GUIDANCE DOCUMENT: SPECT-SRB

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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 Scientific 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-SRB. It shall have its office situated at 503, NDM-2, Netaji Subhash Place, Pitampura, New Delhi-110034.

DEFINITION

SPECT-SRB is an independent review committee/board, constituted of medical and non-medical members, whose responsibility is to ensure the protection of the rights, safety and well being of human subjects involved in research study and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on, the study, the suitability of the Investigator(s), and the methods and material to be used in obtaining and documenting informed consent of the study subjects.

DECLARATION

SPECT-SRB operates as per the SOP that is in compliance with ICH-GCP and applicable regulatory requirements.

SCOPE

The scope of review for SPECT-SRB includes research studies viz. surveys, dissertation, non-interventional study(ies), epidemiological study(ies) and any other study proposed to be conducted in India which does not fall under the purview of Schedule-Y of Drugs and Cosmetics Rules, 1945 and all subsequent amendments.

OBJECTIVES

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

RESPONSIBILITY

The SPECT-SRB is responsible to ensure that the proposed research study wherever applicable,

- is sound in scientific design and conducted as per the applicable regulatory requirements,
- do not compromise the safety, rights and well being of the subjects participating in the study,
- is conducted under the supervision of the person with the required qualification and experience/expertise.

SPECT-SRB shall perform ongoing review of all the research studies approved by it at intervals appropriate to the degree of risk to the study subjects. The committee shall maintain a list of proposal submitted/ approved/disapproved and the outcome of each study. The SPECT-SRB shall take utmost effort to protect the data privacy and subject confidentiality for all the proposals submitted to it. If visible subject identifiers are present in any document submitted to SPECT-SRB (*e.g.* study report, *etc*.) the same shall be obscured using a black marker pen before circulation to the members. The access to data and records of SPECT-SRB shall be limited to any governmental or regulatory authorities, members of the SPECT society and SPECT-SRB as well as any internal or external auditors.

COMPOSITION

SPECT-SRB shall be composed of no less than six and no more than ten members sufficiently qualified through the experience, expertise, and diversity, to ensure a comprehensive review (scientific and ethical) of the research proposals submitted to it. SPECT-SRB shall consist of both men and women. It shall not consist of members entirely of one profession. The composition shall be as follows:

1. Clinician
2. Research Scientist/Pharmacologist
3. Legal Expert
4. Social Scientist/Representative of non-governmental voluntary agency
5. Lay Person

Members amongst themselves shall appoint a Chairperson and Member Secretary (office bearers) to carry out the functioning of SPECT-SRB. The 'quorum' requirements shall be considered as fulfilled if at least 5 members with the above representations are present at a meeting. Only those members who are independent of the study team of the research proposal shall vote/provide opinion on a study-related matter. If any of the members is unable to attend the meeting but the 'quorum' requirements being fulfilled, the meeting shall be held without that person. 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 shall be documented in the minutes of the meeting. In the event of Member-Secretary remaining absent, but the 'quorum' requirements being fulfilled the members may delegate the responsibility of writing the minutes of the meeting to any member and the same shall be documented in the minutes of the meeting.

OPERATING PROCEDURE

i) Review Documents

The applicant (generally the Investigator) of the research proposal is required to submit 1 original and 7 copies of his/her application letter and following documents (whichever applicable) at least 5 days before a scheduled meeting:

1. Research Protocol/Summary of the research
2. Informed Consent Document in English
3. Translation of Informed Consent Document in vernacular language(s) if applicable, along with translation certificate(s)
4. Product information/literature, where applicable
5. Curriculum vitae of Investigator(s)
6. Subject recruitment procedure (e.g. advertisement, if applicable)
7. Undertaking by the Investigator
8. Insurance/Indemnity (if applicable)
9. Data Collection Form/Tools
10. Draft Study Agreement
11. Relevant Approvals, if any
12. Any other project-specific document(s)

ii) Frequency of Meeting

The committee shall meet as and when required and at least once in six months. At least 5 days notice period is stipulated before each meeting. The Investigator/study team member shall present the research proposal during the SPECT-SRB meeting.

iii) Notification of Meetings and Distribution of Materials

The application materials shall be distributed to all SPECT-SRB members well in advance of the meeting to allow sufficient time for review. The members shall be contacted telephonically to fix-up a mutually convenient date, time and venue followed by circulation of Agenda via e-mail/fax/courier.

iv) Meeting Procedure

- The member secretary, shall record the minutes of the meeting, which shall be circulated at the end of the meeting for sign-offs before the members, depart. The Investigator/study team member shall be called at meeting to present the research proposal or answer specific queries. However, he/she shall not participate in the decision making/voting process of the study even if he/she is a regular member of the SPECT-SRB.
- An Investigator/study team member shall be deemed as interested party with regard to review.
- The study team member's non-participation in the decision making/voting process shall be recorded in the response letter from the SPECT-SRB.
- The SPECT-SRB shall give its opinion on the research proposal in one of the following ways:
  - Approval (duration specified)
  - Conditional Approval _____(condition specified)
  - Disapproval
  - Modification before approval
  - Discontinuation of previously approved project
- Informed Consent Document (English and all applicable vernacular language) approved during the meeting shall be duly stamped and the Investigator is expected to use the copies of the stamped documents only while obtaining the consent from the study subject(s).
- The member-secretary shall convey the decision of the SPECT-SRB to the Investigator/study team member in writing.

v) Amendment(s) to Essential Study Documents

Any amendment(s) to the Protocol and Informed Consent Document shall follow the same process for approval. Should an amendment to a study-related document be administrative in nature it may be approved in writing by the Chairperson/Member Secretary of the SPECT-SRB without calling a full meeting. The Chairperson/ Member Secretary shall inform other members of the amendment and his/her decision during the subsequent meetings of the committee. The decision shall be ratified and recorded in the minutes of the meeting.

vi) Expectation from PI

The committee expects from the Principal Investigator:

- To provide the Informed Consent Document in the relevant vernacular language to the subject who cannot understand English;
- A report of the study on completion or termination. However, an annual progress report is mandatory for all studies continuing for more than a year;
- A prompt report on safety issues, if any;
- A prompt report on deviation from, or changes of the study protocol.

vii) Safety Reporting and Review

For all the safety issues, communication from the Investigator shall be circulated to all the SPECT-SRB members. If any of the members raises concern a meeting shall be held to discuss the concern.

viii) Continuing Review

Research proposals approved by SPECT-SRB shall be reviewed on an ongoing basis at least once per year.

ix) Record Retention

Correspondence between the SPECT-SRB and the Investigator/study team member along with other study documents shall be retained for a minimum period of 5 years after completion of study or as per the applicable requirements.