Standard Operating Procedures

Bhaktivedanta Hospital Ethics Committee

NABH Accreditation certificate Number - EC-CT-2017-0002

(Valid Till 04 March 2027)

Bhaktivedanta Hospital Ethics Committee

(Bhaktivedanta HEC)

Bhaktivedanta Hospital Ethics Committee Office,
3rd floor,
Bhaktivedanta Hospital and Research Institute
Srishti Complex, Bhaktivedanta Swami Marg
Mira Road (E), Dist: Thane-401107
Phone no: 022-29452614
Email: Bhaktivedantahec@gmail.com
Website- www.Bhaktivedantahospital.com

STANDARD OPERATING PROCEDURES

Version 14

Date: 25.09.2025

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Valid Till : 23.10.2028

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Bhaktivedanta Hospital Ethics Committee

Standard Operating Procedures

Version 14

	Name	Designation	Signature & Date
Prepared By	Dr. Suraj Bhagde	Member Secretary Internal	
	Dr.Komal Dalal	Member Clinician Internal	
Reviewed By	Dr. Reena Patel	Member Clinician Internal	
	Dr. Nirmal Raut	Member Clinician Internal	
Approved By	Dr. Raakhi Tripathi	Chairperson	
Accepted By	Dr. Ajay Sankhe	Head of Institute	
Distribution	Bhaktivedanta Hospital Ethics Committee Members and Applicants		
Version No.	14		
Version Date	24-10-2025		

Bhaktivedanta Hospital Ethics Committee ★ Bhaktivedanta Hospital & Research Institute ★ COSCO Reg. No. ECR/396/INST/MH/2013 Re...

Amendment Versions of Bhaktivedanta HEC SOPs	
1	Bhaktivedanta HEC SOPs Version 01 dated 9 March 2013
2	Bhaktivedanta HEC SOPs Version 02 dated 9 August 2014
3	Bhaktivedanta HEC SOPs Version 03 dated 12 March 2016
4	Bhaktivedanta HEC SOPs Version 04 dated 12 April 2017
5	Bhaktivedanta HEC SOPs Version 05 dated 21 August 2017
6	Bhaktivedanta HEC SOPs Version 06 dated 11 December 2017
7	Bhaktivedanta HEC SOPs Version 07 dated 01 March 2019
8	Bhaktivedanta HEC SOPs Version 08 dated 06 May 2019
9	Bhaktivedanta HEC SOPs Version 09 dated 27 May 2020
10	Bhaktivedanta HEC SOPs Version 10 dated 25 November 2020
11	Bhaktivedanta HEC SOPs Version 11 dated 11 October 2022
12	Bhaktivedanta HEC SOPs Version 12 dated 13 March 2023
13	Bhaktivedanta HEC SOPs Version 13 dated 25 June 2024
14	Bhaktivedanta HEC SOPs Version 14 dated 18 October 2025

Accreditation and Registration

National Accreditation Board for Hospital and Healthcare Providers (NABH) Ethics Committee accreditation under Clinical Trial program	EC-CT-2017-0002	Valid till 04th March 2027
Bhaktivedanta HEC Registration Number under CDSCO as Bhaktivedanta HEC	ECR/396/Inst/MH/2013/RR-19	Valid till June 2029

Summary of Amendments:

Section	Version 12 dated 13 March 2023	Version 13 dated 25 June 2024
Comprehensive Revision	All sections, sub-sections and Annexures	All SOP sections and annexures have been extensively revised, restructured, and updated. Several new sections added, existing content reworded or expanded, and annexures reorganized for greater relevance and logical flow. Detailed tabulation not feasible due to the extent of changes.
Section	**Version 13 dated 25 June 2024**	**Version 14 dated 18 October 2025**
7	Storage, Distribution, Retention of SOPs	Added note on Destruction of SOPs
8.2.4.1	Role of Ethics Committee Admin Manager	Minor submissions can be acknowledged by the admin manager.
8.2.7 and 17.1 and Annexure 13	List of current Ethics committee and SAE sub-committee members with their affiliations and qualifications, Protocol Decision and Voting sheet	Deleted the name of Dr Sunita Prasad, Basic Medical Scientist, Internal member - who resigned from the committee
9.1.iii	If the DCG(I) permission is awaited, a provisional approval letter will be issued and final EC approval will be given after a copy of DCG(I) permission is submitted to the EC. A study cannot begin until the final letter of permission is issued by the EC.	iii.If the DCG(I) permission is awaited, the approval letter mentions that the Approval is granted subject to Regulatory Approval by the DCG(I). The site can initiate the study only after submission of the copy of DCG(I) approval. The site is mandated to notify the EC about the enrollment of the first patient in the study.
9.1.v	Fees to be paid by the sponsors for different kinds of Review by the Ethics committee	The Fees have been revised
9.2	Policy and Procedures for Subject Expert	A list of Subject Experts will be prepared in advance for sending out invitation at the time of need for any review by them. Subject expert shall

		be invited for the meeting, in person or in virtual mode on online platform
18.iv	SOP for reviewing proposals involving vulnerable populations	Included a note on Hospital employees as vulnerable population
22.iii	Self-Assessment shall be conducted every six monthly	Self-Assessment shall be conducted at least once a year.
Annexure 12	What about the confidentiality of my data?	Added a statement - Your data will be identified by a unique study code, not by your name.
Annexure 31	-	Added - Checklist for Review of CTA by the Legal Experts

CONTENTS

Introduction

The first International statement on the ethics in medical research using human subjects, the Nuremberg Code was formulated in 1947 and it laid emphasis on consent and voluntariness. In 1964, the eighteenth World Medical Assembly at Helsinki, Finland adopted a code of ethics for the guidance of doctors involved in clinical research. This is popularly known as the "Declaration of Helsinki." In 1980, the Indian Council of Medical Research released a 'Policy Statement on Ethical Considerations involved in Research in Human Subjects' for the benefit of all those involved in clinical research in India.

Moreover in 1996, the International Conference on Harmonization (ICH) published a tripartite guideline for Good Clinical Practice (GCP) to harmonies technical requirements for registration of pharmaceutical products in three regions namely the United States, the European Union and Japan). Today, the ICH GCP guideline is followed globally for clinical research. This guideline forms the basis of the composition and functioning of an Bhaktivedanta HEC to review clinical research proposals. 0n 20th January 2005, the Ministry of Health and Family Welfare, after consultation with the Drugs Technical Advisory Board, amended the NDCT Rules 2019 of Drugs and Cosmetics Rules, 1945. In addition to requirements concerning clinical trials, the new NDCT Rules 2019 also outlines requirements of an Institutional Review Board or Institutional Ethics Committee.

It was thus felt necessary to establish an Bhaktivedanta Hospital Ethics Committee (Bhaktivedanta HEC) consistent with the ICH GCP Guideline so as to facilitate the ethical review of any human research project. It is an Institutional Ethics Committee. With the completion of more than a decade and a half for this hospital, a need was felt by the doctors working in the Bhaktivedanta Hospital for carrying out research on human participants either by themselves (self-funded) or those offered by the pharmaceutical companies. Thus a need was felt to start a Bhaktivedanta HEC for reviewing the scientific as well as ethical aspects in the Research projects planned in the Bhaktivedanta Hospital and Research Institute and its branches (within 50 km) such as P.V.Doshi Hospital (Mira Road), Bhaktivedanta Clinic (Mira road), Swami Shraddhanand Hospital (Vasai) which are conducted by Bhaktivedanta Hospital and Research Institute.

The Bhaktivedanta HEC presently functions according to the requirements laid down in NDCT Rules 2019 and is guided by the ICH GCP guidelines for Good Clinical Practice, ethical principles set forth in the Declaration of Helsinki and the Ethical Guidelines for Biomedical Research on Human Subjects laid down by the Indian Council of Medical Research.

Standard Operating Procedures

1. Name of the Institutional Ethics Committee

This Institutional Ethics Committee will be known as the **Bhaktivedanta Hospital Ethics Committee (Bhaktivedanta HEC)**. This name will remain unchanged until the members choose to change it by a vote of at least three-fourths of the current strength.

2. Purpose of Bhaktivedanta Hospital Ethics Committee

The primary purpose of this committee will be:

i. To evaluate the ethical, scientific, and regulatory aspects of the clinical research involving human subjects to ensure that the rights, safety, and well-being of research participants are protected.

ii. To provide the public with assurance of such a protection.

The other purposes and responsibilities of the committee are as follows:

iii. The Bhaktivedanta HEC conducts ethical review and approval of research protocols to assess the scientific validity, methodological rigor, and ethical soundness of proposed studies

iv. The committee reviews research protocols to assess the potential risks and benefits of participation, ensuring that research is conducted ethically and in accordance with established regulatory standards.

v. The committee evaluates the research design, participant recruitment methods, informed consent procedures, data collection methods, and plans for participant safety and confidentiality.

vi. The committee reviews informed consent documents to ensure that participants receive clear and comprehensive information about the study purpose, procedures, risks, benefits, and rights

vii. The committee conducts periodic reviews of study progress and safety reports, protocol amendments, and adverse event reports to ensure that participants are protected throughout the course of the research.

viii. The Bhaktivedanta HEC ensures the protection of participant confidentiality and privacy by reviewing data management and security protocols.

ix. The Bhaktivedanta HEC engages with relevant stakeholders, including subject experts, research participants, community representatives, advocacy groups, and healthcare providers, to solicit input, feedback, and perspectives on research proposals.

x. The Bhaktivedanta HEC ensures compliance with national, regional, and international regulatory standards governing the conduct of clinical research. The committee also facilitates vists and inspections by any regulatory authorities whenever they visit the hospital.

xi. The Bhaktivedanta HEC promotes quality assurance and continuous improvement in the conduct of clinical research by evaluating institutional policies, procedures, and practices related to research ethics.

3. Scope of Bhaktivedanta Hospital Ethics Committee

The scope of this committee is to review following varieties of protocols -

i. Clinical Trials: include regulatory trials under DCG(I) that evaluate the safety, efficacy and/or effectiveness of medical interventions, such as drugs, biologics, devices or procedures in human participants. Clinical trials belonging to Phase I, II, III and IV will be reviewed.

ii. Interventional Studies: Interventional studies under the regulatory authority of DCG(I) that involve the deliberate intervention or manipulation of participants' conditions or exposures to assess the effects of an intervention on health outcomes. This may include randomized controlled trials (RCTs), non-randomized controlled trials, or other interventional study designs.

iii. Genetic and Genomic Research: Protocols involving genetic and genomic research investigate the role of genetic factors in health and disease, genetic variations, inheritance patterns, or the impact of genetic testing. This may include studies on gene therapy, genetic screening, genetic epidemiology, or pharmacogenomics.

Exclusions : BioAvailability and BioEquivalence studies, Behavioural and Social Sciences research, Observational studies, Epidemiological studies, Quality Improvement initiatives and studies involving simple Biomedical Research not under the purview of the DCG(I).

4. Authority for formation of Bhaktivedanta HEC

i. Bhaktivedanta HEC is established under authority of Director - Bhaktivedanta Hospital and Research Institute, Mira Road, Thane. It is administratively governed under the same authority.

ii. The Institution will support establishment of ethics committee and the SAE sub-committee. It will facilitate the committees' functions including finance, manpower, training, resources and infrastructure etc.

iii. Bhaktivedanta HEC has been assigned to oversee clinical research involving human subjects in Bhaktivedanta Hospital and Research Institute and its branches such as P.V.Doshi Hospital (Mira Road), Bhaktivedanta Clinic (Mira road), Swami Shraddhanand Hospital (Vasai) which are conducted by Bhaktivedanta Hospital and Research Institute.

iv. Bhaktivedanta HEC is an independent body in its function and decision making. The management of the institution shall not take part in its functioning and decision making. The Director of Hospital will ensure independence of Bhaktivedanta HEC.

v. Bhaktivedanta HEC shall adhere to existing applicable rules and regulations (i.e NDCT Rules 2019, CDSCO guidelines, ICH-GCP, Indian GCP, ICMR 2017 guidelines for biomedical research etc.) for its formation and functioning including registration, criteria for selection of members, appointment, tenure, resignation, scheduling of meetings, reporting to regulatory authorities and other administrative processes. Principally, it shall conform to NDCT Rules, 2019. Any change in existing regulations shall be applicable as and when with immediate effects.

5. Location and Address:

The location and address of the Bhaktivedanta Hospital Ethics Committee is as follows:

Bhaktivedanta Hospital Ethics Committee (Bhaktivedanta HEC)

Bhaktivedanta HEC Office, 3rd floor

Bhaktivedanta Hospital and Research Institute

Srishti Complex, Bhaktivedanta Swami Marg,,

Mira Road(E), Dist: Thane-401107

Phone no: 022-2945 2614

Email: Bhaktivedantahec@gmail.com

6. SOP on SOPs

i. Member Secretary shall be responsible for overseeing the drafting of Bhaktivedanta HEC SOPs. Two members shall draft the SOP. SOP would be shared with all members for their inputs. SOP will then

be reviewed by two other members and approved by chairperson. SOP shall be effective 3 working days post chairperson approval.

ii. Bhaktivedanta HEC SOPs shall be valid for 3 years from effective date. Member secretary will review SOPs at least once in 3 years. SOPs can be amended in between 3 years, if required on the directive of the EC members.

iii. Amendments to the Standard Operating Procedures of the Bhaktivedanta HEC shall be proposed in writing or can be proposed in Bhaktivedanta HEC meeting by regular Bhaktivedanta HEC members.

iv. Only regular members shall vote to accept or reject the proposed amendment.

v. If the changes on the final version are minor the version will be indicated as Version 1.1, version 1.2 etc. If there are major amendments, the version will be indicated as Version 2.

7. Storage, Distribution, Retention and Destruction of SOPs

Hard copies of current and superseded SOPs are maintained in SOPs master file. A soft copy (PDF format) of the SOPs shall be made available for distribution, and the Admin Manager of Bhaktivedanta HEC shall be responsible for sharing them with members, hospital staff, and concerned project investigators. Previously distributed controlled copies will be retrieved and archived. When superceded by later versions, the previous versions will be archived for 5 years and then discarded by shredding. The members will be informed.

Soft copy of Bhaktivedanta HEC SOPs (PDF format) can be downloaded from Website (on public domain) after completion of online SOP download form

http://www.Bhaktivedantahospital.com/medical-research/hospital-ethics-committee/

8. Terms of Reference of the Bhaktivedanta HEC and Members details

The committee will consist of members who collectively have the experience and expertise to review and evaluate the scientific, medical and ethical aspects of a proposed research project. A list of committee members, their qualifications and their affiliations (hospitals, colleges etc.) are described in this section of the document and will be maintained in the committee's records.

8.1 Composition of the Bhaktivedanta HEC

i. Composition shall be multidisciplinary and multi-sectorial and adequate for its functioning.

ii. The regular members of the committee will be at least 7 and a maximum of 15 individuals from the following categories: One each of these categories will constitute the Quorum for any full board meeting, along with the Chairperson and the Member Secretary.

   a. Medical scientists and clinicians with expertise in diverse health care specialties.

   b. Basic medical scientist/pharmacologist

   c. Legal expert.

   d. Social worker/representative of a non-governmental organization/theologian.

   e. Lay person from the community.

iii. The committee will have representation from both men and women and 50% members need to be non-affiliated to the institute. At least one female member is required.

iv. Members from other areas, such as a journalist or a member from a consumer protection activity may be included in the committee.

v. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated in writing to the Central Licensing Authority within 30 working days.

8.2 Committee Members and Criteria for Members' selection

The criteria for selection to the membership of Bhaktivedanta HEC are as under:

i. Expertise and Experience: Members should have relevant expertise and experience in areas such as clinical research, bioethics, medicine, pharmacy, law, social sciences, and other relevant fields.

ii. Ethical Competence: Members should possess a strong understanding of ethical principles, guidelines, and regulations governing human subjects research, such as the Declaration of Helsinki, ICH-GCP guidelines, and local regulatory requirements.

iii. Independence and Impartiality: Members should be free from conflicts of interest or biases that could unduly influence their decision-making.

iv. Communication and Collaboration Skills: Members should possess strong communication and interpersonal skills to effectively engage with researchers, colleagues, and research participants.

v. Training and Education: Members should be willing to participate in ongoing training and education activities to enhance their knowledge and skills in research ethics and regulatory compliance.

8.2.1 Chairperson

i. The Chairperson will be from outside the institution. The Chairperson will be selected and appointed by Director of Bhaktivedanta Hospital and Research Institute.

ii. The Chairperson will be responsible for conducting all committee meetings, and will lead all discussions and deliberations pertinent to the review of research proposals.

iii. The Chairperson will preside over the administrative matters pertinent to the committee's functions.

iv. Ratify minutes of the previous meetings.

v. Handle complaints against researchers, EC members, Conflict of Interest issues and request for use of EC data etc.

vi. In case of anticipated absence, the other Members will elect (by consensus or voting) an external committee member, as Acting Chairperson. The Acting Chairperson will have all the powers of the Chairperson for that meeting, but only one vote.

8.2.2 Member Secretary

i. The Director will appoint a Member Secretary from among the the internal members of the Bhaktivedanta HEC.

ii. In consultation with the Chairperson, the Member Secretary will be responsible for the following functions:

- Receiving all research proposals.
- Numbering the proposals.
- Forwarding all proposals to committee members for review.
- Establishing time limits for receipt of reviewers' comments.
- Preparation of agenda for all committee meetings.
- Inviting experts from relevant therapeutic areas to the scheduled meetings.
- Notification of review outcome to investigators of research proposals.
- Preparation and circulation of minutes of the meetings
- Retention and safekeeping of all records and documentation.
- Performance of other duties assigned by the Chairperson.
- Preparation and amendments of SOPs

- Communication to Investigators regulatory bodies or any other concern authority on behalf of Bhaktivedanta HEC

8.2.3 Members

i. Director shall appoint members in consultation with the chairperson provided they are willing to work as an Ethics Committee member.

ii. A member shall be willing to publicize his/her full name, profession and affiliation.

iii. A member will sign a Confidentiality Agreement and a Conflict of Interest Agreement described in Annexure 01 and Annexure 02 of this manual respectively.

iv. A member will be trained in all aspects of functioning of the Bhaktivedanta HEC including ethical issues, regulatory requirements, scientific aspects of the protocol.

8.2.3.1 Specific Roles of Members

Basic Medical Scientists:

- Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report.
- For clinical trials, pharmacologist shall review the drug safety and pharmacodynamics including adverse drug reaction profile.

Clinicians:

- Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics.
- Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report).
- Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation.
- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

Legal Experts:

- Ethical review of the proposal, ICD along with translations, MOU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc.
- Interpret and inform EC members about new regulations if any.
- Contract and budget shall be evaluated, for indemnity, compensation, roles and responsibilities as per applicable rules and regulations.

Social Scientists:

- Ethical review of the proposal, ICD along with the translations.
- Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any.
- Serve as a patient/participant/societal/community representative and bring in ethical and societal concerns.

Lay Persons:

- Ethical review of the proposal, ICD along with translations.
- Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.
- Serve as a patient/participant/community representative and bring in ethical and societal concerns; effects on societal aspects if any.

8.2.3.2 Hierarchy of Committee Members

- There will be one Chairperson and one Member Secretary.
- The Chairperson will be the head of the committee.
- The Member Secretary will be the guardian of all documents and funds in the committee's possession.
- All other members will be regular committee members with equal ranking.
- Members will elect 'Acting Chairperson' among available external members in case of chairperson absence or his/her conflict of interest. Elected Acting Chairperson will chair respective ethics

committee meeting including all discussion as mentioned in agenda. In case chairperson has declared conflict of interest for particular proposal, the acting chairperson will convene the meeting for that particular proposal.

- Similarly, whenever the regular Member Secretary is not able to attend the meeting, the Chairperson will appoint an 'Acting Member Secretary' from one of the internal members of the committee. All the official documents pertaining to this meeting will be signed by the 'Acting Member Secretary'.

8.2.3.3 Tenure of Membership

i. A member will be a regular member for a period of up to 3 years.
ii. Extension of membership will be determined based on willingness of the member to continue and approval by director of hospital
iii. Membership can be extended maximum 1 time (Maximum total of 2 terms).
iv. New members will be appointed to replace the out-going members.

8.2.3.4 Resignation / Termination of Members

i. Members may resign before completing their terms by writing their intention to the chairperson and director of the Hospital.
ii. The membership will stand to be terminated under the following circumstances:
   - If a member resigns from the committee
   - If a member remains absent for 3 consecutive meetings without informing either telephonically or email or giving a valid reason.
   - If a member is incapable of performing his/her duty as an ethics committee member
   - In case of development of a new conflicts of interest which limits independent functioning as an impartial member of the ethics committee
   - In case of demise of a member.

8.2.3.5 Appointment of New Members

i. New members will be selected and appointed under the following circumstances:

- When a regular member completes his tenure and does not wish to continue his/her membership.
- If a regular member resigns.
- In case of the termination of membership of a regular member

ii. A new member will be preferably but not necessarily nominated from the same category as that of the member being replaced. Prospective new members will be short-listed based on the selection criteria as detailed in section 8.2

iii. Induction: The new prospective member will initially be invited as an observer for one EC meeting without any voting right. If the prospective member is interested to join, they will formally request the Director of the hospital to be appointed as a regular member. Upon their appointment, the new member will be given an orientation and induction training on various aspects of the EC functioning by the member secretary.

8.2.4 Ethics Committee Admin Manager

i. Ethics Committee Admin Manager will be appointed by the Director of the Hospital

ii. Ethics Committee Admin Manager may be present during course of meeting however they will not participate in voting or in decision making process.

Ethics Committee Admin Manager shall be appointed for the period of 3 years and there is no limit to the number of times appointment can be extended. The admin manager will have to accept and sign the Confidentiality Agreement and Conflict of Interest Declaration at the time of joining. This document serves as a binding agreement to protect the integrity of the Bhaktivedanta HEC and to ensure that all staff conduct their duties with the highest ethical standards.

8.2.4.1 Role of Ethics Committee Admin Manager

- Collect documents received for Ethics committee submission or notification and submit to member secretary for acknowledgement. Minor submissions can be acknowledged by the admin manager.
- Review documents received for each proposal for completion as per checklist
- Preparation, maintenance and distribution of study files

- Organizing Ethics committee meeting regularly
- Communicating Ethics committee meeting agenda to applicants and members
- Maintaining Ethics committee documentations and to archive the documents
- Communicating with Ethics committee members and applicants
- Communicate decision of Bhaktivedanta HEC to Principal Investigator of research proposal
- Organizing the distribution of SOPs and guidelines
- Maintaining record for inward outward communications of Ethics committee
- Providing the necessary administrative support for Ethics committee related activities to the Member Secretary (e.g. communicating a decision to the applicant)
- To receive fees and maintain record of Ethics committee fees and all financial transactions.
- Maintaining Ethics committee documentations and to archive the documents
- Any other work as told by Member Secretary

8.2.5 Ethics Committee Co-ordinator

Role:

- The EC co-ordinator will assist the Admin Manager in all the functions related to the Bhaktivedanta HEC. He/She will have access to all the documents, records and meetings pertaining to the Ethics committee.
- The EC co-ordinator will also interact with the Clinical Research Coordinators from the site (Bhaktivedanta Hospital and Research Institute) for to-and-fro communications between the Principal Investigators and Bhaktivedanta HEC.

8.2.6 Office Attendant

Bhaktivedanta HEC Office Attendant will be appointed by Director of Hospital

Role:

- Arrange ethics committee meeting including maintenance of meeting room, circulating documents during meeting, food arrangements, water etc.

- Technical assistance for meetings including Computer, projector, telecom etc.
- Maintenance of documents, filing of documents, storage cupboard etc.

8.2.7 List of current committee members with their affiliations and qualifications

The present composition of the Bhaktivedanta HEC is listed in the table below:

Sr	Name	Position on Ethics committee	Qualification and Affiliation	Gender
1	Dr. Raakhi Tripathi	Chairperson	Associate Professor, (Pharmacology) GSMC & KEMH, Mumbai MBBS,MD Pharmacology	Female
2	Dr. Suraj Bhagde	Member Secretary, Internal	Consultant Ophthalmologist Bhaktivedanta Hospital and Research Institute MBBS, MS, DNB Ophthalmology	Male
3	Dr.Prashant Dhotre	Member Clinician , Internal	Consultant and Intensivist in Department of Critical Care. Bhaktivedanta Hospital and Research Institute MBBS , MD EDIAC	Male
4	Dr. Komal Dalal	Member Clinician , Internal	Consultant Acupuncture Bhaktivedanta Hospital and Research Institute MBBS, Diploma in Acupuncture	Female
5	Dr.Reena Patel	Member Clincian , Internal	Consultant ENT Surgeon Bhaktivedanta Hospital and Research Institute	Female

			MS (ENT), D.O.R.L, M.B.B.S , DOHNS	
6	Dr.Nirmal Raut	Member Clinician, Internal	Consultant Medical Oncologist, Bhaktivedanta Hospital and Research Institute MBBS, MD	Male
7	Dr.Kshama Shah	Member Clinician, Internal	HOD Anesthesia Department, Bhaktivedanta Hospital and Research Institute MD (Anesthesia), D.A (Diploma in Anesthesia), MBBS.	Female
8	Dr. Tejal Patel	Basic Medical Scientist, External	Lecturer in department of pharmacology in HBT medical college and Dr. R.N. Cooper hospital. MBBS, MD Pharmacolgy	Female
9	Dr.Anita Panot	Social Worker, External	Associate Professor College of Social Work M.A. M.S.W., Ph.D.	Female
10	Mrs. Mayuri Mistry	Member, Social scientist, External	Heading CSR and social development work at Navneet Education Ltd BSc (Chem), MBA in Human Resources	Female
11	Mr.Manohar Mhaskar	Legal Expert, External	Advocate High Court B.Com.,LLB, LLM	Male
12	Mr.Jaiprakash Mishra	Legal Expert, External	Advocate High Court MA, LLB	Male
13	Meera Singh	Member, Lay person, External	B.Com	Female
14	Poonam Tiwari	Member, Lay person, External	BA, B.ED	Female

8.3 Declaration of Conflict of Interest and Confidentiality Agreement

i. Every member at beginning of the tenure must declare conflict of interest and sign conflict of interest and confidentiality agreement form (Annexures 01 and 02) and submit it to chairperson for acknowledgement. The admin staff will sign Annexure 02 A.

ii. Every observer attendee attending Bhaktivedanta HEC meeting must sign confidentiality agreement form (Annexure 03) before initiation of meeting and submit it to chairperson for acknowledgement.

iii. Every Independent Consultant/Independent Monitor/Auditor should sign confidentiality agreement (Annexure 04) and submit it to chairperson for acknowledgement.

iv. At start of every meeting, Chairperson will ask every member attending Bhaktivedanta HEC meeting to declare conflicts of interest for study projects to be discussed in respective meeting. Every member must read and sign Conflict of Interest form (Annexure 05) and submit it to chairperson before initiation of meeting. After acknowledging, Chairperson will ask concerned member to leave meeting venue and he/she will not participate in voting or decision making process. The same will be recorded in minutes of meeting. In case conflict of interest is declared by a particular member , members absence will be called recusal and not an abstention.

v. The chairperson will re-assess the quorum if any member withdraws from the discussion and decision making. This will be recorded in the minutes.

vi. Every Bhaktivedanta HEC member should declare any new Conflict of Interest arising during his/her tenure to the chairperson.

8.4 Frequency of meetings

i. The committee will hold a regular meeting once every month. Third or fourth Saturday will be chosen depending on the availability of most number of members.

ii. When there are no research proposals to review, the meeting for that month may be skipped with prior intimation to all members. However ethics committee will ensure that there is atleast one meeting in each quarter.

iii. All members will receive notification of meeting schedules at least 2 weeks in advance.

iv. The committee members will review all the proposals before the meeting.

v. The proposal may be sent to a subject expert for his/her assessment and opinion of the research proposal. The subject expert may be invited for the meeting.

vi. The investigator and/ or co-investigator is/are invited to the meeting to present the study protocol and provide clarifications on the questions asked by the members.

vii. The meetings will be conducted physically but hybrid mode (virtually on Google Meet/Zoom platform) for the meetings can be allowed for the members who are unable to attend the meeting physically. The members attending on virtual platform will be counted amongst the quorum members.

8.5 Quorum of the meeting:

Meetings will be held as scheduled provided the quorum requirement is met. In accordance with NDCT Rules 2019, the quorum of the EC will be a chairperson, a member secretary and at least five members with the following representations:

- Basic Medical Scientist/Pharmacologist
- Clinician,
- Legal expert,
- Social scientist/worker/representative of NGO
- Lay person.

8.6 Agenda of the Meeting:

i. The agenda of the meeting will be prepared by the member secretary taking help from the admin manager and EC coordinator of the secretariat. The format of the agenda is as per Annexure 06.

ii. The agenda will be circulated to all members at least seven days prior to the scheduled date of the meeting.

iii. The agenda will consist of three parts called 'Periods'.

iv. Period 1 inlcudes roll-call and confirmation of the quorum by the chairperson and declaration of conflicts of interest by the concerned members.

v. Period 2 includes all the issues to be discussed in the Full Board. This period involves active deliberations by the members on diverse matters such as new protocols submitted, answers to the query letters handed to PIs previously, protocol and ICD amendments, protocol deviations and violations,

continuing review reports, completion reports, SAE occured at site and reported from other sites, study monitoring reports etc.

vi. Period 3 inlcudes issues and matters informed to the members. The committee members note the approved protocol modifications in response to the query letters previously raised, approved minor protocols and ICD amendments etc.

8.7 Minutes of the Meeting

The Member Secretary will be responsible for coordination and recording of the proceedings of the meeting. The proceedings of the meetings shall be recorded in English and in the form of minutes. The minutes shall be prepared by the member secretary and approved by the chairperson and circulated within 14 days of the EC meeting.

9. Functions and Proceedings of the Meeting

All the different aspects of the functioning of the Bhaktivedanta HEC are detailed below:

9.1 Submission of the Research Proposal

i. All prospective studies (on drugs, investigational techniques as well as devices or any other procedure), involving human volunteers or patients to be conducted at Bhaktivedanta Hospital and Research Institute and its branches (Sister concerns) P.V.Doshi Hospital, Bhaktivedanta Clinic (Mira road), Swami Shraddhanand Hospital (Vasai) which are conducted by Bhaktivedanta Hospital and Research Institute, shall have EC permission before commencing such a study.

ii. Each project with its complete documentation along with a duly completed Bhaktivedanta HEC application form (Annexure 07) shall be submitted through soft copy (PDF format) as well as one hard copy of the same. The application form will be available at the office of the Bhaktivedanta HEC. It shall have the designation and signatures of Principal Investigator. All details in the form such as type of patients, phase of drug trial, duration of study, sponsoring agency, budget of the trial, availability of Drugs Controller General of India [DCG(I)] permission and other relevant approvals etc. shall be completed while submitting the proposal. Also, a Check-list for Protocol submission (Annexure 08) will be filled up to ensure that all the necessary documents are submitted. The Delegation of Responsibilities log (Annexure 09) of the study team members will also be filled up and submitted.

iii. Studies which plan to use a new drug (as defined in 122-E of the Drugs and Cosmetics Act, 1945) shall submit along with the Protocol submission application form, a copy of the permission letter issued by the DCG(I) to the pharmaceutical company/investigator. If the DCG(I) permission is awaited, the approval letter mentions that the Approval is granted subject to Regulatory Approval by the DCG(I). The site can initiate the study only after submission of the copy of DCG(I) approval. The site is mandated to notify the EC about the enrollment of the first patient in the study.

iv. In case a clinical study is planned on an "alternative system of medicine" a co-investigator from that system will be required on that study. For Ayurveda or herbal drugs, which are not marketed, a copy of the marketing/manufacturing license issued by FDA to the company shall be submitted. The scientific validity of the protocol will be determined based on AYUSH ministry's guidelines.

v. All required fees shall be collected at the time of submission of the project. The amount to be collected, as processing fee will be reviewed at the end of 1 year. The cheque/DD/NEFT payment must be in favor of *"**Sri Chaitanya Health And Care Trust**"*.(PAN-AABTS6166N)

Type Of Review	**Category**	**Fees**
Full board	First / Initial Submission	INR 1,00,000/- (Excluding TDS/GST)
	Amendment	INR 75,000/- (Excluding TDS/GST)
Expedite	-	INR 1,50,000/- (Excluding TDS/GST)
Annual Approval	-	INR 50,000/- (Excluding TDS/GST)
SAE	-	INR 30,000/- (Excluding TDS/GST)

vi. The Hospital administration may consider institutional waiver to the payment of Investigator initiated / Academic projects in the interest of development of Clinical Research at the institute and in the absence of any external sponsor.

vii. The project proposal shall be submitted in soft copy (PDF format) via email and one hard copy. Documents should be submitted at least 10 days prior to scheduled ethics committee meeting for initial review and amended documents. Each set shall contain the documents on A4 size paper arranged in a file in the order mentioned below. Answers to Bhaktivedanta HEC queries and other documents will

be included for any upcoming EC review provided they are submitted atleast 5 days and 3 days prior to the date of EC meeting respectively.

a. EC application form duly filled.
b. Protocol Synopsis (For Clinical Trials)
c. Protocol and any amendments to it with version and date
d. The informed consent document (ICD), including any amendments / addendum and its translation(s) into regional language(s).
e. A copy of Informed Consent Document for Audio visual Consent, if applicable.
f. Case Record Form / Questionnaire.
g. Principal investigator's current Curriculum vitae.
h. Subject recruitment procedures (e.g. advertisements/letters to doctors/posters)
i. Investigator Brochure (This should give details of the study drug, toxicology studies, phase I, II, III data wherever available, safety information etc)
j. Insurance policy (if applicable)
k. DCG(I) clearance[for Phase I, II, III studies]
l. Investigator's agreement with sponsor
m. Investigator's undertaking to DCG(I) [for Phase I, II, III studies]
n. Health Ministry Screening Committee (HMSC) clearance wherever applicable
o. Food and Drug Administration (FDA) marketing/manufacturing license for herbal drugs.
p. Any other applicable documents

viii. The submitted project/s will be circulated at least 07 days prior to Bhaktivedanta HEC meeting for initial review to all committee members via email / hard copy (only upon request) and the proposal shall be reviewed for elements described in § 9.3.1.

9.2 Policy and Procedures for Subject Expert

- Decision for inviting Subject Expert would be taken in two ways. Member Secretary shall decide at the time of initial submission if subject expert opinion is required. Members may also decide requirement of Subject Expert while reviewing the protocol in the meeting.

- A list of Subject Experts will be prepared in advance for sending out invitation at the time of need for any review by them. Ethics Committee secretariat shall get the resume of the Subject Expert to ensure their competency so that they have the required acumen to achieve the desire objective of getting an expert opinion on the subject matter to be reviewed.
- Post confirmation of competency and credibility Ethics Committee secretariat shall get the confidentiality agreement and conflict of interest signed.
- Ethics Committee Secretariat shall share the essential documents with Subject Expert in such a way that Subject Expert will get sufficient time to review the documents.
- Member Secretary shall present the subject expert's opinion in full board/Expedite/SAE subcommittee.
- Ethics Committee members discussion about the opinion of subject expert shall be minuted by Member Secretary.
- Ethics Committee secretariat would file the Subject expert opinion in ethics committee clinical trial file.
- If required the Subject expert shall be invited for the meeting, in person or in virtual mode on online platform, however they will not vote or participate in the decision making procedures.

9.3 Types of Review Processes

The Bhaktivedanta HEC undertakes following types of Reviews

1. Full Board Review

2. Expedited Review

3. Review of Modified Proposals

4. Review of Subject Recruitment procedures

5. Periodic Review of on-going trials

6. Review of Amended protocol / Protocol related documents for Approved Projects

9.3.1 Elements of Full Board Review

The submitted proposal shall be reviewed both for scientific content and ethical principles. The members will use the format of 'Study Assessment Form' (Annexure 10) to fill in their reviews.

The committee members shall review the proposal with reference to the following:

- Scientific design of the study
- Justification/Rationale of the study
- Selection criteria for subjects
- Justification for use of placebo, if any
- Potential benefits to the study subjects
- Predictable risks to the study subjects
- Criteria for discontinuation/withdrawal of subjects
- Monitoring of serious adverse events
- Compensation to subjects for participating in the study
- Subject recruitment procedures
- Patient retention activities.
- Compensation for study related injury
- Post trial benefits
- Protection of privacy and confidentiality
- Statistical analysis
- Informed consent document in English and regional languages
- Competence of investigators, supporting staff and infrastructure facility
- Approval of regulatory authorities wherever applicable
- Risk-Benefit Analysis : Members shall refer to the Risk Benefit assessment tool (Annexure 11) to categorize research study project into any one of following categories
  a. Class A:: High Risk Low Benefit
  b. Class B: High Risk High Benefit
  c. Class C: Low Risk High Benefit
  d. Class D: Low Risk Low Benefit

9.3.1.1 Review of Informed Consent documents (ICD)

The Bhaktivedanta HEC will examine for the presence of the following points (if applicable) while reviewing the patient information sheet/Informed Consent Form.

(Sample format of ICD - Annexure 12)

- Bhaktivedanta HEC shall make sure that subjects are informed and comprehend (initial and ongoing) the associated risks and benefits of the trial.
- Voluntary, non-coercive recruitment, participation and withdrawal
- Procedures for obtaining informed consent
- Consent for Audio-Video Recording
- Contents of the patient information sheet - title, objective, study design and procedures
- Contents and language of the informed consent document
- Translation of the informed consent document in the local languages
- Language used – plain and easy to understand by general public
- Contact persons with address and phone numbers for questions about research participants rights and study or injury
- Privacy and confidentiality
- Risks and discomforts – physical / mental / social
- Alternative treatments
- Benefits – to participants, community, institution and society
- Compensation for participation: (Whether it will act as undue inducement)
- Involvement of vulnerable participants
- Provisions for medical/ psychosocial support
- Treatment for study related injuries
- Compensation for study-related injuries: Reasonable
- Travel Reimbursement
- Use of biological materials
- Check for provision for signatures with dates of participant, person conducting informed consent discussion, investigator and witness

All members of Bhaktivedanta HEC present during meeting will be responsible for review of projects. However specific members are expected to review specific documents in detail which are in their own expertise e.g. legal expert are expected to review Clinical trial agreement (as per Annexure 31) and insurance policy, lay person should review the Informed Consent Document in details.

Every member should fill the Study Assessment Form (Annexure 10) and should enter their comments in the Protocol Decision and Voting sheet (Annexure 13) present during meeting. Study assessment form can be shared either as signed hard copy or filled soft copy through email. Admin officer will keep all filled study assessment forms in respective study project file.

9.3.1.2 Travel Reimbursement

The ethics committee member should review the compensation provided to the trial patient travelling to clinical trial site for study visits and procedures. Due deliberation should be done on the justifiable amount of travel reimbursement being offered to the patient.

9.3.1.3 Decision making

- Decisions shall be based on risk assessment, scientific validity and adherence to ethical principles for the initial and periodic approvals.
- Decisions will be arrived at through consensus/unanimous or majority opinion amongst the voting members. When a consensus is not possible, the members will vote.
- All members present at the Bhaktivedanta HEC meeting will be eligible to vote on the research proposal. Absent members will not vote.
- Member(s) of the committee who is/are listed as investigator(s) on a research proposal will opt out from all deliberations on the proposal and will not vote on the proposal.
- An investigator or study team member invited for the meeting will not vote or participate in the decision making procedures of the committee.
- Specific patient groups or Subject experts invited for the meeting will not vote or participate in the decision making procedures of the committee.
- Voting Process - a simple majority will be adopted for decision making.
  i. This may be in the form of voice vote, show of hands, or by secret ballot, as determined by the Chairperson.

ii. All the eligible members are entitled to one vote.

iii. However, in case of a tie, the Chairperson will have the casting vote

- The Decision and the Voting process (if adopted) will be noted in the Protocol Decision and Voting Sheet and will be approved by the Chairperson.

9.3.1.4 Types of decisions

The Bhaktivedanta HEC will arrive at one of the following decisions at the end of deliberation executed on each and every submitted proposal.

i. Approval / Final Approval - The study is approved in its present form. On the directive of the Chairperson, the member secretary will prepare an Approval Letter (Annexure 14) and will issue to the Principal Investigator within 14 days of the meeting.

ii. Site Approval subject to regulatory approval - from DCG(I) or CTRI registration or any other regulatory compliance as per requirement.

iii. Approved with modifications - This is a conditional approval. The revisions are required. Additional information is sought or revisions are suggested in the form of a Query Letter (Annexure 15) addressed to the PI. These shall be reviewed jointly by the Member Secretary and one clinician designated by the chairperson. Such revised proposals will not be taken up for the full board review. If revisions are found satisfactory, approval will be granted by the Member Secretary.

iv. Pending - Queries which are finalised during the deliberation in the meeting shall be raised in the Query Letter to the PI. The responses and the modified proposal shall be reviewed in the full board. Those proposals in which a few major revisions or queries are suggested are earmarked for opinion of all the members and hence reviewed in the full board.

v. Re-submit - Extensive revisions are necessary. Principal Investigator has to comply with the changes suggested by EC and respond to the queries. The revised project will then be reviewed in the next full board meeting.

vi. Not approved - The study is not approved in its current form. A negative decision on an application will be supported by clearly stated reasons. If the investigator wishes to appeal against the decision, he/she may do so by contacting the EC Secretariat.

vii. Defer - The decision cannot be arrived at present and therefore postponed to next meeting. Grounds for this: lack of quorum, lack of expertise in the review by committee, etc

9.3.1.5 Notification of Review Outcome

The outcome of committee's review shall be communicated to the investigator within 14 working days of the meeting and the reply for the same must be submitted by the principal investigator within 90 days of receipt of the letter. If there is no reply or any other communication within 90 days, the project will be considered closed and shall be archived .

9.3.1.6 Approval Period

- All projects will be given approval for one year period, which further can be continued post satisfactory report of annual study report .

  Such continuation approval shall be given by member secretary. If member secretary finds annual / periodic study report unsatisfactory such study will be discussed in full board meeting.

9.3.1.7 Procedures for Appeal

For research proposals rejected/disapproved by the committee, the applicant may appeal for a repeat review within twelve (12) weeks of the receipt of the committee's decision. While doing so, the applicant shall give justification relevant to the issues/objections raised by the committee.

9.3.2 Expedited Review Procedures

i. The committee may use expedited review procedure in case of minor changes / amendments in the previously approved research proposal that appear to involve no more than minimal risk to the study subjects.

ii. Under an expedited review procedure, the review may be carried out by the Member Secretary of the committee, or by one or more experienced reviewers designed by the chairperson from among the members of the committee. The reviewers may exercise all of the authorities of the committee except that the reviewers may not disapprove the research.

iii. An on-going research activity may be disapproved only after review in accordance with non-expedited review procedure as in a full board review.

iv. The secretariat will keep all members of the committee informed of these approvals under the expedited review procedure.

v. Only the Member Secretary shall make the decision to allow an expedited review.

In a case of minor/administrative changes in protocol/ Protocol related amendments approved by Member Secretary under the expedited review process, Member Secretary will send a signed and dated Amendment Approval Letter to the Principal Investigator (PI) within 7 days of submission of documents.

9.3.3 Review of Subject Recruitment Procedures

i. Bhaktivedanta HEC will verify that PI has a recruitment policy that ensures unbiased and equitable selection of adequate number of suitable subjects according to the inclusion and exclusion criteria.

ii. Recruitment strategy will be reviewed by the ethics committee during the presentation of the study protocol by the PI. One of the slides should indicate the details of the recruitment strategy to be employed by the PI.

iii. The EC ensures that the language and content of the ICF is verified and it does not induce the participants. The Ethics committee should be informed of the date of start of the receruitment (screening) and signing of consent of the first subject.

iv. The Recruitment Strategy employed by the PI will again be reviewed during the Study Monitoring visit by the Bhaktivedanta HEC.

v. All advertisements, letters to doctors, posters, notices to be used for recruitment of subjects shall be reviewed and approved by the committee in full Board meeting prior to their implementation in the study. Recruitment strategy will again be verified during the study monitoring visit.

9.3.4 Review of Modified Proposals

i. During the full board meeting, if the committee has arrived at a decision to seek further information from the PI or has suggested modifications in the protocol, the corresponding queries are raised to the PI in the form of a Query Letter (Annexure 14). The approval status is kept ‘Pending’.

ii. The PI submits their item-wise responses in a ‘Response to the Query Letter’ format to the member secretary. If the mandate during the previous EC meeting was to review the submitted Responses in

the subsequent full board meeting then the Modified Proposal is included in the agenda for the next full board meeting. If approved by all memebrs then Approval letter is prepared and signed by the member secretary and issued to the PI within 14 days of the meeting.

iii. If the mandate was to review the Responses at the level of the member secretary and one more designated member clinician, then the Responses are circulated by the admin manager to these members by email and their opinion is sought.

iv. These two designated committee members will deliberate upon the Responses and decide by concensus if the responses have satsifactorily addressed the concerns raised during the full board meeting. If found satisfactory then the Modified Proposal is approved and approval letter is issued within 14 days of the submission.

v. If the submitted Responses are not found satisfactory then further queries are raised and sent to the PI for further clarifications or modifications. The Responses shall be submitted within 90 days by the PI for subsequent deliberation and approval.

9.3.5 Review of On-going Studies

i. The committee will conduct a continuing review of each on-going study by reviewing the clinical trial update reports submitted by the Principal Investigator every 6 monthly (Annexure 17)

ii. The committee can monitor study as is felt appropriate to the degree of risk to the human subjects. Such monitoring shall be conducted at least once a year.

iii. The committee may also ask for a status report from the investigator at earlier intervals as is felt appropriate to the degree of risk to the human subjects.

iv. On the basis of the review, the committee shall recommend continuation with/without modifications, temporary suspension or termination of on-going clinical trials for reasons such as patient safety.

9.3.6 Review of Amended protocol/ Protocol related documents for Approved Projects

i. No changes in the protocol, case record form, ICD or any other protocol related documents shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the subject

ii. The amendment package (hard and soft copy) forwarded by the Principal Investigator will be received by the Admin officer of Bhaktivedanta HEC.

iii. The documents should highlight changes from previous version and mention:

- the amendment/list of the amendments
- provide the rationale for the amendments
- state any untoward effects with original protocol
- state expected untoward effects, if any because of the amendment

iv. Member Secretary will acknowledge amended documents along with all requirements after confirmation from Admin officer. The Member Secretary will decide whether the proposed protocol amendment(s) need to undergo a full board review, review by designated Bhaktivedanta HEC members or a review by the Member Secretary alone. The Member Secretary can take the decision if the amendment(s) is / are of administrative nature.

v. The Protocol or other study related amendments which increase risk to study participants on account of a change in study design may include but is not limited to the following:

- Additional treatments or the deletion of treatments
- Changes in inclusion/exclusion criteria.
- Change in method of dosage formulation, such as, oral changed to intravenous
- A significant change in the number of research participants (if the decrease/increase in the number of research participants alters the fundamental characteristics of the study, it is significant)
- Change in study schedule or any study procedures
- Significant Changes in informed consent documents which may affect subject decision to participate
- Significant change in case record form / Additional data recording

vi. The Member Secretary will indicate decision on the Protocol/Protocol related Documents Amendment request. Documents will be considered for next full board review if the amendments pose additional risks to the study participants as detailed above.

vii. If the Bhaktivedanta HEC approves the Protocol/Protocol related documents amendment, the Member Secretary will send a signed and dated Amendment Approval Letter to the Principal Investigator (PI) within 14 days of the meeting. The decision regarding disapproval (stating reasons) or request for modifications (stating specific changes needed) shall be communicated in writing to the investigator within 14 days of the meeting.

9.3.7 Notification received from Principal Investigator regarding on-going approved projects

i. Notification along with supporting documents if any (hard and soft copy) forwarded by the Principal Investigator will be received by the Admin Manager of Bhaktivedanta HEC.

ii. Notification received from Principal Investigator regarding on going approved projects may include but not limited to

- Change in study team delegation
- Administrative Change in Clinical Trial Agreement/Signed Clinical Trial Agreement
- Updated Insurance policy
- CTRI registration number
- Administrative changes related to Principal Investigator / Institute or Sponsor

iii. Member Secretary will acknowledge and review notification received from PI along with any supporting documents. Member Secretary may send a letter to PI requesting more clarification or any documents if required within 7 working days of notification.

iv. In the absence of the Member Secretary, the Admin manager of Bhaktivedanta HEC can sign the acknowlegements of the above category of notifications from the PI.

v. Member Secretary will inform all notification received from PI to all members in next full Board meeting

10. Protocol Deviation / Violation / Non-Compliance / Waiver

10.1 Definitions of the Terminologies

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

ii. Protocol Violation: A protocol deviation that may affect the subject’s rights, safety, or well being or alter the risk benefit ratio, and/or affect the subjects’ willingness to participate in the study, and/or impact the completeness, accuracy and reliability of the study data.

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

iv. Protocol Waiver: Protocol Waiver is analogous to a Protocol Deviation, except that prior EC approval must be obtained before implementing the necessary departures from the protocol.

10.2 Detection : Protocol deviation/non-compliance/violation may be detected by the EC through one of the following mechanisms :

- It is reported by Investigator / CRC within 10 days of occurrence or being detected during the Site monitoring visit by the Sponsor. The PI will fill-up the Protocol Deviation Reporting form as per Annexure 16 and submit to the Bhaktivedanta HEC secretariat.
- Through site monitoring visit of the project by the Bhaktivedanta HEC.
- When scrutinizing annual / periodic reports / SAE reports / any other communication received from the Investigator or site.
- From failure by the Investigator / sponsor to comply with the regulatory requirements or EC communications
- Communication / complaint / information received from an enrolled research participant
- Any other communication received from the hospital management or any other sources

10.3 Acknowlegement :

i. Member secretary will acknowledge the reported Protocol deviation/non-compliance/violation and evaluate its seriousness.
ii. The deviations will be included in the agenda in the next formal full board EC meeting.
iii. Member secretary shall inform serious Protocol violation to all members considering seriousness and may schedule urgent full board meeting within 7 working days.

10.4 Review, Decision and Action :

i. The Bhaktivedanta HEC members will review the information available and take a decision depending on the nature of seriousness of the deviation/violation in full board meeting. The protocol violations will be scrutinized for the nature of its gravity. The present committee members will assess its implications on the safety of the study participants and any compromise with the rights of the research participants. The decision will be taken to ensure that appropriate corrective and preventive actions are taken by the PI in the context of the current event; and the safety and rights of the research participants

are safeguarded in future. The decision will be taken by consensus In case, the decision is not reached by consensus, voting will be taken.

ii. The actions taken by Bhaktivedanta HEC could include one or more of the following:

- Inform the Principal Investigator that Bhaktivedanta HEC has noted the violation/ non-compliance/ deviation and direct the PI to ensure that deviations/non-compliances/violations do not occur in future and follow Bhaktivedanta HEC recommendations.
- Enlist measures that the PI would undertake to ensure that deviations/non-compliances/violations do not occur in future. Reprimand the PI.
- Call for additional information / investigation into the details of the matter
- Suspend the study till additional information is made available and is scrutinized.
- Suspend the study till recommendations made by the Bhaktivedanta HEC are implemented by the PI and found to be satisfactory by the Bhaktivedanta HEC.
- Inform the Director of Institute
- Revoke approval of the current study and Inform DCGI/ Other relevant regulatory authorities (if applicable).
- Refuse to review subsequent applications from an investigator cited for non-compliance for a specified duration of time.
- Any other action considered appropriate by the Bhaktivedanta HEC for safeguarding the interests of the research participants participating in the current trial or in future trials.
- Modification of the research protocol;
- Modification of the informed consent form or process;
- Additional information provided to past participants;
- Notification of current participants (required when such information may be related to participants' willingness to continue to take part in the research;
- Requirement that the current participants re-consent to participation;
- Modification of the continuing review schedule;
- Monitoring of research;
- Monitoring of the consent process;
- Referral to other organizational entities (e.g., legal counsel, risk management, institutional official, etc.);

- Requirement of additional training or re-training;
- Other appropriate actions

Bhaktivedanta HEC will send communication with action to concerned PI / Institute director (If applicable) / Regulatory body (If applicable) signed by the Member Secretary within 14 days of the meeting. The HEC will confirm documentary evidence of closure of Protocol Deviation/Violation by verifying the closure documents during routine study monitoring visits or earlier if deemed necessary.

11. Reports Required of Research Investigators

The research investigator shall submit the following reports to the Ethics committee:

i. The investigator should notify the enrolment/recruitment of the first study participant.

ii. Continuing Review report (Annexure 17) should be submitted 6 months following the date of the final Bhaktivedanta HEC approval. Subsequent reports shall be submitted at every 6 monthly following the first report.

iii. The investigator should ask written permission to recruit more patients than no. of patients approved by Bhaktivedanta HEC along with Continuing Review report.

iv. Study completion report: A brief report of the study shall be submitted to the committee at the end of the study as per Annexure 18.

v. Member Secretary will present all the received Continuing Review reports / Study completion reports to all members in next full board meeting.

vi. If the Principal Investigator fails to submit the Continuing review report within one month of the due date (i.e. 6 months from the date of approval or last review report, unless specified otherwise), Member Secretary will send a reminder within 14 working days of this due date. If there is no response within 15 days after the date of reminder, Member Secretary will put up the matter for discussion at the forthcoming full board meeting for appropriate action which may consist of but not limited to

- A letter of reprimanding the Investigator.
- Not reviewing future projects from the PI for a specified period of time.
- A letter asking the Investigator to put recruitment of new participants on hold.

In addition, the investigator shall also promptly report the following to the committee:

- Deviations from / changes to the protocol to eliminate immediate hazards to trial subjects.
- Changes that may increase the risk to subjects and / or affect the conduct of the trial.
- New information that may affect adversely the safety of the subjects or the conduct of the trial.

12. Maintaining Confidentiality And Privacy of Documents

i. Ethics committee members will ensure that they will maintain strict confidentiality and privacy of documents shared with them by Hard/Soft copy by the Bhaktivedanta HEC for their review before the EC meeting.

ii. Ethics committee members will return the hard copy of the documents (if any) submitted for review back to the Ethics committee secretariat. These documents will then get shredded after the EC meeting.

iii. The Ethics committee members will ensure that they shall delete all the soft copies of the shared protocol related documents from their laptop/PC after reviewing the protocols / after the EC meeting involving the said protocol is over.

13. Study Monitoring

The Bhaktivedanta HEC collects and passively reviews the Continuing Review Reports submitted by the PI for each of their approved Clinical Trials every six months (Annexure 17). Additionally, Bhaktivedanta HEC has protocols in place for active on-site monitoring (Annexure 19) of all the study proposals approved by the committee. Such monitoring is of two types - Regular Monitoring and For-Cause Monitoring.

13.1 Regular Monitoring

i. All the ongoing clinical trials shall be monitored at least once a year. The Chairperson will identify and select two/three members to conduct monitoring of a clinical trial site. The structured Monitoring Visit calendar will include one monitoring visit scheduled over two days every three months by the monitoring team members. At least one-fourth the number of ongoing clinical studies will be monitored in each visit. Not less than 45 minutes will be allotted for each clinical trial monitoring. The Bhaktivedanta HEC will aim to cover the monitoring visits for all the ongoing trials within every calendar year.

ii. The Member Secretary will inform the Principal Investigator in writing about the date/time of monitoring visit and request for confirmation from the Principal Investigator, study team members and study participants (if necessary) to be available for the monitoring visit.

iii. Designated Monitors will conduct monitoring of all study documents including but not limited to ICD, AV Consent recording, Source documents, Case record forms, Subject files, study Master file IP, storage facility, Clinical Examination, lab reports etc.

iv. Monitor shall make sure that subjects are recruited into the trial only after written approval from Ethics Committee and approval by regulatory authority. The Recruitment Strategy employed by the PI will also be reviewed by the monitoring team. Monitoring of trials shall be done to ensure equitable selection of subjects with special attention to vulnerable and high risk subjects.

v. Monitors shall ensure adequacy and continuity of consent process.

vi. Monitors shall conduct interview of PI, other study team members and few study participants during monitoring visit. Monitors will complete monitoring report.

vii. The member-secretary will present the monitoring report at the next full board meeting and the concerned member will provide additional details/ clarifications to members, as required.

viii. The Bhaktivedanta HEC will discuss the findings of the monitoring process and take appropriate specific action by voting or combination of actions, some of which are listed below:

- Continuation of the project with or without changes,
- Restrictions on enrollment,
- Recommendations for additional training,
- Recruiting additional members in the study team,
- Revising qualifications/experience criteria for members of the study team,
- Termination of the study,
- Suspension of the study

13.2 For-Cause Monitoring

Additionally, Bhaktivedanta HEC may also initiate 'For-Cause' monitoring which involves conducting focused assessments or investigations in response to specific concerns, complaints, incidents, or regulatory requirements. A 'For-Cause' Monitoring may be initiated by the directive of the Ethics Committee due to following reasons but not limited to

- High number of protocol violations or non-compliance
- Large number of studies carried out at the study site or by the investigator
- Remarkable number of SAE reports
- High recruitment rate
- Non-compliance
- Suspicious conduct
- Complaints received from participants

The activities performed during 'For-Cause' monitoring may include:

- Investigating complaints, allegations, or reports of non-compliance, misconduct, or adverse events related to the conduct of the clinical trial.
- Reviewing study documents, records, and source documents to verify the accuracy, completeness, and integrity of data collected during the trial.
- Conducting interviews or surveys with trial participants to assess their understanding of the study, satisfaction with the informed consent process, experiences during the trial, and perceptions of the risks and benefits of participation.
- Evaluating adherence to the study protocol, including protocol deviations, amendments, or violations.
- Assessing the informed consent process to ensure that participants are adequately informed about the study purpose, procedures, risks, benefits, and alternatives.
- Evaluating compliance with regulatory requirements, ethical standards, and institutional policies governing the conduct of clinical trials.

The Secretariat will convey the decision to the Principal Investigator in writing within 14 days of the monitoring visits including any recommendation and will ask PI to submit action item report including Corrective action and Preventive action (if applicable) for Bhaktivedanta HEC review.

14. Training of Members - New Members and ongoing training

i. All new members will be trained on Good Clinical Research Practices guidelines, Current ethical and regulatory guidelines and Bhaktivedanta HEC SOPs training

ii. The Chairperson will identify the training requirements of the committee members. New members will also be given induction training.

iii. The Chairperson and the Member Secretary will organize workshops or training programs for the committee members. It is recommended to conduct GCP refresher training and training on current regulatory guidelines once a year. There will also be a Training Calendar (Annexure 20) which will specify the periodicity and topics for training to all EC members.

iv. Bhaktivedanta HEC secretariat shall keep required documentation of such training namely, Agenda, Training material, trainers credentials, pre-test and post-test records, training assessment sheet, feedback on the program and action items for members who could not score minimum requirement.

v. The type of programs, areas for training and mentors (Internal/External) for these workshop or training programs will be decided by Member secretary. Members shall also be requested by the chairperson to attend workshops for training. Pre-tests and post-test assessments shall be conducted for members during in-house training programs. Minimum 70% scoring on post test assessment is required by members, failure of which, retraining shall be arranged till members score minimum 70%.

vi. The Chairperson and the Member Secretary will inform all members about any updates on ethical and regulatory guidelines regularly during meetings.

15. Records Retention

i. All records including study documents shall be kept at Bhaktivedanta HEC office. All documents will be accessed only by Bhaktivedanta HEC staff, members and whenever chairperson instructs. This arrangement is to maintain confidentiality of the documents.

ii. Bhaktivedanta HEC will maintain 1 copy of Hard copy and soft copy of all documents submitted and Ethics committee communications for every study submitted for Bhaktivedanta HEC review. Member secretariat will maintain individual study project file for each projects submitted for Bhaktivedanta HEC review.

iii. The committee will archive the following records for a period of at least five (5) years

- Standard operating procedures (SOPs) of the committee
- Guidelines for submission established by the committee.
- Membership list
- Curriculum Vitae of the members
- Agenda of meetings
- Minutes of meetings

The committee will also archive the following records for a period of at least 5 years following the completion of a study:

i. One copy of all materials submitted by a research investigator
ii. All correspondence by the committee with the research investigator regarding application, decision and follow–up
iii. A copy of the decision and any advice or requirements sent to an applicant
iv. All written documentation received during the study
v. The notification of the completion, premature suspension or premature termination of a study
vi. A summary of the final report of the study

The records shall be made available to relevant statutory authorities upon request.

16. Reports to the Bhaktivedanta Hospital Authority

The committee will make a yearly activity report for submission to the relevant Hospital Authority-Director which will include the following elements:

- A quantitative evaluation of the activities of the committee in a year
- The list of the proposals reviewed in a year
- Status of each study proposal

17. Review of Serious Adverse Event (SAE) Reports

The purpose of this SOP is to describe the process on the submission, reporting, review of serious adverse events (SAEs) and unexpected adverse events (UAEs) for any active study approved by the Bhaktivedanta HEC.

The Head of the Institute appoints a SAE sub-committee to deal with these reports. It has a tenure of three years. The members will be chosen from amongst the Bhaktivedanta HEC. The member secretary shall convene and arrange the sub-committee meetings whenever needed and prepare the minutes of the meetings held. The SAE Subcommittee is established and functions in accordance with the NDCT Rules 2019 guidelines and any other relevant national law and regulations in force from time to time.

17.1 List of SAE Sub-Committee Members

Name of Members	Position on Ethics Committee	Designation & Affiliation	Qualification	Gender
Dr. Suraj Bhagde	Member Secretary, Internal	Consultant Ophthalmologist Bhaktivedanta Hospital and Research Institute	MBBS, MS, Ophthalmology	Male
Dr. Komal Dalal	Member clinician , Internal	Consultant Acupuncture Bhaktivedanta Hospital and Research Institute	MBBS, Diploma in Acupuncture	Female
Mrs Meera Singh	Member, Lay person, External	B.Com	Back to Godhead magazine, Office staff	Female
Mr. Manohar Mhaskar	Member, Legal Expert, External	Advocate High Court	B. B.Com.,LLB, LL.M	Male

17.2 Roles and Responsibilities of the SAE Subcommittee members

The key roles and responsibilities of SAE Subcommittee members are:

i. Review and Assessment: SAE Subcommittee members are responsible for reviewing and assessing reports of serious adverse events occurring in research participants enrolled in clinical trials or studies under the purview of the Bhaktivedanta HEC. They evaluate the severity, causality, expectedness, and relatedness of each SAE to the investigational product or study intervention.

ii. The SAE subcommittee while reviewing may solicit opinion of one or more Subject Expert(s) in writing, if the Sub-committee decides to consult Subject Experts. The information can be provided to expert after he/ she/ they agree(s) to the confidentiality cause and abide by the rules and regulations of the ethics committee or the necessary confidentiality documents are signed. The Subject Expert would be requested to provide an opinion in writing within 3-5 working days, depending upon the gravity and seriousness.

iii. Causality-Assessment and Decision-Making: SAE Subcommittee members participate in decision-making processes related to the management of SAEs, including determining the need for protocol amendments, study modifications, participant follow-up, or study termination based on safety considerations. They weigh the benefits and risks of continuing the study against participant safety and ethical considerations.

The following decisions/actions including the following but not limited to, are listed below:

a. To opine on compensation entitled to research participants (as per NDCT Rules 2019), experiencing Serious Adverse Event and unexpected adverse events and adverse events and recommend appropriate action(s)

b. Request further follow up information and/ or additional details on causality of the event, provision of medical treatment till SAE is resolved and financial compensation as per the formulae given under NDCT Rules 2019.

c. Provide periodic follow-up of the research participant till SAE is resolved or till death occurs (whichever is earlier). In case of pregnancy as SAE to send follow up reports of the child in utero and post delivery of the baby till 1 year

d. If appropriate to the discussions, the recommendation regarding a specific action or combination of actions to be taken is arrived at by the SAE subcommittee meeting. The recommendations will be communicated to all members within 5 working days.

iv. Safety Monitoring: SAE Subcommittee members monitor participant safety throughout the duration of the study by reviewing cumulative safety data, trends in adverse events, and emerging safety concerns. They identify any patterns or clusters of adverse events that may indicate potential safety risks and recommend appropriate actions to mitigate risks and protect participant welfare.

v. Communication and Reporting: SAE Subcommittee members communicate with investigators, sponsors, regulatory authorities, and other relevant stakeholders regarding the reporting, documentation, and management of SAEs. They ensure that all required SAE reports are submitted in a timely manner, accurately documented, and appropriately escalated as per regulatory requirements and institutional policies.

vi. Documentation and Record-Keeping: The member secretary mainitains the minutes of the meetings. The SAE Subcommittee ensures that all SAE documentation is accurate, complete, and securely stored in compliance with regulatory requirements and confidentiality standards.

vii. Confidentiality and Privacy: SAE Subcommittee members uphold strict confidentiality and privacy standards in handling sensitive information related to SAE reports and participant medical records. They ensure that participant confidentiality is protected throughout the SAE review process and that only authorized individuals have access to confidential information. Members are required to declare any conflict of interest. Members having conflict of interest shall not participate in the discussion.

17.3 Flow Chart of Activities :

No.	Activity	Responsibility
1	Receipt of SAE Initial Report within 24 hrs of occurance of the SAE. Verification that the report is complete in all aspects (as per Appendix XI of NDCT Rules 2019) along with Annexure 12- SAE assessment report.	Ethics Committee Admin Manager/ Coordinator – Bhaktivedanta HEC
2.	Circulation of SAE report to the all members within 2 days of receipt of Initial SAE reports	Member Secretary /Ethics Committee Admin Manager / Coordinator
3	Decide to call SAE subcommittee meeting or discuss in coming full Board meeting as per regulatory time lines.	Member Secretary
4	Agenda and Minutes of the Subcommittee	Ethics Committee Admin Manager
5	Review and discussion of SAE report at the Subcommittee meeting	SAE Subcommittee members
6	Communication of the SAE Subcommittee opinion about SAE review to Chairperson and other Bhaktivedanta HEC members within 5 days of meeting	Ethics Committee Admin Manager
7	Schedule Bhaktivedanta HEC full board emergency meeting as and when required.	Member secretary and Chairperson
8	Communication of the decision about SAE review to the principal investigator within 7 days of the EC meeting.	Member Secretary
9	Communication of the Bhaktivedanta HEC decision about SAE review to the Licensing authority / DCGI if applicable within 30 days	Member secretary - Bhaktivedanta HEC

	post incorporation on inputs from all members.	
10	Discussion / Information at the full board Bhaktivedanta HEC meeting	Member secretary - Bhaktivedanta HEC
11	The follow up reports of all on site SAE / unexpected AE reports till the event is resolved	Ethics Committee Admin Manager

17.4 Causality Assessment :

Here's an overview of how the SAE Subcommittee conducts causality assessment:

i. Gather Information: The SAE Subcommittee collects all relevant information related to the SAE, including the participant's medical history, concomitant medications, study interventions, clinical trial protocol, and any other pertinent details provided by the investigator.

ii. Review Clinical Data: Members of the SAE Subcommittee review the clinical data associated with the SAE, including medical records, laboratory results, diagnostic tests, and imaging studies. They assess the nature, severity, onset, duration, and outcome of the adverse event.

iii. Assess Temporal Relationship: The SAE Subcommittee evaluates the temporal relationship between the administration of the investigational product or intervention and the onset of the SAE. They determine whether the timing of the SAE is consistent with the expected pharmacological effects or known adverse reactions of the study intervention. They consider de-challenge and re-challenge effects, if applicable.

iv. Consider Alternative Explanations: Members of the SAE Subcommittee consider alternative explanations for the SAE, such as underlying medical conditions, concomitant medications, intercurrent illnesses, procedural complications, or environmental factors. They assess whether these factors may have contributed to the occurrence or severity of the adverse event.

v. Apply Causality Assessment Tools: The SAE Subcommittee may use standardized causality assessment tools or algorithms to systematically evaluate the likelihood of the investigational product or intervention being the cause of the SAE. These tools may include the Naranjo Algorithm, the World Health Organization-Uppsala Monitoring Centre (WHO-UMC) criteria, (Annexure 21) or other established frameworks for assessing causality.

vi. Consideration of injury or death or permanent disability to be related to clinical trial - Any injury or death or permanent disability of a trial subject occurring during clinical trial due to any of the following reasons shall be considered as clinical trial related injury or death or permanent disability, namely:-

a. Adverse effect of the investigational product
b. Violation of the approved protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator leading to serious adverse event
c. Failure of investigational product to provide intended therapeutic effect where, the required standard care or rescue medication, though available, was not provided to the subject as per clinical trial protocol
d. Not providing the required standard care, though available to the subject as per clinical trial protocol in the placebo controlled trial
e. Adverse effects due to concomitant medication excluding standard care, necessitated as part of the approved protocol
f. Adverse effect on a child in-utero because of the participation of the parent in the clinical trial
g. Any clinical trial procedures involved in the study leading to serious adverse event.

vii. Weight of Evidence: Members of the SAE Subcommittee consider the overall weight of evidence supporting or refuting causality between the investigational product or intervention and the SAE. They weigh factors such as the strength of the temporal relationship, the presence of dose-response relationships, consistency with known adverse reactions (as per the Investigator's Brochure), and biological plausibility.

viii. Document Findings: The SAE Subcommittee documents their causality assessment findings, including the rationale for their determination and any uncertainties or limitations in the assessment process. They ensure that the documentation is thorough, objective, and transparent, providing clear justification for the final determination of causality.

ix. Reach Consensus: In cases where there is uncertainty or disagreement among SAE Subcommittee members regarding causality assessment, they engage in discussions and deliberations to reach a consensus. They may seek additional information, expert opinion, or consultation with the principal investigator or other relevant stakeholders to inform their decision-making process.

x. Communicate Findings: The SAE Subcommittee communicates their causality assessment findings to the principal investigator, Ethics committee secretariat, regulatory authorities, and other relevant

stakeholders as appropriate. They provide clear and concise explanations of the basis for their determination, including any implications for participant safety, study conduct, or regulatory reporting requirements.

17.5 For SAEs occurring at other sites:

The investigator will need to submit the SAEs occurring at other sites (CIOMS, SUSARS and Appendix XI) in the form of soft copies (in CD/over Email / hard copies along with the appropriate covering letter (hard copy) mentioning the total number of reports and its details preferably in the following format:

Sr No	Country	MFR Control No.(If applicable)	Type of Report	SAE event	Date of onset of ADR	Date of ADR report	Outcome	Causality	
								PI	Sponsor

i. The SAEs occurring at other sites will be acknowledged by Member secretary and discussed in the forthcoming scheduled SAE Subcommittee or Full Board meeting whichever is earliest. The agenda and minutes of the SAE Subcommittee/Full Board meeting will include the information on SAEs at other sites.

ii. The discussion will be communicated by the SAE Subcommittee Executive Secretary (if discussed in SAE subcommittee meeting) to all Bhaktivedanta HEC members

17.6 Presentation to the Full board Bhaktivedanta HEC meeting

i. In case of the SAE occurring at the site - the details are presented at the full board meeting. The member secretary will also provide the relevant information including updates on SAE that have occurred earlier at the site. The Chairperson will invite members to voice their opinions and ensure free and frank discussion.

ii. After due deliberation on the SAE by all the members, the decision can be arrived at by voting (a majority vote for a decision is a simple majority of the members present) or by consensus.

iii. After review by the Full Board, the recommended actions may include one or more of the items listed below:

- Terminate the study
- Suspend the study till review is completed (safety monitoring of ongoing patients to be continued)
- Suspend the study till additional information is available
- Suspend the study for a specified duration of time
- Suggest changes/ amendments in protocol, Patient Information Sheet/ Informed Consent Document/ Investigators' Brochure/ any other study-related documents
- Suspend the study till amendments requested for by the Bhaktivedanta HEC are carried out;
- Suspend enrolment of new participants;
- Suspend certain activities under the protocol
- Direct the Investigator to inform participants already enrolled in the study about the AEs and if required obtain their consent again (re-consent) regarding continuation in the research trial
- Direct the Investigator to inform participants already enrolled in the study about the AE and request them to undertake additional visits, additional procedures, additional investigations, etc. as prescribed in the amendment
- Note the information about the SAE in records for future reference
- Request further follow up information and/ or additional details
- Provide periodic follow-up of the research participant till SAE is resolved or till death occurs (whichever is earlier)
- Any other appropriate action;

The decision shall be recorded in the minutes of the full board Bhaktivedanta HEC meeting.

iv. If the recommendation from the Bhaktivedanta HEC includes suspension of the study or suspension of any one or more of the study-related procedures or activities, amendments in the protocol or other study-related documents (excluding Investigators' brochure), re-consenting of research participants, the decision will be conveyed to the Principal Investigator through telephone, fax or email within 24 hours. Such a communication will be documented by the Bhaktivedanta HEC Member-Secretary in the study file. A formal letter to the Principal Investigator informing about the Bhaktivedanta HEC

recommendations in such situations will be sent within 7 working days of the Bhaktivedanta HEC meeting having taken place.

v. Bhaktivedanta HEC will ensure that appropriate compensation is paid to the research participant as per applicable regulatory requirements

vi. Investigator should ensure safety monitoring of recruited patients to be continued till SAE is resolved.

17.7 Compensation in case of injury or death in clinical trial of a new drug or investigational new drug or device or intervention:

i. Where any death of a trial subject occurs during a clinical trial, the legal heir of the trial subject shall be provided financial compensation by the sponsor or its representative, who has obtained permission to conduct the clinical trial in accordance with the procedure specified in New Drugs and Clinical Trials Rules 2019.

ii. Where permanent disability or any other injury occurs to a trial subject during a clinical trial, the trial subject shall be provided financial compensation by the sponsor or its representative, who has obtained permission to conduct the clinical trial, in accordance with the procedure specified in New Drugs and Clinical Trials Rules 2019.

iii. The financial compensation shall be in addition to any expenses incurred on medical management of the trial subject.

iv. In the event of an injury, not being permanent in nature, the quantum of compensation shall be commensurate with the loss of wages of the subject as provided in New Drugs and Clinical Trials Rules 2019 .

17.8 Medical Management in case of injury or SAE in clinical trial of new drug or investigational new drug or device or intervention:

i. Where an injury occurs to any subject during clinical trial of a new drug or an investigational new drug or device or intervention, the sponsor, shall provide free medical management to such subject as long as required as per the opinion of investigator or till such time it is established that the injury is not related to the clinical trial, as the case may be, whichever is earlier. The responsibility for medical management as referred here, shall be discharged by the sponsor.

ii. PI / Sponsor is also obliged to pay the expenses of the patients' treatment till the time that it is proved that the SAE is not related.

17.9 Formulae to determine the quantum of compensation in the cases of clinical trial related injury or death

1. Formula in case of clinical trial related death:

Compensation = (B x F x R) / 99.37

Where,

B = Base amount (i.e. 8 lacs)

F = Factor depending on the age of the trial subject as per Annexure 1 (based on Workmen Compensation Act)

R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the trial subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as under:

(1) 0.5 terminally ill patient (expected survival not more than (NMT) 6 months)

(2) 1.0 Patient with high risk (expected survival between 6 to 24months)

(3) 2.0 Patient with moderate risk

(4) 3.0 Patient with mild risk

(5) 4.0 Healthy Volunteers or trial subject of no risk.

However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of Rs. 2 lacs should be given.

2. Formula in case of clinical trial related injury (other than death): For calculation of quantum of compensation related to injury (other than death), the compensation shall be linked to the criteria considered for calculation of compensation in cases of death of the trial subject as referred to in section of this Schedule. The quantum of compensation in case of Clinical Trial related SAE should not exceed the quantum of compensation which would have been due for payment in Case of death of the trial subject since the loss of life is the maximum injury possible.As per the definition of SAE, the following sequelae other than death are possible in a clinical trial subject, in which the trial subject shall be entitled for compensation in case the SAE is related to clinical trial.

(i) A permanent disability: In case of SAE causing permanent disability to the trial subject, the quantum of compensation in case of 100% disability shall be 90% of the compensation which would have been due for payment to the nominee (s) in case of death of the trial subject.

The quantum for less than 100% disability will be proportional to the actual percentage disability the trial subject has suffered.

Accordingly, following formula shall be applicable for determination of compensation:

Compensation = (C x D x 90) / (100 x 100)

Where:

D = Percentage disability the trial subject has suffered.

C = Quantum of Compensation which would have been due for payment to the trial subject's nominees) in case of death of the trial subject.

(ii) Congenital anomaly or birth defect: The congenital anomaly or birth defect in a baby may occur due to participation of anyone or both the parent in clinical trial. Following situations may arise due to congenital anomaly or birth defect.

(a) Still birth;

(b) Early death due to anomaly;

(c) No death but deformity which can be fully corrected through appropriate intervention;

(d) Permanent disability (mental or physical).

The compensation in such cases would be a lump sum amount such that if that amount is kept by way of fixed deposit or alike, it shall bring a monthly interest amount which is approximately equivalent to half of minimum wage of the unskilled worker (in Delhi). The quantum of compensation in such cases of SAE shall be half of the base amount as per formula for determining the compensation for SAE resulting into death.

In case of birth defect leading to sub-clause (c) and (d) of this clause to any child, the medical management as long as required shall be provided by the Sponsor or his representative which will be over and above the financial compensation.

(iii) Chronic life-threatening disease; and

(iv) Reversible SAE in case it is resolved.

In case of clinical trial related SAE causing life-threatening disease and reversible SAE in case it is resolved, the quantum of compensation would be linked to the number of days of hospitalisation of

the trial subject. The compensation per day of hospitalization shall be equal to the wage loss. The wage loss per day shall be calculated based upon the minimum wage of the unskilled worker (in Delhi).

Since, in case of hospitalisation of any patient not only the patient loses his/her wage, there will be direct or indirect losses of various kind including inconvenience, wage loss of attendant, etc. The compensation per day of hospitalisation in such case shall be double the minimum wage.

Accordingly, following formula shall be applicable for determination of compensation:

Compensation = 2 X W X N.

Where,

W = Minimum wage per day of the unskilled worker (in Delhi)

N = Number of days of hospitalization

The Ethics committee will maintain a copy of the documentary proof of the compensation received from the sponsor to the subject or the legal heir (as the case may be).

18. SOP for reviewing proposals involving vulnerable populations

When reviewing clinical trials involving vulnerable populations, such as prisoners, armed forces personnel, staff and students of medical, nursing, and pharmacy academic institutions, patients with incurable diseases, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, or other individuals incapable of personally giving consent, Bhaktivedanta HEC must exercise utmost care to protect the rights, welfare, and dignity of these vulnerable participants. Some key considerations when reviewing clinical trials involving such vulnerable populations are:

i. Conduct a thorough ethical review of the study protocol to assess the risks, benefits, and ethical implications of involving vulnerable populations in the research. Consider the scientific validity, social value, and methodological rigor of the study, as well as the potential impact on the rights, welfare, and autonomy of participants.

ii. Evaluate the informed consent process to ensure that vulnerable participants receive adequate information about the study purpose, procedures, risks, benefits, alternatives, and rights.

iii. Assess the potential consequences of research participation for vulnerable participants' physical health, mental well-being, privacy, confidentiality, and socio-economic status. Ensure that vulnerable participants are not unduly burdened or disadvantaged by their participation in research.

iv. Ensure that measures are in place to protect the privacy, confidentiality, and anonymity of vulnerable participants, as well as their sensitive personal information.

v. Ensure that vulnerable participants have access to appropriate medical care, support services, and resources to address their needs and mitigate potential harms or adverse events arising from research participation.

vi. Facilitate meaningful participation and collaboration with vulnerable populations throughout the research process, including study design, implementation, and dissemination of findings. Promote transparency, accountability, and trust-building to foster mutual respect and cooperation between researchers and vulnerable communities.

vii. Implement risk management plans, contingency measures, and response protocols to protect the safety, rights, and well-being of vulnerable participants.

viii. Establish mechanisms for reporting and addressing concerns, complaints, or grievances raised by vulnerable participants or their representatives.

ix. Promote the development of ethical guidelines, policies, and standards that reflect the needs, values, and perspectives of vulnerable populations and guide responsible conduct of research in diverse socio-cultural contexts.

x. Bhaktivedanta HEC Chairperson / Member Secretary is responsible for ensuring that the committee members are well versed in new and evolving regulations and guidelines pertaining to vulnerable populations.

xi. The Chairperson will appoint two or more members of the Bhaktivedanta HEC who have a thorough understanding of the ethical review process and experience in the field of research to review such type of protocols.

xii. Subject experts or representative of Vulnerable subjects shall / may be invited as required with prior intimation for their inputs or opinion on respective research projects. They will not participate in voting or decision making process.

xiii. Bhaktivedanta HEC Chairperson may allocate primary review of such a proposal to one or two EC members. Guidelines for review may be taken from Annexure 22.

xiv. Employees of the institution, including faculty, staff, and other personnel, shall be considered a vulnerable group when invited to participate in clinical trials, due to the potential for perceived or actual coercion, undue influence, or conflict of interest. Participation of employees must be entirely voluntary, with explicit assurance that refusal or withdrawal will not affect employment status, appraisals, promotions, or workplace relationships. Investigators should avoid direct recruitment by supervisors or persons in authority, and use neutral channels such as open invitations or general announcements. Privacy and confidentiality of employee-participants must be safeguarded. Information regarding their health or participation status shall not be accessible to their superiors or colleagues, and any conflicts of interest must be declared and reviewed by the HEC. Inclusion of employees in research should be scientifically and ethically justified and allowed only when essential for answering the research question. Employees shall receive the same compensation and reimbursement as other participants, and participation shall not be tied to employment-related benefits.

19. Policy of communication with different stake holders

i. Bhaktivedanta HEC communicates with different stakeholder involved in research process including Principal Investigator or any other study team designee, Regulator (DCGI), Director of Institute and Sponsor (If required)

ii. Details about commutation to these stake holders including timeline is mentioned in respective applicable sections.

iii. Bhaktivedanta HEC may communicate following to respective stakeholder but not limited to

a) Principal Investigator

- Study Project Approval/Rejection letter/ Query Letter
- Study documents Amendments Approval/Rejection letter/ Query Letter
- Response to Serious Adverse event notification
- Opinion on compensation of Study injury/death
- Response to Protocol deviation/Violation/Waiver
- Response to Continue review/study completion report
- Study termination letter

b) DCGI

- Opinion on compensation of Study injury/death
- Study Termination letter
- Ethics Committee registration Communications
- Submission of protocol and protocol related documents in case of academic study with change of dose/administration route/indication etc.

c) Director of Institute

- Annual reports of Bhaktivedanta HEC including status of all studies

d) Study Participants

- Response to complaints filed by Subjects participants

e) All Bhaktivedanta HEC members

- Study documents for review
- Agenda and Minutes of meeting
- Agenda and Minutes of SAE subcommittee

20. Policy on Financial declaration of payments received and disbursed

i. All payment received as Bhaktivedanta HEC submission fee are separately maintained under 'Sri Chaitanya Seva Trust'

ii. Ethics Committee Manager/ Coordinator will receive all payment cheque/DD and will submit to account department of institute.

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

iv. Internal member of Bhaktivedanta HEC shall not be provided any remuneration. All External Members will be provided honorary remuneration of Rs. 2000 per meeting, External Basic Medical Scientist will be provided Rs 4000, and Chairperson will be provided honorary remuneration of Rs. 5000 per meeting .

v. All financial payments received and disbursed shall be reviewed at end of every financial year and presented to all Bhaktivedanta HEC members

vi. All financial communication is liable under Institute's internal routine financial Audit and to be certified by the Chartered Accountant.

21. Procedure of complaints/grievance redressal by the research participants and other stakeholders

i. The purpose of this SOP is to provide guidelines for dealing with requests by research participants / patients / other stakeholders regarding their rights as a participant or to resolve their complaint(s) that is / are related to their participation in research / trial approved by Bhaktivedanta HEC.

ii. Subject Participants can contact Secretariat of Bhaktivedanta HEC for any request complaints or query as contact details are mentioned on Bhaktivedanta HEC approved Informed Consent Documents. Stake holders may also contact Member Secretary. Complaints can be submitted through a written and signed letter or over an email addressed to the official email ID - Bhaktivedantahec@gmail.com from the patient's or their next-of-kin or LAR.

iii. Member Secretary will promptly investigate all subject grievances in a fair, thorough, and impartial manner. Gather relevant information, interview involved parties including the Investigator and/or other relevant stake holders, and review study documentation to understand the nature and circumstances of the grievance. Appropriate corrective actions will be undertaken to address the grievance and prevent recurrence, such as providing additional information, modifying study procedures, or implementing disciplinary measures if warranted.

iv. Member Secretary will inform to all Bhaktivedanta HEC members within 7 days of receipt of complaints.

v. Member Secretary may consider matter for next full board meeting with confirmation from chairperson. All available information along with required documents will be discussed in meeting

vi. Chairperson may appoint 1 or 2 members from Bhaktivedanta HEC for enquiry in order to resolve the matter.

vii. The Chairperson/ Member Secretary will assess the situation and mediate a dialogue between the research participant and the investigator or relevant stake holders in an attempt to resolve the matter. Meanwhile, the member secretary will maintain open lines of communication and address participants' concerns and questions in a respectful and empathetic manner.

viii. The final decision will be informed to the research participant, concerned investigator, stake holders and Head of Institute by the Member Secretary within 4 weeks from filing of complaint. The Bhaktivedanta HEC members are informed about the action taken and the outcomes in the forthcoming meeting. All relevant records and communications regarding complaints, investigative steps and resolution decisions are maintained.

ix. The EC will maintain strict confidentiality and privacy standards throughout the grievance redressal process to protect the identity and confidentiality of participants raising grievances. All the documentations will be stored securely.

x. Any opportunities for improvement will be identified through regular review and evaluation of the effectiveness of the subject grievance redressal process.

22. Self-Assessment of Bhaktivedanta HEC

i. Self-Assessment of Bhaktivedanta HEC shall be done on the basis of Performance and Self-Assessment format as mentioned in Annexure 23.

ii. Additionally, each committee member will also fill up a Members Self-assessment form (Annexure 24), either physically on paper or electronically using GoogleForms as administered by the EC secretariat.

iii. Self-Assessment shall be conducted at least once a year. Member Secretary and Admin officer will together conduct self-assessment and review performance of ethics committee. Chairperson may appoint other ethics committee internal/external member to conduct self-assessment if required.

iv. The Member Secretary will present Quality Assurance self-assessment reports to all members in subsequent full Board meeting. The Ethics committee will do Root-Cause Analysis to determine if there is a process failure or a system failure for any deficiency observed.

v. After reviewing Quality Assurance self-assessment, recommendation including corrective and preventive actions (CAPA) will be finalized in full board meeting for its future implementation.

23. Procedures to safeguard and monitor Research Participant's rights, safety and Well Being

i. Bhaktivedanta HEC ensures that Rights and Responsibilities of Research participants (Annexure 25) are displayed at research site including Medical Research Department, Research OPD room, Bhaktivedanta HEC office in English and Hindi languages. Rights and responsibilities of Research participants are also displayed at electronic display of hospital and on Hospital website in English and Hindi languages.

ii. Bhaktivedanta HEC will instruct Principal Investigator in Bhaktivedanta HEC approval letter to ensure that all rights and responsibilities of research participants are informed to all research participants to be enrolled in study.

iii. Bhaktivedanta HEC verifies translations and back-translations of ICD for appropriateness of language and scientific contents.

iv. Bhaktivedanta HEC ensures contact details of Bhaktivedanta HEC are included in Informed consent document to contact research participants in case of any issue related to rights and integrity.

v. Ethics committee has the authority to
   a. verify with the subject
   b. witness a consenting process
   c. review the consent process in the written record and the audio video consent DVD for vulnerable subjects.

vi. The ethics committee ensures that the subject/LAR participates and withdraws in the trial without any coercion or influence.

vii. Research participant can raise any complaint to Bhaktivedanta HEC at any point as mentioned in section 21 - Procedure of complaints by the research participants

viii. Bhaktivedanta HEC shall monitor violation of any rights of research participants by interviewing research participants during on site Bhaktivedanta HEC monitoring.

ix. Bhaktivedanta HEC will gather feedback (Annexure 26) from the Research Participants on voluntary basis towards the end of their study period.

x. Bhaktivedanta HEC will monitor safety and well being of research participants of ongoing study by reviewing

a. Continue review report and study completion reports
b. Review of Serious Adverse Events at site and other sites. If there is a major amendment of SUSAR from other sites which can have an impact on patient safety at our site, the EC will ensure that the enrolled subjects are informed of these developments. Re-consenting of the subjects to be done wherever applicable and upon the directive of the EC.
c. Review of period safety updates report and Investigational brochure or any other new information available which may affects participants' safety
d. Periodic On-site Monitoring of flagged High risk studies

xi. Bhaktivedanta HEC shall arrange periodic training of Institute Administrators, Research Managers, Investigators and other study staff on procedures to safeguard and monitor Research Participant's rights, safety and well being.

24. Procedures to ensure that confidentiality and privacy of the subjects shall be protected :

Bhaktivedanta HEC ensures that -

a. The site does not reveal subject details publicly.
b. Provision is made for safe storage of all the subjects' documents.
c. Access to the trial records is restricted to ensure their confidentiality.
d. There are security protocols for data storage, such as password protection, encryption, firewalls, and physical security measures for electronic and paper records.
e. Unique coding of the study subject's file is done (e.g. assigning subject ID for the clinical trial)
f. No identifiable information will be collected, stored, and used, and whether any data sharing or disclosure to third parties is necessary.
g. The PI anonymizes or de-identifies participant data whenever possible before sharing to the sponsor or any third party.

25. Review for studies in special population groups:

Information supporting the use of the drug in children, pregnant women, nursing women, elderly patients, patients with renal or other organ systems failure, and those on specific concomitant medication is required to be submitted if relevant to the clinical profile of the drug and its anticipated usage pattern.

25.1 Geriatrics:

Geriatric patients (age 60 years and older) should be included in Phase III clinical trials (and in Phase II trials, at the Sponsor's option) in meaningful numbers, only if—

a. the disease intended to be treated is characteristically a disease of aging or
b. the population to be treated is known to include substantial numbers of geriatric patients or
c. when there is specific reason to expect that conditions common in the elderly are likely to be encountered or
d. when the new drug is likely to alter the geriatric patient's response (with regard to safety or efficacy) compared with that of the non-geriatric patient.

When reviewing clinical trials involving special population groups such as geriatric patients, Bhaktivedanta HEC shall exercise particular care to ensure the protection of these vulnerable populations and uphold ethical principles such as,

i. Ensure that informed consent procedures are appropriate for the cognitive ability, sensory deficits, communication skills, decision making ability and health status of geriatric participants.
ii. Evaluate the potential benefits and risks of the research intervention in relation to the specific health needs and vulnerabilities of geriatric patients.
iii. Assess the adequacy of safety monitoring plans, including protocols for detecting, reporting, and managing adverse events in geriatric participants.
iv. Review study protocols to ensure that the study design, interventions, and outcome measures are suitable for the age, health status, and clinical characteristics of geriatric patients.
v. Evaluate recruitment strategies to ensure the inclusion of a representative sample of geriatric patients

vi. Consider the ethical implications of proxy decision-making for geriatric patients who may lack decision-making capacity or autonomy.

vii. Provide additional scrutiny and oversight for clinical trials involving geriatric patients, recognizing their vulnerabilities and unique ethical considerations.

viii. Evaluate plans for long-term follow-up of geriatric patients to monitor safety, efficacy, and potential long-term effects of the research intervention.

25.2 Paediatrics:

For the Clinical Trials involving Paediatric population, special care should be exercised to protect their safety and rights such as -

i. Ensure that informed consent procedures are appropriate for the age, cognitive development, and maturity level of pediatric participants. Assess the capacity of pediatric participants to provide assent, generally, above the age of 12 years, in addition to obtaining consent from parents or legal guardians.

ii. Evaluate the potential benefits and risks of the research intervention in relation to the specific health conditions, developmental stages, and vulnerabilities of pediatric patients.

iii. Assess the adequacy of safety monitoring plans, including protocols for detecting, reporting, and managing adverse events in pediatric participants. Evaluate the appropriateness of dosage forms, formulations, and delivery methods for pediatric use.

iv. Review study protocols to ensure that the study design, interventions, and outcome measures are suitable for the age, developmental stage, and clinical characteristics of pediatric patients.

v. Evaluate recruitment strategies to ensure the inclusion of a representative sample of pediatric patients, considering factors such as disease prevalence, patient demographics, and accessibility to research sites.

vi. Consider the ethical implications of proxy decision-making for pediatric patients who may lack decision-making capacity or legal autonomy.

vii. Provide additional scrutiny and oversight for clinical trials involving pediatric patients, recognizing their vulnerabilities and unique ethical considerations. Consider the composition of the review panel to include members with expertise in pediatrics, child psychology, bioethics, and pediatric research ethics.

viii. Evaluate plans for long-term follow-up of pediatric patients to monitor safety, efficacy, and potential long-term effects of the research intervention.

ix. Ensure compliance with regulatory requirements and ethical guidelines governing research involving pediatric patients, including specific provisions for the protection of vulnerable subjects.

x. Guidelines to the EC member for review of such proposals are summarised in a check-list as in Annexure 27.

25.3 Pregnant or nursing women and foetus:

For the Clinical Trials involving Pregnant and Nursing women, special care should be exercised to protect their safety and rights such as

i. Pregnant or nursing women should be included in clinical trials only when the drug is intended for use by pregnant or nursing women or fetuses or nursing infants and where the data generated from women who are not pregnant or nursing, is not suitable.

ii. For new drugs intended for use during pregnancy, follow-up data (pertaining to a period appropriate for that drug) on the pregnancy, foetus and child will be required. Where applicable, excretion of the drug or its metabolites into human milk should be examined and the infant should be monitored for predicted pharmacological effects of the drug.

iii. Ensure that informed consent procedures are appropriate for pregnant and nursing women, taking into account their unique circumstances, vulnerabilities, and decision-making capacity.

iv. Evaluate the potential benefits and risks of the research intervention for pregnant and nursing women, as well as for their fetuses or infants.

v. Evaluate the appropriateness of dosage adjustments, monitoring parameters, and follow-up procedures for pregnant and nursing participants.

vi. Consider the inclusion of relevant maternal and neonatal endpoints, pregnancy-related outcomes, and breastfeeding parameters. Assess the feasibility and acceptability of study procedures, visits, and assessments for pregnant and nursing participants.

vii. Evaluate recruitment strategies to ensure the inclusion of a representative sample of pregnant and nursing women, considering factors such as gestational age, breastfeeding status, maternal health conditions, and access to prenatal and postnatal care.

viii. Consider the ethical implications of proxy decision-making for pregnant and nursing women who may lack decision-making capacity or legal autonomy.

ix. Consider the composition of the review panel to include members with expertise in obstetrics, maternal-fetal medicine, neonatology, bioethics, and women's health.

x. Evaluate plans for long-term follow-up of pregnant and nursing participants to monitor safety, efficacy, and potential long-term effects of the research intervention on the mothers as well as the infants.

xi. Guidelines to the EC member for review of such proposals are summarised in a check-list as in Annexure 28.

xii. Additional guidelines for review of Research involving cognitively impaired adults are summarised in a check-list as in Annexure 29.

xiii. Additional guidelines for review of Genetic Research are summarised in a check-list as in Annexure 30.

26. Record Keeping of Bhaktivedanta HEC Documents:

The Bhaktivedanta HEC has procedures for systematic record-keeping as per NDCT Rules, 2019 of all documentation and communication of the ethics committee proceedings. The documents are stored in fire safe cabinets under lock and key under authorised access control within the jurisdiction of the Bhaktivedanta HEC office. Proper pest control and fire safety measures are taken to ensure safe storage and integrity of the records.

The Bhaktivedanta HEC master file includes the following documents:

- Master copies and controlled copies of the SOP manuals together with all its released versions.
- Details of the committee members along with the credentials and privileging of the members
- Terms of Reference of the committee
- Communications with the hospital authorities
- Self-assessment activity documentation
- Copies of the budget and other financial details

The Bhaktivedanta HEC will also maintain records of following documents:

- Every Clinical Trial proposal submitted for review

- Inward and outward copies of the communications between the EC and the PI of every Clinical Trial
- Details of the Full Board meetings along with the agenda, attendance sheet, declarations of conflict of interest, filled up protocol assessment review forms by the members present for the meeting
- Details of the SAE sub-committee together with the Terms of Reference, the minutes of its meetings
- Copies of the Study monitoring visit reports conducted by the Bhaktivedanta HEC
- Communications documentation with patients and other stake holders
- Accounting file with a summary of its expenses.

27. Retrieval of Documents :

Retrieval Procedure for all the EC documents is as follows:

i. The EC study file for clinical trials will be made available to EC members and relevant statutory authority upon request. These files will also be made available for inspection and copying by authorized representative of regulatory authorities or Investigator after receiving the request in writing.

ii. Ethics Committee secretariat won't need permission for retrieval of documents for regular internal assessments.

iii. The EC Secretariat will furnish a copy of the required document within a week after receiving the retrieval request. The Member Secretary and Admin Manager of ethics committee are authorized for retrieval.

iv. The EC Secretariat will maintain register stating details of retrieval which will include name of the person seeking retrieval, purpose of the retrieval , EC secretariat person name and sign who retrieved document, date of retrieval and date or return along with the acknowlegement of return.

28. Archival and Final Disposal of Bhaktivedanta HEC Documents:

Bhaktivedanta HEC ensures that essential records are appropriately maintained, organized, and retained in accordance with regulatory requirements and institutional policies.

i. The documents are properly organized, labeled, and indexed before archival to facilitate retrieval and access.

ii. The laptop being used for the purpose of Ethics committee documentation has appropriate password protection, firewall measures and anti-virus for protection from cyber-threats and any unauthorised misuse. USB pendrive use is disabled on this laptop.

iii. Retention period: All the files and documentation in connection to a clinical trial are archived for a period of 05 years after the clinical trial is over and the site close out is declared through official communication to the EC.

iv. Disposal of closed files and copies of protocols and documents submitted for EC review: All the closed study files after completion of archival period, will be shredded and disposed off. A log book of disposed documents will be maintained, providing details of documents being disposed off as per Annexure no. The Ethics Committee will not have to notify anyone about this activity.

29. Ethics Committee SOP in COVID-19 Pandemic period : These guidelines shall be immediately effective post Members Approval on email. It will be effective in Pandemic period of Covid-19 , post which regular SOP would be followed .

29.1 Ethics Committee Review in Emergency Situation :

i. Research during emergencies will be reviewed through expedited review/unscheduled full committee meetings on a case-to-case basis depending on the urgency and need. If an expedited review is done, full ethical review will follow, whenever next full board meeting will be scheduled.

ii. In exceptional and emergency situations, preliminary research procedures including but not restricted to data/ biological sample collection that are likely to rapidly deteriorate or perish may be allowed while the ethics review process is still underway.

iii. Quorum for decision-making would as per NDCT Rules 2019 .

iv. Ethics Committee shall take into account, that Obtaining valid informed consent in humanitarian emergencies such as COVID-19, due to practical difficulties in reaching out to a patient, who may be in a COVID ward, isolation or quarantine facility. In addition, the decisional capacity of the hospitalised patient with moderate or critical disease condition would be very low and it may not be possible to differentiate between reliefs offered and research components.

29.2 Arranging Virtual or tele/web conferences and e-copy review :

i. Ethics Committee will accept Submission of e-copy of research protocol and relevant documents followed by their screening by Secretariat for completeness and categorization as exempt/ expedited review/ emergency full committee review depending on the urgency and need.

ii. All kinds of review (Full board , Expedite, SAE sub-committee) will be conducted through Virtual or Tele/Video conferences to ensure social distancing .

iii. The EC will plan a prior review by subject experts/obtain clarifications from researchers before the meeting or/ invite independent consultants (non-voting) or representative from a specific group as special invitee. The special invitees invited for the web-meeting will be asked to leave the meeting before final decision making.

iv. Ethics Committee Secretariat will circulate agenda and study documents via email or Google link.

v. Conflict of interest would be declared to the Chairperson in video conferencing itself , which will be documented by the Member Secretary .

vi. Minutes of meeting would be circulated via email . Chairperson would approve the minutes of meeting via email .

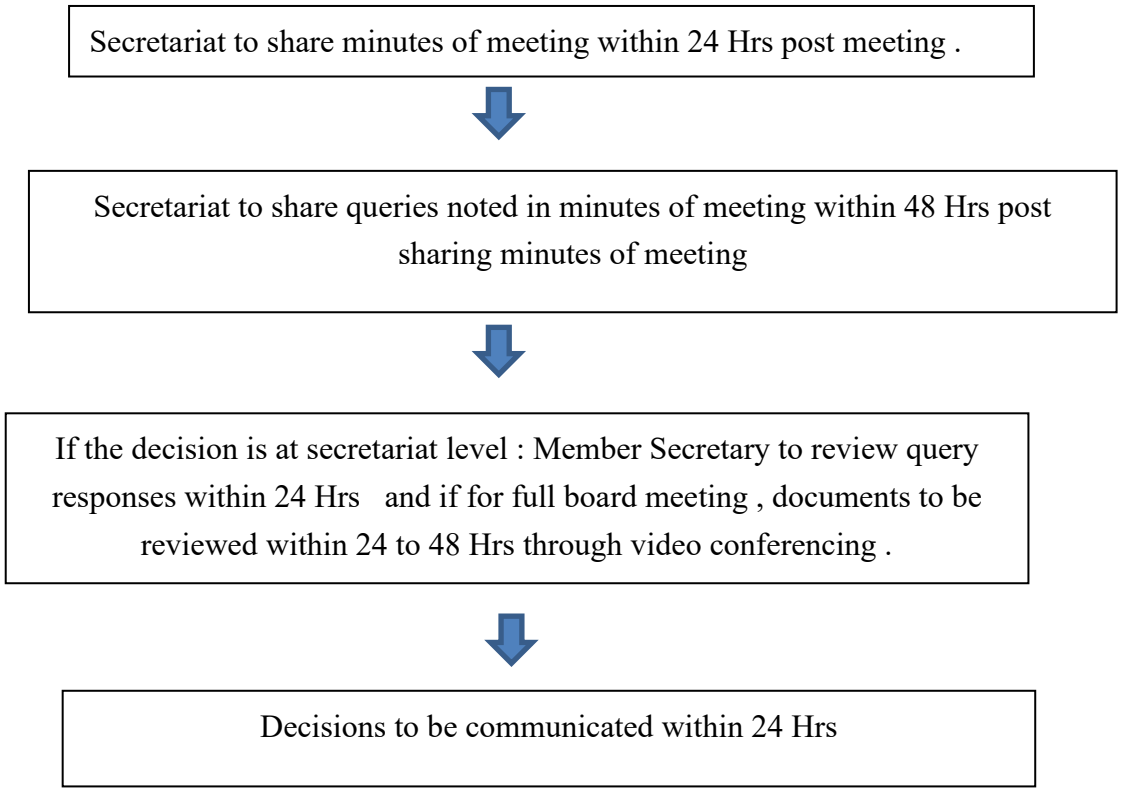
vii. Review and Documentation :

viii. Ethics Committee will consider possibility of alternate way of consenting (orally/electronic methods to document and record) if written consent is not possible for studies involving less than minimal injuries. In such studies contact/communication can be made via phone, to enquire and identify adverse events, serious adverse events and ensure medical care and oversight with documentation.

ix. EC members present during the virtual meeting shall decide through consensus or cast online vote expressing their decision. Any disagreement shall be recorded with reasons. Secretariat is responsible to note the attendance/ participation in the online meeting. Secretariat shall share minutes of the meeting for members review . Review timelines for non-covid studies would remain the same as per previous version of SOP.

29.3 Time lines for reviewing for Covid-19 related studies :

Review of documents within 24 to 48 Hrs post receipt of EC dossier through video - conferencing.



29.4 Process for Non-covid ongoing studies Review :

i. Ethics Committee shall review possibility of extension of study duration; temporary halt of study , Suspension/ Postponement of study ,Continuation of study with limited parameters; conversion of physical visits into phone or video visits, postponement or complete cancellation of visits to ensure that if any site visit any procedure to be done such visits will be done at site.

ii. Ongoing study may need to take re-consent of already enrolled participants to implement urgent changes; it can be done via phone or video-calls and obtaining oral consents supplemented with email confirmation.

iii. EC should review and assess if a planned study may have a negative impact on participants' safety or increase risk to participants (as a result of the ongoing COVID-19 pandemic), and make a decision to allow or not allow it so. It may also make relevant suggestions for additional safeguards for conducting research in such emergency.

29.5 Electronic Consent: (For observational study) Ethics Committee shall review alternate ways of consenting such as technology can be utilized to prepare interactive formats and using electronic tools such as text, graphics, audio, video, podcasts, interactive website, platforms to explain information related to a study and to electronically document informed assent/consent the same. Electronic methods (e.g. digital signature) must be reviewed and approved by the EC a priori.

29.6 Studies involving Vulnerable Persons: COVID-19 patients may be additionally vulnerable of being stigmatized due to the contagious nature of the disease. Terminally ill patients ready to consent in search of new interventions. Ethics Committee shall consider following mentioned Additional Safeguards:

- Research to address the needs of participants and justify inclusion of vulnerable persons.
- Benefits and risks carefully determined and the risk minimization strategies are examined.
- There is no coercion, force, undue influence, threat or misrepresentation or incentives.
- Informed consent process is conducted in a respectful manner.
- Efforts to set up support systems to deal with associated medical and social problems.
- Protection of their privacy, confidentiality and rights is required at all times. Whenever possible, ancillary care may be provided.

29.7 Privacy and Confidentiality:

- Ethics Committee Members shall ensure that there is mechanism for data privacy and confidentiality , as Information related to COVID-19 infection may be highly sensitive in nature with a lot of scope for stigmatization, discrimination, violence etc. Maintaining confidentiality of research related data and its publication is important to protect the privacy of individuals and avoid any discrimination against them.
- The privacy and security features of the virtual tool used must be assessed to a reasonable extent. Collection of identifying information, GPS location, IP address tracking, etc. should be reviewed by EC on case-case basis.

29.8 Guidelines for Investigators :

- Ethics Committee Members shall encourage Investigators to undertake various measures to educate the public or communities about pandemic (COVID-19 infection), proposed research, risks and benefits, persons to be contacted etc.
- Ethics Committee Members will encourage Investigators to make efforts to communicate the research findings to the individuals/communities.
- EC to ensure that all COVID-19 related research (all clinical trials as well as biomedical and health research) be registered on Clinical Trial Registry of India (CTRI) and seek approvals as per relevant guidelines and applicable regulations
- Stakeholders are to consider the fact that technological requirements of the study design may exclude participants without access to the technology. For obtaining quality data, verification of identity of research participant is required. However, exchanging confidential information electronically is prone to security threats.
- Biosafety in laboratories and hospitals :There are four biosafety levels from BSL-1 to BSL-4 with specific controls for containment of microbes and biological agents. Virus isolation in cell culture and initial characterization of infectious viral particles recovered in cultures of SARS-CoV-2 specimens should only be conducted in a Biosafety Level 3 (BSL-3) laboratory or BSL-4 laboratories which offer highest safety environments.
- In an on-going study, if the designated principal investigator (PI) is indisposed for a period, she/he may need delegate parts of her/his duties temporarily to others/ co-investigator and the same should be documented and reported to EC at the earliest.
- Waiver of Consent: Investigator need to specify justification for wavier of consent. Research cannot practically be carried out without the waiver and the waiver is scientifically justified like, cluster randomization trials, retrospective studies, where the participants are de-identified or cannot be contacted. Research on anonymized biological samples/data. Certain types of public health studies/surveillance programs/program evaluation studies .Research on data available in the public domain. Research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent.

- When consent of the participant/LAR/assent is not possible due to the emergency situation, informed consent can be administered at a later stage, when the situation allows for it, and if it is so envisaged, prior permission must be obtained from the EC.

29.9 Post research access and benefit sharing: Ethics Committee shall consider the need for an a priori agreement between researchers and sponsors regarding post-research access of the community to successful interventions and benefit sharing if relevant. Facilitate post-trial access of the successful investigational drug/ vaccine free of cost to the trial participants till the same is available in the market.

Annexure 01

Confidentiality Agreement Form for Bhaktivedanta HEC Members

In recognition of the fact, that I _____

_____

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

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

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

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

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

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the Bhaktivedanta HEC. Any written information provided to the undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

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

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

Agreement on Confidentiality

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

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

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

_____ _____

Signature **Date**

_____ _____

Chairperson's Signature **Date**

Acknowledgement

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

_____ _____

Signature **Date**

Annexure 02

Conflict of Interest Agreement Form for Bhaktivedanta HEC Members

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

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

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

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

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

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

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

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

Agreement on Conflict of Interest

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

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

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

_____ _____

Signature **Date**

_____ _____

Chairperson's Signature **Date**

Acknowledgement

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

_____ _____

Signature **Date**

Annexure 02 A

Confidentiality Agreement and Conflict of Interest declaration form for Admin Staff

Definitions:

i. Confidential Information: Any non-public information that is discussed or handled by the Bhaktivedanta HEC, including but not limited to research protocols, data, deliberations, minutes, correspondence, and personal information about participants.
ii. Conflict of Interest (COI): A situation where an individual's personal, financial, or other interests could compromise, or appear to compromise their professional judgment and integrity in relation to Bhaktivedanta HEC duties.

Confidentiality Agreement:

i. Confidential information pertaining to all the aspects of functioning of Bhaktivedanta HEC must not be disclosed to unauthorized individuals or entities.
ii. Bhaktivedanta HEC documents and data must be securely stored and accessed only by authorized personnel.
iii. Staff must take all necessary steps to prevent accidental disclosure, including proper disposal of sensitive documents and careful handling of electronic communications.
iv. Breach of confidentiality may result in disciplinary action, including termination of employment.

Conflict of Interest Declaration:

i. Staff must disclose any potential conflicts of interest to the Bhaktivedanta HEC Member Secretary as soon as they arise.
ii. Staff members must avoid participating in discussions or influencing decisions where they have a conflict of interest.
iii. Financial interests, personal relationships, or any other factor that might compromise impartiality while interacting with the CRC from the site or members of Bhaktivedantra HEC must be disclosed.
iv. Staff will be required to recuse themselves from Bhaktivedanta HEC activities where a conflict of interest is identified.
v. Failure to disclose a conflict of interest may result in disciplinary action, including termination of employment.

I, ..., working in the capacity of ..... for the Bhaktivedanta HEC have read and understood the Bhaktivedanta HEC Confidentiality agreement and Conflict of Interest declaration as stated above. I agree to comply with these policies and understand that any breach may result in disciplinary action, including termination of my employment.

Staff Signature : _____ Date: _____

Member Secretary : _____ Chairperson : _____

Annexure 03

Confidentiality Agreement Form for Observer Attendees to Bhaktivedanta HEC Meetings

I, _____ (name), understand that I am being allowed to attend the **Bhaktivedanta HEC** meeting scheduled on _____ at _____am/ pm as an Observer. The meeting will be conducted in the Bhaktivedanta Hospital and Research Institute. In the course of the meeting of the **Bhaktivedanta HEC** some confidential information may be disclosed or discussed. Upon signing this form, I ensure to take reasonable measures to keep the information as confidential and not share with anyone else.

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

_____ _____

Signature **Date**

_____ _____

Chairperson's Signature **Date**

Acknowledgement

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

_____ _____

Signature **Date**

Annexure 04

Confidentiality Agreement Form for Independent Consultants / Independent Monitors

I,_____
_____ (Name and Designation) as a non-member of **Bhaktivedanta HEC** understand that the copy / copies given to me by the Bhaktivedanta HEC is/are confidential. I shall use the information only for the indicated purpose as described by the Bhaktivedanta HEC and shall not duplicate, give or distribute these documents to any person(s) without prior permission from the Bhaktivedanta HEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

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

_____ _____

Signature **Date**

_____ _____

Chairperson's Signature **Date**

Acknowledgement

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

_____ _____

Signature **Date**

Annexure 05

Conflict of Interest form for declaring Conflicts during Bhaktivedanta HEC Meeting

Full Board Meeting date: __/___/_____

Following proposals shall be discussed

Sr No	Bhaktivedanta HEC Protocol Code	Name of the PI
1		
2		
3		

I hereby declare the Conflict of Interest for projects to be discussed during today's meeting dated ____/____/_____ (Please tick any one of the following)

☐ I do not have any conflict of interest

☐ I have conflict of interest for following project/s

Bhaktivedanta HEC Protocol Code	Reason for Conflicts

Note : Also specify if COI for any other discussion topic on today's agenda.

Agenda Discussion Topic	Reason for Conflicts

Name of Member: _____

Role in Bhaktivedanta HEC :_____

Signature: _____

_____

Date: _____

_____

Acknowledged by Chairperson,

Bhaktivedanta HEC.

Signature:

Date:

Annexure 06

Agenda of the Full Board Meeting

Date :

Time :

Venue : Conference Room no 1&2, Medical Research wing, Third floor, Bhaktivedanta Hospital and Research Institute, Mira Road east.

Period 1: Quorum

- Welcoming members by Chairperson
- Roll call and apologies from absent Bhaktivedanta HEC members.
- Confirmation of Quorum by the Chairperson
- Declaration of Conflict of Interest by the members

Period 2: Issues to be discussed.

A. New protocol presentation, review, discussion and reaching a consensus to approve/raise queries (n = --)

Inward Number	Bhaktivedanta HEC Code	Title	Name of PI and Co-PI	Conflict

B. Review the responses forwarded by the Principal Investigator to the query letter / resubmitted protocols (n = --)

Inward Number	Bhaktivedanta HEC Code	Title	Name of PI and Co-PI	Report

C. To discuss protocol / ICD amendments and other project related documents (n = --)

Inward Number	Bhaktivedanta HEC Code	Title	Name of PI and Co-PI	Report

D. To discuss continue review report/ completion report/ final clinical trial report (n =--)

Inward Number	Bhaktivedanta HEC Code	Title	Name of PI and Co-PI	Report

E. To discuss Protocol Deviations / Violations (n=---)

Bhaktivedanta HEC Code	Study Title	Name of PI	Date of letter	No of protocol deviation till date

Sr. No	Patient No.	Protocol Deviation	Date of Protocol Deviation	Reason For Protocol Deviation	Corrective and Preventive action

F. To discuss SAE occurred at site (n = --)

Bhaktivedanta HEC Code	Study Title	Name of PI	Date of letter	No of SAE

MFR no	Site No.	Sub No.	Type of Report	SAE Event	Date of onset of ADR/SAE	Date of ADR/SAE report	Status	Causality PI

G. To discuss SAE occurred at other sites follow up reporting (n = ...)

Inward Number	Bhaktivedanta HEC Code	Title	Name of PI and Co-PI	Letter

H. To discuss other letters related to the projects (n = ...)

I. Monitoring report of study monitored by Bhaktivedanta HEC (n = ...)

J. To inform about the Bhaktivedanta HEC meeting held previously to read out minutes (n = ...)

K. Other points for discussion (n = ...)

<u>Period 3 Issues to be informed to the members at Full Board</u>

A. Responses forwarded by the Principal Investigator to the query letter/resubmitted protocols reviewed and approved by the Bhaktivedanta HEC member Secretary and Chairperson (n = ...)

B. Responses forwarded by the Principal Investigator to the query letter/resubmitted protocols reviewed and approved by the Bhaktivedanta HEC member Secretary and Chairperson and letters already sent to the PI (n = ...)

C. Minor Protocol / ICD amendments and other project related documents reviewed and approved by the Bhaktivedanta HEC member Secretary and Chairperson (n = ...)

D. Minor Protocol / ICD amendments and other project related documents reviewed and approved by the Bhaktivedanta HEC member Secretary and Chairperson and letters already sent to the PI (n = --)

Inward Number	Bhaktivedanta HEC Code	Study Title	Name of PI and Co-PI	Letter

Annexure 07

Bhaktivedanta HEC Project Submission Application Form for Initial Review

***For Office use only**
Bhaktivedanta HEC Protocol No. _____/_____

Title of the protocol

_____
_____
_____
_____

1. Study Investigators	***Name***		**Designation & Qualifications**	**Department & Institution**	***Sign***
Principal Investigator					
Co-Investigator					
Co-Investigator					

	2. Sponsor Name and Address : _____ _____
	3. Total Budget : Rs._____
	4. Regulatory Approvals : i) DCGI approval available : Yes / No Details: ..... ii) CTRI registration available : Yes / No Details: .....
	5. Duration of study : _____

	6. Method of Recruitment of study participants _____ _____
	7. Vulnerable research participant Yes ☐ ☐ No ☐ NA
	8. Type of Patients : _____
	9. Phase of Drug Trial : _____
	10. Consent : ☐ Written Informed Consent only ☐ Written Informed Consent & Audio-Visual Consent
	11. Will any advertising be done for recruitment of research participants ☐ Yes ☐ No ☐ NA

Annexure 08

Check List for Protocol Submission

Check List of Documents for Protocol Submission to the Bhaktivedanta HEC to be filled in by the study team

***For Office use only**
Bhaktivedanta HEC Protocol No. _____/_____

* Compulsory documents for initial review.

Sr. No.	Document	Yes	No
1	*Project submission application form duly filled		
2	*Letter to Member Secretary / Chairperson		
3	Synopsis (For Clinical Trials)		
4	*Protocol Document		
5	*Informed consent document in English		
6	*Informed consent documents in Regional languages (Total No:- .....)		
7	*Case Record Form		
8	*Research participants recruitment procedures: advertisement, notices (If applicable)		
9	*Patient instruction card, identity card, diary etc. (If applicable)		
10	*Research participants Questionnaire/s (If applicable)		
11	*Investigator Brochure (If applicable)		
12	*Insurance certificate and policy (If applicable)		
13	*Investigator's undertaking to DCG(I) (If applicable)		
14	DCG(I) approval (Only one copy is needed for submission)[if DCGI approval is awaited, the same is mentioned in the covering letter to the Ethics Committee]		

15	*Clinical Trial Agreement for drug trial / Memorandum Of Understanding, as applicable, for other trials (draft if final not ready)		
16	FDA marketing/manufacturing license for herbal formulations/ nutraceutics (Only one copy is needed for submission)		
17	*Signed and dated brief current curriculum vitae of the study team members (principal investigator, co-investigator, study co-coordinator) (one copy only)		
18	*Log of delegation of responsibility of the study team members - Sample Format Enclosed)		
19	Documentation of CTRI registration / any other WHO platform registry (whenever applicable) (one copy only)		
20	*GCP training certificates of Principal investigator		
21	Any other Documents submitted		

Annexure 09

Delegation of Responsibilities log of Study team members

***For Office use only**
Bhaktivedanta HEC Protocol No. _____/_____

If there are any more study team members, add list with role accordingly and may add column separately
(Please place tick marks against assigned duties for each member in the following table)

Name	**Designation**	**Role No.**

Code	**TASKS**	**Role 1**	**Role 2**	**Role 3**	**Role4**	**Role5**	**Role6**
A	All relevant documents pertaining to protect blinding						
B	Research participants selection/ Screening						
C	Obtain informed consent						
D	Evaluate inclusion/ exclusion criteria						
E	Conduct the visit assessments						
F	Physical examination						
G	Complete the source documents						
H	Complete Case Record Form						

I	Final review and sign Case Record Form						
J	Collect laboratory safety test samples						
K	Processing of blood samples						
L	Preparing aliquots & keeping a track of the samples sent						
M	Review & sign of the lab reports						
N	Receive the study drug**, ,** document drug dispensing, storage & accountability						
O	Person to whom research participants should contact in case of adverse event						
P	Report all serious adverse events						
Q	Follow up of Serious Adverse Event						
R	Maintaining study site master file						
S	In-charge of inventory & supplies						
T	Archiving of study documents						
U	Resolution of queries						
V	Overall coordination and supervision						
W	Any other function						

Annexure 10

Study Assessment Form to be used by the Reviewer

(Hard copy or Via Email)

Bhaktivedanta HEC Protocol Number :			Date:
Protocol Title:			
Principal Investigator: Co-Investigator(s):			
No. of Participants at the site:		No. of Study site(s):	

Section 1 : Scientific Validity:

1	Is the scientific rationale for the study sound and well-supported by literature? ☐ ☐ Yes ☐ No	Comments:
2	Are the study objectives clearly stated and justified? ☐ ☐ Yes ☐ No	Comments:
3	Is the study design appropriate to achieve the objectives? ☐ ☐ Yes ☐ No	Comments:
4	Are the methods adequately described and suitable for the study? ☐ Yes ☐ No	Comments:
5	Are the Inclusion and Exclusion Criteria appropriate? ☐ ☐ Yes ☐ No	Comments:
6	Are the Withdrawal and Discontinuation Criteria appropriate? ☐ ☐ Yes ☐ No	Comments:
7	Are the plans for data analysis appropriate and clearly described? ☐ Yes ☐ No	Comments:

Section 2 : Ethical Considerations:

8	Are the Language and Content of Informed Consent Document appropriate? ☐ ☐ Yes ☐ No	Comments:
9	Is there voluntary non-coercive non-inducive recruitment of Participants? ☐ Yes ☐ No	Comments:

10	Are there adequate measures to protect participant Privacy & Confidentiality? ☐ Yes ☐ No	Comments:
11	If Vulnerable / Special Group population involved, are additional safeguards in place? ☐ Yes ☐ No	Comments:
12	Are the potential risks to participants justified by the potential benefits? ☐ ☐ Yes ☐ No Risk-Benefit Analysis Class : _____	Class A : High Risk Low Benefit ☐ Class B : High Risk High Benefit ☐ Class C : Low Risk High Benefit ☐ Class D : Low Risk Low Benefit ☐

Section 3 : Compliance with Regulatory Requirements:

13	Are all necessary regulatory approvals and clearances obtained or in process? ☐ Yes ☐ No	Comments:
14	Are blood/tissue samples sent abroad? Is HMSC clearance in place? ☐ ☐ Yes ☐ No	Comments:
15	Is provision for Treatment & Compensation of Study related injury appropriate? ☐ ☐ Yes ☐ No	Comments:
16	Is provision for Travel Reimbursement adequate? ☐ ☐ Yes ☐ No	Comments:

Section 4 : Summarize your overall assessment of the protocol. Highlight strengths and any major concerns.

Section 5 : Recommendation: Approved / Approved with Modifications / Pending /

Re-submit / Not Approved / Approved subject to Regulatory approval

Reviewer's Name:_____ **Designation:**_____

Reviewer's Signature:_____ **Date:**_____

Annexure 11

Risk Benefit Assessment Tool

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

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

Annexure 12

Sample format for Patient Information and Consent Form

Version no XXXX dated XXXXX

Title of the Study - XXXXXX

Principal Investigator

Name- XXXX

Designation- XXX

Address: XXXXXX, (Bhaktivedanta Hospital and Research Institute)

Invitation paragraph

You are being invited to take part in a research study titled "_____." Before you decide, it is important that you understand why the study is being done and what it will involve. Please take time to read this information carefully. You may ask the doctor or research team any questions or request clarification about anything that is not clear to you. If you decide to take part, you will be asked to sign the consent form. You will be given a copy of this information sheet and consent form for your records.

Introduction and Purpose of this Study -

This study is being conducted to understand _____ (Briefly explain in lay terms the background of the problem, the need & purpose of the study, Use simple explanatory language / words that can be understood by an averagely literate individual such as non matriculate). The information obtained may help in improving treatment or diagnosis of patients with this condition in the future.

Why am I being requested to participate in this study?

You are requested to participate because you meet the criteria for inclusion in this study, based on your medical condition and clinical suitability as determined by your doctor. Participation is voluntary and entirely your choice.

What are the benefits of my participation?

State possible benefits of the study, if any or state that your participation may or may not benefit you directly, however the information obtained from the study will be of benefit in the treatment of future patients

What will the study involve?

(Explain how long the patient will be required to be in the research. How often will he / she will require to visit a clinic if applicable). Provide details of the study procedure e.g. examination,

intervention (drugs, surgery) tests, radiology etc. Explain (allotment to a study group) if it is a blinded study.

What are the risks involved?

*For non intervention studies- state none as no extra investigations or new therapy is involved.

* For intervention studies- or where extra investigations are involved- list possible side effects (common & uncommon)

What will be the cost of participation?

All costs of the treatment or diagnostics, over & above those involved in standard diagnosis & treatment will be borne by the hospital. Costs as involved in routine care will be borne by the patient

Will my results be informed to me?

(print as applicable)

What are my responsibilities?

Explain if there are any lifestyle restrictions, dietary restrictions, advise to follow all study related instructions, keep follow up dates, report any adverse reactions etc.

Is my participation compulsory?

No, your participation is not compulsory. Your participation is voluntary and non participation will not in any way affect your treatment at the hospital.

Can I withdraw from the study?

You are free to withdraw from the study at any time without giving any explanation. This will not affect your care at the hospital. No further test(s) etc will be done. However data already collected may be used for analysis of results.

If something goes wrong what happens? Who treats & bears the cost?

Any study related complication (diagnostic procedures & therapy) will be treated by the hospital. The hospital will bear the costs. (State if no additional or new intervention is done the patient will bear the cost for such events.)

What about the confidentiality of my data?

All the information obtained in this study will be kept strictly confidential and used for scientific purposes only. Data taken from this study may be published or presented in scientific meetings. However your name and other identifying information will be kept confidential and will not be made publicly available. Your data will be identified by a unique study code, not by your name. Investigators and Ethics committee members & regulatory authorities (if required by law) may review your personal and medical records.

Is the study approved by the Bhaktivedanta HEC?

Yes. The study has been reviewed & approved by the Bhaktivedanta HEC (Bhaktivedanta HEC).

Whom can I contact for more information?

For study related information:-Dr PI / Research fellow and 24 hours contact details

For your rights contact: - Dr. Suraj Bhagde , Member Secretary Bhaktivedanta HEC, Mobile No.: 9833547425

Informed Consent Form

Study Title:

_____

_____

Subject's Initials: _____ Subjects Name :_____

Date of Birth / Age: _____

Address of the subject _____

Contact No.: _____

Qualification: _____

Occupation: student/self- employed/service/Housewife/other (Please tick appropriate)

Annual Income of Subject _____

Name, address of nominee, relation to the subject

_____

_____

		Please put your initial in the box (Subject)
(i)	I confirm that I have read and understood the information sheet dated ___ for the above study and have had the opportunity to ask questions.	[ ]
ii)	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	[ ]
(iii)	I understand that the Study team member, Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	[ ]

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

Signature (or Thumb impression) of Subject/Legally Acceptable Representative		Date: ___/_____/_____
Signatory's Name		
Signature of the Impartial Witness		Date: ___/_____/_____
Name of the Impartial Witness		
Signature of the Investigator		Date: ___/_____/_____
Study Investigator's Name		

(On every Page of ICF - Version no XXXX dated XXXXX Page No XX)

Annexure 13

Protocol Decision and Voting Sheet

Bhaktivedanta HEC Code	Protocol Title	Name of PI and Co-PI	EC Meeting Date

Sr No	Name of the EC Members	Risk Benefit Analysis (Class A,B,C,D)	Decision (Approved/Disapproved/ Approved with modifications / Resubmit)	Sign
1	Dr. Prashant Dhotre (Member clinician, Internal)			
2	Dr. Komal Dalal (Member clinician, Internal)			
3	Dr. Reena Patel (Member Clincian, Internal)			
4	Dr. Nirmal Raut (Member Clinician, Internal)			
5	Dr. Kshama Shah (Member Clinician, Internal)			
6	Dr. Tejal Patel (Basic Medical Scientist, External)			
7	Dr. Anita Panot (Social Worker, External)			
8	Mrs. Mayuri Mistry (Social Worker, External)			
9	Mr. Manohar Mhaskar (Legal Expert, External)			
10	Mr. Jaiprakash Mishra			

	(Legal Expert, External)			
11	Mrs. Meera Singh (Member, Lay person, External)			
12	Mrs. Poonam Tiwari (Member, Lay person, External)			
13	Dr. Suraj Bhagde (Member Secretary, Internal)			
14	Dr. Raakhi Tripathi (Chairperson)			

Whether Consensus achieved? YES / NO

Any need for Voting: YES / NO

If Voting conducted:

No. of Votes in favour of granting approval to the Proposal: ____ / NA

No. of Votes against granting approval to the Proposal: ____ / NA

No. of Voters Recused: ____ / NA

No. of Voters Absent/Non-Voting: ____ / NA

Concluding Remarks :

_____

_____

Chairperson's Signature : _____

Date : _____

Annexure 14

Format of the Query Letter

Bhaktivedanta HEC Outward letter No: ---/2024
Date: .....

To,

Dr. .....

Principal Investigator

Bhaktivedanta Hospital and Research Institute

Protocol Bhaktivedanta HEC/--/--: ----------

Reference: Initial study submission on **.....**.

Sub: Bhaktivedanta Hospital Ethics Committee query letter for above reference study.

Dear Dr.**.....**,

The meeting of the Bhaktivedanta HEC was held on **.....** from 14.00 Hrs to 16.00 Hrs in the Conference room of Bhaktivedanta Hospital and Research Institute.

..... members attended the meeting held on **.....** The list of members who attended the meeting is as follows:

Sr	Name	Position on Ethics committee	Qualification and Affiliation	Gender

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee. We have reviewed the documents submitted to Bhaktivedanta HEC and the following queries were raised.

QUERIES:

A. Queries in the Protocol:

B. Queries in the Informed Consent Document:

C. Queries in the Case Record Form:

D. Other Queries:

Responses to the queries to be reviewed by the member secretary and a clinician. Final approval can be granted, if the responses is found satisfactory and the submitted modifications meets all the scientific, ethical, and regulatory requirements.

You are requested to submit a reply to queries and amended documents within 90 days of receipt of this letter.

Kindly revert in need of any clarification.

With regards,

Dr. Suraj Bhagde

Member Secretary

Bhaktivedanta HEC

Annexure 15

Format of the Approval Letter

Bhaktivedanta HEC Outward letter No: ---/2024
Date: .....

To,

Dr. .....

Principal Investigator

Bhaktivedanta Hospital and Research Institute

Protocol Bhaktivedanta HEC/---/----: .....

Sub: .....

Dear Dr. .....

The meeting of the Bhaktivedanta HEC was held on ..... from 14.00 Hrs to 16.00 Hrs in the Conference room of Bhaktivedanta Hospital and Research Institute.

..... no. of members attended the meeting held on ..... The list of members who attended the meeting is as follows:

The list of members who attended the meeting is as follows:

Sr No	Name	Position on Ethics committee	Qualification and Affiliation	Gender

As per full board meeting dated ..... recommendation, the responses to the queries were to be reviewed by the Member secretary and a Clinician. The following members reviewed responses to the queries submitted from your end vide letter dated ..... were discussed and approved.

Sr No	Name	Position on Ethics committee	Qualification and Affiliation	Gender

Sr. No.	Documents	Version / Date	Reviewed	Approved

The Bhaktivedanta HEC hereby approves the proposal entitled "----------".

Note: Approval for the study is valid for period ..... to ..... You are required to submit study update report along with application for extension of the study period at least 2 weeks prior to expiry of approval period. Ethics Committee shall accord approval letter for extension of the period after reviewing study update report.

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

It is understood that the study will be conducted under your direction, at Bhaktivedanta Hospital and Research Institute as per the submitted protocol. No deviations from, or changes of the approved documents should be initiated without prior written approval or notifications (whichever is applicable) by the Bhaktivedanta HEC.

The Bhaktivedanta HEC expects that the investigator should promptly report to the Bhaktivedanta HEC for any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the study.

Your recruitment policy must ensure unbiased and equitable selection of suitable subjects according to the protocol.

Please submit a continuing review report every 6 months from the date of initial study approval. A copy of the final report should be submitted to the Bhaktivedanta HEC for review at the end of study.

The Bhaktivedanta HEC functions in accordance with New Drug and Clinical Trials Rules 2019, ICH GCP, Indian GCP and ICMR guidelines 2017.

Dr. Suraj Bhagde

Member Secretary
Bhaktivedanta HEC

Annexure 16

Protocol Deviation / Non-compliance / Violation Report

Title of the study: _____

_____

Principal Investigator Name: _____

Participant ID: _____ **Date of Occurrence**: _____

Total no. of deviations/violations reported till date in the study: _____

Deviations / Violations identified by: PI / study team / Sponsor / Monitor / SAE sub-committee / Bhaktivedanta HEC

Type of Deviation / Violation: ☐ Protocol Deviation ☐ Protocol Violation

Is the Deviation related to? (Tick the appropriate option):

☐ Consenting ☐ Source Documentation ☐ Enrollment ☐ Investigator/Staff Error

☐ Laboratory assessment ☐ Participant-Noncompliance ☐ Safety Reporting

☐ Others. If other, please specify_____

Does this Deviation/Violation increase the risk to the study participant? ☐ Yes ☐ No

If yes, provide details: _____

_____

Does this Deviation/Violation adversely affect Integrity & Quality of Data? ☐ Yes ☐ No

If yes, provide details: _____

_____

Is there any potential impact on the study's outcomes or conclusions? ☐ Yes ☐ No

If yes, provide details: _____

Identify and describe the root cause(s) of the deviation or violation: _____

_____

Any Contributing Factors: _____

_____

Describe the Immediate Corrective Actions Taken: _____

_____

Are any changes to the study/protocol required? ☐ Yes ☐ No

Outline the steps to prevent the occurrence of similar deviations or violations in the future:

_____

_____

Timeline for Implementation: _____

Is there any need to notify the relevant Regulatory Authorities? ☐ Yes ☐ No

If yes, provide details including the name of the authority and date of notification: _____

_____

Principal Investigator:

Signature: _____

Date: _____

Study Coordinator (if applicable):

Signature: _____

Date: _____

For Bhaktivedanta HEC Use Only

Date Received: _____

Review Date: _____

Bhaktivedanta HEC Decision:

☐ No Further Action Required ☐ Further Information Required

☐ Corrective Actions Approved ☐ Further Review Needed

☐ Other (Specify): _____

Bhaktivedanta HEC Member Secretary:

Signature: _____

Date: _____

Annexure 17

Continuing Review Report

Bhaktivedanta HEC Protocol No:	**Start date of study:** ____/____/_____
Study Title:	
Principal Investigator:	**Period of Continuing Review Report:**

Project Status:

☐ Ongoing ☐ Recruitment Completed ☐ Closed ☐ Completed ☐ Suspended

☐ Terminated ☐ Closed Prematurely

Recruitment Status:

Total participants to be recruited - _____ Screened: _____ Screen failures: _____

Enrolled: _____ On-going: _____ Follow up: _____ Completed: _____

Withdrawn: _____Reason:

_____

Discontinued: _____Reason: _____

Protocol

a) Have there been any amendments to the Protocol? ☐ Yes ☐ No

b) Is the amended Protocol version approved by Bhaktivedanta HEC? ☐ Yes ☐ No

c) Is the latest version of the protocol being used for the study? ☐ Yes ☐ No

Ethical concerns

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

If Yes, Give details_____

_____

Informed Consent

a) Is Informed consent obtained from all enrolled participants? ☐ Yes ☐ No

b) Have there been any amendments to the ICF? ☐ Yes ☐ No

c) Is the amended ICF version approved by Bhaktivedanta HEC? ☐ Yes ☐ No

d) Was re-consent sought from the applicable study participants? ☐ Yes ☐ No

Protocol Deviations/Violations

Any Protocol Deviations/Violations noted? ☐ Yes ☐ No

Have all the deviations/violations notified to Bhaktivedanta HEC? ☐ Yes ☐ No a) No. of PD: _____ b) No. of PV: _____ c) No. of Protocol Waiver: _____
Adverse Events / Serious Adverse Events Have there been any AE/SAE on the study? a) No. of AE: _____ b) No. of SAE: _____ c) No. of deaths reported: _____ d) Were all the SAE reported within 24 hours of onset? ☐ Yes ☐ No e) In case of multicentric trials, have reports of off-site SAE's been submitted to the EC? ☐ Yes ☐ No
Are there any changes to the study personnel team? ☐ Yes ☐ No Is the change notified to Bhaktivedanta HEC? ☐ Yes ☐ No ☐ NA
Recent Site Monitoring Visit (SMV) done by Sponsor: Date ____/____/_____ ☐ NA Deficiencies pointed out by the Sponsor along with CAPA suggested: 1. _____ 2. _____ 3. _____
Any other Comments? _____ _____

Signature of the Principal Investigator: _____

Date: _____

Annexure 18

Study Completion Report Form

Protocol No. : _____ **Date of Bhaktivedanta HEC approval:** _____

No. of Patients Pre-Screened or Screened	No. of Pre-Screen or Screen Failures		No. of Patients Randomised	No. of Patients Withdrawn	No. of Patients Completed
Total no. of Adverse Events	Total no. of SAEs		Any Deaths	Total Protocol Deviations	Total Protocol Violations
	Related	Not-Related			

Summarize the key findings from the data analysis. Include primary and secondary outcomes.

_____

_____

Provide the main conclusions drawn from the study results. Discuss whether the study objectives were met.

_____

_____

Discuss any ethical issues that arose during the study and how they were addressed.

_____

_____

Confirm that all required reports (e.g., progress reports, safety reports) were submitted to the Bhaktivedanta HEC and other regulatory bodies as required.

☐ **Yes** ☐ **No**

If No, give details

_____

_____

Confirm if all the pending study injury compensations and/or medical bills reimbursement payments have been done to the eligible participants.

☐ **Yes** ☐ **No**

If No, give details

_____

_____

Attach if study completion report available from the Sponsor side.

_____

_____

Signature of the Principal Investigator: _____

Date: _____

Annexure 19

Study Monitoring Visit Report

1)	Bhaktivedanta HEC Protocol No:
2)	Title:
3)	Principal Investigator: _____ Dept. of _____
4)	Institute: Bhaktivedanta Hospital and Research Institute
5)	Type of study:
6)	a) Date of Bhaktivedanta HEC approval: b) Is the period of Bhaktivedanta HEC approval valid : ☐ Yes ☐ No
7)	Start date of study: ____/____/_____
8)	Duration of study:
9)	Date of monitoring visit: ____/____/_____
10)	Reason for monitoring: A.) Routine monitoring B.) For Cause monitoring (State reason) ☐ Protocol Violations/Deviations ☐ SAE reporting ☐ Recruitment rate ☐ Any complaints related to the research ☐ Non Compliance / Suspicious conduct ☐ Other _____
11)	Last Monitoring done: ☐ Yes Date of last monitoring ____/____/_____ ☐ No
12)	Project Status: ☐ Ongoing ☐ Recruitment Completed ☐ Completed ☐ Suspended ☐ Terminated ☐ Closed Prematurely

	☐ Closed
13)	Recruitment Status: ➢ Total participants to be recruited - _____ ➢ Screened: _____ ➢ Screen failures: _____ ➢ Enrolled: _____ ➢ Withdrawn: _____ Reason: _____ ➢ Discontinued: _____ Reason: _____ ➢ Completed: _____ ➢ On-going: _____ ➢ Follow up: _____
14)	Is the recruitment on schedule? ☐ Yes ☐ No If 'No' is it acceptable? ☐ Yes ☐ No ☐ NA If 'No' State reasons/Steps taken by PI to improve recruitment: _____ _____
15)	Does the Recruitment Policy ensure unbiased and equitable selection of the approved number of subjects according to the inclusion and exclusion criteria? ☐ Yes ☐ No If 'No' is it acceptable? ☐ Yes ☐ No ☐ NA If 'No' State reasons/Steps taken by PI to improve recruitment: _____ _____
16)	Protocol a) Have there been any amendments to the Protocol? ☐ Yes ☐ No If Yes, then state nature of changes leading to amendment: _____ b) Is the amended Protocol version approved by Bhaktivedanta HEC? ☐ Yes ☐ No

	c) Is the latest version of the protocol being used for the study? ☐ Yes ☐ No
17)	Informed Consent a) Is Informed consent obtained from all enrolled participants? ☐ Yes ☐ No b) Have there been any amendments to the ICF? ☐ Yes ☐ No If Yes then state nature of changes leading to amendment: _____ _____ c) Is the amended ICF version approved by Bhaktivedanta HEC? ☐ Yes ☐ No d) Is the latest version of the ICF being used for the study? ☐ Yes ☐ No e) Was re-consent sought from the study participants? ☐ Yes ☐ No f) Is there source documentation of the ICF process? ☐ Yes ☐ No g) Is ICF signed by PI/Co-I? ☐ Yes ☐ No h) Is ICF signed by Participant? ☐ Yes ☐ No i) Is ICF signed by LAR? ☐ Yes ☐ No ☐ NA j) Is ICF signed by Impartial Witness? ☐ Yes ☐ No
18)	Any Protocol Deviations/Violations noted? ☐ Yes ☐ No Have all the deviations/violations notified to Bhaktivedanta HEC? ☐ Yes ☐ No Comments (If Any)
19)	Have the eligibility, inclusion exclusion criteria been adhered to? ☐ Yes ☐ No
20)	Are all the Case report forms complete? ☐ Yes ☐ No
21)	Have there been any AE/SAE on the study? ☐ Yes ☐ No If Yes a) No. of Adverse events: _____ b) No. of Serious adverse events: _____ c) No. of deaths reported: _____ ➢ Deaths unrelated to participation in the trial: _____ ➢ Deaths possibly related to participation in the trial: _____ ➢ Deaths related to participation in the trial: _____ d) Were all the SAE reports notified initially and submitted to SAE sub-committee within 24 hours of onset ? ☐ Yes ☐ No

	Comments (If Any) _____ _____
22)	Are the Investigational drugs/devices accountability and prescription procedures performed and documented? ☐ Yes ☐ No ☐ NA If 'No' kindly state the issues: _____ _____
23)	Are there any changes to the study personnel team? ☐ Yes ☐ No Is the change notified to Bhaktivedanta HEC? ☐ Yes ☐ No ☐ NA
24)	No of participants monitored during this visit: _____
25)	Duration of the visit: _____
26)	Any outstanding tasks/action items/opportunities for improvement identified from this visit? _____ _____ _____ _____
27)	Name and Signs of the Bhaktivedanta HEC members who attended the monitoring visit: 1. _____ 2. _____ 3. _____

Final Decision at the Bhaktivedanta HEC meeting held on _____:

_____

_____

Signature of the Chairperson: _____

Date: _____

Annexure 20
Training Calendar

Months	Topics Category	Sub-Topics	Duration	Trainer name / designation
Jan-Feb	ICH-GCP, Regulatory Guidelines	Fundamental ethical principles, Belmont Report, and Declaration of Helsinki. National and international regulations, NDCT Rules 2019	60 mins	Chairperson
Mar-Apr	Informed Consent Process and Documentation	Best practices for obtaining and documenting informed consent. Informed consent under special situations	45 mins	Lay Person
May-Jun	Review and Assessment of Clinical Trial Protocols	Detailed review process, Criteria for Protocol approval	45 mins	Member Secretary
Jul-Aug	Risk-Benefit Analysis in Clinical Trials	Assessing potential risks and benefits, Risk mitigation strategies	45 mins	Member Clinician
Sep-Oct	Vulnerable Populations in Research	Special considerations for research involving vulnerable groups	45 mins	Social Worker
Nov-Dec	Handling Protocol Deviations and Violations	Identifying, reporting, and managing protocol deviations and violations Causality Assessment process	45 mins	Member Clinician

Annexure 21

Summary Description of Causality Assessment as per WHO-UMC system

Causality Term	Assessment Criteria
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable / Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional / Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable / Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

Annexure 22

Guidelines for Research Involving Students, Employees or Residents

Bhaktivedanta HEC protocol no. _____

Name of the Principle Investigator _____

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

Does the employer or supervisor of the research subject need to be aware of the research project?	☐ No	☐ Yes
Is there a letter of support and / or internal services checklist?	☐ No	☐ Yes
Have the subjects been assured that their status (education, employment, and/or promotion) will not be affected by any decision to participate or not?	☐ No	☐ Yes
Have the risks to subjects been minimized?	☐ No	☐ Yes
Have subjects been assured that participation is voluntary (no signs of coercion)?	☐ No	☐ Yes
Have subjects been assured that confidentiality will be protected or maintained?	☐ No	☐ Yes

Comments:

_____

_____

_____

Sign of the Primary Reviewer(s)

_____ Name: _____

_____ Name: _____

Date: _____

Annexure 23

Performance & Self Assessment Format for Bhativedanta HEC

This self-assessment format is designed to help the Bhaktivedanta Hospital Ethics Committee (Bhaktivedanta HEC) to evaluate its performance and ensure adherence to ethical standards and regulatory requirements in the review and oversight of clinical trials.

Assessment Period: _____

Date of Assessment:_____

A.) Performance of Bhaktivedanta Hospital Ethics Committee:

Items	From_____ to _____
Number of Full Board meetings	
Number of new Protocols reviewed in Full Board meetings	
Number of Protocols approved in Full Board meetings	
Number of Protocols disapproved in Full Board meetings	
Number of Protocol Amendments reviewed in Full Board	
Number of continuing review reports / study completion reports reviewed in Full Board	
Number of Serious Adverse Events (at site) reviewed	
Number of Protocol Deviation/Violation reviewed	
Number of Bhaktivedanta Hospital Ethics Committee Monitoring visits of ongoing studies	

B. <u>Self-Assessment of Bhaktivedanta Hospital Ethics Committee</u>:

	Items	Yes (count)	No (count)	Total Count	Percentage Compliance (%) Remarks (if any)
SECTION I - ORGANIZATIONAL ASPECTS					
1.	Does the Bhaktivedanta HEC have documented evidence to confirm appointment of Chairperson and all Bhaktivedanta HEC members by Head of Institute?				
2	Whether Bhaktivedanta HEC has submitted its annual report to the relevant Hospital Authority?				
3	Has the institution evaluated the operations of the Bhaktivedanta HEC (e.g., budgetary needs, adequacy of material resources, adequacy of policies and procedures and practices, the training requirements of the Bhaktivedanta HEC members) in the last year?				
4	Any incidence wherein the independence in functioning and decision making of Bhaktivedanta HEC has been compromised or breached?				
SECTION II - MEMBERSHIP AND TRAINING					
5	Has the Bhaktivedanta HEC maintained updated credentials (i.e Curriculum Vitae, Medical registration certificate or any other supporting documents etc.) of all members?				
6	Has all the members of Bhaktivedanta HEC attended ICH-GCP training or ICH-GCP refresher training at least once in the last year?				
7	Has all the members of Bhaktivedanta HEC attended the updated SOPs training and can provide SOP training records?				
SECTION III - MANAGING CONFLICT OF INTEREST					

8	Has all the Bhaktivedanta HEC members declared written conflict of interest at the time of initial appointment?				
9	How many incidences were noticed wherein the members had conflict of interest during the review of a clinical trial? Were all the above incidences documented in a written conflict of interest form signed by the respective members?				
10	Did the corresponding minutes of those meetings reflect that the members who had conflict of interest did not participate in the decision making process of the related protocols?				
SECTION IV - INITIAL REVIEW OF PROJECTS					
11	Did all the new study projects submitted to the Bhaktivedanta HEC comply with the checklist provided in its SOPs?				
12	Did the Bhaktivedanta HEC secretariat circulate the protocol and other study related documents for all the discussed studies (initial dossier - either as soft copy or hard copy) to all the members at least seven days prior to the Full Board meeting?				
13	Did the Bhaktivedanta HEC perform the risk-benefit assessment in all the reviewed clinical trials to evaluate the benefit against risks involved to the human subjects while participating in the research project?				
14	Is there documented evidence that the Bhaktivedanta HEC has reviewed Clinical Trial Agreement including study budget for every clinical trial discussed in the meetings?				
15	Did the Bhaktivedanta HEC review English and other vernacular informed consent documents for adequate and comprehensive information provided to study participants for all the discussed clinical trials?				

16	Did the required Quorum as per regulations meet for all the Full Board meetings conducted by Bhaktivedanta HEC?				
17	Did the Bhaktivedanta HEC follow its SOP for communicating the study decisions to all the investigators within the defined timeframes?				
18	Did the Bhaktivedanta HEC ensure final CTRI registration of Clinical trials which includes the name of PI, Site and Bhaktivedanta HEC before enrollment of first subject at the site for all the clinical trials?				
SECTION V - AGENDA AND MINUTES OF MEETINGS					
19	Did the member secretary of Bhaktivedanta HEC circulate agenda prior to all the Full board meetings as per timeline mentioned in SOPs to all members?				
20	Were the minutes of the meeting circulated among all the members for review and approval within the defined timeframe?				
SECTION VI - ONGOING REVIEW OF PROJECTS					
21	Did the Bhaktivedanta HEC review continuing review reports and study completion reports submitted by Principal Investigator in the Full Board meetings?				
22	Did the Bhaktivedanta HEC review all the Protocol Deviation/Violation or non-compliance submitted by PIs?				
SECTION VII - REVIEW OF SERIOUS ADVERSE EVENTS					
23	Did the Bhaktivedanta HEC follow strict timelines with regard to SAE Analysis (Initial and FU Review), Compensation calculation and reporting to the licensing authority within the stipulated timelines?				
24	Did the Bhaktivedanta HEC verify whether adequate medical care was provided to all the patients with serious adverse events as per applicable rules and regulations?				

25	Did the Bhaktivedanta HEC check whether compensation was paid timely to the deserving patients or their next-of-kin and whether amount was verified? Is there a copy of documentary evidence of the receipt by the patients?				
SECTION VIII - PERIODIC MONITORING					
26	Did the Bhaktivedanta HEC periodically monitor all the ongoing research project as per procedures defined in its SOPs?				
27	Were all the Monitoring reports discussed in Full Board meetings?				
28	Did the Bhaktivedanta HEC communicate the follow up with the PIs to assess closure of action items including preventive and corrective actions?				
SECTION IX - STORAGE AND ARCHIVAL					
29	Did the Bhaktivedanta HEC store one hard copy and one soft copy of all documents and communications submitted by PI from ongoing research projects in a secure and protected place?				
30	Did the Bhaktivedanta HEC archive documents of eligible studies (1 soft copy and 1 hard copy) as per its SOPs for at least 5 years from date of study closeout / termination?				

Sections	Title	Avg Percentage Compliance
I	**Organizational Aspects**	
II	**Membership and Training**	
III	**Managing Conflict of Interest**	
IV	**Initial Review of Projects**	
V	**Agenda and Minutes of Meetings**	
VI	**Ongoing Review of Projects**	
VII	**Review of Serious Adverse Events**	
VIII	**Periodic Monitoring**	
IX	**Storage And Archival**	
Total Average Percentage Compliance		

C. OVERALL ASSESSMENT

a. Strengths: _____

_____

b. Areas for Improvement: _____

_____

c. Root Cause Analysis :

1. _____

2. _____

3. _____

d. Action Plan - Corrective and Preventive Actions :

1. _____

2. _____

3. _____

Sign of the Admin Manager : _____ **Date :** _____

Sign of the Member Secretary : _____ **Date :** _____

Sign of the Chairperson : _____ **Date :** _____

Annexure 24

Self-Assessment Form for Bhaktivedanta HEC Members

This self-assessment form is designed for individual members of the Bhaktivedanta Hospital Ethics Committee (Bhaktivedanat HEC) to evaluate their performance, contributions, and adherence to ethical standards and regulatory requirements. Complete all sections and provide detailed information where applicable.

Name of the Bhaktivedanta HEC member: _____

Designation in the Bhaktivedanta HEC: _____

Assessment Period: _____ **Date of Assessment:** _____

Please grade your performance qualitatively into one of the five options on the basis of following parameters:

1. My attendance at the Full Board meetings was -

Excellent / Good / Fair / Poor / Very Poor

2. My preparation for the Full Board meetings in terms of reading the protocols, consent forms, other relevant documents, etc was -

Excellent / Good / Fair / Poor / Very Poor

3. My active participation in the discussions and deliberations within the Full Board meetings was -

Excellent / Good / Fair / Poor / Very Poor

4. The quality of ethical and/or scientific review of protocols/relevant documents done by me was -

Excellent / Good / Fair / Poor / Very Poor

5. My participation and active involvement in the Training sessions conducted by the Ethics committee was -

Excellent / Good / Fair / Poor / Very Poor

6. I would rate my overall performance as a Bhaktivedanta Hospital Ethics committee member as -

Excellent / Good / Fair / Poor / Very Poor

I can improve in the following areas of my role as an active Ethics committee member -

_____

_____

_____

_____

My plan for the improvement is as follows -

_____

_____

_____

_____

Sign of the Bhaktivedanta HEC member: _____

Designation in the Bhaktivedanta HEC: _____

Date: _____

Annexure 25

Rights and Responsibilities of Research Participants

Rights of Research Participants

i. Right to information about Research study in an understandable language.

ii. Right to informed consent before participation in any research study

iii. Right to information on the expected cost of treatment, duration, alternative treatment available traveling or any other compensation provided for participation

iv. Right to personal dignity, privacy and confidentiality

v. Right to get the information on plan of care

vi. Right to uniform care for all classes of patients.

vii. Right to information on how to voice a complaint against any violation in rights and integrity (e.g. Ethics committee contact details)

viii. Right to get 24 hours emergency contact details of Research doctor

ix. Right to refusal of participation or withdrawal of participation any point of study without disclosing any reason.

x. Rights to get information on medical management of any injury and compensation in case of any study related injury or death

xi. Right to confidentiality of patient information/details recorded in the hospital.

xii. Right to access clinical records.

Responsibilities of Research Participants

i. Provide complete and accurate information about

   a) Your health including present and past illness, hospitalization, medication and allergies and surgeries.

   b) Full name, address and other information.

   c) Medical Insurance.

ii. To follow the prescribed treatment plan, schedule and instructions given by doctors carefully.

iii. To ask question when he/she does not understand what the Doctors or other healthcare team members tells about diagnosis or treatment.

iv. Not to take any medications without the knowledge of Doctor and healthcare professionals.

v. To accept the measures taken by the Hospital to ensure personal privacy and confidentiality of medical records.

vi. To inform your study doctor immediately in case of any injury or development of any new medical conditions

vii. Treat hospital staff, other patients and other visitors with courtesy

Annexure 26

Clinical Trial Participant Feedback Form

Patient Initials: ---------- Subject ID: ---------- CT Protocol No. ----------

Dear Sir / Madam,

We would like to thank you for giving us an opportunity to serve you. We wish you a speedy recovery to good health. At Bhaktivedanta Hospital & Research Institute, our mission is to serve you holistically, keeping in mind your need to get the topmost quality of health care. To achieve this goal your inputs are of utmost importance.

This feedback form is designed to gather valuable insights from clinical research participants like you about their experience during the study. The feedback will help improve the quality of future research and ensure the highest ethical standards. Your responses are confidential and will be used solely for the purpose of improving the research process.

1. Did you receive enough information about the study including the risks and the benefits before agreeing to participate ?

☐ Yes ☐ No Comments: _____

_____

2. Was the information provided in a clear and understandable manner?

☐ Yes ☐ No Comments: _____

_____

3. Did you have the opportunity to ask questions and receive satisfactory answers before consenting?

☐ Yes ☐ No Comments: _____

_____

4. Were you treated with respect and dignity throughout the study?

□ Yes □ No Comments: _____

_____

5. Did the study team protect your privacy and confidentiality?

□ Yes □ No Comments: _____

_____

6. Was the communication with the study team clear and adequate during your participation?

□ Yes □ No Comments: _____

_____

7. Did you receive the support and assistance you needed during the study?

□ Yes □ No Comments: _____

_____

8. Were you comfortable during the procedures and visits required by the study?

□ Yes □ No Comments: _____

_____

9. Did you receive satisfactory medical care during the study period?

□ Yes □ No Comments: _____

_____

10. How satisfied are you with your overall experience in the study?

Very Satisfied Satisfied Neutral Dissatisfied

Very Dissatisfied

Comments: _____

_____

11. Did you perceive any benefits from participating in the study?

□ Yes □ No Comments: _____

_____

12. Were there any concerns or issues that you faced during the study?

□ Yes □ No If yes, please describe: _____

_____

13. Do you have any recommendations for improving the experience for future participants?

□ Yes □ No If yes, please describe: _____

_____

14. Please provide any additional comments or feedback you would like to share about your experience in the study.

_____

_____

Participant's Signature : _____ Date: _____

Confidentiality Statement:

Your feedback is confidential and will be used solely for the purpose of improving the research process and participant experience. Thank you for your valuable input.

Annexure 27

Guidelines for Research Involving Children

Bhaktivedanta HEC protocol no._____

Name of Principal Investigator _____

Risk Determination	**Benefit Assessment**	**Bhaktivedanta HEC Action**
Minimal	With or without direct benefit	Approvable
Greater than minimal risk	Potential benefit to child	Approvable
Greater than minimal risk	No direct benefit to individual offer general knowledge about the child's condition or disorder.	Approvable case –by- case (ii)

(i) Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or occurring during the performance of routine physical or psychological examinations or tests.
(ii) Risk may not be more than a minor increase over minimal risk, consent of both parents is required under normal circumstances.
(iii) Approval to proceed with this category of research must be made by the Administrator of the IRB, with input from selected experts

	Yes	No	NA
Does the research pose greater than minimal risk to children?			
If yes: Are convincing scientific and ethical justifications given?			
If yes: Are adequate safeguards in place to minimize these risks?			
Does the study involve normal volunteers?			
If yes: Is the inclusion of normal volunteers justified?			

Are the studies conducted on animals and adults, appropriate and justified?			
If No: Is the lack of studies conducted on animals and adults justified?			
Will older children be enrolled before younger ones?			
Is permission of both parents necessary?			
If Yes: Are conditions under which one of the parents may be considered: “not reasonably available” described?			
If Yes: Are the conditions acceptable?			
Will efforts be made ensure that parents’ permission to involve their children in research studies is free from coercion, exploitation, and /or unrealistic promises?			
Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?			
Are provisions made to protect subjects’ privacy and the confidentially of information regarding procedures?			
Are there special problems that call for the presence of a monitor or Bhaktivedanta HEC member during consent procedures?			
Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?			
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
Does the research involve a. which has implications for other family member ?(for example, genetic risk , HIV infection , Hepatitis C)			
If Yes: Are there adequate mechanisms in place to deal with other members of the family?			

Are parents being required to be present during the conduct of the research? (Are proposed subjects to be very young? Are the procedures involved painful? Must the subject stay overnight in the hospital when they otherwise would not have to?)			

Comments:_____

_____

Primary Reviewer _____

Sign and Date _____

Annexure 28

Guidelines for Research Involving Pregnant Women & Foetus

Bhaktivedanta HEC protocol no. _____

Name of Principal Investigator _____

SECTION 1

THIS RESEARCH INVOLVES PREGNANT WOMEN OR FETUSES PRIOR TO DELIVERY

	Yes	No	NA
Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and foetus;			
The risk to the foetus is not greater than minimal, or any risk to the foetus which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the foetus;			
Any risk is the least possible for achieving the objectives of the research;			
The woman's consent or the consent of her legally authorized representative is obtained in accord with the informed consent provisions , unless altered or waived in accord with 45 CFR			
The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the foetus or resultant child;			
If the research involves children as defined in 45 CFR 46.402(a) who are pregnant, assent and permission will be obtained in accord with the provisions of sub-part D of that part;			
No inducements, monetary or otherwise, will be offered to terminate a pregnancy;			
Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and			

Individuals engaged in the research will have no part in determining the viability of a foetus.			

If the response to any of the above is **No**, the research is not approvable by the Bhaktivedanta HEC at this time. See Section 3

SECTION 2

THIS RESEARCH INVOLVES FETUSES AFTER DELIVERY

	Yes	No	NA
Where scientifically appropriate, pre-clinical and clinical studies have been conducted and provide data for assessing potential risks to foetuses;			
The individual(s) providing consent is fully informed regarding the reasonably foreseeable impact of the research on the foetus or resultant child;			
No inducements, monetary or otherwise, will be offered to terminate a pregnancy;			
Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate pregnancy;			
Individuals engaged in the research will have no part in determining the viability of a foetus.			

AND

Foetus of uncertain viability	Yes	No	NA
Does the research hold out the prospect of enhancing the probability of survival of the particular foetus to the point of viability, and any risk is the least possible for achieving the objectives of the research;			
OR			
The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the foetus resulting from the research;			

The legally effective informed consent of either parent of the foetus or , if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained.			

AND/OR

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

If the response to any of above is **No**, the research is not approvable by the Bhaktivedanta HEC at this time. See section 3.

SECTION 3

THIS RESEARCH CAN BE CONDUCTED ONLY AFTER:

The Bhaktivedanta HEC finds that the research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of pregnant women or foetus and,

The secretary, after consultation with a panel of experts in pertinent disciplines (for examples: science, medicine, ethics, law) to determine either:

That the research in fact satisfies the conditions of 45 CRF, as applicable, or

The following:

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

The research will be conducted in accord in sound ethical principles; and

Informed consent will be obtained in accord with informed consent provisions of 45CFR 46 subpart A and other applicable sub-parts, unless altered or waived in accord with 45 CFR or (d).

Comments:

_____

_____

_____

Primary Reviewer _____

Sign and Date _____

Annexure 29

Guidelines for Research Involving Cognitively Impaired Adults

Bhaktivedanta HEC protocol no._____

Name of Principal Investigator _____

The purpose of this checklist is to provide support for Bhaktivedanta HEC members when reviewing research involving cognitively impaired adults as subjects.

1. For review using the expedited procedure this checklist is to be completed by the Designated Reviewer to document determinations required by the regulations and protocol specific findings justifying those determinations and retained.
2. For review using the convened Bhaktivedanta HEC is to document determinations required by the regulations and protocol specific findings justifying these determinations.

Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the subject **(All items must be "Yes")**	**Yes**	**No**
One of the following is true (Check the box that is true) • The risk to the subjects is presented by an intervention or procedure that holds out prospect of direct benefit for the individual subject. • More than minimal risk to subjects is presented by monitoring procedure that is likely to contribute to the subjects well – being.		
The risk is justified by the anticipated benefit to the subjects.		
The relation of anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.		
The proposed plan for the assessment of the capacity to consent is adequate.		
Assent is required of: (One of the following must be **"Yes")** One of the following is true **(Check box that is true)** • All Subjects • All Subjects capable of being consulted. • None of the subjects		
The consent document includes a signature line for a legally authorized representative.		

2. Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the subject (All items must be "Yes")		
Yes	No	The proposed plan for the assessment of the capacity to consent is adequate.
Yes	No	The objectives of the trial cannot be met by means of study of subjects who can give consent personally.
Yes	No	The foreseeable risks to the subjects are low.
Yes	No	The negative impact on the subject 's well-being is minimized and low.
Yes	No	The trial is not prohibited by law.
Yes	No	Subjects have a disease or condition for which the procedures in the research are intended.
Yes	No	Subjects will be particularly closely monitored.
Yes	No	Subjects will be withdrawn if they appear to be unduly distressed.
Yes	No	The proposed plan for the assessment of the capacity to consent is adequate.
Yes	No	Assent is required of (One of the following must be **"Yes")** One of the following is true **(Check box that is true**) All Subjects All Subjects capable of being consulted. None of the subjects
Yes	No	The consent document includes a signature line for a legally authorized representative.

Primary Reviewer _____

Sign and Date _____

Annexure 30

Guidelines Considerations for Genetic Research

Bhaktivedanta HEC protocol no. _____

Name of Principle Investigator _____

	Yes	No
Will the samples be made anonymous to maintain confidentiality? If yes, stop here		
Has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result?		
Has the appropriateness of the various strategies for recruiting subjects and their family members been considered?		
Does the proposed study population comprise family members?		
Will family members be implicated in the studies without consent?		
Will the samples be destroyed in the future?		
Is genetic counselling being offered?		

Comments:_____

_____

Primary Reviewer _____

Sign and Date _____

Annexure 31

Checklist for Review of CTA by the Legal Experts

1. Regulatory & Ethical Compliance
    - Contract states adherence to ICMR Guidelines, ICH-GCP, NDCT Rules, and institutional policies.
    - Participant rights and safety are explicitly prioritized over commercial interests.
2. Liability, Indemnity & Insurance
    - Sponsor accepts responsibility for trial-related injury/compensation.
    - Adequate insurance coverage for participants is specified.
    - Clear indemnity to investigators/institution, except in cases of negligence or misconduct.
3. Confidentiality, Data & Publications
    - Confidentiality obligations balanced with participants' access to their own medical records.
    - Compliance with data protection laws ensured.
    - Investigators' right to publish safeguarded, with reasonable sponsor review timelines.
4. Financial & Administrative Terms
    - Payment terms transparent and free from undue inducement.
    - Responsibilities for archiving, record retention, and protocol amendments clearly defined.
5. Termination & Dispute Resolution
    - Conditions for contract termination are fair and clear.
    - Dispute resolution mechanism (arbitration/jurisdiction) specified.

Annexure 32
Subject Expert List

Sr. No.	Name of Members	Designation & Affiliation	Qualification	Gender
1.	Dr. Sharad Waje	Consultant Plastic Surgeon , BhaktiVedanta Hospital and Research Institute	MBBS, M.S., M.Ch (Plastic Surgery)	Male
2.	Dr. Sandeep Garg	Consultant Pediatrics BhaktiVedanta Hospital and Research Institute	MBBS ,MD, DNB, Fellowship in Pediatric Cardiology	Male
3.	Dr. Sivaprasad Gourabathini	Consultant Urologist, HOD-Urology, BhaktiVedanta Hospital and Research Institute	MBBS,MS MCh Urology	Male
4.	Dr. Dhaval Dalal	Consultant General Medicine BhaktiVedanta Hospital and Research Institute	MD Medicine	Male
5.	Dr. Swapnil Gautam	Consultant Physician and Intensivist BhaktiVedanta Hospital and Research Institute	MBBS, MD,DNB (General Medicine) MRCP	Male
6.	Dr. Jyotsna Zope	Consultant Nephrologist BhaktiVedanta Hospital and Research Institute	DM Nephrology	Female
7.	Dr. Ameya Joshi	Consultant Endocrinologist BhaktiVedanta Hospital and Research Institute	MBBS MD (Internal Medicine) DM(Endocrinology)	Male
8.	Dr. Sandeep Patil	Consultant Cardiologist BhaktiVedanta Hospital and Research Institute	DM Cardiology	Male

Bhaktivedanta Hospital Ethics Committee
Bhaktivedanta Hospital & Research Institute
CDSCO Reg. No. ECR/396/INST/MH/2013 NR-24

-

Annexure 33

NABH Accreditation Certificate Bhaktivedanta HEC

National Accreditation Board
for Hospitals & Healthcare Providers
(Constituent Board of Quality Council of India)

CERTIFICATE OF ACCREDITATION

Bhaktivedanta Hospital Ethics Committee
Bhaktivedanta Hospital and Research Institute
Bhaktivedanta Swami Marg
Opp Isckon Temple, Mira Road
Thane - 401107, Maharashtra

has been assessed and found to comply with NABH Accreditation Standards for Ethics Committee (EC) under clinical trial program.
This certificate is valid subject to continued compliance with NABH Accreditation Requirements.

Date of first Accreditation: November 27, 2017
Date of Previous Cycle
March 05, 2021 to March 04, 2024
Valid from : March 05, 2024
Valid thru : March 04, 2027

PATIENT SAFETY & QUALITY OF CARE
NABH
ACCREDITED

Certificate No.
EC-CT-2017-0002

Dr. Atul Mohan Kochhar
Chief Executive Officer

National Accreditation Board for Hospitals & Healthcare Providers, 5th Floor, ITPI Building, 4A, Ring Road, IP Estate, New Delhi 110 002, India
Phone: +91-11-42600600, Fax: +91-11-2332 3415 • Email: helpdesk@nabh.co • Website: www.nabh.co

ISQuaEEA Accredited Organisation 2022-2026

Sl No. 023146

NABH as an organisation is ISQua Accredited
To verify the authenticity of certificate, reach us on verification@nabh.co

References

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