae **Template**	CDUHREC FORM	14
		Version No.	3
		Version Date	09 Jul 2015
		Effective Date	09 Jul 2015

Curriculum Vitae

Surname:	Name:
Position: Date of 1st Appointment: Term of Office:	Address:
Educational Background	
Post-graduate degree	
Graduate degree	
Bachelor's degree	
Other qualifications and specializations	
Work Experience	
Present Work Experience	
Previous Work Experience	

CDUHREC Member Signature: _____

Date: _____

APPENDIX A15

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Guidelines	CDUHREC FORM	15
		Version No.	3
		Version Date	09 July 2015
		Effective Date	09 July 2015

TRAINING RECORDS

LAST NAME	FIRST NAME	BASIC COURSES	DATE	VENUE	ORGANIZER	FUNDING SOURCE
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						

	Cebu Doctors' University Hospital **Research Ethics Committee** **(CDUHREC)** **GLOSSARY**

Active principle or ingredient(s) – The substance(s) in a medicinal preparation that brings about the clinical effects expected; the constituent(s) in a medicinal preparation that exert an effect pharmacologically as distinct from the fillers, wetting agents and other excipients included in the preparation. Similar terms used are active pharmaceutical ingredient (API) and bulk active in medicine or active substance in pesticide formulations.

Adverse drug reaction – In the pre-approval clinical experience with new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established, all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to a medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, that is, the relationship cannot be ruled out. Regarding marketed medicinal products, a response to a drug which is noxious and unintended and which occurs at doses normally used in human for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function.

Adverse events – Any untoward or undesirable medical occurrence in a patient or participant in clinical investigation after use or administration of an investigational product. This is not necessarily caused by the treatment. See also adverse drug reaction, serious adverse event, unexpected adverse event and suspected unexpected serious adverse reaction.

AIDS – Acquired Immunodeficiency Syndrome. It is the clinical manifestations in the advanced stages of HIV infection characterized by the breakdown of the immune system.

Alternative medicine or alternative healthcare modalities – Other forms of non-allopathic, occasionally non-indigenous or imported healing methods, though not necessarily practiced for centuries nor handed down from one generation to another. Some alternative healthcare modalities include reflexology, acupressure, chiropractic, nutritional therapy, and other similar methods (Traditional and Alternative Medicine Act, 1997). See also complementary and alternative medicine.

Amendment to the protocol – A written description of a change(s) to, or formal clarification of a protocol and changes on any other supporting documentation made from the originally approved protocol by the research ethics review body after the study has began. See protocol amendment.

Anonymized – When processing of personal data ensures that association or connection with the subject or research participant cannot be traced and determined.

Anonymized sample or data – Biological sample or data that cannot be linked to an identifiable person through destruction of that link to any identifying information about the person who provided the sample or data.

Approval – Favorable or affirmative decision of the Research Ethics Committee following a review of the protocol and other required documents and thus research may already be started and undertaken as set forth by the ethics committee, CPG, the institution, and relevant regulatory terms.

Archival work – Research involving the examination of records or documents.

Assent – Authorization for one's own participation in research given by a minor or another participant who lacks the capability to give informed consent. The assent is a requirement for research, in addition to consent, given by a parent or legal guardian. It is an agreement by an individual not competent to give legally valid informed consent like a child or cognitively impaired person to participate in research. See also child's assent and surrogate assent.

Assisted reproductive technology – All treatment or procedures that include the in-vitro handling of human oocytes and human sperm or embryos for the purpose of establishing a pregnancy. For example, in-vitro fertilization and transcervical embryo transfer, gamete intrafallopian transfer, zygote intrafallopian transfer, tubal embryo transfer, gamete and embryo cryopreservation, oocyte and embryo donation, gestational surrogacy.

Autonomy – The right or power or ability or capacity to govern oneself or make an informed or uncoerced decision. See also collective autonomy and shared autonomy.

Behavioral genetics – The study of genes that determine behavioral traits and phenotypes or study of whether and how behavior traits are inherited.

Behavioral research – Studies that apply social and behavioral theories and principles to understand the actions or reactions of persons in response to external or internal stimuli or to an intervention. In health and medicine, it includes studies on basic biobehavioral mechanisms and social processes that are relevant to public health or disease prevention and promotion, etiology, diagnosis, treatment and rehabilitation. See also social and behavior research.

Belmont Report – A statement of basic ethical principles governing research involving human participants issued by the National Commission for the Protection of Human Subjects in 1978 on the conduct of biomedical and behavioural research involving human subjects including guidelines to ensure that research is conducted in accordance with the principles.

Beneficence – The ethical obligation to maximize benefits and to minimize harms. (CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002). It entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

Benefits – Any direct or indirect good effect or something of positive value to health or welfare from the research study to the participants; something that promotes or enhances well-being. See also direct benefits, indirect benefits and beneficence.

Bias – The systematic tendency of any factors associated with the design, conduct, analysis and evaluation of the results of a clinical trial to make the estimate of a treatment effect deviate from its true value.

Bioavailability – The rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action. For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action (Food and Drug Administration, US Department of Health and Human Services. (2009). Code of Federal Regulations, Food and Drugs, 21(5), Subchapter D, Part 320. USA: FDA).

Bioequivalence – The absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Where there is an intentional difference in rate (e.g., in certain extended release dosage forms), certain pharmaceutical equivalents or alternatives may be considered bioequivalent if there is no significant difference in the extent to which the active ingredient or moiety from each product becomes available at the site of drug action.

Biologic or biological product – Any attenuated or inactivated virus or bacteria, or subcomponents attached to adjuvants, toxoids, hyperimmune serum and analogous products applicable to diagnosis, prevention, treatment, or cure of diseases or injuries to man, obtained or **Derived from living matter** – animals, plants

or microorganisms or parts thereof. It includes preparations primarily designed to develop a type of immunity or preparations that are concerned with immunity.

Biosafety Committee – An institutional committee that reviews and approves research projects involving the use of genetically modified organisms and biohazardous materials, including human tissue samples. The committee is in-charge of registration of clinical trials on recombinant DNA, pathogens, infectious agents, human and human primate materials, established cell lines, biological toxins, and human gene therapy/pathogen. It ensures that all activities involving these agents are conducted in a safe manner and in conformity with generally accepted standards to protect the researchers, laboratory workers, human research subjects, the public and the environment, including laboratory animals and other organisms, and to prevent damage to property.

Biosimilar medicines – Follow-on versions of original biological medicines. They are independently developed after the patent protecting the original product has expired. Biosimilar medicines are intended to have the same mechanism of action as the original biological medicines, and are designed to treat the same diseases as the innovator product. The name, appearance and packaging of a biosimilar medicine differ to those of the biological reference medicine.

Blinding – Also known as masking, is a procedure in which one or more parties of the trial are kept unaware of the treatment assignment(s). Single blinding usually refers to the subjects being unaware which treatment he/she is receiving, while double-blinding usually refers to the subjects, investigator(s), monitor(s), and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

Bureau of Food and Drug – The national regulatory agency under the Department of Health that is mandated to guarantee the safety and effectiveness of all pharmaceutical products, biologics, vaccines, and medical devices used in the diagnosis, treatment, and prevention of disease. It is now called the Philippine Food and Drugs Authority by virtue of Republic Act 9711 of 2009.

Carrier testing – A test to identify individuals who carry recessive genes; testing designed for healthy people who have no symptoms of disease, but who are known to be at high risk because of family history.

Case-control study – Type of investigation that attempts to look backward in time to identify characteristics that may have contributed to disease development by comparing responses of cases or those affected with the disease and controls or those unaffected persons. It is a study comparing persons with a given condition or disease (the cases) and persons without the condition or disease (the controls) with respect to antecedent factors (IRB Guidebook, US Department of Health and Human Services.

Cellular metabolites – The molecular substrates and products of various cellular processes.

Child's assent – An agreement or expressed willingness of a minor to take part in the research when a child cannot give full consent. Children often can understand some, but not all parts of a research study. Assent is the child's way of saying that he/she agrees to take part in the research to the degree that he/she understands it. It differs from consent since consent is the permission given by a parent or guardian to a child to take part in the research. Older children or youth may give their own consent if they are mature enough to completely or totally understand the research, and the consent or decision to participate is freely given with the premise that they are given enough information to make a choice and they understood the information provided to them.

Clinical equipoise – A state of clinical equipoise means that on the basis of available data, a condition of genuine uncertainty on the part of the clinical investigator(s) and/or a community of medical experts exists regarding the comparative therapeutic merits of each arm in a trial. Thus, they would be content to have their patients or clients pursue any of the treatment strategies being tested since none of them have been clearly established as preferable.

Clinical research – A study undertaken involving a particular person or group of people with the purpose of increasing knowledge and determining how well treatment or diagnostic test works in a particular patient population. Patient-oriented research involves a particular person or group of people or uses materials from humans. This research can include: studies of mechanisms of human disease; studies of therapies or interventions for disease; clinical trials; and studies to develop new technology related to disease. Epidemiological and behavioral studies examine the distribution of disease, the factors that affect health, and how people make health-related decisions.

Clinical trial – A planned scientific research or study among human volunteers to determine the effects of treatment or diagnostic test on their safety, efficacy, and its effect on quality of life. It is also a systematic study on pharmaceutical products in human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reactions to investigational.

Cloning human genes – Transfer of human DNA sequences of interest into nonhuman cells with the purpose of expression, genetic manipulation, and amplification.

Cluster Ethics Review Committee – An ethics review committee shared by (common to) several institutions where the volume of researches and resources do not make it feasible to have an ethics committee in each institution. The functions of the cluster committee and the respective institutional responsibilities shall be contained in a memorandum of agreement amongst the institutions concerned.

Cognitively impaired – Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g.,

mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished.

Cohort – A group of individuals who have common traits or identical or similar in many characteristics such as birth year.

Cohort study – A longitudinal study of the same group of people observed over time. This is a type of investigation in which exposure is assessed among the same unaffected persons and subjects and then observed for subsequent development of the disease over time.

Collective autonomy – The exercise of decision-making by an indigenous people (IP) community as an autonomous group which decisionmaking is usually characterized by dialogue, consultations and consensus building among the group members.

Comparator (product) – An investigational or marketed product (i.e., active control), or placebo, used as reference in a clinical trial a pharmaceutical or other product (which may be a placebo) used as a reference in a clinical trials (WHO, Guidelines for Good Clinical Practice for Trials of Pharmaceutical Products).

Compassionate use – Permission given by the national regulatory authority in particular the Bureau of Food and Drugs/Food and Drug Administration to make investigational new drugs and devices that are not yet approved for marketing for use of very or terminally ill patients having no other treatment alternatives.

Compensation – Payment and/or medical care received or provided to subjects injured in research. Payment received by the research participants may include reimbursement for lost earnings, travel costs and other expenses incurred as a study participant, as recompense for inconvenience and time spent. It does not include remuneration for participating in the study. See remuneration.

Competence – Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.

Complementary and alternative medicine (CAM) – A group of diverse medical and healthcare systems, practices, and products that are not generally considered part of conventional medicine. Conventional medicine (also called Western or allopathic medicine) is medicine as practiced by holders of M.D. (medical doctor) and D.O. (doctor of osteopathy) degrees and by allied health professionals, such as physical therapists, psychologists, and registered nurses.

Conception – The period from fertilization to form a zygote up to birth of the infant; – The period of pregnancy beginning from implantation of the fertilized ovum up to birth of the fetus.

Conditional approval – Approval of the protocol by the Ethics Committee to proceed after certain conditions or modifications set by the EC are met.

Confidentiality – The expectation from respondents and research participants that data or information relayed or communicated are kept secret. It also pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

Conflict of interest – A conflict of interest arises when a member(s) of the Ethics Committee holds interests with respect to specific applications for review that may jeopardize his/her ability to provide free and independent evaluation of the research focused on the protection of the research participants. Conflict of interests may arise when an EC member has financial, material, institutional or social ties to the research.

Contract research organization – Also called Clinical Research Organization, a service organization with whom a drug or device manufacturer or sponsor contracts to perform clinical trial related activities which may include, among others, development of protocols, recruitment of patients, collection and analyis of data, and preparation of application documents to a national regulatory agency. It is a person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions. Likewise, the US FDA defines a CRO as "a person [i.e., a legal person, which may be a corporation] that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the FDA."

Control – The standard by which experimental observation are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is either given a standard treatment for the illness or a placebo.

Controlled trials – A trial in which one group of participants is given an experimental drug, while another group (the control group) is given either a standard treatment for the disease or a placebo; a prospective clinical trial comparing two or more treatments, or placebo and treatment(s) in similar groups of patients or within patients. A controlled trial may or may not use randomization to assign patients to groups, and it may or may not use blinding to prevent them from knowing which treatment they get.

Conventional medicine – Also referred to as Western medicine, biomedicine, and allopathic medicine; A system in which medical doctors and other healthcare professionals treat symptoms and diseases using drugs, radiation, or surgery; also

called allopathic medicine, biomedicine, mainstream medicine, orthodox medicine, and Western medicine.

Counseling – Non-coercive interaction between a health professional and a patient or client and/or family that is meant to clarify personal values and priorities, healthcare options, expectations, risks, benefits, and resources in order to help in decision-making. It needs to be offered prior to sensitive testing (pre-test counseling) and/or after testing (post-test counseling) for comprehensive care.

Criminal violence – Behaviors by individuals that intentionally threaten, attempt, or inflict physical harm on others (National Research Council's Panel on the Understanding and Control of Violent Behavior, citing Reiss and Roth, 1993, p. 2).

Cultural bias – Prejudice based on community values and traditions.

Culture – The way of life of groups of people that is defined by mores, shared values, traditions and sociopolitical structures and institutions.

Debriefing – The process of obtaining information about an experience from an individual who has participated in, or observed particular events. It is also "giving subjects previously undisclosed information about the research project following completion of their participation in research. Note that this usage, which occurs within the behavioral sciences, departs from standard English, in which debriefing is obtaining rather than imparting information.

Deception – An act characterized by dishonesty, fraud, trickery or sham for the purpose of manipulating another person into making a decision that he or she would not have made otherwise.

Declaration of Helsinki – A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries. This is World Medical Association's (WMA) response to the Nuremberg Code. The Declaration of Helsinki was adopted by the WMA in 1964 and has been amended five times, at regular intervals. A note of clarification about placebo-controlled trials was added in 2002.

De-identified – Removal of elements connected with data which might aid in associating those data with an individual. Examples include name, birth date, social security number, home address, telephone number, e-mail address, medical record numbers, health plan beneficiary numbers, full-face photographic images.

Deoxyribonucleic acid (DNA) – The fundamental substance of which genes are composed. It is an antiparallel double helix of nucleotides (having deoxyribose as their sugars) linked by phosphodiester (sugarphosphate) bonds to adjacent nucleotides in the same chain and by hydrogen bonds to complementary nucleotides in the opposite chain.

Deoxyribonucleic acid sequencing – Method of analyzing the base sequence composition and order of a DNA sample using chemical tagging and physical measurements.

Descriptive study – A study that is not truly experimental in nature such as quasi-experimental studies, correlational studies, record reviews, case histories, and observational studies.

Device – An instrument, apparatus, implement, machine, invention, implant, in vitro reagent, or other article intended for use in the diagnosis, treatment, or prevention of disease. A device is intended to affect the structure or function of the body, but it does not function through chemical action within or on the body.

Diagnostic – Procedure or technique used in the identification of a disease or determination of the health status of an individual. Professionally accepted level and type of examination to determine a patient's health condition.

Direct benefits – Gain or advantage or good effect derived by a research subject immediately or closely arising from the use of an experimental substance or device. See also benefits.

Disapproval – A negative action of the Ethics Committee on the protocol. The study cannot be implemented if it has been disapproved by the Committee.

Disclosure of data – The giving of information in connection with proposed research undertaking or the sharing of the results of the study especially as they pertain to the individual's or the family's health situation.

Discontinuation – The deed of terminating participation in a clinical trial by a research subject (dropout) earlier than the completion of all protocolrequired terms. In some case, the discontinuation may be initiated by the investigator for a cause or inability to locate or follow up subject or by the sponsor.

Disease allele – One of the variant forms of a disease gene at a particular locus, or location on a chromosome. Different alleles produce variation in inherited characteristics such as hair color or blood type. In an individual, one form of the allele (the dominant one) may be expressed more than another form (the recessive one).

Domestic violence – Or domestic abuse, is brutality or cruelness committed by one family /household member against another. It is violent conflict between household members resulting to physical harm, sexual assault, or fear of physical harm and other vicious action.

Double blinding – One in which neither the subject nor any of the investigator or sponsor staff who are involved in the treatment or clinical evaluation of the subjects are aware of the treatment received.

Drug – A substance used as medication or used in the diagnosis, cure, mitigation, treatment or prevention of disease.

Dual-use research – Scientific studies undertaken for beneficial purposes but at the same time with harmful applications [WHO. (2009). Bulletin of the World Health Organization, 87(9)]. The legitimate technologies that are studied to promote scientific advances likewise create potential risks. The knowledge, tools, and techniques gained and used in these biotechnology researches can be utilized misappropriately or wrongly to create biological weapons or for bioterrorism.

Duress – Wrongful and usually unlawful compulsion (as threats of physical violence) that induces a person to act against his or her will: "coercion".

Effectiveness – The degree to which a diagnostic test or treatment produces a desired result in patients in the daily practice of medicine.

Efficacy – An indication that the therapeutic effect of a clinical trial intervention is acceptable; that is, at least as good as the control intervention or standard of care to which it is compared. It is the ability of a treatment modality to produce an effect to alleviate a disease. This is the "degree to which a diagnostic test or treatment produces a desired result in patients under the idealized circumstances of a clinical trial."

Eligibility criteria – The list of criteria or conditions that guide enrollment of participants into a study. The criteria describe both inclusionary and exclusionary factors (e.g., inclusion criterion – participants must be between 55 and 85 years old; exclusion criterion – must not take drug X three months prior to the study).

Embryo – The stage of human development following implantation (starting 10-14 days), when the primitive streak begins to form up to fetal stage.

Energy therapy or medicine – One of five domains of "complementary and alternative medicine" (CAM) identified by the National Center for Complementary and Alternative Medicine (NCCAM) in the United States. There are two categories namely: biofield therapies, and bioelectromagnetic-based therapies. The former are therapies intended to affect energy fields that purportedly surround and penetrate the human body such as Qigong, Reiki, and Therapeutic touch. The later therapies involve the use of electromagnetic fields, such as pulsed fields, magnetic fields, or alternating-current or directcurrent fields.

Epidemiologic research – Investigative studies intended to establish "the distribution and determinants of disease frequency in human populations." It is a study undertaken on a systematic and rigorous basis to generate new knowledge regarding the determinants of the incidence of diseases as well as their related risk factors, etiology and causation.

Epidemiology – The basic medical science that focuses on the distribution and determinants of disease frequency in human populations.

Equipoise – A state in which an investigator is uncertain about which arm of a clinical trial would be therapeutically superior for a patient. An investigator who has a treatment preference or finds out that one arm of a comparative trial offers a clinically therapeutic advantage should disclose this information to subjects participating in the trial

Ethical clearance – A certification that a research proposal has complied with ethical requirements; action of an ethics review committee on a research protocol that signifies approval and permission to proceed with the research.

Ethical principles – "Refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions" (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. US NIH, Office of Human Research Subjects). Three basic principles, among those generally accepted, that are particularly relevant to the ethics of research Involving human subjects are the principles of respect of persons, beneficence and justice. See also respect of persons, beneficence and justice, autonomy and non-maleficence.

Ethics review – The evaluation of a research protocol by an ethics review committee to promote the safety and protection of the dignity of human participants. This is a systematic process by which this independent committee evaluates a study protocol to determine if it follows ethical and scientific standards for carrying out biomedical research on human participants. It checks if the protocol complies with the guidelines to ensure that the dignity, rights, safety and well- being of research participants are promoted.

Ethics review committee – Also called research ethics committee (REC), institutional ethics review board (IERB), independent ethics committee (IEC) or institutional review board (IRB); a committee constituted to review the ethical aspects of a research proposal and its possible implementation. This is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human participants involved in a trial and to provide public assurance of that protection.

Exclusion criteria – Factors utilized to determine whether an individual is ineligible for a clinical trial or research study.

Expedited review – An ethics review of research protocol by the IRB chair or a designated voting member or subgroup of voting members rather than by the entire IRB. This is done for some research involving no more than minimal risk and maybe for minor

changes in approved research, annual renewals of approved projects, approval of protocol amendments, research conducting health record review, and for confirming changes required by the ethics committee for approval of the protocol.

Experimental design – The structure of research, identifying the various elements of a research project and how they relate to one another. The structure specifies treatment conditions or independent variables, the variables which are planned to be measured or the dependent variables and methods of assigning subjects to groups wherein these subjects are randomly assigned to treatment conditions.

External Expert – An expert who gives advice(s), comment(s) and suggestion(s) upon review of the study protocols with no affiliation to the institute(s) or investigator(s) proposing the research proposal.

Family studies (in genetic research) – Mapping of disease genes through the establishment of genetic linkage within a family.

Feasibility - Possibility or likelihood to be accomplished or implemented.

Fetus – Stage of human development when the first neural cells start differentiating, that is, starting from six to eight weeks up to birth.

Focus group discussion (FGD) – Qualitative method of eliciting in-depth information on concepts and perceptions on selected topics or issues by having a structured and/or unstructured group discussion of 6–12 persons facilitated by a trained professional.

Food and Drug Administration (FDA) – The new name and the reorganized and strengthened Bureau of Food and Drugs by virtue of the "Food and Drug Administration (FDA) Act of 2009" or Republic Act No. 9711 of August 18, 2009, "An act strengthening and rationalizing the regulatory capacity of the Bureau of Food and Drugs (BFAD) by establishing adequate testing laboratories and field offices, upgrading its equipment, augmenting its human resource complement, giving authority to retain its income, renaming it the Food and Drug Administration, amending certain sections of Republic Act No. 3720, as amended, and appropriating funds thereof."

Full board review – Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in non-scientific areas.

Gamete – Cell that fuses with another cell during conception; a reproductive cell containing half of the genetic material necessary to form a complete human organism. During fertilization, male (sperm) and female (ovum) gametes join together, producing a zygote.

Gender – Socially defined feminine or masculine roles, attitudes, and values.

Gender bias – Partiality, unfairness, prejudice manifested towards an individual or group of individuals based on sex and sexual orientation.

Gender-sensitive counseling – Counseling that includes awareness of existing gender differences, issues and inequality in its framework for interaction with the patient or client.

Gender sensitivity – The ability to perceive existing gender differences, issues, and inequality and to incorporate these into strategies and actions.

Gene – The functional and physical unit of heredity passed from parent to offspring. Genes are pieces of DNA, and most genes contain the information for making a specific protein.

Gene activity – The degree of expression of a particular gene or levels of transcription.

Gene testing – Analysis done on affected persons or carriers within family already identified because of a history of high risk for having or transmitting a specific genetic disorder.

Genetic association studies – Describes a situation in which a particular allele is found either significantly more or less frequently in a group of affected individuals than would be expected from the frequency of the allele in the general population from which the affected individuals were drawn.

Genetic counseling – The provision of information and assistance to affected individuals or family members at risk of a disorder that may be genetic, concerning the consequences of the disorder, the probability or developing or transmitting it, and the ways in which it may be prevented or ameliorated.

Genetic research – The study of the structure and functions of individual genes, genetic variation in human populations, and the applications of genetics in diagnosis and patient care.

Genetic screening – A population-based method for identifying a subset of individuals at risk of developing or of transmitting a specific genetic disease or disorder.

Good clinical practice (GCP) guidelines – An international ethical and scientific quality standards for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with these standards provide public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the International Declaration of Helsinki, and that the clinical trial data are credible (CPMP/ICH/135/95). These are standards and procedures for clinical trials that encompass the design, protocol approval, monitoring, termination, audit, analyses, reporting, and documentation

of human studies. It defines the responsibilities and activities of the sponsor, principal investigators and monitor involved in the clinical trials. The GCP ensures that the studies are scientifically and ethically sound, and all the clinical properties of the product under investigation are properly documented.

Good laboratory practices – Standards and procedures whereby a laboratory achieves a defined consistent, and reliable standard in performing laboratory tests and activities.

Good manufacturing practice guidelines – National standards and regulations for licensing of laboratories engaged in the manufacture and production of drugs, vaccines and other pharmaceuticals intended for human administration or consumption. It is that part of quality assurance which ensures that products, including vaccines and biologics are consistently produced and controlled to quality standards appropriate for their intended use, including all phases of vaccine clinical trials, and as required by registration and marketing authorization. For supplementary guidelines for the manufacture of investigational pharmaceutical products for human studies.

Government-sponsored health research – Health research that is undertaken using government funds or resources.

Guardian – One who is legally responsible for the care and management of the person or property of an incompetent person or a minor or someone who can make important personal decisions in behalf of another person. See also legally authorized representative.

Guidelines – A set of rules or recommendations intended to effect a course of action.

Health equity – The absence of systematic disparities in health (or in major social determinants of health) among groups with different levels of underlying advantage/disadvantages, e.g., wealth, power, prestige.

Health research – Generation of new knowledge (biomedical, clinical, social) to identify and deal with health problems, health systems and policies as well as those that impact on health such as socioeconomic, environment, energy and agricultural policies. This is composed of investigational activities that aim to generate data that shall contribute to improvement in the diagnosis, prevention and management of diseases, and in the delivery of care and for the enhancement of the quality of life of individuals and health conditions in communities.

Herbal medicine research – Study undertaken to generate new knowledge regarding the use of herbs and plants to prevent and treat diseases and ailments or to promote health and healing.

Herbal medicines – Finished, labeled medicinal products that contain, as active ingredient(s), serial or underground part(s) of plant or other materials or combination thereof, whether in the crude state or as plant preparations. Plant materials include juices, gums, fatty oils, essential oils, and other substances of this nature. Herbal medicines, however, may contain excipients in addition to the active ingredient(s). Medicines containing plant material(s) combined with chemically defined active substances, including chemically defined isolated constituents of plants, are not considered herbal medicines.

High-risk group – Social group known to have a high prevalence of a health problem because of shared environmental, occupational, nutritional or genetic factors including practices that contribute to ill-health.

HIV (human immunodeficiency virus–type 1) – Viral infectious agent that causes destruction of cellular immunity in individuals acquired through tissue fluid transmission from infected persons.

HIV and AIDS research – Study undertaken on a systematic and rigorous basis to generate new knowledge regarding the prevention and/or treatment of HIV and AIDS.

HIV test – Immunology-based laboratory test that establishes the presence of HIV infection in an individual.

Homeopathy – A system of medicine which involves treating the individual with highly diluted substances, given mainly in tablet form, with the aim of triggering the body's natural system of healing. Based on their specific symptoms, a homeopath will match the most appropriate medicine to each patient.

Human subjects – See research participants and respondent.

Hypothesis – A tentative explanation for an observation, phenomenon, or scientific problem that can be tested by further investigation.

Incapacity – A person's mental status and means, inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence.

Inclusion criteria – The factors used to judge a participant's eligibility to be part in a trial or research. These factors are justified by the purpose of the researcher in conducting the research. See also eligibility criteria.

Incompetence – Technically, a legal term meaning inability to manage one's own affairs.

Identifiable personal information – Information on a particular person who expects that such information shall be held in privacy such as culture, age, religion and social

status, as well as their life experience and educational, medical, family, relationship, or employment histories.

Indigenous knowledge (IK) – The information base for a society, which facilitates communication and decision-making. Indigenous information systems are dynamic, and are continually influenced by internal creativity and experimentation as well as by contact with external systems; the local knowledge – knowledge that is unique to a given culture or society. IK contrasts with the international knowledge system generated by universities, research institutions and private firms. It is the basis for local level decision-making in agriculture, healthcare, food preparation, education, natural resource management, and a host of other activities in rural communities.

Indigenous peoples (IP) – Distinct communities, the land on which they live and the natural resources on which they depend are inextricably linked to their identities and cultures (World Bank). These are cultural groups that are continuously associated with a given geographic area and who formerly or currently inhabit the area and are independently or largely isolated from the influence of the existing governance, and have maintained, at least in part, their distinct cultural, social, organizational and/or linguistics attributes or practices so that they continue to be different in some degree from the prevailing or main culture of the country.

Indirect benefits – An unintended or unlikely gain or advantage or good effect from participating in a research. See also benefits and direct benefits.

Information in the public domain – See public domain information.

Informed consent – The process of obtaining approval to participate in an investigative study or permission to a medical intervention. Consent must be freely given in verbal, video or written form. An important part of the process is the adequacy, appropriateness, and timeliness of the information for decision-making; It is "a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation."

Institutional Ethics Review Committee or Board – Ethics review committee organized in a particular institution to ensure that health research is conducted according to international ethical principles, national and institutional guidelines. This is an independent body constituted of medical, scientific, and non-scientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

Intellectual property rights (IPR) – The Convention establishing the World Intellectual Property Organization (WIPO), concluded in Stockholm on July 14, 1967 (Article 2(viii)), that states, "intellectual property shall include rights relating to: literary, artistic and scientific works, performances of performing artists, phonograms and broadcasts, inventions in all fields of human endeavor, scientific discoveries, industrial designs, trademarks, service marks and commercial names and designations, protection against unfair competition, and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

Intellectual property sharing – To participate in, use, enjoy, or experience jointly or in turns the property that derives from the work of the mind or intellect or an idea, invention, trade secret, process, program, data, formula, patent, copyright, or trademark or application, right, or registration relating thereto (Merriam-Webster's Dictionary of Law (c), 1996).

Intentional environmental exposure study – A controlled experiment that deliberately exposes human subjects to an agent (such as a chemical) found in the environment. The investigators control the amount of exposure (or dose), the length of the exposure period, the route of exposure (dermal, oral, respiratory), and other variables, such as the age, health, diet and activity of participants. Researchers carefully monitor the subjects' clinical signs and symptoms, and collect blood, urine, and other biological samples for biomedical testing (such as tests for the presence of a chemical or its metabolites, blood counts, etc.).

Intentional human dosing studies – Scientific studies that deliberately or purposely and calculatedly expose research subjects to environmental agents.

Interaction – The chemical or biological reactivity of the active principle or herbal preparation with other administered substances.

International collaborative research - Joint or shared conduct of research by at least two countries or governments (e.g., Philippines and one other foreign government/country). It is an investigative work conducted at an international level, with involvement by investigators coming from different countries.

Intervention – A drug product or medicinal product, device, test articles, therapy, or process being investigated in a research or clinical study that is hypothesized to have an effect on the outcome(s) of the research being conducted.

Intervention (interventional) study – A research that includes measures or technology to purposely affect the course of an illness. These measures aim to improve health or condition of an individual or a group of individuals or change the course of disease.

Invasive procedure – Biological sampling using a method involving intrusion into the human body, such as obtaining a blood sample by using a needle and syringe (UNESCO International Declaration on Human Genetic Data).

Investigational or study product – A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use; Department of Health Administrative Order No. 47-A series of 2001, Rules and regulations on the registration including approval and conduct of clinical trials, and lot or batch release certification of vaccines and biologic products). Developmental or investigational vaccine or biologic refers to vaccine or biologic product that needs or is undergoing pre-clinical and clinical studies to determine safety, potency, efficacy and therapeutic/prophylactic value. It refers to a vaccine or biologic product which has never been registered or licensed by the national regulatory authorities, in particular FDA.

Investigator – A person responsible for the conduct of the critical trial at a trial site. If trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and be called the principal investigator. It is a person responsible for the trial and for the rights, health and welfare of the subjects in the trial. The investigator should have qualifications and competence in accordance with local laws and regulations as evidenced by an upto- date curriculum vitae and other credentials.

Justice – The ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. In the ethics of research involving human subjects, the principle refers primarily to distributive justice, which requires the equitable distribution of both the burdens and the benefits of participation in research (CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002), requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

Legally authorized representative – One that represents another or others, upon their permission in accordance with law, in a special capacity (Merriam-Webster's Dictionary of Law (c), 1996). This is the person who has authority, under the law, to stand for, or make decisions in behalf of another.

Legally competent person – Qualified or fit to perform an act, in accordance with law, free from addiction or mental defects that renders one incapable of taking care or oneself or one's property (Merriam- Webster's Dictionary of Law (c), 1996).

Linkage analysis – Gene hunting technique that traces patterns of disease in high risk families for the purpose of locating a disease-causing gene by identifying genetic

markers of known chromosomal location that are co-inherited with the trait of interest.

Material transfer agreement – An agreement between the source institution (or community) and the recipient institution (agency or community) that defines responsibilities and ownership of the material under study.

Medical device – A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.

Minimal risk – A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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.

Minimal toxicity data – The lowest dose of the preparation that shall elicit toxicity signs and symptoms in human participants or in animals.

Minors – Persons who have not yet reached the age of majority, 18 years old.

Monitor – A person appointed by and responsible to the sponsor or contract research organization for monitoring and reporting progress of the trial and for verification of data.

Monitoring – The process of checking or scrutinizing research participants' health status during a clinical trial, and/or to oversee the progress of a trial or research and/or to check researcher's compliance with the protocol and regulatory requirements with in which the protocol is given ethical approval.

Moral agent – Person competent of acting with reference to what is ethical or what is right and wrong; a sentient individual whose acts impact on others and are affected by the act of others.

Multicenter trial – A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.

Multifactorial inheritance – Heredity characterized by the involvement of several genes and environmental factors.

Mutagenicity – The capacity of a chemical or physical agent to cause genetic alterations.

Nanomedicine – An "offshoot of nanotechnology, that refers to highly specific medical intervention at the molecular scale for curing disease or repairing damaged tissues,

such as bone, muscle, or nerve. A nanometer is one-billionth of a meter, too small to be seen with a conventional lab microscope. It is at this size scale – about 100.

Nanometers or less – that biological molecules and structures inside living cells operate. It is the application of nanotechnology in biomedicine for repair, construction, control and monitoring of biological systems on a molecular scale. It utilizes various different engineered nanoparticles.

Nanotechnology – The understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering, and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale.

National healthcare delivery system – The country's total structures both private and public organizations, agencies, and individuals, including policies and mechanisms, that provide healthcare to individuals and communities.

National Unified Health Research Agenda (NUHRA) – An evolving plan that lists the priority research areas and topics that need to be addressed with in a five-year period based on global and national initiatives influencing the health sector like the Millennium Development Goals, the Medium Term Philippine Development Plan, the Health Sector Reform Agenda, and the National Objectives for Health and the Science and Technology Agenda. The list is drawn from multisector regional and national consultations involving representations from the government, academe, research institutions, professional organizations, non-government agencies, civil society and funding agencies.

Non-disclosure of data – The withholding of or refusal to reveal information derived from research.

Non-invasive procedure – Biological sampling using a method which does not involve intrusion into the human body (e.g., oral smears).

Non-maleficence – This principle proscribes the deliberate infliction of harm on persons. It is the duty of the researcher(s) to do no harm and to prevent harm. It is further defined as "the principle of doing, or permitting, no foreseeable harm including infringement of rights as a consequence of the research. It is the principle of doing no harm in the widest sense."

North-South research collaboration – The relationship or interaction between the developed and developing countries or rich and poor countries.

Nuremberg Code – A "code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects. It is a series of 10 principles for permissible

medical experiments involving human subjects, articulated in 1947 as part of the judgment in Nuremberg against some of the physicians who led the experiments on inmates of the Nazi concentration camps.

Participatory research – Research that involves the participation of the investigator in the activities of the research population. It could also involve research subjects in the definition of the research agenda, the conduct of research, monitoring and evaluation, and dissemination of results.

Patent – Government instrument that assigns ownership of a product or creative work that is accompanied by certain rights.

Peer review – The examination of the research design and methodology of a research by expert(s) in the same field or similar level of expertise.

Permit for clinical investigational use (PCIU) – A registration document issued by the FDA for the purpose of allowing the conduct of Phase I, Phase II and Phase III clinical trials of developmental or investigational biologic product in the country.

Perspective (**Critical)** – This perspective is recursive and focused on bringing about change in practices. Researchers utilizing this perspective generally have an agenda for social change. Studies under this perspective begin with an important stance about social issues and are aimed at creating political debate and discussion to bring about change. It is practical and collaborative.

Perspective (**Interpretive)** – This perspective holds that in seeking to understand their world, people develop subjective meanings of their experiences which are varied and multiple. The researcher then looks into the complexity of views rather than reducing them to a few ideas. Open-ended questions suit this perspective. Historical and social contexts are important to consider. The assumption is that the basic generation of meaning is always resulting from the interaction within social groups.

Perspective (**Positivist)** – This is sometimes referred to as the "scientific method" and is likewise called quantitative research, empirical science or positivist/post positivist research. This reflects a deterministic philosophy which says that causes probably determine effects or outcomes. It is reductionist because it reduces ideas into discrete sets to test in hypotheses and research questions. It utilizes careful observation and measurement of objective reality. Most of research in this perspective starts with test of a theory.

Pharmacodynamics – The study of what a drug does to the body.

Pharmacogenetics – The field of biochemical genetics concerned with drug responses due to genetically controlled variations.

Pharmacokinetics – The study of what the body does to a drug.

Phase I clinical trial – The first trial(s) of a new active ingredient or new formulations in human, often carried out in healthy volunteers. Their purpose is to establish a preliminary evaluation of safety, and a first outline of the pharmacokinetic and, where possible, a pharmacodynamics profile of the active ingredients in humans.

Phase II clinical trial – Trial(s) performed in a limited number of subjects, often at a later stage of a comparative (e.g., placebo-controlled) design. Their purpose is to demonstrate therapeutic activity and assess short-term safety of the active ingredient in patients suffering from a disease or condition for which the active ingredient is intended. This phase also aims at the determination of appropriate dose ranges or regimens and (if possible) clarification of dose- response relationships in order to provide an optimal background for the design of extensive therapeutic trials.

Phase III clinical trial – Trial(s) in larger (and possibly varied) patient groups with the purpose of determining the short- and long-term safety/ efficacy balance of formulation(s) of the active ingredient, and of assessing its overall and relative therapeutic value. The pattern and profile of any frequent adverse reactions must be investigated and special features of the product must be explored (e.g., clinically relevant drug interactions, factors leading to differences in effect such as age). These trials should preferably be of a randomized double-blind design, but other designs may be acceptable (e.g., long-term safety studies).

Phase IV clinical trial – Studies performed after marketing of the pharmaceutical product. Trials in this phase are carried out on the basis of the product characteristics on which the marketing authorization was granted and are normally in the form of the post-marketing surveillance, or assessment of therapeutic value or treatment strategies. Although methods may differ, these studies should use the same scientific and ethical standards as applied in pre-marketing studies. After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations, among others, are normality considered as trials for new pharmaceutical products.

Philippine Health Research Ethics Board – Created on 1 March 2006 through DOST Special Order No. 091 series of 2006 as a policy-making body for research ethics in the Philippines. Philippine National Health Research System – Formally organized in 2004, it was conceptualized in support of a vibrant, dynamic, and responsible health research community working on a unified health research agenda with enhanced cooperation between the Department of Health, the Department of Science and Technology, and the Commission on Higher Education. The Philippine Health Research Ethics Board is one of the six groups working under its Governing Council.

Placebo – A substance that is not biologically active, does not interact with other substances nor is it expected to affect the health status of an individual. It is an inactive pill, liquid, or powder that has no treatment value. In clinical trial, experimental

treatments are often compared with placebos to assess the experimental treatment's effectiveness. In some studies, the participants in the control group will receive a placebo instead of an active drug or experimental treatment.

Placebo-controlled trials – Clinical trials that assign the administration of a placebo to the control group while the test drug is given to the experimental group.

Population-based genetics – The study of the distribution of genes in populations and of how the frequencies of genes and genotypes are maintained or changed.

Pre-clinical trials or study – Investigation of the pharmacologic properties of a drug or preparation done in animals prior to human studies. Pre-clinical studies shall include pharmacodynamics, pharmacokinetics, and toxicity studies.

Predictive testing – Determination of the presence of disease-associated genes prior to the onset or manifestation of the disease.

Predisposition or risk testing – Determination of genetic parameters in an individual associated with increased risk of disease.

Prenatal testing – Determination of whether a fetus has (or probably has) a designated condition for which an increased risk is indicated by later maternal age, family history, or other well-defined risk factors.

Principal investigator – The chief or person primarily responsible for the implementation of a research project. See also investigator.

Prior dose finding – Quantity or dosage of the herbal medicine established in earlier studies or practice to be effective.

Privacy – The right or claim or state or ability or condition of an individual or group or institution to conceal or seclude or hide themselves or information about themselves and thus reveal or expose themselves selectively. It is a conceptual space defining the individual's boundary as a person, intrusion of which is limited by human rights and by law. It is right to determine when, how, and to what extent information about someone is communicated to others.

Product adulteration – Presence of foreign substances or impurities in the drug preparation that results in dilution or loss of its efficacy.

Prophylactic – Professionally accepted level and type of preventive management to prevent the occurrence of a particular health condition.

Prospective study – Research that watches for outcomes, such as the development of a disease, during the study period and relates this to other factors such as suspected risk or protection factor(s). The study usually involves taking a cohort of

subjects and watching them over a long period. The outcome of interest should be common; otherwise, the number of outcomes observed will be too small to be statistically meaningful (indistinguishable from those that may have arisen by chance).

Protein – A macromolecule composed of subunits of linear chains of amino acids attached to each other by peptide bonds.

Proteomic data – Information from the comprehensive analysis and cataloguing of the structure and function of all the proteins present in a given cell or tissue.

Protocol – A document that provides the background, rationale, and objective(s) of a biomedical research project and describes its design, methodology, and organization, including ethical and statistical considerations.

Protocol amendment – A written description of a change(s) to, or formal clarification of a protocol.

Protocol approval by sponsor – The affirmative action of the sponsor on the protocol development when the technical and ethical reviewers have finally approved all the changes of the protocol. This usually act as the signal for the submission of the protocol and the other required documents to an IRB, national regulatory authorities and research sites as applicable.

Protocol Waiver – An intentional deviation from the approved protocol, such as the enrollment of a participant in violation of the protocol's inclusion/exclusion criteria.

Psychosocial needs – The needs of an individual pertaining to her social and psychological well-being.

Public domain information – Data or information available and open to public observation like the list of names in the telephone directory, or events in streets and public transportation.

Quality of life – A state or condition wherein an individual is able to live as how one normal person wants to live his/her life.

Quasi-experimental design – A research design that does not make use of random assignment to groups, that is, it is like an experimental design but lacks the random assignment.

Radiopharmaceuticals – Drugs that are used in the field of nuclear medicine as tracers in the diagnosis and treatment of certain diseases. Drugs that are labeled or tagged with a radioisotope that in many cases functions much like materials found in the body and do not produce special pharmacological effects. It can be radioactive tracer with medical applications that are administered like other drugs. It contain

radioactive substances that is used in the diagnosis and treatment like cancer and in pain management of bone metastases or for enabling the production of a useful nuclear medicine image to diagnose a disease.

Randomization, random assignment – The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias. Random, random assignment, randomization, is the assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematically (e.g., as dictated by the standard or usual response to their condition, history, or prognosis, or according to demographic characteristics).

Regional Health Research Ethics Board – Policy-making body for research ethics in a particular region in the Philippines.

Regulatory requirements – Necessary prerequisites for the approval and conduct of clinical trial by a national regulatory authority. For example, for pharmaceutical and biologic products, it means obtaining a "permit for clinical investigational use" which is a "registration document issued by the FDA for the purpose of allowing the conduct of Phase I, Phase II, and Phase III clinical trials of investigational biologic products in the country" (Department of Health Administrative Order No. 47-Aseries of 2001, Rules and regulations on the registration including approval and conduct of clinical trials, and lot or batch release certification of vaccines and biologic products).

Remuneration – Payment for participation in research. See also compensation.

Report ability (of test results) – The inclusion of an event (e.g., a diagnosis, evidence of violence against persons) in a list of items that are mandated by law to be reported to the Department of Health by designated individuals or health professionals because of their impact on public health and safety.

Rescue medication – Quick-relief or fast-acting medications or procedure used to immediately manage or relieve symptoms when they occur.

Research – Organized set of activities intended to generate data that are generalizable into new knowledge, principle or technology. Investigative work undertaken on a systematic and rigorous basis using quantitative and qualitative methods to generate new knowledge.

Research ethics committee – An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on, the trial protocol, the

suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

Research involving traumatized populations – Study undertaken on a systematic and rigorous basis to generate new knowledge regarding groups living in communities that have experienced hardships and stress due to natural calamities or human atrocities.

Research on assisted reproductive technology – Study undertaken on a systematic and rigorous basis to generate new knowledge regarding reproduction that makes use of modern technology.

Research participants or subjects – An individual who participates in a biomedical research project, either as the direct recipient of an intervention (e.g., study product or invasive procedure), as a control, or through observation. The individual may be a healthy person who volunteers to participate in the research, or a person with a condition unrelated to the research carried out who volunteers to participate, or a person (usually a patient) whose condition is relevant to the use of the study product or questions being investigated.

Research protocol – A document that provides the background rationale and objective(s) of a biomedical research project and describes its design, methodology and organization, including ethical and statistical considerations. Some of these considerations may be provided in other documents referred to in the protocol. See also protocol.

Respect for persons – Involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.

Respondent – The person or group of persons answering or replying to research questions or providing the data that are collected during the research. They are also referred as subject or participant in a research and further as a unit, unit of analysis, experimental unit, during sampling or data analysis. See also research participants.

Retrospective study – A research that looks backwards and examines exposures to suspected risk or protection factors in relation to an outcome that is established at the start of the study. Many valuable case-control studies, such as Lane and Claypon's 1926 investigation of risk factors for breast cancer, were retrospective investigations. Most sources of error due to confounding and bias are more common in retrospective studies than in prospective studies. For this reason, retrospective investigations are often criticized. If the outcome of interest is uncommon, however, the size of prospective investigation required to estimate relative risk is often too large to be feasible. In retrospective studies the odds ratio provides an estimate of relative risk. Special care should be taken to avoid sources of bias and confounding in retrospective studies.

Ribonucleic acid (RNA) – A single-stranded nucleic acid similar to DNA but having ribose sugar rather than deoxyribose sugar and uracil rather than thymine as one of the pyrimidine bases.

Risk – The probability of discomfort or harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Risks to research participants must be justified by the anticipated benefits to the subjects or to society. The investigator(s) and IRB must assess the risks and benefits of proposed research. See also minimal risk.

Risk factors – Variables or conditions that increase the risk or chances of disease or infection; determinants of disease development.

Scientific review – Also called technical review, is the evaluation of the research protocol to ascertain scientific soundness and appropriateness of the objectives and design of the proposed study and the qualifications of the researcher.

Selective disclosure of information – Deliberate withholding of certain information from a patient or from a research participant usually justified by the principle of non-maleficence or, in the case of research, avoiding the introduction of bias on the part of the patient.

Serious adverse event – Or serious adverse drug reaction, is an adverse event that results to death, life threatening incident or causes immediate risk of death from the event; results to inpatient or prolongation of hospitalization, causes significant disability, incapacity, and congenital anomaly or another episode which is considered a significant hazard to the participant. See also adverse event or unexpected adverse event. Also, any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.

Shared autonomy – The autonomy of an individual member of an IP community that he/she exercises as part of a group. This concept is embedded with the notion that individual autonomy and group autonomy are complementary and not contradictory. See also autonomy and collective autonomy.

Side effect – Undesired effect of a treatment which is either immediate or long-term.

Single-gene diseases – A disorder that is determined by mutant alleles at a single locus.

Site management organization (SMO) - is an organization that provides clinical trial related services to a contract research organization, a pharmaceutical company, a biotechnology company, a medical device company or a clinical site. The site is

usually a hospital or a similar healthcare institution that has adequate infrastructure and staff to meet the requirements of the clinical trial protocol.

Social and behavioral research – Study undertaken on a systematic and rigorous basis to generate new knowledge regarding the impact of sociological, psychological, anthropological and other social factors on health and well-being.

Social research – Research covering broad range of disciplines and perspectives in sociology, anthropology, political science, economics, psychology, population studies, history, geography, linguistics, and other social sciences that are directly concerned with health issues. Interdisciplinary social research involves two or more of these disciplines utilizing both quantitative and qualitative approaches which are consistent with either positivist, interpretive or critical perspectives.

Sponsor – An individual, a company, an institution or an organization which take responsibility for the initiation, management and/or financing of a clinical trial.

Standard of care or treatment – Healthcare intervention or regimen that is generally accepted by health practitioners and experts as beneficial to an individual needing such care. Standard treatment is the treatment that is currently thought to be effective in medical practice.

Stem cell research – The study of the properties, development, and transformation of primordial progenitor cells prior to establishment of specialized cells.

Stigma – The negative regard (e.g., shame and dishonor) of the community or society to particular groups because of disability, illness, occupation, poverty, among others as dictated by culture.

Surrogate assent – Necessary when an adult is not able to provide consent for themselves to participate in research due to: cognitive impairment, lacking capacity, or suffering from a serious or life-threatening disease.

Susceptibility or predisposition (to disease) – The pathophysiological conditions and genetic inclination or condition that favor the development of a disease condition.

Suspected unexpected serious adverse reaction (SUSAR) – A serious adverse reaction in research participants who were given a drug, that may or may not be dose related, but are not expected or anticipated since these reactions are not consistent with current information about the medicinal product in question. This may occur during clinical trials or clinical care.

Technical review – The process of examining, assessing or evaluating a research protocol by technical experts, seasoned researchers, statisticians and other relevant specialist or authority to ensure the scientific soundness and appropriateness of the objectives and design of the study and the qualifications of the investigator(s).

Teratogenicity – The degree or measure of the ability to cause malformations of an embryo or fetus.

Termination of the research – Ending or discontinuing a research study before its scheduled completion when the safety or benefit of the study participants is doubtful or at risk.

Test preparation – The formulation or preparation of the herbal remedy or product that is going to be used in the study.

Therapeutic – Professionally accepted level and type of treatment or assistance for a particular health condition.

Therapeutic window – The time period, based on available scientific evidence, during which the test article must be administered to have its potential clinical effect.

Toxicity – Level or extent of being poisonous to a living organism or person; ability to cause grave harm or death.

Traditional and alternative healthcare – The sum total of knowledge, skills and practices on healthcare, other than those embodied in biomedicine, used in the prevention, diagnosis and elimination of physical and mental disorder.

Traditional and Alternative Medicine Act (TAMA) – The 1997 law creating the Philippine Institute of Traditional and Alternative Health Care (PITAHC) to accelerate the providing for a Traditional and Alternative Health Care Development Fund and for other purposes including its integration to the national healthcare delivery system.

Traditional healer – The relatively old, highly placed respected person in the community, with a profound knowledge of traditional remedies

Traditional medicine – The sum total of knowledge, skills, and practices in healthcare, not necessarily explicable in the context of modern, scientific, philosophical framework, but recognized by the people to help maintain and improve their health towards the wholeness of their being, the community and society, and their interrelations based on culture, history, heritage, and consciousness.

Traditional medicine expert – A healthcare provider employing traditional medicine modalities to cure disease.

Traumatized populations – Individuals who live in communities that have experienced extreme forms of life-threatening stress due to natural calamities or human atrocities such as armed conflict, political repression as well as criminal and domestic violence.

Trial-related expenses – Expenses incurred by study participants related to their participation in a research study such as transportation, meals, loss of income.

Undue influence – An inappropriate power, pressure or control or domination which may be mental, moral or physical that deprives a person of freedom of judgment, choice and thus, substitutes another's choice or desire in place of its own.

Unexpected adverse event – An adverse reaction that has not been anticipated, nor previously experienced, or observed, and is not consistent with the informed consent, information sheets or applicable product information in the investigator's protocol or brochure, product or package insert or summary of product characteristic.

United Nations Declaration of Rights of Indigenous Peoples – A statement adopted by the UN General Assembly on Resolution 61/295 on 13 September 2007 affirming that indigenous peoples are equal to all other peoples, while recognizing the right of all peoples to be different, to consider themselves different, and to be respected as such; that indigenous peoples, in the exercise of their rights, should be free from discrimination of any kind; and that indigenous peoples have the right to the full enjoyment, as a collective or as individuals, of all human rights and fundamental freedoms as recognized in the Charter of the United Nations, the Universal Declaration of Human Rights and international human rights law.

Voluntary – Free of coercion, duress, or undue inducement; used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

Vulnerability – A substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group.

Vulnerable persons/groups – Individuals whose willingness to volunteer in clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of retaliatory response from senior members of a hierarchy in case of refusal to participate. Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests.

Waiver of informed consent – The act of intentionally or knowingly relinquishing or abandoning the right to consent to medical treatment by a patient or to participate in a medical experiment by a subject after achieving an understanding of what is involved, especially the risks (Merriam-Webster's Dictionary of Law (c), 1996). It is also refers to the permission given by an Ethics Review Committee for research to be conducted without the informed consent of subjects, under exceptional

circumstances, such as when research has to be undertaken in an emergency situation.

Western medicine – Or biomedicine, allopathy, regular medicine, conventional medicine, mainstream medicine, orthodox medicine or cosmopolitan medicine.

Withdraw – Decision of the subject or respondent or patient to continue participating in research or clinical trial. See discontinuation.

Zygote – The product of the biological union of the human sperm and egg (process of fertilization) until the blastocyst (32-cell) stage prior to implantation in the endometrium (0 to 4-5 days).

	Cebu Doctors' University Hospital **Research Ethics Committee** **(CDUHREC)** **REFERENCES**

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Cebu Doctors' University Hospital
Research Ethics Committee
(CDUHREC)

List of Acronyms

ADR	Adverse Reaction
CIOMS	Council for International Organization of Medical Sciences
CRF	Case Report Form
CRO	Clinical Research Organization
CDUH	Cebu Doctors' University Hospital
CDUHREC	Cebu Doctors' University Hospital Research Ethics Committee
CTA	Clinical Trial Agreement
CV	Curriculum Vitae
DOH	Department of Health
DSMB	Data Safety Monitoring Board
DSMC	Data Safety Monitoring Committee
ERB	Ethics Review Committee
ERC	Ethics Review Committee
FDA	Food and Drug Administration
FERCAP	Forum for Ethical Review Committees in the Asia and the Pacific Region
GCP	Good Clinical Practice
IB	Investigator's Brochure

ICF	Informed Consent Form
ICD	Informed Consent Form
IP	Investigational Product
IERC	Institutional Ethics Review Committee
IRB	Institutional Review Board
ICH-GCP	International Conference on the Harmonization of Good Clinical Practice
MOA	Memorandum of Agreement
NIH	National Institutes of Health
PCHRD	Philippine Council for Health Research and Development
PHREB	Philippine Health Research Ethics Board
PNHRS	Philippine National Health Research System
PI	Principal Investigator
RERC	Research Ethics Review Committee
SAE	Serious Adverse Event
SIDCER	Strategic Initiative for Developing Capacity in Ethical Review
SOP	Standard Operating Procedures
SUSAR	Suspected, Unexpected Serious Adverse Reaction
WHO	World Health Organization