(ANNEX-09-01)

JNMC INSTITUTIONAL ETHICS COMMITTEE STANDARD CHECKLIST FORMAT

Project Title: [Type here]

Date of submission:

Protocol submission for initial review (Tick accordingly)

Sr. No.	Document	Yes	No
1.	Is the Project reviewed for scientific details by the guide/scientific committee/departmental review committee		
2.	Principal Investigators signature		
3.	Head of the department signature		
4.	Requisition for ethical clearance to Member Secretary/ Chairperson		
5.	Informed consent in English		
6.	Informed consent in regional languages (as applicable).		
7.	Case Record Form/Data collection proforma		
8.	Request letter for waiver of consent (if applicable)		
9.	Project/study synopsis submitted 15 days prior to the ethical committee meeting.		
10.	Six hard copies and one soft copy submitted		

Date : Name & Signature of Principal Investigator

(ANNEX-08-01)

STANDARD APPLICATION FORMAT
FOR FACULTY

JNMC Institutional Ethics committee Reference No:

INSTITUTIONAL ETHICS COMMITTEE
KAHERs JAWAHARLAL NEHRU MEDICAL COLLEGE
RECEIVED DATE:
REVIEWED DATE:
REVISED DATE:
SIGNATURE OF REVIEWER:
SIGNATURE OF MEMBER SECRETARY:

(Six hard copies and one soft copy to be submitted)

1.	**Name of the Principal Investigator, Address (in Block Letters) and contact details (mobile no and email ID)**	
2.	**Name of the Department**	
3.	**Name of the Co-Investigator(s) if any (in Block Letters) (mobile no and email ID)**	
4.	**Name of the Institution**	KAHERs JAWAHARLAL NEHRU MEDICAL COLLEGE
5.	**Title of the proposed research project:** [Type here]	
6.	**6.1 Introduction and Need for the study:** [Type here] **6.2 Objective of the study** [Type here] **6.3 Review of Literature** [Type here]	
7.	**Materials and Methods** **7.1 Source of Data:** [Type here]	

	7.2 Study Design: [Type here] **7.3 Study Period:** [Type here] **7.4 Sample Size:** [Show the calculation] **7.5 Sampling technique:** [Type here] **7.6 Inclusion Criteria:** **7.7 Exclusion Criteria:** **7.8 Study protocol:** **7.9 Data collection procedure:** **7.10 Data processing and analysis/statistical analysis:** **7.11 Does the study require any investigations or interventions to be conducted on patients or other humans or animals? If so, please describe briefly.** **7.12 Budget analysis:** **7.13 Data analysis table:**	
8.	**List of references in Vancouver style** 1.	
9.	**Name and Signature of Principal Investigator**	
10.	**Name and Signature(s) of Co-investigator(s)**	
11.	**Remarks from the Head of department**	
12.	**Signature Head of Department**	
13.	**Signature of In-charge department synopsis review committee**	

14.	**Signature of In-charge scientific review committee**	
15.	**The Principal, J N Medical College, Belagavi**	Dr N.S. Mahantashetti, MBBS.MD (Pediatrics) Fellowship in pediatric cardiology
	Signature of Principal	
16.	**Chairperson, JNMC Institutional Ethics Committee**	Dr Harsha Hegde
	Signature of Chairperson	

Annexure-1 Attach consent from in English and vernacular language as applicable.

Annexure-2 Attach data collection format.

Consent form format

KAHERs JNMC
BELAGAVI
INFORMED CONSENT FORM

"TITLE OF THE PROJECT/STUDY"

Name of Student/Principal Investigator:
Name of Guide/Co Investigators:

Objective:

Introduction:

Explanation of procedure:

Withdrawal from participation in the study: Participation in this study is voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You will/will not have nor get any benefits by participating in this study. The data gathered will help the population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person from identifying you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups. However, your identity will never be revealed.

Questions: In case of any questions with regard to this study, you are free to contact: "Name of student/PI, mobile number, email ID" If you have any question or complaints with regard to your right as study participant you may contact Dr Harsha Hegde, Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

Legal rights: By signing this consent form, we are not waving any of your legal rights.

CONSENT STATEMENT

I am making a voluntary decision to participate in the study "**TILE OF THE PROJECT/STUDY**". My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant:

Name of the witness:

Signature or left thumb impression of the witness:

Name of the investigator:

Signature of the investigator:

******following information is for the Principal Investigator, do not include it with submission******

GUIDELINES FOR PREPARING
THESIS/RESEARCH PROTOCOL

Preparing the protocol is initial but an important step in the thesis or dissertation work. The following is intended to help you in preparing the protocol.

1. TITLE OF THE TOPIC:
   The title should be as brief as possible but should carry as much information as required.

2. BRIEF RESUME OF THE WORK:
   a. Give a brief introduction to the work you intend doing by focusing on present literature on the subject, gaps in the knowledge, if any, and the reasons for undertaking the study. You may have to quote a few references or other studies (About 100-200 words of introduction)
   b. Give the objectives of the study. The objectives usually should not be more than 2 to 4 and should relate to the points or key questions raised in introduction (about 50-100 words for objectives).
   c. Review the literature and give 3-5 references pertaining to the subject and work already published. It should be related to the objectives of the study.

3. MATERIAL AND METHODS: (About 100-150 words)
   Briefly explain the source from which you would collect data for the study. For example, in clinical settings, it may be patients in hospitals, or in community settings, or it may be households or it may be a laboratory-based study.
   Describe the method of collection of data. For instance, it may be interview or study of records or by animal experiments or by performing tests or laboratory investigations, or even through some intervention. In case of human or animal study, mention the inclusion and exclusion criteria. If there are any ethical issues involved, mention them and state how you intend to overcome them.
   If you are taking a sample, mention the sampling procedure and sample size. Thus, it is important to mention the subjects of your study, parameters and the procedures.

4. REFERENCES:
   Give about 3-5 references quoted in your introduction or those related to your study. Following are the guidelines given for writing references.

GUIDELINES FOR WRITING REFERENCES

The following table summarizes the components of a reference and how they should be typed. Later, a few examples are given for different types of references.

DIFFERENT COMPONENTS OF REFERENCE AND METHOD OF TYPING

Indentation	Overhanging first line flush with margin Second line indented five spaces.

Name order	Last name first (of first author when more than one author)
Placement	End of body of report-listed alphabetically by last name of first author
Punctuation	Author name, Title, Place of Publication: Publisher, State of publication.
Page reference	Total number of pages in a book or in articles.

EXAMPLES OF QUOTING REFERENCES

1. *Standard journal article*

a) List the first six authors followed by et al.

Halpern SD, Ubel PA, Caplan AL. Solid-organ transplantation in HIV-infected patients. N Engl J Med. 2002;347:284-7.

b) More than six authors:

Rose ME, Huerbin MB, Melick J, Marion DW, Palmer AM, Schiding JK, et al. Regulation of interstitial excitatory amino acid concentrations after cortical contusion injury. Brain Res. 2002;935(1-2):40-6.

2. *Books/ Monograms*

a) Personal / single author(s)

Murray PR, Rosenthal KS, Kobayashi GS, Pfaller MA. Medical microbiology. 4th ed. St. Louis: Mosby;2002. p.215 -8

b) Chapter in a Book

Meltzer PS, Kallioniemi A, Trent JM. Chromosome alterations in human solid tumors. In: Vogelstein B, Kinzler KW, editors. The genetic basis of human cancer. New York: McGraw-Hill; 2002. p. 93-3.

3. Journal article on the Internet

Abood S. Quality improvement initiative in nursing homes: the ANA acts in an advisory role. Am J Nurs [serial on the Internet]. 2002 Jun [cited 2002 Aug 12];102(6):[about 3 p.]. Available from: http://www.nursingworld.org/AJN/2002/june/Wawatch.htm

4. CD-ROM ; Vancouver System

Anderson SC, Poulsen KB. Anderson's electronic atlas of hematology [CD-ROM]. Philadelphia: Lippincott Williams & Wilkins; 2002. p.875-9

(ANNEX-10-01)

STANDARD PROTOCOL FOR INFORMED CONSENT

1. Checklist of informed consent documents for clinical trial subject–

1.1 Essential Elements:

i) Statement that the study involves research and explanation of the purpose of the research
ii) Expected duration of the participation of the subject.
iii) Description of the procedures to be followed, including all invasive procedures.
iv) Description of any reasonably foreseeable risks or discomforts to the Subject.
v) Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.
vi) Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
vii) Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records.
viii) Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials).
ix) Statement describing the financial compensation and the medical management as under:
    a) In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.
    b) In the event of a trial related injury or death, the sponsor or his representative or the investigator or center, as the case may be, in accordance with the rule 39, as the case may be, shall provide financial compensation for the injury or death.
x) An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.
xi) The anticipated prorated payment, if any, to the subject for participating in the trial.
xii) Responsibilities of subject on participation in the trial.
xiii) Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.
xiv) Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect.
xv) Statement that in the case of placebo-controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.
xvi) Any other pertinent information.

1.2 Additional elements, which may be required:

i) Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent.
ii) Additional costs to the subject that may result from participation in the study.
iii) The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.
iv) Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the

research which may affect the Subject's willingness to continue participation will be provided.

v) A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant), which are currently unforeseeable.

vi) Approximate number of Subjects enrolled in the study