(ANNEX-09-01)

JNMC INSTITUTIONAL ETHICS COMMITTEE
STANDARD CHECKLIST FORMAT

Project Title: [Type here]

Date of submission: DD/MM/YYYY

Protocol submission for initial review (Remove the highlights and Tick accordingly)

Sr. No.	Document	Yes	No
1.	Is the Project reviewed for scientific and Ethical details by the guide		
2.	Signature of Incharge Departmental Review Committee		
3.	Signature of Scientific reviewer (Synopsis Review Committee of JNMC)		
4.	Signature of Statistician		
5.	Guide signature and remarks		
6.	Head of the department signature		
7.	Requestion for ethical clearance to Chairperson JNMC Ethics Committee.		
8.	Informed consent in English		
9.	Assent form if applicable		
10.	Informed consent in regional languages (as applicable).		
11.	Case Record Form/Data collection performa		
12.	Request letter for waiver of consent (if applicable)		
13.	Project/study synopsis submitted 15 days prior to the ethical committee meeting. (Ethical committee meets in the month of January, March, June and October)		
14.	Two hard copies to department of JNMC Ethics Committee.		

Date :

Name & Signature of Principal Investigator

(ANNEX-08-01)

STANDARD APPLICATION FORMAT
FOR UNDERGRADUATE AND POSTGRADUATE STUDENTS

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:

(TWO HARD COPIES TO BE SUBMITTED, AFTER FINAL APPROVAL EDITED SOFT COPY TO BE SUBMITTED TO JNMCIEC@GMAIL.COM)

1.	**Name of the student, Address (in Block Letters) and contact details (mobile no and email ID)**	
2.	**Name of the Department**	
3.	**Name of the Guide (in Block Letters) and contact details (mobile no and email ID)**	
4.	**Name of the Co Guide (in Block Letters) and contact details (mobile no and email ID)**	
5.	**Name of the Institution**	KAHERs JAWAHARLAL NEHRU MEDICAL COLLEGE
6.	**Title of the proposed research project:** [Type here]	
7.	**7.1 Introduction and Need for the study:** [Type here] **7.2 Objective of the study** [Type here] **7.3 Review of Literature** [Type here]	
8.	**Materials and Methods** **8.1 Source of Data:** [Type here] **8.2 Study Design:** [Type here] **8.3 Study Period:** [Type here]	

8.4 Sample Size: [Show the calculation]

8.5 Sampling technique: [Type here]

8.6 Inclusion Criteria: [Type here]
8.7 Exclusion Criteria: [Type here]

8.8 Study protocol: Consort flow chart for RCTs [Type here]

8.9 Data collection procedure: [Type here]

8.10 Data processing and analysis/statistical analysis: [Type here]

8.11 Are there any anticipated serious adverse events (SAE) or adverse events which may occur during course of your study. [Type here]

8.12 Does the study require any investigations or interventions to be conducted on patients If so, please describe briefly. [Type here]

8.13 If there are any investigations / Interventions necessary which have to be conducted for completion of your study, in such situation who will bear the cost of the investigations. [Type here]

8.14 Budget analysis: Example given below

BUDGET

INCOME DETAILS	ACTUAL	BUDGETED
EXPENSE DETAILS	**ACTUAL**	**BUDGETED**

8.15 Data analysis table: Example given below

		Variables		
SlNo	IP/OP No	Independent variable 1	Independent variable 2	Dependen/Independent 1

9. List of references in Vancouver style

1.

10.	**Name and Signature of Student with date**	
11.	**Remarks from the Guide**	
12.	**Name, Designation and Signature of Guide with seal and date**	

13.	**Name, Designation and Signature of co guide with seal and date**	
14.	**Name and Signature Head of Department with seal and date**	
15.	**Name and Signature of In-charge department synopsis review committee with seal and date**	
16.	**Name and Signature of Scientific reviewer (Synopsis Review Committee of JNMC) with seal and date**	
17.	**Name and Signature of Statistician with seal and date**	
18.	**The Principal, J N Medical College, Belagavi**	Dr N.S. Mahantashetti, MBBS.MD (Pediatrics) Fellowship in pediatric cardiology
	Signature of Principal	
19.	**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 assent form if applicable. Annexure-3 Attach data collection format.		

Consent form format

TAKE help of ANNEXURE 10-01 to make your consent form

Deleted the highlighted text before submission

KAHERs JNMC
BELAGAVI
INFORMED CONSENT FORM

"TITLE OF THE PROJECT/STUDY"

Name of Student/Principal Investigator:
Name of Guide/Co Investigators:
Introduction: (In simple language, which can be understood by a layman as applicable to your study)

Explanation of procedure: (In simple language, which can be understood by a layman as applicable to your study)

Withdrawal from participation in the study: (In simple language, which can be understood by a layman as applicable to your study) Participation in this study in 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 get any benefits by participating in this study. **(In simple language, which can be understood by a layman as applicable to your study)** The data gathered will help population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study. **(In simple language, which can be understood by a layman as applicable to your study)**

Privacy and confidentiality: The information collected from you will be coded, to prevent any person to identify 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.

Cost of investigations done during the course of study will be paid by the **principal investigator / Participant.** (Strike out which is not applicable)

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purpose 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:

(ANNEX-10-01)

STANDARD PROTOCOL FOR INFORMED CONSENT (look for ICMR Guidelines)

1. Checklist of informed consent.

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 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 foetus, if the Subject is or may become pregnant), which are currently unforeseeable.
vi) Approximate number of Subjects enrolled in the study.

CONSIDERATIONS FOR ASSENT (look for ICMR Guidelines)

There is no need to document assent for children below 7 years ot age.
• For children between 7 and 12 years verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded.
For children between 12 and 18 years, a written assent must be obtained. This assent form also has to be also signed by the parents/_AR.
•Adolescents may have the capacity to give consent like adults. However, as they have not attained the legal age to provide consent, it is termed as assent and the consent of the parent/LAR should be obtained. If the latter will affect the validity of the study, waiver of consent from the relevant adult should be taken and recorded with approval of EC
•Content of the assent form has to be in accordance with the developmental level and maturity of the children
• The language must be consistent wit the cognitive, social and emotional status of the child and be simple and age appropriate

Verbal/Oral consent: Verbal assent from minor (7-12 yrs) along with parental consent
Witnessed consent: Written assent from minor (13-18 yrs) along with parental consent

FOLLOWING ARE SOME EXAMPLES OF VULNERABLE POPULATIONS OR GROUPS:

• economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/ gay/bisexual and transgender (LGBT), etc.);
• unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent;
• children (up to 18 years);
• women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare);
• tribals and marginalized communities;
• refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations;
• afflicted with mental illness and cognitively impaired individuals, differently abled –mentally and physically disabled;
• terminally ill or are in search of new interventions having exhausted all therapies;
• suffering from stigmatizing or rare diseases; or
• have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defence services personnel, healthcare workers, institutionalized individuals, under trials and prisoners).

DUTIES OF RESEARCHER (look for ICMR Guidelines)

- Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection.
- Justify inclusion/exclusion of vulnerable populations in the study.
- COI issues must be addressed.
- Have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio.
- Ensure that prospective participants are competent to give informed consent.
- Take consent of the LAR when a prospective participant lacks the capacity to consent.
- Respect dissent from the participant.
- Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc.
- Research should be conducted within the purview of existing relevant guidelines/regulations.