National Institute of Cardiovascular Diseases, Karachi, Pakistan

RESEARCH DEPARTMENT

CENTRALIZED RESEARCH COMMITTEE

1 POLICY STATEMENT

1.1 This policy sets out the requirements for scientific approval of research studies across the National Institute of Cardiovascular Diseases, Pakistan. This policy forms part of a suite of policies designed to guide researchers to maintain the scientific integrity of all research undertaken across the NICVD, notwithstanding the geographic origins of such research.

1.2 No fee will be charged for the CRC reviews of the submitted research, projects, and trials.

2 DEFINITIONS

2.1 **The centralized Research Committee (CRC)** is a governing body of NICVD responsible for systematically reviewing and overseeing of scientific research proposals within an organization, institution, or multi-institutional setting. It ensures that research meets established scientific, ethical, and methodological standards before approval and implementation.

2.2 **"Quorum"** refers to the availability in CRC meetings of at **least 4 members** along with the CRC members of the respective department.

3 SCOPE

3.1 This policy applies to full-time national faculty members and management / professional staff at all NICVD sites.

4 RESPONSIBILITY OF THE CRC

4.1 The **(CRC)** in its pure intent provides voluntary services to the faculty and staff of the NICVD of reviewing, suggesting, approving or rejecting all scientific review applications of the studies that are to be conducted at NICVD.

4.2 The (**CRC)** is responsible for assessing the scientific merit of the research ensuring that submitted research proposals meet high standards of scientific rigor and adhere to established methodologies that promote the reliability and validity of results.

4.3 The **(CRC)** focuses exclusively on the scientific and methodological aspects of research proposals, including:

- 4.3.1 Study design (e.g., randomized controlled trials, observational studies, etc.).
- 4.3.2 Feasibility and clarity of research objectives.
- 4.3.3 Statistical analysis plans.
- 4.3.4 Use of appropriate methods for data collection and analysis.
- 4.3.5 Justification of sample size.
- 4.3.6 Relevance of the study to current scientific gaps.

4.4 The **(CRC)** operates independently of the IRB and regulatory bodies to avoid overlap and ensure focus on scientific rigor.

4.5 Board members must disclose any conflicts of interest related to the proposal under review and recuse themselves from discussions and decisions if necessary.

4.6 All materials reviewed by the **(CRC)** are confidential and must not be shared outside the board without proper authorization.

4.7 The**(CRC)** will provide constructive feedback to investigators, including:

- 4.7.1 Recommendations for improving scientific quality.
- 4.7.2 Identification of methodological gaps and how to address them.
- 4.7.3 Suggestions for alternative approaches where applicable.

4.8 The **(CRC)** will meet regularly (e.g., bi-weekly or monthly) to review submitted proposals, depending on the volume of submissions.

4.9 Minutes of meetings and decisions made on each proposal will be documented and securely archived.

4.10 The **(CRC)** will forward approved research proposals to the IRB to review the ethical aspects of the research.

5 PROCESS OF CRC APPLICATION REVIEW

5.1 Investigator to submit the complete IRB Application Form (online) along with the Protocol of the study and Data collection instrument to the Research Department.

5.2 Investigator to submit the complete IRB Application pack (available with the Research Dept.), which includes the IRB Application Form (online), Protocol of the study, Consent form in the relevant language(s), Study Instrument(s), all investigators' GCP / Biomedical Research Certificate copy, and the Declaration of the Conflict of Interest Form, to the Research Department. Incomplete applications cannot be included in the **(CRC)** review.

5.3 **DRC** is not mandatory for applying to **(CRC)**

5.4 All complete application packages shall be presented at the**(CRC)** meeting

5.5 **The principal investigator and his/her supervisor** must present the study and explain the scientific aspects of the research proposal.

5.6 **FCPS Trainees should present their study to either the department head or supervisor**

5.7 The research department assigns an ID number to every research proposal. Presentations are made in order according to the **assigned ID number.**

5.8 Only 8 proposals will be presented at each (**CRC)** meeting.

5.9 CRC members shall record any comments or suggestions and communicate them to the minute recorder and the investigator (or their assignee). Additionally, the **(CRC)** shall inform whether the study is approved or rejected (with reasons provided) during the meeting.

5.10 If the study needs amendments in any of the documents of the study, the investigator shall address those and resubmit the complete application pack with a cover letter (mentioning the changes that have been made by him/her in light of the (**CRC)** comments) to the Research Department.

5.11 Study documents

5.12 The Research Department will verify those amendments and, if found satisfactory, will forward them to the IRB for ethical approval.

6 MEMBERSHIP OF (CRC)

6.1 The membership of **(CRC)** is governed and directed by the Executive Director, NICVD.

6.2 The **(CRC)** expects members to attend **(CRC)** review meetings regularly. If a member is unable to attend **three consecutive meetings**, his/her membership will stand canceled.

6.3 **The quorum of four** should be present at every meeting if the quorum is not complete**, the CRC** meeting shall be postponed.

6.4 As per international regulations, the **(CRC)** membership should consist of professionals from diverse fields, including biostatistics, epidemiology, and clinical specialties, to provide comprehensive reviews.