National Institutes of Health
Health Research Institute
National Bioethics Committee (NBC) Pakistan

Review Process of Clinical Validation Studies of Electro Medical Devices by Research Ethics Committee (REC) of NBC:

All Clinical Validation Studies (CVS) of electromedical devices that require human testing will be required to be reviewed by the NBC-REC. Only after approval of the NBC the study be submitted to DRAP for further processing and approval. The submission of the application must be on the prescribed REC form, together with all relevant supporting documents.

All CVS applications must submit evidence of scientific validation by a Technical Committee. Names and credentials of members of the Technical Committee must be furnished with the application. The scientific approval of the device undergoing CVS will be the sole responsibility of the Technical Committee, and the REC will have no responsibility to validate the scientific and technical reliability and safety of the device.

With regards to Class C & D applications, the applicant must also submit all the relevant non-clinical information in support of the application. The clinical investigator or manufacturer can submit the Clinical Validation Study (CVS), the patient informed consent form (ICF), and evidence of approval from all applicable IRBs.

Processing of application:

Timeline: The Clinical Validation S review, like all reviews by NBC-REC, may take 4 to 6 weeks after the full application with all required supporting documents is submitted to the secretariat. The NBC-REC may consider applying the Rapid Turnaround Reviews (RTR) system, with a response time of no more than a week in extenuating circumstances. The determination of applicability of RTR for a particular application will be made by the NBC-REC itself.

Application Fee: All applicable fees would be required to be submitted prior to the review.

Review Process: Following are 03 major steps of review process.

1. The CVS will be reviewed by the regular members of the NBC-REC. Additional reviewers may be specially co-opted for specific cases. The co-opted members will have relevant scientific and/or experiential background in the device being reviewed.
2. The REC will provide its review at the end of the stipulated period which will be communicated to the applicant by the secretariat. The outcome of a review can be one of the following:

    - Acceptance of proposal;
    - Amendments followed by approval of proposal;
    - Refusal of application;
    - Cancellation of an approved proposal.

3. Even after issuing an approval, the NBC-REC may ask the applicant to stop CVS, or withdraw its approval to a CVS entirely based on additional information regarding safety concerns coming to light after an initial approval.

4. The application of Clinical Validation Study (CVS) or revised application may be rejected if:
    - The application or the required supporting documents are incomplete
    - Safety concerns have not been adequately addressed
    - The objective of the testing cannot be achieved

The REC secretariat will issue a "Letter of Refusal" stating the reasons for rejection. The applicant will have the right to apply again with a fresh application

Reporting of changes: The applicant will be required to report to REC if any changes in the device or any changes in the protocol of the CVS taking place after having been granted an approval, This must be communicated to the REC secretariat on an immediate basis. Failure to do so will result in a cancellation of the approval.

ANNEX I: ***CLASSIFICATION SYSTEM FOR MEDICAL DEVICES-*** *(available at: https://dra.gov.pk/Home/Download?ImageName=FFSCHEDULEACLASSIFICATIONOFMEDICALDEVICES.pdf)*

CLASS	LEVEL	DEVICE EXAMPLES
A	Low Hazard	Tongue depressors/ disposable masks
B	Low-moderate Hazard	Hypodermic Needles / suction equipment
C	Moderate-high Hazard	Lung ventilator / bone fixation plate
D	High Hazard	Heart valves / implantable defibrillator