DEEN DAYAL UPADHYAYA GORAKHPUR UNIVERSITY

GORAKHPUR

POLICY DOCUMENT

Internal Quality Assurance Cell (IQAC)

INSTITUTIONAL HUMAN ETHICAL POLICY AND COMMITTEE (IHEC)

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As per the ICMR Ethical Guidelines for Biomedical Research On Human Participants that all proposals on biomedical research in Deen Dayal Upadhyaya Gorakhpur University, Gorakhpur, involving human participants should be cleared by an appropriate Institutional Human Ethics Committee; in this case, the IHEC- DDUGU to safeguard the welfare and the rights of the participants. The IHEC is entrusted not only with the initial review of the proposed research protocols before initiation of the projects but also has a continuing responsibility of regularly monitoring the approved programs to foresee ethics compliance during the project period.

The basic responsibility of the IHEC is to ensure a thoughtful review of all ethical aspects of the project proposals it receives objectively. IHEC will advise the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through the appropriate Technical Review Committee.

THE MAJOR ASPECTS THAT IHEC – DDUGU FOCUSES ON ARE AS FOLLOWS:

- To ensure that any research using human beings as participants in DDUGU shall follow the standards and principles prescribed for such trials in the ICMR Ethical Guidelines for Biomedical Research on Human Participants, and
- To protect the potential research participants' dignity, rights, and well-being.
- To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
- To assist in developing and educating a research community responsive to local health care requirements

COMPOSITION

IHEC is multidisciplinary and multisectoral in composition

1. Chair Person/ Clinical representative
2. Co-Chair Person/ Basic Bio- Medical Scientist
3. Member Secretary/ Basic Bio- Medical Scientist
4. 1-2 Clinical representative
5. Basic Bio- Medical Scientist
6. Social Science Scientist
7. Legal Expert
8. Lay person from the community (A literate person who has not pursued a medical science/health related career in the last 5 years and is aware of the local language, cultural and moral values of the community)

The members of the IHEC will be appointed for three years. The appointment procedure for membership will be followed to allow for continuity, the development and maintenance of expertise within the IHEC, and the regular input of fresh ideas. The membership can be renewed for another term of 3 years. However, there will be a one-year break after two terms before re-appointment. Membership extension will be based on the recommendation of the Chairperson and Member-Secretary of IHEC.

REQUIREMENTS FOR EC MEMBERS

Every EC member must:

1. Provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable;
2. Either be trained in human research protection and/or GCP at the time of induction into the EC or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy);
3. Be willing to undergo training or update their skills/knowledge during their tenure as an EC member;
4. Read, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time; sign a confidentiality and conflict of interest agreement/s;
5. Be willing to place her/his full name, profession, and affiliation to the EC in the public domain; and be committed and understanding to the need for research and for imparting protection to research participants in research.

RESPONSIBILITY OF IHEC:

The responsibilities of the IHEC are to ensure that following:

1. The research study protocols are sound in design, scientifically justified, and statistically valid.
2. The research studies are conducted according to the Indian Council of Medical Research and Good Clinical Practice guidelines.
3. The research study does not compromise rights, safety, and benefits of the patients/volunteers/study participants.
4. The research studies are conducted under the supervision of trained medical/bio-medical persons with the required expertise.
5. The research studies include only those patients or participant who has given voluntary and informed consent without any inducement or coercion.

Ethical approval of a research study: Each research proposal must be submitted to the appropriate institutional ethics committee for approval. It should be ensured that no research project is started unless Ethics Clearance/approval is obtained and that no retrospective/Post facto Ethics Clearance/Approval can be provided to research projects which were neither submitted nor vetted by the Institute Human Ethical Committee.

QUORUM REQUIREMENTS

The quorum of IHEC is decided by the presence of 50% plus one members of the total strength. In the case of clinical trials, as per the revised schedule Y of Drugs and Cosmetics Act 2005, the following specialties should be represented in the meeting.

1. One basic medical scientist (preferably one pharmacologist).
2. One clinician
3. One legal expert
4. Social scientist/ Philosopher/ theologian/ ethicist
5. Layperson.

No quorum should consist entirely of members of one profession or one sex. In the absence of the Chairperson, Co-Chairperson will chair the meeting. On a rare occasion of the absence of both, any member who is independent of the institution will chair the meeting as Acting Chairperson

PARTICIPATION OF INVESTIGATORS/EXPERTS IN IHEC:

IHEC may call upon subject experts who may provide special inputs on selected research protocols if need be. They are required to give their specialized views but not to take part in the decisions making process which will be made by the members of the IHEC only. Investigators whose proposals are to be discussed can also be called to present their cases to the IHEC.

APPLICATION PROCEDURE:

- All proposals should be submitted in the prescribed application form.
- All relevant documents with a checklist should be enclosed with the application form.
- Required number of copies of the proposal along with application and documents in prescribed format duly signed by Principal Investigator (PI) and Co-investigators/ Collaborators should be submitted to IHEC.

REVIEW PROCEDURE :

Researchers should submit research proposals as soft or hard copies to the Secretariat for review in the prescribed format and required documents as per EC SOPs. The EC should prepare a checklist for the required documents as given below. This list is subject to modifications depending on the type of research, EC SOPs, and institutional policies.

1. Cover letter to the Member Secretary
2. Application form for initial review
3. The correct version of the informed consent document (ICD) in English and the local language(s).
4. Case record form/questionnaire

5. Recruitment procedures: advertisement, notices (if applicable)
6. Patient instruction card, diary, etc. (if applicable)
7. Investigator's brochure (as applicable for drug/biologicals/device trials)
8. Details of funding agency/sponsor and fund allocation (if applicable)
9. Brief curriculum vitae of all the study researchers
10. A statement on COI, if any
11. GCP training certificate (preferably within 5 years) of investigators (clinical trials)
12. List of ongoing research studies undertaken by the principal investigator (if applicable)
13. Undertaking with signatures of investigators
14. Regulatory permissions (as applicable)
15. Relevant administrative approvals (such as HMSC approval for International trials)
16. MoU in case of studies involving collaboration with other institutions (if applicable)
17. Clinical trial agreement between the sponsors, investigator, and the head of the institution(s) (if applicable)
18. Insurance policy and Protocol

VULNERABILITY

Individuals/ groups/ populations are considered vulnerable if they are incapable of protecting their interests because of personal disability, environmental burdens, social injustice, lack of power, understanding or ability to communicate, or other reasons. Individuals are considered to be vulnerable if they are:

- Socially, economically or politically disadvantaged and susceptible to exploitation
- Incapable of making a voluntary informed decision for themselves or if their autonomy is compromised temporarily or permanently (e.g., unconscious people, differently abled)
- They can consent, but their voluntariness or understanding is compromised due to situational conditions.
- They are 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.

CLINICAL TRIALS OF DRUGS AND OTHER INTERVENTIONS

1. Clinical trials must be conducted in accordance with the Indian GCP guidelines, Declaration of Helsinki, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017), amendments to the Drugs & Cosmetics Act (1940), and Rules (1945) and other applicable regulations and guidelines.

2. Clinical trial interventions could be drugs, vaccines, biosimilars, biologics, phytopharmaceuticals, radiopharmaceuticals, diagnostic agents, public health or socio-behavioral interventions, technologies, devices, surgical techniques or traditional systems of medicine, etc.

3. An investigator should determine if the clinical trial is within the regulatory ambit and if so, all Central Drug Standards and Control Organisation (CDSCO) requirements should be followed.

4. If students are conducting clinical trials as part of their thesis, guides/and institutions should take the responsibilities of the sponsor.

5. Clinical trials must be prospectively registered with CTRI, which is mandatory for trials under the purview of CDSCO.

6. ECs should register and follow the quorum requirements specified by CDSCO before reviewing clinical trials on 'new drugs' as per Schedule Y and its amendments.

7. Ancillary care may be provided to clinical trial participants for non-study/trial-related illnesses arising during the period of the trial.

8. Adverse effects of drugs should be reported promptly.

9. Institutions must obtain grants, insurance coverage, or set up corpus funds to meet the costs related to treatment/ management and payment of compensation as decided by EC.

10. Clinical trials should be scientifically and ethically sound, and preclinical studies should precede trials on humans.

11. BA/BE studies involving healthy volunteers may pose risks due to adverse effects of drugs and require safeguards.

12. Precautions should be taken to protect participants from harm when a placebo is used.

13. Trials on devices should follow the same requirements as for new drugs. Similarly, surgical interventions must also follow ethical guidelines.

14. If a study involves biosimilars, the product quality, preclinical data, and bioassay must demonstrate similarity with a reference biologic.

15. Clinical trials with stem cells should follow the National Guidelines for Stem Cell Research, 2017.

16. Community trials may be conducted to evaluate preventive strategies like mass drug administration.

17. Research on traditional medicine interventions, such as Ayurveda, Yoga, Naturopathy, Unani, Siddha, and Homeopathy (AYUSH), should be conducted in accordance with ethical guidelines ASU-GCP (Ayurveda, Siddha, Unani GCP) guidelines as well as other applicable regulations.

18. Trials using diagnostic agents should follow the same protocols as for trials on new drugs.

19. Radioactive materials and X-rays should be used with more precaution in persons who have not completed the family.

20. Clinical trials among women for contraceptives or if they are pregnant or lactating should involve abundant precautions and care.

21. Any product using new technology should be GLP (Good Laboratory Practices), GMP (Good Manufacturing Practices), and GCP compliant, which appropriate authorities should duly approve.

PUBLIC HEALTH RESEARCH & SOCIAL AND BEHAVIOURAL SCIENCES RESEARCH FOR HEALTH

1. Benefits and risks in public health research may not be limited to an individual but may influence communities, populations, and the environment.

2. Social and behavioral studies must ensure social equity and intersectionality. Ethical relativism applies to moral diversity among different cultures and societies.

3. ECs must review different types of research such as program evaluations, demographic surveillance, registries, implementation research, demonstration projects, community trials, surveys, etc.

4. Based on specific research, appropriate consent processes may be considered by the EC, such as verbal/oral consent, broad consent; group consent; waiver of consent, and reconsent.

5. Special provisions should be provided in the design and execution of research if they are likely to have the potential to exploit socioeconomically deprived people.

6. Stakeholders (researchers, health providers/ sponsors, Govt. agencies, participants, ECs, institutions, NGOs, etc.) must make every effort to provide post-research public health interventions and use of findings for the sustainability of public health action.

7. The EC may require appropriate experts to address the specific ethical challenges related to socio-behavioral or public health research.

8. Safety measures should be in place to protect the privacy and confidentiality of research participants and/or research teams in the field collecting sensitive data.

9. The EC should carefully review studies where the use of deception is necessary to achieve the study objectives for the larger public good and consider debriefing after completion of the study.

10. Support systems such as counseling centers, rehabilitation centers, police protection, etc., should be in place for sensitive studies.

11. The EC should ensure that the researcher has taken appropriate measures for data security and confidentiality of the information and also that disclosure permissions have been taken, and appropriate use of the accessed data is stated by the researcher.

HUMAN GENETICS TESTING AND RESEARCH

1. Genetic test results have familial/societal implications; therefore, maintaining the confidentiality and providing pre-and post-test non-directive counseling by qualified persons is important.
2. Written consent should be obtained for genetic screening, confirmatory tests, specific interventions, pre-symptomatic testing, next-generation sequencing, prenatal or carrier testing, genomic studies, use of embryos/ foetal tissue, etc.
3. Informed consent should explain the nature and complexity of information, choices, implications, data/sample storage, etc.
4. Genetic screening should be purposive, with established provisions for disease management, treatment, and counseling.
5. Genetic test reports of multifactorial/late-onset diseases should be communicated carefully to prevent unnecessary worry or fear.
6. Information about a patient's disease and investigations may not be shared with others.
7. Screening for late-onset diseases should not be done in children unless there is suitable childhood intervention.
8. Confidentiality must be maintained while using new technologies like chromosomal microarray (CMA), whole exome sequencing, whole genome sequencing, etc.
9. Publication of pictures, pedigrees, or other identifying information about individuals/ families requires fresh or re-consent.
10. Laboratories offering genetic testing should participate in quality assurance programs specific to genetic testing.

BIOLOGICAL MATERIALS, BIOBANKING AND DATASETS

1. Biological material may be prospectively collected or may be left over from earlier studies or clinical services, e.g., biological fluids, dried blood spots, tissues, organs, etc.
2. Datasets are collections of health data in disease registers, surveys, surveillance, census, personal records, etc.
3. Ethical issues such as ownership of samples or data, transfer of bio-specimens, custodianship, secondary use, return of results, etc., are essential.
4. Samples/data may be anonymous (unidentified), anonymized (coded reversibly or irreversibly), or identifiable.
5. Multiple layered consents provide options to allow samples/data to be used for future research. Types of consent include blanket or broad; tiered; specific; delayed; dynamic; waiver; re-consent, etc.

6. Informed consent should provide information about the commercial value of samples or data, if applicable, with clarity about benefit sharing.

7. Material transfer agreement (MTA) should be executed if the bio-specimens are likely to be shipped to collaborators within or outside the country.

8. Data privacy, accuracy, security, and legal liability should be clarified if the data is outsourced or sold.

REFERENCES

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4. International guidelines for health related research involving humans. Geneva: Council for International Organizations of Medical Sciences; 2016.

5. National ethical guidelines for biomedical and health research involving human participants. Indian Council of Medical Research; 2017. Available from: https://icmr.nic.in/sites/default/files/guidelines/ ICMR_Ethical_Guidelines_2017.pdf (accessed 20 August 2018).

6. National ethical guidelines for bio-medical research involving children. Indian Council of Medical Research; 2017. Available from:
https://icmr.nic.in/sites/default/files/guidelines/National_Ethical_Guidelines_for_BioMedical_Research_Involving_ Children_0.pdf (accessed 20 August 2018).