Kokilaben Dhirubhai Ambani
hospital & medical research institute

Every Life Matters

INSTITUTIONAL ETHICS COMMITTEE

Standard Operating Procedures (SOP)

Effective Date: 26th August 2019

Validity Date: 25th August, 2022

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Institutional Ethics Committee SOP Approval Certificate

	NAMES	DESIGNATION	SIGNATURE	DATE
PREPARED BY	Dr. Varsha Vadera	Member Secretary		7th Aug 2019
REVIEWED BY	Dr. Sanjay Mehta	Clinician		8.8.2019
	Dr. Barnali Das	Basic Medical Scientist		12.8.2019
APPROVED BY	Dr. Renuka Munshi	Chairperson		12.08.2019
ACCEPTED BY	Dr. Santosh Shetty	Executive Director, CEO		13/08/19

SOP VERSION: 11

EFFECTIVE DATE: 26/08/19

IEC Communication Details

Name Of IEC:

Institutional Ethics Committee (IEC)

Mailing Address IEC:
Institutional Ethics Committee
2nd Floor
Kokilaben Dhirubhai Ambani Hospital
& Medical Research Institute,
Rao Saheb Achutrao Patwardhan Marg,
Four Bunglows, Andheri (West), Mumbai 400 053.
Tel: 022 30970213

Chairperson of IEC:
Dr. Renuka Munshi
Associate Professor&
In-Charge Dept. of Clinical Pharmacology,
TN Medical College & BYL Nair Charitable
Hospital, Mumbai:400 008.
Mobile: 9820377409
E mail :renuka.munshi@gmail.com

Member Secretary IEC:
Dr. Varsha Vadera
Consultant & Head - Laboratory Medicine
and Advanced Diagnostics
Mailing Address Member Secretary:
7thFloor
Kokilaben Dhirubhai Ambani Hospital
& Medical Research Institute,
Rao Saheb Achutrao Patwardhan Marg,
Four Bunglows, Andheri(West),
Mumbai: 400 053.
Mobile: + 91 9321197083
E –mail: varsha.vadera@relianceada.com

IEC Admin Manager:

Mr. Amol Rane
Kokilaben Dhirubhai Ambani Hospital
& Medical Research Institute,
Rao Saheb Achutrao Patwardhan Marg,
Four Bunglows, Andheri(West),
Mumbai - 400 053.
Mobile: +91 8082045398
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IEC Co-ordinator:

Dr. Nitin Kulkarni
Kokilaben Dhirubhai Ambani Hospital
& Medical Research Institute,
Rao Saheb Achutrao Patwardhan Marg,
Four Bunglows, Andheri (West),
Mumbai - 400 053.
Mobile: +91 9866625222
Fax: +91-22-30970177
E –mail: Nitin.Kulkarni@relianceada.com

Note: Previous IEC Co-ordinator, Dr. Vijaykumar Gawali served IEC from 09th Dec 2009 to 19th Oct 2018.

Dr. Nitin Kulkarni is serving IEC with effect from 19th Oct 2018.

Institutional Ethics Committee Version : 11 (Approval date: 26th August 2019)

SOP No	SOP Title	SOP Version : 10	SOP Version : 11
	Change in Member Secretary IEC:	**Member Secretary IEC:** Dr. Mahesh Menon Consultant- Pain Management and Palliative Care Mailing Address Member Secretary: General OPD, 1st Floor Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute, Rao Saheb Achutrao Patwardhan Marg, Four Bunglows, Andheri (West), Mumbai 400 053. Mobile : +91 7498242830 Tel : + 91 22 30970189 E –mail : mahesh.menon@relianceada.com	**Member Secretary IEC:** Dr. Varsha Vadera Consultant & Head - Laboratory Medicine and Advanced Diagnostics Mailing Address Co-Member Secretary: General OPD, 1st Floor Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute, Rao Saheb Achutrao Patwardhan Marg, Four Bunglows, Andheri (West), Mumbai 400 053. Mobile : + 91 9321197083 E –mail : varsha.vadera@relianceada.com
	Change in IEC Admin Manager :	**IEC Admin Manager :** Mr. Kamlesh Sankpal Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute, Rao Saheb Achutrao Patwardhan Marg, Rao Saheb Achutrao Patwardhan Marg, Four Bunglows, Andheri (West), Mumbai 400 053. Mobile : +91 9870115463 Fax: +91-22-30970177 E –mail : iseb.kh@relianceada.com	**IEC Admin Manager :** Mr. Amol Rane Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute, Rao Saheb Achutrao Patwardhan Marg, Rao Saheb Achutrao Patwardhan Marg, Four Bunglows, Andheri (West), Mumbai 400 053. Mobile: +91 8082045398 Fax: +91-22-30970177 E –mail : iseb.kh@relianceada.com

	Change in IEC Co-ordinator	**IEC Co-ordinator :** Dr. Vijaykumar Gawali Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute, Rao Saheb Achutrao Patwardhan Marg, Rao Saheb Achutrao Patwardhan Marg, Four Bunglows, Andheri (West), Mumbai 400 053. Mobile : +91 9320199122 Fax: +91-22-30970177 E –mail : vijaykumar.gawali @relianceada.com	**IEC Co-ordinator :** Dr. Nitin Kulkarni Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute, Rao Saheb Achutrao Patwardhan Marg, Rao Saheb Achutrao Patwardhan Marg, Four Bunglows, Andheri (West), Mumbai 400 053. Mobile: +91 9866625222 Fax: +91-22-30970177 E –mail : nitin.kulkarni @relianceada.com
	New Legal Expert Added In IEC Membership List	Ms. Anuradha Iyer Qualification: B.com., LLB Expertise: Lawyer Organisation: Tatva Legal Address: 75, 7th Floor Free Press House, Free Press Journal Road, Nariman Point, Mumbai-400021 Contact: 022-67202500; E –mail : anu.iyer@tatvalegal.com	Mrs. Kshama D. Mankar Qualification: B.A.,L.L.B. Expertise: Lawyer Organisation: Individual Practice Address: 202/New Krishna Apt., Opp. Royal Shopping Center, Ambadi Road, Vasai (W) 401 202. Contact: 8208344311 / 9960730143 E-mail : kshamamanker72@yahoo .com

	New Clinician Added In IEC Membership List	Dr. Durga Gadgil Qualification: M.D. (Chest Diseases and Tuberculosis), M.B.B.S. Expertise: Chest Medicine Organisation: Tata Memorial Research &Administrative Council Address: B-63, Twin Towers, Prabhadevi Seaface, Mumbai 400025 Contact:9869081033 E-mail:durgagadgil@gmail.com	Dr. Abhishek Srivastava Qualification:MBBS, MD, DNB, MNAMS, PhD Expertise: Neurological Rehabilitation Organisation: Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute Address: Director- Center for Physical Medicine and Rehabilitation Consultant in Rehabilitation Medicine: Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute Contact: 9324582986 E-mail: abhishek.m.srivastava @relianceada.com
	New Clinician Added In IEC Membership List	NA	Dr. Sharad Maheshwari Qualification: M.B.B.S., MD (Radio-Diagnosis) Expertise: Abdominal Imaging, Scientific Review of Research Documents Organisation: Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute Address: Consultant Radiologist, Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute

			Contact: 9322164919 E-mail: sharaddoc@gmail.com
	New Lay Person Added In IEC Membership List	Mrs. Akhila Das Blah Qualification: Bachelor of Commerce Expertise: Teaching Organisation: The Juniors Club, Mumbai Address: 31/32, Eden Roc Apartments, 3rd road, Union Park, Pali Hill, Bandra west, Mumbai – 400050 Contact: 9820062881. E-mail: akhila.dasblah@gmail.com	Mr. Nitin Sheth Qualification: B.Tech (Civil) from IIT Mumbai Expertise: Ethics Organisation: Retired Address: 701, Horizon View 1/a, Raheja Complex, 7 Bungalows, Versova, Andheri West, Mumbai-400061. Contact: 9820014860. E-mail: nitin.sheth@gmail.com
	New Basic Medical Scientist Added In IEC Membership List	NA	Dr. Barnali Das Qualification: M.B.B.S., MD (Biochemistry), DNB (Medical Biochemistry), CCCR (Clinical Research) Expertise: Scientific Review of Research Documents Organisation: Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute Address: Consultant Laboratory Medicine, Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute

			Contact: 9324349519 E-mail: barnali.das@relianceada.com
	New Social Scientist Added In IEC Membership List	NA	Mr. Rajiv Kamlakar Patil Qualification: M.A. Expertise: Community Development Organisation: Pratham Infotech Foundation Address: A/14, Shivashakti Co-Op Society, Prabhadevi, Sayani Road, Dadar (W), Mumbai 400025. Contact: 9987824148 E-mail: rajivpatil26@gmail.com
	New Social Worker Added In IEC Membership List	Mr. Yogesh Patil Qualification: B.Com., Masters Of Social Work Expertise: Medical Social Work Organisation: Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute Address: Medical Social Worker Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute Contact: 9022908598	Mr. Rohit Khude Qualification: B.A., Master in Social Work Expertise: Community Development Organisation: Khan Bahadoor Haji Bachooali Charitable Ophthalmic & ENT Hospital, Parel Address: 110/D Laxmi Sadan, near Maval Maratha Gym., Golfadevi road, Worli Village, Mumbai- 400 025

		E-mail: yogmanu24april@gmail.com	Contact: 9664232582 E-mail: rohitkhude@yahoo.com
1.6	PREPARING SOP		Added : Document Control
1.7	Approve a new/ revised SOP	Member Secretary or IEC Secretariat shall email or courier the approved SOP to all members. 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 Institutional Ethics Committee.	Member Secretary or IEC Secretariat shall courier /email the Controlled copy of approved SOP to all members. When the revised version is distributed, old version is retrieved from all members and destroyed, except for one master copy of the earlier version will be placed in the file entitled 'Past SOPs of Institutional Ethics Committee.
1.7	Manage current and archive superseded SOPs	Superseded SOPs should be retained and clearly marked "superseded" and archived in the file entitled 'Past SOPs of Institutional Ethics Committee by the Member Secretary or IEC co-ordinator	Superseded SOPs will be marked "Obsolete" and archived in the file entitled 'Past SOPs of Institutional Ethics Committee by the Member Secretary or IEC co-ordinator.
2.2	Ethical basis	NA	Added In Declaration of Helsinki: 59th WMA General Assembly, Seoul, Republic of Korea, October 2008, 64th WMA General Assembly, Fortaleza, Brazil, October 2013)

2.5(H)	Training Of Members	IEC members should attend at least one refresher GCP workshop annually.	IEC members should attend GCP workshop once every 3 years.
2.5(F)	Terms of References	NA	Added : Common Roles and Responsibilities of IEC members in detail
4.1.4.2	Informed Consent Form review with respect to associated risks and benefits of the trial.	Investigator need to maintain complete narration of the process for obtaining informed consent, including the identification of those who consented patient.	Investigator / designated person is authorized to take informed consent and need to maintain complete narration of the process for obtaining informed consent, including the identification of those who consented patient.
4.1.4.2	Informed Consent Form review with respect to associated risks and benefits of the trial.	NA	Added : Definition of Legally Acceptable Representative and Impartial Witness
8.3.1	On-Site SAE Reports Review	NA	Added: If any subject is withdrawn due to SAE, the same will be discussed in SAE sub-committee and in IEC full board meeting.
8.6	SAE Sub-Committee Membership List	Dr Mahesh Menon	Added New member: Dr. Abhishek Srivastava

19.2	Overall IEC Self Assessment	Chairperson designated IEC Member shall conduct self assessment of IEC as per Annexure	Chairperson designated IEC Member shall conduct self assessment based on NABH standards of IEC, as per Annexure
19.3	IEC Members and Secretariat Self Assessment	Two periodic reviews per year shall be conducted as mentioned below.	One periodic review per year shall be conducted as mentioned below
19.4	IEC Self Assessment Procedure	There should be at a minimum two periodic review per year	There should be atleast one periodic review per year

Institutional Ethics Committee Version : 10 (Approval date 22nd January 2018)

IEC Communication Details:

Chairperson of IEC:

Dr. Renuka Munshi
Associate Professor &
In-Charge Dept. of Clinical Pharmacology,
TN Medical College & BYL Nair Charitable
Hospital, Mumbai: 400 008.
Mobile: 9820377409
E mail: renuka.munshi@gmail.com

Member Secretary IEC:

Dr.Mahesh Menon
Consultant- Pain Management and Palliative Care
Mailing Address Member Secretary:
General OPD, 1st Floor
Kokilaben Dhirubhai Ambani Hospital
& Medical Research Institute,
Rao Saheb Achutrao Patwardhan Marg,
Four Bunglows, Andheri(West),
Mumbai 400 053.
Mobile: +91 7498242830
Tel: + 91 22 30970189
E –mail:mahesh.menon@relianceada.com

Co-Member Secretary IEC:

Dr. Varsha Vadera
Consultant & Head - Laboratory Medicine
and Advanced Diagnostics
Mailing Address Co-Member Secretary:
General OPD, 1st Floor
Kokilaben Dhirubhai AmbaniHospital
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Four Bunglows, Andheri (West),
Mumbai 400 053.
Mobile: +91 9321197083
E –mail: varsha.vadera@relianceada.com

Updated Institutional Ethics Committee Member List

Section 3.2: Initial Review Application:-

Three hard copies and one soft copy are required to be submitted for IEC review.

4.1.2.1 : Review the protocol :-

IEC Secretariat will email protocol and related documents to the respective Institutional Ethics Committee members (hard copies shall be shared to those members who have requested for hard copies).

8.6 : SAE Sub-Committee Membership List :-

Dr. Sanjay Mehta is inducted as SAE Sub-Committee Member.

18.4 : IEC Fees Details:

IEC Fees revised.

AX 04 / 10: Instructions to Principal Investigator:

Principal Investigator or designee needs to submit 3 hard copies and one soft copy for IEC record.

AX 05 /10 : Chairperson details changed
Chairperson of IEC : Dr. Renuka Munshi
In-charge Dept of Clinical Pharmacology,
5th floor, G bldg, Dr AR Nair Road,
TN Medical College & BYL Nair Charitable Hospital,
Mumbai : 400 008.
Mobile : 9820377409
E mail :renuka.munshi@gmail.com

AX 07 /10 : Chairperson details changed
Chairperson of IEC : Dr. Renuka Munshi
In-charge Dept of Clinical Pharmacology,
5th floor, G bldg, Dr AR NairRoad,
TN Medical College & BYL Nair Charitable Hospital,
Mumbai : 400 008.
Mobile : 9820377409
E mail : renuka.munshi@gmail.com

Institutional Ethics Committee Version : 9 (Approval date 10th November 2017)

In SOP 4, **4.1.2.1 :Review the protocol :-** Principal Investigator to submit documents to IEC atleast three weeks in advance to IEC meeting for IEC review.

Institutional Ethics Committee Version : 8 (Approval date 24th October 2017)

In SOP 2, New Member Induction procedure section is amended so as to mention tenure, role and responsibilities in the appointment letter.

In SOP 4, protocol review section is amended to have separate section guiding scientific review of submitted studies to IEC. In SOP 4, subsection 4.1.2.2 titled "Specific Responsibilities to members for study documents review" is added under section 4.1.2.

In SOP 4 protocol review section is amended so that, subjects are informed and comprehended (initial and ongoing) of the associated risks and benefits of the trial. In SOP 4, subsection 4.1.4.2 titled "Informed Consent Form" review with respect to associated risks and benefits of the trial" is added under section4.1.4.

In SOP 4, protocol review section is amended so that, at the time of consenting, patient Charter mentioning rights and responsibilities are offered to the patient in a language that the patient can easily understand. In SOP 4, subsection 4.1.4.3 titled "Patient Charter" is added under section 4.1.4.

In SOP 4, subsection 4.1.4.4 titled "Waiver for written Consent" is added under section 4.1.4.

In SOP 8, SAE Report review section is amended so that, Root Cause Analysis for Serious Adverse Event is properly done. In SOP 8, subsection 8.3.2 titled "Process for Root Cause Analysis for Serious Adverse Event" is added under section 8.3. In SOP8, subsection 8.3.3 titled "Off Site SAEs Review" is added under section 8.3.

SOP 19.3 IEC Members and Secretariat Self Assessment frequency is amended to two periodic reviews per year.

Institutional Ethics Committee Version : 7 (Approval date 10th June 2017)

Following is summary of Amendments in Institutional Ethics Committee SOP Version 6:

A. Amendments in Existing SOP:
B. Additions in Existing SOP:
C. Addition of New SOP:

A) Amendments in Existing SOP:

SOP No	SOP Title	SOP Version : 6	SOP Version :7
	Change in EC Name	EC Name : Institutional Scientific and Ethics Board	EC Name : Institutional Ethics Committee
1.3	Secretariat	Chairperson constitutes IEC secretariat	Executive Director appoints Admin Manager and Co-ordinator to assist IEC Functions. Both have equal responsibilities
1.3	Secretariat	Secretariat comprises of Member Secretary and co-ordinator	Secretariat comprises of Member Secretary , Co-Member Secretary , Admin manager and co-ordinator
1.6	New SOP	The Chairperson signs and dates the SOP Approval page. This date of approval is declared as the effective date from where by the SOP is implemented.	The Chairperson signs and dates the SOP Approval page. Approved SOP shall be sent for acceptance from Executive Director. Effective date of the SOP shall be, post ten working days , from the acceptance date from the Executive Director's end. Members Secretary shall mention final effective date on SOP (Post acceptance from Executive Director), post which SOP need to be made accessible to all stake holders for reference.

2.5(A)	Membership Requirements	The Chairperson and Members of IEC are responsible for appointing new board members.	The Chairperson and Members of IEC may identify and suggest appointing new board members to Executive Director , Alternately Executive Director may also identify suitable new members . Executive Director appoints new members.
2.5(B)	Tenure of Membership	The tenure of Institutional Scientific and Ethics Board is amended to period of **three years** from the date of appointment	The tenure of Institutional Scientific and Ethics Board is amended to period of **two years** from the date of appointment
2.6	Chairperson and Member Secretary	The Board members will elect a Chairperson from among themselves.	Executive Director appoints Chairperson, Co-Chairperson, Member Secretary and Co-Member Secretary.
2.6	Chairperson and Member Secretary	New Section is added in version 7, which was not available in version 6.	Co-Chairperson has equal powers as Chairperson. Co-Member Secretary has equal powers as Member Secretary.
2.6	Chairperson and Member Secretary	New Section is added in version 7 , which was not available in version 6.	It should be noted that whenever SOP mentions about Chairperson and Member Secretary, it should be understood that it is also equally applicable to Co-Chairperson and Co- Member Secretary respectively.
3.3	Resubmission of Protocols with corrections	For resubmitted protocol the Principal Investigator will submit 11 copies (10 for IEC members circulation and 1 for IEC record , depending on IEC decision on, of the Protocol and related documents as informed to him/her by the Member Secretary or IEC co-ordinator).	For resubmission of protocol , if re-submission is for full board discussion, Principal Investigator need to submit copies equivalent to total number of IEC members and one for IEC record , and if resubmission is for secretariat review then Principal Investigator need to submit 3

			copies unless particularly specified by the Member Secretary or IEC co-ordinator .
3.4	Protocol Amendments	The Principal Investigator will submit 11 copies of Protocol amendment/protocol related documents	For protocol amendments , if submission is for full board discussion, Principal Investigator need to submit copies equivalent to total number of IEC members and one for IEC record , and if resubmission is for secretariat review then Principal Investigator need to submit 3 copies unless particularly specified by the Member Secretary or IEC co-ordinator .
3.5	Annual Continuing Reviews of Approved Protocols	The Principal Investigator will l submit 11 copies of Annual Study Report and related documents	Principal Investigator need to submit copies equivalent to total number of IEC members and one for IEC record.
3.6	Protocol Completion	The Principal Investigator will submit 1 copy of Study Completion Report and related documents	Principal Investigator need to submit copies equivalent to total number of IEC members and one for IEC record.
9.4	After the site monitoring visit	Full board recommendations to change the study/ premature termination/ continuation of the project will go to the Principal Investigator in writing within **6 days** of the meeting.	Full board recommendations to change the study/ premature termination/ continuation of the project will go to the Principal Investigator in writing within **10 days** of the meeting. The ethics committee can suggest any areas that need to be improved based on the findings of their monitoring reports.

11.3	Minutes of Meeting	The Member Secretary will check the correctness and completeness of the minutes and prepare it within **3 working days** of the meeting held.	The Member Secretary will check the correctness and completeness of the minutes and prepare it within **10 working days** of the meeting held.
13.2	Record Keeping	IEC shall follow, regulatory guidelines 122 DD, serial number 4- maintenance of record	IEC shall follow, regulatory guidelines 122 DD, serial number 4- maintenance of records and all records shall be maintained in IEC Office located on 2nd Floor, Kokilaben Dhirubhai Ambani Hospital and Medical research Institute. It shall be restricted access to authorized people, and also with proper provision for pest-control and fire control.

A) Additions in Existing SOP:

1.7 : Definitions of Following mentioned Glossary Added

- Revision date:
- Recipients: Stakeholders who would receive a copy of SOP.
- SOP Team:
- Institutional Ethics Committee(IEC):

2.1.2 : Authority for formation of IEC :

IEC is established under authority of Executive Director, Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute, Andheri, Mumbai, Maharashtra. It is administratively governed under same authority. Institution will support establishment of ethics committee including training, resources and infrastructure etc.

2.4 : Quorum Requirements:-

- Decisions will be arrived at through consensus/unanimous or majority opinion amongst the voting members of IEC.
- When a consensus is not possible, the IEC will vote. Voting may be in the form of voice vote, show of hands, or by secret ballot, as determined by the Chairperson, IEC.
- All members are entitled to one vote. However, in case of a tie, the Chairperson will vote to arrive the final decision.
- Opinions of absent members that are transmitted by mail or telephone or fax may be considered by the attending members during discussion. But absent member cannot be counted as voting member or quorum member for formally convened full board meetings.

2.5 A : New Member Induction procedure:

Executive Director, KDAH appoints the IEC Chairperson, Member Secretary and Members. The licensing authority shall be informed in writing about the constitution of the Ethics Committee or in case of any change in the membership. Institution will support establishment of ethics committee including training, resources and infrastructure etc.

Appointment letter should mention tenure, role and responsibilities of the member.

Members must submit CV and required training certificates.

Member secretary designate or any other member designate should be trained in SOP and regulations before attending IEC meeting.

Members must apprise themselves of the Schedule Y, GCP for clinical trials in India, ICH GCP guidelines, ICMR guidelines and Institutional IEC SOP and Institutional SITE SOP.

2.5(G) : Training Of Members :

Member Secretary shall arrange for courses in bioethics, applicable rules and regulations, local social and cultural norms and relevant SOPS. Members are trained on assessing the risk benefit, evaluating the scientific validity and assessing the ethical issues. Subject experts in bioethics may be called for training in ethical issues. Demonstrate schedules for orientation. Participate in continuing education activities in biomedical ethics and biomedical research. IEC members should attend at least one refresher GCP workshop annually.

IEC members are required to continue training in required regulations and KDAH IEC SOP.
All IEC members must be conversant with ICMR Guidelines for Research involving Human Subjects 2006, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines.

The IEC will conduct workshops from time to time to impart training to the IEC members. The Chairperson and the Member Secretary will inform all members about any updates on ethical and regulatory guidelines regularly.

2.7.1 : Member Secretary Responsibility :

Member Secretary shall submit progress of IEC activities annually to Executive Director, which need to include, brief information about IEC activities, list of the research proposals reviewed and their status.

2.10 : Definitions of Following mentioned Glossary Added

- Scientific member
- Non-Scientific member
- Non-affiliated member

3.2 : Initial Review Application :-

Investigator shall declare any conflict of interest while submitting the documents for review. He also submits the budget of the trial to the ethics committee for financial transparency.

3.5: Annual Continuing Reviews of Approved Protocols:
The EC will send reminder for annual report to Individual PI at least 30 days prior to actual annual report timeline. The IEC Secretariat will verify the completeness of the annual review report and will sign and date the documents. It will be discussed in the expedited review meeting or full board meeting of IEC.

3.7 : Definitions of Following mentioned Glossary Added:

- Amendment:
- Case Record Form
- Clinical Trial Agreement
- Case Record Form:
- Essential Documents
- Informed Consent
- Investigator's Brochure
- Investigational Product(IP):
- Material Transfer Agreement (MTA):
- Memorandum of Understanding:
- Study Protocol:

4.1.2.1 : Review the protocol :
Members while reviewing protocol ,ensures that the advertisements do not induce the participants and that principal Investigator has a recruitment policy to ensure unbiased selection of adequate number of suitable subjects according to the protocol.

4.1.2.2 : Specific Responsibilities to members for study documents review:
The Ethics committee assigns responsibilities to the members with the objective to involve every member in decision making process. There should be every attempt to ensure meaningful participation of lay person, social scientist and legal person.

- There may be primary reviewers for the protocol
- The Legal person of the Ethics committee may be the primary reviewer of the contract (in evaluating the contract to ensure protection of the research participant, indemnification, and arbitration)
- Lay person may be the primary reviewer for the informed consent document language - whether it would be understandable to the subjects.

4.1.6: Final communication of the IEC decision taken on the project to the Principal Investigator:-

The decision letter is signed by the IEC Chairperson or IEC Member Secretary and sent to the Principal Investigator within 15 working days.

Letter should specify , If any regulatory clearance , CTRI registration pending with note that study may be initiated only post required regulatory clearances and CTRI registration (where applicable).

Principal Investigator is also required to communicate with IEC about initiation of patient recruitment.

SOP 4.5 : Reviewing proposals involving vulnerable Populations is separately defined in Separate SOP; this section is replaced with Periodic Review.

4.5 : Periodic Review

Periodic review of trial shall be done for continuation, risk evaluation and adverse event monitoring.

Periodic review is review of the trial status and analysis of risk to subjects in an ongoing trial previously approved by the ethics committee. Periodic review can be once in three months or six months depending on the risk status of the trial or if it involves vulnerable population. Principal Investigator (PI) is made aware of the periodicity to submit the documents for review. It can be communicated through final IEC decision letter to PI.

IEC has the authority to revert the decision of a proposal initially approved based on the periodic assessment of risk to the trial subject.

4.6 : Definitions of Following mentioned Glossary Added:

- Document
- Expedited review/meeting
- Exemption from review:

5.2: Detection of Protocol deviation/ non-compliance/ violation:-

The ethics committee should evaluate protocol violations to make sure to track for injury to the subject due to noncompliance of protocol.

5.5 : Definitions of Following mentioned Glossary Added:

- Protocol deviation
- Protocol violation

6.2: Independent Consultants:-
Name and qualifications of the experts and representatives should be documented; their attendance and viewpoints should be reflected in the meeting minutes.

8.1 : SAE
PI is required to share information on compensation is paid to the subject as per informed consent document contract and applicable rules and regulations. The amount paid should be approved (to be verified only) by the ethics committee.

Members reviewing SAE documents shall evaluate if adequate medical care is provided for serious adverse events as per applicable rules and regulations.

8.4 : Definitions of Following mentioned Glossary Added:

- Adverse Event

9.3 : During site Monitoring visit the IEC member will -
Review the informed consent document to make sure that the site is using the most recent version, also to ensure that subjects are well informed of all the risks and benefits in the clinical trial initially and on an on-going basis throughout the trial period. New safety information should be promptly communicated to subjects and should be documented in the source notes and re-consenting should be done in a timely manner. There should be evidence that queries and concerns of subject are addressed .There should be a provision for subjects to take opinion from family physician if they want.

Review SAE documents to ensure that compensation is paid to the subject as per informed consent document contract and applicable rules and regulations. The amount paid should be approved (to be verified only) by the ethics committee. Members conducting site monitoring visit shall evaluate if adequate medical care is provided for serious adverse events as per applicable rules and regulations.

Members conducting site monitoring visit shall evaluate protocol violations to make sure to track for injury to the subject due to noncompliance of protocol.

Ensure that the advertisements do not induce the participants and that principal Investigator has a recruitment policy to ensure unbiased selection of adequate number of suitable subjects according to the protocol.

Members conducting site monitoring visit may contact the patient randomly to understand if there are any patient grievance.

9.4: Definitions of Following mentioned Glossary Added:

- Monitoring Visit
- Monitoring Report

11.2 : Meeting Schedule and its conduct :-
The chairman will reassess the quorum when any member withdraws from the decision making and this will be recorded in the minutes.

11.3 : Minutes of Meeting:-
The chairman will reassess the quorum when any member withdraws from the decision making and this will be recorded in the minutes.
Details of risk-benefit assessment for protocols reviewed.

11.4 : Definitions of Following mentioned Glossary Added:

- Agenda
- Minutes
- Quorum

12.2 : Responsibilities of IEC Reviewer :- Following section deleted as it is repetition .
It is the responsibility of each and every newly-appointed Institutional Scientific and Ethics Board member to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form with the Institutional Ethics Committee.

13.4 : Definitions of Following mentioned Glossary Added:

- Active Study File

B) Additions of New SOP:

Following New SOP added: Brief Summary is mentioned here, refer details in respective SOP.

SOP-15 : Reviewing Research Studies Involving Vulnerable Populations :

IEC shall protect rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders. Proper consent process and documentation of consent should be as per IEC SOP.

Pregnant or nursing women : Pregnant or nursing women should in no circumstances be the participant of any research unless the research carries no more than minimal risk to the foetus or nursing infant and the object of the research is to obtain new knowledge about the fetus, pregnancy and lactation.

If objective of the research can be met by carrying out research with adults, children should not be involved in the research.

For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults. For studies prior to Phase III the drug has a therapeutic value in a primary disease of the children.

SOP-16 : Dealing with participants / patients/any relevant personnel, requests and complaints :

Primary responsibility of IEC is to protect rights and welfare of the human subjects participating in a clinical research approved by the IEC.

This SOP provides guidelines for dealing with and accommodating requests by participants/patients /any relevant personnel, regarding their rights as a participant or to resolve their complaints in any IEC approved research study. IEC Members may contact the patient randomly to understand if there is any patient grievance.

Query/complaint received will be recorded in the request record form The Member Secretary will inform the Chairperson about the query/complaint received.

SOP-17 : Policy of communication with different stake holders:
IEC communicates with following mentioned stakeholder as per regulatory mandate and specifications:

- Principal Investigator /study team designee
- DCGI
- Executive Director of the Institute
- Sponsor
- Study Participants

SOP-18 : Policy Financial declaration of payments received and disbursed:

The ethics committee maintains financial records which include; a) details of ethics committee fees for their services b) Honorarium Payment to each of the members and c) Other expenses incurred.
All payment received as Institutional Ethics committee submission fee are separately maintained under "Mandke Foundation".

Admin Manager will receive all payment cheque / DD and will submit to account department of the institute.

All expenditure of IEC are managed through payment received as fee including Admin Manager/EC supporting staff Salary, meeting arrangement cost, Travel arrangement to chairperson and external members, Stationary charges, Cupboard, Electricity and telephone bills infrastructure requirement including Computer, Xerox, Scanner, Ethics Committee Member Training arrangement.

SOP-19 : IEC Self Assessment

Chairperson designated IEC Member shall conduct self assessment of ethics committee as per Annexure. It will be done at least annually.

The Member Secretary will present self-assessment reports to all members in subsequent full Board meeting. If there are any recommendations shall be implemented accordingly.

Ethics committee conducts self-evaluation. Example: a) ethics committee evaluates the appropriateness of its composition b) Attendance of members is reviewed c) Review whether there are adequate resources for ethics committee functioning.

The ethics committee shall do a root cause analysis to identify if there is a process failure or a system failure. There should be at a minimum two periodic reviews per year.

Institutional Scientific and Ethics Board Version : 6 (Approval date 13th September 2014)

A) Communications Details Change :

Mailing Address ISEB :
Institutional Scientific and Ethics Board
2nd Floor
Kokilaben Dhirubhai Ambani Hospital
& Medical Research Institute,
Rao Saheb Achutrao Patwardhan Marg,
Four Bunglows, Andheri (West), Mumbai 400 053.

Member Secretary ISEB:

Dr. Jyotsna Oak
Consultant- Rheumatology
Mailing Address Member Secretary:
General OPD, 1st Floor
Kokilaben Dhirubhai Ambani Hospital
& Medical Research Institute,
Rao Saheb Achutrao Patwardhan Marg,
Four Bunglows, Andheri (West), Mumbai 400 053.
Mobile : +919324717618
Tel: + 91 2230970189
E –mail : jyotsna.oak@relianceada.com

B) SOP No : 2.3 : Composition of the Institutional Scientific and Ethics Board :
Following section amended:

The ISEB will be composed of at least 8 to a maximum of 15 members.

C) SOP No : 3.2 : Initial Review Application :-
Following Note added:
Note: Back translation can be exempted if translators qualification certificates and process of translation method is submitted to ISEB. ISEB secretariat will have the final authority to exempt back translation on case to case basis. ISEB secretariat will communicate to PI if back translations are still required even if translator's qualification certificates and process of translation method is submitted to ISEB. No such correspondence from ISEB office shall mean that back translation is exempted.

D) SOP No : 4.1.2 : Review the protocol:-

Submission timelines changed to 10 working days:
PI to submit documents to ISEB at least 10 working days prior to ISEB meeting , however Chairman or Member Secretary are authorized to permit exception to this requirement as per their discretion.

E) SOP No :4.5 Reviewing proposals involving vulnerable Populations:

Above SOP is added:

It describes the requirements concerning review of research that involves groups that could be potentially vulnerable to coercion in regard to autonomy, and present conditions that may affect risk/benefit determinations or bearing unequal burden in research.

4.5.1 : Which are vulnerable Populations:
These are sections of our society who may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable persons include patients with incurable diseases, people in nursing homes, unemployed or impoverished people, and patients in emergency situations, ethnic minority groups, homeless people, nomads, refugees, minors, and those incapable of giving consent. This list may not be exhaustive as there may be circumstances in which other groups are considered vulnerable, women for example, in an orthodox society.

4.5.2 : Requirement of expertise to review studies where vulnerable Populations is involved:

ISEB members should have knowledge concerning potential harm or risk of such population participating in the study. There should be sufficient rationale required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly adhered to.

In a event vulnerability status of the participants changes for e.g.; unconscious patient gaining consciousness, then relevant documents should be amended and resubmitted to ISEB (which would be case to case basis and ISEB shall intimate concerned PI about it) for reconsideration and approval following which if necessary the participant should be re-consented and reconsidered for the same.

4.5.3 : Record Keeping

It is the responsibility of the ISEB Secretariat to have proper methodology for review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines. ISEB Secretariat would be more careful and extra sensitive and supervising such studies and maintaining documents for such studies.

C) SOP No. 8 : SAE:-

Following sections amended:

If Patients enrolled at site experiences SAE :
Principal Investigator needs to submit SAE report within 24 hours of their occurrence and with due analysis within 14 calendar days and necessary follow up reports .Sponsor needs to submit SAE report with due analysis within 14 calendar days .
All adverse events should be included in the Annual Study Progress Report submitted to ISEB.

Unanticipated risks are sometimes discovered during the course of studies. Information that may impact on the risk/benefit ratio should be promptly reported to and reviewed by the ISEB to ensure adequate protection of the welfare of the study participants.

The unanticipated risks may as well include any event that in the investigator's opinion, may adversely affect the rights, welfare or safety of subjects in the study.

The ISEB Member Secretary or ISEB co-ordinator will receive the SAE report or the unexpected event report occurring at the trial sites approved by the ISEB for a given project. The Member Secretary or ISEB co-ordinator will review reports to make sure they are complete, signed and dated by the Principal Investigator (PI) or qualified study team member (in absence of PI) and is received at the ISEB office within 24hours of occurrence of the SAE.

Member Secretary shall make necessary arrangement for ethics committee to discuss the SAE and opine about opinion and compensation (where ever applicable).Minimum 3 members shall discuss the SAE. Minutes of the meeting shall be again discussed in subsequent full board meeting.

As per regulatory guidelines, Member Secretary or designated member shall report to Licensing authority (DCGI) within 30 calendar days.

G) SOP No : 11.2 :Meeting Schedule and its conduct :-

Following para is added:

Post Meeting all members shall submit documents to ISEB coordinator for destruction. ISEB members who couldn't attend meeting shall courier or submit documents personally to ISEB coordinator for destruction purpose. ISEB coordinator shall destroy documents using paper shredder. Exception: If study needs further discussion, ISEB members shall secure documents with them till final conclusion and then submit documents to ISEB coordinator for shredding purpose.

H) SOP No : 13.2 : Record Keeping :-

Following para is added:

ISEB shall follow regulatory guidelines 122 DD, serial number 4- maintenance of record.

I) References:

Following section amended:
5. Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) and recent amendments till date

Institutional Scientific and Ethics Board Version : 5 (Approval date 3rd Nov 2012)

1. Following changes done in Membership list: -
As per SOP, members had completed 3 years tenure and so few members were replaced.
Following members were requested to quit their services in order to select few new members.
Dr. Ram Narain
Dr. Suchitra Pandit
Dr. Vijaykumar Gawali
Dr. Tanu Singhal

New Members added: -

Dr. Tanu Singhal: As Clinician
Mrs. Rajni Malhotra: As Lay Person

2. ISEB secretariat constituted as follows:-
Dr. Mohit Bhatt was elected as member secretary, and Dr. Shubhangi Take appointed as ISEB Co-ordinator to assist member secretary. Roles and responsibilities of ISEB secretariat clearly defined. Following are updates in ISEB secretariat

Mailing Address ISEB :
Medical Research Department
2nd Floor
Kokilaben Dhirubhai Ambani Hospital
& Medical Research Institute,
Rao Saheb Achutrao Patwardhan Marg,
Four Bunglows, Andheri (West), Mumbai 400 053.

Mailing Address Member Secretary:
Neurology Department, 2nd Floor
Kokilaben Dhirubhai Ambani Hospital
& Medical Research Institute,
Rao Saheb Achutrao Patwardhan Marg,
Four Bunglows, Andheri (West), Mumbai 400 053.
Mobile : +919320260404
Tel: + 91 2230970284
Fax: +91-22-30970177
E –mail : mohit.h.bhatt@relianceada.com

ISEB Co-ordinator :

Dr. Shubhangi Take
Research Co-ordinator
2ndFloor , Medical research Department
Kokilaben Dhirubhai Ambani Hospital
& Medical Research Institute,
Rao Saheb Achutrao Patwardhan Marg,
Four Bunglows, Andheri (West), Mumbai 400 053.
Mobile : +91 9004773037Fax: +91-22-30970177
E –mail : shubhangi.take@relianceada.com

3. Annexures Amendment : -
Annexure 07, 08, 11 deleted.
Annexure 04, 05, 06amended

Information regarding whether it is a mandate to use these templates added as follows: It is as per the discretion of PI to utilize Annexure No 5 , 6 ,7,8,9, and 15 , PI may opt to use other format, provided it satisfies regulatory requirements and guidelines.

4. Archival of documents details incorporated :-

Documents will be archived as per requirement of national regulations.
Documents of ISEB will be archived at following address and can be made available for any regulatory authority inspection (if atleast 3 working days notice provided to ISEB).
IRON MOUNTAIN (INDIA) PRIVATE LIMITED
WORK OFF: Logitech Park,
Near Mumbai-Pune Express Highway,
Post Ajivali, Arivali Village,
Panvel, District: Raigad
Telephone: (952143) – 239273 / 239274
FAX: 02143239273

5. Other Amendments : -

Previously ISEB approval letters had a validity period from the time the approval is given by ISEB. This clause is amended and now ISEB would provide approval letter for the entire period of the study

Procedure for how ISEB members destroy their copy of protocol after review is incorporated: ISEB members as usual would handover documents to Member secretary or ISEB Co-ordinator for destruction.

Institutional Scientific and Ethics Board Version : 4 (Approval date 25 June 2011)

Name of Institutional Ethics Committee changed to Institutional Scientific and Ethics Board
Dr. Tushar Motiwala resigned from IEC and so his name deleted from Institutional Scientific and Ethics Board Membership list.

Institutional Ethics Committee Version : 3 (Approval date 13 May 2011)

Following IEC members role and designation changed :
Dr. Mohit Bhatt and Dr. Jamshed Dalal would serve as basic medical scientist.

Institutional Ethics Committee Version: 2 (Approval date 18 Sep 2010)

As per the previous SOP version:1 section 2.5-B (Tenure of Membership) the tenure of Institutional Ethics Committee members was for the period of one year from the date of appointment. As per the amendment the tenure of Institutional Ethics Committee members is revised to the period of three year from the date of appointment. Other information in the previous SOP version: 1 section 2.5-B (Tenure of Membership) was kept as it is. The changes agreed upon unanimously by all the IEC members.

INSTITUTIONAL ETHICS COMMITTEE MEMBERS LIST

No.	Name	Member Details	IEC Designation	Affiliation to Institution
1	Dr. Renuka Munshi	Qualification : M.B.B.S., M.D. (Pharmacology), DNB (Clinical Pharmacology) Expertise: ClinicalPharmacology Organisation: TN Medical College & BYL Nair Charitable Hospital Address: In-charge Dept of Clinical Pharmacology, 5th floor, G bldg, Dr AL Nair Road, TN Medical College & BYL Nair Charitable Hospital, Mumbai: 400 008. Contact: 9820377409, renuka.munshi@gmail.com	Chairperson	No
2	Dr. Varsha Vadera	Qualification: MD (Pathology) Expertise: Pathology Organisation: Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute Address: Consultant & Head - Laboratory Medicine and Advanced Diagnostics: Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute Contact: 9821097083; varsha.vadera@relianceada.com	Member Secretary	Yes

3	Mrs. Kshama D. Mankar	Qualification: B.A., L.L.B. Expertise: Lawyer Organisation: Individual Practice Address: 202/New Krishna Apt., Opp. Royal Shopping Center, Ambadi Road, Vasai (W) 401 202. Contact: 8208344311;9960730143 kshamamanker72@yahoo.com	Legal Expert	No
4	Dr. Abhishek Srivastava	Qualification:MBBS, MD, DNB, MNAMS, PhD Expertise: Neurological Rehabilitation Organisation: Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute Address: Director- Center for Physical Medicine and Rehabilitation Consultant in Rehabilitation Medicine: Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute Contact: 9324582986; abhishek.m.srivastava@relianceada.com	Clinician	Yes
5	Dr. Sharad Maheshwari	Qualification: M.B.B.S., MD (Radio-Diagnosis) Expertise: Abdominal Imaging, Scientific Review of Research Documents Organisation: Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute Address: Consultant Radiologist, Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute Contact: 9322164919; sharaddoc@gmail.com	Clinician	Yes

6	Mr. Nitin Sheth	Qualification: B.Tech (Civil) from IIT Mumbai Expertise: Ethics Organisation: Retired Address: 701, Horizon View 1/a, Raheja Complex, 7 Bungalows, Versova, Andheri West, Mumbai-400061. Contact: 9820014860; nitin.sheth@gmail.com	Lay Person	No
7	Dr. Sanjay Mehta	Qualification: M. B. B. S., MD (Internal Medicine) Expertise: Emergency Medicine Organisation: Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute Address: Director – Accident &Emergency, Consultant- Emergency Medicine & Internal Medicine: Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute Contact: 8080023456; sanjay.mehta@relianceada.com	Clinician	Yes

8	Dr. Barnali Das	Qualification: M.B.B.S., MD (Biochemistry), DNB (Medical Biochemistry), CCCR (Clinical Research) Expertise: Scientific Review of Research Documents Organisation: Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute Address: Consultant Laboratory Medicine, Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute Contact: 9324349519; barnali.das@relianceada.com	Basic Medical Scientist	Yes
9	Mr. Ravindra Dalal	Qualification:B.com Expertise: Ethics Organisation: Retired Address: 20/B Neelashish, 92 JP Road, Andheri (West), Mumbai-400058 Contact: 9833490350; ravi_dalal@hotmail.com	Lay Person	No
10	Mr. Rajiv Kamlakar Patil	Qualification: M.A. Expertise: Community Development Organisation: Pratham Infotech Foundation Address: A/14, Shivashakti Co-Op Society, Prabhadevi, Sayani Road, Dadar (W), Mumbai 400025. Contact: 9987824148; rajivpatil26@gmail.com	Social Scientist	No

11	Mr. Rohit Khude	Qualification: B.A., Master in Social Work Expertise: Community Development Organisation: Khan Bahadoor Haji Bachooali Charitable Ophthalmic & ENT Hospital, Parel Address: 110/D Laxmi Sadan, near Maval Maratha Gym., Golfadevi road, Worli Village, Mumbai- 400 025 Contact: 9664232582; rohitkhude@yahoo.com	Social Worker	No

SOP NO. 01 / 11:-PREPARING SOP

1.1 : Purpose:-

The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing and amending SOPs of Institutional Ethics Committee, Mumbai.

The SOPs provide clear, unambiguous instructions so that the related activities of the Committee are conducted in accordance with:-

- Schedule Y (Drugs and Cosmetic Act1940;
- amendment 20th January2005),
- ICMR's Ethical Guidelines for Biomedical Research on Human Participants 2 0 1 7 Indian GCP Guidelines (2001),
- WHO Operating Guidelines for Ethical Review Board that Review Biomedical Research (2000)
- The International Conference on Harmonization - Good Clinical Practices (ICH-GCP) Guidelines 2015
- Amendments from CDSCO office

1.2 : Chairperson of the IEC will:-

- Approve the SOPs
- Sign and date the approved SOPs

1.3 : Secretariat IEC :

1. Executive Director appoints Admin Manager and Co-ordinator to assist IEC Functions. Both have equal responsibilities.
2. Secretariat comprises of Member Secretary , Co- member Secretary, Admin manager and co-ordinator
3. Member Secretary shall vote in IEC decisions but Admin Manager and Co-ordinator IEC can't vote in any decision making procedure of the IEC.

1.3.1 :Member Secretary of Institutional Ethics Committee will:-

- Co-ordinate activities of writing, reviewing, distributing and amending SOPs
- Maintain on file all current SOPs and the list of SOPs
- Maintain an up-to-date distribution list for each SOP distributed
- Distribute the SOPs with a receipt to all users
- Maintain on file all past SOPs of Institutional Ethics Committee
- Propose new/ modified SOPs as needed
- Select the format and coding system for SOPs
- Draft the SOP in consultation with the IEC members and involved administrative staff
- Review the draft SOP
- Submit the draft for approval to Chairperson

1.3.2 : Co-ordinator of Institutional Ethics Committee will:-

- Maintain on file all current SOPs and the list of SOPs
- Maintain an up-to-date distribution list for each SOP distributed
- Distribute the SOPs with a receipt to all users
- Maintain on file all past SOPs of Institutional Ethics Committee
- Assist Member Secretary.

IEC members

- Sign and date the acknowledgement form when they would receive approved SOP.
- Assist in all decision making procedure of IEC.

1.4 : 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 agree to the request, the Member Secretary shall proceed with the revision process/ formulation process of the SOP. 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 with reasons for the same.

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.

1.5 : Format and layout:-

Each SOP should be given a number and a title that is self-explanatory and is easily understood. A unique code number with the format

SOP aa / bb :will be assigned to each SOP item by the Member Secretary.

aa will be a two-digit number assigned specifically to that SOP.
bb will be a two-digit number identifying the version of the SOP

The number of version should be started from 01 hence for example, SOP01/01 is the SOP number 01 with version 01.

Each annex will be given unique code number with the format AX MM/NN

AX refers to Annex Form, MM is a two-digit number identifying the number of the annex, NN is a two digit number identifying the version of the annex form

1.6 : Document Control:-

Master Copy: -This would be the original signed copy of **SOP and** will be filed in **SOP** Master file and will be under control of the Member Secretary or IEC co-ordinator. This will not be disturbed except for removal of an inactive **SOP**. This copy will have the "MASTERCOPY" stamp on it in black ink.

Controlled copies- This is a reference copy of the master copy with "CONTROLLED COPY" stamp on it with black ink.Controlled copies of the IEC SOP will be maintained in the IEC office which will be available at all times with restricted access.
Controlled copies are kept in e-format, which are given to authorized personnel whenever asked and a record is maintained.
If there is recommendation for revision, the following procedure will be followed:

-Revision is possible either by recommendations after a yearly review or any time in-between due to circumstances forcing it, but only after the approval of the IEC members.
-In-case of Revision, earlier version of **SOP** will be active till the revised SOP is approved and made effective from a DATE.
-All the controlled copies of the earlier SOP (INACTIVE) will be withdrawn, except for the original and destroyed.

Obsolete copies-This shall be the master copy of Old SOPs (Inactive) which would be marked as "OBSOLETE COPY" with red ink stamp. The obsolete copies shall be retained by the IEC as per the archival SOP.

1.7 : New SOP:-

When the need for a new SOP has been identified and agreed on, a draft will be written by Member Secretary with one / two IEC members which will then be reviewed by the other two IEC members After incorporating the suggestions put forth by the members; the copy of the revised draft SOP will be circulated to all the other IEC members.

Preparation and submission of final draft

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

Approve a new/ revised SOP

- The Chairperson signs and dates the SOP Approval page. Approved SOP shall be sent for acceptance from Executive Director. Effective date of the SOP shall be, post ten working days, from the acceptance date from the Executive Director's end. Members Secretary shall mention final effective date on SOP (Post acceptance from Executive Director), post which SOP need to be made accessible to all stake holders for reference. Member Secretary or IEC Secretariat shall courier /email the Controlled copy of approved SOP to all members.
- The SOP should be agreed upon by all Institutional Ethics Committee members.

- 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, except for one master copy of the earlier version will be placed in the file entitled 'Past SOPs of Institutional Ethics Committee.

- One complete original set of current SOPs will be filed centrally in the SOP Master file, by the Member Secretary or IEC co-ordinator of the IEC in the office of Institutional Ethics Committee.

Review and request for a revision of existing SOPs

- If the IEC members agree to the request made by any member, Member Secretary will proceed with the revision process. If the IEC members do not agree, the Chairperson will inform the person who made the request of the decision.
- Revision of the SOPs will be reviewed and approved in the same manner as a new SOP
- The Member Secretary is expected to review the SOPs at least every 3 years and record the dates of review on the SOP Master file. SOP should mention Issue Date, Revision Date and Validity Date. Revision shall occur at least once in 3Years.

Manage current and archive superseded SOPs

- Superseded SOPs will be marked "Obsolete" and archived in the file entitled 'Past SOPs of Institutional Ethics Committee by the Member Secretary or IEC co-ordinator.

1.8 : Glossary:-

- Revision date: Date/year by which the SOP may be revised or reviewed.
- Recipients: Stakeholders who would receive a copy of SOP.
- SOP (Standard Operating Procedure) : Detailed, written instructions, in a certain format, describing activities and actions undertaken by the IEC to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the functioning, whilst maintaining high standards of Good Clinical Practice.
- Institutional Ethics Committee (IEC): It is an independent body formally designated to review, approve, and monitor biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the participants. It is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human participants involved in a clinical trial and to provide public assurance of that protection.

SOP NO. 02 / 11 : Constitution, Responsibilities, and activities of the Institutional Ethics Committee.

2.1.1 :The primary purpose of this Committee will be to:-

1. Ensure the protection of the rights, safety and well-being of human subjects involved in a research project and

2. Provide public assurance of that protection.

The IEC is composed of both scientists and non-scientists. It is independent in its reflection, advice and decision.

2.1.2 : Authority for formation of IEC:

IEC is established under authority of Executive Director, Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute, Andheri, Mumbai, Maharashtra. It is administratively governed under same authority. Institution will support establishment of ethics committee including training, resources and infrastructure etc.

As per the Institution Policy statement communicated from Executive Director to IEC Chairperson, ethics committee is independent in its functioning and decision making.

2.2 :Ethical basis:-

- The Committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of a proposed research project.
- In evaluating protocols and ethical issues, the IEC is aware of the diversity of laws, culture and practices governing research and medical practices in various countries around the world and especially in India.
- The IEC also seeks to be informed, as appropriate, by other IECs approving other trial sites and researchers of the impact of the research it has approved. The IEC is guided in its reflection, advice and decision by the ethical principles expressed in Declaration of Helsinki (Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; 35th World Medical Assembly,

Venice, Italy, October 1983; 41st World Medical Assembly, Hong Kong, September 1989; 48th World Medical Assembly, Somerset West, Republic of South Africa, October 1996; and the 52ndWorldMedicalAssembly,Edinburgh,Scotland,October2000;NoteofClarificationon

Paragraph 29 added by the World Medical Assembly, Washington 2002; Note of Clarification on Paragraph 30 added by the World Medical Assembly, Tokyo 2004, 59th WMA General Assembly, Seoul, Republic of Korea, October 2008, 64th WMA General Assembly, Fortaleza, Brazil, October 2013)

- It makes further reference to the International Ethical Guidelines for e.g.: The Nuremberg Code (1945), Belmont Report (1979), The Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva 2002), and the European Convention on Human rights and Biomedicine (1997).

- The IEC established its own Standard Operating Procedures based on the Operational Guidelines for IECs that review Biomedical Research (WHO, 2000), International Conference on Harmonization - Good Clinical Practices (ICH-GCP) Guidelines (1996), Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) and Ethical Guidelines for Biomedical Research on Human Participants by ICMR(2017)

- The IEC is established and functions in accordance with the relevant national law and regulations in force from time to time.

2.3 : Composition of the Institutional Ethics Committee:

- The IEC will be multidisciplinary and multisectorial in composition
- The IEC will be composed of at least 8 to a maximum of 15members.
- The members should be a mix of medical / non-medical, scientific and non-scientific persons including lay person to represent the different points of view.
- The members should have various backgrounds to promote complete and adequate review of research activities commonly conducted by that given institute / centre.
- The IEC will have representation that is varied in terms of gender, age and social background. The Composition may be as follows:

1. Chairperson
2. One / two persons from basic medical science area
3. One / two clinicians from various institutes
4. One legal expert or retired judge
5. One social scientist / representative of non-governmental agency philosopher / ethicist / theologian
6. One lay person from community
7. Member Secretary

2.4 : Quorum Requirements:-

- Meeting will be held as scheduled provided there is quorum. A quorum will be defined as one-half of the current regular members of the Committee, rounded off to the next higher whole number as per the Schedule Y (20th January 2005), the quorum must include members with the following representations:-

  a) One Basic medical scientist (preferably one pharmacologist)

  b) One Clinician

  c) One Legal Expert

  d) One Social Scientist / representatives of non-governmental voluntary agency / Philosopher / ethicist / theologian or a similar person.

  e) One Lay person from the community.

- Decisions will be arrived at through consensus/unanimous or majority opinion amongst the voting members of IEC.
- When a consensus is not possible, the IEC will vote. Voting may be in the form of voice vote, show of hands, or by secret ballot, as determined by the Chairperson, IEC.
- All members are entitled to one vote. However, in case of a tie, the Chairperson will vote to arrive the final decision.
- Opinions of absent members that are transmitted by mail or telephone or fax may be considered by the attending members during discussion. But absent member cannot be counted as voting member or quorum member for formally convened full Committee meetings.

2.5 : Membership of Institutional Ethics Committee

:- 2.5(A) : Membership Requirements:-

- The Chairperson and Members of IEC may identify and suggest appointing new Committee members to Executive Director; Alternately Executive Director may also identify suitable new members. Executive Director appoints new members.
- Executive Director, KDAH appoints the IEC Chairperson, Co- Chairperson, Member Secretary, Co- Member Secretary and Members. The licensing authority shall be informed in writing about the constitution of the Ethics Committee or in case of any change in the membership. Institution will support establishment of ethics committee including training, resources and infrastructure etc.
- Members must submit their CV and required training certificates.
- Member Secretary designate or any other member designate should be trained in SOP and

regulations (if member designate is not trained in regulation in last one year) before attending the first meeting. Chairperson, Member Secretary or Co-Member Secretary shall conduct the training for member designate.

- Members must apprise themselves of the Schedule Y, GCP for clinical trials in India, ICH GCP guidelines, ICMR guidelines and Institutional IEC SOP and Institutional SITE SOP.
- Members are selected in their personal capacities based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC work.
- Members must disclose in writing any interest or involvement-financial, professional or otherwise- in a project or proposal under consideration.
- The IEC will decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision.
- Members will be required to sign a confidentiality agreement at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IEC in the course of it work.

2.5(B) : Tenure of Membership:-

- The tenure of Institutional Ethics Committee members will be for a period of two years from the date of appointment.
- Membership may be extended for maximum 4 Terms.

2.5(C): Appointment of new members :-

New members will be appointed under the following circumstances:

1. When a regular member completes his / her tenure.
2. If a regular member resigns before the tenure is completed.
3. If a regular member ceases to be a member for any reason including death, Disqualification.
4. To fulfill the membership requirements as mentioned above.
5. This appointment will be effective for the remaining tenure of the existing committee.

2.5(D): Resignation and Disqualification of Members :-

- Members may resign their position by submitting a letter of resignation to the Chairperson.
- Members may be disqualified from continuance should any of the IEC members provide written arguments to the Committee. There should be three fourth majorities of quorum and voting members.

- If a regular member fails to attend more than 3 meetings of the Institutional Ethics Committee in succession without prior intimation, his / her membership will be reviewed by the IEC and terminated if necessary.

2.5(E) : Roles and Responsibilities of IEC members :-

- Participate in the IEC Meeting.
- Review, discuss and consider research Proposals submitted for evaluation.
- Monitor Serious Adverse Event reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies as appropriate.
- Evaluate final reports and outcomes.
- Maintain confidentiality of the documents and deliberations of IEC meetings.
- Declare any conflict of interest.
- Participate in continuing education activities in biomedical ethics and biomedical research. IEC members should attain at least one clinical trial regulations workshop annually.
- IEC members would provide documents to Member Secretary or IEC Co-ordinator for destruction of these documents after review.

2.5(F): Terms of References:-

Common Roles and Responsibilities of IEC members in detail :-

The Committee shall:

1. Provide independent and competent review of all ethical aspects of research proposals.
2. Review research proposals submitted to it within a reasonable time and document its views in writing to the applicant(s).
3. Safeguard the dignity, rights, safety, and well-being of all study participants and communities paying special attention to investigations that may involve vulnerable participants.
4. Provide guidance to the Investigator on all aspects of the welfare and safety of research participants.
5. Obtain relevant documents including but not limited to the following:

- Ciinical Trial Protocol (including protocol amendments)
- Patient Information Sheet and Informed Consent Form (including updates if
- any) in any) in English and/ or vernacular language.
- Investigator's Brochure
- Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for

the purpose.

- Principal Investigator's current CV.
- Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.
- Investigator's Clinical Trial Agreement with the Sponsor.
- Investigator's Undertaking (Appendix VII of Schedule Y)

6. Consider the suitability of the Investigator(s) for the proposed study with respect to relevant qualification, training and experience, as documented by current curriculum vitae and/or by any other relevant documentation.

7. Review both the amount and type of benefit to participants to ensure that neither presents problems, coercion or undue influence on the study participants.

8. Review and revise SOPs from time to time not exceeding 3 years.

9. Be trained and up to date on regulatory requirements

10. When documents are no longer required, share documents to secretariat for shredding purpose, alternately member may shred documents by himself/herself.

Common Role of All Members

1. The members' (including Chairperson and Secretary) primary responsibilities will be determining the scientific and ethical validity of the research and the protection of the safety, rights and confidentiality of the research subjects.

2. Participate in the IEC meeting.

3. Review and discuss research proposals assigned for evaluation.

4. Review progress reports and monitor ongoing studies.

5. Conduct site monitoring visit, IEC Self Assessment and recommend appropriate action(s).

6. Maintain confidentiality of the documents and deliberations of the IEC meetings.

7. Declare conflict of interest, if any - Such disclosure shall be sufficiently detailed and timely to allow the IEC Administration to transfer the project to another IEC member or allow time for an alternate member to attend the IEC meeting to meet the quorum.

8. Carry out work delegated by the Chairperson, Co-Chairperson and/or Member Secretary.

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

10. Review justification for vulnerable population and specific group population.

Responsibilities of Member Secretary

1. Organization of an effective and efficient tracking procedure for each proposal received.
2. Preparation, maintenance and distribution of study files.
3. Organization of IEC meetings.
4. Preparation of the agenda and the minutes of the meetings.
5. Maintenance of the IEC records and archives.
6. Arrangement of trainings/workshops for personnel and IEC members.
7. Maintain financial records, which include details of IEC fee received, honorarium payment to members and other expenses incurred.
8. Organizing the preparation, review, revision and distribution of SOPs
9. Providing the necessary administrative support for IEC related activities to the Chairperson/Co-chairperson of the Committee.
10. Correspondence with Regulatory Authority, Chairperson, IEC Members, Investigator, Head of the Institute and patients enrolled in the Research Study.

Specific Role of Chairperson:

1. Chair the meetings
2. Facilitate and participate in IEC educational activities.
3. Keep abreast of regulations and policies governing IEC review of research and the conduct of human subjects research.
4. Appoint IEC SAE Sub – Committee members.

Specific Role of IEC Clinician/Basic Medical Scientist/Member Secretary:

1. Review scientific validity of the research study in order to make sure protection of the safety, rights and confidentiality of the research subjects.
2. Review appropriateness of study design and methodology to achieve the stated aim and objectives.
3. Review if there is enough justification of predictable risks and inconveniences weighed against

the anticipated benefits for the research participants and the concerned communities.

4. Review justification for the use of control arms (if controlled arms are involved in the study).

Specific Role of IEC Legal Person:

1. Review Clinical Trial Agreement and Memorandum of Understanding.
2. Review insurance document to ensure protection of the research participant.

Specific Role of IEC Lay Person:

1. To review informed consent document content and language - whether it would be understandable to the subjects.
2. To review documents which would be shared with patient as part of study activity.

Specific Role of IEC Social Worker:

1. To review informed consent document content and language - whether it would be understandable to the subjects.
2. To review documents which would be shared with patient as part of study activity.

2.5(G) : Independent Consultants :-

IEC may call upon subject experts as consultants for review of selected research protocols. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups
E.g. cancer patients, HIV/AIDS positive persons or ethnic minorities. They will not take part in the decision making process.

Conditions of appointment:-

Members and Independent consultants will be appointed to the IEC if they accept the following conditions.

- Willingness to publicize his/her full name, profession and affiliation.
- All IEC members and Independent consultants must sign the Confidentiality/Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.

2.5(H): Training Of Members:

Member Secretary shall arrange for courses in bioethics, applicable rules and regulations, local social and cultural norms and relevant SOPS. Members are trained on assessing the risk benefit, evaluating the scientific validity and assessing the ethical issues. Subject experts in bioethics may be called for training in ethical issues. Participate in continuing education activities in biomedical ethics and biomedical research. IEC members should attend GCP workshop once every 3 years.

- IEC members are required to continue training in required regulations and KDAHIEC SOP.

- All IEC members must be conversant with ICMR Guidelines for Research involving Human Subjects 2006, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines.

- The IEC will conduct workshops from time to time to impart training to the IEC members. The Chairperson and the Member Secretary will inform all members about any updates on ethical and regulatory guidelines regularly.

2.6 : Chairperson and Member Secretary:-

- Executive Director appoints Chairperson, Co-Chairperson, Member Secretary and Co-Member Secretary.
- Co-Chairperson has equal powers as Chairperson. Co-Member Secretary has equal powers as Member Secretary.
- It should be noted that whenever SOP mentions about Chairperson and Member Secretary, it should be understood that it is also equally applicable to Co-Chairperson and Co- Member Secretary respectively.
- The Chairperson will be responsible for conducting all Committee meetings, and will lead all discussions and deliberations pertinent to the review of research proposals. In the absence of Chairperson, Co-Chairperson shall execute chairperson's functions.
- The Chairperson will preside over all elections and administrative matters pertinent to the Committee's functions.
- In case of anticipated absence of Chairperson and Co-Chairperson, IEC members will elect Acting Chairperson among themselves. The Acting Chairperson will have all the powers of the Chairperson for that meeting.
- In case of anticipated absence of Member Secretary, Co-Member Secretary will conduct business of the meeting.
- In case of anticipated absence of both Member Secretary and Co-Member Secretary, Member Secretary shall delegate responsibility of Acting Member Secretary to Clinician or Medical Scientist to conduct business of the meeting. Designated Member shall receive proper handover from member secretary so as to properly conduct business for that particular meeting. Acting Member secretary will have all the powers of the Member Secretary for that meeting.
- Chairperson must not be affiliated with The Institution.

2.7 : The IEC Secretariat shall have the following functions:-

2.7.1 : Member Secretary shall have the following functions:-

1. Organizing an effective and efficient tracking procedure for each proposal received.
2. Preparation, maintenance and distribution of study files.
3. Organizing IEC meeting regularly
4. Preparations and maintenance of meeting agenda and minutes.
5. Maintaining the IEC documentations and to Archive the documents.
6. Communicating with the IEC members and applicants.
7. Notification of review outcome to Principal Investigator of research proposal.
8. Arrangement of training Decembers.
9. Organizing the preparations, review, revision and distribution of SOPs and guidelines.
10. Providing the necessary administrative support for IEC related activities to the Chairperson (e.g. communicating a decision to the applicant).
11. Providing updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the Committee members.
12. Signing all IEC documents Ex. Agenda, Minutes, Submission and Approval Letters, approved ICF etc.
13. Acknowledge all kind of documents submitted to IEC.
14. To receive fees and maintain record of IEC fees.
15. Member Secretary shall submit progress of IEC activities annually to Executive Director, which need to include, brief information about IEC activities, list of the research proposals reviewed and their status.

2.7.2 : Admin Manager IEC & Co-ordinator IEC shall have the following functions:-

1. Organizing an effective and efficient tracking procedure for each proposal received.
2. Preparation, maintenance and distribution of study files.
3. Organizing IEC meeting regularly
4. Communicating IEC meeting agenda to applicants and IEC members.
5. Maintaining the IEC documentations and to Archive the documents.
6. Communicating with the IEC members and applicants.
7. Notification of review outcome to Principal Investigator of research proposal.

8. Arrangement of training IEC members.
9. Organizing the distribution of SOPs and guidelines.
10. Providing the necessary administrative support for IEC related activities to the Member Secretary (e.g. communicating a decision to the applicant).
11. To receive fees and maintain record of IEC fees.
12. On behalf of Member Secretary acknowledge all kind of documents (submitted to IEC) handover these documents to Member Secretary for review and decisions of Member Secretary. If Member Secretary is not available, then handover these documents to Co-Member Secretary and if Co-member Secretary is not available, then handover these documents to Clinician, if Clinician is not available then to Basic Medical Scientists for review and decisions.

2.8 : Responsibilities of the Institutional Ethics Committee:-

To ensure that the research projects that are carried out in the hospital :

- Are sound in design, have statistical validity and are conducted according to the ICMR and ICH/GCP guidelines.
- Do not compromise safety of the patients or volunteers.
- Are conducted under the supervision of trained medical / bio medical persons with the required expertise.
- Include, solely, patients or participant who have given voluntary and informed
- Consent.
- Are planned conducted and reported in a way so that cardinal principles of research ethics viz. Autonomy, Beneficence, Non - maleficence and Justice are taken care. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required.
- Are reviewed before start of the study as well as monitor it throughout the study until and after completion of the study through appropriate well documented procedures, for example, annual reports, final reports and site visits etc. The Committee will also examine compliance with all regulatory requirements, applicable guidelines and laws.

2.9 : Alternative to Member Secretary / Admin Manager /IEC Co-ordinator

If Member Secretary / Admin manager /IEC co-ordinator are involved in a particular study then the responsibility of IEC Secretariat for that particular study will be done by Basic Medical

Scientists and if Basic Medical Scientist is not available then responsibility of IEC Secretariat will be done by IEC Clinicians.

2.10 : Glossary:

Scientific member- Individual who possesses the clinical and/or scientific knowledge and ability to effectively evaluate the research and clinical investigation.

Non-Scientific member - Individual who possesses expertise and/or experience outside scientific areas and serves to represent either vulnerable populations or local cultural and community attitudes relative to the rights and welfare of human research participants.

Non-affiliated member - Individual who is a scientific or non-scientific member, is knowledgeable about clinical or scientific matters or local cultural and community attitudes and has no association with Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute.

SOP NO. 03 / 11 : PROTOCOL SUBMISSION TO IEC

3.1 : Purpose:-

Standard Operating Procedure (SOP) implies how the Member Secretary of the Institutional Ethics Committee (IEC) manages protocol submissions to the IEC

Protocol submissions include:

- Submission for Initial Review of the Protocol
- Resubmission of Protocols with Corrections
- Protocol Amendment
- Continuing Review of Approved Protocols

Receive submitted packages

The Principal Investigator can submit research proposal to the Institutional Ethics Committee office for review and approval under any of the 5 sections mentioned below.

1. Initial Review Application
2. Resubmission of Protocols with Corrections
3. Protocol Amendment
4. Continuing Review of Approved Protocols

3.2 : Initial Review Application:-

Check for submission items

The IEC co-ordinator or member secretary will check the following items

1. A completely filled IEC Project Submission Performa for Initial Review

2. A checklist (as mentioned in Proforma) for contents of a submitted package (All the forms are available at Institutional Ethics Committee office)

Investigator shall declare any conflict of interest while submitting the documents for review. He also submits the budget of the trial to the ethics committee for financial transparency. Secretariat need to check for these documents.

Verify contents of Submitted Package:-

The IEC co-ordinator or Member secretary will:

- Use the checklist for contents of a submitted package, to verify the applicable documents to ensure that all required forms and documents are contained within the submitted package are received at the IEC office.
- Verify the completeness of the contents of the protocol submitted package to include the following documents:
- Project submission application Performa for initial review
- Submission Letter to Chairman or Member Secretary.

Protocol to include:-

1. Title of the Protocol
2. Name and contact details of Principal Investigator
3. Name and contact details of Sponsor
4. Abstract(summary/synopsis)
5. Type of Protocol (screening, survey, clinical trial and phase)
6. Objectives
7. Anticipated Outcome
8. Inclusion/Exclusion Criteria
9. Withdrawal or discontinuation Criteria
10. Schedule and Duration of Treatment
11. Modes of Treatment Studied
12. Methodology
13. Activity plan /Timeline
14. Efficacy or Evaluation Criteria(Response/Outcome)
15. Safety Parameters Criteria(Toxicity)
16. Analysis(methods)

Other Essential Documents :

- Information about Investigational Product
- Investigator's Brochure
- Amendments to protocol (if any)
- Informed consent document in English
- Informed consent document in Regional languages
- Back translations of Informed consent documents
- Back translation certificate
- Amendments to the Informed consent document (if any)
- Case Record Form
- No Objection Certificate from Hospital Management (Executive Director or Senior Manager Clinical Administration)
- Subject recruitment procedures: advertisement, notices
- Patient instruction card, identity card, diary etc.
- Regulatory permissions (as applicable)
- Principal Investigator's Curriculum Vitae
- Investigator's agreement with Sponsor
- IEC clearance of other centers if available
- No. of centers & Sample size for each center
- Clinical Trial Agreement
- Material Transfer Agreement (MTA)
- Memorandum of Understanding:
- Insurance and Indemnification policy.

- Investigator shall declare any conflict of interest while submitting the documents for review. He also submits the budget of the trial to the ethics committee for financial transparency.
- Check the total number of copies received for all documents. Three hard copies and one soft copy are required to be submitted for IEC review.

Dispatch and Store the received packages

The IEC co-ordinator or Member Secretary will

- Bind the packages together appropriately.

- Prepare required sets of all protocol and protocol related documents and circulate to members.
- Store one protocol package in the project submission cupboard in the Institutional Ethics Committee office.

Note: Back translation can be exempted if translators qualification certificates and process of translation method is submitted to IEC. IEC secretariat will have the final authority to exempt back translation on case to case basis. IEC secretariat will communicate to PI if back translations are still required even if translator's qualification certificates and process of translation method is submitted to IEC. No such correspondence from IEC office shall mean that back translation is exempted.

3.3 : Resubmission of Protocols with corrections :-

- For resubmission of protocol, if re-submission is for full Committee discussion, Principal Investigator need to submit copies equivalent to total number of IEC members and one for IEC record , and if resubmission is for secretariat review then Principal Investigator need to submit 3 copies unless particularly specified by the Member Secretary or IEC co-ordinator.

- The Member Secretary or IEC co-ordinator will verify the completeness of the checklist form and reconfirm that all the copies contain the modification highlighted with respect to the earlier protocol submitted mentioning the justification for the modification. The protocol related documents incorporating the change in the protocol are also submitted and verified by the Member Secretary or IEC co-ordinator.

- The Member Secretary or IEC co-ordinator will perform the steps as mentioned in initial review application. The protocol related documents which do not require to be changed and are already submitted for the Institutional Ethics Committee office during initial review are not resubmitted again.

3.4 : Protocol Amendments :-

- For protocol amendments , if submission is for full Committee discussion, Principal Investigator need to submit copies equivalent to total number of IEC members and one for IEC record , and if resubmission is for secretariat review then Principal Investigator need to submit3 copies unless particularly specified by the Member Secretary or IEC co-ordinator.

- The Member Secretary or IEC co-ordinator will verify the completeness of the checklist for contents of a submitted package,
- Check all the copies contain the modification highlighted with respect to the earlier protocol submitted mentioning the justification for the modification.

3.5 : Annual Continuing Reviews of Approved Protocols:-

- Principal Investigator need to submit copies equivalent to total number of IEC members and one for IEC record.
- The IEC will send reminder for annual report to Individual PI at least 30 days prior to actual annual report timeline. The IEC Secretariat will verify the completeness of the annual review report and will sign and date the documents. It will be discussed in the expedited review meeting or full Committee meeting of IEC

3.6 : Protocol Completion :-

- Principal Investigator need to submit copies equivalent to total number of IEC members and one for IEC record.
- The Member Secretary or IEC co-ordinator will verify the completeness of the Study Completion Report Form filled by the Principal Investigator

3.7 : Glossary:-

Amendment: A written description of a change(s) to or formal clarification of a protocol. Case Record Form: A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject

Case Record Form: A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial patient.

Clinical Trial Agreement: A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters.

Essential Documents: Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced

Informed Consent: A process by which a patient voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

Investigator's Brochure: The Investigator's Brochure (IB) is a compilation of the clinical and non-clinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects

Investigational Product (IP): A pharmaceutical product (including the Comparator Product) being tested or used as reference in a clinical study. An Investigational Product may be an active chemical entity or a formulated dosage form.

Investigator Undertaking (IU): A formal written, commitment (submitted to regulatory authorities) by trial investigator(s) assuring their compliance with the study protocol and all the applicable regulatory requirements.

Material Transfer Agreement (MTA): A contract that governs the transfer of tangible research materials between two organizations when the recipient intends to use them for their own research purposes.

Memorandum of Understanding: A document intended to describe a bilateral or multilateral agreement between parties. It is often a preliminary document and is generally not intended to create a legal commitment between the parties but to set out the working principles of the relationship.

Study Protocol: A document that describes the objective(s), design, methodology, statistical considerations and organization of a trial.

4.1 INITIAL REVIEW

4.1.1 :Purpose :-

This SOP applies to the review and assessment of all protocols submitted for initial review and approval from the IEC. Relevant points made during discussion and deliberation about a specific protocol should be recorded in the minutes of the meeting. The decision reached by the IEC and the reasons for its decision is recorded on the IEC Decision letter.

Responsibility

IEC Secretariat will email protocol and related documents to the respective Institutional Ethics Committee members (hard copies shall be shared to those members who have requested for hard copies). The IEC Member Secretary or IEC co-ordinator will telephonically inform the members of the IEC document packet and also reconfirm the receipt of the IEC document packet by the IEC members telephonically or through email.

The Institutional Ethics Committee member will notify the IEC Member Secretary or IEC co-ordinator if there are documents missing or the specified date of the IEC meeting cannot be met.

4.1.2.1 :Review the protocol:-

- PI to submit documents to IEC at least three weeks in advance to IEC meeting. The Institutional Ethics Committee member will check the Project Application Proforma for completeness of the information and signatures of the Principal Investigator. Chairman or Member Secretary, on case to case basis may permit dossier submission which is not within the specified submission timeline.
- The protocol will be reviewed by each member as per guidelines to review a study protocol
- The Institutional Ethics Committee member will consider the following criteria when performing the review of the study protocol:
    - minimize risks to participants;
    - risks must be reasonable in relation to anticipated benefits;
    - participants are selected equitably;
    - informed consent is adequate, easy to understand and properly documented;
    - the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants, where appropriate;

- there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data, where appropriate and
- Appropriate safeguards are included to protect vulnerable participants.
- Ensure that the advertisements do not induce the participants and that principal Investigator has a recruitment policy to ensure unbiased selection of adequate number of suitable subjects according to the protocol.

4.1.2.2 Specific Responsibilities to members for study documents review

The Ethics committee assigns responsibilities to the members with the objective to involve every member in decision making process. There should be every attempt to ensure meaningful participation of lay person, social scientist and legal person.

- There may be primary reviewers for the protocol
- The Legal person of the Ethics committee may be the primary reviewer of the contract (in evaluating the contract to ensure protection of the research participant, indemnification and arbitration)
- Lay person may be the primary reviewer for the informed consent document language - whether it would be understandable to the subjects.
- Clinicians and Medical Scientists may be the primary reviewers of scientific aspects of the studies. Other members may also review scientific aspects. Following mentioned elements shall be considered while reviewing scientific aspects of the study. They shall consider following elements while reviewing scientific aspects of the studies.

    1. Appropriateness of study design and methodology to achieve the stated objectives.
    2. There is adequate conceptual or clinical framework, design, methods and analyses to achieve the aim of the study.
    3. The statistical methodology (including sample size calculation), is adequately justified to draw sound conclusions.
    4. There is enough justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.
    5. The justification for the use of control arms (If controlled arms are involved in the study).
    6. Criteria for prematurely withdrawing research participants, and criteria for suspending or terminating the research as a whole.
    7. There is adequate rationale to conduct the study and to contribute to existing scientific knowledge or clinical practice .Or whether study intends to validate, prove or disapprove the validity of existing knowledge.

8. For pilot study design, there needs to be potential to lead into a larger and high impact study.
9. There is enough rational that study challenge existing clinical practice, contributes in addressing critical barrier to progress in the respective field. Whether overall study design is such that results of the study can be published.
10. Regulatory permission for conduct of the study, including but not limited to Health Ministry Screening Committee clearance for international collaborative studies, Memorandum of Understanding and Material Transfer Agreement for national and international collaborative research.

4.1.3 : Examine the qualification of investigators :-

- The IEC members must consider whether the qualifications and training background of the participating investigators relate to the study by reviewing their CVs.
- The IEC members must examine disclosure or declaration of potential conflicts of interest
- The IEC members must confirm whether the facilities and infrastructure at study sites can accommodate the study by reviewing the qualification of study team and by necessary discussion with PI.

4.1.4 : Review study participation:-

4.1.4.1 : Informed Consent Review (Overall Review)

The IEC member will examine for the presence of the following points while reviewing the patient information sheet/Informed Consent Form as per guidelines to review Informed Consent Document/Patient Information Sheet

- Voluntary, non-coercive recruitment/participation /withdrawal
- Procedures for obtaining informed consent
- Contents of the patient information sheet - title, objective, study design and procedures
- Contents and language of the informed consent document
- Translation and back translation of the informed consent document in the local languages
- Language used – plain and easy to understand by general public
- Contact persons with address and phone numbers for questions about subject's rights and studyorinjury
- Privacy and confidentiality
- Risks and discomforts – physical / mental / social

- Alternative treatments
- Benefits – to participants and to others
- Compensation for participation / for injury– reasonable/unreasonable
- Involvement of vulnerable participants
- Provisions for medical/psychosocial support
- Treatment for study related injuries
- Use of biological materials

- Check for provision for signatures with dates of participant, person conducting informed consent discussion, investigator and witness

Examine community involvement and impact.

The IEC members will also consider the following points in the protocol, Informed Consent Form/ Patient Information Sheet

- Community consultation
- Involvement of local researchers and institutions in the protocol design, analysis and publication of the results
- Contribution to development of local capacity for research and treatment
- Benefit to local communities
- Availability of study results

4.1.4.2 : Informed Consent Form review with respect to associated risks and benefits of the trial.

IEC members shall review consent form. Lay person and Social Worker shall have specific responsibility to review consent form. Review shall be done to make sure that subjects are well informed of all the risks and benefits in the clinical trial initially and whenever there is new information available, patient information sheet is amended and patient is informed of such changes on an on-going basis throughout the trial period. Subject should be assured that he/she will receive information that becomes available during the course of the research relevant to their participation including their rights, safety, and well-being. New safety information should be promptly communicated to subjects and should be documented in the source notes and re-consenting should be done in a timely manner (as and when new information is received).

Informed consent document should include the risks and benefits of the trial in a language that the subject can easily understand.

Investigator / designated person is authorized to take informed consent and need to maintain complete narration of the process for obtaining informed consent, including the identification of those who consented patient. Narration should include written and oral information to be given

to the research participants, and, when appropriate, their Legally Acceptable Representative(s) (LAR) and/or Impartial witness (wherever applicable).

There need to be justification whenever LAR and Impartial witness are involved in the consent process.

Legally Acceptable Representative: An individual or judical or other body authorized under applicable law to consent, on behalf of a prospective participant, to the participant's involvement in the clinical trial.

a. Spouse of the person
b. An adult son or daughter of the person
c. A custodial parent of the person
d. Any adult brother or sister of the person
e. Any adult grandchild of the person
f. The guardian of the person having the authority to make health care decisions for the person
g. An available adult relative with the closest degree of kinship to the person

Impartial Witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the participant or the participant's legally acceptable representative cannot read, and who reads the ICF and any other written information supplied to the participant. The impartial witness should also sign and date the consent form in addition to the participant or participant's legally accepted representative.

There needs to be provision made for addressing to queries and complaints from research participants or their representatives during the course of the study.

New safety information should be promptly communicated to subjects and should be documented in the source notes and re-consenting should be done in a timely manner.

Members may use checklist to verify contents of the Patient Information Sheet:

Checklist for reviewing Patient Information Sheet and Consent Form	
1	Voluntary, non-coercive recruitment/participation / withdrawal
2	Procedures for obtaining informed consent
3	Contents of the patient information sheet - title, objective, study design and procedures
4	Contents and language of the informed consent document
5	Translation and back translation of the informed consent document in the local languages

6	Whenever necessary provision for assent form
7	Proper justification whenever vulnerable and special group patients need to be enrolled
8	Language used – plain and easy to understand
9	Contact persons with address and phone numbers for questions about subject's rights
10	Privacy and confidentiality of patient is covered
11	Adequate information on risks and discomforts – physical / mental / social
12	Provision for subjects are informed and comprehend (initial and ongoing) of the associated risks and benefits of the trial
13	Explanation of Alternative treatments
14	Mention of Benefits – to participants and to others (If there is any)
15	Medical Management Provision for injuries due to study participation .
16	Compensation for participation / for injury
17	Check for provision for signatures with dates of participant, person conducting informed consent discussion, investigator and witness
18	Patient address , Nominee Details and annual Income
19	If Audio Consenting is required , availability of separate Audio- Video Consenting (Seeking permission from patient for audio video recording)before beginning Audio Video Consenting Process
20	Provision for sharing copy of signed and dated consent form to the patient.

4.1.4.3 : Patient Charter

At the time of consenting, patient Charter mentioning rights and responsibilities should be offered to the patient in a language that the subject can easily understand. There need to be documentation and evidence that such a charter is offered to the patient.

Patient Charter should include Patients' Rights and Responsibilities as mentioned below.

Rights of Research Participant:

- Right to voluntary participate in the Research Study.
- Right to information about Research Study in an understandable language.
- Right to information regarding investigational product, duration of study, treatment options available as per standard of care, anticipated expenditure, information on medical management of any injury and compensation in case of any study related injury or death or any compensation provided for participation , in an understandable language.
- Right to be informed of the risks, benefits and alternatives of proposed treatment.

- Right to know about Institutional Ethics Committee and its responsibilities towards protecting patient's rights, safety and well-being involved in a research project and to provide public assurance of that protection.
- Right to get contact details of Chairperson and Member Secretary of Institutional Ethics Committee.
- Right to informed consent and if necessary audio-video consent before participation in any Research Study.
- Right to privacy and confidentiality.
- Right to refusal of participation or withdrawal of participation at any point in the study without disclosing any reason.
- Right to be informed on how to voice a complaint to express concerns, violation of rights and/or grievance.
- Right to receive quality healthcare in a safe, clean environment without discrimination on the basis of race, age, color, religion, nationality, culture, ethnicity, language, disability, sex or manner of payment.
- Right to be treated with dignity, respect and courtesy in a non-judgmental and non-threatening manner.
- Right to consent for diagnostic and therapeutic procedures.
- Right to access clinical records.
- Right to get 24 hours emergency contact details of research study team.

Responsibilities of Research Participant:

- To provide correct and complete demographic information including full name, age, address, telephone number and e-mail ID (If available).
- To be compliant with Research Protocol and Procedures.
- To follow instructions, advice and restrictions regarding treatment plan and visit schedules.
- To ask question whenever any information (ex. research study details, diagnosis, treatment…).explained by research study team or other healthcare team members, is not understood or any clarification is required.
- To immediately inform research study team, in case of any injury or development of any new medical condition.
- Not to consume any medications without the knowledge of research study team.
- To disclose to research study team if currently part of any other Clinical Trial or had participated in any other Clinical Trial in last one year, on the first visit itself.
- Provide complete and accurate information about current health status including previous medical history, and all the medications currently ongoing including alternative treatments like Ayurveda, Homoeopathy, Unani or Herbal Medications , all records of previous investigations ,treatment and of allergic reactions especially sensitivity to any drug.
- To treat hospital staff and study team with courtesy.

4.1.4.4 : Waiver for written Consent:

The purpose of this subsection is to describe the type of research studies for which the IEC may approve for waiver for written Consent to the Participants.

Applicant should submit waiver of consent request to IEC along with dossier as per annexure is Specifying the reasons for the consent waiver

The IEC Secretariat shall check if the concerned documents are filled completely and the required list of documents is enclosed.

While reviewing such application The IEC will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining confidentiality of the study data.

The decision whether to grant the waiver can be taken during expedited or full board review.

The decision regarding approval/disapproval of waiver should be informed to the Principal Investigator in writing, also reasons should be mentioned if waiver request is disapproved.

Type of research projects which may qualify for consent waiver:

1. The proposed research presents no more than minimal risk to subjects. (ICMR guidelines) e.g. a retrospective review of patient case records to determine the incidence of disease/ recurrence of disease. Minimal risk would be defined as that which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests.
2. In case of telephonic interviews, waiver of written informed consent may be approved however in such cases verbal consent may be obtained.
3. Research on publicly available information, documents, records, work performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies.
4. Research on anonymised biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognized institutions or qualified investigators, samples or data from repositories or registries and data, documents, records, or specimens that have been collected for non-research (clinical) purposes.
5. In emergency situations when no surrogate consents can be taken. (ICMR guidelines) when consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible, the IEC can allow waiver of consent for recruiting participant in a

research study. However, informed consent should be administered whenever participant regains consciousness / capacity to voluntary consent.

6. When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout research as maybe required by the sensitivity of the research objective. (ICMR guidelines).e.g. conducting interviews with citizens about their religious beliefs/ people with HIV and AIDS/conducting phone interviews with homosexuals.

4.1.5 : Institutional Ethics Committee decision:-

- If the IEC decision is 'Approved', it implies the approval of the study as it is presented with no modifications and the study can be initiated.
- If the IEC decision is 'Approved with recommendation', it implies that
  - ✓ Requires modifications to items noted in the query letter and project to be re-submitted for review for full Board.
  - ✓ Expedited review to be performed by at least 2 members designated by the Chairperson.
- If the IEC decision is 'Dis-Approved', it implies that the study is Dis-approved in its presented form.

<u>Full Committee review of the documents if :</u>

- Even if any one of the IEC members raises an objection for expedite process, the objections are noted in the minutes and conveyed to the Principal Investigator as query letter. If any member/ members of the Committee is /are participating in the research project under discussion, they will opt out from all deliberations on the project. This will be recorded in the minutes of the meeting. The investigator/sub-investigator may be called in to provide clarifications on the study protocol that he/she has submitted for review to the IEC.
- If the study is approved, the Committee determines the frequency of Continuing Review from each investigator.
- The Member Secretary will list participating members in the meeting and summarize the guidance, advice and decision reached by the IEC members.

4.1.6 : Final communication of the IEC decision taken on the project to the Principal Investigator:-

- The Member Secretary or IEC co-ordinator sends an approval letter to the principal investigator when the IEC decision is approved.
- The letter contains, at a minimum, a listing of each document approved, and a review of other obligations and expectations from the investigator throughout the course of the study.
- The approval is for the entire duration of the approved study.

- The IEC Decision Letter is signed by the IEC Chairperson or IEC Member Secretary and sent to the Principal Investigator within 10 working days.
- If the Committee reaches a consensus to disapprove the study, the Member Secretary or IEC co-ordinator immediately notifies the investigator in writing about the decision and the reason for not approving the study. A notifying letter to the investigator should state the following: "If you wish to appeal to this decision, please contact the IEC and submit your appeal in writing, addressed to the IEC Chairperson or IEC Member Secretary with justification as to why the appeal should be granted".
- If the Committee requires modifications to any of the documents, the Member Secretary sends a written request of the specific changes in the form of query letter to the investigator asking him or her to make the necessary changes and resubmit the documents to the IEC. The Principal Investigator has to respond to the query within 90 Days of receipt of the Query Letter.
- If the Principal Investigator fails to reply within 90 working days the project is declared closed for IEC records.
- The Member Secretary or IEC co-ordinator will verify the correctness of the wordings and spelling in all the letters and process all the above tasks within 10 days after the meeting.
- The Member Secretary or IEC co-ordinator will keep a copy of the Approval letter/Query letter/Disapproval letter in the project file along with all the reviewed documents.
- Letter should specify , If any regulatory clearance , CTRI registration pending with note that study may be initiated only post required regulatory clearances and CTRI registration (where applicable).

•Principal Investigator is also required to communicate with IEC about initiation of patient recruitment.

4.2 EXPEDITED REVIEW:-

4.2.1 :Purpose:-

Standard Operating Procedure (SOP) implies to provide criteria for determination of which study protocols can be reviewed through as well as instructions on management, review and approval of the expedited review

This SOP applies to the review and approval of study proposals with minimum risk to participants, protocol amendments or informed consent changes of currently approved studies.

It is the responsibility of the Institutional Ethics Committee (IEC) members to define of which study protocols should be reviewed and approved through expedited channel.

Expedite review can be done in following 2 conditions:

1. If IEC final decision in Full Board Meeting mentions expedited review of amended documents.
2. If PI request any study document to review in expedite review process.

Upon receipt of the Expedite review document package, the Member Secretary or IEC co-ordinator will inform the Chairperson of the IEC verbally and share documents for chairperson review. Chairperson and member secretary would decide if study documents can be reviewed in expedite process. Member secretary or IEC co-ordinator will communicate this decision to PI.

4.2.2 :Receive the submitted documents:-

- The Member Secretary or IEC co-ordinator will receive any of the following documents which can be submitted for Expedited Review.

1. Submission Letter, Protocol and protocol related documents submitted by the investigators for projects sent for review for the first time.
2. Protocol amendments and related documents
3. Re-submitted protocol

- The Member Secretary or IEC co-ordinator will get the contents of submitted package (checklist) form, as per to check items received and stamp the receiving date on the documents.

4.2.3 : Determine protocols for expedited review:-

The IEC Member Secretary and Chairperson will determine whether a study is qualified for expedited review according to the following criteria:

1. Proposals submitted for initial review satisfying any of the following criteria

- Interviewing of a non-confidential nature, not likely to harm the status or interests of the individual.
- Collection of data for research purposes through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice and using medical devices which have been already approved for use. Examples of such procedures include collection of data through application of EEG or ECG electrodes, acoustic testing, tests using the Doppler principle, non-invasive blood pressure and other routine clinical measurements, exercise tolerance etc. However procedures involving the use of x-rays or microwaves are NOT recommended for expedited review.
- Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis.

3. Modification /amendment of protocol & related documents (approved earlier) if the change involves any of the following:

- Administrative revisions
- Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc.
- Non-significant risk research activity
- The research activity includes only minor changes from previously approved protocol.

2.1.1.1.Project reviewed earlier and IEC decision was to 'Approve after the Principal Investigator incorporates the suggestions to be subjected for Expedited Review

4.2.4 : Expedited Process:-

- Chairperson nominates 2 or more IEC members to review the revised protocol, who then report the decision to the full Committee meeting. An expedited review is a speedy one for minor changes to the approved protocol and for research proposal with minimal risk in nature.
- The Member Secretary or IEC co-ordinator sends the revised protocol to the selected members who will perform the expedited review on the complete proposal
- If consensus cannot be reached, the members conducting expedite meeting will refer the proposal back to the IEC for a full review. The IEC decision will be recorded on the IEC Decision Form.
- The expedited review should not take longer than 14 Working days post submission of amended documents from Principal Investigator.
- The Member Secretary will inform the IEC members of the proposals approved by expedited review at its regular meetings and source documentation of the items in the meeting agenda / notes.

4.2.5 :Communicate with the IEC and the Principal Investigator:-

- The Member Secretary or IEC co-ordinator will forward the Project IEC Decision letter to the Principal Investigator.
- If it is approved, disapproved or requires resubmission after certain modifications, this is informed to the Principal Investigator in writing within 5 Working days.

4.3 :RESUBMITTED STUDY PROTOCOLS REVIEW:-

4.3.1 :Purpose :-

This SOP applies to study protocols that have been reviewed earlier with recommendations from IEC for some corrections in the initial review process.

IEC Member Secretary or IEC co-ordinator will ensure the completeness of the resubmitted documents and to notify the Chairperson that a protocol previously approved with conditions for revision has been resubmitted to the IEC for reconsideration.

A re-submitted protocol may be reviewed and approved by either the Chairperson or some IEC members designated by the Chairperson, or full IEC as per IEC decision determined by the IEC at the time of the initial review of the project during the full Committee IEC meeting.

Resubmitted Protocol should be submitted with following documents.

- Reply to the query letter addressing the corrections, within 90 days of receipt of the letter
- Revised version of protocol and related documents such as the informed consent document, data collection or case report forms, diary sheets, etc are included as part of the package with the changes made to the documents are underlined or highlighted.

4.4 :AMENDED PROTOCOL &DOCUMENTS REVIEW:-

4.4.1 :Purpose :-

Institutional Ethics Committee (IEC) will manage and review amended protocol/ protocol related documents if they are previously approved study protocols but later being amended.

Amendments made to protocols will not be implemented until reviewed and approved by the IEC.

The Member Secretary or IEC co-ordinator will confirm the request for Amendment Memorandum of the Protocol/Protocol related documents from the Principal Investigator on an existing and previously approved Protocol/Protocol related documents. The memorandum should:

- state/describe the amendment
- provide the reason for the amendment
- state any untoward effects with original protocol
- state expected untoward effects because of the amendment

The changes or modifications should be underlined or highlighted or Summary of changes to be submitted.

• Review process would be similar as initial review.

4.4.2 : Full Committee Review for amended protocol/ protocol related document:-

The Protocol amendment which increases risk to study participants, as judged by the Chairperson and Member Secretary, such as a change in study design, which may include but is not limited to:

- Additional treatments or the deletion of treatments any changes in inclusion/exclusion criteria.
- change in method of dosage formulation, such as, oral changed to intravenous
- significant change in the number of subjects if the decrease/increase in the number of subjects alters the fundamental characteristics of the study, it is significant.
- significant decrease or increase in dosage.

Expedite review or Initial review guidelines would remain the same.

4.4.3 : Communication of the Decision to the Principal Investigator:-

- If the IEC approves the protocol amendment, the Member Secretary or IEC co-ordinator communicates this decision to the Principal Investigator. The Member Secretary or IEC co-ordinator sends a signed and dated Amendment Approval letter to the Principal Investigator (P.I.) for their records no later than 10 working days of the meeting of the IEC
- If the IEC does not approve the protocol amendment, the Member Secretary or IEC co- ordinator immediately notifies the Principal Investigator in writing of the decision and the reason for not approving the amendment
- If the IEC requires modifications to any of the documents, or the protocol amendment, the Member Secretary sends a written request about the specific changes to the Principal Investigator asking him or her to make the necessary changes and resubmit the documents to IEC

Store documents.

- The Member Secretary or IEC co-ordinator will keep the forms, minutes of the meeting relevant to the discussion and the decision reached by the IEC as the official records of the amendment review process.
- The Member Secretary or IEC co-ordinator will place the original completed documents, the amended version of the protocol and related documents in the protocol file with the other documents pertaining to the amendment.

4.5 : Periodic Review

Periodic review of trial shall be done for continuation, risk evaluation and adverse event monitoring.

Periodic review is review of the trial status and analysis of risk to subjects in an ongoing trial previously approved by the ethics committee. Periodic review can be once in three months or six months depending on the risk status of the trial or if it involves vulnerable population. Principal Investigator (PI) is made aware of the periodicity to submit the documents for review. It can be communicated through final IEC decision letter to PI.

IEC has the authority to revert the decision of a proposal initially approved based on the periodic assessment of risk to the trial subject.

4.6 : Glossary

Document: Document may be of any forms, e.g., paper, electronic mail (e-mail), faxes, audio or video tape, etc.

Expedited review/meeting: An expedited review is an accelerated review of research proposal with minimal risk, minor changes to the approved protocol and documents of minor nature. A review process is by members designated by Chairperson and the decision is notified to the full board.

Exemption from review: A research study is said to be exempt from review when it does not require the IEC approval for its conduct.

SOP NO. 05 /11 : DEVIATION/NON-COMPLIANCE/VIOLATION

5.1 : Purpose:-

The purpose of this Standard Operating Procedure (SOP) is to provide instructions for taking action and maintaining records that identify investigators/trial sites that fail to:

- Follow the procedures written in the approved protocol,
- Comply with national / international guidelines or procedures mandated by the Institutional Ethics Committee (IEC) for the conduct of human research.
- Respond to the IEC requests regarding statutory, ethical, scientific or Administrative matters.

5.2 : Detection of Protocol deviation/ non-compliance/ violation:-

The Protocol deviation/non-compliance/violation can be detected in any of the following ways:

1. The Institutional Ethics Committee members performing monitoring of the project at trial site can detect protocol deviation/non-compliance/violation.
2. The Member Secretary or IEC co-ordinator can detect protocol deviation/non-compliance/violation for failure to comply with statutory requirements/failure to respond to requests from Institutional Ethics Committee within reasonable time limit/failure to respond to communication made by Institutional Ethics Committee.
3. The Principal Investigator himself may forward protocol deviation/non-compliance/violation reports to inform the Institutional Ethics Committee.

<u>Noting protocol deviation / non-compliance / violation by the Member Secretary:</u>

- The IEC members who have performed monitoring of a particular trial site and detect protocol deviation/non-compliance/violation will inform the Member Secretary or IEC co-ordinator.
- Member Secretary or IEC co-ordinator would keep record of protocol deviation/non-compliance/violation from the project files/protocol deviation/non-compliance/violation letters forwarded by the Principal Investigator or forwarded by IEC members.
- Whenever protocol deviation / non-compliance / violation has been observed the Member Secretary will ensure that the issues as well as the details of non-compliance involving research investigators are included in the agenda of the Full Committee Institutional Ethics Committee meeting.
- The ethics committee should evaluate protocol violations to make sure to track for injury to the subject due to noncompliance of protocol.

5.3 : Institutional Ethics Committee Decision:-

- If the protocol deviation / non-compliance / violation is detected by IEC member during monitoring visit he/she will forward these findings to Member Secretary . Member secretary will discuss the findings with Chairperson and decision will be taken whether to discuss in regular upcoming meeting or emergency meeting required to discuss these findings.
- IEC will review and will take any one of the following action in 'consensuses'.
  - Ask PI for required training to avoid deviation.
  - Suspend the study till information available
  - Terminate approval of the current study
  - Refuse subsequent applications from an investigator cited form on-compliance.
- The IEC will take appropriate action depending upon the nature and severity of deviation / non-compliance/violation.
- This action is recorded by Member Secretary or IEC co-ordinator.

5.4 : Notification to the Principal Investigator:-

- The Member Secretary or IEC co-ordinator will send a recommendation letter signed by the Institutional Ethics Committee Chairperson or member secretary to the Principal Investigator if the decision was 'request the Principal Investigator not to perform such deviations/non-compliances/violations in future'.
- The Member Secretary or IEC co-ordinator will send a project suspension/termination letter signed by the Institutional Ethics Committee IEC Chairperson or member secretary to the Principal Investigator if the decision was 'suspend the study till information available/terminate approval of the current study'.
- If the decision was 'refusal of subsequent project applications from the Principal Investigator, this notification letter signed by Institutional Ethics Committee IEC Chairperson or Member Secretary will be sent to the Principal Investigator.
- The copy of Project suspension/ project termination/ Principal Investigator notification of refusal to accept application from him/her due to Non-compliance will also be sent to the DCGI/Sponsor.
- OnecopyofallthelettersiskeptintheprojectfilebytheMemberSecretaryorIECco-ordinator.
- The Member Secretary or IEC co-ordinator will maintain a file that identifies investigators who are found to be non-compliant at monitoring visits or with national/international regulations or who fail to follow protocol approval stipulations or fail to respond to the IEC request for information / action.

5.5 : Glossary:

Protocol deviation: Changes or alterations in the conduct of the trial which do not have a major impact on the participant's rights, safety or well-being, or the completeness, accuracy and reliability of the study data.

Protocol violation: A protocol deviation that may affect the participant's rights, safety, or well being or alter the risk benefit ratio, and/or affect the participants' willingness to participate in the study, and/or impact the completeness, accuracy and reliability of the study data.

Non-compliance: Non-performance of the study in compliance with the approved protocol, national regulations, ICH GCP, and other applicable regulations and/or failure to respond to the IEC request for information / action.

SOP NO. 06 / 11 : INDEPENDENT CONSULTANT

6.1 : Purpose:-

The purpose of this Standard Operating Procedure (SOP) implies procedures for engaging the expertise of a professional as an Independent Consultant (IC) to the Institutional Ethics Committee (IEC).

- During the review process of any given clinical project which involve procedures or information that is not within the area of expertise of the IEC members, the Chairperson/ Member Secretary on behalf of the IEC may invite individual/individuals with competence in special area(s) to assist in the review of issues that require expertise beyond or in addition to those available with the IEC.
- The Independent Consultant will be identified by the IEC members.
- The IEC members will conduct a qualification review of the prospective consultant and make a decision based on expertise, availability and independence criteria.
- The IEC Chairperson will nominate the Independent Consultants whose expertise will be taken for the given clinical project.
- The Member Secretary or IEC co-ordinator will contact the consultant and request him/her to provide : A curriculum vitae

6.2 :Selection of Independent Consultants:-

- The CV of the Independent Consultant will be reviewed by the IEC members and final approval from the IEC Chairperson to refer the project to the specified Independent Consultant will be taken by the Member Secretary. If majority of IEC member disagrees with the selection of the Independent Consultant, the above procedure will be repeated procedure and a new Independent Consultant will be selected.
- The Independent Consultants will sign and date both the copies of the Confidentiality / Conflict of Interest Agreement document before receiving any study related documents.
- They will give the forms back to the Member Secretary to obtain sign and date of the IEC Chairperson. The Member Secretary will obtain the signatures of IEC Chairperson and forward one copy of the Confidentiality / Conflict of Interest Agreement to the Independent Consultant for their records (duly signed and dated by them and IEC Chairperson).
- The Member Secretary or IEC co-ordinator provides study protocol documents to the appropriate consultant for review.

- Name and qualifications of the experts and representatives should be documented, their attendance and viewpoints should be reflected in the meeting minutes.

- The Independent Consultant could be invited to attend a meeting if deemed necessary by the Chairperson/ IEC members for getting additional information/ clarifications. However, the Independent Consultant should not be study team member for study under review. He / She can also be contacted for additional information or clarifications if sought by the Chairperson / Member Secretary/ IEC members. All communications from the IEC should be routed through the Member Secretary or IEC co-ordinator. Name and qualifications of the experts and representatives should be documented; their attendance and viewpoints should be reflected in the meeting minutes.
- As the Independent Consultant is appointed for a particular task or project, the services get automatically terminated once the final decision regarding the project is taken by the IEC.
- Remuneration for Independent Consultant will be provided to reimburse expenses on travel, time spent, documents referred to in library/ internet, incidental expenses.

6.3 :Glossary:-

Independent Consultant: An expert who gives advice, comments and suggestion upon review of the study protocols with no affiliation to the institutes or investigators proposing the research protocols.

SOP NO. 07 /11 : PREMATURE TERMINATION OF A RESEARCH STUDY

7.1 : Purpose:-

Standard Operating Procedure (SOP) implies to describe how the Institutional Ethics Committee (IEC) proceeds and manages the premature termination of a research study.

Protocols are usually terminated at the recommendation of the IEC, Data Safety Monitoring Board (DSMB), Principal Investigator, sponsor or other authorized bodies wherein subject enrollment and subject follow-up are discontinued before the scheduled end of the study.

This SOP applies to any study approved by IEC that is being recommended for termination before its scheduled completion.

- The Member Secretary or IEC co-ordinator will receive recommendation and comments from DSMB, Principal Investigator, Sponsor or other authorized bodies for premature termination of study protocol.

7.2: The IEC members/Chairperson can prematurely terminate the study if:-

1. Protocol non-compliance/violation is detected and IEC decision is to terminate the study.
2. SAE occurring at trial site may require the study to be prematurely terminated for the safety of the patients.

- The Member Secretary or IEC co-ordinator will inform the Principal Investigator to submit Premature Termination Report.
- The Member Secretary or IEC co-ordinator will verify the Premature Termination Report signed and dated by the Principal Investigator should contain a brief written summary of results, and accrual data.
- The Member Secretary or IEC co-ordinator will check the completeness of the information, including accrual data since the time of the last continuing review.
- The Member Secretary or IEC co-ordinator will initial and date the package upon receipt.

7.3 : Institutional Ethics Committee Decision:-

- The Member Secretary will notify the Chairperson regarding the recommendation for premature termination of study protocol and send a copy of the termination package to the Chairperson within one working day upon receipt.

- The Chairperson reviews the results, reasons and accrual data and calls for an emergency meeting/regular Full Committee meeting to discuss about there commendation.
- The Member Secretary or IEC co-ordinator will do the necessary arrangement as per decision of chairperson.
- The Member Secretary in the meeting will inform of the premature termination of the project and the IEC members will review the Premature Termination Report
- The Chairperson / Member Secretary sign and dates the study termination report in acknowledgment and approval of the termination.
- If the Premature Termination Report is unclear/more information is required from the Principal Investigator the Member Secretary or IEC co-ordinator is instructed to send a query letter to the Principal Investigator.

Store the protocol documents.

- The Member Secretary or IEC co-ordinator will keep the original version of the Premature Termination Report in the Protocol file and send the file to archive.
- The protocol documents will be archived as per guidelines specified in IECSOP.
- If query letter is sent to Principal Investigator, on receipt of the reply letter, it is reviewed in the forthcoming Full Committee meeting

SOP NO. 08 / 11 : Serious Adverse Event :-

8.1 : Purpose of SAE Subcommittee

- The SAE Subcommittee will review serious adverse events (SAE) occurring in studies approved by IEC at Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute.
- The committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of adverse event reports involving human participants.
- The SAE Subcommittee shall function as per IEC SOP and relevant national law and regulations in force from time to time.
- Notified safety information at other sites shall be discussed in Full Board.

8.2 : Composition of the SAE Subcommittee

- The SAE Subcommittee will be appointed by the IEC Chairperson for tenure of 2years
- The SAE Subcommittee will be comprised of Member Secretary and at least 3 other Members.
- Quorum of at least three members from SAE Sub-committee shall be required to conduct SAE review meeting.
- All members will be from Existing IEC Members list , preferably should be from medical and scientific backgrounds
- IEC Secretariat shall look after conduct of the Sub-committee.
- Current SAE Sub-committee.

8.3.1 : On-Site SAE Reports Review:

- If Patients enrolled at site experiences SAE ,Principal Investigator needs to submit SAE report within 24 hours of their occurrence and with due analysis within 14 calendar days and necessary follow up reports .Sponsor needs to submit SAE report with due analysis within 14 calendar days.
- PI is required to share information on compensation is paid to the subject as per informed consent document contract and applicable rules and regulations. The amount paid should be approved (to be verified only) by the ethics committee.
- In case of pregnancy as SAE , PI to send follow up reports of the child in utero and post delivery of the baby till 1 year.
- The IEC Secretariat will receive the SAE report or the unexpected event report occurring at the trial sites approved by the IEC for a given project. The IEC Secretariat will review reports to make sure they are complete, signed and dated by the Principal Investigator (PI) or qualified

study team member (in absence of PI)and is received at the IEC office within 24 hours of occurrence of the SAE.

- IEC Secretariat will verify that the report for it's completeness and also shall verify if stipulated timelines are followed as per relevant regulations.
- Members (SAE sub-committee) reviewing SAE documents shall evaluate if adequate medical care is provided for serious adverse events as per applicable rules and regulations
- SAE reports will be reviewed by SAE sub-committee so as to determine relatedness to the clinical trial, medical management and financial compensation to be given to the research participant as per relevant guidelines with effect from time to time.
- If any subject is withdrawn due to SAE, the same will be discussed in SAE sub-committee and in IEC full board meeting.
- If appropriate to the discussions, the members may call for a consensus on whether to: Request an amendment to the protocol or the consent form, request further information, terminate the study.
- The SAE Sub-committee recommendation will be communicated to all IEC Members within 3 working days to get inputs from members, if any. Minutes of meeting shall be signed by any SAE Sub-Committee Member.
- Minutes of the meeting shall be discussed in subsequent Full Board Meeting. One of the Sub-Committee Member shall brief the Full Board about SAE Sub-Committee Meeting and it's decision.
- If consensus can't be reached in SAE Sub-Committee, IEC Secretariat shall call Full Board Meeting to discuss SAE. Full Board Meeting shall be arranged so as to meet regulatory reporting timelines.

8.3.2 : Process for Root Cause Analysis for On-Site Serious Adverse Event.

- IEC SAE Sub-committee would be responsible for Root Cause Analysis (RCA) of Serious Adverse Event occurring at site. RCA process would be able to trace root causes of a SAE and thereby enabling changes to be made to protocol or processes to prevent the incident from reoccurring. An RCA shall cover, what happened? Why did it happen? What are the underlying causes?

- Root Cause Analysis will also help to determine of whether there is a reasonable possibility that the product is causally related to the serious adverse event. Root Cause Analysis shall also include evaluation of temporal relationships, dechallenge/rechallenge information (If available), association with (or lack of association with) underlying disease, presence (or absence) of a more likely cause, and biologic plausibility.

SAE Sub-Committee shall be guided by following mentioned assessment Criteria for Root Cause Analysis of Serious Adverse Events.

1. SAE is Certainly related to study drug if it satisfies following criteria's:
- Event or laboratory test abnormality, with plausible time relationship to drug intake
- Cannot be explained by disease or other drugs
- Response to withdrawal plausible (pharmacologically, pathologically)
- Event definitive a recognized pharmacological phenomenon
- Re-challenge satisfactory (If such data is available)

2. SAE is Probable/Likely related to study drug if it satisfies following criteria:
- Event or laboratory test abnormality, with reasonable time relationship to drug intake
- Unlikely to be attributed to disease or other drugs
- Response to withdrawal clinically reasonable
- Re-challenge not required

3. SAE is Possible related to study drug if it satisfies following criteria:
- Event or laboratory test abnormality, with reasonable time relationship to drug intake
- Could also be explained by disease or other drugs
- Information on drug withdrawal may be lacking or unclear

4. SAE is Unlikely related to study drug if it satisfies following criteria:
- Event or laboratory test abnormality, with a time to drug intake that Makes a relationship improbable (but not impossible)
- Disease or other drugs provide plausible explanations

SAE is un-assessable if more data for proper assessment needed, or if additional is under examination or if information is insufficient or contradictory or if data cannot be supplemented or verified

8.3.3 : Off Site SAEs Review:

- Principal Investigator or Designate Study Team should report Off Site SAEs to IEC.
- If Principal Investigator notices any particular trend in SAEs should be informed to IEC.
- At-least one member from SAE Sub-committee should review Off Site SAE and present it in Full Board Meeting.

Off site SAEs (PSUR) :

- Member Secretary of SAE Sub-Committee shall file the PSUR/Line listings submitted by PI as a detailed review of the same is out of the scope of IEC/IEC Sub-committee.
- It is the PI's responsibility to review the listings in detail and report if a trend is observed and communicate the same to Member Secretary , IEC SAE Sub-Committee
- The offsite SAEs are received in the format as per SOP and one copy is acknowledged and returned back to PI.
- If any queries are raised by the IEC Member Secretary or Member Secretary for IEC SAE Sub-committee shall write to PI (email or letters as applicable) or else the Offsite SAEs are filed in the respective project files.
- Depending on the trend observed by the PI, if appropriate, IEC shall take required action.
    - Direct the PI to inform participants already enrolled in the study about the SAE and if required re-consent these patients.
    - Request additional details or recommend an amendment to the protocol, the ICD, Participant information sheet, investigator brochure and/ or any other document.
    - Suspend enrolment of new research participants;
    - Suspend the study till amendments requested for by the IEC are accepted
    - Suspend the study till additional information is obtained;
    - Suspend the study till review is completed;
    - Terminate the study;
    - Any other appropriate action

8.4 : Independent Consultant for SAE Review:

- The SAE subcommittee while reviewing may solicit opinion of one or more independent consultant.
- The CV of the Independent Consultant will be reviewed by the Sub-Committee
- The Independent Consultants will sign and date both the copies of the Confidentiality / Conflict of Interest Agreement document before receiving any study related documents.
- They will give the forms back to the Member Secretary to obtain sign and date of the IEC Chairperson. The Member Secretary will obtain the signatures of IEC Chairperson and forward one copy of the Confidentiality / Conflict of Interest Agreement to the Independent Consultant for their records (duly signed and dated by them and IEC Chairperson).
- The IEC Secretariat provides study protocol documents and SAE related documents to the appropriate consultant for review.
- Name and qualifications of the experts and representatives should be documented, their attendance and viewpoints should be reflected in the meeting minutes.

- The Independent Consultant could be invited to attend a meeting if deemed necessary. However, the Independent Consultant should not be study team member for study under review. He/She can also be contacted for additional information or clarifications if sought by Sub-committee.

8.5 : Decision Communication:

- IEC Secretariat shall communicate the decision to the Licensing authority (DCGI) within 30 calendar days of the occurrence of the SAE.
- IEC Secretariat shall also communicate final decision to Principal Investigator within a period of 5 days from the date of the SAE Discussion
- If any query is asked to The Principal Investigator need to be replied within 3 working days.
- If there are any recommendations from Full Board Meeting Discussion shall be communicated to Licensing authority (DCGI) and PI.

8.6 : SAE Sub-Committee Membership List :-

1. Dr. Varsha Vadera
2. Dr. Abhishek Srivastava
3. Dr. Sanjay Mehta

8.7 : Glossary:-

Serious Adverse Event- Any untoward medical occurrence (due to the participation in the concerned trial) that at any dose that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability / incapacity, congenital anomaly / birth defect.

SOP NO. 09 / 11: SITE MONITORING

9.1: Purpose:-

The purpose of this Standard Operating Procedure (SOP) implies the procedures as to when and how to select a site for monitoring.

Monitoring could be initiated, in any of the following:

High number of protocol violations, large number of studies carried out by PI at the study sites, remarkable SAE reports, high recruitment rate, Non-compliance or suspicious conduct and any other cause as decided by IEC.

Clinical trials sponsored by external funding sources and industry are continually audited for compliance and monitored for progress by the external monitors. However IEC shall monitor all studies irrespective of study monitoring by external monitors.

9.2 : Before the visit:-

- For cause/routine monitoring of the project, the IEC Chairperson or Member Secretary will designate an IEC member to perform the task of monitoring.
- The Member Secretary or IEC Secretariat will inform the Principal Investigator in writing about the date/time of monitoring visit and request for confirmation letter from the Principal Investigator to be available for the monitoring visit.

The IEC member will review the IEC project files for the study and site profile and make appropriate notes.

The IEC member may refer IEC project files for comparison with the site files.

9.3: During site Monitoring visit the IEC member will-

1. Review the informed consent document to make sure that the site is using the most recent version, also to ensure that subjects are well informed of all the risks and benefits in the clinical trial initially and on an on-going basis throughout the trial period. New safety information should be promptly communicated to subjects and should be documented in the source notes and re-consenting should be done in a timely manner. There should be evidence that queries and concerns of subject are addressed. There should be a provision for subjects to take opinion from family physician if they want.

2. Review randomly the subject files to ensure that subjects are signing the correct informed consent.
3. Observe the informed consent process, if possible,
4. Observe laboratory and other facilities necessary for the study at the site, if possible.
5. Review the project files for the study to ensure that documentation is filed appropriately.
6. Collect views of the study participants, if possible.
7. Review SAE documents to ensure that compensation is paid to the subject as per informed consent document contract and applicable rules and regulations. The amount paid should be approved (to be verified only) by the ethics committee.
8. Evaluate if adequate medical care is provided for serious adverse events as per applicable rules and regulations.
9. Fill the Site Monitoring Visit Report Form and write the comments.
10. Evaluate protocol violations or Deviations to make sure to track for injury to the subject due to noncompliance of protocol.
11. Members conducting site monitoring visit may contact the patient randomly to understand if there are any patient grievance.
12. Ensure that the advertisements do not induce the participants and that principal Investigator has a recruitment policy to ensure unbiased selection of adequate number of suitable subjects according to the protocol.

9.4 : After the visit:-

- The IEC member will complete the report within 14 working days describing the findings of the monitoring visit and during the Full Committee meeting present them. If the monitor is unable to attend the IEC meeting he/she can courier the Monitoring Visit Report with comments and the IEC Member Secretary can present the same.
- The Member Secretary or IEC co-ordinator will place the report in the correct site files.
- Full Committee recommendations to change the study/ premature termination/ continuation of the project will go to the Principal Investigator in writing within 10 working days of the meeting. The ethics committee can suggest any areas that need to be improved based on the findings of their monitoring reports.

9.5 : Glossary:

Monitoring Visit - The act of overseeing the progress of a study, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP, & the applicable regulatory requirements.

Monitoring Report - Reports should include a summary of what the monitor reviewed and the monitor's statements concerning the significant findings/facts, deviations and deficiencies, conclusions, actions taken or to be taken and /or actions recommended to secure compliance.

SOP NO. 10 / 11 : EMERGENCY MEETING :-

The purpose of this Standard Operating Procedure (SOP) implies review and approval of study activities using the Emergency Meeting Procedures.

This SOP applies to emergency Institutional Ethics Committee (IEC) meetings. Emergency meetings may be scheduled to approve safety / life threatening issues, SAE and other study activities that require Full Committee review.

Criteria for Emergency Meeting:-

The Chairperson will decide to call an emergency meeting based on the following criteria:

- Urgent issues (if delayed will affect or have impact on patient safety, to the public benefit, national economics, etc.)
- Occurrence of unexpected serious adverse events.
- A matter of life and death for the patients continuing in the trial.
- Other appropriate reasons.

• IEC secretariat will contact the IEC members and inform them about the meeting especially to meet the quorum i.e.

- At least one basic medical scientist member
- At least one Clinician member
- At least one Legal Expert
- At least one Social Worker/Religious person
- At least one Layperson.

• IEC Secretariat will prepare packets for distribution to the members containing the information of the SAE/other matter for which Emergency Meeting is scheduled.

• The Chairperson/Member Secretary will determine if there is a quorum. However if after 30 minutes the quorum is not met, in view of emergency of the situation, meeting will proceed if a minimum 3 members are present, one of which should have a scientific background.

• The IEC member will follow the related SOPs as deemed necessary.

SOP NO. 11 / 11 : AGENDA, MINUTES, AND CONDUCT OF IEC MEETING

11.1 :Purpose:-

Standard Operating Procedure (SOP) implies preparation, review, approval and distribution of meeting agenda, minutes and action, invitation, and notification letters IEC meetings.

The Chairperson or Member Secretary should review and approve the agenda and the minutes sent to him/her.

- The IEC Secretariat will prepare the agenda to include:

1. All projects submitted for initial review.
2. All resubmitted protocols wherein IEC decision was Full Committee review.
3. Review of Amended protocol/protocol related documents wherein decision was Full Committee review.
4. Continuing review of study protocols.
5. Review of Study Completion Reports.
6. Review of premature study termination.
7. Review of Site Monitoring Visit Reports.
8. SAE reports/CIOMS forms/Safety letters.

- The Member Secretary or IEC co-ordinator will collect and verify all forms/documents for completeness to keep all these papers in the meeting.
- The Member Secretary or IEC co-ordinator will prepare the meeting agenda which should mention Location of meeting , date and time of meeting
- IEC Members will meet on 2nd Saturday of every month for IEC Meeting. If meeting couldn't be held on 2nd Saturday some other day can be considered for the meeting.
- Circulate the agenda and documents for review for the meeting to IEC members 10 working days in advance of the scheduled meeting.

11.2 : Meeting Schedule and its conduct :-

- The Committee will hold regular meetings at least once a month. When there are no research proposal store views, the meeting may be held less frequently, but no less than once every twelve weeks.

- Meeting will be held as scheduled provided there is quorum. A quorum will be defined as one-half of the current regular members of the Committee rounded off to the next higher whole number. As per the schedule Y (dated 20th Jan 2005) the quorum must include members with the following representations;

  1. One Basic medical scientist (preferably one pharmacologist)
  2. One Clinician
  3. One Legal expert.
  4. One Social scientist/representative of non-governmental voluntary

  Agency/Philosopher/ethicist/theologian or a similar person.

  5. One Lay person from the community.

- The Member Secretary will obtain signatures on the Confidentiality /Conflict of Interest Agreement Form from newly appointed members/Guests/observers /Independent Consultants prior to the start of the meeting.
- The Member Secretary will also obtain the signatures of all the IEC members on the attendance register.
- The Chairperson will initiate the meeting once the quorum has been met. The chairman will reassess the quorum when any member withdraws from the decision making and this will be recorded in the minutes.
- The Member Secretary then reports on the minutes of the previous meeting and presents the agenda for discussion.
- The meeting proceeds in the order organized in the agenda; however, the Chairperson or Member Secretary may allow some switching depending on the situation.
- Investigators are allowed to present their projects in brief and attend the IEC meeting to clarify any questions related to their project that the IEC members may have.
- During the approval process member secretary gives the briefing about the study by reading the comments and evaluation of the reviewers.
- The other members give their comments right after the presentation and the discussion about the study takes place.
- The Member Secretary records the discussions and the decisions made during the meeting.

Post Meeting all members shall submit documents to IEC coordinator for destruction. IEC members who couldn't attend meeting shall courier or submit documents personally to IEC coordinator for destruction purpose. IEC coordinator shall destroy documents using paper shredder. Exception: If study needs further discussion, IEC members shall secure documents with them till final conclusion and then submit documents to IEC coordinator for shredding purpose.

11.3 : Minutes of Meeting :-

• The Member Secretary will compose the summary of each meeting discussion and decision in a concise and easy-to-read style in the minutes.

• The Member Secretary will make sure to cover all contents in each particular category to include the following:

- Name of person preparing the minutes
- Location where the meeting was held.
- Meeting date/duration of the meeting.
- Names of the attending Committee members and guests
- Name of the individual serving as Chairperson of the meeting
- Determination of a duly constituted quorum by the Chairperson to proceed with the meeting .The chairman will reassess the quorum when any member withdraws from the decision making and this will be recorded in the minutes.
- Details of risk-benefit assessment for protocols reviewed.

• The Member Secretary will check the correctness and completeness of the minutes and prepare it within 10 working days of the meeting held. Member Secretary or IEC secretariat shall email Minutes of Meeting to all members for review and comment. Members shall reply within 5 working days shall there be comments, suggestions or modifications required. if there is no reply in 5 working days, shall be considered that Minutes of the meeting are accepted.

• The Member Secretary or IEC co-ordinator will send minutes of meeting for Chairman or Member Secretary's signature.

• The Member Secretary or IEC co-ordinator will place the minutes in the minutes file.

• The chairman will reassess the quorum when any member withdraws from the decision making and this will be recorded in the minutes.

• Details of risk-benefit assessment for protocols reviewed.

11.4 : Glossary

Agenda: A list of things to be done; a program of business for the meeting
Minutes: An official record of proceedings at a meeting.
Quorum: Number of IEC members required to act on any proposal presented to the committee for action.

SOP NO.12 / 11 : CONFIDENTIALITY / CONFLICT OF INTEREST AGREEMENT

12.1 : Purpose:-

The purpose of this Standard Operating Procedure (SOP) implies Confidentiality / Conflict of Interest Agreement and identifies who should sign and date the form.

12.2 : Responsibilities of IEC Reviewer:-

- It is the responsibility of each and every newly-appointed Institutional Ethics Committee member to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form with the Institutional Ethics Committee before beginning ethical and/or scientific review tasks and prior to his/her attending the meetings of IEC held to review research studies to protect the rights of study participants.
- It is the responsibility of the guest/observers attending the Institutional Ethics Committee meeting to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form at the beginning of the Institutional Ethics Committee meeting and/or before ethical review tasks with the Institutional Ethics Committee are commenced.
- It is the responsibility of the Independent Consultant (IC) to read, understand, accept and sign the agreement contained in the Confidentiality/Conflict of Interest form before beginning their ethical review tasks with the IEC and/or attending a meeting of IEC.
- The Member Secretary will ensure that the Confidentiality /Conflict of Interest Agreement Forms are duly signed and dated by the IEC members, Guests /observers for IEC meetings/Independent Consultants and notify to the IEC Chairperson. These documents will be filled in the files entitled 'Confidentiality /Conflict of Interest Agreement Forms'
- They will give the forms back to the Member Secretary to obtain sign and date of the IEC Chairperson. The Member Secretary will obtain the signature of the IEC Chairperson on both the copies of the Confidentiality /Conflict of Interest Agreement Form.
- The Members/Guests /Observers for Institutional Ethics Committee meetings/Independent Consultants will receive one copy of the Confidentiality /Conflict of Interest Agreement Form for their records (duly signed and dated by them and IEC Chairperson).
- IEC secretariat keeps the second copy of the signed Agreement at the Institutional Ethics Committee office.

• The Member Secretary or IEC co-ordinator will store the file in a secure cabinet with limited key holders.

• The IEC members/Guests/observers for Institutional Ethics Committee meetings/Independent Consultants must adhere to the highest standards of ethical conduct and must ensure that the cardinal principles of ethics i.e. autonomy of the individual, beneficence, non maleficence and justice are followed while reviewing the project.

• The IEC members/Guests /observers for Institutional Ethics Committee meetings/Independent Consultants must implement the clauses of the signed Confidentiality Agreement Form.

12.3 : MAINTAINING CONFIDENTIALITY:-

IEC members and staff have signed confidentiality agreements that enforce confidentiality.

If non-members of the IEC need copies of study documents, study documents can be given only after permission of Chairperson or Member secretary and after confidentiality agreement signed by requester.

• The IEC members must sign a confidentiality agreement before the start of the new tenure of IEC.
• Any member who is appointed in between a given tenure signs the confidentiality and conflict of interest agreement.
• The members shall have access to all IEC documents and are free to request and to use original documents or copies of original documents.

12.4 : Regulations for copying IEC Documents:-

Log of Copies

• A Log of Copies must be kept by the Member Secretary or IEC co-ordinator. The information should be captured as provided on log.

Copies requested by non-members of the IEC

• Copies of IEC documents (Apart from IEC SOP) requested by non-members of the IEC can only be given after the permission from the Chairperson or Member Secretary of the IEC and the person requesting for the document signs a confidentiality agreement form. Regulatory authorities need not require such permission.
• Copies made for non-members of the IEC must be recorded in the log of Copies.

File Log of Copies

- The Log of Copies of Original Documents will be stored in master file.
- The Log of Copies of Original Documents is not a confidential document and can be reviewed upon request.
- A Log of Copies of Original Documents must be maintained.

12.5 : Glossary:

Confidentiality:

The nonoccurrence of unauthorized disclosure of information

Confidentiality Agreement Sometimes called Secrecy or Non-disclosure agreement :

An agreement designed to protect trade secrets, information and expertise from being misused by those who have learned about them. The type of information that can be included under the umbrella of confidential information is virtually unlimited. Most confidentiality agreements exclude certain types of information from the definition of confidential information. It is very important that the recipient include these exceptions in the confidentiality agreement. An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information. The agreement must establish a time period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.

Conflict of Interest:

A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties. There are three key elements in this definition: financial interest, official duties, professional interest.

A conflict of interest occurs when:
- An individual's private interest differs from his or her professional obligations to the institute.
- Professional actions or decisions occur that an independent observer might reasonably question.
- Potential conflicts of interest must be disclosed and managed as per policy.

SOP NO. 13 / 11 : MAINTENANCE OF ACTIVE STUDY FILES :-

13.1 :Purpose:-

The purpose of this Standard Operating Procedure (SOP) implies circulation and maintenance of active study files and other related documents approved by the Institutional Ethics Committee (IEC).

13.2 : Record Keeping:-

IEC shall follow, regulatory guidelines 122 DD, serial number 4- maintenance of records and all records shall be maintained in IEC Office located on 2nd Floor, Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute. It shall be restricted access to authorized people, and also with proper provision for pest-control and fire control.

The Member Secretary or IEC co-ordinator will:

- Get the master copy of the study files.
- Gather, classify and combine all related documents together.
- Check if a study file contains, at a minimum, the following documents:
    - Original applications of projects for initial review and any updates received during the study.
    - Investigator's brochures or similar documents.
    - Agreements signed by appropriate authorities, such as: Clinical trial agreement, Insurance document.
    - Photocopies of statutory permissions as applicable
    - Approved documents (protocols, amendment, informed consent form, advertising materials, etc.)
    - Approval letters for protocol & protocol related documents
    - Adverse experience reports or IND safety reports received/SAE reports
    - Continuing review reports
    - Copy of all original letters received from the Principal Investigator.
    - Copy of all correspondence letters sent to the investigator.
    - The name of the sponsor/Principal Investigator
    - The protocol number assigned by the IEC Member Secretary or IEC co-ordinator.
    - Sponsor details with address and contact phone/e-mail id of contact person, protocol number, investigator name (with address, e-mail, telephone and fax) and title of the study.
    - ApplicationformoftheIEC,Protocol,CaseReportForm,Investigator'sBrochure(drug studies), Informed consent documents with translations in the relevant languages, advertising material and recruitment procedures, investigator bio data, any other material submitted by the investigator.

- Correspondence
- Initial Approval with the final version of all above documents (protocol, ICD, CRF etc.)
- Revisions/Amendments
- Approval of amended protocol/protocol related documents
- Adverse Events
- Continuing Review, if applicable
- Final report

13.3 : Maintain the active study files:-

- Combine related documents of the approved study files appropriately.
- Attach an identity Label to the package.
- Keep all active and potential study packages in a secure file cabinet.
- Maintain the study files in an easily accessible and secure place until the final report is reviewed and accepted by the IEC.
- Send all closed study files to archive.
- Store the closed study files for guidelines mentioned as per IECSOP.

13.4 : Glossary:

Active Study File: Any approved protocol, supporting documents, records containing communications and reports that correspond to each currently approved study.

Closed Study File: Any approved protocol, supporting documents, records containing communications and reports that correspond to a study which is completed or terminated or discontinued or suspended or not initiated.

SOP NO. 14 / 11 : ARCHIVAL AND RETRIEVAL :-

14.1 : Purpose:-

Standard Operating Procedure (SOP) implies instructions for storing inactive study files and administrative documents in a secure manner while maintaining access for review by auditors and inspectors.

This SOP applies to archiving the study files and administrative documents that are retained for duration required, as per regulatory requirement. (After completion of the research so that the records are accessible for auditors and inspectors).Copying files and documents by authorized representatives of the national and international regulatory authority is allowed.

14.2 : Record Keeping and Archiving:-

- IEC Member Secretary and Members review the Final Report of the study.
- Member Secretary or IEC co-ordinator should
  - Remove the contents of the entire file from the active study filing area.
  - Verify that all documents are present in an organized manner.
  - Shift it to a cupboard where in all files to be archived are placed.
- The Member Secretary or IEC co-ordinator will hold the files of multi-center studies, until all the study sites are closed.
- The IEC Member Secretary or IEC co-ordinator maintains past Committee membership information as well as the active administrative documents as permanent records.

Documents will be archived as per requirement of national and international regulations.

Documents of IEC will be archived at following address and can be made available for any regulatory authority inspection (if at least 3 working days notice provided to IEC).

IRON MOUNTAIN (INDIA) PRIVATE LIMITED
WORK OFF: Logitech Park,
Near Mumbai - Pune Express Highway,
Post Ajivali, ArivaliVillage,
Panvel, District: Raigad
Telephone: (952143) – 239273 / 239274
FAX: 02143239273

14.3 : Retrieving Documents:-

- Retrieval of documents can only be done with a request form signed and dated by the IEC Chairperson or IEC Member Secretary.
- The requestor must also sign and date the request letter.
- The Member Secretary or IEC co-ordinator retrieves archived documents and returns the file back to its place.
- The Member Secretary or IEC co-ordinator will also record, sign and date when the document has been returned and kept.

SOP NO. 15 / 11: REVIEWING RESEARCH STUDIES INVOLVING VULNERABLE POPULATION

15.1 : Purpose:

- The purpose of this Standard Operating Procedure (SOP) is to describe procedures to review proposals involving vulnerable populations. The SOPs provide clear, unambiguous instructions so that the related activities of the Committee are conducted in accordance with Indian laws and relevant, National and International Guidelines.
- It describes the requirements concerning review of research that involves groups that could be potentially vulnerable to coercion in regard to autonomy, and present conditions that may affect risk/benefit determinations or bearing unequal burden in research.

15.2 : IEC Members Responsibilities in reviewing studies:

- IEC shall protect rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders. Proper consent process and documentation of consent should be as per IECSOP.
- Research involving vulnerable populations is not eligible for expedited review or exemption from review and would be always discussed in full Committee meeting.
- This list may not be exhaustive as there may be circumstances in which other groups are considered vulnerable, women for example, in an orthodox patriarchical society, or terminally ill cancer patients , pregnant women, human fetuses and neonates, Prisoners, Children, Cognitively impaired person, Students ,employees, sub-ordinates, AIDS/HIV+ subjects , terminally ill Participants geriatric population, vulnerable populations:
- Representative for the vulnerable group is an individual who understands the issues of that population and has been working with this group. Representative for the vulnerable group may be invited on case to case basis.

15.3 : Review Process :-

- The IEC evaluates whether additional safeguards have been included in the study to protect the rights and welfare of vulnerable participants.
- There needs to be at least one or more individuals who are knowledgeable about or have experience in working with these participants as part of the review process. Member of the IEC who would be reviewing such protocols should be well versed with the potential harm or risk of such population participating in the study.

15.4 : The following is required when children are enrolled in research:

- If objective of the research can be met by carrying out research with adults, children should not be involved in their search.
- For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults .For studies prior to phase III the drug has a therapeutic value in a primary disease of the children.

- There needs to be provision for medical and psychological support for child and parent. Before enrolling child in the study, parent or legal guardian of child needs to sign parent consent and child age between 7 to 18 yrs needs to sign assent form.

- Interventions intended to provide direct diagnostic, therapeutic, or preventive benefit for the individual child participants must be justified in relation to potential risks involved in the study and potential benefits to society.
- 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. 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.
- If research involves adults unable to consent, the ethics committee must consider additional safeguards to protect their rights and welfare: When conducting non-therapeutic research, consent must be obtained directly from the participant, unless the objectives of the clinical trial cannot be met by means of a trial in participants who can give consent personally. However in such studies the foreseeable risks to the participants must below, risk to the participant's wellbeing is minimized and low.

15.5 : The following is required when Pregnant or nursing women are enrolled in research:

- Pregnant or nursing women : Pregnant or nursing women should in no circumstances be the participant of any research unless the research carries no more than minimal risk to the foetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy and lactation.
- The justification for participation of these women in clinical trials would be 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 perinatal transmission of HIV infection from mother to child, trials for detecting foetal abnormalities and for conditions associated with or aggravated by pregnancy etc.
- 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. Alternative provision such as supplying supplementary food such as milk formula should be considered in such instances.
- Research related to termination of pregnancy: Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made participants for such research as per The Medical Termination of Pregnancy Act, GOI,1971.
- Research related to pre-natal diagnostic techniques: In pregnant women such research should be limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus.

SOP NO. 16 / 11 : DEALING WITH PARTICIPANTS/PATIENTS/ANY RELEVANT PERSONNEL'S REQUESTS AND COMPLAINTS:

16.1 : Purpose:

- Primary responsibility of IEC is to protect rights and welfare of the human subjects participating in a clinical research approved by the IEC.
- This SOP provides guidelines for dealing with and accommodating requests by participants/patients /any relevant personnel, regarding their rights as a participant or to resolve their complaints in any IEC approved research study. IEC Members may contact the patient randomly to understand if there are any patient grievances.

16.2 : Responsibilities of IEC Members:

- IF there is any complaint received from participants/patients /any relevant personnel, Member Secretary/Chairperson shall initiate a process of identifying and addressing any injustice that has occurred. Study Participants can contact IEC Chairperson or Member Secretary for any request/complaints or query as contact details of IEC Chairperson and Member Secretary are mentioned on IEC approved Informed Consent Documents. Alternately IEC Members may contact the patient randomly to understand if there are any patient grievances.

16.3 : Procedure for resolving requests and Complaints:

- Query/complaint received will be recorded in the request record form
- The Member Secretary will inform the Chairperson about the query/complaint received.
- If any information is requested from IEC Office, the Chairperson / Member Secretary will share required information, as per regulatory norms.
- If there is any complaint received from participants/patients /any relevant personnel, Chairperson/Member Secretary shall initiate a process of identifying and addressing any injustice that has occurred.
- Chairperson/Member Secretary shall decide to consider the matter for discussion at a full Committee meeting or to call an emergency meeting of 2 or more IEC members for discussion or to appoint a subcommittee of 2 or more IEC members for enquiry in order to resolve the matter.
- The Chairperson/ Member Secretary/ designated IEC members will study the situation and will mediate a dialogue between the complainer and the investigator to address the issue. If required, Member Secretary will call for relevant information and documents from the Investigator.

- The Chairperson / Member Secretary/ designated IEC members shall study the entire issue to understand facts of the issue involved and if required shall interview complainer and Investigator / Investigator Study Team Members individually .The final decision will be informed to the complainer by the Secretariat.
- The information including any action taken or follow-up will be recorded in the form and the form will be signed and dated. Action taken and the outcome shall be communicated to all members in the forthcoming IEC meeting.
- Request document and the record form will be filed in the "response" file by the Member Secretary / Administrative staff.
- A copy of the same will be kept in the respective study file.

SOP NO. 17 / 11 IEC: POLICY OF COMMUNICATION WITH DIFFERENT STAKE HOLDERS:

17.1 : Purpose:

Policy defines IEC communication with different stakeholder as per regulatory mandate and specifications.

IEC communicates with following mentioned stakeholder as per regulatory mandate and specifications:

- Principal Investigator /study team designee
- DCGI
- Executive Director of the Institute
- Sponsor
- Study Participants

IEC may mention inward number on letters received at IEC office and may mention outward number for letters sent to all concerned stakeholders.

17.2 : Principal Investigator:

IEC writes to Principal Investigator or emails regarding following mentioned communications but not limited to, whenever deemed necessary.

- Study Project Initial Dossier and Amendments, Approval/Dis-Approval letter/ Query Letters
- Reply to Serious Adverse Event notification
- Opinion on EC analysis and compensation of Study injury/Death
- Response to Protocol deviation/Violation/Waiver
- Response to Continue review/study completion report
- Study termination letter.

17.3 : DCGI:

IEC writes to DCGI or emails regarding following mentioned communications but not limited to, whenever deemed necessary.

- Opinion on EC Analysis and Compensation of Study injury/death
- Study Termination letter
- Issues with Investigators or different stake holders involved
- Recommendations on DCGI Approved and other studies (If necessary)
- Ethics Committee Registration Communications

17.4 : Executive Director of the Institute:

IEC writes to Executive Director or emails regarding following mentioned communications but not limited to, whenever deemed necessary.

- Annual reports of IEC.
- Sharing amended SOP for final acceptance.
- Any issues in IEC functioning
- IEC Requirements

17.5 : Sponsor:

IEC writes to Sponsor or emails regarding following mentioned communications but not limited to, whenever deemed necessary.

- Response to any queries raised.
- Confirmation of free medical management and compensation in applicable cases (If deemed necessary).

17.6 : Study Participants:

IEC writes to study participants or emails regarding following mentioned communications but not limited to, whenever deemed necessary.

- Reply for complaints
- Reply if any information requested from IEC Office

SOP NO. 18 / 11 : POLICY FOR FINANCIAL DECLARATION OF PAYMENTS RECEIVED AND DISBURSED

18.1 :Purpose :

SOP defines procedures to keep record of payments received and disbursed for IEC activities. It entails procedure to maintain financial records which include; a) details of ethics committee fees for their services b) Honorarium Payment to each of the members and c) Other expenses incurred.

18.2 : Procedure to maintains financial records:

- All payment received as Institutional Ethics committee submission fee are separately maintained under "Mandke Foundation".
- Admin Manager will receive all payment cheque/DD and will submit to account department of the institute.
- All expenditure of IEC are managed through payment received as fee including Admin Manager / EC supporting staff Salary, meeting arrangement cost, Travel arrangement to chairperson and external members, Stationary charges, Cupboard, Electricity and telephone bills infrastructure requirement including Computer, Xerox, Scanner, Ethics Committee Member Training arrangement.
- Internal member of IEC shall not be provided any remuneration. External Members including chairperson will be provided remuneration for their services; however, if external member wish to refrain from accepting remuneration for rendering services , may do so by writing letter to chairperson . The chairperson shall be remunerated Rs. 4500/- (TDS shall be deducted on this amount) and other members shall get Rs. 3000/- (TDS shall be deducted on this amount).
- All financial payments received and disbursed shall be reviewed at end of every financial year and presented to IEC members.
- All financial communications are liable under Institute's internal routine account Audit.

18.3 : IEC Bank Details:

Name of Beneficiary:	Mandke Foundation
Ethics Committee Name:	Institutional Ethics Committee
Hospital Name:	Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute
Address:	Rao Saheb Achutrao Patwardhan Marg, Four Bunglows, Andheri (West)
State:	Maharashtra
City:	Mumbai
Country:	India
Postal Code:	400 053
Bank Name Branch	Yes Bank Ltd. Unit 11, 12 Ground Floor, Unit 1A, 2A, 1st Floor Sunil Niwas CHS Ltd., Lokhandwala, Four Bungalow, Andheri (W), Mumbai 400053.
Type of Account & Bank Account No.:	Saving A/c No.: 026794600001024
IFSC Code:	YESB0000267
MICR Code:	400532045
SWIFT Code:	YESBINBB

18.4 : IEC Fees Details:

Type of Study	Submission	Amendment (Full Board Review Only)
Clinical Research Phase-II III and IV	Rs 75,000/-	Rs 50,000/-
Initial Review for Registry involving only collection of data.	50,000 Rupees	NIL
Expedited Review	75,000 Rupees	NIL
Emergency Review	75,000 Rupees	NIL
Investigator Initiated	NIL	NIL
Academic	NIL	NIL

SOP NO. 19 / 11: IEC SELF ASSESSMENT:

19.1 :Purpose:

Purpose of the SOP is to evaluate quality of IEC ethics review systems and to review IEC policies and processes against recognized international standards. SOP shall also provide directions of evaluations of Chairperson, Individual Members, Member Secretary, Admin Manager, IEC Co-ordinator.

19.2: Overall IEC Self Assessment:

Chairperson designated IEC Member shall conduct self assessment based on NABH standards of IEC, as per Annexure. It will be done once annually.

19.3: IEC Members and Secretariat Self Assessment:

One periodic review per year shall be conducted as mentioned below.

- Self Evaluation of Chairperson will be done as per annexure
- IEC members/Member Secretary will be done by Chairperson. Chairperson shall communicate the individual feedback to be communicated to members to Member Secretary. Chairperson shall also communicate Member Secretary's feedback to Member Secretary. Secretariat shall communicate individual feedback to Members via email or through letters.
- IEC staff will be done by Member Secretary as per annexure. The individual feedback will be provided to the staff.

19.4: IEC Self Assessment Procedure:

- The Member Secretary will present self-assessment reports to all members in subsequent full Committee meeting. If there are any recommendations shall be implemented accordingly
- Ethics committee conducts self-evaluation. Example: a) ethics committee evaluates the appropriateness of its composition b) Attendance of members is reviewed c) Review whether there are adequate resources for ethics committee functioning.
- The ethics committee shall do a root cause analysis to identify if there is a process failure or a system failure.
- There should be atleast one periodic review per year.

AX: 01/11 CONFIDENTIALITY AGREEMENT FORM FOR IEC MEMBER

In recognition of the fact, that I, ----------

(Member's Name, his/her affiliation) herein referred to as the "Undersigned", has been appointed as a member of the Institutional Ethics Committee (IEC) has been asked to assess research studies involving human subjects in order to ensure that they are conducted in a human and ethical manner, with the highest standards of care according to the applied National/International regulations, institutional policies and national/International guidelines.

Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review; whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The undersigned, as a member of the IEC, is expected to meet the same high standards of ethical behavior to carry out its mandate. This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.

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

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

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

IEC Member Signature Date:----------

Chairperson Signature
Institutional Ethics Committee Date:----------

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

IEC Member Signature Date:----------

AX: 02/11 CONFLICT OF INTEREST AGREEMENT FORM FOR IEC MEMBER

In recognition of the fact, that I, ----------

(Member's name and his/her affiliation) herein referred to as the "Undersigned", has been appointed as a member of the IEC has been asked to assess research studies involving human subjects in order to ensure that they are conducted in a human and ethical manner, with the highest standards of care according to the applied national/International regulations, institutional policies and national/International guidelines.

Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

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

It is the policy of the IEC that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IEC.

The Undersigned will immediately disclose to the Chairperson of the IEC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations or voting in respect of such proposals.

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

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

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

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

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

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me toward a quorum for voting.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

IEC Member Signature Date:----------

Chairperson Signature
Institutional Ethics Committee Date:----------

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

IEC Member Signature Date:----------

AX: 03/11: CONFIDENTIALITY AGREEMENT FORM FOR GUEST / OBSERVER ATTENDEES TO IEC

I ----------, understand that I am allowed to attend the

Institutional Ethics Committee meeting scheduled on----------at----------am/ pm as a Guest or observer.

In the course of the meeting of the Institutional Ethics Committee some confidential information may be disclosed or discussed. Upon signing this form, I ensure to take reasonable measures to keep the information as confidential.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____

Signature of the Guest/Observer

Date: _____

_____

Chairperson of IEC

Date: _____

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

IEC Member Signature

Date: ----------

AX: 04/11. INSTRUCTIONS TO PRINCIPAL INVESTIGATOR

Clinical research projects may be either Clinical Trials (Pharma sponsored OR Government Bodies), Investigator Initiated (sponsored by KDAH OR self funded) or Academic Projects (Undertaking Thesis as a part of their curriculum).

What is Institutional Ethics Committee (IEC)?
Institutional Ethics Committee is an independent body constituted of medical, non-medical, scientific and non-scientific members whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in the trial by, among other things, reviewing, approving and providing continuing review of trial protocol and amendments.

The IEC has incorporated a series of documents in IEC-SOP and provides guidance to assist Investigators to meet the requirements of the IEC as per national and international guidelines for undertaking research activities.

A) Submission of research project (Initial Review)

- All prospective and retrospective studies (on drugs, investigational techniques as well as devices or any other procedure or observational studies), involving human volunteers or patients to be conducted at Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute shall have IEC permission before commencing such a study.

- Principal Investigator or designee needs to submit 3 hard copies and one soft copy for IEC record. Investigator also needs to submit One Soft Copy for IEC Record. Please refer to section SOP NO. 03/10: PROTOCOL SUBMISSION TO IEC for further guidance. Also submit AX08/10: Protocol Submission Proforma for IEC submission(very clearly in legible handwriting), AX 08/10: Submission Letter and Delegation log AX 20/10.

Incompletely filled form / form without signatures will not be accepted.

- Investigator should seek Institutional NOC from Executive Director of KDAH to conduct the Clinical Project at KDAH prior to submission of a research project. Institutional NOC will be considered valid for the Clinical Research Project till the end of the Clinical Research Project.

- Documents should be submitted at least three weeks in advance to IEC meeting for IEC review.

- The submitted project/s will be circulated 10 days prior to IEC meeting for review to all committee members via email/ hard copy and the proposal shall be reviewed for elements described in SOP No 04/09: Protocol Review Section4.1.2.

- IEC fees for initial review Rs. 75,000/- (excluding TDS and service tax) for all the pharmaceutical based research projects will be applicable. All required fees shall be collected before the submission of the research project. The cheque/DD/NEFT payment must be drawn in favour of *"**Mandke Foundation**"*.

- All communications with the committee shall be in writing letter or email to iseb.kh@relianceada.com.

- A meeting of all members will be held preferably on second Saturday of every month where each research proposal will be discussed and decisions arrived at.

B) Submission of Amended Protocol and Protocol Related Documents

- Principal Investigator or designee needs to submit 3 hard copies and one soft copy for IEC record.
- Please refer to SOP 04/10, section 4.3: Resubmitted study protocols Review for further guidance.
- No changes in the protocol, case record form and /or Informed Consent Document shall be initiated without prior written approval from the IEC. A covering letter should be submitted mentioning reason/s for amendments and summary of changes and the amended text may be highlighted in the revised Protocol and Protocol Related Documents.
- Please refer and submit AX 11/10: Submission Letter

C) Notification of protocol deviation / non-compliance / violation

- A covering letter should be submitted mentioning reason/s for protocol deviation / non-compliance / violation along with AX 21/10: Protocol deviation / non-compliance/ violation report form.

D) Submission of annual study report for studies continuing more than year

- For studies which will continue for more than a year, an Annual Study Report as per the format AX 23/10 will need to be submitted for review. Also investigator needs to enclose list of adverse event with relevant details along with Annual Study Report Form. Principal Investigator or designee need to submit hard copies equivalent to total number of IEC members and one hard copy for IEC record.

E) Once a study is over: Submission of Study Completion Report

- For studies which are completed within the IEC approval period, a covering letter along with study completion report as per the format given in AX 29/10 should be submitted to the IEC by the investigator. The study completion report is expected for review within 1 week of completion of the study at the site. Principal Investigator or designee needs to submit hard copies equivalent to total number of IEC members and one hard copy for IEC record.

F) In case a study is not initiated or terminated

- The same should be communicated to the IEC stating reasons for the same. In addition please submit AX 28/10: Premature Termination report
- The IEC archives all the study related documents for a period of 5 years after the study is completed / terminated/ reported as not initiated at our site. In case, an investigator needs a copy of any document submitted to the IEC, a written request can be made for retrieval of the same. Principal Investigator or designee need to submit hard copies equivalent to total number of IEC members and one hard copy for IEC record

G) Reporting of On-sightsee

- On site SAE report to be submitted by the Principal Investigator or designee within 24 hours of its occurrence (Initial reporting) as per the format specified in AX 22/10 (as per Appendix XI of Schedule Y)
- In the case of SAE, the follow-up report with due analysis will be submitted by the Principal Investigator designee within 14 calendar days along with the format specified in AX22/10
- The follow up reports of all on site SAE / unexpected AE reports till the event is resolved.
- The IEC Secretariat will verify that the report is complete in all respects and is signed and dated by the Principal Investigator (PI) or Sponsor as the case may be and that it has been received at the IEC office within the specified timelines above. If the report has been received beyond the specified time, this will be considered as a violation.
- The IEC Secretariat will sign and write the date on which the report is received.

H) Informed Consent Process:

- Preparing informed consent documents: Principal Investigator may refer to AX05/10, AX 06/10 or AX 07/10 (as applicable) for detail guidance

- The process of seeking informed consent: Principal Investigator or Designee to make sure

that they use photo copy of the most recent version, stamped and signed by Member Secretary, also to ensure that subjects are well informed of all the risks and benefits in the clinical study initially and on an on-going basis throughout the study period. New safety information should be promptly communicated to patients and should be documented in the source notes and re-consenting should be done in a timely manner. There should be evidence that queries and concerns of patient are addressed .There should be a provision for subjects to take opinion from family physician if they want. Whenever required audio-video consenting should be done. Soft copy of audio-video consenting should be archived as per relevant regulatory guidelines.

I) Regulatory permissions

- DCGI approval: Studies which plan to use a new drug (as defined in 122-E of the Drugs and Cosmetics Act, 1945) require DCGI permission. For such studies, a copy of the permission letter issued by the DCGI to the pharmaceutical company/investigator also needs to be submitted to the IEC. If the DCGI permission is awaited, a letter of provisional 'approval will be issued by the IEC and the final IEC approval will be given after a copy of DCG(I) permission is submitted to the IEC . No study should be initiated until the final letter of permission is issued by the IEC and required regulatory authorities.
- It is mandatory as per the directive by the DCGI (w.e.f.15th June 2009, which is applicable for clinical trials initiated after 15th June 2009) to register clinical trial at ICMR clinical trial registry at www.ctri.in before enrolling first patient in the study. (Registration is mandatory for interventional clinical trials)

J) General Instructions:

- Any new information that may adversely affect the safety of the research participants or conduct of the trial should be informed to the IEC.
- If an investigator wishes to appeal against the decision about rejection of a research proposal by the IEC, please submit your appeal in writing, addressed to Institutional Ethics Committee (IEC): 2nd Floor, Institutional Ethics Committee, Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute, Raosaheb Achutrao Patwardhan Marg, Four Bunglows, Andheri (West), Mumbai-400053,with justification relevant to the issues/ objections raised by the committee within 90 days of the receipt of the committees decision. In absence of appeal, the project will be declared closed for the IEC office records.
- IEC meetings will be held on second Saturday of every month. In case a meeting is to be preponed, postponed or cancelled due to unavoidable circumstances, the decision will be taken by the Member Secretary in consultation with Chairperson.
- The SOPs and relevant annexures are available on institute's website and also with the IEC Secretariat in the office of the IEC and will be shared on request (Preferably soft copy).
- Investigator needs to present the Project in the IEC meeting. The venue and timing for his / her Project presentation will be conveyed to the Investigator through email 10 days prior

to the IEC meeting.

- Investigator may enquire IEC meeting schedule from IEC Office.
- Investigator is expected to submit reply to the letter of recommendations/ queries sent by the IEC within 90 days of date of receipt of the query letter. In the absence of any response, the project will be declared closed for the IEC Office records.
- Once the study is approved by IEC, an approval will be granted for the entire duration of the study.

IEC fees for review of Clinical Projects (excluding TDS)

Type of Study	Submission	Amendment (Full Board Review Only)
Clinical Research Phase-II III and IV	Rs. 75,000/-	Rs 50,000/-
Initial Review for Registry involving only collection of data.	Rs. 50,000/-	NIL
Expedited Review	Rs. 75,000/-	NIL
Emergency Review	Rs. 75,000/-	NIL
Investigator Initiated	NIL	NIL
Academic	NIL	NIL
Government Initiated Projects	NIL	NIL

Location and Office Institutional Ethics Committee
2nd Floor, Institutional Ethics Committee,
Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute, Raosaheb Achutrao Patwardhan Marg, Four Bunglows, Andheri (West), Mumbai-400053.
Phone no: 022-30937206 Fax: +91-22-30970177.
E-mail: iseb.kh@relianceada.com
The IEC office hours for submission of documents, enquiries and telephonic communication with the IEC Secretariat are as follows:
Monday to Saturday -10:00 am to 5:00 pm.
The office will remain closed on Sundays and all national holidays.

AX: 05/11. INFORMED CONSENT FORM TEMPLATE

Part – 1: Participant Information Sheet

Principal Investigator: Dr._____
Primary/Secondary DNB Trainee (If Applicable)
Department of _____
Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute

Study Title: _____

1. Introduction:-

You are invited to participate in a study/research project titled_____.

I am, diplomat of national board student, ……., in department …….. in Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute under guidance of Dr. …… (specify name and designation of guide). We are doing study on …… disease, which is very common in this country (Paragraph for DNB Candidate).

Before you agree to participate in this study, you need to know the risks and benefits so you can make an informed decision. This process is known as "informed consent".

This consent form tells you about the study that you may wish to join. Please read the information carefully and discuss it with anyone you want. If you have questions please ask the Study Doctor or study staff to answer them.

Your participation in this research study is strictly voluntary. You may decide not to participate or you may withdraw from the study at any time without any penalty or loss of benefits to which you are entitled at this site. In case you decide to participate in the study and then choose to step out at a later time, no new information will be collected post your withdrawal decision; however, any previously collected information will be utilized in the study.

Your Study Doctor may withdraw you from the study at any time should he/she feel it is in your best interest.

2. Purpose of the Study:-

The purpose of this study is to_____

Briefly explain in lay language- the background of the problem, the need & purpose of the study, Use simple self-explanatory language / words that can be understood by 7th Std student.

3. Participant selection

You have been asked to participate as you meet the eligibility criteria's for the study.

(explain eligibility criteria in layman language , Ex. Patients of 18 years old and above, of either gender, diagnosed with ---------- would be eligible to participate in the study …….).

4. Procedures & Type of Study Intervention:-

The study will involve your answering a few questions about yourself, and going through your clinical and laboratory findings to ascertain the possibility of ---------- (Disease). I will provide you information and invite you to be part of the study. There won't be any additional study procedures apart from routinely required.

Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and any drugs that will be given. Explain from the outset what some of the more unfamiliar procedures involve (randomization, biopsy, etc.) Indicate which procedure is routine and which is experimental. Participants should know what to expect and what is expected of them.

In the first visit, we will also ask you a few questions about your general health. You will be asked at-------visits to complete questionnaires about your general health, your ----------(Disease) , your pain, fatigue, general condition and your experience with the medication.

Explain in brief about follow up visits (If Any)

Include a statement about the time commitments of the study for the participant including both the duration of the study and follow-up(if relevant).For Ex.... n total, you will be asked to come 5 times to the clinic in 6 months. At the end of six months, the study will be completed.

Mention about the questionnaire/ interview, in case these are a part of the study procedure and provide all details - about its timing i.e. when it would be administered / conducted, purpose and what will be asked / information collected through these. Also mention if the participants have an option to not answer certain questions in the questionnaire / interview.

Briefly state the type of intervention that will be undertaken. for example, the study involves a vaccine, an interview, a biopsy or a series of finger pricks. If there is no intervention, please mention there is no intervention.

5. Duration of participation.

It should include time period from first visit (consenting visit) to last follow up visit of the patient which would be at ---------weeks/months/years.

6. Your responsibilities

If you decide to participate in the study, you are required to follow up regularly, For Ex . at 3 weeks, 3 months, 6months …….. These are routine clinical visits.

You need to answer few questions regarding your symptoms and allow us for clinical examination and to go through all the investigations done in the past or at the time of the current visit.

7. Side Effects

There are no side effects related to your participation in the study.

8. Risks

There will not be any additional risk other than those observed in routine care and procedure.

9. Benefits

There may not be any direct benefit for you but your participation is likely to help us find the answer to the study question. There may not be any benefit to the society at this stage of the study, but future generations are likely to benefit because the information provided will help us get insight into ----------
(Ex …the spectrum of clinical manifestations of scleroderma and the association between skin and lung manifestations.)

10. Reimbursements

As all visits are as per routine care, no travel reimbursement will be given. There won't be any kind reimbursement as study participant does not incur any additional cost by participating in the study.

11. Confidentiality and who will review data and have access to data.

Unless required by law, your name will not be disclosed outside your treating clinic/hospital. Your name will be available only to the following people or agencies: the Study Doctor and staff; and authorized representatives of the Study Doctor; ethics committees, health authority inspectors, such as (but not limited to) the Drug Controller General of India. Authorized study monitors and auditors.

The above mentioned individuals will use the personal information collected as part of this study, including your medical records ("Study Information") to check that the study is conducted correctly and to ensure the accuracy of the Study Information. These people are all obligated to maintain confidentiality by the nature of their work, or are bound by confidentiality agreements.

While participating in this study, the Study Doctor will replace your name with a special code that identifies you. This code, along with your Study Information, will be used for the study purposes as mentioned above. Also this code will not be linked to hospital records.

12. Alternatives to participating

This section is to be included only if the study involves administration of investigational drugs or new therapeutic procedures. It is important to explain and describe the established standard of care.

Example: If you do not wish your child to take part in the research, your child will be provided with the established standard treatment available at the hospital.

13. Sharing the Information and Results

The knowledge that we get from doing this study may be published so other interested people may learn from our study.

14. Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Investigator ….. (Name and Contact number)

Guide ….. (Name and Contact number if applicable)

This proposal has been reviewed and approved by Institutional Ethics Committee (IEC) which is a committee whose task is to make sure that study participants are protected from harm. If you wish to find about more about the IEC, following are communication details.

Mailing Address IEC:
Institutional Ethics Committee (IEC)
2nd Floor,
Kokilaben Dhirubhai Ambani Hospital
& Medical Research Institute,
Rao saheb Achutrao Patwardhan Marg,
Four Bunglows, Andheri West, Mumbai 400053.

Chairperson of IEC : Dr. Renuka Munshi
In-charge Dept of Clinical Pharmacology,
5th floor, G bldg, Dr AR Nair Road,
TN Medical College & BYL Nair Charitable Hospital,
Mumbai : 400 008.
Mobile : 9820377409
E mail : renuka.munshi@gmail.com

You will be given a copy of the Participant Information Sheet & signed Informed Consent Document.

Part 2 : Informed Consent Form

Participant's Initials:_____ Participant's Name: _____

Date of Birth /Age: _____

Please Initial Box

(i) I confirm that I have read and understood the information sheet dated_____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the study investigator and study team, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand my identity will not be revealed in any information which may get published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provide such a use is only for scientific purpose(s). [ ]

(v) I agree to take part in the above study. [ ]

---	---	---
Name of the Parent	Sign / Thumb Impression	Date
---	---	---
Name of LAR (Legally Acceptable Representative)	Sign / Thumb Impression	Date
---	---	---
Name of the Investigator	Sign	Date
---	---	---
Name of Impartial Witness	Sign	Date

AX: 06/11. INFORMED ASSENT FORM TEMPLATE

Instructions to Investigator :

1. Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute has developed the template in accordance with regulatory guidelines, to assist Investigator in the design of informed Assent document (ISD). Please note student need to adapt their own ISD to the outline and requirements of their particular study (Adhere to guidelines and template)

2. In order to make you understand the language and content of ISD we have added guidance and examples. Please note guidance and examples are for your understanding and you need not include it in your ISD which you intend to develop and share to participants in your study

3. In this template square brackets indicate where specific information is to be inserted. The explanation and examples are provided so as to enable you to properly write the ISD.

4. Please note ISD need to be administered for children of age group 7 to 18 Years and hence language used in ISD should be as simple as possible.

5. For age group 7 to 18 Years you need to administer ISD and ICD both.

6. Regarding requirements of audio-video consenting please refer to IEC SOP.

TEMPLATE ON FOLLOWING PAGE

Title of the Study:

1. **Introduction:**

Briefly state who you are and explain that you are inviting them to participate in the study you are doing.
(Example: We are doing study on disease, which is very common in this country. I am going to give you information and invite you to be part of this study. You do not have to decide today whether or not you will participate in the study. Before you decide, you can talk to anyone you feel comfortable with about the study.)

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them to me, or my Guide (Guide will be applicable for academic students).

2. **Purpose of theStudy**

Explain in lay terms why you are doing the study. Use local and simplified terms for a disease, e.g. local name of disease instead of malaria, mosquito instead of anopheles, "mosquitoes help in spreading the disease" rather than "mosquitoes are the vectors
(Example: Malaria is one of the most common and dangerous diseases in this region. The study is been undertaken to know more about the disease)

3. **Participant selection and voluntariness**

State why this participant has been chosen for this study. People often wonder why they have been chosen to participate and may be fearful, confused or concerned.

(Example: We intend to enroll all children of age group --- to attend clinic to participate in the study)

Indicate clearly that they can choose to participate or not. And child need not participate if don't want to.

(Example: Your participation in this study is as per your wish. You need not participate if don't want to. You may change your mind later and stop participating even if you agreed earlier.)

4. **Procedures & Type of Study Intervention**

Describe or explain the exact procedures that will be followed on a step-by-step basis In the first visit, We will also ask you a few questions about your general health and measure how tall you are and how much you weigh. At the next visit, which will be two weeks later, you will again be asked some questions about your health ….

Include a statement about the time commitments of the study for the participant including both the duration of the study and follow-up (if relevant). In total, you will be asked to come 5 times to the clinic in 6 months. At the end of six months, the study will be finished.

(Example: The study takes place over (number of) days/ or (number of) months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility _____(number of) days , for(number of) hours each day. We would like to meet with you three months after your last clinic visit for a final check-up.)

5. **Side Effects**

Potential participants should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

(Example: As already mentioned, this interview or procedure can have some unwanted effects. You may mention. There are no side effects related to your participation in the study.)

6. **Risks**

Explain and describe any possible or anticipated risks.

(Example: By participating in this study it is possible that you will be at higher risk than you would otherwise be. OR There is no risk apart from what is encountered in routine care and procedure Or You may mention There are no side effects related to your participation in the study)

7. **Benefits**

Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

(Example: There may not be any direct benefit for you but your participation is likely to help us find the answer to the study question.)

8. **Confidentiality and who will review data and have access to data.**

Study Doctor will replace your name with a special code that identifies you so that the data collected from your recorded is protected from unauthorized people. This code, along with your Study Information, will be used for the study purposes as mentioned above. Also this code will not be linked to hospital records.

I would like to participate in the study:

--- --- ---

Name of the Child Sign Date

--- --- ---

Name of Parent / Guardian Sign Date

--- ---

Relationship with the subject Contact Details Parent / Guardian

--- --- ---

Name of Person conducting Assent Form Sign Date

AX: 07/11. INFORMED PARENT CONSENT TEMPLATE

Principal Investigator:
Department of_____
Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute

1. Introduction:-

Your child is invited to participate in this study / research project titled. Before you agree that your child participates in this study, you need to know the risks and benefits so that you can make an informed decision. This process is known as "informed consent".

This information sheet tells you about the research project for which your child is invited to participate. Please read the information carefully and discuss it with anyone you want. If you or your child have questions please ask the Study Doctor or Study staff to answer them.

Your decision to have your child participate in this study is entirely voluntary. It is your choice whether to have your child participate or not. If you choose not to consent, all the services you and your child receive at this clinic will continue and nothing will change. You may also choose to change your mind later and stop participating, even if you agreed earlier, and the services you and/or your child receives at the clinic will continue. In case you decide to participate in the research project and then choose to step out at a later time, no new information will be collected post your withdrawal decision; however, any previously collected information will be utilized for the study analysis.

2. Purpose of the Study:-

The purpose of this study is to_____

Briefly explain in lay language- the background of the problem, the need & purpose of the study, Use simple self-explanatory language / words that can be understood by 7th Std student.

3. Participant selection:-

We intend to enroll all children of age group --- (Brief eligibility criteria) to attend clinic to participate in the study)

4. Procedures & Type of Study Intervention:-

The study will involve you answering a few questions about your child, and going through your child's clinical and laboratory findings to collect information as per requirements of the study. There won't be any additional procedures required just for study purpose.

5. Duration of participation.

It includes time period from baseline visit (consenting visit) to first follow-up visit with the Institute.

6. Your responsibilities

You need to answer few questions regarding your child's symptoms and allow us for clinical examination and to go through all the investigations done in the past or at the time of the current visit in order to collect information as per requirements of the study.

7. Side Effects

There are no side effects related to your child's participation in the study.

8. Risks

There will not be any additional risk other than those observed in routine care and procedure. Your child's treating doctor should have already explained about these to you.

9. Benefits

There may not be any direct benefit for your child but your child's participation is likely to help to generate reliable data.

10. Reimbursements

As all visits are as per routine care, no travel reimbursement will be given. There won't be any kind of reimbursement as study participant does not incur any additional cost by participating in the study.

11. Confidentiality and who will review data and have access to data.

While participating in this study, the Study Doctor will replace your child's name with a special code that identifies your child; however, as per the study requirement at least one name need to be entered (either first, middle or last name). This code, along with your child's Study Information, will be used for the study purposes as mentioned above. Also this code will not be linked to hospital records.

12. Alternatives to participating

This section is to be included only if the study involves administration of investigational drugs or new therapeutic procedures. It is important to explain and describe the established standard of care.

Example: If you do not wish your child to take part in the research, your child will be provided with the established standard treatment available at the hospital.

13. Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact:
Name of PI: _____

This proposal has been reviewed and approved by Institutional Ethics Committee (IEC) which is a committee whose task is to make sure that study participants are protected from harm. If you wish to know more about the IEC, following are communication details.

Mailing Address IEC:
Institutional Ethics Committee (IEC)
2nd Floor,
Kokilaben Dhirubhai Ambani Hospital
& Medical Research Institute,
Rao saheb Achutrao Patwardhan Marg,
Four Bunglows, Andheri West, Mumbai 400053.

Chairperson of IEC : Dr. Renuka Munshi
In-charge Dept of Clinical Pharmacology,
5th floor, G bldg, Dr AR Nair Road,
TN Medical College & BYL Nair Charitable Hospital,
Mumbai : 400 008.
Mobile : 9820377409
E mail : renuka.munshi@gmail.com

You will be given a copy of the Parent Information Sheet & signed Informed Consent Document.

Part 2 : Informed Consent Form

Participant's Initials:_____ Participant's Name: _____

Date of Birth /Age: _____

Please Initial Box

(i) I confirm that I have read and understood the information sheet dated_____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my child's participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my child's medical care or legal rights being affected. [ ]

(iii) I understand that the study investigator and study team, the Ethics Committee and the regulatory authorities will not need my permission to look at my child's health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand my child's identity will not be revealed in any information which may get published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provide such a use is only for scientific purpose(s). [ ]

(v) I agree to take part in the above study. [ ]

---	---	---
Name of the Parent / Guardian	Sign / Thumb Impression	Date
---	---	---
Name of the Investigator	Sign	Date
---	---	---
Name of Impartial Witness	Sign	Date

AX: 08/11. PROTOCOL SUBMISSION PROFORMA

Form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Board

Board (IEC) for initial review only :
(for attachment to each copy of the proposal)

Code No. of IEC : - ----------
(To be filled by IEC Member Secretary/Admin Manager/IEC co-ordinator)

Proposal Title----------

A) Investigators Information:-

	Principal Investigator	Co-Investigator Collaborators	Co-Investigator Collaborators
Name			
Qualification			
Designation			
Mobile			
Landline			
Email			
Sign			

Note : Please attach Curriculum Vitae of Principal Investigator (with subject specific publications limited to previous 5 years) . The investigator should sign their CV.

B) Sponsor Information (Note : Circle whatever applicable):

Indian	Govt	Central	State	Institutional
	Private			
International	Govt	Private	Any Agency	Others
Contact No. and Address				

C) Study Information (Note : Circle whatever applicable) :-

1. Type of study:-

Epidemiological	Basic Sciences	Behavioral
Clinical	Single Centre	Multicentric

2. Clinical Trials (Drug/Vaccines/Device/Herbal Remedies):-

i) Does the study involve use of		
Drugs	Devices	Vaccines
Others : Specify		None

ii) Is it approved and marketed			
India	UK & Europe	USA	Other

iii) Does it involve a change in use, dosage, route, of administration?	Yes	No
If yes, whether DCGI's/Any other Regulatory Authority's Permission obtained	Yes	No
If yes, copy of permission attached	Yes	No

iv) Is it an Investigational New Drug				Yes	No
If Yes provide following information					
Investigator's Brochure enclosed				Yes	No
Preclinical studies data available				Yes	No
Clinical studies data available				Yes	No
Clinical study	Phase I	Phase II	Phase III	Phase IV	NA
DCGI's permission obtained				Yes	No
If yes, copy of letter enclosed				Yes	No

3. Brief description of the proposal (Maximum 500 words):

Aim &Objectives----------

Justification for study ----------

Methodology----------

Potential risks and benefits----------

Outcome measures ----------

Statistical analysis----------

National significance----------

---

4. Subject Selection :-

i) Number Of Subjects : ----------		
ii) Duration of study :----------		
iii)Duration Participant :----------		
iv) Would Participant from both sexes be recruited	Yes	No
If No , Specify the reason.		
v) Inclusion/Exclusion criteria given	Yes	No
vi) Type of subjects	Volunteers	Patients
vii) Vulnerable subjects	Yes	No
If Yes (Circle): Pregnant Women, Children, Elderly , Fetus , Illiterate, Handicapped Terminally ill, Seriously ill, Mentally Challenged Economically & socially backward Any other----------		
viii) Special group subjects	Yes	No
If Yes (Circle): Captives , Institutionalized, Employees, Students , Nurses/Dependent, Armed Forces , Any Other		

5. Privacy and confidentiality:-

Study Involves		
Direct Identifiers	Indirect Identifiers/Coded	Completely, Anonymised /Delinked
Confidential handling of data by staff	Yes	No

6. Will any advertising be done for recruitment of Subjects?

(Posters, flyers, brochure, websites – if so attach a copy)	Yes	No

7. Is there compensation for injury?

Compensation for injury		Yes (by whom)	No
Sponsor	Investigator	Insurance Company	Any Other

8. Use of biological/hazardous materials:-

i. Use of fetal tissue or abortus. If yes provide details	Yes	No
ii. Use of organs or body fluids. If yes provide details	Yes	No
iii. Use of recombinant/gene therapy products	Yes	No
If yes, has Department of Biotechnology (DBT) approval for DNA products been obtained?	Yes	No
iv. Use of pre-existing/stored/left over samples	Yes	No
v. Collection for banking/future research	Yes	No
vi. Use of ionizing radiation/radioisotopes	Yes	No
If yes, has Bhabha Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	No
vii. Use of Infectious/biohazardous specimens	Yes	No
viii. Proper disposal of material	Yes	No
ix. Will any sample collected from the patients be sent abroad? If yes, give details and address of collaborators	Yes	No
a. Sample will be sent abroad because (Circle) Facility not available in India Facility in India inaccessible Facility available but not being accessed If so, reasons		
b. Has necessary clearance been obtained	Yes	No

9. Risks & benefits:-

i. Is the risk reasonable compared to the anticipated benefits to subjects/community/country?	Yes	No
ii. Is there physical/social/psychological risk/discomfort?	Yes	No
If yes: Minimal or no risk More than minimum risk High risk		
iii. Is there benefit to the subject?	Yes	No
	Direct	Indirect
iv Is there benefit to the society	Yes	No

10. Consent:-

Written, Oral, Audio-Visual

i. Patient Information Sheet attached :	Yes	No
Tick the included elements: 1.Understandable language 3. Statement that study involves research 5. Sponsor of study 7. Purpose and procedures 9. Risks & discomforts 11.Benefits 13. Compensation for study related injury 2. Alternatives to participation 4. Confidentiality of records 6. Contact information of Investigator 8. Statement that consent is voluntary 10. Right to withdraw Consent 12. Compensation for participation 14. Contact Information IEC		
ii. Translation of information sheet in local Language If Yes which languages :----------	Yes	No
iii. Back translation of local languages in English for review	Yes	No
iv. Who will obtain consent? PI , Co-PI ,Nurse/Counselor, Research Staff Any Other----------		
v. If written consent is not obtained, give reasons :		

11. Data monitoring:-

i. Is there a data & safety monitoring board/Board (DSMB)?	Yes	No
ii. Is there a plan for interim analysis of data	Yes	No
iii Is there a plan for reporting of adverse events?	Yes	No
If yes, reporting will be done to :- Sponsor , IEC , DSMB		

12. Do you have conflict of interest?

i. Do you have conflict of interest?	Yes	No
Financal or Non-financial Please specify :-		

13. Hospital Support in terms of:

- Manpower
- Financial
- Sundrey
- Space

14. Budget Allocation Details:-

D) Investigators Declaration:

1. The investigators agree that the grant money will be spent in accordance with the budget proposal only
2. The investigators will declare any financial gain from the commercial sponsor and any conflict of interest in the drug or product by way of consultations, share holding, etc
3. The study documents will be made available to members of the IEC any time for random verification and monitoring. The study documents must ensure archived for 15 years post study close out or until the sponsor confirms that the records are no longer required; whichever is earlier.
4. All the findings and conclusions of the proposed project such as review of case records, analysis of forms of treatment, investigations, etc will be first presented to KDAH Management before they are released or presented elsewhere.

E) Financial Disclosure Form for Researchers

Project entitled: .....
Name of PI:

1. **Employment or Leadership Position**

   Check yes if you or an immediate family member currently holds any full-time or part-time employment or service as an officer or board member for an entity having an investment, licensing, or other commercial interest in the research study under consideration.

   ☐ Yes ☐No If yes, amount received in last 12 months in Rs._____

2. **Consultant or Advisory Role**

   Check yes if you or an immediate family member holds or has held any consultant or advisory arrangements with an entity having an investment, licensing, or other commercial interest in the research study under consideration.

   ☐ Yes ☐No If yes, amount received in last 12 months in Rs. _____

3. **Stock Ownership**

   Check yes if you or an immediate family member currently holds any ownership interest in any company (publicly traded or privately held) that has an investment, licensing, or other commercial interest in the research study under consideration.

   ☐ Yes ☐No If yes, amount received in last 12 months in Rs. _____

4. **Honoraria**

   Check yes if you or an immediate family member has been paid directly any honoraria (reasonable payments for specific speeches, seminar presentations, or appearances) from an entity that has an investment, licensing, or other commercial interest in the research study under consideration.

   ☐ Yes ☐No If yes, amount received in last 12 months in Rs. _____

5. **Research Funding**

   Check yes if you or an immediate family member currently conducts any clinical research project(s) funded, in whole or in part, or has received any post study awards by an entity that has an investment, licensing, or other commercial interest in the research study under consideration.

   ☐ Yes ☐No If yes, amount received in last 12 months in Rs. _____

6. **Patent or Royalty interests**

   Check yes if you or an immediate family member has received any patent or royalty from an entity having an investment, licensing, or other commercial interest in the research study under consideration.

   ☐ Yes ☐No If yes, amount received in last 12 months in Rs. _____

7. **Other Remuneration**

   Check yes if you or an immediate family member has received any trips, travel, gifts, or other in-kind payments at any point from an entity having an investment, licensing, or other commercial interest in the research study under consideration.

   ☐ Yes ☐No If yes, amount received in last 12 months in Rs. _____

I hereby agree to recuse myself from any deliberations and actions involved in the approval or re-approval of a protocol for which I have a real or apparent conflict of interest, and from discussions of these matters unless my presence for discussions is requested by the IEC Chair.

☐ I hereby declare that I have no conflict of interest in my project.

☐ I have above conflict of interest:

_____ _____

Signature of PI **Date**

F). Budget Sheet for the Proposed Study

1	Title of the Project:			
2	Principal Investigator			
3	Designation and address of the PI			
5	Source of funding			
	Intramural			
	Extramural			
	a) Government (please specify)	☐ Central	☐ State	☐ Local
	b) Private Foundation: (please specify)	☐ Indian	☐ Foreign	
	c) Industry: (please specify)	☐ Private	☐ Public	☐ Other
	d) Other:			
	Pharma sponsored	☐ Indian	☐ Foreign	
	Address, phone, fax. E-mail of sponsor with the name of the contact person			
	No funding required			
6	Total Budget for the entire project in Rs.			
7	Duration of the Project in months			
8	Proposed date of starting the project			
9	Direct payments to investigators, if any			
10	Any other benefits to the investigators			
11	Name of PI:	Signature:		Date:

Detailed Budget for the Proposed Study*

1. **Source of funding**	**Please specify**			
Items	1st Year	2nd Year	3rd Year	Total
2. **Salaries-personnel (Numbers)**				
Doctor / Post-Doc (Research Fellow)				
Research Nurse				
Data operator				
Any other specify				
3.**Equipment and Hardware-kindly specify**				
-				
-				
-				
-				
4. **Drugs and Consumables**				
-				
-				
-				
-				
5. **Clinical Investigations**				
-				
-				
-				
-				
6. **Hospitalization**				
-				

-				
-				
7.**Travel expenditure for investigators**				
-				
-				
8. Travel expenditure for Research Participant and one attendant				
9. Honorarium to doctors/technicians				
10. Insurance				
i. for investigators				
ii. any unforeseen, accidental trial related injury				
11. **Any other expenditures**				
12.**Miscellaneous (<5% of budget)**				
13. Grand Total				
Name of PI:	**Signature:**			**Date:**

Note:

- PI should devise incremental budget whenever necessary.
- Please provide the complete break-up of item nos. 3, 4 & 5 on separate sheet.
- Please specify year-wise total in grand total column

Project No.	
Trial Register No.	
Project Title (To be filled by PI)	..
Revised Title if any (To be filled by IEC)	
Principal Investigator	..

G) Check List for attached Documents: (Tick)

- Protocol Submission Proforma
- Submission letter
- Copy of the Protocol/Project and questionnaire (if any)
- Investigator's Brochure
- Copy of Patient information sheet & Consent form in local language (Hindi, Marathi, Gujarati) and English language.
- Back Translation of local languages
- Copy of Advertisements/Information brochures (if any)
- DCGI/DBT/BARC clearance if obtained
- Copy of Insurance Policy and Indemnification agreement
- Copy of Clinical trial agreement
- Copy of Case Report Form
- Copy of NOC from Institution
- PI undertaking
- IEC processing fee (applicable for pharma sponsored trials)
- Investigators Declaration ,Conflict of Interest
- Package insert/label
- Appendix VII (Schedule Y), Undertaking By The Investigator
- CV and MRC (If applicable) of Principal Investigators and Co-investigators
- Copy of Good Clinical Practice training certificate for all investigators
- Application for waiver of consent
- Specify if any other document enclosed

Signature of PI / Co-investigator

AX: 09/11. RISK BENEFIT ASSESSMENT TOOL

Number:

Effective Date:

Supersedes:

HIGH RISK/LOW BENEFIT (CLASS-A)	HIGH RISK/HIGH BENEFIT (CLASS-B)
Risks: - Completely new drug/formulation - Highly Toxic substances - Safety/Effectiveness not established throughhearlier studies - High incidence of SAEs/side effects in prelimstudies - Inadequate or no risk AE handling mechanisms - High data disclosure and data leakage possibilities - Affects large no. Of participants - Violation legal/statutory regulations - Inadequate project documentation - Inadequate PI/Staff expertise - New/untried procedures	**Risks:** - Completely new drug/formulation - Highly Toxic substances - Safety/Effectiveness not established through earlier studies - High incidence of SAEs/side effects in prelim studies - Inadequate or no risk AE handling mechanisms - High data disclosure and data leakage possibilities - Affects large no. Of participants - Violation legal/statutory regulations - Inadequate project documentation - Inadequate PI/Staff expertise - New/untried procedures
Benefits: - Cost of treatment/drug borne by participant - Replaces current drugs with no extra benefits either treatment wise or cost wise - Short term relief as opposed to long term action - No post trial alternatives	**Benefits :** - Completely new cure - Preventive for life ie. Vaccinations - Significant improvement over existing cures/treatments - Minimal side effects vis avis existing treatments - Elimination of disease rather than temporarily curative - Significant reduction in treatment costs/mode (ex. Pill vs

	surgery) - Extension of benefits / availability of treatment post trial

LOW RISK/LOW BENEFIT (CLASS-D)	LOW RISK/HIGH BENEFIT (CLASS-C)
Risks: - Proven/Acceptable toxicity - Proven safety and efficacy - Drug/formulation a variation of approved drug/class of drugs - SAEs indicate minor/acceptable reactions , side effects - No drug but only data analysis - Minimal data disclosure/leakage possibilities - Minimal risk to legal/statutory regulations - Standard operating / surgical procedures	**Risks:** - Proven/Acceptable toxicity - Proven safety and efficacy - Drug/formulation a variation of approved drug/class of drugs - SAEs indicate minor/acceptable reactions , sideeffects - No drug but only data analysis - Minimal data disclosure/leakage possibilities - Minimal risk to legal/statutory regulations **Standard operating / surgical procedures**
Benefits: - Cost of treatment/drug borne by participant - Replaces current drugs with no extra benefits either treatment wise or cost wise - Short term relief as opposed to long term action - No post trial alternatives	**Benefits :** - Completely newcure - Preventive for life i.e. Vaccinations - Significant improvement over existing cures/treatments - Minimal side effects vis a vis existing treatments - Elimination of disease rather than temporarily curative - Significant reduction in treatment costs/mode (ex. Pill vs surgery) - Extension of benefits / availability of treatment post trial - Benefits large no. of patients

AX: 10/11. STUDY ASSESSMENT FORM

IEC Code No : Review Date :

Principal Investigator : Initial / Resubmission

Study Title : ----------

Note: Reviewer may tick the appropriate box and may mention comments if any

1. Conflict of interest of IEC Member

   Yes ☐ No ☐

   ---

2. Objectives of the study:

   Clear ☐ Unclear ☐ NA ☐

   ---

3. Need for Human Participants

   Yes ☐ No ☐ NA ☐

   ---

4. Methodology and Eligibility Criteria:

   Appropriate ☐ Inappropriate ☐ NA ☐

   ---

5. Justification for Vulnerable Population/Special Group Population

Appropriate ☐ Inappropriate ☐ NA ☐

---

6. Risks and Benefits Assessment

Acceptable ☐ Unacceptable ☐ NA ☐

---

7. Control Arms (Placebo) , If any:

Yes ☐ No ☐ NA ☐

---

8. Contents and Language of Consent : Appropriate /Inappropriate

Appropriate ☐ Inappropriate ☐ NA ☐

---

9. Provision for Insurance ,compensation for participation and study related injury

Appropriate ☐ In Appropriate ☐ NA ☐

---

10. Treatment for study related Injury:

Appropriate ☐ In Appropriate ☐ NA ☐

Additional Comments:

Reviewer's Name: _____

Reviewer's Signature: _____

Date : _____

AX: 11/11. SUBMISSION LETTER

(On letter head of Institute/Personal)

Date:

To,
Chairman / Member secretary
Institutional Ethics Committee
Kokilaben Dhirubhai AmbaniHospital
& Medical Research Institute,
Mumbai 400053.

Reference: Study number: Study title----------

Subject: Institutional Ethics Committee Submission of following documents for the conduct of above referenced study at Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute

Dear Sir /madam

The referenced study has been discussed with me by the representatives of Contract Research Organisation/Sponsor. I have considered the proposal and feel that the recruitment for this clinical trial can be met at our hospital. The Inclusion /Exclusion criteria and other study–related details are described in the referenced Protocol. A study team has been appointed and will work on the conduct of study according to the ICH GCP guidelines, Indian GCP guidelines and national and international guidelines under my direction, as I shall be working as the Principal Investigator for the referenced protocol.

I am submitting ----copies of the following documents for the above mentioned clinical study for Institutional Ethics Committee Review:

- Protocol----------
- Investigator's Brochure- Version -- Dated -----
- Informed Consent Form in English and other regional languages.
- Case Report Form-------
- Questionnaire or scales used in the
- Patient Emergency Card- in English and other regional languages if applicable.
- Regulatory – DCGI – Submission letter for approval of study -Dated------

- Regulatory –DCGI – Study approval Letter – Dated--------
- Import Drug License –Dated----------
- NOC for biological sample – Dated---------
- IND Safety Report– Date ------- If Applicable.
- Project proposal-12copies
- Curriculum Vitae and MRC (If Applicable)Investigators
- Financial Disclosure of Investigator
- Copy of Advertisements/Information brochures
- Copy of Insurance Policy
- Copy of Clinical trial agreement
- Copy of IEC Proforma
- Copy of PI undertaking
- Copy of NOC from Institution.
- Copy of MRC and GCP Certificate.

I wish to assure IEC that Initiation of study and enrolment of patients will commence only after receiving IEC approval letter as well as required regulatory approvals.

The study will be conducted in accordance with the Indian GCP, ICH GCP guidelines and national and international regulations.

Voluntary consent (written consent) will be obtained from each participating subject/ relative, on the IEC approved Informed Consent form, prior to start of any protocol related procedures on the patients, audio-video consenting shall be carried out as per national regulations.

May I request you to review and opine on the aforementioned proposal & enclosed study documents, for the conduct of the study in our centre.

Please revert to me should you wish further information or any clarification.

Thanks and look forward to hearing from you.

Dr. ------- ----------
Principal Investigator
Protocol –:----------

AX: 12/11. EXPEDITED REVIEW APPLICATION

IEC Code:_____

1. Principal Investigator's Name:_____
2. Title of Project: _____
3. Names of study team members
   _____
   _____
4. Brief description of the project:
   _____
   _____
5. State reasons why expedited review from IEC is requested? (Tick applicable)
   - ☐ Risks to subjects is more than minimal
   - ☐ Risks to subjects are minimal
   - ☐ Research involving materials (data, documents, records, or specimens) that have been collected, for non-research (clinical)purposes

   Are children included in the study? ☐Yes ☐No

   Does the research involve vulnerable population? ☐Yes ☐No

Any other reasons: _____

Principal Investigator's signature:_____ Date_____

Recommendations by the IEC Member Secretary:

- ☐ Consider for expedited review
- ☐ Cannot be consider for expedited review, Reasons _____
  _____
  _____

Signature of the Member Secretary:

Date-_____

Final Decision: ☐ Expedited Review ☐For Full Board Meeting

AX: 13/11. CONSIDERATIONS FOR GENETIC RESEARCH

Investigator:
IEC Code:
Study Title:

1. The samples must be made anonymous to maintain confidentiality.
2. The investigator must establish clear guidelines for disclosure of information, including interim or inconclusive research result.
3. The appropriateness of the various strategies for recruiting participants and their family members must be considered.
4. Are there family members involved in research.
5. Family members must not be implicated in the studies without consent.
6. The samples destruction procedure
7. Genetic counseling should be offered.
8. Genetic Consenting if available.

Comments:

Primary Reviewer

Date

AX: 14/10. RESEARCH INVOLVING CHILDREN

Principal Investigator
Study Title:

1. If the study is determined to have minimal risk, with or without any direct benefit, then the study is approvable
2. If the study is determined to have greater than minimal risk, with potential benefit to the child, then the study is approvable
3. If the study is determined to have greater than minimal risk, with no direct benefit to the individual or offers any general knowledge about the child's condition or disorder then the study is approvable by a case to case basis

Comments: _____

	Yes	No	NA
If there is greater than minimal risk to children, confirm if convincing scientific and ethical justifications given, and are adequate safeguards in place to minimize these risks	☐	☐	☐
If the study involves healthy volunteers, Is the inclusion of healthy volunteers justified?	☐	☐	☐
Will efforts be made to ensure that parents' permission to involve their children in research studies, is free from coercion, exploitation, and /or unrealistic promises?	☐	☐	☐
Appropriateness of assent and parent form like privacy and confidentiality clauses	☐	☐	☐
If the research involves other family members, are there (for example, genetic risk, HIV infection, Hepatitis C), adequate mechanisms in place to address other members of the family?	☐	☐	☐

Primary Reviewer Date

AX: 15/11. RESEARCH INVOLVING COGNITIVELY IMPAIRED ADULT

*IEC Code.*_____

*Name of Principle Investigator*_____

1. **Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the subject** (All items must be "Yes")	
The risk is justified by the anticipated benefit to the subjects, if more than minimal risk is involved, and also if is it contributing to the subjects well – being?	☐ Yes ☐ No
Is the consent form appropriate?	☐ Yes ☐ No

2.Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the subject (All items must be "Yes")	
The objectives of the trial cannot be met by means of study of subjects who can give consent personally.	☐ Yes ☐ No
The foreseeable risks to the subjects are low.	☐ Yes ☐ No
Would participants be closely monitored to minimize risk on subject 's well-being	☐ Yes ☐ No
Subjects have a disease or condition for which the procedures in the research are intended.	☐ Yes ☐ No

Primary Reviewer

Date

AX: 16/11. RESEARCH INVOLVING PREGNANT WOMEN & FOETUS

*IEC Code*_____

*Name of Principle Investigator*_____

Study Title:

4. If the study is determined to have minimal risk, with or without any direct benefit, then the study is approvable
5. If the study is determined to have greater than minimal risk, with potential benefit, then the study is approvable
6. If the study is determined to have greater than minimal risk, with no direct benefit to the individual or offers any general knowledge about the child's condition or disorder then the study is approvable by a case to case basis

SECTION 1

☐ **THIS RESEARCH INVOLVES PREGNANT WOMEN, FOETUSES &NURSING INFANT**

	Yes	No	NA
Is pre clinical study data available for assessing potential risks to pregnant women and foetus?	☐	☐	☐
Are risks involved to the foetus more than minimal by interventions or procedures which claim direct benefit for the woman or the foetus?	☐	☐	☐
Are there provisions for woman's consent or consent of her legally authorized representative, assent in case of minors who are pregnant unless waived in accordance with 45 CFR?	☐	☐	☐
Is there reasonably foreseeable impact of the research on the foetus or resultant child mentioned in the consent form	☐	☐	☐
Are researchers involved in determining the timing, method, or procedures used to terminate a pregnancy; and the viability of the foetus	☐	☐	☐
Does the study involves discontinuation of nursing for the sake of participation in research Is the cessation of breast-feeding to the nursing child justified? Is breast feeding harmful to the infant?	☐	☐	☐

Does the research has provisions for compensation in terms of supplying supplementary food such as milk formula?			
Can this research be conducted in women who are not pregnant or nursing?	☐	☐	☐
Does this research protect or advance the health of pregnant or nursing women or foetuses or nursing infants?	☐	☐	☐
Is this research related to termination of pregnancy and is it as per the Medical Termination of Pregnancy Act, GOI, 1971. Does this research violate any provisions of the Medical Termination of Pregnancy Act, GOI, 1971	☐	☐	☐
Is this research related to pre-natal diagnostic techniques in pregnant women Is this research limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus Does this research violate any provisions of the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse)Act, GOI,1994	☐	☐	☐

SECTION 2

A. Foetus of uncertain viability	**Yes**	**No**	**NA**
1. Does the research project hold the prospect of increasing the probability of survival of the foetus to the point of viability, and are there any risks for achieving the objectives of the research project?	☐	☐	☐
OR			
Does the above risk outweigh the purpose of research project in the development of important biomedical knowledge which cannot be obtained by other means which also implies that there will be no risk to the foetus resulting from the research project	☐	☐	☐

2. In circumstances where the legally effective informed consent of either parent of the foetus is not available due to unavailability, incompetence, or temporary incapacity, the informed consent of either parent's legally authorized representative is obtained.	☐	☐	☐

And/or

B. Nonviable fetuses	Yes	No	NA
1. Vital functions of the foetus will not be artificially maintained	☐	☐	☐
2. There will be no risk to the foetus resulting from the research	☐	☐	☐
3. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means	☐	☐	☐
4. The legally effective informed consent of both parents of the foetus will be obtained in accord with the subpart A of 45 CFR 46, except that the waiver and alteration provisions of and (d) do not apply. However if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable foetus will suffice to meet the requirements of this paragraph. The consent of a legally authorized representative of either or both of the parents of a nonviable foetus will not suffice to meet the requirements of this paragraph.	☐	☐	☐

Note for reviewers –

Asses if research presents a reasonable opportunity to further the understanding, prevention and the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women or foetus;

Primary Reviewer Date:

AX: 17/11. RESEARCH INVOLVING STUDENTS

IEC Code_____

Name of Principle Investigator_____

Subjects who are students, employees or residents require special considerations.

Has the employer of the research subject been made aware of the subject's participation in research project?	☐ No	☐ Yes
Have subjects been assured that their participation is voluntary & that their status (education, employment, and/or promotion) will not be affected by their decision to participate or not?	☐ No	☐ Yes
Have the risks been minimized?	☐ No	☐ Yes
Is there adequate protection to the patient's confidentiality?	☐ No	☐ Yes

Comments:

_____ _____

Primary Reviewer Date

AX: 18/11. REVIEW EXEMPTION APPLICATION FORM

IEC Code:_____

1. Principal Investigator's Name:_____
2. Title of Project: _____
3. Names of study team members

_____

4. Brief description of the project:

Please give a brief summary (approx. 300 words) of the nature of the proposal, including the aims/objectives/hypotheses of the project, rationale, participants' description, and procedures/methods to be used in the project.

Please check that your application / summary includes:

- Procedures for voluntary, informed consent
- Privacy &confidentiality
- Risk to participants
- Needs of dependent persons
- Conflict of interest
- Permission for access to participants from other institutions or bodies
- Inducements

6. State reasons why exemption from IEC review is requested? (Tick applicable)
   - ☐ Audit of educational practices
   - ☐ Analysis of data freely available in the public domain
   - ☐ Any other (please specify)----------

Principal Investigator's Signature:_____ Date_____

AX: 19/11. DECISION LETTER

Date:

To

PI

Ref: Protocol Title:

IEC Code:

Subject: Decision letter for referenced study.

Dear PI,

The Institutional Ethics Committee has received_____ copies of following documents vide your letter dated _____:

1.
2.
3.

The members who attended the meeting held on ----------at ----------hrs at ---------- 6th Floor Conference room, Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute, at which your proposal was discussed, are listed below:

Sr	Name	Institutional Designation	Gender	IEC Designation	Affiliation to the Institute

At the Ethics Committee meeting held on --------- your letter dated ---------- along with the above documents were examined and discussed.

Decision:

Please follow following guidelines:

a) Initiate the study only after requisite regulatory approvals.
b) Conduct the research as specified in the study and ICH GCP as well as Indian GCP Guidelines.
c) Use photo copies of IEC approved and Member Secretary signed and stamped ICF.
d) Promptly report to IEC any new information that may adversely affect the safety of the subjects or the conduct of thesis. Also we request you to report us about the progress of the study at least half yearly.
e) Promptly report to IEC all the Serious Adverse Events observed during the conduct of Study as per relevant regulations.
f) Promptly report to IEC any new information that may adversely affect the safety of the subjects or the conduct of trial.

You are hereby informed that any modification to the protocol must be submitted to IEC for review and approval and the study should not be initiated without appropriate approvals.

We confirm that neither you nor any study team member was present during the decision-making procedures at this meeting.

Institutional Ethics Committee works in accordance with the Schedule Y, Indian GCP and ICH GCP guidelines.

Yours truly,

Chairperson or Member Secretary IEC

AX: 20/10. DELEGATION LOG

IEC Code-

Study title-

Sr.	Name	Specify Role (Principal investigator, Co investigator, Study Coordinator)
1		
2		
3		
4		
5		
6		

Sr No	TASKS	Sr 1	Sr 2	Sr 3	Sr 4	Sr 5	Sr 6
1	Research participants eligibility						
2	Consenting Participants						
3	Conduct the visit assessments						
4	Clinical Examination						
5	Complete the source documents						
6	Complete Case Record Form						
7	Final review and sign Case Record Form						
8	Collect & process laboratory samples						
9	Review & sign of the lab reports						
10	Study drug- Receiving, Dispensing, Storage, and Accountability & Documentation.						
11	Evaluation of SAE's						
12	Documenting and Maintaining study site master file						

(Please place tick marks against assigned duties for each member in the following table)

Signature and Date of Principal Investigator: _____

AX: 21/11. DEVIATION / NON-COMPLIANCE/ VIOLATION REPORTING FORM

INSTRUCTIONS:-

Please report single event in one reporting form
Specify if Deviation (D) / Violation (V)

Date of Occurrence:

Study status:

D/V identified by- ☐ Principal Investigator / study team
☐ Sponsor / Monitor
☐ IEC

Complete Details of D/V:

Action taken by PI/Co-PI/Co-I:

Impact on Trial participant (if any):

Are any changes to the project/protocol required?
☐ Yes ☐No

Name of PI:
Sign of PI:
Date:

IEC Secretariat Comments:

AX: 22/11. SERIOUS ADVERSE EVENT ASSESSMENT FORM

SERIOUS ADVERSE EVENT REPORT	IEC Code-
	Regulated by DCGI: Yes / No CTRI Reg. No:

1.	Title of project:		
2.	Principal Investigator:		
3.	Report Date : Report Type : ☐ Initial ☐ Follow-up_____If Follow-up report, State Date of Initial report_____ ☐ Final_____If Final report, State Dates of Initial/Follow up report_____		
4.	Date of Occurrence of SAE :		
5.	Subject Case No : Subject Trial ID :	5a. Age : 5b. Gender :☐Male ☐ Female	
6.	State SAE Event term :		
7.	SAE Relatedness and causality assessment justification:		
8.	The cost of treatment/hospitalization was borne by, ☐ Patient ☐ Institute ☐Sponsor/CRO		

Drug information (refers to drug/ device/ procedure under investigation)

9.	IP/ Placebo (include generic name)/device/intervention:		
10.	Dose : Dosage Form :	15.	Route(s) of administration :

11.	Therapy Dates (From/To) :	17.	Therapy duration :
	Was study intervention discontinued due to event? ☐ Yes ☐ No		
12.	Did the reaction decline after stopping the drug / procedure (Dechallenge & Rechallenge information) ☐ Yes ☐No ☐NA		

	Concomitant drugs and history (drugs that the patient maybe on)
13.	Concomitant drug(s) and date of administration :
14.	Patient relevant history (e.g. diagnosis, allergies): (Tick in the applicable box) (This is applicable only for regulated clinical trials) R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as under: a) 0.5 Terminally ill patient (expected survival not more than (NMT) 6 months)☐ b) 1.0 Patient with high risk (expected survival between 6 to 24 months) ☐ c) 2.0 Patient with moderate risk ☐ d) 3.0 Patient with mild risk ☐ e) 4.0 Healthy Volunteers or subject of no risk☐

	SAE Details
15.	Description of serious adverse event (indicate if this is follow-up report and if so, include follow-up information only)

16.	Describe the medical treatment provided (if any) to the research subject: This is an update on treatment given during hospitalization and /or used for management of the SAE.

Medication	Dose	Start date	End date

17.	Outcome was ☐Resolved ☐Ongoing ☐Death
18.	Was the research subject continued on the research protocol? ☐ Yes ☐No ☐NA (Mark 'NA' in case of death)
19.	In your opinion, does this report require any alteration in trial protocol? ☐ Yes ☐No If yes then please specify. Name of Principal investigator : Profession (Specialty) : Signature of Principal investigator _____ Date: _____ Contact No. of PI: _____ Upon receipt of this report, the IEC/DSMSC will decide whether additional information is needed or whether further investigation of the incident is required. A follow-up report with further details should be submitted by PI within 10 days or earlier (of occurrence of the SAE) to the IEC

For IEC use only

Final Assessment of IEC		
Response of IEC at meeting held on: ……		
Changes to the protocol recommended?	Yes	No

If Yes , Specify ----------		
Changes to the informed consent form recommended?	Yes	No
If Yes , Specify ----------		
Terminate Project		
Request for additional information ----------		
Till additional information is received trial will be	Continued	Suspended
IEC Recommendation on causality assessment and compensations		

_____

IEC Chairperson / Member Secretary Sign & date

AX: 23/10. ANNUAL/PERIODIC REVIEW STUDY REPORT

IEC Code:

Protocol title:

Principal Investigator:

Is the study expected to extend beyond the projected duration: ☐ Yes ☐ No

If Yes - provide reasons for not being able to complete the work in stipulated time

Are you applying for extension for the same: ☐ Yes ☐ No
If yes- period of extension requested?

Section B: Mandatory for Interventional Research

If the study pertains to retrospective case series / paraffin blocks / MRI or other radiological studies, etc. Please provide information on the status/progress of the study so far with regards to the final accrual/objective. Please mark what is not relevant as not applicable.

1) a) Have any SAEs been noted since the last status report?
☐ Yes ☐ No ☐ NA

If 'Yes', attach in format below

Sr no	SAE Event	Date of occurrence	Report type	IEC notification date	At site\ other site

b) In case of multicentre trials state whether reports of offsite SAEs have been submitted to the IEC –
☐ Yes ☐ No ☐ NA

2) Have any Deviations/Violations been noted since the last status report?

☐ Yes ☐ No ☐ NA

If 'Yes', attach in format below

Deviation description	Date of deviation	IEC notification	Is patient safety affected, if yes, explain measures to explain measures taken to address safety

3) Have any unanticipated problems involving risks to participants or others (including but not limited to adverse events) been noted?

☐ Yes ☐No ☐NA

If Yes please provide a summary-

Patient No.-
Adverse Event Description-
Severity-
Start Date-
End Date-
Relatedness-
Outcome-
Action Taken- If Yes, Specify Details as mentioned below:

Sr	Medication	Dose	Frequency	Route	Start Date	Stop Date /Ongoing
1						

4) Have there been any amendments in any study documents?

☐ Yes ☐No

If 'YES', please provide in format below

Amendment No. Version Dated	Date of submission	Date of IEC Approval

5) Have any Informed Consent documents been amended since the last status report?

☐ Yes ☐No ☐NA

If 'YES', fill in format below

Amendment No. Version Dated	Date of submission	Date of IEC Approval	Did Ongoing Patients consented

6) Have any participating investigators been added or deleted since the last status report was submitted to IEC?

☐ Yes ☐No

(If 'YES', kindly attach duty delegation log)

7) Have any new sites (institutions) been added or deleted since the last status report was submitted to IEC? (if applicable)

PI Name Site name Site address

8) Has there been any presentation/publication related to the data generated in this trial?

☐ Yes ☐No

(If, 'YES', kindly attach a publication copy)

SIGNATURES:

Principal Investigator:

Date

AX: 24/11. REMINDER LETTER TO INVESTIGATOR

Name of Principal Investigator:-

Ref: - Project Title:

The above referenced project was approved by the IEC on XXXXXXX and is due for Continuing annual review by the IEC.

Kindly submit the annual study report / Periodic Review report application on or before. In case the projects, have been completed / terminated, kindly complete the appropriate forms and submit to
IEC on or before_____

Thanking you for your co-operation,

Yours truly,

Signature with date
Member Secretary/ Admin Manager/ IEC Co-ordinator

Table 1: Summary List of Changes

Name of document	Revised version/Date	Section	Page No	Change(s)	Risk/Benefit Assessment /Justification

Instructions for applicant while filling the form.

1- Please highlight\ underline\ submit the changes of summary in the amended version.

Signature of the Principal Investigator & Date:

AX: 27/11. SITE MONITORING VISIT REPORT

1) IEC Code:

2) Title:

3) Principal Investigator:

4) Date of IEC approval:

5) Start Date of study:

6) Duration of study:

7) Date of monitoring visit:

8) Reason for monitoring:
- ☐ Routine
- ☐ For Cause (State reason)
- ☐ Protocol Violations/Deviations
- ☐ SAE reporting
- ☐ Recruitment rate
- ☐ Other _____

9) Last Monitoring done: ☐ Yes Date of last monitoring_____
☐ No

AX: 25/11. REQUEST OR COMPLAIN RECORD FORM

Received by:	Date Received:
Request from : ☐ Participant ☐ CRO ☐ Sponsor ☐ Government ☐ Any other Please Specify: _____	**Mode of request** ☐ Telephone call No…….. ☐ Fax No …….. ☐ Letter/Date…….. ☐ E-mail /Date…….. ☐ Walk-in/ Date /Time…….. ☐ Other, specify……..
Requester's Name:	
Contact Address: Phone:	
Title of the Study :	
Starting date of participation (if request by participants) :	
Request:	
Action taken:	
Outcome:	

Name of the Chairperson/ IEC Secretariat - _____

Signature of the Chairperson/IEC Secretariat _____Date- _____

AX: 26/11. AMENDMENT REPORTING FORM

IEC Code:
Protocol No. And title:
Principal Investigator :
Date of IEC Approval:
Status of Study:
Amended Document Protocol / ICF / IB / Specify if necessary_____ Nature of amendment ☐ Major ☐Minor
• Screened: _____ • Screen failures: _____ • Enrolled: _____ • Withdrawn Subject:_____Reason: (Attach in format below) • Ongoing Subjects: _____ • Completed treatment: _____ • Patients lost to follow up: _____ • Vulnerable patients enrolled YES \NO If yes, please specify: _____

(**Important note:** Please submit summary list of changes should include document/Revised version no Section, page no, change(s) and risk/benefit or justification.)

10) Project Status: ☐Ongoing
- ☐ Accrual Completed
- ☐ Follow-up
- ☐ Completed
- ☐ Suspended
- ☐ Terminated
- ☐ Closed
- ☐ Closed Prematurely

In case of the response to the question Suspected ,Terminated or Closed Prematurely is ticked , Kindly provide reason

_____

11) Recruitment Status:
- Total participants to be recruited-_____
- Screened: _____
- Screen failures:_____
- Enrolled: _____
- Withdrawn:_____ Reason: _____
- Discontinued:_____ Reason: _____
- Completed: _____
- Ongoing: _____

12) Protocol

a) Have there been any amendments to the Protocol? ☐Yes ☐No

If Yes then state changes leading to amendment:

b) Is the Protocol version approved by IEC? ☐Yes ☐No

c) Is the latest version of the protocol being used for the study? ☐Yes ☐No

13) Informed Consent

a) Is Informed consent obtained from all enrolled participants? ☐ Yes ☐No

b) Have there been any amendments to the ICF? ☐Yes ☐No

If Yes then state changes leading to amendment:

_____

_____

c) Is the Informed consent form version approved by IEC? ☐Yes ☐No
d) Is the latest version of the ICF being used for the study?☐Yes ☐No
If No, Specify Reasons……..

14) Any Protocol Deviations/Violations noted? ☐Yes ☐ No ☐ NA
Have all the deviations/violations notified to IEC? ☐Yes ☐ No
Comments (If Any)

15) Have the eligibility, inclusion exclusion criteria been adhered to? ☐Yes ☐No

16) Are all the Case report forms complete? ☐Yes ☐No ☐NA

Has there been any AE/SAE on the study? ☐Yes ☐No ☐NA
If Yes
a) No. of Adverse events: _____
b) No. of Serious adverse events: _____
c) No. of deaths reported: _____
- Deaths unrelated to participation in the trial: _____
- Deaths possibly related to participation in the trial: _____
- Deaths related to participation in the trial: _____

Comments (If Any)

17) Are Study documents secured and confidentiality maintained :☐Yes ☐No

18) Are the Investigational drugs accountability and prescription procedures performed and documented?
☐Yes ☐No ☐ NA
If 'Yes' kindly state the issues:

19) Any are there any changes to the study personnel? ☐Yes ☐No ☐NA
If 'Yes' kindly state the same:

Is the change notified to IEC? ☐Yes ☐No ☐NA

20) No of participants monitored during this visit: _____

21) Duration of the visit: _____

22) Any outstanding tasks/action items from the visit?

_____

_____

_____

_____

Monitoring visit conducted by:

Signature and Date _____

Name of study team member present: _____

Signature and Date: _____

AX: 28/11. PREMATURE TERMINATION / SUSPENSION / DISCONTINUATION REPORT

IEC Code.
Protocol Title:
PI:
Sponsor:
IEC Approval Date:

Please tick the appropriate
☐ Premature Termination
☐ Suspension
☐ Discontinuation

Reason for Termination/Suspension/Discontinuation:

Study Start Date:	Termination / Suspension / Discontinuation Date:

Study Participants

- Screened: _____
- Screenfailures: _____
- Enrolled: _____
- Withdrawn Subject: _____
- Ongoing Subjects: _____
- Completed treatment: _____
- Patients lost to followup: _____
- Vulnerable patients enrolled

  YES \NO

  If yes, please specify: _____

Type of SAEs (Total Nos.): Have any adverse events or outcomes reported to the IEC-	
Have there been participant complaints or feedback about the study ☐ Yes ☐No If yes Describe _____	
Summary of Results (if any) :	
PI Signature:	Date:

AX: 29/11. STUDY COMPLETION REPORT

IEC Code. -
Study Title: -
PI name: -

Sponsor -

Duration of the study -

Study Start Date –
Completion Date -

Summary of Protocol participants:

Study Participants

- Screened: _____
- Screen failures: _____
- Enrolled: _____
- Withdrawn Subject: _____
- Ongoing Subjects: _____
- Completed treatment: _____
- Patients lost to follow up: _____
- Vulnerable patients enrolled
  YES \NO
  If yes, please specify: _____

Results (brief) (use extra blank sheets, if more space is required)-

a) * 250-300 words, with aims, methods, results, discussion and conclusion as in an abstract
b) Summary and Conclusions
c) Details of new leads/information obtained, if any:

*Note: In case of Pharma sponsored projects, if the final report is not available from sponsor, it may be submitted later to the IEC once it is ready.

Conclusion *
Presentation/publication related to the data generated in this trial If yes: please enclose reprint of research publication
Serious Adverse Events at our center (Total number and type) Note : applicable for Interventional study
Whether all Serious Adverse Events were intimated to the IEC (Yes/No)
Protocol deviations/violations (Type and Number) Whether all Protocol deviations/violations were intimated to the IEC (Yes/No)
Signature of PI Date:

***mandatory fields**

AX: 30/11. IEC Minutes Template

____Agenda for Year___
Date &Time:
Venue:
Period 1

- Incitation of IEC Meeting By Chairperson
- Confirmation of quorum by the chairperson
- Discussion of Minutes of Previous Full Board and Expedite Meeting
- Attendance of Members and apologies from absent members

Attendance: List of members present

Members Absent:
1.
2.

Non Voting Member:

Other Members (Independent Consultant/Guest/Observer):

Quorum met: Yes/No

Conflict of Interest (If any):

Period 2

- IEC Members specific and ongoing trainings.

Period 3
A. Resubmission Protocols

B. New Protocol (Initial Review):

Period 4

- Section A:Notifications
- Section B: To discuss periodic review report, Annual Report, completion report, final clinical study report, IEC Audit reports
- Section C: SAE at Site
- Section D: CIOMS and Safety Information at other sites
- Section E: Protocol Deviations

Period 5

- Section A: Decision Letters Minor Protocol/ ICD amendments and other project related documents reviewed and approved by the IEC Secretariat.
- Section B: To discuss any other information.

AX: 31/11. DOCUMENT REQUEST FORM FOR INACTIVE FILES

Principal Investigator :		
Sponsor :		
Title of the study		
Protocol No.:	IEC Code	IEC Approval Date:

Name of Document requested:

Document Date and Version (If applicable)

Requested by:

Sign & Date of Requester

Sign & date of IEC Member Secretary or Chairperson.

AX: 32/11. LOG OF REQUESTS FOR COPIES OF IEC SOP

Sr	Documents requested	Reason for Request	No. of copies	Name of Issuer	Name of Recipient	Date

AX: 33/11. LOG OF COPIES OF ORIGINAL DOCUMENTS

Sr	Document Requested	Reason for Request	Name of Issuer	Name of Recipient	Issue Date	Return Date

AX 34/11 : INSTITUTIONAL ETHICS COMMITTEE ATTENDANCE LOG

IEC MEETING: ATTENDANCE LOG

Sr.	Name	Sign	Date

AX: 35/11 : UNDERTAKING BY THE INVESTIGATOR

UNDERTAKING BY THE INVESTIGATOR

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

2. Name and 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 any other statement(s) of qualification(s))

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

4. Name and address of the IEC that is responsible for approval and 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 bythe Investigator.

7. Commitments:

   (i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary IEC and regulatory approvals have been obtained.

   (ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval / favorable opinion from the IEC of the amendment, except where necessary to eliminate an immediate hazard(s) to the

trial Subjects or when the change(s) involved are only logistical or administrative in nature.

(iii) I agree to personally conduct and/or supervise the clinical trial at my site.

(iv) I agree to inform all Subjects, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and IEC review and approval specified in the GCP guidelines are met.

(v) I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory and GCP guidelines.

(vi) I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

(vii) 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 their obligations in meeting their commitments in the trial.

(viii) I agree to maintain adequate and accurate records and to make those records available for audit / inspection by the Sponsor, IEC, Licensing Authority or their authorized representatives, 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.

(ix) I agree to promptly report to the IEC all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.

(x) I agree to inform all unexpected serious adverse events to the Sponsor as well as the IEC within seven days of their occurrence.

(xi) I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.

(xii) I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

7. Signature of Investigator with Date.

AX: 36/11. SELF ASSESSMENT OF IEC MEMBERS

FORM A

For Assessment of overall IEC performance

Document Available: Yes/No.

Section	Assessment Elements	Yes/ No	Comments Regarding Compliance
Section 1	**Authority for formation of IEC and Induction Procedure**		
1	Authority for formation of Ethics Committee and Induction of IEC Members		
2	Was the IEC Chairperson, Co-Chairperson, Member Secretary, Co-Member Secretary, Secretariat appointed by high ranking authority of the institute?		
3	Was the induction procedure conducted as per the IEC SOP?		
Section 2	**Training of IEC Members**		
4	Were the members trained atleast annually regarding schedule Y, ICH GCP, ICMR guidelines, IEC & Site SOP?		
5	Does IEC office have required training records for all Members filed under Individual Members Records		
Section 3	**Periodic Study Documents Review**		
6	Does the IEC request Annual Report from the investigator?		
7	Are study annual reports being reviewed by the IEC regularly?		
Section 4	**Protocol Review**		
8	Do the IEC members receive protocol and other study related documents (initial dossier) at a specified time prior to IEC meeting?		
9	Does the IEC review the investigators qualification and experience in clinical trials to conduct the study?		

10	Does the IEC review adequacy of study team including the supporting staff, facilities available or management in case of emergencies arising from the research project?		
11	Does IEC evaluate the appropriateness of study design with respect to objectives of the study, methodology, risks involved to the human subjects while participating in the research project?		
12	Does the IEC identify the anticipated risk to the human subject and whether these risks have been minimized?		
13	Does the IEC assess risk benefit?		
14	Does the IEC follow IEC SOP on conditions for expedited meetings?		
15	Does the IEC follow IEC SOP regarding how the decisions for approval or disapproval for the study are made?		
16	Does the IEC follow IEC SOP for communicating the study decision to the investigator?		
17	Does the IEC follow IEC SOP for continuous review of the studies?		
18	Does the IEC ensure that the human participant is not subjected to unnecessary or risky intervention during the study participation?		
19	Does the IEC consider whether the study sponsor has adequate insurance to cover treatment of injury related to the study?		
Section 5	**ICF Review**		
20	Does IEC have an informed consent template to guide the investigators in writing the ICF?		
21	Does IEC supervise Informed consent processor, is the process reviewed?		
22	Does the IEC follow IEC SOP that lists conditions requiring wavier of ICF?		

Section 6	**Deviation/Non-compliance/Violation**		
23	Does IEC take required action against the investigator in case of violation, deviation, non compliance or in condition where patient safety has been compromised?		
Section 7	**Review of Serious Adverse Events**		
24	Does IEC follow strict timelines with regard to SAE Analysis (Initial and FU Review), Compensation Calculation and reporting to the licensing authority within the stipulated time?		
25	Does IEC check whether compensation is paid to patient and whether amount is verified by IEC?		
26	Does IEC verify whether adequate medical care is provided for serious adverse events as per applicable rules and regulations?		
Section 8	**Site Monitoring**		
27	Does the IEC follow IEC SOP to review all adverse events of the research project?		
28	Does the IEC ensure that the ICF is in a simple language and understood well by the patient?		
29	Does the IEC reviews possibilities of any financial or other incentives offered to the participants for their study participation?		
30	Document listing all the rights and responsibilities of the subject in a charter.		
31	Does the IEC reviews the data collected to ensure patient safety?		
32	Does IEC regularly monitor the site as per IEC SOP, and are monitoring reports discussed in Full Board Meeting?		
Section 9	**Agenda ,Minutes , Conduct of Meeting**		
33	Are the timelines for IEC meeting and expedited meetings being followed as per IEC SOP?		

34	Does the IEC consider whether the quorum is been met during the full board meeting?		
35	Does Minutes cover all required deliberations?		
36	Does chairman reassess the quorum when any member withdraws from the decision making and is recorded in the minutes?		
Section 10	**Confidentiality / Conflict of interest agreement**		
37	Does the IEC follow IEC SOP for Confidentiality disclosure and, is there a provision to address potential conflict of interest of IEC members?		
Section 11	**Maintenance of active study files**		
38	Are the IEC documents being properly maintained and stored as per the IEC SOP?		
Section 12	**Complaints**		
39	Does the IEC have provision whereby enrolled human subjects can file complaints and address their grievance regarding their study participation?		
Section 13	**Policy Financial declaration of payments received and disbursed**		
40	Details of ethics committee compensation for their services. Separate human resource and budget allocation for ethics committee functioning.		
Section 14	**Reviewing Research Studies Involving Vulnerable Populations**		
41	Does the IEC identify the potential for enrolling vulnerable participant?		
42	Does the IEC reviews justification for including vulnerable patients in the study?		
Section 15	**Overall Assessment**		
43	The ethics committee should do a root cause analysis to identify if there is a process failure or a system failure		

44	Does the Ethics committee assign responsibilities to the members with the objective to involve every member in decision making process?		

Assessment Performed by:

Signature and Date of Assessor

FORM B

Performance of Chairperson/ Co-Chairperson/ Member Secretary/ Co-Member Secretary/ Secretariat

Mention individual (tick) who is performing the evaluation

☐ IEC Chairman

☐ IEC Member Secretary

Name of individual who is conducting self performance: .....

Total number of meeting attended annually ..... Out of .....

Number of protocol review (initial)	
Pharma Sponsored	
Investigator Initiated	
Others	
Number of SAE reviewed	
Number of annual study reports reviewed	
Preparedness of meeting	
Periodic Reviews Conducted.	

Evaluation regarding regulatory training:

Overall performance is poor/ fair/ average/ good/ excellent

Areas of improvement required:

Signature of Assessor:

Name of Assessor:

AX: 37/11. RIGHTS AND RESPONSIBILITIES OF RESEARCH PATIENT

Rights of Research Participant

- Right to voluntary participation in research study.
- Right to know about Institutional Ethics Committee and its responsibilities towards protecting patients rights, safety and well-being involved in a research project and to provide public assurance of that protection
- Right to information about Research Study in an understandable language.
- Right to informed consent and if necessary audio-video consenting before participation in any Research Study.
- Right to refusal of participation or withdrawal of participation at any point in the study without disclosing any reason.
- Right to receive quality healthcare in a safe, clean environment without discrimination because of race, age, colour, religion, nationality, culture, ethnicity, language, disability, sex or manner of payment.
- Right to be treated with dignity, respect and courtesy in a non-judgemental and non-threatening manner.
- Right to information regarding investigational product, duration of study, treatment option available as per standard of care, anticipated expenditure, information on medical management of any injury and compensation in case of any study related injury or death or any compensation provided for participation in an understandable language.
- Right to be informed of the risks, benefits and alternatives of proposed treatment
- Right to privacy and confidentiality.
- Right to be informed on how to voice a complaint to express concerns, violation of your rights and/or grievance and seek redressal
- Right to participation in research and innovative therapies.
- Right to consent for diagnostic and therapeutic procedures.
- Right to access clinical records
- Right to get 24 hours emergency contact details of Research doctor
- Right to get contact details of Chairperson and Member Secretary of Institutional Ethics Committee.

Responsibilities of Research Participant

- To provide correct and complete demographic information including full name, age, address, telephone number and e-mail ID (If available).
- To be compliant with Research Protocol and Procedures.
- To ask question when he/she does not understand what the Doctors, Research study team, or other healthcare team members tells about diagnosis or treatment.
- To inform your research study doctor and research study team, immediately in case of any injury or development of any new medical conditions
- Not to take any medications without the knowledge of Research Doctor and Research Study team.
- To disclose to Doctors and Research study team if currently part of any other Clinical Trial or had participated in any other Clinical Trial in last one year.
- Provide complete and accurate information about your health including your previous medical history, and all the medications you are taking including alternative treatments like Ayurveda, Homoeopathy, Unani or herbal medications you are taking, all records of previous investigations and treatment and of allergic reactions especially sensitivity to any drug.
- To follow instructions, advice and restrictions regarding treatment plan and visit schedules.
- To treat hospital staff and study team with courtesy.

AX: 38/11 : Waiver of Consent Request Form

Application form for requesting waiver of consent

Principal Investigator's name: ……..
Study Title: ……
……

Please specify reason(s) for requesting waiver. (You may tick option(S))
1. Research involves 'not more than minimal risk'
2. There is no direct contact between the researcher and participant
3. Emergency situations as described in ICMR Guidelines
4. Any other (please specify) ……

Also confirm if protocol mentions following statements (Kindly tick)
1. Statement assuring that the rights of the participants is not violated
2. State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant.

Principal Investigator's signature with date:……

IEC decision at full board meeting dated……, Waiver granted : Yes / No

If not granted, reasons ……
……

AX: 39/11 : REFERENCES

1. World Health Organization, Operational Guidelines for IECs that Review Biomedical Research, 2000. (Geneva 2000 www.who.int/tdr/publications/publications/-

2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996-http://www.ich.org/LOB/media/MEDIA482.pdf

3. CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects http://www.cioms.ch/frame_guidelines_nov_2002.htm

4. ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR(2017)- http://www.icmr.nic.in/ethical_guidelines.pdf

5. Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005), and recent amendments till date http://www.cdsco.nic.in/html/Schedule-Y%20(Amended%20Version-2005)%20original.htm

6. European Convention on Human rights and Biomedicine (1997). http://conventions.coe.int/treaty/en/treaties/html/164.htm

7. Code Federal Regulation Title21

8. Draft Guidelines for Compensation to Participants for Research Related Injuryin India.http://icmr.nic.in/guidelines.htm

9. Code of Federal Regulations45cfr46