CHAPTER 2: PROTOCOL REVIEW

1. **Protocol Submission**
2. **Type of Review**
3. **Use of the Protocol Assessment Forms**
4. **Preparing for Meeting**
5. **Conduct of Meeting**
6. **Version History**

Authored by:	DLSMHSI-IEC Secretariat
Approval/Effective Date:	November 2019
Approved by:	(original signed) Charles Y. Yu, MD, MSc, FPCP, FPCCP Vice Chancellor for Research

1. Protocol Submission

1.1 Purpose

To describe the De La Salle Medical and Health Sciences Institute - Independent Ethics Committee (DLSMHSI-IEC) protocol review requirements and submission process from the time of receipt of the protocol and related documents.

1.2 Scope

The DLSMHSI-IEC accepts the protocols for review: 1) De La Salle Medical and Health Sciences Institute (DLSMHSI) funded researches, 2) researches done in DLSMHSI, 3) researches referred from the PNHRS, PHREB, DOH, industry organization, etc., on the condition that the host hospital/institution where the proposal will be done accepts the review of DLSMHSI-IEC and agrees to abide by the rules and regulations that the DLSMHSI-IEC follows (based on PHREB and FERCAP rules). The other research sites also agree to provide the necessary environment to ensure the safe and ethical conduct of the research, including oversight and stewardship functions as necessary as they agree to monitor procedures that the Committee may deem necessary. These conditions should be written in a document and signed by other hospital/institutions that accept DLSMHSI-IEC review.

1.3 Responsibility

The DLSMHSI-IEC Secretariat manages and ensures completion of all protocol submissions to the DLSMHSI-IEC. It covers the actions to be done from the time of submission to the filing of the original protocol package in the Active Study File cabinet and the preparation of copies of the documents for distribution to the reviewers.

1.4 Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Receive the 10 copies of initial protocol package for review and check the completeness of document requirements with the IEC Application Form signed by the Principal Investigator and the protocol summary sheet.	Secretariat
Step 2	Assign a permanent code to the package.	Secretariat
Step 3	Make a duplicate of the application form and give the duplicate to the person submitting the package and attach the original copy to the protocol package to be kept in the IEC.	Secretariat

Step 4	Log the received protocol in the IEC Database.	Secretariat
Step 5	Chair assigns the primary reviewers.	Chair
Step 6	Prepare the 10 copies of protocol package for distribution to the reviewers	Secretariat
Step 7	File the original package in a properly coded Protocol File folder and place it in the Active Study File cabinet	Secretariat

1.5 Description of Detailed Procedures

1.5.1 The IEC Secretariat receives the 10 copies of initial protocol package for review and check the completeness of document requirements with the IEC Protocol Review Checklist signed by the Principal Investigator and the protocol summary sheet.

- The DLSMHSI-IEC receives complete proposal submission packages only between the 1st and the 15th day of each month to ensure consideration at the following month's meeting. The cut-off period will not be extended under any circumstances. All protocols, which are determined to undergo a full board review, are scheduled for review and deliberation on the next scheduled meeting. All protocols need technical approval prior to ethical review.
- For DLSMHSI funded protocols, the Center Clinical Epidemiology and Biostatistics (CCEB) should have addressed the technical issues apparent to the study protocol.
- For non-DLSMHSI funded protocols, a document stating that the research protocol has undergone and passed technical review should be attached to the study protocol submitted for ethical review.
- Upon submission of the initial protocols for DLSMHSI-IEC review, the PI or his/her representative should ensure that the protocol follows the standard protocol format and contains a Protocol Review Checklist (FORM 2A/V1/2012)
- Ensure that the PI has signed the Protocol Review Application (FORM 2B/V1/2012), make a copy of the filled-in application form, to keep the original copy for the IEC files and give the duplicate to the principal investigator (PI) or his/her representative.

- Check the documents being submitted based on the DLSMHSI-IEC Form 2A/V2/2019 Protocol Submission Checklist:

I. Protocol Documents

- Cover Letter

- Accomplished Submission Checklist (DLSMHSI-IEC FORM 2(A) V2-2019)
- Review Application Form (DLSMHSI-IEC FORM 2(B) V1-2012)
- Study Protocol (10 copies, complete with relevant documents)
- Informed Consent Form (for studies involving human participants)
    - English version
    - Tagalog, and/or other Local Version(s)

N.B. Must have Version No, Date, Page No. in the footer

- Parent's Consent Form (for studies involving children/minors and relevant populations)
    - English version
    - Tagalog, and/or other Local Version(s)

N.B. Must have Version No, Date, Page No. in the footer

- Assent Form (from children cognitively capable of giving consent)
    - English version
    - Tagalog, and/or other Local Version(s)

N.B. Must have Version No, Date, Page No. in the footer

- Pharmacogenetic /Pharmacogenomic ICF (as needed by the study)

N.B. Must have Version No, Date, Page No. in the footer

- Data Collection Forms (specify)
- Updated CV of PI and study team members (DLSMHSI-IEC FORM 2(C) V1-2012)
- Proof of GCP Training in the last 3 years (for those doing clinical studies)
- Ethical and/or Technical Approval from other Ethics/Technical Review Committee(s)
- Institutional Endorsement (from the VC, Dean, or Medical Director)
- Regulatory clearances (FDA approval for Phase I,II, II, IV clinical trials)

Electronic copy of:

Submission Checklist
Review Application Form
Study Protocol
Informed Consent Assessment Form (for studies involving human

participants)
English version
Tagalog, and/or other Local Version(s)
Parent's Consent Form, Assent Form (for studies involving children/minor relevant populations)
English version
Tagalog, and/or other Local Version(s)
Assent Form (from children cognitively capable of giving consent)
English version
Tagalog, and/or other Local Version(s)
Pharmacogenetics ICF

II. OTHER REQUIRED DOCUMENTS (depending on the particular study/project application being submitted

- Investigator's Brochure (for clinical trials phase I, II, III); Basic Product Information Document (for clinical trials phase IV)
- CRFs
- Recruitment advertisements (as needed by the study)
- Other information/ documents for participants (such as diaries, etc., questionnaire)
- Site Resources Checklist (for clinical Trials)
- Memorandum of Agreement (for collaborative studies)
- Details of Funding Agency/Sponsor
- Institutional Biosafety Committee Approval (for studies involving hazardous biological materials)
- Material Transfer Agreement (for studies involving transfer of biological specimens)
- National Commission for Indigenous People (NCIP) Clearance (for studies with indigenous populations)
- Insurance/Indemnity Policy
- Others (specify)

1.5.2 The IEC Secretariat Assign a permanent code to the package.
The code will be communicated to the PI in subsequent communications regarding the protocol.

- It is necessary to use a unique identifier or code to refer to this file for efficient file management. Code study files as follows: Year submitted (ie 2012) – assigned (arbitrary) protocol number 001 – Type of Research – Status of Research.
  - Code for Type of Research

- 1 – Clinical Trial
- 2 – Epidemiological (Cohort/Case-Control/Cross-sectional)
- 3 – Basic Science
- 4 – Behavioral
- 5 – Social Science
- 6 – Community
- 7 – Medical Devices
- 8 – Bioavailability/Bioequivalence Studies
- 9 – Health Economics
- 10 – Others

- Code for Status of research
  - A – Active (Ongoing study, no close-out or final report notification)
  - I – Inactive (Final Study Report approved or no post-review response from PI more than 90 days or no notification of termination)
  - C – Completed (Close-out notification submitted or Final Report not yet approved)
  - T – Terminated (Termination notification submitted before/during study implementation)

1.5.3 The IEC Secretariat makes a duplicate of the application form and give the duplicate to the person submitting the package and attach the original copy to the protocol package to be kept in the IEC.

1.5.4 The IEC Secretariat logs the received protocol in the IEC Database.

1.5.5 The Chair assigns the primary reviewers.

- Primary reviewers are selected based on expertise related to the protocol. Research proposals are given to both medical and non-medical or lay members, institutional and non-institutional members for review. The medical/ scientific members analyze the scientific and ethical procedures in the protocol while the lay/ non-institutional members focus their assessment on the informed consent form. Review assignments should take into consideration the appropriate mix of old and new members.

- Secondary reviewers are the IEC members that are not assigned as the primary reviewers of the study but may give their comments on their assessment during the IEC meeting.

- Member/Chair, nominates two or more DLSMHSI-IEC members (Medical member with related expertise to review the protocol and a non-medical person to review the informed consent). The assignments will be equitably distributed taking in consideration the expertise of the reviewers. Secretariat sends the protocol and related documents to the selected primary reviewers.

- Enter in the DLSMHSI-IEC database the names of the primary reviewers to whom the packages are to be delivered. Prepare the logbook with the names of the reviewers, the title of the protocol studies, and the date of actual delivery to be signed by the reviewer or a representative upon receipt.

1.5.6 The IEC Secretariat prepares the 10 copies of protocol package for distribution to the reviewers.

Protocols for Expedited review are forwarded the next working day to the primary reviewers while the protocols for Full Board review are distributed one week before the scheduled IEC meeting. The protocols and related documents for distribution must also include copies of the Protocol and Informed Consent Assessment Forms (Form 2D/V2/2019) in the package.

1.5.7 The IEC Secretariat files the original package in a properly coded Protocol File folder and place it in the Active Study File cabinet.

2. Type of Review

2.1 Exempt from Review

2.1.1 Purpose

To describe the process of review of protocols that qualify for exempted from review.

2.1.2 Scope

This SOP applies to exemption for review of protocols that do not need to undergo either full or expedited review as decided upon by the Chair of the IEC.

2.1.3 Responsibility

It is the responsibility of the Chair to assess whether a study protocol may be exempted from review of the IEC.

2.1.4 Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Receive the submitted documents and forward to the Chair immediately for initial review	Secretariat
Step 2	Review and determine per criteria that the protocol is exempt from IEC review within 5 days	Chair
Step 3	Prepare a letter of exemption to the PI indicating the protocol is exempted from IEC review	Secretariat
Step 4	Keep copies of all related documents and compiles them in their respective protocol files	Secretariat
Step 5	Update the IEC database	Secretariat

2.1.5 Description of Detailed Procedures

2.1.5.1 The Secretariat receives the submitted documents and forwards them to the Chair immediately for initial review.

The application documents received from investigator submission are checked using the Protocol Checklist (FORM 2A-V2-2019) as guide. After checking the documents are complete, the Secretariat signs a copy of the Application Form (FORM 2B-V1-2012) to acknowledge receipt of the

documents and return a copy to the principal investigator or a duly designated representative.

2.1.5.2 The Chair reviews and determines per criteria that the protocol is exempt from IEC review within 5 days.
In compliance to the National Ethical Guidelines for Health and Health-Related Research 2017 (NEGHHRR 2017), the DLSMHSI-IEC considers the following Exempt from Review criteria:

(3.1.1. Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) shall be exempted from ethical review.

3.1.2. Provided that the following do not involve more than minimal risks or harms, these protocols may be considered by the REC for exemption from review:

3.1.2.1. Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;

3.1.2.2. Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:

3.1.2.2.1. There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to `their financial standing, employability, or reputation; and

3.1.2.2.2. The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.

3.1.2.3. Protocols that involve the use of publicly available data or information.)

2.1.5.3 The IEC Secretariat prepares a letter of exemption (FORM 4I-V2-2019) to the PI indicating the protocol is exempted from IEC review.

2.1.5.4 The IEC Secretariat keeps copies of all related documents and compiles them in their respective protocol files.

2.1.5.5 The IEC Secretariat updates the IEC database.

2.2 Expedited Review

2.2.1 Purpose

To describe the process of review of protocols that qualify for expedited review.

2.2.2 Scope

2.2.2.1 This SOP applies to the review and approval of the study protocol or amendments with minimal risks to the study participants and minor revisions in the protocol or informed consent. The submissions procedures are the same as first time submission.

2.2.2.2 The following are types of protocols can be subjected to expedited Review after initial submission:

- Protocol of a non-confidential nature (not of a private character, e.g. relate to sexual preference etc., or not about a sensitive issue that may cause social stigma), not likely to harm the status or interests of the study participants and not likely to offend the sensibilities nor cause psychological stress of the people involved.

- Protocols <u>not</u> involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to retaliate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority group, homeless persons, nomads, refugees, minors and those incapable of giving consents).

- Protocols that involve collection of anonymized biological specimens for research purposes by non-invasive means (e.g. collection of small amounts of blood, body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).

- Research involving data, documents or specimen that have been already collected or will be collected for ongoing medical treatment or diagnosis.

- Proposed continuing reviews, protocol amendments and end of study reports that have minor modifications and no significant risk to study participants.

2.2.2.3 Criteria for Expedited Review of Resubmissions, Amendments, Reports

- Administrative revisions, such as correction of typing errors
- Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc.
- The research activity includes only minor changes from previously approved protocol.
- Minor protocol amendments that do not change the risk/benefit assessment.
- Progress/Final reports that do not deviate from approval given by the IEC
- SAEs from foreign sites

2.2.3 Responsibility

Expedited review is the responsibility of primary reviewers appointed to assess and make recommendations for appropriate reaction any protocol that qualifies for the expedited process. The same assessment forms used for full board review should be used to evaluate the scientific and ethical merits of the protocol.

2.2.4 Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Receive the submitted documents for initial review and forward them to the Chair for assessment	Secretariat
Step 2	Determine that the protocol is for expedited review and assigns reviewers	Chair
Step 3	Forwards the copies of protocols and related documents for expedited review to the assigned primary reviewers the next working day	Secretariat
Step 4	Do the expedited review and submit the decision to the Secretariat	Reviewers
Step 5	Communicate the decision for approval or revision to the Principal Investigator through a letter of notification within the last 2 weeks of the month	Secretariat

Step 6	If modifications are required, revise the protocol or related document and resubmit to the IEC	Principal Investigator
Step 7	Review revisions and recommend if for approval	Reviewers
Step 8	Prepare an Approval Letter to be signed by the Chair and sent to the Principal Investigator	Secretariat
Step 9	Report results of expedited review to full board as part of the meeting agenda	Secretariat
Step 10	Keep copies of all related documents and compiles them in their respective protocol files.	Secretariat
Step 11	Update the IEC database	Secretariat

2.2.5 Description of Detailed Procedures

2.2.5.1 The Secretariat receives the submitted documents for initial review and forwards them to the Chair for assessment.
The application documents received from investigator submission are checked using the Protocol Checklist (FORM 2A-V2-2019) as guide. After checking the documents are complete, the Secretariat signs a copy of the Application Form (FORM 2B-V1-2012) to acknowledge receipt of the documents and return a copy to the principal investigator or a duly designated representative.

2.2.5.2 The Chair determines that the protocol is for expedited review and assigns reviewers.
The Chair assigns two or more DLSMHSI-IEC members (Medical member with related expertise to review the protocol and a non-medical person to review the informed consent).

2.2.5.3 The Secretariat forwards the copies of protocols and related documents for expedited review to the assigned primary reviewers the next working day.

2.2.5.4 The assigned Primary reviewers do the expedited review and submit their decision to the Secretariat.
Primary reviewers carry out the expedited review on the protocol and related documents (patient information sheet, consent form, advertisements, etc.). An independent consultant may be invited to provide expert opinion about a protocol.

2.2.5.5 The Secretariat communicates the decision for approval or revision to the Principal Investigator through a letter of notification within the last 2 weeks of the month.
If consensus cannot be reached, the Chair will refer the protocol to IEC board for full review.

2.2.5.6 If modifications are required, the PI makes the necessary revisions and resubmits to the IEC as referred to the Notification Letter (FORM 2H-V2-2019) prepared by the Secretariat.

2.2.5.7 The assigned Primary Reviewers review the revisions and recommend if for approval.

2.2.5.8 The Secretariat prepares an Approval Letter (FORM 2I-V2-2019) to be signed by the Chair and sent to the Principal Investigator

2.2.5.9 The Secretariat reports results of expedited review to full board as part of the meeting agenda.

2.2.5.10 The IEC Secretariat keeps copies of all related documents and compiles them in their respective protocol files.

2.2.5.11 The IEC Secretariat updates the IEC database.

For the Expedited Review of Protocol Amendments and Reports:

- The Secretariat checks if the appropriate IEC forms were used and checks the completeness of documents.
- The documents are sent to the original reviewers to review.
- The reviewers review the documents and make sure that there is no change in the risk/benefit ratio before approving the documents. Reviewers may request for clarification before recommending approval. Reviewers may refer the documents for full board in case there are issues that need resolution.
- The reviewers recommend approval if there are no issues.
- The PI is notified about approval.
- The results are summarized and reported to full board for information purposes.
- Copies of all documents are kept in the protocol files.
- The IEC database is updated.

2.3 Full Board Review

2.3.1 Purpose

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

2.3.2 Scope

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

2.3.3 Responsibility

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

2.3.3.2 The Secretariat is responsible for receiving, verifying and managing the contents of both the hard copies and the electronic version (if any) of the submitted protocol package. In addition, the Secretariat should create a specific protocol file, make copies of the file and then distribute the copies to the De La Salle Health Sciences Institute-Independent Ethics Committee (DLSMHSI-IEC) reviewers, together with a cover letter where the due date for returning the reviewed protocol is indicated as well as the schedule of meeting when the protocol will be discussed.

2.3.3.3 It is the responsibility of the assigned reviewers to thoroughly review the study protocols and related documents by using the assessment forms and make a recommendation for appropriate action give their decision, observation and comments and put all of this in the Protocol Assessment and Informed Consent Assessment Forms (Form 2D/V2/2019) before returning the reviewed protocol and assessment form to the Secretariat on the due date.

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

- Clinical Trials about investigational new drugs, biologics or device in various phases (Phase 1, 2,3)

- Phase 4 intervention research involving drugs, biologics or device
- Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g. related to sexual preferences etc., or about sensitive issues that may cause social stigma) that may cause psychological, legal, economic and other social harm
- Protocols involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to retaliate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority group, homeless persons, nomads, refugees, minors and those incapable of giving consents) that require additional protection from the IEC during review
- Protocols that involve collection of identifiable biological specimen for research

2.3.3.5 Criteria for Full Board review of Resubmissions, Amendments, Reports

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

2.3.4 Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Receive the submitted documents and forward to the Chair for assessment	Secretariat
Step 2	Determine that the protocol qualifies for full board review and assign reviewers to review the protocol and related documents	Chair
Step 3	Forward the protocol and related documents a week before the meeting to be reviewed within the last 2 weeks of the month	Secretariat
Step 4	Do the review of the protocol and related documents as well as the reports deemed for full board review	Reviewers

Step 5	Include the protocol in the meeting agenda for discussion to arrive at a decision through full board	Secretariat
Step 6	If modifications are required, revise the protocol or related document and resubmit to the IEC.	Principal Investigator
Step 7	When protocol is approved, prepare an Approval Letter (FORM 2I-V2-2019) to be signed by the Chair and sent to the Principal Investigator	Secretariat
Step 8	Keep copies of all related documents and compiles them in their respective protocol files	Secretariat
Step 9	Update the IEC database	Secretariat

2.3.5 Description of Detailed Procedures

2.3.5.1 The Secretariat receives the submitted documents for initial review and forwards them to the Chair for assessment.
The application documents received from investigator submission are checked using the Protocol Checklist (FORM 2A-V2-2019) as guide. After checking the documents are complete, the Secretariat signs a copy of the Application Form (FORM 2B-V1-2012) to acknowledge receipt of the documents and return a copy to the principal investigator or a duly designated representative.

2.3.5.2 The Chair determines that the protocol qualifies for full board review and assign reviewers to review the protocol and related documents with appropriate qualifications (clinician/ scientist with expertise related to the protocol and a non-medical person to review the consent form).

2.3.5.3 The Secretariat forwards the protocol and related documents a week before the meeting to be reviewed within the last 2 weeks of the month.
Additionally, the Protocol and Informed Consent Assessment Forms (Form 2D/V2/2019) are included in the submission to the primary reviewers/independent consultant for review.

2.3.5.4 The IEC reviewers (primary and secondary reviewers) do the review of the protocol and related documents as well as the reports deemed for full board review using the Protocol and Informed Consent Assessment Forms (Form 2D/V2/2019) which will be discussed in the scheduled IEC

meeting. An independent consultant may be invited to provide expert opinion about a protocol.

Primary reviewers carry out the expedited review on the protocol and related documents (patient information sheet, consent form, advertisements, etc.) and are advised to note the following Review Guidelines:

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

The review and assessment should also include:

- Checking the CV or information about the investigators (including GCP training for clinical trials), the study sites and other protocol related documents, including advertisements.
- Considering whether the study and training background of the principal investigator/s are related to the study.
- Looking for disclosure or declaration of potential conflict of interest.
- Non-physician principal investigators should be advised by a physician when necessary.
- Determining if the facilities and infrastructure at study sites can accommodate the study.
- Checking the "Assent Form" if the protocol involves children or other vulnerable groups as study participants based on PHREB guidelines. The procedure for getting the assent of vulnerable participants should be clear (the objective of the study and the procedure to be done should be explained to the child or vulnerable participant separately).
- Examining community involvement and impact benefit of the study to the community and/or the institution. If relevant, the reviewer looks for the following in the protocol:
    - Community consultation
    - Involvement of local researchers and institutions in the protocol design, analysis and publication of the results.
    - Contribution to development of local capacity for research and treatment in benefits to local communities.
    - Sharing of study results with the participants/community.
- Addressing COI, Disapproval as well as process of appeal
    - The member who declares COI on a study for review leaves/ steps out of the room/ meeting during the discussion of the study in conflict of interest
- For DLSMHSI funded proposals, a member of the Center Clinical Epidemiology and Biostatistics (CCEB) shall sit in the full board meeting as a consultant to explain technical issues. For non-funded DLSMHSI proposals, the IEC may request for comments/ approval from other IEC independent consultants to provide additional inputs as deemed necessary.

2.3.5.5 The Secretariat includes the protocol in the meeting agenda for discussion to arrive at a decision through full board.

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

- Record the decision by marking the appropriate block in the assessment form: Approved, Minor revision, Major revision for resubmission, or Disapproved.
- Include comments and reasons for disapproval

- Check the completeness and correctness of marked items in the assessment forms. Indicate the date and affix the reviewer's signature in the decision form.

2.3.5.6 If modifications are required, the PI should revise the protocol or related document and resubmit to the IEC as referred to the Notification Letter (FORM 2H-V2-2019) prepared by the Secretariat.

- If the decision is to Disapprove the study, the Secretariat immediately notifies the principal investigator in a letter (FORM 4P-V1-2012) about the decision and the reason for not approving the study.
    - If the principal investigator wishes to appeal the IEC decision, he/she may do so through a written request submitted to the De La Salle Health Sciences Institute-Independent Ethics Committee.
    - The consideration of the appeal shall be included in the agenda of the next full board meeting. If the appeal merits a favorable approval, the PI is informed to submit the revised protocol following the IEC recommendations to resolve the reason(s) for disapproval.

2.3.5.7 When the protocol is approved, the Secretariat shall prepare an Approval Letter (FORM 2I-V2-2019) with a list of approved documents to be signed by the Chair and sent to the Principal Investigator to be sent to the PI.
The Approval Letter (FORM 2I-V2-2019) contains identification of the document approved with version numbers and dates, the frequency of continuing review and the responsibilities of the principal investigator throughout the course of the study.
There should be a file/received copy with specific date.

2.3.5.8 The Secretariat keeps copies of all related documents and compiles them in their respective protocol files.
All meeting deliberations and decisions regarding a protocol are noted in the meeting minutes, with relevant sections filed in the specific protocol file.

2.3.5.9 The IEC Secretariat updates the IEC database.
All information regarding the date of the DLSMHSI-IEC decision such as the dates when the decision was written and signed by the Chair, and date when it was delivered to the PI, are entered in the IEC Database.

2.4 Review of the Medical Device Protocol

2.4.1 Purpose

To describe process in the review of medical device protocols submitted to the IEC.

2.4.2 Scope

2.4.2.1 This SOP provides instructions for review and approval of medical device protocols intended for human participants submitted to the De La Salle Health Sciences Institute-Independent Ethics Committee (DLSMHSI-IEC).

2.4.2.2 Medical device protocols are reviewed through the same expedited or full board procedures depending on the level of risks involved in the study. An investigational new device is given a Significant Risk (SR) or Non-Significant Risk (NSR) classification by the regulators in the sponsor country. This information should be provided by the sponsor to the IEC. The IEC should make provisions to minimize the risks to human participants during review of the protocol and related documents.

2.4.3 Responsibility

It is the responsibility of the IEC members to review medical device protocols in accordance with international and national guidelines and regulations.

2.4.4 Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Receive the submitted documents and forward to the Chair for assessment	Secretariat
Step 2	Determine if the protocol is for Expedited or Full board review depending on SR or Non-SR determination and assign reviewers to review the protocol and related documents	Chair
Step 3	Review the protocol documents using the assessment forms and submit the decision/recommendation to the Secretariat	Chair
Step 4	Expedited Review: Communicate the decision to the expedited reviewers for approval or revision to the PI	Secretariat

Step 5	Full Board Review: Include the protocol in the next meeting agenda for discussion and decision by full board.	Secretariat
Step 6	If modifications are required, revise the protocol or related documents and resubmit to the IEC	Principal Investigator
Step 7	When approval decision is reached; the Approval Letter (FORM 2I-V2-2019) is prepared by the Secretariat, signed by the Chair and communicated to the Principal Investigator	Secretariat
Step 8	Keep copies of all related documents and compiles them in their respective protocol files	Secretariat
Step 9	Update the IEC database	Secretariat

2.4.5 Description of Detailed Procedures

2.4.5.1 The Secretariat receives the submitted documents and forward to the Chair for assessment.

2.4.5.2 The Chair determines if the protocol is for Expedited or Full board review depending on SR or Non-SR determination and assign reviewers to review the protocol and related documents.
The information/communication from the principal investigator are checked as related to the Significant Risk (SR) or Non-Significant Risk (NSR) determination by regulators (FDA) from the sponsor country. The protocol is assigned to expedited review or full board review depending on the risk assessment.

2.4.5.3 The Primary Reviewers review the protocol documents using the Protocol and Informed Consent Assessment Forms (Form 2D/V2/2019) and submit the decision/recommendation to the Secretariat.
Primary reviewers with appropriate expertise are assigned to review the protocol and related documents. It is advisable that a bioengineer with appropriate experience related to the medical device together with a medical doctor with related clinical experience are assigned to review the protocol while a lay person/non-medical member reviews the consent form.
When reviewing a medical device protocol, the reviewer should also consider the following:

- Proposed investigational plan (use of the device in the study)
- Informed Consent Form
- Description of the device/ Product information
- Description of study participant selection criteria
- Reports of prior investigations conducted with the device

- CV of the Principal Investigator
- Risk assessment determination for new investigational device (Significant Risk or Non-Significant Risk)
- Safety Monitoring procedure
- Copies of all labeling for investigational use
- Statistical plan and analysis

2.4.5.4 For Expedited Review: The Secretariat communicates the decision to the expedited reviewers for approval or revision to the Primary Investigator.

2.4.5.5 For Full Board Review: Include the protocol in the next meeting agenda for discussion and decision by full board.
On full board review, a decision is made after discussion. If the protocols are for revision, they are sent back to the Principal Investigator for modification. Documents are resubmitted and reviewed by primary reviewers through expedited channel for minor revision or sent to full board for review of major revisions.

2.4.5.6 If modifications are required, the Principal Investigator is to revise the protocol or related documents and resubmit to the IEC.

2.4.5.7 When approval decision is reached; the Approval Letter (FORM 2I-V2-2019) is prepared by the Secretariat, signed by the Chair and communicated to the Principal Investigator. The frequency of continuing review is indicated in the approval letter.

2.4.5.8 The Secretariat keeps copies of all related documents and compiles them in their respective protocol files.

2.4.5.9 The IEC Secretariat updates the IEC database.

3. Use of the Protocol Assessment Forms

3.1 Purpose

To describe the process related to the use of the protocol assessment forms in the ethics review.

3.2 Scope

3.2.1 This SOP applies to the use of the Protocol Assessment Forms in the review and assessment of protocols and related to documents submitted to De La Salle Health Sciences Institute - Independent Ethics Committee (DLSMHSI-IEC) for initial review and approval by the IEC. The IEC uses FORM 2D/V2/2019 – Protocol and Informed Consent Assessment Forms. The assessment form is accomplished by the reviewers. Any comments, evaluation, recommendations and the initial decision of each reviewer regarding a protocol are all noted in the form.

3.2.2 The Protocol and Informed Consent Assessment Forms (FORM 2D/V2/2019) are designed to standardize the review process and to facilitate reporting of recommendations and comments give to each individual protocol and related documents. The DLSMHSI-IEC's Protocol assessment consists of Study protocol evaluation and Informed Consent Evaluation.

3.3 Responsibility

It is the responsibility of the De La Salle Health Sciences Institute - Independent Ethics Committee (DLSMHSI-IEC) reviewers to individually fill-in the Protocol and Informed Consent Assessment Forms (FORM 2D/V2/2019) after reviewing each study protocol. The Secretariat is responsible for recording and filing the DLSMHSI-IEC's action, relevant points and deliberation about a protocol, including the comments for specific action. The consensus/ agreement regarding the decisions on each reviewed protocol will be reflected in the minutes of the meeting.

3.4 Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Fill up the Protocol and Informed Consent Assessment Forms (FORM 2D/V2/2019) during review of the study protocol and related documents	Primary Reviewers
Step 2	Forward the accomplished Protocol Assessment Forms to the Secretariat	Primary Reviewers

Step 3	File copies of duly accomplished forms in the Study File folder of the particular protocol.	Secretariat

3.5 Description of Detailed Procedures

3.5.1 The Primary Reviewers fill up the Protocol and Informed Consent Assessment Forms (FORM 2D/V2/2019) during review of the study protocol and related documents.

The Protocol Assessment Form (FORM 2D/V2/2019) ensures evaluation of the scientific and ethical aspects of the protocol that may include:

- Rationale and significance of the study
- Objectives of the study
- Review of literature
- Sample size
- Methodology and data management
- Inclusion/exclusion criteria
- Control arms (placebo, if any)
- Withdrawal or discontinuation criteria
- Vulnerability determination
- Risk/ benefit assessment

The Informed Consent Assessment Form (FORM 2D/V2/2019) checks if the following are complied with:

- Full disclosure of information, including risks
- Benefits that may be derived from the study
- Use of understandable language
- Voluntary participation
- Confidentiality
- Appropriate person is to sign the consent form

In addition, the DLSMHSI-IEC reviewers should ensure compliance with the provisions of the Data Privacy Act of 2012 in terms of research adherence to the principles of transparency, legitimate purpose, and proportionality in the collection, storage/retention, processing and disposal of personal information and specimens. The review of medical records is treated with strict confidentiality which must comply in anonymizing and de-identification of participant information. Additionally, *"The use of human data from biobanks, registries, and databases shall comply with the Data Privacy Act of 2012 and it's IRR of 2016." (National Ethical Guidelines for Health and Health-Related Research 2017)*
At the institutional level, the DLSMHSI-IEC work alongside the Data Privacy Office in ensuring the proper implementation of security measures

in dealing sensitive personal information. Part of its policy uses the following as basis in securing such information:

- Patient consent
- Redacted document as defined by the Privacy Rule of HIPAA.
  A redacted document has simply had personal data deleted or blacked out; as a consequence, redacted is often used to describe documents from which sensitive information has been expunged. The Policy Adviser of the National Privacy Commission recommends the use of Safe Harbor Method in de-identification of the patients as described under the HIPAA Privacy Rule. Under this method, the 18-identifiers are "taken out" to anonymize the patient's data.
- Safe Harbor Method (18-Identifiers):
  1. Names
  2. All geographic subdivisions smaller than a state usually except for the initial three digits of the ZIP code
  3. All elements of dates except years (this includes the age)
  4. Telephone numbers
  5. Fax numbers
  6. Email addresses
  7. Social security numbers
  8. Medical record numbers
  9. Health plan beneficiary numbers
  10. Account numbers
  11. Certificate/license numbers
  12. Vehicle identifiers and serial numbers including license plates
  13. Device identifiers and serial numbers
  14. Web URLs
  15. Internet protocol addresses
  16. Biometric identifiers (i.e. retinal scans, fingerprints)
  17. Photos
  18. Any unique identifying number, characteristic or code

- Approval of the DLSMHSI-IEC

3.5.2 The Primary Reviewers forward the accomplished Assessment Forms to the Secretariat.
The primary reviewer signs and submits the forms together with the reviewed protocol back to the Secretariat.

3.5.3 The Secretariat files the copies of duly accomplished forms in the Study File folder of the particular protocol.

4. Preparing for Meeting

4.1 Purpose

To describe the process in preparing for IEC Meeting.

4.2 Scope

This SOP provides the procedures for preparing a meeting for discussion and deliberation of protocols submitted to the IEC for review and approval.

4.3 Responsibility

It is the responsibility of the IEC Secretariat to ensure that the protocols and related documents are well-prepared before the IEC meeting.

4.4 Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Schedule the monthly IEC Meeting	Secretary
Step 2	Distribute the meeting agenda	Secretariat
Step 3	Prepare the meeting documents and materials	Secretariat
Step 4	File the meeting documents and materials	Secretariat

4.5 Description of Detailed Procedures

4.5.1 The Secretariat schedules the monthly IEC Meeting.

- The DLSMHSI-IEC must have its regular monthly meeting, on the last two (2) weeks of the month (except for the month of December) to facilitate preparations and regular attendance of Committee Members. The Secretariat confirms for the scheduled meeting date and time one (1) week before the meeting.
- Members should confirm their attendance within three (3) days before the meeting. So that the Secretariat can verify presence of quorum on the meeting date. In Case of anticipated lack of quorum, the meeting is postponed at a later or earlier date where there is quorum viability.

4.5.2 The Secretariat distributes the meeting agenda.

The Secretariat distributes the approved Notice of the Regular Meeting (FORM 4A-V1-2012), together with the approved Minutes of Regular Meeting (FORM 4B-V2-2019) and related study protocols to meeting attendees (members, invited PIs, independent consultants, and others) at least two (2) weeks before the IEC meeting through email and personal delivery.

4.5.3 The Secretariat prepares the meeting documents and materials.

- The Secretariat collects the folders containing the study protocol documents, materials and reports to be discussed before the actual meeting.
- The Secretariat prepares the IEC Conference Room, equipment, and facilities.
- The Secretariat Staff also sends meeting reminders to all persons who will be in attendance, through mobile phone, email, or regular telephone the day before the meeting. Non-members who will be attending only specific portions of the meeting should be informed accordingly, as specified in their invitation to attend the meeting.
- The IEC Members must bring all meeting-related documents distributed to them during the actual meeting to serve as their reference during the review. In studies involving children, a pediatrician or child development expert should be present.
- For review of resubmissions, the Chair calls the primary reviewers to present findings on the response of the PI to the previous recommendations of the committee summarized in the IEC Review of Resubmitted Protocol (FORM 2E-V2-2020).

4.5.4 The Secretariat files the meeting documents and materials.

- The Secretariat collects all meeting documents, including the documentation collected for the Minutes of Regular Meeting (FORM 4B-V2-2019) for filing; mindful that these materials are confidential and must be handled in accordance with SOP IV.
- The Secretariat files all meeting documents that must be stored in the relevant protocol files in a manner prescribed by instruction found in SOP IV.

5. Conduct of Meeting

5.1 Purpose

To describe the process in conducting an IEC Meeting.

5.2 Scope

This SOP provides the procedures for conducting a meeting to discuss and deliberate on protocols submitted to the IEC for review and approval.

5.3 Responsibility

It is the responsibility of the IEC chairs and members to ensure a well-prepared and orderly meeting.

5.4 Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Determine quorum	Secretariat
Step 2	Call the meeting to order	Chair / Co-Chair
Step 3	Confirm quorum	Member-secretary
Step 4	Disclosure of Conflict of Interest	Chair and Members
Step 5	Review and approve minutes of previous meeting	Chair and Members
Step 6	Review and deliberate on initial protocol submissions and resubmission	Chair and Members
Step 7	Conduct face to face interview with PI for clarifications and resolution of protocol-specific issues and concerns	Chair and Members
Step 8	Review and deliberate on post-approval submissions	Chair and Members
Step 9	Report on review and deliberation results of expedited review	Chair and Members
Step 10	Adjourn the meeting	Chair

5.5 Description of Detailed Procedures

5.5.1 The Member-Secretary determines the quorum for the meeting.

- On the appointed meeting time, the Member-Secretary determines quorum viability and informs the IEC Chair to indicate readiness to call the meeting to order.
- Quorum is defined as the presence of 50%of IEC members, at least five of whom are described as follows:
    - Scientific and/or medical member(s) with expertise on the study protocols being reviewed
    - At least one (1) non-scientific or lay member
    - At least one (1) member independent of the institution (who can be represented by the non-scientific member as the case may be)
    - Representation of both female and male members

5.5.2 The IEC Chair, or Co-Chair in the Chair's absence, calls the meeting to order upon confirmation of quorum by the Member-Secretary.

- The DLSMHSI-IEC also allows, at the discretion of the Chair, guests or observers to observe IEC meetings. Non-members attending any DLSMHSI-IEC Meeting are required to sign a Confidentiality Agreement for Guests/Observers (FORM 4C/V1/2012).
- The Secretariat documents the proceedings of the meeting under the supervision of the Member-Secretary, as soon as the meeting is called to order by the Chair, noting the time. The Secretariat documents the development of the agenda, specifically all board opinions and action with respective reasons, for inclusion in the meeting minutes, and subsequent communication with the principal investigator. For details regarding preparation of the minutes of the meeting, refer to SOP IV.

5.5.3 The Chair calls upon the Member-Secretary to formally confirm quorum by citing the attendance requirements.

5.5.4 The Chair calls for disclosure of Conflict of Interest (COI) in respect of any study protocol scheduled for review.

- Members disclosing COI are documented by the Secretariat. The Chair instructs the members who disclose COI to exempt themselves from the deliberation of the respective study protocol for which the COI disclosure was made by leaving the conference room. The Secretariat documents the time at which the member leaves and comes back to the meeting.

5.5.5 The Chair presides over the review of the minutes of the previous meeting.

- Any member can declare a motion for approval, which any member can second. The Chair then declares approval of the Minutes of the previous meeting.
- The Chair proceeds to facilitate discussion of matters arising from the minutes, the results of which are noted by the Secretariat for inclusion in the Minutes of the current meeting (FORM 4B-V2-2019).

5.5.6 The Chair presides for the review and deliberation of initial protocol submissions and resubmission.

- Full board review of study protocol and study protocol-related submissions typically includes review of the following items sequence:

1. Initial Study Protocol Submissions
2. Resubmission or Study Protocols for Modification
3. Clarificatory Interview
4. Study Protocol Amendment Applications
5. Continuing Review Applications
6. Noncompliance (Deviation or Violation) Reports
7. Early Study Termination Applications
8. Expedited Review Results
9. Site Visit Reports
10. Serious Adverse Event Reports
11. Withdrawal of Study Protocol Applications
12. Close-out Reports or Final Reports
13. Additional Protocol Documents/Materials
14. Other Matters

- The Members deliberate on the study assessment points and informed consent elements as detailed in the Protocol and IC Assessment Forms (FORM 2D/V2/2019).
- The scientific primary reviewer is instructed to focus presentation of findings on scientific and ethical soundness and its impact on human subject protection, while the non- scientific primary reviewer is instructed to focus presentation of findings on the informed consent process and Informed Consent Form (ICF) and its compliance with the requirements of international and national ethical guidelines, as well as national and institutional policies. All primary reviewers are to lead the discussion and shall be given the priority to present their assessment. The secondary reviewers may provide additional inputs and are given the opportunity to ask questions and make clarifications.
- The Chair may allow some modifications of the sequence of review in exigent circumstances. For example, if a clarificatory interview is included in the agenda, the panel may opt to move this up in the review sequence.
- In case of unavailability of the primary reviewers to attend the meeting, said members are required to forward the completed assessment forms to the

Secretariat seven (7) days before the meeting. The findings summarized therein will be presented by the Chair or his designee when the study protocol is deliberated on. If the Chair feels that the present committee composition does not have the expertise to proceed with the review, the discussion of the protocol may be deferred till next meeting or a special meeting. Also, the committee may request comments or clarificatory interview with the PI.

- The DLSMHSI-IEC allows investigators and other resource persons such as an Independent Consultant of highly specialized areas to attend the part of the panel meeting related to specific studies for purposes of clarifying issues related to the study protocol only (and not to present the study protocol to the board).

- For decision on both initial study protocol submission and resubmission, the Chair calls for any of the following actions:

  - Approve
  - Major Modification, which require full board deliberation
  - Minor Modification, which can be expedited at the level of the Panel Chair
  - Disapprove
  - Pending, if major clarifications are required before a decision can be made

5.5.7 The Chair and members conduct face to face interview with PI for clarifications and resolution of protocol-specific issues and concerns.

- The Committee conducts, as necessary, clarificatory interviews with PIs and/or study team members whose submissions raise ethical issues that are better addressed by the PI himself/herself. The Secretariat sends a letter of the Invitation for the interview (FORM 4T-V1-2012). Principal Investigator or study team members to be interviewed by the Committee must sign Confidentiality Agreement for (Guest/Observers) (FORM 4C-V1-2012) prior to the interview.

5.5.8 The Chair presents, of any, post-approval submissions items for discussion and deliberation by the committee members:

1. Study Protocol Amendment Applications
2. Continuing Review Applications
3. Noncompliance (Deviation or Violation) Reports
4. Early Study Termination Applications
5. Expedited Review Results
6. Site Visit Reports
7. Serious Adverse Event Reports
8. Withdrawal of Study Protocol Applications
9. Close-out Reports or Final Reports
10. Additional Protocol Documents/Materials

- The Chair calls for any of the actions on these items appropriate as listed in the

corresponding forms:

- Approve
- Minor modification to the study protocol amendment, subject to expedited review at the level of the Panel Chair
- Major modification to the study protocol amendment, subject to full board review Disapprove
- Pending, if major clarifications are required before a decision can be made

5.5.9 The Chair proceeds with the reporting of results from the review and deliberation of protocols and reports on expedited review.

5.5.10 The Chair calls to adjourn the meeting.

- Before closing the meeting, the Chair calls for other matter or any non-study protocol matters that need attention or action, as the need arises.
- With no further matters for discussion, the Chair formally adjourns the meeting, with the time noted by the Secretariat who is documenting the meeting.

6. Version History

Version No.	Authors	Reviewer/s	Approved Date	Approved By	Effectivity Date
1	Dr. Frias	NA	22 Oct 2012	IEC Committee	22 Oct 2012
2	Dr. Frias & Ms. Bayas	PHREB	15 Jun 2016	PHREB	15 Jun 2016
3	Dr. Frias	PHREB			

PROTOCOL SUBMISSION CHECKLIST (FORM 2A/V2/2019)

To the Principal Investigator:

Please be advised that IEC receives complete proposal submission packages only between the 1st and the 15th day of each month to ensure consideration at the following month's meeting. The cut-off period will not be extended under any circumstance.

You are requested to obtain an electronic copy of this Form, fill-out the requested information, and make your submission both in electronic version and hard copy. Print in letter-sized paper with printer default set at A4.

STUDY PROTOCOL INFORMATION	
Protocol Submission Date	<dd/mm/yy>
Title	Version Number, Date
Principal Investigator (PI)	(Title, Name. Surname>
PI Address	Tel No. Cell No. Email
Sponsor/CRO	
Study Site	
Type of Submission	☐ Initial Review ☐ Continuing Review of Approved Protocols
Mode of submission	☐ Post ☐ E submission ☐ in Person
Documents submitted	☐ Complete ☐ Incomplete; will submit on……..
Received By:	Name Signature Date:

I. MANDATORY COMPONENTS	Version/ Date	Remarks
☐ Cover Letter		
☐ Accomplished Review Checklist **(DLSMHSI-IEC FORM 2(A) V1-2012)**		
☐ Review Application Form **(DLSMHSI-IEC FORM 2(B) V1-2012)**		
☐ Study Protocol (*10 copies, complete with relevant documents)*		
☐ Informed Consent Form (*for studies involving human participants*) ☐ English version ☐ Tagalog , and/or other Local Version(s) *N.B. Must have Version No, Date, Page No. in the footer*		
☐ Parent's Consent Form (*for studies inv children/minors and relevant populations*) ☐ English version ☐ Tagalog , and/or other Local Version(s) *N.B. Must have Version No, Date, Page No. in the footer*		
☐ Assent Form (*from children cognitively capable of giving consent*) ☐ English version ☐ Tagalog , and/or other Local Version(s) *N.B. Must have Version No, Date, Page No. in the footer*		
☐ Pharmacogenetic /Pharmacogenomic ICF (as needed by the study) *N.B. Must have Version No, Date, Page No. in the footer*		
☐ Data Collection Forms (*specify*)		
☐ Updated CV of PI and study team members **(DLSMHSI-IEC FORM 2(D) V1-2012)**		
☐ Proof of GCP Training in the last 3 years (*for those doing clinical studies*)		
☐ Ethical and/or Technical Approval from other Ethics/Technical Review Committee(s)		

☐ Institutional Endorsement (from the VC, Dean, or Medical Director)		
☐ Regulatory clearances (FDA approval for Phase I,II, II, IV clinical trials)		
☐ **Electronic copy of :** ☐ Review Checklist ☐ Review Application Form ☐ Study Protocol ☐ Informed Consent Assessment Form (*for studies involving human participants*) ☐ English version ☐ Tagalog , and/or other Local Version(s) ☐ Parent's Consent Form, Assent Form (*for involving children/minors and relevant popul* ☐ English version ☐ Tagalog , and/or other Local Version(s) ☐ Assent Form (*from children cognitively capable of giving consent*) ☐ English version ☐ Tagalog , and/or other Local Version(s) ☐ Pharmacogenetics ICF		
II. OTHER REQUIRED DOCUMENTS (*depending on the particular study/project application being submitted*		
☐ Investigator's Brochure (*for clinical trials phase I III*); Basic Product Information Document *clinical trials phase IV*)		
☐ CRFs		
☐ Recruitment advertisements (*as needed by the study*)		
☐ Other information/ documents for participants (*such as diaries, etc*., questionnaire)		
☐ Site Resources Checklist (*for clinical Trials*)		
☐ Memorandum of Agreement (*for collaborative studies*)		
☐ Details of Funding Agency/Sponsor		
☐ Institutional Biosafety Committee Approval (*for studies involving hazardous biological materials*)		

☐ Material Transfer Agreement (*for studies involving transfer of biological specimens*)		
☐ National Commission for Indigenous People (NCIP) Clearance (*for studies with indigenous populations*)		
☐ Insurance/Indemnity Policy		
☐ Others (*specify*)		

I understand that this Application for IEC Review and Approval will NOT be accepted unless all necessary documents are submitted.

I declare the authenticity of the documents submitted with this Application.

_____ _____

Signature Over Printed Name of Principal Investigator ***Date***

PROTOCOL REVIEW APPLICATION (FORM 2B/V1/2012)

To the Principal Investigator:

Please obtain an electronic copy of this Form, fill-out the requested information, and make your submission both in electronic version and hard copy. Print in letter-sized paper with printer default set at A4.

I. PROTOCOL INFORMATION		**IEC Protocol Tracking No.** *(to be assigned by IEC)*
Title		Version Number, Date
Study Protocol No.		Protocol Submission Date
Principal Investigator	Name: Contact Nos.:	☐ DLSMHSI Faculty ☐ DLSMHSI Student ☐ DLSMHSI Resident/Fellow ☐ Non-DLSMHSI (indicate):
Status of Review	☐ New ☐ Revised/Amended (*Please indicate version and date of version in resubmitted document footer*)	
Research Category	☐ Research involving human participants ☐ Animal Research ☐ Others (indicate)	
Type of Study	☐ Pre-Clinical ☐ Clinical ☐ Observational ☐ Interventional (Clinical Trial) ☐ Phase ____ ☐ Non-Clinical ☐ Epidemiological ☐ Document-based ☐ Socio-behavioral ☐ Controlled laboratory studies ☐ Herbal/CAM Research ☐ Diagnostics ☐ Medical Device ☐ Genetic/genomic research ☐ Operations/Process Research ☐ Others (indicate)	☐ Single-Center ☐ Multi-Center; No. of Study Sites ____ ☐ Screening ☐ Interim Analysis ☐ Randomized ☐ Stratified randomized ☐ Single-blind ☐ Double blind ☐ Open-labeled ☐ Parallel ☐ Cross-over ☐ Placebo-controlled ☐ Treatment-controlled ☐ Use of: ☐ Blood samples ☐ Tissue samples ☐ Genetic materials
Purpose and Duration of Study:	Purpose: ☐ Academic requirement ☐ Independent research work	Duration (in months): _____

	☐ Contract research ☐ Collaboration/Joint venture ☐ Others (indicate)	

Total No. of Participants in the Study _____	Groups of participants: ☐ Healthy Volunteers ☐ Patients ☐ Women of child-bearing potential ☐ Others (indicate)	Vulnerable Participants: ☐ In-utero ☐ Pre-term Newborns (up to ≤37weeks) ☐ Newborns (0-27days) ☐ Infant & Toddlers (28days-23months) ☐ Children (2-11years) ☐ Adolescents (12-17years) ☐ Elderly (>65years) ☐ Pregnant women ☐ Illiterate ☐ Seriously ill ☐ Terminally ill ☐ Handicapped ☐ Mentally challenged ☐ Others (indicate):
Gender ☐ Male ☐ Female		
Age Groups ☐ <18 yrs ☐ Adults (18-65yrs) ☐ Elderly (>65yrs)		

PROTOCOL SYNOPSIS (*maximum of 500 words*) clearly describing the following:
1. Justification for the Study
2. Study Design/Methodology
3. Participant Selection including vulnerability
4. Risks & Benefits
5. Respect for the dignity of the study participants

Previous Approval from other Technical/ Ethics Committees ☐ Approval Start and End Date ☐ Not Applicable	☐ Name of Technical Review Committee/ Ethics Review Committee _____
Funding Source:	☐ Investigator ☐ DLSMHSI ☐ Others (indicate):

I declare that I have:
- ☐ *NO Conflict of Interest in any form (personal, professional, financial, proprietary) with sponsor, the study, or the site*
- ☐ *personal/family interest in the study results*
- ☐ *proprietary interest in the study (patent, trademark, copyright, licensing etc)*

I declare that the above study has not commenced or been completed.

I declare that the information provided above is true and correct to the best of my knowledge.

I understand that it will require 30-60 days for the IEC to review and grant approval.

_____ _____

Signature Over Printed Name of Principal Investigator *Date*

CURRICULUM VITAE (for PI) (FORM 2C/V1/2012)

To the Principal Investigator:

Please obtain an electronic copy of this Form, fill-out the requested information, and make your submission both in electronic version and hard copy. Print in letter-sized paper with printer default set at A4.

Last Name	**First Name**	**Middle Name**	**TITLE: Ms/ Mr/ MD/ PhD**
Date of Birth		Sex	
Professional Mailing Address (*include Name of Institution*)		Study Site Address (*include Name of Institution*)	
Telephone (Ofc): Telephone (Res.)		Mobile No.: E-Mail:	

ACADEMIC QUALIFICATIONS (*from most current*)		
Degree/Certificate	**Year**	**Institution, Country**

PROFESSIONAL EXPERIENCE (*from most current*)		
	Year	**Institution, Country**

RELEVANT POSITIONS INCLUDING ACADEMIC APPOINTMENTS (*from most current*)		
Title	**Year**	**Institution, Country**

Brief Summary of Relevant Research Experience *(from most current)*		
I declare that the above information are true and correct to the best of my knowledge. _____ _____ *Principal Investigator Signature Over Printed Name* *Date*		

PROTOCOL ASSESSMENT FORM (FORM 2D/V2/2019)

To the IEC Reviewer:

Please describe or comment on how the assessment points were addressed by the study protocol. Indicate your conclusions under the "RECOMMENDATION".

Please obtain an electronic copy of this Form, fill-out the requested information, and submit to the Secretariat both in electronic version and hard copy. Print in letter-sized paper with printer default set at A4.

I. PROTOCOL INFORMATION *(to be filled out by the Primary Investigator/s)*	**IEC Protocol Tracking No.**
Study Protocol No.	Protocol Submission Date
Title	Version Number, Date
Name of Principal Investigator	Contact Nos.
Sponsor/CRO	
Study Site	
Type of Review (*to be filled out by the DLSMHSI-IEC*) ☐ Full Board ☐ Expedited	

ASSESSMENT POINTS		
1. SCIENTIFIC SOUNDNESS		**COMMENTS**
1.1. Study Objectives	☐ Clear ☐ Unclear	
1.2. Background information/data	☐ Sufficient ☐ Insufficient	
1.3. Study/ Sampling Design	☐ Appropriate ☐ Inappropriate	
1.4. Use of control arm/ placebo	☐ Justifiable ☐ Hardly justifiable	
1.5. Inclusion/ Exclusion/ Withdrawal Criteria	☐ Appropriate ☐ Inappropriate	
1.6. Statistical/ Data Analysis Plan	☐ Plausible ☐ Implausible	

1.7. Specimen Collection, Processing, Storage Procedures	☐ Adequate ☐ Inadequate	
1.8. Facilities/ Infrastructure at Study Site	☐ Adequate ☐ Inadequate	
1.9. PI Qualification, Competence, and Experience	☐ Suitable ☐ Unsuitable	
1.10 Contribution to science, research capacity, health care, treatment	☐ Yes ☐ No	
1.11. Benefit to Local Communities	☐ Yes ☐ No	
2. ETHICAL SOUNDNESS		**COMMENTS**
2.1. Privacy and Confidentiality Safeguards	☐ Yes ☐ No	
2.2. Involvement of human participants	☐ Necessary ☐ Not necessary	
2.3. Involvement of Vulnerable Populations	☐ Yes ☐ No	
2.4. Voluntary, non-coercive recruitment	☐ Yes ☐ No	
2.5. Participant Selection	☐ Equitable ☐ Not equitable	
2.6. Risk - Benefit Ratio	☐ Favorable ☐ Not favorable	
2.7. Informed Consent Process	☐ Appropriate ☐ Inappropriate	
2.8.Translation(s) of the ICF	☐ Accurate ☐ Inaccurate	

RECOMMENDATION	Justification for the Recommendation
☐ APPROVAL ☐ MINOR MODIFICATIONS	

☐ MAJOR MODIFICATIONS ☐ DISAPPROVAL	

Reviewer ☐ Primary ☐ Secondary	_____ *Reviewer's Signature Over Printed Name* *Date*

INFORMED CONSENT FORM (ICF) ASSESSMENT FORM (FORM 2D/V2/2019)

To the IEC Reviewer:

Please describe or comment on how the assessment points were addressed by the study protocol. Indicate your conclusions under the "RECOMMENDATION".

Please obtain an electronic copy of this Form, fill-out the requested information, and submit to the Secretariat both in electronic version and hard copy. Print in letter-sized paper with printer default set at A4.

I. PROTOCOL INFORMATION *(to be filled out by the Primary Investigator/s)*	**IEC Protocol Tracking No.**
Study Protocol No.	Protocol Submission Date
Title	Version Number, Date
Name of Principal Investigator	Contact Nos.
Sponsor/CRO	
Study Site	
Type of Review (*to be filled out by the DLSMHSI-IEC*) ☐ Full Board ☐ Expedited	

ASSESSMENT POINTS		
2.10. Provision for the following Information in the ICF		
2.8. Language of the Informed Consent/Assent document	☐ Clear ☐ Unclear	
2.10.1. Title of the Study	☐ Yes ☐ No ☐ NA	
2.10.2. Name of PI, Sponsor	☐ Yes ☐ No ☐ NA	
2.10.3. Investigative nature of the study	☐ Yes ☐ No ☐ NA	
2.10.4. Purpose of the Study	☐ Yes	

	☐ No ☐ NA	
2.10.5. Study Procedures/ Methods	☐ Yes ☐ No ☐ NA	
2.10.6. Number of participants involved in the study, in this site	☐ Yes ☐ No ☐ NA	
2.10.7. Nature of participation (treatment or control)	☐ Yes ☐ No ☐ NA	
2.10.8. Possibility of random allocation	☐ Yes ☐ No ☐ NA	
2.10.9. Expected duration of study participation	☐ Yes ☐ No ☐ NA	
2.10.10. Freedom to withdraw from the study at anytime without prejudice to appropriate medical care	☐ Yes ☐ No ☐ NA	
2.10.11. Time to consider whether to participate or not in the study	☐ Yes ☐ No ☐ NA	
2.10.12. Circumstances under which subject's participation may be terminated without regard to subject's consent	☐ Yes ☐ No ☐ NA	
2.10.13. Information about Study Product	☐ Yes ☐ No ☐ NA	
2.10.14. Responsibilities of the participant	☐ Yes ☐ No ☐ NA	
2.10.15. Possible benefits to the participant	☐ Yes ☐ No	

	☐ NA	
2.10.16. Foreseeable risks, discomforts, if any, to the participant	☐ Yes ☐ No ☐ NA	
2.10.17. Possible adverse effects of study drug/ procedure	☐ Yes ☐ No ☐ NA	
2.10.18. Free contraceptive choice	☐ Yes ☐ No ☐ NA	
2.10.19. Available alternative procedures/ treatment, if any	☐ Yes ☐ No ☐ NA	
2.10.20. Medical/ psychological support	☐ Yes ☐ No ☐ NA	
2.10.21. Participants to receive information relevant to their participation	☐ Yes ☐ No ☐ NA	
2.10.22. Participants to be informed of results of the tests/study	☐ Yes ☐ No ☐ NA	
2.10.23. Post-trial access to study product (drug/device) shown to be beneficial	☐ Yes ☐ No ☐ NA	
2.10.24. Financial cost to participants which are likely to result from participation	☐ Yes ☐ No ☐ NA	
2.10.25. Treatment/ compensation of study-related injury/ disability/ death	☐ Yes ☐ No ☐ NA	
2.10.26. Compensation/ reimbursement for time, inconvenience, travel and other similar costs	☐ Yes ☐ No ☐ NA	

2.10.27. Insurance/ Indemnity Arrangement, where applicable	☐ Yes ☐ No ☐ NA	
2.10.28. Extended access to, emergency use of, and/or compassionate use of study product	☐ Yes ☐ No ☐ NA	
2.10.29. Whom to contact for queries/ complaints about the research, participant's rights, and in the event of trial-related injury	☐ Yes ☐ No ☐ NA	
2.10.30. Name and contact numbers PI/ Study coordinator	☐ Yes ☐ No ☐ NA	
2.10.31. Name and contact number Chair of DLSMHSI-IEC	☐ Yes ☐ No ☐ NA	
2.10.32. Name of Impartial Witness	☐ Yes ☐ No ☐ NA	
2.10.33. Participants to be given duplicate copy of signed ICF	☐ Yes ☐ No ☐ NA	

RECOMMENDATION	**Justification for the Recommendation**
☐ APPROVAL ☐ MINOR MODIFICATIONS ☐ MAJOR MODIFICATIONS ☐ DISAPPROVAL	

Reviewer ☐ Primary ☐ Secondary	_____ *Reviewer's Signature Over Printed Name* *Date*

REVIEW OF RESUBMITTED STUDY PROTOCOL (FORM 2E/V2/2020)

To the IEC Member:

Study protocols which have been reviewed earlier with recommendations for corrections or modifications are revised and resubmitted for IEC reconsideration. The protocol-related documents including the changes(s) made are attached for your perusal.

Please obtain an electronic copy of this Form, fill-out the requested information, and forward to the Secretariat both in electronic version and hard copy. Print in letter-sized paper with printer default set at A4.

I. PROTOCOL INFORMATION	**IEC Protocol Tracking No.**
Study Protocol No.	Initial Review Date: <dd/mm/yy> Last Review Date: <dd/mm/yy>
Title:	Version Number, Date
Name of Principal Investigator	Contact Nos.:
Sponsor/CRO	
Study Site	
Type of Review (*To be determined by IEC*) ☐ Full Board ☐ Expedited	

II. INFORMATION REQUIRED	**PROTOCOL RESUBMISSION DATE <dd/mm/yy>**
List of IEC recommendations from last review	**IEC Reviewer Comments**

2. Were all the recommendations addressed? ☐ YES ☐ NO *explain/comment)*

III. IEC RECOMMENDATION	Justification for the Recommendation
☐ APPROVAL ☐ MINOR MODIFICATION ☐ MAJOR MODIFICATION ☐ DISAPPROVAL	
Reviewer ☐ Primary ☐ Secondary	_____ _____ *Reviewer's Signature Over Printed Name* *Date*

DLSMHSI-IEC FORM 2F-V1-2012- Acknowledgement Letter (for Protocol Submission)

dd/mm/yy>

< TITLE, NAME, SURNAME>
<Position>
<Institution/Affiliation>
<Address>

Re:

Study Protocol No.	
Protocol Submission Date:	
Title:	*Version Number, Date*
Name of Principal Investigator	
Sponsor/CRO	
Study Site	

Dear <Title, Surname>:

This has reference to the above study protocol which was submitted to the IEC for scientific and ethical review. It will be tabled for discussion on <date of full board meeting>. You will be notified in writing of the outcome of the IEC review within 10 working days of the meeting.

Should you have any question or need additional information/clarification, please feel free to contact the undersigned at (046) 481-8000 local 8042.

Thank you for your submission.

Respectfully yours,

<NAME OF REVIEW PANEL CHAIR>
Chair, DLSMHSI Independent Ethics Committee

PROTOCOL TRACKING SHEET (Form 2G/V1/2012)

I. PROTOCOL INFORMATION	IEC Protocol Tracking No.
Study Protocol No.	Protocol Submission Date
Title	Version Number, Date
Name of Principal Investigator	Contact Nos.
Sponsor/CRO	

II. REQUIRED SUBMISSION	DATE DUE	REMINDER SENT?	REMARKS
Continuing Review		☐ Yes ☐ No	
Final Report		☐ Yes ☐ No	

III. DOCUMENT LOG	DATE IN	Received by:	DATE OUT	Issued by:	REMARKS

DLSMHSI-IEC FORM 2H-V2-2019-Notification Letter (for Modification Prior to Approval)

<dd/mm/yy>

< TITLE, NAME, SURNAME>
<Position>
<Institution/Affiliation>
<Address>

Re:

Study Protocol No.	
Protocol Submission Date:	
Title:	*Version Number, Date*
Name of Principal Investigator	
Sponsor/CRO	
Study Site	

Dear <Title, Surname>:

This has reference to the above protocol in which the <study protocol/resubmitted study protocol/proposed amendments> were submitted to the DLSMHSI-IEC for review and approval.

We wish to inform you that the **De La Salle Medical and Health Sciences Institute – Independent Ethics Committee** reviewed your study protocol during its regular meeting <dd/mm/yy> and is requesting further clarification.

As a result of the review, DLSMHSI-IEC action is ***MAJOR MODIFICATIONS PRIOR TO APPROVAL /MINOR MODIFICATIONS PRIOR TO APPROVAL.*** Recommended revisions and/or clarifications are summarized below:

1.

A resubmission of one copy/10 copies within 90 days of receipt using the assigned IEC Protocol Code in all the succeeding transactions is required, otherwise the study will be declared closed for DLSMHSI-IEC records. Please note that the recommended revisions must be:

1. Integrated in a revised version of the protocol or other study documentation, with the revisions tabbed and clearly highlighted. Include a footer in all pages that indicates the Version Number and Date of the revised version.
2. Summarized in a cover letter indicating in which the page/section/paragraph of the revised version the specific revisions may be found

Should you have any question or need further clarification/information, please feel free to contact the undersigned at (046) 481-8000 local 8042.

The DLSMHSI-IEC looks forward to hearing from you soon.

Respectfully yours,

<NAME OF REVIEW PANEL CHAIR>
Chairman, DLSMHSI Independent Ethics Committee

DLSMHSI-IEC FORM 2I-V2-2019- Approval Letter (for Reviewed Protocols)

<dd/mm/yy>

< TITLE, NAME, SURNAME>
Principal Investigator
<Institution/Affiliation>
<Address>

Re:

Study Protocol No.	***IEC Protocol Tracking No***
Protocol Submission Date: <dd/mm/yy>	*Date of Initial Review:*
Title:	*Version Number, Date*
Sponsor/CRO	

Dear <Title, Surname>:

Thank you for submitting the above protocol for scientific and ethical review by the IEC which is constituted and operated in accordance with the Declaration of Helsinki, National Ethical Guidelines for Health Research, Council for International Organizations of Medical Sciences (CIOMS), and the International Conference on Harmonization/Good Clinical Practice (ICH/GCP).

The IEC is pleased to inform you that the above study protocol has been granted ***APPROVAL*** for implementation, in its meeting held on <dd/mm/yy>, with the following IEC members in attendance.

<Name >	<Name >
<Name >	<Name >
<Name >	<Name >
<Name >	<Name >
<Name >	<Name >
<Name >	<Name >

The approval is valid for one (1) year from the date of this letter or for the duration of the study whichever is earlier. Specifically, approval relates to the following:

1. <document>

2. <document>

Please be advised that any change in the protocol or informed consent document that may affect the scientific and/or ethical aspects of this IEC-approved study must be promptly reported and must use the assigned IEC Protocol Code to all the succeeding transactions, and that an on-site visit may be conducted if deemed necessary. Moreover, continued approval is contingent upon the submission of the following post-approval requirements, whichever is applicable.

1. **Protocol Amendment Submission** (IEC FORM 3A/V1.2012) – must be filed within 7 days of the modification
2. **Continuing Review Application** (IEC FORM 3B/V1/2012) – must be filed 60 days prior to expiry date of current IEC approval
3. **Final Report** (IEC FORM 3C/V1/2012) – must be filed within 90 days after study completion
4. **Non-Compliance (Deviations/Violations) Report(s)** (IEC FORM 3D/V1/2012) - must be reported not later than 7 days of discovery for Major non-compliance; minor/administrative deviations can be submitted with the Continuing Review Application
5. **Early Study Termination Application** (IEC FORM 3E/V1/2012) – must be filed within 15 days of the termination
6. **SAE Report** (IEC FORM 3F/V2/2014) – for *on-site* SAE and in the event of death, must be reported within *24 hours when Principal Investigator is informed of the event*; for *off-site* SAE and in the event of death, must be reported within *24 hours when Principal Investigator receives report from the Sponsor*.

Should you have any question or need further clarification/information, please feel free to contact the undersigned at (046) 481-8000 local 8042.

The IEC wishes you great success in this endeavor.

Respectfully yours,

<NAME OF IEC CHAIR
Chairman, DLSMHSI Independent Ethics Committee