# National Bioethics Committee

Government of Pakistan

Ministry of National Health Services, Regulations and Coordination

Islamabad

**NBCRESEARCH ETHICS FORM (REC)**

**FOR**

**CLINICAL VALIDATION STUDIES**

**FOR TESTING ELECTROMEDICAL DEVICES**



**Secretariat**

Pakistan Health Research Council

Shahrah-e-Jamhuriat, off Constitution Avenue

Sector G-5/ 2

Islamabad

# National Bioethics Committee

**Pakistan Health Research Council**

**Ministry of National Health Services, Regulations and Coordination**

**Note:** All research projects must be submitted to NBC secretariat i.e. Pakistan Health Research Council located at Shahrah-e-Jamhuriat, off Constitution. Avenue, Sector G-5/ 2 Islamabad

###### Checklist

This checklist is prepared in order to facilitate an investigator in preparing a complete application and to help Research Ethical Committee of National Bioethics Committee for expedited review. Your cooperation in completing it will be highly appreciated.

Onecopy of REC Application form with checklist

Onecopy of Clinical Validation Study protocol

Onecopy of informed consent in English and Urdu or any other local language of the population study

Pakistan Engineering Council certification of safety

Signed copy of quality check certificate by the manufacturer of the medical device

List of members of the independent Technical Committee

Evidence of all pre Clinical Validation Studies safety testing performed on the device (simulator studies, animal studies, others as applicable)

Letter/s of collaboration from hospitals/institutions where CVS will be performed

Institutional Ethical Review Board (IERB) approval letter/s from institution/s where Clinical Validation Study (CVS) will be performed

I have submitted the application form, research protocol and informed consent with Urdu translation by e-mail.

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Signature: Manufacturer (Name of company)

Date: -------------------------------

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_

Signature: Lead Clinical Investigator (Name of institution)

Date: ------------------------------------

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Instructions / guidelines for Researchers

1. Form to be filled out and submitted with the research protocol when requesting REC review.
2. Please use the NBC-REC Research Ethics Framework – Guidance document to help answer the questions below. If appropriate, you may directly copy-paste text from the research protocol sections in the protocol.
3. Please answer all questions. It is the responsibility of researcher to fill the application form appropriately. Incompletely and inappropriately filled form will not be accepted/ considered for review and discussion in the meeting. This may result in delay in approval of the proposal.
4. On normal circumstances, the review process will take 4 to 6 weeks in granting approval.
5. Rapid Turnaround Review may be applicable in certain cases, at the discretion of the NBC-REC
6. Application must be signed by both, the representative of the manufacturer, and also the Lead Clinical Investigator performing the Clinical Validation Study (CVS).

NBC-REC Application for

Clinical Validation Study (CVS) of

Electro Mechanical Device

|  |
| --- |
| Nature/name of device: |
| Title of CVS: |
| Version number: |
| Date created: |
| Duration of CVS: |
| Name of the manufacturer, and organization with address: |
| Name of the Lead Clinical Investigator of CVS and organization with address: |
| Country of investigators Institute/Organization: |
| Collaborating Institutions:  (Please provide information about all Institutions/Organizations collaborating in this CVS) |
| Has the CVS been submitted to or approved by other/institutional Ethics Review Committee(s)?  If not yet submitted, please indicate when and to which committee the protocol will be submitted.  Please name the various IERB/ ERCs. |

|  |
| --- |
| **1.0Research Question and Methodology:** |
| * 1. **Rationale for seeking approval for the electro mechanical device:**   2. **Details of preclinical validation tests performed on the device so far:**   3. **Methodology of performing Clinical Validation on human participants:**   **(1.4) Is the funding secure to perform the validation?**  **(1.5) Describe all potential Conflict of Interest situations in this CVS** |
| **2.0 Collaborating institutions roles and responsibilities** |
| **(2.1) Details of designated roles of collaborating institutions where CVS will be performed on human participants:**  **(2.2) Are the personnel trained to perform the validation?**  **(2.3) Does the validation site have all the necessary interventions for the safe conduct of the CVS?** |
| **3.0 Respecting and Protecting Research Participants** |
| **(3.1) What are the anticipated harms and benefits for volunteers on whom the CVS will be performed?**  **(3.2)What is the process for obtaining informed consent?**  **(3.3)How will confidentiality be protected?** |
| **( 4.0)Implications and Implementation of the Research Findings** |
| **(3.1) What will happen when the clinical validation study is either stopped or is complete?**  **(3.2) How will the findings be disseminated?** |

Guidelines for drafting an informed consent form for

Clinical Validation Studies for testing electro mechanical devices

Although a sample of informed consent form is attached, additional guidelines are given here in order to help and facilitate the researchers in drafting a proper, acceptable consent form.

1. All studies involving human subjects should have a properly drafted consent form. No study should be done on human subjects without obtaining informed consent and sufficiently before the start of the study, at an appropriate time, and not at a time when s/he is under stress such as surgical procedure, and is unable to understand the study.

2. Consent for CVS always has to be written, by the volunteer himself/herself or a legally valid surrogate decision maker in case the volunteer cannot consent directly. The consent process must be witnessed by a second person.

3. CVS may not be performed on children unless, in the exceptional circumstances when the device is only for use in the pediatric age group. In case of children, an assent form from the child, when applicable, and consent from legal guardian / parents is needed. .

4. The consent form should be in English and Urdu with translation into other local language if needed. These should be identical in such a way that the translation of one into other is similar. The language should be easy which can be understood by study subjects (uneducated or primary passed). Use of technical terms should be avoided.

5. The consent document should be written in “second or third person” and not in “first person”. For example, “You will be asked to give 10 cc blood” or “you will be asked few questions” etc.

6. A properly drafted consent form should contain the following important points.

a) Information sheet. There should be one paragraph or page giving information about the nature of the CVS, its purpose and need, possible benefits of the study, and procedures to be carried out on the study subjects.

b) Possible risks and benefits to the study subjects

c) Availability of alternate treatment modalities

d) Voluntary participation without any compulsion, moral or otherwise and without any financial incentive or coercion. However, appropriate financial assistance or reimbursement for time lost should be provided to volunteers.

e) Right to withdraw from the study at any time without affecting their rights and continuation of treatment.

f) Confidentiality

g) Name and contact number of the investigator in case the study subject or their surrogates want further clarification or information about the CVS.

h) Authorization from study subjects or their legal surrogatesa with their signature, thumb impression, signature of witness etc.

Important Notes

1. Studies should not be done on patient’s expenses. The participant ought not to be worse off than he was outside of the study.

2. If any new or additional tests are to be done as a requirement of study, their cost should be supported by the study.

3. If a new device is being compared with an existing and established one OR two devices are being evaluated and compared, cost of treatment or difference in cost of treatment should be borne by the study.

4. Any expected or unexpected complication arising as a result of new device under evaluation should also be borne by the investigators.

Sample Informed Consent

This is a generic sample form to help you address most situations. Please adapt it to suit the requirements of your CVS protocol.

*In case the CVS is recruiting participants who cannot consent themselves due to their medical conditions, please read “you” and “your” as “your patients” in the document below.*

|  |  |
| --- | --- |
| **Project Information** | |
| Name of device: |  |
| Project Title: | Project Number: |
| ERC Ref No: | Sponsor: |
| Principal Investigator: | Organization: |
| Location: | Phone: |
| Other Investigators: | Organization: |
| Location | Phone: |

Consent document must be clearly written and understandable to subjects. The language must be nontechnical (comparable to the language in a newspapers or general circulation magazine), and scientific, technical or medical terms must be plainly defined.

#### Informed Consent may not include language that appears to waive subjects’ legal rights or appears to release the investigators or anyone else from liability for negligence.

#### PURPOSE OF THIS RESEARCH STUDY

* + Include 3-5 sentences written in nontechnical language. “You are being asked to participate in the clinical validation study designed to test the (name of the device under investigation)”

#### PROCEDURES

* + Describe procedures: “You will be ….....”
  + Identify any procedures that are experimental/investigational/non-therapeutic.
  + Define expected duration of subject's participation.
  + Indicate type and frequency of monitoring during and after the study.

1. **POSSIBLE RISKS OR DISCOMFORT**

Note that these include not only physical injury, but also possible psychological, social or economic harm, discomfort, or inconvenience.

* + Describe known or possible risks of intervention with the device under study. If unknown, state so.

#### POSSIBLE BENEFITS

* + Describe any benefits to the participant that may be reasonably expected. If the device under investigation is not of direct benefit to the participant, explain possible benefits to others.

#### FINANCIAL CONSIDERATIONS

* + Explain any financial compensation involved or state: “There is no financial compensation for your participation in this research.”
  + Describe any additional costs to the subject that might result from participation in this study.
  + Please indicate any financial benefits to the subjects including therapeutic or diagnostic costs being covered by the study.

#### AVAILABLE TREATMENT ALTERNATIVES

* + Describe the availability of alternative devices available (conventional, non experimental) for meeting the requirements of the participant, and that he/she may choose not to participate in the CVS without risk of any penalty.

#### AVAILABLE MEDICAL TREATMENT FOR ADVERSE EXPERIENCES

* + The informed consent must describe whether “This CVS involves (minimal risk) or (greater than minimal risk).”
  + Informed consent document must provide information that if the participant is injured as a direct result of taking part in this research study, emergency medical care will be provided by [name] medical staff at the same facility, or if needed, he/she may be moved to a different facility for continuity of care. Indicate who will pay for this treatment.

#### CONFIDENTIALITY

* + Describe how and to what extent confidentiality of records identifying the subject will be maintained.

“Your identity in this CVS will be treated as confidential. The results of the CVS, including laboratory or any other data, may be published for scientific purposes but will not give your name or include any identifiable references to you.”

#### TERMINATION OF CLINICAL VALIDATION STUDY

You are free to choose whether or not to participate in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or to withdraw after agreeing to participate. In the event you decide to discontinue your participation in the study,

* + These are the potential consequences that may result: (list)
  + Please notify (name, telephone no., etc.) of your decision or follow this procedure (describe), so that your participation can be orderly terminated.

In addition, your participation in the study may be terminated by the investigator without your consent under the following circumstances. (Describe) It may be necessary for the sponsor of the study to terminate the study without prior notice to, or consent of, the participants in the event that (Describe circumstances, such as loss of funding.)

#### AVAILABLE SOURCES OF INFORMATION

* + Any further questions you have about this study will be answered by :

Name:  
Phone Number:

* + Any questions you may have will be answered by:

Name:  
Phone Number:

* + In case of a research-related emergency, call:

Day Emergency Number:

Night Emergency Number:

#### AUTHORIZATION BY PARTICIPANT

I have read and understood the consent form, and I volunteer to participate in this Clinical Validation Study of ……. (name the device). I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study, or the malfunction of the device under testing. I further understand that nothing in this consent form is intended to replace any applicable laws.

#### AUTHORIZATION BY SURROGATE

I have read and understood the consent form, and on behalf of the patient ……..(name of the patient) I volunteer to include him/her in this Clinical Validation Study of ……. (name the device). I understand that on behalf of the participant I will receive a copy of this form. I understand that this consent does not take away any legal rights of the participant in the case of negligence or other legal fault of anyone who is involved in this study, or the malfunction of the device under testing. I further understand that nothing in this consent form is intended to replace any applicable laws.

Participant Name (Printed or Typed): OR Participant’s surrogates Name and signature   
Date:

Participant Signature:  
Date:

Principal Investigator Signature:   
Date:

Signature of Person Obtaining Consent:  
Date: