

#### I. STRUCTURE AND COMPOSISTION

**DLSMHSI-IEC SOP Chapter 1** 

Standard Operating Procedures Effective Date: November 2019

#### **CHAPTER 1: STRUCTURE AND COMPOSISTION**

- 1. Ethical Framework and Constitution of the De La Salle Medical and Health Sciences Institute -**Independent Ethics Committee (DLSMHSI-IEC)**
- 2. Appointment of DLSMHSI-IEC Members
- 3. Selection of Independent Consultants
- 4. Selection and Function of Serious Adverse Event (SAE) Subcommittee
- 5. Training of IEC Members and Staff
- 6. IEC Review Fee and Honoraria of IEC Members
- 7. Version History

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



#### INDEPENDENT ETHICS COMMITTEE

Cavite (046) 481-8000 loc. 8042/ Manila (02) 988-3100 Local 4000

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1. Ethical Framework and Constitution of the De La Salle Medical and Health Sciences Institute – Independent Ethics Committee (DLSMHSI-IEC)

#### 1.1 Purpose

To describe the composition and structure of the De La Salle Medical and Health Sciences Institute – Independent Ethics Committee (DLSMHSI-IEC) in compliance with national and international guidelines in ethical research

#### 1.2 Specific Objectives

To describe the following De La Salle Medical and Health Sciences Institute – Independent Ethics Committee (DLSMHSI-IEC) procedures and define the Terms of Reference (TOR) for DLSMHSI-IEC related to the:

- Constitution of the IEC
- Confidentiality/Conflict of Interest Agreement with DLSMHSI-IEC members, staff and consultants
- Training of Personnel and DLSMHSI-IEC Members
- Selection of Independent Consultants
- Selection and Function of Serious Adverse Event (SAE) Subcommittee
- Incentives for DLSMHSI-IEC Members and Consultants

#### 1.3 Scope

- **1.3.1** The DLSMHSI-IEC reviews and monitors health researches that involve:
  - Protocols developed and implemented by DLSMHSI faculty, consultant and resident staff utilizing patients and research participants within the DLSMHSI or De La Salle University Medical Center and the Angelo King Medical Research Center.
  - Protocols developed by non-affiliated organizations and researchers and implemented by commissioned DLSMHSI faculty and consultant staff or non-affiliated researchers utilizing patients and research participants within the DLSMHSI or De La Salle University Medical Center and the Angelo King Medical Research Center.
  - Protocols developed by non-affiliated organizations and researchers and implemented by commissioned DLSMHSI faculty and consultant staff or non-affiliated researchers utilizing patients and research participants in areas outside the DLSMHSI campus (i.e. hospitals and institutions in Region IV without ethics committees).
- **1.3.2** This Standard Operating Procedure (SOP) provides the Terms of Reference (TOR) that describe the framework for the constitution of the DLSMHSI-IEC, the responsibilities and activities of its officers, members, staff and consultants.

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#### 1.4 Responsibilities

It is the responsibility of the DLSMHSI-IEC members, officers, and secretariat to understand and implement the SOPs of the DLSMHSI-IEC.

#### 1.5 Ethical basis

- **1.5.1** The DLSMHSI-IEC is guided in its reflection, advice, and decision by the ethical principles and procedures expressed in the following international guidelines and documents:
  - Declaration of Helsinki (2008 and subsequent revisions)
  - Council for International Organizations of Medical Sciences (CIOMS) 2002, 2009 and 2016
- **1.5.2** The DLSMHSI-IEC shall function in accordance with the national laws, regulations, and guidelines.
- **1.5.3** The DLSMHSI-IEC provides its own standard operating procedures based on:
  - Operational Guidelines for Ethics Committees that Review Biomedical Research (2000) by the World Health Organization (WHO)
  - Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) by the World Health Organization (WHO)
  - International Conference on the Harmonization of Good Clinical Practice (ICH-GCP)
  - National Ethical Guidelines for Health and Health-Related Research 2017 by the Philippine Health Research Ethics Board (PHREB)
  - Philippine Food and Drug Authority regulations and other relevant laws and regulations
- **1.5.4** The DLSMHSI-IEC recognizes that the protocols it approves may also be approved by the national and/or local ethics committees prior to their implementation in specific localities.
- **1.5.5** In evaluating protocols and ethical issues, DLSMHSI-IEC is cognizant of the diversity of laws, cultures and practices governing health research in various countries around the world.
- **1.5.6** It attempts to inform itself, whenever possible, of the regulations and requirements of the sponsor countries conducting global protocols in the Philippines; and of the requirements and conditions of the various localities



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where a proposed De La Salle Medical and Health Sciences Institute research is being considered.

**1.5.7** The DLSMHSI-IEC takes the initiative to be informed, as appropriate, by the national/local ethics committees and researchers of the impact of the research that it has approved.

#### 1.6 Constitution – Organizational Structure

The Vice Chancellor for Research (VCR) appoints the DLSMHSI-IEC Chair and Member - Secretary to facilitate the discharge of functions of the DLSMHSI-IEC along the line of authority indicated by the following chart:

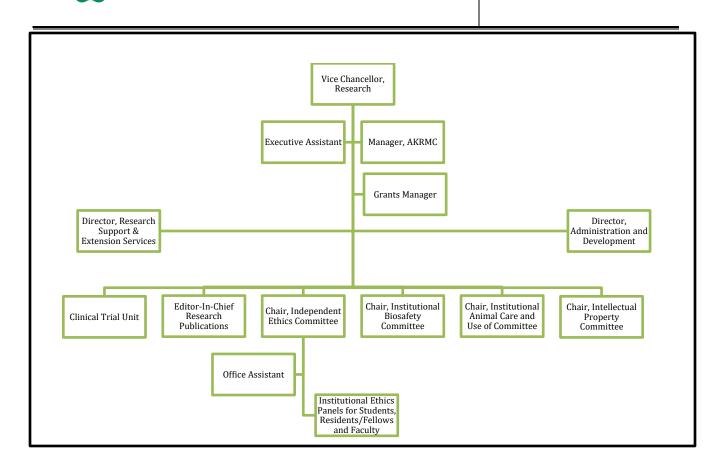
# De La Salle Medical and Health Sciences Institute Dasmariñas, Cavite 4114 INDEPENDENT ETHICS COMMITTEE

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#### 2. Appointment of DLSMHSI-IEC Members

#### 2.1 Purpose

To describe the appointment process of the members of the DLSMHSI-IEC and to identify the roles and responsibilities of the IEC officers, members and secretariat.

#### 2.2 Scope

While the DLSMHSI-IEC remains under the authority of the Vice Chancellor for Research (VCR), it has to maintain its independence and develop its competence related to decision making as defined in the international and national guidelines. The membership's Standard Operating Procedures (SOPs) cover the nomination and appointment procedures of IEC members, officers, independent consultants and SAE Subcommittee.

#### 2.3 Responsibility

It is the responsibility of the DLSMHSI VCR to formally appoint the members, officers and consultants of the DLSMHSI- IEC after due consultation with the current members of the IEC.

#### 2.4 Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Ask the DLSMHSI-IEC members to nominate	Chair
	potential new members.	
Step 2	Propose/submit names of potential members to	Members/ Chair
	the Chair. The Chair evaluates the	
	qualifications of the nominee(s) and selects	
	and invites the candidates(s)	
Step 3	The new member/s accept invitation	New Members
Step 4	Recommend and submit a list of	Chair/ Secretariat
	potential members to the VCR	
Step 5	Appoint new DLSMHSI-IEC members	VCR
Step 6	Receive appointment letter (DLSMHSI-IEC	New Members
	FORM 1A1-7-V2-2019) and sign Confidentiality	
	and Conflict of Interest (COI) Agreement (FORM	
	1B-V1-2012) for Members and submit updated	
	Curriculum Vitae (FORM 1C-V1-2012)	
Step 7	Members render services according to terms,	New Members
-	conditions, roles and responsibilities set by the	
	IEC	



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#### 2.4 Description of Detailed Instructions

- **2.4.1** The Chair asks the DLSMHSI-IEC members to nominate potential new members.
- **2.4.2** The IEC Members propose/submit names of potential members to the Chair. The Chair evaluates the qualifications of the nominee(s) and elects and invites the candidates(s).
- **2.4.3** The new member/s accept invitation.
- **2.4.4** The Chair recommends and submit a list of potential members to the VCR for appointment.
- 2.4.5 Appoint new DLSMHSI-IEC members.
- **2.4.6** Receive appointment letter (DLSMHSI-IEC FORM 1A1-7-V2-2019) and sign Confidentiality and Conflict of Interest (COI) Agreement (FORM 1B-V1-2012) for Members and submit updated Curriculum Vitae (FORM 1C-V1-2012).
- **2.4.7** Members render services according to terms, conditions, roles and responsibilities set by the IEC

#### 2.5 Requirements for Membership/Independent Consultants

DLSMHSI-IEC Membership

- **2.5.1** The DLSMHSI-IEC is composed of at least 5 members.
- **2.5.2** Membership is multidisciplinary and multi-sectoral.
- 2.5.3 Membership includes persons whose primary concerns are in medical science, at least one member who is a pediatrician, at least one member who is in a nonmedical/non-scientific area and at least one member who is non-affiliated. Members have diverse background and experience to foster a comprehensive and efficient review of research activities commonly conducted by the De La Salle Medical and Health Sciences Institute staff and non-affiliated organizations.
- **2.5.4** Relevant expertise may include medicine and research, social or behavioral science, law, philosophy, environmental science and public health. It is recommended that the DLSMHSI-IEC should include a person who will represent the interest and concerns of the community.
- **2.5.5** The DLSMHSI-IEC aims for gender balance in its membership with equal representation of men and women members in order to promote gender sensitivity in its review procedures.
- **2.5.6** The DLSMHSI-IEC shall have representatives from both the older and younger generations.
- **2.5.7** Independent consultants are invited whenever necessary to provide expert opinion related to protocols under review.
- **2.5.8** The DLSMHSI-IEC shall have an office and adequate support staff for carrying out its responsibilities.
- **2.5.9** The DLSMHSI-IEC shall adhere to quorum requirements as defined in international and national guidelines for RECs that review health research. For RECs with five to nine members, quorum requires at least five members present, otherwise, quorum shall follow the 50%+1 rule. Quorum also requires the presence of at least one non-medical or non-scientist and one non-affiliated



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member(s) to make decisions about the proposed research (WHO, 2011). In the absence of these required members, there is no quorum (NEGHHRR, 2017).

2.5.10 When reviewing clinical trials involving children or pediatric patients, a pediatrician or child development specialist shall be present during its board meeting.

#### 2.6 Terms of Reference

- 2.6.1 The VCR shall indicate in the appointment letter (Form 1A1-7/V2/2019) the IEC's function, terms of office, scope of work, conditions of appointment, system of replacement or recall, and compensation, if any. Members are initially appointed for a term of one (1) year. After one year, their appointments may be renewed by the VCR upon recommendation of the IEC chair, for a one (1) three (3) year-term, then renewable up to three (3) consecutive terms.
- **2.6.2** The IEC shall adopt a mechanism for rotation of its membership roster to enable participation of new members with fresh outlook and approaches, but it shall also strive to ensure continuity, development and maintenance of expertise.

#### 2.7 Qualifications of Members

- **2.7.1** Members are selected based on their good moral character and personal capacities, their ethical and/or scientific knowledge and expertise, as well as their willingness to volunteer their time and effort to perform their functions in the IEC.
- 2.7.2 Members shall have prior training in Good Clinical Practice, research methodology and research ethics, or should be willing to undergo such training during their membership which will be recorded in the Training Records Form (FORM 1D-V1-2012).
- **2.7.3** Members shall disclose in writing any financial, professional or personal interest or involvement in a project or proposal under consideration which is in conflict with their function as a reviewer.
- **2.7.4** Members shall submit their curriculum vitae (Form 1C/V1/2012), properly signed and dated, and update them at least once every two (2) years.
- 2.7.5 Members will be required to sign a confidentiality/conflict of interest agreement (Form 1B/V1/2012) at the start of their term. The agreement should cover all applications, meeting deliberations, information on research participants and related matters. The secretariat staff is likewise expected to sign a similar document.
- **2.7.5** The IEC shall decide on how to manage specific conflict of interest of members related to their participation in committee deliberations or actions regarding a particular protocol covered by the provisions of the Confidentiality/Conflict of Interest Agreement (Form 1B/V1/2012).
- **2.7.6** The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IEC in the course of its work.

#### 2.8 Conditions of Appointment of Members



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All prospective IEC members shall be willing:

- **2.8.1** To make public his/her full name, profession, and affiliation as an IEC member.
- 2.8.2 Disclose all financial accountability, reimbursement for work and expenses, related to their work in the DLSMHSI IEC that shall record and publicly disclose its financial records upon request.
- **2.8.3** All IEC members and independent consultants shall sign the Confidentiality/Conflict of Interest Agreement (Form 1B/V1/2012) regarding meeting deliberations, applications, information on research participants and related matters.

#### 2.9 Resignation, Disqualification and Replacement of Members

- **2.9.1** Members may resign their positions by submitting a letter of resignation to the Chair and endorsed to the VCR.
- **2.9.2** Members may be separated from the committee by disqualification for valid reasons as determined by majority vote of the committee members.
- **2.9.3** Members that have resigned or have been disqualified may be replaced by following the nomination and appointment procedures previously stated.
- **2.9.4** The terms of replacement shall be limited to the remaining term of the member that he/she has replaced.

#### 2.10 IEC Officers

The following officers through the exercise of their respective responsibilities contribute to efficient IEC operation:

#### 2.10.1 Chair

- Presides over the IEC meetings and is accountable to the VCR
- Prepares an annual report summarizing IEC activities and decision outcomes to the VCR.
- Ensures sufficient financial and administrative support for IEC operations.
- Represents the IEC interests within the institutional administration.
- Represents the IEC to the outside world.
- Evaluates the protocol whether it is for expedited, full board or exempted from review.
- Assigns the primary reviewers of the initial protocols submitted for review.

#### 2.10.2 Co-Chair

- Presides over meetings in the absence of the Chair.
- Performs other duties as designated by the Chair.

#### 2.10.3 Member-Secretary



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- Assist the Chair in implementing assignment of reviewers and invitation of Independent Consultants of the protocols.
- Oversees that the functions of the Secretariat are done properly and in a timely manner.
- Supervises and supports the Secretariat in resolving administrative issues and concerns.

#### 2.11 DLSMHSI IEC Secretariat

- **2.11.1** The DLSMHSI IEC secretariat is composed of the administrative support staffs who are employees of the DLSMHSI and appointed by the VCR. The staff is composed of two IEC Secretariats.
- **2.11.2** The IEC coordinators shall have the following functions:
  - Organizing an effective and efficient tracking procedure for each proposal received.
  - Preparation, maintenance and distribution of protocol/study files.
  - Organizing IEC meetings regularly.
  - Preparation and maintenance of meeting agenda and minutes.
  - Maintaining reliable IEC documentation and archiving procedures.
  - Communicating with the IEC members and investigators.
  - Arrangement of training for personnel and IEC members.
  - Organizing the preparation, review, revision and distribution of SOPs and guidelines.
  - Providing the necessary administrative support for IEC-related activities of the Chair.
  - Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant literature to the IEC members.
  - Maintaining a library of relevant resource materials and references.

## 2.12 Roles and Responsibilities of IEC Scientific/Medical Members (Affiliated/Non-Affiliated)

- 2.12.1 Participate in IEC meetings.
- **2.12.2** Review, discuss and consider the ethical and scientific merits of research proposals/protocols submitted for evaluation.
- 2.12.3 Assess serious adverse event reports and recommend appropriate action.
- **2.12.4** Review progress reports and monitor ongoing studies as appropriate.
- 2.12.5 Evaluate final reports.
- **2.12.6** Maintain confidentiality of the documents and deliberations during IEC meetings.
- **2.12.7** Declare any conflict of interest.
- **2.12.8** Participate in continuing education activities in health research and ethics.



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#### 2.13 Roles and Responsibilities of IEC Lay Members (Affiliated/Non-Affiliated)

- 2.13.1 Participate in IEC meetings.
- **2.13.2** Review, discuss and consider the ethical merits of the informed consent form and process of research proposals/protocols submitted for evaluation.
- **2.13.4** Review progress reports and monitor ongoing studies as appropriate.
- 2.13.5 Evaluate final reports.
- **2.13.6** Maintain confidentiality of the documents and deliberations during IEC meetings.
- 2.13.7 Declare any conflict of interest.
- 2.13.8 Participate in continuing education activities in health research and ethics.

#### 2.14 Confidentiality and Conflict of Interest Agreement

- **2.14.1** The Secretariat provides a copy of the agreement form (Form 1B/V1/2012) to each member of the IEC together with the appointment letter
- **2.14.2** It is the responsibility of all IEC members to read, understand, accept and sign the agreement contained in the Confidentiality and Conflict of Interest form before beginning their ethical review functions.
- **2.14.3** If a member refuses to sign such agreement, this may be a ground for his/her disqualification to serve in the IEC.
- **2.14.4** Newly appointed members obtain two copies of the agreement form, read the text very carefully, fill in their names, sign and date the forms.
- **2.14.5** Any member may ask questions, or ask for a clarification from the Chair of Secretariat related to the contents of the document.
- **2.14.6** The members keep a copy for their records. The Secretariat keeps a copy of the signed agreement in the membership files.



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#### 3. Selection of Independent Consultants

#### 3.1 Purpose

To describe the process for the appointment of IEC Independent Consultants.

#### 3.2 Scope

This SOP describes the procedures for engaging the services of a professional/expert as a consultant to the IEC. If the Chair of the IEC determines that a study involves procedure(s) that are not within the area of competence or expertise of the IEC members, the Chair may invite individuals with expertise in special areas to assist in the review of the protocols that require such expertise in addition to those available within the IEC. The consultant is expected to impart expert knowledge especially in risk / benefit assessment; and mitigation; any new knowledge pertaining to the topic of inquiry, procedures.

#### 3.3 Responsibility

Upon the advice or recommendation of the Chair or any IEC member, it is the responsibility of the IEC members to request, nominate and endorse the name of the independent consultants to be invited and appointed by the Chair.

#### 3.4 Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Chair/ IEC Members request and nominate	Chair/Member
	potential independent consultant(s).	
Step 2	IEC Secretariat provides the list of Independent	Chair/Secretariat
	Consultants to the Chair. The Chair evaluates	
	the qualifications and selects/invites the	
	candidates.	
Step 3	The independent consultant accepts invitation	Independent Consultant
Step 4	Appoint new DLSMHSI-IEC consultants	Chair
Step 5	Receive appointment letter (FORM 1A6-V2-	Independent Consultant
	2019) and sign Confidentiality and Conflict of	
	Interest (COI) Agreement for Independent	
	Consultants (FORM 1B-V1-2012) and submit	
	updated Curriculum Vitae (FORM 1C-V1-2012)	
Step 6	Consultants render services	Consultant

#### 3.5 Description of Detailed Instructions

3.5.1 Chair/ IEC Members request and nominate potential independent consultant(s). An IEC member nominates independent consultant(s) to help review research where the IEC lacks expertise.



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- **3.5.2** IEC Secretariat provides the list of Independent Consultants to the Chair. The Chair evaluates the qualifications and elects/invites the candidates. The IEC Secretariat compiles a list of independent consultants and the Chair conducts a qualification review of the potential consultant(s).
- **3.5.3** The independent consultant accepts invitation. The Chair invites the independent consultant(s) and awaits the acceptance of the consultant.
- 3.5.4 Appointment of the new DLSMHSI-IEC consultants by the Chair.

  The Chair appoints independent consultant(s) to help the IEC in protocol review.

  Upon appointment the independent consultant(s) is/are informed of procedures and schedule of meetings of the IEC.
- 3.5.5 The New Appointed Independent Consultant/s receive appointment letter (FORM 1A6-V2-2019) and sign Confidentiality and Conflict of Interest (COI) Agreement for Independent Consultants (FORM 1B-V1-2012) and submit updated Curriculum Vitae (FORM 1C-V1-2012).

Independent Consultant signs agreements. Store pertinent documents in IEC files for independent consultants. Maintain a list of consultants and the areas of their expertise. Contact the new independent consultant who will be asked to provide:

- A signed Letter of Appointment (FORM 1A6-V2-2019)
- An updated curriculum vita (FORM 1C-V1-2012)
- A signed Confidentiality and Conflict of Interest Agreement (FORM 1B-V1-2012)
- **3.5.6** The Independent Consultant/s render services.

The IEC Secretariat provides study protocol documents to the concerned consultant for review, after the latter has signed the confidentiality and conflict of interest agreement.

The consultant must complete the assessment form, in accordance with his/her field of expertise, for the protocol under review at the same time the study protocol is being reviewed by the committee.

The consultant may attend the IEC meeting, present his/her assessment, and participate in the discussion but without the right to vote. The assessment form becomes a permanent part of the study protocol file.

As a consultant, you are asked to impart your expert knowledge especially in risk / benefit assessment; and mitigation; any new knowledge pertaining to the topic of inquiry, procedures.

The independent consultant's services may be terminated by either the consultant or by the IEC.

Upon termination of services, the Secretariat shall ensure that all the necessary documentation is filed with the other administrative documents.



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#### 4. Selection and Function of Serious Adverse Event (SAE) Subcommittee

#### 4.1 Purpose

To describe the process for the appointment and roles and responsibilities of IEC SAE Subcommittee members.

#### 4.2 Scope

This SOP describes the procedures for engaging the services of a professional/expert as an SAE Subcommittee member to the IEC. The assessment is focused on the submitted on-site adverse events (AE), serious adverse events (SAEs) and suspected unexpected serious adverse reaction (SUSAR) by the selected SAE Subcommittee members must be reported to the next IEC board meeting for information of the safety status of the participants involved in the approved studies. On the other hand, off-site AE, SAEs and SUSARs are to be analyzed as trending and reported to the Committee every six months.

#### 4.3 Responsibility

Upon the advice or recommendation of the Chair or any IEC member, it is the responsibility of the IEC members to request, nominate and endorse the name of the SAE subcommittee consultant to be appointed by the Chair.

#### 4.4 Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Chair/ IEC Members request and nominate potential SAE subcommittee member(s).	Chair/Member
Step 2	IEC Secretariat provides the names of the potential SAE Subcommittee member(s) to the Chair. The Chair evaluates the qualifications and selects/invites the candidates.	Chair/Secretariat
Step 3	The SAE Subcommittee member accepts invitation	SAE Subcommittee member
Step 4	Appoint new DLSMHSI-IEC SAE Subcommittee member	Chair
Step 5	Receive appointment letter and sign Confidentiality and Conflict of Interest (COI) Agreement for SAE Subcommittee member and submit updated Curriculum Vitae	SAE Subcommittee member
Step 6	SAE Subcommittee member render services	SAE Subcommittee member

#### 4.5 Description of Detailed Instructions

**4.5.1** Chair/ IEC Members request and nominate potential SAE subcommittee member(s).



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An IEC member nominates SAE Subcommittee member(s) to help review the adverse events (AE), serious adverse events (SAEs) and suspected unexpected serious adverse reaction (SUSAR) that are not within the area of competence or expertise of the IEC members.

**4.5.2** IEC Secretariat provides the names of the potential SAE Subcommittee member(s) to the Chair. The Chair evaluates the qualifications and selects/invites the candidates.

The Chair conducts a qualification review of the potential SAE Subcommittee member(s) and invites the selected SAE Subcommittee member(s).

- **4.5.3** The SAE Subcommittee member accepts invitation.
- **4.5.4** Appoint new DLSMHSI-IEC SAE Subcommittee member by the Chair. The Chair appoints the SAE Subcommittee member(s) to help the IEC in adverse events, serious adverse events and suspected unexpected serious adverse reaction (SUSAR) review.
- 4.5.5 Receive appointment letter (FORM 1A7-V1-2019) and sign Confidentiality and Conflict of Interest (COI) Agreement for SAE Subcommittee member (FORM 1B-V1-2012) and submit updated Curriculum Vitae (FORM 1C-V1-2012). SAE Subcommittee member signs agreements. Store pertinent documents in IEC files for SAE Subcommittee members. Contact the new SAE Subcommittee members who will be asked to provide:
  - A signed Letter of Appointment (FORM 1A7-V1-2019)
  - An updated curriculum vita (FORM 1C-V1-2012)
  - A signed Confidentiality and Conflict of Interest Agreement (FORM 1B-V1-2012)
- **4.5.6** SAE Subcommittee member render services.

SAE Subcommittee member render services pertaining to protocol adverse events (AE), serious adverse events (SAEs) and suspected unexpected serious adverse reaction (SUSAR) review.

The IEC Secretariat provides on-site and off-site adverse events, serious adverse events and suspected unexpected serious adverse reaction (SUSAR) reports to the concerned SAE Subcommittee member for review, after the latter has signed the confidentiality and conflict of interest agreement.

The on-site AE, SAE and SUSAR reports are reviewed regularly and the recommendation are consolidated for reporting in the next IEC board meeting. The off-site AE, SAE and SUSAR reports are to be analyzed as trends and reported to the IEC committee board meeting twice a year.

The SAE Subcommittee member's services may be terminated by either them or by the IEC.

Upon termination of services, the Secretariat shall ensure that all the necessary documentation is filed with the other administrative documents.



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#### 5. Training of IEC Members and Staff

#### 5.1 Purpose

To describe DLSMHSI IEC procedures to ensure initial and continuing training and professional education of members and staff.

#### 5.2 Scope

The DLSMHSI is cognizant of the importance of training and continuing professional development. This SOP describes the training requirements of DLSMHSI IEC members and staff from initial training to continuing education to maintain and update IEC competence in the review of different types of protocols.

#### 5.3 Responsibility

It is the responsibility of all the IEC officers, members and staff to have themselves educated and trained regularly. The Secretariat keeps track of the training needs of all members and staff and prepares a training plan.

#### 5.4 Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	The Chair/Secretariat provides initial training for new IEC members and staff.	Chair/Secretariat
Step 2	Secretariat and members keep track of training needs and plan for continuing professional education.	Chair/Members/ Secretariat
Step 3	Secretariat and members regularly monitor for educational and training opportunities. Decide appropriateness and feasibility of the course and apply accordingly.	Chair/Members/ Secretariat
Step 4	Member and staff attend and participate in the course or conference and document the attendance.	Members/Secretariat
Step 5	Secretariat files training records of the IEC members and staff (Form 1D/V1/2012)	Secretariat

#### 5.5 Description of Detailed Instructions

**5.5.1** The Chair/Secretariat provides initial training for new IEC members and staff. Initial research ethics training shall consist of basic training in research ethics principles, GCP, and in-house mentoring in IEC standard operating procedures (SOPs).

The IEC officers shall ensure that training is provided to all new members.



#### INDEPENDENT ETHICS COMMITTEE

Cavite (046) 481-8000 loc. 8042/ Manila (02) 988-3100 Local 4000

# I. STRUCTURE AND COMPOSITION

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Standard Operating Procedures Effective Date: November 2019

**5.5.2** The Secretariat and members keep track of training needs and plan for continuing professional education.

IEC members shall maintain competence by ensuring that they have updated knowledge on the following:

- Good Clinical Practice (GCP)
- Declaration of Helsinki
- Council for International Organizations of Medical Sciences (CIOMS)
- Ethical Guidelines
- Relevant laws and regulations
- Relevant developments in Science, health and safety, etc.
- International meetings and conferences
- 5.5.3 The Secretariat and members regularly monitor for educational and training opportunities and decide appropriateness and feasibility of the course and apply accordingly.

Continuing Professional Education of IEC members

- All members should have training in IEC SOPs. In addition, they should be provided with external training opportunities at least once a year.
- The IEC officers shall acquire information about training courses or conferences that are periodically announced on websites, bulletin boards and various media channels in coordination with the Secretariat.
- Plan the training activities of individual IEC members based on their training needs.
- Ensure sufficient budgetary support for training activities.
- Facilitate attendance of IEC members and staff once specific training activities are scheduled.
- **5.5.4** Member and staff attend and participate in the course or conference and document the attendance.

Documentation of training records

- Prepare attendance sheets of in-house training with relevant information about the topic, speakers, facilitators, trainers, duration, date and venue. Ask member attendees to sign the attendance sheet.
- File copies of training records (Form 1D/V1/2012) of IEC members and staff in the membership and staff files.
- Update the CV of individual member/staff to reflect attendance of training activities.
- 5.5.5 The Secretariat files training records of the IEC members and staff.

  The Training Record Form (Form 1D/V1/2012) should be kept updated by the Secretariat whenever any of the IEC members attend relevant ethics trainings.



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# I. STRUCTURE AND COMPOSITION

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#### 6. IEC Review Fee and Honoraria of IEC Members

#### 6.1 Purpose

- **6.1.1** To describe the coverage of the IEC review fee and the procedures to facilitate charging of fees for the review of research protocols.
- **6.1.2** To describe the procedures to facilitate granting of honorarium to each IEC members, independent consultants and Serious Adverse Effects (SAE) subcommittee members participating in the review and approval process of research protocols or proposals.

#### 6.2 Scope

This SOP describes (1) who is covered by and how much is the IEC review fee and (2) when and how much each IEC and SAE subcommittee members and independent consultants shall be given honorarium for their work in the DLSMHSI IEC.

#### 6.3 Responsibility

It is the responsibility of the IEC Secretariat under the leadership of the Chair to charge an IEC review fee and provide honoraria to all IEC members, independent consultants and SAE subcommittee members.

#### 6.4 Process Flow

#### 6.4.1 IEC Review Fee

IEC Review Fee coverage:

- Industry (i.e. pharmaceutical company) or sponsor-initiated or commissioned research protocols.
- Externally generated research protocols with local or foreign private or government funding agency research grants.
- Non-DLSMHSI faculty generated research protocols.
- DLSMHSI faculty, resident and student generated research protocols are not covered by the IEC review fee.
- In special or exceptional cases, the IEC review fee may be waived just like the institutional fee provided this is recommended or endorsed by the IEC and/or the research executive committee. In such cases, it is elevated to the Executive Committee for approval.

	ACTIVITY	RESPONSIBILITY
Step 1	The IEC secretary issues a statement of account (SOA) to the client for the payment of a	Secretariat
	fee for each protocol submitted for ethics review	



#### INDEPENDENT ETHICS COMMITTEE

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	and approval.	
Step 2	The client pays at the accounting department	Sponsor/CRO/
	which in turn issues an official receipt (OR).	Investigator
Step 3	The client returns to the IEC office and presents	Sponsor/CRO/
	the OR to the IEC secretary who in turn logs the	Investigator/
	details of the payment. The review shall not	Secretariat
	commence without the OR.	
Step 4	The IEC secretary informs the chair or the co-	Secretariat
	chair and the member-secretary of the payment.	
	The protocol is classified as either full board or	
	expedited review and included in the next	
	meeting's agenda.	

#### 6.4.2 Description of Detailed Procedures

- **6.4.2.1** The IEC secretary issues a statement of account (SOA) to the client for the payment of a fee for each protocol submitted for ethics review and approval.
  - The IEC secretary issues a statement of account (SOA) to the sponsor/CRO or investigator for an IEC Review Fee amounting to fifty thousand pesos (PhP 50.000.00) per protocol.
  - It is a one-time fee paid to the DLSMHSI Accounting Department prior to the conduct of an initial review application and inclusive of subsequent continuing review and post-approval review procedures
  - The IEC Review fee is a separate fee with a separate account folder from that of the Institutional Fee which is fifteen percent (15%) of the protocol budget excluding personnel honoraria or forty thousand pesos (PhP 40,000.00) whichever is higher.
- **6.4.2.2** The client pays at the accounting department which in turn issues an official receipt (OR).
  - The initial review shall not be conducted without the Official Receipt (OR) from the accounting department. However, the payment of the institutional fee is not a prerequisite for the conduct of the initial review.
- **6.4.2.3** The client returns to the IEC office and presents the OR to the IEC secretary who in turn logs the details of the payment. The review shall not commence without the OR.
- **6.4.2.4** The IEC secretary informs the chair or the co-chair and the member-secretary of the payment. The protocol is classified as either full board or expedited review and included in the next meeting's agenda.
  - Once OR is presented, the protocol shall be classified as either full board or expedited review and reviewed accordingly. It shall be included for discussion or for information in the next IEC meeting's agenda.



#### INDEPENDENT ETHICS COMMITTEE

Cavite (046) 481-8000 loc. 8042/ Manila (02) 988-3100 Local 4000

# I. STRUCTURE AND COMPOSITION

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#### 6.4.3 Reviewers' Honoraria

	ACTIVITY	RESPONSIBILITY
Step 1	The IEC secretary accomplishes a reviewers' fee/honoraria form approved by the chair which contains the names of members and consultants who participated in the review process and the protocol(s) they reviewed. It also includes the list of members who participated/attended the meeting or reviewed the SAE reports.	Secretariat
Step 2	The IEC secretary accomplishes and submits a fund requisition form duly signed by the IEC chair, within one week after each IEC meeting, to the accounting department for processing of checks.	Chair/Secretariat
Step 3	Once checks are released by the accounting department, the IEC secretary distributes these to the payees who shall in turn sign a receipt form.	Secretariat/Members

#### 6.4.4 Description of Detailed Procedures

- **6.4.4.1** The IEC secretary accomplishes a reviewers' fee/honoraria form approved by the chair which contains the names of members and consultants who participated in the review process and the protocol(s) they reviewed. It also includes the list of members who participated/attended the meeting or reviewed the SAE reports.
  - The honoraria of the chair, members and consultants of the IEC and members of the SAE subcommittee shall be charged to the IEC review fees.
  - The DLSMHSI-IEC chair/co-chair/member-secretary shall receive a fixed monthly honorarium.
  - The members and consultants shall receive variable honoraria per review as:
    - Primary reviewer of sponsor-initiated or funded investigator-initiated (externally-generated/non-DLSMHSI faculty) researches
    - Primary reviewer of DLSMHSI faculty or residents' researches.
    - Primary reviewer of DLSMHSI students' researches.
  - The members and consultants shall receive an honorarium per attendance



#### **INDEPENDENT ETHICS COMMITTEE**

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- and participation in IEC en banc (full board review) meetings.
- The members of the SAE subcommittee shall receive a fixed monthly honorarium.
- **6.4.4.2** The IEC secretary accomplishes and submits a fund requisition form duly signed by the IEC chair, within one week after each IEC meeting, to the accounting department for processing of checks based on the corresponding approved rates of honoraria for reviewers.
- **6.4.4.3** Once checks are released by the accounting department, the IEC secretary distributes these to the payees who shall in turn sign a receipt form. Payment shall be made after each IEC meeting.

#### 7. Version History

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

#### INDEPENDENT ETHICS COMMITTEE

Cavite (046) 481-8000 loc. 8042/ Manila (02) 988-3100 Local 4000

# I. STRUCTURE AND COMPOSITION

**DLSMHSI-IEC SOP 01/03-1-2019** 

Standard Operating Procedures Effective Date: November 2019

# LETTER OF APPOINTMENT OF DLSMHSI-IEC CHAIR (FORM 1A2/V2/2019)

<dd/mm/yy>

#### < TITLE, NAME, SURNAME>

- <Position>
- <Institution/Affiliation>
- <Address>

Dear <Title, Surname>:

I have the honor to appoint you as Chair of the De La Salle Medical and Health Sciences Institute – Independent Ethics Committee (DLSMHSI-IEC) for a Period of three (3) years, effective <date> until <date>. As Chair, you will have the following roles and responsibilities:

- Presides over the IEC meetings and is accountable to the VCR
- Prepares an annual report summarizing IEC activities and decision outcomes to the VCR.
- Ensures sufficient financial and administrative support for IEC operations.
- Represents the IEC interests within the institutional administration.
- Represents the IEC to the outside world.
- Evaluates the protocol whether it is for expedited, full board or exempted from review.
- Assigns the primary reviewers of the initial protocols submitted for review.

If you agree with the terms of this appointment, please sign on the space provided below, dated your signature, and return one copy of this letter to the DLSMHSI-IEC Secretariat. Sign, date and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Respectfully yours,

<NAME OF VICE CHANCELLOR FOR RESEARCH> Vice Chancellor for Research Division

Conforme:

<Name of Appointee> (Signature over Printed Name/Date) Chair, DLSMHSI-Independent Ethics Committee



#### INDEPENDENT ETHICS COMMITTEE

Cavite (046) 481-8000 loc. 8042/ Manila (02) 988-3100 Local 4000

# I. STRUCTURE AND COMPOSITION

**DLSMHSI-IEC SOP 01/03-1-2019** 

Standard Operating Procedures Effective Date: November 2019

# LETTER OF APPOINTMENT OF DLSMHSI-IEC CO-CHAIR (FORM 1A3/V2/2019)

<dd/mm/yy>

#### < TITLE, NAME, SURNAME>

- <Position>
- <Institution/Affiliation>
- <Address>

Dear <Title, Surname>:

I have the honor to appoint you as Co-Chair of the De La Salle Medical and Health Sciences Institute – Independent Ethics Committee (DLSMHSI-IEC) for a Period of three (3) years, effective <date> until <date>. As Co-Chair, you will have the following roles and responsibilities:

- Presides over meetings in the absence of the Chair.
- Performs other duties as designated by the Chair.

If you agree with the terms of this appointment, please sign on the space provided below, dated your signature, and return one copy of this letter to the DLSMHSI-IEC Secretariat. Sign, date and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Respectfully yours,

<NAME OF VICE CHANCELLOR FOR RESEARCH> Vice Chancellor for Research Division

Conforme:

<Name of Appointee>
(Signature over Printed Name/Date)
Co-Chair, DLSMHSI-Independent Ethics Committee



#### INDEPENDENT ETHICS COMMITTEE

Cavite (046) 481-8000 loc. 8042/ Manila (02) 988-3100 Local 4000

# I. STRUCTURE AND COMPOSITION

**DLSMHSI-IEC SOP 01/03-1-2019** 

Standard Operating Procedures Effective Date: November 2019

# LETTER OF APPOINTMENT OF DLSM+SI-IEC MEMBER-SECRETARY (FORM 145/V2/2019)

<dd/mm/yy>

#### < TITLE, NAME, SURNAME>

- <Position>
- <Institution/Affiliation>
- <Address>

Dear <Title, Surname>:

I have the honor to appoint you as a Member of the De La Salle Medical and Health Sciences Institute – Independent Ethics Committee (DLSMHSI-IEC) for a Period of three (3) years, effective <date> until <date>. As a member, you will have the following roles and responsibilities:

- Assist the Chair in implementing assignment of reviewers and invitation of Independent Consultants of the protocols.
- Oversees that the functions of the Secretariat are done properly and in a timely manner.
- Supervises and supports the Secretariat in resolving administrative issues and concerns.
- Participate in IEC meetings.
- Review, discuss and consider the ethical merits of the informed consent form and process of research proposals/protocols submitted for evaluation.
- Review progress reports and monitor ongoing studies as appropriate.
- Evaluate final reports.
- Maintain confidentiality of the documents and deliberations during IEC meetings.
- Declare any conflict of interest.
- Participate in continuing education activities in health research and ethics.

If you agree with the terms of this appointment, please sign on the space provided below, dated your signature, and return one copy of this letter to the DLSMHSI-IEC Secretariat. Sign, date and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Respectfully yours,

<NAME OF VICE CHANCELLOR FOR RESEARCH> Vice Chancellor for Research Division

Conforme:

<Name of Appointee> (Signature over Printed Name/Date) Member, DLSMHSI-Independent Ethics Committee

# II

#### INDEPENDENT ETHICS COMMITTEE

Cavite (046) 481-8000 loc. 8042/ Manila (02) 988-3100 Local 4000

# I. STRUCTURE AND COMPOSITION

**DLSMHSI-IEC SOP 01/03-1-2019** 

Standard Operating Procedures Effective Date: November 2019

# LETTER OF APPOINTMENT OF DLSMHSI-IEC MEMBER (FORM 1A1/V2/2019)

<dd/mm/yy>

#### < TITLE, NAME, SURNAME>

- <Position>
- <Institution/Affiliation>
- <Address>

Dear <Title, Surname>:

I have the honor to appoint you as a Member of the De La Salle Medical and Health Sciences Institute – Independent Ethics Committee (DLSMHSI-IEC) for a Period of three (3) years, effective <date> until <date>. As a member, you will have the following roles and responsibilities:

- Participate in IEC meetings.
- Review, discuss and consider the ethical and scientific merits of research proposals/protocols submitted for evaluation.
- Assess serious adverse event reports and recommend appropriate action.
- Review progress reports and monitor ongoing studies as appropriate.
- Evaluate final reports.
- Maintain confidentiality of the documents and deliberations during IEC meetings.
- Declare any conflict of interest.
- Participate in continuing education activities in health research and ethics.

If you agree with the terms of this appointment, please sign on the space provided below, dated your signature, and return one copy of this letter to the DLSMHSI-IEC Secretariat. Sign, date and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Respectfully yours.

<NAME OF VICE CHANCELLOR FOR RESEARCH> Vice Chancellor for Research Division

Conforme:

<Name of Appointee> (Signature over Printed Name/Date) Member, DLSMHSI-Independent Ethics Committee



#### INDEPENDENT ETHICS COMMITTEE

Cavite (046) 481-8000 loc. 8042/ Manila (02) 988-3100 Local 4000

# I. STRUCTURE AND COMPOSITION

**DLSMHSI-IEC SOP 01/03-1-2019** 

Standard Operating Procedures Effective Date: November 2019

# LETTER OF APPOINTMENT OF DLSMHSI-IEC LAY MEMBER (FORM 144/V2/2019)

<dd/mm/yy>

#### < TITLE, NAME, SURNAME>

<Position> <Institution/Affiliation> <Address>

Dear <Title, Surname>:

I have the honor to appoint you as a Lay Member of the De La Salle Medical and Health Sciences Institute – Independent Ethics Committee (DLSMHSI-IEC) for a Period of three (3) years, effective <date> until <date>. As a member, you will have the following roles and responsibilities:

- Participate in IEC meetings.
- Review, discuss and consider the ethical merits of the informed consent form and process of research proposals/protocols submitted for evaluation.
- Review progress reports and monitor ongoing studies as appropriate.
- Evaluate final reports.
- Maintain confidentiality of the documents and deliberations during IEC meetings.
- Declare any conflict of interest.
- Participate in continuing education activities in health research and ethics.

If you agree with the terms of this appointment, please sign on the space provided below, dated your signature, and return one copy of this letter to the DLSMHSI-IEC Secretariat. Sign, date and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Respectfully yours,

<NAME OF VICE CHANCELLOR FOR RESEARCH> Vice Chancellor for Research Division

Conforme:

<Name of Appointee>
(Signature over Printed Name/Date)

Member, DLSMHSI-Independent Ethics Committee



#### INDEPENDENT ETHICS COMMITTEE

Cavite (046) 481-8000 loc. 8042/ Manila (02) 988-3100 Local 4000

# I. STRUCTURE AND COMPOSITION

**DLSMHSI-IEC SOP 01/03-1-2019** 

Standard Operating Procedures Effective Date: November 2019

# LETTER OF APPOINTMENT OF DLSMHSI-IEC INDEPENDENT CONSULTANT (FORM 1A6/V2/2019)

<dd/mm/yy>

#### < TITLE, NAME, SURNAME>

<Position>

<Institution/Affiliation>

<Address>

Dear <Title, Surname>:

I have the honor to appoint you as an Independent Consultant of the De La Salle Medical and Health Sciences Institute – Independent Ethics Committee (DLSMHSI-IEC) for a Period of three (3) years, effective <date> until <date>. As an independent consultant, you will have the following roles and responsibilities:

- The IEC Secretariat provides study protocol documents to the concerned consultant for review, after the latter has signed the confidentiality and conflict of interest agreement.
- The consultant must complete the assessment form for the protocol under review at the same time the study protocol is being reviewed by the committee.
- The consultant may attend the IEC meeting, present his/her assessment, and participate in the discussion but without the right to vote. The assessment form becomes a permanent part of the study protocol file.
- As a consultant, you are asked to impart your expert knowledge especially in risk / benefit assessment; and mitigation; any new knowledge pertaining to the topic of inquiry, procedures.

If you agree with the terms of this appointment, please sign on the space provided below, dated your signature, and return one copy of this letter to the DLSMHSI-IEC Secretariat. Sign, date and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Respectfully yours,

<NAME OF VICE CHANCELLOR FOR RESEARCH> Vice Chancellor for Research Division

Conforme:

<Name of Appointee>
(Signature over Printed Name/Date)
Independent Consultant, DLSMHSI-Independent Ethics Committee



#### INDEPENDENT ETHICS COMMITTEE

Cavite (046) 481-8000 loc. 8042/ Manila (02) 988-3100 Local 4000

# I. STRUCTURE AND COMPOSITION

**DLSMHSI-IEC SOP 01/03-1-2019** 

Standard Operating Procedures Effective Date: November 2019

# LETTER OF APPOINTMENT OF SAE SUBCOMMITTEE MEMBER (FORM 147/V1/2019)

<dd/mm/yy>

#### < TITLE, NAME, SURNAME>

- <Position>
- <Institution/Affiliation>
- <Address>

Dear <Title, Surname>:

I have the honor to appoint you as a Member of Serious Adverse Events (SAE) Subcommittee of the De La Salle Medical and Health Sciences Institute – Independent Ethics Committee (DLSMHSI-IEC) for a Period of three (3) years, effective <date> until <date>. As a SAE Subcommittee member, you will have the following roles and responsibilities:

- The IEC Secretariat provides on-site and off-site adverse events, serious adverse events and suspected unexpected serious adverse reaction (SUSAR) reports to the concerned SAE Subcommittee member for review, after the latter has signed the confidentiality and conflict of interest agreement.
- The on-site AE, SAE and SUSAR reports are reviewed regularly and the recommendation are consolidated for reporting in the next IEC board meeting.
- The off-site AE, SAE and SUSAR reports are to be analyzed as trends and reported to the IEC committee board meeting twice a year.

If you agree with the terms of this appointment, please sign on the space provided below, dated your signature, and return one copy of this letter to the DLSMHSI-IEC Secretariat. Sign, date and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Respectfully yours,

<NAME OF VICE CHANCELLOR FOR RESEARCH>
Vice Chancellor for Research Division

Conforme:

<Name of Appointee>
(Signature over Printed Name/Date)
SAE Subcommittee Member, DLSMHSI-Independent Ethics Committee



#### INDEPENDENT ETHICS COMMITTEE

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# I. STRUCTURE AND COMPOSITION

**DLSMHSI-IEC SOP 01/03-1-2019** 

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# CONFIDENTIALITY and CONFLICT OF INTEREST AGREEMENT (For IEC Members/Independent Consultants) FORM 1B/V1/2012

In view of the selection of Dr. <TITLE NAME, INSTITUTIONAL AFFILIATION> as a member/consultant of the De La Salle Medical and Health Sciences Institute-Independent Ethics Committee (DLSMHSI-IEC), 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 selection of the Undersigned as a member/ consultant of the DLSMHSI-IEC 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 DLSMHSI-IEC member/ consultant is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits thereof under review; and

the DLSMHSI-IEC 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 the DLSMHSI-IEC member/ consultant's functions are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the Independent Ethics Committee (IEC) to carry out its mandate.

#### Confidentiality

This Agreement 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/ consultant of the DLSMHSI-IEC.

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 the DLSMHSI-IEC.



#### INDEPENDENT ETHICS COMMITTEE

Cavite (046) 481-8000 loc. 8042/ Manila (02) 988-3100 Local 4000

# I. STRUCTURE AND COMPOSITION

**DLSMHSI-IEC SOP 01/03-1-2019** 

Standard Operating Procedures Effective Date: November 2019

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 "Confidential 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 his/her performance under this Agreement is consistent with De La Salle Health Sciences Institute-Independent Ethics Committee (DLSMHSI-IEC) policies 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 DLSMHSI-IEC 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 DLSMHSI-IEC that no member/ consultant 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 DLSMHSI-IEC.

The **Undersigned** will immediately disclose to the Chair of the De La Salle Health Sciences Institute-Independent Ethics Committee (DLSMHSI-IEC) any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the DLSMHSI-IEC, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that a DLSMHSI-IEC member/consultant has a potential conflict, the investigator may request that the member/ consultant be excluded from the review of the protocol.

The request must be in writing and addressed to the Chair of DLSMHSI-IEC. The request must contain evidence that substantiates the claim that a conflict exists with the DLSMHSI-IEC member/ consultant in question. The DLSMHSI-IEC elects to investigate the applicant's claim of the potential conflict.

When DLSMHSI-IEC member/consultant has a conflict of interest, the DLSMHSI-IEC member/consultant should notify the Chair and may not participate except to provide information requested by the Board.

Examples of conflict of interest cases may include, but is not limited to, any of the following: A member/ consultant is involved in a potentially competing research program.

Access to funding or intellectual information may provide an unfair competitive advantage. A member/consultant's personal biases may interfere with his/her impartial judgment.

# De La Salle Medical and Health Sciences Institute Dasmariñas, Cavite 4114 INDEPENDENT ETHICS COMMITTEE Cavite (046) 481-8000 loc. 8042/ Manila (02) 988-3100 Local 4000

# I. STRUCTURE AND COMPOSITION

**DLSMHSI-IEC SOP 01/03-1-2019** 

Standard Operating Procedures Effective Date: November 2019

#### 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 DLSMHSI- IEC. A copy will be given to you for your records.]

In the course of my activities as a member/ consultant of the DLSMHSI-IEC, 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 DLSMHSI- IEC's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to immediately return all Confidential Information (including any minutes or notes I have made as part of my Board duties) to the Chair upon termination of my functions as an DLSMHSI-IEC member/ consultant.

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

Agreement.	апа ассерг	uie .	arorementioned	terris	anu	Conditions	as	ехріашей	""	un
Title/Name							ate			
Chairman. DLS	SMHSI- Indepe	ndent l	Ethics Committee				— Dat	re		

# De La Salle Medical and Health Sciences Institute Dasmariñas, Cavite 4114 INDEPENDENT ETHICS COMMITTEE Cavite (046) 481-8000 loc. 8042/ Manila (02) 988-3100 Local 4000

# I. STRUCTURE AND COMPOSITION

**DLSMHSI-IEC SOP 01/03-1-2019** 

Standard Operating Procedures Effective Date: November 2019

# CURRICULUM VITAE (for DLSMHSI-IEC Members) FORM 1C/V1/2012

To the IEC Member:

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	F	irst Name	Middle Na	ıme	TITLE: Ms/ Mr/ MD/ PhD
Date of Birth			Sex		
Professional Mailing Address (in	nclude Nar	ne of Institution)	Study Site Address	(include Nan	ne of Institution)
Telephone (Ofc):			Mobile No.:		
, ,					
T. I. (D.)			- M ''		
Telephone (Res.)			E-Mail:		
ACADEMIC QUALIFICAT	TONS (fr	rom most current)			
Degree/Certificate	Ì	Ye	ar	II.	nstitution, Country
PROFESSIONAL EXPER	RIENCE				
		Ye	ar	lı .	nstitution, Country
RELEVANT POSITIONS	INCLUD			TS (from mo	
Title		Y	'ear		Institution, Country
				1	

#### **INDEPENDENT ETHICS COMMITTEE**

Cavite (046) 481-8000 loc. 8042/ Manila (02) 988-3100 Local 4000

# I. STRUCTURE AND COMPOSITION

**DLSMHSI-IEC SOP 01/03-1-2019** 

Standard Operating Procedures Effective Date: November 2019

RESEARCH ETHICS TRAINING	(within the last three years, from most curre	ent)			
Course	Year	Venue			
I declare that the above information of	are true and correct to the best of my ki	nowledge.			
, and the second	, ,	G			
Member Signature Over Printed Nar	Date				

# De La Salle Medical and Health Sciences Institute Dasmariñas, Cavite 4114 INDEPENDENT ETHICS COMMITTEE Cavite (046) 481-8000 loc. 8042/ Manila (02) 988-3100 Local 4000

# I. STRUCTURE AND COMPOSITION

**DLSMHSI-IEC SOP 01/03-1-2019** 

Standard Operating Procedures Effective Date: November 2019

# TRAINING RECORD OF DLSMHSI-IEC MEMBER/STAFF (FORM 1D/V1/2019)

To the IEC Member:

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Last Name	First Nar	ne M		iddle Name	TITLE: N	Ms/ Mr/ MD/ PhD
BASIC COURSES		ORGANIZER		VENUE	DATE	FUNDING SOURCE
1. GCP Training						
2. Research Ethics						
3. IEC Standard Op Procedures	oerating					
CONTINUING ETHICS EDUCATION: Research Ethics Workshops, Conferences, Meetings, Lectures		ORGA	NIZER	VENUE	DATE	FUNDING SOURCE
1.						
2.						
3.						
4.						
5						

# De La Salle Medical and Health Sciences Institute Dasmariñas, Cavite 4114 INDEPENDENT ETHICS COMMITTEE

Cavite (046) 481-8000 loc. 8042/ Manila (02) 988-3100 Local 4000

# I. STRUCTURE AND COMPOSITION

**DLSMHSI-IEC SOP 01/03-1-2019** 

Standard Operating Procedures Effective Date: November 2019

#### **DLSMHSI-IEC FORM 1E-V2-2019- Recommendation Letter**

<dd mm="" yy=""></dd>
< TITLE, NAME, SURNAME> <position> <institution affiliation=""> <address></address></institution></position>
Dear <title, surname="">:</title,>
I would like to recommend <name> to be a member/Chair/Co-Chair/Member-Secretary/Independent Consultant/SAE Subcommittee Member of the De La Salle Medical and Health Sciences Institute - Independent Ethics Committee (DLSMHSI-IEC) for a period of one (1) year, effective <date> until <date>.</date></date></name>
Thank you.
Respectfully yours,
<name chair="" of=""> Chair, DLSMHSI Independent Ethics Committee</name>