



Ethics Review Committee  
Guidelines  
**KLE Technological University, Hubballi**  
**2015**  
(Established under Karnataka Act No.22, 2013)



**KLE** Technological  
University  
Creating Value  
Leveraging Knowledge



**Content of Ethical Review Policy**

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## 1. Introduction and purpose

The motto of the KLE Technological University is 'Creating Value and Leveraging Knowledge'. The mission of the University is to embrace the ethics of discovery, to inspire and encourage research by acquiring, investigating and developing knowledge for the good of society, and to ensure that all research is carried out in accordance with ethical principles.

The paramount principle governing all the research activities at KLE Tech involving human participants, personal data and human tissue is to respect the participant's dignity, rights, safety and well-being.

## 2. Participant's rights

Participants have a right, as a principle of research ethics, to:

- a) be fully informed about how and why their data will be collected and used as part of a research project, and by whom;
- b) consent to participate, withdraw from, or refuse to take part in research projects;
- c) maintain confidentiality (personal information or identifiable data should not be disclosed without participants' consent);
- d) ensure security of their data (data and samples collected should be kept secure and anonymised wherever appropriate);
- e) guarantee safety (participants should not be exposed to unnecessary or disproportionate levels of risk), and;
- f) request for erasure of their data if and when it is no longer required for research purposes.

## 3. Researchers' obligations

Researchers have an obligation to ensure that their research is conducted with:

- honesty;
- integrity;
- minimal possible risk to participants and to themselves; and
- respect for other people, their values and their cultures.

Guidance on the interpretation and application of these principles is detailed in this Policy document. The principles and requirements outlined in this Policy reflect the principles of research ethics but do not displace a researcher's obligation to comply with any relevant legal and regulatory requirements and their responsible management. Ethical research is therefore a matter of being risk aware, not risk averse. This policy specifies an ethics review procedure that is evolved to academic departments.

## 4. INTRODUCING RESEARCH ETHICS

The University's definition of research is as stated in the KLE Research Policy Document of KLE Technological University 2015. This applies to all research undertaken by, or on behalf of, the University, across all academic disciplines of KLE Tech.

The University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue, applies only to research involving human participants, personal data and human tissue.

### **5. RESEARCH ETHICS AT KLE Tech**

The University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue recognises that the responsibility for maintaining ethical conduct lies, in the first instance, with researchers themselves. If researchers do not take responsibility for the ethical conduct of their own research, defensible research ethics will be an unrealisable goal. To this end, responsibility for operating the University's Ethics Review Procedure, informed by the Policy, is devolved to academic departments and funding units.

This means that the formal ethical review of research proposals involving human participants, personal data or human tissue is carried out within the broad parameters provided by this Policy and the Research Ethics Approval Procedure.

The University Research Ethics Committee (UREC) is responsible to the University's Academic Council for: Reviewing the Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue every 3 years and reporting its findings to the University's Academic Council;

- Offering guidance within the University on the interpretation of the Policy;
- Resolving disputed or uncertain ethics approval decisions;
- Auditing and accrediting the ethics review arrangements in place on at least a 3 yearly basis, and monitoring the ethics review arrangements.
- In the event of concerns arising about whether a research proposal or ongoing research activity complies with the Policy, suspending the approval process, or the research activity in question, pending further investigation;
- Actively promoting awareness and knowledge of the Policy, and research ethics more generally, within the University via training events and other activities;
- Keeping abreast of externally-driven developments, policies and regulations concerning research ethics, and ensuring that the University meets all necessary requirements;
- Providing advice on any ethical matters relating to research that are referred to it from within the University.

### **6. SCOPE AND APPLICABILITY OF THE RESEARCH ETHICS POLICY**

- The University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue applies to:
- All faculty and students who conduct, or contribute to, research activities involving human participants, personal data or human tissue, whether these take place within or outside University premises and facilities, or are part of a work placement undertaken in fulfilment of a University degree award; and

- all individuals who, although they are not members of the University, conduct, or contribute to, research activities involving human participants, personal data or human tissue that take place within University premises and facilities.

## 7. RESEARCH ETHICS APPROVAL PROCEDURE

The University's approach to research ethics requires that all research involving human participants, personal data, or human tissue should be reviewed, and research ethics approval obtained, before data gathering commences.

## 8. COMPOSITION : Institutional Ethics Committee for Human Research (IEC)

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The members are supposed to attend meetings arranged at the University for reviewing the research proposals in light of ethical concerns by invitation against receipt of an application from the candidate for approval. It is the responsibility of the candidate as well as supervisor/s to make sure that such ethical approval has been obtained prior to any data collection/analysis taking place. Applications for ethical approval should be submitted to the ethical committee with necessary documents. Approval from REC is required for the following cases:

**Sources of Data** All research that involves collecting new data from human participants and/or using pre-existing personal data. It covers all forms of collection process, e.g. experimental procedures/retreatment/intervention, focus group, telephone/internet survey, observation, personal interviews, or self-administered questionnaire, etc. It also includes physical settings, particularly in architectural research, whose anonymity needs to be safeguarded.

**Usage of pre-existing data** refers to retrieving readily available personal data from existing documents/records for secondary analysis, irrespective of whether or not the data are publicly available, whether or not the data originally collected are intentionally for research purpose, and whether the personal data from existing documents/records will be extracted for secondary analysis.

Candidate should safeguard participant's privacy and confidentiality. Candidate should inform participants how their provided data will be deployed in the research, and how and how long the data will be safely kept.

**Informed Consent** Researchers must accordingly obtain appropriate informed consent assure the voluntary capacity of the participant by providing sufficient opportunity to

consider whether or not to participate, and minimizing the possibility of coercion, undue influence, or harassment.

**Parental Consent** The candidate should be to seek written consent from parents and to obtain assent from students themselves for research involving children under 18, even in cases where children were able to decline participation.

**Privacy and Confidentiality** of Data Researchers must maintain the confidentiality of data related to individual research participants. Except by public observation, researchers should clearly indicate the purpose of the collection of data and the method to ensure the confidentiality of collected data. Researchers must also avoid use of any personal identifiers such as individual names and addresses in their research reports which could lead to the human participants being identified.

**Benefits** Prospective participants should not be adversely induced by financial reward or be pressured to participate in research. All reimbursement of expenses, such as traveling expenses, should be commensurate with standard practice and be reasonable.

**Studies Involving External Parties** If an external party is involved in co-organizing the research project (e.g. in recruitment or data collection), a formal contract/letter of agreement or consent form should be signed before commencement of the project, and such document should be submitted together with the ethical application.

### APPROVAL PROCESS

**Approved:** A letter of approval will be issued to the PI with indication of the ethics approval period granted.

**Conditionally Approved:** The approval letter will be issued with comments/concerns need to be satisfactorily addressed.

**If Approval is Not Given:** The Committee will specify its comments/recommendations on the notification to the PIs of protocols which are not approved.

**Reconsideration of Decision:** The Committee will further consider the resubmitted proposals according to the Committee's recommendations.

The formats and guidelines for the various R&D activities as envisaged in the aforesaid provisions made in this document shall be prepared and approved by the competent academic bodies of the University from time to time. The approved guidelines are shared with the faculty time to time.

Dean R & D

KLE Technological University, Hubballi