Standard Operating Procedure (SOP)

Dr. RK Diabetic Foot and Podiatry Institute
&
Rakesh Jhunjhunwala Amputation Prevention Center

Dr. RK Diabetic Foot and Podiatry Institute &

Rakesh Jhunjhunwala Amputation Prevention Center

Institutional Ethics Committee

RKDF -IEC

Version no: SOP/RKDF-IEC, /001 Dated:

03/03/2023

Effective date: 03/03/2023

Valid for: 3 years

Next Review Date: 03/03/2026

1 Review and Authorization

We, the undersigned have reviewed the working Standard Operating Procedure (SOP) of **"Dr. RK Diabetic Foot and Podiatry Institute & Rakesh Jhunjhunwala Amputation Prevention Center – Institutional Ethics Committee, (RKDF -IEC)"**and authorize that it complies with "New Drugs and Clinical Trials Rules, 2019", "Indian Good Clinical Practice", "Indian Council of Medical Research's (ICMR) National Ethical Guidelines for Biomedical Research" and ICH – Good Clinical Practices.

Version no: SOP/ RKDF-IEC / 001

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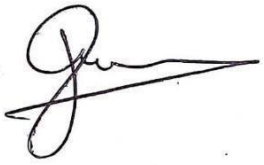
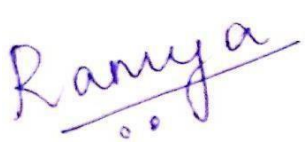
2.Dr D Darwin Britto	

Reviewed by: Dr S Ramya	
Approved by  Dr Rajesh Kesavan, Member Secretary	 Mr M.Jeeva Chairperson
Date - 03.03.2023	Date -03.03.2023

Mission of RKDF-IEC

The mission of **Dr. RK Diabetic Foot and Podiatry Institute & Rakesh Jhunjhunwala Amputation Prevention Center – Institutional Ethics Committee, (RKDF -IEC) Institutional Ethics Committee (IEC)**, Chennai, is to protect the rights, safety, and well-being of research participants in clinical trials and other academic studies conforming to high standards of ethics and with integrity.

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4. Introduction

Dr. RK Diabetic Foot and Podiatry Institute &Rakesh Jhunjhunwala Amputation Prevention Center (A Unit of SAARA RS Private Limited) Chennai. It is here in referred as '**RKDF'.** The Ethics Committee is constituted to review and approve the research proposals conducted by the faculty. The committee will be known as **"Dr. RK Diabetic Foot – Institutional Ethics Committee (RKDF -IEC)"**

The committee will review Clinical trials of drugs and devices, BA and BE proposals and academic proposals (Research and funded proposals) to ensure that the rights, safety and well-being of the Participants are ensured. The Committee functions within the campus of the Institute located in Second Floor, No. 1, Jayanti Nagar Extension, off 200 feet Road, Kolathur, Chennai, Tamil Nadu, 600099. The RKDF-IEC contact number is 044-41115500/9283143681

The committee will evaluate the research proposals for Clinical evaluation of Drugs/Procedures/ Devices/ Diagnostics/ Vaccine/Herbal Remedies, Bio-Availability /Bio-Equivalence studies, Research Projects involving human subjects is to maintain effective functioning of the IEC and to ensure quality and technical excellence and consistent ethical review of all the submitted research proposals and the ongoing approved research projects involving human participants in accordance with the ICMR Ethical guidelines for biomedical research on human subjects.

RKDF-IEC is established in accordance with the Applicable Indian & International regulatory guidelines & regulations such as "New Drugs and Clinical Trials Rules, 2019", "Indian Good Clinical Practice", "Indian Council of Medical Research's (ICMR) National Ethical Guidelines for Biomedical Research" and ICH – Good Clinical Practices and in accordance with the cultural & ethical values and principles of India.

Declaration The composition and working procedure of RKDF-**IEC** is based on Operational Guidelines for IEC that review Biomedical Research (WHO, 2000), International Conference on Harmonization-Good Clinical Practices (ICH-GCP) Guidelines (1996), New Drugs and Clinical Trials Rules, 2019, Indian GCP guidelines (2016) and Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017).

5. IEC – Aim & Objectives:

Aim: RKDF IEC, has been constituted with a purpose to provide public assurance of protection, reviewing and approving the clinical trial protocol, the suitability of the investigator(s), facilities and the methods and material to conduct clinical research at RKDF under compliance of New Drugs and Clinical Trials Rules, 2019, National Ethical Guidelines for Biomedical Research on Human Participants by ICMR and its requirements.

Objective of RKDF-IEC

The objective of RKDF-IEC, is to safeguard the rights, Dignity, safety, and well-being of clinical research participants without considering any direct financial or other material benefit from the research as the outcome of the review.

RKDF-IEC , will ensure quality and consistency in review of clinical research proposals not only with the initial review of the clinical trial/proposals but also has a continual responsibility of regular monitoring of the approved projects to foresee the compliance of the ethics during the period of the project.
The Goal of research, however important, will never be permitted to override the health and well-being of the research participants.

6. Authority to constitute RKDF-IEC

Dr. RK Diabetic FOOT and Podiatry Institute &Rakesh Jhunjhunwala Amputation Prevention Center (A Unit of SAARA RS Private Limited) Chennai has authorized the formation of RKDF- IEC, as an independent body which functions independently with respect to decision making and its working in order to provide public assurance of protection, by, among other things, reviewing and approving the clinical trial protocols, bioavailability and bioequivalence studies and Biomedical and Health Research projects, the suitability of the investigator(s), facilities and the methods and material to conduct clinical research at our site.

In addition to this, the institute will provide all support to the ethics committee activities which including training, resources, and infrastructure at the same time

RKDF-IEC is constituted by the Director of "Dr. RK Diabetic FOOT and Podiatry Institute &Rakesh Jhunjhunwala Amputation Prevention Center who will appoint the qualified, experienced, and eligible members, both the affiliated and non-affiliated members, including the Chairperson of the Ethics Committee.

7. Preparation of Standard Operating Procedures (SOPs) for IEC:

Purpose:

- The purpose of this SOP is to define the process for writing, reviewing, distributing and amending SOPs of IEC.
- The SOPs provide clear, unambiguous instructions so that the related activities of the Committee are conducted in accordance with: New Drugs and Clinical Trials Rules (2019), National Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017), Indian GCP Guidelines (Access time 2003) http://cdsco.nic.in, WHO Operating Guidelines for Ethical Review Board that Review Biomedical Research (2000), The International Conference on Harmonization - Good Clinical Practices (ICH-GCP) Guidelines (1996), Declaration of Helsinki and the prevailing amendments from time to time and Amendments from CDSCO office.

Responsibility:

IEC Secretarial staff:

- Co-ordinate activities of writing, reviewing, distributing and amending SOPs
- Maintain on file all current SOPs and past SOPs
- Ensure that all the IEC members and involved staff have access to the SOPs
- Chairperson /Member Secretary appoints coordinating staff to assist IEC Functions.
- Member Secretary shall vote in IEC decisions but coordinating staff of IEC can't vote in any decision-making procedure of the IEC.

SOP Team (Medical Scientist/Clinician/Scientific Member):

- Assess the requests for SOP revision in consultation with the Secretariat, Member Secretary Chairperson
- Propose new / modified SOPs as needed
- Draft the SOP/modify SOP in consultation with the IEC members and involved staff
- Review the draft SOP
- Submit the draft for approval to Chairperson and Member Secretary

Chairperson of IEC:

- Chairperson of IEC to appoint the SOP team
- Approve the SOPs
- Sign and date the approved SOPs Coordinating

Coordinating Staff of IEC:

- Maintain on file all current SOPs and the list of SOPs
- Maintain an up-to-date distribution list for each SOP distributed
- Maintain the SOPs with a receipt to all users
- Maintain file of all past SOPs of IEC
- Assist in the formulation of SOPs
- Assist Member Secretary

IEC members:

- Sign and date the acknowledgement form when they would receive approved SOP.

- Assist in all decision-making procedures of IEC.
- Assist secretariat for any help in management

Identify the Need for New or Amending SOP:

• Any member of the IEC, Member Secretary would like a revision or notices an inconsistency/ discrepancy / has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP can put forth his request

• The Chairperson will inform all the IEC members about this request in a regular full-committee IEC meeting.

• If the IEC members do not agree, the Chairperson will inform the person/ IEC member who made the request for modification of the SOP in the same meeting

• The SOPs will be updated regularly at the interval of 3 year or if there are major changes whichever is earlier.

Appoint the SOP Team:

• The Chairperson will identify appropriate members of the IEC who have a thorough understanding of the ethical review process to constitute the SOP writing team.

List of relevant SOPs: (SOP writing team will carry out the subsequent steps)

• Write down step by step all the procedures of the IEC

• Organize, devise and name each process

New Standard Operating Procedures:

• When the need for a new SOP has been identified and agreed, a draft will be written by the Member Secretary and designated IEC members of SOP team, appointed by the Chairperson.

Review by Consultation:

• The draft SOP written by one or more members of the SOP team will be reviewed by the remaining members of the SOP team.

- After incorporating the suggestions put forth by the SOP team members, a copy of the revised draft SOP will be sent to the Member-Secretary, who will circulate it to all the IEC members to invite suggestions.

Preparation and Submission of Final Draft:

- IEC members will review the revised draft SOP in IEC meeting
- The suggestions agreed upon unanimously, by all the IEC members will be discussed and incorporated in the revised draft SOP and the final draft SOP will be formulated.

Approve a New/Revised SOP:

- The revised SOPs will be reviewed and approved in the same manner as a new SOP.
- The Chairperson and member Secretary signs and dates the SOP Approval page will be made accessible to all stakeholders for reference.

IEC Secretariat shall e-mail / share the approved SOP to all members.

Ensure Implementation and File all SOPs:

- The approved SOPs will be implemented from the effective date.
- When the revised version is distributed, old version is retrieved from all members and destroyed for except for one copy; this copy of the earlier version will be placed in the file entitled 'Past SOPs of IEC'.
- One complete original set of current SOPs will be filed centrally in the SOP Master file, by the Member Secretary or IEC coordinating staff, in the IEC office for review and request for a revision of existing SOPs and record the dates of review on the SOP Master file.
- Revision of approved SOPs shall occur at least once a year

Manage Current and Archive Superseded SOPs:

- IEC office will manage current and archive old versions (superseded) of SOPs

8. Procedure for constitution of RKDF-IEC and Terms of References

RKDF-IEC is constituted by the Director of Dr. RK Diabetic Foot and Podiatry Institute &Rakesh Jhunjhunwala Amputation Prevention Center

- The chairperson of the Committee will be from outside the Institution to maintain the independence of the Committee.
- The Member Secretary will belong to the same institution and will conductthe business of the Committee.
- The members will be a mix of medical / non-medical, legal, scientific, and non-scientific persons and also include members of public to reflect the differed viewpoints.
- During the constitution, it will be ensured that at least 50% of the members are not affiliated to the Institute.
- The RKDF-IEC, may call upon subject experts as independent consultants who may provide special review of selected research protocols, if needed. These experts may be specialists in ethical or Legal aspects, specific diseases, or methodologies, or represent specific Communities.

9. Composition Shall be as Follows:

IEC will have a minimum of 9 members. It is mandatory to have the following category of members to represent multidimensional structure.

- Basic Medical scientists (Preferably one Pharmacologist)
- Clinicians
- Legal experts (Advocate / retired Judge)

- Social scientists or representatives of nongovernmental voluntary agency or philosophers or ethicists or theologians
- Lay persons from Community
- Scientific Member

The appointing authority may further appoint an EC secretary or EC Co-ordinator to help conduct the business of the RKDF- IEC, who will not be a member of the EC.

Criteria for Selection of Members.

Members are selected based on their personal capacities, the interest, ethical and/or scientific knowledge and expertise, experience in domain field and profile.

The following qualities are sought in RKDF- IEC, members:

•Education, Experience and Interest

•Commitment and availability ensured that at least 50% of the Members are non-affiliated to the Institute.

•Respect for divergent opinions

•Integrity and diplomacy

The IEC may appoint alternate members who can take part in the IEC activities in absence of regular members to maintain the quorum.

The IEC may invite member(s) of specific patient groups or other special interest groups for an IEC meeting (if required, based on the requirement of research area, e.g., HIV AIDS, genetic disorders, stem cell research etc.) for eliciting their views. Such individuals will have to sign confidentiality agreement and declare in writing, conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of 'Observer' and will not have right to vote.

Membership Requirements:

- The Director is responsible for appointing new committee members.
- The Chairperson, Member Secretary or any member can suggest names of potential members but the final decision will remain with the Director.
- Members will be designated in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience as well as their commitment and willingness to volunteer the necessary time and effort for IEC.
- Members must disclose their interest and involvement by providing a Consent letter and in line with, the Appointment letters will be issued to members along with the Confidentiality agreement which will be required to sign for record of IEC

Tenure of Membership:

- The appointment of the members would be for a period of three years; after which they may be either replaced or reappointed with a fresh appointment letter prior to the end of tenure of members by the IEC secretariat.

Resignation:

- A member can resign by submitting the resignation letter addressing to IEC - Chairperson; and emailed/delivered to Member Secretary.
- The Member secretary will inform the appointing authority for formal acceptance and to initiate the necessary replacement/recruitment procedure for filling up the vacancy.
- The members if opts to step down due to any genuine cause may do so with prior notice and proper information to the appointing authority.

Disqualification:

- If Director, IEC, Chairperson or member secretary received a communication in writing alleging misconduct by a member.
- A member can be disqualified if fails to attend more than 3 regular consecutive IEC meetings without prior intimation.
- A list of members of the IEC, their appointment letters, bio-data and consent forms would be maintained by Member Secretary of the IEC. This list and the copy of the working procedures would be made available to any investigator, for the purpose of filing of research projects, upon written request for the same to the Member Secretary.

10. Roles and Responsibilities of RKDF -IEC,

The basic responsibility of RKDF- IEC, is to ensure a competent review of all ethical & scientific aspects of the Research project received and execute the same free from any bias and influence that could affect its objectivity.

The following are the roles and responsibilities of RKDF- IEC,

•To protect the dignity, rights, safety and well-being of the potential research participants.

•To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.

•To assist in and tune the development and education of research community according to the local health care requirements.

•The RKDF- IEC, will ensure that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non -maleficence and Justice are taken care of, in planning, conduct and reporting of the proposed research.

•For this purpose, RKDF- IEC, shall look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required.

• RKDF- IEC, shall review the proposals before start of the study as well as monitor throughout the study.

11. Roles and Responsibilities of RKDF- IEC, Members

Members are appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting. The role of Chairperson/Member Secretary is an additional activity to their primary responsibility based on their qualifications. (For example, if the Chairperson is a lawyer, she or he can serve as both the Lawyer and the Chairperson)

•The Committee's primary responsibilities will be protection of safety, rights and confidentiality of the research participants. Special attention will be paid to trials that may include Vulnerable Subjects, for example, involving children, pregnant and lactating women, and those with diminished autonomy.

•Members of RKDF- IEC, are expected to approach this position with the seriousness and professionalism, to show interest and motivation, commitment and availability, respect for divergent opinions and ability to work as a team, integrity, diplomacy and ability to maintain confidentiality.

•Participate in the RKDF-IEC, meeting.

•Review all research documents Submitted for approval before the Meeting.

•The RKDF- IEC, shall thoroughly review the information regarding compensation in case of trial related injury or illness, or death, is set forth in the written informed Consent Form and any other written information to be provided to subjects. Further, it shall also confirm that the sponsor, CRO or the Principal

investigator (Pl) shall provide complete medical care along with compensation for any injury or death caused by the study drug/device under investigation as per the Govt. regulations.

•The RKDF- IEC, will review both the financials proposed to be paid and method of payment to subjects.

•Review progress reports and monitor ongoing studies.

•Monitor SAEs and recommend appropriate action(s).

•Maintain confidentiality of the documents and deliberations of the EC meetings.

•Declare conflict of interest, if any

•Remaining impartial and objective when reviewing protocols.

•Carry out work delegated by the Chairperson and/or Member Secretary.

•Participate in continuing education activities in biomedical ethics and biomedical research and Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat.

•Respecting each other's' views and the deliberative process.

•Members should not make copies of any material provided to them and ensure destruction or return of all materials sent for review after the Ethics Committee meetings.

Chairperson

Chairperson will be Non-affiliated.

A well-respected person from any background with prior experience of having served/ serving in an EC.

Roles and Responsibilities of 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

•Seek Conflict of Interest 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

•Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.

Member Secretary

Member Secretary will be affiliated to the institution. He / she should be a staff member of the institution, having knowledge and experience in clinical research and ethics, motivated and having good communication skills and able to devote adequate time to this activity.

Roles and Responsibilities of Member Secretary

•Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review

•Ensure training of EC secretary / Coordinator 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 or full review

Basic Medical Scientist

Medical scientist can be Affiliated/ non-affiliated. He/she should be a medical person with PG medical qualifications in basic medical sciences. In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist. The representative of medical scientist category should have postgraduate qualification (minimum MD/MS) & adequate experience in them respective fields.

Roles and Responsibilities of Basic Medical Scientist

•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

Clinician

Clinician can be affiliated/ non-affiliated. He/she should be individual/s with recognized Post Graduate medical qualification, expertise and training

Roles and Responsibilities of Clinician

•Scientific review of protocols including review of the intervention, benefit- risk analysis, research design, methodology, sample size, site of study and statistics

•Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)

•Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation.

Legal expert

Legal Expert can be Affiliated/ non-affiliated with the institution. He / She should have a basic degree in Law from a recognized university, with experience.

Roles and Responsibilities of Legal expert

•Ethical review of the proposal, ICD along with translations, MoUs, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, compliance with guidelines etc. Social scientist or representative of nongovernmental voluntary agency or philosopher or ethicist or theologian Non-affiliated / affiliated persons with social/ behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. He / she can be from an NGO involved in health-related activities.

Roles and Responsibilities of Social Scientist

•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.

Lay person

Non-affiliated and Literate person from the public or community, has not pursued a medical science/ health related career in the last 5 years, May be a representative of the community from which the participants are to be drawn, Is aware of the local language, cultural and moral values of the community and Person involved in social and community welfare activities are desirable. The person may have

basic school education (SSLC) or basic non-medical / non-scientific UG / PG degrees.

Roles and Responsibilities of Lay person

•Ethical review of the proposal, ICD along with translation(s).

•Evaluate benefits and risks from the participant's perspective and opine

•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 Independent Consultants

The IEC may call upon, or establish a standing list of, independent consultants who may provide special expertise to the IEC on proposed research protocols, when the Chairperson / Member secretary or the IEC members determine that a study will involve procedures or information that is not within the area of expertise of the IEC members. These consultants may be specialists in ethical or legal aspects, specific diseases or methodologies (e.g., genetic disorders, stem cell research etc.), or they may be representatives of communities, patients, or special interest groups. These consultants must sign the confidentiality agreement regarding meeting, deliberations, and related matters. These consultants or subject experts cannot vote for a decision. A formal invitation letter will be sent to the consultant and confidentiality also will be signed before submitting the study documents. Updated CV of the independent consultant will be collected and filed.

12. Membership Requirements:

•All members will serve for a period of 3 years and the tenure may be extended through consensus among the members.

•There is no limit to the number of times that the membership can be extended.

•New members will be appointed to replace members.

•New members will be included in the committee in such a way that there will be a mix of recently included members and members with some years of experience.

•A member can tender resignation of his /her office of membership from the committee to the Chairperson/member secretary.

•Conflict of interest, if any, must be disclosed.

•Members are required to sign the confidentiality disclosure agreement

•Members are required to sign the confidentiality disclosure agreement (Annexure II) at the start of their term and maintain absolute confidentiality of all discussions during the meeting.

•Willing to undergo training or update their skills/knowledge during their tenure

•Members must provide their training certificates on human research protection orGCP to the EC.

Resignation/Replacement Procedure

•Member can resign from the committee after giving written notification to the Chairperson / Member Secretary

•A member can be replaced in the event of death or long-term assignments outside the country or for any misconduct deemed unfit for a member.

•A member can tender resignation with proper reasons to do so, in writing to the Chairperson / Member Secretary of Ethics committee.

•A new member with suitable background may be appointed to replace an outgoing member.

•Membership will be updated and notified to the Regulatory authority periodically

Training of the Members

The RKDF- IEC, members will be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics. The training can be provided by the EC / Institution or external members or agencies so that they become aware of their role and responsibilities.

•Members will be trained on their roles and responsibilities in the committee.

•SOP training will be completed, before participation.

•Members will be trained by the Chairperson/Member secretary /Other Members/ Experts from outside regarding the new developments /Guidelines/Regulations.

•Any change in the regulatory requirements will be brought to the attention of

•Any change in the regulatory requirements will be brought to the attention of the RKDF- IEC, members as and when required.

•Prior notice will be given to the members regarding the date of Training

•Attendance will be recorded and maintained.

•Training letter will be prepared and the same will be maintained at the RKDF-IEC

•New members will be trained.

Responsibilities of the Secretariat/Administrative staff

•The supporting staff such as EC secretary / EC Coordinator of the RKDF- IEC, will be appointed by the Director who will report to the Member Secretary.

•Member Secretary/Chairperson will delegate following function. To the support staff but not limited to,

- Organizing RKDF- IEC, meetings regularly, Maintaining attendance,
- Preparation of agenda and minutes of the meetings, Approval letter
- Communicating with RKDF- IEC, members and Institution/Site/Investigator
- Arrangement of training for personnel and RKDF- IEC, members
- Providing necessary administrative support for RKDF- IEC, related activities to the Member Secretary.
- Pre and post arrangements of RKDF- IEC, meetings
- Answering queries of the investigators
- Filing study related documents, Maintenance of study files and Archiving
- Performing Site audit visit. Organizing an effective and efficient tracking procedure for each proposal received.
- Training for IEC members and/or IEC staff.
- Participate in the development and subsequent implementation of SOPs

13. RKDF- IEC, fee details and honorarium to members

•For sponsored clinical trials, a specific amount will be collected from the Sponsor/CRO/ Investigator. Payment should be made along with the submission letter.

•For academic proposals, there will be a subsidized fee which may be at times waived at the discretion of the EC / Institute.

•Ethics Committee fee is collected for its functioning, maintenance and to meet any administrative requirements (for example stationary)

• RKDF- IEC, Fee details are given in Annexure XI.

•Honorarium for the external members and transport arrangement / allowance will be fixed based on the Institute's recommendations.

•There will not be any Honorarium and transport support for internal members.

14. Procedure for conducting RKDF- IEC, meetings

• RKDF- IEC, Meetings usually will be held once in 3 months, except for emergency or special meeting.

•The Member Secretary or secretariat Staff is responsible for the conduct of meetings, maintaining the records and communicating with all the members of the Committee.

•Meeting dates will be informed by the Secretariat Staff/Member Secretary in advance to all the Members and/or Investigators.

•After confirmation from the all the members or majority members, Meeting date will be decided.

•Agenda will be prepared by the secretariat Staff and signed by the Member Secretary.

•Agenda will have the following - The date, time, purpose of the meeting and Protocol that are going to be reviewed in the meeting. (Refer attachment for IV for draft Agenda)

•Agenda will be circulated to the members and/or Investigator.

•The Chairperson will preside over the meetings.

•Investigator/ Co Investigator may be invited to present the proposal or elaborate on specific issue.

•In case of the academic projects, the postgraduate or undergraduate student or faculty shall be informed that they can do the presentation only along with the guide's presence.

•Attendance will be maintained.

•Meeting will be conducted only if the quorum is present. A minimum of five persons is required to form the quorum without which a decision regarding the research would not be taken and if taken, it is not valid.

Quorum Requirements

Minimum of five members are required to compose a quorum for the RKDF- IEC, meeting of which at least one member will be from outside the institution, and one member will be non-scientific member. For review of each protocol the quorum of RKDF- IEC, shall
have the following representations:

•One Basic medical scientist

•One Clinician

•One Legal expert

•One social scientist or representative of nongovernmental voluntary agency or philosopher or ethicist or theologian

•One Lay person

Conflict of Interest Declaration for RKDF- IEC, members

•Members shall declare to the Committee any interests they may have in relation to an application for ethical review or any other matter for consideration at that meeting. Such a declaration may be made orally at the meeting, prior to the matter being considered or in writing to the Chair prior to the meeting.

•If any member has Conflict of interest, they will not be participating in the voting procedure.

•Secretariat staff is responsible to collect all the signed conflict of interest form.

•All such forms are filed in the RKDF- IEC, binders.

•If a RKDF- IEC, member is the key investigator/collaborator in a research proposal, the member may be asked to leave the meeting room and take no part in

the voting. The minutes should record all declarations of interest and the decision of the RKDF- IEC, on the procedure followed.

15. Procedure for submission of research project

•An application for review of proposed biomedical research should be submitted by a qualified applicant responsible for the ethical and scientific conduct of the research. Principal Investigator can submit the documents for RKDF- IEC, for review under any of the 5 categories mentioned below:

- Initial Review Application
- Resubmission of Study with Corrections
- Protocol Amendment or any other amendments
- Annual Status Reports /Continuing Review of the study
- Study Completion / Termination

•The RKDF- IEC, prefers that all the research projects should be addressed to the Member secretary/Chairperson for Submission.

•All the research projects should be submitted at least 2 weeks prior to the meeting

•For Certain Studies like BA/BE Studies or in certain extra ordinary situations, exemption in 2 weeks' timeline will be provided. EC application can be submitted at least 7 days before the EC meeting in those situations, provided the study drug/protocol was reviewed and approved by the EC earlier.

•Two copies of the Submission/ covering letter duly signed by the Principal Investigator (PI) or Co-investigators needs to be submitted along with the research documents. The submission letter should clearly mention all the list of documents that are enclosed and also the pending documents that needs to be submitted for review. Refer annexure V– for draft Submission template.

•Two (2) Hard copies of all the research documents should be enclosed along with the submission letter. A soft copy of all the submitted documents should be sent to RKDF- IEC, email ID – drrkdiabeticfoot@gmail.com. The EC members will receive only the softcopy of the submitted proposals by email to review.

•Prescribed fee as per the Fee Structure should be remitted along with the application.

•Refer Annexure VI for List of minimum required documents that has to be submitted with the submission letter.

•The date of RKDF- IEC or Faculty Research meeting will be intimated to the Principal Investigator to attend the meeting. The Principal Investigator/Designee should send the Protocol presentation at least 3 days before the scheduled meeting. Secretariat Staff will circulate the Protocol presentation to the members.

•Agenda will be prepared by EC office and distributed to all EC members at least 3 days prior to the meeting.

•The Principal Investigator will present the protocol. When the PI is not available any of the co-Investigators can present the protocol and clarify the points raised by the members.

•In case of the academic projects, the postgraduate or undergraduate student or faculty shall do the presentation only along with the guide.

•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.

Receipt of submission packages

•The procedure for the receipt of documents (2 hard copies and 1 soft copy by mail) is as follows

•The office of the EC will review the documents submitted comparing with the submission checklist and verify by ticking the EC receipt section in the check list

•If any missing documents are there EC will inform the applicant to submit the required documents

•If the application is intact, the member secretary will give acknowledgement in the submission letter by signing and stamping for investigator use.

•Every valid application will receive a unique RKDF- IEC, reference number for further correspondence.

•The Member Secretary/Secretariat Staff will acknowledge the receipt of the submission/covering letter and a copy of the same will be handed over to the concerned person. The Secretariat staff will circulate the research documents to the members by email.

•One hard copy will be labelled and stored at EC office and this copy will be archived at EC office. The other copy will be handed over to the Investigator with approval or disapproval stamp.

16. Procedure for reviewing the research projects

•The submitted proposal shall be reviewed both for scientific content and ethical principles.

•The Following aspects will be considered during Review of Research Proposal:

- Scientific design and conduct of the study.
- Approval of appropriate scientific review committees.

- Patient information sheet and informed consent form in English and regional language.
- Procedure for selection of participants including inclusion/exclusion, withdrawal criteria and other issues like advertisement details.
- Potential benefits to the study subjects
- Predictable risks to the study subjects
- Compensation to subjects for participating in the study
- Justification for use of placebo, if any.
- Management of research related injuries, Such as adverse events/Serious Adverse events.
- Monitoring of serious adverse events
- Compensation for study related injury
- Protection of privacy and confidentiality.
- Involvement of the community, wherever necessary
- Plans for data analysis and reporting
- Adherence to all regulatory requirements and applicable guidelines.
- Competence of investigators, research and supporting staff.
- Facilities and infrastructure of study sites.

•The IEC will assess the appropriateness of the Investigator for the conduct of respective clinical trial. The suitability of the Investigator to conduct the trial will be assessed based on the educational qualification, clinical experience, clinical trials experience and training in clinical research.

•At the time of review of clinical trial protocols, the EC will assess the appropriateness of the trial site for the conduct of respective clinical trial. The suitability of the trial site to conduct the trial will be assessed based on

infrastructure, equipment, doctors available, number of in patients and out- patients and the experience of the investigators in conducting the trials.

•The Ethics Committee shall undertake through review of the informed consent forms and patient information sheets in English and vernacular language whenever the clinical trial protocols are reviewed.

•The EC will ensure that all study related injuries (AE/SAE) are treated free of the cost by the investigator. There shall be no cost imposed on the patient for investigations, medical or surgical treatment or hospital expenses.

•In case of SAEs, the EC will review the protocol for appropriate section defining the compensation for SAEs. The EC will ensure that the compensation for SAEs is as per the guidelines provided in "New Drugs and Clinical Trials Rules, 2019".

•The review will be done through formal meetings and will not resort to decision through circulation of proposal.

•If required Principal Investigator and/or Designee will leave the meeting hall for further discussion of EC Members.

•If required independent consultants/experts will be invited to offer their opinion on specific research proposals.

• Experts will give their specialized views but will not take part in the decision making or voting.

•These consultants must sign the confidentiality agreement before participating in the deliberations.

17. Expedited Review

•An expedited review will be conducted when the Research documents for a new Protocol are submitted later than the period for a normal submission, (i.e., within 1

week prior to the day of the meeting - excluding the day of dispatch and the day of the meeting).

•An expedited review shall be conducted in the following categories of research proposal also,

- Research investigations that present no more than minimal risk to the study participants.
- Minor amendment in previously approved research during the period for which approval was granted.
- Definitions of "minimal risk" and "minor amendment" will be based upon accepted guidelines/categories and/or at the discretion of the Chairperson/Member secretary.

•All revised proposals, submitted will be reviewed for expedited review.

•Review will be conducted by the Chairperson or Member Secretary or by any other nominated member.

•The committee should keep all members of the committee informed of these approvals under the expedited review procedure.

18. Procedure for decision making and communicating the decision

•Decisions will be made only in meetings where quorum is complete.

•Only members can make the decision. The expert consultants will only offer their opinions.

•Decisions will be taken by consensus after discussions, and whenever needed voting will be done.

•Any Opinions of absent members that are transmitted by mail or telephone or fax may be considered by the attending members during discussion but may not be counted as votes or quorum for formally convened full board meetings.

•Any member with a conflicting interest in a proposal will abstain from deliberations and in decision making process on that proposal, except to provide information as requested by the committee.

•Such abstentions will be recorded in the minutes.

•Deliberations will be done in the absence of the Investigators /representatives.

•Decision of the meeting on the proposals will be communicated by the Member Secretary/ Secretariat staff.

•The Principal Investigator/ Team should clarify the queries-if any raised during the meeting within a stipulated time as communicated.

•The clarification from the Principal Investigator will be circulated to the members by the secretariat Staff.

•Decision may be to approve/ conditionally approve / reject / modify the proposals.

•If the proposal is approved then the approval letter will be sent to the respective Principal Investigator.

•If the proposal is rejected, then a letter with reason for its decision will be sent.

•If the approval of the project is kept pending for any clarifications, it will be intimated in writing to the Principal Investigator.

•In case RKDF- IEC, revokes its approval accorded to a trial protocol, it will record the reasons for doing so and at once communicate such a decision to the Investigator as well as to the Licensing Authority.

•All the details of the discussions and deliberations in the meetings will be minute, and signed by the Member Secretary /Chairperson.

Minutes of the Meeting

•Secretariat Staff is responsible to prepare the minutes.

•The draft document will be sent to the Member secretary, Chairperson and other members for approval.

•The minutes of the meeting shall contain a record of the following:

- The members present
- Proposals discussed
- Any decision taken by the Committee
- Comments by members
- The decision on the applications
- The outcome of voting, if any.

Note: Minutes of Meeting are the internal documentation and will not be circulated to the outside parties.

Procedure for approval

•The Chairperson should ensure that one of the opinions is taken for every application considered at RKDF- IEC, meeting. "Approval" or "Rejection" or "Conditional Approval" subject to receipt of further information or modifications.

•Where the RKDF- IEC, decides that further information or clarification is required, the Chairperson/member secretary ensures that the further information or clarification required reaches the committee.

•The Secretariat Staff will prepare the draft approval letter as per RKDF- IEC, approval template given in Annexure–VII.

•Approval draft will be sent to Chairperson for any correction.

•The Approval letter will then be signed by the Member Secretary / Chairperson.

•The Signed Approval letter will be sent to the Investigator by the Member secretary/secretariat staff within 2 weeks after the meeting.

•Copy of the Approval Letter is maintained in the specific study file at RKDF-IEC.

•The positive decision can be changed after receiving any information that affects the benefit/ risk ratio.

•Duration of the Approval Validity for the Research project will be 1year from the date of approval. In the case of the project continuing beyond the validity period, the Principal Investigator should apply for continued approval of the same within 30 days prior to the date of expiry of validation.

19. Research protocol amendments and other study related documents

Any change to a protocol shall be considered as a protocol amendment.

•The amendments shall be classified as Major or Minor.

•Major: Amendment that alters the potential risk of the safety of the trial subjects, change in the Protocol design etc. Minor: any administrative amendment.

•The Member Secretary in consultation with Chairperson will decide whether to Carry out a full board meeting or not.

•The Investigator /Designee should submit one copy of the Amended protocol or any other study related documents along with the covering letter duly signed by the Investigator to the Secretariat Staff. Soft copy of the same should be sent to RKDF- IEC, email-Id. The modification should be highlighted.

Procedure for continuing research projects

•Approval Validity for the Research project will be 1year from the date of approval. In the case of the project continuing beyond the validity period, the Principal Investigator should apply for continued approval of the same within 30 days prior to the date of expiry of validation.

•The Investigator or the study team should submit the Application for Renewal of Approval for Continuing the Research to the RKDF- IEC, in the format given in

Annexure VIII or Investigator can use own format but all the information should be furnished. The renewal fee has to be submitted along with the application, if applicable.

•The Secretariat staff will verify the completeness of the submission letter for extension of approval of the project. Member secretary will acknowledge the receipt. If required the Principal Investigator/Designee will be invited.

•The submission will be tabled in the meeting.

20. Procedure for monitoring the approved research

•Once the study is approved, RKDF- IEC, starts monitoring the Research.

•The Approved Study/Research has to be conducted as per protocol, adhere to

•The Approved Study/Research has to be conducted as per protocol, adhere to the ICH-GCP, Indian GCP and New Drugs and Clinical Trials Rules 2019, and other applicable national and International Guidelines.

•The EC shall ensure that the Investigator uses only the EC approved informed consent form and patient information sheet. The EC will also instruct the Investigator to obtain informed consent before start of any trial related procedures in a particular study participant. There will be on site assessment by the EC to ensure informed consent is administered properly by the Investigator.

•Any amendment to the protocol/study documents should be resubmitted for renewed approval. Any new information related to the study should be communicated by the Investigator to the EC.

•All SAEs occurred and the interventions undertaken at Investigator's site must have to be notified within 24 hours. All other sites' SAEs have to be notified as per the timelines given in the guidelines or within 7 days of receipt. All the SAEs will

be reviewed by the RKDF- IEC, and appropriate action will be taken as & when required.

•All Protocol deviation/Violation/ non-compliance/waiver have to be notified. All Such notification will be circulated to RKDF- IEC, members, reviewed & assessed by the committee during the meeting for the seriousness of the deviation / Non-Compliance / Violation with respect to the safety & health aspects of the subjects and the necessary actions will be taken by the committee accordingly.

•Investigator or designee has to inform periodically the status of the study once in 6 months. Status report of the study has to be submitted in the given format mentioned in Annexure X or Investigator can use own format but all the information should be furnished.

•Premature termination of study should be notified with reasons along with summary of the data obtained so far.

•Change of investigators / sites should be informed.

•Final report should be submitted at the end of study.

•The Secretariat staff will verify the completeness of all the reports sent to RKDF- IEC, the reports will be circulated in the meeting.

• RKDF- IEC, has the authority to stop the conduct of the research project if there is any misconduct pertaining to the trial or safety issues for the trial participants.

•If the Investigator is audited by the sponsor or external body it has to be informed to the RKDF- IEC, and Audit report from the sponsor or external body has to be submitted and also resolution for audit report has to be notified to the RKDF- IEC.

21. Procedure for review of safety reports

•The Principal Investigator/Co-Investigator will submit the safety updates of the research projects.

•All SAEs have to be notified to the RKDF- IEC, within 24 hours from the time of occurrence of the event. The Investigator shall submit a detailed follow up report within 14 days of occurrence of the SAE to the EC.

•SAE has to be notified using the SAE form given in Annexure IX or the investigator can use his site-specific template for SAE notification, provided all the necessary information as prescribed in the RKDF- IEC, SAE form is made available. The SAE form should be compliant to the rules defined in New Drugs and Clinical Trials Rules 2019.

•All other site SAEs, SUSARs, CIOMS and any other safety information pertaining to the trial have to be notified to RKDF- IEC, as per the timelines given in the guidelines or upon within 7 days of receipt.

•Safety Reports will be acknowledged by the Member Secretary and copy will be retained in the RKDF- IEC, study file/binder.

•All the safety Reports or updates will be circulated to the members by the member secretary during the meeting. If any Clarification required related to the SAE, it will be raised to the Investigator and Investigator should clarify within required time frame.

•The SAE will be reviewed in the routine meeting or a special meeting can be arranged for reviewing the submitted SAE, if considered necessary based on the safety issues of the study participants.

•The EC will do due analysis of causality assessment of the SAEs and will classify the event as related or unrelated based on established scientific practices and published literature and drug labels.

•The EC will calculate the compensation for SAEs as prescribed in New Drugs and Clinical Trials Rules 2019 and will recommend to the CDSCO for the agency to consider the view of the EC while it is analysing the SAE reports.

•The views and the decision made by the RKDF- IEC, on the submitted SAE including the causality assessment and compensation will be communicated to the regulatory authorities within 30 days of occurrence of the SAEs.

•Ethics Committee has an authority to suspend or terminate approval of research project that has been associated with unexpected serious harm to subjects.

22. Procedure for documentation and record retention

•For each project a separate file will be maintained.

•All the research related documents and communications of RKDF- IEC, will be dated and filed in the respective binders.

•All the Documents pertaining to the committee will be separately filed. The RKDF- IEC, documents are as follows,

- Invitation Letter/Acceptance Letter, CV and certificates, Training Records, Appointment letters/Resignation letter, Signed Confidentiality agreement, and any declaration by members.
- Membership, Attendance, Meeting agenda and Minutes
- SOP
- Copies of all communications

•All the Study related documents will be filed in the respective study specific binders. Each Study file will contain the RKDF- IEC, Reference Number, Protocol No, and Investigator's Name.

•Secretariat Staff is responsible for secured maintenance of documentation.

•After receiving the study completion report from the Investigator, the study specific file will be archived.

•Documents that will be maintained by the RKDF- IEC, during archival.

- One Copy of all the study documents submitted for review and approval. All additional copies of document will be destroyed, in order to ensure confidentiality.
- Copy of - Composition of the committee, Minutes of the meeting.
- Copy of the decision sent to the applicants.
- Copy of all correspondence with investigators and regulatory bodies, if any. All other documents received during the study. All relevant AEs and SAEs, Study progress reports
- Final report of the approved projects and other microfilms, CDs, Videos submitted to the committee.

•All the completed study related documents will be archived in a separate cupboard.

•Member Secretary/Secretariat staff will have an access to the documents and are responsible for Archival of records.

•Upon receiving request in writing from the relevant authorities, documents will be made available for the inspection/audit.

•Confidentiality will be maintained in Retention and Archival of documents.

•All the Approved study documents will be archived for the period of 5 years and non-approved study documents will be archived for a period of 1year.

•Documents will be discarded after the archival period.

23. Procedure for review of external projects

•An External Institution can form alliance with RKDF- IEC, for their research proposals that are to be carried out in their institutions for the review & approval by the RKDF- IEC.

•External Institution which requires facility of RKDF- IEC, should submit the request letter from the Head of the Institute and Investigator addressing to the Member Secretary/Chairperson of RKDF- IEC, for reviewing the research proposal. Member secretary/Secretariat Staff will acknowledge the receipt and forward the request letter to chairperson.

•The Institutional profile and brief Curriculum vitae of the Investigator will be collected and forwarded to the chairperson and upon acceptance the project would be undertaken for review by RKDF- IEC.

•If required Member secretary/Secretariat Staff will conduct the site visit to verify the suitability of the facility to conduct the research activities. Other members may also participate in this feasibility assessment.

•Memorandum of Understanding (MoU) will be made by the External Institution and RKDF- IEC. Refer Annexure XII for draft MoU.

•MoU will be signed by the Chairperson or Member Secretary on behalf of RKDF- IEC.

•All other process will be similar as that of internal research project and external Institution has to follow the SOP of RKDF- IEC.

•Periodic review of the external institution will be performed. RKDF- IEC, will conduct audits at the External site as and when required. If the audit is planned, Investigator and the team will be given prior notice or in some situations, a surprise audit can also be conducted by the RKDF- IEC.

• RKDF- IEC, has authority to terminate or withheld the conduct of the research project at the external institution if there is any misconduct pertaining to the trial.

24. Monitoring of the own conduct of RKDF- IEC,

•The EC is open for any external audit / inspection by the sponsor or regulatory agency.

•Periodic internal audit is scheduled once in 6 months.

•During internal audits, the functioning of the EC will be assessed for compliance to the EC SOP and regulatory requirements. The scope of the audit will also include the timely disposal of cases for which the adherence of timelines specified in the SOP and regulatory requirements will be scrutinized.

•The records and registers will be scrutinized and if needed appropriate corrective and preventive actions will be initiated.

•The Chairperson in consultation with the member secretary will appoint anyone of the members RKDF- IEC, or any technically competent person from the Institute "Dr. RK Diabetic FOOT and Podiatry Institute" or outside of the Institute to audit and submit the report.

•The audit report will be placed in a full board EC meeting and discussed regarding the status of operational compliance to SOP and regulatory requirements and documentation practice prevailing.

•The EC shall decide suitably if any corrective action is required for any of the deviations and an action plan will be drawn and implemented.

25. Responsibilities of the investigator

•Investigator should not start the study unless and until the final approval is obtained from RKDF- IEC, and in case of conditional Approval as the necessary information/documents should be submitted before the study starts.

•Investigator should conduct the study in accordance with all applicable national and international guidelines.

•Investigator should adhere to the study protocol which is approved by the RKDF- IEC, throughout the conduct of the study.

•Audio Video of Informed consent should be obtained from all the participants before their participation in the trial. Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject or his / her attendant.

•The Investigator should submit written summaries of the research status to the RKDF- IEC, as mentioned in the SOP.

•Any breaches of investigator undertaking should be immediately notified to the RKDF- IEC, and the actions will be taken by the committee as appropriate.

•Final Clinical Study Report should be submitted at the end of the study.

•All SAEs should be intimated within 24 hours from the time of receipt of information by the investigator and within 14 days, a detailed report should be submitted to the EC.

•Protocol deviation, if any, should be informed with adequate justifications.

•Any amendment to the protocol should be resubmitted for approval.

•Trial budget should be submitted and approved by RKDF- IEC, before commencing the study. There should be a transparent financial transaction during the trial.

•Any new information related to the study should be notified.

26. Information to research participants

•Investigators have a responsibility to keep the research participants informed of the progress of research by appropriate means, at suitable time-frames in simple and non-technical language.

•The Investigator shall provide information to the clinical trial subject through informed Consent process and the subject's right to claim compensation in case of trial related injury or death.

•Investigator should inform when:

- the research study is terminated or cancelled
- any changes occur in the context of the research study that alter the potential benefits or risks
- the research project is completed
- Results of the research are available.

Informed consent form requirements

•Site Specific Informed Consent Form is Mandatory

•ICF along with translation in regional languages is mandatory.

•Back translation and translation certificate is required.

•All elements of consent form should be present as per regulatory guidelines

•Details of Ethics Committee and the contact person should be printed on the ICF.

•ICF amendments should be submitted for approval.

•However administrative changes can be submitted for notification provided the basic ICFs are reviewed and approved by RKDF- IEC, earlier for that particular study.

27. Guidelines for Compensation for Research Participants

RKDF- IEC, strongly claims that issuing suitable compensation to the Research Participants whenever applicable is the primary obligation of the Sponsor be it a pharmaceutical company, a government agency, or an institution.

Compensation in case of injury or death during clinical trial

•In the case of an injury occurring to the clinical trial subject, he or she shall be given free medical management as long as required.

•In case the injury occurring to the trial subject is a SAE and related to the clinical trial, such subject shall also be entitled for financial compensation as per New Drugs and Clinical Trials Rules 2019, and the financial compensation will be over and above any expenses incurred on the medical management of the subject.

•In the case of clinical trial related death of the subject, his/her nominee(s) would be entitled for financial compensation, as per the order of the licensing authority defined in New Drugs and Clinical Trials Rules 2019, and the financial compensation will be over and above any expenses incurred on the medical management of the subject.

•The expenses on medical management and the financial compensation in the case of clinical trial injury or death of the trial subject shall be borne by the sponsor of the clinical trial.

•Any injury or death of the subject occurring in clinical trial due to following reasons shall be considered as clinical trial related injury or death and the subject or his/her nominee(s), as the case may be, are entitled for financial compensation for such injury (SAE) or death:

- Adverse effect of investigational product(s);
- Violation of the approved protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator;
- Failure of investigational product to provide intended therapeutic effect;
- Use of placebo in a placebo-controlled trial;

- Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol;
- For injury to a child in-utero because of the participation of parent in clinical trial;
- Any clinical trial procedures involved in the study.

•The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall provide financial compensation, if the injury or death has occurred because of any of the above reasons.

•The Sponsor, whether a pharmaceutical company or an institution shall give an undertaking along with the application for clinical trial permission to the licensing authority defined in clause (b) of Rule 21, to provide compensation in the case of clinical trial related injury or death for which subjects are entitled to compensation.

•In case the sponsor fails to provide medical management for the injury to the subject and / or financial compensation to the trial subject for clinical trial related injury or financial compensation to the subject's nominee(s) in case of clinical trial related death of the subject, the licensing authority may after giving an opportunity to show cause why such an order should not be passed, by an order in writing , stating the reasons thereof, suspend or cancel the clinical trial and / or restrict sponsor including his representative(s) to conduct any further clinical trials in the country or take any other action deemed fit under the rules.

Responsibilities of Sponsor

•Any report of serious adverse event of death occurring in clinical trial, after due analysis shall be forwarded by the sponsor to chairperson of the Ethics Committee and Chairman of the Expert Committee constituted by the Licensing authority with a copy of the report to the Licensing Authority and the head of the institution

where the trial has been conducted within 14 calendar days of occurrence of the serious adverse event of death.

•The report of the serious adverse event other than death, after due analysis, shall be forwarded by the sponsor to the Licensing authority, Chairperson of the Ethics Committee and the head of the Institution where the trial has been conducted within 14 calendar days of occurrence of the serious adverse event.

•In case of injury or death occurring to the clinical trial subject, the sponsor (whether a Pharmaceutical Company or an institution) or his representative, whosoever had obtained permission from the Licensing authority for conduct of the clinical trial, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in the New Drugs and Clinical Trials Rules 2019.

•The sponsor (whether a Pharmaceutical Company or an institution) or his representative, whosoever had obtained permission from the Licensing authority for conduct of the clinical trial, shall submit details of compensation provided or paid for clinical trial related injury or death to the Licensing Authority within thirty days of the receipt of the order of the Licensing Authority.

Responsibilities of the Investigator(s):

•During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events.

•Investigator(s) shall report all serious and unexpected adverse events to the Licensing Authority, Sponsor or his representative, whosoever had obtained Permission from the Licensing Authority for conduct of the clinical trial and the Ethics committee that accorded approval to the study protocol, within twenty four hours of their occurrence.

•The report of the serious adverse event of death, after due analysis shall be forwarded by the Investigator to chairperson of the Ethics Committee and Chairman of the Expert Committee constituted by the Licensing Authority with a copy of the report to the Licensing Authority and the head of the institution where the trial has been conducted within 14 calendar days of occurrence of the serious adverse event of death.

•The report of the serious adverse event other than death, after due analysis shall be forwarded to the Licensing Authority, Chairperson of the Ethics Committee and the head of the Institution where the trial has been conducted within 14 calendar days of occurrence of the serious adverse
event.

Responsibilities of the Ethics Committee

•In case of serious adverse event of death occurring to the trial subject, the Ethics Committee shall forward it's report on the serious adverse event of death, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had Obtained permission from the Licensing for conducting the clinical trial, to the Chairman of the Expert committee Constituted by the Licensing Authority with a copy of the report to the Licensing Authority within 30 calendar days of the occurrence of the Serious adverse event of death.

•In case of serious adverse event other than death occurring to the clinical trial subject, the Ethics Committee shall forward its report on the serious adverse event after due analysis along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, to the Licensing Authority within 30 calendar days of the occurrence of the serious adverse event.

Serious Adverse Event

•A serious adverse event is an untoward medical occurrence during clinical trial that is associated with death, in patient hospitalization (in case the study was being conducted on out-patient), prolongation of hospitalization (in case the study was being conducted on in-patient), persistent or significant disability or incapacity, a congenital anomaly or birth defect or is otherwise life threatening.

28. Protection of Vulnerable Population in Clinical Trial

RKDF- IEC , emphasize & exercise particular care to protect the rights, safety and well-being of all Vulnerable subjects participating in the study, e.g., members of a group with hierarchical structure (e.g. prisoners, armed forces personnel, staff and students of medical, nursing and pharmacy aca1demic institutions), patients with incurable diseases, um-employed or impoverished persons, patients in emergency situation, ethnic minority groups, homeless persons, nomads, refugees, foetuses/neonates, pregnant women, minors or others incapable of personally giving consent. RKDF- IEC, will take all possible efforts to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed such as,

•Research on genetics should not lead to racial inequalities;

•Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them;

•Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioural disorders must be protected and hence RKDF- IEC, will take all necessary safeguarding measures for the same. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The

entire consent process should be properly documented- RKDF- IEC, may even ask the Investigator for the copy of the ICF signed by such participants along with the ICF administration process and may also oversee the ICF administration & consent process taking place at the site;

•Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, employees, service personnel etc. Who have reduced autonomy as research participants, since the consent provided may be under duress or various other compelling reasons.

Research involving Pregnant Women & Foetuses

•Research involving pregnant women and foetuses should involve the least possible risk.

•The RKDF- IEC, will document specific findings to minimize the potential for risk or harm to the foetus, and additional attention must be given to the conditions for obtaining informed consent.

• RKDF- IEC , Vigilantly ensures that the Pregnant or nursing women should in no circumstances be the participant of any research unless the research carries, the objective of obtaining new knowledge about the foetus, pregnancy and lactation, the design to protect or advance the health of pregnant or nursing women or foetuses or nursing infants, and for which women who are not pregnant or nursing would not be the suitable participants.

• RKDF- IEC, demands a proper justification for participation of Pregnant or nursing women that they should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits. Example of such trials are, to test the efficacy and safety of a drug for reducing prenatal transmission of HIV infection from

mother to child, trials for detecting foetal abnormalities and for conditions associated with or aggravated by pregnancy etc.

• RKDF- IEC, always makes sure that women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast- feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant. Compensation in terms of supplying supplementary food such as milk formula should be considered in such instances.

• RKDF- IEC, in the event of research related to pre-natal diagnostic techniques, will ensure that such research is limited to detect foetal abnormalities or genetic disorders and not for sex determination as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994

Research Involving Children

RKDF- IEC, has strong concerns on undertaking the research on Children by the Investigator and also ensures the following,

•Children will not be involved in research that could be carried out equally well with adults;

•The purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug, the study in children should always be carried out after the phase III clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children;

•A parent or legal guardian of each child has given proxy consent;

•The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors from the age of seven years up to the age of 18 years.;

•Research should be conducted in settings in which the child and parent can obtain adequate medical and psychological support;

•Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participant must be justified in relation to anticipated risks involved in the study and anticipated benefits to society;

•The child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents / guardian;

•Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions;

•The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained.

29. Request for RKDF- IEC SOP

•Investigator/Site/CRO can send a mail for request of SOP.

•It is understood that the SOP is a confidential and private document of RKDF-IEC and shall not be made accessible/available to anyone outside the recipient's organization.

30. References

•New Drugs and Clinical Trials Rules, 2019

•Indian Good Clinical Practice

•Indian Council of Medical Research's (ICMR) National Ethical Guidelines for Biomedical Research, 2017

•ICH – Good Clinical Practices

Annexure 1: Template for Membership List

List of RKDF-IEC Members will be in the format given below

S.No	Name	Qualification with Specialization	Current Organization	Designation	Mailing Address with contact detail	Affiliation with Institution

Annexure 2: Template for Confidentiality Disclosure Agreement

As Chair/member of RKDF- IEC, I hereby declare that,

1. I will strictly follow the confidentiality regarding the committee and Research Projects.

2. I will not disclose any information disclosed at RKDF- IEC, meetings

3. I will use confidential information only to fulfil the obligations of reviewing proposals.

4. I will not reproduce information disclosed during RKDF- IEC, deliberations.

5. I will not disclose any confidential information to third party

This applies for a period of 3 years from my acceptance.

Signature:

Name:

Designation in Committee:

Date:

Annexure 3: Conflict of Interest Declaration Form

In accordance with the policy of the RKDF- IEC,

I have a conflict of interest, and shall not participate in the review, comment or approval of any activity.

Please mention reason – If any

Signature:

Name:

Date:

Annexure 4: Template for IEC meeting Agenda

Date:

Venue:

Room No,200

Registrar Office,

Dr. RK Diabetic FOOT and Podiatry Institute & Rakesh JhunjhunwalaAmputation Prevention Center

No. 1, Jayanti Nagar Extension, off 200 feet Road, Kolathur, Chennai, Tamil Nadu, 600099

Meeting Date:

Time:

General Discussion:

Please mention list of topics for General discussion

Protocol for Discussion:

Please mention Protocols for discussion including Investigator details

The soft copy / hard copy of the study documents for above mentioned Protocol(s) were submitted for your review.

The Principal Investigator/Designee will present the protocols during the meeting.

Member Secretary

Annexure 5: EC submission template

"On Institution/ Investigator Letter Head"

Date:

To

Member Secretary

<EC Address>

Protocol #/Protocol Title

Subject: Submission of Clinical Study Documents for Review and Approval

Dear Sir/Madam,

Please find enclosed study documents with version number for the above-mentioned study for review and approval in the forthcoming Ethics committee meeting.

<Mention list of documents enclosed>

Thanking you,

Sincerely

Principal Investigator (Name and Signature)

Annexure 6: List of documents to be enclosed with EC submission

The following documents are to be enclosed but not limited to,

- Submission letter/ Request letter in the Institutional letter head along with the 2 hard copies of the study documents and 1 soft copy (preferably sent via email to drrkdiabeticfoot@gmail.com)

- Trial protocol(s)/amendment(s) – Full text of the Protocol, Protocol should contain all the elements as per Regulatory requirements.

- Investigator's Brochure (IB), Results of Previous trials and Available safety information.

- Patient information sheet and Informed consent form in English and local language(s)- All the elements of the Informed consent should be present as per Regulatory Requirement and Ethics committee details should be printed.

- Any other study material such Subject questionnaires, follow – up cards, Patient diary, advertisements etc.

- Back Translations & Translation Certificates for all Subject related documents.

- Annotated Case report forms,

- Copy Insurance policy details or Certificates

- Investigator's current curriculum vitae with research experience and/or other documentation evidencing qualifications and Letter of undertaking

- Copy of Regulatory Approval and any regulatory clearances required.

- Clinical Trial Agreement (CTA) duly signed by all the stakeholders of the study or draft CTA

- CTRI Number

- Information about payments and compensation available to subjects.

- Statement of conflicts of interest, if any.

- Procedure for seeking and obtaining informed consent (SOP)

- If the study is Placebo controlled then Justification for the use of placebo

- MOU (for external project).

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal.

Annexure 7: Format for approval letter

Date

To

"Principal Investigator Name and Site Address"

Ref No:

Dear Dr. Investigator Name",

Sub: Approval Letter for protocol #

With reference to your submission letter, the below mentioned documents were received.

Dr. RK Diabetic FOOT and Podiatry Institute &Rakesh Jhunjhunwala Amputation Prevention Center – Institutional Ethics Committee, (RKDF -IEC,.) reviewed and discussed your application to conduct the clinical trial titled "Protocol title" on "date of the Meeting".

The following documents were reviewed:

"List of documents reviewed on Meeting"

The following members of the ethics committee were present at the meeting Held on “date” at “time” in the conference Hall, Registrar Office, Dr. RK Diabetic FOOT and Podiatry Institute & Rakesh Jhunjhunwala Amputation Prevention Center

No. 1, Jayanti Nagar Extension, off 200 feet Road, Kolathur, Chennai, Tamil Nadu, 600099

S. No	Name of the Member	Qualification/Designation	Affiliation with the Institution

This is to confirm that neither Principal Investigator nor the study staff participating in this study was involved in the voting procedures and decision-making process.

“**Status of the Approval**”

The RKDF-IEC, expects to be informed,

(i) Progress of the study,

(ii) If any SAE occurring in the course of the study, it should be informed within 24hours.

(iii) Any change in the protocol and subject information/informed consent

(iv) Any Protocol deviation/Violation,

(v) Copy of the final report.

Yours sincerely,

Member Secretary

Annexure 8: Details to be submitted in the Application for Renewal of approval

- RKDF-IEC, Reference number
- Title of the research proposal
- Name of the Principal Investigator (PI) with qualification and designation
- Approval date
- Date study initiated, if no, specify reason
- Has subject recruitment begun?
- If subject recruitment has not begun, give reasons
- How many subjects have been screened?
- How many subjects have been randomized?
- How many Screen failures and or dropouts? Reason
- Is subject recruitment continuing?

- Is the Subjects completed the study, if no number of pending visits.
- Expected date for study completion?
- Have there been any adverse events/ Serious Adverse Events? If yes, give details
- Any Protocol deviation/Violations?
- Have there been any unanticipated study-related problems? If yes, give details.
- List of attachments for review, if any
- Remarks, if any
- Signature of the Principal Investigator with date.

NOTE

- Investigator can use own format but all the information should be furnished.
- Investigator should attach the renewal fee along with the application.

Annexure 9: SAE Notification Template

(On the Institution or Investigator Letter Head)

Date:

To

Member Secretary

RKDF-IEC,

RKDF-IEC, Ref Number:

Protocol #/ Title:

Subject: Notification of SAE to RKDF-IEC

Dear Sir/Madam,

We would like to notify the SAE occurred for one of the participants at our site. The details of SAE are given below.

- Subject Information (includes Subject #/ Initials, hospital/OPD record number, Gender, Age and/or date of birth, Height and Weight)
- Event Term and description of the event in detail
- Start date of the event and stop date

- Criteria for SAE

- Is the Event related to study/ study drug

- Details of the study drug/Investigational Product administered to the subject during the trial: (includes Generic name of the drug, Indication(s), dose given, Route of administration, start date, Stop date,)

- Other Treatment(s): Provide the same information for concomitant drugs (including non- prescription/OTC drugs) and non-drug therapies, as for the study drug(s).

- Action taken with the study drug

- Medical History of the patient

- Dechallenge and rechallenge information – If any

- Outcome (Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted, Resolved date, If Hospitalized, discharge summary)

    - Details about the Investigator

    - Date of reporting the event to Licensing Authority:

- Date of reporting the event to Ethics Committee overseeing the site:

- Report type – Initial/Follow-up

- Is the subject continuing his/her participation in the study?

(Attach SAE form given by the sponsor with this notification – If any) Kindly review and do revert for any other information or clarification. Thanking you

Sincerely,

(Signature with date)

(Principal Investigator/ any other Investigator) and Site Address.

NOTE:

- Investigator can use RKDF-IEC, format or format given by the Regulatory Authority.

- SAE Form sent to the Sponsor should be attached along with this notification.

Annexure 10: Information to be submitted in the status report

- RKDF-IEC, Reference number
- Title of the research proposal
- Principal Investigator and contact details
- Changes in the Study team details, if any.
- Total No of Sites and Total No. Of Subjects – Overall
- Date study initiated, if no, specify reason
- Number of subject Screened and enrolled in the study
- Number of subjects screen failure/drop outs
- Number of subjects Ongoing/Completed
- Total Number of subjects discontinued with reason,
- SAE – if any with details
- Any Protocol Deviation/Violation – if yes, give details.
- Other issues, if any- give details

Annexure 11: RKDF-IEC, fee for review

Review type (Phase trial I, II, III and IV) / BABE studies / any Industry sponsored trial

EC review fee (Initial review – full board meeting)

Review of Major amendments (for full board meeting)

Ratification of minor amendments to protocol

Expedited review

Reasonable processing fees in consultation with the institution will be charged

Annexure 12: MoU draft between RKDF-IEC, & External site

C1.0PARTIES

This MoU made and entered into on -- <Date> (effective date) between AAA, a company incorporated under the Companies Act, 1956 of India and having its registered office "---" of the first part,

AND

Dr. RK Diabetic FOOT and Podiatry Institute & Rakesh Jhunjhunwala Amputation Prevention Center – Institutional Ethics Committee (RKDF -IEC) No. 1, Jayanti Nagar Extension, off 200 feet Road, Kolathur, Chennai, Tamil Nadu, 600099

(Herein after called "RKDF-IEC," which expression shall, where the context so admits, include its successors and permitted assigns) of the second part.

C.2BACKGROUND

C2.1 WHEREAS RKDF-IEC, and AAA are desirous of collaborating with each other using the facilities and expertise that is specific to the collaborative work proposed (hereinafter called the PROJECT) as per the scope of the work detailed in section C.3.2

C2.2 The parties have identified that a strong relationship between them is mutually beneficial and wish to establish a more formal relationship through this MOU.

C.3 SCOPE OF THE MOU

C3.1 The MOU details the terms and conditions, financial arrangements, modalities of collaboration, responsibilities and obligations of RKDF-IEC, and AAA pertaining to the collaboration undertaken under the PROJECT.

C3.2 AAA will submit their clinical trial or BA/BE study protocols to RKDF-IEC, for ethical review. The submission, review and decision making will be in compliance to the guidelines stipulated in "New Drugs and Clinical Trials Rules, 2019", "Indian Good Clinical Practice", "Indian Council of Medical Research's (ICMR) National Ethical Guidelines for Biomedical Research" and ICH – Good Clinical Practices.

C.4 FINANCIAL ARRANGEMENTS

C4.1 AAA has decided to accept RKDF-IEC, as its Ethics Committee to execute the clinical trial or BA/BE study together, each party contributing their knowledge and expertise to the project.

C4.2 AAA will provide fee to RKDF-IEC, to cover the costs of services as outlined in Appendix 1.

C4.3 RKDF-IEC, ethics committee and AAA are to
Undertake this project at their own risk.

C5. MODALITIES OF COLLABORATION

C5.1 RKDF-IEC, will enjoy all the rights of an institutional ethics committee and AAA is agreeable to have RKDF-IEC, as their ethics committee to achieve the goals of the PROJECT.

C5.2 The RKDF-IEC, hereby agrees that it will be acting, in the performance of this MOU, as an independent contractor. The Services will be performed directly by the RKDF-IEC, who will provide the Services in a timely, competent and professional manner having at all times due regard to the AAA business operations.

C6. RESPONSIBILITIES

C6.1 Both the parties shall engage the necessary manpower, infrastructure, materials, etc., required for undertaking the PROJECT.

C6.2 Neither party shall be responsible for any damage to the property/material of the other party caused by its personnel during or consequent to the work carried out under this MOU.

C7. COMPLETION

C7.1 The work envisaged to be done by AAA/ RKDF-IEC, shall be deemed to have been successfully completed by AAA/ RKDF-IEC, on submission of the Final Report / fulfilment of its / their responsibilities as detailed in the PROJECT.

C8. RESULTS OF PROJECTS

C8.1 Any intellectual property rights patents / design / trademark / copyrights obtained by the parties hereto pertaining to the PROJECT prior to signing of the MOU shall remain the property of the respective party.

C8.2 The procedural formalities for securing and maintaining the intellectual property rights (patents / trademark / copyright) if any, shall be the joint responsibility of AAA and RKDF-IEC.

C9. CONFIDENTIALITY

C9.1 During the tenure of the MOU and for six months thereafter both AAA and RKDF-IEC, undertake on behalf of their subcontractors / employees / representatives / associates to maintain strict confidentiality and prevent disclosure thereof, of all the information and data exchanged / generated pertaining to work under this MOU for any purposes other than in accordance with this MOU.

C10. FORCE MAJEURE

C10.1 Neither party shall be held responsible for non-fulfilment of their respective obligations under this MOU due to the exigency of one or more of the force majeure events such as but not limited to Acts of God, war, flood, earthquakes, strike, lockouts, epidemics, civil commotion, etc., provided on the occurrence and cessation of any such events, the party affected thereby shall give a notice in writing to the other party within one month of such occurrence or cessation. If the force majeure conditions continue beyond 6 months, the parties shall then mutually decide the future course of action.

C11. EFFECTIVE DATE, DURATION, TERMINATION OF THE MOU

C11.1 The MOU shall be effective from the effective date written above and shall remain in force for a period of----- years from the said date, in the first instance.

C11.2 The MOU shall terminate on the expiry of the period, as in clause 12.1, unless extended by both the parties.

C11.3 During the tenure of the MOU, parties hereto can terminate the MOU either for breach of any of the terms and conditions of this MOU or otherwise by

giving 1 months' notice in writing to the defaulting party. Failure of either party to terminate the MOU on account of breach or default by the other shall not constitute a waiver of that party's right to terminate this MOU.

C11.4 In the event of termination vide clause C12.3, the rights and obligations of the parties thereto shall be settled by mutual discussion;

C11.5 Even if the agreement is terminated, the indemnity clause will be binding on both the parties as defined in clause 17 with regard to the studies reviewed by RKDF-IEC.

C12. NOTICES

C12.1 All notices and other communications required to be served on RKDF- IEC, under the terms of this MOU shall be considered to be duly served if the same shall have been delivered to, left with or posted by registered mail to RKDF-IEC, at its address mentioned in this document. Similarly, any notice to be given to the AAA shall be considered as duly served if the same have been delivered to, left with or posted by registered mail to the AAA at its registered address mentioned in this document.

C13. AMENDMENTS TO THE MOU

C13.1 No amendment or modification of this MOU shall be valid unless the same is made in writing by both the parties or their authorized representatives and specifically stating the same to be an amendment of this MOU. The modifications / changes shall be effective from the date on which they are made / executed, unless otherwise agreed to.

C14. ASSIGNMENT OF THE MOU

C14.1 The rights and / or liabilities arising to any party to this MOU shall not be assigned except with the written consent of the other party and subject to such terms and conditions as may be mutually agreed upon.

C15. ARBITRATION

C15.1 In the event of any dispute arising out of or in connection with this MOU, the parties wish to seek an amicable settlement as per the laws of India and Tamil Nādu within the legal jurisdiction of Chennai.

C16. INDEMNITY

C16.1 AAA indemnifies the current members of the RKDF-IEC , and will keep indemnified all the current members of RKDF-IEC , against all claims, liabilities, demands, charges, loss, injuries, costs and expenses in respect of all and any decisions taken in good faith and acts done as members of the towards the review and / or approval of the clinical trial, as detailed in the RKDF-IEC , approved study protocol and documents.

C16.2 This Indemnity will cover the said members during their tenure of office and also cover claims etc. Made after their tenure.

C16.3 As and when there are fresh nominations to the Ethics Committee this Indemnity will cover such members also.

SEAL OF PARTIES

In witness whereof the parties hereto have signed this MOU on the day, month, and year mentioned hereinabove.

Parties

For and on behalf of	For and on behalf of
AAA	RKDF-IEC,
	Signature
Signature	
	Name:
Name	
	Designation:
Designation	
	Seal
Seal	

Annexure 13 - Undertaking by the Investigator

1. Full name, address and title of the PI (or Investigator(s) when there is no PI)

2. Name & address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, and /or other statement(s) of qualification(s)

3. Name & address of all clinical laboratory facilities to be used in the study.

4. Name & address of the EC that is responsible for approval and continuing review of the study.

5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation(s).

6. Protocol Title and study number (if any) of the clinical trial to be conducted by the Investigator.

Commitments:

- I reviewed the study protocol; it contains all the required information; no revisions will be made to it. I agree, to personally conduct the study in our site following the protocol approved by EC and regulatory agencies. No amendments to the protocol will be made without prior approval from sponsor and IEC. Except where necessary to eliminate an immediate hazard(s) to the trial subjects or when the changes(s) involved are only logistical or administrative in nature.
- As per the GCP guidelines, the informed consent will be obtained from the study subjects; I ensure that they understand the study protocol clearly, including the interventions given and diagnostic tests performed; and I will report all adverse events that occur during the study to both EC and sponsor.

- I have read and understood the information in the Investigator' brochure, including the potential risks and side effects of the drugs.
- I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about obligations in meeting their commitments in the trial.
- I agree to maintain adequate and accurate records and to make those records available for audit/inspection by the sponsor, EC, Licensing authority or their authorized representative, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the sponsor.
- I agree to promptly report to the EC and sponsor about all changes in the clinical trial activities and all unanticipated adverse events within 7 days.
- I will maintain confidentially of the identification of all participating study patients and assure security and confidentially of study data.
- I agree to comply with all other requirement, guidelines and statutory obligations as applicable to clinical Investigator participating in clinical trials.

PI signature & date

Annexure 14 – Short CV Template

First Name	
Last Name	
Middle Initial	
Date of Birth (dd/mm/yy):	
Sex	
Study Site Affiliation (e.g., Principal Investigator, Co-Investigator, Coordinator)	
Professional Mailing Address (Include institution name)	
Study Sited Address (Include institution name)	
Telephone (Office):	
Mobile Number:	

E-Mail:	
Academic Qualifications (Most current qualification first)	
Degree/Certificate Year Institution, Country	
Current and Previous 4 Relevant Positions Including Academic Appointments (Most current position first)	
Title Institution/Company, Country	
Brief Summary of Relevant Clinical Research Experience:	
Principal Investigator Signature & Date	

Annexure 15 – IEC SOP revision – request form

Title of SOP	
Revision required in SOP	
Identified by:	
Signature of person requesting revision:	
To be filled by IEC Member Secretary	
Discussed with SOP writing committee by (Name) and date	
SOP revision required:	
If SOP revision is required, Date SOP re-finalized:	
Date SOP approved:	
Date SOP becomes effective:	
Signature of Member secretary and date:	

Annexure 16 – IEC member Training Record Form

Name	Tick one of the following		
Membership since	Chair person	Member secretary	Member

Ethics related Training Experience

S. No.	Courses / Workshops / Conferences / Meetings	Title	Organizer	Date and Duration.

Signature of IEC member & date:

Annexure 17 -- IEC decision on proposed study protocol; Decision of Full board/Expedited Review/Re-submissions/Protocol Amendment

Institutional Ethics Committee:

List of IEC members

To

Principal Investigator,

Designation, Subject:

Ref: No: IEC/Year/Month/Meeting No/Proposal No.

The Institutional Ethics Committee (IEC) met on_____under the Chairperson ship of_____and reviewed the documents submitted (listed below)

For the project titled "_____" IEC No:_____which was presented by_____.

The following IEC members were present at the meeting held in the meeting Room

Table 1. List of documents reviewed:

S. No.	Documents	Version No. And Date
S. No.	Documents	Version No. And Date

Table 2. List of members attended:

Name	**Destination**	**Affiliation.**

The Committee reviewed the following documents to be listed with version number and date in a tabular form and after deliberations,_____the project with the following recommendations, if required:

IEC approval validity period: 18 months from the date of approval frequency of ongoing project review

Note to PI:

1. To comply with the following before which the study should not be started at this center (proof for regulatory approval to be submitted)
2. To inform the IEC the actual date of starting the study within the 10days of starting the study.
3. To obtain the IEC approval prior to implementing any change in study procedures
4. To report Serious Adverse Events (SAE) as per DCGI guidelines

5. IECs limitations of liability: This letter of approval just indicates clearance in regard to conformity of the study protocol of the sponsor/ Investigator with the prescribed ethical standards. Neither the IEC nor any of its members shall be liable for any liability what so ever under any circumstances in relation to the conduct of the clinical trial or in connection with the study drug/devices to be administered or used as per the study protocol.

6. Clinical Trial Agreement (CTA)/Memorandum of Understanding (MOU) (as applicable) should be processed and signed as per the guidelines for conduct of clinical trial

in IEC. A copy of the CTA/MOU duly signed by the parties concerned as mentioned above should be submitted to IEC.

7. Note that the IEC has the right to monitor the study with prior intimation.

8. To apply for extension of IEC approval if required before expiry of the validity period along with appropriate justification and summary of study findings.

9. To submit the ongoing review details of the study at the frequency mentioned.

10.To quote the IEC reference number in all communications

Signature of the Chairperson/ Member Secretary

Annexure 18 - Clinical Trial Site Audit Form

Study Title	
Trial site	
Name of PI and Co-PI	
Date and time of audit	
Visiting IEC member	
Name of the members present at the time of audit	

Details of Audit: Template used by member for site visit

A. Observation of the study site setting: Patient reception; receptionist and the protocol

1. How patients are – received at reception, receptionist details, identified as study subjects.
2. Patient waiting areas?
3. Informed consent – satisfactory?

B. Observation of procedure of drug administration / device: Person administering the drug, level of competence of the person, training on the procedure and protocol of the study during patient visit.

1. Who brings the medicine to the clinical site and the protocol followed for the same?

2. Who examines the study participants and administers the drug?

3. Who collects the blood samples?

4. Patient stay – duration in each visit?

5. Patient monitored post drug administration? If, so mention by whom & where?

6. Does the study warrant any special training like anaphylaxis preparedness, follow-up for acute complications, important patient/attender education after administration of therapeutic agent(s)?

7. Details of training given to the medical and para-medical staff involved in the particular study and proof for the same.

C. Preparedness for adverse events (AE) at the time of intervention:

1. Protocol for AE in the site? Subject attended by? Availability of appropriate drugs? Hospitalization requirement, if needed?

2. Does the trial involve device implant? If so, where is the implant done? Who does the implant procedure? How is follow-up care done? What is the in-hospital duration of patient stays for device implant procedure?

D. Record management – Study documents including ICF storage – by whom and where?

NOTE – Additional points can be added depending on the trial and purpose of Audit

Annexure 19 - Format for Site visit report

Date;

IEC No:

- Name and details of the visiting team; date and time.
- PI name and affiliation, Study title
- Sponsor details
- Details of the site visit as per the checklist:
- Remarks of the site visit team:

Signature of the team members

S.No.	Name	Role in EC	Whether to Affiliated to Institute
1	Mr M. Jeeva B.Sc., B.L.,	Chair Person	No
2.	Dr Rajesh Kesavan MBBS., MS General Surgery	Member Secretary	Yes
3.	Dr Ramya. S MBBS., MD Pharmacology	Medical Scientist	No
4.	Dr D Darwin Britto MBBS ., MS General Surgery	Clinician	Yes
5.	Dr C Sheela Sasikumar M.Sc., M.Phil., Ph d	Scientific Member	Yes
6.	Mrs Savitha R B.Sc., MCA	Social Scientist	No
7.	Dr Deepa B PhD., LLB	Legal Expert	No
8.	Dr Sockalingam M MBBS., MD Anaesthesiology	Member	Yes
9.	Mr Ganesan R B.Sc	Lay Person	No