



TAMIL NADU OPEN UNIVERSITY
Research Programme Section
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ETHIC COMMITTEE

I. PREAMBLE

The Ethic Committee (EC) has an important role to play in ensuring the ethical standards and scientific merit of research involving human subjects. Each institution involving research activities should have an Institutional Ethic Committee to prevent studies that pose an unacceptable risk of harm to the learners as well as to society. In this connection, an Ethic Committee is formed in Tamil Nadu Open University as an Advisory Body for reviewing the research related activities in M.Phil. & Ph.D. research programmes. It will review and recommend the Research Proposals involving human subjects received from Faculty and Research Scholars with a view to safeguard the dignity, rights, safety and well being of all actual and potential Research Participants. The goals of Research, however important, should never be permitted to override the health and well being of the Research Subjects.

The EC will take care that all the cardinal principles of research ethics *viz.* Autonomy, Beneficence, Non – malfeasance, Justice are taken care of in planning, conduct and reporting of the proposed Research. The Committee will also examine compliance with all regulatory requirements, applicable guidelines and laws as amended by the Government from time to time.

II. THE OBJECTIVES OF THE EC

- To ensure the ethical standards and scientific merit of research and researchers.
- To ensure the ethical standards on the research which involving human subjects
- To prevent the research activities that poses an unacceptable risk of harm to the learners as well as to society.
- To safeguard the dignity, rights, safety and well being of all actual and potential Research Participants.

III. ROLE OF THE EC:

The Ethic Committee must ensure

1. The rights, safety and well being of researchers.
2. The appropriate strategies are in place to protect the researchers from potential adverse consequences of the research.
3. All researchers are aware about the pros and cons for their research activities and have given appropriate Informed Consent.
4. To promote fair ethical policies and procedures which will maximize the likelihood of achieving application-oriented research outcomes.
5. To enhance the ethical tenor between health care professionals and organizations conducting clinical trials.
6. On offering due consideration to community views.

IV. COMPOSITION OF EC

Ethic Committee should be multidisciplinary and multisectorial in composition. The number of persons in an ethical committee should be kept fairly small (7-9 members). It is generally accepted that a minimum of five persons is required to compose a quorum. There is no specific recommendation for a widely acceptable maximum number of persons but it should be kept in mind that too large a Committee will make it difficult in reaching consensus opinions. 12-15 is the maximum recommended number.

The Chairperson of the Committee should preferably be from within the Institution and not head of the same Institution to maintain the independence of the Committee. The Member Secretary who generally belongs to the same Institution should conduct and record the business of the Committee in the absence of Chairman. Other members should be a mix of medical / non-medical scientific and non-scientific persons including lay public to reflect the differed viewpoints.

The composition may be as follows:-

1. Chairperson
2. Basic Medical scientists
3. Clinicians
4. Biologist
5. Legal expert
6. Social scientist / representative of non-governmental voluntary agency
7. Philosopher / ethicist / theologian
8. Lay person
9. Coordinator

The committee can have as its members, individuals from other institutions or communities if required. Generally, it is better to have more external members. There should be adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community / society. Members should be aware of local, social and cultural norms, as this is the most important social control mechanism. If required, experts could be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, should be included. Similarly, based on the requirement of research area also. The membership of IEC will include Epidemiologist(s), Sociologist(s), Lawyer(s), Theologian, Statistician(s), Clinician(s), Basic scientists, Pharmacist(s)/Clinical Pharmacologist(s) etc. They should be appointed by the Head of the Institute based on their competencies and integrity and could be drawn from any public or private Institute from anywhere in the country.

EC should be constituted in the following pattern:

- A Chairperson
- A Deputy Chairman, if need be,
- Coordinator
- 5-7 members from different Departments/Specialties/Disciplines

V. MEMBERS REQUIREMENT FOR EC:

- The duration of appointment is initially for a period of 3 years.
- At the end of 3rd year, as the case may be, the committee may be reconstituted, and 50% of the members will be replaced by a defined procedure.
- The membership of the council ceases along with their service/tenure in their parent institution for a period of 3 years whichever is earlier.
- A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
- A member can tender resignation from the committee with proper reasons to do so.
- All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.
- Conflict of interest should be declared by members of the Research Council.
- All members are eligible for Sitting fee and TA as per TNOU norms.

VI. QUORUM REQUIREMENTS:

The meeting of the EC may be conducted once in a Year to facilitate faster forwarding process, or as and when need arises (A special sitting may be arranged based on the need). The minimum of 5 members are required to compose a quorum. Preferably all decisions may be taken in meetings and not by circulation except in needy cases.

The minimum of 5 members are required to compose a quorum. All decisions should be taken in meetings and not by circulation. The members of the Research Council shall be nominated by the Hon'ble Vice Chancellor, TNOU, from the panel of the Expert as submitted by the Research Programme Section.

1. Chairman : One member
2. Basic Medical scientist : One member
3. Clinicians : One member

- 4. Biologist : One member
- 4. Legal Expert : One member
- 5. Social Science Expert : One member
- 6. One philosopher / ethicist / theologian : One member
- 7. Academic Council Member : One member from AC of TNOU
- 8. Lay person : One member
- 9. Coordinator : One member

VII. MEMBER'S RESPONSIBILITIES:

The Chairman will conduct all meetings of the EC. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson or an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary/Coordinator is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers with the approval of the appropriate authority.

Independent consultants

The EC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects.

Member for Ethic Committee re-constituted on 12.03.2021		
1.	Director Research, TNOU	Chairperson
2.	Dr. D. DINAKARAN Medical Superintendent	Medical Scientist
3.	Dr. M. ARESHKUMAR PGDAW, Chief Consultant	Clinician Expert
4.	Dr. T. RAVIMANICKAM Associate Professor of Zoology	Biologist Expert
5.	Mr. P. SANJAY GANDHI Advocate	Legal Expert
6.	Dr. VIJAYARAM Social Development Scientist	Social Scientist Expert
7.	Dr. K. JAMES PONNAIAH Assistant Professor & Head i/c	Philosopher Expert
8.	Dr. Mrs. A. MERCY SENTHILKUMAR Founder, Mercy Foundations	Lay Person
9.	Dr. D. Sumathi Research Coordinator	Coordinator