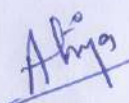

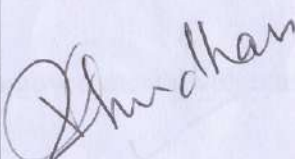

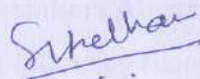
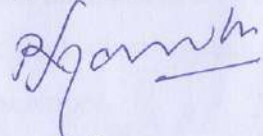




**DES'S
BRIJLAL JINDAL COLLEGE
OF PHYSIOTHERAPY,
PUNE**

**INSTITUTIONAL ETHICS COMMITTEE
STANDARD OPERATING
PROCEDURE DOCUMENT**

Title	Standard Operating Procedures(SOPs) for Institutional ethics Committee of DES Brijlal Jindal College of Physiotherapy, Pune(IECDESBJCOP)
Version	SOP version 1
Effective	From: 1 Aug 2020 Upto:31 July 2025

Prepared by	Reviewed by	Approved by	Accepted by
Dr Atiya Shaikh(PT) Member Secretary- IECDESBJCOP 	Dr Snehal Joshi(PT) Professor-DESBJCOP 	Dr Vivek Patwardhan Chairperson- IECDESBJCOP 	IECBESBJCOP 
	Dr Savita Kelkar Member- IECDESBJCOP 		
	Dr Sharad Agarkhedkar LMC Chairman, DESBJCOP 		



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SECTION 1- CONSTITUTION OF IEC

I IEC will be established by head of the Institution.

II IEC will have members as per guidelines of ICMR ,i.e

- a) Chairperson
- b) Member secretary
- c) Basic medical scientists
- d) Clinician/s
- e) Legal expert
- f) Social scientist/representative of non-governmental voluntary agency/Philosopher/ethicist
- g) Educated person from the community
- h) Members
- i) The IEC may invite member(s) of specific patient groups or other special interest groups for an IEC meeting

III **Qualification of members/Membership requirements**

The members should meet following requirements before being appointed by HOI

- a) Chairperson-A well respected person from any background with prior experience of serving in IEC and should not be affiliated to the institute. He/She will be appointed by HOI.
- b) Member secretary-He/she will staff of institute, should have knowledge and experience in clinical research ethics, be motivated and have good communication skills. He/she should be able to devote adequate time to this activity which should be protected by institution. He/She can be appointed by EC/suggested by HOI and Chairman .
- c) Basic medical scientist/s-can be affiliated/non-affiliated. Should have qualification in basic medical sciences.



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- d) Clinician/s- can be affiliated/non-affiliated. Should have recognized medical qualification, expertise and training.
- e) Legal expert- can be affiliated/non-affiliated. Should have recognized medical qualification, expertise and training.
- f) Social scientist /theologian Philosopher/ethicist -can be affiliated/non-affiliated. Should have recognized appropriate qualification, expertise and training. Should be sensitive to local cultural and moral values. Can be from NGO.
- g) Lay person-Should be non-affiliated .Should be a lay person from community. Should not have persuaded medical career in last 5 yrs. should be aware of local language, cultural and moral values of community.

1. All IEC members should be certified in Good clinical practice (GCP)
2. The external members shall be in majority to ensure the independence of the committee.
3. The Member Secretary will be a chosen staff from DESBJCOP, Pune. He/She will conduct the committee proceedings on behalf of institute.

IV Hierarchy-

1. There will be one Chairperson, one Member Secretary. A Joint Member Secretary may be appointed amongst the members if necessary.
2. The Chairperson will be the head of the committee.
3. The Member Secretary and the Joint Member Secretary (whenever applicable) will be the guardian of all documents and funds in the possession of the committee.
4. Other IEC members will be regular committee members with equal ranking.
5. The Chairperson will be appointed by the Head of the Institute,
6. The Member-secretary, Joint Member-Secretary (if necessary) will be nominated from amongst the IEC members by HOI at first time .Should they resign or be disqualified; the IEC members will elect a replacement for him/her.



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V Roles and Responsibilities of IEC members

1. To attend IEC Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
2. To review, discuss and consider research Proposals submitted for evaluation.
3. To monitor Serious Adverse Event reports and recommend appropriate action(s)
4. To review clinical trial agreement, Insurance policy and informed consent document
5. To maintain confidentiality of the documents and deliberations of IEC meetings.
6. To declare any conflict of interest.
7. To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
8. To provide an updated CV when requested for by the IEC secretariat
9. To carry out the work delegated by Chairperson, Member-secretary and Jt. Member-secretary.
10. To assist Chairperson, Member-secretary and Jt. Member-secretary in carrying out IEC work as per SOPs

Individual roles of members are as follows-

- A) Chairperson- Conduct EC meetings and be accountable for independent and efficient functioning of the committee
- Ensure active participation of all members in all discussions
 - Ratify minutes of the previous meetings
 - In case of anticipated absence of both 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 Conflict of Interest (COI) declaration from members and ensure quorum and fair decision making.



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- Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
- b) 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.
- c) Basic Medical Scientist/s-
 - 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.
- D) . Clinician-
 - 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)



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- Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation.
- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents
- d) Legal expert/s-
 - 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
- e) Social scientist/ philosopher/ ethicist/theologian-
 - 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.
- e) Lay person-
 - 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

VI Responsibilities of the Institutional Ethics Committee

1. Protection of safety, rights and confidentiality of the research participants.



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2. Participation in activities that promote ethical research in the institution and community.
3. The Committee will participate in and organize programs aimed at educating and training community members, members of the public, investigators, IEC members in ethical research

VII Terms of reference of Ethics Committee

- The head of the institution will appoint all EC members, including the Chairperson.
- The appointment letter issued to all members will specify the TORs. The letter issued by the head of the institution will include, the following:
 - ❖ Role and responsibility of the member in the committee
 - ❖ Duration of appointment
 - ❖ Conditions of appointment
- EC members may be given a reasonable honorarium for attendance at the meeting.
- Members to be appointed on the EC should be willing to fulfil the EC requirements as below-
 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
 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



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7. be willing to place her/his full name, profession and affiliation to the EC in the public domain; and be committed and understanding to the need for research and for imparting protection to research participants in research

VIII Quorum Requirements-

- At least 60% members are required. Preferably, one regular member (preferably medical faculty, the social worker, a clinician, the lay person and the legal expert besides Member Secretary and Chairperson.

IX Condition of appointment-

- HOI will invite the chairman. Chairman and HOI will invite member secretary (for first time appointment) and EC as per ICMR guidelines.
- Members will be selected in their personal capacities based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC work
- This appointment term will be for 5 years which can be extended as per HOI,EC decision and willingness of the member.

X Registration/replacement/removal of members-

New members can be invited by EC by consensus as per requirement. A member can be removed/replaces by consensus of EC in case of breach of IEC policies or conflict of interest policies. Once appointed a member can be a part of IEC till he voluntarily withdraws or is replaced/removed by EC.

XI Training of members-



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1. Care will be taken that all members will be trained in human research protection, EC functions and SOPs, and will be conversant with ethical guidelines, GCP guidelines (if applicable) and relevant regulations of the country.
2. All EC members will undergo initial and continuing training in human research protection, applicable EC SOPs and related regulatory requirements.
3. Any change in the relevant guidelines or regulatory requirements will be brought to the attention of all EC members. Any training related to that will be carried out if required.
4. EC members will be made aware of local, social and cultural norms and emerging ethical issues time to time. Any training related to that will be carried out if required.
5. All trainings will be documented.

XII Remuneration/Honorarium of members-

1. Members will be given honorarium as per institute guidelines for each sitting.

XIII IEC Charges for processing of proposed studies-

1. Investigators will have to pay IEC processing charges at the time of submission of proposal
2. These charges will be decided by institution policy from time to time.

XIV Registration/removal/replacement of members

1. Tenure of Membership-

- a) The tenure of Institutional Ethics Committee members will be for a continuous period of five years from the date of appointment and can be extended in future as per willingness of the member to continue in future. Final decision will be of the EC members and HOI.
- b) The IEC member secretary and HOI will initiate the process of filling up the forthcoming vacancies three months prior to the end of tenure of a member, The Chairperson will recommend names of individuals to the HOI. The HOI will select and appoint a member for the new tenure from the list



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provided by the IEC or otherwise. The retiring member will be eligible to be appointed for the new tenure any number of times.

2. Appointment of new members and alternate members-

The IEC members will be appointed by the HOI. New members will be appointed under the following circumstances:

- (i) When a regular member completes his/ her tenure.
- (ii) If a regular member resigns before the tenure is completed.
- (iii) If a regular member ceases to be a member for any reason including death or disqualification.

3. Resignation and Disqualification of Members-

a) Resignation: An IEC member may resign from membership by submitting a letter of resignation to the Chairperson.

- The member may or may not assign reasons for resignation. The resignation will become effective from the day it is accepted by the Chairperson.

b) Disqualification for conduct unbecoming of an IEC member:

A member may be disqualified from continuance should IEC determine by a three-fourth majority specifically called for the purpose that the member's conduct has been unbecoming of an IEC member.

- (i) The process will be initiated if IEC Chairperson or Member-secretary receives a communication in writing (provided by IEC member or a member of the public) alleging misconduct by a member.
- (ii) The Chairperson will satisfy himself/ herself that a prima facie case exists before initiating action. If, in the opinion of the Chairperson, the matter is of grave significance where integrity of IEC could be questioned, the Chairperson may suspend the membership of the concerned IEC member till final decision is taken by IEC. During the period of suspension, the concerned individual will not have any



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- rights, privileges or responsibilities of an IEC member and will not perform any duties of IEC member.
- (iii) The Chairperson may call for a meeting of the IEC specifically to discuss this issue or the matter will be taken up for discussion. The meeting convened will follow the usual rules of quorum. The allegation will be discussed at the IEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself / herself.
- (iv) The member would stand disqualified if members present approve of disqualification by voting (voting by 2/3rd of majority of members present in the meeting and voting). The Chairperson will convey the disqualification to the concerned member through a written communication.
- c) Disqualification for not attending IEC meetings: A member may be disqualified from IEC membership if the member fails to attend more than 3 regular consecutive IEC meetings without prior intimation. The process conducted will be as follows:
- d) The member-secretary will inform Chairperson, in writing, if a member has not attended more than three consecutive regular meetings of the IEC.
- The Chairperson will initiate the process of review of membership of such a member by including the matter in the Agenda of the next regular IEC meeting
- (i) A written communication will be sent to the concerned IEC member informing him/ her that the issue of disqualification would be discussed at the meeting inviting the member to be present at the meeting to put up his/ her case. Alternately, the concerned IEC member will be allowed to state his/ her arguments regarding unauthorized absence in writing by a letter addressed to the Chairperson
- (ii) The matter will be discussed and reviewed at the IEC meeting. The concerned member will be provided adequate opportunity to represent his/ her case. A written communication, if received from the concerned member will be read and reviewed at the meeting.



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- e) The Chairperson or Member-Secretary will inform the IEC members about the cessation of membership by a confidential written communication to other members of IEC or at the next meeting of IEC
4. Replacement of member-
This will be done in case of either termination or resignation of the member or when a member is disqualified to fulfill the required member quorum.

SECTION 2- SOP FOR IEC WORKING

1 Regular Meeting-

1. DESBJCOP will have IEC meeting as per requirement .Minimum one per year.
2. Meeting will be announced by member secretary after consulting with the chairperson and after considering availability of members
3. IEC meeting will be held after 1 year MPT admissions as per availability of members and preparedness of students.
4. Emergency IEC meeting can be called in case of any SAE/breach in protocol or as per the need during academic year.
5. Proposed studies of MPT/interns/students/staff/any other departmental studies can be presented in IEC.
6. Proposals have to be submitted in a prescribed format. Incomplete proposals will not be entertained.
7. Proposals submitted in prescribed format and with all annexures will be accepted for IEC review.
8. Proposed protocols will be mailed/sent by post in desired format to all IEC members by secretary 15 days prior to meeting.
9. Meeting will be conducted once quorum of 60% members is fulfilled
10. MPT Proposal has to be approved by Departmental Review Board (DRB)/Board of Studies (BORS) of that subject to be discussed in IEC.
11. Investigator/guide should be available at the time of IEC to provide clarifications if required.



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12. IEC will discuss proposed study in view of ICMR ,GCP,MUHS guidelines before giving its decision.
13. IEC will review the proposal with reference to IEC checklist before giving decision i.e accepted/Not accepted/Accepted with modifications/suggested for expedited review(in case of modifications suggested by IEC).
14. Revised proposals may be subjected to an expedited review as per suggestion by IEC which will be done by BORS/DRB of same subject/chosen IEC members. The report should be sent to IEC within 15 days from IEC meeting.
15. Proposals which are recommended for minor revisions will be reviewed and approved after submission of revised proposal. The revised proposal should be submitted to IEC within 15 days.IEC should issue permission letter within 15 days of receiving this revised proposal.
16. Revisions/Modifications will be conveyed to Investigator at the time of meeting in written format. Acceptance for conducting the study will be given only after ensuring that those modifications have been done by the Investigator.
17. Independent consultants/Experts may be invited to offer their opinion on specific research proposals.
18. A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises.
19. The decisions of the meeting shall be recorded in a separate book and shall be confirmed during the next meeting with signature of Chairperson.
20. The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicating with all concerned members. He/she will prepare the minutes of the meetings and get them approved by the Chairperson before communicating to the Investigators.
21. Investigator has to submit study results once the study is complete.
22. All documents will be preserved for 10 yrs after IEC approval.



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2 Review of submitted protocol

1. Proposed protocol should be reviewed by subject expert and should have a departmental review board certificate(DRB)/Board of studies(BORS)(committee already existing at institute level as per MUHS norms.
2. The protocol will be reviewed as per guidelines given by MUHS.(Maharashtra University of Health Sciences) by BORS/DRB
3. Following criteria should be considered while reviewing the proposed protocol
 - a) Qualification of investigator to conduct assessment
 - b) Appropriateness of study design, work plan and structure to achieve the stated objectives
 - c) Adequacy of proposed sample size in view of proposed study
 - d) Adequacy of study site for meeting required sample size
 - e) Risk benefit ratio to participants
 - f) Explanation/Consent/assent in relation to participant and study
 - g) Guidelines related to patient safety and confidentiality and GCP will be followed
 - h) Criteria for prematurely withdrawing research participants, and for suspending or terminating the research
 - i) informed consent is adequate, easy to understand and properly documented
 - j) information is given about the contact persons with phone numbers for questions about research participants rights and study or injury
4. Primary investigator will be informed about decision of IEC in following manner- Accepted/rejected/accept with modification in 15 days.
5. A letter will be issued after acceptance of proposal within a months time.PG students will also be provided with letter of acceptance in prescribed format of MUHS .



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SECTION-3- DOCUMENTS TO BE MANTAINED BY IEC FOR RECORDS

Following documents will be maintained by IEC –

1. Administrative documents

- a) Constitution and composition of the EC
- b) Appointment letters
- c) Signed and dated copies of the most recent curriculum vitae of all EC members at the time of appointment
- d) Signed confidentiality agreements
- e) COI declarations of members
- f) Training records of EC members
- g) Financial records of EC
- h) Registration/accreditation documents, as required
- i) A copy of national and international guidelines and applicable regulations
- j) Regulatory notifications
- k) Meeting-related documents
- l) Agenda and minutes
- m) All communications received or made by the EC
- n) SOPs

2. Proposal-related documents

- a) One hard copy and a soft copy of the initial research proposal and all related documents
- b) Decision letters
- c) Any amendments submitted for review and approval
- d) Regulatory approvals
- e) SAE, AE reports



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- f) Protocol deviations/violations
- g) Progress reports, continuing review activities, site monitoring reports
- h) All correspondence between the EC and researchers
- i) Record of notification issued for premature termination of a study with a summary of the reasons
- j) Final report of the study

SECTION 4-EMERGENCY MEETING

Definition: When IEC meeting is called out of scheduled time it will be called as emergency meeting

Events when such meeting will be called are as follows:

- SAE
- Protocol violation
- Safety of participant/public is being compromised
- Any event deemed appropriate by chairman/secretary
- Expedited review in case of emergency eg covid 19

Guidelines for conducting Emergency meeting

1. Chairman/secretary will call for such meeting
2. Review of DRB/BORS committee/selected members on SAE/related issues will be considered in this meeting.
3. Investigator may have to be present on the day of meeting if called for explanation. It should be informed to the investigator prior to the meeting.
4. Meeting will be held within a 15 days duration as per convenience of members.
5. Relevant details/information will be provided to members by secretary when the meeting is called for.



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6. 60 % quorum will have to be present to start the meeting or minimum 5 members of the committee.
7. If the quorum is not met, meeting will be started with one scientific committee member, member from community/chairman and secretary.
8. Decision will be taken as per IEC SOPs,ICMR guidelines.
9. Decision will be informed to concerned parties by IEC letter.
10. Minutes of meeting and all other communication will be maintained by secretary.

SECTION 5- CONFIDENTIALITY AND CONFLICT OF INTEREST

Conflict of interest

Definition- Conflict of interest is a set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research ends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain.

[http://icmr.nic.in/ethical_guidelines.pdf accessed on 23rd Nov 2015].

Types of COI

a) A personal COI will be considered if,

- There is immediate family relationship (spouse, parent or parent of a spouse, child or child of a spouse, sibling or sibling of a spouse, or a dependent -who resides with an IEC member or consultant or who receives 50% or more support from an IEC member, regardless of age) or other close personal relationship with the investigator, or with co-investigators.
- IEC member or his/her immediate family member is a contributor in the research project

b) A professional COI if,

- The IEC member or his/her immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research.



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- c) A financial COI if,
- For IEC members and immediate family exists the IEC member or the spouse or dependent of a member receives monetary benefits including salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests) and intellectual property rights (e.g., patents, copyrights, product or service being valued).

There should be no conflict of interest of any type.

The members shall voluntarily withdraw from the Ethic committee meeting while making a decision on an application which evokes conflict of interest and will not participate any proceedings related to such proposal.

CONFIDENTIALITY AGREEMENT

Confidentiality-The nonoccurrence of unauthorized disclosure of information

Confidentiality Agreement- Sometimes called Secrecy or Non-disclosure agreement. It is an agreement designed to protect trade secrets, information and expertise from being misused by those who have learned about them. The type of information that can be included under the umbrella of confidential information is virtually unlimited.

- IEC will prove appropriate Confidentiality and / or Conflict of Interest Agreement Form to the IEC member, Guest attendee, Observer and Independent Consultant
- IEC member, Guest attendee, observer, Independent Consultant, advisory committee/ board member will fill up the details such as name, designation and official address and sign conflict of interest form before starting the meeting.



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- If any of the IEC members/Guests /observers for IEC meetings/Independent Consultants have any doubts, need clarifications or if any part or sentences is not clear, they will seek clarifications or additional information from the Secretariat. The Member Secretary will provide explanations, additional information and / or clarifications. If any further explanations are needed they can be provided by the Chairperson / Legal expert/other IEC members.
- The newly appointed IEC member, before the beginning of their tenure, Guests /observers for IEC meetings, Independent Consultants / advisory committee/ board member will sign and date the document before joining.
- The form will also have signature of the IEC Chairperson.
- A copy of this form will be provided to IEC member, Guests or observers for IEC meetings, Independent Consultants for their records (duly signed and dated by them and IEC Chairperson) and acknowledge the receipt of agreement by their signature.
- Original copies will be stored safely.
- It is mandatory for the IEC members/Guests /observers for Institutional Ethics Committee meetings/Independent Consultants / advisory committee/ board member that they must implement the clauses of the signed Confidentiality Agreement Form.

Confidentiality Agreement Form for IEC Members of DESBJCOP, Pune

In recognition of the fact, that _____

(Member's name, and his/her affiliation) herein referred to as the "undersigned", have been appointed as a member of the IEC, have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines; Whereas, the appointment of the undersigned as a member of the IEC is based on



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individual merits and not as an advocate or representative of a home province, territory or community nor as a delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of research participants;

The undersigned, as a member of the IEC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly. As such, the undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

Agreement on Confidentiality

- *Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC.*
- *A copy will be given to you for your records.*



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- In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation (which we will refer to as the Confidential Information; subject to applicable legislation, including the Access to "Confidential Information"). I agree to take reasonable measures to protect the Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to destroy all

Confidential Information (including any minutes or notes I have made as part of my duties) to the Chairperson upon termination of my functions as a Committee member.

I, _____ (name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement.

Signature with date:

Chairperson's Signature with Date:

Acknowledgement by member-

I acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me.

Signature with Date:

Conflict of Interest Agreement Form for IEC Members

It is recognized that the potential for conflict of interest will always exist but has faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of research participants.

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It is the policy of the IEC that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IEC. The Undersigned will immediately disclose to the Chairperson of the IEC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations or decision making in respect of such proposals.

If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IEC review or approval except to provide information requested by the Committee.

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

Agreement on Conflict of Interest

- *Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC.*
- *A copy will be given to you for your records.*

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me for discussion or decision making in respect of such proposal.



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I, _____ (name) have read and accept the aforementioned terms and conditions as explained in this Agreement.

Signature of member with Date:

Chairperson's Signature with Date:

Acknowledgement-

I acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me.

Signature of member with Date:

Confidentiality Agreement Form

For Guest / Observer Attendees to IEC Meetings/ Subject Experts/ advisory committee/ board member (Affiliated / nonaffiliated to the institution)

I, _____ (name), understand that I am being allowed to attend the Institutional Ethics Committee meeting scheduled on _____ at _____ am/ pm as a Guest. The meeting will be conducted in the _____, DES Brijlal Jindal College of Physiotherapy, Pune. In the course of the meeting of the Institutional Ethics Committee some confidential information may be disclosed or discussed. Upon signing this form, I ensure to take reasonable measures to keep the information as confidential.

Signature of the Guest with date:

Signature of Chairperson with date:



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Acknowledgement-

I, _____ (name) acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me.

Signature of the Guest with date:

Signature of Chairperson with date:

SECTION 6-PROTOCOL DEVIATION/NON COMPLIANCE/VOIATION/SERIOUS ADVERSE EFFECT

Definitions

Protocol Deviation - A protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the IEC. Upon discovery, the Investigator is responsible for reporting protocol deviations to the IEC using the standard reporting form.

Protocol Violation :If the deviation meets any of the following criteria, it is considered a protocol violation.

- I. The deviation has harmed or posed a significant or substantive risk of harm to the research subject.
- II. The deviation compromises the scientific integrity of the data collected for the study.(eg eligibility criteria,outcome measure,changing protocol without IEC permission)
- III. The deviation is a willful or knowing breach of human subject protection regulations, policies, or procedures on the part of the investigator(s). For example
 - Inadequate /improper consent obtaining method /Failure to obtain informed consent prior to initiation of study-related procedures.
 - Falsifying research or medical records.



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- Performing tests or procedures beyond the individual's professional scope or privilege status.
- A breach of confidentiality.
- Any serious or continuing noncompliance with federal, state, local or institutional human subject protection regulations, policies, or procedures.

1. Protocol deviation/ non-compliance/ violation will be considered when,

- a) Communication (oral/written) received from the Head of the Institution/site of data collection/participants informing IEC about such event.
- b) The IEC members/guide performing monitoring of the project at trial site may detect protocol deviation/non-compliance/violation
- c) Any report/ communication brought to the notice of Member, Secretary/ Chairperson of IEC by some independent person/guide/investigator.

2. Review of protocol deviation/non compliance/violation/SAE

Subject BORS/DRB/ 2 independent reviewers from IEC will review ,prepare a report and discuss the issue in upcoming IEC meeting/chairperson/secretary within 10 days of such reporting . Action will be taken according to IEC decision.

3. Guidelines for actions

- a) The Chairperson / member secretary / BORS/DRB will review the submitted protocol deviations and assess the impact of the deviation on the safety wellbeing of the participants and data integrity of the study.
- b) Committee will send the comments to the member secretary with the decision.
- c) The Chairperson/member secretary / IEC members will review the information available and take a decision depending on the seriousness of the deviation / violation. The decision will be taken to



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ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by consensus.

4. IEC action

IEC will take action based on seriousness of such event/frequency of such deviations by investigator in same study and previous studies.

It could include one or more of the following:

- a) Inform the Investigator that IEC has noted the deviation / violation
- b) Direct the PI to ensure that deviations/violations do not occur in future and follow IEC recommendations.
- c) Reprimand the PI.
- d) Call for additional information.
- e) Suspend the study till additional information is made available /study is scrutinized/investigator implements the recommendations/satisfactory steps have been taken by investigator.
- f) Revoke approval of the current study.
- g) Review and/ or inspect other studies undertaken by that investigator.
- h) Refuse to review subsequent applications from an investigator cited for non-compliance for a specified duration of time.
- i) Any other action considered appropriate by the IEC.

5. Record and communication of the decision to the Investigator

- Proceedings will be recorded in Minutes of meeting of IEC.
- IEC decision will be conveyed to investigator in a month's time .
- SAE report will be given as per prescribed format.



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PROTOCOL DEVIATION/VIOLATION/NON COMPLIANCE RECORD DOCUMENTATION

(To be filled by relatives/participant/site manager/PI/Guide/HOI/any other informant)

Title of Project:

IEC Approval letter No and date:

Investigators: (name/dept/designation)

Description of deviation (s)/violation(s):

Impact of the deviation on:

- Safety wellbeing of the participants
- Data integrity
- Methodology

Measures taken by Instigator in case of such event :

Reported by (Name and designation):

Signature with date: _____

IEC DECISION RECORD/LETTER TO INVESTIGATOR

Title of Project:

IEC Approval letter No and date:

Investigators: (name/dept/qualification)

Protocol deviation report No and date:

Informed by:

BORS/DRB committee/review committee members: (name/designation/date)

Description of deviation (s)/violation(s):

Impact of the deviation as per BORS/DRB:

- Safety wellbeing of the participants

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- Data integrity
- Methodology
- Any other

IEC decision:

Signature of Chairperson with Date: _____

Serious Adverse Effect

1. In case of any SAE being reported, chairperson and member secretary will appoint a subcommittee which will evaluate the SAE as per guidelines by ICMR and WHO. They will present a report to IEC and appropriate decision will be taken.
2. The committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of adverse event reports involving human participants.
3. Members will be selected in their personal capacities based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the SAE Subcommittee work.
4. Members will be appointed to the SAE Subcommittee if they accept the following conditions.
 - Willingness to publicize his/her full name, profession and affiliation.
 - Willingness to sign the Confidentiality and Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation and related matters.
 - Willingness and commitment in terms of time to perform the role and responsibility as SAE Subcommittee member.
5. Main role of this committee will be to ensure the protection of the rights, safety and wellbeing of human participants involved in a research project.



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6. Minutes of SAE subcommittee meeting, decision taken and all the paperwork will be prepared by SAE committee and will be stored separately .

SAE REPORTING AND DECISION FORMAT

(To be filled by PI/relative of participant/participant/HOI/site incharge/any other informant)

Title of study:

Investigators:

IEC approval letter no:

Date of reporting:

To be filled by Investigator		To be filled by respective authority
Was it one of the expected risks mentioned in proposal	Did precautionary measures mentioned in proposal were followed by investigator. Explain in detail.	Comments of BORS/DRB



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To be filled by Investigator							To be filled by respective authority	
S A E	Date of occurrence	Place of occurrence	Steps taken to avoid SAE	Expected/unexpected event	Repercussions of SAE	Explanation by PI	Comments of DRB/BO RS	IEC comments

Compensations provided:

IEC decision:

Signature of Chairperson with Date: _____

SECTION-7- VULNERABLE POPULATION REVIEW

1. Definition:

Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests.

These may be the subjects who;

- May have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests.



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- b) Whose willingness to volunteer in a research study may be unduly influenced by the expectation, of benefits associated with participation, or fear of response from senior members of a hierarchy in case of refusal to participate
- c) Some patients with incurable diseases, nursing homes residents, unemployed or impoverished people, patients in emergency situations, ethnic minority groups, homeless people, nomads, refugees, minors, and those incapable of giving consent.
 - a. Following are some examples of vulnerable populations or groups:
- d) 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.)
- e) 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
- f) children (up to 18 years)
- g) women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare)
- h) tribal and marginalized communities;
- i) refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations
- j) afflicted with mental illness and cognitively impaired individuals, differently abled –mentally and physically disabled;
- k) terminally ill or are in search of new interventions having exhausted all therapies;
- l) suffering from stigmatizing or rare diseases; or
- m) have diminished autonomy due to dependency or being under a hierarchical system
- n) (students, employees, subordinates, defence services personnel, healthcare workers,
- o) Institutionalized individuals, under trials and prisoners).



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2. Principles of research among vulnerable populations

- a) Vulnerable populations have an equal right to be included in research so that benefits accruing from the research apply to them as well.
- b) If any vulnerable group is to be solely recruited then the research should answer the health needs of the group.
- c) 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.
- d) In vulnerable populations, when potential participants lack the ability to consent, a LAR should be involved in decision making.
- e) Special care must be taken to ensure participant's privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.
- f) 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.

3. Additional safeguards/protection mechanisms

- a) 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.
- b) Researchers must justify the inclusion of a vulnerable population in the research.
- c) IECs must satisfy themselves with the justification provided and record the same in the proceedings of the EC meeting.
- d) Additional safety measures should be strictly reviewed and approved by the IECs.



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- e) The informed consent process should be well documented. Additional measures such as recording of assent and re-consent, when applicable, should be ensured.
- f) IECs should also carefully determine the benefits and risks of the study and examine the risk minimization strategies.
- g) 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.
- h) Vulnerable persons may require repeated education/information about the research, benefits, risks and alternatives, if any.
- i) Research on sensitive issues such as mental health, sexual practices/preferences, HIV/ AIDS, substance abuse, etc. may present special risks to research participants.
- j) Researchers should be cognizant of the possibility of conflicting interests between the prospective participant and LAR and should be more careful.
- k) 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.
- l) Efforts should be made to set up support systems to deal with associated medical and social problems.
- m) Protection of their privacy, confidentiality and rights is required at all times – during conduct of research and even after its completion.
- n) 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 centre.

4. IEC action guidelines

- a) IEC will review the check list before discussion of such study.
- b) IEC will refer guidelines provided by ICMR as per concerned vulnerable population before taking any decision.
- c) IEC will consider autonomy protection, risk/benefit determinations



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- d) If such people are willing to participate and are selected, then the means of protecting their rights and welfare must be strictly reviewed and followed.
- e) IEC may recommend written / verbal Informed consent /audio –visual consent /audio consent
- f) Assent and parent's consent in case of children, both parents consent in case of cognitively impaired child and consent of care taker/ relative in case of a unconscious/cognitively impaired adult or any other condition when the subject is unable to give consent.

CHECKLIST FOR VULNERABLE POPULATION

(To be filled by PI/IEC)

Title of study:

Need of study in one line:

Investigators: (name/designation/dept)

Value addition by proposed research:

Considerations	Benefit	IEC action
The participant will be benefited from proposed research	Direct benefit /no direct benefit/harmful	Approvable/Not approvable
Risks that the participant may face(enlist)		
1)		Approvable/Not approvable
2)		Approvable/Not approvable
3)		Approvable/Not approvable
4)		Approvable/Not approvable
Availability of scientifically	Yes/No/NA	Approvable/Not approvable



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appropriate, preclinical and clinical studies provide sufficient evidence about risks and benefits involved in case of current vulnerable population		
Supervision by PI/parent/care taker is required while doing data collection	Yes/No/NA	Approvable/Not approvable
Patient confidentiality is maintained	Yes/No	Approvable/Not approvable
In case of pregnant woman, prospective participant or her legally authorized representative, is fully informed regarding the reasonably foreseeable impact of the research on the fetus/child/her health	Yes/No/NA	Approvable/Not approvable/NA
In case of research involving new born or an infant, the guardian is completely informed about impact of study on infant currently and in future	Yes/No/NA	Approvable/Not approvable/NA
In case of a cognitively	Yes/No/NA	Approvable/Not



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<p>impaired child, the guardian is completely informed about impact of study on the child currently and in future</p>		<p>approvable/NA</p>
<p>In case of an adolescent, 1) Participant is well explained about the study and its implications on him/her in his language 2) Guardian consent and child ascent is available</p>	<p>Yes/No/NA</p>	<p>Approvable/Not approvable/NA</p>
<p>In case of unconscious patients, 1) Participant is well explained about the study and its implications 2) Participant will be closely monitored for discomfort 3) Participants will be withdrawn if they appear to be unduly distressed 4) Participants have a disease or condition for which the procedures in the research are intended</p>	<p>Yes/No/NA</p>	<p>Approvable/Not approvable/NA</p>



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IEC decision: Approved/Not approved/Approved with revisions

Signature of Chairperson with date:

SECTION-8-INFORMED CONSENT PROCESS

The researcher must 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.

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 should 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 must be obtained.
4. It is mandatory for a researcher to administer consent before initiating any study related procedures involving the participant.
5. It is necessary to maintain privacy and confidentiality of participants at all stages.



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2. Essential information for prospective research participants

Before requesting an individual's consent to participate in research, the researcher must 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 has 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.

3. Essential and additional elements of an informed consent document

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



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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)

4. In addition, the following elements may also be required, depending on the type of study:

1. 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
2. If there is a possibility that the research could lead to any stigmatizing condition, for example HIV and genetic disorders, provision for pretest- and post-test counseling
3. Insurance coverage if any, for research-related or other adverse events
4. 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:
 5. period of storage of the sample/data and probability of the material being used for secondary purposes.
 6. whether material is to be shared with others, this should be clearly mentioned.
 7. 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
 8. conduct of the research.
 9. risk of discovery of biologically sensitive information and provisions to safeguard confidentiality.
 10. post research plan/benefit sharing, if research on biological material and/or data leads to commercialization.
11. Publication plan, if any, including photographs and pedigree charts.

5. Responsibility of researchers

1. The researcher should only use the EC approved version of the consent form, including its local translations.



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2. Adequate information necessary for informed consent should be communicated in a language and manner easily understood by prospective participants.
3. 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.
4. 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.
5. The researcher should not give any unjustifiable assurances or influence or intimidate a prospective participant to enroll in the study.
6. 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.
7. 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.
8. When a participant is willing to participate but not willing to sign or give a thumb
9. 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.
10. 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 to be practiced routinely

6. Re-consent/Fresh Consent-

Re-consent or fresh informed consent of each participant must be taken under circumstances described below-



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1. 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.
2. Reimbursement may be given for travel and incidental expenses/participation in research after approval by the EC.
3. 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.
4. The researcher should ensure that the participant can continue to access routine care even in the event of withdrawal of the participant.

7. Online Consent-

Online consent may be obtained, for example, in research involving sensitive data such as unsafe sex, high risk behavior, use of contraceptives (condoms, oral pills) etc or in any case/survey where participant is not seen in person and the information is being collected.

1. Prior approval of IEC is mandatory for such situation.
2. Investigators must ensure that privacy of the participant and confidentiality of related data is maintained.

8. Conditions for granting waiver of consent

1. research cannot practically be carried out without the waiver and the waiver is scientifically justified
2. retrospective studies, where the participants are de-identified or cannot be contacted
3. research on anonymized biological samples/data
4. certain types of public health studies/surveillance programmes/programme evaluation studies
5. research on data available in the public domain



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6. research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempt should be made to obtain the participant's consent at the earliest,

SECTION 9- STUDY COMPLETION REPORTING

1. Once the study is complete the Investigators will submit the study report to IEC within 3 months of completion.
2. It should be reported in given format (Annexure 10.13) in hard copy and soft copy.
3. These reports will be stored for 10 years.

STUDY COMPLETION REPORTING FORMAT

Title of study:

IEC Approval No:

Investigators: (name/designation/dept)

1)

2)

1. Date of Start of Study:

Date of completion of Study:

2. Provide details of:

a) Total number of study participants approved by the EC for recruitment:

b) Total number of study participants recruited:

c) Total number of participants withdrawn from the study (if any):



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3. Provide the reasons for withdrawal of participants:

4. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared)

5. Describe the main ethical issues encountered in the study (if any)

6. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period

Deviations:

Violation:

Amendments:

7. Describe in brief plans for archival of records / record retention:

8. Is there a plan for post study follow-up? Yes/ No (If yes, describe in brief):

9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily? Yes/No (If yes, describe in brief):



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10. Is there a plan for post study benefit sharing with the study participants? Yes/no

(If yes, describe in brief):

11. Describe results (summary) with Conclusion:

12. Number of SAEs that occurred in the study:

13. Have all SAEs been intimated to the EC ? Yes/No(if no give explanation)

14. Is medical management or compensation for SAE provided to the participants? Yes/No If yes, provide details

Signature of Investigator with date:



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SECTION 10- ANNEXURES

10.1 BORS/DRB APPROVAL LETTER

Date _____

To,

Dr. _____ (name, designation, dept of the
Guide/ Investigator/ Student)

Sub: BORS/DRB approval for project entitled, _____

Dear Dr. _____,

The meeting of the BORS/DRB of _____ department was held on _____ at _____ with Dr. _____ as
Chairperson and _____ as members.

It is hereby confirmed that, you have submitted study proposal titled, _____ as
per prescribed format and neither you nor any of the study team members have participated in the
voting/decision making procedures of the DRB/BORS.

It is understood that,

- 1) Proposed study will be undertaken by _____ (name of the student/investigator) under the guidance
of _____ during _____ (period) .
- 2) All investigators will follow the principle of Good Clinical Practices(GCP) and cause no harm in
any form to participants while collecting required data

The BORS/DRB hereby approves the given study proposal at the meeting.

Sincerely yours

Signature of Chairperson of BORS/DRB with date:

Fergusson College Campus, Shivaji Nagar 411004

Contact: lec.desbjcop@despune.org / 020-67656467/469



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10.2 INITIAL SUBMISSION FORM FOR IEC REVIEW

Title:

Details of Primary investigator: Name:

Qualification:

Email for correspondence:

Co-investigators: Name:

Qualification:

Email for correspondence:

Course:

Department:

Date of submission:

BORS/DRB approval letter attached: Yes/No/NA/Awaited

Duration of study:

Conflict of interest:

Funding: Self/Institution/Other funding agency

Site of study/data collection:

Benefits of proposed study:

STUDY RELATED DETAILS



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Need of study:

Aims and Objectives:

Hypothesis:

Type of study:

Sample size with formula and reasoning:

Outcome measures with psychometric properties:

Statistical analysis:

PARTICIPANT RELATED INFORMATION

Type of participants: healthy/vulnerable

If vulnerable specify the population and fill checklist of proposed study on vulnerable population

Participant recruitment method: direct approach/posters,pamphlets/social media/centers/referral/other

Duration of assessment:

Risks involved in participation/data collection:

Risks involved	Precautionary measure to avoid it
1)	
2)	
3)	
4)	



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Reimbursement/participation incentive/compensation for participant: Yes/No provide details

CONSENT FORM

Form with information sheet:

Type of consent: Informed/written/oral/ascent

Who will give consent? : self/guardian/care taker-nurse/administrator

Elements

Easy language	Yes/No/NA
Study details	Yes/No/NA
Risks and benefits involved	Yes/No/NA
Compensation/reimbursement/incentive details	Yes/No/NA
Contact details for queries	Yes/No/NA
Voluntary participation	Yes/No/NA
Confidentiality	Yes/No/NA

DATA MANAGEMENT

Who will do the analysis:

Use of data in future? Provide details

Measures to avoid duplicating/tampering with data:

How long will the data be stored?



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10.3 IEC CHECKLIST

Title:

Details of Primary investigator: Name:

Qualification:

Email for correspondence:

Co-investigators: Name:

Qualification:

Email for correspondence:

Course:

Department:

Date of review:

BORS/DRB approval letter attached: Yes/No/NA/Awaited

	IEC decision			Modification suggested
	Accepted	Not accepted	NA	
Conflict of interest:				
Funding:				
Site of study/data collection:				
Benefits of proposed study:				
Need of study:				



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Aims and Objectives:				
Hypothesis:				
Type of study:				
Sample size with formula and reasoning:				
Outcome measures with psychometric properties:				
Statistical analysis:				
checklist of proposed study on vulnerable population:				
Participant recruitment method:				
Duration of assessment:				
Risks involved in participation/data collection:				
Reimbursement/participation incentive/compensation for participants:				
Consent Form with information sheet:				
Type of consent:				
Who will give consent? :				
Who will do the analysis:				
Use of data in future?				
Measures to avoid duplicating/tampering with data:				
Other issues raised during IEC review:				



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10.4 UNDERTAKING BY INVESTIGATOR

1. Study will be initiated only after obtaining all regulatory clearances.
2. Care will be taken not to implement any deviation from the approved protocol. If so it will be informed to IEC at the earliest and definitely within 7 days of such event.
4. Utmost care will be taken to ensure that ethical requirements of ICMR and National Regulatory Guidelines and MUHS are adhered to.
5. Accurate and complete record of all cases in accordance with GCP provisions will be made. They will be made available for audit/inspection by regulatory authorities.
6. Unexpected or serious adverse event/protocol deviation will be informed to IEC at the earliest and definitely within seven days of its occurrence.
7. Confidentiality /security of the participants and security/confidentiality of data will be maintained.
8. Full compliance with statutory obligations, requirements and guidelines provided by IEC, MUHS, ICMR and other regulatory bodies will be done.
9. Results of the study will be submitted to IEC once the study is over and before my course is over.

Name of the Investigator:

Sign with date:



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10.5 GUIDELINES FOR INVESTIGATORS

All MPT studies, any other personal studies and other departmental studies have to be submitted to IEC in prescribed format (refer form attached in annexures)

All prescribed forms, checklists, IEC processing fees has to be submitted at the time of study proposal submission.

The submission has to be done 4 weeks before IEC meeting which will be announced in advance.

Investigators should refer GCP, ICMR, MUHS guidelines, IEC SOPs before submitting the proposal.

For, studies involving vulnerable population, separate checklist has to attached with the proposal (refer form given in annexure)

BORS/DRB approval certificate is must before submission to IEC.

Incomplete forms/proposals will not be accepted. Acceptance/Non acceptance will not be informed separately.

PI should be present during IEC meeting for clarifications related to proposal if required.

IEC will review the protocol and related documents and will take the decision regarding the proposal. It will be in accepted/not accepted /accepted with modification format.

Proposals which are suggested modification/minor changes by IEC will have to undergo Expedited review.

IEC certificate will be issues only after acceptance from expedited review/BORS/DRB committee.

Once approval for a study is granted,



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- a) An approval will be granted for the entire duration of the study.
- b) It is the responsibility of the investigator to protect patient confidentiality, protect the data report SAE, protocol violation/breach and submit the results /findings at the end of the study to IEC.
- c) Investigator has to inform study results to IEC in prescribed format (refer form given in annexures)

IEC CONTACT DETAILS:

IEC mail ID: Ethics.desbjcop@despune.org

Contact person: Dr. Atiya Shaikh (PT)

Day: Wednesday, Thursday

Time: 2PM -4PM



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10.6 CONFIDENTIALITY AGREEMENT FORM FOR IEC MEMBERS OF DESBJCOP,PUNE

In recognition of the fact, that _____

(Member's name, and his/her affiliation) herein referred to as the "undersigned", have been appointed as a member of the IEC, have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines; Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province, territory or community nor as a delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well being of research participants;

The undersigned, as a member of the IEC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly. As such, the undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms

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that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

Agreement on Confidentiality

- *Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC.*
- *A copy will be given to you for your records.*
- *In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation (which we will refer to as the Confidential Information; subject to applicable legislation, including the Access to "Confidential Information"). I agree to take reasonable measures to protect the Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to destroy all Confidential Information (including any minutes or notes I have made as part of my duties) to the Chairperson upon termination of my functions as a Committee member.*

I, _____ (name of the member) have read and accept the
aforementioned terms and conditions as explained in this Agreement.

Signature with date:

Chairperson's Signature with Date:

Acknowledgement by member-

I acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me.

Signature with Date:



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10.7 CONFLICT OF INTEREST AGREEMENT FORM FOR IEC MEMBERS OF
DESBJCOP,PUNE

Agreement on Conflict of Interest

- Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC.
- A copy will be given to you for your records.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me for discussion or decision making in respect of such proposal.

I, _____ (name) have read and accept the aforementioned terms and conditions as explained in this Agreement.

Signature of member with Date:

Chairperson's Signature with Date:

Acknowledgement-

I acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me.

Signature of member with Date:

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10.8 CONFIDENTIALITY AGREEMENT FORM

(For Guest / Observer Attendees to IEC Meetings/ Subject Experts/ advisory committee/ board member (Affiliated / nonaffiliated to the institution))

I, _____ (name), understand that I am being allowed to attend the Institutional Ethics Committee meeting scheduled on _____ at _____ am/ pm as a Guest. The meeting will be conducted in the _____, DES Brijlal Jindal College of Physiotherapy, Pune. In the course of the meeting of the Institutional Ethics Committee some confidential information may be disclosed or discussed. Upon signing this form, I ensure to take reasonable measures to keep the information as confidential.

Signature of the Guest with date:

Signature of Chairperson with date:

Acknowledgement-

I, _____ (name) acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me.

Signature of the Guest with date:

Signature of Chairperson with date:



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10.9 PROTOCOL DEVIATION/VIOLATION/NON COMPLIANCE RECORD

DOCUMENTATION

(To be filled by relatives/participant/site manager/PI/Guide/HOI/any other informant)

Title of Project:

IEC Approval letter No and date:

Investigators: (name/dept/designation)

Description of deviation (s)/violation(s):

Impact of the deviation on:

- Safety wellbeing of the participants
- Data integrity
- Methodology

Measures taken by Instigator in case of such event :

Reported by (Name and designation):

Signature with date: _____



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10.10 IEC DECISION RECORD/LETTER TO INVESTIGATOR

Title of Project:

IEC Approval letter No and date:

Investigators: (name/dept/qualification)

Protocol deviation report No and date:

Informed by:

BORS/DRB committee/review committee members: (name/designation/date)

Description of deviation (s)/violation(s):

Impact of the deviation as per BORS/DRB:

- Safety wellbeing of the participants
- Data integrity
- Methodology
- Any other

IEC decision:

Signature of Chairperson/secretary with Date: _____



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10.11 SAE REPORTING AND DECISION FORMAT

(To be filled by PI/relative of participant/participant/HOI/site incharge/any other informant)

Title of study:

Investigators:

IEC approval letter no:

Date of reporting:

To be filled by Investigator		To be filled by respective authority
Was it one of the expected risks mentioned in proposal	Did precautionary measures mentioned in proposal were followed by investigator. Explain in detail.	Comments of DRB/BORS

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To be filled by Investigator							To be filled by respective authority	
S A E	Date of occurrence	Place of occurrence	Steps taken to avoid SAE	Expected/unexpected event	Repercussions of SAE	Explanation by PI	Comments of BORS/DRB	IEC comments

Compensations provided:

IEC decision:

Signature of Chairperson/secretary with Date: _____



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10.12 CHECKLIST FOR VULNERABLE POPULATION

(To be filled by PI/IEC)

Title of study:

Need of study in one line:

Investigators: (name/designation/dept)

Value addition by proposed research:

Considerations	Benefit	IEC action
The participant will be benefited from proposed research	Direct benefit /no direct benefit/harmful	Approvable/Not approvable
Risks that the participant may face(enlist) 1) 2) 3) 4)		Approvable/Not approvable Approvable/Not approvable Approvable/Not approvable Approvable/Not approvable
Availability of scientifically appropriate, preclinical and clinical studies provide sufficient evidence about risks and benefits involved in case of current vulnerable population	Yes/No/NA	Approvable/Not approvable



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Supervision by PI/parent/care taker is required while doing data collection	Yes/No/NA	Approvable/Not approvable
Patient confidentiality is maintained	Yes/No	Approvable/Not approvable
In case of pregnant woman, prospective participant or her legally authorized representative, is fully informed regarding the reasonably foreseeable impact of the research on the fetus/child/her health	Yes/No/NA	Approvable/Not approvable/NA
In case of research involving new born or an infant, the guardian is completely informed about impact of study on infant currently and in future	Yes/No/NA	Approvable/Not approvable/NA
In case of a cognitively impaired child, the guardian is completely informed about impact of study on the child currently and in future	Yes/No/NA	Approvable/Not approvable/NA
In case of an adolescent, 1) Participant is well	Yes/No/NA	Approvable/Not approvable/NA



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<p>explained about the study and its implications on him/her in his language</p> <p>2) Guardian consent and child ascent is available</p>		
<p>In case of unconscious patients,</p> <p>1) Participant is well explained about the study and its implications</p> <p>2)Participant will be closely monitored for discomfort</p> <p>3)Participants will be withdrawn if they appear to be unduly distressed</p> <p>4) Participants have a disease or condition for which the procedures in the research are intended</p>	<p>Yes/No/NA</p>	<p>Approvable/Not approvable/NA</p>

IEC decision: Approved/Not approved/Approved with revisions

Signature of Chairperson with Date: _____



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10.13 STUDY COMPLETION REPORTING FORMAT

(To be filled by PI)

Title of study:

IEC Approval No:

Investigators: (name/designation/dept)

1)

2)

1. Date of Start of Study:

Date of completion of Study:

2. Provide details of:

a) Total number of study participants approved by the EC for recruitment:

b) Total number of study participants recruited:

c) Total number of participants withdrawn from the study (if any):

3. Provide the reasons for withdrawal of participants :

4. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared)

5. Describe the main ethical issues encountered in the study (if any)

6. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period
Deviations:

Violation:

Fergusson College Campus, Shivaji Nagar 411004

Contact: iec.desbjcop@despune.org / 020-67656467



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Amendments:

7. Describe in brief plans for archival of records / record retention:

8. Is there a plan for post study follow-up? Yes/ No (If yes, describe in brief):

9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily? Yes/No(If yes, describe in brief):

10. Is there a plan for post study benefit sharing with the study participants? Yes/no (If yes, describe in brief):

11. Describe results (summary) with Conclusion:

12. Number of SAEs that occurred in the study:

13. Have all SAEs been intimated to the EC ? Yes/No(if no give explanation)

14. Is medical management or compensation for SAE provided to the participants? Yes/No If yes, provide details

Signature of Investigator with date: _____



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10.14 IEC APPROVAL LETTER

To,

Name of Investigator,

Ref: Your project entitled, _____

Dear Dr.

IEC meeting for IEC review of studies submitted in year _____ month _____ was conducted on _____ (date of IEC review) with following members:

1. _____
2. _____
3. _____
4. _____
5. _____

Following documents of the above mentioned project were reviewed and approved:

1. Synopsis
2. Information sheet and consent form
3. Evaluation form

It is understood that the study will be conducted under your direction as per the submitted protocol.

The IEC approves the above mentioned study.

This approval is valid for the entire duration of the study.

It is expected that the investigator follows the directions given by IEC i.e:

- No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the IEC of an appropriate amendment.
- The investigator should promptly report to the IEC any deviations, changes or any new information that may affect adversely the safety of the research participants during study period.
- Investigator will submit copy of report to IEC after completion of project.

Sincerely,

Signature of Chairman with Date: _____