File No. - EC/NEW/INST/2022/2677

सत्यमेव जयते

Government of India
Ministry of Health & Family Welfare
Department of Health Research

2nd Floor, IRCS Building,
New Delhi - 110001
Dated : 30-Aug-2022

Provisional Certificate

Subject: Provisional registration of the Ethics Committee relating to Biomedical and Health Research with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR).

In exercise of the powers conferred by sub-rule (3) of rule 17 of the New Drugs and Clinical Trials Rules, 2019, the designated authority in the Department of Health Research, Ministry of Health & Family Welfare, hereby provisionally registers and permits the following Ethics Committee to perform the duties of ethics committee as specified in Chapter–IV of the New Drugs and Clinical Trials Rules, 2019.

Name :	**Sree Balaji Dental College and Hospital IEC**
Address :	**Sree Balaji Dental College and Hospital, Velachery main Road, Narayanapuram, Pallikaranai, Chennai , Kanchipuram, Tamil Nadu - 600100**
Contact No:	**04422460619**
Fax :	**-NA-**

2. The Ethics Committee shall observe all the conditions as stipulated in Chapter-IV of the aforesaid Rules, i.e., New Drugs and Clinical Trials Rules, 2019 and the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, specified by the Indian Council of Medical Research (ICMR).

3. The designated authority shall scrutinize the documents and information furnished with the application by the Ethics Committee for the issue of final registration certificate.

4. The above provisional registration shall be valid for a maximum period of two years from the date of its issue or till grant of final registration or rejection of provisional registration, whichever is earlier.

ANU NAGAR
Digitally signed by ANU NAGAR
Date: 2022.08.30 12:16:01 +05'30'

(Anu Nagar)
Joint Secretary
Department of Health Research
Designated Authority

ECR/1298/Balaji Dental/Inst/TN/2015/Re-Registration-2018

सत्यमेव जयते

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India
Dated: 12 NOV 2018

To

The Chairman
Institutional Ethics Committee
Sree Balaji Dental College and Hospital
Velachery Main Road, Narayanapuram, Pallikaranai
Chennai- 600100, Tamil Nadu, India

Sub:- Ethics Committee Re-Registration No. **ECR/761/Inst/TN/2015/RR-18** issued under Rule 122DD of the Drugs & Cosmetics Rules,1945.

Sir/Madam,

Please refer to your application submitted to this Directorate for the Re-Registration of Ethics Committee.

Based on the documents submitted by you, this office hereby re-registers the **INSTITUTIONAL ETHICS COMMITTEE** situated at **SREE BALAJI DENTAL COLLEGE AND HOSPITAL, VELACHERY MAIN ROAD, NARAYANAPURAM, PALLIKARANAI, CHENNAI-600100, TAMIL NADU, INDIA** with Re-Registration Number **ECR/761/Inst/TN/2015/RR-18** as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

1. The re-registration shall be in force from 21.08.2018 to 20.08.2021, unless it is sooner suspended or cancelled.
2. This registration is subject to the conditions specified under Rule 122DD and Appendix VIII of Schedule-Y of Drugs and Cosmetics Act, 1940 and Rules 1945.
3. The Ethics Committee shall review and accord its approval to a clinical trial at appropriate intervals as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well-being of the trial subjects.
4. In the case of any serious adverse event occurring to the clinical trial subjects during the clinical trial, the Ethics Committee shall analyze and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.
5. The Ethics Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of clinical trial.
6. The licensing authority shall be informed in writing in case of any change in the membership or the constitution of the ethics committee takes place.

7. All the records of the ethics committee shall be safely maintained after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).
8. If the Ethics Committee fails to comply with any of the conditions of registration, the Licensing Authority may, after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, suspend or cancel the registration of the Ethics Committee for such period as considered necessary.
9. Ethics Committee shall consist of not less than seven members and is subject to a maximum of 15. One among its members, who is from outside the institute, shall be appointed as chairman, one member as a Member Secretary and rest of the members shall be from Medical, Scientific, Non-Medical and Non-scientific fields including lay public.
10. The committee shall include at least one member whose primary area of interest or specialization is Non-scientific and at least one member who is independent of the institution besides; there should be appropriate gender representation on the Ethics Committee.
11. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.
12. Members should be conversant with the provisions of clinical trials under this Schedule, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.
13. For review of each protocol the quorum of Ethics Committee shall be at least five members with the following representations:
    - I. Basic medical scientist (preferably one pharmacologist)
    - II. Clinician
    - III. Legal expert
    - IV. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person.
    - V. Lay person from community
14. The members representing medical scientist and clinicians should have Post graduate qualification and adequate experience in their respective fields and aware of their role and responsibilities as committee members.
15. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.
16. There should be no conflict of interest. The members shall voluntarily withdraw from the Ethics Committee meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the Chairman prior to the review and be recorded so in the minutes. All members shall sign a declaration on conflict of interest.
17. Subject experts or other experts may be invited to the meetings for their advice. But no such expert shall have voting rights.
18. This certificate is issued to you on the basis of declaration/submission by you that yours is an Institution and re-registration is sought for Institutional Ethics Committee.

19. Funding mechanism for the Ethics Committee to support their operations should be designed to ensure that the committee and their members have no financial incentive to approve or reject particular studies.

20. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

21. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained as long as required.

22. Ethics Committee may undertake the review and monitoring of clinical trial protocols of other investigator(s) and site(s) who do not have their IEC, subject to the condition that the other sites are within the loco- regional and community settings similar to that of the registered Ethics committee. The approving ethics committee must be willing to accept their responsibilities for the study at such trial site(s) and the trial site(s) willing to accept such an arrangement.

23. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial. The ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts where required, for deciding relatedness and compensation, as per condition no (4) mentioned above.

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (I) & Licensing Authority

Dr. S. ESWARA REDDY
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

ECR/1298/Balaji Dental/Inst/TN/2015/Re-Registration-2018

सत्यमेव जयते

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India
Dated: 12 NOV 2018

To

The Chairman
Institutional Ethics Committee
Sree Balaji Dental College and Hospital
Velachery Main Road, Narayanapuram, Pallikaranai
Chennai- 600100, Tamil Nadu, India

Sub: - Ethics Committee Re-Registration No. **ECR/761/Inst/TN/2015/RR-18** issued under Rule 122DD of the Drugs & Cosmetics Rules,1945.

Sir/Madam,

Please refer to your application submitted to this Directorate for the Re-Registration of Ethics Committee.

Your Ethics Committee is hereby re-registered under Rule 122DD vide Re-Registration No. **ECR/761/Inst/TN/2015/RR-18** with the following composition and all the condition mentioned under the Re-Registration certificate issued to you.

Sr. No.	Name of member	Qualification	Role/Designation in Ethics Committee
1.	Dr. Sathish Kumar	MDS (Oral Pathology & Microbiology)	Chairman
2.	Dr. K. Mahalakshmi	Ph.D (Medical Microbiology)	Member Secretary
3.	Dr. A. Subbiya	MDS (Conservative Dentistry & Endodontics)	Clinician
4.	Dr. R. Karthikeyan	MD (Physical Medicine & Rehabilitation)	Clinician
5.	Dr. Arul Amutha Elizabeth	MD (Pharmacology)	Basic Medical Scientist
6.	Dr. Vidya Rani	MDS (Oral Pathology & Microbiology)	Basic Medical Scientist
7.	Mrs. Divya Damodaran	M.Sc. (Physics)	Lay Person
8.	Mrs. Anuradha Balaji	BL	Legal Expert
9.	Dr. Anitha Mahendran	MA, M.Phil, Ph.D (Sociology)	Social Scientist
10.	Dr. A. Julius	Ph.D (Biochemistry)	Scientific Member
11.	Dr. K. Padmavathy	Ph.D (Medical Microbiology)	Scientific Member

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (I) & Licensing Authority

DR. S. ESWARA REDDY
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

File No. EC/21/000139

सत्यमेव जयते

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 25-May-2021

To

The Chairman
BHAARATH INSTITUTIONAL ETHICS COMMITTEE
Bhaarath Medical College And Hospital
173. Agaram Main Road Selaiyur Chennai
Kanchipuram Tamil Nadu - 600073 India

Subject: Ethics Committee Registration No. ECR/1551/Inst/TN/2021 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/NEW/INST/2021/10694 dated 27-Apr-2021 submitted to this Directorate for the Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/1551/Inst/TN/2021. The said registration is subject to the conditions as mentioned below:

Yours faithfully

VENUGOPAL GIRDHARILA L SOMANI

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

Conditions of Registration

1. The registration is valid for a period of five years from the date of its issue, unless suspended or cancelled by the Central Licencing Authority. Provided that if the application for renewal of registration is received by the Central Licencing Authority ninety days prior to the date of expiry, the registration shall continue to be in force until an order is passed by the said authority on such application.

2. This certificate is issued to you on the basis of declaration/submission made by you.

3. Composition of the said Ethics Committee is as per the Annexure.

4. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee in meeting unless at least five of its members as detailed below are present in the meeting, namely:-

(i) medical scientist (preferably a pharmacologist);
(ii) clinician;
(iii) legal expert;
(iv) social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person;

(v) lay person.

5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical, non-medical, scientific and non-scientific areas with at least,

(i) one lay person;

(ii) one woman member;

(iii) one legal expert;

(iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.

6. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization and one member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.

7. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.

8. The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of the institution.

9. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

10. Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

11. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.

12. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

13. The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any

14. No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the Clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.

15. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.

16. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated inwriting to the Central Licencing Authority within thirty working days.

17. The Ethics Committee shall review and accord approval to a Clinical trial, Bioavailability and Bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule of New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.

18. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7: provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site.

19. Where a Bioavailability or Bioequivalence study centre does not have its own Ethics Committee,bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the protocol from the Ethics Committee registered under rule 8:Provided that the approving Ethics Committee shall in such case be responsible for the study at the centre:Provided further that both the approving Ethics Committee and the centre, shall be located within the same city or within a radius of 50kms of the bioavailability or bioequivalence study centre.

20. Ethics committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority.

21. Ethics committee shall make, at appropriate intervals, an on-going review of the trials for which they have reviewed the protocol. Such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.

22. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI, New Drugs and Clinical Trials Rules, 2019.

23. The Ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts wherever required, for deciding relatedness and quantum of compensation, as per condition no (22) mentioned above.

24. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.

25. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

26. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.

27. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

28. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.

29. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

30. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained.

31. The Ethics Committee shall allow any officer authorized by the Central Licencing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.

32. Where Central Licencing Authority is of the opinion that Ethics Committee fails to comply with any provision of the Drugs and Cosmetics Act, 1940and New Drugs & Clinical Trials Rules, 2019, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee, the Central Licencing Authority may take one or more actions specified under provision of Rule 14, Chapter III of New Drugs and Clinical Trials Rules, 2019.

Annexure

File No. EC/21/000139

सत्यमेव जयते

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 25-May-2021

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Dr. Suresh Kanna S	MBBS (MD - General Medicine)	Clinician
2	Dr. Venkateswarlu D	MBBS (MD - General Medicine)	Clinician
3	Dr. Arulparithi C S	MBBS (MD - Paediatrics)	Clinician
4	Dr. Elango P	MBBS (MD-Pharmacology)	Member Secretary
5	Dr. Muthiah N S	MBBS (MD-Pharmacology)	Chair Person
6	Dr. Mohana Sundaram J	MBBS (MD,DNB-Pharmacology)	Medical Scientist
7	Dr. Vidya D C	MBBS (MD,DNB-Community Medicine)	Clinician
8	Mr. Sivakumar R	BA (BL)	Legal Expert
9	Mr. Kurian T Samuel	BSc (MA)	Social Scientist
10	Mr. Vasu R	HSC,SSC (BA)	Lay Person
11	Dr. Vasuki R	BSc (M.Sc., Ph.D-Biomedical Science)	Scientific Member

VENUGOPAL GIRDHARILA L SOMANI

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

FORM CT-02

(See rules 8, 9, 10 and 14)

GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALNENCE STUDY

Registration No. ECR/1551/Inst/TN/2021

The Central Licencing Authority hereby registers and permits BHAARATH INSTITUTIONAL ETHICS COMMITTEE , Bhaarath Medical College And Hospital 173. Agaram Main Road Selaiyur Chennai Kanchipuram Tamil Nadu - 600073 Contact No.: 04422291012 Fax No.: 04422291014 to perform duties of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

2. The ethics committee shall observe the conditions of registration specified in Chapter III of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME AFFAIRS, ou=CDSCO DGHS, postalCode=431401, st=Maharashtra, 2.5.4.20=[illegible], cn=VENUGOPAL GIRDHARILAL SOMANI
Date: 2021.05.25 14:30:51 +05'30'

Place : New Delhi

Date : 25-MAY-2021

Central Licencing Authority
Stamp

सत्यमेव जयते

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 25-May-2021

Composition of the Ethics Committee

Sr. No.	Name of Member	Qualification	Role / Designation in Ethics Committee
1	Dr. Muthiah N S	MBBS, MD (Pharmacology)	Chair Person
2	Dr. Elango P	MBBS, MD (Pharmacology)	Member Secretary
3	Dr. Mohanasundaram J	MBBS, MD, DNB (Pharmacology)	Medical Scientist
4	Dr. Suresh Kanna S	MBBS, MD (General Medicine)	Clinician
5	Dr. Venkateswarlu D	MBBS, MD (General Medicine)	Clinician
6	Dr. Arulparithi C S	MBBS, MD (Paediatrics)	Clinician
7	Dr. Vidya D C	MBBS, MD, DNB (Community Medicine)	Clinician
8	Dr. Vasuki R	BSc, M.Sc., Ph.D (Biomedical Science)	Scientific Member
9	Mr. Sivakumar R	BA, BL	Legal Expert
10	Mr. Kurian T Samuel	BSc, MA	Social Scientist
11	Mr. Vasu R	BA	Lay Person

VENUGOPAL GIRDHARILAL SOMANI

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

Bhaarath
Medical College & Hospital
173. Agaram Main Road, Selaiyur, Chennai 600073

BHAARATH MEDICAL COLLEGE AND HOSPITAL

173. Agaram, Main Road, Chennai – 600073

Bhaarath Institutional Ethics Committee
Standard Operating Procedures

Prepared as per GCP guidelines and New Drugs and Clinical Trials Rules, 2019

SECOND EDTION – 2023

Edited by	Reviewed by	Approved by
Dr P Elango Professor & Head, Pharmacology, Member Secretory, IEC	Dr Vidya D C Associate Professor, Community Medicine. Member, IEC	Dr Arunachala D Edukondalu Dean BHAARATH MEDICAL COLLEGE AND HOSPITAL

Standard Operating Procedures
For
Bhaarath Institutional Ethics Committee

CONTENTS

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road, Selaiyur, Chennai - 600073

Standard Operating Procedures

For

Bhaarath Institutional Ethics Committee

SOP 01: Introduction:

I. Scope:

The following may be called as "Standard Operating Procedures (SOP) for the Bhaarath Institutional Ethics Committee (BIEC) of Bhaarath Medical College Hospital, (BMCH) Chennai 600073". This SOP covers functioning of Ethics Committee reviewing all research on Human subjects done at BMCH as well as those done at other locations under the aegis of a principle investigator / co-investigator employed at BMCH.

II. Name of the Ethics Committee:

Bhaarath Institutional Ethics Committee (BIEC)

Bhaarath Medical College and Hospital

173. Agaram Main Road, Selaiyur

Chennai 600073

III. Address of the Office of the Ethics Committee

The Member Secretary

Bhaarath Institutional Ethics Committee (BIEC)

Bhaarath Medical College And Hospital,

173. Agaram Main Road, Selaiyur,

CHENNAI - 600073

Phone No : 044-61116222

Fax No : 044-61116222

Email ID : iec@bmch.ac.in

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road, Selaiyur, Chennai-600073

SOP 03: Terms Of Reference:

The Ethics committee is mandated to examine research proposals where research is to be wholly or partially carried out at BMCH and any other associated institution of Bharath University which approaches this committee to ensure that research is carried out in accordance with ethical principles.

- To ensure that the research projects carried out at BMCH are sound in design, have statistical validity and are conducted according to the ICMR and ICH / GCP guidelines.
- Do not compromise safety of the patients or volunteers.
- Are conducted under the supervision of medical persons with the required expertise.
- Include solely, patients who have given voluntary and informed consent.

I. Authority, under which the Ethics Committee has been constituted, Membership Requirements, the term of reference, conditions of appointment and the quorum required:

   a. Authority under which the Ethics Committee has been constituted:

      i. The Academic Council Bhaarath Medical College Hospital, Chennai 600073, is the competent authority for constitution of the BIEC.

      ii. The Dean is authorized to nominate members in consultation with the Chairperson of the BIEC among those who possess the qualifications and experience as per the norms prescribed under Drugs and Cosmetics Rules.

   b. Members of the BIEC

      i. Bhaarath Institutional Ethics Committee is constituted with the following members (Table: 1)

      ii. Presence of at least one woman on the committee is compulsory.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

	Selaiyur, East Tambaram – 600073	
12	Mr. Sivakumar R, BA, BL, Legal Consultant for Legal Aid BIHER, Selaiyur, East Tambaram – 600073	Legal Expert
13	Rtn. Mr. J. K. N. Palani, MA, Rotary Member No: 14, Ambedkar street, Anandhapuram, East Tambaram, Chennai - 600059	Lay Person

Table: 1: Members Institutional Ethics Committee

vi. All members are required to have good moral character and should not have been convicted for any offence.

c. Chairperson:

i. The Chairperson of the Committee should be from outside the Institution to maintain the independence of the committee.

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

iii. The Chairperson presides overall administrative matters pertinent to the committee's functions.

d. Member Secretary:

i. The Member Secretary should be a Medical Scientist who belongs to BMCH and should conduct the business of the committee.

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

iii. Receiving all research proposals.

iv. Forwarding all materials for review by the committee members.

v. Preparation and dissemination of agenda for all committee meetings (10 days prior to the meeting date).

vi. Inviting special attendees / expert, from relevant specialties to the scheduled meetings, if needed.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road Selaiyur, Ch

SOP 04: Procedures for Appointment, Resignation, Replacement or Removal of members:

I. Appointment:

a. The Dean, after appointing the chairperson, in consultation with the Chairperson, nominate the members of BIEC, who have the qualification and experience to review and evaluate the science, medical aspect and ethics of the proposed study.

b. The normal term for BIEC member will be for 5 Year.

c. The membership may cease, if a member resigns from the Committee, if a member is incapable of performing his / her duty as a Committee member and in case of demise of a member.

d. The Dean can renew the appointment of the member on the basis their contribution.

e. Each member is required to sign the membership acceptance regarding BIEC activities, confidentiality, agreement and conditions of appointment. (Vide infra – APPENDIX- I - BIEC MEMBERSHIP ACCEPTANCE):

II. Resignation:

a. Any member may resign before completing their terms by writing their intention to the Chairperson. The members have to serve for 1 (one) month notice period before they can be relieved. However, the Chairperson shall review the same and decide whether to allow the member to leave the Committee with immediate effect or after serving the notice period of 1 (one) month.

b. A member can resign by submitting a letter of resignation addressed to the Chairman and delivered to the Member Secretary the same will be informed by the Secretary to the appointing authority for formal acceptance and to initiate necessary replacement/recruitment procedure for filling up the

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER

during full committee review meeting. The meeting convened will follow the usual rules of quorum. The allegation will be discussed at the IEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend herself/himself.

d. The member would stand disqualified, if members present approve of disqualification by voting (voting by 2/3rd majority of members present in the meeting). The Chairperson will convey the disqualification to the concerned member through a written communication.

V. Disqualification following continued absence:

a. Disqualification for not attending IEC meetings: A member may be disqualified from IEC membership if the member fails to attend more than 3 consecutive IEC meetings without prior intimation. The process concerned will be as follows:

b. The Member Secretary will inform Chairperson, in writing, if a member has not attended more than three consecutive regular meetings of the IEC without prior intimation to the IEC or is on long leave extending for more than six months without valid reasons.

c. The Chairperson will initiate the process of review of membership of such a member by including the matter in the agenda of the next IEC meeting.

d. A written communication will be sent to the concerned IEC member informing her/him that the issue of disqualification would be discussed at the meeting, inviting the member to be present at the meeting to clarify her/his position. Alternatively, the concerned IEC member will be allowed to explain her/his uninformed absence in a letter addressed to the Chairperson, which will be read and reviewed at the meeting. The Chairperson or Member-Secretary will inform the other IEC members about the cessation of membership of the member, in consultation with

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER

SOP 05: Quorum Requirements:

Eleven persons are appointed as members in BIEC. The quorum required shall be a minimum of 5 members. It includes both medical and non-medical members, with at least one of the members present being not affiliated to BMCH apart from Chairman.

The quorum for review of clinical trial or bioavailability or bioequivalence Proposal and related documents shall be at least five members with the following representations:

I. Medical scientist (preferably a pharmacologist);

II. Clinician;

III. Legal expert;

IV. Social scientist or representative of non- governmental voluntary agency or philosopher or ethicist or theologian or a similar person;

V. Lay person.

The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

decision making procedure.

XIII. In case of conditional approval of a proposal the same will be communicated to the investigators, with clear suggestions for modifications and Re-review procedure.

XIV. Negative decision will be supported clearly by stated reasons.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

SOP 08: Type Of Clinical Research Reviewed By The Committee (E.G. Pharmaceuticals, Devices, Epidemiological, Retrospective, Herbals, Etc.,):

I. Drug trials,

II. Prospective clinical studies, on both medical and surgical patients and blood and pathology specimens,

III. Bioavailability and Bioequivalence studies

IV. Epidemiological studies,

V. Retrospective studies.

VI. AYUSH proposals which may be included for consideration, if one of the co – author is from that same specialty of studies involved.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

SOP 10: Review Of Subject Recruitment Procedures:

I. The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status and ethnicity).

II. The means by which initial contact and recruitment is to be conducted.

III. The means by which full information is to be conveyed to potential research participants or their representatives.

IV. Inclusion criteria for research participants.

V. Exclusion criteria for research participants.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

c. Research related to pre-natal diagnostic techniques: In pregnant women such research should be limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus.

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

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

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

c. The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors, adolescents etc.;

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

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

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

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

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

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER

{ } Place Initial box (Subject)

XIV. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.

{ } Place Initial box (Subject)

XV. 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 purposes

{ } Place Initial box (Subject)

XVI. I agree to take part in the above study.

{ } Place Initial box (Subject)

Signature or Thumb impression of the Subject / Legally Acceptable Representative:

Date:.....

Signatory's Name:

.....

Signature of the Investigator:.....

Date:.....

Study Investigator's Name:.....

.....

Signature of the Witness.....

Date.....

Name of the Witness:.....

Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject his or her attendant

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

j. An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.

k. The anticipated prorated payment, if any, to the subject for participating in the trial.

l. Responsibilities of subject on participation in the trial.

m. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.

n. Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect.

o. Statement that in the case of placebo controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.

p. Any other pertinent information.

II. Additional elements, which may be required:

a. Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent.

b. Additional costs to the subject that may result from participation in the study.

c. The consequences of a Subject's decision to withdraw from the research and procedures for orderly

d. Termination of participation by Subject.

e. Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.

f. A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or foetus, if the Subject is or may become pregnant), which are currently unforeseeable.

g. Approximate number of Subjects enrolled in the study.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road, Selaiyur, Chennai-600073

SOP 15: Care And Protection Of Research Participants:

I. Plan and reason out to withdraw or withhold standard therapies for the purpose of the justification for such action;

II. The medical care to be provided to research participants during and after the course of the research;

III. The adequacy of medical supervision and psycho-social support for the research participants.

IV. Steps to be taken if research participants voluntarily withdraw during the course of the research.

V. The criteria for extended access to the emergency use of and / or the compassionate use of study products.

VI. The arrangements, if appropriate for informing the research participant's general practitioner (family doctor), including procedures for seeking the participant's consent to do so.

VII. A description of any plans to make the study product available to the research participants following the research.

VIII. A description of any financial costs to research participants.

IX. The rewards and compensations for research participants (including money, services, and /or gifts.

X. The provisions for compensation / treatment in the case of the injury disability/ death of a research participant attributable to participation in the research.

XI. The insurance and indemnity arrangements.

XII. The ethics committee shall look into the details of the Proposal for formation of a Data and Safety Monitoring Board (DSMB). In the absence of any such provision in the Proposal. The BIEC may insist on the same prior to approval or recommend to The Dean, BMCH to constitute a DSMB for monitoring the trial.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

SOP 17: Protection Of Research Participant Confidentiality:

I. A description of the persons who will have access to personal data of the of the research participants, including medical records and biological samples;

II. The measures taken to ensure the confidentiality and security of personal information concerning research participants.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

SOP 19: Procedure For Addressing The Issues Related To Proposal Deviation / Non-Compliance / Violations:

A decision of a follow-up review will be issued and communicated to applicant indicating modification / suspension / termination / continuation of the project.

BIEC will also require the investigators to inform the committee about any SAE and payment of any compensation for the same.

It shall also review the adequacy of treatment given to participants following an SAE.

In case of premature suspension/termination, the applicant must notify the BIEC of the reasons for suspension/termination with a summary of results.

Applicant must inform at the time of completion of study and must send the result summary to BIEC.

BIEC must receive a copy of final summary of study completed from the applicant.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

a. Information on recovery and any sequelae; results of specific tests or treatment that may have been conducted.
b. For a fatal outcome, cause of death and a comment on its possible relationship to the suspected event; Any post-mortem findings.
c. Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

VIII. Details about the Investigator

a. Name and Address
b. Telephone number
c. Profession (specialty)
d. Date of reporting the event to Central Licencing Authority:
e. Date of reporting the event to ethics committee overseeing the site:
f. Signature of the Investigator or Sponsor

Note: Information marked * must be provided.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

a. ADVERSE DRUG REACTION REPORTING FORM recommended by INDIAN PHARMACOPOEIA COMMISSION (vide infra - APPENDIX- VI, ADVERSE DRUG REACTION REPORTING FORM)
b. Initial SAE report to be submitted by the Principal Investigator within 24 hours of occurrence.
c. Due analysis should be submitted by the PI within 14 days from the occurrence of the SAE
d. Due analysis will also be submitted by the sponsor within 14 days
e. The follow up reports of all on-site SAE till the event is resolved.

IX. The IEC Secretariat will sign and write the date on which the report is received.

X. The Secretariat will forward these reports to the SAE Subcommittee.

a. Composition of the SAE Subcommittee
    i. The SAE Subcommittee will be appointed by the Chairperson of BIEC
    ii. The composition shall be as follows:
        1. Chairperson of the SAE Subcommittee
        2. One Member Secretary
        3. At least one member with Post-Graduate qualification as Clinician /Clinical Pharmacology/any other relevant clinical specialties in the institution.
        4. One or two members of BIEC including non-scientist of BIEC preferably legal person.
        5. BIEC Member Secretary will be Ex-Officio member of the SAE Subcommittee
        6. A quorum will consist of at least four (4) members as follows-
            a. one member (preferably pharmacologist),
            b. one member (preferably clinician),
            c. member secretary and

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER

SOP 22: Determination Of The Quantum Of Compensation In The Cases Of Clinical Trial Related Injury Or Death:

I. Formula in case of clinical trial related death:

Compensation = (B x F x R) / 99.37

Where,

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

F = Factor depending on the age of the trial subject as per annexure (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:

a. 0.5 terminally ill patient (expected survival not more than (NMT) 6 months)
b. Patient with high risk (expected survival between 6 to 24months)
c. Patient with moderate risk
d. Patient with mild risk
e. 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.

II. 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

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road, Selaiyur, Chennai 600073

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.

c. Chronic life-threatening disease; and
d. 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

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

- site staff,
- Sponsor or designates,
- Central laboratory etc.

VIII. Introduction:

- Product development rationale

IX. Study Objective:

- Purpose of the study and the primary and secondary objectives to be achieved should be mentioned here.

X. Investigational Plan:

- Overall trial design:
- Selection criteria of the Subject
- The treatment / intervention procedures
  - Blinding or randomisation techniques
  - (allowed or disallowed)
  - Concomitant treatment, the efficacy and safety criteria assessed
  - Quality assurance procedures
  - Statistical methods planned for the analysis

XI. Trial Subjects:

- Total no of trial Subjects
- Dropouts
- Proposal deviations.
- Patients screened, randomised, and prematurely discontinued.
- Reasons for premature discontinuation of therapy

XII. Efficacy evaluation:

- Results of evaluation of all the efficacy variables
- demographic characteristics of the trial patients (Tables and graphical representation)

XIII. Safety Evaluation:

- List of all serious adverse events
  - Expected
  - Unexpected

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road, Selaiyur, Chennai-600073

SOP 24: Contents Of The Proposed Proposal To Conduct Clinical Trials:

CONTENTS OF THE PROPOSED PROPOSAL FOR CONDUCTING CLINICAL TRIALS

I. Title Page

II. Full title of the clinical study,

III. Proposal, Study number, and Proposal version number with date.

IV. The Investigational New Drug (IND) name/number of the investigational drug.

V. Complete name and address of the Sponsor and contract research organization if any. (e) List of the investigators who are conducting the study, their respective institutional affiliations and site locations

VI. Name of clinical laboratories and other departments and/or facilities participating in the study.

VII. Table of Contents

   a. Background and introduction
   b. Preclinical experience
   c. Clinical experience

VIII. Previous clinical work with the new drug should be reviewed here and a description of how the current Proposal extends existing data should be provided. If this is an entirely new indication, how this drug was considered for this should be discussed. Relevant information regarding pharmacological, toxicological and other biological properties of the drug/biologic/medical device, and previous efficacy and safety experience should be described.

IX. Study rationale:

X. This section should describe a brief summary of the background information relevant to the study design and Proposal methodology. The reasons for performing this study in the particular population included by the Proposal should be provided.

XI. Study objective (primary as well as secondary) and their logical relation to the study design.

   a. Study design:

      i. Overview of the study design: Including a description of

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road, Selaiyur, Chennai-600073

including conditions where the study will be terminated for noncompliance with the Proposal.

XVII. Study treatment:

a. Dosing schedule (dose, frequency, and duration of the experimental treatment) Describe the administration of placebos and/or dummy medications if they are part of the treatment plan. If applicable, concomitant drug(s), their doses, frequency, and duration of concomitant treatment should be stated.

b. Study drug supplies and administration: A statement about who is going to provide the study medication and that the investigational drug formulation has been manufactured following all regulations Details of the product stability, storage requirements and dispensing requirements should be provided.

c. Dose modification for study drug toxicity: Rules for changing the dose or stopping the study drug should be provided.

d. Possible drug interactions

e. Concomitant therapy: The drugs that are permitted during the study and the conditions under which they may be used are detailed here. Describe the drugs that a Subject is not allowed to use during parts of or the entire study. If any washout periods for prohibited medications are needed prior to enrolment, these should be described here.

f. Blinding procedures: A detailed description of the blinding procedure if the study employs a blind on the Investigator and/or the Subject

g. Un-blinding procedures: If the study is blinded, the circumstances in which un-blinding may be done and the mechanism to be used for un-blinding should be given

XVIII. Adverse Events:

Description of expected adverse events should be given. Procedures used to evaluate an adverse event should be described.

XIX. Ethical considerations: Give the summary of:

a. Risk/benefit assessment:

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road Selaiyur, Chennai 600073

sample size, how the sample size was determined, including assumptions made in making this determination, efficacy endpoints (primary as well as secondary) and safety endpoints.

XXII. Statistical analysis:

Give complete details of how the results will be analysed and reported along with the description of statistical tests to be used to analyse the primary and secondary endpoints defined above. Describe the level of significance, statistical tests to be used, and the methods used for missing data; method of evaluation of the data fortreatment failures, non-compliance, and Subject withdrawals; rationale and conditions for any interim analysis if planned. Describe statistical considerations for Pharmacokinetic (PK) analysis, if applicable.

XXIII. Undertaking by the Principal Investigator (*vide infra* - APPENDIX – II, UNDERTAKING FROM PRINCIPAL INVESTIGATOR)

XXIV. Annexures:

a. Provide a study synopsis
b. Copies of the informed consent documents (patient information sheet, informed consent form etc.);
c. Case Record Form (CRF) and other data collection forms;
d. A summary of relevant preclinical safety information and any other documents referenced in the clinical Proposal.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

SOP 26: Elements Of Review:

Following are the elements to be reviewed by the BIEC member taking in account the scientific design and conduct of the study:

I. The appropriateness of the study design in relation to the objectives of the study, the statistical methodology and the potential for reaching sound conclusions with the smallest number of research participants.

II. The appropriateness of clinical trial site in terms of facilities to conduct the intended research and taking clinical care of the patients as per their requirements.

III. This shall include investigations, treatment facilities, supportive staff follow-up facilities etc.

IV. The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.

V. The justification for the use of control arms.

VI. Criteria for prematurely withdrawing the research participants

VII. Criteria for suspending or terminating the research as a whole

VIII. The adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a Data and Safety Monitoring Committee (DSMC).

IX. The manner in which the results of the research will be reported and published.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

SOP 28: Format For According Approval To Clinical Trial Proposal By The Ethics Committee:

To

Dr.

Dear Dr.....

The Institutional ethics committee reviewed and discussed your application to conduct the clinical trial entitled "....." on.....(date).

The following documents were reviewed:

I. Trial Proposal (including Proposal amendments), dated.....version No.(s) .....

II. Patient information sheet and informed consent form (including updates, if any) in English or vernacular language.

III. Investigator's brochure dated ....., Version no..... Proposed methods for patient accrual including advertisements etc. Proposed to be used for the purpose.

IV. Principal investigator's current Curriculum Vitae.

V. Insurance policy or compensation for participation and for serious adverse events occurring during the study participation.

VI. Investigator's agreement with the sponsor. (vide infra - APPENDIX- V, INVESTIGATOR'S AGREEMENT WITH THE SPONSOR)

VII. Investigator's undertaking (vide infra - APPENDIX- II, UNDERTAKING FROM PRINCIPAL INVESTIGATOR).

The following members of the ethics committee were present at the meeting (Table 2) held on

Date: Time: Place:

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

All the issues presented in the study proposal were thoroughly discussed and reviewed.

Members present & voted for approval.....

Members present & voted against approval.....and

Members were absent.....

After all considerations, the committee has decided to approve / not to approve / suggested resubmission after required modification / subject to. Please provide the following clarifications / documents for re-review.

1.

2.

3.

The present approval is valid only for one year; investigator must take the re-approval after one year.

The investigator is requested to submit the progress report after 6 months to BIEC for review. Any change, modification or deviation in the Proposal, or any adverse event must be informed to ethics committee. Any Proposal modification or amendment must be approved by BIEC. Investigator should conduct the study as per the recommended GCP guidelines.

We approve the trial to be conducted in its presented form.

The ethics committee to be informed about the progress of the study, any Serious Adverse Events (SAE) occurring in the course of the study, any changes in the Proposal and patient information or informed consent and to be provided with a copy of the final report.

Yours sincerely

Member Secretary

Chairperson

NOTE: A Certificate of Approval is issued in the format as in Appendix VII

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,

VI. A decision of a follow-up review will be issued and communicated to applicant indicating modification / suspension / termination / continuation of the project.

VII. BIEC will also require the investigators to inform the committee about any SAE and payment of any compensation for the same. It shall also review the adequacy of treatment given to participants following an SAE.

VIII. In case of premature suspension/termination, the applicant must notify the BIEC of the reasons for suspension/termination with a summary of results.

IX. Applicant must inform at the time of completion of study and must send the result summary to BIEC.

X. BIEC must receive a copy of final summary of study completed from the applicant.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

SOP 31: Review Of Performance Of Ethics Committee:

The Dean, BMCH who is the constituting authority of the BIEC shall periodically assess the performance of BIEC members in consultation with the Chairperson and Member secretary of the BIEC, in terms of attendance, punctuality, participation in discussion and willingness to learn. The member secretary shall evaluate performance of the BIEC itself in terms of time interval between submission of proposal and approval / rejection, maintenance of records, arrangements for meetings etc and shall carry out corrective action. Records shall be maintained of the review and any corrective and preventive action.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

the study.

VI. No documents (except agenda) will be retained by any BIEC member.

VII. At the end of each meeting every member will return all the research proposal documents to BIEC office staff.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

APPENDIX- I

BIEC MEMBERSHIP ACCEPTANCE

To

The Dean

Bhaarath Medical College and Hospital,

173. Agaram main Road

Chennai 600073

Respected Sir,

Sub: Consent to be a member of Bhaarath Institutional Ethics Committee

- I accept the invitation to become a member of BIEC of BMCH, Chennai 600073
- I shall regularly participate in the BIEC meeting to review and give my unbiased opinion regarding the ethical issues.
- I shall be willing to publicize my full name, profession and affiliation
- I shall not keep any literature or study related document with me after the discussion and final review.
- I shall maintain the confidentiality regarding BIEC activities.
- I herewith enclose my CV.

Thanking you,

Yours sincerely,

Signature

Name of member

Date

Address

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

.....

.....

VIII. Commitments:

a. I have reviewed the clinical Proposal and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.

b. I agree to conduct the study in accordance with the current Proposal. I will not implement any deviation from or changes of the Proposal without agreement by the Sponsor and prior review and documented approval or favourable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

c. I agree to personally conduct or supervise the clinical trial at my site.

d. I agree to inform all trial subject, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.

e. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.

f. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

g. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

APPENDIX- III

SUBMISSION OF STUDY PROPOSALS

Date:

To

The Chairperson

Bhaarath Institutional Ethics Committee

Bhaarath Medical College Hospital

Chennai – 600 073

- Full Name of Applicant :
- Designation :
- Complete Address :
- Telephone No :
- Fax No :
- E mail :
- Site of Study :
- Proposal No :
- Date :
- Amendment No :
- Date :
- Title of Project :
- Type of Study :
- Local / National /
- International :
- Type of trial :
- Single center / multi center :
- Sponsor Name :
- Address :
- Name Signature :
- Principal Investigator :
- Co – Investigator :

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road Selaiyur, Chennai-600073

12. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants.
13. A description of the arrangements for indemnity, if applicable.
14. A description of the arrangements for insurance coverage for research participants, if applicable.
15. A statement of agreement to comply with ethical principles set out in relevant guidelines.
16. All previous BIEC's decisions (e.g., those leading to a negative decision or modified Proposal) and by other regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the Proposal made on that account. The reasons for previous negative decisions must be provided.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road, Selaiyur, Chennai-600073

APPENDIX- V

INVESTIGATOR'S AGREEMENT WITH THE SPONSOR

This indemnity agreement is between Bhaarath Medical College Hospital, Chennai 600073, India (herein after BMCH) and .....

..(Name of the second party / sponsor) (herein after SPONSOR)

Whereas BMCH engages in medical research that involves experimental and investigational products, drugs, devices or therapy and

Whereas SPONSOR owns or has right to such experimental or investigational products, drugs, devices specifically as it relates to this agreement, products, devices, drugs shall mean the following.

1.

2.

3.

Whereas,

BMCH and SPONSOR have agreed that BMCH will use SPONSOR'S experimental and investigational products, drugs, devices for research purpose.

Now therefore, the parties agree as follows:

I. UNDESIRABLE SIDE EFFECTS, INJURIES, ILLNESS OR REACTIONS.

The SPONSOR agrees to indemnify, protect, defend and hold harmless BMCH, its officers, employees against cost or expenses associated with the diagnosis and treatment of undesirable side effects, injuries, illness or reactions that arise specifically from SPONSOR's products, devices and drugs.

II. LOSS, DAMAGE OR LIABILITY

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

party will compromise or settle any claim or action without prior written consent of the other part y.

VII. OTHERS

This indemnity agreement does not displace, supersede or in any way limit any other agreements between the parties.

PARTIES:

Signed and delivered on behalf of BMCH .....

.....(First Party)

Signed and delivered for ..... (Second Party)

Signature	Signature
Name	Name
Designation	Designation
Seal	Seal

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

Appendix- VII: Certificate of Approval

BHAARATH MEDICAL COLLEGE AND HOSPITAL

173. Agaram, Main Road, Chennai – 600073

Bhaarath Institutional Ethics Committee

Certificate of Approval to Clinical Trial Proposal

Proposal No	**BIEC-.....-23**
Title of the Proposal	
Principal Investigator	
Submitted on	
Presented before BIEC on	
Resubmitted / Represented on	
Date of Approval	

Dear Dr. .....

The Institutional ethics committee examined your Proposal and considered your application to conduct the clinical trial entitled as above on .....between 10.00 and 1.00 PM at BMCH.

After all the considerations after submission / presentation / resubmission / representation of the Proposal and the related documents, the committee has decided to approve your Proposal subjected to the following conditions.

1. Investigator should conduct the study as per the recommended GCP guidelines.
2. The investigator is requested to inform The Ethics Committee about the progress of the study and submit the report in every 6 months
3. Any change, modification or deviation, or amendment in the Proposal must be informed to BIEC and the same must be approved by BIEC
4. Any Serious Adverse Events (SAE) occurring in the course of the study should be informed to BIEC immediately.
5. Any changes in the Proposal and patient information or informed consent are to be provided with the final report.
6. The investigator is informed to register in **Clinical Trials Registry- India** ***(CTRI)*** *before starting your project*
7. The investigator is requested to submit a final report after completion of the study to BIEC
8. The Proposal is approved on .....and the present approval is valid only for one year; The investigator must take the re- approval after one year.

BIEC - Member secretary BIEC – Chairperson

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

Tips to prepare proposals

SOP		Prospective clinical studies from human subjects or human samples or Epidemiological studies, or AYUSH proposals	Retrospective studies or retrospective data collection from computer or data collection without human samples
SOP 08	Type Of Clinical Research Reviewed By The Committee (E.G. Pharmaceuticals, Devices, Epidemiological, Retrospective, Herbals, Etc.,)	IEC approval required	
SOP 09	Appropriateness Of Investigator	Applicable	Applicable
SOP 10	Review Of Subject Recruitment Procedures	Applicable	Not Applicable
SOP 11	Selection Of Special Groups As Research Subjects	Applicable	Not Applicable
SOP 12	Format Of Informed Consent Form For Subjects Participating In A Clinical Trial	Applicable	Not Applicable
SOP 13	Checklist Of Informed Consent Documents For Clinical Trial Subject	Applicable	Not Applicable
SOP 14	Review Of Informed Consent Documents	Applicable	Not Applicable
SOP 15	Care And Protection Of Research Participants	Applicable	Not Applicable
SOP 16	Policy On Protection Of Vulnerable Population	Applicable	Not Applicable
SOP 17	Protection Of Research Participant Confidentiality	Applicable	Applicable
SOP 18	Community Considerations	Applicable	Applicable

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road, Selaiyur, Chennai-600073

	Going Clinical Trials		
	APPENDIX – II	Applicable	Applicable
	APPENDIX – III	Applicable	Applicable
	APPENDIX - IV	Applicable	Applicable
	APPENDIX - V	Applicable	Applicable
	APPENDIX- VI	Applicable	Not Applicable

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road, Selaiyur, Chennai-600073

Bhaarath Medical College & Hospital
Bhaarath Institutional Ethics Committee
173, Agaram Main Rd, Selaiyur, Chennai, Tamil Nadu 600073

Date: 2-8-2021

1st Bhaarath Institutional Ethics Committee Meeting

1st Bhaarath Institutional Ethics Committee Meeting was conducted on 30th June, 2021 for all research scholars from 10 am at BMCH College Lecture Hall 1. Inauguration program of BIEC started with prayer.

The welcome address was given by Dr. Vidya DC, Associate Professor, Department of Community Medicine and a member of BIEC. Dr P Elango, Member Secretary of BIEC & Professor of Pharmacology introduced Dr.Sundarajan, Pro Vice Chancellor (Academic) and Dr.Suresh Kumar, Pro Vice Chancellor (Grants and Publication), all the members of BIEC, and other dignitaries. Inaugural address was given by both Pro Vice Chancellors and this event was felicitated by Dr Muthiah NS, Chairperson of BIEC and Dr. J. Mohana Sundaram, Vice Principal, BMCH and Medical Scientist, BIEC. Inauguration program was concluded with vote of thanks by Dr P Elango followed by national anthem.

It was followed by scientific session with power point presentation by research scholars. Thirteen research proposals (enclosed) were considered and recommended for approval. Two special homeopathic experts Dr. P.V. Venkatraman and Dr.Sandhya Kalidas also attended this program. All the members of IEC including the chairperson gave their remarks and asked the presenters to update and include the corrections in their research proposals. After correcting and updating the research proposals, all the members of BIEC including the chairperson finally approved their proposal and gave approval form dated and signed by all the members and granted permission to start their research work.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

Dr P Elango
Member Secretary
BIEC

Dr J Mohanasundaram
Medical Scientist
BIEC

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

Bhaarath Medical College & Hospital
Bhaarath Institutional Ethics Committee
173, Agaram Main Rd, Selaiyur, Chennai, Tamil Nadu 600073

Date: 8-9-2021

2nd Bhaarath Institutional Ethics Committee Meeting

2nd Bhaarath Institutional Ethics Committee Meeting was conducted on 8th September, 2021 from 10 am at BMCH College Lecture Hall 1. The meeting started with welcome address by Dr. P. Elango, Member Secretary, BIEC. Dr Muthiah NS, Chairperson, BIEC, delivered the keynote address and this event was felicitated by Dr. J. Mohana Sundaram, Vice Principal, BMCH and Medical Scientist,BIEC. Then the scientific session started with powerpoint presentation of 7 research proposals of research scholars which also included 2 PhD proposals for getting IEC approval. One Unani medicine expert Dr.N.Zaheer Ahmed, Deputy Director, Regional Research Institute of Unani Medicine came as an expert reviewer for one PhD project involving Unani drug formulation. All the members of IEC including the chairperson gave their remarks and asked the presenters to update and include the corrections in their research proposals for getting final approval. After the Scientific session, Dr P Elango, has proposed two important agendas to the committee as follows

Agenda 1: To reconstitute Bhaarath Institutional Ethics Committee by including the following members:

1.Dr. Ashvind, Associate Professor of Pediatitics as a Member -Clinical (affiliated) instead of Dr.Arulparithi C.S who left the institute.

It is resolved as above and accepted

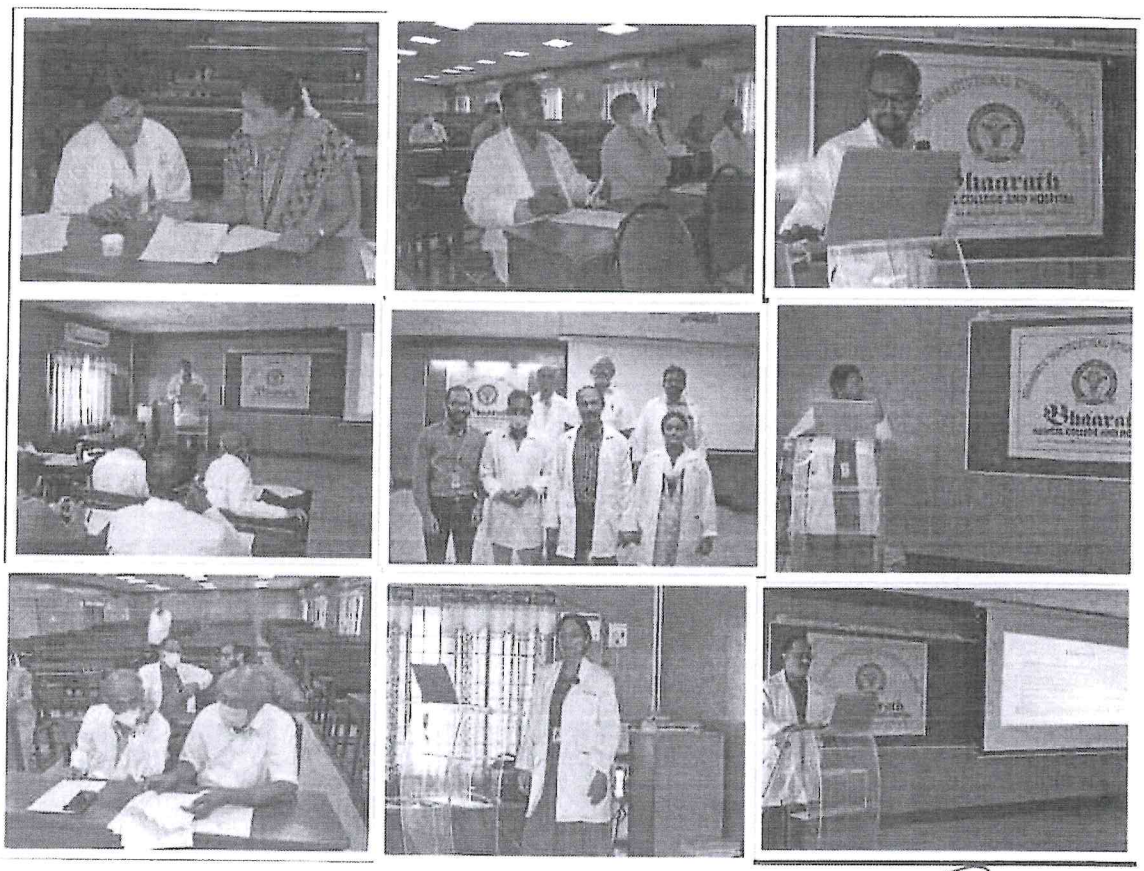
2. Mr. P. Kalyanasundaram as a Member – Lay person (non-affiliated) instead of Mr. R. Vasu who passed away recently

Agenda 2: To consider to collect the processing fee from the research scholars to meet out the expenses in conducting the IEC meeting.

It is resolved to collect the processing fee from such projects having commercial background and for the proposals from other institutions.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

Finally, this meeting was concluded with vote of thanks by Dr P Elango.



Dr P Elango
Member Secretary
BIEC

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road, Selaiyur, Chennai-600073

Bhaarath Medical College & Hospital

173. Agaram Main Road, Selaiyur, Chennai 600073

Bhaarath Institutional Ethics Committee

INVITATION

3rd IEC Meeting

Dear IEC Members,

We cordially invite you for the 3rd Institutional Ethics Committee Meeting scheduled on 29th September, 2021, Wednesday from 10.00 AM onwards on virtual link.

As it is mandatory, All the members are requested to attend without fail.

Agenda

1. To consider the research proposals for approval
   Submitted in proposals – consolidated by email
2. Any other agenda with the permission of Chairperson.

The link for the meeting

Bhaarath Institutional Ethics Committee - 3rd IEC Meeting

Wednesday, September 29 · 10:15am – 12:15pm

Google Meet joining info

Video call link: https://meet.google.com/kpp-nwdw-gsd

Or dial: (US) +1 347-201-0060 PIN: 815 844 038#

Dr P Elango
BIEC - Member secretary

Dr. Muthiah N
BIEC - Chairperson

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

Bhaarath Medical College & Hospital

173. Agaram Main Road, Selaiyur, Chennai - 600073

Bhaarath Institutional Ethics Committee

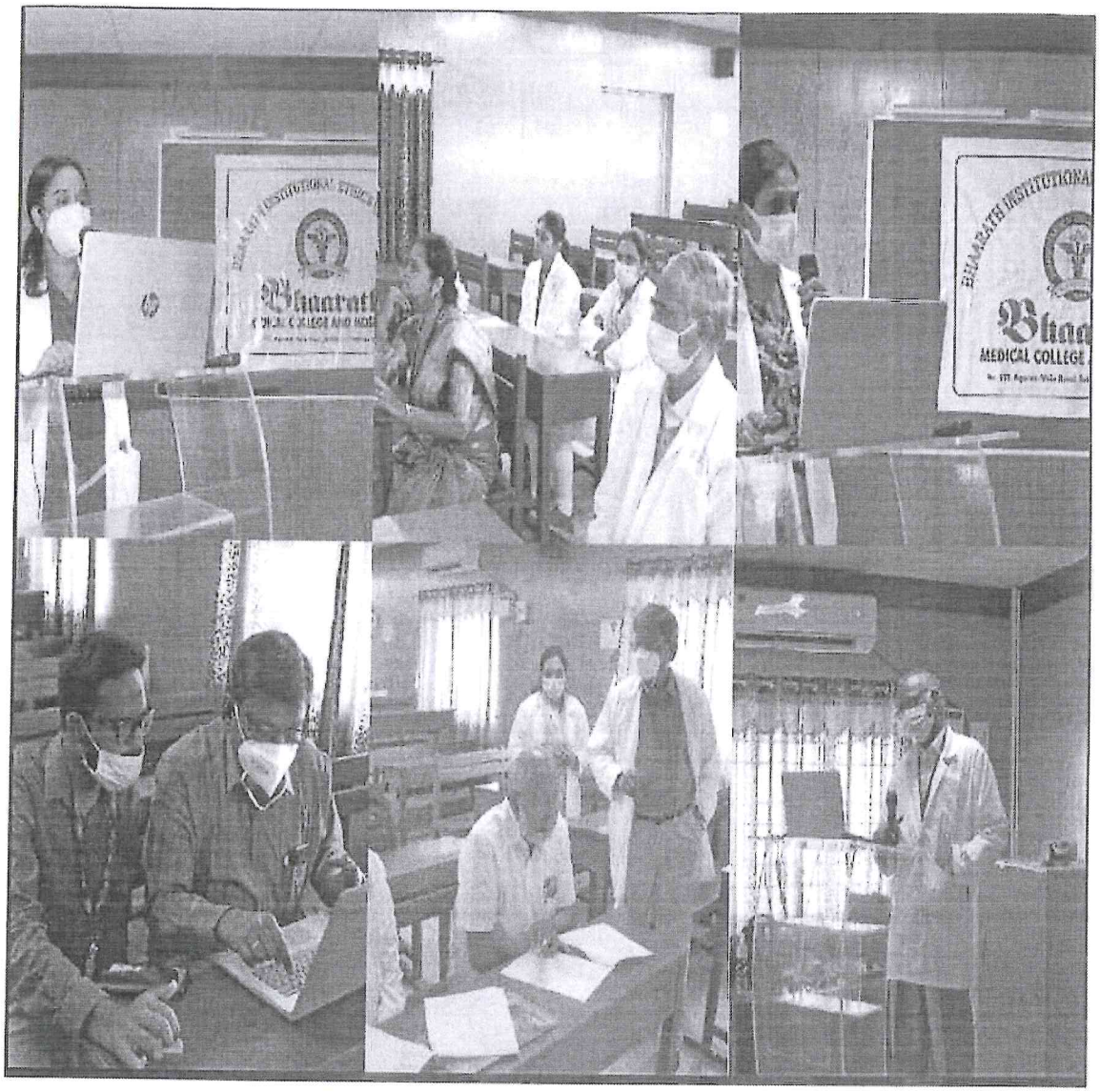
Date: 31-12-2021

4th Bhaarath Institutional Ethics Committee Meeting

4th Bhaarath Institutional Ethics Committee Meeting was conducted on 15th December, 2021 from 9.30am at Lecture Hall 1, BMCH College complex1. The meeting started with welcome address by Dr. P. Elango, Member Secretary, BIEC. Dr Muthiah NS, Chairperson, BIEC, delivered the keynote address and this event was felicitated by Dr. J. Mohana Sundaram, Vice Principal, BMCH and Medical Scientist, BIEC. Then the scientific session started with powerpoint presentation of 14 research proposals including 2 PhD proposals, which are going to be submitted for the call for research proposals of AD-HOC Project under extramural research program of Indian Council of Medical Research (ICMR) for the year 2021. It was presented by 10 research scholars for getting IEC approval. After the Scientific session, this meeting was concluded with vote of thanks by Dr P Elango.

All the members of IEC including the chairperson approved their proposals after updating the corrections/remarks in their research protocol.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073



Dr P Elango
Member Secretary
BIEC

Dr Muthiah N S
Chairperson
BIEC

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

Bhaarath
Medical College & Hospital
173, Agaram Main Road, Selaiyur, Chennai 600073

Bhaarath Institutional Ethics Committee

5th BIEC meeting – Proposals Approved

Dated 16th June 2022

S.No	Proposals	
1	Research Proposal No	BIEC-036-22
	Title	Effect of blood glucose on auditory functions in normal, pre-diabetic, and diabetic individuals – A comparative study
	Principal Investigator	Dr Priyadarsini D, Assistant Professor of Physiology, Bhaarath Medical College and Hospital, Selaiyur, Chennai - 600073
2	Research Proposal No	BIEC-037-22
	Title	Randomized control trial of ventilator associated pneumonia among mechanically ventilated patients by feasible circuit changing technique.
	Principal Investigator	Dr Shameemunisha, Senior Resident of Pharmacology, Bhaarath Medical College and Hospital, Selaiyur, Chennai - 600073
3	Research Proposal No	BIEC-038-22
	Title	Maternal colonization of Group B streptococci and its clinical outcome
	Principal Investigator	Dr P Sneka, Associate Professor of Microbiology, Bhaarath Medical College and Hospital, Selaiyur, Chennai – 600073
4	Research Proposal No	BIEC-039-22
	Title	Vaginal dysbiosis in Pregnant women with gestational diabetes and its adverse perinatal outcome
	Principal Investigator	Dr P Sneka, Associate Professor of Microbiology,

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road, Selaiyur, Chennai-600073

		Bhaarath Medical College and Hospital, Selaiyur, Chennai – 600073
5	Research Proposal No	BIEC-040-22
	Title	Prevalence of association of HBV and HCV infections among haemodialysis patients in a tertiary care hospital
	Principal Investigator	Dr KP Hamsadwani, Assistant Professor of Microbiology, Bhaarath Medical College and Hospital, Selaiyur, Chennai - 600073
6	Research Proposal No	BIEC-041-22
	Title	Seroprevalence of Rubella antibodies among women of reproductive age group attending a tertiary care hospital
	Principal Investigator	Dr Sangamithra V, Professor & Head of Microbiology, Bhaarath Medical College and Hospital, Selaiyur, Chennai - 600073
7	Research Proposal No	BIEC-042-22
	Title	Faecal calprotectin as a diagnostic marker of inflammatory bowel disease
	Principal Investigator	Dr S Kandasamy, Associate Professor of Microbiology, Bhaarath Medical College and Hospital, Selaiyur, Chennai - 600073
8	Research Proposal No	BIEC-043-22
	Title	Correlation between the cardiovascular autonomic reflex tests and short-term heart rate variability indices in healthy adults
	Principal Investigator	Dr N Swarnalatha, Professor of Physiology, Bhaarath Medical College and Hospital, Selaiyur, Chennai - 600073
9	Research Proposal No	BIEC-044-22
	Title	A study on the effect of sensitization programme to doctors on prescription errors in a multispeciality hospital
	Principal Investigator	Dr Rohita R, Quality officer, Department of Quality,

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road, Selaiyur, Chennai-600073

		Bhaarath Medical College and Hospital, Selaiyur, Chennai - 600073
10	Research Proposal No	BIEC-045-22
	Title	Prevalence of asymptomatic bacteriuria among pregnant women attending tertiary care hospital in Chengalpattu district
	Principal Investigator	Mr K Raja, Tutor, Department of Microbiology, Bhaarath Medical College and Hospital, Selaiyur, Chennai - 600073
11	Research Proposal No	BIEC-046-22
	Title	Blood culture contaminants and their clinical implications. A prospective observational study
	Principal Investigator	Dr Swathi K, Assistant Professor of Microbiology, Bhaarath Medical College and Hospital, Selaiyur, Chennai – 600073
12	Research Proposal No	BIEC-047-22
	Title	A study on histopathological spectrum of ovarian lesions in women reporting at tertiary care unit (BMCH)
	Principal Investigator	Dr MNK Dhanalakshmi, Associate Professor of Pathology, Bhaarath Medical College and Hospital, Selaiyur, Chennai – 600073
13	Research Proposal No	BIEC-048-22
	Title	Cytomorphological variations in Pap smears in postmenopausal age groups women reporting at tertiary care unit (BMCH)
	Principal Investigator	Dr MNK Dhanalakshmi, Associate Professor of Pathology, Bhaarath Medical College and Hospital, Selaiyur, Chennai – 600073
14	Research Proposal No	BIEC-049-22
	Title	Utilization and expenditure pattern of monetary benefits provided through direct benefit transfer scheme under NTEP among TB patients in Chengalpattu district. A sequential explanatory mixed-method study.

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital

	Principal Investigator	Dr Anugraha J, Senior Resident of Community Medicine, Bhaarath Medical College and Hospital, Selaiyur, Chennai – 600073
15	Research Proposal No	BIEC-050-22
	Title	Effect of obesity on pregnancy and delivery and its impact on fetus.
	Principal Investigator	Dr. Asha E, Assistant professor of Obstetrics and Gynecology, Bhaarath Medical College and Hospital, Selaiyur, Chennai – 600073
16	Research Proposal No	BIEC-051-22
	Title	"Evaluation of Antihypertensive Effect of SGLT-2 Inhibitors in Essential Hypertension as Monotherapy"
	Principal Investigator	Dr MM Sulthan Al Rashid, Assistant Professor of Pharmacology, Bhaarath Medical College and Hospital, Selaiyur, Chennai – 600073

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road, Selaiyur, Chennai-600073

Dr P Elango
Member Secretary
BIEC

Bhaarath

Medical College & Hospital

173, Agaram Main Road, Selaiyur, Chennai 600073

Bhaarath Institutional Ethics Committee

1st IEC Meeting – Proposals Approved

Dated: 30th June, 2021

S. No	Proposals	
1	Research Proposal No	BIEC – 001 - 21
	Title	"A triple blinded randomized controlled trial on neuro cognitive & psychomotor effects of melatonin versus midazolam, when administered as Preanaesthetic medication before surgery."
	Principal Investigator	Dr.S.SreeRanjini PROFESSOR & HEAD, Dept. of Anesthesiology, Pain & Critical Care, Bhaarath Medical College Hospital, Selaiyur, Chennai-600073
2	Research Proposal No	BIEC – 002 - 21
	Title	Immunological response to Covid -19 vaccines among health care workers in a tertiary care hospital
	Principal Investigator	Dr.P.Sneka MD Associate professor Bhaarath Medical college and Hospital, No 173 ,Agaram road, Selaiyur, Chennai-600 073 Mail Id : drsneka87@gmail.com Mobile No : 9047644998
3	Research Proposal No	BIEC – 003 - 21
	Title	To evaluate the role of Biomarkers in COVID 19 for the early diagnosis of Severe COVID disease
	Principal Investigator	Dr. V. Sangamithra MD Professor & Head Department of Microbiology

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER

		Bhaarath Medical College and Hospital, Chennai sangamithrav1978@gmail.com 9790976343
4	Research Proposal No	BIEC – 004 - 21
	Title	Study of early onset of Coronary Artery Disease with glucose intolerance and hyperinsulinemia
	Principal Investigator	Dr. K. Piruthivirajan, MD Assistant Professor Department of Biochemistry Bhaarath Medical College and Hospital, Chennai sangamithrav1978@gmail.com 9790976343
5	Research Proposal No	BIEC – 005 - 21
	Title	Prevalence of Metabolic Syndrome among reproductive aged women with Polycystic Ovarian Syndrome
	Principal Investigator	Dr. K. Piruthivirajan, MD Assistant Professor Department of Biochemistry Bhaarath Medical College and Hospital, Chennai sangamithrav1978@gmail.com 9790976343
6	Research Proposal No	BIEC – 006 - 21
	Title	Platelet count, d- dimer and NLR ratio as biomarkers predicting the disease severity in COVID 19 patinets
	Principal Investigator	Dr. Preethi. S, MD Assistant Professor Department of Pathology Bhaarath Medical College and Hospital, Chennai sangamithrav1978@gmail.com 9790976343
7	Research Proposal No	BIEC – 007 - 21
	Title	Incidence and Prevalence of Influenza virus and Sars Cov2 coinfection in a tertiary care hospital

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

Bhaarath
Medical College & Hospital
172, Agaram Main Road, Selaiyur, Chennai-600073

Bhaarath Institutional Ethics Committee

6th BIEC meeting – Proposals

S.No	Proposals	
1	Research Proposal No	BIEC-052 - 23
	Title	Assessment of medication regimen complexity, medication related burden and adherence among type 2 Diabetes Mellitus patients: An evaluation of factors associated from the patient perspective.
	Principal Investigator	Dr. W. Helen Research Scholar Department of pharmacy practice Faculty of Pharmacy Bharath Institute of Higher Education and Research
2	Research Proposal No	BIEC-053 - 23
	Title	Comparison between tapentadol nasal spray and buprenorphine transdermal patch in post-operative pain management for abdominal surgeries – randomised controlled trial.
	Principal Investigator	DR. S. GIRIDHARAN M.S., DNB ASSISTANT PROFESSOR DEPT. OF GENERAL SURGERY Bhaarath Medical College Hospital Chennai 600073
3	Research Proposal No	BIEC-054 - 23
	Title	"Awareness About Labour Analgesia Amongst Patients Visiting A Tertiary Care Hospital In Chennai, India.
	Principal Investigator	Ms. Esha Yenugonda Medical student, 3rd year MBBS, Bhaarath Medical College Hospital Chennai 600073
4	Research Proposal No	BIEC-055 - 23
	Title	Effects of epigallocatechin-3-gallate (EGCG) on cluster of differentiation 151 (cd151) andLaminin-332 associated extra cellular matrix remodeling in triple negative breast cancer.
	Principal Investigator	Dr Jamuna Rani S Professor and HOD Department of Pathology Bhaarath Medical College and Hospital Chennai

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
172, Agaram Main Road Selaiyur, Chennai-600073

5	Research Proposal No	BIEC-056 - 23
	Title	A Cross-Sectional Study among Doctors & Medical Students from South India
	Principal Investigator	Dr Jamuna Rani S Professor and HOD Department of Pathology Bhaarath Medical College and Hospital Chennai
6	Research Proposal No	BIEC-057 - 23
	Title	Evaluation of the foundation course conducted for the first year Medical undergraduate students
	Principal Investigator	DR.MARIO LEESHA FERNANDO Associate Professor Department of Biochemistry Bhaarath Medical College and Hospital Chennai
7	Research Proposal No	BIEC-058 - 23
	Title	To evaluate the incidence of meconium-stained amniotic fluid and meconium aspiration syndrome in relation with gestational age, mode of delivery and birth weight of new-borns and their immediate postnatal outcome in tertiary care institute – A Retrospective study.
	Principal Investigator	Dr. Apeksha Anand Assistant Professor Department of Paediatrics Bhaarath Medical College and Hospital Chennai
8	Research Proposal No	BIEC-059 - 23
	Title	Analyse breath carbon monoxide level among automobile drivers in south Indian population and to compare the difference in breath carbon monoxide level between urban and rural population.
	Principal Investigator	Mr. Jai guru Prasad V. S II year MBBS student, Bhaarath Medical College and Hospital, Selaiyur, Chennai.
9	Research Proposal No	BIEC-060 - 23
	Title	Assessing the perception of undergraduate medical students towards artificial intelligence in medical education – A cross-sectional study.
	Principal Investigator	Dr.K.Vanathy, Senior Resident, Department of Physiology, Bhaarath medical college & Hospital, Chennai – 600 073

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173 Agaram Main Road,Selaiyur, Chennai-600073

10	Research Proposal No	BIEC-061 - 23
	Title	Correlation Of Anthropometric Indices With Rate Pressure Product And Pulse Respiration Quotient In Normotensives, Pre Hypertensives And Hypertensives.
	Principal Investigator	Mr. Kavin Raaj, II year MBBS student, Bhaarath Medical College and Hospital, Selaiyur, Chennai.
11	Research Proposal No	BIEC-062 - 23
	Title	Association of red blood cell distribution width with glycaemic status in Type 2 diabetics: RDW as a prognostic marker
	Principal Investigator	Ms. G Lakshmi Priya III MBBS Bhaarath Medical College and Hospital Chennai – 600073
12	Research Proposal No	BIEC-063 - 23
	Title	Association between Heart rate variability and premature greying of hair - A cross sectional study
	Principal Investigator	Mr. Sumair.Khan.A, II MBBS Bhaarath Medical College and Hospital Chennai – 600073
13	Research Proposal No	BIEC – 064 - 23
	Title	Assessment And Correlation Of Altered Leucocyte Count In Diabetics And Prediabetics
	Principal Investigator	Ms. V. Rubica, Ii Year MBBS Student, Bhaarath Medical College and Hospital, Biher, Selaiyur, Chennai.

Dr P Elango
Member Secretary

Dr. Geetha. M,
Chairperson

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

Bhaarath
Medical College & Hospital
173 Agaram Main Road Selaiyur Chennai 600073

Bhaarath Institutional Ethics Committee

7th BIEC meeting – Proposals consolidated

31st August, 2023

S. No	Proposals		Remarks
1	Research Proposal No	BIEC-065 - 23	1. Duration: 2 months. 2. To add that the study will be done in tertiary care hospital (In the objective). 3. Approved.
	Title	Circulating Respiratory Syncytial Virus (RSV) Incidence and Molecular Identification in South India	
	Principal Investigator	MR. DEEPAN SURYA R S III YEAR, MBBS, BMCH	
	GUIDE	DR. HAMSADWANI K.P Assistant Professor Department of Microbiology BMCH DR. V. SANGAMITHRA Professor and Head Department of Microbiology BMCH DR.K. SWATHI Assistant Professor Department of Microbiology BMCH	
2	Research Proposal No	BIEC-066 - 23	1. Samples may be from hospitals directly. 2. To revise first objective (to make it relevant to quantitative component). 3. Can do an MOU with TB hospital Tambaram for a
	Title	A mixed method study on psychosocial barriers and challenges experienced by multi drug resistant tuberculosis (MDRTB) patients and their caregivers through the course of diagnosis and treatment in Chengalpattu district	
	Principal Investigator	MR. JERIN.S III YEAR, MBBS, BMCH	

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173 Agaram Main Road,Selaiyur, Chennai-600073

	GUIDE	DR. REKHA PALANI Senior Resident Department of Community Medicine, BMCH	consignment study sample. 4. Approved.
3	Research Proposal No	BIEC-067 - 23	1. Collect the data about the children from village health nurses. 2. To specify areas in study setting. 3. To remove 2nd inclusion and 2nd exclusion criteria. 4. To include children of orphan and with either one or both parents. 5. To include all areas of north Chennai. 6. Up to 14 years age, street children 7. Approved.
	Title	"A comparative study of exposure to air pollution and respiratory morbidity among street children and children residing in their houses in North Chennai"	
	Principal Investigator	MS. SIVANESH. K II YEAR, MBBS, BMCH	
	GUIDE	DR. ZUBAIDABEGUM A Senior Resident Department of Community Medicine, BMCH	
4	Research Proposal No	BIEC-069 - 23	1. Approved.
	Title	Effective Implementation of ABHA mobile application among patients with chronic diseases in selected Govt. Health centres of Chengalpattu District, Tamil Nadu: An operational Research.	
	Principal Investigator	MS NIRANJANA II YEAR, MBBS, BMCH	
	GUIDE	DR A. KALAIVANI Professor & Head, Department of Community Medicine, BMCH	
5	Research Proposal No	BIEC-071 - 23	1. Uncertainty may be defined cleanly. 2. Approved
	Title	"Managing uncertainty in Daily Practice among Family Physicians of South Chennai: A Mixed Method Study"	
	Principal	MS. ASIFA THANZILA.J	

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road, Selaiyur, Chennai-600073

	Investigator	III YEAR, MBBS, BMCH	
	GUIDE	DR SHARATH U Assistant Professor, Department of Community Medicine, BMCH	
6	Research Proposal No	BIEC-072 - 23	1. To carry out other in - vitro study using cell cultures and docking study 2. Approved.
	Title	Thymoquinone and derivatives as potential Phyto molecules in altering the tumor microenvironment in triple negative breast cancers – An in vitro analysis	
	Principal Investigator	MS. SAUNDARYA V.L III YEAR, MBBS, BMCH	
	GUIDE	DR JAMUNA RANI S Professor and HOD, Department of Pathology BMCH	
7	Research Proposal No	BIEC-073 - 23	1. To do flow cytometry analysis. 2. To revise study design (Cross-sectional). 3. Remove smear +ve in inclusion criteria. 4. Can get the sample from TB Hospital Tambaram after an MOU request. 5. Any pre-existing data or text book 6. Approved
	Title	Haematological parameters and cell population data – its clinical application value in tuberculosis	
	Principal Investigator	MR. M HARISH ADITYA III YEAR, MBBS, BMCH	
	GUIDE	DR. R. VEENA Associate Professor Department of Pathology BMCH	
8	Research Proposal No	BIEC-075 - 23	1. To revise study design (cross – sectional, comparative). 2. After 20 weeks of pregnancy. 3. Approved.
	Title	Platelet Indices As A Predictive Indicator Of Preeclampsia : A Cross Sectional Study In A Tertiary Care Center	
	Principal Investigator	MS. MALAVI B III YEAR, MBBS, BMCH	
	GUIDE	DR. KHOWSALYA SUBRAJAA K Assistant Professor Department of Pathology	

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road, Selaiyur, Chennai-600073

		BMCH	
9	Research Proposal No	BIEC-076 - 23	1. Approved.
	Title	To study the variations in haematological parameters amongst paediatric population presenting with acute febrile illness in tertiary care centre, Chennai , India	
	Principal Investigator	MR. NITISH KEVIN.F III YEAR, MBBS, BMCH	
	GUIDE	Dr M.N.K. DHANALAKSHMI Associate Professor Department of Pathology BMCH	
10	Research Proposal No	BIEC – 078 - 23	1. To select the papers in short term (One year) 2. To revise study 3. Omit the year of 2020 and 2021. 4. Newspapers from can be reviewed from 2022- 2023. 5. 2022 will be included. 6. Approved.
	Title	The quality of reporting of Public Health News: A Content Analysis of four major Newspapers of Tamil Nadu for 2020 to 2022.	
	Principal Investigator	MS. A. LEKHA PRIYA III YEAR, MBBS, BMCH	
	GUIDE	Dr. A. KALAIVANI Professor & Head, Department of Community Medicine, BMCH	
11	Research Proposal No	BIEC – 079 - 23	1. Title needs modification. 2. To mention RCT in title 3. To include only preterm babies. 4. Approved.
	Title	Effect Of Umbilical Cord Milking Versus Delayed Cord Clamping On The Haematological Parameters In Preterm And Term Infants At 72 Hours Of Life And Their Developmental Status At 6 Months Of Age	
	Principal Investigator	MS. A S SHIVAANI II YEAR, MBBS, BMCH	
	GUIDE	DR JAMUNA RANI S Professor and HOD Department of Pathology BMCH DR. APEKSHA Pediatrician	

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road,Selaiyur, Chennai-600073

		Department of Pediatrics, BMCH	
12	Research Proposal No	BIEC – 080 - 23	1. Check the Type of Tea leaves and the methodology of preparing tea. 2. Change of inclusion and Exclusion criteria 3. Calculate sample size 4. Inclusion criteria can be the subject without any medication to analyse for a better impact. 5. Quantitative of tea company 6. Type of tea exclusion criteria. 7. $2^0 \rightarrow 1^0$ Objectives. 8. Exercise without medication 9. Age group 18 -60 years 10. Before and after study 11. Approved.
	Title	Impact of consumption of green tea on a range of biochemical parameters	
	Principal Investigator	MS. MAHERA R II YEAR, MBBS, BMCH	
	GUIDE	DR.T. VIDHYALOGINI Associate Professor, Biochemistry, BMCH	
13	Research Proposal No	BIEC-068 - 23	1) Value may be less than 0.05 (statistically significant) 2) Phase 2 Approved. 3) Approved.
	Title	Effectiveness of Communication Skills Training for Informed Consent Among Phase 2 Medical Students Using Standardized Patients	
	Principal Investigator	DR. V. SANGAMITHRA Professor and Head Department of Microbiology Bhaarath Medical College and Hospital	
14	Research Proposal No	BIEC-074 - 23	1) To revise title (To consider alternate word for "impact".
	Title	Impact Of Changes In Volume ,	

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road, Selaiyur, Chennai-600073

		Conductivity, Scatter Parameters Of Neutrophils In Differentiating Causes Of Macrocytic Anaemia	2) Approved. 3) Change the title. 4) Approved. 5) Reframe title – materials and methods. Modify – in inclusion criteria.
	Principal Investigator	DR. KHOWSALYA SUBRAJAA K Assistant Professor Department of Pathology BMCH	
15	Research Proposal No	BIEC – 077 - 23	1) To revise study population 2) Approved.
	Title	"Reflective writing in log book: Assessment of workshop and performance review in executing sustained effective reflective writing skills among undergraduate medical students"	
	Principal Investigator	Dr. A. KALAIVANI Professor & Head, Department of Community Medicine, BMCH	
16	Research Proposal No	BIEC-070 - 23	1) Approved.
	Title	"Development, validation and implementation of Module for Clinical Photography in Electives of CBME curriculum through ADDIE Model."	
	Principal Investigator	DR ARUNACHALA D EDUKONDALU Professor, Department of Anesthesiology, BMCH	
17	Research Proposal No	BIEC-081 - 23	
	Title	Screening of phytochemical active molecules to inhibit efferocytosis and to suppress tumour immune evasion in leukaemia	1) Approved.
	Principal Investigator	Dr P Elango Professor & Head Department of Pharmacology BMCH	

Dr P Elango
Member Secretary

Dr. Geetha. M,
Chairperson

Member Secretary
Bhaarath Institutional Ethics Committee
Bhaarath Medical College and Hospital
BIHER
173, Agaram Main Road, Selaiyur, Chennai-600073

SREE BALAJI MEDICAL COLLEGE & HOSPITAL

A constituent college of

BHARATH INSTITUTE OF HIGHER EDUCATION AND RESEARCH

(Declared as Deemed to be University under section 3 of UGC Act, 1956)

(Vide Notification No.F.9-5/2000-U.3,Ministry of Humand Resource Development, Govt. of India, dated 4th July, 2002)

one: 044-42911000, Telefax:044-22415051
bsite: www.sbmch.ac.in

7, Works Road, Chromepet,
Chennai 600 044,Tamil Nadu

Ref.No.1096/SBMC&H/IAEC/2015 **Date: 17.08.2019**

The Director (AW), & Member Secretary (CPCSEA),
(Animal Welfare Division)
Ministry of Environment & Forest
Government of India (Animal Welfare Division),
5th Floor, Vayu` Wing,
Indira Paryavaran Bhawan
Jor Bagh Road,
New Delhi – 110 003
Telephone No. 011-24695356

Sir.

Sub: Sree Balaji Medical College & Hospital, Animal House Facility, Chennai – Renewal of CPCSEA Registration for a further period of five years from 2016 – 2021and submission of DD towards renewal fees – request - reg.

Ref: Our Registration No. 863/PO/Re/S/2004/CPCSEA.

--o0o--

I have to state that in Sree Balaji Medical College & Hospital, there is one small animal house facility which has been registered with CPCSEA for Education and Research dated: 13.12.2004. The Registration number was 893 / AC / 04 / CPCSEA. It was renewed for a period of three years from 2008 to 2010, dated: 29.05.2009. It was further renewed for Research for Education purpose on small animals from 2010 to 2013 dated: 04.04.2012 and then from 2013 to 2016. dated: 23.11.2005. The new registration No. is 863 / PO / Re / S / 2004 / CPCSEA.

As the registration of our institution at CPCSEA expired in December 2016, necessary proposals for the renewal of registration was sent to the CPCSEA, New Delhi vide this office letter No.1096/SBMC&H/IAEC/2015, dated: 14.12.2016. As it was ascertained that the renewal of registration is to be done only by 'online', necessary action was taken to download the application for renewal, to fill up the columns in the form and to submit the proposals. But, it was found very difficult to fill up certain columns and we could not complete the process. Hence, in this office letter No.1096/SBMC&H/IAEC/2015, dated: 07.03.2017, necessary proposals were submitted to the CPCSEA (**by hard copy**) for the renewal of registration along with the DD for Rs.2500/- being the renewal fee. Again necessary proposal for the renewal of registration was sent by **online** vide this office letter No.1096/SBMC&H/IAEC/2015, dated: 31.07.2017 and a sum of Rs.10,000/- was paid as renewal fee inadvertently, which is fixed for registration.

p.t.o.

Meanwhile, Dr. Geetha Ramesh, Professor & HOD of Anatomy, Madras Veterinary College, Chennai appointed by CPCSEA inspected our Animal House on 03.04.2018 and made certain suggestions to be carried out. The suggestions made by the inspector were carried out and necessary fresh proposals for the renewal of registration was sent on 05.06.2019, but so far no orders have been received from CPCSEA in this regard.

I therefore request you sir to kindly look in to the matter and pass necessary orders for the renewal of registration at an early date.

SREE BALAJI MEDICAL COLLEGE & HOSPITAL * Chromepet, Chennai-44

Yours faithfully,

Dean

Dr. P. SAIKUMAR. MD.,Ph.D.,
DEAN
Sree Balaji Medical College & Hospital
No. 7, Works Road, Chromepet,
Chennai - 600 044.

Copy to:

The Member Secretary, IAEC, SBMCH
The Vice Principal
Dean's File

No. 25/314/2011 – AWD
Government of India
Ministry of Fisheries, Animal Husbandry and Dairying
Department of Animal Husbandry and Dairying
O/o Committee for the purpose of Control and Supervision of Experiments on Animals
*****

Krishi Bhawan, New Delhi – 110001
Date: 04/May/2021

To,

Dr. WMS Johnson, Chairman IAEC,
Sree Balaji Medical College & Hospital No.7,
Works Road, Chrompet, Chennai- 600044, Tamil Nadu
Email: deanjohnson@bharathuniv.ac.in
Mobile: 9841201965

Subject: Renewal of Registration and Reconstitution of Institutional Animals Ethics Committee (IAEC)-regarding

Sir,

The registration of Animal House Facility of your establishment with CPCSEA has been **renewed for a period of five years from the date of issue of this letter**.

2. The new registration number of Animal House Facility of your establishment is **863/PO/Re/S/04/CPCSEA for Research for Education purpose on small animals**. Henceforth, the new registration number may kindly be quoted in all your future correspondence.

3. The CPCSEA has accepted the following members recommended by the establishment:

Name of the IAEC Members	Designation in IAEC
1) Dr WMS Johnson	Biological Scientist, Chairperson
2) Dr Farhana Rahman	Scientist In-charge of Animal House Facility, Member Secretary
3) Dr S Parijatham	Scientist from different biological discipline
4)Dr. K Raveendran	Veterinarian
5) Dr. K Sumathi	Scientist from different biological discipline

4. CPCSEA hereby nominates the following members to the Institutional Animals Ethics Committee (IAEC) of your establishment:

Details of Nominee(s)	Nominated as
1) Dr. S. Meenakshi Sundaram, No. 2/1036, Maniammal Street, Raja Rajeswari Nagar, Madipakkam, Chennai – 600091, Tamil Nadu Contact No :Mob: 9444739475 Email :drsundha22@yahoo.co.in	Main Nominee
2) Dr. S. Vairamuthu Professor & Head, Centralised Clinical Laboratory, Madras Veterinary College, Vepery, Chennai-600 007, Tamil Nadu Contact No :9444182357 Email :drvairu@yahoo.com	Link Nominee

Contd..

3) Dr. Vasanthi Balan 162, Chowdry Nagar, 14th Street, Valasaravakkam, Chennai – 600087, Tamil Nadu Contact No :Mob: 9094057354 Email :vasdivi@yahoo.co.in	Scientist from outside the Institute
4) Shri C. Ronald Darwin 25/43, Devanand, Main Road Marthandam, Kanyakumari district, Tamilnadu - 629165 Contact No :9444428759 Email :ronaldpharma@gmail.com	Socially Aware Nominee

(Please note that any change in IAEC members can be made only with prior approval of CPCSEA.)

5. The IAEC is valid for a period of five years and is coterminous with renewed period of registration. IAEC is required to be reconstituted at the time of renewal of registration as per CPCSEA guidelines.

6. You are requested to convene the meeting of the re-constituted IAEC within a period of 30 days and upload the same on the website of the CPCSEA.

7. It is stated that only above approved IAEC members shall sign, with date, on the attendance sheet of the IAEC meetings, and decisions will be taken only in meetings where quorum is complete. The quorum for holding IAEC meeting is six (6), and Main Nominee, Scientist from outside the Institute and Socially Aware Nominee must be present in such meetings. Link Nominee can attend in case main nominee conveys his unavailability in writing to the chairman IAEC. However, the Link Nominee must be invited once a year to update him/ her about the activities of IAEC. Any decision taken in the meetings of IAEC without quorum shall be considered invalid.

8. It is also to inform you that before commencing any research on large animals you are required to send research protocols with due recommendation of IAEC to CPCSEA for further approval (procedure for submission of Research Protocols is available on the website of CPCSEA).

Yours sincerely,

(Dr. S. K. Dutta)
Member Secretary (CPCSEA)

Copy for necessary action to: Nominees of CPCSEA.

The Main Nominee is requested to ensure that the IAEC meetings are held regularly as stipulated in the SOP of CPCSEA and submit the Annual Inspection Reports of the Animal House Facility regularly on the Website of CPCSEA.

The Main Nominee is requested to conduct the Inspection of Animal House Facility within a period of 30 days and submit the Inspection Report on the Website of CPCSEA.

Sree Balaji Medical College & Hospital
Chennai-44

Ref.No.8775/SBMC&H/IAEC/2021 Date: 14.12.2021

Sub: SBMC&H, Chromepet – conduct of Institutional Animla Ethics Committee - review meeting on 18th December 2021 (Saturday) at 09.30 p.m. – reg.

Ref: O.O. No. 034/SBMC/IAEC/2012 dated 03.07.2012.

--o0o--

It is hereby informed that the review meeting of the Institutional Animal Ethical Committee will be held at 9.30 a.m. on 18.12.2021 (Saturday). The meeting will be held at the Macleod Hall (Central Library - Second Floor)

The Agenda for the meeting are:

1. Project Proposals presentation by the faculty
2. Physical Meeting

All members of IAEC are requested to attend the meeting through online without fail.

DEAN

To:

Dr. W.M.S. Johnson	Dean	Chairman
Dr. Farhana Rahman	Professor of Pharmacology	Scientist & Member Secretary
Dr. S. Parijatham	Associate Professor of Physiology	Scientist
Dr. K. Raveendran	Veterinary Medical Officer	Veterinarian
Dr. K. Sumathi	Associate Professor of Biochemistry	Scientist
Dr. S. Meenakshi Sundaram	No.2/1036, Maniammal Street, Raja Rajeswari Nagar, Madipakkam, Chennai – 600 091	Main Nominee from the CPCSEA
Dr. S. Vairamuthu	Prof. & HOD, Centralised Clinical Laboratory Madras Veterinary College, Vepery, Chennai – 600 007	Link Nominee from the CPCSEA
Dr. Vasanthi Balan	No.162, Chowdry Nagar 14th Street, Valasaravakkam Chennai – 600 087	Scientist from outside the Institute
Shri C. Ronald Darwin	No.25/43, Devanand Main Road, Marthandam, Kanyakumari – 629165	Socially aware Nominee

Copy to

- Expert Consultant, CPCSEA, Ministry of Environment and Forests, Govt. of India, No.13/1, 3rd Seaward road, Valmiki Nagar, Thiruvanmiyur, Chennai – 41
- The Director, AW & Member Secretary, CPCSEA, Animal Welfare Division, Ministry of Environment, Forest & Climate changes Govt. of India, 5th Floor, Vayoo block Indira Pariyavaran Bhavan, Ali Ganj, Jor Bagh Road, New Delhi – 110 003
- The Medical Superintendent
- The Vice Principal
- A.O. Hospital
- Dean's file

MINUTES OF THE MEETING

Animal Facility - Sree Balaji Medical College and Hospital, Chrompet

Date : 18.12.21
Time : 9.30 AM to 11.30 AM
Venue : Sree Balaji Medical College and Hospital, 2nd floor

Members present:

1. Dr. Farhana Rahman	(Member Secretary)
2. Dr. K. Raveendran	(Veterinarian)
3. Dr. S. Meenakshi Sundaram	(CPCSEA Main Nominee)
4. Dr. S. Vairamuthu	(CPCSEA Link Nominee)
5. Dr. C. Ronald Darwin	(Socially aware member)
6. Dr. Parijatham	(Scientist from different discipline)
7. Dr. K. Sumathi	(Scientist from different discipline)

Dr. WMS Johnson, Dean Sree Balaji Medical College, and Hospital, Chennai -Chairperson. **&Dr.Vasanthi Balan**, scientist from other institute could not attend the meeting

The Member Secretary welcomed all the members and discussed the agenda for the meeting

As discussed in the last meeting, a physical animal ethics committee meeting was arranged.

The committee members went for an inspection of the animal house by about 9.40 AM

The following things were insisted

- Installing a signboard showing the name – "Animal House with CPCSEA register number" in the front entrance of the animal house.
- Individual name board for each room
- CCTV footage frequent observation by the member secretary
- Maintenance of registers for the process in animal house

The committee returned to the Audio-visual room on the 2nd floor, Sree Balaji Medical College and Hospital. The member secretary outlined the project proposals to be submitted for approval.

MINUTES OF THE MEETING

Animal Facility - Sree Balaji Medical College and Hospital, Chrompet

Date : 18/12/21
Time : 9.30 AM to 11.30 AM
Venue : Sree Balaji Medical College and Hospital. 2nd floor

	IAEC Protocol Number	Project Title	PI	No of Animals Requested	No of Animals Approved/ Recommended	Remarks
	01/2021	Efficacy of novel microencapsulated seaweed polysaccharides synbiotics on inflammation-induced metabolic syndrome in elderly rats: metabolomics and transcriptomes	Dr. R. Raja	100 Wistar albino rats.	60 Wistar albino rats.	Investigator was advised to reduce the number of rats in all the groups and take 6 rats per group
	02/2021	Neuronal MAP2: Novel target for mood stabilizer medication therapy in bipolar disorder	Dr. Thangavel Muthusamy	40 Sprague Dawley rats.	32 Sprague Dawleyrats.	The Investigator was advised to reduce the number of rats in the normal control group from 10 rats to 6 rats and in the experimental control group from 10 rats to 6 rats
	03/2021	Effect of methoxy flavones in animal models of Alzheimer's disease	Dr. P. Nithya	40 male Sprague Dawley rats 180 Zebrafish	32 male Sprague Dawley rats, 180 zebrafish	Expert help to be taken for ICV injection
	04/2021	Effect of Aspirin in high carbohydrate-fed male Wister rats.	Dr. Dinesh Jothimani	24 Wistar albino rats	20 Wistar albino Rats	Investigator has made 6 groups for his study consisting of 4 animals pe group (Total = 24 rats). He was advised to eliminate the group with a high cholesterol diet with a placebo.

MINUTES OF THE MEETING

Animal Facility - Sree Balaji Medical College and Hospital, Chrompet

Date : 18/12/21
Time : 9.30 AM to 11.30 AM
Venue : Sree Balaji Medical College and Hospital, 2nd floor

	27/12/21	27/12/21
Chairman Prof. Dr.WMS Johnson, MS Dean, Sree Balaji Medical College, and Hospital CLC Works Road, Chennai - 600044	**CPCSEA Main Nominee** Dr.S.Meenakshi Sundaram Professor and Head, Livestock farm complex, TANUVAS, Chennai	**CPCSEA Link Nominee** Dr. S. Vairamuthu Professor and Head, Centralised Clinical Laboratory, Madras Veterinary College, Vepery
27/12/21		
Scientist In-charge of Animal House facility & Member Secretary Dr. Farhana Rahman, MD Professor, Department of Pharmacology Sree Balaji Medical College and Hospital Chrompet, Chennai - 44	**Scientists from Other Institute** Dr.Vasanthi Balan 162, Chowdry Nagar, 14th Street, Valasaravakkam Chennai - 600087	**Veterinarian** Dr. K. Ravindran Veterinarian, Animal House Sree Balaji Medical College and Hospital Chennai
27/12/21	27/12/21	27/12/2021
Socially Aware Member Dr. Ronald Darwin, M.Pharm, PhD., Professor & Head, Pharmacology School of Pharmaceutical Sciences Vels Institute of Science Technology & Advanced Studies Chennai - 600 117	**Scientists from different Discipline** Dr. K. Sumathi, MD Associate Professor, Department of Biochemistry, Sree Balaji Medical College and Hospital, Chrompet, Chennai - 44	**Scientists from different Discipline** Dr.Parijatham, MD Associate Professor, Department of Physiology, Sree Balaji Medical College and Hospital, Chrompet, Chennai - 44

Sree Balaji Medical College & Hospital
Chennai-44

Ref.No.8775/SBMC&H/IAEC/2021 **Date: 14.12.2021**

Sub: SBMC&H, Chromepet – conduct of Institutional Animla Ethics Committee - review meeting on 18th December 2021 (Saturday) at 09.30 p.m. – reg.

Ref: O.O. No. 034/SBMC/IAEC/2012 dated: 03.07.2012.

--o0o--

It is hereby informed that the review meeting of the Institutional Animal Ethical Committee will be held at 9.30 a.m. on 18.12.2021 (Saturday). The meeting will be held at the Macleod Hall (Central Library - Second Floor).

The Agenda for the meeting are:

1. Project Proposals presentation by the faculty
2. Physical Meeting

All members of IAEC are requested to attend the meeting through online without fail.

DEAN

To:

Dr. W.M.S. Johnson	Dean	Chairman
Dr. Farhana Rahman	Professor of Pharmacology	Scientist & Member Secretary
Dr. S. Parijatham	Associate Professor of Physiology	Scientist
Dr. K. Raveendran	Veterinary Medical Officer	Veterinarian
Dr. K. Sumathi	Associate Professor of Biochemistry	Scientist
Dr. S. Meenakshi Sundaram	No.2/1036, Maniammal Street, Raja Rajeswari Nagar, Madipakkam, Chennai – 600 091	Main Nominee from the CPCSEA
Dr. S. Vairamuthu	Prof. & HOD, Centralised Clinical Laboratory Madras Veterinary College, Vepery, Chennai – 600 007	Link Nominee from the CPCSEA
Dr. Vasanthi Balan	No.162, Chowdry Nagar 14th Street, Valasaravakkam Chennai – 600 087	Scientist from outside the Institute
Shri C. Ronald Darwin	No.25/43, Devanand Main Road, Marthandam, Kanyakumari – 629165	Socially aware Nominee

Copy to:

- Expert Consultant, CPCSEA, Ministry of Environment and Forests, Govt. of India, No.13/1, 3rd Seaward road, Valmiki Nagar, Thiruvanmiyur, Chennai – 41
- The Director, AW & Member Secretary, CPCSEA, Animal Welfare Division, Ministry of Environment, Forest & Climate changes Govt. of India, 5th Floor, Vayoo block Indira Pariyavaran Bhavan, Ali Ganj, Jor Bagh Road, New Delhi – 110 003
- The Medical Superintendent
- The Vice Principal
- A.O. Hospital
- Dean's file

MINUTES OF THE MEETING

Animal Facility - Sree Balaji Medical College and Hospital, Chrompet

Date : 18/12/21
Time : 9.30 AM to 11.30 AM
Venue : Sree Balaji Medical College and Hospital, 2nd floor

Members present:

1. Dr. Farhana Rahman (Member Secretary)
2. Dr. K. Raveendran (Veterinarian)
3. Dr. S. Meenakshi Sundaram (CPCSEA Main Nominee)
4. Dr. S. Vairamuthu (CPCSEA Link Nominee)
5. Dr. C. Ronald Darwin (Socially aware member)
6. Dr. Parijatham (Scientist from different discipline)
7. Dr. K. Sumathi (Scientist from different discipline)

Dr. WMS Johnson, Dean Sree Balaji Medical College, and Hospital, Chennai -Chairperson, **&Dr.Vasanthi Balan**, scientist from other institute could not attend the meeting

The Member Secretary welcomed all the members and discussed the agenda for the meeting

As discussed in the last meeting, a physical animal ethics committee meeting was arranged.

The committee members went for an inspection of the animal house by about 9.40 AM

The following things were insisted

- Installing a signboard showing the name – "Animal House with CPCSEA register number" in the front entrance of the animal house.
- Individual name board for each room
- CCTV footage frequent observation by the member secretary
- Maintenance of registers for the process in animal house

The committee returned to the Audio-visual room on the 2nd floor, Sree Balaji Medical College and Hospital, The member secretary outlined the project proposals to be submitted for approval.

MINUTES OF THE MEETING

Animal Facility - Sree Balaji Medical College and Hospital, Chrompet

Date : 18/12/21
Time : 9.30 AM to 11.30 AM
Venue : Sree Balaji Medical College and Hospital, 2nd floor

Sl. No.	IAEC Protocol Number	Project Title	PI	No of Animals Requested	No of Animals Approved/ Recommended	Remarks
1	01/2021	Efficacy of novel microencapsulated seaweed polysaccharides synbiotics on inflammation-induced metabolic syndrome in elderly rats: metabolomics and transcriptomes	Dr. R. Raja	100 Wistar albino rats.	60 Wistar albino rats.	Investigator was advised to reduce the number of rats in all the groups and take 6 rats per group
2	02/2021	Neuronal MAP2: Novel target for mood stabilizer medication therapy in bipolar disorder	Dr . Thangavel Muthusamy	40 Sprague Dawley rats.	32 Sprague Dawleyrats.	The Investigator was advised to reduce the number of rats in the normal control group from 10 rats to 6 rats and in the experimental control group from 10 rats to 6 rats
3	03/2021	Effect of methoxy flavones in animal models of Alzheimer's disease	Dr. P. Nithya	40 male Sprague Dawley rats 180 Zebrafish	32 male Sprague Dawley rats, 180 zebrafish	Expert help to be taken for ICV injection
4	04/2021	Effect of Aspirin in high carbohydrate-fed male Wister rats.	Dr. Dinesh Jothimani	24 Wistar albino rats	20 Wistar albino Rats	Investigator has made 6 groups for his study consisting of 4 animals pe group (Total = 24 rats). He was advised to eliminate the group with a high cholesterol diet with a placebo.

MINUTES OF THE MEETING

Animal Facility - Sree Balaji Medical College and Hospital, Chrompet

Date : 18/12/21
Time : 9.30 AM to 11.30 AM
Venue : Sree Balaji Medical College and Hospital, 2nd floor

	27/12/21	27/12/21
Chairman Prof. Dr.WMS Johnson, MS Dean, Sree Balaji Medical College, and Hospital CLC Works Road, Chennai - 600044	**CPCSEA Main Nominee** Dr.S.Meenakshi Sundaram Professor and Head, Livestock farm complex, TANUVAS, Chennai	**CPCSEA Link Nominee** Dr. S. Vairamuthu Professor and Head, Centralised Clinical Laboratory, Madras Veterinary College, Vepery
27/12/21		
Scientist In-charge of Animal House facility & Member Secretary Dr. Farhana Rahman, MD Professor, Department of Pharmacology Sree Balaji Medical College and Hospital Chrompet, Chennai - 44	**Scientists from Other Institute** Dr.Vasanthi Balan 162, Chowdry Nagar, 14th Street, Valasaravakkam Chennai - 600087	**Veterinarian** Dr. K. Ravindran Veterinarian, Animal House Sree Balaji Medical College and Hospital Chennai
27/12/21	27/12/21	27/12/2021
Socially Aware Member Dr. Ronald Darwin, M.Pharm, PhD., Professor & Head, Pharmacology School of Pharmaceutical Sciences Vels Institute of Science Technology & Advanced Studies Chennai - 600 117	**Scientists from different Discipline** Dr. K. Sumathi, MD Associate Professor, Department of Biochemistry, Sree Balaji Medical College and Hospital, Chrompet, Chennai - 44	**Scientists from different Discipline** Dr.Parijatham, MD Associate Professor, Department of Physiology, Sree Balaji Medical College and Hospital, Chrompet, Chennai - 44

MINUTES OF THE MEETING - Sree Balaji Medical College and Hospital

Date: 12/6/21
Time: 3pm

Venue: Online mode (Google meet)

Meeting called by: Dr. WMS Johnson, Dean
Sree Balaji Medical College and Hospital, Chennai
Chairperson, Institutional Animal Ethics Committee

Members present

1. Dr. WMS Johnson
2. Dr. Farhana Rahman
3. Dr. K. Raveendran
4. Dr. K. Suhathi
5. Dr. S. Meenakshi Sundaram
6. Dr. S. Veiramuthu
7. Dr. Vasanthi Balan
8. Dr. C. Ronald Darwin

Members absent
Dr. S Parijatham

Agenda for the meeting

Re-registration of Animal House Facility was approved by CPSCEA on 4/5/2021 and asked to conduct a meeting with the new constituted members. Meeting started with a welcome address by Dr. WMS Johnson, Chairperson IAEC. He welcomed all the members present in the meeting and gave a brief description of the animal house facility.

Dr. K Raveendran, Veterinary doctor of the animal house introduced the committee members

Dr S Meenakshi Sundaram and Dr S Veiramuthu appointed by CPSCEA gave their valuable advices regarding animal house. They encouraged to do projects related to animal experiment by the students and faculties. They also advice to install surveillance camera in the animal house facility.

Agenda for the next meeting

A physical meeting would be conducted after the pandemic situation is under control to discuss various animal experimental projects

Adjournment

Meeting was adjourned at 4 pm with a thanks note from Dr Farhana Rahman, member secretary IAEC

Minutes submitted by: Dr Farhana Rahman

Minutes approved by: Dr WMS Johnson

Sree Balaji Medical College & Hospital
Chennai-44

Ref.No.1096/SBMC&H/IAEC/2015 Date: 10.06.2021

Sub: SBMC&H, Chromepet – conduct of Institutional Animla Ethics Committee - review meeting on 12th June 2021 at 3.00 p.m. – reg.

Ref: O.O. No. 034/SBMC/IAEC/2012 dated: 03.07.2012.

–o0o–

It is hereby informed that the review meeting of the Institutional Animal Ethical Committee will be held at 3.00 p.m on 12.06.2021 through online.

The Agenda for the meeting are:

1. Reregistration of Institutional Animal Ethical Committee
2. Any other issues

All members of IAEC are requested to attend the meeting through online without fail.

DEAN

To:

Dr. W.M.S. Johnson	Dean	Chairman
Dr. Farhana Rahman	Professor of Pharmacology	Scientist & Member Secretary
Dr. S. Parijatham	Associate Professor of Physiology	Scientist
Dr. K. Raveendran	Veterinary Medical Officer	Veterinarian
Dr. K. Sumathi	Associate Professor of Biochemistry	Scientist
Dr. S. Meenakshi Sundaram	No.2/1036, Maniammal Street, Raja Rajeswari Nagar, Madipakkam, Chennai – 600 091	Main Nominee from the CPCSEA
Dr. S. Vairamuthu	Prof. & HOD, Centralised Clinical Laboratory Madras Veterinary College, Vepery, Chennai – 600 007	Link Nominee from the CPCSEA
Dr. Vasanthi Balan	No.162, Chowdry Nagar, 14th Street, Valasaravakkam Chennai – 600 087	Scientist from outside the Institute
Shri C. Ronald Darwin	No.25/43, Devanand Main Road, Marthandam, Kanyakumari – 629165	Socially aware Nominee

Copy to:

- Expert Consultant, CPCSEA, Ministry of Environment and Forests, Govt. of India, No.13/1, 3rd Seaward road, Valmiki Nagar, Thiruvanmiyur, Chennai – 41
- The Director, AW & Member Secretary, CPCSEA, Animal Welfare Division, Ministry of Environment, Forest & Climate changes Govt. of India, 5th Floor, Vayoo block Indira Pariyavaran Bhavan, Ali Ganj, Jor Bagh Road, New Delhi – 110 003
- The Medical Superintendent
- The Vice Principal
- A.O. Hospital
- Dean's file