ECR/1644/VELS/Indt/TN/2017/Re-Registration-2021

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
VISTAS-SPS-IEC
School of Pharmaceutical Sciences, VISTAS,
Velan Nagar, P V Vaithyalingam Road Pallavaram,
Chennai, Kanchipuram, Tamil Nadu – 600117, India.

20 JAN 2023

Subject: Ethics Committee Registration No. **ECR/288/Indt/TN/2018/RR-21,** amendment to the composition of the Ethics Committee–regarding.

Sir/Madam,

Please refer to your application dated 07.01.2023 submitted to this Directorate vide no. P-2972148 dated 12.01.2023 for change in composition of the Re-Registered Ethics Committee.

Based on the documents submitted by you, the composition of your Ethics Committee bearing Registration number **ECR/288/Indt/TN/2018/RR-21** dated **01.06.2021** valid until **31.05.2026** 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 also 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.	Dr. Melvin George	MBBS, MD (Pharmacology)	Chairperson
2.	Dr. A. Vijayalakshmi	M.Pharm (Pharmacognosy), PhD	Member Secretary
3.	Dr. Naresh Kumar Krishnamurthy	MBBS, MS (Ortho)	Clinician
4.	Dr. Deepa Gurunathan	MDS, PhD	Clinician
5.	Dr. A. Maduram	MBBS, MD (Pharmacology)	Medical Scientist
6.	Mrs. Selin Semila Rani	MA (English)	Lay Person
7.	Dr. Dilshad Shaik	LLM, PhD	Legal Expert
8.	Dr. V. Karthikeyan	LLM	Legal Expert
9.	Mr. Bijukumar K Gopinathan	BBA, Hons. Doctorate in Social Work	Social Scientist
10.	Dr. Paul Ravikumar B	MTh, DD.	Social Scientist
11.	Dr. C. Ronald Darwin	M.Pharm (Pharmacology), PhD	Scientific Member

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12.	Dr. A. Kathiresan	M.Sc (Microbiology), PhD	Scientific Member
13.	Dr. B. Prem Kumar	M.Pharm (Pharmacology), PhD	Scientific Member
14.	Dr. R.J. Hemalatha	ME (Biomedical), PhD	Scientific Member

Yours faithfully

(Dr. V. G. Somani)
Central Licensing Authority

VISTAS SPS

Ethics Committee

Standard Operating Procedures –Human Studies

Standard Operating Procedures for Institute Ethics Committee, School of Pharmaceutical Sciences

Vels Institute of Science Technology and Advanced Studies (VISTAS)

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SPS-VISTAS IEC

I. Description of SOP

The following may be called as "Standard Operating Procedures for the Institutional ethics committee (IEC) of Vels Institute of Science Technology and Advanced Studies". Vels Institute of Science Technology and Advanced Studies herein after referred to as "VISTAS SPS" has adopted this written Standard Operating Procedures (SOP) to ensure the protection of the rights and welfare of human participants in biomedical, experimental and behavioral research conducted at VISTAS SPS.

II. Objectives of SOP

The objective of this Standard Operating Procedures of the Institutional ethics committee (IEC) of Vels Institute of Science Technology and Advanced Studies is to maintain effective functioning of the VISTAS SPS-IEC and to ensure quality and technical excellence and consistent ethical review of all the submitted health and biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human subjects.

III. Authority for constituting the VISTAS SPSIEC

The Director, School of Pharmaceutical Sciences, VISTAS, Vels University will appoint the Chairperson and all the committee members based on their competence, experience and integrity by sending an official request letter. Members will confirm their acceptance to the Director, VISTAS SPS by providing all the required information for membership. The Chairperson will furnish any information or report to the Director, VISTAS SPS when required.

Address of the IEC

School of Pharmaceutical Sciences
Vels Institute of Science Technology and Advanced Studies (VISTAS)
Velan Nagar, P.V.Vaithiyalingam Road,
Pallavaram, Chennai- 600117.

IV. Role and Responsibilities of VISTAS SPS IEC

The VISTAS SPS-IEC will review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of all actual and potential research participants before approving the research proposals. The goals of research, however important, should never be permitted to override the health and wellbeing of the human participants.

The VISTAS SPS-IEC will ascertain whether all the cardinal principles of research ethics viz., *Autonomy, Beneficence, Non – malfeasance, Respect for Free and Informed Consent, Respect for Human Dignity, Respect for Vulnerable Persons , Respect for Privacy and Confidentiality and Justice* are taken care of in planning, conducting and reporting of the proposed research. For this purpose, it will look into the aspects of *protocol review, selection of participants, voluntary participation of potential participants, informed consent process, risk benefit ratio, distribution of burden and benefit, maintenance of privacy and confidentiality and provisions for appropriate compensations*. It will review the proposals before the commencement of the study as well as review periodically until the completion of the study through appropriate well documented procedures. Such a review may be based on the periodic study progress reports furnished by the investigators and/or monitoring and internal audit reports furnished by the Sponsor and /or by visiting the study sites.

The mandate of the IEC shall be to review all research projects to be conducted at the Institution involving human beings directly or indirectly, irrespective of whether the research project is funded or non-funded, and if funded, then irrespective of the funding agency.

VISTAS SPS IEC will provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research.

In case VISTAS SPS IEC revokes its approval accorded to a trial protocol, it will record the reasons for doing so and at once communicate such a decision to the Investigator as well as to the Licensing Authority.

In case of serious adverse event or death occurring to the clinical trial participant, the VISTAS SPS IEC shall forward it's report on the serious adverse event or death, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to the Chairman of the Expert committee constituted by the Licensing authority under Appendix XII (gazette notification 30th January 2013) with a copy of the report to the Licensing Authority within twenty one calendar days of the occurrence of the serious adverse event of death. In case of serious adverse event, other than death occurring to the clinical trial subject, the VISTAS SPS IEC shall forward it's report on the serious adverse event after due analysis along with its opinion on the financial compensation, if any, to be paid by the sponsor of his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, to the licensing authority within twenty one calendar days of the occurrence of the serious adverse event.

V. Composition of VISTAS SPS-IEC

VISTAS SPS-IEC will be a multidisciplinary and multi sectorial body in composition and independent. The number of members of the Review Board may range from 7 to 15.

The chairperson of the IEC will be from outside the Institution to maintain the independence of the Committee. The Member Secretary will belong to the same Institution and will conduct the business of the Committee. Other members will be a mix of medical / non-medical, legal, scientific and non- scientific persons and may also include members of public to reflect the different points of view.

There will be representation of age and gender in the Committee to safeguard the interest and welfare of all sections of the society. Member should be aware of local, social and cultural norms, as this is an important social control mechanism. IEC may

invite subject experts to take their views, whenever it is needed.

The VISTAS SPS-IEC will include

1. Chairperson –from outside the institute
2. One or more persons from basic medical science area (Preferably pharmacologist)
3. One or more clinicians
4. One legal expert or retired judge
5. One social scientist/ representative of non-governmental voluntary organization/agency
6. One philosopher/ ethicist/theologian
7. One layperson (non-medical background) from the community
8. Member Secretary – from within the institute

VI. Requirements for IEC Membership

1. All members will serve for a period of 3 years on renewable basis. New members will be Included in the IEC in such a way that there will be a mix of recently included members and members with some years of experience.
2. During the term, Director, SPS VISTAS in consultation with the Chairman can disqualify any member if, the contribution is not adequate and/or there is long period of non-availability.
3. A member can tender resignation of his office of membership from the IEC to the Director SPS VISTAS, through the Chairperson after serving on a month advance notice.
4. Director SPS VISTAS can replace the member of IEC as and when required.
5. Each member is required to sign the declaration and confidentiality agreement regarding IEC activities
6. Conflict of interest should be declared by members of the VISTAS SPS-IEC prior to review meeting . (Annexure 8)

VII. Quorum requirements

Minimum of 50% of committee strength and not less than 6 members are required to constitute the quorum for the meeting of which at least one member has to be from outside the institution, and one member will be a non-scientific member & one from opposite gender. All decisions will be taken in meetings and not by circulation of

project proposals. Quorum will have 6 members with following representations:

(a) Basic medical scientists (preferably one pharmacologist).
(b) Clinician
(c) Legal expert
(d) Social scientist / representative of non-governmental voluntary agency / philosopher / ethicist / theologian or a similar person
(e) Lay person from the community.

Details of the supporting staff

Clerk – Mrs. Lakshmi, Assistant, School of Pharmaceutical Sciences, VISTAS, Pallavaram, Chennai

Data Entry Operator – Mrs. Uma, Assistant, School of Pharmaceutical Sciences, VISTAS, Pallavaram, Chennai

VIII. Removal & Resignation of Members

a) Any members with valid reasons may submit a letter of resignation to the Director SPS, VISTAS through the Chairman VISTAS SPS IEC with a minimum notice period of 15 days
b) Resignation of Chairman can be through a letter of resignation to the Director SPS VISTAS through the member secretary VISTAS SPS IEC
c) The Director SPS VISTAS may remove any member from the Ethics Committee at any point of time if he feels that there is no lack of contribution in the ethics committee
d) On recommendation of the member secretary VISTAS SPS IEC the Director may include any member to the IEC for proper regulation of IEC

RENEWAL AND REPLACEMENT OF MEMBERS

- ✓ The tenure of appointment is for 3 years
- ✓ Around 50% of members will be replaced with new members every 3 years
- ✓ The remaining members will be retained based on their performance

IX. Conduct of VISTAS SPS IEC meetings

The Chairperson will conduct all meetings of the VISTAS SPS IEC. In the absence of the Chairperson an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary is responsible

for organizing the meetings, maintaining the records and communicating with all concerned. She/he will prepare the minutes of the meetings and get it approved by the Chairperson and all the members.

An IEC Member may serve as a research guide for the projects of PG students/Research Scholars. In such case that person will abstain from voting and suggestion of opinions in the corresponding meeting. The member, in the aforementioned case will attend the meeting only as a Co-investigator (of that particular study) and will not take part in the decision making processes. In similar case, if the research guide happens to be the Member Secretary, then he/she shall abstain from the proceedings of the meeting and an interim Member Secretary will be selected from the available quorum in the discretion of the Chairman, VISTAS SPS IEC and the Director, SPS VISTAS.

X. Independent consultants

The VISTAS SPS IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. cancer patients, HIV/AIDS positive persons or ethnic minorities. They will be required to give their specialized views but should not take part in the decision making process which will be made by the members of the VISTAS SPSIEC.

XI. Application procedures

a. All proposals should be submitted on any working day three ***weeks in advance*** ***of*** scheduled meeting in the prescribed application form, the details of which are given under "XII Documentation". The applicant may ask for copy of SOP from the IEC, if the same has not been circulated earlier or not available on the website.

b. All relevant documents should be enclosed with application form. (Documents will be available with Member - Secretary, VISTAS SPS IEC and Institutional Websitewww.velsuniv.ac.in).

c. Required number of copies of the proposal along with the application and

documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators/Research Scholars shall be guided to the Chairperson VISTAS SPS IEC, through member secretary. In his absence via any person nominated by Chairperson, receipt of the application will be acknowledged by the IEC office.

d. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the PI to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members.

e. The decision of the committee on the proposal will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

XII. Documentation

All Research proposals (6 copies) shall be submitted along with the information and documents as specified in Annexure-2-4

XIII. Review procedures

a. The meeting of the IEC will be held on periodic intervals, i.e. every 3 months, unless otherwise specified by the member secretary. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the workload. The Director, VISTAS SPS may call in for a meeting any time depending on the workload.
b. TheproposalsshouldbesenttotheIECatleast10 days in advance of scheduled meeting.
c. The IEC's member-secretary or 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 review* (as described below).
d. Decisions will be taken by consensus after discussion, and whenever needed voting will be done. Decision of chairperson will be final.

e. Researchers will be invited to offer clarifications if need be. The PI/ Research Scholar will then present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co-PI will present the proposal.

f. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.

g. The decisions will be noted in minutes and Chairperson's approval taken in writing.

Exemption from review

Proposals which present *less than minimal risk* fall under this category as may be seen in following situations:

Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

1. Exceptions:

1. When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psycho-social harm.
2. When interviews involve direct approach or access to private papers.

2. Expedited Review

The proposals presenting *no more than minimal risk* to research participants may be subjected to expedited review. The Member- Secretary and the Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC may do expedited review only if the protocols involve -

1. Minor deviations from originally approved research during the period of approval.
2. Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
3. Research activities that involve only procedures listed in one or more of the following categories:
   - Clinical studies of drugs and medical devices only when -

1. Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or
2. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.

4. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
5. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and **the same participants should not be included** in the clinical trial that may be initiated later based on the findings of the pilot study.

a. Research on interventions in emergency situation

When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND) / devices / vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients-

i. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/ legal guardian when available later;

ii. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI;

iii. Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.

iv. If Data Safety Monitoring Board (DSMB) is constituted to review the data;

b. Research on disaster management

A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or

state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

i. Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.
ii. Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.
iii. Extra care must be taken to protect the privacy and confidentiality of participant's and communities.
iv. Protection must be ensured so that only minimal additional risk is imposed.
v. The research undertaken should provide direct or indirect benefits to the participants, the disaster- affected community or future disaster- affected population and a priori agreement should be reached on this, whenever possible, between the community and the researcher.
vi. All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.
vii. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

6. Expedited review may also be taken up for nationally relevant proposals requiring urgent review.

3. Full Review

All research presenting with *more than minimal risk*, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members.

While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

a. Collection of blood samples by finger prick, heel prick, ear prick, or vein puncture:

i. From healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8 week period and frequency of collection is not more than 2 times per week;

ii. From other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8 week period and not more than 2 times per week.

iii. From neonates depending on the hemodynamic, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 – 72 hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion;

iv. Prospective collection of biological specimens for research purposes by noninvasive means. For instance:

1. Skin appendages like hair and nail clippings in a non-disfiguring manner;
2. Dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;
3. Excreta and external secretions (including sweat);
4. Uncannulated saliva collected either in an unstipulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue;
5. Placenta removed at the delivery;
6. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
7. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
8. Sputum collected after saline mist nebulization and bronchialla vages.

b. Collection of data through noninvasive procedures routinely employed in clinical practice. Where medical devices are employed, they must be cleared/

approved for marketing, for instance

i. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;
ii. Weighing or testing sensory acuity;
iii. Magnetic resonance imaging;
iv. Electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electro retino graphy, ultrasound, diagnostic infrared imaging, Doppler blood flow,
v. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

c. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.
d. Collection of data from voice, video, digital, or image recordings made for research purposes.
e. Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

XIV. Aspects considered during review of research proposal

a. Scientific design and conduct of the study.
b. Approvalbyappropriatescientificreviewcommittees/Researchcommittee, if any.
c. Examination of predictable risks/harms
d. Examination of potential benefits.
e. Procedure for selection of subjects including inclusion / exclusion, withdrawal criteria and other issues like advertisement details.
f. Management of research related injuries, adverse events.
g. Compensation provisions.
h. Justification for placebo in control arm, if any
i. Availability of products, benefits to subjects after the study is completed if applicable.
j. Patient information sheet, informed consent form in English and in local languages.

k. Protection of privacy and confidentiality.
l. Involvement of the community, wherever necessary
m. Plans for data analysis and reporting.
n. Adherence to all regulatory requirements and applicable guidelines.
o. Competence of investigators, research and supporting staff.
p. Facilities and infrastructure of study sites.
q. Criteria for withdrawal of patients, suspension or premature termination of a study in VISTAS SPS.

XV. Decision-making

a. Members will discuss the various issues before arriving at a consensus decision. When consensus is not arrived at, the decision will be made by voting procedure.
b. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
c. Decision will be made only in meetings where quorum is complete.
d. Only the members can make the decisions. The expert consultants will only offer their opinions.
e. Decision may be to approve, reject or revise the proposals. Specific *suggestions for modifications and reasons for modifications and reasons for rejection* will be given.
f. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.
g. *Modifiedproposalswillbereviewedbyanexpeditedreview*throughidentifiedmembers.
h. Procedures for appeal by the researchers will be clearly defined.

XVI. Communicating the decision

a. Decision of the meeting on the proposals will be communicated by the Member Secretary /secretariat in writing to the PI / Research Scholar within two weeks after the meeting at which the decision was taken in the specified format. All the approvals will be valid for one year or for the duration of the project whichever is

less. Investigator has to get his or her project re- approved after one year, where required.

b. The communication of the decision will include:
    a. Name and address of IEC.
    b. The date, place and time of decision.
    c. The name and designation of the applicant.
    d. Title of the research proposal reviewed.
    e. The clear identification of protocol no., version no., date, amendment no., date.
    f. Along with protocol, other documents reviewed- Clear description of these documents along with Version No. and Date.
    g. List of EC members who attended the meeting- clear description of their role, affiliation and gender.
    h. A clear statement of decision reached.
    i. Any advice by the IEC to the applicant including the schedule / plan of ongoing review by the AIIMS IEC
    j. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.
    k. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.
    l. Signature of the member secretary with date.

XVII. Following up procedures for approved proposals by PI /Sponsor

a. IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.

b. Progress of all the research proposals will be followed at a regular interval of at least once a year. But in special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.

c. Periodic status report of study should be submitted at prescribed intervals for review, along with information and documents as specified in Annexure-5, 6& 7 based on the safety concerns and this prescribed interval should be specified in the Letter of Communication of Decision to the PI from the IEC.

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

e. Followinginstancesandeventswillrequirethefollow-upreview/RenewedApproval:
    a. Any protocol amendment likely to affect rights, safety or well-being of research subject of conduct of study.
    b. Serious or unexpected ADR related to study or product, action taken by Investigator, Sponsor and Regulatory Authority.
    c. Any event or information that may affect the benefit/risk ratio of the study.
f. Protocol deviation, if any, should be informed with adequate justifications.
g. Any new information related to the study should be communicated.
h. Premature termination of study shall be notified with reasons along with summary of the data obtained so far.
i. Change of investigators/sites must be informed to the office of IEC.
j. Monitoring: Oversight mechanism will be in place to monitor the approved studies. Actual site visits can be made especially in the event of reporting of adverse events or violations of human rights and appropriate action will be taken when required and communicated to the applicant indicating modification/suspension/termination /continuation of the project. In case the IEC desires so, reports of monitoring done by the sponsor and the recommendations of the DSMB may also be sought.
k. Applicant must inform the time of completion of study and must send the result summary to IEC. IEC must receive a copy of final summary of study completed from the applicant.

XVIII. Responsibilities of Sponsor/Investigator

Responsibilities of Sponsor

(i) The clinical trial Sponsor is responsible for implementing and maintaining quality assurance systems to ensure that the clinical trial is conducted and data generated, documented and reported incompliance with the protocol and Good Clinical Practice (GCP) Guidelines issued by the Central Drugs Standard Control Organization, Directorate General of Health Services, Government of India as well as with all applicable statutory provisions. Standard operating procedures should be documented to ensure compliance with GCP and applicable regulations.

(ii) Sponsors are required to submit a status report on the clinical trial to the

Licensing Authority at the prescribed periodicity.

(iii) In case of studies prematurely discontinued for any reason including lack of commercial interest in pursuing the new drug application, a summary report should be submitted within 3 months. The summary report should provide a brief description of the study, the number of patients exposed to the drug, dose and duration of exposure, details of adverse drug reactions (Annexure 8), if any, and the reason for discontinuation of the study or non-pursuit of the new drug application;

(iv) Any report of serious adverse event of death occurring in clinical trial, after due analysis shall be forwarded by the sponsor to chairman of the ethics committee and chairman of the expert committee constituted by the licensing authority as defined under rule 21(b) under appendix XII of gazette notification dated 30th January 2013 with a copy of the report to the Licensing authority and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of serious adverse event of death. The report of the serious adverse event other than death, after due analysis, shall be forwarded by the sponsor to the Licensing authority, Chairman of the Ethics Committee and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event. (See Annexure7).

(v) In case of injury or death occurring to the clinical trial subject, the sponsor (whether a pharmaceutical company or an Institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in Appendix XII of gazette notification dated 30th January 2013.

(vi) The sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall submit details of compensation provided or paid for clinical trial related injury or death, to the Licensing Authority within thirty days of the receipt of the order of the Licensing Authority.

Responsibilities of the Investigator(s)

(i) The Investigator(s) shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines and also for compliance as per the undertaking given in Appendix VII of schedule Y. Standard operating procedures are required to be documented by the investigators for the tasks performed by them. During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events. Investigator(s) shall report all serious and unexpected adverse events to the Licensing Authority defined under clause (B) of rule 21 (Schedule Y and Gazette notification 30th January 2013), the sponsor or his representative, whosoever had obtained permission from the licensing authority for conduct of the clinical trial, and the ethics committee that accorded approval to the study protocol, within twenty four hours of their occurrence. The report of the serious adverse event of death, after due analysis shall be forwarded by the investigator to Chairman of the ethics committee and Chairman of the Expert Committee constituted by the Licensing authority under Appendix XII with a copy of the report to the Licensing Authority and the head of the institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event of death. The report of the serious adverse event other than death, after due analysis shall be forwarded to the Licensing Authority, Chairman of the Ethics Committee and the Head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.

(ii) The investigator shall provide information to the clinical trial subject through informed consent process as provided in Appendix V of Schedule Y about the essential elements of the clinical trial and the subject's right to claim compensation in case of trial related injury or death. He shall also inform the subject or His/ Her nominee(s) of their rights to contact the sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial for the purpose of making claims in the case of trial related injury or death.

XIX. Record keeping and archiving at the office of VISTAS SPSIEC

a. All the documents and communications of IEC will be dated, filed and archived in a secure place.
b. Only the member secretary or persons, who are authorized by the Chairman of IEC will have the access to the various documents.
c. All the documents related to research proposals will be archived for a **minimum period of 5 years** in the Institute, following the completion/termination of the study.
d. No document (except agenda) will be retained by any IEC member.
e. At the end of each meeting, every member must return all the Research proposals and documents to IEC office staff. They will archive one copy in IEC office and other copies will be destroyed after one year.
f. Following documents will be filed and archived with proper label on the top of file for easy identification
    a. Constitution and composition of VISTAS SPS IEC
    b. Curriculum Vitae (CV) of all members of VISTAS SPS IEC with records of training in Human ethics if any.
    c. Standard Operating Procedures of VISTAS SPS IEC.
    d. Annual reports
    e. A record of all income and expenses of the EC, including allowances and reimbursements made to the secretariat and EC members;
    f. The published guidelines for submission established by the EC.
    g. Copy of all study protocols with enclosed documents, progress reports and SAEs.
    h. Agendas and Minutes of all IEC meetings duly signed by the Chairperson / Member secretary.
    i. Copy of all existing relevant national and international guidelines on ethics and laws along with amendments.
    j. Copy of all correspondence with members, Principal Investigators and other regulatory bodies.
    k. Record of all notification issued for premature termination of a study with a summary of the reasons;
    l. Final report of the approved projects, including microfilms, and Video

XX. Updating VISTAS SPS IEC members

a. All relevant new guidelines should be brought to the attention of the members.
b. The IEC members should be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body/ bodies, so that they become aware of their role and responsibilities. For drug trial review it is preferable to train the IEC members in Good Clinical Practice. Any change in the regulatory requirements should be brought to their attention and they should be aware of local, social and cultural norms, as this is the most important social control mechanism. This is needed for maintaining quality in ethical review

XXI. Terms of reference

Terms of reference will be maintained in the office of VISTAS SPS IEC. This includes

A. Membership Requirements
B. Terms of Appointment with reference to the duration of the term,
C. The policy for removal, replacement, resignation procedure,
D. Frequency of meetings, and

The SOPs will be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage of members could be changed on regular basis. Preferably, IEC would appoint persons trained in bioethics or persons conversant with ethical guidelines and laws of the country. Substitute member may be nominated if meetings have been continuously missed by a member due to illness or other unfore seen circumstances.

XXII. Administration and Management

A full time secretariat and space for keeping records is required for a well-functioning IEC. The members could be given a reasonable compensation for the time spared for reviewing the proposals.

XXIII. Special Considerations / Protection of Vulnerable Population

While all the above requirements are applicable to biomedical research as a whole irrespective of the specialty of research, there are certain specific concerns pertaining to specialized areas of research which require additional safe guards / protection and specific considerations for the IEC to take note of. Examples of such instances are research involving children, pregnant and lactating women, vulnerable participants and those with diminished autonomy besides issues pertaining to commercialization of research and international collaboration. The observations and suggestions of IEC will be given in writing in unambiguous terms in such instances. ICMR guidelines as applicable will be followed for protection of vulnerable population.

XXIV. Training of Members

It is the responsibility of the IEC Chairperson with the assistance of Member Secretary to ensure that there is adequate initial and continued training of the IEC members and the Secretariat. The Chairperson is responsible for assessment of all IEC members and completes a self-assessment exercise at prescribed intervals.

IEC members should have knowledge of the following:

- ✓ Relevant research ethics and regulatory guidelines
- ✓ Roles and Responsibilities of IEC members
- ✓ Review of protocol and related documents, including concepts of Risk Benefit assessment, Equity in recruitment, Autonomy, Confidentiality and Privacy
- ✓ Recent Developments in relevant health science specialties
- ✓ SOPs of the IEC

Every time a new committee is constituted, the members must undergo initial training on ethics in clinical research and good clinical research and SOPs. One training every year at the minimum should be provided.

The IEC Member Secretary, member, Chairperson will be encouraged to receive continued training by participating in a workshop, conference and/ or retraining program related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year.

The IEC will conduct workshops on ethics in clinical research and good clinical research practices from time to time to impart training to the IEC Members to the

Institutional faculty members.

The IEC may sponsor or reimburse the expenses of an IEC member or prospective members for attending conference, continuing education session workshop and/ or training program (if applicable).

Annexure 1

IEC MEMBERS LIST

S.No	Name of the Member	Qualification	Role/Designation in Ethics Committee	Institution
1	Dr. Melvin George	MBBS., MD (Pharmacology)	Chair Person	Professor, Dept of Clinical Pharmacology, SRM MCH &RC, Kattankulathur, Chengalpet. Nodal officer, ICMR Centre for Clinical Trials, SRM MCH &RC
2	Dr.A. Maduram	MBBS., MD (Pharmacology	Medical Scientist	Professor& Head in Shri Sathya Sai Medical College and Research Institute Tiruporur-Guduvancherry Main Road, Ammapettai, Chengalpet Taluk, Kancheepuram District, Nellikuppam, Tamil Nadu 603108
3	Dr. Naresh kumar Krishnamurthy	MBBS., MS (Ortho)	Clinician	Clinical Lead in Orthopedics & Director of Trauma & Emergency Medicine, St.Isabel's Hospital, Mylapore, Chennai
4	Dr. Deepa Gurunathan	MDS., Ph.D.	Clinician	Professor and Head(Admin) Department of Pediatric and Preventive Dentistry Saveetha Dental College and Hospital, Chennai 77
5	Dr. Dilshad Shaik	LLM., Ph.D.	Legal Expert (External)	Dean School of law Sathyabama University
6	Dr. V. Karthikeyan	LLM	Legal Expert (Internal)	School of Law, VISTAS
7	Dr. B. Prem Kumar	M.Pharm., Ph.D.	Scientific Member (External)	Head, Dept. of Pharmacology, KK College of Pharmacy
8	Dr. C. Ronald Darwin	M.Pharm., Ph.D.	Scientific Member (Internal)	Head, Dept. of Pharmacology, School of Pharmaceutical Sciences, VISTAS
9	Dr.A. Kathiresan	M.Sc., Ph.D.	Scientific Member (Internal)	Head, Dept. of Microbiology, SLS,VISTAS
10	Dr.R.J. Hemalatha	ME., Ph.D.	Scientific Member (Internal)	Head, Dept. of Biomedical Engineering
11	Dr.A. Vijayalakshmi	M.Pharm., Ph.D.	Member Secretary	School of Pharmaceutical Sciences, VISTAS
12	Mr. Bijukumar K Gopinathan	BBA Hons. Directorate in Social Work	Social Scientist	The Noble Trust, President, Human Protective Organization, Chief Organiser South Chennai

13	Dr. Paul Ravikumar B	MTh., DD.	Social Scientist	Pastor in Hope of Jesus Mission., Thalambur., Chennai
14	Mrs. Selin Semila Rani	MA (English)	Lay Person	

Annexure 2

VISTAS-SPS- INSTITUTIONAL ETHICS COMMITTEE

INITIAL REVIEW SUBMISSION FORM FOR RESEARCH PROPOSAL

1. Title of the research proposal
2. Name of the principal investigator with qualification and designation
3. Name of the co-investigator(s) with qualification and designation
4. Name of the Institute/Hospital/Field area where research will be conducted
5. Forwarding letter from the Head of the department/Institution/Guide
6. Protocol of proposed research
7. Ethical issues in the study and plans to address these issues
8. Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaire, follow-up cards etc.
9. Informed consent process, including patient information sheet and informed consent form in English and local language(s)
10. For any drug/device trail, all relevant pre-clinical animal data and clinical trial data from other centers within the country/other countries, if available
11. Usefulness of the project
12. Expected benefits to volunteers/community
13. Benefits to other categories if any
14. Anticipated risk (Adverse events, injury, discomfort) of the project
15. Effort taken to minimize the risks
16. Risk-Benefit Ratio
17. Research proposal approval by Scientific Advisory Committee, Drug Controller General of India, Health Ministry Screening Committee etc.
18. Any regulatory clearance is required
19. Source of funding and financial requirement for the project.
20. Other financial issues including those related to insurance.
21. Agreement to report all serious adverse events (SAE) to VISTAS SPS IEC.
22. Statement of conflict of interest.
23. Agreement to comply with the relevant national and applicable international guidelines.
24. Statement describing any compensation given to study participation (including expenses and access to medical care).

25. Description of the arrangements for indemnity, if applicable in study- related injuries and description of the arrangements for insurance coverage for research participants, if applicable.
26. All significant decisions (e.g., those leading to a negative decision or modified protocol) by other Ecs or regulatory authorities for the proposed study (whether in the same location or else where) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.
27. Specific ethical issues, as identified by the investigating team
28. Curriculum vitae of all the investigators with relevant publications in last five years.
29. Statement on Confidentiality
30. Plans for the publication of the results/positive or negative/ while maintaining the privacy and confidentiality of the study participants.
31. Any other information relevant to the study.
32. Signature of all the investigators with date.

Annexure 3
Checklist for Submissions

S.No	Documents	Write "Yes" if submitted and "NA" if not applicable
1.	Cover Page for submission	
2.	Initial review submission form for Research Proposal	
3.	Protocol of the proposed research (2 copies)	
4.	Informed Consent form (in English and its translation in local language as applicable)	
5.	Questionnaire (in English and its translation in local language as applicable)	
6.	Case Report Form (Proforma)	
7.	CV of the Principal Investigator	
8.	Patient Information leaflets and any other supporting materials	
9.	Any other Relevant Documents	

Annexure 4

Vels Institute of Science Technology and Advanced Studies

Institutional ethics committee

Ongoing Approved Research Review Submission Form

1. Reference number
2. Month / Year of approval
3. Number of ongoing review
4. Title of the research proposal
5. Name of the Principal Investigator (PI) with qualification and designation
6. Name of the Co-investigator(s) (Co-PI) with qualification and designation
7. Duration of the Project
8. Source of funding & financial allocation for the project / trial
9. Has subject recruitment begun?
10. If subject recruitment has not begin, give reasons and proceed toNo:20
11. How many subjects have been screened?
12. How many subjects have been recruited?
13. How many more to be recruited
14. Is subject recruitment continuing?
15. Are there any 'dropouts'?
16. Are subjects still receiving active intervention?
17. Have there been any adverse events? If yes, give details
18. Have there been any Serious Adverse Events adverse events ?If yes, give details.
19. Have there been any unanticipated study-related problems?
20. Is there any new risk or benefit information? If yes, give details.
21. Are there any interim changes to the protocol or consent form? If yes, give details including submission of revised protocol and consent form for approval
22. Does the scientific literature indicate changes in knowledge relevant to the conduct of the study?
23. List of attachments for review, if any
24. Remarks, if any
25. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal.

Annexure 5

Institute Ethics Committee, SPS, VISTAS

Format for ***submission of revised/additional documents, protocols and information regarding already approved projects*** to be submitted by the Principal Investigator (PI) (Two copies of this form along with the revised documents to be submitted)

1. IEC Reference No:

2. Approval Date and Number:

3. Title:

4. Principal Investigator:

5. Purpose of this submission:

6. New documents being submitted: Please list the documents being submitted along with the differences from the previously approved documents in a tabular form as below:

S. No.	List of Documents being submitted	List the modifications/revisions made from previously approved proposal, wherever applicable

Place:
Date:

Signature PI/Collaborator _____
Name:

Annexure 6

Six monthly progress of Project

Institute Ethics Committee Reference No._____

Study title:_____

Name of the Principal Investigator_____

Designation /Department _____

Duration of Study _____

Date of Starting of the Study _____

Period of Six monthly progress report: from_____to _____

Progress:

Side Effect if any:

Amendments if any:

Discontinuation reasons:

Progress:

Signature of Principal Investigator _____
Date:_____

Annexure 7

Data Elements for reporting serious adverse events occurring in a clinical trial

1. Patient Details

Initials & other relevant identifier (hospital/OPD record number etc.)*
Gender
Age and/or date of birth
Weight
Height

2. Suspected Drug(s)

Generic name of the drug*
Indication(s) for which suspect drug was prescribed or tested
Dosage form and strength
Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)
Route of administration
Starting date and time of day
Stopping date and time, or duration of treatment

3. Other Treatment(s)

Provide the same information for concomitant drugs (including nonprescription/OTC drugs) and non-drug therapies, as for the suspected drug(s).

4. Details of Suspected Adverse Drug Reaction(s)

Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.*

Start date (and time) of onset of reaction
Stop date (and time) or duration of reaction
Dechallenge and rechallenge information
Setting (e.g., hospital, out-patient clinic, home, nursing home)

5. Outcome

Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted

For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; Any post-mortem findings.

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.

*6. Details about the Investigator**

Name
Address
Telephone number
Profession (specialty)

Date of reporting the event to Licensing Authority:
Date of reporting the event to Ethics Committee overseeing the site:

Signature of the Investigator

*Note: Information marked * must be provided."*

Annexure 8

Confidentiality and Conflict of Interest Document for IEC Members

In recognition of the fact, that I, …….. herein referred to as the ―Undersigned, have been appointed as a member of the Institutional Ethics Committee (IEC), would be asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines; Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest; Whereas, the fundamental duty of an IEC member is to independently review research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects; The undersigned, as a member of the IEC is expected to meet the same high standards of ethical behavior to carry out its mandate. This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly. As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party.

Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC. The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that the performance of this agreement is consistent with the Institute‘s policies and any contractual obligations they may have to third parties. Conflict of Interest It has been recognized that the potential for conflict of interest will always exist but I have faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects. In accordance of the policy of the IEC, I shall not participate in the review, comment or approval of any activity in which I have a conflict of interest, except to provide information as requested by the IEC.

I will disclose to the Chairperson of the IEC any actual or potential conflict of interest that I may have in relation to any particular proposal submitted for review by the committee, and abstain from participation in discussions or recommendations in respect of such proposals. Examples of conflict of interest cases may be any of the

following:

1. A member is involved in a potentially competing research program
2. Access to funding or intellectual information may provide an unfair competitive advantage.
3. A member‘s personal biases may interfere with his or her impartial judgment.
4. If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IEC member(s) in question. The committee may elect to investigate the applicant‘s claim of the potential conflict. In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation.

I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee‘s mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any agenda items) to the Bioethics cell upon termination of my functions as a Committee member.

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

I, ……...…….. have read and I accept the Afore mentioned terms and conditions as explained in this Agreement.

Signature_____

Name_____

Date:_____