स्वामी राम हिमालयन विश्वविद्यालय
Swami Rama Himalayan University

Ethics Committee of Swami Rama Himalayan University is constituted as per the following guidelines

The Ethics Committee of Swami Rama Himalayan University is constituted in strict accordance with the E6(R2) Good Clinical Practice Integrated Addendum to ICH E6(R1) guidelines. The Committee comprises multidisciplinary members, including medical experts, scientists, legal experts, and laypersons, to ensure a comprehensive ethical review. Members are selected based on their expertise, independence and ability to evaluate clinical research impartially. The composition reflects diversity in gender, profession and experience to address various ethical aspects effectively. The Committee operates with a balanced representation to uphold participant rights and safety. Appointments are made for fixed terms, with provisions for renewal to maintain continuity and institutional knowledge. The constitution mandates adherence to confidentiality, impartiality, and avoidance of conflicts of interest. This structured composition ensures that the Committee functions with integrity, transparency, and accountability in overseeing clinical research.

E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

March 2018
Procedural

OMB Control No. 0910-0014
Current expiration date available at https://www.reginfo.gov
(Search ICR and enter OMB control number)
See additional PRA statement in section 9 of this guidance

3. INSTITUTIONAL REVIEW BOARD/INDEPENDENT ETHICS COMMITTEE (IRB/IEC)

3.1 Responsibilities

3.1.1 An IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid to trials that may include vulnerable subjects.

3.1.2 The IRB/IEC should obtain the following documents:

Trial protocol(s)/amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in the trial, subject recruitment procedures (e.g., advertisements), written information to be provided to subjects, Investigator's Brochure (IB), available safety information, information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications, and any other documents that the IRB/IEC may need to fulfil its responsibilities.

The IRB/IEC should review a proposed clinical trial within a reasonable time and document its views in writing, clearly identifying the trial, the documents reviewed and the dates for the following:

- Approval/favorable opinion;
- Modifications required prior to its approval/favorable opinion;
- Disapproval/negative opinion; and
- Termination/suspension of any prior approval/favorable opinion.

3.1.3 The IRB/IEC should consider the qualifications of the investigator for the proposed trial, as documented by a current curriculum vitae and/or by any other relevant documentation the IRB/IEC requests.

3.1.4 The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year.

3.1.5 The IRB/IEC may request more information than is outlined in paragraph 4.8.10 be given to subjects when, in the judgment of the IRB/IEC, the additional information would add meaningfully to the protection of the rights, safety, and/or well-being of the subjects.

3.1.6 When a nontherapeutic trial is to be carried out with the consent of the subject's legally acceptable representative (see sections 4.8.12, 4.8.14), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials.

3.1.7 Where the protocol indicates that prior consent of the trial subject or the subject's legally acceptable representative is not possible (see section 4.8.15), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials (i.e., in emergency situations).

3.1.8 The IRB/IEC should review both the amount and method of payment to subjects to assure that neither presents problems of coercion or undue influence on the trial subjects. Payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject.

3.1.9 The IRB/IEC should ensure that information regarding payment to subjects, including the methods, amounts, and schedule of payment to trial subjects, is set forth in the written informed consent form and any other written information to be provided to subjects. The way payment will be prorated should be specified.

3.2 Composition, Functions, and Operations

3.2.1 The IRB/IEC should consist of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial. It is recommended that the IRB/IEC should include:

(a) At least five members.

(b) At least one member whose primary area of interest is in a nonscientific area.

(c) At least one member who is independent of the institution/trial site.

Only those IRB/IEC members who are independent of the investigator and the sponsor of the trial should vote/provide opinion on a trial-related matter.

A list of IRB/IEC members and their qualifications should be maintained.

3.2.2 The IRB/IEC should perform its functions according to written operating procedures, should maintain written records of its activities and minutes of its meetings, and should comply with GCP and with the applicable regulatory requirement(s).

3.2.3 An IRB/IEC should make its decisions at announced meetings at which at least a quorum, as stipulated in its written operating procedures, is present.

3.2.4 Only members who participate in the IRB/IEC review and discussion should

vote/provide their opinion and/or advice.

3.2.5 The investigator may provide information on any aspect of the trial, but should not participate in the deliberations of the IRB/IEC or in the vote/opinion of the IRB/IEC.

3.2.6 An IRB/IEC may invite nonmembers with expertise in special areas for assistance.

Swami Rama Himalayan University
Office of the Registrar

SRHU/Reg/OO/2024-132 Date: 4th September, 2024

OFFICE ORDER

I am directed to inform that **Ethics Committee** of the University is hereby re-constituted, comprising of the following:

1. Dr. Manisha Bisht, Professor, Department of Pharmacology, AIIMS Rishikesh : Chairperson
2. Dr. Rajeev Mohan Kaushik, Professor, Department of General Medicine, HIMS : Member
3. Dr. Jayanti Semwal, Professor, Department of Community Medicine, HIMS : Member
4. Dr. Abha Srivastava, Professor & Head, Department of Physiology, HIMS : Member
5. Mr. Arun Kundra, Advocate, Legal Expert : Member
6. Shri GNS Gurudutt, Representative of NGO : Member
7. Mr. Sagar Manwal, Layman person from Community : Member
8. Dr. D.C. Dhasmana, Professor, Department of Pharmacology, HIMS : Member Secretary

This bears approval of the competent authority.

By Order,

Registrar

Copy to:

Hon'ble President
Hon'ble Vice Chancellor
Director General (Academic Development)
All concerned members of the Ethics Committee

for kind information please

Swami Rama Himalayan University
Registrar