Sri MANAKULA VINAYAGAR

Medical College and Hospital

PROTECTING RESEARCH PARTICIPANTS

AND

GUIDING INVESTIGATORS

Version number: 4

Effective Date: 02nd January, 2024

STANDARD OPERATING PROCEDURES

FOR

INSTITUTIONAL ETHICS COMMITTEE (HUMAN STUDIES)

SMVMCH-EC

Standard Operating Procedures
Version **4**

Institutional Ethics Committee (Human Studies)
Sri Manakula Vinayagar Medical College and Hospital
(SMVMCH-EC)
Puducherry – 605107

Date published: 02nd January, 2024

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SOP Version number: 4

Effective Date: 02nd January, 2024

PREFACE

Sri Manakula Vinayagar Educational Trust was formed with the avowed objective of imparting quality technical education and medical education especially to the weaker sections of the society. Sri Manakula Vinayagar Medical College & Hospital is an Ultra-modern multi-specialty tertiary care hospital and a medical research center.

The institute is also active in research in various fields of modern medicine & health and medical education. A research committee at institute level looks after the research activities and there is an Institute Ethics Committee (Human Studies) which provides protecting to participants and guidance to investigators for the research work.

The research work is conducted and research papers are published by faculty, postgraduate and undergraduate students every year. There is an Institute Ethics Committee (human studies) which reviews all the research proposals by investigators who conduct research in this institute. As Ethics Committee plays a major role in protecting to participants and guidance to investigators, Standard Operating Procedures (SOP) for Ethics Committee is an important document for any educational institute involving in research. It's also necessary to update the SOP on regular basis.

I congratulate Dr. Vimal. M, Professor of Pathology, Dr. Girija. S, Professor and Head of General Medicine and Dr. Nishanthi. A, Associate Professor of Pharmacology of Sri Manakula Vinayagar Medical College and Hospital Ethics Committee for bringing out version 4 of SMVMCH-EC SOP.

I am confident that SMVMCH-EC SOP version 4 (amended by incorporating latest national and international ethical guidelines) will help all the researchers for preparing the research protocols and ensure smooth functioning of the our Institute Ethics Committee named as Sri Manakula Vinayagar Medical College & Hospital Ethics Committee (SMVMCH-EC).

Dean,
Sri Manakula Vinayagar Medical College &
Hospital,
Puducherry

Dr. KAGNE. R.N
DEAN
SRI MANAKULA VINAYAGAR
MEDICAL COLLEGE & HOSPITAL
KALITHEERTHALKUPPAM,
PUDUCHERRY-605107.

Preamble

Vision

Our vision is to ensure the safety and wellbeing of human beings by reviewing and enforcing ethical and scientific conduct of research process.

Mission

Our mission is to protect human research participants, researchers and institution by ensuring that:

- the rights, safety and wellbeing of the research participants are protected,
- the safety and protection of researchers,
- the institutional reputation and dignity will be protected and
- research is conducted according to the Indian regulations and relevant national (ICMR 2017 guidelines on biomedical research) and international ethical guidelines.

History of the SMVMCH Ethics Committee

Sri Manakula Vinayagar Medical College and Hospital was established in the year 2004 and Medical Council of India permitted to start MBBS course in the year 2006. The ethics committee (EC) was constituted in the year 2007. It was registered with DCGI in the year 2014 and since then it was named as SMVMCH Ethics committee (SMVMCH-EC) vide file no. ECR/1088/SMVMCH/Inst/PY/2013; dated: 10.12.2014 It was re-registered with DCGI in the year 2018 vide file no. ECR/1088/SMVMCH/Inst/PY/2013/Re-registration-2017; dated: 28.03.2018.

S. No	Name of the Chairman	From Date	To Date
1.	Dr. A. Shaw Nawan Khan	28.06.2007	19.08.2008
2.	Dr. D. Rajagovindan	20.08.2008	27.06.2010
3.	Dr. Selvaraj Stephen	28.06.2010	29.05.2013
4.	Dr. Gautam Roy	30.05.2013	27.03.2018
5.	Dr. T. Thiagarajan	28.03.2018	Till date

S. No	Name of the Secretary	From date	To date
1	Dr. Maruthi Shripati Sawadkar	28.06.2007	17.01.2011
2	Dr. R. N. Kagne	18.01.2011	22.09.2020
3	Dr. Vimal. M	23.09.2020	Till date

The SOP (Standard Operating Procedure) of SMVMCH-EC on Protecting research participants and guiding investigators, was first developed in the year 2013 (version 1) by Dr. R.N. Kagne (Member Secretary) and Dr. Amol R. Dongre (Member). The SOP booklet had 50 pages and contained 12 SOPs with supporting forms and documents (annexures). The SOP booklets

photocopy was provided to all the members of the SMVMCH-EC. Also, the scanned pdf copy was provided on the college website for open access to the researchers. The first amendment of the SOP (version 2) was done by the SOP committee in the year 2018 by Dr. R.N. Kagne (Member Secretary), Dr. Amol R. Dongre (Member), Dr. Vimal. M (Member), and Dr. Nishanthi. A (Member), after the SIDCER survey of the SMVMCH Ethics Committee. The second amendment of the SOP (version 3) was done by the SOP committee in the year 2021 by Dr. Vimal. M (Member Secretary), Dr. Nishanthi. A (Member) and Dr. Ganesh. R (Member), after the NABH inspection of the SMVMCH-EC. The third amendment of the SOP (version 4) was done by the SOP committee in the year 2024 by Dr. Vimal. M (Member Secretary), Dr. Girija. S (Member) and Dr. Nishanthi. A (Member) after the NABH inspection of the SMVMCH-EC.

Documentation of History of the SOPs

Details of superseded SOP

Name of the team of authors	SOP version number	Effective date	Comments (if any)
Dr. R.N. Kagne and Dr. Amol R. Dongre	Version 1.0	21.11.2013	First written SOP
Dr. R.N. Kagne, Dr. Amol R. Dongre, Dr. Vimal. M, and Dr. Nishanthi. A.	Version 2.0	01.11.2018	Major Revision after SIDCER Survey (3-5 October 2018) recommendations.
Dr. Vimal. M, Dr. Nishanthi. A, and Dr. Ganesh. R	Version 3.0	31.12.2021	Major Revision after NABH inspection (24th December 2021) and their recommendations.
Dr. Vimal. M, Dr. Girija. S and Dr. Nishanthi. A,	Version 4.0	02.01.2024	Major Revision after NABH inspection (01st December 2023) and their recommendations.

The Director of the Institute has been empowered to appoint the Chairman and Member-Secretary of SMVMCH -EC. The Director in consultation with the Chairman and Member-Secretary will appoint all other office bearers, and members. The appointed members detail list along with prescribed registration/re-registration format will be processed for approval by DCGI. Only after the approval from DCGI, the newly re-registered body of SMVMCH-EC will start functioning.

SMVMCH-EC shall receive, review, approve (or otherwise) and monitor research proposals involving human study volunteers of students and faculties of Sri Manakula Vinayagar Medical College and Hospital.

SMVMCH-EC is functionally autonomous. Its activities lie outside the administrative jurisdiction of the Director of SMVMCH, except in the dispute cases where he will be the appellate authority and has the administrative right for decision making.

Approval of SOP (Names) for Version 2

Prepared by

Name	Designation in EC
Dr. Vimal. M	Member
Dr. Nishanthi. A	Member

Reviewed by

Name	Designation in EC
Dr. R.N. Kagne	Member secretary
Dr. Amol R. Dongre	Member

Approved by

Name	Designation in EC
Dr. Thiagarajan. T	Chairman

Issued by

Name	Designation
Dr. D. Rajagovindan	Director

Approval of SOP (Names) for Version 3

Prepared by

Name	Designation in EC
Dr. Nishanthi. A	Member
Dr. Ganesh. R	Member

Reviewed by

Name	Designation in EC
Dr. Vimal. M	Member secretary

Approved by

Name	Designation in EC
Dr. Thiagarajan. T	Chairman

Issued by

Name	Designation
Dr. R. N. Kagne	Dean

Approval of SOP (Names) for Version 4

Prepared by

Name	Designation in EC
Dr. Girija. S	Member
Dr. Nishanthi. A	Member

Reviewed by

Name	Designation in EC
Dr. Vimal. M	Member secretary

Approved by

Name	Designation in EC
Dr. Thiagarajan. T	Chairman

Issued by

Name	Designation
Dr. R. N. Kagne	Dean

List of Members of the SMVMCH-EC (2017-2020)

The Patrons

S. No.	Name	Designation
1	Thiru.Dhanasekharan M	Chairman & Managing Trustee
2	Thiru.Sukumaran SV	Vice-Chairman
3	Thiru.Narayanasamy K	Secretary
4	Dr.Rajagovindan D	Director
5	Dr.Kagne RN	Deputy Director and Dean

The Members

S. No	Name of Recipients	Designation
1.	Dr. Thiagarajan. T	Chairman
2.	Dr. R. N. Kagne	Member Secretary
3.	Dr. Amol Dongre	Clinician
4.	Dr. Bupathy. A	Clinician
5.	Dr. Gautam Roy	Clinician
6.	Dr. Girija. S	Clinician
7.	Dr. T. Mahalakshmy	Clinician
8.	Dr. P. Ravikumar	Clinician
9.	Dr. D. Rajagovindan	Basic Medical Scientist
10.	Dr. Nishanthi. A	Basic Medical Scientist
11.	Dr. Sandhiya. S	Basic Medical Scientist
12.	Dr. Vimal. M	Basic Medical Scientist
13.	Mr. Saravanan	Lay Person
14.	Mr. A. Karunamoorthy	Legal Expert
15.	Mrs. Malar. R	Social Scientist

Secretariat: Mrs. Gajalakshmi

List of Members of the SMVMCH-EC (2021-2022)

The Patrons

S. No.	Name	Designation
1	Thiru.Dhanasekharan M	Chairman & Managing Trustee
2	Thiru.Sukumaran SV	Vice-Chairman
3	Thiru.Narayanasamy K	Secretary
4	Dr.Rajagovindan D	Director
5	Dr.Kagne RN	Deputy Director and Dean

The Members

S. No	Name of Recipients	Designation
1.	Dr. Thiagarajan. T	Chairman
2.	Dr. Vimal. M	Member Secretary
3.	Dr. Bupathy. A	Clinician
4.	Dr. Girija. S	Clinician
5.	Dr. P. Ravikumar	Clinician
6.	Dr. K. N. Viswanathan	Clinician
7.	Dr. Suresh Kumar. S	Clinician
8.	Dr. T. Mahalakshmy	Clinician
9.	Dr. Amol R Dongre	Clinician
10.	Dr. Nishanthi. A	Basic Medical Scientist
11.	Dr. Ganesh. R	Basic Medical Scientist
12.	Dr. Sandhiya. S	Basic Medical Scientist
13.	Mrs. Meenakshi	Lay Person
14.	Mr. A. Karunamoorthy	Legal Expert
15.	Mrs. Chitra Shah	Social Scientist

Secretariat: Mr. Vijai. A

List of Members of the SMVMCH-EC (2022-Till Date)

The Patrons

S. No.	Name	Designation
1	Thiru.Dhanasekharan M	Chairman & Managing Trustee
2	Thiru.Sukumaran SV	Vice-Chairman
3	Thiru.Narayanasamy K	Secretary
4	Dr.Rajagovindan D	Director
5	Dr.Kagne RN	Deputy Director and Dean

The Members

S. No	Name of Recipients	Designation
1.	Dr. Thiagarajan. T	Chairman
2.	Dr. Vimal. M	Member Secretary
3.	Dr. Bupathy. A	Clinician
4.	Dr. Girija. S	Clinician
5.	Dr. P. Ravikumar	Clinician
6.	Dr. K. N. Viswanathan	Clinician
7.	Dr. Suresh Kumar. S	Clinician
8.	Dr. T. Mahalakshmy	Clinician
9.	Dr. Amol R Dongre	Clinician
10.	Dr. Bhagwati Wadwekar	Clinician
11.	Dr. Nishanthi. A	Basic Medical Scientist
12.	Dr. Sandhiya. S	Basic Medical Scientist
13.	Mr. Dhanaselvam	Lay Person
14.	Mr. A. Karunamoorthy	Legal Expert
15.	Mrs. Chitra Shah	Social Scientist

Secretariat: Mr. Vijai. A

List of Independent consultants of SMVMCH-EC

Sl. No.	Name	Qualification	Specialty
1	Dr. Ashish Anand Susvirkar	MD (Medicine), DM (Neurology)	Neurology
2	Dr. P. Ravi Kumar	MD (Medicine), DNB (Nephrology)	Nephrology
3	Dr. Ashida. T. S.	MD (Medicine), DNB (Cardiology)	Cardiology
4	Dr. Thirumal. P	MD (Paediatrics), DM (Gastroenterology)	Gastroentrology
5	Dr. Karthik S Bandari	MS (Surgery), M.Ch.(Paediatric Surgery)	Paediatric Surgery
6	Dr. Shivaji. P.R	MS (Surgery), DNB (Urology)	Urology
7	Dr. Elangovan. D	M.B.B.S, M.Ch. (Neuro Surgery)	Neurosurgery
8	Dr. Vijayeswaran. N	MS (Surgery), M.Ch.(Neuro Surgery)	Neurosurgery
9	Dr. Arun Kumar Arasappa	MS (Surgery), M.Ch. (Cardio Vascular & Thoracic Surgery)	Cardiothoracic Surgery
10	Dr. Riaz. B	MS (Surgery), M.Ch. (Cardio Vascular & Thoracic Surgery)	Cardiothoracic Surgery
11	Dr. Ravi Sankar. P	MS (Surgery), M.Ch.(Oncology Surgical)	Surgical Oncology
12	Dr. Vijay Ganapathy. S	MS (Surgery), M.Ch.(Urology)	Urology
13	Dr. Vijayaraghavan. N	MS (Surgery), M.Ch. (Plastic Surgery)	Plastic Surgery
14	Dr. Damodara Kumaran. P	MD (Radio Theraphy), Diploma (Radio Theraphy)	Radiotheraphy & Oncology

List of Abbreviations / Acronyms

SOP Version: 4; Effective Date: 02.01.24

AX	- Annexure
CV	- Curriculum vitae
COI	- Conflict of interest
CFR	- Code of Federal Regulations
CDSCO	- Central Drug Standard Control Organization
CRT	- Cluster randomized trials
CTRI	- Clinical trial registry – India
DSMB	- Data Safety Monitoring Board
EC	- Ethics Committee
FERCI	- Forum for Ethics Review Committees in India
GCP	- Good Clinical Practice
GLP	- Good laboratory practices
HOI	- Head of the Institute
ICMR	- Indian Council of Medical Research
IC	- Independent Consultants
IRB	- Institutional review board
ICD	- Informed consent document
ICF	- Informed consent form
MOU	- Memorandum of understanding
PI	- Principal Investigator
SIDCER	- Strategic Initiative for Developing Capacity in Ethical Review
SOP	- Standard Operating Procedures
SMVMCH-EC	- Sri Manakula Vinayagar Medical College and Hospital Ethics Committee
SAE	- Serious adverse events
TOR	- Terms of reference

GLOSSARY

Accountability	The obligation of an individual or organization to account for its activities, accept responsibility for them and to disclose the results in a transparent manner.
Adverse event	Any untoward medical occurrence in a patient or participant involved in a study which does not necessarily have a causal relationship with the intervention. The adverse event can therefore be any unfavorable or unintended sign or experience, whether or not related to the product under investigation.
Appellate authority	It decides on the appeal filed against a decision of the lower authority. Its mandate is to ensure that due process of law is followed.
Assent	To agree or approve after thoughtful consideration an idea or suggestion to participate in research by a young person below the age of 18 years who is old enough to understand the implications of any proposed research but not legally eligible to give consent. The assent has to be corroborated with informed consent of parent/ LAR
Audit	A systematic and independent examination of research activities and documents to determine whether the review and approval activities were conducted, data recorded and accurately reported as per applicable guidelines and regulatory requirements.
Autonomy	The ability and capacity of a rational individual to make an independently informed decision to volunteer as a research participant.
Biomedical and health research	Research including studies on basic, applied and operational research designed primarily to increase the scientific knowledge about diseases and conditions (physical or socio-behavioral), their detection, cause and evolving strategies for health promotion, prevention, or amelioration of disease and rehabilitation including clinical research.
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.
Caregivers	A caregiver or care is an unpaid or paid person who helps another individual with illness or impairment with daily activities/ performance.
Case record/ report form (CRF)	Case record form or case report form is a printed, optical or electronic document designed to record all the required information in the protocol on each study participant for reporting to the sponsor.
Clinical research	Research that directly involves a particular person or group of people to study the effect of interventions, or uses materials/data from humans indirectly, such as their behavior or samples of their tissue for prevention, treatment and diagnosis of a disease condition/health disorder
Clinical trial	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 pharmacodynamics 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 intended for academic purposes in respect of approved drug formulations for any new indication or new route of administration or new dose or new dosage form
Clinical trial registry	An official platform for registering a clinical trial, such as Clinical Trial Registry-India
Clinician	A person with recognized medical qualification and expertise/ training
Cognitive impairment	When a person has trouble remembering, learning new things, concentrating, or making decisions that affect their everyday life.
Coercion	An overt or implicit threat of harm to a participant which is intentional to force compliance.
Collaborative research	An umbrella term for methodologies that actively engage researchers, communities and/ or policy makers in the research process from start to finish.
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 biomedical and health research.
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
Confidentiality agreement	Secrecy or non-disclosure agreements designed to protect trade secrets, information and expertise from being misused by those who have learned about them.
Contract Research Organization (CRO)	An institution or service organization which represents a sponsor in providing research support/services on a contractual basis nationally or internationally.
Custodian	A person who has responsibility of taking care of or protecting entrusted assets, either biological samples or data
Debriefing	A process of providing a summary update of a condition or situation to the affected or concerned parties. It is an important ethical consideration in studies involving deception. Such post experimental follow-up is considered beneficial even if no deception is used or there is only minimal risk to participants
Deception	Deception occurs when investigators provide false or incomplete information to participants to misleading them to achieve the study objectives and for larger public good. Research employing any type of deception should undergo full committee review.
Distributive justice	Fair distribution of burden, resources and benefits. In research, it means fair selection of participants.
Ethicist	One whose judgement on ethics and ethical codes is based on knowledge/experience through qualification or training.
Exploitation	The action or fact of treating someone unfairly in order to benefit from their participation.
Exploratory research	Preliminary research conducted to gain insights for a problem that has not yet been clearly defined.
Impartial witness	A literate person, who is independent of the research and would not be

	unfairly influenced by people involved with the study, who attends the informed consent process if the participant and/or their LAR cannot read, and understand the informed consent form and any other written information supplied to the participant.
Independent consultant	An expert who gives advice, comments and suggestions to the EC and has no affiliation to the institute or researchers proposing the research protocols. This individual has no voting power for decision making.
Inducement	A motive or consideration that leads one to action or to additional or more effective actions without considering the harm that may occur
Informed consent document (ICD)	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.
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 ethics committee.
Maleficence	The act of committing harm or a harmful act.
Marginalized communities	A group of people actively separated or excluded from the rest of society.
Minimal risk	Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of a healthy individual or general population 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 since it would be undertaken as part of current everyday life
Non therapeutic trial	A trial which is unlikely to produce any direct benefit to the participants involved. The aim of a non-therapeutic trial is to obtain knowledge which may contribute towards the future development of new forms of treatment or procedures.
Ostracization	To exclude, by general consent, from society, friendship, conversation,

	privileges, etc
Particularly vulnerable tribal group (PVTG)	These are a special class of tribal groups, classified as such by the Government of India, due to their especially low development indices when compared to other local tribes. These were classified under the Dhebar Commission (1960–1961), so as to better facilitate their growth, at par with other scheduled tribes on a national scale, and help them to get included in mainstream development, while using their indigenous knowledge. They have a pre-agricultural system of existence as mainly hunters with zero or negative population growth, extremely low level of literacy and no written language.
Pilot studies	A pilot study, project or experiment is a small-scale preliminary study conducted in order to evaluate feasibility, time, cost, adverse events and effect size (statistical variability) in an attempt to predict an appropriate sample size and improve upon the study design prior to performance of a full-scale research project.
Pivotal trial	A clinical trial or study intended to provide evidence for drug marketing approval from the licensing authority; usually a Phase III study which presents the data that the licensing authority uses to decide whether or not to approve a drug. A pivotal study will generally be well-controlled, randomized, of adequate size, and whenever possible, double-blind.
Post-marketing surveillance	The practice of monitoring the safety of a pharmaceutical drug or medical device after it has been released on the market. This is an important part of the science of pharmacovigilance.
Professional competence	The broad professional knowledge, attitude and skills required in order to work in a specialized area or profession
Principal investigator	An individual or the leader of a group of individuals who initiates and takes full responsibility for the conduct of biomedical health research; if there is more than one such individual, they may be called co-principal investigators/ co-investigators
Psychosocial harm	Research, particularly psychology studies, can put participants in situations that may make them feel uncomfortable while learning about their reaction to a situation. The result can be psychological harm that can manifest itself through worry (warranted or unwarranted), feeling upset or depressed, embarrassed, shameful or guilty, and/or result in the loss of self-confidence.
Quorum	Minimum number and/or kind of EC members required for decision making during a meeting.
Research-related injury	Harm or loss that occurs to an individual as a result of participation in research, irrespective of the manner in which it has occurred, and includes both expected and unexpected adverse events and serious adverse events related to the intervention, whenever they occur, as well as any medical injury caused due to procedures.
Risk	Probability of harm or discomfort to research participants. Acceptable risk differs depending on the conditions inherent in the conduct of research.
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.
Sexual minorities	A group whose sexual identity, orientation or practices differ from majority of the surrounding society. It refers to lesbian, gay, bisexual and transgender (LGBT), queer (including the third gender) or intersex individuals.
Social scientist	A person who is an expert on societal and social behavior with specialization/experience in the area.
Socio-behavioral research	Refers to the socio-behavioral studies on response of individuals, groups, organizations or societies to external or internal stimuli.
SOP (standard operating procedure)	Detailed written instructions in a certain format describing all activities and actions to be undertaken by an organization to achieve uniformity in performance of a specific function
Sponsor	An individual, institution, private company, government or nongovernmental organization from within or outside the country who initiates the research and is responsible for its management and funding.
Stigmatization	Negative perceptions about an individual because of perceived differences from the population at large. It may occur on the basis of physical appearance, race or sex.
Surrogate	A substitute or deputy for another person in a specific role.
Theologian	A person who is an expert in the study of religious faith(s), including the system of spirituality, practice and experience about the nature of the divine
Test of understanding	A simple oral or written test designed to identify if the participant has understood the details related to her/his voluntary participation in research before signing the ICD form. (Questions such as "If you decide not to take part in this research study, do you know what your options are?", "Do you know that you do not have to take part in this research study, if you do not wish to?", "Do you have any questions?", etc. will clarify the understanding of the participant.)
Transparency	It implies intentional openness, communication, and accountability operating in such a way that it is easy for others to see what actions are performed.
Therapeutic misconception	It is a misconception by participants believing that the purpose of clinical trials/research study is to administer treatment rather than to conduct research.
Undue inducement	Offer of disproportionate benefit in cash or kind that compromises judgment which may lead to acceptance of serious risks that threaten fundamental interests.
Unexpected ADR	An adverse reaction, the nature or severity of which is not described in the informed consent/information sheet or the applicable product information, such as an investigator's brochure for the unapproved IP or package insert/summary of product characteristics for an approved product.
Vulnerability	Vulnerability in research pertains to individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability, environmental burdens or social injustice, lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so.