SOMAIYA AYURVIHAR

K J Somaiya College of Physiotherapy

Somaiya TRUST

Standard Operating Procedure of Institutional Ethics Committee of K J Somaiya College of Physiotherapy, Mumbai

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Standard Operating Procedure

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Standard Operating Procedure of Institutional Ethics Committee of K J Somaiya College of Physiotherapy, Mumbai

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Section 1: Statement of General Principles

1.0 Research on human participants pertains to a broad range of scientific enquiry aimed at developing generalizable knowledge that improves health, increases understanding of disease and is ethically justified by its social value. Every research has some inherent risks and probabilities of harm or inconvenience to participants/communities. Therefore, protection of participants will be built into the design of the study.

Do no harm (non-maleficence) has been the underlying universal principle guiding health care in all systems of medicine around the world. While conducting biomedical and health research, the four basic ethical principles namely; respect for persons (autonomy), beneficence, non-maleficence and justice have been enunciated for protecting the dignity, rights, safety and well-being of research participants. These four basic principles have been expanded into 12 general principles described below, and are to be applied to all biomedical, social and behavioral science research for health involving human participants, their biological material and data at K J Somaiya College of Physiotherapy

1.1 General Principles of Ethics to be followed by Institutional Ethics Committee of K J Somaiya College of Physiotherapy

1.1.1 Principle of essentiality:
whereby after due consideration of all alternatives in the light of existing knowledge, the use of human participants is considered to be essential for the proposed research.This should be duly vetted by an ethics committee (EC) independent of the proposed research.

1.1.2 Principle of voluntariness:
whereby respect for the right of the participant to agree or not to agree to participate in research, or to withdraw from research at any time, is paramount. The informed consent process ensures that participants' rights are Safeguarded.

1.1.3 Principle of non-exploitation:
whereby research participants are equitably selected so that the benefits and burdens of the research are distributed fairly and without arbitrariness or discrimination. Sufficient safeguards to protect vulnerable groups should be ensured.

1.1.4 Principle of social responsibility:
whereby the research is planned and conducted so as to avoid creation or deepening of social and historic divisions or in any way disturb social harmony in community relationships.

1.1.5 Principle of ensuring privacy and confidentiality:
whereby to maintain privacy of the potential participant, her/his identity and records are kept confidential and access is limited to only those authorized. However, under certain

circumstances (suicidal ideation, homicidal tendency, HIV positive status, when required by court of law etc.) privacy of the information can be breached in consultation with the EC for valid scientific or legal reasons as the right to life of an individual supersedes the right to privacy of the research participant.

1.1.6 Principle of risk minimization:
whereby due care is taken by all stakeholders (including but not limited to researchers, ECs, sponsors, regulators) at all stages of the research to ensure that the risks are minimized and appropriate care and compensation is given if any harm occurs.

1.1.7 Principle of professional competence:
whereby the research is planned, conducted, evaluated and monitored throughout by persons who are competent and have the appropriate and relevant qualification, experience and/or training.

1.1.8 Principle of maximization of benefit:
whereby due care is taken to design and conduct the research in such a way as to directly or indirectly maximize the benefits to the Research participants and/or to the society.

1.1.9 Principle of institutional arrangements:
whereby institutions where the research is Being conducted, have policies for appropriate research governance and take the responsibility to facilitate research by providing required infrastructure, manpower, funds and training opportunities.

1.1.10 Principle of transparency and accountability:
whereby the research plan and outcomes emanating from the research are brought into the public domain through registries,reports and scientific and other publications while safeguarding the right to privacy of the participants. Stakeholders involved in research should disclose any existing conflict of interest and manage it appropriately. The research should be conducted in a fair,honest, impartial and transparent manner to guarantee accountability. Related records,data and notes should be retained for the required period for possible external scrutiny/Audit.

1.1.11 Principle of totality of responsibility:
whereby all stakeholders involved in research are responsible for their actions. The professional, social and moral responsibilities Compliant with ethical guidelines and related regulations are binding on all stakeholders directly or indirectly.

1.1.12 Principle of environmental protection:
whereby researchers are accountable for ensuring protection of the environment and resources at all stages of the research, in compliance with existing guidelines and regulations.

Section 2: General Ethical Issues

2.0 The Institutional Ethics Committee will ensure that all research involving human participants shall be conducted in accordance with the basic and general ethical principles. The researcher and the team will be responsible for protecting the dignity, rights, safety and well-being of the participants enrolled in the study. The Institutional Ethics Committee will ensure that the researcher/s have the appropriate qualifications and competence in research methodology and should be aware of and comply with the scientific, medical, ethical, legal and social requirements of the research proposal. The Institutional Ethics Committee will be responsible for ensuring that the research is conducted in accordance with the aforementioned principles.

2.1 Benefits Risk Assessment:

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.

The researcher, sponsor and EC should attempt to maximize benefits and minimize risks to participants so that risks are balanced to lead to potential benefits at individual, societal and/or community levels.

The EC should assess the inherent benefits and risks, ensure a favorable balance of benefits and risks, evaluate plans for minimizing the risk and discomfort and decide on the merit of the research before approving it. The EC should also assess any altered risks in the study at the time of continuing review. Categories of the risk can be referred from ICMR guidelines.

2.2 Informed Consent Process:

Informed consent protects the individual's autonomy to freely choose whether or not to participate in the research. The process involves three components – providing relevant information to potential participants, ensuring the information is comprehended by them and assuring voluntariness of participation.

The Institutional Ethics Committee will ensure that Informed consent explains medical terminology in simple terms and be in a language that the participant understands. The informed consent document (ICD), which includes patient/participant information sheet (PIS) and informed consent form (ICF) should have the required elements (As per ICMR Guidelines) and should be reviewed and approved by the EC before enrolment of participants. It is the primary responsibility of the researcher to obtain the written, informed consent of the prospective participant or legally acceptable/authorized representative (LAR). In case of an individual who is not capable of giving informed consent, the consent of the LAR should be obtained. If a

participant or LAR is illiterate, a literate impartial witness should also be present during the informed consent process. Verbal/oral consent/waiver of consent/re-consent may be obtained under certain conditions after due consideration and approval by the EC.

2.3 Privacy and Confidentiality:

Privacy is the right of an individual to control or influence the information that can be collected and stored and by whom and to whom that information may be disclosed or shared. Confidentiality is the obligation of the researcher/research team/organization to the participant to safeguard the entrusted information.

It includes the obligation to protect information from unauthorized access, use, disclosure, modification, loss or theft. The IEC will ensure that the researcher safeguards the confidentiality of research related data of participants and the community.

Potential limitations to ensure strict confidentiality shall be explained to the participant. Researchers must inform prospective participants that although every effort will be made to protect privacy and ensure confidentiality, it may not be possible to do so under certain circumstances.

The IEC will ensure that any publication arising out of research shall uphold the privacy of the individuals by ensuring that photographs or other information that may reveal the individual's identity are not published. A specific re-consent would be required for publication, if this was not previously obtained.

The IEC will ensure that information that may be sensitive shall be protected to avoid stigmatization and/or discrimination (for example, HIV status; sexual orientation such as lesbian, gay, bisexual, and transgender (LGBT); genetic information; or any other sensitive information).

While conducting research with stored biological samples or medical records/data, coding or anonymization of personal information is important hence the IEC will ensure that access to both samples and records should be limited. .

The IEC will permit data of individual participants/community may be disclosed in certain circumstances with the permission of the EC such as specific orders of a court of law, threat to a person's or community's life, public health risk that would supersede personal rights to privacy, serious adverse events (SAEs) that are required to be communicated to an appropriate regulatory authority etc.

2.4 **Distributive Justice:**

The IEC will require that efforts must be made to ensure that individuals or communities invited for research are selected in such a way that the benefits and burdens of research are equitably distributed. The IEC will ensure that vulnerable individuals/groups should not be included in research to solely benefit others who are better-off than themselves.

The IEC will ensure that research should not lead to social, racial or ethnic inequalities Plans for direct or indirect benefit sharing in all types of research with participants, donors of biological materials or data should be included in the study, especially if there is a potential for commercialization. This shall be decided a priori in consultation with the stakeholders and reviewed by the IEC.

2.5 Payment for Participation:

If applicable, The IEC will permit participants to be reimbursed for expenses incurred relating to their participation in research, such as travel related expenses.

Participants may also be paid for inconvenience incurred, time spent and other incidental expenses in either cash or kind or both as deemed necessary (for example, loss of wages and food supplies).

The IEC shall ensure that participants should not be made to pay for any expenses incurred beyond routine clinical care and which are research related including investigations, patient work up, any interventions or associated treatment. This is applicable to all participants, including those in comparator/control groups.

If there are provisions, participants may also receive additional medical services at no cost.

When the LAR is giving consent on behalf of a participant, payment should not become an undue inducement and to be reviewed carefully by the EC. Reimbursement may be offered for travel and other incidental expenses incurred due to participation of the child/ward in the research. The IEC shall review and approve the payments (in cash or kind or both) and free services and the processes involved, and also determine that this does not amount to undue inducement.

2.6 Compensation for Research related harm:

Research participants who suffer direct physical, psychological, social, legal or economic harm as a result of their participation are entitled, after due assessment, to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability. In case of death, participant's dependents are entitled to financial compensation. The research proposal should have an in-built provision for mitigating research related harm.

The researcher shall be responsible for reporting all SAEs to the IEC within 24 hours of knowledge. Reporting of SAE may be done through email or fax communication (including on non working days).

A report on how the SAE was related to the research must also be submitted within 14 days.

The IEC shall be responsible for reviewing the relatedness of the SAE to the research, as reported by the researcher, and determining the quantum and type of assistance to be provided to the participants.

All research participants who suffer harm, whether related or not, should be offered appropriate medical care, psycho-social support, referrals, clinical facilities, etc.

Medical management should be free if the harm is related to the research.

Compensation should be given to any participant when the injury is related to the research. This is applicable to participants in any of the arms of research, such as intervention, control and standard of care.

While deliberating on the quantum of compensation to be awarded to participants who have suffered research-related injury, the EC should consider aspects including the type of research (interventional, observational, etc.), extent of injury (temporary/permanent, short/long term), loss of wages, etc.

All AEs shall be recorded and reported to the IEC according to a pre-planned timetable, depending on the level of risk and as recommended by the EC.
In investigator initiated research/student research, the investigator/institution where the research is conducted becomes the sponsor. It is the responsibility of the host institution to provide compensation and/or cover for insurance for research related injury or harm to be paid as decided by the IEC. The institution shall create an in-built mechanism to be able to provide for compensation, such as a corpus fund in the institution.

In the applications for research grants to funding agencies – national or international, government or non-government agencies – the researcher should keep a budgetary provision for insurance coverage and/or compensation depending upon the type of research, anticipated risks and proposed number of participants.

2.7 Ancillary care:
Participants may be offered free medical care for non-research-related conditions or incidental findings if these occur during the course of participation in the research, provided such compensation does not amount to undue inducement as determined by the EC.

2.8 Conflict of Interest:
Conflict of interest issues COI refers to a set of conditions whereby professional judgment concerning a primary interest, such as participant's welfare or the validity of research either is, or perceived to be unduly influenced by a secondary interest.

The secondary interest may be financial or non-financial, personal, academic or political. This is not inherently wrong, but COI can influence the choice of research questions and methods, recruitment and retention of participants, interpretation and publication of data and the ethical review of research.

The IEC will develop and implement policies and procedures to identify, mitigate and manage such COI which can be at the level of researcher, ethics committee or at the level of institution.
The IEC shall develop policies and SOPs to address COI issues that are dynamic, transparent and actively communicated; The IEC shall implement policies and procedures to address COI and conflicts of commitment, and educate their staff about such policies The IEC shall monitor the research or check research results for accuracy and objectivity; and not interfere in the

functioning and decision making Researchers must ensure that documents submitted to the EC include disclosure of COI (financial or nonfinancial) that may affect their research

Researchers must guard against conflicts of commitment that may arise from situations that place competing demands on researchers' time and loyalties; and prevent intellectual and personal conflicts by ensuring they do not serve as reviewers for grants and publications submitted by close colleagues, relatives and/or students.

Identifying, Mitigating and Managing COI

The institution shall:

- develop policies and SOPs to address COI issues that are dynamic, transparent and actively communicated;
- implement policies and procedures to address COI and conflicts of commitment, and educate their staff about such policies;
- monitor the research or check research results for accuracy and objectivity; and
- not interfere in the functioning and decision making of the EC.

Researchers shall:

- ensure that documents submitted to the EC include disclosure of COI (financial or nonfinancial) that may affect their research;
- guard against conflicts of commitment that may arise from situations that place competing demands on researchers' time and loyalties; and
- prevent intellectual and personal conflicts by ensuring they do not serve as reviewers for grants and publications submitted by close colleagues, relatives and/or students.

The IEC shall:

- evaluate each study in light of any disclosed COI and ensure appropriate action is taken to mitigate this; and
- require their members to disclose their own COI and take appropriate measures to recuse themselves from reviewing or decision making on protocols related to their COI; and
- make appropriate suggestions for management, if COI is detected at the institutional or researchers level

2.9 Selection of vulnerable and special groups as research participants:

Vulnerable groups and individuals may have an increased likelihood of incurring additional harm as they may be relatively (or absolutely) incapable of protecting their own interests.

Characteristics that make individuals vulnerable are 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 which have hierarchical relationships, institutionalized persons, humanitarian emergencies, language barriers and cultural differences).

In general, such participants should be included in research only when the research is directly answering the health needs or requirements of the group. On the other hand, vulnerable populations also have an equal right to be included in research so that benefits accruing from the research apply to them as well. The IEC as well researchers need to put the above to careful consideration.

The EC should determine vulnerability and ensure that additional safeguards and monitoring mechanisms are established. It should also advise the researcher in this regard.

Characteristics of vulnerable individuals/populations/group

Individuals may be considered to be vulnerable if they are:

- socially, economically or politically disadvantaged and therefore susceptible to being exploited.
- incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled.
- able to give consent, but whose 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.

The key principle to be followed by the IEC when research is planned on vulnerable persons is that others will be responsible for protecting their interests because they cannot do so or are in a compromised position to protect their interests on their own.

Principles of Research among Vulnerable Populations

Vulnerable populations have an equal right to be included in research so that benefits accruing from the research apply to them as well. If any vulnerable group is to be solely recruited then the research should answer the health needs of the group. Participants must be empowered, to the maximum extent possible, to enable them to participate in research, or if the caregiver stands to benefit from the dependent's participation, the feeling of being pressed to participate may be irresistible which will undermine the potential voluntariness of the consent to participate.

Researchers must justify the inclusion of a vulnerable population in the research.
The IEC must satisfy themselves with the justification provided and record the same in the proceedings of the EC meeting. Additional safety measures should be strictly reviewed and approved by the IEC. The informed consent process should be well documented.

Additional measures such as recording of assent and consent, when applicable, should be ensured. The IEC should also carefully determine the benefits and risks of the study and examine the risk minimization strategies.

As potential participants are dependent on others, there should be no coercion, force, duress, undue influence, threat or misrepresentation or incentives for participation during the entire research period. Vulnerable persons may require repeated education/information about the research, benefits, risks and alternatives, if any.

Research on sensitive issues such as mental health, sexual practices/preferences, HIV/ AIDS, substance abuse, etc. may present special risks to research participants. Researchers should be cognisant of the possibility of conflicting interests between the prospective participant and LAR and should be more careful. Participants may be prone to stigma or discrimination, specifically when the participant is enrolled as a normal control or is recruited from the general population in certain types of research. Efforts should be made to set up support systems to deal with associated medical and social problems.

Protection of their privacy, confidentiality and rights is required at all times – during conduct of research and even after its completion. Whenever possible, ancillary care may be provided such as setting up of a facility, school for unattended children of the participants or a hospital, or counseling centers.

2.10 Community Engagement:

Community can be defined as a social group of people of any size sharing the same geographical location, beliefs, culture, age, gender, profession, lifestyle, disease, etc. The community should be meaningfully engaged before, during and after the research to mitigate culturally sensitive issues and ensure greater responsiveness to their health needs and requirements. 2.10.1 The community can be engaged in many ways and can provide valuable opinions. The degree of community engagement should depend on the type of research that is being conducted.

Members of the community can also be represented in the EC either as members or special invitees. 2.10.4 Community engagement does not replace individual informed consent. It ensures that the community's health needs and expectations are addressed, informed consent is appropriate, and access to research benefits are provided through research that is designed and implemented in the best interests of science and the community. 2.10.5 After the study is completed, the researcher may communicate with the community representative, local institution or the government department from where the data was collected to help in dissemination of the results to the entire community. See sections 8 and 9 for further details.

2.11 Post Research Access and Benefit Sharing:

The IEC will strive to ensure that the benefits accruing from research should be made accessible to individuals, communities and populations whenever relevant. Sometimes more than the benefit to the individual participant, the community may be given benefit in an indirect way by improving their living conditions, establishing counseling centers, clinics or schools, and providing education on good health practices.

IEC/ Researchers will strive to make efforts to communicate the findings of the research study to the individuals/communities wherever relevant. The researcher/s should make plans wherever applicable for post-research access and sharing of academic or intervention benefits with the participants, including those in the control group. Post-research access arrangements or other care must be described in the study protocol so that the EC may consider such arrangements during its review.

In studies with restricted scope, such as student projects, post study benefit to the participants may not be feasible, but the IEC will strive to see that efforts shall be made by the institution to take steps to continue to support and give better care to the participants.

Section 3. Responsible Conduct of Research

All students and faculty of K J Somaiya College of Physiotherapy are expected to maintain high standards and to uphold the fundamental values of research. The responsible conduct of research (RCR) involves the following major components: values; policies; planning and conducting research; reviewing and reporting research; and responsible authorship and publication.

3.1 Values of research:
RCR is guided by shared values including honesty, accuracy, efficiency, fairness, objectivity, reliability, accountability, transparency, personal integrity, and knowledge of current best practices.

Researchers should be aware that the resources of biomedical research are precious and to be used judiciously. Wherever possible they should also seek opportunities to plan translation of research findings into public health outcomes.

To understand the social and cultural impact of research, one must analyze how the health sector and general public engage with the results of biomedical and health research. It is essential that researchers bear this in mind while planning, conducting and evaluating research as it will improve public accountability and enhance public, private and political advocacy.

Mentoring is one of the primary means for one generation of scientists to pass on their knowledge, values and principles to succeeding generations. Mentors, through their experience, can guide researchers in ways above and beyond what can be gathered from reading textbooks. The relationship between mentors and trainees should enable trainees to become responsible researchers. Mentors should ensure their trainees conduct research honestly, do not interfere with the work of other researchers and use resources judiciously. A mentor should be knowledgeable, teach and lead by example and understand that trainees differ in their abilities. She/he should devote sufficient time and be available to discuss, debate and guide trainees ably. A mentor should encourage decision making by the trainees and the trainee should take an active role in communicating her/his needs.

3.2 Policies:
The protection of human participants Institutions must establish policies and mechanisms for the protection of human research participants. Such policies should assign responsibilities to the institution, the EC and the researchers. Additionally, there should be mechanisms and policies for monitoring research including data capture, management , conflicts of interest, reporting of scientific misconduct, and appropriate initial and continuing training of researchers and EC members. Policies can be made available on the websites of the institutes or organizations. Researchers should also follow their respective professional codes of conduct.

3.3 Planning and conducting Research - Specific Issues

3.3.1 Conflict of interest issues:

COI refers to a set of conditions whereby professional judgment concerning a primary interest, such as participant's welfare or the validity of research either is, or perceived to be unduly influenced by a secondary interest. The secondary interest may be financial or non-financial, personal, academic or political. This is not inherently wrong, but COI can influence the choice of research questions and methods, recruitment and retention of participants, interpretation and publication of data and the ethical review of research. It is, therefore, necessary to develop and implement policies and procedures to identify, mitigate and manage such COI which can be at the level of researcher, ethics committee or at the level of institution.

The broad responsibilities of those involved in research, with respect to COI, are given below:

1. **Research institutions must:**
   - Develop policies and SOPs to address COI issues that are dynamic, transparent and actively communicated;
   - Implement policies and procedures to address COI and conflicts of commitment, and educate their staff about such policies;
   - Monitor the research or check research results for accuracy and objectivity; and
   - Not interfere in the functioning and decision making of the EC.

2. **Researchers must:**
   - Ensure that documents submitted to the EC include disclosure of COI (financial or nonfinancial) that may affect their research;
   - Guard against conflicts of commitment that may arise from situations that place competing demands on researchers' time and loyalties; and
   - Prevent intellectual and personal conflicts by ensuring they do not serve as reviewers for grants and publications submitted by close colleagues, relatives and/or students.

3. **ECs must:**
   - Evaluate each study in light of any disclosed COI and ensure appropriate action is taken to mitigate this; and
   - Require their members to disclose their own COI and take appropriate measures to recuse themselves from reviewing or decision making on protocols related to their COI; and
   - Make appropriate suggestions for management, if COI is detected at the institutional or researchers level.

3.3.2 Data acquisition, management, sharing and ownership:

- There is no single best way to collect data. Different collection techniques are needed for different types of research. Researchers should be sensitive to participants and use best practices for data collection.

- Data collection involves the physical process of recording data in hard copy, soft or electronic copy, or other permanent forms. The physical formats for recording data vary considerably, from measurements or observations to photographs or interview recordings. To be valuable, research data must be properly recorded.
- Institutes receiving research funds have responsibilities for budgets, regulatory compliance and management of collected data with funded research. This means that researchers should obtain appropriate permissions/approvals to take their data and funding with them if they move to another institution.
- Ownership issues and responsibilities need to be carefully worked out well before data are collected and researchers should ensure clarity about data ownership, publication rights and obligations following data collection. MoUs vetted by the institution and/or EC should be in place.
- For biological samples, donors (participants) maintain the ownership of the sample. She/he could withdraw both the biological material and the related data unless the latter is required for outcome measurement and is so mentioned in the initial informed consent document.
- Institutes hosting/implementing the research are the custodians of the data/ samples.
- Research must be conducted using appropriate and reliable methods to provide reliable data. The use of inappropriate methods in research compromises the integrity of research data and should be avoided.
- Quality research requires attention to detail at every step. Proper protocols need to be established and the results accurately recorded, interpreted and published. Implementation of poorly designed research wastes resources and should be avoided.
- Data protection and storage is important and once collected, data must be properly protected, as it may be needed at a later stage to confirm research findings, establish priority, or be re-analysed by other researchers. Responsible data handling begins with proper storage and protection from accidental damage, loss or theft. Care should be taken to reduce the risk of fire, flood and other catastrophic events. Computer files should be backed-up and the back-up data saved in a secure place at a site that is different from the original data storage site.
- Data sharing is important as research data is valuable and needs to be shared, but deciding when and with whom to share may raise difficult questions. Once a researcher has published the results of an experiment, it is generally expected that all the information about that experiment, including the final data, should be freely available for other researchers to check and use. Data should be shared or placed in a public domain in a de-identified/anonymized form, unless required otherwise, for which applicable permissions/re-consent should be sought unless obtained beforehand.

3.4 Reviewing and reporting research:

The public's trust in published research is an essential component of ethical and responsible research.

3.4.1 The basic premise of all reviewers and editors evaluating research is that the work has been performed honestly, its reporting is transparent and truthful and the researchers' integrity is beyond doubt.

3.4.2 Transparency pertains to both the research site and the researcher(s). This would require disclosure of the location of the research as well as the collaborating sites/institutions and the authors of that research.

3.4.3 Research that is completed, irrespective of results, must be published, since it would be unethical to expose another set of participant/patients/volunteers to the same risks to obtain the same results. 3.4.4 Researchers should provide results of study in the public database of the Clinical Trial Registry-India (CTRI)

3.5 Responsible authorship and publication:

3.5.1 Authorship:
The researchers should follow the guidance of International Committee of Medical Journal Editors (ICMJE) on authorship23 which is largely accepted as a standard and is endorsed by the World Association of Medical Editors (WAME).

According to the ICMJE, authorship entails the following criteria:
1. substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of data for the work;
2. drafting the work or revising it for important intellectual content;
3. final approval of the version to be published;
4. agreement to be accountable for all aspects of the work and ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

- Institutions and departments should have authorship policies. Editors of journals do not adjudicate on authorship disputes and would almost always refer these to the institution/researchers themselves to resolve.
- Authorship should never be gifted and 'ghost' authors are not acceptable. The authorship of research should be considered at the time of its initiation.
- The primary author should be the person who has done most of the research work related to the manuscript being submitted for publication. Research performed

as part of a mandatory requirement of a course/fellowship/training programme including student research should have the candidate as the primary author. All efforts must be made to provide

the candidate with an opportunity to fulfill the second, third and fourth criteria of the ICMJE guidelines.

3.5.2 Peer review Scientific disclosure and progress has been dependent largely on peers evaluating research and judging the quality and utility of conducting and publishing research.

- The present peer review system depends on fairness, honesty and transparency of all stakeholders – editors, reviewers and researchers. It can involve one or more reviewers and should be completed within a reasonable period of time.
- Researchers must avoid mentioning friends, well-wishers and mentors as reviewers and must decline to review research of close associates, friends and students.
- Funding agencies and journals must ask reviewers and researchers to inform them of COI, if any.
- Reviewers must maintain the confidentiality of manuscripts sent to them for review.
- If reviewers feel they are not competent to review papers, then they should inform editors immediately and should not pass on the manuscripts to friends and colleagues without seeking the consent of the editors.
- Reviewers who are researchers must not misguide editors in an attempt to self evaluate their research (using another email ID and profile)

Section 4 : Ethical Review Procedures

It is necessary for all research proposals on biomedical, social and behavioral science research for health involving human participants, their biological material and data to be reviewed and approved by an appropriately constituted EC to safeguard the dignity, rights, safety and well-being of all research participants.

- ECs 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 ethics.
- compliance during the conduct of research.
- The IEC shall be independent in its functioning.
- The institution shall be responsible for establishing an IEC to ensure an appropriate and sustainable system for quality ethical review and monitoring.
- The institution shall be responsible for providing logistical support, such as infrastructure, staff, space, funds, adequate support and protected time for the Member Secretary to run the EC functions.

The IEC shall be responsible for scientific and ethical review of research proposals. Although ECs may obtain documentation from a prior scientific review, they must determine that the research methods are scientifically sound, and should examine the ethical implications of the chosen research design or strategy.

All types of biomedical and health research (whether clinical, basic science, policy, implementation, epidemiological, behavioral, public health research, etc) shall be reviewed.

4.1 Terms of reference (TOR) for ECs

- The TOR for the IEC and its members shall be clearly specified by the institution in the EC SOPs.
- The IEC shall have written SOPs according to which the committee should function.
- The EC can refer to ICMR guidelines in preparing the SOPs for all biomedical and health research and to CDSCO guidelines for drug and device trials under the purview of licensing authority.
- The SOPs shall be updated periodically to reflect changing requirements.
- A copy of the latest version of SOPs shall be made available to each member and they shall be trained on the SOPs. The SOPs shall be available in the secretariat of the EC as both hard and soft copies.
- The scope, tenure and renewal policy of the EC should be stated.
- The members of the IEC shall not have any known record of misconduct.
- The IEC shall have subcommittees such as the SAE subcommittee or expedited review committee. These should be part of the main committee and comprise Chairperson/ Member Secretary and one to two appropriate designated members of the main IEC as defined in the SOPs. These subcommittees shall report to the main IEC.

4.2 Composition of the IEC:

- The IEC shall be multi-disciplinary and multi-sectoral.
- There shall be adequate representation of age and gender.
- Preferably 50% of the members shall be non-affiliated or from outside the institution.
- The number of members in an EC shall preferably be between seven and 15 and a minimum of five members shall be present to meet the quorum requirements.
- The IEC shall have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution.

4.3 REQUIREMENTS FOR IEC 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. Be aware of relevant guidelines and regulations
5. Read, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time.
6. Sign a confidentiality and conflict of interest agreement/s
7. Be willing to place her/his full name, profession and affiliation to the EC in the public domain
8. Be committed and understanding to the need for research and for imparting protection to research participants in research.

COMPOSITION, AFFILIATIONS, QUALIFICATIONS, MEMBER SPECIFIC ROLES AND

RESPONSIBILITIES OF THE IEC

Sr. No.	Member	Definition/Description
	Chairperson/ Vice Chairperson (optional) Non-affiliated Qualifications - A well-respected person from any background with prior experience of having served/	Conduct EC meetings and be accountable for independent and efficient functioning of the committee • Ensure active participation of all members (particularly non-affiliated, non- medical/ non- technical) in all discussions and deliberations • Ratify minutes of the previous meetings

	serving in an EC	• In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting. • Seek COI declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data etc
	Member Secretary/ Alternate Member Secretary (optional) Affiliated Qualifications – • Should be a staff member of the institution • Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skill Should be able to devote adequate time to this activity which should be protected by the institution	Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule EC meetings, prepare the agenda and minutes • Organize EC documentation, communication and archiving • Ensure training of EC secretariat and EC members • Ensure SOPs are updated as and when required • Ensure adherence of EC functioning to the SOPs • Prepare for and respond to audits and inspections • Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. • Assess the need for expedited review/ exemption from review or full review • Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. • Ensure quorum during the meeting and record discussions and decisions.
	Basic Medical Scientist(s) Affiliated/ non-affiliated Qualifications - • Non-medical or medical person with qualifications in basic medical sciences • In case of EC reviewing	• Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report • For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.

	clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist	
	Clinician(s) Affiliated/ non-affiliated Qualifications – • Should be individual/s with recognized medical qualification, expertise and training	• Scientific review of protocols including review of the intervention, benefit- risk analysis, research design, methodology, sample size, site of study and statistics • Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) • Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation. • Thorough review of protocol, investigator's brochure (if applicable) and all other protocol details and submitted documents
	Legal expert/s Affiliated/ non-affiliated Qualifications - • Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law.	• Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher’s undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc. • Interpret and inform EC members about new regulations if any
	Social scientist/ philosopher/ ethicist/theologian Affiliated/ non-affiliated Qualifications - • Should be an individual with social/ behavioral science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and	• Ethical review of the proposal, ICD along with the translations. • Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any • Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

	moral values. Can be from an NGO involved in health-related activities	
	Lay person(s) Non-affiliated Qualifications - • Literate person from the public or community • Has not pursued a medical science/ health related career in the last 5 years • May be a representative of the community from which the participants are to be drawn • Is aware of the local language, cultural and moral values of the community • Desirable: involved in social and community welfare activities	• Ethical review of the proposal, ICD along with translation(s). • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. • Serve as a patient/participant/ community representative and bring in ethical and societal concerns. • Assess on societal aspects if any.

4.4 CRITERIA FOR SELECTION OF MEMBERS

1.Members shall be selected in their personal capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the IEC.

2.Members shall be appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting.

3.The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility based on their qualifications. Hence, if the Chairperson is a lawyer, she or he can serve as both the lawyer and the Chairperson.

4.5 QUORUM FOR IEC MEETING:

1.A minimum of five members present in the meeting room.
2. The quorum should include both medical, non-medical or technical or/and non-technical members.
3. Minimum one non-affiliated member should be part of the quorum.
4. Preferably the lay person should be part of the quorum.
5. The quorum for reviewing trials should be in accordance with current requirements.
6. No decision is valid without fulfillment of the quorum.

So as to maintain independence, the head of the institution shall not be part of the IEC but shall act as an appellate authority to appoint the committee or to handle disputes. The Chairperson and Member Secretary shall have dual roles in the ethics committee. They shall fulfill a role based on their qualifications (such as that of clinician, legal expert, basic scientist, social scientist, lay person etc.) in addition to taking on the role of Chairperson or Member Secretary.

The IEC shall also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements. These members have the same TORs as regular members and can attend meetings in the absence of regular members. The IEC shall maintain a panel of subject experts who are consulted for their subject expertise, for instance, a pediatrician for research in children, a cardiologist for research on heart disorders, etc. They shall be invited to attend the meeting to give an expert opinion on a specific proposal but will not have decision making power/voting rights. The IEC shall invite subject experts as independent consultants or include a representative from a specific patient group as a member of the EC or special invitee, for opinion on a specific proposal, for example HIV, genetic disorders, or cancer, with appropriate decision making Power.

4.6 Terms of reference for EC members:

The head of the institution shall appoint all IEC members, including the Chairperson. The appointment letter issued to all members shall specify the TORs. The letter issued by the head of the institution should include, at the minimum, the following:

1.Role and responsibility of the member in the committee
2.Duration of appointment
3.Conditions of appointment

The term of IEC membership will be 2–3 years. The duration shall be extended as specified in the SOPs. A defined percentage of EC members shall be changed on a regular basis.

The IEC members may be given a reasonable honorarium for attendance at the meeting. IEC members shall undergo initial and continuing training in human research protection, applicable EC SOPs and related regulatory requirements. All training shall be documented. Any change in the relevant guidelines or regulatory requirements shall be brought to the attention of all IEC members. IEC members shall be aware of local, social and cultural norms and emerging ethical issues.

4.7 Roles and responsibilities of the IEC:

The basic responsibility of IEC shall be to ensure protection of the dignity, rights, safety and well-being of the research participants. The IEC shall ensure ethical conduct of research by the investigator team. The IEC shall be responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.

The IEC shall perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.

The IEC shall ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs. The EC should assist in the development and education of the research community in the given institute (including researchers, clinicians, students and others), responsive to local healthcare requirements.

The responsibilities of members shall be clearly defined . The SOPs should be given to EC members at the time of their appointment. The IEC shall ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.
The IEC shall review progress reports, final reports and AE/SAE and give needful suggestions regarding care of the participants and risk minimization procedures, if applicable. The IEC shall recommend appropriate compensation for research related injury, wherever required. The IEC shall carry out monitoring visits at study sites as and when needed. The IEC shall participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.

4.8 Submission and review procedures:
Researchers shall 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 IEC shall prepare a checklist for the required documents . This list shall be subject to modifications, depending on the type of research, IEC SOPs and institutional policies.

The Member Secretary/Secretariat shall screen the proposals for their completeness and, depending on the risk involved, categorize them into three types, namely, exemption from review, expedited review, and full committee review.

A researcher shall not decide that her/his proposal falls in the exempted, expedited or full review category. All research proposals must be submitted to the EC.

The decision on the type of review required rests with the EC and will be decided on a case-to-case basis. Researchers can approach the EC with appropriate justification for the proposal to be considered as exempt, expedited or if waiver of consent is requested.

Expedited review may be conducted by Chairperson, Member Secretary and one or two designated members or as specified in SOPs. Approval granted through expedited review and the decisions of the SAE subcommittee shall be ratified at the next full committee meeting. IEC members shall be given enough time (at least 1 week) to review the proposal and related documents, except in the case of expedited review.

All IEC members should review all proposals. However, the EC may adopt different procedures for review of proposals in accordance with their SOPs. The IEC shall adopt a system for pre-meeting peer review by subject experts and obtain clarifications from the researchers prior to the meeting in order to save time and make the review more efficient during the full committee meeting, especially in institutions where there are no separate scientific review committees. The IEC shall have a system of appointing primary and secondary reviewers.

The Member Secretary shall identify the primary and secondary reviewers for reviewing the scientific content and the ethical aspects in the proposal as well as the informed consent document, depending upon their individual expertise. The Member Secretary shall identify subject experts to review the proposal as per need. These experts may be invited to the EC meeting or join via video/teleconference but will not participate in final decision making. The IEC shall meet regularly, adopt best practices, try to reduce turnaround time or have procedures in place for early decision making so that research is not delayed.

No.	Types of Review	
	Exemption from review	Proposals with less than minimal risk where there are no linked identifiers, for example; research conducted on data available in the public domain for systematic reviews or meta-analysis; observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person; quality control and quality assurance audits in the institution; comparison of instructional techniques, curricula, or classroom management methods; consumer acceptance studies related to taste and food quality; and public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).
	Expedited Review	Proposals that pose no more than minimal risk may undergo expedited review, for example; research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and lover clinical samples;

		research involving clinical documentation materials that are non-identifiable (data, documents, records); modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s); revised proposals previously approved through expedited review, full review or continuing review of approved proposals; minor deviations from originally approved research causing no risk or minimal risk; progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and for multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review. research during emergencies and disasters (See Section 12 for further details).
	Full committee review	any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment; research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need; prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

4.9 SOP for Conduct of a Full Committee Meeting:

1. All proposals that are determined to undergo full committee review shall be deliberated and the decision about the proposal taken at a full committee meeting.
2. The IEC shall conduct regular full committee meetings to deliberate proposals in accordance with a pre-decided schedule, as described in the SOPs.

3. A meeting shall be considered valid only if the quorum is fulfilled. This shall be maintained throughout the meeting and at the time of decision making.
4. If a member has declared a COI for a proposal then this shall be submitted in writing to the Chairperson before beginning the meeting and should be recorded in the minutes.
5. The member who has declared COI shall withdraw from the IEC meeting (leave the room) while the research proposal is being discussed upon. This shall be minuted and the quorum rechecked.
6. A list of absentee members as well as members leaving or entering in-between the meeting shall be recorded. Proposals shall be taken up item-wise, as given in the agenda.Number of proposals reviewed in a meeting shall justify that there is ample time devoted for review of each proposal.
7. Time allotted for the meeting shall be reasonable to allow ample discussion on each agenda item.
8. The minutes of the previous meeting and list of protocols that were exempt from review or underwent expedited review shall be ratified.
9. Depending on the risk involved, the progress of the proposal may be monitored annually or at shorter intervals (quarterly, half yearly) as per EC decision. Approval may be continued if progress is satisfactory.
10. The IEC may decide to reverse its positive decision on a study if it receives information that may adversely affect the benefit-risk assessment.
11. The Member Secretary (assisted by the Secretariat) shall record the discussions and prepare the minutes which shall be circulated to all the members for comments before final approval by the Chairperson/Vice-Chairperson/designated member of the committee.
12. The decision of the IEC shall be communicated to the researcher along with suggestions, if any. The researcher shall have an opportunity to reply/clarify to EC comments or to discuss or present her/his stand.

4.10 Continuing review:

Ongoing research shall be reviewed at regular intervals, at least once a year, (or more often, if deemed necessary depending on the level of risk) or as may be specified in the SOP of the EC and at the time of according approval, and as indicated in the communication letter.

The IEC shall continually evaluate progress of ongoing proposals, review SAE reports from all sites along with protocol deviations/violations and non-compliance, any new information pertaining to the research and assess final reports of all research activities.

The IEC shall examine the measures taken for medical management of SAEs. Participants should not have to bear costs for the management of study-related injury whether they are in the intervention arm or the control arm.

Compensation shall be given for research-related injuries if applicable, as determined by the EC and as per regulatory requirement (if applicable). For protocol deviations/violations the EC shall examine the corrective actions. If the violations are serious the EC may halt the study3.10. The

EC may report to the institutional head/government authorities where there is continuing non-compliance to ethical standards. Reports of monitoring done by the sponsor and DSMB reports may also be sought.

4.11 Site monitoring:

The IEC shall follow mechanism to monitor the approved study site until completion of the research to check for compliance or improve the function.

4.12 Record keeping and archiving:

1. All documentation and communication of IEC shall be dated, filed and preserved according to written procedures.
2. Confidentiality shall be maintained during access and retrieval procedures by designated persons.
3. All active and inactive (closed) files shall be appropriately labeled and archived separately in designated areas.
4. Records shall be maintained in hard copies as well as soft copies. All records shall be archived for a period of at least 3 years after the completion/ termination of the study. IEC records shall be accessible for inspection by authorized representatives of regulatory agencies.

Type of Document	Document Specifics
Administrative documents	Constitution and composition of the EC Appointment letters Signed and dated copies of the most recent curriculum vitae of all EC members Signed confidentiality agreements COI declarations of members Training records of EC members Financial records of EC Registration/accreditation documents, as required A copy of national and international guidelines and applicable regulations Regulatory notifications Meeting-related documents Agenda and minutes All communications received or made by the EC SOPs
Proposal-related documents	One hard copy and a soft copy of the initial research proposal and all related documents Decision letters Any amendments submitted for review and approval

	Regulatory approvals SAE, AE reports Protocol deviations/violations Progress reports, continuing review activities, site monitoring reports All correspondence between the EC and researchers Record of notification issued for premature termination of a study with a summary of the reasons Final report of the study Publications, if any

4.13 Administration and management:

1. The institution shall have an office for the EC.
2. The institution shall provide space, infrastructure and staff to the EC for maintaining a full-time secretariat, safe archival of records and conduct of meetings.
3. The institution shall allocate reasonable funds for smooth functioning of the EC.
4. A reasonable fee for review shall be charged by the EC to cover the expenses related to optimal functioning in accordance with Institutional policies.

4.14 Registration:

The IEC will ensure that processes are in place to safeguard the quality of ethical review as well as compliance with national/international and applicable regulations. The IEC shall register with the relevant authority as per the regulatory requirements.

Section 5 : INFORMED CONSENT PROCESS

The researcher shall obtain voluntary written informed consent from the prospective participant for any biomedical and health research involving human participants. This requirement is based on the principle that competent individuals are entitled to choose freely whether or not to participate or continue to participate in the research. Informed consent is a continuous process involving three main components – providing relevant information to potential participants, ensuring competence of the individual, ensuring the information is easily comprehended by the participants and assuring voluntariness of participation. Informed voluntary consent protects the individual's freedom of choice and respects the individual's autonomy.

5.1 Requisites:

1. The participant must have the capacity to understand the proposed research, be able to make an informed decision on whether or not to be enrolled and convey her/his decision to the researcher in order to give consent.
2. The consent shall be given voluntarily and not be obtained under duress or coercion of any sort or by offering any undue inducements.
3. In the case of an individual who is not capable of giving voluntary informed consent, the consent of LAR shall be obtained.
4. It will be mandatory for a researcher to administer consent before initiating any study related procedures involving the participant. It will be necessary to maintain privacy and confidentiality of participants at all stages.

5.2 Essential information for prospective research participants

Before requesting an individual's consent to participate in research, the researcher shall provide the individual with detailed information and discuss her/his queries about the research in the language she/he is able to understand. The language should not only be scientifically accurate and simple, but should also be sensitive to the social and cultural context of the participant. The ICD shall have two parts – patient/participant information sheet (PIS) and the informed consent form (ICF). Information on known facts about the research, which has relevance to participation, is included in the PIS. This is followed by the ICF in which the participant acknowledges that she/he has understood the information given in the PIS and is volunteering to be included in that research.

Adequate time should be given to the participant to read the consent form, if necessary discuss it with family and friends, and seek clarification of her/his doubts from the researchers/research team before deciding to enroll in the research.

Informed Consent Process
Essential and additional elements of an informed consent document An informed consent form must include the following: 1. Statement mentioning that it is research 2. Purpose and methods of the research in simple language 3. Expected duration of the participation and frequency of contact with estimated number of participants to be enrolled, types of data collection and methods 4. Benefits to the participant, community or others that might reasonably be expected as an outcome of research 5. Any foreseeable risks, discomfort or inconvenience to the participant resulting from participation in the study 6. Extent to which confidentiality of records could be maintained, such as the limits to which the researcher would be able to safeguard confidentiality and the anticipated consequences of breach of confidentiality 7. Payment/reimbursement for participation and incidental expenses depending on the type of study 8. Free treatment and/or compensation of participants for research-related injury and/ or harm 9. Freedom of the individual to participate and/or withdraw from research at any time without penalty or loss of benefits to which the participant would otherwise be entitled 10. The identity of the research team and contact persons with addresses and phone numbers (for example, PI/Co PI for queries related to the research and Chairperson/Member Secretary/ or helpline for appeal against violations of ethical principles and human rights) In addition, the following elements may also be required, depending on the type of study: Any alternative procedures or courses of treatment that might be as advantageous to the participant as the ones to which she/he is going to be subjected If there is a possibility that the research could lead to any stigmatizing condition, for example HIV and genetic disorders, provision for pre- test- and post-test counseling Insurance coverage if any, for research-related or other adverse events Foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research. Other specifics are as follows: i period of storage of the sample/data and probability of the material being used for secondary purposes. ii whether material is to be shared with others, this should be clearly mentioned. iii right to prevent use of her/his biological sample, such as DNA, cell-line, etc., and related data at any time during or after the conduct of the research. iv risk of discovery of biologically sensitive information and provisions to safeguard confidentiality. v post research plan/benefit sharing, if research on biological material and/or data leads to commercialization. vi Publication plan, if any, including photographs and pedigree charts.

5.3 Responsibility of researchers:

The researcher should only use the IEC approved version of the consent form, including its local translations. Adequate information necessary for informed consent should be communicated in a language and manner easily understood by prospective participants.

In case of differently abled participants, such as individuals with physical, neurological or mental disabilities, appropriate methods should be used to enhance the participants' understanding, for example, braille for the visually impaired. There should be no restriction on the participant's right to ask questions related to the study or to discuss with family and friends or take time before coming to a decision.

The researcher should not give any unjustifiable assurances or influence or intimidate a prospective participant to enroll in the study. The researcher must ensure that the participant is competent and has understood all aspects of the study and that the consent is given voluntarily. Where the participant and/or the LAR are illiterate, an impartial literate person, not connected to the research, should be present throughout the consent process as witness.

The researcher should administer a test of understanding whenever possible for sensitive studies. If need be, the test may be repeated until the participant has really understood the contents.

When a participant is willing to participate but not willing to sign or give a thumb impression or cannot do so, then verbal/oral consent may be taken on approval by the EC, in the presence of an impartial witness who should sign and date the consent document. This process can be documented through audio or video recording of the participant, the PI and the impartial witness, all of whom should be seen in the frame. However, verbal/oral consent should only be taken in exceptional circumstances and for specific, justifiable reasons with the approval of the EC. It should not be practiced routinely.

The researcher must assure prospective participants that their decision whether or not to participate in the research will not affect their rights, the patient–clinician relationship or any other benefits to which they are entitled. Reimbursement may be given for travel and incidental expenses/participation in research after approval by the EC.

The researcher should ensure free treatment for research related injury (disability, chronic life-threatening disease and congenital anomaly or birth defect) and if required, payment of compensation over and above medical management by the investigator and/institution and sponsor(s), as the case may be.The researcher should ensure that the participant can continue to access routine care even in the event of withdrawal of the participant.

5.4 Documentation of informed consent process:

Documentation of the informed consent process is an essential part of this exercise. Each prospective participant should sign the informed consent form after going through the informed

consent process of receiving information, understanding it and voluntarily agreeing to participate in the research.

In case the participant is incompetent (medically or legally) to give consent, the LAR's consent must be documented The process of consent for an illiterate participant/LAR should be witnessed by an impartial literate witness who is not a relative of the participant and is in no way connected to the conduct of research, such as other patients in the ward who are not in the study, staff from the social service department and counsellors. The witness should be a literate person who can read the participant information sheet and consent form and understand the language of the participant. If the participant cannot sign then a thumb impression must be obtained. The researcher who administers the consent must also sign and date the consent form.

In the case of institutionalized individuals, in addition to individual/LAR consent, permission for conducting the research should be obtained from the head of that institution.In some types of research, the partner/spouse may be required to give additional consent. Online consent may be obtained, for example, in research involving sensitive data such as unsafe sex, high risk behaviour, use of contraceptives (condoms, oral pills), or emergency contraceptive pills among unmarried females in India etc. Investigators must ensure that privacy of the participant and confidentiality of related data is maintained.

5.5 Electronic consent:

Electronic media can be used to provide information as in the written informed consent document, which can be administered and documented using electronic informed consent systems. These are electronic processes that use various, and possibly multiple, electronic formats such as text, graphics, audio, video, podcasts or interactive websites to explain information related to a study and to document informed assent/consent from a participant or LAR.

The process, electronic materials, method of documentation (including electronic/ digital signatures), methods used to maintain privacy of participants, confidentiality, and security of the information as well as data use policies at the research site must be reviewed and approved by the EC a priori.

The electronic consent must contain all elements of informed consent in a language understandable by the participant. See Box 5.1 for further details. The PI or her/his designee must supervise the process. In addition to electronic consent, if required a paper/soft copy of the document is needed for archiving and a paper/soft copy is also given to the participant. Interactive formats, if used, should be simple to navigate. Electronic methods should not be used if participants, for any reason, indicate a lack of comfort with electronic media. Such tools may be reviewed and approved by IEC before implementation.

5.6 Waiver of consent:

1. The researcher can apply to the IEC for a waiver of consent if the research involves less than minimal risk to participants and the waiver will not adversely affect the rights and welfare of the participants.
2. The EC may grant consent waiver in the following situations.
3. Research cannot practically be carried out without the waiver and the waiver is scientifically justified.
4. Retrospective studies, where the participants are de-identified or cannot be contacted; research on anonymized biological samples/data.
5. 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. Attempts should be made to obtain the participant's consent at the earliest.

Section 6: SOP FOR VULNERABLE POPULATIONS

6.1 selection of vulnerable and special groups as research participants:
Vulnerable groups and individuals may have an increased likelihood of incurring additional harm as they may be relatively (or absolutely) incapable of protecting their own interests. Characteristics that make individuals vulnerable are 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 which have hierarchical relationships, institutionalized persons, humanitarian emergencies, language barriers and cultural differences). In general, such participants should be included in research only when the research is directly answering the health needs or requirements of the group.

On the other hand, vulnerable populations also have an equal right to be included in research so that benefits accruing from the research apply to them as well. The IEC as well researchers need to put the above to careful consideration. The EC should determine vulnerability and ensure that additional safeguards and monitoring mechanisms are established. It should also advise the researcher in this regard. Characteristics of vulnerable individuals/populations/group Individuals may be considered to be vulnerable if they are:

- Socially, economically or politically disadvantaged and therefore susceptible to being exploited.
- Incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled.
- Able to give consent, but whose 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.

The key principle to be followed by the IEC when research is planned on vulnerable persons is that others will be responsible for protecting their interests because they cannot do so or are in a compromised position to protect their interests on their own.

6.2 Principles of research among vulnerable populations

6.1.1 Vulnerable populations have an equal right to be included in research so that benefits accruing from the research apply to them as well.

6.1.2 If any vulnerable group is to be solely recruited then the research should answer the health needs of the group.

6.1.3 Participants must be empowered, to the maximum extent possible, to enable them to decide by themselves whether or not to give assent/consent for participation.

6.1.4 In vulnerable populations, when potential participants lack the ability to consent, a LAR should be involved in decision making.

6.1.5 Special care must be taken to ensure participant's privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.

6.1.6 If vulnerable populations are to be included in research, all stakeholders must ensure that additional protections are in place to safeguard the dignity, rights, safety and wellbeing of these individuals.

6.3 Vulnerable populations or groups:

Following are some examples of vulnerable populations or groups:

- Economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/ gay/bisexual and transgender (LGBT), etc.);
- 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;
- Children (up to 18 years);
- Women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare);
- Tribals and marginalized communities;
- Refugees, migrants, homeless, persons or populations in conflict zones,riot areas or disaster situations;
- Afflicted with mental illness and cognitively impaired individuals, differently abled – mentally and physically disabled;
- Terminally ill or are in search of new interventions having exhausted all therapies; suffering from stigmatizing or rare diseases; or
- Have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defense services personnel, healthcare workers, institutionalized individuals, under trials and prisoners).

6.4 Additional safeguards/protection mechanisms:

When vulnerable individuals are to be recruited as research participants additional precaution should be taken to avoid exploitation/retaliation/reward/credits, etc., as they may either feel intimidated and incapable of disagreeing with their caregivers, or feel a desire to please them. In the first case, they may be subjected to undue pressure, while in the second, they may be easily manipulated. If they perceive that their caregivers want them to participate in research, or if the caregiver stands to benefit from the dependant's participation, the feeling of being pressed to participate may be irresistible which will undermine the potential voluntariness of the consent to participate.

6.4.1 Researchers must justify the inclusion of a vulnerable population in the research.

6.4.2 ECs must satisfy themselves with the justification provided and record the same in the proceedings of the EC meeting.

6.4.3 Additional safety measures should be strictly reviewed and approved by the ECs.

6.4.4 The informed consent process should be well documented. Additional measures such as recording of assent and reconsent, when applicable, should be ensured.

6.4.5 ECs should also carefully determine the benefits and risks of the study and examine the risk minimization strategies.

6.4.6 As potential participants are dependent on others, there should be no coercion, force, duress, undue influence, threat or misrepresentation or incentives for participation during the entire research period.

6.4.7 Vulnerable persons may require repeated education/information about the research, benefits, risks and alternatives, if any.

6.4.8 Research on sensitive issues such as mental health, sexual practices/preferences, HIV/ AIDS, substance abuse, etc. may present special risks to research participants.

6.4.9 Researchers should be cognisant of the possibility of conflicting interests between the prospective participant and LAR and should be more careful.

6.4.10 Participants may be prone to stigma or discrimination, specifically when the participant is enrolled as a normal control or is recruited from the general population in certain types of research.

6.4.11 Efforts should be made to set up support systems to deal with associated medical and social problems.

6.4.12 Protection of their privacy, confidentiality and rights is required at all times – during conduct of research and even after its completion.

6.4.13 Whenever possible, ancillary care may be provided such as setting up of a facility, school for unattended children of the participants or a hospital, or counseling center.

6.5 Obligations of stakeholders for vulnerable populations

Stakeholder	Obligation/Duties
Ethics Committee	• During review, determine whether the prospective participants for a particular research are vulnerable. • Examine whether inclusion/exclusion of the vulnerable population is justified. • Ensure that COI do not increase harm or lessen benefits to the participants. • Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible. • Suggest additional safeguards, such as more frequent review and monitoring, including site visits. • Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations. • ECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. ECs should ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD. • ECs should have SOPs for handling proposals involving vulnerable populations.
Researchers	Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection. • Justify inclusion/exclusion of vulnerable populations in the study. • COI issues must be addressed. • Have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio. • Ensure that prospective participants are competent to give informed consent. • Take consent of the LAR when a prospective participant lacks the capacity to consent. • Respect dissent from the participant. • Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc. • Research should be conducted within the purview of existing relevant guidelines/regulations

Sponsors	The sponsor, whether a government, an institution or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety. • The sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC). • The sponsor should ensure protection of the participants and research team if the research is on sensitive topics.

When vulnerable individuals are to be recruited as research participants additional precaution shall be taken to avoid exploitation/retaliation/reward/credits, etc., as they may either feel intimidated and incapable of disagreeing with their caregivers, or feel a desire to please them.

6.6 Women as subjects in research studies:

Women have equal rights to participate in research and should not be deprived arbitrarily of the opportunity to benefit from research. Informed consent process for some women can be challenging because of cultural reasons. Hence, the women may consider consulting their husbands or family members, if necessary. Although autonomy of the woman is important, the researcher must follow the requirements of local cultural practices so as not to disturb the harmony in the household/family/community

6.7 Research on sensitive topics:

When research is planned on sensitive topics, for instance, domestic violence, genetic disorders, rape, etc., confidentiality should be strictly maintained and privacy protected. In risk mitigation strategies, appropriate support systems such as counseling centers, police protection, etc. should be established. At no time should information acquired from a woman participant be unnecessary, hurtful or appear voyeuristic. The IEC should be especially vigilant regarding these sensitive issues.

6.8 Research on children:

Children are individuals who have not attained the legal age of consent (up to 18 years). At younger ages, children are considered vulnerable because their autonomy is compromised as they do not have the cognitive ability to fully understand the minute details of the study and make decisions.

At older ages, although they may attain the cognitive ability to understand the research, they still lack legal capacity to consent. Therefore, the decision regarding participation and withdrawal of a child in research must be taken by the parents/ LAR in the best interests of their child/ward. More details are available in ICMR.

Research on children can be carried out in a situation, condition, disorder or diseases as The IEC should do the benefit–risk assessment to determine whether there is a need to put into place additional safeguards/protections for the conduct of research in children. For example, research should be conducted in child-friendly settings, in the presence of parent(s) and where child participants can obtain adequate medical and psychological support. The IEC should take into consideration the circumstances of the children to be enrolled in the study including their age, health status, and other factors and potential benefits to other children with the same disease or condition, or to society as a whole. Consent of the parent/LAR shall be required when research involves children.

6.9 Assent:

In addition to consent from parents/LARs, verbal/oral or written assent, as approved by the EC, shall be obtained from children of 7–18 years of age. As children grow, their mental faculties develop and they are able to understand and respond. Respecting the child's reaction, the child is made a party to the consent process by the researcher, who explains the proposed research in a very simple manner, in a language that ensures that the child understands the request to participate in the research. A child's agreement to participate in research is called assent. If the child objects, this wish has to be respected. At the same time, mere failure to object should not be construed as assent.

Conditions for research on children

Children can be included in research if the situation, condition, disorder or disease fulfills one of the following:

conditions:

1. It is exclusively seen in childhood.

2. Both adults as well as children are involved, but the issues involved are likely to be significantly different in both these populations.

3. Both adults as well as children are involved in a similar manner and are of similar nature in terms of morbidity, severity and/or mortality, wherever relevant, and studies in adults have demonstrated the required degree of safety and efficacy.

4. Test interventions are likely to be at least as advantageous to the individual child participant as any available alternative intervention.

5. Risk of test interventions that is not intended to benefit the individual child participant is low as compared to the importance of the knowledge expected to be gained (minor increase over minimal risk).

6. Research is generally permitted in children if safety has been established in the adult population or if the information likely to be generated cannot be obtained by other means

7. The physiology of children is different from that of adults, and the pharmacokinetics of many drugs is age-dependent based on the maturation of the drug metabolism pathways. For example, children metabolize many drugs much more rapidly as compared to adults, hence the dose of the drug per kg of body weight that needs to be given, is much higher in children as compared to adults. The absorption of drugs also varies with age. Pharmacokinetics and toxicity profile varies with growth and maturation from infancy to adulthood.

8. The adverse effects of many drugs may also be different in children as compared to adults. For instance, tetracyclines cause teeth discoloration in young children, aspirin use is associated with Reye's syndrome in children.

9. Age appropriate delivery vehicles and formulations (e.g. syrups) are needed for accurate, safe, and palatable administration of medicines to infants and children.

10. The pathophysiology of many disorders is dependent on a child's growth, development and adaptive plasticity.

6.10 Consent of parent/LAR

The IEC shall determine if consent of one or both parents would be required before a child could be enrolled. Generally, consent from one parent/LAR may be considered sufficient for research involving no more than minimal risk and/or that offers direct benefit to the child. Consent from both parents may have to be obtained when the research involves more than minimal risk and/or offers no benefit to the child.

Only one parent's consent is acceptable if the other parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, irrespective of the risk involved. Whenever relevant, the protocol should include a parent/LAR information sheet that contains information about specific aspects relevant to the child such as effects on growth and development, psychological well-being and school attendance, in addition to all components described in the participant information sheet.

When the research involves sensitive issues related to neglect and abuse of a child, the EC may waive the requirement of obtaining parental/LAR consent and prescribe an appropriate mechanism to safeguard the interests of the child. Cognitively impaired children or children with developmental disorders form one of the most vulnerable populations. In fact, their parents are also vulnerable and there is a high likelihood of therapeutic misconception. The potential benefits and risks must be carefully explained to parents so as to make them understand the proposed research.

Research involving institutionalized children would require assent of the child, consent of parents/LAR, permission of the relevant institutional authorities (for example, for research in a school setting: the child, parents, teacher, principal or management may be involved).

Content of the assent form has to be in accordance with the developmental level and maturity of the children to be enrolled and explained while considering the differences in individual understanding. The language of the assent form must be consistent with the cognitive, social and emotional status of the child. It must be simple and appropriate to the age of the child.

Points to be included in the assent form are: An explanation about the study and how it will help the child; An explanation of what will be done in the study, including a description Waiver of assent.

All the conditions that are applicable to waiver of informed consent in adults also apply for waiver of assent in children. If the available intervention is anticipated to definitely benefit the child but would be available only if the child participates in the study, waiver of assent could be allowed. However, this situation should be accepted only in exceptional cases where all forms of assent/consent have failed. In such cases, approval of the IEC should be obtained. Considerations for assent.

There is no need to document assent for children below 7 years of age. For children between 7 and 12 years, verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded. For children between 12 and 18 years, written assent must be obtained. This assent form also has to be signed by the parents/LAR. Adolescents may have the capacity to give consent like adults. However, as they have not attained the legal age to provide consent, it is termed as assent and the consent of the parents/LAR should be obtained. If the latter will affect the validity of the study, waiver of consent from the relevant adult should be taken and recorded with the approval of the IEC

Section 7: Annexures

Annexures 1: List of Documents for Submission to the IEC

List of Documents for Submission to the IEC	
No.	Doucement
1	Cover Letter to the Member Secretary
2	Application form for Initial Review
3	Detailed draft of research proposal
4	Informed Consent Document in English and local documents (if applicable)
5	Case Record Form or Questionnaire
6	Patient Information Sheet
7	Details of funding agency and fund allocation (if applicable)
8	A statement on COI (If applicable)
9	MoU in case of studies involving collaborations with other institutions (If applicable)

Annexure 2 : Format of Letter of Approval

Report of Institutional Ethics Committee, KJSCPT

Department	
Candidate admitted year	
Course and Subject	
College Name and Address	

Ref. No. KJSCPT/ /2022-23. Date:

To, (Candidate Name and Department)

SUB : Research Proposal entitled "....."
Ref : Submission of your Research Synopsis in reply to IEC, KJSCPT (Letter/Proposal of Student)

Dear Student,

The above mentioned research proposal of Title & Synopsis of Dissertation was discussed in the Ethics Committee meeting held on …….. It is declared that:

1. The said Title of Synopsis is not repeated.
2. You are registered under _____ who is University Recognized P.G. Teacher vide University letter no. _____for guidance and supervision during the course of studies.
3. The Ethics Committee has unanimously approved your Title & Synopsis of Dissertation.
4. The Title is recommended for study by the student from Date ……

(Note: 1) It will be mandatory for the student to work on the University approved Title for a minimum period of 18 months after its approval.

2) It is the responsibility of the student and guide to inform the Ethics Committee about completion of said research work.)

Dr. Asmita Karajgi
Chairperson
Institutional Ethics Committee
K J Somaiya College of Physiotherapy

Dr. Mayur Revadkar (PT)
Member Secretary
IEC, K J Somaiya College of PT

Dr. Shweta Manwadkar (PT)
Principal
K J Somaiya College of PT

Dr. Mayur Revadkar (PT)
Member Secretary
IEC, K J Somaiya College of PT

Dr. Shweta Manwadkar (PT)
Principal
K J Somaiya College of PT

K.J. SOMAIYA COLLEGE OF PHYSIOTHERAPY ★ MUMBAI 400 022

IRB SOP for UG Research

Purpose : IRB of the institute shall ensure the ethical practice is followed while conducting the research in the practice.

Scope : This SOP applies to the constitution of the IRB ,guide allotment to the students, reviewing the research projects and maintenance of all activities and documents related to the research.

Procedure:

1. Members for the IRB are selected by the Administration committee/ Code of conduct committee at the start of the academic year.
2. Guides for the research projects will be allotted at the beginning of the final BPTh academic term.
3. After completion of the Research methodology module,, each student should be ready with two suggested study projects (one main & one back up). This should have the following details:-
   Title
   Research question
   Introduction in short
   Need for the study
4. A meeting will be held with the Institutional Review Board (IRB) with the students and respective guides between Ist -7th March 2022. Meetings will be as per slots allotted roll number wise and ideally in between 9am-10am, 12 noon-1 pm; Monday- Saturday.
5. If any modifications are suggested by the IRB, the same should be done and presented to the IRB within 4 days.
6. Once the study is approved by the IRB, each student will prepare the synopsis and is expected to present the same in a Powerpoint Presentation. This will be not more than 7 slides and should be as per the following guidelines:
   Introduction and need-1 slide
   Aim and objectives-1 slide
   Review of Literature (ROL); mention 3-5 research studies-1 slide
   Methodology including proposed statistical tests that may be used- 4 slides (Total 7)
   Time: 7 minutes for the presentation by the student & 3 minutes for Q & A

These presentations will be held between 15th-21st march 2022.
If any synopsis would require any modifications as suggested by IRB, it should be done on priority and should be presented to the IRB within 2-3 days.

8. Once the IRB approves the synopsis, the student should be ready with a spiral bound hard copy of the synopsis, for the Guide's and Principal's signature in the first week of April 2022. The same will need to be submitted prior to the prelims examination.
9. Some guidelines for the study project:
   a. Sample size: Observational study-Minimum is 50-100
      Experimental study- 15 in each groups, total 30
      Correlational study-20-25
   b. If a survey based project is underway, the synopsis should include main domains of the questionnaire in the synopsis ppt.
   c. Self made questionnaires will need to be face validated by three experts from the same field.
   d. Students are encouraged to publish their research work. In that case, the synopsis should request for an IRB approval letter. Authorship should also be proposed and decided during this phase.
   e. Students who are planning to conduct the studies outside the campus, need a permission letter from the external authorities. Such a request for permission will need to be processed via College with the sign of the Principal.
   f. Once permission is granted by the external authorities, the copy of the letter stating so needs to be submitted to the IRB.
   g. Keeping point e. and f. in mind, students should take geotagged photographs and / or videos and update the guide regularly.
   h. Students need to sign a consent form regarding the publication & authorship details. This will be drafted by the IRB and shared with the students.
   i. If the study involves a novel or a new technique, the student should provide a certification prior to data collection.
   j. If statistical guidance is sought, the cost should be borne by the student.

Guides to note:

1. The aim of the MUHS research study project for the final BPTh is that the students have a brief idea about how research is conducted. Guides are therefore requested to bear this in mind and decide on study topics accordingly.
2. The topics should be simple, feasible and time bound.
3. While the same subject population can be taken for more than one observational study, the same population cannot be taken for two different experimental studies. The same population can be taken for an observational and an experimental study project. In this case, the experimental study will commence after the observational one.
4. The guide can invite one research topic and their allotted students can explore this with different objectives.
5. Guides are encouraged to have collaborative interdepartmental study projects. In this case, the study population may remain the same and that different departments have different objectives. For points 3 and 5, the group research and interdepartmental research studies, the IRB needs to be informed prior.
6. The proposed study should not have been conducted in the last 5 years. It is preferable that the topic may be modified (new dimension/ new outcome measure) and the need of the study should be justified.
7. During the IRB presentation, it is preferable that the students answer the questions put forth by the IRB. Guides can opine if asked by the IRB.

Students should be encouraged to take research studies for publications in future. It should be voluntary by the student in free or paid journals. Propose authorship details for the same.

9. If the guide wants the student's study to go for IEC approval, they may do so after the IRB approval. This approval should be taken prior to data collection and well in advance so that it can be included and cleared in IEC .
10. If the student publishes the research, the student will be the first author and the guide will be the corresponding and the second author.
11. If a student is not willing to publish the research, the guide may be allowed to publish the research, keeping the IRB informed. This can be done 6 months after the completion of the research study.If the guide publishes the research, the guide will be the first author and the corresponding author.
12. Students will sign a declaration form regarding the publication & authorship details. This will be drafted by the IRB and shared with the students.
13. If the study involves a novel or a new technique, the student should provide a certification prior to data collection.
14. Students, if required, can approach the statistician on their own.
15. After presentation, a soft copy of the manuscript to be submitted to the College within 2 weeks.

Members:
Dr. Shweta Manwadkar(PT)
Dr. Geeta Bhatt (PT)
Dr. Khyati Kothary(PT)
Dr. Pothiraj Pitchai (PT)

PRINCIPAL
K. J. SOMAIYA COLLEGE OF PHYSIOTHERAPY
Somaiya Ayurvihar Complex, Eastern Express Highway,
Sion (East), Mumbai - 400 022.

K.J. SOMAIYA COLLEGE OF PHYSIOTHERAPY
MUMBAI
400 022

SOMAIYA AYURVIHAR

K J Somaiya College of Physiotherapy

Somaiya TRUST

PG Research Committee

Purpose: To ensure and encourage good research practice at K. J. Somaiya College of Physiotherapy and to increase the quantity and quality of research projects.

Scope of Application: This SOP applies to the constitution of the PG Research committee, roles and responsibilities of members of the research committee and maintenance of all activities and documents. It is applicable to all the faculty and PG students at K. J. Somaiya College of Physiotherapy.

Objectives:

1. To conduct regular research meetings for the update of research activities at the institute.
2. To conduct research seminars for developing research aptitude amongst faculty.
3. To coordinate with ethical committee for approval of research projects.
4. To facilitate paper and poster presentations in various conferences by student and faculty.
5. To plan research budget.

Chairperson: Principal : Dr. Shweta Manwadkar (PT)

Members:

1. Dr. Annamma Varghese (PT)
2. Dr Isha Tajane (PT)
3. Dr. Mayur Revadkar (PT)

Roles and Responsibilities:

A. Any PG research activity at K. J. Somaiya College of Physiotherapy would undergo the following steps:

1. Plan the synopsis in consultation with the guide.
2. Present the synopsis in Institutional Review Board meetings and incorporate the suggestions given by the committee.
3. Present the corrected synopsis in Institutional Ethical Committee Meeting for final approval.
4. After obtaining IEC approval, collect the data and submit the review report to the research committee.
5. Prepare the final manuscript and submit it to the appropriate journal indexed in web of science/ pubmed/ scopus/ UGC after discussing it with the research committee.
6. If the student publishes the research, the student will be the first author and the guide will be the corresponding and second author.
7. If a student is unwilling to publish the research, the guide may be allowed to publish it 6 months post-completion, after informing the PG research committee. If the guide publishes said research, the guide will be the first and corresponding author.
8. Institution shall provide financial support for the publication as per the policy.

Research Committee should:

1. Inform all students and faculty about the university research circulars.
2. Conduct regular research meetings and maintain the minutes of the meeting.

B. Any Faculty research activity at K. J. Somaiya College of Physiotherapy would undergo the following steps:

1. All research projects have to be informed to the research committee once the topic is conceptualized, irrespective of the data collection center. In case any faculty has concerns about the confidentiality of the research topic, the same can be informed only to the Principal via email.
2. Research proposals where data will be collected from outside centers, will have to take IRB/IEC approval from the particular center and submit an approval letter of same to Somaiya Research Committee.
3. Research proposals where data collection will be done at Somaiya hospital and physiotherapy center will have to undergo IRB/IEC approval of K J Somaiya College of physiotherapy.
4. All communication must be in written email format only, not verbal communication with any research committee members.
5. Authorship has to be defined at the time of synopsis submission. Later, if there is any change in authorship, it should be informed to the research committee.
6. Present the synopsis in Institutional Review Board meetings and incorporate the suggestions given by the committee.
7. Present the corrected synopsis in Institutional Ethical Committee Meeting for final approval.
8. After obtaining IEC approval, collect the data and submit the review report to the research committee.
9. Prepare the final manuscript and submit it to the appropriate journal after discussing it with the research committee.

Principal
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