RIVERSIDE MEDICAL CENTER, INC.

DR. PABLO O. TORRE MEMORIAL HOSPITAL

METRO PACIFIC HEALTH
THE HEART OF FILIPINO HEALTHCARE

DEPARTMENT: Office of the President		**POLICY NUMBER:** DPOTMH-APP-DPO-P006-(01)	
TITLE/DESCRIPTION: **POLICY ON THE APPLICATION FOR APPROVAL TO CONDUCT RESEARCH**			
EFFECTIVE DATE: June 10, 2024	**REVISION DUE:** June 9, 2027	**REPLACES NUMBER:** N/A	**NO. OF PAGES:** 1 of 10
APPLIES TO: All Employees of RMCI, MRCCC, and Una Konsulta regardless of classification		**POLICY TYPE:** Administrative	

PURPOSE:

1. To protect the safety of human subjects involved in research.
2. To protect the confidentiality of data.
3. To protect the security of data used in research projects from unauthorized use or release.
4. To foster research that meets prevailing methodological standards and is relevant to the company's mission or furthers knowledge in the field of study.

DEFINITIONS:

Research – It is the systematic process of knowledge production for the development of new concepts or the advancement of existing knowledge and theories, leading to a new understanding that was not previously known.

- **Business Research** – It is a process of acquiring detailed information of all the areas of business and using such information in maximizing the sales and profit of the business.
- **Social Research** – It is a method used to learn about people and societies and the various socio-economic groups belonging to different parts of a country.
- **Clinical/Health Research** – It is the study of health and illness in people and the way we learn how to prevent, diagnose and treat these illnesses.

Feasibility and exploratory study – It is an assessment of the practicality of a proposed project plan or method. This is done by analyzing technical, economic, legal, operational and time feasibility factors.

Company – Operationally, company pertains to Riverside Medical Center, Inc. (RMCI), Una Konsulta (UK), and Metro Riverside Cancer Care Center (MRCCC).

RESPONSIBILITY:

Designated RMCI Personnel, DPO, RERC, President & CEO, Researcher/s

POLICY:

A) **Request for Approval**

1. Only qualified researchers may conduct research involving the use of company data. To be considered qualified and therefore eligible to conduct research, the researcher/study proponent

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must secure a written consent/approval from the President and Chief Executive Officer PRIOR to the conduct of research.

2. All research proposals shall go through a two-tiered review process, depending on the nature of the research.

3. The proposal must undergo a review by the company's Data Protection Officer (DPO) to ensure compliance with all relevant data protection regulations.

4. All clinical and health related research requests must be reviewed and assessed by the Research Ethics Review Committee (RERC), prior to the approval of the President and Chief Executive Officer. As referenced in the Research Ethics Committee Terms of Reference, the said committee is responsible for reviewing health research that involves patients, employees, residents, and fellows of RMCI. They are also responsible for reviewing pharmaceutical industry-sponsored research and other health/clinical related research that will utilize the facilities of RMCI.

5. Other types of research not mentioned in Item #4 will no longer go through the Research Ethics Review Committee (RERC) and will be forwarded to the President and Chief Executive Officer for final approval.

6. Research or studies conducted without the written consent or approval from the President and Chief Executive Officer, or its authorized representative/s is considered unauthorized and unlawful. Hence, the Company reserves the right to file a formal complaint or legal suit for anybody who will be found guilty of violating the Company's research approval policy.

7. For approved research or studies, the Researcher or proponent must demonstrate a capacity to complete the research project according to prevailing academic and professional standards, particularly if the research involves contact with human subjects. The Researcher and organization must have a demonstrated record of using sensitive data according to commonly accepted standards of research ethics.

8. Statutory provisions prohibit the release of certain data for research purposes. These data

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include:

a. Individually identifiable data such as but not limited to personnel records and disciplinary records;
b. Personal information such as but not limited to individual's name, signature, address, phone number, photograph or date of birth;
c. Sensitive information such as but not limited to racial or ethnic origin, political opinions or associations, religious or philosophical beliefs, sexual orientation or practices, health or genetic information.

9. All request for research approval from the COMPANY should include the following:
   a. Competent evidence of identification (i.e. government ID, company ID, school ID) for all researchers involved.
   b. Letter of Intent indicating the purpose of the research, its relevance to the company, and information on whether the research is supported by the government or a specific agency/ organization. If the research is supported by an organization, it must be supported by a certification of approval from all involved organizations.
   c. A one-page abstract summarizing the proposal and the methodology of the research, specifying the ethical considerations, scope, and limitations of the study.
   d. A projected timeline of research completion inclusive of the location and the persons responsible for each task.
   e. Certificate of approval from a certified Institutional Review Board (if required)

10. The Matrix for Research Approval is illustrated below:

Type of Research	Receipt of Request	Initial Review by	Second Review by	Final Approval	Permission to Publish
Social Research, Business Research, Feasibility, etc.	Authorized Personnel	Data Protection Officer	NA	President & Chief Executive Officer	President & Chief Executive Officer
Health and/or	Authorized	Data Protection	Research	President &	Research Ethics

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Clinical Research	Personnel	Officer	Ethics Review Committee	Chief Executive Officer	Review Committee

B) **Confidentiality**

1. Only the Researcher and individuals directly involved in the collection, processing, analysis, interpretation, or reporting of the subject data and have submitted signed confidentiality agreements (NDAs) are authorized to access them.
2. The Researcher shall not make any release of subject data listing information regarding individuals, even if the individual identifiers have been removed, unless such release has been authorized in the confidentiality agreement with the Company.
3. The Researcher may publish the results, analysis, or other information developed as a result of any research based on subject data made available under the confidentiality agreement with the Company only in summary, aggregated, or statistical form so that the identity of individuals contained in the subject data is not revealed.

C) **Conduct of Data Gathering**

1. Only when a request is approved and the researcher is granted clearance to conduct, that the researcher shall proceed to data gathering. The researcher/s shall stay in touch with the designated personnel throughout the data gathering process.

D) **Communicating of Results**

1. Once the research is accomplished, the researcher shares findings with the company in a mutually agreeable format.
2. If the researcher publishes the research findings, he/she shall seek permission prior to publication.
3. Research proposals and related documents are retained according to company record-keeping policies.

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PROCEDURE (SOP):

1. The researcher submits a hard copy of the request for research approval, defined in this policy, to the designated RMCI personnel. The request is acknowledged by the designated personnel and endorses it to the Data Protection Officer (DPO).

2. The DPO conducts the review, focusing on data protection aspects and assessment of the nature of the research:
   a. Necessity and proportionality of data collection.
   b. Anonymization or pseudonymization of data (where possible).
   c. Secure data storage, retention, disposal, and handling procedures.
   d. Participant consent forms and processes
   e. Nature of research (Health, Social, Business, etc.)

3. The DPO endorses the research to the RERC if it is identified as health or clinical in nature.

4. The second-tier review will be conducted by the RERC. The committee convenes to review the proposal, considering:
   a. Alignment with company objectives and potential benefits.
   b. Protection of confidential information and intellectual property.
   c. Ethical research practices, particularly for health research.
   d. Qualifications of the research team.
   e. DPO recommendations

5. If the research is identified as non-health or non-clinical research (social research, business research), the request will be forwarded to the President and Chief Executive Officer for final approval.

6. The RERC makes a final decision (approve, reject with explanation, or request revisions). The request will then be forwarded to the President and Chief Executive Officer for final approval.

7. Once approved by the President and the Chief Executive Officer, the DPO processes the

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Non-Disclosure Agreement/s (NDAs) for the researcher/s. The DPO then forwards the approved request to the designated personnel.

8. The designated personnel informs the researcher of the decision.

9. The researcher conducts the research according to the approved proposal and relevant regulations. The designated point of contact maintains communication with the researcher throughout the process.

10. The researcher shares findings with the company in a mutually agreeable format. (if applicable).

11. Publication requires prior approval, with potential for company anonymity or data redaction to protect confidentiality.

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WORK INSTRUCTION:

KEY TASKS	PERSON RESPONSIBLE
1. Submits a hard copy of the request for research approval.	Researcher/s
2. Acknowledges the request and endorses the request to the DPO.	Designated RMCI Personnel
3. Conducts a data protection review.	DPO
4. Endorses to the RERC if identified as health or clinical research.	DPO
5. Approves, reject with explanation, or request revisions.	RERC
6. Forwards the request to the President and CEO for approval if research is non-clinical.	DPO
7. Final Approval.	President & CEO
8. Prepares NDAs and forwards the documents to the designated RMCI personnel.	DPO
9. Informs the researcher of the decision.	Designated RMCI Personnel

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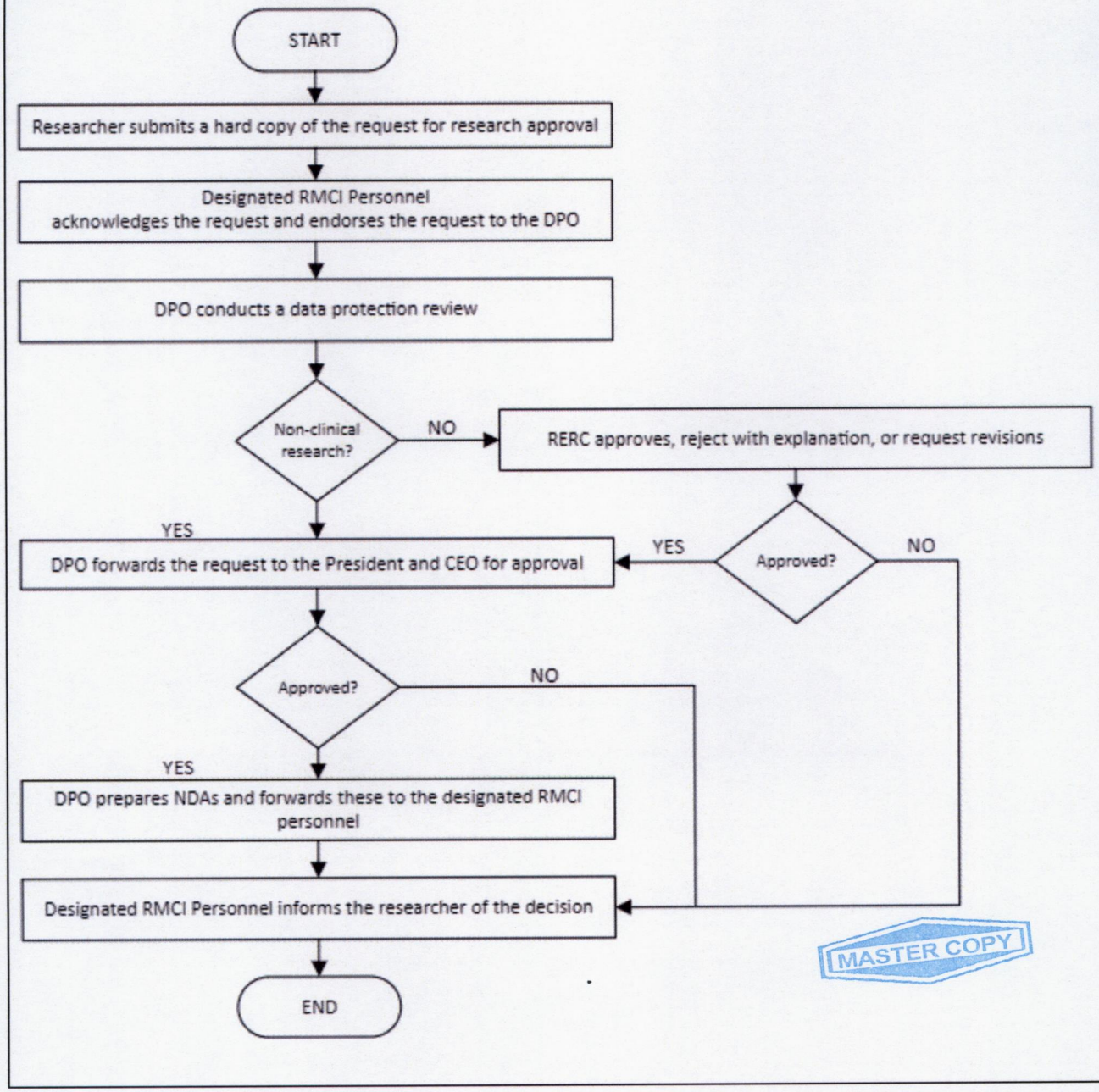
WORK FLOW:



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FORMS: DPOTMH-DPO-F006 (01)
EQUIPMENT: N/A
REFERENCES: N/A

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APPROVAL:

	Name/Title	Signature	Date	TQM Stamp
Prepared by:	**NUBBIN BITO-ON** Data Protection Officer		5/14/2024	TQD
	LANCE CARY FUENTES Organizational Development Specialist		5/14/24	
Reviewed by:	**RODEL J. LLAVE** Total Quality Division Head		5/14/24	
Approved by:	**ANDREW I. MALLEN, MD** Research and Ethics Review Committee - Chairman		5/20/24	
	NANCY B. HIZON Human Resources Division Head		5/21/24	
	JOSE PEPITO B. MALAPITAN, MD Medical Director		May 21, 2024	
	MA. ANTONIA S. GENSOLI, MD VP/Chief Medical Officer		5-22-24	
	SOCORRO VICTORIA L. DE LEON VP/Chief Operating Officer		April 2024	
Final Approved by:	**GENESIS GOLDI D. GOLINGAN** President and Chief Executive Officer		5/30/24	

MASTER COPY