DEEN DAYAL UPADHYAYA GORAKHPUR UNIVERSITY

GORAKHPUR

POLICY DOCUMENT

Internal Quality Assurance Cell (IQAC)

RESEARCH ETHICS POLICY AND COMMITTEE

RESEARCH ETHICS POLICY AND COMMITTEE

Maintaining ethics in research and governance is important in organizations that perform research. This necessitates the development of appropriate research guidelines, as well as the public release of scientific/technical/biomedical data and findings and their use in scientific administration at all levels.

The University Committee for Research Ethics in the Sciences, Social Sciences, Humanities and Law is an independent administrative agency under the Deen Dayal Upadhyaya Gorakhpur University, Gorakhpur.

It should serve as a consultative body for research ethics guidelines and advice. It should set out the guidelines, which are crucial resources for encouraging good scientific practice in the university research framework.

VISION

This ethics committee's mission is to create guidelines for ethical research and to educate researchers and the research community about accepted research ethics standards. They're meant to aid in the development of ethical discretion and reflection, as well as the clarification of ethical dilemmas and the promotion of good scientific practice. They're also meant to keep scientific fraud at bay. They can be used in a variety of ways, including assessing individual cases, organizing research projects, and documenting and publishing findings and reports.

RESEARCH ETHICS

Research ethics encompasses a broad range of principles, standards, and institutional structures that help to define and govern research activities. Research ethics is a practical codification of scientific morality. The basic norms and principles of the research community are defined in research ethics guidelines. They are focused on general scientific ethics, just as general ethics is based on societal morality.

SCIENTIFIC MISCONDUCT

Scientific misconduct is when anyone publishes professional scientific research without observing the laws of academic conduct and ethics. All acts ranging from the conception of an idea to its experimental verification, accuracy of results, accurate reporting without resorting to any malpractice in the presentation of data/images, and due recognition of all sources of information and people fall under this category.

STATEMENTS OF THE POLICY

- Institutional Research Ethics Committee of research studies (IREC)
- A research study may be started only after it should be reviewed and approved by the Institutional Ethics Committee in writing. The IEC will assess the study in terms of the ethical guidelines.
- The above criterion applies to all research projects, including faculty or student research projects, as well as, dissertations and theses. For research studies authorized by a reputable external research funding agency / entity, review by the Institutional Ethics Committee may be waived.

- The processes for forming and operating the Institutional Research Review Board(s), as well as the standards that Investigators must meet, will be governed by the Standard Operating Procedures developed for the purpose.

The Institutional Research Ethics Committee (IREC) centre at Deen Dayal Upadhyaya Gorakhpur University has developed a systematic ethical scrutiny mechanism to resolve related ethical concerns, which is subject to effective ethical review.

- The approval of an ethical committee is necessary to protect both the researchers conducting the study and the freedom, protection, integrity, and well-being of research participants.
- Obtaining ethical approval also makes it easier to conduct ethical research that benefits both participants and society.
- The centre will ensure that the research it conducts is of a high ethical standard, has sound credibility, and is done in compliance with good research governance and legal standards with the aid of an independent committee's ethical approval.

COMPOSITION OF IREC

IREC should be multi-disciplinary and multi-sectoral. There should be adequate representation of age and gender. 50% of the members should be non-affiliated or from outside the institution. The number of members in an IREC should preferably be between seven and 15 and a minimum of five members should be present to meet the quorum requirements. Members are expected to attend meetings held at the centre for the purpose of evaluating research proposals in light of ethical questions, which they are invited to do upon receipt of a candidate's application for approval. It is the candidate's and supervisor's duty to ensure that such ethical approval has been obtained prior to any data collection or review. Applications for ethical approval, along with all necessary documentation, should be sent to the centre. This committee must operate in a transparent manner, be independent of the researcher, sponsor, and any other undue influence. It must take into account the laws and regulations of the country.

Chairperson: Senior Most Dean of the Faculty of Arts/Science/Commerce/Law/Education (Conduct IREC meetings and be responsible for the committee's independent and productive operation).

Internal Members: One Senior Professor from each of Faculty of Arts/Science/Commerce/Law/Education of university nominated by the Vice-chancellor of DDU Gorakhpur University, Gorakhpur

External Members: Five Professors of repute from other university/research institutes/institutions nominated by the Vice-chancellor of DDU Gorakhpur University, Gorakhpur

IREC members' terms of reference: The following should be included in the letter issued by the Vice Chancellor to IREC member to be appointed-

- The committee member's position and responsibilities
- The appointment's length
- Terms and conditions of jobs

The period of IREC membership is for usually for 3 years, but can be extended. On a regular basis, a certain percentage of IREC members could be updated. For attending the meeting, IREC members will be paid a generous honorarium. Members should be selected in their personal capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the IREC.

RESPONSIBILITIES OF IREC, RESEARCHERS AND INSTITUTIONS AND APPROVAL GUIDELINES

- **The protection of human participants**: Human subjects study must follow widely accepted scientific principles and be focused on a detailed understanding of the scientific literature, other applicable sources of evidence, and sufficient laboratory and animal experiments, as necessary.

- **Animal experimentation**: Animals used in testing must be treated with care.Those who perform animal experiments must adhere to all relevant laws and regulations, including the Prohibition of Cruelty to Animals Act, 1960, as amended in 1982, the Breeding and Experimentation Rules, 1998, as amended in 2001 and 2006, the Guidelines for Treatment and Use of Animals in Scientific Research (Indian National Science Academy, 1982, as amended in 2000), and the ICMR Guidelines on Humane Causing of Animals.

- **Research protocol** must clearly explain and justify the design and conduct of each research study involving human subjects. A statement of the ethical issues involved should be included in the protocol, as well as how the values of this Declaration have been discussed. Details about funding, sponsors, institutional affiliations, possible conflicts of interest, topic benefits, and arrangements for managing and/or compensating subjects who are injured as a result of participating in the research study should all be included in the protocol.

- **Data Collection**: Both study involving the collection of new data from individual subjects and/or the use of previously collected personal data. It includes all types of data collection methods, such as focus groups, telephone/ internet surveys, observation, informal interviews, and self-administered questionnaires, among others. It also involves physical environments, which must be kept anonymous, particularly in architectural study. The term "use of pre-existing data" refers to the retrieval of readily accessible personal data from existing documents/ records for secondary analysis, regardless of whether the data are publicly available, whether the data is gathered for research purposes, or whether the personal data from existing documents/records would be retrieved for secondary analysis.

- **Risk Analysis**: Candidates should carefully consider whether the research study would include any potential hazards that may cause more than minimal physical and/or psychological stress/pain/discomfort to participants

to ensure that their interests and rights are protected. If there are threats, participants should be told about the nature and severity of the risk they may be taking, as well as the steps that will be taken to mitigate the risk and the remedial assistance that will be provided to those who are at risk.

- **Informed Consent**: Researchers must obtain adequate informed consent in order to ensure the participant's voluntary capacity by giving them enough time to decide whether or not to participate and mitigating the risk of intimidation, undue control, or abuse.
- **Privacy and Confidentiality**: The candidate must protect the privacy and confidentiality of the participants. Participants should be informed about how their data will be used in the study, as well as how and for how long the data will be stored safely.
- **Collaborative Research**: If an outside party is involved in co-organizing the research project (for example, in recruiting or data collection), a written contract/letter of agreement or consent form should be signed before the project begins, and this document should be submitted with the ethical application.
- **Potential for conflict of interest:** A conflict of interest (COI) is a collection of circumstances under which a professional's judgment on a primary interest, such as the wellbeing of subjects or the validity of study, is unduly affected by a secondary interest, either financial or non-financial (personal, academic or political). Researchers, IREC members, institutions, and sponsors may all have COI. If COI is a factor in the study, it's critical to acknowledge it right away and put in place mechanisms to deal with it.
- **Selection of vulnerable and special groups as research participants:** Vulnerable groups and individuals may be more vulnerable to more damage because they are relatively (or completely) incapable of defending their own interests. Legal status – children; clinical conditions – cognitive impairment, unconsciousness; or situational conditions – including but not limited to being economically or socially disadvantaged (for example, certain ethnic or religious groups, individuals/communities with hierarchical relationships, institutionalized persons, humanitarian emergencies) are all characteristics that make people vulnerable. In general, such groups can only be used in research if it specifically discusses the group's health needs or specifications. Vulnerable people, on the other hand, have an equal right to be included in research so that the research's benefits can be shared with them. Researchers as well as the European Commission must think about this carefully. The IREC should evaluate the risk and ensure that additional precautions and monitoring measures are placed in place. In this respect, it should also inform the researcher.
- Since research methods in the social and behavioral sciences are not always positivist, articulation of a hypothesis may not be feasible at the outset of the study. Instruments/documents are generated during the analysis process, are reflective, and can change as the study progresses. The EC must be kept aware of these changes, and participants must have sufficient re-consent.
- Prior approval from the IREC for audio/video recording of participant interviews must be obtained for justifiable reasons.

- **Deception in Study:** Deception happens when researchers provide participants with inaccurate or incomplete details in order to deceive them in order to achieve the study's goals and the greater good. Any study that uses manipulation should be subjected to a rigorous analysis by a committee. Any research that includes deception should: represent no more than a minor hazard; not jeopardize the participants' well-being and safety; only be used if the testing can't be carried out without deception; have a good strategy in place for debriefing the participants after the event and if necessary, disseminate study findings to participants; and be subjected to a detailed analysis by the IREC.
- **Qualitative Research:** Qualitative research produces interpretative information based on observation and interpretation by the researcher or research team, and it is socially constructed at both the individual and socio-cultural levels. Informed consent is often complex and negotiable in nature. Other methods could be used and registered if written approval is not possible. The IREC may investigate issues relating to the research design, such as researcher–participant relationships, informed consent, and research behavior. Preliminary observation for the purpose of taking notes does not need to be submitted to the EC for approval before starting study based on the observation. Any ethical questions that occur during this preliminary process, prior to data collection, should be included in the study proposal for IREC review. The IREC can authorize waiver of consent in some cases/in some observational studies if mechanisms for preserving privacy and confidentiality are justified.

PROCESS OF APPROVAL :

Approved: A letter of approval will be sent to the principal investigator, along with the length of the ethics approval period.

Conditionally Approved: The acceptance letter will include comments/concerns that must be resolved satisfactorily.

If Approval Is Not Given: The Committee will include its comments/recommendations on the notification of non-approved protocols to the PIs.

Reconsideration of the Committee's Decision: The Committee will consider the resubmitted proposals in light of the Committee's recommendations.

DOCUMENTS TO BE MAINTAINED BY IREC FOR RECORD

- The EC's role and obligations in ensuring the dignity, freedom, safety, and well-being of research participants.
- Ensure that the investigator team conducts research in an ethical manner.
- If there are any conflicts of interest, they must be declared to the Chairperson at each meeting and reported in the minutes.
- Perform its work by attending meetings, engaging in discussion and debates, and conducting a professional initial and ongoing analysis of all scientific, legal, medical, and social aspects of research proposals received by it in an impartial, timely, and independent manner.

- In terms of local community principles and traditions, ensure that basic ethical values and international scientific standards are observed.
- Assist in the creation and education of the research community (including researchers, clinicians, students, and others) at the given institute, in response to local healthcare needs.
- Ensure that individual privacy and data confidentiality, including records from EC meetings, are covered.
- Reviews progress reports, final reports, and AE/SAE and makes appropriate recommendations for participant treatment and risk minimization procedures, as needed.
- Wherever practicable, propose adequate compensation for research-related injuries.
- Monitoring visits to study sites will be made as required.
- Participate in research ethics continuing education programs and stay current on applicable guidelines and regulations.
- Ensure that various investigators from the same organization are doing the same or identical research. Research that is replicative should not be promoted, and the application of the same research to several funding agencies should be discouraged.