PROPOSED INSTITUTIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND BIO-MECHANICAL PROJECTS AT IGDTUW INVOLVING HUMAN PARTICIPANTS

Commencement:

(a) These guidelines may be called the "**Indira Gandhi Delhi Technical University for Women (IGDTUW) Institutional Ethical Guidelines for biomedical and biomechanical projects"**.
(b) These guidelines will be applicable to the faculty, staff and students (B.Tech, M.Tech and PhD) who aspire to work in the field of biomedical or biomechanical projects at IGDTUW.

Definitions:

(a) **IEC** shall mean Institutional Ethical Committee.
(b) **Ethical Guidelines** shall mean guidelines for ensuring ethical code and moral conduct to be followed in the biomedical and biomechanical projects at IGDTUW.
(c) **Chairperson** shall mean the person appointed by VC of the Institute to chair and convene the IEC, preferably someone outside the institution.
(d) **Basic Medical Scientist** shall mean medical scientist and researcher, who shall has expertise on the biological aspects of the projects.
(e) **Clinician** shall mean doctors, surgeons and medical experts from colleges and hospitals relative with projects under consideration.
(f) **Legal Expert** shall mean lawyer or legal counsel who has keen understanding on legalities related to conflicts of interests, ethics, patents, approvals and trials.
(g) **Social Scientist** shall mean an expert of social and behavioural sciences, constitutional and fundamental rights of humans as well as expertise on regulations of protections of animals involved in testing and trials.
(h) **Ethicist** shall mean an expert whose judgement on ethics and ethical codes has been trusted by a specific community.
(i) **Member Secretary** shall mean the member of IEC who will be appointed by VC of the Institute to coordinate IEC meetings.

Composition of IEC:

1) An Institute Ethical committee (EC) of 7-9 persons will be formed which will meet once in a year to approve research projects at initiation level related to bio-medical field.

2) The IEC shall be multi-disciplinary and multi-sectored. Preferably, 50% of the members shall be non-affiliated or from outside the institution.
3) The number of members shall be no less than 7 and not more than 15 and a minimum of 5 members should be present to meet the quorum requirements.
4) The head of the institution shall appoint all IEC members, including the Chairperson (if nominated).
5) The IEC shall be registered with the relevant regulatory authorities, i.e. CDSCO.
6) There will be an office for the IEC, and the IEC will be registered and will work for accreditation from regulatory authorities.
7) It is necessary for all research proposals on biomedical, social and behavioural sciences, research for health involving human participants, their biological material and data to be reviewed and approved by an appropriately constituted IEC to safeguard the dignity, rights, safety and well-being of all human or animal participants.
8) IECs are entrusted with the initial review of research proposals prior to their initiation, and also have a continuing responsibility to regularly monitor the approved research to ensure ethical compliance during the conduct of research.
9) The IEC shall be competent and independent in its functioning. The IEC is responsible for scientific and ethical review of research proposals.
10) All related research proposals must be reviewed and approved by an IEC before project commencement for approval.
11) IEC shall have written SOPs (standard operating procedures) according to which the IEC will function. The scope, tenure and renewal policy of IEC shall be clearly stated.
12) IEC will be formed for a period of 2-3 years as per ICMR guidelines.
13) Researchers shall submit research proposals in prescribed format and EC will review the proposal and give its decision.

Ethical General Principles:

Free informed consent by participants in a medical study is a prime aspect of the ethical considerations concerning medical research. The Declaration of Helsinki states that: “The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data”, and “After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject’s freely-given informed consent, preferably in writing”.

IEC will further evaluate biomedical research projects to comply with following 12 general principles:

1. Principle of essentiality;
2. Principle of voluntariness;
3. Principle of non-exploitation;
4. Principle of social responsibility;
5. Principle of ensuring privacy and confidentiality;

6. Principle of risk minimization;
7. Principle of professional competence;
8. Principle of maximization of benefit;
9. Principle of institutional arrangements;
10. Principle of transparency and accountability;
11. Principle of totality of responsibility;
12. Principle of environmental protection.

Responsibilities of IEC:

IEC will evaluate biomedical research projects to comply with major ethical principles namely:

i) Autonomy of the patient/participant (individual patient / participant has the freedom to make choices for all matters);
ii) Beneficence of the patient/participant (healthcare professionals to take actions that benefit others, providing for their good. The professional has to show compassion and understand the patient's value system, which is further highly individual and dependent on each person's preferences);
iii) Justice (Researchers are always fair to the participants in their research and that the needs of research participants shall always be taken care of) and
iv) Primum non-nocere (avoid doing harm to others).

Ethical Review Procedures:

Following are the ethical review procedures or standard operating procedures (SOPs) to be followed for approval and commencement of biomedical and biomechanical projects at IGDTUW with cognizance to ICMR guidelines:

Collection of data:

1. Ethical collection of patient identifiable electronic medical data should be carried out with informed consent and with direct consideration to the scope of use of data.
2. Where electronic medical data is anonymous or sufficiently de-identified, it is ethical to collect without consent when there is independent approval for the use of that data from the concerned department for non-medical use.
3. Data collection should not exceed the necessary amount of electronic medical data required.
4. Subjects have the right to request information pertaining to the scope of use of their electronic medical data.
5. Data collectors have an ethical responsibility to ensure the maximum feasible transparency.
6. Those that collect the electronic medical data are ethically accountable for the data and to the persons on which it is based.
7. Subjects should not be additionally disadvantaged if they decline electronic medical data collection and should be adequately informed of the possible consequences of this.

8. Consent should not be required for the ethical transfer and distribution of de-identified electronic medical data.
9. Electronic medical data, when transferred and distributed, should have a maximum level of de-identification if consent has not been obtained.

Informed Consent:

To fulfil the requirements of free informed consent, a participant has to have the right:

a. to know that participation is voluntary;
b. to ask questions and receive understandable answers before making a decision;
c. to know the degree of risk and burden involved in participation;
d. to know who will benefit from participation;
e. to know the procedures that are implemented in the case of incidental findings;
f. to receive assurance that appropriate insurance cover is in place;
g. to withdraw themselves, their samples and data from the project at any time;
h. to know how their biological samples and data are collected, protected during the project and destroyed at the end; and
i. to know of any potential commercial exploitation of the research.

Trials of medical devices:

1. In last few years several medical devices have been developed. There is to be a well-developed system of evaluation and certification of medical devices. India lacks any such system presently.
2. A proposal has been drafted for setting up of a regulatory authority 'Indian Medical Devices Regulatory Authority' (IMDRA).
3. Until the guidelines are formulated and regulated by this regulatory authority, Institutional Ethical committee shall approve clinical trials with biomedical devices on case-to-case basis.
4. Depending upon the risk involved to the subjects, the devices will be classified as critical or Non-critical.
5. All the general principles of clinical trials as described by ICMR or other regulatory bodies shall be considered for trials of medical devices.

Marketing of medical devices:

After conceptualization of the medical device, following steps are involved before it can be marketed.

1. Animal and biocompatibility studies;
2. Approval by controlling authority for clinical trials;
3. Clearance from IEC;
4. Two stage premarketing evaluation /Clinical trials;
5. Certification by specially constituted certifying authority;
6. Permission for marketing;
7. Continuous post marketing evaluation.

All submissions to IEC have to be made in forms as attached and the committee will give its decision. For all other related guidelines in case-specific requirements, guidelines laid down by ICMR shall be followed and considered.

Any case of doubt or dispute arising about the interpretation of these Ordinances and Regulations or anything not contained in the ordinance, shall be referred to the Vice Chancellor whose decision shall be final.