K. J. Somaiya College of Physiotherapy

Institutional Code of Ethics for Research

An institutional Code of Ethics for research helps faculty and students practice fair and respectful treatment of patients while conducting research by defining clear standards of ethical behavior that they must uphold. A written Code does not ensure ethical conduct, but it is the first step toward creating an ethical organizational culture. This Code of Ethics document is prepared in alignment with guidelines from ICMR. It is applicable to all students and faculty of K. J. Somaiya College of Physiotherapy. The purpose of these guidelines is to safeguard the dignity, rights, safety and well-being of the human participants involved in biomedical and health research.

STATEMENT OF GENERAL PRINCIPLES

1. Every research has some inherent probabilities of harm or risk and thus, protection of research participants and/or communities should be built into the design of the study.

2. While conducting biomedical and health research, the four basic principles namely; respect for persons (autonomy), beneficence, non-maleficence and justice must guide research in order to protect the dignity, rights, safety and well-being of research participants.

3. The basic principles have been expanded into 12 general principles (Table 1), that are applicable to all biomedical and health research involving human participants or research using their biological material or data.

Table 1: General Principles

1. Principle of Essentiality	7. Principle of Professional Competence
2. Principle of Voluntariness	8. Principle of Maximization of Benefit
3. Principle of Non-exploitation	9. Principle of Institutional Arrangements
4. Principle of Social Responsibility	10. Principle of Transparency & Accountability
5. Principle of Ensuring Privacy & Confidentiality	11. Principle of Totality of Responsibility
6. Principle of Risk Minimization	12. Principle of Environmental Protection

4. All research at the institute must be approved by Institutional Ethics Committee.

GENERAL ETHICAL ISSUES

There are some general issues that must be kept in focus during the conduct of biomedical and health research involving human participants (Table 2).

Table 2: General Ethical Issues

Benefit–risk assessment	Informed consent process	Privacy and confidentiality
Distributive justice	Payment for participation	Compensation for research related harm
Ancillary care	Conflict of interest	Selection of vulnerable and special groups as research participants
Community engagement	Post-research access and benefit sharing	

2.1. Researchers must protect the dignity, rights, safety and well-being of research participants.

2.2. Researcher should have appropriate qualifications, competence in research methodology and be compliant towards the scientific, medical, ethical, legal and social requirements of research.

2.3. The researcher must conduct a benefit–risk assessment and actively attempt to maximize benefits and minimize risks to participants.

2.4. Benefits to the individual, community or society refer to any sort of favorable outcome of the research, whether direct or indirect. The social and scientific value of research should justify the risk, which is the probability of causing discomfort or harm anticipated as physical, psychological, social, economic or legal.

2.5. Risk can be categorized as less than minimal risk, minimal risk, and minor increase over minimal or low risk and more than minimal or high risk.

2.6. The researcher must obtain informed consent from the participant/legally acceptable/ authorized representative (LAR) in writing.

2.7. Informed consent documents (participant information sheet and informed consent form) should carry the specified elements in simple, layman's language. These documents should be approved by the EC.

2.8. Oral consent/waiver of consent/re-consent may be obtained under certain conditions, after due approval by the EC.

2.9. Researcher(s) should safeguard the privacy and confidentiality of participants and research-related data from unauthorized access.

2.10. Benefits and burdens of research should be equitably distributed among the participating individuals or communities.

2.11. Participants should not be made to pay for research-related expenses incurred beyond routine clinical care. Reimbursement for expenses incurred can be made in cash or kind or both.

2.12. The researcher must report all serious adverse events (SAEs) to the EC within 24 hours of knowledge and submit a report on SAE relatedness to research within 14 days.

2.13. Research participants who suffer direct physical, psychological, social, legal or economic harm are entitled to financial compensation or other forms of assistance.

2.14. In investigator initiated/student research, the investigator/institution where the research is conducted becomes the sponsor and must provide compensation for research-related injury through insurance, corpus funds or grants.

2.15. Free medical care may be offered as ancillary care for non-research-related conditions or incidental findings if it does not amount to undue inducement as determined by EC.

2.16. The selection of vulnerable and special groups needs careful consideration, with provisions for additional safeguards and close monitoring.

2.17. Engaging with the community from the beginning of research till after its completion helps to improve design and conduct of research and ensures greater responsiveness to health needs. However, every individual participant's consent is essential.

2.18. Post-research access and benefit-sharing may be done with individuals, communities and populations, wherever applicable after completion of study.

RESPONSIBLE CONDUCT OF RESEARCH (RCR)

3.1. Major components of RCR are values and policies; planning and conducting research; reviewing and reporting research; responsible authorship and publication aspects.

3.2. Institutional Research Committee must facilitate research, manage grants and provide research oversight.

3.3. Researchers must follow professional codes of conduct and have personal conviction about ethical requirements.

3.4. The following should be established prior to conducting research:

- Conflict of Interest policies
- Safeguards for data acquisition, management, sharing and ownership
- Policies for handling research misconduct including fabrication, falsification and plagiarism

3.5. Completed research, irrespective of results, must be published in accordance with the guidelines of the International Committee of Medical Journal Editors (ICMJE).

3.6. Clinical studies on human participants should be registered prospectively with the Clinical Trial Registry - India (CTRI). This is mandatory for regulatory trials.

3.7. Issues related to ownership, sharing of materials/data, IPR, joint publications, research findings, conflict of interest, and commercialization should be addressed in collaborative research.

3.8. In multicenter research, common ethics review by a designated EC can help to reduce time for getting ethical approvals from across the sites and improve coordination among participating sites. However, the local EC will look at site specific concerns and monitor research.

INFORMED CONSENT PROCESS

4.1. Voluntary written informed consent should be obtained in an informed consent document (ICD) from each participant to protect each individual's freedom of choice.

4.2. Informed consent is a continuous process involving three main components:

- Providing relevant information to potential participants
- Ensuring competence and comprehension of the information and
- Voluntariness of participation

Table 3: Characteristics of an ICD

Elements of an ICD	Additional elements (optional)

1. Statement mentioning that it is research	1. Alternative procedures or treatment
2. Purpose and methods	2. Insurance coverage
3. Duration, frequency, methods	3. Possible stigmatizing condition
4. Benefits to participant, community or others	4. Biological material and data, including:
5. Foreseeable risks, discomfort or inconvenience	i) Current and future uses
6. Confidentiality of records	ii) Period of storage and secondary use
7. Payment/reimbursement for participation	iii) Sharing of data and biological materials
8. Treatment and/or compensation for injury	iv) Right to prevent use of biological sample
9. Freedom to participate/withdraw	v) Provisions to safeguard confidentiality
10. Identity of research team and contact persons	vi) Post-research plan/benefit sharing
vii) Publication plan/photographs/pedigrees	

4.3. Researchers should only use the EC approved version of the consent form and its translation in local languages.

4.4. Informed consent should be voluntary and be signed by the participant after receiving information, understanding it and discussing with family/friends (if required).

4.5. Verbal/oral consent/waiver of consent/re-consent may be obtained only after approval by the EC. Table 4 gives conditions for granting waiver of consent.

Table 4: Conditions for granting waiver of consent

The EC may grant consent waiver in the following situations:

• research cannot practically be carried out without the waiver and the waiver is scientifically justified;
• retrospective studies, where the participants are de-identified or cannot be contacted;
• research on anonymized biological samples/data;
• certain types of public health studies/surveillance programmes/programme evaluation studies;
• research on data available in the public domain; or
• Research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempt should be made to obtain the participant's consent at the earliest.

4.6. Appropriate ICD should be prepared for differently abled participants.

4.7. In case of research involving children, in addition to parental consent, verbal (7-12 years) or simplified written (>12 – 18 years) assent should also be taken from the participant.

4.8. The LAR's consent is required in case a participant is incompetent (medically or legally).

4.9. Electronic/online consent may be obtained for research involving sensitive topics while safeguarding information and data and also if required for regulatory clinical trials.

4.10. Individual consent is important and required, even if the community gives permission for participation in a research study.

VULNERABILITY

Individuals/ groups/ populations are considered vulnerable if they are relatively or absolutely incapable of protecting their own 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., people who are unconscious, differently abled)

• Able to give consent, but their voluntariness or understanding is compromised due to their situational conditions

• 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

5.1. Researchers must justify the inclusion/exclusion of a vulnerable population.

5.2. A community representative may be invited to EC meetings to make sure the research is responsive to their needs and the informed consent process is appropriate.

5.3. Additional precautions should be taken by all stakeholders such as researchers, ECs and sponsors to avoid exploitation of vulnerable participants.

5.4. Informed consent process should be well documented and additional measures adopted if required, such as audiovisual/audio recording of assent/consent/re-consent.

5.5. Research proposals will undergo review in a full committee meeting.

5.6. Protection of privacy and dignity as well as provision of quality health care is required in dealing with vulnerable people, especially the minorities.

5.7. Research involving children, in addition, should follow the National Ethical Guidelines for Biomedical Research Involving Children, ICMR, 2017.

5.8. Due approvals are needed from competent authorities before entering tribal areas.

5.9. Research involving cognitively impaired individuals or those with mental illness must be done carefully, especially if there is risk to themselves, to others or suicidal ideation.

5.10. The EC will carry out the benefit–risk analysis and examine risk minimization strategies.