INDEX

INDEX

INDEX

INDEX

INSTITUTIONAL ETHICS COMMITTEE-CLINICAL STUDIES(IEC-CS) APOLLO HOSPITALS

SOP No.:	**2(Addendum-1)**
TITLE:	**Formation of the IEC-CS and Terms of Reference for Membership**

Version : AH- 014	Issue Date:	Revision Date:	Validity: 3 years
Date of Addendum		-do-	-do-

	Name	**Designation**	**Sign and Date**
Approved By		**Member Secretary**	

Formation of the IEC-CS and Terms of Reference for Membership

2.1Objective: To describe the procedure for Formation of the IEC-CS, Membership requirements, Terms of Reference and allowing a guest/observer

2.2 Scope: This SOP covers the methods and activities to be performed to constitute the IEC-CS, requirements for Members, Terms of Reference, Re-constitution process and Signatory Authority.

2.3 Attachments:
2.3.1 List of Institutional Ethics Committee -Clinical Studies Members
2.3.2 Honorarium Structure
2.3.3 Confidentiality and Conflict of Interest Undertaking (Ethics Committee member)
2.3.3.a Confidentiality and Conflict of Interest Undertaking (Guest/Observer)

2.4 Responsibility: Head of the Institution, IEC-CS Members.

2.5. Procedures

i. The Head of the Institution shall identify the persons who are qualified to become members of IEC-CS as per their education and experience, and send them invitation letters
ii. During the selection of members, the Head of the Institution shall ensure that the selected persons do not have any conflict of interest with the scientific/research activities and/or are not directly or indirectly related to the researchers or sponsors. Senior officers in the institution who are responsible for business development shall not be made members or involved in the daily operation.
iii. The selection of members shall be based on the review of their CV, prior training in GCP, and with the contemplation of including few members with experience in medical research. The non-scientific members should

have the relevant qualification and exposure to the field/role that they will represent as per their position in the committee.

iv. The IEC-CS composition shall reflect adequate representation of age, gender (at least one woman member), community/participant representative, and non-affiliated members (at least 50%)

v. **Criteria for selection of members:**

a. Members shall be selected on their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in domain and profile.
b. Conflict of interest shall be avoided when making appointments, but where unavoidable, there will be transparency with regard to such interests with appropriate documentation in constitution records.
c. New members will be identified according to the requirement as per the composition.

The following qualities are sought in IEC-CS members:

1. Interest and motivation
2. Ability to devote sufficient time and effort
3. Experience and education
4. Respect for divergent opinions
5. Integrity and diplomacy

vi. The policy followed in appointment of IEC-CS members will be such that it allows for continuity, development and maintenance of expertise within the committee, and regular input of fresh ideas and approaches.

vii. The prospective members shall be given a written invitation letter from the Head of the Institute to which they shall provide an acceptance in writing and updated signed and dated CVs (and valid MRCs if applicable) to the IEC-CS Secretariat

viii. The Head of the Institution /designated IEC-CS Secretariat shall organize a formation meeting and ensure that most of the members are present at the meeting, introduce the members to each other; and give an introduction about the objectives and functions of IEC-CS.

ix. A Confidentiality and Conflict of Interest Undertaking signed by the members shall be obtained at the time of formation of (or joining) the

committee. A welcome letter with terms of reference (TOR) shall be given to each member as per their role in the committee.

x. During formation meeting, members will select from among themselves a Chairperson and a Member Secretary. The member selected as Chairperson should NOT be affiliated to the Institution. The elected Chairperson will act as the Chairperson for all future IEC-CS meetings. The Member Secretary shall be affiliated to the institution and will be responsible for all day-to-day operations of IEC-CS.

xi. The Member Secretary, with the help of the secretariat, will prepare the agenda and the minutes of the meetings.

xii. The Member Secretary, with the help of the secretariat, shall maintain all the documents related to IEC-CS membership, such as a copy of invitation letters given to each member and their acceptance, member's latest CV (and valid MRCs if applicable) and their training certificates, resignation letters, leave letters or letters of absence.

xiii. The list of IEC-CS Members shall be prepared as per Attachment 2.3.1 having the 'effective date' which will be the starting date of the Term of the Committee. The PIs of all ongoing research studies shall be updated with the latest membership list. The List of IEC-CS Members will be submitted/ uploaded to the office of the HOI and the regulatory authorities within 30 days timeline.

xiv. **Composition:**

The EC is multisectoral and multi-disciplinary with adequate age and gender representation. The IEC-CS shall consist of Institute affiliated and non-affiliated members from medical, non-medical, scientific, and non-scientific fields, lay public from local community/society to reflect different viewpoints and the need of the institution. Non-affiliated members should constitute at least 50% of the composition.

The members shall represent their positions in the committee with common responsibilities as declaring conflict of interest, reviewing and attending IEC-CS meetings, participate in discussions and deliberations, review the progress reports and final reports, review the SAE reports and Noncompliance reports, recommend appropriate actions, carry out monitoring visits at the sites as per

plan, maintain confidentiality of the documents, participate in continuing education activities in research and ethics and getting updated on relevant guidelines and regulations.

The defined responsibilities of each member are as follows:

a. Chairperson: (*non affiliated – well respected person from any background with prior experience of having served/serving an EC*)

1. Conduct and preside at the committee meetings and ratify the minutes of the previous meeting
2. Ensure active participation of all members in all discussions and deliberations
3. Seek COI, ensure quorum and fair decision making
4. Communicate with committee members.
5. Review study documents received.
6. Handle complaints against researchers, IEC-CS members, COI issues and requests for use of IEC-CS data.
7. General oversight and perform other duties as deemed necessary.

b. Member Secretary: (*affiliated- staff of the organization, knowledge and experience in clinical research and ethics, motivated and good communication skills, able to devote adequate time to the activity with institutional support)*

1. Organize an effective procedure for receiving, preparing and maintaining proposals for review.
2. Schedule and participate in meetings.
3. Communicate with the committee members.
4. Schedule EC meetings; prepare the agenda and minutes of meeting.
5. Ensure training of EC members and EC secretariat
6. Liaison between the institution and IEC-CS.
7. Ensure SOPs are updated. Ensure EC functioning as per SOPs.
8. Prepare for and respond to audits and inspections.
9. Ensure completeness of documentation at the time of receipt and timely inclusion in the agenda for EC review

10. Assess the need for type of review.
11. Assess the need for obtaining prior scientific review, invite experts, patient or community representatives
12. Record the discussions and decisions during the meeting.
13. Coordinate and manage the subject feedback and Redressal.
14. Signing the MOM and Approval Letters
15. Perform other duties as deemed necessary with the help of EC secretariat.

c. Basic Medical Scientist/Pharmacologist :(Affiliated/Un affiliated- non medical or medical person with qualifications in basic medical sciences.
For clinical trials-basic medical scientist should be a pharmacologist)

1. Review of the scientific aspects of the study proposals with emphasis on intervention, risk-benefit analysis, Design, Methodology, SAE, Protocol Deviation, Progress and Completion Report.
2. Completeness of Primary reviewer form including the safety and pharmacodynamics

d. Clinician:(Affiliated/Unaffiliated- should have a recognized medical qualification, expertise and training)

1. Review of the scientific aspects of the study proposals with emphasis on intervention, risk-benefit analysis, Design, Methodology, SAE, Protocol Deviation, Progress and Completion Report.
2. Review medical care facility appropriateness of the PI, provision for medical care management and compensation.
3. Thorough review of protocol, IB, other study documents and completeness of Primary reviewer form(Assess the need for type of review).

e. Legal expert:(Affiliated/Unaffiliated- basic degree in law from a recognized university and knowledge)

1. Ethical review of the proposal, ICD along with the translations, draft and final clinical trial agreement, regulatory approval, Insurance,

Investigators Undertaking, Protocol specific permissions if any.
2. Interpret and inform about new regulations.

f. Social scientist /philosopher/ethicist/theologian :(Unaffiliated-trained and experience in social/behavioral/philosophy/religions and be sensitive to local cultural and moral values. Can be a representative from an NGO involved in health-related activities)

1. Review of Informed consent document along with translations.
2. Assess the ethical and societal impact and concerns.
3. Serve as a patient/participant/societal/community representative and bring in ethical and social concerns

g. Layperson (as participant's representative): (Non-Affiliated – literate person who has not pursued a medical science/health related career for last 5 years, maybe a community representative and is aware of local language, cultural and moral values)

1. Review of Informed consent document along with translations.
2. Evaluate benefit and risk from participant's perspective and opines if benefits justify risks.
3. Assess the ethical and societal impact and concerns.

The IEC-CS will have a minimum of seven (7) and a maximum of fifteen (15) members, including Chairperson and Member Secretary as office bearers. The office bearers will not hold dual responsibilities. When a particular specialty or population is not represented in the membership list, an expert opinion is sought. This person may or may not be affiliated to the Organization.

2.6. TERMS OF REFERENCE:

i. Responsibilities of IEC-CS members

a. Membership of the IEC-CS is a position of responsibility and IEC-CS Members are expected to approach this position with the seriousness and professionalism befitting their role in aiding the advancement of science and protection of research participants.
b. Members are expected to show interest and motivation in the science and ethics of research, respect for divergent opinions, ability to work as a team,

and ability to maintain confidentiality.

c. Members should submit an updated signed and dated CV at the time of joining the IEC-CS.
d. Members are required to sign a Confidentiality and Conflict of Interest Undertaking on joining
e. Meetings will be conducted at monthly intervals on designated day (site specific) of every month; provided there are applications to be reviewed and approved or there are any of the yearly activities like training or evaluation.If there are no agenda items, the meeting shall be deferred. Interim meetings may be called for, if required.
f. Member should be keen to attend all the meetings and give prior intimation in writing to IEC-CS Member Secretary if the member is unable to attend the meeting.
g. Member should inform the Chairperson in writing beforehand if he/she anticipates being unavailable for three (or more) consecutive meetings.
h. Member should assess in detail the proposals allotted to them as primary reviewer/ ICD reviewer/CTA reviewer and be there for discussion during the review meeting.
i. Member shall declare competing conflicts of interest in writing, if any, with respect to the agenda items, in the attendance sheet, before commencement of each meeting.
j. If any IEC-CS Member or member of his family is part of study team (in any capacity) in a particular proposal, he/she shall not be present during the decision making of such proposal; they may present proposals, if they are Principal Investigators and answer clarifications; but should leave the room before IEC-CS discusses and decides. The attendance of such an IEC-CS Member will not be counted for fulfillment of quorum.
k. The Member Secretary shall send prior intimation about his/her absence to the IEC-CS Chairperson. An affiliated member present in the meeting can then minute the proceedings. The Chairperson's absence also needs prior intimation. An unaffiliated senior member of the IEC-CS, present for the meeting, can be chosen for chairing the session/s. The same shall be documented in the Minutes of the Meeting.
l. Members should not make copies of any study document/material provided

to them for review and IEC-CS will ensure and document its return after the meetings.

m. Members will receive the honorarium for reviewing the documents and attending the meetings as per the honorarium structure in Attachment 2.3.2.

ii. Terms and Conditions of Appointment as IEC-CS Member:

a. Duration (Tenure)

1. The Term of the duly constituted IEC-CS shall be for2 years from the date of constitution/reconstitution. The members shall be appointed for tenure of 2 years.
2. The IEC-CS members will go through regular orientation Programs which will keep them updated and familiar with the contemporary developments in the field. The quality assessments will be on a half-yearly basis on an electronic platform. The assessments will be designed by the quality manager taking the need of the hour and the earlier evaluation report into consideration. The feedback of the evaluation will be shared with each member individually electronically. The plan for improvement shall also be discussed by the quality manager. The composite report will be shared with the Head of the Institution
3. A new member, if needed, may be appointed during the Term of the committee. In such case, the tenure of appointment of the Member will be effective for the remaining period of the existing committee.

b. Conditions of Appointment

1. Name, qualification, age, gender, profession, and affiliation of IEC-CS members shall be available on public domain.
2. Members must provide written acceptance of the appointment.
3. Submit an updated CV, valid Medical Registration Certificates (UG & PG), if applicable, training and GCP certificates at the earliest.
4. Conflict of interest, if any, must be disclosed.
5. Members must apprise themselves of the New Drugs and Clinical Trial Rules, 2019, relevant codes, ICH - GCP guidelines, the ICMR guidelines, Indian GCP &IEC-CS procedures and any new regulatory updates.
6. Members are required to sign the Confidentiality and Conflict of Interest

Undertaking at the start of their term. The Confidentiality and Conflict of Interest Undertaking protects the privacy and confidentiality of all documents shared with the members for the meeting.

c. Reconstitution

The IEC-CS membership will be reconstituted before the completion of stated term of 2 years. A defined (minimum 20%) of EC members shall be changed at every reconstitution. Reconstitution shall imply formation of a new committee for the next Term of 2 years (unlike Inclusion or Relieving of members during the current Term). Extension of membership to the reconstituted committee/members will be based on the recommendation of the Chairperson and Member Secretary, and also at the member's discretion to continue/not. The membership may be reviewed by the HRPP Board/Head of the Institution and changes made, if required.

The process of reconstitution will be as follows:

1. Identification/Selection of members shall be done at least two months in advance.
2. The appointment letters issued by the HOI to all members should specify the TORs including, at the minimum:
    a) Role and responsibility of each member
    b) Duration of appointment
    c) Condition/s of appointment
3. Newly selected members shall read, understand, accept and sign the Confidentiality and Conflict of Interest Undertaking as observers.
4. These members shall attend one or two meetings, if possible, as observers, before starting their tenure. Honorarium shall not be applicable for the observers.
5. If a regular member resigns, or ceases to be a member due to unforeseen circumstances like relocation, sickness or death, a new member may be appointed for the remaining term of the existing constitution.
   Any change in membership or constitution of the registered Ethics committee shall be intimated in writing /online to the HOI and the Central Licensing Authority within thirty working days

iii. Signatory Authority:

a. The MOU between the chairperson and the HOI shall be signed by the designated persons only
b. "EC Membership list" and "Undertaking by the Ethics committee" will be signed by the designated Member Secretary and Chairperson only.
c. The minutes of meeting shall be signed by the office bearers who attended the meeting as the chairperson and the member secretary
d. IEC-CS Chairperson, Member Secretary and an affiliate IEC-CS member will be the signatory authority for the SOP on behalf of all members.
e. IEC-CS member who officiated the meeting as Member Secretary will be primary signatory authority for signing the approval letters,
f. Member secretary/designate will be responsible for correspondence with the office of regulatory authorities and all other correspondence on behalf of IEC-CS.
g. The Secretariat shall be the signatory authority for correspondence to members and Principal Investigators regarding the meeting schedule and any requirements of IEC-CS review

2.7 Allowing a Guest /Observer

i. Any person interested to be a part of the ethics committee meeting as an observer/guest maybe allowed after a written permission is asked for and granted by the secretariat. The permission letter must accompany a short CV.
ii. The permission maybe granted on the basis of reason/s given for attending the meeting.
iii. There should not be any conflict of interest
(Members from the Sponsors/Institute decision makers shall not be allowed)
iv. People seeking such permission will have to sign the confidentiality and conflict of interest form
v. Such permissions will be only for a particular meeting and not a blanket permission throughout
vi. The MOM must capture the same and the documents furnished for the

same shall be kept filed.

SOP No.:	**2, Attachment 2.3.1**
TITLE:	**List of Institutional Ethics Committee Members**

List of Institutional Ethics Committee Members

(Effective from: ----------)

(Effective till: ----------)

Ethics Committee Members

S. No	Name	M/F	Qualification	Affiliation to Institution Y/N	Designation	Position in The Committee

Prepared by: EC Member Secretary
Name:
Sign & Date:

Authorized by: EC Chairperson
Name:
Sign & Date:

SOP No.	**2, Attachment 2.3.2**
TITLE:	**Honorarium Structure**

Honorarium Structure

(Effective from: _____)

(for new protocol reviews<25/year)

POSITION	AMOUNT (in Rs.)	*CONVEYANCE
Chairperson	Rs. 3000	Rs. 3000
Member Secretary	Rs. 2500	Rs. 2500
Members	Rs. 2000	Rs. 2000

(for new protocol reviews>25/year)

POSITION	AMOUNT (in Rs.)	*CONVEYANCE
Chairperson	Rs. 3500	Rs. 3500
Member Secretary	Rs. 3000	Rs. 3000
Members	Rs. 2500	Rs. 2500

*This will be reviewed at the end of every year
** Payable only for Offline meetings

EC Member Secretary:
Name:
Sign:
Date:

SOP No.:	**2, Attachment 2.3.3**
TITLE	**Confidentiality and Conflict of Interest Undertaking (Ethics Committee member)**

Confidentiality and Conflict of Interest Undertaking
(Ethics Committee member)

In recognition of the fact that I, _____hereinafter referred to as the "Undersigned", have been appointed as a member of the Ethics Committee (EC), IEC-CS Apollo Hospitals established by Apollo Hospitals,(---), and would be asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care, according to the applicable international, national, local regulations, institutional policies and guidelines;

Whereas, the appointment of the undersigned as a member of the EC 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 the EC member is to independently review 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 EC 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 by commenting on the scientific validity of the proposed research projects.

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

a. Confidential or Proprietary Information

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the EC. 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 EC.

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

b. Conflict of Interest

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

In accordance of the policy of the EC, the undersigned shall not 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 EC.

The Undersigned will immediately disclose to the Chairperson of the EC 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 in respect of such proposals. If an applicant submitting a protocol believes that a EC member has a potential conflict, the applicant may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question.

When a member has a conflict of interest, the member should notify the Chairperson in writingand not participate in the EC 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 (as involvement in research or relationship with researcher) may interfere with his or her impartial judgment.

c. Undertaking on Confidentiality and Conflict of Interest.

In the course of my activities as a member of the EC, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the

Confidential Information; subject to applicable legislation, including the access to it, as per the right to 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 duties) to the Chairperson upon termination of my functions as a member.

Whenever I have a conflict of interest, I shall immediately inform the committeein writing.

I, _____, have read and I accept the aforementioned terms and conditions.

EC Member's Signature: _____

Date: _____

SOP No.:	**2, Attachment 2.3.3a**
TITLE	**Confidentiality and Conflict of Interest Undertaking (Guest/observer)**

Confidentiality and Conflict of Interest Undertaking
(Ethics Committee member)

In recognition of the fact that I, _____ hereinafter referred to as the "Undersigned", have come as a guest/observer of the Ethics Committee

(EC), IEC-CS Apollo Hospitals established by Apollo Hospitals().

a. Confidential or Proprietary Information

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction as a guest/observer of the EC proceedings. 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 not be used for any other purpose or disclosed to any third party.

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

b. Conflict of Interest

The Undersigned will immediately disclose to the Chairperson of the EC 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 in respect of such proposals.

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.

c. Undertaking on Confidentiality and Conflict of Interest.

In the course of my activities as a guest/observer of the EC, I agree to take

reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to 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.

Whenever I have a conflict of interest, I shall immediately inform the committeein writing.

I, _____, have read and I accept the aforementioned terms and conditions.

Guest/observer Signature: _____

Date: _____

INSTITUTIONAL ETHICS COMMITTEE-CLINICAL STUDIES (IEC-CS) APOLLO HOSPITALS

SOP No.:	**6(Addendum-2)**
TITLE:	**Submission of Documents For Review of New Study**

Version : AH- 014	Issue Date:	Revision Date:	Validity: 3 years
Date of Addendum		-do-	-do-

	Name	Designation	Sign & Date
Approved by		**Member Secretary**	

Submission Of Documents For Review Of New Study

6.1 Objective: To describe the procedure and requirements for submission, receipt and circulation of study documents for a new study and categorization to the type of review needed by the members secretary/ secretariat

6.2 Scope: This SOP covers the methods and activities to be followed by PI/study team for submission of documents for review by IEC members and the requirements pertaining to these submissions, to ensure a diligent review of new studies. It also explains a detailed process followed by the Member secretary/secretariat on the categorization of the submitted protocols for the type of review needed including the Fast track review

6.3 Attachments:
6.3.1Documents Checklist for New Study Review
6.3.2Institutional Ethics Committee Fees Structure
6.3.3 Checklist for Types of Review

6.4 Responsibility: Principal Investigator, Member Secretary, and IEC Secretariat

6.5 Procedures:

i. The applicant of the protocol, Principal Investigator ("PI"), is required to submit 2 copies of New Protocol Application along with the soft copy/required number of hard copies of the study documents as per the Attachment 6.3.1.

ii. The investigator in his submission letter shall also write the number of trials he is involved in and the phase in which the trials are. This will help the IEC decide on the Investigator's ability to take up a new study.

iii. The IEC fees for review of the study will be as per the Attachment 6.3.2.The fees will be applicable for the first submission and on the submission date annually, till the study close out.

iv. The Principal Investigator shall submit the PI checklist for Protocol review all documents, which are related to the New Study, shall be submitted to IEC Office at least three weeks prior to the meeting. Documents can be submitted for review within 7 calendar days for a Fast track review

v. The submission letter to the IEC shall be signed, dated and acknowledged by the Member Secretary.

vi. The member secretary/secretariat will then categorize the submission based on risk and timeline involved into three types:, Expedited , Scheduled or Fast Track review(Att 6.3.3)

vii. The IEC Secretariat shall ensure that the new study is listed in the Agenda accordingly for the IEC meeting (expedited/full board/Fast Track) and shall circulate the Agenda and study documents to all the IEC members online. The applications received (for both new and approved research) shall be categorized for review through full board (as per SOP No. 7)/expedited (as per SOP No. 10) process. If an Investigator submits the documents for an ongoing study after the circulation of agenda and requests for its review at the forthcoming meeting, the Member Secretary includes the same as an Addendum to Agenda, keeping the chairperson informed, the documents and Addendum to agenda is circulated again online to all IEC members. The process for Fast Track review will be the same as SOP 7, except that the time between submission and review is less than the regulatory requirement of 21 days.

viii. The IEC secretariat shall send the complete set of documents to the members. In addition to that, following documents shall be circulated to the members who are scheduled to attend the meeting:

a. To primary reviewer and scientific members(Basic medical scientist and clinicians):
    1. Primary Review Form

b. To non-scientific members(Lay person and Social Scientist):
    1. ICD Review Form

c. To legal person/s:
    1. CTA
    2. Insurance
    3. DCGI (CDSCO) submission/approval letter
    4. Indemnity
    5. ICD
    6. Any other legal document
    7. CTA review form

ix. The secretariat shall consult the member secretary and chairperson to decide the number of new research proposals that can be accepted for each meeting.

SOP No.:	**6, Attachment 6.3.1**
TITLE:	**Documents Checklist for New Study Review**

Documents Checklist for New Study Review

Protocol No/Title:

PI:

DOCUMENTS	Copies to be Submitted	Received (Y / N)
1. **New Protocol Application**(Application letter from Principal Investigator for Study Approval).	**2 Original copies on the PI's letterhead**	
2. Signed Trial Protocol (including protocol amendments), (with date & version no).		
3. PI's checklist for protocol review		
4. Investigator's Brochure (with date & Version no.)		
5. Patient Information Sheet and Informed Consent Form (including amendments if any) in English and vernacular languages with back translations		
6. Certificate of Translation and Back translation of ICD		
7. Copy of case report forms (if not in protocol)		
8. Any other written information to be provided to the subjects		
9. Current CV (Signed & Dated) of PI and Co-Investigator,		
10. List of team members with Qualification & Role.		
11. Insurance Policy / Compensation for participation and for any serious adverse event/s occurring during the study participation period.		
12. Investigator's Agreement with the Sponsor – Clinical trials Agreement (CTA).		
13. Indemnity from the Sponsor (if not provided in CTA).		

14. Financial aspects of the trial - Budget.		
15. Investigator's Undertaking		
16. Regulatory Approval Status: a.DCGI (CDSCO) approval for the study/Marketing Approval for post-marketing/phase IV Study. b. Notified/Non-Notified list of DCGI gazette no.----- c. CE mark/FK 510 approval/any other regulatory approval d. Registration status in India		
17. DGFT / NOC from DCGI (CDSCO) (if required to send (Biological) samples outside India).		
18. Import License for test drug (if applicable)		
19. ICMR-CTRI registration certificate/number		
20. PI's Declaration regarding Conflict of Interest (if not provided by the sponsor)		
21. GCP training certificates of PI & study team members		
22. HRPP purview determination (photocopy)		

***Please provide soft copies for all the possible documents**

IEC Secretariat:

Sign & Date:

SOP No.:	**6, Attachment 6.3.2**
TITLE:	**Institutional Ethics Committee Fees Structure**

Institutional Ethics Committee Fees Structure

Effective from:

Study Category	A* EC fees (Rs.)	B**. Annual renewal (Rs.)	C Expedited (Rs.)	D Fast Track(Rs.)
Phase 1	1,50,000/-	75,000/-	NA	NA
Phase II, III,IV, PMS/product based registry	1,10,000/-	55,000/-	87,500/-	1,30,000/-
Medical devices (listed or non-listed)	1,10,000/-	55,000/-	87,500/-	1,30,000/-
Observational, retrospective, disease registry study	95,000/-	47,500/-	64,000/-	NA
Bio-equivalence/bio-availability/therapeutic/equivalence of generic formulations	1,10,000/-	55,000/-	87,500/-	1,30,000/-

Amount will be payable with additional service tax as per government rates applicable.
TDS may be deducted as per Govt. regulations and Form 16 provided.

	Fees (Rs)	Comments
Protocol Amendments	20,000/-	For every approval
Serious Adverse Events	20,000/-	1st SAE onwards

1. This fee structure will be applicable to new protocols as well as the ongoing ones.
2. This EC fee structure shall be revised every financial year

* Applicable for new protocols, valid for 1 year from the date of protocol submission.

** Will be chargeable for subsequent years till study close out.

EC Fees Payment Particulars:

Payee name for EC fees	:	Apollo Hospitals Enterprise Limited
PAN No.	:	
Postal Address	:	

EC Member Secretary Name:

Sign /Date:

SOP No.:	**6, Attachment 6.3.3**
TITLE:	**Checklist for Type of Review**

Checklist for Type of Review

	Scenarios	Type of review
A	Proposal that pose no more than minimal risk like research involving : ➢ Modification or amendment to an approved protocol (admin changes/typo errors/change in researchers) ➢ Minor deviations from approved research posing causing no risk or minimal risk ➢ Progress reports or annual reports-activity limited to data analysis ➢ Research during emergency and disasters And all those as mentioned in SOP 10, 10.5 (iv)	Expedited

B	All proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review ➢ Research involving vulnerable population ➢ Research with minor increase over minimal risk ➢ Studies involving deception of participants ➢ Research proposals that have been exempt from review/undergone expedited review/sub committee review should be ratified by a full board, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee ➢ Amendments of protocols or related documents ➢ Major deviations or violations from the protocol ➢ Any information that arises during conduct which needs to decide on whether or not to terminate the study in view of the altered benefit-risk assessment ➢ Prior approval of research on predictable emergencies	Scheduled meeting

C	Protocols in which there is a societal, community or national need to be reviewed in the least possible time, to be able to let research processes be hastened.	Fast Track Review

INSTITUTIONAL ETHICS COMMITTEE-CLINICAL STUDIES (IEC-CS) APOLLO HOSPITALS

SOP No.:	**7.(Addendum-3)**
TITLE:	**Review and Decision-Making Procedures**

Version : AH-014	Issue Date:	Revision Date:	Validity: 3 years
Date of Addendum		-do-	-do-

	Name	Designation	Sign & Date
Approved by		**Member Secretary**	

Review and Decision-Making Procedures

7.1 Objective: To describe the procedures for reviewing and decision making for new studies as well as approved ongoing studies.

7.2 Scope: This SOP deals with the process involved in the review of applications submitted for initial review, continuing review, or review of modifications to approved research; preparing agenda for the meeting; circulating the documents for review; suspension or termination of research; preparation and circulation of the Minutes of the Meeting; and correspondence to the PI/researcher regarding outcome of IEC review. The processes can be now done virtually, F2F or in a hybrid fashion, as the time and situation demands

7.3 Attachments:
7.3.1. Primary Review Form
7.3.2. Format for Conditional Approval Letter
7.3.3. Format for Final Approval Letter
7.3.4. Template for Agenda/Minutes of Meeting
7.3.5. Checklist for Clinical Trial Agreement review
7.3.6. Format for attendance and COI

7.4 Responsibility: IEC Members, and the secretariat

7.5* Procedures:

i. The IEC secretariat shall send the complete set of study documents, online , along with the agenda to the IEC members. The Primary review form, ICD review form, CTA checklist will be sent to the members identified and delegated for the same. The members shall review the proposal and also complete the review forms and checklist (as per delegation) with a sign and date and share with EC either physically or online. If an IEC member is unable to participate in a particular meeting, he/she shall inform the Member Secretary about the same prior to the meeting. Care shall be taken to ensure majority of the EC members are available for the meeting. If the members

available for the meeting do not fulfill the quorum requirements, Chairperson shall be consulted and the meeting will be postponed. Quorum is a majority of members consisting of at least one representation from each of the following category:

a. Basic medical scientist
b. Clinician
c. Legal expert
d. Social scientist / social worker/activist/theologian
e. Layperson

If the IEC reviews research that involves categories of participants vulnerable to coercion or undue influence, one or more individuals who are knowledgeable about or experienced in working with such participants are also invited. When the protocol needs a subject expert opinion and that expertise is not found in the members of the Ethics committee, a subject expert is invited and the process is followed as per SOP 5.

ii. The secretariat shall assign an Application number to each new protocol and mention in the minutes of the meeting by filling in the boxes "☐☐☐-☐☐-☐☐☐/☐☐-☐☐" with alphabets/numbers in sequential order - prefix of site, CS (Clinical Studies), the new protocol application no. in the first three boxes, the month of submission after the slash and the current year after the dash sign. The numbers would start with 001with the first submission every new year.

iii. The IEC members may send their queries to the Member Secretary in advance (before the meeting) and this will be informed to the Principal Investigator. The P.I. may send the response to the Member Secretary in advance or discuss the same during the IEC meeting

iv. The PI/Co-I/Researcher will be requested to attend the meeting (online/offline) to provide the outline of the study and discuss/clarify any queries. Decision regarding the new study shall be taken when sufficient time has been allowed for review and discussion on the application by the Quorum.

v. The review by IEC shall be focused on following criteria for approval of research during initial review, continuing review, or review of modifications to previously

approved research:

a. **Risks to Participants:**
   1. Risks to participants are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose participants to risk.
   2. Risks to participants are minimized whenever appropriate, by using procedures already being performed for diagnostic or treatment purposes.
   3. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

b. **Access to participants &selection:** Any advertisement material proposed to be used for the trial include name and address of the Researcher or Research facility, purpose of research, eligibility criteria, risk & benefits, study duration & contact details. Such material should not imply any certainty of outcome, exculpatory language or focus on the trial related payment or free treatment. Selection of participants is equitable, taking into account the purpose of the research, the setting in which the research will be conducted, the special concerns in research involving vulnerable populations, the selection criteria, and the recruitment procedures.

c. **Safety and Data Monitoring plan:** When appropriate, the protocol has a provision for an external Data Monitoring Committee and Safety Monitoring Board which periodically reviews the cumulative safety data. The protocol makes adequate provision for periodic and timely assessment of the Safety data, including SAEs (using study documents, CRF, patient visits, telephone calls) to ensure the safety of participants. The above provisions if not met, study approval may get suspended or terminated.

d. **Privacy:** There are adequate provisions to protect the privacy of participants.

e. **Confidentiality:** There are adequate provisions to maintain the confidentiality of data.

f. **Vulnerable populations:** When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons orany other condition that compromises the voluntariness or understanding, additional safeguards are included in the study to protect the rights and welfare of these participants.

g. Contract (with legal clearance) specifying the obligations of parties for protection of research participants, safety, rights and wellbeing with adequate provisions for

insurance, indemnity, compensation and budget will be reviewed by the legal expert along with the checklist for clinical trial agreement review, right at the draft stage. The final CTA will be taken up for approval later.

h. **Consent:** Consent is sought from each prospective participant or the participant's legally authorized representative/ impartial witness as appropriate. Assent is practiced for children participating as subjects.

vi. The IEC members /external experts shall review the protocols in-depth on scientific aspects. A Primary reviewer, an ICD reviewer and a CTA reviewer shall be designated by the member secretary for each new application. Member with Medical qualification will be considered as Primary reviewer while the nonscientific members (representing the participants) will be considered as ICD reviewer. For the translated versions of the ICD, care shall be taken to ensure the reviewer knows the language, or else, it is reviewed along with an IEC member who is conversant with the language of the ICD being approved. The legal member of the EC will be the CTA reviewer.

vii. During the meeting, the Chairperson shall ascertain availability of the quorum members and the office bearers (with no dual role). The members will also declare their Conflict of Interest in writing. Same will be duly recorded in minutes

The decisions shall be taken with a broad consensus in the presence of the quorum as per the regulatory requirements. If the quorum is lost during the meeting, the decision making shall be kept on hold until quorum is restored and this will be duly mentioned in the minutes. Total agreement and consensus by all the members to the point in the agenda is what constitutes approval. In case of any disagreement on an ethical or scientific issue, an appropriate expert opinion shall be sought and the research project discussed again at a later date for decision making. Recusing or withdrawing by members because of Conflict of Interest would be duly recorded in the minutes. The primary review/ICD review/CTA review shall be discussed in the meeting before a decision is reached. For the draft CTA, comments raised, if any, has to be shared with the central legal team (a copy of the CTA review form must be forwarded after the Meeting). Care shall be taken while reviewing and approving the final CTA

a. The decision shall be made on the research as per following:

1. Approved – with or without suggestions or comments
2. Decision pending- more literature/info/discussions needed
3. Revision with minor modifications/amendments – approval is given after examination by the Member Secretary or expedited review, as the case may be;
4. Revision with major modifications for resubmission – this will be placed beforethe full committee for reconsideration for approval; or
5. Not approved (or termination/revoking of permission if applicable) – clearly defined reasons must be given for not approving/terminating/revoking of Permission.

viii. The attendance of the IEC members attending the meeting online or offline shall be recorded and declare their COI for agenda item, if any (Att. 7.3.6). The IEC discussions and decisions shall be recorded in the Minutes of the meeting by the Member Secretary / IEC secretariat along with fulfillment of quorum requirement. The receipt of the Agenda and dossier by mail will be confirmed and previous dossier deleted shall be documented after confirmation. The procedure for deliberations and maintaining the Minutes of the meeting shall comprise of the following:

a. Attendance at the meeting
b. Decision taken by the IEC
c. Deliberations for each action
d. Consensus
e. Basis for suggestions/query/revision
f. Basis for disapproval
g. Members who leave the meeting because of conflict of interest
h. Determination justifying waivers and research involving vulnerable population
i. Statement on Risk benefit justification
j. While rejecting or asking for a change or notification in the protocol, the EC shall indicate in writing and a copy of such reasons shall be made available to the Central licensing committee

The Minutes of the Meeting duly signed and dated by IEC Chairperson and Member Secretary shall be ready within 7 calendar days and circulated among all members of the committee. A copy of Minutes of the Meeting shall also be provided to Head of the Institution, HRPP and Quality team.

ix. The decisions of the IEC shall be communicated to the PI/researcher in writing within 7 working days from the IEC meeting in the form of a letter duly signed by the Member Secretary.

x. The IEC may decide to reverse its decision on a study approval in the event of receiving information that may adversely affect the risk-benefit ratio for the subjects participating in the research. Such a suspension or termination shall be on an urgent basis. The Chairperson of EC, Institute head, regulatory body is authorized to suspend or terminate the study approval and such action shall be reported to the IEC specifying the reasons. Suspensions and terminations of EC approval for US federally funded research are promptly (no longer than within 30 days) reported to OHRP.

xi. If any IEC member has his/her own proposal for review, then the particular member shall not participate in decision making when the proposal is discussed.

xii. Any IEC member having conflict of interest in a study shall voluntarily withdraw from the proceedings of decision making on that study. Any information requested by the IEC though, maybe furnished. The conflict of interest shall be informed to the Chairperson in writing as per the Att. 7.3.6 of the application and the same shall be recorded in the minutes

xiii. **Conflict of interest is defined as:**
   a. Financial conflict of interest: This includes a financial interest in the research with value that cannot be readily determined, a financial interest in the research with value that is unreasonably high, receiving compensation with value that may be affected by the outcome of the study, having a proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement, or holding an executive or director position in the company sponsoring the research.
   b. Non-financial conflict of interest: IEC Member (or their spouse/children/parent) is part of study team as Principal Investigator/Co-investigator in a particular proposal, or has an interest that, the member believes, is in conflict with his or her ability to objectively review a protocol.

xiv. Only the IEC members who participate in the review shall participate in the decision

making

xv. The final approval shall be given once the needed conditions are met and shall be valid for one calendar year from the date of the approval letter

xvi. If any proposal/protocol has been disapproved, the reasons for the rejection shall be clearly stated in a letter to the PI stating the possible course of action for re-submission.

xvii. The communication of the decision shall include (as applicable):

a. The exact title of the research proposal reviewed
b. IEC application number
c. The clear identification of the protocol of the research or amendment, date and version number on which the decision is based.
d. The name and title of the applicant and site address
e. The names and specific identification numbers (version numbers, dates) of the documents reviewed, including the Subject information sheet or material and informed consent form.
f. The name of the Institutional Ethics Committee-Clinical Studies taking the decision.
g. The list of Institutional Ethics Committee-Clinical Studies' members who have participated in decision-making.
h. The date, time ,venue and mode of the IEC meeting.
i. Clear statement of the decision reached.
j. Any advice by the Institutional Ethics Committee.
k. Period of validity

xviii. The following requirements from the P.I. shall be mentioned:

a. IEC to be kept informed about the date of initiation of the study, the date of first and last patient recruitment and site close out at the earliest and not later than 5 working days
b. Submit a report of the clinical trial as directed, and submit the final study report.
c. Submit a complaints and non-compliance form to IEC after each monitoring/inspection. Submit a report of each protocol deviations/violations and serious adverse event with regard to the study. The AEs to be reported before each IEC meeting.
d. IEC to be kept informed of amendments/revisions to any study-related documents as

well as patient safety related information.

e. IEC to be informed about study close-out / discontinuation with reasons.

In case, if the above requirements are not met, the IEC might consider the actions like suspension or termination of the research.

xix. For studies approved as: decision pending- more literature/info/discussions needed revision with minor modifications/amendments (e.g. essential documents are pending), such approval will remain effective for one year from the date of initial approval. The documents, once received, shall be reviewed and approval given. A reminder letter to be sent from the EC 3 months prior to expiry of the approval intimating that the study has to be initiated within one year from the date of initial approval. If the study is not initiated within one year, the PI shall submit a fresh application again for approval. This will generate a new application number. The protocol file for the study can be the same as made earlier, with both the application numbers cited and all documents filed. Any and every procedure that needs to be handled virtually or in a hybrid fashion can be done ensuring seamless transition and adequate documentation.

xx. For proposals / protocols which have been disapproved as per # xvi above, if the PI re-submits the study with modifications/clarifications, the same shall be verified by Member Secretary. If found appropriate, it shall be included in the next convened IEC meeting for full board review by the IEC.

xxi. Periodic review of ongoing clinical trials/research will be done based on amended study documents (Protocol, IB, ICF), study progress reports submitted by PI/researcher, protocol non-compliance, or any evidence of safety concerns as per the reported adverse events. The ethics committee will continue its oversight and plan at least one monitoring visit during the recruitment phase of the approved protocol. This will also be a Bi-annual activity of the EC. This will also ensure equitable selection of subjects with special attention to vulnerable and high risk subjects. The PI shall update the EC with the continuing review information (study progress report) at the intervals specified in the approval letter. The IEC will send a reminder (for re-approval) 3 months prior to the expiry and also add it as an agenda item in the subsequent EC meeting to ensure re-approval happens on time

If a PI/researcher does not provide "continuing review information" to the IEC on time or the IEC has not "approved" a protocol on/ before the expiration date, a written notification shall be sent to the Researchers saying:

a. All research activities stop.

b. Interventions and interactions on current participants stop, unless the EC finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating.

c. New enrollment of participants may not occur.

xxii. The IEC Secretariat shall store and archive one copy of all the study documents submitted by the PI/researcher after the same has been discussed at the IEC meeting and the additional copies shall be destroyed.

xxiii. **Suspension/termination of approval:**

a. Suspensions and terminations represent an action by the IEC to temporarily or permanently withdraw approval for some or all research procedures.
b. If the IEC finds any continuing safety issues, fraud, misconduct, serious/ continuing non-compliance by the PI/study team, research not conducted in accordance with IEC requirements, research associated with unexpected serious harm to participants, or unanticipated problems involving risk to participants or others, the IEC may suspend or terminate the approval of the study, as decided during convened full-board meeting.
c. While determining such action, IEC shall consider actions to protect the rights and welfare of currently enrolled participants, whether procedures for withdrawal of enrolled participants take into account their rights and welfare (e.g., making arrangements for medical care outside of a research study, transfer to another Researcher, and continuation in the research under independent monitoring), and informing current participants of the termination or suspension. IEC shall also ask for continued recording of any adverse events or outcomes, if in the same facility.
d. Such action shall be recorded in the Minutes with written intimation to PI/researcher, Head of the institution, HRPP office, Quality team, informing appropriate

Sponsor/CRO/regulatory authorities. The process of reporting shall be completed within 30 calendar days from the determination of action.

7.6 SAE Review: SAEs will be reviewed by full board or in an expedited meeting of IECmembers satisfying the quorum requirements and an expert if needed. The opinion generated shall be communicated to the stakeholders concerned as per the regulatory guidelines. In case it is an expedited meeting, the opinion generated will be ratified in the next full board meeting

7.7 Guidelines to be followed while reviewing Vaccine trials:

a. Trials should be scientifically and ethically sound.

b. Adequate data from pre-clinical studies should be available to indicate that the intervention is safe for proposed investigations in humans.

c. The sponsor and investigator should be aware of the approval process (es) involved in conducting clinical trials of vaccines. They should familiarize themselves with the guidelines provided by Drug Controller General (India), National Ethical Guidelines for Biomedical and Health Research involving Human Participants, Department of Biotechnology (DBT) and Ministry of Environment and Genetic Engineering Approval Committee (GEAC) in the case of vaccines produced by recombinant DNA technology.

d. Some vaccines that contain active or live-attenuated microorganisms can possibly possess a small risk of producing that particular infection. The subjects to be vaccinated should be informed of the same.

e. The subjects in control groups or when subjected to ineffective vaccines run a risk of contracting the disease.

f. The risks associated with vaccines produced by recombinant DNA techniques are not completely known. However, for all the recombinant vaccines/products the guidelines issued by regulatory authorities should be strictly followed. Trials should be conducted by investigator with the requisite experience and having necessary infrastructure for the laboratory evaluation of seroconversion.

g. Protocols for such trials should include appropriate criteria for selection of subjects, plan of frequency of administration of the test vaccine in comparison with the reference vaccine. It should accompany detailed validation of testing method to detect the antibody titter levels.

h. It should specify methodology to be adopted for prevention of centrifuged serum for the purpose of testing.

i. The investigator should be provided with Quality Control da

j. The sponsor should provide the Independent Ethics Committee approval of the nodal body (ies) to carry out clinical trials with the vaccine.

k. The generic version of new vaccines already introduced in the other markets after step up clinical trials including extensive Phase III trials should be compared with the reference vaccine with regard to seroconversion in a comparative manner in a significant sample size.

l. Post Marketing Surveillance (PMS) should be required following seroconversion studies. PMS data should be generated in a significant sample size sensitive to detect side effects and address other safety issues.

m. Protocols for test of new vaccine should contain a section giving details of steps of manufacture, in-process quality control measures, storage conditions, stability data and a flow chart of various steps taken into consideration for manufacture of vaccine. It should also contain detailed method of quality control procedure with the relevant references.

7.8 Guidelines for reviewing Clinical trials for Diagnostic Agents and Use of Radio-active Materials and X- Rays

a. The EC must review the pharmacology, toxicology, pharmacokinetics and safety data (preclinical and clinical data as applicable) especially for diagnostic agents which come in contact with skin or mucosal surfaces in the human body (in vivo use).Expert

opinion may be sought for review of protocols of such products.

b. The protocol must state clearly the choice of the reference with justification. Likewise, omission of a reference standard as comparator must also be justified.
c. There have to clear justifications in the protocol for the use of a placebo and no irreversible harm should occur to the participant. Post-trial access to the standard of care diagnostic test must be assured.
d. Safety follow-up of patients in these trials should be extended for a longer period if applicable.
e. Long term safety should be assessed.
f. Informed consent should be obtained before any diagnostic procedures.

Guidelines for reviewing Clinical trials with the Use of Radio-active Materials and X-Rays

a. The protocol and ICD should clearly state the potential radiation exposure to which participants are likely to be exposed. This should be within the applicable limits.

b. Information to be gained should be gathered using methods that do not expose subjects to more radiation than exposed normally.

c. Research should be performed on patients undergoing the procedures for diagnostic or therapeutic purposes.

d. Safety measures should be taken to protect research subjects and others who may be exposed to radiation.

e. The protocol should make adequate provisions for detecting pregnancies to avoid risks of exposure to the embryo.

f. Information to subject about possible genetic damage to offspring should be given.

g. Non-radioactive diagnostic agents are considered as drugs and the same guidelines should be followed when using them.

h. Ultrasound to be submitted wherever possible.

7.9 Guidelines to be followed while reviewing clinical trials on Traditional Systems of Medicine:

a. It is important that plants and herbal remedies currently in use or mentioned in literature of recognized Traditional System of Medicine is prepared strictly in the same way as described in the literature while incorporating GMP norms for standardization. It may not be necessary to undertake phase I studies. However, it needs to be emphasized that since the substance to be tested is already in used in Indian Systems of Medicine or has been described in their texts, the need for testing its toxicity in animals has been considerably reduced. Neither would any toxicity study be needed for phase II trial unless there are reports suggesting toxicity or when the herbal preparation is to be used for more than 3 months. It should be necessary to undertake 4-6 weeks toxicity study in 2 species of animals in the circumstances pointed out in the preceding sentence or when a larger multicentric phase III trial is subsequently planned based on results of phase II study.

b. Clinical trials with AYUSH and TM should be carried out in accordance with the ethical principles described in National Ethical Guidelines for Biomedical and Health Research involving Human Participants, AYUSH GCP guidelines and other applicable regulations. The recommendations made earlier regarding informed consent, subject, inducements for participation, information to be provided to the subject, withdrawal from study and research involving children or persons with diminished autonomy, all apply to trials on plant drugs also. These trials have also got to be approved by the appropriate scientific and ethical committees of the concerned Institutes.

However, it is essential that such clinical trials be carried out only when a competent Ayurvedic, Siddha or Unani physician is a co-investigator in such a clinical trial.

References in ancient literature of above-mentioned traditional systems of Medicine, carries out clinical evaluation of the plant without any concept or training in these systems of medicine. Hence, it is necessary to associate a specialist from these systems and the clinical evaluation should be carried out jointly.

c. When a Folklore medicine / Ethno-medicine is ready for commercialisation after it has been scientifically found to be effective, then the legitimate rights/ share of the Tribe or Community from whom the knowledge was gathered should be taken care of appropriately while applying for the Intellectual Property Rights and / Patents for the product.

**Any and every procedure that needs to be handled virtually or in a hybrid fashion can be done ensuring seamless transition and adequate documentation.*

SOP No.:	**7, Attachment 7.3.1**
TITLE:	**Primary Review Form**

Primary Review Form

Protocol No & Title:

Principal Investigator:	**Sponsor:**	**CRO:**

Date of Review:

A. Purpose:

_____
_____
__

B. StudyRationale:

_____
_____

C.

1. Protocol

i) *Research Design:*

a) Scientifically sound:

b) Relevant to contribute to further knowledge :

c) Of national importance:

ii) Principal research question/ objective mentioned? **Yes / No**

iii) Secondary research question/ objective? **Yes / No**

iv) Scientific justification/rationale? **Yes / No**

v) Has similar research been done before? **Yes / No**
If yes:

vi) Statistics:

a. Is the sample size of study as per protocol and synopsis? **Yes / No**

b. Is the sample size statistically justified? **Yes / No**

2. Ethical Issues

i. Placebo **Yes / No**

ii. Vulnerable population **Yes / No** (if yes: complete 5 (ii)

iii. /Continuity of treatment (post-trial access) **Yes / No**

3. Risks to subjects (physical, psychological, social, economic, or legal)

i. Novel Procedures: **Yes / No**

ii. Is the monitoring plan adequate? **Yes / No**

iii. Is there a plan to mitigate the physical/social/psychological risk or discomfort? **Yes / No**

iv. Does the inherent risk still ensure a favorable risk/ benefit balance? **Yes / No**

v. Risk level : (based on checklist on page 4)
a. Less than Minimal
b. Minimal
c. Minor increase over minimal risk or low risk
d. More than minimal risk or High risk

vi. Is the overall risk/benefit ratio: **Acceptable / Unacceptable**

vii. Type of review :
a.Expedited review
b.Fullboardreview

4. Benefits (e.g. therapy, education, information, resources, or empowerment)

i. Direct: Reasonable / Undue / None

ii. Indirect: Improvement in knowledge / Benefit to society / any other:

5. Subject selection:

i) Subject selection: Inclusion / exclusion criteria addressed? **Yes** / **No**

ii) Vulnerable subjects: **Yes** / **No** **(if yes, please answer (a-k)**

a) Economically and socially disadvantaged **Yes / No**

b) Unduly influenced either by expectation of benefits or fear of retaliation **Yes / No**

c) Children (up to 18 years of age) **Yes / No**

d) Women in special situations (pregnant/lactating/poor decision making powers/poor access to health care **Yes / No**

e) Tribal's and marginalized communities **Yes / No**

f) Refugees, migrants, homeless, people in conflicting zones **Yes / No**

g) Afflicted with mental illness and cognitively impaired **Yes / No**

h) Terminally ill, and in search of new interventions having exhausted all therapies **Yes / No**

i) Suffering from stigmatizing or rare diseases **Yes / No**

j) Diminished autonomy due to dependency or being in a hierarchical symptom (students, ,employees, subordinates, defence services personnel ,health care workers,institutionalized individuals, under trials and prisoners) **Yes / No**

k) Any other condition that compromises the voluntariness or understanding **Yes / No**

If yes for any of the items in 5 ii)

- Is the inclusion justified **Yes / No**
- COI jeopardizing risk/benefit ratio **Yes / No**
- Risk/benefit justified **Yes / No**
- Additional safeguards needed **Yes / No**

6. Privacy & Confidentiality maintained? **Yes / No**

7. i) The available nonclinical and clinical information in the Investigator Brochure on the investigational product is adequate to support the proposed research: **Yes / No**

ii) Patient Information Sheet & Consent form**:** Applicable / NA
(If NA, please skip no. 8)

8. Consent form components addressed adequately? **Yes / No**

9. Compensation, (if applicable) addressed adequately**?**

10. Is there a Conflict of Interest from the PI? **Yes / No**

If yes: **Acceptable / Unacceptable**

Comments:

11. Are the PI and research team members competent and fully equipped with adequate resources to conductthe study and protect the participants?
Yes / No

12. Is the research activity going to be monitored and scrutinized in an impartial and transparent manner?

Yes / No (if yes, answer (i-iii)

i. Does the study require DSMB? **Yes / No**

ii. Will the DSMB report be shared? **Yes / No**

13. Are the findings of the study going to be brought into the public domain so that its results are generally made known through scientific and other publications? **Yes / No**

14. Interval for Periodic Status/Progress Report to be submitted by PI (based on phase of the study, risk involved and continuing review):

Quarterly/ Half-yearly / Yearly

Checklist for Risk analysis* Ref: ICMR		
A	**Less than minimal Risk**	
i	Research on anonymous data/ samples.	
ii	Research on data available in public domain.	
B	**Minimal Risk**	
i	Research involving routine questioning or history taking	
ii	Research involving observation of physical examination/ obtaining body fluids without invasive intervention	
C	**Low Risk/ Minor increase over minimal risk**	
i	Routine research on children or adolescents	
ii	Research on persons incapable of giving consent	
iii	Withholding/delaying a proven intervention in randomized trials	

iv	Research involving use of minimally invasive procedures	
v	Trying new diagnostic technique in pregnant/breastfeeding women	
vi	Use of personally identifiable data imposing indirect risk	
vii	Research involving patients incapable of giving consent	
viii	Research involving social risks and psychological harm or discomfort	
D	**High Risk**	
i	Research involving interventional study using drug/ device/ invasive procedure	

15. Any other remarks/suggestions

Reviewer's name: _____ _____

Signature & Date

SOP No.:	**7, Attachment 7.3.2**
TITLE	**Format for conditional approval letter**

Format for conditional approval letter

Date:

To
Dr. ------

Ref: IEC Application No:

Protocol No:

Title:

Sub: Conditional Approval (Subsequent to your letters dated --------).

Dear Dr. _____ ,

The Institutional Ethics Committee – Clinical Studies- Apollo Hospitals reviewed and discussed the documents submitted by you related to the conduct of above-mentioned study at the meeting held on -------.

The following documents were reviewed:
(a) Trial Protocol (including protocol amendments), dated_____ version no (s). _____
(b) Patient Information Sheet and Informed Consent Form -----
(c) Investigator's Brochure, dated_____, Version no._____
(d) Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.
(e) Principal Investigator's current CV.

The following members of the ethics committee were present at the meeting held on (date, time, and place)

S. No	Name	M/F	Qualification	Affiliated to institution Y/N	Designation	Position In The Committee

- (Member) cited conflict of interest and didn't participate in the decision making process.

After due ethical and scientific considerations, the Ethics Committee has conveyed/opined/suggested the following changes:
1.
2.
.
The following documents needs to be submitted by you for review and final approval before the study can be initiated.
1.
2.

The Institutional Ethics Committee – Clinical Studies is constituted and works as per ICH-GCP, National Ethical Guidelines for Biomedical and Health Research involving Human Participants (ICMR 2017) and New drugs and Clinical Trial Rules March 2019.

Yours sincerely,

Member Secretary,
Institutional Ethics Committee – Clinical Studies,
Apollo Hospitals,

IEC Application No.:□□□-□□-□□□/□□-□□ (NOTE: Please quote this application no. in all your future communications)

Status:

1. Decision pending – more literature/info/discussions needed
2. Approved with or without suggestions or comments
3. Revision with minor modifications/amendments
4. Revision with major modifications for re-submission
4. Not approved (or termination/revoking of permission, if applicable)

SOP No.:	**7, Attachment 7.3.3**
TITLE:	**Format for Final Approval Letter**

Format for Final Approval Letter

Date:

To
Dr.------

Ref: IEC Application No:
Protocol No:

Title:

Sub: Final Full Board Approval(Subsequent to your letters dated --------).

Dear Dr. ----------,

The Institutional Ethics Committee- Clinical Studies, Apollo Hospitals,……. reviewed and discussed the documents submitted by you related to the conduct of the above referenced study at its meeting held on ----------.

Documents Submitted:

1.
2.
3.

The following members of the ethics committee were present at the meeting held on (date, time, and place, online/offline)

S. No	Name	M/F	Qualification	Affiliation to the institute Y/N	Designation	Position In The Committee

- (Member) cited conflict of interest and didn't participate in the decision making process.

After due ethical and scientific consideration, the Ethics Committee has approved all the documents and the study to be conducted by you in the presented form.

Please note that the date of initiation of the study, the date of first and last patient recruitment and the site close out should be informed to the Ethics Committee at the earliest and not later than 5 working days. The Ethics Committee should also be informed about the progress of the study on **Quarterly / Half yearly / Annual basis.** Any changes in the protocol and patient information / informed consent, and a copy of the final clinical study report should be submitted Please submit a complaints and non-compliance form to EC after each monitoring/inspection..The AEs are to be reported before each EC meeting. Submit a report of protocol deviations/violations and serious adverse event as per regulatory timeline and mention the reason for delay, if any.

Please note the period of validity of this Approval is for one calendar year and ends on ----------.

The Institutional Ethics Committee – Clinical Studies is constituted and works as per ICH-GCP, National Ethical Guidelines for Biomedical and Health Research involving Human Participants (ICMR 2017) and New drugs and Clinical Trial Rules March 2019

Yours Sincerely,

_____

Member Secretary,
Institutional Ethics Committee – Clinical Studies,
Apollo Hospitals,

IEC Application No.:□□□-□□-□□□/□□-□□ (NOTE: Please quote this application no. in all your future communications)

Status: Approved

SOP No.:	**7, Attachment 7.3.4**
TITLE	**Template for Agenda* / Minutes of Meeting**

Template for Agenda* / Minutes of Meeting

Institutional Ethics Committee – Clinical Studies,
Apollo Hospitals, ----------

Minutes of the Ethics Committee Meeting

Date:----------,Day----------: Time: ----------
Venue: ----------

Members Present:

S. No	*Name*	*Position in the committee*
1		*Chairperson (Designation)*
2.		*Member Secretary (Designation)*
3		*Basic Medical Scientist*
4		*Legal Expert*
5		*Social Scientist*
6		*Lay Person*
7		*Clinician*

Absentees:

	Name	*Position in the committee*

S.No		

IEC Secretariat: Name of the person (s)

Name of Chairperson welcomed all the members. The minutes of the previous meeting were reviewed and approved and the meeting was initiated.

I- NEW PROTOCOLS

1. **PRINCIPAL INVESTIGATOR**:
   Protocol No.:
   Title:
   SPONSOR:
   IEC Application No.:
   Documents Submitted: Refer to the Agenda

   Primary Reviewer:
   ICD Reviewer:
   CTA Reviewer:
   Subject Expert: (if any)

   Chairperson confirmed quorum was met and members declared their conflict of interest /Members did not recuse from the meeting due to Conflict of interest.

   The PI explained the following:

EC Review:

The below mentioned points were discussed by the members.

Reviewed elements	Comments
Patient recruitment strategy	
Sound Research design	
Subject selection in equitable manner	
Alternate procedure	
Risk-benefit ratio	
Privacy and confidentiality maintained	
Elements of the consent form addressed	
Safeguard for vulnerable subjects	
Protocol specific findings	
CTA requirements and clauses meet the requirement	

EC Discussion:

Expert opinion: (if any)

Justification to the concerns raised by the subject expert: (if any)

The documents (1-….Nos.) submitted was reviewed and approved. Suggestions were made in document no. ------

For -
Against –
Abstained –

Recused –

Risk level:

Quarterly/half yearly/yearly progress report needs to be submitted

EC Decision:

II.PROTOCOLS AWAITING APPROVAL

1. **PRINCIPAL INVESTIGATOR:**
   Protocol No. :
   Title:
   SPONSOR:
   IEC Application No.
   Documents Submitted:

   Chairperson confirmed quorum was met and members declared their conflict of interest /Members did not recuse from the meeting due to Conflict of interest.

   EC Review and comments:

   The documents (1-…Nos.) were reviewed and approved.

   For -
   Against –
   Abstained –
   Recused -

   EC Decision:

III. APPROVED STUDY CONTINUING REVIEW SUBMISSIONS

1. **PRINCIPAL INVESTIGATOR:**

PROTOCOL NO. :
Title:
SPONSOR:
IEC Application No.:

Documents submitted:

a. OTHER NOTIFICATIONS:

- Notification of ……..

EC Review and comments:

b. STUDY DOCUMENTS AMENDMENTS
Chairperson confirmed quorum was met and members declared their conflict of interest /Members did not recuse from the meeting due to Conflict of interest.

EC Review and comments:

For
Against
Abstained
Recused

EC Decision:

c. PROGRESS REPORTS / REAPPROVAL OF ONGOING STUDIES:

Chairperson confirmed quorum was met and members declared their conflict of interest /Members did not recuse from the meeting due to Conflict of interest.

EC Review and comments:

For
Against

Abstained
Recused

EC Decision:

d. .OWN-SITE SAE- Nil

EC Review and comments:

e. PROTOCOL DEVIATIONS: Nil

EC Review and comments:

IV. AEs from (date) to (date)

Protocol Name/ Number						
Total number of AE's in the month						

S. No	Protocol Name/ Number	Patient initials/ Rand. No	Event term	Date of onset	Relationship to the study drug	Study drug status	Outcome	If resolved: stop date of the event

EC Review and comments

V. General Discussion:

Prepared by Member Secretary			Approved by Chairperson	
Name	:		Name	:
Signature	:		Signature	:
Date	:	Date		:

SOP No.:	**7, Attachment 7.3.5**
TITLE:	**Checklist for Clinical Trial Agreement review**

Checklist for Clinical Trial Agreement review

Protocol #: _____ Principal Investigator: _____

CRO: _____ Sponsor: _____ Date: _____

S. NO.	DESCRIPTION OF REQUIRED CLAUSES	YES	NO
1.	**PREAMBLE: Name & Address as PARTIES to the Agreement should be mentioned of:** **A. Principal Investigator** **B. Institution** **C. Sponsor / CRO (reference made to both)**	☐ ☐ ☐	☐ ☐ ☐
2.	**The PROTOCOL DESCRIPTION should be mentioned with:** **A. TITLE of protocol** **B. PHASE of the study (preferable)** **C. PROTOCOL NUMBER**	☐ ☐ ☐	☐ ☐ ☐
3.	**Statement for COMPLIANCE with the national and international guidelines, Protocol, Ethics Committee Approval, etc. by:** **A. Principal Investigator.** **B. Sponsor / CRO.** **C. Institution**	☐ ☐ ☐	☐ ☐ ☐

4.	**OBLIGATIONS in the conduct of the study of** **A. Principal Investigator** **B. Institution** **C. Sponsor/CRO (reference made to both)**	☐ ☐ ☐	☐ ☐ ☐
5.	**CONFIDENTIALITY clause for confidential information provided by the Sponsor / CRO to the Site.**	☐	☐
6.	**LIABILITY / INDEMNITY (with Insurance) for any injury caused to the study subjects (or claims) to be undertaken by:** **A. Sponsor - for the study drug or protocol related, with PI/institution providing medical care, and cost (or compensation in case of research-related injury/death) to be reimbursed by the sponsor.(as per GSR 53E and GSR 889E)** **B. Institution –if related to negligence of its staff.** **C. Investigator - for negligence on his part.**	☐ ☐ ☐	☐ ☐ ☐

Reviewed By: _____
Name: _____(Legal Expert)
Sign :_____
Date: _____

SOP No.:	**7, Attachment 7.3.6**
TITLE:	**Format for attendance and COI**

Format for attendance and COI

S. No	Name	M/F	Position in the Committee	*COI in any of the agenda items Y/N	If yes, reason for conflict and action taken	Signature

Signature of the Chairperson

INSTITUTIONAL ETHICS COMMITTEE-CLINICAL STUDIES (IEC-CS) APOLLO HOSPITALS

SOP No.:	**17.(Addendum-4)**
TITLE:	**General Administration**

Version : AH-014	Issue Date:	Revision Date:	Validity: 3 years
Date of Addendum		-do-	-do-

	Name	Designation	Sign& Date
Approved by		**Member Secretary**	

General Administration

17.1 Objective: To describe the administrative process related to the funding mechanism, various other functions and activities including records handling, training, self-assessments, physical facility, quality assurance, disaster recovery, requirements to meet the continuity of registrations and accreditations of the Institutional Ethics Committee-Clinical Studies.

17.2 Scope: This SOP deals with the administrative aspects of day-to-day functioning of the Institutional Ethics Committee-Clinical Studies.

17.3Attachments

17.3.1 Template for income and expenditure of the EC
17.3.2Template for Study documents record keeping
17.3.3.a. Template for list of documents stored in the cupboard/cabinet
17.3.3.b. Template for study documents archival and retrieval
17.3.4: Format for request of retrieval of archived documents
17.3.5: Format for Back up of IEC records (Hard Disk)
17.3.6: Template for EC Tracker
17.3.7. Delegation log for IEC-CS secretariat Personnel
17.3.8. Annual Training Template

17.4 Responsibilities: EC Members, secretariat, site in charge, HRPP leader/coordinator and HOI

17.5 Procedures:

i. Funding Mechanism:

a. The EC shall have a robust mechanism to support its operations as per the regulatory requirements and SOP.
b. HOI shall ensure that the committee and the members inducted into the committee have no conflict of interest and any extra financial incentive to approve/reject a particular proposal/study (att 2.3.3 and att 2.3.2)

c. The EC income (proposed fees for initial review / approval/re-approval /SAE review/review of amendments and other activities) should be clearly stated and open for revision at least once every 3 years (att 6.3.2)
d. The proposed EC expenditure (honorarium/trainings/ third party audits, if any and other miscellaneous activities) should be planned in advance
e. A record for income and expenditure shall be maintained (17.3.1)

ii. The IEC Office shall maintain the following documents in their records:

a. Curriculum Vitae, training certificates and related documents of the IEC.
b. Copy of Invitation and acceptance letters of all IEC members.
c. The IEC Standard Operating Procedures, Membership list and related documents.
d. Copy of all study submissions including Protocol, Investigator Brochure, Recruitment materials (if any), Consent forms and translations, progress reports, SAEs, records of continuing review, Data and safety monitoring reports, Amendments, Records of protocol deviations/violations.
e. Final report of the approved projects/protocols (wherever applicable).
f. Agenda
g. Minutes of all meetings duly signed by the Member Secretary and the Chairperson.
h. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.
i. Copy of all correspondence with members, researchers and other regulatory bodies.
j. Security, confidentiality and integrity of all proposals and associated documents shall be reviewed from time to time and maintained as per regulatory requirements
k. Record of all notifications issued for premature termination of a study with a summary of the reason

iii. **Record keeping, archival and retrieval:**

a. **Record keeping** The IEC Protocol file , which comprises of all the essential documents and correspondence related to the protocol, is established at the time of initial submission and Excel sheet as per att.

17.3.2 is updated. The ongoing files (IEC Protocol files and Administrative files) will be kept in the file cupboards/cabinets with proper labels and identifiers as below:

IEC App. No.	PI to EC letter date
PI Name	Date of EC meeting
Protocol No.	Documents Submitted
Protocol Name	

These are kept easily accessible and secure with access control in the IEC secretariat/ storage room in dedicated cupboards/cabinets. Att. 17.3.3.a tabulates the placement of each EC protocol file/packets/documents as per their submission dates in the given cupboards /cabinets.

b. **Archival** is planned after study close out. All documents shall be archived as per the applicable regulatory requirements with utmost confidentiality for a prescribed period as follows:
    1. IEC Membership and Administrative documents: 5 years after completion of tenure.
    2. Study documents for Approved /terminated studies/: 5 years after study close-out (hard & soft copy).
    3. Study documents for Not Approved studies: 5 years.

Each EC protocol file documents archived will be packed in covers with the following details:

EC App. No.	PI to EC letter date
PI Name	Date of EC meeting
Protocol No.	Documents Submitted
Protocol Name	

Multiple EC protocol document packets shall be kept in cupboard/cabinet till third party archival happens. Each EC protocol file shall be archived along with the needed documents as per regulatory guidelines and SOP along with 17.3.3.a. sheets. The archival and retrieval register will capture details (Att. 17.3.3.b.) The archived documents are disposed off once the tenure is met. The PI will be

informed and the documents will be shredded at the site/third party archival. The same will be updated in the register

c. **Retrieval**

Retrieval of the archived documents maybe done if needed during any inspection or audit. A prior written request (Att.17.3.4) for retrieval, stating the purpose for accessing the documents shall be entertained. Documents are then retrieved at the earliest. The same has to be returned once the purpose of retrieval is met. This has to be to be documented in the register.

iv. **Training and self assessments:** The IEC members are encouraged to keep themselves abreast of all the recent regulatory guidelines and developments in the field of Ethics and Clinical research. They shall undergo F2F/ Virtual trainings three times a calendar year(Feb/Mar, Jun/Jul, and Oct/Nov)on latest versions of ICH-GCP, ICMR guidelines, New Drugs and Clinical Trial Rules 2019, Drugs and Cosmetics Act, Indian GCP, NABH and AAHRPP standards as well as the EC SOPs. Self assessments of the EC members shall be conducted online on a half yearly basis by the quality team and the corrective and preventive actions shall be planned after evaluating the assessments. Composite assessment report would also help decide the topics needed for training. An annual assessment of the EC functioning also shall be done and actions planned for improvement every calendar year. This shall also include the results of the Quality Indicators (QI) for the present year and the plan for the next year. The EC shall train new members before induction and/or existing members annually/earlier, as per need. The documentation of any training conducted has to be complete with a minimum of the following available in the file: the mode of training, the agenda, the material used, the trainer's CV (if possible) and the attendance log. The documentation of the training to be available in the MOM.

v. **Quality Assurance:** The quality team/IEC Member Secretary/designated member and the institution will ensure the quality of IEC functioning from time to time.

vi. The IEC Member Secretary/the designated member shall allow and assist any

regulatory / competent authority to inspect the records and activities of the IEC. The IEC Secretariat shall inform all the IEC Members of such inspection and present the report at the IEC meeting.

vii. An account of the honorarium paid will be maintained by IEC secretariat.

viii. The IEC secretariat will consist of adequate full-time/part-time staff(s) who will assist the Member Secretary in all the functions. The IEC Secretariat will be appointed after assessing the qualification/experience required to perform the required roles and responsibilities. The Member Secretary will delegate the secretariat his/her functions for smooth functioning of the Ethics Committee (Att. 17.3.7).

ix. The IEC secretariat shall maintain a list of all the trials reviewed by IEC and keep it updated on real time.(att. 17.3.6)

x. **Complaints /concerns**: In the event of any complaints / concerns raised by any Principal Investigator or study participant, the same shall be informed using the feedback form. The IEC chairperson, Member secretary, HRPP leader/coordinator, site in charge shall follow the process as per SOP 9. If need be, Head of the institution shall be taken into confidence. Suitable corrective action or response shall be sent to the concerned applicant within 30 days.

xi. **Physical Facility:** The physical work area and records storage for IEC shall be demarcated separately in the clinical trials unit of the Institution. The entry to this area shall be controlled by the staff and the access to any physical/electronic records shall be restricted to authorized persons using locked cupboards/password protected access. This facility shall have provision for temperature & humidity control (maintained through standard air conditioning) and fire extinguishers and pests/rodents control services.

xii. **a. Disaster Recovery and Business Continuity**: In the event of any disaster damage IEC records and/or IEC facilities and/or IEC personnel, the Head of the Institution will make arrangements to appoint suitable staff to continue the functions of IEC and provide suitable working space. The IEC-/new staff shall contact the Principal Investigators / Sponsor-CRO teams and inform them about the disaster and damages and work with them to try and replace the records with the copies available. A system for back-up of data and records of IEC will be planned from time-to-time as per the requirements. This back up data will be taken on a weekly basis on the hard disk and kept with the site incharge. The same will be documented in the register showing the proof of back up taken and identity of the person authorized with who the back up is stored (Att 17.3.5)

b. Pandemic and Emergency situations: Care shall be taken to ensure continuity of research activities with the maximization of benefits and minimization of risk at any given situation. The regulatory guidelines issued shall be followed for compliance. Necessary documentation shall always be maintained.

xiii. The IEC Member Secretary with the help of the secretariat shall maintain and renew the registration of IEC with the Office of Drugs Controller General (India), Ministry of Health and Family Welfare, as per the rule.

xiv. The IEC Member Secretary with the help of the secretariat shall, maintain and renew the IEC accreditation with NABH.

xv. The AAHRPP accreditation maintenance and renewal will be taken care by the chosen AHEL representative/s.

xvi. The IEC Member Secretary with the help of the secretariat shall also maintain and renew the registration of IEC with US Based Department of Health and Human Services (online registration) as per 21 CFR Part 56.

xvii. **Any negative action**: Any negative action on the organization or a researcher/s taken by a government oversight office, any sanction by the regulatory agencies, any litigations , arbitrations, settlements initiated related to human research protections, any press coverage of negative nature regarding the organizations, the same has to be reported to the IEC and the quality team by the site within 48hours of knowing.

SOP No.:	**17, Attachment 17.3.1**
TITLE:	**Template for income and expenditure of the EC**

Template for income and expenditure of the EC

Apollo Research & Innovations-2019-20	
Particulars	
(A) Ethics Committee Fee	-
Total (A)	-
Indirect Expenses	
(B) Employee Cost	
7201002 - Salaries - Employees	
Coordinator Salaries Trials	-
7207001 - Staff Welfare - O.P Lab Investigation	
Total (B)	-
('C)Adminstrative Expenses	
7304002 - Repairs & Maintenance Building	-
7305003 - Travel Expenses Others	-
7309002 - Postages & Courier Exp	
7309003 - Telephone Expenses	
7312004 - Printing & Stationery	-
7319007 - Expenses Others	
Refreshment - Admin	
Refreshment - EC	-
Registration Fee - EC	
Sitting Fee - EC	
Total ('C)	-
Total (B+C) = D	-
Profit and Loss Account (A- D)	-

SOP No.:	**17, Attachment 17.3.2**
TITLE:	**Template for study document Record keeping**

Template for study document Record keeping(Xcel Sheet)

S. No	IEC App.#	Protocol Number	PI Name	Sponsor / CRO	Date of 1st Submission	Cupboard / Cabinet No.	Shelf No.(if any)	Close out Date	Archival Date

SOP No.:	**17, Attachment 17.3.3.a**
TITLE:	**Template for list of documents stored in the cupboard/cabinet**

Template for list of documents stored in the cupboard/cabinet

Cupboard/Cabinet No. -

S. No	IEC App.#	Protocol Number	PI Name	PI to EC letter Dated

SOP No.:	**17, Attachment 17.3.3. b**
TITLE:	**Template for study document archival, retrieval**

Template for study document Archival and retrieval

S. No	IEC App. #	Protocol Number	PI Name	Sponsor / CRO	Archived			Retrieved		Re-Archived on
					on	*at	by	by/on	Purpose	

*** Premises/Cupboard or Cabinet number**

SOP No.:	**17, Attachment 17.3.4**
TITLE:	**Format for request of retrieval of archived documents**

Format for request of retrieval of archived documents

1. IEC APPLICATION No :

   _____

2. PROTOCOL No./NAME :

   _____

   _____

   _____

3. DOCUMENT(S) NEEDED :

   _____

   _____

4. REQUESTED BY :

   _____

5. PURPOSE OF RETRIEVAL :

   _____

   _____

   _____

6. DATE ON WHICH DOCUMENT :

_____

IS NEEDED

7. DATE ON WHICH DOCUMENT :

_____

WILL BE RETURNED

_____

_____

Name Sign& Date

RETURNED ON :

_____

RETURNED BY :

_____

EC ACKNOWLEDGEMENT :

_____

SOP No.:	**17, Attachment 17.3.5**
TITLE:	**Format for Back up of IEC records(Hard Disk)**

Format for Back up of IEC records (Hard Disk)

Location: Office of site in-charge,_____

Date	Handed Over by:	Sign And Date	Handed Over to :	Sign And Date

SOP No.:	**17, Attachment 1.3.6**
TITLE:	**Template for EC Tracker**

Attached the Xcel sheet in the Zip folder

SOP No.:	**17, Attachment 17.3.7**
TITLE:	**Delegation log for Institutional Ethics Committee secretariat personnel**

Delegation log for Institutional Ethics Committee secretariat personnel

S.No	Name	Job Role	Roles & Responsibilities
1			
2			
3			

S.No.	Roles & Responsibilities
i	Receiving documents
ii	To check the details as per the covering letter
iii	Helping in making the agenda
iv	Inviting IEC-CS members for the meeting
v	Dispatching documents to members
vi	Sending intimation circular to PI
vii	Raising IEC-CS invoice for new/ongoing studies
viii	Updating the EC tracker for studies/payments
ix.	To help in writing MOM and sharing it with members
x	Sending approval letters
xi	Updating record keeping tracker
xii	Sending re-approval reminder letters to PI
xiii	Scanning correspondence (PI to EC and vice versa) and save it in protocol specific folders
xiv	To discuss a need for subject expert and do the needful
xv	Collecting documents from the members post EC meeting and obtaining their signatures
xvi	Sharing MOM with HRPP coordinator, HOI and quality in-charge
xvii	To help in conducting training for the IEC-CS members on regulations and guidelines
xviii	To help in Self-assessment of members on half yearly basis
xix	To help in conduct of IEC-CS inspection

xx	To help in planning a meeting for reviewing own-site SAE
xxi	Sharing list of new protocols with accounts dept end of the month
xxii	Sending mail to accounts dept. for the IEC-CS members/subject expert honorarium
xxiii	Giving a feedback to the subject expert with PI's responses to the concerns raised by them
xxiv	Packing and archiving the documents after the meeting (IEC-CS copy)
xxv	Post archival, updating the register with the details
xxvi	Any other responsibilities as required

Member Secretary Signature:.....

Date:.....

SOP No.:	**17, Attachment 17.3.8**
TITLE:	**Annual Training**

Annual Training (I/II/III)

Date	Agenda Items	Time	Trainer