National Institute of Cardiovascular Diseases, Karachi, Pakistan

RESEARCH DEPARTMENT

INSTITUTIONAL REVIEW BOARD POLICY

1 POLICY:

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

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

2 DEFINITIONS

2.1 "Institutional Review Board" pertains to the official ethics review board of the NICVD formed through the Hospital Order by the Executive Director.

2.2 any human being, biological samples enrolled or intended to be enrolled in any study of NICVD including trials

2.3 "Quorum" refers to the availability of at **least 4 members** in IRB meetings**.**

3 SCOPE

3.1 This policy is applicable to full-time national faculty members and management / professional staff across all sites of NICVD.

4 RESPONSIBILITY OF THE IRB

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

4.2 The IRB is responsible for the ethical assessment of research proposals submitted.

4.3 The IRB is also responsible to track progress of the studies at NICVD, ask for progress reports, adverse event/serious adverse event reports and project closure reports from the respective investigators of the studies.

4.4 IRB shall also undertake independent reviews of ongoing studies, including surprise audits, on a need-basis. It may assess the workflow to ensure patient safety protocols as agreed upon in the proposal are being adhered to, reviews of ongoing studies, including surprise audits, and may assess the workflow to ensure patient safety protocols and all aspects of ethics.

5 PROCESS OF IRB APPLICATION REVIEW

5.1 IRB will provide ethical assessment of research proposal after the approval of Centralize Research committee

5.2 The IRB Administrative staff on behalf of IRB shall undertake a preliminary review of the application for completeness, if any deficiencies are found in the application pack, the said application shall be returned to the applicant if not resubmitted within the given time it shall not be made part of upcoming IRB meeting.

5.3 Complete application packages shall be presented at the IRB meeting

5.4 **The principal investigator and his/her supervisor** must present the trial study and explain the safety and overall ethical aspects related to human subjects.

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

5.6 Only 16 proposals, including new amended ones, will be presented at each IRB meeting.

5.7 IRB administrative staff shall record any comments or suggestions regarding the study's safety and all ethical aspects. The IRB shall inform whether the study is approved or rejected, deferred pending amendments (most common), or rejected (very rarely without several rounds of review) with reasons provided during the meeting.

5.8 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 IRB comments) to the Research Department.

5.9 The Research Department will verify those amendments and if found satisfactory, will issue the approval letter of the study in hard copy, as well as in soft copy to all the investigators mentioned in the study protocol.

5.10 The approval of all studies shall be given initially for 6 months. Investigators shall be asked to submit a request for an extension in approval post 6 months (if the study continues), or submit a project closure report (if the study is closed) to the Research Department. The request for extension is to be submitted BEFORE the expiration of the study approval.

5.11 Studies conducted **without active approval from IRB** shall be considered a violation of the regulatory rules of NICVD IRB, and the data collected during that "non-approved" period **cannot be used** in the study or for any publications. If any researcher publishes their proposal without prior approval from the IRB and data use before IRB approval, they shall be held accountable. The committee and the chair will issue a letter to the respective journal or College of Physicians and Surgeons requesting the cancellation and blacklisting of the study. Additionally, **the promotions of supervisors involved in the study may be withheld by the Executive Director.**

5.12 IRB shall also have an "Exemption Request for IRB Application" process whereby investigators can request an exemption of the full review of their studies. The investigators need to ONLY submit the IRB Application Form and Study proposal to the Research Dept. The Department shall review this application, and forward its recommendation to the members and Head of IRB who have the capacity to grant approval for an exemption or not. Research that mostly qualifies for the "Exemption" category consists of a) Chart Reviews, b) Literature search, c) Retrospective data reviews, d)

research involving normal educational purposes without affecting students and their opportunity to learn, e) Secondary research for which consent is not needed f) Case Reports/Case series

Post-Approval Responsibilities

Researchers must:

5.13 Notify the IRB of any changes to the protocol before implementation.

5.14 Report adverse events or unanticipated problems immediately.

5.15 Submit renewal applications for ongoing projects as required.

6 MEMBERSHIP OF IRB

6.1 The membership of IRB is governed and directed by the Executive Director, NICVD.

6.2 The IRB expects members to attend IRB review meetings on a regular basis. 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 IRB meeting shall be postponed. Out of 13 members**, 1/3** majority will be required

6.4 For Approval, all members who attend the IRB meeting should sign the proposal.

6.5 As per international regulations, the IRB membership should consist of clinicians, researchers, public health professionals, laypersons, someone with a legal background, and someone outside the institution

6.6 A valid CITI IRB members module certificate is mandatory for all IRB Members

References : GoodYear MD, Krleza_JericK, LemmensT. The Declaration of Helsinki.Bmj.2007Sep27