GUIDANCE DOCUMENT: SPECT-ERB

Dated 27th March 2012

Society for the Promotion of Ethical Clinical Trials

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BACKGROUND

Society for the Promotion of Ethical Clinical Trials (SPECT), a Society registered under Societies Registration Act XXI of 1860 is a non-profit organization set-up with an objective of promoting ethical clinical trials in India. The various activities performed under the aegis of the society include:

- Training programs related to clinical research education
- Constitution of an Independent Ethics Review Board
- Organization of awareness programs such as lectures, conferences, workshops, and symposia's highlighting the conduct of ethical clinical trials etc.

The Independent Ethics Review Board is being founded under the aegis of SPECT and it shall always be known and referred to as, by and in the name of SPECT-ERB. It shall have its registered office situated at 119, State Bank Colony, G.T. Karnal Road, New Delhi – 110 009. SPECT-ERB is registered with the U.S. Department of Health and Human Services **(DHHS # IRB00005032).**

DEFINITION

SPECT-ERB is an independent body (a review board or a committee), constituted of medical professionals and non-medical members, whose responsibility is to ensure the protection of the rights, safety and well being of human subjects involved in a clinical trial or BA/BE study and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

DECLARATION

SPECT-ERB operates as per the SOP that is in compliance with the guidelines laid down for ERBs by ICH-GCP (1997), WHO (2000), ICMR (2006), CDSCO (2001), Drugs and Cosmetics (IInd Amendment) Rules (2005).

SCOPE

Includes clinical trials, BA/BE and Medical Device studies proposed to be conducted in India.

OBJECTIVES

The SPECT-ERB is intended to ensure a competent review of scientific and ethical aspects of the project proposals received. It has a continuing responsibility of regular monitoring for the compliance of the ethics of the approved programmes till the same are completed.

RESPONSIBILITY

The SPECT-ERB is responsible to ensure that the research protocols wherever applicable,

- are sound in scientific design, have statistical validity and are conducted according to the parameters of ICH-GCP as well as applicable regulatory requirements.
- do not compromise the safety, right and well being of the patients/volunteers participating in the research study.
- are conducted under the supervision of medical persons with the required qualification and experience/expertise.
- include safety of patients/volunteers who, either by themselves or through their legally acceptable representatives has given informed consent for participation in the research study.

SPECT-ERB will review all new research projects and also the ongoing research projects at intervals appropriate to the degree of risk to the study subjects. The committee will maintain a list of projects submitted approved/disapproved and the outcome of each project.

The SPECT-ERB would take utmost effort to protect the data privacy and subject confidentiality for all the projects submitted to it. If visible subject identifiers are present in any document submitted to SPECT-ERB (*e.g.* SAE report, study report *etc*.) the same would be obscured using a black marker pen before circulation to the individual members. The access to data and records of SPECT-ERB would be limited to any governmental or regulatory authorities, members of the SPECT society and SPECT-ERB as well as any internal or external auditors.

COMPOSITION

SPECT-ERB will be composed of no less than seven and no more than twelve members sufficiently qualified through the experience, expertise, and diversity, to ensure a comprehensive review (scientific and ethical) of the projects submitted to it. SPECT-ERB will consist of both men and women. It will not consist of members entirely of one profession. The composition is as follows:

1. Basic Medical Scientists (preferably one Pharmacologist)
2. Clinicians
3. Legal experts
4. Social Scientist/ representative of non-governmental voluntary agency/ philosopher/ ethicist/ theologian or similar person (non-science member)
5. Lay person from the community
6. Clinical research experts

Members amongst themselves will appoint a Chairperson and Member Secretary (office bearers) to supervise the functioning of SPECT-ERB. The membership is as follows:

Sl. No.	**Name**	**Qualification**	**Functional Role**
1.	Dr. Sunil Kr. Gupta	MD (Medicine), DM (Medical Oncology)	Chairperson (Clinician)
2.	Mr. Sanjay Gupta	M.Pharm (Clinical Pharmacy)	Member-Secretary (Clinical Research Expert/ Social Scientist/ Representative of NGO)
3.	Dr. N.R. Biswas	MD (Pharmacology), DM (Clinical Pharmacology)	Member (Pharmacologist)
4.	Mr. Alishan Naqvee	LLB	Member (Lawyer)
5.	Ms. Rashmi Bhatia	M.A.(Psychology)	Member (Social Scientist)
6.	Ms. Nirmal Kaul Naqvee	M.A (Hindi)	Member (Lay Person/Non-Science Member)
7.	Dr. T Velpandian	Ph.D (Pharmacology)	Member (Pharmacologist)
8.	Dr. Amit Verma	MBBS, MD (Biochemistry)	Member (Clinician)

In the event if total number of members becomes less than quorum requirements, the Chairperson with the approval of the SPECT-ERB by majority vote shall co-opt the required number of members, for the purpose of ensuring the proper and efficient functioning of the SPECT-ERB and/or providing wider representation thereon.

OPERATING PROCEDURE

i) Review Documents

The applicant of the proposal (generally the Principal Investigator) is required to submit at a maximum 9 copies (one original and rest copies) of his/her application letter and copies of the following documents at least 5 days before a scheduled meeting.

1. Approved Protocol
2. Investigator's Brochure/Package Inserts/any other safety-related information available
3. Informed Consent Form and subject information sheet in English
4. Translation of Informed Consent Form in vernacular language(s) if applicable. However translation validation document/certificate is required to be submitted for all vernacular language(s) documents
5. Curriculum Vitae of Investigator(s)
6. Any other project-specific documents
7. Subject recruitment procedure (e.g. advertisement, if applicable)
8. Undertaking by the Investigator
9. Insurance/Indemnity

Optional documents:

- Clinical Trial Approval from the "Drug Controller General of India" however it is the responsibility of Investigator(s) to ensure that the document is obtained prior to first subject entry in the trial
- Case Report Forms/Clinical Report Forms
- Copy of the site assessment report/ Letter from the sponsor
- Investigator's agreement with the sponsor

ii) Frequency of Meeting

The committee will meet as and when required and at least once in six months. At least 5 days notice period is stipulated before each meeting and the Investigator/Sponsor has to present the proposal with required documents personally during the meeting.

iii) Responsibility of Chairperson, Member Secretary and Members

The member secretary, will record the minutes of the meeting, which is circulated at the end of the meeting and necessary documentation is completed before the members depart. The minutes of the meeting and necessary documentation is signed and dated by Chairperson and all the other members present during the meeting. A study team member may be called to meeting to present the study or answer specific queries. However, he/she will not participate in the decision making/voting process of that study even if he/she is a regular member of the SPECT-ERB.

If required, SPECT-ERB may invite nonmembers with expertise in special areas for assistance in review process. Such an invitation can be made by chairperson/member secretary of the SPECT-ERB and is documented by means of all the correspondence that takes place in this regard. If required, the designated personnel of the SPECT-ERB may visit the premise where the proposed study is planned to be conducted in order to evaluate the suitability of the Investigator(s)/study site(s) with regards to the conduct of study. Such visit can take place at any new site, as part of routine auditing activity and in case of whistle blower or significant non-compliance by the Investigator(s)/study site(s). An audit report is prepared by the designated personnel which is communicated to Investigator/ Study site after review and acceptance of all the members.

iv) Voting Process and Quorum Requirements

The decision of the committee will be taken by a majority vote after the quorum requirements are fulfilled to recommend/reject/suggest modifications for a repeat reviews or advise appropriate steps.

A 'quorum' requirement is considered as fulfilled if at least 5 members with the following representations are present at a meeting:

1. Basic Medical Scientists (preferably one Pharmacologist)
2. Clinicians
3. Legal Experts
4. Social Scientist (non-science member)
5. Lay person from the community

The decision of the committee will be taken by a majority vote in the absence of PI after the quorum requirement is fulfilled. The decision of Chairperson would be final and abided by if there are equal number of votes for and against the approval of a project. If subject experts are invited to offer their view they will not take part in the voting process.

In the event of Chairperson remaining absent, but the quorum requirements being fulfilled the members present shall elect an ad-hoc Chairperson, for the purpose of that meeting only. This is documented in the minutes of the meeting.

v) Study Documents

If desired, an original copy of the study documents duly stamped along with the signature of Chairperson/Member-Secretary can be issued to the Principal Investigator for records. Subject Information Sheet and Informed Consent Document (English and all applicable vernacular language) will be duly stamped along with the signature of Chairperson/ Member-Secretary. Investigator is expected to use the copies of the stamped/signed documents only while obtaining the consent from the study subject(s).

vi) Amendment(s) To Essential Study Documents

Any amendment(s) to the Protocol and Informed Consent Document follows the same process for approval.
Should an amendment to a study-related document be administrative in nature and not involving study design or safety criteria it may be provisionally approved in writing by the Chairperson of the committee without calling a full meeting. The Chairperson will inform other members of the SPECT-ERB of the amendment and his/her decision during the subsequent meetings of the committee. The decision will be ratified and minutes recorded.

vii) Expectations from PI

The committee expects from the Principal Investigator:

- to provide the Informed Consent Form in the relevant vernacular language to the subject who cannot understand English
- a report of the clinical trial/BA-BE studies on completion or interim(if required). However, an annual progress report is mandatory for all studies continuing for more than a year.
- a prompt report of each serious adverse event and safety report with regard to the study.
- a prompt report on deviation from, or changes of, the protocol to eliminate immediate hazards to the trial subjects.
- a prompt report on changes increasing the risk to subjects and/or affecting significantly the conduct of the trial.
- to be kept informed of study completion and discontinuation with reasons.
- to submit a justification for not conducting a study for which SPECT-ERB approval is obtained.
- to submit justification for approval to restart studies discontinued earlier.

viii) Safety Reporting and Review

For all the serious adverse events, letter from the Principal Investigator along with the copies is circulated to all the SPECT-ERB members. If any of the members raises concern a meeting is held and the minutes are recorded.

If a serious adverse event requires an immediate attention with regards to the amendment of the study protocol/any of the study procedure, chairperson is informed telephonically. He/she in turn can take a decision to give opinion in this regard or choose to call an urgent SPECT-ERB meeting. All communications in this regard (telephonic, fax, letter etc.) is appropriately documented. In case of safety concern or availability of any new safety information that can affect study conduct of ongoing trials an urgent meeting can be called to review and provide opinion thereon.

ix) Ongoing Review

For all other periodic reports, Investigator's brochure update etc., letter from the Principal Investigator is circulated to all the SPECT-ERB members. If any of the members raises concern a meeting is held and the minutes are recorded. The copy of Investigator's brochure is kept in the office of the SPECT-ERB and anybody who wants to review the updated data contacts the Chairperson/Member Secretary.

x) Archival of essential documents

Correspondence between the SPECT-ERB and the PI/Hospital/Sponsor etc. and other relevant records (communication, minutes of the meetings, composition etc.) will be retained for a minimum period of 5 years after completion of study or as per the applicable requirements.

Name: Sanjay Gupta

Functional Role: Member Secretary

Signature:

Date: 27/Mar/2012