NATIONAL INSTITUTE OF CARDIOVASCULAR DISEASES, RAFIQUI (H.J) SHAHEED ROAD, KARACHI, PAKISTAN.
ETHICAL REVIEW COMMITTEE

ERC Ref#:_____

APPLICATION FORM
CHECKLIST

This checklist was prepared in order to aid investigation in preparing a complete application and to help expedite review by the Ethical Review Committee. Your cooperation in completing it will be greatly appreciated.

STUDY TITLE	
PRINCIPAL INVESTIGATOR:	
DESIGNATION:	
DEPARTMENT& INSTITUTE:	
PHONE #:	
EMAIL ID:	

- ☐ ERC Application form with checklist
- ☐ A copy of Research Protocol
- ☐ A copy of Drug Brochure or any supplementary information enclosed (if applicable).
- ☐ Informed consent both in English and Urdu or any other local language of the population study.
- ☐ Questionnaire (Urdu & English) being administered during the study (if applicable)
- ☐ Assurance that a copy of this entire application form is with the applicant.

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(Signature / Date) (Signature / Date)

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(Name: Principal Investigator) (Name: Co- Investigator/Supervisor)

FOR OFFICIAL USE ONLY

Ethical Review Committee Decision:

◯ Approved ◯ Suggested Changes ◯ Not Approved

If approved; signature(s) of Ethical Review Committee members

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INTRODUCTORY QUESTIONNAIRE

Please answer all questions. Inappropriately filled form will not be accepted.

TITLE OF PROTOCOL:	

Principal Investigator and Co-Investigators (including NICVD Investigator):

1. PRINCIPAL INVESTIGATOR				
	NAME	DESIGNATION	DEPARTMENT	INSTITUTE
2. CO-INVESTIGATOR				
	NAME	DESIGNATION	DEPARTMENT	INSTITUTE
3. CO-INVESTIGATOR				
	NAME	DESIGNATION	DEPARTMENT	INSTITUTE
4. CO-INVESTIGATOR				
	NAME	DESIGNATION	DEPARTMENT	INSTITUTE
5. CO-INVESTIGATOR				
	NAME	DESIGNATION	DEPARTMENT	INSTITUTE

1. PROJECT INVOLVES THE USE OF: (CHECK ALL PERTINENT ONES)

a) Drugs (including experimental drug)*
b) Radiation / Radioactive agents *
c) Non-therapeutic research
d) Surgical intervention *
e) Non-Surgical Intervention *
f) Other Invasive Procedures *
g) Behavioral research
h) Gene molecular cloning
i) Other (please specify): _____

Please provide details in case **a**,**d, d, e or f** is checked

2. WHAT IS THE PURPOSE OF THE STUDY?

3. ENUMERATE THE RATIONAL OF THE STUDY

4. BRIEF DESCRIPTION OF METHODS USED IN PROTOCOL (STUDY DESIGN, SAMPLING TECHNIQUES & DATACOLLECTION)

5. A) EXPECTED DURATION OF THE STUDY PERIOD (TO COMPLETION).

5. B) EXPECTED DURATION OF STUDY ON EACH INDIVIDUAL SUBJECT.

6. A) PLEASE INDICATE SOURCE OF FUNDING.

6. B) HAS FUNDING BEEN APPROVED?

7. SUBJECT INFORMATION

a) Group: ◉ Patients ◯ Students ◯ Others

b) Records: _____

c) Age Range: _____

d) Sex ◉ Male ◯ Female ◯ Both

e) If subjects are children, pregnant women, mentally retarded, or prisoners, or if it includes foetal research, give brief explanation of need to use these particular individuals.

8. CRITERIA FOR INCLUSION AND EXCLUSION OF PATIENTS AND CONTROLS

Inclusion Criteria	Exclusion Criteria

ERC Ref#:_____

9. A) COMPENSATION (TO RESEARCH SUBJECT):

Monetary:	No	☐	Yes	☐	Amount:	_____
Other:	No	☐	Yes	☐	Specify:	_____
Reimbursement of expenses:	No	☐	Yes	☐	Type & amount:	_____

9. B) COMPENSATION (TO INVESTIGATORS):

◯ Monetary ◯ Travel ◯ Gifts

◯ Amount: _____ Other (please specify): _____

10. ADVERSE EFFECTS:

a) Describe adverse effects/risks expected to the subjects involved in the investigation during the study?

b) What is the provision for managing these effects?

c) Who will pay for them?

11. IN CASES WHERE THERAPEUTIC NEED OF THE RESEARCH SUBJECT IS IDENTIFIED DURING THE COURSE OF THE STUDY:

a) What is the provision for managing these cases?

b) Who will pay for them?

12. LABORATORY AND RADIOLOGICAL STUDIES:

a) Will any tests be performed which are not routinely included as part of the work-up for these types of patients?

b) Who or what agency will pay for these tests?

13. LOCATION OF STUDY:

◉ Outpatients Units ○ Inpatients Units ○ NICVD Department

○ Other than NICVD, (Please Specify): _____

14. WHAT ARE ACTUAL POTENTIAL BENEFITS IF ANY, TO BE OBTAINED?

a) By participants.

b) By society as a result of this study?

c) Please specify benefit of the study to the funding agency or sponsors.

d) Please specify benefit of the study to institution where study is being conducted.

15. HOW WILL CONFIDENTIALITY OF THE SUBJECTS BE ENSURED?

16. HOW WILL THE STUDY FINDINGS BE SHARED WITH?

a) Study subjects

b) Community at large

17. DISCUSS ETHICAL ISSUES INVOLVE IN THE STUDY.

18. ANY OTHER INFORMATION RELEVANT TO THE STUDY IN CONTEXT TO PAKISTAN?

19. HAS THIS STUDY OR SIMILAR STUDY BEEN CONDUCTED ELSEWHERE EARLIER?
(Please provide evidence)

ERC Ref#:_____

INSTRUCTIONS AND GUIDELINES FOR RESEARCHERS

a) Principal Investigator should be full time NICVD faculty.

b) NICVD investigator's name should be mentioned in the first three authors, when the article is published.

c) It should be considered mandatory that in any study where sample is taken from NICVD, NICVD's name should be mentioned as acknowledgement.

d) For patient's convenience all the investigators are requested to collect patient information and blood collection during official timings (08:00 AM to 03:00 PM).

e) 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.

f) Application must be signed by Principal Investigator& Supervisor of the Study.

g) For No. 2 on page # 3, please give a brief background of the study indicating the need for this study.

h) For No. 4 on page # 3, please do not give details of laboratory or scientific procedures. Only mention the procedures to be carried out on human subjects such as blood, body fluid collection or biopsy and storage of these samples, treatment to be provided to study subjects, observations, interviews, focus group discussions etc.

i) For No. 9 on page # 5, only direct compensations should be mentioned. Traveling in connection of studies and presentation should not be included here.

j) For No. 10 on page # 5, All possible adverse events that are likely to occur as a result of the study should be included, with a plan to help the patient get appropriate treatment.

k) Consent form & Questionnaire must be attached in Urdu or English (as per need).

l) Separate guidelines are given for drafting consent form which should be strictly followed. In case of improperly drafted consent form or its absence on preliminary scrutiny, no application will be considered for discussion in the meeting.

_____ _____

Name of Investigator / Researcher Signature: Investigator / Researcher

ERC Ref#:_____

GUIDELINES FOR DRAFTING AN INFORMED CONSENT FORM

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 may be written or verbal or telephonic. In case of unwritten consent, it should be signed by the person taking the consent and witnessed by a second person.

3. In case of children, an assent form from children and consent from guardian / parents is needed.

4. In case of mentally or physically incapacitated subject, consent should be obtained from immediate guardian or close relative

5. In case of community studies, community leaders, elders, local political leaders, religious leaders (in certain cases), and governmental officials should be taken into confidence, and a written consent should be obtained.

6. In case of doing a study in other locations such as other hospitals and clinics, permission from appropriate authority or physicians should also be obtained.

7. 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.

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

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SAMPLE INFORMED CONSENT

This is a generic sample form to help you address most situations. Please adapt as appropriate for your research protocol and institution.

Project Information	
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, whether oral or written, may not include language that appears to waive subjects' legal rights or appears to release the investigators or anyone else from liability for negligence.

1. PURPOSE OF THIS RESEARCH STUDY

- Include 3-5 sentences written in nontechnical language. "You are being asked to participate in a research study designed to..."

2. PROCEDURES

- Describe procedures: "You will be asked to do..."
- 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.

3. 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. If unknown, state so.
- Indicate if there are special risks to women of child bearing age; if relevant, state that study may involve risks that are currently unforeseeable, e.g., to developing fetus
- If subject's participation will continue over time, state: "any new information developed during the study that may affect your willingness to continue participation will be communicated to you."
- If applicable, state that a particular treatment or procedure may involve risks that are currently unforeseeable (to the subject, embryo or fetus, for example.)

4. POSSIBLE BENEFITS

- Describe any benefits to the subject that may be reasonably expected. If the research is not of direct benefit to the participant, explain possible benefits to others.

5. 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.

6. AVAILABLE TREATMENT ALTERNATIVES

- If the procedure involves an experimental treatment, indicate whether other non-experimental (conventional) treatments are available and compare the relative risks (if known) of each.

7. AVAILABLE MEDICAL TREATMENT FOR ADVERSE EXPERIENCES

- "This study involves (minimal risk) (greater than minimal risk)." In the event that greater than minimal risk is involved, provide the subject with the following information.
- If you are injured as a direct result of taking part in this research study, emergency medical care will be provided by [name] medical staff or by transporting you to your personal doctor or medical center. Indicate who will pay for this treatment.

8. CONFIDENTIALITY

- Describe the extent to which confidentiality of records identifying the subject will be maintained.

  "Your identity in this study will be treated as confidential. The results of the study, 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."

  "However, any records or data obtained as a result of your participation in this study may be inspected by the sponsor, or by NICVD ERC members".

  In addition, list steps to protect confidentiality such as codes for identifying data.

9. TERMINATION OF RESEARCH 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. You will be provided with any significant new findings developed during the course of this study that may relate to or influence your willingness to continue participation. 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.)

10. AVAILABLE SOURCES OF INFORMATION

- Any further questions you have about this study will be answered by the Principal Investigator:
  Name:
  Phone Number:
- Any questions you may have about your rights as a research subject will be answered by:
  Name:
  Phone Number:
- In case of a research-related emergency, call:
  Day Emergency Number:
  Night Emergency Number:

11. AUTHORIZATION

I have read and understand this consent form, and I volunteer to participate in this research study. 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. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws.

Participant Name (Printed or Typed):
Date:

Participant Signature:
Date:

Principal Investigator Signature:
Date:

Signature of Person Obtaining Consent:
Date: