DR. PABLO O. TORRE MEMORIAL HOSPITAL
B.S. Aquino Drive, Bacolod City, Negros Occidental, 6100

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Document Title:	**POLICY ON INSTITUTIONAL FEE FOR RESEARCH AND OTHER CLINICAL TRIALS**

PURPOSE

To create a standardized institutional fee for research and other studies conducted at the DPOTMH.

RESPONSIBLE PERSON

Research Ethics Review Committee, Finance Department, and Medical Director

DEFINITION OF TERMS

Research Ethics Review Committee. An independent body created by Dr. Pablo O. Torre Memorial Hospital under the Medical Director, whose primary responsibility is to ensure the protection of the rights, safety, and well-being of patients who are research participants involved in health related research and to provide public assurance of that protection.

Administrative Fee. The sponsor pays the institution a non-refundable administrative start-up fee. This covers the cost of preparing and submitting regulatory documents / required documentation.

Research Ethics Review Committee (RERC) Fee. This fee includes review and monitoring of researchers compliance on research ethics protocol for all research studies conducted at DPOTMH.

Laboratory Set-Up Fee. The institution pays a one-time lab set-up fee upon receipt.

Archive/Storage Fee. The sponsor pays archive or storage fees for study documents for the duration of required storage as stated in the contract or memorandum. These fees are inclusive of all items charged to the study site for preparation and storage of study documents.

Pre-Screening. The sponsor pays the institution a quarterly fee for pre-screening. This fee is only requested if applicable to the study and covers the cost of reviewing medical records for potential eligible subjects.

Pharmacy Fee. The sponsor pays a drug storage and accountability fee when study drug is stored and dispensed from the DPOTMH Pharmacy Clinical Trials Unit. This fee covers the costs of drug storage, accountability and inventory keeping, dispensation per protocol, and destruction of study drug.

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APPROVAL

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POLICY

1. All research studies, and clinical trials shall be approved by the Medical Director or his/her designated person upon the recommendation of Dr. Pablo O. Torre Memorial Hospital (DPOTMH) Research Ethics Review Committee before it can commence it's study.

2. All research studies and clinical trials shall adhere to the ethical standards and other policies set forth by the DPOTMH Research Ethics Review Committee at all times.

3. Institutional fee and other fees related to the conduct of the study or research shall be paid directly to the cashier of DPOTMH.

4. Researchers and or Principal Investigator and his/her members shall always adhere to the policies and Standard Operating Procedures (SOP's) by DPOTMH especially those that shall affect patient safety, occupational or environmental safety, and DPOTMH's institutional values and or objectives.

5. If applicable and or needed, there shall be a signed and notarized Memorandum of Agreement, or Memorandum of Understanding between the researcher/principal investigator and DPOTMH.

6. Institutional fee shall be 12% of the study cost per research subject. However, other fees shall be charged separately on the following but not limited to:

Administrative start-up Fee
Research Ethics Review Committee (RERC) Fee
Clinical Trial Management System Fee
Laboratory Set-Up Fee
Archive/Storage Fee
Pharmacy Fee
Pre-Screening Fee

PROCEDURE

1. Researcher sends letter addressed to the Medical Director for approval to conduct research study or clinical trials.

2. Medical Director approves/disapproves research or clinical trial proposals based on but not limited to the Research Ethics Review Committee's recommendation.

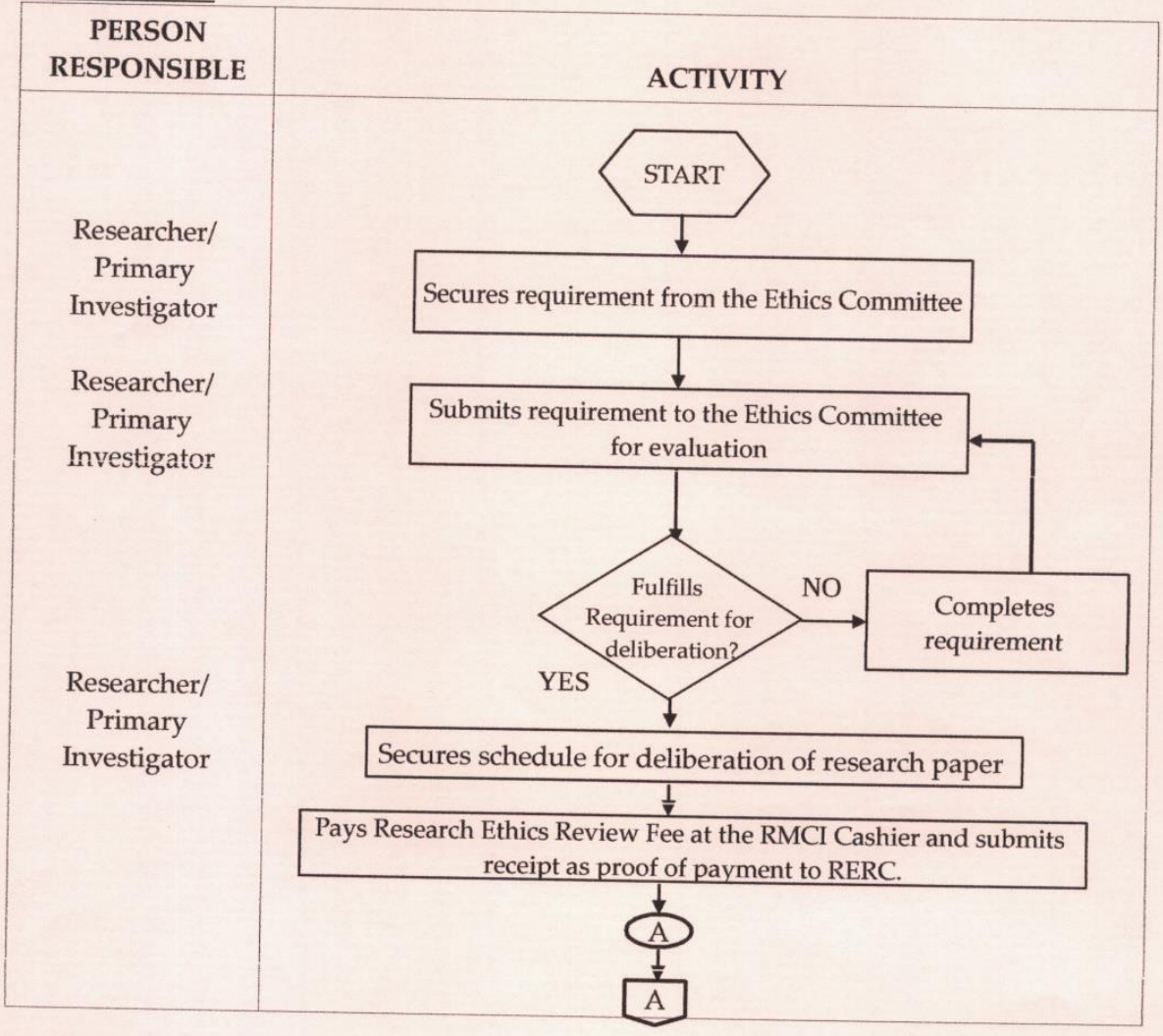
3. Researcher/Principal investigator secures requirement from the Ethics Committee

4. Submits requirement to the Ethics Committee for evaluation.

5. Secures schedule for deliberation of research paper.

6. Pays Research Fee at the RMCI Cashier and submits receipt as proof of payment for Ethics Fee.

FLOWCHART:



WORK INSTRUCTION:

Researcher/Primary Investigator

1. Submits letter of intent to conduct research at DPOTMH.
2. Secures approval from Research Ethics Review Committee (RERC).
3. Conducts study with compliance to Policies and Standard Operating Procedures of DPOTMH.

Cashier

1. Receives payment and issues Official Receipt (OR) for payment of institutional fee.

Research Ethics Review Committee

1. Reviews research proposals and clinical trials for Ethical Compliance.

2. Ensures the protection of the rights, safety, and well-being of patients who are research participants involved in health related research and to provide public assurance of that protection.

Medical Director

1. Approves/Disapproves Research and Clinical Trial Proposals

DOCUMENTATION:

1. Manual of Policy

DISSEMINATION:

1. Communicators' Bulletin Board
2. Research Ethics Review Committee Meeting

Researcher/ Primary Investigator	A A Attends scheduled date for Ethics Committee deliberation Submits to RERC requirement. Approved? NO Complies with RERC requirement. YES
Researcher/ Primary Investigator	Submits approval letter from DPOTMH RERC to the Office of the Medical Director
Researcher/ Primary Investigator	Pays Institutional Fee at the DPOTMH Cashier
	END