1. FUNCTION:

The Department of Research and Development (R&D) oversees all research projects at the Lung Center of the Philippines (LCP). It receives, evaluates and coordinates all research activities. It establishes policies and guidelines for the development, writing, presentation and approval of research proposal and budget. Thru its Technical Review Board (TRB), it provides guidance and technical expertise on protocol development, including sample size calculation and statistical analysis plan. It conducts workshops on Research Methods and Protocol Writing. It spearheads institutional researches and runs the TB Research Team at the LCP's National Center for Pulmonary Research (NCPR), as well as coordinates research collaboration with other national and international agencies. The R&D organizes and conducts the hospital-wide Annual Research Forum as a venue to present the latest completed institutional researches and to train fellows and other hospital staff in oral presentation of scientific papers.

The R&D publishes the Scientific Proceedings, the official journal of the LCP, to share local relevant educational material in the field of respiratory medicine. The Scientific Proceedings publishes original clinical investigations, epidemiological studies, case reports, review articles, evaluation of diagnostic and surgical techniques, and latest updates on management guidelines.

The R&D spearheads the Lung Cancer Registry to gather and collate the most comprehensive local data on lung cancer.

2. GENERAL POLICIES:

2.1. All researches to be conducted in LCP shall be registered with the R&D and shall obtain endorsement by the R&D and clearance by the Institutional Ethics Review Board (IERB) prior to final approval by the Executive Director.

2.2. The LCP shall accept both Institutional Researches (initiated by LCP Personnel and External Researches (initiated by non-LCP personnel including but not limited to Clinical Trials from pharmaceutical companies or collaborative work from other government or non- government groups, and Student Researches).

2.3. Institutional and External Researches, excluding Student Researches, shall have a Principal Investigator who is a consultant/staff with a current or former Plantilla of the LCP.

2.4. For Institutional Researches, all Principal Investigators shall first have their research proposals reviewed and endorsed by the Research Committee or Unit

Head and Manager of their respective Departments prior to having their research protocols registered at the R&D.

2.5. All Institutional Researches shall be subject to R&D's Technical Review Board (TRB) clearance as outlined in 3.1.1.2 prior to endorsement to the IERB.

2.6. For External Researches consisting of multi-center Clinical Trials from multinational pharmaceutical companies, or collaborative work from other government or non-government groups the LCP shall collect an Administrative and Overhead Fee (formerly known as Institutional Fee) for each Clinical Trial from the Research Sponsor in accordance with the prescribed guidelines of the R&D as outlined in 3.2.1.2.

2.7. In addition to Administrative and Overhead Fees, Clinical Trials, and collaborative works shall be subject to the Clinical Research Facility Fee as outlined in 3.2.1.3.

2.8. Multi-center Clinical Trials from multinational pharmaceutical companies shall not be subjected to technical review by the TRB provided that technical clearances have been approved by their study sponsor, as required by the IERB. However, such Clinical Trials shall still be submitted to R&D for registration purposes.

2.9. For External Researches consisting of Student Researches, the LCP shall collect a Student's Registration Fee of Five Thousand Philippine Pesos (PhP5,000.00) upon registration for each research study to cover for the administrative and overhead cost incurred by the R&D and IERB in having the student's study carried out at the LCP.

2.10. Student Researches shall not undergo review by the TRB since their Principal Investigator is not a staff of the LCP.

2.11. All research protocols shall be subject to IERB clearance.

2.12. Final draft of all research studies shall be submitted to the R&D for filing.

2.13. Institutional Researches seeking funding assistance from the institution shall be reviewed by the R&D. Assistance, subject to the availability of funds shall be categorized as follows:

2.13.1. Full assistance: 100% of the budget requested

2.13.2. Partial assistance: up to 50% of the budget requested

Quarterly reporting of expenses shall be submitted to the R&D for filing.

2.14. All researches shall be subject to a Study Launch meeting presided by the Clinical Trials Division Head as assigned by the department manager of the R&D, presented by the Principal Investigator, and attended by representatives of the different areas in LCP concerned with the study prior to carrying out the study maneuver.

2.15. All researches and technical papers approved by the R&D, appropriately revised and finalized by their respective Principal Investigators, shall automatically be printed in the Scientific Proceedings. Oral presentation of the approved studies shall take place during the Research Forum usually scheduled on the 1st Monday of July or 1st Monday of December.

3. SPECIFIC POLICIES AND PROCEDURES:

3.1. EVALUATION OF INSTITUTIONAL RESEARCHES (INITIATED BY LCP PERSONNEL)

3.1.1. POLICIES:

3.1.1.1. Submission of needed requirements which consist of the following must be complete for registration to proceed:

3.1.1.1.1. Research Registration Form

3.1.1.1.2. Letter of request for approval from the Principal Investigator.

3.1.1.1.3. Certification of approval from the Research Committee, Adviser, Unit Head or Department Manager of the Principal Investigator.

3.1.1.1.4. Hard copies #05 and a soft copy of the research protocol, signed and dated by the Adviser.

3.1.1.1.5. Budget proposal, with or without request for funds.

3.1.1.2. Upon completion of requirements in 3.1.1.1, the research protocol shall be subject to technical review by the TRB as follows:

3.1.1.2.1. R&D shall distribute the soft copy of the research protocol to all TRB members for Preliminary Technical Review. The following aspects shall be subject to review: Introduction, Literature Review, Research

Questions, Research Objectives, Methodology (Study Design, Study Population, Procedure, Outcome Measures, Sample Size Calculation, Statistical Analysis), Ethical Consideration, Time Frame, Budget, References, other matters). Questions or comments or recommendations from the TRB members shall be submitted to the R&D within one (1) week of distribution.

3.1.1.2.2. Three (3) TRB members shall be designated as primary reviewers for each research protocol with at least one primary reviewer having the same specialty as the Principal Investigator or topic of research. During the 2nd week after distribution, the 3 primary reviewers shall collate questions/comments/recommendations from all preliminary reviewers in preparation for a TRB meeting. where the Principal Investigator shall present the protocol.

3.1.1.2.3. A TRB meeting will be scheduled after two weeks of research protocol distribution where the Principal Investigator shall present the protocol and questions / comments / recommendations from TRB reviewers shall be discussed. The assigned primary reviewers shall act as moderators during this meeting.

3.1.1.2.4. Final recommendation will consist of: (1) approval without revision; (2) disapproval (with reasons given); or (3) Re-evaluation after major or minor revisions (Appendix A: Preliminary Technical Review Form). All answers to questions or comments or recommendations for re-evaluation purposes shall be submitted two (2) weeks after the TRB meeting. The Final disposition of the primary reviewers and final approval of the Vice Chair and the Chair of the TRB shall be made prior to endorsing to the IERB.

3.1.1.1. After obtaining IERB clearance, if there is a need for funding assistance, the researcher shall submit a letter of request to the Department of Research & Development stating the amount/budget needed. Specific indications for the procedures, tests, services, drugs and/or equipment shall be explained.

3.1.1.2. R&D Manager shall endorse said study and budget, if requested, to the Executive Director for final approval.

3.1.1.3. If approved by the Executive Director, a Study Launch shall be scheduled and the study protocol shall be presented by the Principal Investigator. The meeting shall be presided by the Clinical Trials and Research Division Head and attended by representatives of the different areas in LCP concerned with the study prior to carrying out the study maneuver.

3.1.1.4. Upon completion of the study, a Preliminary Report shall be submitted to the Research Adviser before a Final Draft is prepared for oral presentation during the next Research Forum.

3.1.1.5. Final Draft/Report of the research study shall be handed in two (2) weeks before the scheduled Research Forum. Three (3) copies of the manuscripts should be submitted to the secretary of the R&D before 5:00 pm of the set date. A soft copy of the Final Draft shall also be submitted.

3.1.1.6. All research papers shall be presented in a Research Forum usually scheduled on the 1st Monday of July or 1st Monday of December.

3.1.1.7. All certificates of completion of training shall be cleared with the R&D before they shall be issued to graduates of training programs.

3.1.2. PROCEDURE:

PERSON RESPONSIBLE	ACTIVITY
Principal Investigator	1. Submits all the requirements to the R&D Office
Secretary, R&D	1. Checks the completeness of the Requirements. 2. Assigns a protocol number. 3. Informs the TRB Chair & endorses the submitted documents to the TRB
Vice Chair, TRB	1. Evaluates and schedules the presentation of the protocol to the Technical Review Board
Technical Review Board	1. Evaluates the research protocol on technical merits. 2. Recommends revisions and approves the protocol

PERSON RESPONSIBLE	ACTIVITY
Chair, TRB	1. Approves the transmittal of the protocol to the Institutional Ethics Review Board (IERB) for evaluation on ethical considerations. 2. Informs the Principal Investigator to submit the requirements to the IERB.
Principal Investigator	1. Submits the requirements to the IERB
Secretary, IERB	1. Checks for completeness of the requirements. 2. Informs the Chair of the IERB of the research protocol for presentation
Chair, IERB	1. Schedules the meeting of the IERB
IERB	1. Evaluates the research protocol on ethical merits. 2. Recommends the revisions and approves the final protocol, or disapproves
Principal Investigator	1. Informs R&D of IERB disposition
Manager, R&D	1. Writes a letter to the Executive Director recommending for the final approval, if applicable
Executive Director	1. Gives final disposition/approval
Clinical Trials and Research Division Head	1. Informs the Principal Investigator of the final disposition/approval 2. Schedules and conducts the study launch/initiation.
Principal Investigator	1. Commences study, if launched

3.2. EVALUATION OF RESEARCHES INITIATED BY EXTERNAL GROUPS (CLINICAL TRIALS)

3.2.1. POLICIES:

3.2.1.1. Submission of needed requirements which consist of the following must be complete for registration to proceed:

3.2.1.1.1. Research Registration Form
3.2.1.1.2. Letter of request for approval from the Principal Investigator.
3.2.1.1.3. Hard copy #01 and soft copy #01 of the research protocol

3.2.1.2. LCP shall collect an Administrative and Overhead Fee (formerly known as Institutional Fee) for each Clinical Trial from the Research Sponsor in accordance with the prescribed guidelines of the R&D as follows:

3.2.1.2.1. Administrative and Overhead Fee shall be computed at 15% of the Site Budget Proposal, and paid to LCP net of all applicable taxes. The Administrative and Overhead Fee shall not exceed a ceiling rate of Six Million Philippine Pesos (PhP6,000,000.00).

3.2.1.2.2. A Start-up Fee of Thirty Thousand Philippine Pesos (PhP30,000.00) shall be collected upfront upon registration of the Clinical Trial to cover for administrative costs. The Start-up Fee shall be nonrefundable but deductible from the LCP Administrative and Overhead Fee.

3.2.1.2.3. An additional nonrefundable Fast Track Fee of Twenty Thousand Philippine Pesos (PhP20,000.00) shall be collected for any Clinical Trial needing expedited processing including IERB clearance.

3.2.1.3. In addition to Administrative and Overhead Fees, Clinical Trials shall be subject to the following Research Fees for use of the Clinical Research Facility:

3.2.1.3.1. Monthly rental of space amounting to Fifteen Thousand Philippine Pesos (PhP15,000.00), inclusive of electricity and water consumption, payable until official site close-out.

3.2.1.3.2. Monthly storage fee for investigational products amounting to Five Thousand Philippine Pesos (PhP5,000.00), payable until official site close-out.

3.2.1.3.3. Monthly use of metal drawer for archiving purposes amounting to Three Hundred Philippine Pesos per drawer (PhP300.00/drawer), the final computation of which shall depend on the number of metal drawers to be occupied and planned number of years for

archiving (Appendix B: Guidelines on Archiving of Post-Trial Records).

3.2.1.4. Multi-center Clinical Trials from multi =national pharmaceutical companies shall not be subjected to technical review by the TRB provided that technical clearances have been obtained by their study sponsor, and these shall be accepted by the IERB. Therefore, Clinical Trials shall proceed with IERB evaluation and clearance parallel to their registration process with the R & D.

3.2.1.5. Upon obtaining clearance from IERB and after payment of all Administrative and Overhead Fees, R&D Manager shall endorse said study and budget, if requested, to the Executive Director for final approval.

3.2.1.6. If approved by the Executive Director, a Study Launch shall be scheduled and the study protocol shall be presented by the Principal Investigator. The meeting shall be presided by the Clinical Trials Division Head and attended by representatives of the different areas in LCP concerned with the study prior to carrying out the study maneuver.

3.2.1.7. During the conduct of the study, the principal investigator shall provide an updated list of enrolled subjects or any protocol amendments to the Department of Research & Development for check and balance purposes.

3.2.1.8. The Principal Investigator shall inform the R&D in writing of any completion or termination of study.

3.2.2. PROCEDURE FOR EVALUATION OF RESEARCHES INITIATED BY EXTERNAL GROUPS (Clinical Trials):

PERSON RESPONSIBLE	ACTIVITY
Principal Investigator	1. Submits all the requirements to the R&D Office 2. Pays LCP the R&D Start-up Fee
Secretary, R&D	1. Checks the completeness of the requirements 2. Assigns a protocol number. 3. Informs the TRB Chair & endorses the submitted documents to the TRB

PERSON RESPONSIBLE	ACTIVITY
Chair, TRB	1. Approves the transmittal of the protocol to the Institutional Ethics Review Board (IERB) for evaluation on ethical considerations
Principal Investigator	1. Submits the requirements to the IERB.
Secretary, IERB	1. Checks for completeness of the requirements. 2. Informs the Chair of the IERB of the research protocol for presentation
Chair, IERB	1. Schedules the meeting of the IERB
IERB	1. Evaluates the research protocol on ethical merits. 2. Recommends the revisions and approves the final protocol or disapproves
Principal Investigator	1. Informs R & D of IERB disposition
Manager, R&D	1. Writes a letter to the Executive Director recommending for the final approval, if applicable
Executive Director	1. Gives final disposition/approval
Clinical Trials and Research Division Head	1. Informs the Principal Investigator of the final disposition/approval 2. Informs the Principal Investigator of the approved administrative fee (which shall be settled prior to study initiation) 3. Schedules and conducts the study launch/initiation once the administrative fee is paid.
Principal Investigator	1. Commences study, if launched

3.3. EVALUATION OF RESEARCHES INITIATED BY EXTERNAL GROUPS (STUDENT RESEARCHES)

3.3.1. POLICIES:

3.3.1.1. Submission of needed requirements which consist of the following must be complete for registration to proceed:

3.3.1.1.1. Research Registration Form.
3.3.1.1.2. Letter of Intent from researcher clearly stating what is needed from LCP.
3.3.1.1.3. Research Protocol, Hard copy #01 and soft copy #01.

3.3.1.2. Letter of Approval/Willingness from the unit involved to assist in the conduct of the study, signed by the Unit Head and noted by the respective Department Manager.

3.3.1.3. Informed Consent Form (if applicable).

3.3.1.4. Filled and Signed LCP R&D Forms: Research Registration; Guidelines Agreement; confidentiality Agreement; Application for release of information (if R&D data is utilized).

3.3.2. PROCEDURE:

PERSON RESPONSIBLE	ACTIVITY
Student Investigator	1. Submits all the requirements to the R&D Office 2. Pays LCP the Student's Registration Fee
Secretary, R&D	1. Checks the completeness of the requirements 2. Assigns a protocol number. 3. Informs the TRB Chair & endorses the submitted documents to the TRB
Chair, TRB	1. Approves the transmittal of the protocol to the Institutional Ethics Review Board (IERB) for evaluation on ethical considerations.
Principal Investigator	1. Submits the requirements to the IERB.
Secretary, IERB	1. Checks for completeness of the requirements. 2. Informs the Chair of the IERB of the research protocol for IERB clearance
IERB	1. Evaluates the research protocol on ethical merits and issues IERB clearance or disapproves
Principal Investigator	1. Informs R&D of IERB disposition
Clinical Trials and Research Division Head	1. Informs the Principal Investigator of the final R&D disposition
Student Investigator	1. Commences study, if approved

3.4. EVALUATION OF RESEARCHES INVOLVING COLLABORATIVE WORK (APPROVAL OF INSTITUTIONAL COLLABORATION)

3.4.1. POLICIES:

3.4.1.1. Appointing or designating a Co-Investigator, a consultant/staff with a current or former plantilla item, from the Lung Center of the Philippines

3.4.1.1.1. Submission of needed requirements which consist of the following must be complete for registration to proceed:

3.4.1.1.1.1. Letter of intent from research proponent and co-investigator from LCP

3.4.1.1.1.2. Capsule proposal or full protocol, hard and soft copies

3.4.1.1.2. Evaluation and Approval of collaboration by the Department of Research and Development and the Executive Director.

3.4.1.2. If LCP Co-Investigator is not yet chosen or appointed, the following procedures will be followed:

3.4.1.2.1. Submission of needed requirements which consist of the following must be complete for registration to proceed:

3.4.1.2.1.1. Letter of intent from the proponent from a different institution

3.4.1.2.1.2. Capsule proposal or full protocol, hard and soft copies

3.4.1.2.2. Evaluation/Deliberation of the collaboration by the Department of Research and Development and the Executive Director.

3.4.1.2.2.1. If the proposal is approved, a Co-Investigator from LCP is suggested.

3.4.1.2.2.2. If the proposal needs re-evaluation after deliberation, suggestions for improvement should be addressed by the proponent and submit a revised/improved proposal.

3.4.1.3. Co-investigator/s from LCP should have inputs to the research and should work with the original team of proponents.

3.4.1.4. Co-investigator/s from LCP should be acknowledged/included as "Co-Investigator" in the final proposal to be submitted for funding.

3.4.1.5. LCP shall collect an Administrative and Overhead Fee for each Research involving collaborative work (Institutional collaboration) following the prescribed guidelines of the R&D for researches initiated by External groups (see 3.2.1.2)

3.4.1.6. In addition to Administrative & Overhead Fees, research involving collaborative work (Institutional Collaboration) that will utilize the Clinical Research Facility shall subject to Research Fees following the prescribed guidelines of the R&D for researches initiated by External groups (see 3.2.1.3)

3.4.1.7. Upon approval of the proposal and payment of start-up fee, the full research protocol shall be subject to technical review by the TRB following the SOP (see 3.1.1.2)

3.4.1.8. Upon obtaining IERB clearance and after payment of all Administrative and Overhead Fee, R&D Manager shall endorse said study and budget, if requested to the Executive Director for final approval

3.4.1.9. If approved by the Executive Director, a Study Launch shall be scheduled and the study protocol shall be presented by the Principal Investigator or Co-Investigator,

3.4.1.10. The Principal Investigator shall inform the R&D in writing of any protocol amendments, completion or termination of study

3.4.1.11. Final Draft/Report of the research study shall be handed in two (2) weeks before the scheduled Research Forum. Three (3) copies of the manuscript should be submitted to the secretary of

the R&D before 5:00 pm of the set date. A soft copy of the Final Draft shall also be submitted.

3.4.1.12. All research papers shall be presented in a Research Forum usually scheduled on the 1st Monday of July or 1st Monday of December.

3.4.1.13. All researches and technical papers approved by the R&D, appropriately revised and finalized by their respective Principal Investigators, shall automatically be printed in the Scientific Proceedings. Oral presentation of the approved studies shall take place during the Research Forum usually scheduled on the 1st Monday of July or 1st Monday of December. =

3.4.2. PROCEDURE:

PERSON RESPONSIBLE	ACTIVITY
LCP Co-Investigator	1. Submits all the requirements to the R&D Office 2. Pays the Start-up Fee to LCP
Secretary, R&D	1. Checks the completeness of the requirements 2. Assigns a protocol number. 3. Informs the TRB Chair and LCP Co-investigator; endorses the submitted documents to the TRB Chair
Chairman, TRB	1. Approves the transmittal of the protocol to the Institutional Ethics Review Board (IERB) for evaluation on ethical considerations
LCP Co-Investigator	1. Submits the requirements to the IERB.
Secretary, IERB	1. Checks for completeness of the requirements. 2. Informs the Chairman of the IERB of the research protocol for presentation
Chairman, IERB	1. Schedules the meeting of the IERB
IERB	1. Evaluates the research protocol on ethical merits. 2. Recommends the revisions and approves the final protocol.

LCP Co-Investigator	1. Informs R&D of IERB disposition
Manager, R&D	1. Writes a letter to the Executive Director recommending for the final approval
Executive Director	1. Gives final disposition/approval
LCP Co-Investigator/Study Coordinator	1. Informs the Research Sponsor for the Collaborative Work of the final disposition/approval 2. Informs the Research Sponsor of the approved administrative and overhead fee
Clinical Trials and Research Division Head	1. Schedules and conducts the study launch/initiation
LCP Co-Investigator	1. Commences study, if approved

3.5. PROCEDURE FOR COLLECTION OF FEES

3.5.1. FOR CLINICAL TRIAL / SPONSORED RESEARCHES (upon approval of protocol)

PERSON RESPONSIBLE	ACTIVITY
Principal Investigator (PI)	1. Coordinates with R & D for the issuance of the Statement of Account (SOA)
Staff, R&D	1. Coordinates with Billing 2. Facilitates preparation of Bill Statement to Sponsor thru PI
Billing	1. Prints itemized details in the Statement of Account (SOA) such as: diagnostic, laboratory procedures and charges, space rental, archiving, etc. 2. Gives a copy of the SOA to R & D
Staff, R & D	1. Issues Statement of Account (SOA) to PI
Secretary, R&D	1. Prepares Order of Payment

PERSON RESPONSIBLE	ACTIVITY
	2. Gives Order of Payment to the Principal Investigator
Principal Investigator	1. Acknowledges receipt of SOA 2. Coordinates with Sponsor for the cheque preparation 3. Updates R & D of cheque (payment) status 4. Goes back to R & D for the issuance of Order of Payment (OP)
Staff, R&D	1. Prepares and issues Order of Payment to PI or Study Coordinator (SC) who proceeds to Cashier for payment
Principal Investigator	1. Gets copy of the Official Receipt (OR) 2. Provides copy of OR to R & D for recording of OR

3.5.2. WIRED TRANSFER (Remittance Payment)

PERSON RESPONSIBLE	ACTIVITY
Staff, R & D	1. Prepares and issues statement of account to sponsor thru the Principal Investigator (PI)
Principal Investigator	1. Verifies with cashier in case of remittance/wired transfer
Cashier	1. Checks and informs R & D of such remittance/money transfer from the bank
Staff, R & D	1. Facilitates preparation and issuance of Order of Payment to PI/SC
Principal Investigator/Sponsor Coordinator	1. Pays to cashier 2. Acknowledges receipt of Official Receipt (OR) 3. Provides copy of OR to R & D

GUIDELINES ON ARCHIVING OF RECORDS POST-TRIAL

1. BACKGROUND:

The Department of Health Guidelines on the Implementation of Clinical Research Policy in DOH Hospitals included a section on Archiving under Ownership of Research Output and Dissemination of Results (Section VI-H item no. 2), stating that, "The storage and disposal of data shall follow existing rules and guidelines such as the National Archives Commission, Data Privacy Act of 2012, etc."

2. PURPOSE AND SCOPE:

This policy aims to provide clear instructions regarding appropriate storage, retention and disposal of documents related to research in accordance with the guidelines of ICH-GCP, National Archives of the Philippines Act of 2007 (R.A. 9470) and Data Privacy Act of 2012 (R.A. 10173).

3. ROLES AND RESPONSIBILITIES:

3.1. DEPARTMENT MANAGER

3.1.1. Assign an Archivist to ensure that all paper records related to research are filed and archived correctly

3.1.2. Inform all employees interacting with the Department of Research and Development that it is their duty to keep confidential information safe (Data Privacy Act of 2012)

3.2. PRINCIPAL INVESTIGATOR

3.2.1. Arrange for the retention of the subject identification codes for a sufficient period of time to permit any medical follow-up which may be warranted, including follow-up for delayed toxic reactions

3.2.2. Identify each trial subject by name against subject and product container identification codes, treatment assignment, and the CRFS.

Subject files and other supporting data must be kept for a period of time required by local regulations.

The protocol, documentation, approvals and all other essential documents related to the trial, including certificates that satisfactory audit and inspection procedures have been carried out, must be retained by the sponsor. Data on adverse events must always be included.

All data and documents should be made available if requested by relevant authorities.

4. IMPLEMENTATION:

4.1. ACQUISITION

The Principal Investigator formally requests the Clinical Research Department for archiving of post-trial documents.

The sponsor must make appropriate arrangements for the retention of all other essential documentation pertaining to the clinical trial in a form that can be retrieved for future reference. Archived data may be kept on microfiche or electronic or optical record (e.g. compact disc), provided that a hard copy can be made available on request.

The Archivist, the Clinical Research Department Manager, the Principal Investigator and the Sponsor must be present during the turn over of the documents for filing/archiving.

All collections of paper forming a file must be checked for duplicates before any archiving process is implemented to ensure that the minimum number of paper is kept.

A Contract of Archiving is then given to the Principal Investigator and Sponsor. The contract contains information on the date of acquisition of documents, condition of documents at the time of acquisition, and the date of disposal or destruction of documents. The contract also contains provisions on the archiving fee.

4.2. STORAGE

Only papers considered essential to the file should be kept. Any duplicates identified must be destroyed in by appropriate confidential methods, e.g. shredding.

All remaining papers must be correctly filed and a file must not contain loose papers unless the file is to be sealed.

Each file must be clearly and appropriately labeled with detail of the file content and agreed review/destruction date as a minimum.

An archive index/log should be maintained to record all essential documents that have been entered into the archive.

4.3. DURATION OF ARCHIVING

4.3.1. For trials that are not to be used in regulatory submissions

Essential documents of the sponsor/trial organizers and investigators, from trials that are not to be used in regulatory submissions, should be retained for at least five years after completion of the trial. These documents should be retained for a longer period, maximum of 15 years, if required by the applicable regulatory requirement(s), the sponsor or the funder of the trial.

4.3.2. For trials that are to be included in regulatory submissions

Essential documents should be retained until at least two years after the last approval of a marketing application. These documents should be retained for a longer period, maximum of 15 years, however, if required by the applicable regulatory requirement(s) or by agreement with the sponsor. It is the responsibility of the sponsor/someone on behalf of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained.

4.4. Destruction of essential documents

The reasons for destruction of essential documents should be documented and signed by a person with appropriate authority, namely, Principal Investigator, Sponsor or study sponsor representative. This record should be retained for a further five years from the date that the essential documents were destroyed. The sponsor or someone on behalf of the sponsor should notify investigators in writing when their trial records can be destroyed.

The destruction will be carried out in a dedicated room for destruction of documents while ensuring that materials confidentiality is maintained. The records of destruction should be retained.

The sponsor, principal investigator, department manager, and archivist should be present during the destruction of records.

4.5. ACCESS TO THE ARCHIVE

Access to an archive should be controlled and restricted to the Archivist, archiving staff and individuals named by the respective Principal Investigator/Sponsor. Access for periodic checking or examination of archived documents may be carried out every 6 months in the presence of the Principal Investigator, Research Assistant and Archivist.

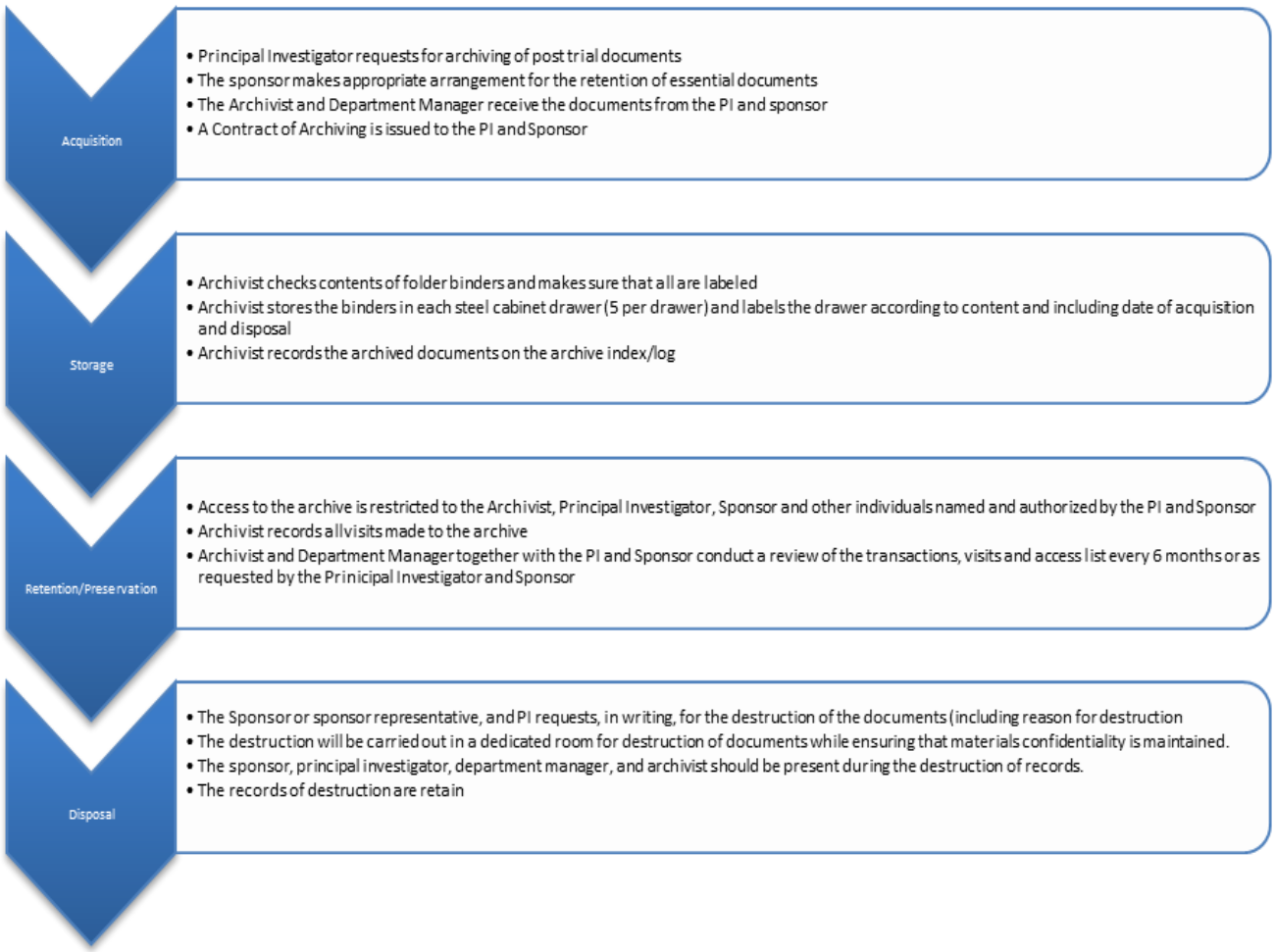
A regular (i.e. annual) review of the access list should be undertaken and documented. A record of visits by anyone not on the list of named individuals should be retained. This record should include the identity of the visitor, the reason for the visit and the date/time of the visit. Access to the archive should not be more than two (2) visits per year. If access to the archive exceeds the allowed maximum number, a corresponding access fee of PhP 1,000.00 per visit will be charged.

If possible, a CCTV camera should be placed in the room where the filed/archived documents are placed. The CCTV recordings should be viewed daily by the Archivist, and/or the Clinical Research Department staff.

4.6. PAYMENT OF ARCHIVING FEES

The computation of archiving fee depends on the number of metal drawers occupied and planned number of years for archiving. The fee for the monthly use of metal drawers for archiving purposes is PhP 300.00 (LCP Memorandum No. 67-B s. 2016) for at least two years after the last approval of a marketing application. The final computation of which, shall depend on the number of metal drawers to be occupied and planned number of years for archiving.

5. PROCESS FLOWS



6. ATTACHMENT:

- Preliminary Technical Review Form

Reviewed by:	Recommending Approval:	Approved by:
SULLIAN S. NAVAL, M.D. Deputy Director for Medical Services	**ELVIRA N. BAURA, RN, MAN** Quality Management Representative	**VINCENT M. BALANAG, JR., MD** Executive Director