PUBLIC HEALTHCARE SOCIETY: SCIENTIFIC REVIEW BOARD
(PHS – SRB)

OPERATIONAL MANUAL

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BACKGROUND

Public Healthcare Society (PHS) is an independent and multidisciplinary society dedicated to the promotion and protection of collective human health and well being. With an objective of promoting public health and awareness for the betterment of the mankind, the various activities to be performed under the aegis of this society includes:

- To run various training programs on public health and hygiene
- To spread awareness on health and wellness through lectures, conferences, workshops, etc.
- To provide general health education to the mankind
- To provide and organize environmental awareness programs
- To constitute Scientific Review Board (SRB)
- To promote patient care, advocacy and social empowerment
- To disseminate information and certification
- To perform audit activities

The Scientific Review Board (SRB) is being founded under the aegis of PHS and it shall always be known and referred to as, by and in the name of PHS-SRB. It shall have its office located at 45/1, Pocket D-12, Sector-7, Rohini, Delhi-110085, India.

DEFINITION

PHS-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 a 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

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

SCOPE

The scope of review for PHS-SRB includes research studies viz. quantitative research and surveys, market research studies, 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 PHS-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

- To protect and safeguard the dignity, rights, safety and well being of all actual and potential research subjects
- To consider the principle of justice, that the benefits and burdens of research be distributed fairly among all groups and classes in society taking into account age, gender, economic status, culture and ethic consideration

- To provide advice to the researchers on all aspects or the welfare and safety of research subjects after ensuring the scientific soundness of the proposed research study
- To ensure that the proposed research study is sound in scientific design and conducted as per the applicable regulatory guidelines

COMPOSITION

PHS-SRB will have a chairperson and member secretary. The PHS-SRB will have total of no less than 6 members and no more than 11 members. The PHS-SRB will be multidisciplinary and multisectorial in composition including relevant qualification and scientific expertise, balanced age and gender distribution and a lay person, to ensure a comprehensive review of the research proposals submitted to it. The composition shall be as follows:

1. Clinician
2. Research Scientist/Basic Medical Scientist
3. Legal Expert
4. Social Scientist/Representative of non-governmental voluntary agency
5. Lay person/Non-science member

PROCEDURE FOR MEMBERSHIP APPOINTMENT

Members amongst themselves shall appoint a Chairperson and Member Secretary (office bearers) who have the required qualification to carry out the functioning of PHS-SRB. Conflict of interest will be avoided when making appointments of the members on board. When needed PHS-SRB will invite subject experts, if required to offer their views.

- Term for PHS-SRB will be of 2 years
- Appointment of member can be renewed on the basis of contribution
- Member can discontinue from membership of PHS-SRB after giving at least one month advance notice.
- Member can be disqualified if there is long period of non-availability or inadequate contribution
- Member is required to sign the confidentiality agreement regarding PHS-SRB activities.

QUORUM REQUIREMENTS

- Minimum 5 members are required with above mentioned representations to fulfill the quorum requirements
- Members who are independent of the proposed study team shall vote/provide opinion on the study related matters

REVIEW PROCEDURE

1. PHS-SRB shall review all research studies that does not fall under the purview of Schedule-Y of Drugs and Cosmetics Rules, 1945 and all subsequent amendments.
2. Every proposal shall be evaluated by the board members to ensure the scientific soundness and technical excellence of the proposed study.
3. PHS-SRB shall evaluate the possible risks to the research subjects with prior justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.
4. PHS-SRB review shall be done through formal meetings and will not restore to decision through circulation of proposals.
5. The applicant of the proposed research study shall be required to submit 1 original and 7 copies of his/her application letter along with the following documents (whichever applicable) at least 7 days prior to a scheduled meeting:

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

MEETING REQUIREMENTS AND PROCEDURES

- All the PHS-SRB meetings shall be held regularly as scheduled dates that are announced and notified in advance. 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.
- Member will be given 5 days time in advance to review study proposals and the relevant documents.
- PHS-SRB meetings will be minuted and all the proceedings and deliberations shall be documented.
- Signature of all the members who have participated in the meeting will be obtained
- At the end of each PHS-SRB meeting, signatures from each member who has participated shall be obtained on the final draft of the minutes of meeting.
- Applicant, sponsor or investigator may be invited to present the proposal or elaborate on specific issues
- Independent expert may be invited to the meeting or to provide written comment, subject to applicable confidentiality agreement.
- Non participation of the study team's member during voting/decision making process shall be documented and recorded in the response letter from the PHS-SRB
- PHS-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 applicant is expected to use the copies of the stamped documents only while obtaining the consent from the research subject(s).

AMENDMENTS TO THE STUDY DOCUMENTS

All amendments to the study document (e.g. research protocol, informed consent document) shall follow the same procedure for approval. If an amendment is administrative in nature, the same shall be approved in writing by the Chairperson/Member secretary of PHS-SRB without calling a full board meeting. This decision shall be communicated to all other members by the Chairperson/Member Secretary in subsequent meetings and shall be recorded in the minutes of the meeting.

FOLLOW-UP PROCEDURES

1. PHS-SRB shall 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.
2. Progress of all the research studies shall be followed at a regular interval of at least once a year. But in special situations, PHS-SRB shall conduct the follow up review at shorter intervals basing on the need, nature and events of research project.
3. Following instances and events will require the follow-up review:
    - Protocol amendment, likely to effect, rights safety, or well being of research subject of conduct of the study.
    - Safety issues or communications raised out of the study
    - Any event or information that may affect the benefit/risk ratio of the study
4. A decision of a follow up review will be issued and communicated to applicant. In case of premature suspension/termination, the applicant must notify the PHS-SRB of the reasons for suspension/termination with a summary of results.
5. Applicant must inform at the time of completion of study and must send the result summary to PHS-SRB
6. PHS-SRB must receive a copy of final summary of study completed from the applicant.

ARCHIVAL AND RECORD RETENTION

All the documents and communication of PHS-SRB shall be dated, filed and archived in a secured place. Only person, who is authorized by the chairman of PHS-SRB shall have the access for the various documents. All the documents related to research proposal shall be archived for a minimum period of 3 years, following the completion of the study.