M. R. Ambedkar Dental College & Hospital-IEC,
1/36, Cline Road, Cooke Town, Bengaluru-560005.

STANDARD OPERATING PROCEDURES (SOP) OF INSTITUTIONAL ETHICS COMMITTEE (IEC)
FOR
BIOMEDICAL AND HEALTH RESEARCH

M R AMBEDKAR DENTAL COLLEGE AND HOSPITAL

No.1/36, Cline Road, Cooke Town, Bangalore-560005

Title: Working Procedures

Section A – SOP Guidelines for IEC Members

SOP Version 2.0 Dated 01 October 2023

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SHORT TITLE:

The following are called as "Standard Operating Procedures for the Institutional Ethics Committee (IEC) for Biomedical and Health Research of M R Ambedkar Dental College and Hospital (MRADC), Bangalore."

I. ADOPTION OF SOP:

M R Ambedkar Dental College and Hospital , Bangalore, herein after referred to as "MRADC" has adopted these written Standard Operating Procedures (SOP) for discussion and approval of institutional/collaborative research projects to safeguard dignity, right, safety and well-being of all research participants and to ensure that the research is carried under prescribed guidelines.

II. OBJECTIVE:

The objective of these Standard Operating Procedures of the Institutional Ethics Committee (IEC) for Biomedical and Health Research of M R Ambedkar Dental College and Hospital , Bangalore is to maintain effective functioning of the IEC-MRADC and to ensure quality and technical excellence and consistent ethical review of all the submitted health and biomedical research proposals and on-going approved research studies involving human participants in accordance with the ICH-GCP, New CT rules March 2019 and ICMR ethical guidelines 2017 for biomedical research on human subjects.

III. AUTHORITY UNDER WHICH MRADC-IEC IS CONSTITUTED:

The Head of the institute, M R Ambedkar Dental College and Hospital will appoint the Chairperson and all the committee members based on their competence, experience and integrity, for which an official request letter will be sent. Members will confirm their acceptance to the Head of the institute by providing all the required information for membership.

IV. TERMS OF REFERENCE FOR IEC ARE AS FOLLOWS

1. Ensure the highest scientific and ethical standards of research.
2. Review and approve, proposals for clinical, basic or translational research projects (Intra and Extra mural) for scientific and ethical content
3. Improve ethical standards and issue guidelines on ethical dilemmas related to patient care services

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4. To function as a forum to advise the administration in case of any ethical issues that may arise from patients, families or public
5. To maintain leadership as a national standard of reference in all fields
6. To issue and periodically, update and revise SOPs and guidelines for effective functioning of IEC as and when necessary
7. Continuing education in clinical research, bioethics and ethical aspects of clinical practice by conducting seminars, workshops and interactive discussions for all categories of staff members including nursing and paramedical
8. To initiate and commission research studies on ethical aspects of practice.

The committee does not address or interfere in matters of administration, nor does the committee function as a grievance cell for staff members.

V. ROLES AND RESPONSIBILITIES OF MRADC-IEC:

The MRADC-IEC will review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well-being of allactual and potential research participants before approving the research proposals. The goals of research, however important, will never be permitted to override the health and well-being of the research subjects.

The MRADC-IEC will ascertain whether all the cardinal principles of research ethics viz., Autonomy, Beneficence, Non-maleficence, Respect for Free and informed Consent, Respect for Human Dignity, Respect for Vulnerable Persons, Respect for Privacy and Confidentiality and Justice are taken care of in planning, conducting and reporting of the proposed research. For this purpose, it will look into the aspects of protocol review, selection of participants, voluntary participation of potential participants, informed consent process, risk benefit ratio, distribution of burden and benefit, maintenance of privacy and confidentiality and provisions for appropriate compensations. It will review the proposals before the commencement of the study as well as review periodically until the completion of the study through appropriate well documented procedures. Such a review may be based on the periodic study progress reports furnished by the investigators/Guides.

The mandate of the IEC shall be to review all clinical study/research projects to be conducted at the Institution involving human beings directly or indirectly, irrespective of the funding agency. MRADC-IEC will provide advice to the researchers on all aspects of

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the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through appropriate Scientific Review by Research Committee. In case an ethics committee revokes its approval accorded to a study protocol, it will record the reasons for doing so and at once communicate such a decision to the investigator.

In case of Serious Adverse Event (SAE) such as death or disability occurring to the clinical study subject, the ethics committee shall forward its report on the serious adverse event of death or disability, after due analysis, along with its opinion on the financial compensation, if any.

i. The basic responsibility of an EC is to ensure protection of the dignity, rights, safety and well-being of the research participants.
ii. The EC must ensure ethical conduct of research by the investigator team.
iii. The EC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.
iv. The EC should 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.
v. TheECmustensurethatuniversalethicalvaluesandinternationalscientificstandards are followed in terms of local community values and customs.
vi. 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 health care requirements.
vii. Responsibilities of members should be clearly defined (details in Table4.1). The SOPs should be given to EC members at the time of their appointment.
viii. TheSecretariatshouldsupporttheMemberSecretaryandAlternateMemberSecretary (if applicable) in all their functions and should be trained in documentation and filing procedures under confidentiality agreement.
ix. TheECshouldensurethatprivacyoftheindividualandconfidentialityofdatainclu

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ding the documents of EC meetings is protected.

x. The EC reviews progress reports, final reports and AE/SAE and gives needful suggestion regarding care of the participants and risk minimization procedures, if applicable.

xi. The EC should recommend appropriate compensation for research related injury, wherever required.

xii. The EC should carry out monitoring visits at study sites as and when needed.

xiii. The EC should participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.

xiv. The EC may see that conduct of same/similar research by different investigators from same institution is harmonized. „Me too" research (replicative) should not to be encouraged and submission of same research to different funding agencies should not be accepted.

VI. COMPOSITION OF MRADC-IEC:

MRADC-IEC will be multidisciplinary and multi-sectorial body in composition and independent. The number of members of the Institutional Ethics Committee [IEC] is maintained between 7 and15.

The chairperson of the IEC will be from outside the Institution to maintain the independence of the Committee. The Member Secretary will belong to the same Institution and will conduct the proceedings of the committee. Other members will be a mix of medical/non-medical, legal, scientific and non-scientific persons and may also include members of public to reflect different points of view. There will be representationof age and gender in the committee to safeguard the interest and welfare of all sections ofthe society. Member will be aware of local, social and cultural norms, as an important social control mechanism. IEC may invite subject experts to take their views, whenever itis needed.

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VII. Membership requirements

The members of MRADC-IEC will include

1. Chairperson
2. Member Secretary
3. Basic medical scientist/s area (including preferably a Pharmacologist)
4. Clinicians
5. legal experts
6. Social Scientist/ philosopher/ ethicist/ theologian
7. Lay person/s from the community

A Sub-Board of the main IEC may review proposals submitted by undergraduate or post-graduate students or if necessary, an IEC may be separately constituted for the purpose, which will review proposals in the same manner as described above.

i. ECs should be multi-disciplinary and multi-sectoral.
ii. There should be adequate representation of age and gender.
iii. Preferably50%ofthemembersshouldbenon-affiliatedorfromoutsidetheinstitution.
iv. The number of members in an EC should preferably be between seven and 15 and a minimum of five members should be present to meet the quorum requirements.
v. The EC should have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution.

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II. The composition, affiliations, qualifications, member specific roles and responsibilities are as below

Composition, affiliations, qualifications, member specific roles and responsibilities of an EC

S. No.	Members of EC	Definition/description
1.	**Chairperson/**	• 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 • 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 anon-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.
	Vice Chairperson (optional)	
	Non-affiliated	
	Qualifications -	
	A well-respected person fromany background with prior experience of having served/ serving in an EC	

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2.	**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 skills	• 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.
	• Should be able to devote adequate time to this activity which should be protected by the institution	• 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.
3.	**Basic Medical Scientist(s)** Affiliated/ non-affiliated Qualifications - • Non-medical or medical person with qualifications in basic medical sciences • In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be pharmacologist	• 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 reviewthe drug safety and pharmacodynamics.

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4.	**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, investigators brochure (if applicable)and all other protocol details and submitted documents.
5.	**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
.6	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 moral values. Can be from an NGO involved in health-related activities	• 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.

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7.	**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 5years • 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.

The quorum should be as below

*Medical members are clinicians with appropriate medical qualifications. Technical members are persons with qualifications related to particular branch in which the study is conducted ,for example social sciences.

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Member Secretary belongs to the institute and conducts the business of the Committee. When member secretary is on leave, documents will be acknowledged by alternateMember Secretary of Institutional Ethics Committee. Chairperson is not affiliated to the Institute.
Ethics Committee members are selected and appointed based on their personal capacity and on Ethical/Scientific knowledge and expertise, Experience, Interest & Commitment. Members are appointed for a period of 3 years.

XIII. QUORUM REQUIREMENTS:

Requirement of the members is 7 to 15, and it is ensured that we have at least 5members for the meeting to meet the requirements of the quorum and in which at least one member will be from outside the institution, and one member will be a non-scientific member and one from opposite gender. All decisions will be taken in meetings. Quorum will have 5 members with the following representation.

a) A minimum of five members present in the meeting room.
b) The quorum should include both medical, non medical or technical or/and non-technical members.*
c) Minimum one non-affiliated member should be part of the quorum.
d) Preferably the lay person should be part of the quorum.
e) The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.

No decision is valid without fulfilment of the quorum

IX: INDEPENDENT CONSULTANTS:

The MRADC-IEC may call upon subject experts as independent consultants to provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups. Eg. Cancer patients, HIV/ AIDS positive persons or ethnic minorities. They will be required to give their specialized views but will not take part in the decision making process which will be made by the members of the MRADC-IEC.

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X. TERMS OF APPOINTMENT, RESIGNATION, TERMINATION/ DISQUALIFICATION AND REPLACEMENT

1. Appointment:

All members are appointed by Head of the institute of Institute of Nephro Urology, and in Consultation with chairman and member secretary, IEC. Member Secretary belongs to the institute and conducts the business of the Committee. When member secretary is on leave, documents will be acknowledged by alternate Member Secretary of Institutional Ethics Committee

1. All members will serve for a period of 2 to 3 years on renewable basis. New members will be included in the IEC in such a way that there will be a mix of recently appointed members and members with experience.
2. During the term, MRADC Head of the institute in consultation with the Chairman can disqualify any member if the contribution is not adequate and/or there is a long period of (member) non availability.
3. A member can tender resignation of membership from the IEC to the MemberSecretary with information to MRADC Head of the institute through the Chairperson after serving one month advance notice.
4. MRADC Head of the institute can replace the member of IEC as and when required.
5. Conflict of interest is to be declared by members of the MRADC IEC prior to review meeting.

2. Resignation:

Any member can resign from the committee with a prior notice of 1 month.

3. Termination/Disqualification:

A member may be disqualified/terminated by the Chairperson in case of:

- Conduct unbecoming for a member
- Relocation to faraway place.
- Absence for 4 consecutive meetings without any valid reason and without prior permission of the chairman.

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4. Replacement:

New member will be appointed by Head of the institute of Institute of Nephro Urology, having requisite qualification and experience in place of a member who has resigned/terminated/upon death.

XI: TRAINING OF ETHICS COMMITTEE MEMBERS: (NEW & EXISTING)

All members are provided with:

1. IEC SOP, Indian-GCP, ICH-GCP (E6) Guidelines,(CDSCO),NDCT rules 2019 March 2019, and ICMR Guidelines one hard copy will be available for reference (with year of publication) at the IEC office M R Ambedkar Dental College and Hospital .
2. All members are informed about their role in protocol review.
3. All members are contMRADCously updated with the latest amendments/modifications in above mentioned guidelines.

All are motivated to attend various conferences/workshops on bioethics.

References:

- Good Clinical Practice (GCP), as per Government of India, Drugs and Cosmetics Act and rules there under, Rule 122-DAA, Amendments 1, 2 and 3 in 2013 and Schedule Y as Amended on 20th January 2005.
- ICMR Guidelines for Biomedical Research on Human Subjects (2017)
- Operational Guidelines for Ethics Committees that review Biomedical Research,WHO, 2000.
- NDCT rules 2019 released by CDSCO office

XII. CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT:

A set of conditions in which professional judgment concerning a primary interest like patients welfare orthe validity of research tends to be unduly influenced by a secondary interest like non-financial (person, academics or political) or financial gain is termed as Conflict of Interest(COI).

There should be no conflict of interest. The members shall voluntarily withdraw from the Institutional Ethics Committee meeting, while making a decision, which evokes conflict of interest and is indicated in writing to Chairperson prior to the reviews and is recorded in the minutes.

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All members of the EC are given an undertaking on confidentially, not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement and Conflict of Interest which is signed by every member and copy of it is maintained in records.

XIII. CONDUCT OF MRADC-IEC MEETINGS:

The Chairperson will conduct all meetings of the MRADC-IEC. In the absence of the chairperson an alternate Chairperson [Dy. Chairperson] or a member elected by the members present, who will conduct the proceedings of the EC meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/She will prepare the minutes of the meetings and get it approved by the Chairperson and all the members. Virtual Meetings may be conducted in case of inability of core committee member to be present physically with justification being recorded.

XIV. APPLICATION PROCEDURE:

1. All proposals will be submitted on any working day at least **3 weeks in advance** of scheduled meeting in the DHR prescribed application form, the details of which are given depending on type of study such as academic/investigator initiated/clinical trial. Copy of SOP of MRADC-IEC will be given to PI/Co-investigators (Co-PI)/Guide if he/she has applied for review for the first time will who in turn bring it to the notice of investigating team.

2. All relevant documents will be enclosed with application form by PI as per DHR checklist and guidelines for PI (Section B), Documents will be made available with office of Member Secretary MRADC-IEC.

3. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the (PI) and/Collaborators/Research Scholars is submitted to the office of IEC of M R Ambedkar Dental College and Hospital and the same will be acknowledged.

4. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of MRADC-IEC meeting will be intimated to

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the PI to attend the meeting and to make a brief presentation using power point slides of the proposal and to clarify the points raised by the members.

5. The decision of the committee on the proposal will be communicated in writing. If revision is to be made, the revised document in required number of copies will be submitted within a stipulated period of time as specified in the communication on/or before the next meeting.

6. All research proposals/ clinical studies involving human subjects funded/sponsored etc., will be charged an administrative fee/processing fee/as specified by the Research Secretariat/Office of IEC of MRADC. Waiver of these fees is permissible for non-funded studies, academic studies and studies funded by organizations like ICMR, UGC, DST Government of India, State Science & Technology Department, UNICEF,WHO, USAID, Non Profitable Organizations etc. In general, waiver of administrativefee will beat the discretion of MRADC-IEC, total approximately15% need to be paid as institutional service charges for maintenance.

7. Applicants are required to mention specific ethical issues separately in their application to be approved by IEC.

XV. APPLICATION:

All clinical research proposals (5 hard copies and 1 soft copy) shall be submitted along with the information and documents as specified in the required format by Biomedical and Health Research (Section B for PIs Annexture - 1).

XVI. REVIEW PROCEDURES:

1. The meeting of the MRADC-IEC will be held at periodic intervals or on quarterly basis. Additional review meetings can also be held with short notice as and when required. Meetings will be scheduled in accordance with the need of the work load. Virtual meeting will be conducted if felt necessary for expedited review
2. The IEC‟s member-secretary/secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely -a] exemption from review b] expedited review and c] full review (explanation is given below).
3. Decisions will be taken by consensus after discussion and voting.

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4. Investigators/researchers may be invited to offer clarifications if need be. The PI will present the proposal in person in the IEC meeting. When the PI is not available due to unavoidable reasons the Co PI will present the proposal.
5. Independent consultants/subject experts may be invited to offer their opinion on specific research proposals if needed.

a) <u>EXEMPTION FROM REVIEW</u>:

Proposals which present less than minimal risk fall under this category as indicated in following situations.

1. Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exceptions:

1. When clinical study/research on use of educational tests, survey or interview procedures, or observation of public behaviour can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.
2. When interviews involve direct approach or access to private papers.

S. No.	Types of review	
1	**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 behavior 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; • comparisonofinstructionaltechniques,curricula,orclassroommanagement methods; • consumer acceptance studies related to taste and food quality; and

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		• public health programmes by Govt agencies such as programe evaluation where the sole purpose of the exercise is refinement and improvement of the programe or monitoring (where there are no individual identifiers).
2	**Expedited review**	Proposalsthatposenomorethanminimalriskmayundergoexpeditedreview, for example; • research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples; • researchinvolvingclinicaldocumentationmaterialsthatarenon-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 activitylimitedtodataanalysis.ExpeditedreviewofSAEs/unexpectedAEs will be conducted by SAE subcommittee; and • for multicenter 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. • researchduringemergenciesanddisasters(SeeSection12forfurtherdetails).

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3	**Full committee review**	Allresearchproposalspresentingmorethanminimalriskthatarenotcovered under exempt or expedited review should be subjected to full committee review, some examples are; • research involving vulnerable populations, even if the risk is minimal; • research with minor increase over minimal risk (see Table 2.1 for further details); • studies involving deception of participants (see section 5.11 for further details); • research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee; • amendments of proposals/related documents (including but not limited to informed consent documents, investigator‟s brochure, advertisements, recruitment methods, etc.) involving an altered risk; • major deviations and violations in the protocol; • any new information that emerges during the course of the research for deciding whether or not to terminate the study in viewof 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; • priorapprovalofresearchonpredictableemergenciesordisastersbefore the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

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XVIII ASPECTS CONSIDERED DURING REVIEW OF RESEARCH PROPOSAL

1	**Social values**	• The basic requirement for health research to be ethically permissible is that it must have anticipated social value. The outcome of the research should be relevant to the health problems of society. All stakeholders, including sponsors, researchers and ECs must ensure that the planned research has social value.
2	**Scientific design and conduct of the study**	• Valid scientific methods are essential to make the research Ethically viable as poor science can expose research participants or communities to risks without any possibility benefit.
		• Although ECs may obtain documentation from a prior scientific review, they should also determine that the research methods are scientifically sound, and should examine the ethical implications of the chosen research design or strategy. • The EC can raise scientific concerns (even if the study has prior approval of a scientific committee) if it may affect quality of research and or safety of research participants.
3	**Benefit-risk assessment**	• The benefits accruing from the planned research either to the participants or to the community or society in general must justify the risks inherent in the research. • Risks may be physical, psychological, economic, social or legal and harm may occur either at an individual level or at the family, community or societal level. It is necessary to first look at the intervention under investigation and assessits potential harm and benefits and then consider the aggregate of harm and benefits of the study as a whole. • The EC should review plans for risk management, including withdrawal criteria with rescue medication or procedures. • The EC should give advice regarding minimization of risk/ discomfort wherever applicable.

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		• Adequate provisions must be made for monitoring and auditing the conduct of the research, including the constitution of a Data and Safety Monitoring Board(DSMB)if applicable (for example in clinical trials)
4	**Selection of the study population and recruitment of research participants**	• Recruitment should be voluntary and non-coercive. Participants should be fairly selected as per inclusion and exclusion criteria. However, selection of participants should be distributive such that a particular population or tribe or economic group is not coerced to participate or benefit. • Participants should be able to opt out at any time withouttheir routine care being affected. • No individual or group of persons must bear the burden of participation in research without accruing any direct or indirect benefits. • Vulnerable groups may be recruited after proper justification Is provided.
5	**Payment for participation**	• Plans for payment for participation, reimbursement toincurred costs, such as travel or lost wages, incidental expenses and other inconveniences should be reviewed. • There is a need to determine that payments are not so large as to encourage prospective participants to participate in the research without due consideration of the risks or against heir better judgment. No undue inducement must be offered.
6	**Protection of research participants' privacy and confidentiality**	• ECs should examine the processes that are put in place to safeguard participants" privacy and confidentiality. • Researcher cords to be filed separately than routine clinical records such as in a hospital setting.

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7	**Community consideratio n**	• The EC should ensure that due respect is given to the community, their interests are protected and the research addresses the community‟s needs. • The proposed research should not lead to any stigma or discrimination. Harm, if any, should be minimized. • Plans for communication of results to the community at the end of the study should be carefully reviewed. • It is important to examine how the benefit soft here search will be disseminated to the community.
8	**Qualifications of researchers and adequacy assessment of studysites**	• The EC should look at the suitability of qualifications and experience of the PI to conduct the proposed research along with adequacy of site facilities for participants.
9	**Disclosure or declaration of potential COI**	• The EC should review any declaration of COI by a researcher and suggest ways to manage these. • The EC should manage COI within the EC and members with COI should leave the room at the time of decision making in a particular study.
10	**Plans for medical management and compensation for study related injury**	• The proposed plan for tackling any medical injuries or emergencies should be reviewed. • Source and means for compensation for study related injury should be ascertained.
11	**Review of the informed consent process**	The informed consent process must be reviewed keeping in mind the following: • The process used for obtaining informed consent, including the identification of those responsible for obtaining consent and the procedures adopted for vulnerable populations; • The adequacy, completeness and understand ability of the information to be given to the research participants, and when appropriate, their LARs;

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		• contents of the patient/participation information sheet including the local language translations (See section 5 for further details); • back translations of the informed consent documenting English, wherever required; • provision for audio-visual recording of consent process, if applicable, as per relevant regulations; and • if consent waiver or verbal/oral consent request has been asked for, this should be reviewed by assessing whether the protocol meets the criteria. See section 5 for further details.

XVIII. DECISION-MAKING:

1. Members will discuss the various issues before arriving at a consensus decision.When consensus is not arrived at, the decision will be made by voting procedure.
2. A member will withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this will be indicated to the chairperson prior to the review of the application and recorded in the minutes.
3. Decision will be made only in meetings where quorum is complete.
4. Only members can make the decision. The expert consultants when present will only offer their opinions.
5. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for modifications and reasons for rejection will be given.
6. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.
7. Modified proposals will be reviewed by an expedited review through identified members.
8. Procedures for appeal by the investigators/researchers will be clearly defined.

XIX.COMMUNICATING THE DECISION

1. Decision of the meeting on the proposals will be communicated by the Member Secretary in writing to the PI/Research Scholar within 14 working days after the meeting and approval letter will be sent to the applicant within 2 weeks. All the

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approvals will be valid for two years or for the duration of the project whichever is less. Investigator has to get his or her project re-approved after two years if necessary.

2. The communication of the decision will include:
   a. Name and address of IEC.
   b. The date, place and time of decision.
   c. The name and designation of the PI/Guide
   d. Title of the research proposal reviewed.
   e. Along with protocol, other documents reviewed- clear description of these documents along with Version No. and Date.
   f. A clear statement of decision reached and follow up procedure with submission of progress reports.
   g. Any advice by the IEC to the applicant including the schedule/plan of on-going review by the MRADC-IEC.
   h. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed are informed.
   i. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.
   j. Signature of the member secretary with date and seal.

XX.FOLLOW UP PROCEDURES FOR APPROVED PROPOSALS BY PI/GUIDE:

1. IEC will review the progress of all the studies for which decision has been reached from the time of decision till the completion/termination of the research.
2. Progress of all the research proposals is a responsibility of PI/Guide to be submitted to IEC Office at a regular interval once in six months. But in special situations, IEC will conduct the follow up review at shorter intervals based on the need, nature and events of research project.
3. Periodic status report of study will be submitted at prescribed intervals in the prescribed format for review based on the safety concerns and this prescribed interval will be specified in the Letter of Communication of Decision to the PI from the IEC office.
4. Final report will be submitted at the end of study.
5. Following instances and events will require the follow-up review/ Renewed Approval:
   a. Any protocol amendment likely to affect rights, safety or well-being of research subject of for conduct of study.

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b. Serious or unexpected ADR related to study or product, action taken by Investigator/Guide
c. Any event or information that may affect the benefit/risk ratio of the study.

6. Protocol deviation, if any, will be informed with adequate justifications.
7. Any new information related to the study will be communicated.
8. Premature termination of study shall be notified with reasons along with summary of the data obtained so far.
9. Change of study title/guide/investigators/sites must be informed to the office of IEC.
10. Monitoring over site mechanism will be in place to monitor the approved studies. Actual site visits can be made especially in the event of reporting of adverse events or violations of human rights and appropriate action will be taken when required and communicated to the applicant indicating modification/suspension/termination/continuation of the project.
11. Applicant must inform the time of completion of study and send the result summary to IEC. IEC must receive a copy of final brief summary of study completed from the applicant in the required format.

XXI.ADVERSE EVENTS:

1. All serious adverse events (SAEs) shall be reported to the IEC within 24 hours from the time of its occurrence.
2. All SAEs reported will be reviewed by the EC for their integrity and will give their opinion on compensation to the study subject.

SAE report should contain the following:

a. Project details – Title, PI name
b. Patient details – Age, Gender Initials and other relevant details.
c. Suspected drug/s
d. Indication for which the drug was prescribed or tested
e. Dosage form and strength
f. Route of administration
g. Therapy dates
h. Details of Concomitant drugs (Including non-prescription/ OTC drugs)
i. Full description of the event with body site and severity, sign and symptoms
j. Start date and time of onset of event
k. Stop date and time or duration of event
l. Information of sequel, results of specific tests, treatment that have been done for outcome of event

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m. Any relevant information of the event
n. Clinical investigator details – name, address, telephone number, profession
o. De-challenge and re-challenge information
p. Causality assessment
q. Information on recovery or sequel, results of specific tests and/or treatment that may have been conducted for a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction, any post- mortem details
r. Anything relevant to facility assessment of the case, such as medical history including allergy, drug or alcohol abuse, family history, findings for special investigations.
s. Date of reporting the event to Licensing Authority
t. Date of reporting of event to Ethics Committee
u. Outcome of the event
v. Any other information for analysis
w. Signature of the Investigator
x. Details of pregnancy

XXII.RECORD KEEPING AND ARCHIVING AT THE OFFICE OF MRADC-IEC:

1. All the documents and communications of IEC will be dated, filed and archived in a secure place.
2. Only persons, who are authorized by the Chairman of IEC will have the access to the study related documents.
3. All the documents related to study/research proposals will be archived for a minimum period of 3 years in the Institute, following the completion/termination of the study.
4. PI/Co-I will present the PPT at IEC meeting for formal approval and will share the same as soft copy by email to drtarulatha@gmail.com for circulation to IEC members.
5. Following documents will be filed and archived with proper label on the top of filefor easy identification
   a. Constitution and composition of MRADC-IEC
   b. Curriculum Vitae (CV) of all members of MRADC-IEC with records of training in Human ethics if any and appointment letters.
   c. Standard Operating Procedures of MRADC-IEC
   d. Annual reports
   e. A record of all income and expenses of the EC, including allowances and reimbursements made to the secretariat and EC members;

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f. The published guidelines for submission established by the EC.
g. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
h. Agendas and Minutes of all IEC meetings duly signed by the Chairperson/Member secretary.
i. Copy of all existing relevant national and international guidelines on ethics and laws along with amendments.
j. Copy of all correspondence with members, Principal Investigators and other regulatory bodies.
k. Record of all notification issued for premature termination of a study with a summary of the reasons;
l. Final report of the approved projects, including microfilms, CDs

XXIII .INSPECTION & AUDITS:

1. IEC is open to inspection with or without notice by the officers authorized by DHR to verify compliance to requirements of–ICMR, Indian GCP& ICH –GCP guidelines.
2. All the IEC related records and communications as required by the authority will be shared by member secretary.
3. Concerned authority can visit any parts of the premises and can interview IEC members, study subject and staff if needed.
4. Based on inspection reports future Improvement in the functioning of IEC will be implemented so as to achieve the fundamental aim of safeguarding the rights, safety and wellbeing of study/trial subjects.

XXIV. SPECIAL CONSIDERATION/PROTECTIONS OF VULNERABLE POPULATION:

While, all the above requirements are applicable to biomedical research as a whole irrespective of the specialty of research there are certain specific concerns pertaining to specialized areas of research which require additional safe guards /protection and specific considerations for the IEC to take a note of. Examples of such instances are research involving – children, pregnant and lactating women, vulnerable participants and those with diminished autonomy besides issues pertaining to commercialization of research and national/international collaboration. The observations and suggestions of IEC will be given in writing in unambiguous terms in such instances. ICMR Guidelines for Biomedical and Health Research as applicable will be followed for protection of vulnerable population.

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XXV : LIST OF ABBREVIATIONS	
ADR	ADVERSE DRUG REACTION
AE	ADVERSE EVENT
BARC	BHABHA ATOMIC RESEARCH CENTRE
CD	COMPACT DISC
CO-PI	CO-PRINCIPAL INVESTIGATOR
DSMB	DATA SAFETY MONITORING BOARD
DBT	DEPARTMENT OF BIOTECHNOLOGY
DST	DEPARTMENT OF SCIENCE & TECHNOLOGY
DCGI	DRUG CONTROLLER GENERAL OF INDIA
DHR	DEPARTMENT OF HEALTH RESEARCH
EC	ETHICS COMMITTEE
GCP	GOOD CLINICAL PRACTICE
HMSC	HEALTH MINISTRY'S SCREENING COMMITTEE
ICMR	INDIAN COUNCIL OF MEDICAL RESEARCH
IEC	INSTITUTIONAL ETHICS COMMITTEE
ICH	INTERNATIONAL COUNCIL OF HARMONISATION
IND	INVESTIGATIONAL DRUG delete
OPD	OUT PATIENT DEPARTMENT
OTC	OVER THE COUNTER
PIS	PARTICIPANT INFORMATION SHEET
PICF	PARTICIPANT INFORMED CONSENT FORM
PI	PRINCIPAL INVESTIGATOR
SAE	SERIOUS ADVERSE EVENTS
SDC	STATE DRUG CONTROLLER
MRADC	M R AMBEDKAR DENTAL COLLEGE AND HOSPITAL
SOP	STANDARD OPERATING PROCEDURE
UNICEF	UNITED NATIONS CHILDREN'S FUND
USAID	UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT
UGC	UNIVERSITY GRANTS COMMISSION

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Appendix 1 – Research proposal Submission – DHR form

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Logo of the Institute

Application Form for Initial Review

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

General Instructions : a) Tick one or more options as applicable. Mark NA if not applicable
b) Attach additional sheets if required

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Organization: .....

(b) Name of Ethics Committee: .....

(c) Name of Principal Investigator: .....

(d) Department/Division: ..... (e) Date of submission: dd mm yy

(f) Type of review requested[1]:

Exemption from review ☐ Expedited review ☐ Full committee review ☐

(g) Title of the study: .....

.....

.....

Acronym/ Short title, (If any): .....

(h) Protocol number (If any): ..... Version number: .....

(i) Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication[2]
Principal Investigator/Guide			
Co-investigator/student/fellow			

(j) Number of studies where applicant is a:

i) Principal Investigator at time of submission .....

ii) Co-Investigator at time of submission: .....

(k) Duration of the study: .....

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[1]*Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 on Page 36 Table 4.2: for types of review*
[2]*Include telephone/mobile, fax numbers and email id*

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for site: .....

At site..... In India..... Globally .....

(b) Self-funding ☐ Institutional funding ☐ Funding agency *(Specify)* ☐

.....

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Lay summary[3] (within 300 words): .....

.....

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.....

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.....

.....

(b) Type of study:

Basic Sciences	☐	Clinical	☐	Cross Sectional	☐
Retrospective	☐	Epidemiological/ Public Health	☐	Case Control	☐
Prospective	☐			Cohort	☐
Qualitative	☐	Socio-behavioural	☐	Systematic Review	☐
Quantitative	☐	Biological samples/ Data	☐		
Mixed Method	☐	Any others *(Specify)*	☐		

.....

4. METHODOLOGY

(a) Sample size/ number of participants *(as applicable)*

At site..... In India..... Globally .....

Control group..... Study group .....

Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation .....

.....

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[3]*Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.*

(b) Is there an external laboratory/outsourcing involved for investigations?[4] Yes ☐ No ☐ NA ☐

(c) How was the scientific quality of the study assessed?

Independent external review ☐ Review by sponsor/Funder ☐ Review within PI's institution ☐

Review within multi-centre research group ☐ No review ☐

Date of review: dd mm yy

Comments of scientific committee, if any (100 words)

.....

.....

.....

.....

SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteers ☐ Patients ☐ Vulnerable persons/ Special groups ☐

Others ☐ *(Specify)* .....

Who will do the recruitment? .....

Participant recruitment methods used:

Posters/ leaflets/Letters ☐ TV/Radio ads/ Social media/ Institution website ☐ Patients / Family/ Friends visiting hospitals ☐ Telephone ☐

Others ☐ *(Specify)* .....

(b) i. Will there be vulnerable persons / special groups involved ? Yes ☐ No ☐ NA ☐

ii. If yes, type of vulnerable persons / special groups

Children under 18 yrs ☐ Pregnant or lactating women ☐

Differently abled (Mental/Physical) ☐ Employees/Students/Nurses/Staff ☐

Elderly ☐ Institutionalized ☐

Economically and socially disadvantaged ☐ Refugees/Migrants/Homeless ☐

Terminally ill (stigmatized or rare diseases) ☐

Any other *(Specify)*: ☐ .....

iii. Provide justification for inclusion/exclusion .....

.....

..... iv.

Are there any additional safeguards to protect research participants?.....

.....

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[4] *If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA / MoU*

(c) Is there any reimbursement to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

.....

(d) Are there any incentives to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

.....

(e) Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution?

If yes, Monetary ☐ Non-monetary ☐ *Provide details* Yes ☐ No ☐

.....

.....

6. BENEFITS AND RISKS

(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes ☐ No ☐

If yes, categorize the level of risk[5] :

Less than Minimal risk ☐ Minimal risk ☐

Minor increase over minimal risk or low risk ☐ More than minimal risk or high risk ☐

ii. Describe the risk management strategy: .....

.....

.....

(b) What are the potential benefits from the study?

	Yes	No	If yes,	Direct	Indirect
For the participant	☐	☐		☐	☐
For the society/community	☐	☐		☐	☐
For improvement in science	☐	☐		☐	☐

Please describe how the benefits justify the risks .....

.....

.....

.....

(c) Are adverse events expected in the study[6] ? Yes ☐ No ☐ NA ☐

Are reporting procedures and management strategies described in the study? Yes ☐ No ☐

If Yes, Specify .....

.....

.....

7. INFORMED CONSENT

(a) Are you seeking waiver of consent? If yes, please specify reasons and skip to item no. 8 Yes ☐ No ☐

.....

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[5]*For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 6 Table 2.1*

[6]*The term adverse events in this regard encompass both serious and non-serious adverse events.*

(b) Version number and date of Participant Information Sheet (PIS):.....

Version number and date of Informed Consent Form (ICF):.....

(c) Type of consent planned for :

Signed consent ☐ Verbal/Oral consent ☐ Witnessed consent ☐ Audio-Video (AV) consent ☐

Consent from LAR ☐ (If so, specify from whom) ..... For children<7 yrs parental/LAR consent ☐ Verbal assent from minor (7-12 yrs) along with parental consent ☐ Written assent from minor (13-18 yrs) along with parental consent ☐

Other ☐

(specify) .....

(d) Who will obtain the informed consent?

PI/Co-I ☐ Nurse/Counselor ☐ Research Staff ☐ Other ☐ *(Specify)* .....

Any tools to be used .....

(e) Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐ Other ☐ *(Specify)*.....

List the languages in which translations were done .....

If translation has not been done, please justify .....

.....

(f) Provide details of consent requirements for previously stored samples if used in the study[7]

.....

.....

(g) Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF)

Simple language ☐	Data/ Sample sharing ☐	Compensation for study related injury ☐
Risks and discomforts ☐	Need to recontact ☐	Statement that consent is voluntary ☐
Alternatives to participation ☐	Confidentiality ☐	Commercialization/ Benefit sharing ☐
Right to withdraw ☐	Storage of samples ☐	Statement that study involves research ☐
Benefits ☐	Return of research results ☐	Use of photographs/ Identifying data ☐
Purpose and procedure ☐	Payment for participation ☐	Contact information of PI and Member Secretary of EC ☐
Others(Specify) ☐		

.....

8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures[8] ?

PI ☐ Institution ☐ Sponsor ☐ Other agencies ☐ *(specify)*

.....

(b) Is there a provision for free treatment of research related injuries? Yes ☐ No ☐ N/A ☐

If yes, then who will provide the treatment? .....

(c) Is there a provision for compensation of research related SAE? If yes, specify. Yes ☐ No ☐ N/A ☐

Sponsor ☐ Institutional/Corpus fund ☐ Project grant ☐ Insurance ☐

(d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes ☐ No ☐ N/A ☐

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(e) Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify. Yes ☐ No ☐ N/A ☐

[7] *Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, Page 54 in Section 5.8.*

[8]*Enclose undertaking from PI confirming the same*

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9. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data. *If Yes, specify* Yes ☐ No ☐ NA ☐

Anonymous/Unidentified ☐ Anonymized: Reversibly coded ☐ Irreversibly coded ☐ Identifiable ☐ If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.) .....

.....

.....

.....

.....

(b)

Who will be maintaining the data pertaining to the study? ..... (c)

Where will the data be analyzed[9] and by whom? .....

(d) For how long will the data be stored? .....

(e) Do you propose to use stored samples/data in future studies? Yes ☐ No ☐ Maybe ☐

If yes, explain how you might use stored material/data in the future?.....

.....

.....

.....

SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

(a) Will the results of the study be reported and disseminated? If yes, specify. Yes ☐ No ☐ NA ☐

.....

.....

(b) Will you inform participants about the results of the study? Yes ☐ No ☐ NA ☐

(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief (Max 50 words) Yes ☐ No ☐ NA ☐

.....

.....

(d) Is there any plan for post research benefit sharing with participants? If yes, *specify* Yes ☐ No ☐ NA ☐

.....

.....

(e) Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details Yes ☐ No ☐ NA ☐

.....

(f) Do you have any additional information to add in support of the application, which is not included elsewhere in the form? If yes, provide details. Yes ☐ No ☐

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[9]*For example, a data entry room, a protected computer etc.*

SECTION E: DECLARATION AND CHECKLIST [10]

11. DECLARATION (Please tick as applicable)	
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and other applicable regulations and guidelines.
☐	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
☐	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports and a final report and also participate in any audit of the study if needed.
☐	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
☐	I/We will protect the privacy of participants and assure confidentiality of data and biological samples.
☐	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
☐	I/We have the following conflict of interest (PI/Co-I): 1. .... 2. ....
☐	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI: .....

Signature: ..... dd mm yy

Name of Co-PI: .....

Signature: ..... dd mm yy

Name of Guide: .....

Signature: ..... dd mm yy

Name of HOD: .....

Signature: ..... dd mm yy

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[10] *These formats are adaptable and can be modified by the Ethics Committee members depending on their needs and requirements*

Acknowledgement for Receipt of Application (Copy to be provided to PI)

12. CHECKLIST

S. No	Items	Yes	No	NA	Enclosure No	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1	Cover letter	☐	☐	☐		
2	Brief CV of all Investigators	☐	☐	☐		
3	Good Clinical Practice (GCP) training of investigators in last 3 years	☐	☐	☐		
4	Approval of scientific committee	☐	☐	☐		
5	EC clearance of other centers*	☐	☐	☐		
6	Agreement between collaborating partners*	☐	☐	☐		
7	MTA between collaborating partners*	☐	☐	☐		
8	Insurance policy/certificate	☐	☐	☐		
9	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	☐	☐	☐		
10	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
11	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol	☐	☐	☐		
PROPOSAL RELATED						
12	Copy of the detailed protocol[11]	☐	☐	☐		
13	Investigators Brochure (If applicable for drug/biologicals/device trials)	☐	☐	☐		
14	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated)	☐	☐	☐		
15	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
16	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		
17	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		

PERMISSION FROM GOVERNING AUTHORITIES						
	Other permissions	**Required**	**Not required**	**Received**	**Applied dd/ mm/yy**	**EC Remarks**
18	CTRI	☐	☐	☐		
19	DCGI	☐	☐	☐		
20	HMSC	☐	☐	☐		
21	NAC-SCRT	☐	☐	☐		
22	ICSCR	☐	☐	☐		
23	RCGM	☐	☐	☐		
24	GEAC	☐	☐	☐		
25	BARC	☐	☐	☐		
26	Tribal Board	☐	☐	☐		
27	Others (Specify)	☐	☐	☐		

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY						
	Item	**YES**	**NO**	**NA**	**Enclosure no.**	**EC remarks**
28		☐	☐	☐		
29		☐	☐	☐		

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**For multicentre research.*

MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India; HMSC- Health Ministry's Screening Committee; NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy; IC-SCR-Institutional committee for Stem Cell Research; RCGM- Review Committee on Genetic Manipulation; GEAC- Genetic Engineering Approval Committee; BARC- Bhabha Atomic Research Centre.

[11]Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, section 4 Page no. 35 Box 4.4(b)

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Annexure

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(Annexure 1)

Logo of the Institute

Application Form for Expedited Review

.....

(Name of the Institution) **EC Ref. No.*** *(For office use):*

Title of study: .....

.....

..... Principal

Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Choose reasons why expedited review from EC is requested[12] ?
   - i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples. ☐
   - ii. Involves clinical documentation materials that are non-identifiable (data, documents, records). ☐
   - iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)). ☐
   - iv. Revised proposal previously approved through expedited review, full review or continuing review of approved proposal. ☐
   - v. Minor deviation from originally approved research causing no risk or minimal risk. ☐
   - vi. Progress/annual report 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. ☐
   - vii. For multicentre research where a designated EC has approved the proposal, a participating EC may review participating centre specific information and modifications in the study proposal through full committee meeting/expedited review depending on the importance of local consent related issues involved specific to the centre. ☐
   - viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017). ☐
   - ix. Any other (please specify) .....

     .....
2. Is waiver of consent being requested? Yes ☐ No ☐
3. Does the research involve vulnerable persons[13] ? Yes ☐ No ☐

   If Yes give details: .....

   .....

   .....

Signature of PI: ..... dd mm yy

Comments of EC Secretariat: .....

Signature of Member Secretary: ..... dd mm yy

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[12] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2*

[13] *For details, refer to application for initial review, Section-C, 5(b)*

* *In case this is first submission, leave it blank*

(Annexure 2)

Logo of the Institute

Application Form for Exemption from Review

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

..... Principal

Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Choose reasons why exemption from ethics review is requested[14]?
   - i. Research on data in the public domain/ systematic reviews or meta-analyses ☐
   - ii. Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person ☐
   - iii. Quality control and quality assurance audits in the institution ☐
   - iv. Comparison among instructional techniques, curricula, or classroom management methods ☐
   - v. Consumer acceptance studies related to taste and food quality ☐
   - vi. Public health programmes by government agencies[15] ☐
   - vii. Any other (please specify in 100 words): .....

.....

.....

.....

.....

Signature of PI: ..... dd mm yy

Comments of EC Secretariat: .....

Signature of Member Secretary: ..... dd mm yy

[14]*Select the category that applies best to your study and justify why you feel it should be exempted from review. For a detailed understanding of the type of studies that are exempt from review, refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2.*

[15]*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)*

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(Annexure 3)

Logo of the Institute

Continuing Review / Annual report format

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

..... Principal

Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC Approval: dd mm yy — Validity of approval: dd mm yy
2. Date of Start of study: dd mm yy — Proposed date of Completion: dd mm yy

Period of Continuing Report: dd mm yy ---- to ------ dd mm yy

3. Does the study involve recruitment of participants? Yes ☐ No ☐

(a) If yes, Total number expected..... Number Screened: ..... Number Enrolled: .....

Number Completed:..... Number on followup:.....

(b) Enrolment status – ongoing / completed/ stopped

(c) Report of DSMB[16] Yes ☐ No ☐ NA☐

(d) Any other remark.....

.....

(e) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ NA☐

If yes, total number withdrawn and reasons: .....

.....

.....

4. Is the study likely to extend beyond the stated period ?[17] Yes ☐ No ☐

If yes, please provide reasons for the extension. .....

.....

.....

5. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period?

If No, skip to item no. 6 Yes ☐ No ☐

(a) If yes, date of approval for protocol and ICD : dd mm yy

(b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes ☐ No☐

If yes, when / how: .....

.....

.....

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[16] *In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.*

[17] *Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC*

6. Is any new information available that changes the benefit - risk analysis of human participants involved in this study? Yes ☐ No ☐

If yes, discuss in detail: .....

.....

.....

7. Have any ethical concerns occurred during this period? Yes ☐ No ☐

If yes, give details: .....

.....

8. (a) Have any adverse events been noted since the last review? Yes ☐ No ☐

Describe in brief: .....

.....

.....

(b) Have any SAE's occurred since last review? Yes ☐ No ☐

If yes, number of SAE's : ..... Type of SAE's: .....

.....

.....

(c) Is the SAE related to the study? Yes ☐ No ☐

Have you reported the SAE to EC? If no, state reasons Yes ☐ No ☐

.....

.....

9. Has there been any protocol deviations/violations that occurred during this period?

If yes, number of deviations .....

Have you reported the deviations to EC? If no, state reasons Yes ☐ No ☐

.....

.....

10. In case of multicenteric trials, have reports of off-site SAEs been submitted to the EC ? Yes ☐ No ☐ NA ☐

11. Are there any publications or presentations during this period? If yes give details Yes ☐ No ☐

.....

.....

Any other comments: .....

.....

Signature of PI: ..... dd mm yy

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(Annexure 4)

Logo of the Institute

Application/Notification form for Amendments

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

..... Principal

Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: dd mm yy Date of start of study dd mm yy

2. Details of amendment(s)

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD [18]

3. Impact on benefit-risk analysis Yes ☐ No ☐

If yes, describe in brief: .....

.....

4. Is any reconsent necessary? Yes ☐ No ☐

If yes, have necessary changes been made in the informed consent? Yes ☐ No ☐

5. Type of review requested for amendment:

Expedited review (No alteration in risk to participants) ☐

Full review by EC (There is an increased alteration in the risk to participants) ☐

6. Version number of amended Protocol/Investigator's brochure/ICD: .....

Signature of PI: ..... dd mm yy

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[18] *Location implies page number in the ICD/protocol where the amendment is proposed.*

(Annexure 5)

Protocol Violation/Deviation Reporting Form (Reporting by case)

Logo of the Institute

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

..... Principal

Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval dd mm yy Date of start of study dd mm yy
2. Participant ID:..... Date of occurrence dd mm yy
3. Total number of deviations /violations reported till date in the study: .....
4. Deviation/Violation identified by: Principal Investigator/study team ☐ Sponsor/Monitor ☐

   SAE Sub Committee/EC ☐
5. Is the deviation related to (Tick the appropriate box) :

Consenting	☐	Source documentation	☐
Enrollment	☐	Staff	☐
Laboratory assessment	☐	Participant non-compliance	☐
Investigational Product	☐	Others *(specify)*	☐
Safety Reporting	☐		

6. Provide details of Deviation/Violation: .....

.....

.....

.....

7. Corrective action taken by PI/Co-I: .....

.....

.....

.....

8. Impact on (if any): Study participant ☐ Quality of data ☐
9. Are any changes to the study/protocol required? Yes ☐ No ☐

   If yes, give details.....

.....

Signature of PI: ..... dd mm yy

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(Annexure 6)

Logo of the Institute

Serious Adverse Event Reporting Format (Biomedical Health Research)

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

..... Principal

Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Participant details :

Initials and ID	Age at the time of event	Gender	Weight: .....(Kgs)
.....	.....	Male ☐ Female ☐	Height: .....(cms)
.....	.....		

2. Suspected SAE diagnosis:.....

3. Date of onset of SAE: dd mm yy

Date of reporting SAE: dd mm yy

Describe the event [19]:

.....

.....

.....

.....

.....

.....

.....

4. Details of suspected intervention causing SAE [20]

.....

.....

.....

.....

.....

.....

5. Report type: Initial ☐ Follow-up ☐ Final ☐

If Follow-up report, state date of Initial report dd mm yy

6. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes ☐ No ☐

.....

.....

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[19] *Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious*

[20] *Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s)*

7. In case of a multi-centric study, have any of the other study sites reported similar SAEs ?

(Please list number of cases with details if available)

.....

.....

8. Tick whichever is applicable for the SAE: (Kindly note that this refers to the Intervention being evaluated and NOT disease process)

A. Expected event ☐ Unexpected event ☐

B.

Hospitalization	☐	Increased Hospital Stay	☐	Death	☐	Congenital anomaly/birth defect	☐
Persistent or significant disability/incapacity	☐	Event requiring intervention (surgical or medical) to prevent SAE	☐	Event which poses threat to life	☐	Others	☐

.....

In case of death, state probable cause of death.....

C. No permanent/significant functional/cosmetic impairment ☐

Permanent/significant functional/cosmetic impairment ☐

Not Applicable ☐

9. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

.....

.....

10. Provide details of compensation provided / to be provided to participants (Include information on who pays, how much, and to whom).....

.....

11. Outcome of SAE

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Other *(specify)*	☐

.....

12. Provide any other relevant information that can facilitate assessment of the case such as medical history

.....

.....

.....

13. Provide details about PI's final assessment of SAE relatedness to research.

.....

.....

.....

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Signature of PI: .....

(Annexure 7)

Logo of the Institute

Premature Termination/Suspension/ Discontinuation Report Format

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

..... Principal

Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: dd mm yy Date of start of study: dd mm yy
2. Date of last progress report submitted to EC: dd mm yy
3. Date of termination/suspension/discontinuation: dd mm yy
4. Tick the appropriate

   Premature Termination ☐ Suspension ☐ Discontinuation ☐

   Reason for Termination/Suspension/Discontinuation: .....

   .....

   .....

   .....

   Action taken post Termination/ Suspension/Discontinuation (if any): .....

   .....

   .....

   .....

5. Plans for post study follow up/withdrawal[21] (if any): .....

   .....

   .....

6. Details of study participants:

   Total participants to be recruited: ..... Screened: ..... Screen failures: .....

   Enrolled: ..... Consent Withdrawn: ..... Reason (Give details): .....

   .....

   .....

   Withdrawn by PI: ..... Reason(Give details): .....

   .....

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[21] *Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study.*

Active on treatment: ..... Completed treatment : ..... Participants on follow-up: .....

Participants lost to follow up: ..... Any other: ..... Number of drop outs:.....

Reasons for each drop-out: .....

.....

.....

.....

7. Total number of SAEs reported till date in the study: .....

Have any unexpected adverse events or outcomes observed in the study been reported to the EC? Yes ☐ No☐

8. Have there been participant complaints or feedback about the study? Yes ☐ No☐

If yes, provide details:.....

.....

9. Have there been any suggestions from the SAE Sub Committee? Yes ☐ No☐

If yes, have you implemented that suggestion? Yes ☐ No☐

10. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? Yes ☐ No☐

(e.g., making arrangements for medical care of research participants): If Yes, provide details

.....

.....

Summary of results (if any): .....

.....

.....

.....

.....

.....

Signature of PI: .....

dd mm yyyy

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Logo of the Institute

(Annexure 8)

Application Form for Clinical Trials

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

..... Principal

Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Type of clinical trial Regulatory trial ☐ Academic trial ☐

   CTRI registration number: ..... NABH accreditation number:..... EC registration number:.....

2. If regulatory trial, provide status of CDSCO permission letter

   Approved and letter attached ☐ Applied, under process ☐

   Not applied (State reason) ☐.....

3. Tick all categories that apply to your trial

Phase - I	☐	Phase II	☐
Phase III	☐	Phase IV or Post Marketing Surveillance	☐
Investigational medicinal products	☐	Investigational New drug	☐
Medical devices	☐	New innovative procedure	☐
Drug/device combination	☐	Bioavailability/Bioequivalence studies	☐
Non-drug intervention	☐	Repurposing an existing intervention	☐
Indian system of medicine (AYUSH)	☐	Stem cells	☐
Phytopharmaceutical drug	☐	Approved drug for any new indication	
Others (specify)	☐	or new route of administration	☐

.....

4. Trial design of the study

I. Randomized	☐	Factorial	☐
Non randomized	☐	Stratified	☐
Parallel	☐	Adaptive	☐
Cross-over	☐	Comparison trial	☐
Cluster	☐	Superiority trial	☐
Matched-pair	☐	Non-inferiority trial	☐
Others *(specify)*	☐	Equivalence trial	☐

.....

II. If there is randomization, how will the participants be allocated to the control and study group(s)?

.....

.....

III. Describe the method of allocation concealment (blinding / masking), if applicable.

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.....

.....

5. List the primary / secondary outcomes of the trial.

……

……

6. Is there a Contract Research Organization (CRO) /Site Management Organisation (SMO) / Any other agency such as public relation/human resource? Yes ☐ No ☐

If yes, Name and Contact details: ……

……

……

State how the CRO/SMO/agency will be involved in the conduct of the trial (tick all that apply)

Project management	☐	Clinical and medical monitoring	☐
Regulatory affairs	☐	Data management	☐
Statistical support	☐	Medical writing	☐
Site management	☐	Audits, quality control, quality assurance	☐
Finance management	☐	Recruitment and training	☐
Administrative support	☐	Others *(specify)*	☐

……

7. Please provide the following details about the intervention being used in the protocol

I. Drug/s, device/s and/or biologics; if yes, provide regulatory approval details. Yes ☐ No ☐ NA ☐

……

……

II. Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration. If yes, provide details. Yes ☐ No ☐ NA ☐

……

……

III. Provide contact details of who prepared and /or is manufacturing the drug/s, device/s and biologics.

……

……

IV. Provide details of patent of the drug/s, device/s and biologics.

……

……

8. Describe in brief any preparatory work or site preparedness for the protocol? Yes ☐ No ☐ NA ☐

If yes, provide details (100words)……

……

……

……

……

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9. Is there an initial screening/ use of existing database for participant selection? Yes ☐ No ☐ NA ☐

If Yes, provide details[22]

10. Is there any anticipated incidence, frequency and duration of adverse events related to the intervention?

If yes, provide details of arrangements made to address them. Yes ☐ No ☐ NA ☐

11. Does the study use a placebo?

If yes, justify the use of the placebo and risks entailed to participants. Yes ☐ No ☐ NA ☐

12. Will current standard of care be provided to the control arm in the study? Yes ☐ No ☐ NA ☐

If no, please justify.

13. Are there any plans to withdraw standard therapy during the study? If yes, please justify. Yes ☐ No ☐ NA ☐

14. Are there any rules to stop the protocol in case of any adverse events? If yes, please specify. Yes ☐ No ☐ NA ☐

15. Does the study have a Data and Safety Monitoring Plan? If no, please justify. Yes ☐ No ☐

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[22] *In order to select participants for your protcol does the protocol require you to screen an initial population or refer to an existing database before shortlisting participants. If yes, provide details on the same*

16. Participant Information Sheet(PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐
(certified that local version (s) is/are a true translation of the English version and can be easily understood by the participants)

Other*(Specify)* ☐

……

List the languages in which translations were done ……

Justify if translation not done……

……

17. Involvement/consultation of statistician in the study design Yes ☐ No ☐ NA ☐

18. Is there any insurance coverage of the trial? If yes, provide details. Yes ☐ No ☐

……

……

……

I. Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration?

Please provide details. Yes ☐ No ☐

……

……

II. Is the PI trained in GCP in last 3 years? If yes, Please enclose certificate Yes ☐ No ☐

Signature of PI: …… dd mm yy

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(Annexure 9)

Serious Adverse Event Reporting Format (Clinical trials)

Logo of the Institute

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

..... Principal

Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Participant details :

Initials and Case No./ Subject ID	Age at the time of event	Gender	Weight:.....(Kgs)
.....	.....	Male ☐	Height:..... (cms)
.....		Female ☐	

2. Report type: Initial ☐ Follow-up ☐ Final ☐

If Follow-up report, state date of Initial report dd mm yy

What was the assessment of relatedness to the trial in the initial report?

By PI –	By Sponsor –	By EC –
Related ☐	Related ☐	Related ☐
Unrelated ☐	Unrelated ☐	Unrelated ☐

3. Describe the event and specify suspected SAE diagnosis:.....

.....

.....

4. Date of onset of SAE: dd mm yy Date of reporting: dd mm yy

5. Onset lag time after administration of intervention: Location of SAE (Clinic/Ward/Home/Other)

....

6. Details of suspected study drug/device/investigational procedure causing SAE:

I. Suspect study drug (include generic name) device/intervention: .....

.....

II. Indication(s) for which suspect study drug was prescribed or tested: .....

.....

III. Route(s) of administration, daily dose and regimen, dosage form and strength : .....

.....

IV. Therapy start date: dd mm yy Stop date: dd mm yy

7. Was study intervention discontinued due to event? Yes ☐ No ☐

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8. Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? Yes ☐ No ☐

If yes, provide details about the reduced dose.....

9. Did the reaction reappear after reintroducing the study drug / procedure? Yes ☐ No ☐ NA ☐

If yes, provide details about the dose.....

10. Concomitant drugs history and lab investigations:

I. Concomitant drug (s) and date of administration: dd mm yy

.....

.....

II. Relevant test/laboratory data with dates: dd mm yy

.....

.....

III. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc).....

.....

.....

11. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes ☐ No ☐

.....

.....

12. Seriousness of the SAE:

Death	☐	Congenitial anomaly	☐
Life threatening	☐	Required intervention to prevent	
Hospitalization-initial or prolonged	☐	permanent impairment / damage	☐
Disability	☐	Others *(specify)*	☐

.....

13. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

.....

.....

14. Outcome of SAE:

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Other *(specify)*	☐

.....

15. Was the research participant continued on the trial? Yes ☐ No ☐ NA ☐

16. Provide details about PI's final assessment of SAE relatedness to trial.

.....

.....

17. Has this information been communicated to sponsor/CRO/regulatory agencies? Yes ☐ No ☐

Provide details if communicated (including date)

18. Does this report require any alteration in trial protocol? Yes ☐ No ☐

19. Provide details of compensation provided / to be provided the participants (Include information on who pays, how much, and to whom).....

.....

Signature of PI: .....

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Logo of the Institute

(Annexure 10)

Application Form for Human Genetics Testing Research

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

..... Principal

Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Describe the nature of genetic testing research being conducted.

   (e.g.- screening/gene therapy/newer technologies/human embryos/foetal autopsy)

   .....

   .....

   .....

2. Does the study involve pretest and post-test counselling? If yes, please describe. Yes ☐ No ☐ NA ☐

   .....

   .....

3. Explain the additional safeguards provided to maintain confidentiality of data generated.

   .....

   .....

   .....

4. If there is a need to share the participants' information/investigations with family/community, is it addressed in the informed consent? Yes ☐ No ☐ NA ☐

   If findings are to be disclosed, describe the disclosure procedures (e.g. genetic counseling)

   .....

   .....

   .....

5. Is there involvement of secondary participants? Yes ☐ No ☐ NA ☐

   If yes, will informed consent be obtained? State reasons if not. Yes ☐ No ☐ NA ☐

   .....

   .....

6. What measures are taken to minimize/mitigate/eliminate conflict of interest?

   .....

   .....

   .....

7. Is there a plan for future use of stored samples for research? Yes ☐ No ☐

   If yes, has this been addressed in the informed consent ? Yes ☐ No ☐

   Signature of PI: .....

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Logo of the Institute

(Annexure 11)

Application Form for Socio-Behavioural and Public Health Research

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

..... Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Data collection method used in the study

Focus group	☐	Questionnaire/Survey	☐	Observation	☐
Interviews	☐	Documents and records	☐	Ethnographies/Oral history/Case studies	☐
Others *(Specify)*	☐				

.....

If it is an interview, will there be audio-video recording of participants' interview? If yes, justify the reasons and storage strategies. Yes ☐ No ☐

.....

.....

.....

2. Type of informed consent used in the study.

Individual consent	☐	Gate-keeper consent	☐	Community consent	☐
Others	☐	*(specify)*.....			

3. Provide details of safeguards to ensure privacy and confidentiality of participants in the event of data sharing.

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4. Describe strategies to manage if any patterns of behaviour of self-harm or harm to the society are identified.(e.g.: Suicide or infanticide) Yes ☐ No ☐ NA ☐

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5. Are cultural norms/Social considerations/Sensitivities taken into account while designing the study and participant recruitment? Yes ☐ No ☐

6. Is there a use of an interpreter? If yes, describe the selection process. Yes ☐ No ☐ NA ☐

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7. Describe any preparatory work or site preparedness for the study Yes ☐ No ☐ NA ☐

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8. I. Type of risk related to procedures involved in the study

Invasive ☐ Potentially harmful ☐ Emotionally disturbing ☐ Involving disclosure ☐

Describe the risk minimization strategies.

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II. Justify reasons if individual harm is overriding societal benefit. Yes ☐ No ☐ NA ☐

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III. Describe how do societal benefits outweigh individual harm.

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9. Does the study use incomplete disclosure or active deception or authorized deception? If yes, provide details and rationale for deception. Yes ☐ No ☐

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10. Describe the debriefing process that will be used to make participants aware of the incomplete disclosure or deception, including their right to withdraw any record of their participation.

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Signature of PI: ..... dd mm yy

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(Annexure 12)

Logo of the Institute

Study completion/Final report format

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(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

..... Principal

Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: dd mm yy
2. Date of start of study: dd mm yy Date of study completion: dd mm yy
3. 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): .....

Provide the reasons for withdrawal of participants[23] : .....

.....

.....

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

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

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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:.....

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[23] *Explanation for the withdrawal of participants whether by self or by the PI*

8. Is there a plan for post study follow-up? Yes ☐ No ☐

If yes, describe in brief: .....

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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: .....

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11. Describe results (summary) with Conclusion [24] : .....

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12. Number of SAEs that occurred in the study: .....

13. Have all SAEs been intimated to the EC ? Yes ☐ No ☐

14. Is medical management or compensation for SAE provided to the participants? Yes ☐ No ☐

If yes, provide details.....

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Signature of PI: ..... dd mm yy

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[24] *For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready.*

(Annexure 13)

Logo of the Institute

Format for Curriculum Vitae for Investigators

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(Name of the Institution) **EC Ref. No.** *(For office use):*

Name:
Present affiliation *(Job title, department, and organisation)*:
Address (Full work address):
Telephone number: Email address:
Qualifications:
Professional registration *(Name of body, registration number and date of registration):*
Previous and other affiliations *(Include previous affiliations in the last 5 years and other current affiliations):*
Projects undertaken in the last 5 years:

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Relevant research training/experience in the area [25] :
Relevant publications *(Give references to all relevant publications in the last five years):*

Signature	Date:

[25] *Details of any relevant training in the design or conduct of research, for example in the Ethics Training, Human participants' protection courses, Clinical Trials Regulations, Good Clinical Practice, consent, research ethics training or other training appropriate to non-clinical research. Give the date of the training*

P.R.P

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