Standard Operating Procedures

Institutional Ethics Committee

Version No. 1

Effective Date 26th September 2019

Approved by

Dr. Nandini K Kumar

Chairperson, IEC

Accepted by

Dr. P. R. Krishnakumar

Chairman, AVPRF

AVP Research Foundation
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SOP Version 1.0	**Effective Date: 26.09.2019**

List of Abbreviations

Abbreviation/Acronym	Full Title/Description
ADR	Adverse Drug Reaction
AE	Adverse Event
BA	Bio-availability
BE	Bio-equivalence
CDSCO	Central Drugs Standard Control Organization
CFR	Code of Federal Regulations
CIOMS	Council for International Organizations of Medical Sciences
CoI	Conflict of Interest
Co-I	Co-Investigator
CRF	Case Record Form
CRO	Contract Research Organization
CTA	Clinical Trial Agreement
DBT	Department of Biotechnology
DCGI	Drug Controller General of India
DCR	Drugs and Cosmetic Rules, 1945
DGFT	Directorate General of Foreign Trade
DHHS	Department of Health and Human Services
DSMB	Data Safety Monitoring Board
ELSI	Ethical, Legal and Social Issues
FDA	Food and Drug Administration
FDC	Fixed Dose Combination
FERCAP	Forum for Ethical Review Committees in Asia and the Western Pacific Region
FWA	Federal wide Assurance
GCP	Good Clinical Practice
HMSC	Health Ministry's Screening Committee
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Committee on Harmonization
ICMJE	International Committee of Medical Journal Editors
ICMR	Indian Council of Medical Research
IND	Investigational New Drug

IHEC	Institutional Human Ethics Committee
IORG	IRB Organization
ISI	Indian Standards Institute
LAR	Legally Acceptable/Authorized Representative
MoU	Memorandum of Understanding
MTA	Material Transfer Agreement
NCE	New Chemical Entity
NDA	New Drug Application
NIH	National Institutes of Health
NOC	No-objection Certificate
OHRP	Office for Human Research Protections
PI	Principal Investigator
RCT	Randomized Controlled Trial
SAE	Serious Adverse Event
SOPs	Standard Operating Procedures
SUSAR	Suspected Unexpected Serious Adverse Reaction
WHO	World Health Organization

GLOSSARY

Adverse Event: Any untoward medical occurrence in a patient or clinical investigation participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavourable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.

Amendment protocol: Amended parts and related documents of the protocol, previously approved by the IEC, AVP research Foundation. In the course of the study, the PI may decide to make changes in the protocol

Assent: To agree to participate in research by children from 7 - 18 years of age who are old enough to understand the implications of any proposed research but not legally eligible to give consent. For children from 7-12 years it will be oral assent and from >12 – 18 years it will be written assent. Informed consent of parent/LAR is necessary except in certain circumstances, e.g. risky behaviour of adolescents.

AYUSH Intervention: Includes any existing/new intervention with drug, therapeutic or surgical procedure or device in the recognized traditional systems of India as per Ministry of AYUSH, GOI (including Ayurveda, Yoga, Naturopathy, Unani, Siddha, Homoeopathy, SOWARIGPA).

Beneficence: To try to do good or an action which weighs the risks against benefits to prevent, reduce or remove harm for the welfare of the research participant(s) in any type of research.

Clinical trial: A clinical trial is any research/study that prospectively assigns human participants or groups of humans to one or more health-related intervention(s) to evaluate the effects on health outcomes. The intervention could be drugs, vaccines, biosimilars, biologics, phytopharmaceuticals, radiopharmaceuticals, diagnostic agents, public health interventions, socio-behavioural interventions, technologies, devices, surgical techniques or interventions involving traditional systems of medicine, etc. As per amended Schedule Y (2005) of the Drugs and Cosmetics Rules, 1945, a clinical trial refers to a systematic study of new drugs in human subjects to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and /or adverse effect with the objectives determining safety and/or efficacy of a new drug. The academic clinical trial as per GSR 313 (e) dated 16 March 2016 is a clinical trial using intervention falling under the definition of 'New Drug' but intended only for academic purposes and not marketing purposes.

Confidentiality: Keeping information confidential, which an individual has disclosed in a relationship of trust and with the expectation that it shall not be divulged to others without permission. Also it means prevention of disclosure of information and documents related to IEC to other than authorized individuals.

Compensation: Provision of financial payment to the research participants or their legal heirs when temporary or permanent injury or death occurs due to participation in regulatory clinical trials as determined by ethics committee and approved by CDSCO. In biomedical and health research of academic nature it will be as per institutional policy.

Document: Document may be of any form, e.g., paper, electronic mail (e-mail), faxes, audio or video tape, etc.

Exemption from review: A research study is said to be exempt from review when the proposals with less than minimal risk with no linked identifiers are submitted and requires only approval of member-secretary. Such proposals are to reported to the full committee during its meeting.

Expedited review/meeting: An expedited review is an accelerated review process for proposals having minimal risk, revised document with minor changes for approval by a sub-committee comprising Chairperson, member-secretary and 1 or 2 designated members of IEC. The decision is reported to the full board in its subsequent meeting.

Full Committee Review: Review of initial, resubmitted, continuing review, amendments of protocols and or PIDs and any other documents, which are tabled in the meeting of the full IEC committee for detailed discussion and decisions. This has to be on regular basis or in emergency/urgent situations this can be reviewed during unscheduled meeting.

Independent Consultants: Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed.

Informed Consent Document: Written signed and dated paper confirming a participant's willingness to voluntarily participate in a particular research, after having been informed of all aspects of the research that are relevant for the participant's decision to participate.

Initial Review: The first-time review of the protocol done during the meeting of the full committee.

Investigator's brochure: The Investigator's Brochure (IB) is a compilation of the clinical and non-clinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects.

Investigational New Drug(s) (IND): IND means a new chemical entity or a product having therapeutic indication but which has never been tested earlier on human beings.

Justice: Pertains to fairness in the way people are dealt with, indicating fair selection and distribution of benefits and risks to participants who should be fully apprised about them.

Lay person: A literate person who has not pursued a medical science/health related career in the last 5 years and is aware of the local language, cultural and moral values of the community.

Legal Expert: A person with a basic degree in law from a recognized university (with experience).

Legally Acceptable Representative (LAR): A person who will give consent on behalf of a prospective participant who, for either legal or medical reasons, is unable to give consent herself/himself to participate in research or to undergo a diagnostic, therapeutic or preventive procedure as per research protocol, duly approved by the EC.

Legally Authorized Representative (LAR): A person who, under applicable law or judicial authority, can give consent on behalf of a prospective participant who, for either legal or medical reasons, is unable to give consent herself/himself to participate in research or to undergo a diagnostic, therapeutic or preventive procedure as per research protocol, duly approved by the EC.

Maleficence: The act of committing harm or a harmful act.

Master SOP files: A collection of the Standard Operating Procedures (SOP) of IEC accessible to all staff, IEC members, auditors and government inspectors as a paper copy and the approval signatures on first page. When a copy of this is provided to members of IEC it is termed controlled copy.

Minimal risk: means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Examples include research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc. (National Ethical Guidelines, 2017)

Non-compliance: Failure or refusal to act in accordance with approved study protocol.

Past SOPs of the IEC: A collection of previous official versions of SOPs and relevant information regarding changes and all pre-planned deviations.

Protocol Deviation: A protocol deviation is a less serious non-compliance with the approved study protocol.

Protocol Waiver: Protocol Waiver is analogous to a Protocol Deviation, except that prior IEC approval has been obtained before implementing the necessary departures from the protocol.

Protocol Violation- A protocol violation is a deviation from the IEC approved protocol that may affect the subject's rights, safety, or wellbeing and/or the completeness, accuracy and reliability of the study data. If the deviation meets any of the following criteria, it is considered a protocol violation. Example list is not exhaustive.

Quorum: Minimum number and/or kind of EC members required for decision making during a meeting.

Risk: (www.icmr.nic.in Ethical Guidelines for Biomedical Research on Human Participants, Indian Council of Medical Research, October 2006)

- Minimal Risk: It means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy, or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life. Example for minimal risk: A retrospective review of patient case records to determine the incidence of disease/ recurrence of disease]
- Less than minimal risk: Research, in which there is no known physical, emotional, psychological, or economical risk to the study participants. This research qualifies as exempt if it does not involve special populations (i.e., minors, prisoners, pregnant women, etc.)

Serious Adverse Event (SAE): An adverse event is serious when the research outcome for the participant is death, life-threatening injury requiring hospitalization, prolongation of hospitalization, significant disability/incapacity, congenital anomaly, or requirement of intervention to prevent permanent impairment or damage.

Social Scientist: A person who is an expert on societal and social behaviour with specialization/ experience in the area.

SOPs (Standard Operating Procedures): Detailed, written instructions, in a certain format, describing activities and actions undertaken by the IEC to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify and standardize the functioning, whilst maintaining high standards of Good Clinical Practice.

SOP Effective date: The date of implementation of SOPs after acceptance by the Chairman, AVP Research Foundation following signed and dated approval of the Chairperson, IEC.

SOP Team: A team of members including the Member Secretary and any other member of IEC identified by the chairperson, which prepares or revises SOPs of the designated ethics committee.

Study Assessment Form: An official record that documents the protocol review process.

Study protocol: A document that describes the objective(s), design, methodology, statistical considerations and organization of a trial.

Institutional Ethics Committee (IEC): It is an independent body responsible for ensuring the protection of the rights, safety, dignity and well-being of human participants involved in a clinical research under the aegis of AVP and to provide public assurance of their protection.

AVPRF-IEC members: Individuals serving as regular members of the Institutional Ethics Committee, AVP Research Foundation.

Vulnerable participants: This category includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence.

Violation: The act of doing something that is not as per the approved study protocol, which violates ethical principles and/or human rights. The IEC monitors whether investigators conduct the study in compliance with the approved protocol, national regulations or not and/or fail to respond to the IEC request for information/action.

SOP Prepared by:

Name and Position on the IEC	Signature with date
Dr. Arun T. – Member Secretary	27/09/2019
Mr. Sujith Subash E. – Alternate Member Secretary	27/09/2019

Reviewed by:

Name and position on IEC	Signature with date
Dr. Ajayan Sadanandan - Member	27/9/19
Dr. Jeevan K Jose - Member	27/9/19
Dr. Krithika - Member	27/9/19

Approved by:

Name and Position on the IEC	Signature with date
Dr. Nandini K Kumar - Chairperson	26.9.2019

Accepted by:

Name and Position on the IEC	Signature with date
P R Krishnakumar – Chairman, AVP Research Foundation	27/9/2019

List of Members

S.No	Name of Members	Area of Expertise	Affiliated to AVPRF	Sex
1	**Dr. Nandini Kumar**	Ethicist	Non affiliated	Female
2	**Dr. S. Ramalingam**	Clinician and Clinical Pharmacology	Non affiliated	Male
3	**Dr. Arun T**	Ayurveda Clinician	Affiliated	Male
4	**Mr. Sujith Eranezhath**	Basic Medical Science (Microbiology)	Affiliated	Male
5	**Dr. Lakshmi B. R**	Clinician	Non affiliated	Female
6	**Dr. Somit Kumar**	Ayurveda Clinician	Affiliated	Male
7	**Dr. Muthiah Ramanthan**	Clinical pharmacology	Non affiliated	male
8	**Adv. Vijay Raghunathan**	Legal Expert	Non affiliated	male
9	**Dr. Krithika**	Ayurveda clinician	Non affiliated	female
10	**Dr. Ajay Sadanadan**	Ayurveda Clinician	Non affiliated	male
11	**Dr. Jeevan K jose**	Ayurveda Clinician	Non affiliated	male
12	**Dr. Sheethal**	Ayurveda Clinician	Non affiliated	female
13	**Prof. Adi Narayanan**	Social scientist and theology	Non affiliated	male
14	**Deepa K V**	Lay person	Non affiliated	Female

List of Independent Consultant

Sl. No	Name	Department
1	Dr. Indulal. U	Ayurveda Researcher
2	Dr. Ram Manohar	Ayurveda Researcher
3	Dr. C J B Gnanaraj	Orthopaedic Surgeon
4	Dr. M. Prasad	Ayurveda Clinician
5	Dr. Reshmi Pushpan	Ayurveda Researcher (Clinical Trial)
6	Dr. Subhashini.K.Sripathi	Researcher (Organic chemistry)
7	Dr. Suresh Damodaran	Clinician (Endocrinologist)
8	Dr. Sudha Ramalingam	Researcher (Bio-ethics)
9	Dr. L Mahadevan	Ayurveda Clinician
10	Dr. Pawan Kumar Godatwar	Ayurveda Researcher

Introduction

1. Background about AVP Research Foundation

AVP Research Foundation began its activities at the Ayurvedic Trust Campus, Coimbatore in 2003 by the name "AVT Institute for Advanced Research" (AVTAR). In the span of ten years, AVP Research Foundation, formerly known as AVTAR has positioned itself into a pioneering research organisation in the field of Ayurveda. AVP Research Foundation is a company incorporated under section 25 of the Companies Act 1956.

Vision

Our vision is to contribute to research by ensuring the highest possible ethical standards in research at the affiliate institutions.

Mission

Our mission is to:

1. Ensure the safety of both participants and researchers involved in research.
2. Establish a model committee in AYUSH and allied sector and lead research.

2. Brief History of Institutional Ethics Committee, AVPRF

The Ayurvedic Trust had established an ethics committee and was monitoring clinical research at the Trust. This committee is now re-established adhering to the contemporary regulations to ensure highest ethics in research at AVP Group of Institutions.

2.1. We do the following to fulfil our mission:

i. The IEC shall be multidisciplinary and multi-sectoral in composition to ensure and accommodate multiple views relevant to ensure the rigor of research while ensuring the safety of participants and researchers.

ii. The IEC will ensure that all the rules and regulations laid by the government of India and competent regulatory bodies are adhered to and updated periodically.

iii. The IEC would establish and maintain publicly available Standard Operating Procedures that state the authority under which the committee is established, the functions and duties of IEC, membership criteria, terms of reference for appointment, quorum requirements, procedures and functioning.

2.2. Autonomy of IEC

Autonomy of IEC must be unfettered, and absolute. It should function without fear or favour, and be able to adhere to the SOPs without hindrance or intimidation. IEC should be fair and impartial, immune from pressure either by the institution's administration, the investigators whose protocols are brought before it, or other professional and non-

professional sources. The SOP is the supreme governing document of IEC thus ensuring its autonomy.

3. Scope of Institutional Ethics Committee, AVPRF

The Institutional Ethics Committee (IEC) of AVP Research Foundation (AVPRF) shall receive, review, approve (or otherwise) and monitor research proposals involving human study volunteers in the following Institutions

1. AVP Research Foundation

2. International Institute of Ayurveda

3. The Arya Vaidya Chikitsalayam & Research Institute under The Ayurvedic Trust

4. The Arya Vaidya Pharmacy (Coimbatore) Ltd.

5. Arya Vaidyan P.V. Rama Variar Birth Centennial Ayurveda Hospital & AVP Training Academy

6. Saranya Ayurveda Hospital under Aashirwad Health and Educational Trust.

7. Artha Herbs Extracts and Derivatives India Limited

8. Aashirwad Ayurveda Pharmacy India Private Limited

9. Medical Research Laboratory

10. Vaidyagrama Ayurveda Hospital under Punarnava Ayurveda Limited.

4. Scope: Administrative requirements.

4.1 All proposals originating from institutions other than AVP Research Foundation & International Institute of Ayurveda must be routed to the IEC through the Chairman, AVP Research Foundation. The IEC will not accept study proposals from such institutions which are not routed through the Chairman, AVP Research Foundation.

4.2 Scope: Approval given to studies

The validity of approval of the IEC, is restricted for studies to be carried out

4.3 All studies including clinical trials proposed to be conducted in institutions referred in 5.0 must obtain approval from the IEC of AVPRF. Approval given by the ethics committee of another institution to carry out a study in AVP Institutions listed under paragraph 3 will not considered valid

4.4 Validity of approval given to multicentre studies by the IEC of AVPRF

For centres other than those listed under Para 3, investigators need to obtain approval from their own centres also.

4.5 Validity of approval for researches from outside institutions

Research proposals submitted to the IEC, AVPRF by researchers from Institutions other than those listed under Para 3.0 above will be considered on a case-by-case basis. In such cases, researchers must adhere to the following conditions:

a. For research involving data collection from affiliates by researchers other than those from institutions listed under Para 3.0 above

i. Letter of introduction from their respective Head of the institution

ii. Letter of consent from research guide

iii. Letter from Head of the institution and / or Guide describing the need for collecting data from AVP Institutions

iv. Approval letter from the researcher's institutional ethics committee (if there is no ethics committee functioning in the researcher's institution, approval from any institutional ethics committee from the researcher's city of work / approval from an independent ethics committee) an

v. All other documents required for scrutiny by IEC, AVPRF

b. For researchers from AVP Institutions/affiliates involving data collection outside institutions listed under Para 5.0 above

i. Letter from Head of the institution and / or Guide describing the need for collecting data outside AVP Institutions

ii. Approval letter from the researcher's institutional ethics committee (if there is no ethics committee functioning in the researcher's institution, approval from any institutional ethics committee from the researcher's city of work / approval from an independent ethics committee)

iii. All other documents required for scrutiny by IEC, AVPRF for scrutiny of study protocols

iv. Samples from participant for research projects approved by IEC shall be collected from AVP Hospitals or its approved sites only

c. For studies involving human participants or data, one Medical personnel with at least BAMS/MBBS qualification to be included as a co-investigator for the proposals submitted by non-medical researchers.

5. Standard Operating Procedure (SOP) of IEC

Since its inception, until 2019, AVP Institutions were considering the ICMR is SOP for which was available on ICMR website. It was in the year 2019, that the IEC of AVPRF scripted (by AVP Institutions and others referred to in paragraph 3.0) its own SOP document, The SOP of AVPRF has been drafted by the SOP Team Incorporating points from ICMR Guidelines 2017 (ethical review procedures section) & relevant regulations adopting FERCI (Forum for Ethics Review Committees in India) templates generally. The milestones of the IEC SOPs shown in the table below:

SOP Version	Effective Date	Remarks
SOP V1.0	September 26, 2019	First Approved version of SOP

6. Business Address of Ethics Committee

Institutional Ethics Committee

42, Perumal Kovil Street, AVP HO Annex Building,

Ramanathapuram PO, Coimbatore - 641045, India.

Phone & FAX: 0422 – 4341967. Email: ethics@avpresearch.org

7.0 Registration/Recognition

7.1 National Ethics Committee Registry for Biomedical and Health Research:

Institutional Ethics Committee of AVP Research Foundation is poised and awaiting to process its registration under Department of Health Research Ministry of Health & Family Welfare, Government of India National Ethics Committee Registry for Biomedical and Health Research (NECRBHR)

LIST OF SOPS

SoP No	Name of SOP
01	Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing and Amending SOPs
02	Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC
03	Handling Conflict of Interest among Ethics Committee Members
04	Selection and Responsibilities of Independent Consultants
05	Procedures for allowing Guest/ Observer to visit Institutional Ethics Committee or attend IEC meeting
06	Management of Submission of Research Study Protocol and Study Related Documents
07	Categorization of New Research Study Protocols received for initial Review
07A	Initial Full-Board Review of New Research Study Protocols
07B	Expedited Review of Research Study Protocols
07C	Exemption from Ethics Review of Research Study Protocols
08	Agenda Preparation, Meeting Procedures and Recording of Minutes
09	Review of Resubmitted, Amended Protocols and Protocol-related Documents
10	Continuing Review of Study Protocols
11	Review of Protocol Deviations / Violations/ Non-compliance
12	Review of Serious Adverse Events (SAE) Reports
13	Review of Study Completion Reports
14	Management of Premature Termination / Suspension / Discontinuation of the Study
15	Waiver of Written/ Verbal Informed Consent
16	Site Monitoring and Post-Monitoring Activities
17	Dealing with Participants' Requests and/ Or Complaints
18	Maintenance of Records Archiving
19	Reviewing Proposals involving Vulnerable Populations
20	Preparing for Ethics Committee Audit/ Inspection
21	Training and Assessment of Ethics Committee Members

Format of SOP Content

SOP Title: **Preparation of Standard Operating Procedures for University Ethics Committee**

List of SOP with Code:

Effective Date:

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