CHAPTER 1: STRUCTURE AND COMPOSITION


2. Appointment of DLSHSI-IEC Members

3. Selection of Independent Consultant

4. Training of IEC Members and Staff

5. IEC Review Fee and Honoraria of IEC Members

Authored by: DLSHSI-IEC Secretariat

Approval/Effective Date: October 22, 2012

Approved by: (original signed)

Melchor Victor G. Frias, MD, Vice Chancellor for Research

1.1 Purpose

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

1.2 Specific Objectives

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

- Constitution of the IEC
- Confidentiality/Conflict of Interest Agreement with DLSHSI-IEC members, staff and consultants
- Training of Personnel and DLSHSI-IEC Members
- Selection of Independent Consultants
- Incentives for DLSHSI-IEC Members and Consultants

1.3 Scope

1.3.1 The De La Salle Health Sciences Institute – Independent Ethics Committee is an independent body created by the De La Salle Health Sciences Institute under the Vice Chancellor for Research (VCR). Its responsibility is to ensure the protection of the rights, safety and well-being of human participants involved in health related research and to provide public assurance of that protection. In accordance with the applicable national/international regulations, the DLSHSI-IEC has the authority to approve, require modifications to, or disapprove research protocols and related documents as well as ensure compliance with its relevant procedures after approval.

1.3.2 The DLSHSI-IEC reviews and monitors health researches that involve:

- Protocols developed and implemented by DLSHSI faculty, consultant and resident staff utilizing patients and research participants within the DLSHSI 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 DLSHSI faculty and consultant staff or non-affiliated researchers utilizing patients and research participants within the DLSHSI 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 DLSHSI faculty and consultant staff or non-affiliated researchers utilizing patients and research participants in areas outside the DLSHSI campus (i.e., hospitals and institutions in Region IV without ethics committees).

1.3.3 This Standard Operating Procedure (SOP) provides the Terms of Reference (TOR) that describe the framework for the constitution of the DLSHSI-IEC, the responsibilities and activities of its officers, members, staff and consultants.

1.4 Responsibilities

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

1.5 Ethical basis

1.5.1 The DLSHSI-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 and 2009

1.5.2 The DLSHSI-IEC shall function in accordance with the national laws, regulations, and guidelines.

1.5.3 The DLSHSI-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 Research (2012) by the Philippine Health Research Ethics Board (PHREB)
- Philippine Food and Drug Authority regulations and other relevant laws and regulations
1.5.4 The DLSHSI-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, DLSHSI-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 where a proposed De La Salle Health Sciences Institute research is being considered.

1.5.7 The DLSHSI-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.
2. Appointment of DLSHSI-IEC Members

2.1 Purpose

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

2.2 Scope

While the DLSHSI-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 memberships Standard Operating Procedures (SOPs) cover the nomination and appointment procedures of IEC members, officers and independent consultants.

2.3 Responsibility

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

2.4 Process Flow

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ask the DLSHSI-IEC members to nominate potential new members.</td>
<td>Chair/ Secretariat</td>
</tr>
<tr>
<td>Submit names of potential members to the Chair. The chair/secretariat evaluates the qualifications of the nominee(s) and selects and invites the candidates(s)</td>
<td>Member/ Secretariat</td>
</tr>
<tr>
<td>Recommend and submit a list of potential members to the VCR</td>
<td>Chair/ Secretariat</td>
</tr>
<tr>
<td>Appoint new DLSHSI-IEC members</td>
<td>VCR</td>
</tr>
<tr>
<td>Receive appointment letter (Form 1A/V1/2012) and sign Confidentiality and Conflict of Interest (COI) Agreement for Members (Form 1B/V1/2012) and submit updated Curriculum Vitae (Form 1C/V1/2012)</td>
<td>New Members</td>
</tr>
</tbody>
</table>
2.5 Requirements for Membership/Independent Consultants

DLSHSI-IEC Membership

2.5.1 The DLSHSI-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 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 DLSHSI-IEC should include a person who will represent the interest and concerns of the community.
2.5.5 The DLSHSI-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 DLSHSI-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 DLSHSI-IEC shall have an office and adequate support staff for carrying out its responsibilities.
2.5.9 The DLSHSI-IEC shall adhere to quorum requirements as defined in international and national guidelines for ERCs that review health research. When reviewing clinical trials involving children or pediatric patients, a pediatrician or child development specialist shall be present during its board meeting.

2.6 Nomination and Appointment

2.6.1 Current IEC members shall nominate candidates for new members and to the chair.
2.6.2 The committee discusses the qualifications of the nominees and the chair recommends the selected qualified candidates to the VCR.
2.6.3 The VCR approves the recommended candidates as members and issues the appointment letters (Form 1A/V1/2012).

2.7 Terms of Office

2.7.1 The VCR shall indicate in the appointment letter 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.

2.7.2 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.

2.8 Qualifications of Members

2.8.1 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.

2.8.2 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.

2.8.3 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.

2.8.4 Members shall submit their curriculum vitae, properly signed and dated, and update them at least once every two (2) years.

2.8.5 Members will be required to sign a confidentiality/conflict of interest agreement 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.

2.8.5 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 Agreements.

2.8.6 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.

2.9 Conditions of Appointment of Members

All prospective IEC members shall be willing:

2.9.1 To make public his/her full name, profession, and affiliation as an IEC member.

2.9.2 Disclose all financial accountability, reimbursement for work and expenses, related to their work in the DLSHSI IEC that shall record and publicly disclose its financial records upon request.

2.9.3 All IEC members and independent consultants shall sign the Confidentiality/Conflict of Interest Agreement regarding meeting deliberations, applications, information on research participants and related matters.
2.10 Resignation, Disqualification and Replacement of Members

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

2.11 IEC Officers

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

2.11.1 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.

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

2.12 DLSHSI IEC Secretariat

2.12.1 The DLSHSI IEC secretariat is composed of the Member-Secretary and administrative support staffs who are employees of the DLSHSI and appointed by the VCR.
2.12.2 The secretariat 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.

2.13 Roles and Responsibilities of IEC Members

2.13.1 Participate in IEC meetings.
2.13.2 Review, discuss and consider research proposals/protocols submitted for evaluation.
2.13.3 Assess serious adverse event reports and recommend appropriate action.
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 1-C/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.
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.

3.3 Responsibility
Upon the advice or recommendation of the Secretariat 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

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC members/secretariat request and nominate potential independent consultant(s).</td>
<td>Member/Secretariat</td>
</tr>
<tr>
<td>Members submit names of potential independent consultants to the chair/secretariat. The chair/secretariat evaluates the qualifications and selects/invites the candidates.</td>
<td>Chair/Secretariat</td>
</tr>
<tr>
<td>The independent consultant accepts invitation</td>
<td>Independent Consultant</td>
</tr>
<tr>
<td>Appoint new DLSHSI-IEC consultants</td>
<td>Chair</td>
</tr>
<tr>
<td>Receive appointment letter (Form 1A/V1/2012) 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)</td>
<td>Independent Consultant</td>
</tr>
<tr>
<td>Consultants render services</td>
<td>Consultant</td>
</tr>
</tbody>
</table>
3.5 Process Guidelines

3.5.1 Nomination, Selection and Appointment of Independent Consultant(s)

- An IEC member-secretariat nominates independent consultant(s) to help review research where the IEC lacks expertise.
- The IEC Secretariat compiles a list of independent consultants and the Chair/Secretariat conducts a qualification review of the potential consultant(s).
- The Chair invites the independent consultant(s) and awaits the acceptance of the consultant.
- The Chair appoints (Form 1A/V1/2012) 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.

3.5.2 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
- An updated curriculum vitae
- A signed Confidentiality and Conflict of Interest Agreement

3.5.3 Independent Consultant renders 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 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.

3.5.4 Termination of services

- 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.
4. Training of IEC Members and Staff

4.1 Purpose

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

4.2 Scope

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

4.3 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.

4.4 Process Flow

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Chair/Secretariat provides initial training for new IEC members and staff.</td>
<td>Chair/Secretariat</td>
</tr>
<tr>
<td>Secretariat and members keep track of training needs and plan for continuing professional education.</td>
<td>Chair/Members/Secretariat</td>
</tr>
<tr>
<td>Secretariat and members regularly monitor for educational and training opportunities. Decide appropriateness and feasibility of the course and apply accordingly.</td>
<td>Chair/Members/Secretariat</td>
</tr>
<tr>
<td>Member and staff attend and participate in the course or conference and document the attendance.</td>
<td>Members/Secretariat</td>
</tr>
<tr>
<td>Secretariat files training records of the IEC members and staff.</td>
<td>Secretariat</td>
</tr>
</tbody>
</table>
4.5 Process Guidelines

4.5.1 Initial training of IEC members

- 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.

4.5.2 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

4.5.3 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.

4.5.4 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. IEC Review Fee and Honoraria of IEC Members

5.1 Purpose

5.1.1 To describe the coverage of the IEC review fee and the procedures to facilitate charging of fees for the review of research protocols.

5.1.2 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.

5.2 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 DLSHSI IEC.

5.3 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.

5.4 Process Flow

5.4.1 IEC Review Fee

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>Secretariat</td>
</tr>
<tr>
<td>The client pays at the accounting department which in turn issues an official receipt (OR).</td>
<td>Sponsor/CRO/Investigator</td>
</tr>
<tr>
<td>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.</td>
<td>Sponsor/CRO/Investigator/Secretariat</td>
</tr>
<tr>
<td>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.</td>
<td>Secretariat</td>
</tr>
</tbody>
</table>
5.4.2 Reviewers’ Honoraria

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RESPONSIBILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>Secretariat</td>
</tr>
<tr>
<td>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.</td>
<td>Chair/Secretariat</td>
</tr>
<tr>
<td>Once checks are released by the accounting department, the IEC secretary distributes these to the payees who shall in turn sign a receipt form.</td>
<td>Secretariat/Members</td>
</tr>
</tbody>
</table>

5.5 Process Guidelines

5.5.1 IEC Review Fee

- 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 DLSHSI 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.
- 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.
- 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.
5.5.2 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-DLSHSI faculty generated research protocols.
- DLSHSI 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.

5.5.3 Reviewers’ Honoraria

- The IEC secretary accomplishes a reviewers' fee form approved by the chair which contains the names of members and consultants who participated in the review process as primary or secondary reviewers and who attended the IEC meeting.
- 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 DLSHSI-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-DLSHSI faculty) researches
  - Primary reviewer of DLSHSI faculty or residents’ researches.
  - Primary reviewer of DLSHSI students' researches.
- The members and consultants shall receive an honorarium per attendance and participation in IEC en banc (full board review) meetings.
- The members of the SAE subcommittee shall receive a fixed monthly honorarium.
- Based on the corresponding approved rates of honoraria for reviewers, 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.
- 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.
LETTER OF APPOINTMENT OF DLSHSI-IEC MEMBER (FORM 1A/V1/2012)

<dd/mm/yyyy>

<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 Health Sciences Institute – Independent Ethics Committee (DLSHSI-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 the IEC meetings
- Review, discuss and consider research proposals submitted for evaluation
- Assess serious adverse reports and recommend appropriate action(s).
- Review the progress reports and monitor ongoing studies as appropriate
- Check progress and final reports
- Maintain confidentiality of the documents and deliberations of IEC meetings
- Declare any conflict of interest;
- Participate in continuing education activities in research methodology and research 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 De La Salle Health Sciences Institute-Independent Ethics Committee (DLSHSI-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, DLSHSI

Conforme:

<Name of Appointee>
(Signature over Printed Name/Date)
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 Health Sciences Institute-Independent Ethics Committee (DLSHSI-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 DLSHSI-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 DLSHSI-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 DLSHSI-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 DLSHSI-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 DLSHSI-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 DLSHSI-IEC.
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 (DLSHSI-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 DLSHSI-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 DLSHSI-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 DLSHSI-IEC.

The Undersigned will immediately disclose to the Chair of the De La Salle Health Sciences Institute-Independent Ethics Committee (DLSHSI-IEC) any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the DLSHSI-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 DLSHSI-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 DLSHSI-IEC. The request must contain evidence that substantiates the claim that a conflict exists with the DLSHSI-IEC member/consultant in question. The DLSHSI-IEC elects to investigate the applicant’s claim of the potential conflict.

When DLSHSI-IEC member/consultant has a conflict of interest, the DLSHSI-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.
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 DLSHSI-IEC. A copy will be given to you for your records.]

In the course of my activities as a member/consultant of the DLSHSI-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 DLSHSI-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 a DLSHSI-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.

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

__________________________________________________________________________  ________________  
Title/Name                                      Date

__________________________________________________________________________  ________________  
Chairman, DLSHSI- Independent Ethics Committee  Date
CURRICULUM VITAE (for DLSHSI-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.

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Middle Name</th>
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<th>Study Site Address (include Name of Institution)</th>
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### RESEARCH ETHICS TRAINING (within the last three years, from most current)

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*I declare that the above information are true and correct to the best of my knowledge.*

______________________________  __________________
Member Signature Over Printed Name   Date
TRAINING RECORD OF DLSHSI-IEC MEMBER/STAFF (FORM 1D/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.

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**BASIC COURSES**

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1. GCP Training

2. Research Ethics

3. IEC Standard Operating Procedures

**CONTINUING ETHICS EDUCATION**

EDUCATION: Research Ethics Workshops, Conferences, Meetings, Lectures

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**ATTACH PHOTOCOPY OF CERTIFICATES**