भारत सरकार/ GOVERNMENT OF INDIA
अटल बिहारी वाजपेयी आयुर्विज्ञान संस्थान
डॉ० राम मनोहर लोहिया अस्पताल, नई दिल्ली
ATAL BIHARI VAJPAYEE INSTITUTE OF MEDICAL SCIENCES
DR. RAM MANOHAR LOHIA HOSPITAL NEW DELHI-11001

File No. IEC/ABVIMS/RMLH/2023/

Date : 23/08/2023

To,

The Chairman,

E-governance,

ABVIMS & Dr. RML Hospital,

New Delhi

Subject : Upload of the documents of Institutional Ethics Committee, ABVIMS & Dr. RMLH in the Website.

Sir,

Kindly upload the enclosed documents of Institutional Ethics Committee in the website of our Institution.

1. Ethics Committee Proforma
2. Constitution of Ethics Committee
3. CDSCO approval letter
4. SoP of Ethics Committee
5. Proforma of ICF & PIS

We are also sending these documents (Soft copy) as email attachments at your email ID.

Thanking You,

Yours faithfully,

Aanchal

(Dr. Aanchal Kakkar)
Member Secretary
Ethics Committee

FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH FOR CLEARANCE BY ETHICS COMMITTEE OF PGIMER Dr RML Hospital

Submit 5 copies (8 copies for drug/Clinical Trial) of the Research Project along with covering letter duly forwarded by Head of the Department and 'soft copy' on CD or mail (ethicsiec@gmail.com) with the following information to the Member Secretary, Institution Ethics Committee at Room No. 414, 4th Floor, Administrative Block.

No research project shall be/ can be started unless ethics clearance/ approval is obtained. Please bear in mind that no retrospective/ post facto ethical clearance can be provided to research projects which were neither submitted nor wetted by the Institution Ethics Committee.

All submissions should be made in the prescribed Format of the Institution Ethics Committee with signatures of all the investigators. The submission must be accompanied with *participant informed consent Form* (PICF) and *participant/Patient Information Sheet* (PIS), Assent form where ever required both in English and Hindi, in a simple layman's language, in a narrative form, directed to participant/ LAR, covering all points, as per New Drugs and Clinical Trial Rules, 2019/ latest ICMR guidelines before it can be considered for placing before the Institution Ethics Committee.

Also ensure that all the pages are numbered.

Project Submission Time: Submissions will be received on all days. Proposals received 15 days before meeting date will be processed in the coming Institution Ethics Committee meeting and those received after that will be processed in the next meeting. All meeting of Institution Ethics Committee will be held as far as possible on (3^{rd}/4^{th} Friday if not a holiday) or within 45 days according to number of proposals received.

While submitting replies to queries raised by the Institution Ethics Committee, the candidates are advised to mention the Institution Ethics Committee reference number/s and also attach a copy of the comments of the Institution Ethics Committee & highlight the changes/modification. The P. I. can request for an expedited review and approval in case the Project is time sensitive.

Amendment Submission: While submitting amendments in protocols a covering letter should be provided clearly stating justification & highlighting the changes and a certificate by the PI that the changes made in the protocol will not hamper the safety of the subjects in anyway.

The PI of any DTCT should have a certificate in Good annual practice (not more than 2 years old. Only after obtaining CT-NOC from CDSCO on SUGAM Portal & registering at Clinical Trial Registry India (CTRI) and Signature on final CTA, P. I. can start/ initiate a Trial. Kindly get necessary administrative/financial approval from Institute/competent authority before starting the project.

The Investigator shall submit the initial report all serious adverse events to the Central Licensing Authority (CDSCO), the sponsor or its representative and the Ethics Committee within twenty-four hours of their occurrence. A detail report must be submitted after due analysis to the Central licensing Authority, Ethics Committee and the head of the Institution within fourteen days of the knowledge of occurrence of serious adverse event.

Ethics review of projects of duration of less than 2 year, will be carried out every 6 months and of all others annually. A detail report of progress should be submitted at the end of 6 months and 12 months respectively. At the end of the project, a copy of the Final report should be submitted. All records of project should be maintained by the Principal investigator for 15 years.

CHECKLIST OF DOCUMENTS FOR SUBMISSION OF PROTOCOLS

TO THE ETHICS COMMITTEE, DR. R.M.L. HOSPITAL, NEW DELHI

Date of submission:

I. Type of study:

Basic Sciences ☐ Clinical ☐ Cross Sectional ☐ Retrospective ☐ Epidemiological ☐

Case Control ☐ Prospective ☐ Public Health Cohort ☐ Qualitative ☐ Socio-

behavioural ☐ Systematic Review ☐ Quantitative ☐ Biological samples/ Data ☐ Mixed

Method ☐ Any others (Specify) ☐

Sr. No. (Tick if included)	Document	Reason for inclusion	Remarks
1.	Application to Member Secretary Ethics Committee		
2.	Research proposal/ drug Protocol/ I.B. (8/4 copies)		
3.	Undertaking to Ethics Committee & CV (8/4 copies)		
4.	Duly filled Performa for Ethics committee with adequate details. (8/4 Copies)		
5.	Bilingual detailed consent form and participant/ information sheet. (8/4 Copies)		patient
6.	Drug Controller General of India Permission letter (8/4 copies, if drug trial)		
7.	Plan for maintenance of confidentiality.		
8.	Agreement (CTA) in the prescribed format for drug trial Tri Party (principal Investigator, Sponsor its representative And Institute)		
9.	Copy of insurance letter of pharmaceutical Company for drug trial in consideration.		
9.	Cheque of Rs. 20,000/- submitted or details of online fund transfer in the account of Medical Superintendent.		

II. FUNDING DETAILS AND BUDGET

Total estimated budget for site:..... .....

At site..... In India..... Globally .....

Self-funding ☐ Institutional funding ☐ Funding agency (Specify) ☐

PROFORMA FOR ETHICAL COMMITTEE CLEARANCE OF RESEARCH PROJECTS IN Dr. RAM MANOHAR LOHIA HOSPITAL, NEW DELHI

Note:

i. All columns should be clearly filled in. Use additional sheet, if necessary.
ii. Send eight copy of Performa duly singed by the applicant.
iii. Attach all annexure as mentioned or else write N.A. against.
iv. Kindly check your protocol is page numbered.
v. Explain/Expand all abbreviation at first place of use or provide list of abbreviation.

1. Title of the Research project: _____

2. Name & Designation of the Principal investigator (Recent Curriculum Vitae indicating Qualification & experience may be Enclosed Annexure I) _____

3. Name (s) & designation of co-investigator(s), If any, (recent curriculum vitae indicating Qualification & experience may be Enclosed Annexure 2) _____

4. Name (s) & designation of investigator(s) not , Belonging to Dr. RML Hospital , New Delhi If any(recent curriculum vitae indicating Qualification & experience may be enclosed Annexure III) _____

5. Name of the Department where Research is proposed to be carried out. _____

6. Name (s) of the departments that would Collaborate in the project _____

7. Name (s) of outside institutions that would collaborate in the study. _____

8. In case the study is multicentre, detail of all Other centre, investigators etc. (Récent Curriculum vitae indicating qualification & experience may be enclosed annexure IV) _____

9. Agency proposed to bear the expenses in the Project and whether any such grant is available

10 Duration of the proposed study with phasing And limitations, if any.

11. Brief description of the work to be undertaken, material methods etc. including intended dosage of Planned duration of treatment and details of invasive procedures if any:

12. Safety of proposed intervention and any drug or vaccine to be tested including results of relevant laboratory and animal research with anticipated risks involved:

13. Is there any provision to compensate the Subjects/patients/ victim (s) in case of any Complication side effects or any other mishap Or litigatation.

14. Is there any provision of reimbursement of Incidental expenses & detail there of.

15. Procedure of subject recruitment with inclusion And exclusion criteria

16. Are the necessary facilities available in Department where the research is proposed To be carried out? If so, detail there of

17. Detail of facilities which are not available in The Department and are proposed to be sought From other Departments.

18. Facilities which are not available in Dr. RML Hospital and now these are to be availed of:

19. Additional assistance sought from Dr. RML Hospital, if any (Details of Space, Staff, Equipment, reagents, chemical and And drug etc.

20. Additional assistance sought from other Institutions in terms of space, staff, equipment Reagents, chemicals and drugs etc.

21. Details of any fees/honorarium payable to Investigator/ collaborators/ patients/ others If any.

22. Is consent necessary? Mention date and version Number of consent (bilingual)

Who will obtain the informed consent?(PI/Co-P/ Nurse/Counselor/Research Staff/ Other(Specify)

.

23. Whether clearance is necessary from any other Agency? (If so, Detail thereof)

24. Whether clearance has been obtained from any Other agency related to the proposed project, If so Detail there of:

25. In case the project is sponsored by a private agency Particularly a multinational agency having Business interest in India, whether prior approval Of the competent authority has been taken

26. Full justification with clear research objectives & rational undertaking for the investigation in human Subjects in light of existing knowledge:

27. A description of plan to withdraw or withhold Standard therapies in the course of research of If any

28. Plans for statistical analysis of the study and Collected during the results

29. Plans for storage & maintenance of all data Collected during the trail

30. Any other information which be useful For consideration of the project for ethical Committee clearance.

Station: _____

Date: _____

_____
Signature of Principal Investigator

Station: _____

Date: _____

_____
Signature of co-Investigator

The members of the Ethics Committee are as under:-

(i)	Chairman	-	Dr. Arun Kumar Agarwal- Ex-Addl DG Ministry of Health and Family Welfare, Government of India.
(ii)	Member Secretary	-	Dr. Aanchal Kakkar, Professor, Dept. of Anesthesia ABVIMS & Dr. RML Hospital.
(iii)	Legal Expert, Member	-	Mr. Dhirendra Kumar Jha, Advocate, Delhi High Court, New Delhi

Members:-

1. Dr. Arunabha ray, Professor Department of Pharmacology, HIMSR	Medical Scientist
2. Dr. Sushma Yadava, Ex-Vice Chancellor Bhagat Phool Singh Mahila Vishwavidyalaya Sonepat, Haryana	Social Scientist
3. Mr. HR Meena, Dy. Secretary, Ministry of Rural Development, 7th floor NDCC-II Building, Jai Singh Road, New Delhi	Lay Person
4. Dr. Nikhil Gupta, Professor Department of Surgery, ABVIMS, Dr. RMLH	Clinician
5. Dr. Piyush Jain, Professor Department of Medicine, ABVIMS, Dr. RMLH	Clinician
6. Dr. Sanjeev Kumar Gupta, Lab-oncology, IRCH, AIIMS, New Delhi	Medical Scientist
7. Dr. Kavita Gulati, Director Professor, Department of Pharmacology, VPCI	Scientific Member
8. Dr. (Prof.) Ghanshyam Pangty Department of Medicine, LHMC	Clinician
9. Dr. Tarun Kumar, Professor, Cardiology ABVIMS, Dr. RML Hospital	Clinician
10. Dr. Anuradha, Professor, Department of Microbiology, ABVIMS & Dr. RMLH	Medical Scientist
11. Mr. Prince Singhal, Social Activist & Founder - CADD	Social Scientist

UNDERTAKING

I, _____

(Name, Education, Designation & Medical Council Registration No. or any other statement of Qualification)_____(Full Official Address_____ (Principal Investigator/ Co-investigator/Co-Supervisor) on the project Titled & Study No. if any"_____

_____

_____" hereby give an undertaking that:-

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

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

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

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

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

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

7. Commitments:

(i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.

(ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favorable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical or administrative in nature.

(iii) I agree to personally conduct or supervise the clinical trial at my site.

(iv) I agree to inform all trial Subjects, 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 (GCP) guidelines are met.

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

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

(vii) I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

(viii) I agree to maintain adequate and accurate records and to make those records available for audit / inspection by the Sponsor, Ethics Committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and GCP guidlines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

(ix) I agree to promptly report to the Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.

(x) I agree to inform all serious adverse events to the Central Licencing Authority, Sponsor as well as the Ethics Committee within 24 hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licencing Authority along with the report of the serious adverse event.

(xi) The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licencing Authority, the Chairperson of the ethics committee and the Head of the Institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.

(xii) I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.

(xiii) I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

8. Signature of Investigator with Date:

Date : Signature of the Investigator

Name & Signature of Co-Investigator/Other Members of the Research Team

The members of the Ethics Committee are as under:-

(i)	Chairman	-	Dr. Arun Kumar Agarwal- Ex-Addl DG Ministry of Health and Family Welfare, Government of India.
(ii)	Member Secretary	-	Dr. Aanchal Kakkar, Professor Dept. of Aneasthesia, ABVIMS & Dr. RML Hospital.
(iii)	Legal Expert, Member	-	Mr. Dhirendra Kumar Jha, Advocate, Delhi High Court, New Delhi

Members:-

1. Dr. Arunabha ray, Professor Department of Pharmacology, HIMSR	Medical Scientist
2. Dr. Sushma Yadava, Ex-Vice Chancellor Bhagat Phool Singh Mahila Vishwavidyalaya Sonepat, Haryana	Social Scientist
3. Mr. HR Meena, Dy. Secretary, Ministry of Rural Development, 7th floor NDCC-II Building, Jai Singh Road, New Delhi	Lay Person
4. Dr. Nikhil Gupta, Professor Department of Surgery, ABVIMS, Dr. RMLH	Clinician
5. Dr. Piyush Jain, Professor Department of Medicine, ABVIMS, Dr. RMLH	Clinician
6. Dr. Sanjeev Kumar Gupta, Lab-oncology, IRCH, AIIMS, New Delhi	Medical Scientist
7. Dr. Kavita Gulati, Director Professor, Department of Pharmacology, VPCI	Scientific Member
8. Dr. (Prof.) Ghanshyam Pangty Department of Medicine, LHMC	Clinician
9. Dr. Tarun Kumar, Professor, Cardiology ABVIMS, Dr. RML Hospital	Clinician
10. Dr. Anuradha, Professor, Department of Microbiology, ABVIMS & Dr. RMLH	Medical Scientist
11. Mr. Prince Singhal, Social Activist & Founder - CADD	Social Scientist

File No. EC/19/000163

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: 03-Sep-2019

To

The Chairman
Ethics Committee, PGIMER, Dr. RML Hospital
PGIMER, DR. RAM MANOHAR LOHIA HOSPITAL,
NEW DELHI
Baba Khadakh Singh Marg New Delhi New Delhi
Central Delhi Delhi - 110001 India

Subject: Ethics Committee Re-Registration No. ECR/78/Inst/DL/2013/RR-19 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2019/2992 dated 18-Apr-2019 submitted to this Directorate for the Re-Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/78/Inst/DL/2013/RR-19. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

V G SOMANI

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

Conditions of Registration

1. The registration is valid from 20-Apr-2019 to 19-Apr-2024, unless suspended or cancelled by the Central Licencing Authority.

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

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 50 kms 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.

File No. EC/19/000163

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: 03-Sep-2019

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Mr. Tarun Kumar	MBBS (DM - Cardiology)	Clinician
2	Dr. Sushma Yadava	BA (MA - Political Science)	Social Scientist
3	Mr. DHIRENDRA KUMAR JHA	LLB (Master of Laws (LL.M.))	Legal Expert
4	Dr. Ghanshyam Pangty	MBBS (MD - Medicine)	Clinician
5	Dr. Ulka Kamble	MBBS (MD - Medicine)	Clinician
6	Dr. Indu Chawla	MBBS (MD/MS - Obstetrics & Gynaecology)	Clinician
7	Dr. ARUNABHA RAY	MBBS (MD-Pharmacology)	Basic Medical Scientist
8	Mr. Hari Ram Meena	B. COM (LLB)	Lay Person
9	Dr. Sanjeev Gupta	MBBS (MD Pathology)	Basic Medical Scientist
10	Dr. Proteesh Rana	MBBS (MD Pharmacology)	Basic Medical Scientist
11	Mr. ARUN KUMAR AGARWAL	MBBS (MS ENT)	Chair Person
12	Mr. Sudha Chandelia	MBBS (MD Paediatrics)	Member Secretary
13	Dr. Kavita Gulati	BSc (MSc., Ph.D)	Scientific Member

V G SOMANI

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

Dir. file

57229/2023/DAD
19/01/2023.

ECR/50/RML/Inst/DL/2013/Re-Registration-2019

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:

To

The Chairman
Ethics Committee
Atal Bihari Vajpayee Institute of Medical Sciences
(ABVIMS) & Dr. Ram Manohar Lohia Hospital
Baba Khadakh Singh Marg
Central Delhi, Delhi -110001, India

13 JAN 2023

Subject: Ethics Committee Re-registration No. **ECR/78/Inst/DL/2013/RR-19,** amendment to the composition of the Ethics Committee–regarding.

Sir/Madam,

Please refer to your application dated 21.12.2022 submitted to this Directorate vide no. P-2952307 dated 28.12.2022 for change in composition of the Re-Registered Ethics Committee.

Based on the documents submitted by you, the composition of your Ethics Committee bearing Re-Registration number **ECR/78/Inst/DL/2013/RR-19** dated **03.09.2019** valid until **19.04.2024** is hereby amended as follows, with all conditions of the Registration Certificate initially granted to you, remaining the same including the condition that **"the Ethics Committee shall review and accord approval to Clinical Trial and BA/BE Study protocol of new drugs and aiso conduct periodic review of the studies as per the New Drugs and Clinical Trial Rules, 2019".**

Sr. No.	Name of member	Qualification	Role/Designation in Ethics Committee
1.	Mr. Arun Kumar Agarwal	MBBS, MS (ENT)	Chairman
2.	Dr. Aanchal Kakkar	MBBS, MD (Anesthesiology)	Member Secretary
3.	Dr. Nikhil Gupta	MBBS, MS (Surgery)	Clinician
4.	Dr. Piyush Jain	MBBS, MD (General Medicine)	Clinician
5.	Dr. Tarun Kumar	MBBS, MD, DM (Cardiology)	Clinician
6.	Dr. Ghanshyam Pangty	MBBS, MD (Medicine)	Clinician
7.	Dr. Arunabha Ray	MBBS, MD (Pharmacology)	Medical Scientist
8.	Dr. Anuradha	MBBS, MD (Microbiology)	Medical Scientist
9.	Dr. Sanjeev Kumar Gupta	MBBS, DNB, DM (Hematopathology)	Medical Scientist
10.	Mr. H.R. Meena	B.Com, LLB	Lay Person
11.	Dr. Dhirendra Kumar Jha	MA, LLB	Legal Expert
12.	Dr. Sushma Yadava	MA (Political Science), M.Phil, PhD	Social Scientist
13.	Dr. Prince Singhal	MA (Social Work)	Social Scientist
14.	Dr. Kavita Gulati	PhD (Medical Pharmacology)	Scientific Member

Yours faithfully

(Dr. V. G. Somani)
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/78/Inst/DL/2013/RR-19

The Central Licencing Authority hereby registers and permits Ethics Committee, PGIMER, Dr. RML Hospital , PGIMER, DR. RAM MANOHAR LOHIA HOSPITAL, NEW DELHI Baba Khadakh Singh Marg New Delhi New Delhi Central Delhi Delhi - 110001 Contact No.: 011 23404744, 011 23365552 Fax No.: 011 23365550 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.

V G SOMANI

Central Licencing Authority

Stamp

Place : New Delhi

Date : 03-SEP-2019

Standard Operating Procedures

Institutional Ethics Committee

2022

ATAL BIHARI VAJPAYEE INSTITUTE OF MEDICAL SCIENCES
अटल बिहारी वाजपेयी आयुर्विज्ञान संस्थान
AND/एवं
DR. RAM MANOHAR LOHIA HOSPITAL, NEW DELHI-11001
डॉ0 राम मनोहर लोहिया अस्पताल, नई दिल्ली

Standard Operating Procedures

Institutional Ethics Committee

Atal Bihari Vajpayee Institute of Medical Sciences and Dr. Ram Manohar Lohia Hospital, New Delhi-110001.

Version 2.0

Approved by

Director & Medical Superintendent, Atal Bihari Vajpayee Institute of Medical Sciences and Dr. Ram Manohar Lohia Hospital, New Delhi

And

Institutional Ethics Committee, Atal Bihari Vajpayee Institute of Medical Sciences and Dr. Ram Manohar Lohia Hospital, New Delhi.

Contents

1. Objective

The objective of Standard Operating Procedure (SOP) is to maintain the effective functioning of the Institutional Ethics committee (IEC), ABVIMS, Dr. RML Hospital, New Delhi and to ensure the quality and consistency in ethical review for health and biomedical research of all the submitted health and biomedical research proposals and ongoing approved research studies involving human participants in accordance with the Indian Council of Medical Research (ICMR) and national ethical guidelines for biomedical and Health research on human participants, Drugs and Cosmetics Act 1940 and Drugs and Cosmetics Rules 1945 (including the amendments), and New Drugs and Clinical Trials Act and Rules 2019.

2. Authority under which IEC is constituted:

Director, ABVIMS, Dr. RML Hospital, New Delhi is the authority to appoint the committee.

3. Composition of Institutional Ethics Committee

EC should be multidisciplinary and multi-sectorial in composition. Independence and competence are the two hallmarks of an IEC. The Chairperson of the Committee will be from outside the Institution. The Member Secretary who generally belongs to the same Institution should conduct the business of the Committee and the other members of EC should be a mix of medical / non-medical scientific and non-scientific persons including lay public to reflect the differed viewpoints. There should be adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community / society. Preferably 50% of the members should be non-affiliated or from outside the institution. The number of members in an EC should preferably be between seven and fifteen.

The composition as recommended by CDSCO/ ICMR guidelines is as follows:-

1. **Chairperson (Non-affiliated)** to be a well-respected person from any background with prior experience of having served/ serving in an EC. Should Conduct EC meetings and be accountable for independent and efficient functioning of the committee. Should ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations. Ratify minutes of the previous meetings. In case of anticipated absence of Chairperson, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting. Should seek conflict of Interest (COI) declaration from members and ensure quorum and fair decision making. Should handle complaints against researchers, EC members, COI issues and requests for use of EC data, etc.

2. **1-2 basic medical scientists. (Affiliated/ non-affiliated)** Should be a Non-medical or medical person with qualifications in basic medical sciences. In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist. Role of Basic Medical scientist is Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, Serious Adverse Events (SAEs), protocol deviation, progress and completion report. For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.

3. **Clinicians. (Affiliated/ non-affiliated)**. Should be individuals with recognized medical qualification, expertise and training. Should perform scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics, ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report), review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation, thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

4. **One Legal Expert or retired judge (Affiliated/ non-affiliated).** Should have a basic degree in Law from a recognized university, with experience. Training in medical law is desirable. Should perform Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, Health Ministry's Screening Committee for international collaboration, compliance with guidelines etc. Interpret and inform EC members about new regulations if any.

5. **One Social Scientist (Affiliated/ non-affiliated).**Should be an individual with social/behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health related activities. Should perform ethical review of the proposal, ICD along with the translations, assess impact on community involvement, socio–cultural context, religious or philosophical context, if any, serves apatient/participant/societal/community representative and bring in ethical and societal concerns.

6. **One Lay Person from the community(Non-affiliated).** Should be Literate person from the public or community, has not pursued a medical science/healthrelated career in the last 5 years. May be a representative of the community from which the participants are to be drawn. Is aware of the local language, cultural and moral values of the community. Involved in social and community welfare activities, Ethical review of the proposal, ICD along with translation(s), evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks, serve as a patient /participant/community representative and bring in ethical and societal concerns, assess on societal aspects if any.

7. **Member-Secretary (Affiliated).** Should be a staff member of the institution. Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills, organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review, schedule EC meetings, prepare the agenda and minutes, organize EC documentation, communication and archiving, ensure training of EC secretariat and EC members, ensure SOPs are updated as and when require, ensure, adherence of EC functioning to the SOPs, prepare for and respond to audits and inspections, ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review, assess the need for expedited review/ exemption from review or full review, should be able to devote adequate time to this activity which should be protected by the institution, assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives, ensure quorum during the meeting and record discussions and decisions.

The EC can also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements. These members have the same TORs as regular members and can attend meetings in the absence of regular members.

4. Criteria for selection of members of an EC

1. Members should be selected in their personal capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the EC.
2. Members are appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting. The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility based on their qualifications. Hence, if the Chairperson is a lawyer, she or he can serve as both the lawyer and the Chairperson.

5. The Ethics Committee of ABVIMS &Dr. Ram Manohar Lohia Hospital, New Delhi comprises of:

(i) **Chairman** - Dr. Arun Kumar Agarwal, Ex Addl. DG MOHFW and Ex Dean MAMC.

(ii) **Member Secretary** - Dr. Aanchal Kakkar, Associate Professor, Department of Anaesthesiology, ABVIMS, Dr. RMLH, New Delhi

(iii) **Legal Advisor, Member**- Mr. Dhirendra Kumar Jha, Advocate, Delhi High Court.

Members:-

S. No.	Names
(i)	Dr. Arunabha Ray, Professor, Department of Pharmacology HIMSR. **(Medical Scientist)**
(ii)	Mr. H.R. Meena, Dy. Secretary, Ministry of Rural Development, 7th floor

	NDCC-II Building Jai Singh Road, New Delhi. **(Lay Person)**
(iii)	Dr. Sushma Yadava, Ex-Vice Chancellor, Bhagat Phool Singh Mahila Vishwavidyalaya Khanpur Kalan, Sonepat , Haryana -131305**(Social Scientist).**
(iv)	Dr. Ulka Kamble, Associate Professor, Department of Medicine, ABVIMS & Dr. RML Hospital, New Delhi, **(Clinician)**
(v)	Dr. Tarun Kumar, Professor, Cardiology, ABVIMS & Dr RML Hospital, New Delhi, **(Clinician)**
(vi)	Dr. Kavita Gulati, Director Professor, Department of Pharmacology, VPCI, New Delhi **(Scientist Member)**
(vii)	Dr. Sanjeev Gupta, Professor, Lab-oncology, IRCH, AIIMS ,New Delhi, **(Medical Scientist)**
(viii)	Dr. (Prof.) Ghanshyam Pangtey, Professor, Department of Medicine, LHMC, New Delhi**(Clinician)**
(ix)	Dr. Nikhil Gupta, Professor, Department of Surgery, ABVIMS & Dr RML Hospital, New Delhi, **(Clinician)**
(x)	Mr. Prince Singhal, Social Activist & Founder of the NGO - CADD, **(Social Scientist)**

6. Membership requirements:

a. The duration of membership will be five years. There will be no bar on the members serving for more than one term.
b. At the end of 5 years, the committee should be reconstituted, and one-third of the members will be replaced by a defined procedure (those who have had the longest standing in the IEC shall be phased out and new members taken in against the vacant posts).
c. A member can be replaced in the event of death or long-term non-availability or absence for consecutive four meetings or for any action not commensurate with the responsibilities laid down in guidelines deemed unfit for a member.
d. A member can tender resignation from the committee with proper reasons to do so.
e. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.
f. Conflict of interest should be declared by members of the IEC and take appropriate measures to rescue themselves from reviewing or decision making on protocols related to their COI.

7. Independent Consultants

IEC may call upon subject experts as consultants for review of selected research protocols. These experts may be specialists in ethical or legal aspects, specific disciplines, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. cancer patients, HIV/AIDS positive persons or ethnic minorities. The comments of an independent consultant (if applicable) could be presented by the Member Secretary or subject experts could be invited to offer their views, but they should not participate in the decision-making process. However, her/his opinion must be recorded. The EC may utilize electronic methods such as video/conference calls for connecting with other subject experts/independent consultants during the meeting.

8. Subcommittees

Institutions could have subcommittees such as the SAE subcommittee or expedited review committee. These should be part of the main committee and comprise Chairperson/ Member Secretary and one to two appropriate designated members of the main EC. These subcommittees can report to the concerned main EC.

Institutions could have separate committee for SAE in which one or two members of EC could be included to facilitate continuity of EC activity and its report should be reviewed by main EC.

9. Training

Members should be trained in human research protection, EC functions and SOPs and should be conversant with ICMR National ethical guidelines, GCP guidelines, and applicable regulations in India i.e. New Drugs and Clinical Trials Rules 2019 .

EC members should undergo initial and continuing training in human research protection, applicable EC SOPs and related regulatory requirements. All trainings should be documented.

Any change in the relevant guidelines or regulatory requirements should be brought to the attention of all EC members. EC members should be aware of local, social and cultural norms and emerging ethical issues.

10. Roles and Responsibilities of EC

1. EC will conduct scientific and ethical review of the research proposals, and can approve all types of research proposals with a view to safeguard the dignity, rights, safety and wellbeing of all actual and potential research participants. Human samples/material likely to affect human health will also come under the purview of the IEC.
2. Involving human to ensure protection of the dignity, rights, safety and well-being of the research participants.
3. The EC must ensure ethical conduct of research by the investigator team.
4. The EC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.
5. The EC should perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.
6. The EC must ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.
7. The EC should assist in the development and education of the research community in the given institute (including researchers, clinicians, students and others), responsive to local healthcare requirements.

8. Responsibilities of members should be clearly defined. The SOPs should be given to EC members at the time of their appointment.
9. The Secretariat should support the Member Secretary in all their functions and should be trained in documentation and filing procedures under confidentiality agreement.
10. The EC should ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.
11. The EC reviews progress reports, final reports and AE/SAE and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable.
12. The EC is responsible for reviewing the relatedness of the SAE to the research, as reported by the researcher, and determining the quantum and type of assistance to be provided to the participants and recommend appropriate compensation for research related injury, wherever required to the authority through SUGAM portal.
13. The EC should carry out monitoring visits at study sites as and when needed.
14. The EC should participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.
15. The EC may see that conduct of same/similar research by different investigators from same institution is harmonized. 'Me too' research (replicative) should not to be encouraged and submission of same research to different funding agencies should not be accepted
16. The EC should assess the inherent benefits and risks, ensure a favorable balance of benefits and risks, evaluate plans for minimizing the risk and discomfort and decide on the merit of the research before approving it.
17. The EC should also assess any altered risks in the study at the time of continuing review
18. ECs must review and approve the payments (in cash) and free services and the processes involved, and also determine that this does not amount to undue inducement. Travel expense to the participants to be fixed Rs. 500/-per visit.

11. Submission of the research proposals

a. The Ethics Committee receives eight hard copies for Drug/clinical Trials and five hard copies for other Research proposals along with one soft copy in CD/DVD or email from Principal Investigator (PI). Each project is required to be submitted by the PI with a covering letter to the Chairman, an Undertaking and duly filled ethics committee performa of ABVIMS & Dr. RML Hospital along with supporting documents. The PI is required to submit the project well in advance preferably at least two weeks before the meeting.
b. EC will charge a fee from Rs. 20000 from funded projects and Drug/Clinical Trial. This should be deposited in the account of Medical Superintendent Dr. RMLH. EC may allow waiver of this fee from the funded projects supported by government agencies and in other circumstances as deemed fit by EC. The funded projects will be

levied institutional overhead charge of 10% of the total budget of the research projects/clinical regulatory trials (as the case may be) when the project begins in ABVIMS & DR. RMLH. The PI shall give the reasons if this provision is not there in a project.

C. EC will not communicate with any CRO/sponsor.

12. Documentation

Researchers should submit research proposals as soft and hard copies to the Secretariat for review in the prescribed format and with the following documents. Incomplete applications would not be accepted

i. Cover letter to the Chairman, EC duly forwarded from the Head of the Department.
ii. Duly filled proforma for initial review with Title of the project, Names of the PI and Co-investigators with designation and Name of any other Institute/Hospital/Field area where research will be conducted.
iii. Protocol of the proposed research.
iv. Ethical issues in the study and plans to address these issues.
v. Proposal with all relevant annexure like Performa, case report forms, questionnaires, follow–up cards, etc. to be used in the study.
vi. The correct version of the informed consent document (ICD) & Patient information sheet in English and Hindi. Translation and back translation certificates (if applicable) as per ICMR guidelines/NDCT rules (simple and understandable to patients).
vii. For any drug/device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country/other countries, if available.
viii. Regulatory clearances from the relevant agencies required. Copy of clearances if obtained must be enclosed. This is necessary for new drug/device not approved for marketing in India, justification for sending of biological samples outside India and use of radioactive pharmaceuticals in clinical studies.
ix. Source of funding and Budget along with the supporting documents
x. Indemnity issues including insurance for the compensation to the participants etc.
xi. An undertaking to immediately report Serious Adverse Events (SAE) to IEC and SUGAM portal & Statement of conflicts of interest, if any. SUGAM Portal Registration of the trial.
xii. A valid project specific Insurance Policy(it is preferable to have the policy and not only the insurance certificate) for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)

xiii. Investigator's brochure (as applicable for drug/biological/device trials)
xiv. Details of funding agency/sponsor and fund allocation (if applicable)
xv. A statement on Conflict of Interest if any
xvi. GCP training certificate
xvii. Brief curriculum vitae of all the study researchers
xviii. Clinical trial agreement between the sponsors, investigator and the head of the institution(s) (if applicable)
xix. Relevant administrative approvals:- A separate approval/concurrence of the Director will also be obtained for administrative aspects of funded research projects before issuing the approval by IEC. However, ethical approval will be solely by IEC and will not require prior approval of the Director.

13. Processing of research projects and fixing of meeting:

1. The Member Secretary/Secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review, and full committee review. A researcher cannot decide that her/his proposal falls in the exempted, expedited or full review category. All research proposals must be submitted to the EC. The decision on the type of review required rests with the EC and will be decided on a case-to-case basis. Researchers can approach the EC with appropriate justification for the proposal to be considered as exempt, expedited or if waiver of consent is requested.
2. Expedited review can be conducted by Chairperson, Member Secretary and one or two designated members.
3. Approval granted through expedited review and the decisions of the SAE subcommittee must be ratified at the next full committee meeting.
4. A file is made for each project and allotted a number for future reference by the office staff of the EC. The Member Secretary then fixes a date for the EC meeting after consulting the chairperson.
5. After the date is fixed, the Member Secretary draws up the agenda of the meeting and then a circular is issued for the meeting.
6. EC members should be given enough time (at least 1 week) to review the proposal and related documents, except in the case of expedited review.
7. All EC members should review all proposals. However, the EC may adopt different procedures for review of proposals in accordance with their SOPs.

14. Conflict of Interest

A member will be required to withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises (e.g. if a member is PI or Co-PI) and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes. Any negative opinion should be recorded with reasons.

15. Full committee meeting

1. All proposals that are determined to undergo full committee review must be deliberated and the decision about the proposal taken at a full committee meeting.
2. ECs should conduct regular full committee meetings to deliberate proposals in accordance with a pre-decided schedule.
3. If a member has declared a COI for a proposal then this should be submitted in writing to the Chairperson before beginning the meeting and should be recorded in the minutes.
4. Proposals should be taken up item-wise, as given in the agenda.
5. Number of proposals reviewed in a meeting should justify that there is ample time devoted for review of each proposal. If there are more number of proposals for consideration per meeting either meetings may be more frequent or more EC's to be constituted as per requirement of the institution.
6. Time allotted for the meeting should be reasonable to allow ample discussion on each agenda item.
7. The minutes of the previous meeting and list of protocols that were exempt from review or underwent expedited review should be ratified.
8. The researcher may be called in to present a proposal or provide clarifications on the study protocol that has been submitted for review but should not be present at the time of decision making.
9. All members of the EC (including the Chairperson and the Member Secretary) present in the room have the right to vote/express their decision and should exercise this right.
10. The decision must be taken either by a broad consensus or majority vote and should be recorded. Any negative opinion should be recorded with reasons.
11. Approval may be granted for the entire duration of the proposed research or can be subject to annual review depending on the type of study. The EC should review the annual report (counted from the day of approval or date of actual start of the study) for continuation.
12. Depending on the risk involved, the progress of the proposal may be monitored annually or at shorter intervals (quarterly, half yearly) as per EC decision. Approval may be continued if progress is satisfactory.
13. An EC may decide to reverse its positive decision on a study if it receives information that may adversely affect the benefit-risk assessment.
14. The Member Secretary (assisted by the Secretariat) should record the discussions and prepare the minutes which should be circulated to all the members for comments before final approval by the Chairperson/Vice-Chairperson/designated member of the committee and Director.
15. The Committee either approves or rejects a project or may seek certain clarifications. The decision of the EC should be communicated to the researcher along with suggestions, if any by the Member Secretary
16. The researcher should have an opportunity to reply/clarify to EC comments or to discuss or present her/his stand.

17. The researcher can also approach the head of the institute who serves as an appellate for EC matters.
18. The head of the institute as appellate has the power to dissolve the EC or reappoint an EC.

16. Conduct of EC meeting

The Member Secretary fixes a date for the EC meeting after consulting the chairperson. After the date is fixed, the Member Secretary draws up the agenda of the meeting and then a circular is issued inviting all members for the meeting at the mentioned time, on the specified date at the fixed venue. A file is made for each new project and allotted a number for future reference by the office staff of the EC. The meeting circular and soft copy of all the research projects submitted are mailed to all the members of the EC and One hard copy is sent to the reviewing member at-least two weeks before the meeting.

17. Ethics Committee meeting

EC meeting is formally started by the member secretary after welcoming all the members.

18. Quorum Requirement

A minimum of five members present is taken as mandatory to start the meeting. The quorum should include both medical, non-medical or technical or/and non-technical members. Minimum one non-affiliated member should be part of the quorum. Preferably the lay person should be part of the quorum. No decision is valid without fulfilment of the quorum.

19. Elements of review

Types of review

S. No	Types of review	
1.	Exemption from review	Proposals with less than minimal risk where there are no linked identifiers, for example; • research conducted on data available in the public domain for systematic reviews or meta-analysis; • observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person; • quality control and quality assurance audits in the institution; • comparison of instructional techniques, curricula, or classroom management methods; • consumer acceptance studies related to taste and food quality; and • public health programmes by Govt agencies such as Programme evaluation where the sole purpose of the exercise

		is refinement and improvement of the programme or monitoring (where there are no individual identifiers).
2	Expedited review	Proposals that pose no more than minimal risk may undergo expedited review, for example; • research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples; • research involving clinical documentation materials that are non-identifiable (data, documents, records); • modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s); • revised proposals previously approved through expedited review,full review or continuing review of approved proposals; • minor deviations from originally approved research causing no risk or minimal risk; • progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and • for multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee. common review. • Research during emergencies and disasters
3	Full committee review	All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, some examples are; • research involving vulnerable populations, even if the risk is minimal; • research with minor increase over minimal risk • studies involving deception of participants • research proposals that have received exemption from review,or have under gone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee; • amendments of proposals/related documents (including but notlimited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk; • major deviations and violations in the protocol;

		• any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment; • research during emergencies and disasters either through an expedited review/scheduled or unscheduled full committee Meetings. This may be decided by Member Secretary depending on the urgency and need; • prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

20. Review of multicentric research

Multicentre research is conducted at more than one centre by different researchers usually following a common protocol. A large number of clinical trials, clinical studies and public health research including surveys are conducted at several research centres within the country or at international sites. Multicentric research studies are carried out with the primary aim of providing a sound basis for the subsequent generalization of its results. All sites are required to obtain approval from their respective ECs, which would consider the local needs and requirements of the populations being researched and safeguard the dignity, rights, safety and well-being of the participants. There are concerns, however, related to duplication of effort in the parallel review by the involved ECs, wastage of time and also those related to communication between the committees. Therefore, in multicentric studies using a common protocol, separate review by ECs of all participating site are done. The ECs/Secretariats of all participating sites should establish communication with one another. If any EC does not grant approval for a study at a site the reasons must be shared with other ECs and deliberated upon. The EC can suggest site-specific protocols and informed consent modifications as per local needs. Separate review may be requested for studies with a higher degree of risk, clinical trials or intervention studies where conduct may vary depending on the site or any other reason which requires closer review and attention.

21. Common review for all participating sites in multicentric research

- In order to save time, prevent duplication of effort and streamline the review process, the ECs can decide to have one designated main EC, the decisions of which may be acceptable to other ECs. This is especially important for research involving low or minimal risk, survey or multicentric studies using anonymized samples or data or those that are public health research studies determined to have low or minimal risk.
- The meeting of the designated main EC can be attended by nominated members of ECs of the participating centres to discuss their concerns, if any, about ethics or human rights and to seek solutions and communicate the decision of the main EC to their respective ECs.

- This EC should be located in India and registered with the relevant authority (if applicable).
- Meetings should be organized at the initial and, if required, intermediary stages of the study to ensure uniform procedures at all centres.
- The site ECs, however, retain their rights to review any additional site specific requirements, ensure need-based protection of participants or make changes in the informed consent document (ICD), translations and monitoring research as per local requirements.
- The protocol may be modified to suit local requirements and should be followed after it is duly approved by the EC of the host institutes/decision of main EC is accepted.
- Adherence to protocols, including measures to terminate the participation of the erring local centres, if required should be monitored.
- The common review is applicable only for ECs in India. In case of international collaboration for research and approval by a foreign institution, etc., the local participating sites would be required to obtain local ethical approval. Sponsor/funding agencies should be informed about any site-specific changes being made, and the modified version should only be used by the concerned site.
- Plans for manuscript publication and a common final report with contributors from the participating sites should be decided upon before initiation of the study.
- Site-specific data may be published only after the appropriate authorities accept the combined report and appropriate permissions are obtained.

22. Continuing review

1. Ongoing research should be reviewed at regular intervals, at least once a year, (or more often, if deemed necessary depending on the level of risk) or as may be specified in the communication letter at the time of according approval.
2. The EC should continually evaluate progress of ongoing proposals, validity of insurance, review SAE reports from all sites along with protocol deviations/violations and non-compliance, any new information pertaining to the research and assess final reports of all research activities.
3. Clinical trials under the preview of a licensing authority must comply with all regulations applicable to SAEs. The EC should also ensure compliance by the researcher. For academic and other trials, an institutional policy should be established.
4. The EC should examine the measures taken for medical management of SAEs. Participants should not have to bear costs for the management of study-related injury whether they are in the intervention arm or the control arm.
5. Compensation must be given for research-related injuries if applicable, as determined by the EC and as per regulatory requirement (if applicable).
6. For protocol deviations/violations the EC should examine the corrective actions. If the violations are serious the EC may halt the study. The EC may report to the

institutional head/government authorities where there is continuing non-compliance to ethical standards.

7. Reports of monitoring done by the sponsor and DSMB reports may also be sought.

23. Site monitoring

It is recommended that ECs should follow mechanisms described in a SOP to monitor the approved study site until completion of the research to check for compliance or improve the function. Monitoring can be routine or "for cause" and must be decided at a full committee meeting. For research that involves higher risk or vulnerable participants or if there is any other reason for concern, the EC at the time of initial review or continuing review can suggest that routine monitoring may be conducted at more frequent intervals. The following situations may justify "for cause" monitoring: high number of protocol violations/ deviations; large number of proposals carried out at the study site or by the same researcher; large number of SAE reports; high recruitment rate; complaints received from participants; any adverse media report; adverse information received from any other source; non-compliance with EC directions; misconduct by the researcher; and any other cause as decided by the EC.

24. Ethical Review Procedures:

a. Examination of predictable risks/harms to study subjects.
b. Examination of potential benefits.
c. Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.
d. Management of research related injuries, adverse events.
e. Compensation provisions.
f. Justification for placebo in control arm, if any.
g. Availability of products after the study, if applicable.
h. Patient information sheet and informed consent form in local language.
i. Protection of privacy and confidentiality.
j. Involvement of the community, wherever necessary.
k. Plans for data analysis and reporting
l. Adherence to all regulatory requirements and applicable guidelines
m. Competence of investigators, research and supporting staff
n. Facilities and infrastructure of study sites
o. Criteria for withdrawal of patients, suspending or terminating the study

For Public Health Research:

a. Are the objectives of the study scientifically sound and linked to the achievement of public health goals?
b. Is individual written informed consent required? If not,
    a. Is gatekeeper consent/permission sufficient? Who is a gatekeeper and how is this decided?
    b. Is it a two-stage process – initially a gatekeeper consent/permission followed by individual consent? The ECs must take decisions regarding consent on a case- by-case basis.

c. If applicable, is respect for the community applied through community engagement? If so, is the methodology appropriate?
d. Which segments of the population are likely beneficiaries and what are the expected benefits?
e. Is individual harm overriding the potentially larger societal benefit?
    a. If so, is it justified?
    b. What are the different types of potential harm?
    c. Who would be harmed?
    d. What, if any, measures can be taken to mitigate/minimize this?
    e. Is the harm fairly distributed?
    f. How do societal benefits outweigh individual harm?
f. Is social justice considered while designing, implementing and assessing outcomes of the study?
g. Research using administrative data does not violate any principle of public health research ethics.
h. The researcher has taken adequate measures for data security, confidentiality of information, disclosure permissions, and stated appropriate use of the accessed data.
i. To give appropriate importance to the social benefit, public good and public health impact these studies may be addressing. EC membership should include experts in public health or the EC should get comments from, or invite experts for, the relevant meeting.

j. ECs should consider the following while assessing a public health research: standards of care in public health; Public Health Research, ancillary care in public health; stakeholder engagement – identifying and defining stakeholders' roles especially in IR, health systems and policy research; and responsibility of the researcher to scale-up, advocate, promote uptake, or sustain the public health intervention.

25. Vulnerable population

- Ethics Committees during review, determine whether the prospective participants for a particular research are vulnerable.
- Examine whether inclusion/exclusion of the vulnerable population is justified.
- Ensure that COI do not increase harm or lessen benefits to the participants.
- Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible.
- Suggest additional safeguards, such as more frequent review and monitoring, including site visits.
- Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations.

ECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. ECs should ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD

26. Communicating the decision

a. Decision will be communicated by the Member Secretary in writing (by printed letter on paper or by email to the PI). In case of Research where the Principal Investigator (PI) happens to be the Member-Secretary of IEC, the decisions of IEC and other routine correspondence shall be signed/countersigned by the Chairperson IEC or a member designated for this purpose.

b. Suggestions for modifications, if any, will also be communicated by Member Secretary.

c. Reasons for rejection should be informed to the researchers.

d. The schedule / plan of ongoing review by the IEC should be communicated to the PI.

27. Follow up procedures

a. Reports should be submitted at prescribed intervals for review.

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

c. All SAEs and the interventions undertaken should be intimated to EC and

SUGAM portal.

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

e. Any amendment to the protocol should be resubmitted for renewed approval.

f. Any new information related to the study should be communicated by the PI

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

h. Change of investigators / sites should be informed.

28. Memorandum of Understanding and Indemnity Agreement for Sponsor Drug/Device/Collaborative Trials

After the approval from IEC, the sponsor/CRO shall submit the final clinical trial

Agreement(Tri-party)/Memorandum of Understanding and Indemnity Agreement document on Rs. 100 stamp paper separately (three copies) to the Institute which will be signed by sponsor, Principal Investigator and the Director, ABVIMS, Dr. RML Hospital, New Delhi.

A drug trial shall be started by the PI only after the agreement is signed by sponsor, Principal Investigator and the Director, Registration in SUGAM portal and mapping as well as approval of DCGI and other relevant regulatory approvals are in order.

29. Record keeping and Archiving

a. All documentation and communication of an EC should be dated, filed and preserved according to written procedures

b. Confidentiality should be maintained during access and retrieval procedures by designated persons.

c. All active and inactive (closed) files should be appropriately labelled and archived separately in designated areas.

d. Records can be maintained in hard copies as well as soft copies.

e. All records(Copy of all study protocols with enclosed documents, progress reports, and SAEs, Final report of the approved projects) must be archived for a period of at least 3 years after the completion/ termination of the study.

f. Documents related to regulatory clinical trials must be archived for 5 years after the completion/termination of the study or as per regulations.

g. Records may be archived for a longer period, if required by the sponsors/regulatory bodies.

h. ECs may adopt methods for electronic storage of records wherever feasible.

30. Administrative documents to be maintained by EC for record

Administrative documents	• Constitution and composition of the EC

	• Appointment letters • Signed and dated copies of the most recent curriculum vitae of all EC members • Signed confidentiality agreements • COI declarations of members • Training records of EC members • Financial records of EC • Registration/accreditation documents, as required • A copy of national and international guidelines and applicable regulations • Regulatory notifications • Meeting-related documents • Agenda and minutes • All communications received or made by the EC • SOPs
Proposal-related documents	• One hard copyand a soft copy of the initial research proposal and all related documents • Decision letters • Any amendments submitted for review and approval • Regulatory approvals • SAE, AE reports • Protocol deviations/violations • Progress reports, continuing review activities, site monitoring reports • All correspondence between the EC and researcher • Record of notification issued for premature termination of a study with a summary of the reasons • Final report of the study • Publications, if any

31. **Privacy and confidentiality**

- Privacy is the right of an individual to control or influence the information that can be collected and stored and by whom and to whom that information may be disclosed or shared. Confidentiality is the obligation of the researcher/research team/organization to the participant to safeguard the entrusted information. It includes the obligation to protect information from unauthorized access, use, disclosure, modification, loss or theft.
- The researcher should safeguard the confidentiality of research related data of participants and the community.
- Potential limitations to ensure strict confidentiality must be explained to the participant. Researchers must inform prospective participants that although every

effort will be made to protect privacy and ensure confidentiality, it may not be possible to do so under certain circumstances.

- Any publication arising out of research should uphold the privacy of the individuals by ensuring that photographs or other information that may reveal the individual's identity are not published. A specific re-consent would be required for publication, if this was not previously obtained.
- Some information may be sensitive and should be protected to avoid stigmatization and/or discrimination (for example, HIV status; sexual orientation such as lesbian, gay, bisexual, and transgender (LGBT); genetic information; or any other sensitive information).
- While conducting research with stored biological samples or medical records/data, coding or anonymization of personal information is important and access to both samples and records should be limited.
- Data of individual participants/community may be disclosed in certain circumstances with the permission of the EC such as specific orders of a court of law, threat to a person's or community's life, public health risk that would supersede personal rights to privacy, serious adverse events (SAEs) that are required to be communicated to an appropriate regulatory authority etc.

The IEC functions in accordance with the the **GCP-CDSCO/New Drugs and Clinical Trial rules 2019/ICMR guidelines (latest amendments).** The Institutional Ethics Committee, Atal Bihari Vajpayee Institute of Medical Sciences, New Delhi-110001, is registered by the DCGI and also by Department of Health Research. IEC shall follow all the provisions in ICMR Ethical Guidelines 2017 as not everything can be included in these SOPs. These ICMR guidelines will be followed for anything not included in these SOPs. This has also been mandated by the New Drug and Clinical Trials Rules, 2019.

The Institutional Ethics committee expects to be informed about the progress of the study, any SAE occurring in the course of study, any changes in the protocol and patient information/Informed Consent form and asks to be provided a copy of the final report.

32. **Validity of the IEC SOPs**

The SOPs enlisted above shall remain in force for a period of five years. However, these may be amended/updated from time to time by the IEC and same shall be archived appropriately. These SOPs have been approved by the Director & Medical Superintendent, Atal Bihari Vajpayee Institute of Medical Sciences and Dr. Ram Manohar Lohia Hospital, New Delhi

(Dr. Aanchal Kakkar)
Member Secretary
Dated 16-02-2022

(Dr. Arun Kumar Aggarwal)
Chairman

Patient Information Sheet

You are being invited to take part in a study ("Title of the study")

This study is being conducted at Department of ..... , Atal Behari Vajpaye Institute of Medical Sciences (ABVIMS) and Dr Ram Manohar Lohia Hospital, New Delhi.

Before you decide to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information.

PURPOSE OF THE STUDY

PROCEDURE OR DESCRIPTION

DO I HAVE TO TAKE PART?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part you are still have the right to not be in the study or to stop at any time. Your decision will not adversely affect your care of cause a loss of benefit to which you might otherwise be entitled.

BENEFITS OF PARTICIPATION: You will receive no direct benefit for participating in this research project although your contribution will help the health professionals in the assessment task and bring about improvements in healthcare.

RISKS OF PARTICIPATION: There are no foreseen risks or discomfort involved OR There is minimal risk involved in this study.

CONFIDENTIALITY: If you consent to take part in the research any information collected will be held in confidence. Data collected in paper will be held securely and will only be accessed by authorized researchers working in the study. All electronic data will be stored on secure computers. The anonymised results of the study will be published in scientific or medical journals and presented at conferences. Your name will not be identified in the publications in any way.

CONTACT: In the event that at any time during the study period you feel that youhave not been adequately informed, please feel free to contact the investigator.

(Name, Department & Contact Number of Investigator and supervisor)

2. **Format of informed consent form for Subjects participating in a clinical trial**

Informed Consent form to participate in a clinical trial

Study Title: Study Number: Please initial box (Subject) 536 Drugs and Cosmetics Rules, 1945 Subject's Initials: ~ __ Subject's Name: _ Date of Birth I Age: _

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

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

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

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) Signature (or Representative: ------ Thumb impression) of the Subject/Legally Acceptable

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

Date: _~/_~/ __ Signatory's Name: _ Signature of the Investigator: _

Date: __ I__ I _ Name of the Witness: --------~----------Signature of the Witness _

1. PATIENT/PARTICIPANT INFORMATION SHEET

1.1 Essential Elements:

1. Statement that the study involves research and explanation of the **purpose** of the research

2. Expected **duration** of the Subject's participation

3. Description of the **procedures** to be followed, including all invasive procedures and

4. Description of any reasonably foreseeable **risks** or discomforts to the Subject

5. Description of any **benefits** to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.

6. Disclosure of specific appropriate **alternative procedures** or therapies available to the Subject.

7. Statement describing the extent to which **confidentiality of records** identifying the Subject will be maintained and who will have access to Subject's medical records.

8. Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)

9. Compensation and/or treatment(s) available to the Subject in the event of a trial related injury

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

11. The anticipated prorated payment, if any, to the Subject for participating in the trial

12. Subject's responsibilities on participation in the trial

13. 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.

14. Any other pertinent information

1.2 Additional elements, which may be required

(a) Statement of foreseeable circumstances under which the Subject's participation may be terminated by the Investigator without the Subject's 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 termination of participation by Subject.

(d) 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.

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

(f) Approximate number of Subjects enrolled in the study