SANSKRITI UNIVERSITY

FOR EXCELLENCE IN LIFE

RESEARCH ETHICS POLICY

Established under section 2(f) of UGC Act, 1956

Campus - 28 K. M. Stone, Mathura - Delhi Highway, Chhata, Mathura (U.P.)

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Notification

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Focusing on the ethical acceptability of research related to financial, chemical, clinical, animal, scientific aspects etc. pertaining to protect dignity, rights, safety & well being of all participants throughout the potential research, Research Ethics Policy has been framed under the regulation of Sanskriti University and approved by Academic Council during the First meeting held on 07.11.2016, which is to be implemented w.e.f. the date of notification.

Research Ethics Policy

Research Ethics govern the standards to conduct research in scientific manner. These focus the ethical acceptability of research before participants can be enrolled in a study. In addition, it examines certain domains related to financial aspects, scientific aspects, clinical aspects, chemical, animal and bio ethics pertaining to protect dignity, rights, safety and well-being of all participants throughout potential research. The norms such as knowledge truth, avoidance of error etc. promote the aims of research. Prohibition against fabricating falsifying or miss presenting research data promote the truth and minimize error. The propose of a code of ethics is to establish a set of standards, guide decision making, enhance reputation, encourage accountability, foster a positive work environment and promote continues improvement in ethical behavior related to research endeavors. Research ethics provide a frame work to ensure that research is conducted properly with respect for humans and others subjects involved by following established moral principals human and professional standards.

Research Ethics adhere to the following considerations in a logical manner with moral principles:

I. Obtaining informed consent from research participant
II. Minimizing/no risk of harm to participants at any cost
III. Protecting their anonymity & confidentiality
IV. Avoiding using deceptive practices
V. Giving participants the right
VI. Not compelling participants to give information without willingness/consent
VII. Maintaining social and clinical values
VIII. Respecting for potential and enrolled subject
IX. Selecting fair subject with justice
X. Using independent review
XI. Using fair and justified research methodology
XII. Striving for honesty in scientific communication report writing data collection methods and processors result preparation and publication status
XIII. Avoiding falsification, fabrication, miss presentation of data and plagiarism

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University Research Ethics Committee (UREC)

UREC should provide independent, competent and timely review of the ethics of proposed studies before the commencement of a study and regularly monitor the ongoing studies.

UREC will review and approve all research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of research participants irrespective of the source of funding. The goals of research, however important, should never be permitted to override the health and well being of the research subjects.

The UREC will ensure that all the cardinal principles of research ethics viz autonomy, beneficence, non-malfeasance and justice are taken care of in planning, conduct and reporting of a proposed study. It will look into the aspects of informed consent process, risk benefit ratio, distribution of burden/benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through periodic reports, final report and site visits etc. The committee will also ensure compliance with all regulatory requirements, applicable guidelines and laws.

Membership Duration and Responsibilities

1. The duration of the membership will be 3 year
2. There will be no bar on the members serving for more than one turn but it is desirable to have around one third fresh member's
3. A member can be replaced in the event of long term non-availability. Authority to replace the member shall be with the Director.
4. Members should maintain confidentiality of all discussion.

Quorum Requirements

A minimum of 5 members including at least three outside members is required for quorum. All decisions should be taken in meetings and not by circulation of project proposals.

Conduct of the Meeting

The Chairperson will conduct all meetings of the UREC. If for reasons beyond control, the Chairperson is not available, an alternate Chairperson will be elected by the members present from among themselves. The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicating with all concerned, He/she will prepare the rates of the meetings and get them approved by the Chairperson before communicating to the PI.

Review Procedure

1. Meetings of UREC shell be held on scheduled intervals as prescribed (once in 3 months; for which the dates will be decided at the end of previous meeting) Additional meetings will be held as and when necessary.
2. The proposals will be sent to members at least 2 weeks in advance.
3. Decision will be taken by consultants after decisions, and voting will be done if necessary.

4. PI should be available during the meeting and may be invited to offer clarifications.
5. Independent consultants/Experts may be invited to offer their opinion on specific arch proposals.
6. The decisions of the meeting shall be recorded in the minutes book and shall be fired during the next meeting with signature of Chairperson at each page.

Independent Consultants

UREC may call upon subject experts as consultants for review of selected research protocols, these experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest group's patients, HIV/AIDS patient persons or ethnic minorities. They will not take part in the decision making process.

Element of Review

1. Scientific design and conduct of the study.
2. Approval of scientific review committee and regulatory agencies.
3. Assessment of predictable risks/hares and potential benefits.
4. Procedure for selection of subjects including inclusion/exclusion, withdrawal criteria and other issues like sample size and advertisement details.
5. Management of research related injuries, adverse events and compensation provisions.
6. Availability of products to the trial subjects after the study, if applicable.
7. Patient Information sheet and informed consent form in English/Hindi and local language.
8. Protection of privacy and confidentiality of subjects.
9. Involvement of the community, wherever necessary.
10. Protocol and Performa of the study including the consent form.
11. Plans for data analysis and reporting.
12. Adherence to all regulatory requirements and applicable guidelines.
13. Competence of investigators, research and supporting staff.
14. Facilities and infrastructure.

Expedited Review

Proposals which are recommended for minor revisions will be reviewed by a sub committee appointed by the EC for clearance and approved by the Chairperson. The approvals will be reported in the next UREC meeting by Member Secretary The revived forms of proposals requiring major changes will be reviewed at the next ethics committee meeting, Rejected proposals may be reconsidered only it a very strong background is there.

Decisions Making

1. A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest scores. This shall be indicated to the chairperson prior to the review of the application and recorded in the minutes.
2. Only members will make the decision. The decisions shall be taken in the absence of Investigators, representatives of sponsors, consultants.
3. Decision may be to approve reject revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
4. Revised proposals may be subjected to an expedited review.

5. All approved proposals will be subject to the following standard conditions. Additional conditions may be added by the UREC.

i. PI should submit annual report of the ongoing project on format presented by the Institute, to the UREC.
ii. The final report of the completed study should be submitted by PI.
iii. The PI should highlight the changes in the protocol/brochures/informed consent form etc. being amended from the previous documents while submitting amended documents to UREC.

Communicating the Decision

1. Decision will be communicated to PI by the Member Secretary in writing.
2. Suggestions for modifications and seasons for rejection shall be communicated to the PI.

Follow up Procedures

1. Annual report should be submitted by the PI prescribed format along with comments.
2. Final report should be submitted at the end of study on prescribed format including a copy of the report which has been sent to sponsoring agency.
3. Protocol deviation if any, should be informed with adequate justifications.
4. Any amendment to the protocol should be submitted for approval.
5. Any new information related to the study should be communicated to UREC.
6. Premature termination of stay should be notified with reasons along with summary of the data obtained so far.
7. Change of investigator should be done with the approval of UREC.

Record Keeping and Archiving

1. Curriculum Vitae (CV) of all members of UREC.
2. Minutes of all meetings duly signed by the Chairperson. Copy of all correspondence with members, researchers and other regulatory bodies.
3. Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.
4. All study related documents should be archived for minimum of ten years after the completion of study. A copy of filed CRF shall remain with the PI for minimum of fifteen years.
5. Final report of the approved projects.

Stated Code of Ethics

- Conscientiousness
- Openness
- Transparency
- Fairness and Integrity
- Objectivity
- Responsibility
- Independence
- Reliability
- Courage
- Concern
- Confidentiality

Conscientiousness in portraying the objectives and intentions of planned or ongoing research, outlining research methods and procedures, interpreting the results, and communicating information about possible threats and well-substantiated predictions regarding benefits and possible applications.

Openness in discussing one's own research with other researchers, which is one of the key conditions for advances in science and contributes to the accumulation of knowledge through the publication of research results, as well as in communicating this knowledge honestly to the public.

Transparency in documenting research, ensuring data availability after the research results is published.

Fairness and Integrity in evaluating the merits and ethical aspects of the work of other researchers and in reviewing and recognizing the scientific achievements of those to whom such recognition is truly due, by properly citing sources and honestly recognizing their contributions to scientific achievements

Objectivity interpretations and conclusions must be based exclusively on facts, verifiable reasoning, and data that can be confirmed by others.

Responsibility towards the subjects of research; studies involving human or animal subjects can only be carried out when this is necessary and with respect for human dignity and animal rights, on the basis of approval issued by the relevant ethics committees, including bioethics committees. Also, researcher's responsibility for the socioeconomic and environmental consequences of the conclusions are formulated and considered.

Independence from external influences over the conduct of research, with respect to both those who commission studies or expert opinions, and to political, ideological, religious, or economic pressure groups.

Reliability in conducting research, a critical approach towards the results, meticulousness, attention to detail, and care in the presentation of research findings.

Courage to oppose views contrary to scientific knowledge and practices incompatible with the principles of research integrity.

Concern for future generations of researchers, manifested not only in respect for coworkers, their fair treatment, and support for their scientific development, but also in the communication of binding standards and ethical norms.

Confidentiality relating to the extend to which the researcher protects the participant's private information/Privacy**.**

Composition of University Research Ethics Committee:

S. No.	**Name**	**Position in Committee**
1	Vice Chancellor	Chairperson
2	Dean, Research	Convener
3	Basic Medical Scientist	Member
4	Bio-technology	Member
5	Legal Expert	Member
6	Social Scientist/ NGO	Member
7	Educationist from the community	Member
8	Ex-officer from Industry	Member
9	HOD (Selected by Dean Research)	Member Secretary