CHAPTER 4: DOCUMENTATION AND ARCHIVING

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

1. Preparation and Distribution of Agenda Meeting

1.1 Purpose

To describe the process of the preparation and distribution of the IEC meeting agenda.

1.2. Scope

This SOP provides instructions related to the preparation of the IEC meeting agenda and its distribution to inform IEC members and other interested individuals about the items for discussion during a full board meeting.

1.3 Responsibility

It is the responsibility of the IEC Secretariat, under the supervision of the Chair, to compile all documents/ information submitted to the IEC within a given period to include them in the next full board meeting agenda for discussion or information of the IEC members.

1.4 Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Collect all documents submitted to the IEC within a given period and put them in the full board meeting agenda for discussion or information of the IEC members	Secretariat
Step 2	Have the agenda approved by the Chair	Secretariat
Step 3	Distribute the notice of meeting or agenda to the IEC members and concerned parties	Secretariat
Step 4	Communicate with the members to check if they can attend the meeting to ensure quorum	Secretariat
Step 5	File the notice of meeting (FORM 4A-V1-2012) in the Notice and Minutes of Meeting Folder	Secretariat

1.5 Description of Detailed Procedures

1.5.1 The IEC Secretariat collects all documents submitted to the IEC within a given period and put them in the full board meeting agenda for discussion or information of the IEC members.

1.5.2 The IEC Secretariat shall have the agenda approved by the Chair.

- The Secretariat informs and consults the Chair about the agenda items (Form 4A/V1/2012).
- Standard notice of meeting or agenda (FORM 4A/V1/2012) contains the following:

- Date of preparation
- Date, time and venue of meeting
- Agenda items:
    - Protocol Review
    - Initial review
    - Resubmission review
    - Approved protocols
    - Post approval monitoring
    - Amended protocols
    - Safety reports
    - Protocol deviations
    - Site visit reports
    - Progress reports
    - Final reports
    - Early study termination
    - Queries or complaints
    - Other matters
- Communications
- Financial report

1.5.3 The IEC Secretariat distributes the notice of meeting or agenda to the IEC members and concerned parties.

- The Secretariat makes copies of the notice of meeting containing the approved agenda to the DLSMHSI-IEC members, at least one (1) week before the meeting.
- The Secretariat arranges the venue and other logistics for the meeting at least one (1) week before the scheduled meeting prior to preparation of the notice of meeting.
- Recommendations on protocols requiring clarifications from the Principal Investigator during an IEC full board meeting are made by the primary reviewers who request the Secretariat to inform the investigators about the meeting schedule. The time slot for their appearance at the IEC meeting is communicated to them.

1.5.4 The IEC Secretariat communicates with the members to check if they can attend the meeting to ensure quorum.

1.5.5 The IEC Secretariat files the notice of meeting (FORM 4A-V1-2012) in the Notice and Minutes of Meeting Folder.

2. Preparation of Minutes of Meeting

2.1 Purpose

To describe the process for the preparation and approval of the minutes of the IEC full board meeting.

2.2 Scope

This SOP provides instructions related to the preparation of the IEC full board meeting minutes and its approval by the IEC members.

2.3 Responsibility

It is the responsibility of IEC Secretariat, under the supervision of the Chair and Member-Secretary, to document the conduct of the full board meeting, including the issues discussed, the decisions and recommendations made in accordance with the items in the IEC meeting agenda.

2.4. Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Organize and document the meeting procedures and the items taken up based on the meeting agenda	Secretariat
Step 2	Prepare the draft of the Minutes of the Meeting using the format (FORM 4B-V2-2019) and sends to the Chair for approval	Secretariat
Step 3	Approve the Minutes of the Meeting	Chair
Step 4	File the signed approved Minutes of the Meeting document (FORM 4B-V2-2019) to the Notice and Minutes of the Meeting Folder	Secretariat

2.5 Description of Detailed Procedures

2.5.1 The IEC Secretariat organizes and documents the meeting procedures and the items taken up based on the meeting agenda.

- The IEC Secretariat uses the Notice of Meeting document (FORM 4A-V1-2012) as a template to organize the meeting discussion in preparation to writing the minutes ahead of the meeting date.
- The IEC Secretariat documents the proceedings of the meeting as the meeting progresses by writing directly into the template prepared.
- The IEC Secretariat reviews the proceedings prepared during the meeting and verifies that it contains the following sections for the Minutes of the Meeting format (FORM 4B-V2-2019):
  - Date and venue of meeting

- Member attendance (members present and absent) to determine quorum
- Guests and observer attendance with signed COI (FORM 4C-V1-2012)
- Time when the meeting was called to order
- Presiding officer
- Conflict of interest declaration by IEC members
- Discussion of items based on the Meeting Agenda
- Decisions, summary of points and recommendations arrived at during the meeting
- Name and signature of person who prepared the Minutes
- Name and signature of the Chair with the date of approval
- Time when the meeting was adjourned

2.5.2 The IEC Secretariat prepares the draft of the Minutes of the Meeting using the format (FORM 4B-V2-2019) and sends to the Chair for approval.

- Opinions and actions included in the minutes are understood to be collective and need not be attributed to specific members, unless in the case of administrative or operational queries from members who require follow-up information or action.
- The IEC Secretariat uses the information in the minutes to communicate full board IEC decisions to the respective Principal Investigators.
- The Secretariat submits a complete draft of the minutes to the Chair within one (1) week after the meeting for corrections and submits the corrected draft to the Chair for approval.
- The minutes of the IEC full board meeting, once they are finalized, are sent to the members for comments or correction. The minutes are formally approved during the next full board meeting.

2.5.3 The Chair approves the minutes of the meeting.

2.5.4 The IEC Secretariat files the signed approved Minutes of the Meeting document (FORM 4B-V2-2019) to the Notice and Minutes of the Meeting Folder.

3. Preparation of Communication Records

3.1 Purpose

To describe the preparation of IEC communication records and the filing of such records.

3.2 Scope

This SOP provides instructions related to the preparation of IEC communication to various parties and the management of such files.

3.3 Responsibility

It is the responsibility of IEC Secretariat, under the supervision of the Chair, to document all communication made by the IEC secretariat to different parties that deal with the IEC.

3.4 Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Organize all communications received and issued by the IEC	Secretariat
Step 2	Record the details of the communication	Secretariat
Step 3	File the communication documents in the corresponding IEC Communications Folder	Secretariat

3.5 Description of Detailed Procedures

3.5.1 The IEC Secretariat organizes all communications received and issued by the IEC.

- IEC communications refer to documented communications and can be in the form of hard copy letters or emails. It is encouraged that all IEC communications, received and issued, are in this form to facilitate documentation of all actions, instructions, and even responses to queries.
- The IEC Secretariat organizes a log of communications which also function as a log of submissions if the communication comes with a submission. IEC communication folder is organized into two (2) sections – outgoing and incoming communications, filed per year. All communication documents are permanent and must be kept confidential.
- Types of communication from the IEC include, but are not limited to the following:
  - Approval letter for reviewed protocol: FORM 2I-V2-2019
  - Approval letter for protocol amendment: FORM 4E-V1-2012
  - Approval letter for additional materials: FORM 4F-V1-2012

- Notification letter to uphold original approval: FORM 4G-V1-2012
- Notification letter for modification prior to approval: FORM 2H-V2-2019
- Notification letter for protocol not requiring review: FORM 4I-V1-2012
- Notification letter for request for information/recommend further action/other: FORM 4J-V1-2012
- Approval letter for final report/early study termination: FORM 4K-V1-2012
- Reminder letter for post-approval requirements: FORM 4L-V1-2012
- Notification letter for site visit: FORM 4M-V1-2012
- Acknowledgment of receipt letter: FORM 4N-V1-2012
- Notice of corrective action: FORM 4O-V1-2012
- Notification letter of disapproval: FORM 4P-V1-2012
- Request letter for content expert: FORM 4Q-V1-2012
- Notification letter of delay (referred to content expert/others): FORM 4R-V1-2012
- Approval letter for continuing review application: FORM 4S-V1-2012
- Letter of invite for clarificatory interview: FORM 4T-V1-2012
- Acknowledgment letter for protocol withdrawal: FORM 4U-V1-2012

3.5.2 The IEC Secretariat records the details of the communication.

- Log of protocol submissions should have at least the following elements:
  - Date of communication/submission
  - Name of IEC party contacted
  - Study information, i.e., sponsor, protocol number, principal investigator, etc.
  - Content of communication or submission
  - Notation of any follow-up necessary
  - Type of submission (if communication refers to a submission)
  - Contact information (address, telephone number, and e-mail) of sending party
  - Name and signature of individual who received the communication and completed the record

3.5.3 The IEC Secretariat files the communication documents in the corresponding IEC Communications Folder.

- A copy of the communication/submission is filed in the:
  - Protocol file folder
  - IEC Communications folder
  - Others, as appropriate

4. Management of Active and Inactive Study Files, Documents and Records

4.1 Purpose

To describe the IEC procedures related to the management of active and inactive study files, documents and records.

4.2 Scope

This SOP provides instructions related to the management of active and inactive study files originating from protocol submissions and includes all documents that reflect all actions taken by the IEC before completion of the study. It also provides instructions for other the maintenance and storage of other IEC documents and records.

4.3. Responsibility

It is the responsibility of IEC Secretariat, under the supervision of the Chair, to manage all protocol submissions and all documents that reflect all IEC actions and organize them into orderly files that are kept at the IEC office. The Secretariat also manages the maintenance and storage of all relevant IEC documents and records.

4.4. Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Design a standard coding system for all protocols submitted to the IEC for review DLSMHSI-IEC	Chair
Step 2	File all submitted documents in a protocol folder and chronologically organize the contents of the active study files according to time of receipt	Secretariat
Step 3	Update the active protocol files regularly and ensure that all actions are also recorded in the database	Secretariat
Step 4	Keep the active and inactive protocol files in the office secured by daily saving of IEC files in the external drive as well ensuring paper documents are stored in proper cabinets with lock and key at the end of the day	Secretariat

4.5 Description of Detailed Procedures

4.5.1 The IEC Chair designs a standard coding system for all protocols submitted to the DLSMHSI-IEC for review.

- De La Salle Health Sciences Institute-Independent Ethics Committee (DLSMHSI-IEC)-approved protocols are considered active from the moment the protocol files are received for review until such time they are archived (completed, withdrawn or terminated).
- Active files are either ongoing review or ongoing study which are assigned a code from initial complete submission of the protocol package.
- Active files become inactive on the following conditions:
    - For protocols with Minor/ Major Modifications undergoing review – If after 90 days of no response to the received Notification Letters for Modifications of the protocol.
    - For Approved protocols – If no submission of the Progress Report, Final Report or Early Study Termination Application upon expiration of the one year IEC approval.

4.5.2 The IEC Secretariat files all submitted documents in a protocol folder and chronologically organize the contents of the active study files according to time of receipt.

- File Protocol documents are filed in sturdy file folders, using one (1) folder per study protocol title.
- The folders are kept in secured well-identified locked cabinets.
- Keys to locked cabinets are kept by assigned staff.
- File folders are labeled using the code of the study file.

- Study file folder contains the following documents and should have protocol index:
    - All versions of study protocol
    - Related documents that came with the study protocol
    - Principal investigator and co-investigators' CVs and other similar documents
    - Reviewers' assessment forms
    - Amendment reports
    - Continuing review applications
    - Serious Adverse Event Reports or Safety Notifications
    - Non-compliance (Deviation or Violation) reports
    - Participant Queries
    - Site Visit Reports
    - Approval letters
    - Notifications of IEC Decision
    - Miscellaneous communication
    - Final report

4.5.3 The IEC Secretariat updates the active protocol files regularly and ensure that all actions are also recorded in the database.

- Active files, records and documents should be properly maintained and updated.
- The IEC Secretariat updates the study file folder and the database every week.
- Protocol index and document tracker is updated whenever a new document is added.
- The IEC Secretariat ensures completeness of filling out of forms before filing.
- Keep all active study files in a secure file cabinet, with access limited only to (personnel allowed) who will be entrusted to keep the lock and key.
- Active files can be accessed outside of regular protocol review in accordance with the SOP on Maintaining Confidentiality of Study Files and IEC Documents.
- The IEC Secretariat creates a secure protocol database to facilitate protocol monitoring including due dates of reports and determining active protocol status. The database can be paper-based (logbook locked in the active files cabinet) or electronic (password protected) and should have at least the following fields:
    - Protocol Code
    - Protocol Title
    - Department
    - PI and details
    - Submission Date
    - Full board or Expedited Review
    - Primary Reviewers
    - Review Decision
    - Board Meeting Date
    - Approval Date
    - Date for Progress Report

4.5.4 The IEC Secretariat keeps the active and inactive protocol files in the office secured by daily saving of IEC files in the external drive as well ensuring paper documents are stored in proper cabinets with lock and key at the end of the day.

5. Archiving of Study Files, Documents and Records

5.1. Purpose

To describe IEC procedures related to archiving of study files, documents and records.

5.2. Scope

This SOP provides instructions to the Secretariat related to requirements for archiving completed documents after the final report or other relevant documents have been received.

5.3. Responsibility

It is the responsibility of IEC Secretariat, under the supervision of the Chair, to archive in an orderly manner all protocol files that have been terminated, completed, withdrawn or are no longer active. They are kept together in a designated place in the hospital where confidentiality and security of the documents can be maintained.

5.4. Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Approve the final report or early study termination application for filing	Primary Reviewers/Members
Step 2	Archive studies with approved final report or early study termination report.	Secretariat
Step 3	Keep the archived protocol files in the office secured by daily saving of IEC files in the external drive as well ensuring paper documents are stored in proper cabinets with lock and key at the end of the day	Secretariat
Step 4	Retrieve protocol documents when needed and record protocol documents retrieval	Secretariat

5.5 Description of Detailed Procedures

5.5.1 The IEC Members and Primary Reviewers approves the final report or early study termination application for filing.

- The IEC Secretariat reviews the contents of the protocol file and transfer it from the active or inactive study filing area to the designated archive room.

5.5.2 The IEC Secretariat archives studies with approved final report or early study termination report.

- The following conditions apply for Archived files:

- Submission of the Final Report and Early Study Termination Application
- For protocols with Minor/ Major Modifications – If after 1 year of no submission of response to the received Notification Letters.
- For Approved protocols – If after 1 year of no submission of the Progress Report, Final Report or Early Study Termination Application from the time of expiration of the IEC approval.

- Archived study files refer to protocol that are completed/inactive/terminated (or withdrawn). They are retained for at least three (3) years (or more for some particular cases) after completion of the research so that the records are accessible for auditors and inspectors.
- The archive code is assigned to the protocol by changing the suffix of the original protocol code from A (Active) or C (Completed) to I (Inactive) and adding an extension of the month and year where the Close-Out, Final Report or Early Study Termination Report is approved. For example, the Final Report for protocol 2012-01-03-A is approved dated May 2014, the archiving code is 2012-01-03-I/ 05-2014.
- The archiving data should be entered accordingly in the protocol database.

5.5.3 The IEC Secretariat keeps the archived protocol files in the office secured by daily saving of IEC files in the external drive as well ensuring paper documents are stored in proper cabinets with lock and key at the end of the day.

5.5.4 The IEC Secretariat retrieves protocol documents when needed and record protocol documents retrieval.

- Archived protocols can be retrieved within the three-year archiving period in accordance with the SOP on Maintaining Confidentiality of Study Files and IEC Documents.
- Protocol database (electronic) should be backed up or copied in an external drive. This should be secured or kept in a fire proof filling cabinet inside the archive room.
- Protocol documents that have been outdated for three (3) years are removed from the archives. These are shredded by the IEC Secretariat and expunged from the electronic database.

6. Maintenance of Confidentiality of Study Files and DLSMHSI-IEC Documents

6.1. Purpose

To describe De La Salle Health Sciences Institute-Independent Ethics Committee (DLSMHSI-IEC) procedures related to maintaining the confidentiality of the study files and other DLSMHSI-IEC documents.

6.2. Scope

This Standard Operating Procedure (SOP) provides instructions to the Secretariat related to maintaining the confidentiality of all study files and documents.

6.3. Responsibility

It is the responsibility of DLSMHSI-IEC Secretariat, under the supervision of the Chair, to ensure that confidentiality is maintained in the management of all study files and records.

6.4. Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Classify which IEC documents are confidential	Chair/ Secretariat
Step 2	Restrict access to confidential documents	Secretariat
Step 3	Record copies made of confidential documents	Secretariat
Step 4	File log of copies of the confidential documents and files	Secretariat

6.5 Description of Detailed Procedures

6.5.1 The IEC Chair and Secretariat classify which IEC documents are confidential.

- Study files submitted to the DLSMHI-IEC and related documents are considered confidential, such as:
  - Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
  - DLSMHI-IEC documents (Meeting minutes, advice, and decisions)
  - Correspondence (experts, auditors, study participants, etc.)

6.5.2 The IEC Secretariat restricts access to confidential documents.

- Access to DLSMHI-IEC confidential documents is subject to the following limitations:

  - DLSMHI-IEC members and staff with a signed Confidentiality Agreement and Conflict of Interest Disclosure (FORM 4C/V1/2012) can access confidential documents outside of regular protocol review access, upon request.
  - Non-members can access specific documents by submitting a formal request. The Secretariat will provide a copy of the Confidentiality Agreement Form for Non-members Requesting for Copies of De La Salle Medical and Health Sciences Institute-Independent Ethics Committee (DLSMHSI-IEC) Documents to be accomplished by the person making the request, and signed by the Chair.
  - Regulatory authorities have full access to De La Salle Medical and Health Sciences Institute-Independent Ethics Committee (DLSMHSI-IEC) documents provided it is within their mandate (e.g. FDA), and upon reasonable notice to make the files available signed by the recognized official of the regulatory authority (e.g. FDA Director).

6.5.3 The IEC Secretariat records copies made of confidential documents.

- The IEC Secretariat makes a record every time a document of the DLSMHSI-IEC is accessed as described above.
- The IEC Secretariat properly handles original documents and copies of IEC documents during the day-to-day operation of the IEC to protect the confidentiality of study files and related documents. Proper handling also involves proper control and care in the distribution and storage of confidential documents of the IEC.
- The IEC Secretariat records the retrieval of De La Salle Medical and Health Sciences Institute-Independent Ethics Committee (DLSMHSI-IEC) documents. Access to DLSMHSI-IEC documents is generally room use only, but requests to make copies can be accommodated on a case to case basis.
- All requests for access are recorded by the Secretariat Staff in the log before copies of any documents are released.
- The IEC Secretariat makes only the exact number of copies requested. Recipient signs for the copies requested in the De La Salle Medical and Health Sciences Institute-Independent Ethics Committee (DLSMHSI-IEC) upon receipt of the copies.
- Access to DLSMHSI-IEC documents is generally room use only, but requests to make copies can be accommodated on a case to case basis.

6.5.4 The IEC Secretariat files log of copies of the confidential documents and files.

- A log filed in the protocol folder is dedicated for purposes of recording access as described above, which contains the following fields of information:

  - Study file code
  - Date borrowed
  - Name of borrower
  - Signature of borrower upon retrieval
  - Signature of DLSMHSI-IEC Secretariat upon return of document to file box
  - Document copied
  - Number of copies made
  - Number of copies received

7. Version History

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

dd/mm/yy>

NOTICE OF REGULAR MEETING
(FORM 4A/V1/2012)

Date of Meeting: <dd/mm/yy>
Time of Meeting : <hh:mm> <AM/PM>
Venue of Meeting: IEC Conference Room, AKMRC

To:

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

AGENDA

1. **OPENING PRAYER**
2. **DETERMINATION OF QUORUM**
3. **CALL TO ORDER AND CONFIRMATION OF QUORUM**
4. **DISCLOSURE OF CONFLICT OF INTEREST**
5. **READING AND APPROVAL OF THE MINUTES OF THE LAST MEETING**
6. **BUSINESS ARISING FROM THE MINUTES OF THE LAST MINUTES**
7. **PROTOCOL REVIEW**

7.1. FULL REVIEW

7.1.1 INITIAL REVIEW

PROTOCOL 1	**PTN <number>**
Date of Submission	<dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Previous Approval from other Technical/Ethics Review Committees	<Name of Technical /Ethics Review Committee> < Approval Start and End Date>
Primary Reviewers	<Title, Name, Surname>

7.1.2. RESUBMISSIONS (*protocols with MAJOR corrections/modifications*)

PROTOCOL 1	**PTN <number>**
Date of Initial Review <dd/mm/yy>	Date of Resubmission <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>

Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

7.1.3. REQUIRING CLARIFICATORY INTERVIEW

PROTOCOL 1	**PTN <number>**
Date of Submission <dd/mm/yy>	Date of Initial Review <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

7.1.4. PROTOCOL AMENDMENT APPLICATIONS *(with MAJOR Amendments that can affect the scientific and/or ethical acceptability of the protocol)*

PROTOCOL 1	**PTN <number>**
Date of Approval <dd/mm/yy>	Amendment Submission Date <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

7.1.5. CONTINUING REVIEW APPLICATIONS

PROTOCOL 1	**PTN <number>**
Date of Approval <dd/mm/yy>	Continuing Review Application Date <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

7.1.6. FINAL REPORTS

PROTOCOL 1	**PTN <number>**
Date of Approval <dd/mm/yy>	Final Report Date <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

7.1.7. SAE and SUSAR REPORTS

PROTOCOL 1	**PTN <number>**
Date of Approval <dd/mm/yy>	SAE/SUSAR Report Submission Date <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

7.1.8. SITE VISIT REPORTS

PROTOCOL 1	PTN <number>
Date of Approval <dd/mm/yy>	Site Visit Report Submission Date <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

7.1.9. PROTOCOL NON-COMPLIANCE (DEVIATION/VIOLATION) REPORTS

PROTOCOL 1	PTN <number>
Date of Approval <dd/mm/yy>	Non-Compliance Report Submission Date <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

7.1.10. EARLY STUDY TERMINATION APPLICATIONS

PROTOCOL 1	PTN <number>
Date of Approval <dd/mm/yy>	Early Termination Application Submission Date <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

7.1.11. QUERIES AND COMPLAINTS

PROTOCOL 1	PTN <number>
Date of Approval <dd/mm/yy>	Query/Complaint Receiving Date <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

7.2. EXPEDITED REVIEW

7.2.1. INITIAL REVIEW

PROTOCOL 1	PTN <number>
Date of Submission	<dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>

Sponsor/CRO	<Name>
Previous Approval from other Technical/Ethics Review Committees	<Name of Technical /Ethics Review Committee> < Approval Start and End Date>
Primary Reviewers	<Title, Name, Surname>

7.2.2. CONTINUING REVIEW APPLICATIONS (*for expedited protocols*)

PROTOCOL 1	**PTN <number>**
Date of Approval <dd/mm/yy>	Continuing Review Application Date <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

7.2.3. PROTOCOL WITHDRAWAL

PROTOCOL 1	**PTN <number>**
Date of Submission <dd/mm/yy>	Date of Withdrawal Application/Letter <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

7.2.4. FINAL REPORTS (*for expedited protocols*)

PROTOCOL 1	**PTN <number>**
Date of Approval <dd/mm/yy>	Final Report Date <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

7.2.5. NON-COMPLIANCE (DEVIATION/VIOLATION) REPORTS (*for expedited protocols*)

PROTOCOL 1	**PTN <number>**
Date of Approval <dd/mm/yy>	Non-Compliance Report Submission Date <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

7.2.6. EARLY STUDY TERMINATION APPLICATIONS (*for expedited protocols*)

PROTOCOL 1	**PTN <number>**
Date of Approval <dd/mm/yy>	Early Termination Application Submission Date <dd/mm/yy>

Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

7.2.7. QUERIES AND COMPLAINTS (*for expedited protocols*)

PROTOCOL 1	**PTN <number>**
Date of Approval <dd/mm/yy>	Query/Complaint Receiving Date <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

7. REPORT ON APPROVED PROTOCOLS

7.1.1 Protocols with MINOR Modifications (Expedited at the Level of Chair)

PROTOCOL 1	**PTN <number>**
Date of Initial Review <dd/mm/yy>	Date of Resubmission <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

7.1.2. Protocol Amendments Expedited at the Level of the Chair (*amendments that are MINOR or administrative in nature)*

PROTOCOL 1	**PTN <number>**
Date of Initial Review <dd/mm/yy>	Date of Resubmission <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>

8. OTHER MATTERS

9. ADJOURNMENT

The meeting was adjourned at <hh:mm>

_____ _____

IEC Chair's Signature Over Printed Name *Date*

MINUTES OF REGULAR MEETING
(FORM 4B/V2/2019)

Date of Meeting: <dd/mm/yy>
Time of Meeting : <hh:mm> <AM/PM>
Venue of Meeting: IEC Conference Room, AKMRC

ATTENDANCE

IEC Members	Position/ Area of Responsibility
	Chair/ Medical
	Co-chair/ Non-medical; Non-scientific
	Member/ Medical
	Member-Secretary/ Non-medical; Non-scientific
	Non-affiliated Member/ Scientific
	Affiliated Member/ Non-medical; Non-scientific
	Non-Affiliated Member/ Medical; Scientific
	Lay Member/ Non-medical; Non-scientific

1. DETERMINATION OF QUORUM

The IEC Secretary declared that a quorum was present, with <number> members, inclusive of <number> non-Institutional and <number> non-scientific/lay members in attendance.

2. CALL to ORDER and CONFIRMATION OF QUORUM

The IEC Chair, upon confirming a quorum, called the meeting to order at <hh:mm> <AM/PM>

3. DISCLOSURE OF CONFLICT OF INTEREST

The IEC Chair called for the disclosure of Conflict of Interest (COI) in any of the study protocols scheduled for deliberation in the meeting.

<The following member<s> inhibited from participation in the deliberations during the meeting for the following reasons>:

Name of IEC Member	Reason(s) Given
<Title, Name, Surname>	Being <Principal Investigator for the study > < TITLE> <PTN>

4. READING AND APPROVAL OF THE MEETINGS OF THE LAST MEETING

Date of Last Meeting : <dd/mm/yy>
Time of Last Meeting : <hh:mm> <AM/PM>

Venue of Last Meeting: IEC Conference Room, AKMRC

The IEC Chair presided over the discussion of the minutes of the last meeting. The minutes were corrected, and approved as amended.

5. BUSINESS ARISING FROM THE MINUTES

6. PROTOCOL REVIEW

6.1. FULL REVIEW

6.1.1 INITIAL REVIEW

PROTOCOL 1	**PTN <number>**
Date of Submission: <dd/mm/yy>	Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Previous Approval from other Technical/Ethics Review Committees	<Name of Technical /Ethics Review Committee> < Approval Start and End Date>
Type of Review:	Primary Reviewers: <Title, Name, Surname>
Quorum Status:	Conflict of Interest
Scientific Soundness (refer to IEC FORM 2C/V1/2012)	**Comments**
1. Study Objectives 2. Background Information/Data 3. Study/Sampling Design 4. Use of Control Arm/Placebo 5. Inclusion/Exclusion/Withdrawal Criteria 6. Statistical/Data Analysis Plan 7. Specimen Collection, Processing, Storage Procedures 8. Facilities/Infrastructure at Study Site 9. PI Qualification, Competence, Experience 10. Contribution to science, research capacity, health care, treatment 11. Benefit to Local Communities	
Ethical Soundness (refer to IEC FORM 2C/V1/2012)	**Comments**
1. Privacy/Confidentiality Safeguards 2. Involvement of Human Participants 3. Involvement of Vulnerable Populations 4. Voluntary, non-coercive recruitment 5. Participant Selection 6. Risk-Benefit Ratio 7 Informed Consent process 8. Language of the Informed Consent/Assent Forms 9. Translation(s) of the Informed Consent/Assent Forms 10. Specific Informed Consent Provisions (*as specified in the Protocol Assessment Form*)	

Conclusions and Recommendations
Action Taken ☐ APPROVAL ☐ MAJOR MODIFICATION (*which require Full Board deliberation*) ☐ MINOR MODIFICATION (*which can be expedited at the level of the Chair*) ☐ DISAPPROVAL

6.1.2. RESUBMISSIONS (*protocols with MAJOR corrections/modifications*)

PROTOCOL 1	**PTN <number>**
Date of Initial Review <dd/mm/yy>	Date of Resubmission: <dd/mm/yy> Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Type of Rreview:	Primary Reviewers: <Title, Name, Surname>
Quorum Status	Conflict of Interest
Assessment of the Responses (*refer to submitted IEC Form 2H/V1/2012*)	
Conclusions and Recommendations	
Action Taken ☐ APPROVAL ☐ MAJOR MODIFICATION (*which require another Full Board deliberation*) ☐ MINOR MODIFICATION (*which can be expedited at the level of the Chair*) ☐ DISAPPROVAL	

6.1.3. REQUIRING CLARIFICATORY INTERVIEW

PROTOCOL 1	**PTN <number>**
Date of Initial Review <dd/mm/yy>	Date of Clarificatory Interview: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator	<Title, Name, Surname>
Sponsor/CRO	<Name>
Primary Reviewers	<Title, Name, Surname>
Quorum Status	
Conflict of Interest	
Assessment of the Responses	
Conclusions and Recommendations	
Action Taken ☐ REQUEST INFORMATION (*specify*) ☐ RECOMMENDED FURTHER ACTION (*specify*)	

6.1.4. PROTOCOL AMENDMENT APPLICATIONS *(with MAJOR Amendments that can affect the scientific and/or ethical acceptability of the protocol)*

PROTOCOL 1	**PTN <number>**
Date of Approval: <dd/mm/yy>	Amendment Submission Date: <dd/mm/yy> Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Type of Review:	Primary Reviewers: <Title, Name, Surname>
Quorum Status	Conflict of Interest
Assessment of the Requested Amendment (*refer to submitted IEC FORM 3A/V1/2012*)	
Conclusions and Recommendations	
Action Taken ☐ APPROVAL ☐ MAJOR MODIFICATION (*which require Full Board deliberation*) ☐ MINOR MODIFICATION (*which can be expedited at the level of the Chair*) ☐ DISAPPROVAL	

6.1.5. CONTINUING REVIEW APPLICATIONS

PROTOCOL 1	**PTN <number>**
Date of Approval: <dd/mm/yy>	Continuing Review Application Date: <dd/mm/yy> Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Type of Review:	Primary Reviewers: <Title, Name, Surname>
Quorum Status	Conflict of Interest
Assessment of the Study Progress (*refer to submitted IEC Form 3B/V1/2012*)	
Conclusions and Recommendations	
Action Taken ☐ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION ☐ REQUEST INFORMATION (*specify*) ☐ RECOMMENDED FURTHER ACTION (*specify*)	

6.1.6. FINAL REPORTS

PROTOCOL 1	**PTN <number>**
Date of Approval: <dd/mm/yy>	Final Report Date: <dd/mm/yy> Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Type of Review:	Primary Reviewers <Title, Name, Surname>

Quorum Status	Conflict of Interest
Assessment of the Final Report (*refer to submitted IEC Form 3C/V1/2012*)	
Conclusions and Recommendations	
Action Taken □ APPROVAL □ REQUEST INFORMATION (*specify*) □ RECOMMENDED FURTHER ACTION (*specify*)	

6.1.7. SAE and SUSAR REPORTS

PROTOCOL 1	**PTN <number>**
Date of Approval: <dd/mm/yy>	SAE/SUSAR Report Submission Date: <dd/mm/yy> Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Type of Review	Primary Reviewers: <Title, Name, Surname>
Quorum Status	Conflict of Interest
Assessment of SAE/SUSAR Report (*refer to submitted IEC FORM 3G/V1.2012*)	
Conclusions and Recommendations	
Action Taken □ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION □ REQUEST INFORMATION (*specify*) □ RECOMMEND FURTHER ACTION (*specify*) □ FORWARD TO SAE SUB-COMMITTEE	

6.1.8. SITE VISIT REPORTS

PROTOCOL 1	**PTN <number>**
Date of Approval : <dd/mm/yy>	Site Visit Report Submission Date: <dd/mm/yy> Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Type of Review:	Primary Reviewers: <Title, Name, Surname>
Quorum Status	Conflict of Interest
Assessment of Site Visit Report (*refer to submitted IEC FORM 3F/V1.2012*)	
Conclusions and Recommendations	
Action Taken □ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION □ REQUEST INFORMATION (*specify*) □ RECOMMEND FURTHER ACTION (*specify*)	

6.1.9. NON-COMPLIANCE (DEVIATION/VIOLATION) REPORTS

PROTOCOL 1	**PTN <number>**

Date of Approval : <dd/mm/yy>	Non-Compliance Report Submission Date: <dd/mm/yy> Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Type of Review:	Primary Reviewers: <Title, Name, Surname>
Quorum Status	Conflict of Interest
Assessment of Non-Compliance Report (*refer to submitted IEC FORM 3D/V1.2012*)	
Conclusions and Recommendations	
Action Taken □ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION □ REQUEST INFORMATION (*specify*) □ RECOMMEND FURTHER ACTION (*specify*)	

6.1.10. EARLY STUDY TERMINATION APPLICATIONS

PROTOCOL 1	**PTN <number>**
Date of Approval <dd/mm/yy>	Early Termination Application Submission Date <dd/mm/yy> Date Received:
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Type of Review:	Primary Reviewers: <Title, Name, Surname>
Quorum Status	Conflict of Interest
Title	<Version Number, Date>
Assessment of Risks from Early Termination (*refer to submitted IEC FORM 3E/V1.2012*)	
Conclusions and Recommendations	
Action Taken □ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION □ REQUEST INFORMATION (*specify*) □ RECOMMEND FURTHER ACTION (*specify*)	

6.1.11. QUERIES AND COMPLAINTS

PROTOCOL 1	**PTN <number>**
Date of Approval: <dd/mm/yy>	Query/Complaint Receiving Date: <dd/mm/yy> Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Type of Review:	Primary Reviewers: <Title, Name, Surname>
Quorum Status	Conflict of Interest
Assessment of Query/Complaint (*refer to submitted IEC FORM 3I/V1.2012*)	
Conclusions and Recommendations	
Action Taken □ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION □ REQUEST INFORMATION (*specify*) □ RECOMMEND FURTHER ACTION (*specify*)	

6.2. EXPEDITED REVIEW

6.2.1. INITIAL REVIEW

PROTOCOL 1	**PTN <number>**
Date of Submission: <dd/mm/yy>	Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigato: r<Title, Name, Surname>	Sponsor/CRO: <Name>
Previous Approval from other Technical/Ethics Review Committees	<Name of Technical /Ethics Review Committee> < Approval Start and End Date>
Type of Review:	Primary Reviewers <Title, Name, Surname>
Quorum Status	Conflict of Interest
Scientific Soundness (refer to IEC FORM 2C/V1/2012)	**Comments**
1. Study Objectives 2. Background Information/Data 3. Study/sampling Design 4. Use of Control Arm/Placebo 5. Inclusion/Exclusion/Withdrawal Criteria 6. Statistical/data Analysis Plan 7. Specimen Collection, Processing, Storage Procedures 8. Facilities/Infrastructure at Study Site 9. PI Qualification, Competence, Experience 10. Contribution to Science, research capacity, health care, treatment 11. Benefit to Local Communities	
Ethical Soundness (refer to IEC FORM 2C/V1/2012)	**Comments**
1. Privacy/Confidentiality Safeguards 2. Involvement of Human Participants 3. Involvement of Vulnerable Populations 4. Voluntary, non-coercive recruitment 5. Participant Selection 6. Risk-Benefit Ratio 7 Informed Consent process 8. Language of the Informed Consent/Assent Forms 9. Translation(s) of the Informed Consent/Assent Forms 10. Inclusion of Specific Provisions in the ICF 11. Specific Informed Consent Provisions (*as specified in the Protocol Assessment Form*) =	
Conclusions and Recommendations	
Action Taken ☐ APPROVAL ☐ MAJOR MODIFICATION (*which require Full Board deliberation*) ☐ MINOR MODIFICATION (*which can be expedited at the level of the Chair*) ☐ DISAPPROVAL	

6.2.2. CONTINUING REVIEW APPLICATIONS (*for expedited protocols*)

PROTOCOL 1	**PTN <number>**
Date of Approval: <dd/mm/yy>	Continuing Review Application Date: <dd/mm/yy> Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Type of Review:	Primary Reviewers: <Title, Name, Surname>
Quorum Status	Conflict of Interest
Assessment of the Study Progress (*refer to submitted IEC Form 3B/V1/2012*)	
Conclusions and Recommendations	
Action Taken □ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION □ REQUEST INFORMATION (*specify*) □ RECOMMENDED FURTHER ACTION (*specify*)	

6.2.3. PROTOCOL WITHDRAWAL

PROTOCOL 1	**PTN <number>**
Date of Submission: <dd/mm/yy>	Date of Withdrawal Application/Letter : <dd/mm/yy> Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Type of Review:	Primary Reviewers: <Title, Name, Surname>
Quorum Status	Conflict of Interest
Assessment of the Reasons for Withdrawal	
Conclusions and Recommendations	
Action Taken □ APPROVAL □ REQUEST INFORMATION (*specify*) □ RECOMMENDED FURTHER ACTION (*specify*)	

6.2.4. FINAL REPORTS (*for expedited protocols*)

PROTOCOL 1	**PTN <number>**
Date of Approval: <dd/mm/yy>	Final Report Date: <dd/mm/yy> Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Type of Review:	Primary Reviewers: <Title, Name, Surname>
Quorum Status	Conflict of Interest
Assessment of the Final Report (*refer to submitted IEC Form 3C/V1/2012*)	
Conclusions and Recommendations	

Action Taken ☐ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION ☐ REQUEST INFORMATION (*specify*) ☐ RECOMMENDED FURTHER ACTION (*specify*)

6.2.5. NON-COMPLIANCE (DEVIATION/VIOLATION) REPORTS (*for expedited protocols*)

PROTOCOL 1	**PTN <number>**
Date of Approval : <dd/mm/yy>	Non-Compliance Report Submission Date: <dd/mm/yy> Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Type of Review:	Primary Reviewers: <Title, Name, Surname>
Quorum Status	Conflict of Interest
Assessment of Non-Compliance Report (*refer to submitted IEC FORM 3D/V1.2012*)	
Conclusions and Recommendations	
Action Taken ☐ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION ☐ REQUEST INFORMATION (*specify*) ☐ RECOMMEND FURTHER ACTION (*specify*)	

6.2.6. EARLY STUDY TERMINATION APPLICATIONS (*for expedited protocols*)

PROTOCOL 1	**PTN <number>**
Date of Approval: <dd/mm/yy>	Early Termination Application Submission Date: <dd/mm/yy> Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Type of Review:	Primary Reviewers: <Title, Name, Surname>
Quorum Status	Conflict of Interest
Assessment of Risks from Early Termination (*refer to submitted IEC FORM 3E/V1.2012*)	
Conclusions and Recommendations	
Action Taken ☐ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION ☐ REQUEST INFORMATION (*specify*) ☐ RECOMMEND FURTHER ACTION (*specify*)	

6.2.7. QUERIES AND COMPLAINTS (*for expedited protocols*)

PROTOCOL 1	**PTN <number>**
Date of Approval: <dd/mm/yy>	Query/Complaint Receiving Date: <dd/mm/yy> Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Type of Review:	Primary Reviewers: <Title, Name, Surname>
Quorum Status	Conflict of Interest
Assessment of Query/Complaint (*refer to submitted IEC FORM 3I/V1.2012*)	
Conclusions and Recommendations	
Action Taken ☐ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION ☐ REQUEST INFORMATION (*specify*) ☐ RECOMMEND FURTHER ACTION (*specify*)	

7. REPORT ON APPROVED PROTOCOLS

7.1 Protocols with MINOR Modifications (Expedited at the Level of Chair)

PROTOCOL 1	**PTN <number>**
Date of Initial Review: <dd/mm/yy>	Date of Resubmission: <dd/mm/yy> Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Type of Review:	Primary Reviewers: <Title, Name, Surname>
IEC Chair's Decision : APPROVAL	

7.2. Protocol Amendments Expedited at the Level of the Chair (*amendments that are MINOR or administrative in nature)*

PROTOCOL 1	**PTN <number>**
Date of Initial Review: <dd/mm/yy>	Date of Amendment Submission: <dd/mm/yy> Date Received: <dd/mm/yy>
Title	<Version Number, Date>
Principal Investigator: <Title, Name, Surname>	Sponsor/CRO: <Name>
Type of Review:	Primary Reviewers: <Title, Name, Surname>
IEC Chair's Decision : APPROVAL	

8. OTHER MATTERS

9. ADJOURNMENT

The meeting was adjourned at <hh:mm>

Prepared by:	
_____	_____
IEC Secretary's Signature Over Printed Name	*Date*
Checked and Approved by:	
_____	_____
IEC Chair's Signature Over Printed Name	*Date*

CONFIDENTIALITY and CONFLICT OF INTEREST AGREEMENT
(For Guests/Observer Attendees)
(Form 4C/V1/2012)

I, _____, understand that I am allowed to attend the IEC Meeting scheduled on _____ at _____am/pm in the IEC Conference Room, AKMRC, as **Guest/Observer Attendee.**

I recognize that, in the course of the IEC meeting, confidential information may be disclosed or discussed.

By signing this form, I agree to take full responsibility for keeping all Information in strict trust and confidence.

If a conflict of interest exists, I shall immediately notify the IEC Chair and request exclusion from the meeting.

_____ _____

Signature over Printed Name of Guest/Observer Attendee *Date*

DLSMHSI-IEC FORM 4D-V1-2012-Notification Letter (Others)

<dd/mm/yy>

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

Re:

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

Dear <Title, Surname>:

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

Approved for use in the study are the following:

1. <document> <Version No.> <date>
2. <document> <Version No.> <date>

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

The IEC wishes you the best in this endeavor.

Truly yours,

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

<dd/mm/yy> **DLSMHSI-IEC FORM 4E-V1-2012-Approval Letter (for Protocol Amendment)**

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

Re:

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

Dear <Title, Surname>:

Thank you for submitting the amendments of the above protocol for review and approval by the De La Salle Medical and Health Sciences Institute – Independent Ethics Committee (DLSMHSI-IEC) which is constituted and operated in accordance with the Declaration of Helsinki, National Ethical Guidelines for Health Research, Council for International Organizations of Medical Sciences (CIOMS), and the International Conference on Harmonization/Good Clinical Practice (ICH/GCP).

The DLSMHSI-IEC is pleased to inform you that, in its regular meeting held on <dd/mm/yy>, the Proposed Amendments to the above protocol, as specified in the submitted IEC FORM 3B/V1/2012, has been granted **APPROVAL** for implementation, with the following members in attendance.

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

Approved for use in the study are the following:

1.

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

The IEC wishes you great success in this endeavor.

Respectfully yours,

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

DLSMHSI-IEC FORM 4F-V1-2012-Approval Letter (for Additional Materials)

<dd/mm/yy>

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

Re:

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

Dear <Title, Surname>:

With reference to the above protocol, the De La Salle Medical and Health Sciences Institute-Independent Ethics Committee (DLSMHSI-IEC) hereby acknowledges receipt letter dated <dd/mm/yy> regarding <documents>.

Upon review of the report, it has decided on <dd/mm/yy>, the additional document to the above protocol has been granted ***APPROVAL*** for implementation.

Approved for use in the study are the following documents;

1.

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

The IEC wishes you the best in this endeavor.

Respectfully yours,

<NAME OF IEC CHAIR>
Chair, DLSMHSI Independent Ethics Committee

DLSMHSI-IEC FORM 4G-V2-2019-Notification Letter (Reviewed Reports)

<dd/mm/yy>

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

Re:

Study Protocol No.	***IEC Protocol Tracking No***
Protocol Approval Date: <dd/mm/yy>	*<Protocol Withdrawal/ Continuing Review Application/ Final Report/ SAE Report/ Site Visit Repor/t Non-Compliance Report/ Early Study Termination/ Queries/Complaints >* *Submission Date: <dd/mm/yy>*
Title:	*Version Number, Date*
Sponsor/CRO	

Dear <Title, Surname>:

This has reference to the <Protocol Withdrawal/ Final Report/ SAE Report/ Site Visit Report Non-Compliance Report/ Early Study Termination/ Queries/Complaints> received by the IEC for review and approval.

Upon review of the <Application/ Report>, the IEC has decided, in its <dd/mm/yy> regular meeting, to **UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION/NO FURTHER ACTION REQUIRED/REQUEST INFORMATION/RECOMMENDED FURTHER ACTION/PENDING WITH MAJOR CLARIFICATION.**

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

The IEC looks forward to hearing from you soon.

Truly yours,

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

DLSMHSI-IEC FORM 4H-V1-2012-Notification Letter (for Modification Prior to Approval) Amendments

dd/mm/yy>

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

Re:

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

Dear <Title, Surname>:

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

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

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

1.

A resubmission within 90 days of receipt will be highly appreciated, otherwise the study will be declared closed for DLSHSI-IEC records. Please note that the recommended revisions must be:

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

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

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

Respectfully yours,

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

DLSMHSI-IEC FORM 4I-V1-2012- Notification letter (for Protocol Not Requiring Review)

dd/mm/yy>

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

Re:

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

Dear <Title, Surname>:

This has reference to the above study protocol which was submitted to the IEC for scientific and ethical review.

Please be informed that proposal does NOT require an IEC review on the basis of:

1. <basis>
2. <basis>

Should you have any question or need further clarification/information, please feel free to contact the undersigned at (046) 410-8000 local 8042.

Thank you for your submission.

Truly yours,

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

DLSMHSI-IEC FORM 4J-V1-2012- Approval Letter (for Final Report, Early Study Termination Application)

dd/mm/yy>

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

Re:

Study Protocol No.	***IEC Protocol Tracking No***
Protocol Approval Date: <dd/mm/yy>	*<Final Report/ Early Study Termination Application>* *Submission Date: <dd/mm/yy>*
Title:	*Version Number, Date*
Sponsor/CRO	

Dear <Title, Surname>:

This has reference to the <Final Report/ Early Study Termination> received by the IEC for review and approval.

Pleased be informed that the IEC has decided, in its <dd/mm/yy> regular meeting, to **APPROVE** the <Final Report/ Early Study Termination Application>, thereby automatically terminating the protocol's **IEC** approval as of this date.

The IEC has now closed and archived your files. Closed files have a 3-year retention period after study termination.

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

The IEC looks forward to hearing from you again in the near future.

Truly yours,

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

DLSMHSI-IEC FORM 4K-V1-2012- Reminder Letter (for Post-Approval Requirement)

<dd/mm/yy>

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

Re:

Study Protocol No.	***IEC Protocol Tracking No***
Protocol Approval Date: <dd/mm/yy>	
Study Initiation Date: <dd/mm/yy>	*Expected End Date: <dd/mm/yy>*
Title:	*Version Number, Date*
Sponsor/CRO	

Dear <Title, Surname>:

This has reference to the above protocol which was granted approval for implementation by the IEC in >dd/mm/yy>.

As you have been advised, it is a condition of the approval of your study that a <continuing review/ final report> must be filed <60 days prior to expiry date of current IEC approval/ within 90 days after study completion>.

The IEC has noted that the above post-approval review requirement has been not been filed as of this date. It would be in your best interest to complete the attached Form and forward to the same to the IEC Secretariat at your earliest convenience.

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

The IEC looks forward to your prompt response.

Truly yours,

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

DLSMHSI-IEC FORM 4L-V1-2012- Notification Letter (for Site Visit)

dd/mm/yy>

< TITLE, NAME, SURNAME>
Member, IEC

Re: Site Visit Team Membership

Dear <Title, Surname>

I am pleased to inform you of your appointment as **MEMBER** of the IEC-Site Visit Team that is responsible for ensuring, through a study file and site profile review, the safety of study participants and adherence to specifications of the approved protocol and related documents.

As an IEC Site Visit Team Member, your responsibilities include, but not limited to the following:

1. Completing the Site Visit Report Form (Form 3G/V1/2012)
2. Ensuring that the investigators and study staff have adequate knowledge about the intervention under study
3. Confirming that only eligible participants are being/have been enrolled
4. Observing the informed consent process, if possible
5. Verifying that investigators and study staff are performing study-related tasks, and have not delegated these to unauthorized individuals
6. Collecting views of study participants, if possible
7. Discussing own findings with the Site Visit Team

The Protocol and Site Visit details are as follows:

	IEC Protocol Tracking No
Study Protocol No.	*Protocol Approval Date: <dd/mm/yy>*
Study Initiation Date: <dd/mm/yy>	*Expected End Date: <dd/mm/yy>*
Title:	*Version Number, Date*
Name of Principal Investigator	*Contact Nos.:*
Sponsor/CRO	
STUDY SITE	*Address*
Date of Visit <dd/mm/yy>	*Time of Visit <hh:mm>*

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

Thank you for your continued assistance and support.

Truly yours,

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

CONFORME OF SITE VISIT TEAM MEMBER:

_____ _____
Signature Over Printed Name *Date*

DLSMHSI-IEC FORM 4M-V1-2012- Acknowledgement of Receipt Letter

<dd/mm/yy>

<Title, Name, Surname>
<Position>
<Institution/Affiliation>
<Address>

Re:

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

Dear <Title, Surname>:

With reference to the above protocol, the IEC hereby acknowledges receipt, last <dd/mm/yy>, <name of document>.

You will be notified, at the earliest possible time, if there are specific concerns/issues with regard to the foregoing.

Thank you and we wish you great success with your project.

Truly yours,

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

DLSMHSI-IEC FORM 4N-V1-2012- Notice of Corrective Action

<dd/mm/yy>

<Title, Name, Surname>
<Institution/Affiliation>
<Address>

Re: Study Protocol: **<Title>**

Principal Investigator (PI): **<Title, Name, Surname>**

Dear **<Title, Surname>:**

With reference to the above protocol, the IEC wishes to inform you that:

1. <information>

2. <information>

The IEC will highly appreciate appropriate course of action to prevent another such occurrence.

Thank you for your cooperation in ensuring that our researches are carried out to the highest scientific and ethical standards.

Truly yours,

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

DLSMHSI-IEC FORM 4O-V1-2012- Notification Letter (Letter of Disapproval)

<dd/mm/yy>

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

Re:

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

Dear <Title, Surname>:

This has reference to the <Application> received by the IEC for review and approval.

Upon review of the <Application/Report>, the IEC has decided, in its <dd/mm/yy> regular meeting, to **DISAPPROVE** the study**.** Specifically, the following are bases for such decision:

1. <basis>
2. <basis>

An appeal and resubmission within 90 days of receipt will be granted, otherwise the study will be declared closed for IEC records.

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

Truly yours,

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

DLSMHSI-IEC FORM 4P-V1-2012- Request Letter (for Content Expert)

<dd/mm/yy>

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

Re:

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

Dear <Title, Surname>:

The IEC, which is constituted and operated in accordance with the Declaration of Helsinki, National Ethical Guidelines for Health Research, Council for International Organizations of Medical Sciences (CIOMS), and the International Conference on Harmonization/Good Clinical Practice (ICH/GCP), is currently reviewing a proposal with particular relevance to your area of expertise.

In this regard, the IEC requests your assistance in reviewing the above protocol. If you are able to assist the IEC in this instance, please confirm your acceptance of this request at your earliest convenience. You will be sent the study-related documents and the Review Form that you will need in the systematic evaluation of the above protocol as soon as we hear from you.

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

Thank you in advance for honoring us with your participation in the IEC review process.

Truly yours,

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

DLSMHSI-IEC FORM 4Q-V1-2012- Notification of Delay (for Protocols Referred to Content Expert)

<dd/mm/yy>

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

Re:

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

Dear <Title, Surname>:

This has reference to the above protocol which was submitted to the IEC for scientific and ethical review. Please be informed that the IEC has referred the protocol to an external reviewer with qualifications or competence in disciplines relevant to your study.

With this development, the protocol will be tabled at a meeting only after receipt of the content expert's feedback. Hence, the review process might be delayed by up to a month. Rest assured that you will be notified of the decision regarding the protocol at the earliest possible date after the regular IEC meeting.

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

The IEC is grateful for your understanding in this matter.

Truly yours,

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

DLSMHSI-IEC FORM 4R-V1-2012- Approval Letter(for Approval of Continuing Review Application)

<dd/mm/yy>

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

Re:

Study Protocol No.	***IEC Protocol Tracking No***
Protocol Approval Date: <dd/mm/yy>	*<Protocol Withdrawal/ Continuing Review Application/ Final Report/ SAE Report/ Site Visit Repor/t Non-Compliance Report/ Early Study Termination/ Queries/Complaints >* *Submission Date: <dd/mm/yy>*
Title:	*Version Number, Date*
Sponsor/CRO	

Dear <Title, Surname>:

This has reference to the <Continuing Review Application> received by the IEC for review and approval.

Upon review of the <Application/ Report>, the IEC has decided, in its <dd/mm/yy> regular meeting, to **REQUEST FURTHER INFORMATION/RECOMMENDED FURTHER ACTION/ UPHOLD ORIGINAL APPROVAL.** Specifically, the following are requested:

1. <information>
2. <information>

A response/submission within 90 days of receipt will be highly appreciated, otherwise the study will be declared closed for IEC records.

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

The IEC looks forward to hearing from you soon.

Truly yours,

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

DLSMHSI-IEC FORM 4S-V1-2012- Invitation for Clarificatory Interview

<dd/mm/yy>

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

Re:

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

Dear <Title, Surname>:

This has reference to the above protocol which was submitted to the IEC for scientific and ethical review.

The IEC has raised, in its <dd/mm/yy> regular meeting, specific issues requiring clarifications which include:

1. <issue>
2. <issue>

In this regard, you are invited for a clarificatory interview on <dd/mm/yy> IEC regular meeting at <hh:mm><AMP/PM>, at the IEC Conference Room, AKMRC. Your prompt response to the invitation will be greatly appreciated.

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

The IEC looks forward to seeing you soon.

Truly yours,

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

DLSMHSI-IEC FORM 4T-V1-2012- Acknowledgement Letter (for Protocol Withdrawal)

<dd/mm/yy>

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

Re:

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

Dear <Title, Surname>:

This has reference to the above protocol which was submitted to the IEC for scientific and ethical review but has been withdrawn on <dd/mm/yy> by <you/Sponsor>.

The submission has been registered as **WITHDRAWN** on the IEC database. Should you wish to re-submit the application in the future, it will be treated as a new submission.

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

The IEC looks forward to hearing from you in the near future.

Truly yours,

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