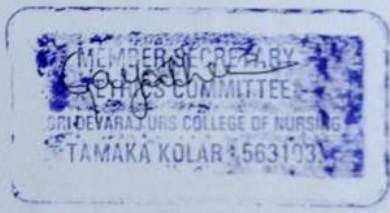
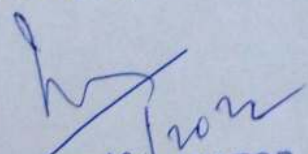
	SRI DEVARAJ URS COLLEGE OF NURSING TAMAKA, KOLAR – 563 103.	Format No.	IEC 01
	INSTITUTIONAL ETHICS COMMITTEE	Issue No.	03
		Rev No.	02
		Date	01-09-2018

## INSTITUTIONAL ETHICS COMMITTEE (Code of Ethics for Research)




Standard Operating Procedures (Code of Ethics for Research)  
Effective Date: 01 September 2021  
Next Review Date: 31 August 2023




ACAR-2  
  
NAAC COORDINATOR  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

  
Principal  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

Approved by

  
Prepared by

	<b>SRI DEVARAJ URS COLLEGE OF NURSING</b>	<b>Format No.</b>	<b>IEC 01</b>
	<b>TAMAKA, KOLAR – 563 103.</b>	<b>Issue No.</b>	<b>03</b>
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		<b>Date</b>	<b>01-09-2018</b>

## 1. Introduction of the Ethics Committee

Institutional Ethics Committee of Sri Devaraj Urs College of Nursing (IECSDUCON), was constituted for discussion and approval of institutional/ collaborative research projects with respect to safeguard dignity, right, safety and well being of all research participants and to ensure that the research is carried under prescribed guidelines.

**“Institutional Ethics Committee, Sri Devaraj Urs College of Nursing (IECSDUCON), was constituted and operates as per ICMR guidelines, Schedule Y and ICH-GCP”**

Head of the Institution of Sri Devaraj Urs College of Nursing, as per the new guidelines has constituted SDUCON/IEC/01/2016-17/ Dated 14-03-2017. Effect from 1<sup>st</sup> of September 2021.

## 2. Basic responsibilities of Ethics Committee/ Objectives

- To ensure the competent review and evaluation of all ethical aspects of research projects received in an objective manner
- To protect the safety, rights and well being of the potential research participants
- To conduct scientific evaluation and to ensure technical appropriateness of the proposed study
- To ensure that universal ethical values and international scientific standards are expressed in terms of local community values/customs.
- To assist in the development and education of a research community responsive to local health care requirement
- Creation, developing, revising and implementing ethical guidelines (SOP's)

### 3. SOP's of institutional Ethics Committee

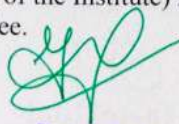
#### 3.1 Establishing and Constituting the Institutional Ethics Committee

##### PURPOSE

To establish and constitute the Institutional Ethics Committee for SDUCON, Kolar as per ICMR Guidelines, Schedule Y and ICH-GCP

##### RESPONSIBILITY


Principal (Head of the Institute) is responsible to initiate the process of constitution of Institutional Ethics Committee.



Principal  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103



Principal  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103  
Approved by

	<b>SRI DEVARAJ URS COLLEGE OF NURSING</b>	<b>Format No.</b>	<b>IEC 01</b>
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## PROCEDURE

- Principal will select and nominate the Chair person (from outside the institute) and member secretary (from institute) for IEC, SDUCON, Kolar.
- IEC will be constituted by the Principal as per ICMR guidelines and also in consultation with Departmental heads of the institution.
- Principal will invite the members to join ethics committee by sending the official request letter (**Document-1AA**)
- Member will confirm their acceptance to the Principal by providing all the required information for membership (**Document-2AA**)
- Principal will designate and instruct Chairperson of IEC or his/her representative to conduct the regular proceedings of IEC for the institute
- Principal will review the function of IEC at regular interval

### 3.2 Procedure for appointing members for the IEC

#### PURPOSE

To appoint suitable members for the IEC, SDUCON, Kolar

#### RESPONSIBILITY

Principal (Head of the Institute) are responsible for implementing this SOP.


#### PROCEDURE


Principal in consultation with heads of department, SDUCON will nominate the members of IEC, who have the qualification and experience to review and evaluate the scientific, nursing and ethical aspect of proposed study.

The regular members of the committee will include at least 5 individuals. Current committee is as follows:

1. Chairperson- 01
2. Basic Medical Scientist-01
3. Clinicians from various institute - 02
4. Social scientist/ Representative of non-governmental voluntary agency/ Philosopher/ Ethicist/ Theologian -01
5. Legal expert/ Retired judge -01
6. Lay person from the community - 01
7. Member Secretary -01
8. Whenever required the expert person on particular subject would be invited.

Prepared by

  
**Principal**  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103  
Approved by

	<b>SRI DEVARAJ URS COLLEGE OF NURSING</b>	<b>Format No.</b>	<b>IEC 01</b>
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### 3.3 Training of IEC members

#### PURPOSE

All IEC members are conversant with Guidelines for Research involving Human Subjects

#### RESPONSIBILITY

A team of trainer is chosen for this purpose. The Member Secretary will ensure that new members will get trained with in fortnight after being inducted.

#### PROCEDURE

All IEC members will be made conversant with ICMR Guidelines for Research involving Human Subjects 2006, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines

#### Training schedule for new members of IEC SDUCON

Sl. No	Session Topic	Facilitator	Time period
1.	Roles & responsibilities of IEC and its members	Member Secretary	1 hour
2.	Discussion on regulatory guidelines on IEC	IEC member nominated by	2 hours
3	Interactive session	With at least two members nominated by Member Secretary	2 hours

Additionally Institutional Ethics Committee will hold retraining for all the members of IEC once in a year for 2-3 hours on the topics listed in the above table

### 3.4 Term of appointment, Policy for removal or Resignation/ Replacement of members

#### PURPOSE


To establish polices for removal or Resignation / Replacement of members

#### RESPONSIBILITY

Principal and Member Secretary are responsible for implementing this SOP.

  
Principal

Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

	<b>SRI DEVARAJ URS COLLEGE OF NURSING</b>	<b>Format No.</b>	<b>IEC 01</b>
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## PROCEDURE

**Term of appointment:** Members of IEC will be appointed for period of 2 years initially which could be extended for another term of 2 years. Extension of membership will be based on the recommendation of the Principal & Member Secretary of IEC.

### Policy for removal of member

- A member may be relieved or terminated of his/her membership in case of conduct unbecoming for a member of the Ethics Committee.
- Inability to participate in the meetings on any grounds for more than 3 meetings of IEC.
- The membership shall be reviewed by the principal & chairperson, if the member is a regular defaulter.
- If deemed necessary, the IEC may decide to terminate the membership and recommend to the Chairperson IEC for necessary action.
- In all such situations/circumstances, member secretary will serve a letter of termination to the member.
- Documentation of the termination will be recorded in the meeting minutes of the next duly constituted IEC meeting and IEC membership circular/roster will be revised.

### Resignation / Replacement procedure

The members who have resigned may be replaced at the discretion of the appointing authority for the same. IEC members who decide to resign must provide the Principal & member secretary of IEC the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting. In case of resignation, Principal & member secretary would appoint a new member, falling in the same category of membership ex. NGO representative with NGO representative.

### 3.5 Procedure for convening and conducting IEC meetings

#### PURPOSE

To hold regular IEC meeting


#### RESPONSIBILITY

Principal & member secretary are responsible for implementing this SOP

  
Prepared by

  
Principal  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

Approved by

	<b>SRI DEVARAJ URS COLLEGE OF NURSING</b> <b>TAMAKA, KOLAR – 563 103.</b>	<b>Format No.</b>	<b>IEC 01</b>
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## PROCEDURE

- The member Secretary in consultation with the Principal may convene the IEC meeting once in a year
- Additional review meeting can also held with short notice as and when required
- All members will receive notification of meeting schedules in advance (**Annexure-I**)
- A minimum of five persons is required to form the quorum without which a decision regarding the research would not be taken. The quorum would have at least one representative from the following group
  1. One basic medical scientist (preferably one Pharmacologist)
  2. One Clinician
  3. One legal expert or retired Judge
  4. One social scientist/ representative of non-governmental organization/ Philosopher/ Ethicist/ Theologian or a similar person
  5. One lay person from the community.

Minutes of the IEC meetings, all the proceeding and deliberation will be documented.

- Applicant investigator may be invited to present the proposal or elaborate on specific issue.

### 3.6 Procedure for submission of research project

#### PURPOSE

To submit a research proposal for review by IEC

#### RESPONSIBILITY

All investigators are responsible for implementing this SOP. All research proposals must be submitted in the prescribed application format, duly filled, along with all necessary documents

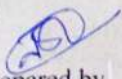
### 3.6 Procedure for submission of research project


#### PURPOSE


To submit a research proposal for review by IEC

#### RESPONSIBILITY

All investigators are responsible for implementing this SOP. All research proposals must be submitted in the prescribed application format, duly filled, along with all necessary documents

  
Prepared by

  
Principal  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-56310

	<b>SRI DEVARAJ URS COLLEGE OF NURSING</b>	<b>Format No.</b>	<b>IEC 01</b>
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### PROCEDURE

- Project investigator has to submit an application in prescribed format (**Annexure 2**) along with study protocol & other study related document necessary for review by IEC.
- The following documents at minimum will be reviewed by ethics committee
  - Trial Protocol (including protocol amendments)
  - Patient information Sheet and informed Consent Form in English and/or vernacular language.
  - Investigator's Brochure and available safety information
  - Proposed methods for sample recruitment including advertisement (s) etc. proposed to be used for the purpose.
  - Principal Investigator's current CV and any document evidencing qualifications
  - Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.
  - Investigator's Agreement with the Sponsor.
  - Investigator's Undertaking (**Form-3**)
  - Any other documents that ethics committee may require to fulfill its responsibilities
- research proposals must be submitted in English language only
- Application may be submitted to the office of member secretary, IEC SDUCON, Kolar (minimum 09 hard copies along with electronic of the same) at least 7 days prior to the date of proposed ethics committee meeting
- Receipt of application will be acknowledged by IEC office. (**Form-2**)
- Every application will be allotted an IEC registration number to be used for future correspondence


### 3.7 Procedure for initial scrutiny of proposal

### RESPONSIBILITY

Office of Member Secretary

### PROCEDURE

- Every proposal will be collected and complied by the IEC office
- Academic assistant will verify the proposal for completeness as per check list (**Form 1**)
- In case of incomplete data, the investigators will be informed by the office after consulting the Member Secretary to make the necessary correction and to resubmit the proposal

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### 3.8 Procedure for reviewing the research proposals

#### RESPONSIBILITY


All members of IEC are responsible for implementing this SOP.

#### Elements of Review


- The submitted proposal shall be reviewed both for scientific content and ethical principles.
- The committee members shall review the proposal with reference to the following:
  - a. Scientific/Research design of the study
  - b. Justification/Rationale /Need of the study
  - c. Selection criteria for subjects
  - d. Justification for use of placebo, if any
  - e. Potential benefits to the study subjects
  - f. Predictable risks to the study subjects
  - g. Criteria for discontinuation/withdrawal of subjects
  - h. Monitoring of serious adverse events
  - i. Compensation to subjects for participating in the study
  - j. Subject recruitment procedures
  - k. Patient retention activities.
  - l. Compensation for study related injury
  - m. Post trial benefits
  - n. Protection of privacy and confidentiality
  - o. Statistical analysis
  - p. Informed consent document in English and regional languages
  - q. Competence of investigators, supporting staff and infrastructure facility
  - r. Approval of regulatory authorities wherever applicable

#### PROCEDURE

- Every proposal will be evaluated by IEC members on ethical issues as per ICMR Guidelines 2006 as amended thereafter,
- Every proposal will be evaluated by IEC members on scientific soundness and technical excellence of the proposed research, before it is taken up for main IEC interview on the same day.
- All members will evaluate the possible risks to the study participants with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue
- The IEC review will be done through formal meetings and will not resort to decision through circulation of proposal
- Expert opinion of additional members would be obtained if necessary

  
Principal  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103





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### Summary of the procedure adopted

1. As per the routine adopted, *Approval of IEC should follow first before synopsis of thesis or any research project is submitted by the candidate for approval from board of study committee.*
2. Every HOD should ensure that candidate undertaking *any kind of research on humans (interventional/ non interventional/observational/investigational or any kind of study directly or indirectly dealing with humans)* should submit a copy of protocol along with application and electronic version (*e-mail us at sduconethicscommittee@gmail.com*) of the same in prescribed Performa, well in advance to **member secretary for IEC approval.**
3. Every candidate appearing before IEC should be directed to submit their presentation in electronic format well in advance to member secretary, which shall be circulated to all worthy members and chair person for reference well in advance.
4. The Certificate may be useful while publishing your valuable research in any of the Indian or International journal of repute and impact factor without producing IEC Number (applicable for all type of studies) and Getting registered in Clinical Trial Registry of ICMR-India quoting clinical trial number (applicable for Only interventional drug trials).
5. *The responsibility of not getting prior IEC approval shall otherwise lie with respective heads of department at the time of any ethical audit of the institution.*
6. *The research protocol need to categorized by the candidates and presented Only if falls in Category-A*  
*Category -A (full review / presentation required): presentation has to be made as per serial number or as decided by IEC*  
*Drug trials/studies*  
*Interventional Trials*  
*Surgical or diagnostic procedure trials being carried for the first time in the institution other than the routine protocol*  
*New drug trials*  
*Trials on high risk population*  
*Not falling in cat B & C*

  
Principal  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

  
Prepared by

	<b>SRI DEVARAJ URS COLLEGE OF NURSING</b>	<b>Format No.</b>	<b>IEC 01</b>
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*Category-B (expedited review/presentation optional/but application and submission of protocol in print /electronic format required for record)*


- a) The committee may use expedited review procedure in case of minor changes/ amendments in the previously approved research proposal that appear to involve no more than minimal risk to the study subjects.
- b) Under an expedited review procedure, the review may be carried out by the Chairperson of the committee, or by one or more experienced reviewers designed by the chairperson from among the members of the committee. The reviewers may exercise all of the authorities of the committee except that the reviewers may not disapprove the research.
- c) The committee will keep all members of the committee informed of these approvals under the expedited review procedure.
- d) Only the Chairperson and Member Secretary shall make the decision to allow an expedited review


#### **Expedited Review Procedures**

- e) The committee may use expedited review procedure in case of minor changes/ amendments in the previously approved research proposal that appear to involve no more than minimal risk to the study subjects.
- f) Under an expedited review procedure, the review may be carried out by the Chairperson of the committee, or by one or more experienced reviewers designed by the chairperson from among the members of the committee. The reviewers may exercise all of the authorities of the committee except that the reviewers may not disapprove the research.
- g) The committee will keep all members of the committee informed of these approvals under the expedited review procedure.
- h) Only the Chairperson and Member Secretary shall make the decision to allow an expedited review

*Category-C (exception from review presentation only Application required)*

7. *It is requested to make arrangement of 5 minutes presentation by each candidate with maximum 8 slides in power point to be presented in front of Institutional Committee on above said date and time, who have submitted proposals for approval.*
8. *Guide and respected Co-guide can Join the meeting for scientific interaction.*
9. *Not more than 30 projects shall be consider in one day or as the situation demands*
10. *Independent Projects as per the same SOP shall be considered first followed by thesis research protocols.*

  
Principal  
Sri Devaraj Urs College of Nu.  
Tamaka, Kolar-563103

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**11. Investigator/Candidate is requested to make and present power point slides of your project proposal which should include following points/guidelines depicted below.**


1. Introduction and Background of the subject
2. Rationale/ Justification/Need of Undertaking the project
3. What new the research/Project is going to contribute to scientific community & Our setup
4. Is your research/project following all basic principal of Bioethics-
  - Principles of essentiality
  - Research is necessary for the advancement of knowledge-Should add New information
  - Rationale Justification of Research Question
  - Principles of precaution and risk minimization
  - Principles of the maximization of the public interest
  - Principles of non-exploitation
  - Principles of voluntariness, informed consent & community agreement
  - Respect for persons: dignity and rights of each trial participant
  - Is there provision for Participants to withdraw at any time? Is there any provision to ensure/ Protect confidentiality
  - Is there any provision for Compensation?
5. Aims and Objectives
6. Materials and Methods to undertake the project
7. Statistical Methods intend to use
8. Flow chart of your project/CONSORT/Gantt chart

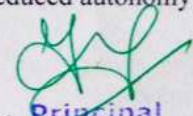
### **3.8. For Vulnerable Groups**


The ethics committee will exercise particular care to protect the rights, safety and well being of all vulnerable subjects participating in the study as per Good Clinical Practices for Clinical Research in India:

Effort will be made to ensure that individuals or communities invited for research is selected in such a way that the burdens and benefits of the research are equally distributed.

- a. Research on genetics does not lead to racial inequalities
- b. Persons who are economically or socially disadvantaged are not used to benefit those who are better off than them:
- c. Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders is protected.
- d. Adequate justification is made for the involvement of subjects such as prisoners, students, subordinates, employees, service personnel etc. who have reduced autonomy as research subjects.

Prepared by 

  
Principal  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103/ Approved by

	<b>SRI DEVARAJ URS COLLEGE OF NURSING</b>	<b>Format No.</b>	<b>IEC 01</b>
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### 3.9 Procedure for decision making regarding the research Project and Communicating the decision of IEC to the Investigator

#### RESPONSIBILITY

All members of IEC of SDUCON, Kolar

#### PROCEDURE

- A decision will only be taken when sufficient time has been allowed for review and discussion on application occurred in the absence of investigator from meeting
- Decision will only be taken at meeting where quorum (minimum of five members) is Complete
- Decision will only be taken after reviewing complete application with all required documents necessary for proposal (**Form-1**)
- Decision will arrive with consensus of members; if consensus appears unlikely voting can be resorted to. Decision will be taken in specified format (**Document-3**)
- A negative decision would always be supported by clearly defined reason
- The Member Secretary would communicate the decision in writing to the Principal Investigator in prescribed format (**Document-5**)
- If one of the members has her/his own proposal for review, then she/he would withdraw from the IEC while the project is being discussed

### 4.0. Procedure for documentation & archiving of documents

#### PURPOSE

To archive the study related documents, proceedings and communications

#### RESPONSIBILITY


The office of the member secretary is responsible for implementing this SOP

#### PROCEDURE(Activities)

- Academic assistant who will help the IEC Member Secretary in executing functions of the IEC, documentation & archiving documents.
  - All documents, communication of IEC will be dated, filed & preserved in a secure place
  - Only person who are authorized by chairman of IEC will have access to various documents
  - All documents related to research project will be archived for a minimum period of three years in the Institute following completion or termination of project
  - All the agenda & minutes of meeting will be filed & archived
- The records shall be made available to relevant statutory authorities upon request.

  
Principal

Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

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**Document -1AA: Request letter by Principal to the members**

Ref: No. SDUCON/ /2019-20

Date: 05-03-2020

To

Respected Madam,

**Sub:** Requesting to be a member/chairperson of Institutional Ethics Committee-reg.  
-----

With subject to the above, I request you to be a member/chairperson of Institutional Ethics Committee of Sri Devaraj Urs College of Nursing. If you are willing for the same, I request you to send your acceptance on or before \_\_\_\_\_ and do the needful.


Thanking you,

**Principal**

  
Principal  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

  
Prepared by

Approved by

	<b>SRI DEVARAJ URS COLLEGE OF NURSING</b>	<b>Format No.</b>	<b>IEC 01</b>
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		<b>Date</b>	<b>01-09-2018</b>

**Document -1AA: Request letter by Principal to the members**

SDUCON/ / 2019-20

Date:

To

**Respected Sir,**

**Sub:** Appointment of Ethical Committee member-reg

We are happy to inform your goodself that, your appointed as one of the Ethical Committee Member of this Institution with effect from \_\_\_\_\_. I request you to kindly send your acceptance for the same & do the needful.


Thanking you,

**Principal**



**Principal**

Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

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		<b>Date</b>	<b>01-09-2018</b>

**Document-2AA: Consent letter by members of IEC**

From

Date:

To  
The Principal,  
Sri Devaraj Urs College of Nursing,  
Tamaka,  
**Kolar-563 103**

Dear Madam,

**Sub:** Acceptance for Chairperson/Members of Institutional Ethics Committee-reg.

**Ref:**  
-----


With reference to the above, I thank you for your letter dated -----, regarding Acceptance of Institutional Ethical Committee and I hereby give my consent to be Chairperson/member Secretary/Member of IEC in the said committee.

Thanking you,

Yours Sincerely,



Principal  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

	<b>SRI DEVARAJ URS COLLEGE OF NURSING</b> <b>TAMAKA, KOLAR – 563 103.</b>	Format No.	IEC 01
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**Document- 3A: SDUCON, IEC Review/Meeting Minutes**

Review/ Meeting Minutes No of IEC \_\_\_\_\_ Date: \_\_\_\_\_

The meeting of the IEC for the year \_\_\_\_\_ was held in SDUCON on \_\_\_\_\_ under the Chairmanship of \_\_\_\_\_ Mrs. Jairakini Aruna, Member Secretary welcomed committee members. Following members attended the meeting

Sl. No.	Name	Position	Signature
1	Dr.Reddemma K.	Chair person	
2	Dr.Dayanand	Member	
3	Dr.Prabhakar K	Member	
4	Dr.Asha B	Member	
5	Mr.Ganesh	Member	
6	Achary Chinmayananda Avadutha	Member	
7	Mrs.Gayathri K V.	Member Secretary	

After the proceeding, the proposals listed for meeting were taken up for discussion. After deliberation the following decisions were arrived

No. of proposal received \_\_\_\_\_  
No. of proposals approved \_\_\_\_\_. Proposals approved subject to correction \_\_\_\_\_

**The recommendation made by the committee to each proposal is detailed below:**

Sl. No.	IEC Reg. No. of proposal	Name of Principal/ Co-Investigator	Title of Research Proposal	Accepted /Rejected	Recommendation of the committee

Sl. No.	Name	Signature
1	Dr.Dayanand	
2	Dr.Prabhakar K	
3	Dr.Asha B	
4	Mr.Ganesh	
5	Achary Chinmayananda Avadutha	

**Member Secretary**


**Chairperson**  
**IEC (Human studies)**

  
Principal

Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

Approved by



	<b>SRI DEVARAJ URS COLLEGE OF NURSING</b>	<b>Format No.</b>	<b>IEC 01</b>
	<b>TAMAKA, KOLAR – 563 103.</b>	<b>Issue No.</b>	<b>03</b>
	<b>INSTITUTIONAL ETHICS COMMITTEE</b>	<b>Rev No.</b>	<b>02</b>
		<b>Date</b>	<b>01-09-2018</b>

Document-04 SDUCON, Trail Approval of Ethics Committee

To,

The Institutional Ethics Committee reviewed and discussed your application to conduct the clinical trial entitled “.....” on .....(date).

The following documents were reviewed:

- Trial Protocol (including protocol amendments), dated \_\_\_\_\_ Version no (s). \_\_\_\_\_
- Patient Information Sheet and Informed Consent Form (including updates if any) in English and/or vernacular language.
- Investigator’s Brochure, dated \_\_\_\_\_, Version no. \_\_\_\_\_
- Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.
- Principal Investigator’s current CV.
- Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.
- Investigator’s Agreement with the Sponsor.
- Investigator’s Undertaking (Form III).

The following members of the ethics committee were present at the meeting held on (date, time, and place).

\_\_\_\_\_ Chairman of the Ethics Committee

\_\_\_\_\_ Member secretary of the Ethics Committee


\_\_\_\_\_ Name of each member with designation

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.


**Yours sincerely,**

**Member Secretary, Ethics Committee.**

  
Prepared by

  
**Principal**  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

Approved by

	<b>SRI DEVARAJ URS COLLEGE OF NURSING TAMAKA, KOLAR – 563 103.</b>	<b>Format No.</b>	<b>IEC 01</b>
		<b>Issue No.</b>	<b>03</b>
	<b>INSTITUTIONAL ETHICS COMMITTEE</b>	<b>Rev No.</b>	<b>02</b>
		<b>Date</b>	<b>01-09-2018</b>

Ref.:No.SDUCON/IEC/ /2021-22

Date:

From  
The Institutional Ethics Committee,  
Sri Devaraj Urs College of Nursing,  
Tamaka, Kolar-563 101.  
To,

This is to certify that the institutional ethics committee of Sri Devaraj Urs College of Nursing, Tamaka, Kolar has examined and unanimously approved the M.Sc.(N) Topic “ \_\_\_\_\_ ” of Ms/Mr. -----, Under the guidance of -----, Sri Devaraj Urs College of Nursing and Co-Guide \_\_\_\_\_ Professor and HOD of SDUCON, Kolar.


**Member Secretary**

**Chairperson**



**Principal**  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

Approved by

	<b>SRI DEVARAJ URS COLLEGE OF NURSING TAMAKA, KOLAR – 563 103.</b>	<b>Format No.</b>	<b>IEC 01</b>
	<b>INSTITUTIONAL ETHICS COMMITTEE</b>	<b>Issue No.</b>	<b>03</b>
		<b>Rev No.</b>	<b>02</b>
		<b>Date</b>	<b>01-09-2018</b>

Ref.:No.SDUCON/IEC/ /2019-20

Date:

This is to certify that the Institutional Ethics committee of Sri Devaraj Urs College of Nursing, Tamaka, Kolar has examined and unanimously the following projects

Sl. No	Name of the Topic	Guide	Investigator	Accepted/ Not accepted	Remarks

Sl. No.	Name	Signature
1	Dr.Dayanand	
2	Dr.Prabhakar K	
3	Dr.Asha B	
4	Mr.Ganesh	
5	Achary Chinmayananda Avadutha	

Member Secretary


Chairperson  
IEC (Human studies)



Principal  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

  
Prepared by

Approved by

	<b>SRI DEVARAJ URS COLLEGE OF NURSING</b>	<b>Format No.</b>	<b>IEC 01</b>
	<b>TAMAKA, KOLAR – 563 103.</b>	<b>Issue No.</b>	<b>03</b>
	<b>INSTITUTIONAL ETHICS COMMITTEE</b>	<b>Rev No.</b>	<b>02</b>
		<b>Date</b>	<b>01-09-2018</b>

**Form -1**

**Initial check list to verify completeness of documents submitted**


**For Office use only**


<b>Sl. No</b>	<b>Content</b>
1	Two (for UG projects/ PG dissertation/ Ph.D thesis/ ICMR Faculty/ studentship) copies of proposal for Ethics committee
2	Performa completely filled & duly signed by the investigators
3	Consent form for patients in English / Local Language
4	case the research involves a study product (such as a pharmaceutical or device under investigation In, an adequate summary of all safety, pharmacological pharmaceutical and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g.: recent investigator's brochure published data, a summary of the product's characteristics); (Product information)
5	Investigator(s) curriculum vitae (updated, signed and dated) if applicable
6	Material to be used (including advertisements) for the recruitment of potential research participants;
7	A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants;
8	A description of the arrangements for indemnity, if applicable
9	A description of the arrangements for insurance coverage for research participants, if applicable
10	A statement of agreement to comply with ethical principles set out in relevant guidelines



Principal  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

Approved by

  
Prepared by

	<b>SRI DEVARAJ URS COLLEGE OF NURSING TAMAKA, KOLAR – 563 103.</b>	<b>Format No.</b>	<b>IEC 01</b>
	<b>INSTITUTIONAL ETHICS COMMITTEE</b>	<b>Issue No.</b>	<b>03</b>
		<b>Rev No.</b>	<b>02</b>
		<b>Date</b>	<b>01-09-2018</b>

**Form-2**

**Acknowledgement Letter**

Institutional Ethics Committee has received entitled -----

-----  
-----  
-----

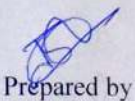
-----IEC Register No. of the  
above research proposal is -----.

**Member Secretary**




Principal  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

Approved by



Prepared by

	SRI DEVARAJ URS COLLEGE OF NURSING TAMAKA, KOLAR – 563 103.	Format No.	IEC 01
		Issue No.	03
	INSTITUTIONAL ETHICS COMMITTEE	Rev No.	02
		Date	01-09-2018

### Form-3

### Declaration Form


I Dr/Mr./Mrs./Ms \_\_\_\_\_ hereby declare that I will not disclose identity of the research participants any time during or after the study period or during publication.

### Signature of Investigator



Principal  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

Approved by

	<b>SRI DEVARAJ URS COLLEGE OF NURSING</b>	<b>Format No.</b>	<b>IEC 01</b>
	<b>TAMAKA, KOLAR – 563 103.</b>	<b>Issue No.</b>	<b>03</b>
	<b>INSTITUTIONAL ETHICS COMMITTEE</b>	<b>Rev No.</b>	<b>02</b>
		<b>Date</b>	<b>01-09-2018</b>

**Annexure -IA**

No. SDUCON/ / 2021-22

Date:

**Notification  
Ethical Committee**

The Ethical Committee meeting of SDUCON is planned on \_\_\_\_\_, \_\_\_\_\_ at \_\_\_\_\_ in the Council Hall of SDUCON for the purpose of according Ethical Clearance to M.Sc(N)/ B.Sc(N)/ Faculty Research Projects for the academic year \_\_\_\_\_.

All the members are requested to attend the same.

Thanking you,

**Member Secreatry**

**(Mrs. Gayathri K V)**


**Principal**

**Copy to:**

1. Dr. Reddemma K, Chairperson, for kind information & needful.
2. Dr. Dayanannd
3. Dr. Prabhakar K
4. Dr. Asha B
5. Mr. Ganesh
6. Acharya Chinmayananda Avadhutha, Ananda Margha School.



**Principal**  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

	<b>SRI DEVARAJ URS COLLEGE OF NURSING</b>	<b>Format No.</b>	<b>IEC 01</b>
	<b>TAMAKA, KOLAR – 563 103.</b>	<b>Issue No.</b>	<b>03</b>
	<b>INSTITUTIONAL ETHICS COMMITTEE</b>	<b>Rev No.</b>	<b>02</b>
		<b>Date</b>	<b>01-09-2018</b>


**Annexure 2A: Application form for Ethics approval -Students**

1	Name of the student & Address	
2	Name of the Guide & Department	
3	Title of the Project	
4	Objectives of study, hypothesis & Assumption, operational definitions	
5	Justification/ need for conduct of study	
6	Review of literature	
7	Methodology- it should provide detail of materials and method	
8	Method of data analysis	
9	Bibliography	
10	Ethical issue involved in study invasive & Noninvasive, if yes give details.	
11	Source of funding if applicable	
12	Cost involved if applicable.	
13	Permission from Drug Controller General of India, if applicable.	
14	Whether patient information sheet & consent form in local language is enclosed.	
		<b>Signature of investigator</b>


  
Principal

Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

Approved by

  
Prepared by



	<b>SRI DEVARAJ URS COLLEGE OF NURSING</b> <b>TAMAKA, KOLAR – 563 103.</b>	<b>Format No.</b>	<b>IEC 01</b>
		<b>Issue No.</b>	<b>03</b>
	<b>INSTITUTIONAL ETHICS COMMITTEE</b>	<b>Rev No.</b>	<b>02</b>
		<b>Date</b>	<b>01-09-2018</b>

**Annexure 2B: Application form for Ethics approval – Faculty**


1	Name of the Principal investigator and department	
2	Name of co-investigator (s) & department	
3	Title of the Project	
4	Objectives of study & hypothesis	
5	Justification/ need for conduct of study	
6	Review of literature	
7	Methodology- it should provide detail of materials and method	
8	Statistical method employed for analysis of data	
9	Bibliography	
10	Ethical issue involved in study invasive & Non invasive, if yes give details.	
11	Source of funding if applicable	
12	Cost involved if applicable.	
13	Permission from Drug Controller General of India, if applicable.	
14	Whether patient information sheet & consent form in local language is enclosed.	
		<b>Signature of investigator</b>



Principal

Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

Approved by

	<b>SRI DEVARAJ URS COLLEGE OF NURSING TAMAKA, KOLAR – 563 103.</b>	<b>Format No.</b>	<b>IEC 01</b>
		<b>Issue No.</b>	<b>03</b>
	<b>INSTITUTIONAL ETHICS COMMITTEE</b>	<b>Rev No.</b>	<b>02</b>
		<b>Date</b>	<b>01-09-2018</b>

**Annexure -3**

**Members list of Institutional Ethics committee (Human Research)**

Sl. No.	Name and Address	Gender	Qualification	Email ID	Position	Affiliation with the Institute
1	Dr. Prashanti Additional Professor NIMHANS	Female	Ph.D(N)	Padi89@gmail.com	Chair Person	No
2	Dr. Dayanand Dean-AH &BS SDUAHER Tamaka Kolar-563103 Mobile-	Male	MD Biochemistry	Dean.ahs@sduaher.ac.in	Member	Yes
3	Dr.Prabhakar K Prof. and HOD of medicine SDUMC, Tamaka, Kolar-563103 Mobile-	Male	MD General Medicine	drprabhakar@yahoo.in	Member	Yes
4	Dr. Asha B Professor Dept. of Pharmacology, SDUMC, Tamaka, Kolar563103 Mobile-	Female	MD Pharmacology	dr.ashareddy@gmail.com	Member	Yes
5	Mr. Ganesh District reporter Sanjay vani 242-Sri Ganesh Nilaya, Gulpete,Kolar Mobile-	Male	Generalist	Ks.ganesh1@gmail.com	Member	No
6	Acharya Chinmayananda Avadhutha, Ananda Marga School, Kitthanduru, Thotli Post, Kolar (T&D) Mobile-9448310979	Male		dadacinmaya@gmail.com	Member	No
7	Mrs. Gayathri K V Assoc. Professor Dept. of OBG, SDUCON, Tamaka, Kolar-563103 Mobile-	Female	M.Sc. (N)	Gayathrikv88@gmail.com	Member Secretary	Yes

ACAR-2

*[Handwritten Signature]*  
20/12/20

*[Handwritten Signature]*

Principal  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

Prepared by

**Annexure -4**

Ref No. SDUCON/ 2021-22

Date:

**APPRECIATION LETTER**

To,

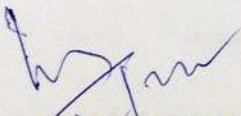
Dear Sir/Madam,


We appreciate and thank you for your support and contribution towards involvement in Institutional Ethical committee as a **Member/chairperson** from \_\_\_\_\_ to \_\_\_\_\_

Thanking You,

ADAR-2

Principal

  
**NAAC CO-ORDINATOR**  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

  
**Principal**  
Sri Devaraj Urs College of Nursing  
Tamaka, Kolar-563103

  
Prepared by

Approved by