MAKATI MEDICAL CENTER

Hospital Policies and Procedures Manual

Governance, Leadership and Direction (GLD)		Document Code: MMC-HPP-GLD-014	Rev. Code : 02
Conduct of Research Involving Patients and Hospital Staff as Research Subjects		Effective Date: Feb 25 2025	Page 1 of 15
Issued by: **Institutional Review Board**	New ☐	Supersedes: Conduct of Research Involving Patients and Hospital Staff as Research Subjects (MMC-HPP-GLD-014 Rev 01)	
Approved by: **Saturnino P. Javier, MD** Medical Director Co-President and CEO — Feb-11-2025 Date Signed (MMM/DD/YYYY)		**Mr. Arnold C. Ocampo** Chief Financial Officer Co-President and CEO — Feb-10-2025 Date Signed (MMM/DD/YYYY)	

Objective:

A. Establish clear guidelines for conducting clinical research involving patients and hospital staff at Makati Medical Center (MMC);
B. Define the conditions under which hospital staff may participate as research subjects;
C. Implement safeguards to uphold the safety, rights, and well-being of hospital staff participating in research studies conducted at Makati Medical Center
D. Provide a structured process for patients and their families to access clinical research and clinical trials while ensuring compliance with applicable regulatory laws and ethical standards.

Scope:

This policy applies to all individuals and entities conducting clinical research involving patients, hospital staff, and students at Makati Medical Center, including but not limited to:

- MMC consultants, fellows, residents, and medical interns;
- Nurses and other allied healthcare professionals;
- Pharmaceutical companies conducting clinical trials;
- External and affiliated investigators conducting research within MMC or involving MMC-affiliated participants; and
- Research studies involving human subjects for publication, whether conducted within MMC or by an MMC-affiliated investigator outside the institution.

Definition of Terms:

Vulnerable Subjects - Individuals who are incapable of protecting their own interests.

Hospital Staff - Employees, interns, residents, fellows, consultants, nurses and other personnel of Makati Medical Center who provide care, treatment and services in the institution and receive pay.

Privacy	-	The state of keeping and protecting patient information from the public.
Confidentiality	-	Non-disclosure of any personal data of the patient during the conduct of a research.
Clinical Trial	-	Study of investigational products (IP) on human subjects to discovers its pharmacological/ pharmacodynamic effects including the absorption, distribution, metabolism and excretion of the IP, safety and efficacy and possible adverse reactions.

Policy:

All research involving human subjects at Makati Medical Center (MMC) must undergo review and receive approval from the Makati Medical Center Institutional Review Board (MMC-IRB) prior to implementation. MMC is committed to safeguarding the safety, well-being, and rights of its patients and hospital staff who participate as research subjects.

When applicable, MMC shall ensure that patients and their families are informed of the latest clinical research and trials that have undergone ethical review by the MMC-IRB. Attending physicians shall be responsible for communicating relevant research opportunities as part of patient care, ensuring that patients receive clear and comprehensive information, including:

a. **Expected benefits** of participation;
b. **Potential discomforts and risks** associated with the study;
c. **Available alternatives** that may be beneficial; and
d. **Required procedures** that must be followed during the research.

All MMC-IRB-approved research studies are subject to Research Compliance Review (MMC-HPP-GLD-012), including but not limited to data validation by the Clinical Research Center to ensure adherence to ethical and regulatory standards.

Additionally, careful consideration must be given to studies involving vulnerable populations, particularly junior or subordinate members within hierarchical groups. Participation of these individuals must be voluntary, with no undue influence, coercion, or fear of repercussions should they choose not to participate.

**For full details regarding the review of research involving human subjects (e.g., patients, medical staff, employees, etc.), please refer to the Makati Medical Center Institutional Review Board Operating Procedures Chapters 1, 2 and 3.*

Guidelines:

I. In having the research reviewed and approved by the MMC IRB and in conducting the research, the following *International Council for Harmonisation* – Good Clinical Practice (ICH GCP) principles are considered:

A. Research studies are conducted based on ethical principles of the Declaration of Helsinki, Good Clinical Practice and other regulatory requirements.
B. Prior to the initiation of the study, the anticipated benefits are weighed against the foreseeable risks whereas the benefits justify the risks.
C. The rights, safety and well-being of the study participants are prioritized throughout the research.
D. There is sufficient clinical and non-clinical information on the investigational product or procedure to support the study protocol.
E. The research study is ethically and scientifically sound. This is presented in a detailed protocol. For the contents of the protocol required by MMC IRB, refer to the Makati Medical Center Institutional Review Board Standard Operating Procedures (MMC IRB SOP).
F. The conducted research is compliant with the protocol reviewed and approved by the MMC IRB.
G. Each clinical department regularly apprises members of the medical staff on the latest trend in research and trials which have been reviewed and approved by the MMC IRB.
H. Each department and respective medical staff shall include research and trials as treatment options for the patient and family, as applicable to the patient's medical needs.
I. A qualified physician is responsible for the provided medical care and medical decisions made on behalf of the study participant.

J. The Principal Investigator, Co-investigator(s) and other members of the research team are qualified through education, training, and experience; thus, individual tasks are performed appropriately.

K. The rule on conflict of interest shall be strictly implemented and the attending physician is required to disclose any conflict of interest, as set in the ethical review. Refer to Policy on Conflict of Interest (MMC-HPP-GLD-020).

L. Prior to study participation, an informed consent is obtained from the participant.

M. Inquiries from patients and families about research and trials are accorded immediate and competent response. Attending physicians endeavor to communicate such information, as necessary, within a reasonable interval from the time of diagnosis and inquiry.

N. For those study protocols which have undergone ethical review from MMC IRB, full disclosure of potential discomfort, risk, and benefits is done, and other requirements of a valid informed consent are satisfied (refer to Policy on Informed Consent, MMC-HPP-PCC-011). Patients and families are also informed of alternatives that might help them and the procedures that must be followed. They are informed that they can refuse to participate or withdraw from participating in the study at any given time without compromising their access to hospital services (refer to Patient and Family Rights and Responsibilities MMC-HPP-PFR-003). The informed consent process is documented in the patient medical record and all necessary documents are signed by the patient or by the patient's legal representative.

O. All study information is documented adequately. Documents are managed and stored appropriately for accurate reporting, interpretation and verification.

P. The participation of patients in research and trials shall be within the bounds of legal and ethical parameters of medical practice.

Q. The privacy and confidentiality of the participants' identity is maintained throughout and after the study in accordance with the Data Privacy Act 2012 and other applicable regulations. Refer to Right to Privacy and Confidentiality of Care and Information (MMC-HPP-PCC-003).

R. All other applicable policies and procedures of MMC-IRB regarding the protection of participants apply.

S. All protocols for clinical research and trials are reviewed and approved by the Institutional Review Board.

T. The manufacture, handle and storage of the investigational products are according to the good manufacturing practice (GMP) and the approved protocol. Refer to Management of Investigational Drugs (MMC-GOP-MMU-006).

U. Assurance of quality of the trial must be implemented. Refer to Research Compliance Review (MMC-HPP-GLD-012)

V. MMC IRB, principal investigator and his/her research team involved in the review and conduct of sponsored clinical trials shall follow the guidelines stated in the Third-Party Management Policy (MMC-HPP-GLD-024) and the Anti-Bribery and Anti-Corruption (ABAC) Policy (MMC-HPP-GLD-021). This includes the management of review fees, clinical trial agreement (CTA) fees (insertion of ABAC and Conflict of Interest Clauses) and signing of the CTAs.

II. Guidelines for Clinical Trials

Based on the National Ethical Guidelines for Research Involving Human Participants 2022, the protocol should include the following:

A. Cover Sheet
This specifies the revision date and number, title of the research, signatures and dates of the authors, implementing agency, cooperating agency and approval of the primary investigator and contact numbers of the authors and cooperating agency.

B. Table of Contents

C. Introduction
To understand the rationale of the study, this provides a brief summary of the background in relation to the research design methodology

D. Title of the Study

E. Program or Project Leader
This specifies information about the Program or Project Leader:
1. Name
2. Designation or Title in his/her agency

3. Field of specialization
4. Email address
5. Telephone
6. Fax Numbers
7. Percentage time to be devoted to the research

F. Implementing Agency
This is the agency(ies) that will implement the research.

G. Cooperating Agency
This is the agency(ies) that will contribute to the research.

H. Significance of the Proposal
This explains the purpose/ rationale of the research.

I. Literature Review
This is the discussion of literature related to the study. This is used to prove that the research proposal is sound information based, addresses current health priorities of the country and contributes something new.

J. Objectives
This is the enumeration of the goals of the research. The general objective(s) is separated from the specific objectives. These are Specific, Measurable, Attainable, Relevant and Time-Bound.

K. Expected Outcome(s)
A specific statement of the primary and secondary endpoints, if any, to be measured during the trial.

L. End-Users or Target Beneficiaries
This specifies the end-users or expected beneficiaries of the research.

M. Duration of Program or Project
Time period when the study is conducted (i.e., start, completion and duration in months).

N. Methodology
1. Research Design

This specifies how the study objectives will be obtained. A description of the type of trial to be conducted (e.g., double- blind, placebo-controlled, parallel design) and a schematic diagram of trial design, procedures and stages.

2. Research Population
   This describes the study participants required. This includes the number of study subjects that will be accrued to complete the study.
   a. Inclusion Criteria
      To be included in the study, this section describes the criteria the subjects must meet (e.g., age, gender, race, diagnosis/condition, etc.).
   b. Exclusion Criteria
      This section specifies the criteria to determine if the subject is not eligible to participate in the study.
   c. Subject withdrawal criteria (i.e., terminating trial/ investigational product treatment and procedures specifying:
      1) When and how to withdraw subjects from the trial/ investigational product treatment
      2) Type and timing of the data to be collected for withdrawn subjects
      3) Whether and how subjects are to be replaced
      4) Follow up of subjects withdrawn from trial/ investigational product treatment.
   d. Sample Size Computation
      This describes the process of computing the sample size (including the assumptions used) and the type of sampling design.

3. Research Site
   This is the location where the research will be conducted.

4. Research Plan
   This is a detailed discussion of the procedures and methods that will be used during the study. This includes the tests, interviews, data collection that will be performed. This includes the assessment of efficacy and safety:
   a. Specification of the efficacy parameters
   b. Methods and timing for assessing, recording and analyzing of efficacy parameters
   c. Specification of safety parameters
   d. The methods and timing for assessing, recording, and analyzing safety parameters.

e. Procedures for eliciting reports of, and for recording and reporting adverse events and intercurrent illnesses.
f. Provision for managing adverse reactions
g. The type and duration of the follow up of subjects after adverse events.

5. Case Report Form
   Printed copy of this form is attached to the study protocol. The Case Report Form is a record used to document information gathered related to the study protocol.

6. Variables to be Investigated
   These are the dependent/ outcome and independent variables

O. Plans for Data Processing and Analysis
This includes the computer facilities to be used, software packages, statistical tools/ tests to be used and dummy tables.

P. Work Plan Schedule
This is the chronological order of study activities. Through the use of a Gantt Chart, the time frame and schedule of the research activities is presented.

Q. Ethical Clearance
Researches that involve human subjects require approval by the Institutional Review Board prior initiation.

R. Research Utilization
This explains how the expected research results will be disseminated and utilized.

S. Estimated Budgetary Requirements
This discusses the annual budget for the proposal wherein the major expenses for the first year is specified. There is a detailed breakdown of financial assistance based on the New Government Accounting System (NGAS) and reflection of the financial requirements and other source of funds.

T. Curriculum Vitae
This presents the proponent's qualifications and capabilities to conduct the research.

U. Endorsement from the Agency Head
This describes the support of the implementing agency in terms of assistance in the conduct including facilities and equipment.

V. Bibliography
This lists the references used for the research.

W. Line Time Budget
This is the table that will present the sources of funds and the amount provided by implementing/ sponsoring agencies.

X. Informed Consent
The rights and welfare of human participants in medical research shall be adequately protected by a legally effective informed consent. For details on the contents of the Informed Consent Form, refer to the Makati Medical Center Institutional Review Board Standard Operating Procedures Appendix on Guidelines on Submitting an Informed Consent Form (FM-MMC-IRB-039).

III. Guidelines in Obtaining Informed Consent

A. Informed consent is obtained from all human research participants or from his/her authorized guardian/representative before the participation. Informed consent is obtained from prospective research participants.
   1. For the mentally-ill, the guardian or the court (in the absence of a guardian) can give the informed consent.
   2. Children and their parents/guardian are given full explanation of the aims, possible hazards, inconveniences, and benefits as research participants. Their consent is obtained in addition to the consent of both parents or legal guardian. Moreover, among street children with no parent or guardian, informed consent is obtained from an appropriate government agency.
   3. For institutionalized children (orphanage, reform schools, etc.), their consent, as well as that of the nearest kin, are obtained.
   4. Research on pregnant and lactating mothers is conducted only without risk to the well-being of the fetus or the healthy development of the nursing infant. Consent must be obtained from both the mother and father. An explanation must be provided in case the father is not available to give consent.
   5. The individual who seeks to obtain the consent of members in the hierarchically-structured group is not from the direct supervisor of the potential participants

but from the individual himself. Further, the consent is obtained without duress or promise of promotion or reward.

6. Community-based research, e.g., experimental treatment of water supplies, trials of new insecticides, prophylactic agents, nutritional adjuvant or substitutes, etc., may dispense with individual consent.
7. A separate consent is obtained if body tissues/fluids of patients are stored or intended for use in other future research.
8. If informed consent is deemed unnecessary, the reason is clearly stated in the protocol.

B. In obtaining consent, no element of force, fraud, deceit, duress of any form of constraint or coercion shall be employed.

C. A written consent is signed and dated by the study participant or by the authorized guardian or representative of the subject and the researcher/person taking the consent. The study participant is provided with a copy of the signed informed consent.

IV. Guidelines on Hospital Staff as a Research Subject

1. The expected benefits of participation must be directly related to the staff member's field of work or professional development.
2. Staff must receive comprehensive information about the study process, including its purpose, benefits, risks, alternative treatments, and procedures, before consenting to participate.
3. Hospital staff may only participate in research studies that have been reviewed and approved by the Makati Medical Center Institutional Review Board (MMC-IRB).
4. The participant's identity and personal data must be kept strictly confidential during and after the study. Investigators may only disclose information with the explicit consent of the participant or as required by law.
5. Staff have the right to refuse or withdraw from the study at any time without any repercussions. Refusal or withdrawal shall not result in penalties, affect access to hospital services, impact employment status, or influence performance evaluations.
6. Whenever possible, supervisors shall not be informed of their employees' participation in research studies to prevent potential bias or undue influence.

7. To prevent conflicts of interest and ensure voluntary participation, research subjects must not be recruited directly by investigators who hold supervisory authority over them.

V. Criteria for Approval of Research Proposals

All research proposals involving human subjects must receive approval from the Makati Medical Center Institutional Review Board (MMC-IRB) before implementation. No study involving unapproved or unregistered drugs by the Food and Drug Administration (FDA) shall be conducted at MMC.

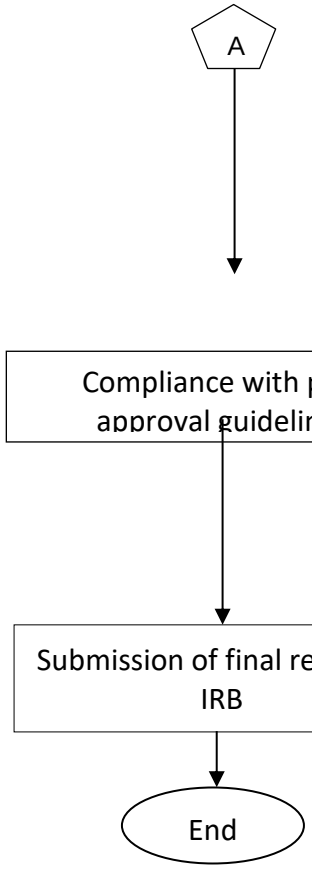
Approval of research protocols is based on the following criteria:

a. Risk Assessment – The nature and severity of potential risks to human subjects;
b. Safeguards and Protections – The adequacy of measures in place to minimize and mitigate risks;
c. Risk-Benefit Evaluation – The balance between potential benefits and potential harm to individuals and the broader community;
d. Informed Consent Process – The validity, clarity, and completeness of the informed consent process to ensure voluntary participation. This includes a clear statement on the ability to compensate patients for injuries resulting from study participation, as outlined in the "Characteristics of Informed Consent";
e. Ecological and Ethical Considerations – The study's impact on the environment, healthcare system, and societal ethics; and
f. Conflict of Interest Disclosure – Transparency in identifying and addressing potential conflicts of interest that may affect the integrity of the study.

All approved research studies must adhere to ethical principles, institutional policies, and applicable regulatory guidelines to ensure the protection of human subjects and uphold the integrity of clinical research at MMC.

Procedure

Process Flow Map	**Person Responsible**	**Details of the step**
Start		
Submission of protocol and protocol-related requirements	Principal Investigator	The principal investigator complies with all the IRB requirements for the submission of a protocol for review by MMC IRB.
Review approval of the protocol	IRB	The IRB reviews the complete protocol documents and recommends approval of the study protocol according to the defined criteria in the MMC IRB SOP.
Conduct study in accordance to the IRB approved protocol	Principal Investigator	The principal investigator implements the approved study protocol while protecting and ensuring the participant's rights and safety.
A		



Principal Investigator	Informed consent is obtained prior to study participation of the patient.
Principal Investigator	The necessary reports are submitted during the conduct of the study.
Principal Investigator	A final report is submitted to IRB to review the result of the study.

Responsibility:

The Department Chairs, Section Chiefs, Training Officers and Research Proponents (Principal and Co-Investigators) ensure compliance to this policy.

A. Investigator
The responsibilities of the Principal Investigator are specified in the Makati Medical Center Institutional Review Board Post Approval Guidelines (Appendix 1).

B. Sponsor
1. Safety Information
   a. The sponsor is responsible for the ongoing safety evaluation of the investigational product.

b. The sponsor promptly notifies all concerned investigators/ institutions and the regulatory authority of findings that could affect adversely the safety of subjects, or alter the IRB's approval/ favorable opinion to continue the trial.

2. Adverse Drug Reaction Reporting
   The sponsor expedites the reporting of all adverse drug reactions (ADRs) that are both serious and unexpected, to all concerned investigators/ institutions, to the IRB, and to the regulatory authority where required.

   Such expedited reports comply with the applicable regulatory requirements and with the International Conference on Harmonization – Good Clinical Practices Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

   The sponsor submits to the regulatory authority all safety updates and periodic report, as required by applicable regulatory requirements.

3. Compensation to Subjects and Investigators
   If required by the applicable regulatory requirements, the sponsor provides insurance or indemnifies (legal and financial coverage) the investigator/ institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence. The sponsor's policies and procedures address the costs of treatment of trial subjects in the event of trial-related injuries in accordance with the applicable regulatory requirements. When trial subjects receive compensation, the method and manner of compensation complies with the applicable regulatory requirements.

Required Education:

Good Clinical Practice (renewed every three years).

Attachment:

1. Appendix 1: Post-Approval Guidelines
2. Appendix 2: MMC IRB Guidelines on Submitting an Informed Consent Form

Review: The IRB Chair or designate reviews this policy every three (3) years or earlier as indicated.

Reference/s:

1. Philippine Health Research Ethics Board Ad Hoc Committee for Updating the National Ethical Guidelines. *National Ethical Guidelines for Research Involving Human Participants*. Department of Science and Technology – Philippine Council for Health Research and Development, 2022.
2. Joint Commission National. *Joint Commission International Accreditation Standards for Hospitals including Standards for Academic Medical Center Hospitals 8th Edition.* USA: Joint Commission International, 2024.
3. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6(R2). Retrieved from https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf

Signatories:

Author (s)	Dr. Carolyn A. Butler Institutional Review Board Chair

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