2020

Institutional Ethics Committee Standard Operating Procedures

SGMC-IEC SOPs

Edited by: Prof.Dr.Regi Jose,Member Secretary SGMC IEC

Sree Gokulam Medical College and Research Foundation Venjaramood

Sree Gokulam Medical College Venjaramoodu
Thiruvananthapuram

Institutional Ethics Committee Standard Operating Procedures (SGMC-IEC: SOPs)

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List of Acronyms

Acronym	Full Title/Description
AAHRPP	Association for the Accreditation of Human Research Protection Programs
ACTREC	Advanced Centre for Treatment, Research and Education in Cancer
ADR	Adverse Drug Reaction
AE	Adverse Event
AIIMS	All India Institute of Medical Sciences
ASU	Ayurveda, Siddha, Unani.
BA	Bio-availability
BARC	Bhabha Atomic Research Centre
BE	Bio-equivalence
BIS	Bureau of Indian Standards
CDC	Center for Disease Control and Prevention
CDSCO	Central Drugs Standard Control Organization
CFR	Code of Federal Regulations
CIOMS	Council for International Organizations of Medical Sciences
CoI	Conflict of Interest
CONSORT	Consolidated standards of reporting trials
CRF	Case Record Form
CRO	Contract Research Organization
CRS	Clinical Research Secretariat
CTA	Clinical Trial Agreement
DAE	Department of Atomic Energy
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
DSMSC	Data Safety Monitoring Sub Committee
DTAB	Drugs Technical Advisory 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
GCP	Good Clinical Practice
GMP	Good Manufacturing Practices
IEC	Human Ethics Committee
HIPAA	Health Insurance Portability and Accountability Act
HMSC	Health Ministrys Screening Committee
IAEA	International Atomic Energy Agency
IB	Investigator's Brochure

ICF	Informed Consent Form
ICH	International Committee on Harmonization
ICJME	International Committee of Medical Journal Editors
ICMR	Indian Council of Medical Research
IDE	Investigational Device Exemption
IMDRA	Indian Medical Devices Regulatory Authority
IND	Investigational New Drug
IRB	Institutional Review Board
IRC	Institutional Research Committee
ISI	Indian Standards Institute
MOU	Memorandum of Understanding
MTA	Material Transfer Agreement
NAC-SCRT	National Apex Committee for Stem Cell Research and Therapy
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
IRC	Institutional Review Committee
SGMC	Sree Gokulam Medical College
SGMC RAC	SGMC-Research Administration Council
WHO	World Health Organization
WMA	World Medical Assembly

Institutional Ethics Committee
Sree Gokulam Medical College&RF
Standard Operating Procedures (SGMC-IEC:SOPs)

SOP Codes SOP 01/V1, SOP 02/V2, SOP 03/V2, SOP 04a/V2, SOP 04b/V2, SOP 04c/V2,SOP 05/V2, SOP 06/V2, SOP 07/V2, SOP 08/V2, SOP 09/V2, SOP 10/V2, SOP 11/V2 SOP, 12/V2, SOP 13/V2, SOP 14/V2, SOP 15/V2, SOP 16/V2

Authors: SOP 2013

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Institutional Ethics Committee Revised SOP 2020(SGMC-IEC/V3)

Date of Revision : 01/05/2020

Authors: Revised SOP 2020

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Dr.Geetha O , Profesor of Forensic Medicine (Member IEC)

Dr.Mamatha Chimmalgi ,Professor of Anatomy (Member)

Approved by: Dr.V Mohanan Nair (Chairman IEC)
Accepted by : Dr. KK Manojan (Director, SGMC)

Reconstituted IEC

Sr No.	Name	Qualification with Specialization	Current Organization	e-mail and Telephone No	Designation /Role of member in Ethics Committee	Affiliation with the Institution	Change from 2013
1	Dr.V MohananNair	MBBS,MPH Public Health Bio Ethics	Kandala cooperative hospital	vmohanannair@gmail.com 91-9447742242	Chairman	No	New Chairman
2.	Dr.Regi Jose	MD,DPH,DNB, Community Medicine MPhil Clinical Epidemiology	Sree Gokulam Medical College	regipaul@gmail.com 91-9446475035	Member Secretary	Yes	Continuing
3	Dr.Remani PT	MD Pharmacology	Sree Gokulam Medical College	Dr.pt.rami@gmail.com 91-9446593762	Basic Medical Scientist	Yes	New Member
4	Mamatha Chimmalgi	MS Anatomy	Sree Gokulam Medical College	mamatachimmalgi@gmail.com 91-9387122769	Basic Medical Scientist	Yes	Continuing
5	Dr.Geetha O	MD Forensic Medicine	Sree Gokulam Medical College	geethatvm@gmail.com 91-9847139090	Basic Medical Scientist	Yes	Continuing

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6	Dr.C.Sudheendra Ghosh	MD Pulmonary Medicine	Sree Gokulam Medical College	sudheendraghosh@gmail.com 91-9895409787	Clinician	Yes	Continuing
7	Dr.Meera Pillai	Msc Nursing	Sree Gokulam Nursing College	Pgknair1@rediffmail.com 9539804176	Principal	Yes	New member
8	Dr.Ajith Kumar	MD General Medicine	Sree Gokulam Medical College	kumarajith38@yahoo.co.in 9447389962	Clinician	Yes	New member
9.	Mrs.Divya Ashok	LLB, MA (Psychology)	Private Practice	divyabenny@gmail.com 91-9995679139	Legal Expert	No	Legal Expert Continuing
10.	Mr.Harikrishanan	M Sc. Nursing, MHA	Sree Gokulam Nursing College	harikrishna041@gmail.com 91-99895299041	Member	Yes	Continuing
11.	Mr.Meera Sahib	BA Economics	Ex-President Venjaramoodu panchayat	meerasahibvenjaramoodu@gmail.com 91-9447906614	Social Scientist & Politician	No	Continuing
12	Mr. Madhu Ramanujan	BA	Representative of lay men	originpharmaceuticals@gmail.com 9447112324	Lay-persons' Representative	No	New member

Changes from SOP2013

1.Change in the IEC: Seven members continued from the previous committee, Five members were replaced by new members

2.Annexure to the following SOPs

1. **1.SOP03/V1 → AX6V1/SOP03/V1**
2. **2.SOP09/V1 → AX4V1/SOP09/V2**
3. **3.SOP15/V1 → AX2V1/SOP15/V1**
4. **4.APP4/V1 → AX1V1/APP4/V1**

3 SOP 10/V2 Date: 01/04/2013→ SOP 10/V3 Date:28/12/2017

Revision regarding the duration of archival ; changed from three to five years

Changes from SOP2017

1.Addition of SOP17, SOP18 and SOP 19

2.Modified SOP2 depicted as Version 3 dated 01/05/2020

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Institutional Ethics Committee Standard Operating Procedures(SGMC-IEC:SOP:01/V1)

Title : Preparing SOPs - Writing, Reviewing, Distributing & Amending SOPs for Institutional Ethics Committee (IEC)

SOP Code: SOP 01/V1 Date : 01/04/2013 Pages:

1.1 Purpose

This SOP defines the process for writing, reviewing, distributing, and amending SOPs within the IEC SGMC.The SOPs will provide clear, unambiguous instructions to conduct activities of the IEC in accordance with the ICMR guidelines 2006, Schedule 'Y" (Drugs and Cosmetic Act 1940: Amendment 8th February 2013), WHO Operating Guidelines for Ethical Review Committee that Review Biomedical Research, and ICH (International Conference on Harmonization) Good Clinical Practice (GCP).

1.2 Scope

This SOP covers the procedures of writing, reviewing, distributing, and amending SOPs within the IEC, SGMC

1.3 Responsibility

It is the responsibility of Chairperson of the IEC to appoint the SOP Team to formulate the SOP. SOP team comprising of Member Secretary of the IEC and a member ; draft an SOP, get it reviewed and approved by the IEC members and amend it as and when required. All members of IEC will review the SOP and approval will be given by the Chairperson.The SOP will be also signed off by Director, SGMC as this is Institutional Ethics Committee.

Secretariat of IEC / IRB:

- Co-ordinates activities of writing, reviewing, distributing, and amending SOP
- Maintains on file current SOP and the list of SOPs
- Maintains an up-to-date distribution list of each SOP circulated to IEC members
- Maintain a record of the investigators to whom SOPs are distributed against a requisition
- Ensures all IEC members and involved administrative staff have access to the SOP
- Ensures the IEC members and involved staff are working according to current version of SOP
- Maintain a file of all past SOP of the IEC
- Assist in the formulation of SOP procedure

SOP team (will consist of Member Secretary and one or two other members)

- Assess the request(s) for SOP revision in consultation with the Secretariat and Chairperson
- Propose new / modified SOPs as needed
  Select the format and coding system for SOPs
- Draft the SOP in consultation with the IEC members and involved administrative staff
- Review the draft SOP
- Submit the draft for approval to chairperson

Chairperson of the ethics committee

- Appoint one or more SOP Teams
- Reviews and approves the SOPs
- Signs and dates the approved SOPs

IEC members and involved administrative staff

- Review, sign and date SOPs
- Maintain a file of all SOPs received
- Return all out-of date SOPs to IRB office

1.4 Detailed instructions

1.4.1 Identify the need for new or amendment to SOP

Any member of the IEC, secretariat or administrative staff or investigators, can make a request for revision or notices an inconsistency / discrepancy / has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP can put forth his request by using the Request Form for Formulation of new SOP / Revision of an SOP Form (AX5-V1/SOP01/V1) to make a request. This AX form is submitted to the Chairperson, IEC. The Chairperson will inform all IEC members about this request in a regular full board meeting.

If IEC members agree to the request, the Chairperson will appoint an appropriate SOP team comprising of Member Secretaries of both committees. The Chairperson may also appoint one or two committee members as members of SOP team, if necessary. This designated team will proceed with the task of revision / formulation process of the SOP. If IEC members do not agree to the request, no further action will be taken.

The Chairperson will inform the person / IEC member who made the request for modification of the SOP in writing about the decision.

1.4.2 Appoint the SOP team

The Chairperson will constitute an SOP team consisting of the Member-Secretary and two or more members of the IEC who have a thorough understanding of the ethical review process.The SOP writing team will carry out the subsequent steps (1.4.3-1.4.7).

1.4.3 List of relevant SOPs

- Write down step by step all the procedures of the IEC
- Organize, devise and, name each process
- Make a list of SOPs with coding reference (AX1-V1/SOP01/V1)

1.4.4 Design a format and layout

Each SOP should be given a number and a title that is self-explanatory and is easily understood.A unique code number with the format SOP xx / Vy will be assigned to each SOP by the secretariat. xx will be a two-digit number assigned specifically to a particular SOP. "V" refers to version of the SOP and "y" will be a number identifying the version e.g. SOP01/V1 is SOP number 01 with V=version no.1.

Each AX will be given unique code number with the format AXn–Vp/SOP xx/Vy. e.g. AX1–V1/SOP01/V1 indicates AX is Annexure, n is Annexure no.1, version 1, belonging to the SOP 01/V1

Each Appendix will be given unique code number with the format APPn/Vy e.g. APP1/V1 indicates APP is Appendix, n is Appendix no 1, V1 is version no.1.

Each SOP will be prepared according to the template for Standard Operating Procedures in AX2– V1/SOP01/V1. Each page of the SOP will bear a header with the effective date which is the date of approval of the SOPs signed and dated by the Chairperson, IEC, and approved by the Director.
The SOP number will be on the left hand corner of the header while the left hand corner of the footer will bear the title of the SOP and page number as Page—of—total pages.
The first two pages of each SOP document will be signed and dated by the authors, the IEC members who have reviewed the SOPs, IEC Chairperson who have approved and Director, SGMC who has accepted the SOPs and subsequently the SOP will be implemented from that date.

1.4.5 Write, Review, and Approve SOP

With reference to section 1.4.1 and 1.4.2, the draft SOP will be prepared by the SOP team.

1.4.6 Review by Consultation

- The draft SOP will be discussed with members of both IECs and all administrative staff.
- The SOP should be approved by all involved in that particular task.
- The final version will be forwarded to the chairperson for review and approval.

1.4.7 Preparation and submission of final draft

- All the members of IEC will review the draft / revised SOP.
- During respective IEC meetings, members can put forth their suggestions / comments on the draft / revised SOP.
- The suggestions agreed upon unanimously by all IEC members will be incorporated and the final draft SOP will be formulated.
- The SOP team would stand automatically dissolved once the IEC takes final decision regarding the SOP.

1.4.8 Final Approval of new/revised SOP

- The final version will be presented to the Chairpersons of both committees for review and approval. The Chairpersons will sign and date the SOP on the first page of the SOP

document. This date of approval is declared as the effective date for implementing the SOP.

- This approved document will then be submitted to the Director, SGMC for acceptance.

1.4.9 Implementation, distribution, and filing all SOPs

- Approved SOPs will be implemented from the effective date.
- The secretariat will discuss the approved SOPs with the administrative staff and instruct them to implement the SOP accordingly.
- Approved SOPs will be distributed to IEC members and IRB staff according to the distribution list (AX4 –V1/SOP 01/V1)
- When revised version is distributed, the old version will be retrieved from all members and destroyed. A copy of the old version will be archived in a master file.
- One complete original set of current SOPs will be archived in the SOP master file,by the IRB Secretariat and maintained in the IRB Office.
- A copy of the SOP master file will be maintained in the individual offices of IEC,and IRB.
- Photocopies made from these official paper versions of the SOP can be considered current or official, if stamped and signed by Member Secretary or authorized individual for distribution, a log of which should be maintained (AX6 –V1/SOP 01/V2)

1.4.10 Review and request for revision of an existing SOP

- Any member of the IEC, secretariat or administrative staff who notices that current SOPs have some lacunae or have any suggestions to improve a procedure should make a written request, using a form (AX5-V1/SOP 01/V1)
- If IEC agrees with the request, the Chairperson will appoint an appropriate team to proceed with the revision process. If the committee does not agree, the chairperson will inform the concerned individual who made the request for revision.
- Revised SOPs will be reviewed and approved in the same manner as new SOPs (Section 1.4)
- The secretariat is expected to review the SOP at least once every 2 years and record the dates of review in the SOP master file.

1.4.11 Manage and archive old SOPs

Old SOPs should be retained and clearly marked “superseded” and archived in a file by the secretariat. The process of evolution of previous SOPs of the IEC will be documented in a defined format (AX3 –V1/SOP01/V1).

Glossary

Effective date: The date of approval of the SOPs signed and dated by the Chairperson, IEC, SGMC, and subsequently the SOP is implemented from that date

IEC members: Individuals serving as regular members of the Institutional Ethics Committee, SGMC.The Committee has been constituted in accordance with the EC membership requirements set forth in Schedule Y (8 February2013)

Master SOP files: An official collection of the Standard Operating Procedures (SOP) of IEC,SGMC accessible to all staff, IEC members, auditors and government inspectors as a paper copy with an official stamp on each page and the approval signatures

Past SOPs of the IEC: A collection of previous official versions of a SOPs and relevant information regarding changes and all preplanned deviations

Requestors: Investigators, Sponsors, CROs, Regulatory authorities, Hospital administrators, and such others

Revision date: Date/year by which the SOP may be revised or reviewed.

Recipients: Stakeholders who would receive a copy of SOP, viz., two categories 1) IEC members 2) Non-IEC members i.e. investigators/sponsors SOP (Standard Operating Procedure): 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 the functioning, whilst maintaining high standards of Good Clinical Practice

SOP Team: A team of members selected from the IEC, SGMC including the Member Secretary,administrative staff, and any other member of IEC as identified by the chairperson who oversee the creation, preparation, review, and periodic revision of the IEC, SGMC SOPs

AX1-V1/SOP 01/V1: List of SOPs of Institutional Ethics Committee (SGMCIEC)

sr. no	SOP TITLE	SOP CODE
1	Preparing Standard Operating Procedures (SOPs): Writing,Reviewing, Distributing, & Amending SOPs for the Human Ethics Committee (IEC), SGMC	O1/V1
2	Constitution of Institutional Ethics Committee, SGMC	02/V2
3	Management of Protocol Submissions	03/V2
4	Review of Submitted Protocol 4a Initial Review of Submitted Protocol	04/V2 04a/V2
	4b Expedited Review of Submitted Protocol	04b/V2
	4c Exemption from the Ethical Review for Research Projects	04c/V2
5	Agenda Preparation, Meeting Procedures and Recording of Minutes	05/V2
6	Review of Amended protocol / Protocol related documents	06/V2
7	Continuing review of study Protocols	07/V2
8	Reporting of Protocol Deviation / Non-Compliance / Violation / Waiver	08/V2
9	Review of Serious Adverse Events (SAE) Reports	09/V2
10	Maintenance of Active Project Files, Archival of closed files and Retrieval of documents	10/V2
11	Documentation of the IEC activities	11/V2
12	Review of study completion reports	12/V2
13	Management of Premature Termination / Suspension /Discontinuation of the study	13/V2
14	Request for Waiver of Written Informed Consent	14/V2
15	Site Monitoring	15/V1
16	Dealing with participants / patients requests and complaints	16/V1

AX2-V1/SOP01/V1: Template for Standard Operating Procedures

Institutional Ethics Committee	
Title: *Title which is self-explanatory and is easily understood*	
SOP No: *SOPxx/Vy*	**Page**: a of b
SOP Code: SOP xx/Vy	
Effective date: DD/MM/YYYY **Authors**: xxxxxxxxx **Reviewed by**: xxxxxxxx **Approved by**: xxxxxxxxx	

AX3-V1/SOP01/V1: Document History of the SOP

Name of the author	Version	Effective date (dd-mm-yy)

Details of superseded SOP

Name of the Team	Version	Type (draft/final)	Date(dd-mm-yy)	Describe the main change

AX4-V1/SOP01/V1: Log of the IEC members receiving SOPs

No.	Name of Recipients	Designation	SOP code number	No. of Copies	Signature	Date
1	XXXX	Chairperson				
2	XXXX	Member Secretary				
3	XXXX	Member				
4	XXXX	Member				
5	XXXX	Member				
6	XXXX	Member				

AX5-V1/SOP01/V1: Request for Formulation of new SOP / Revision of SOP

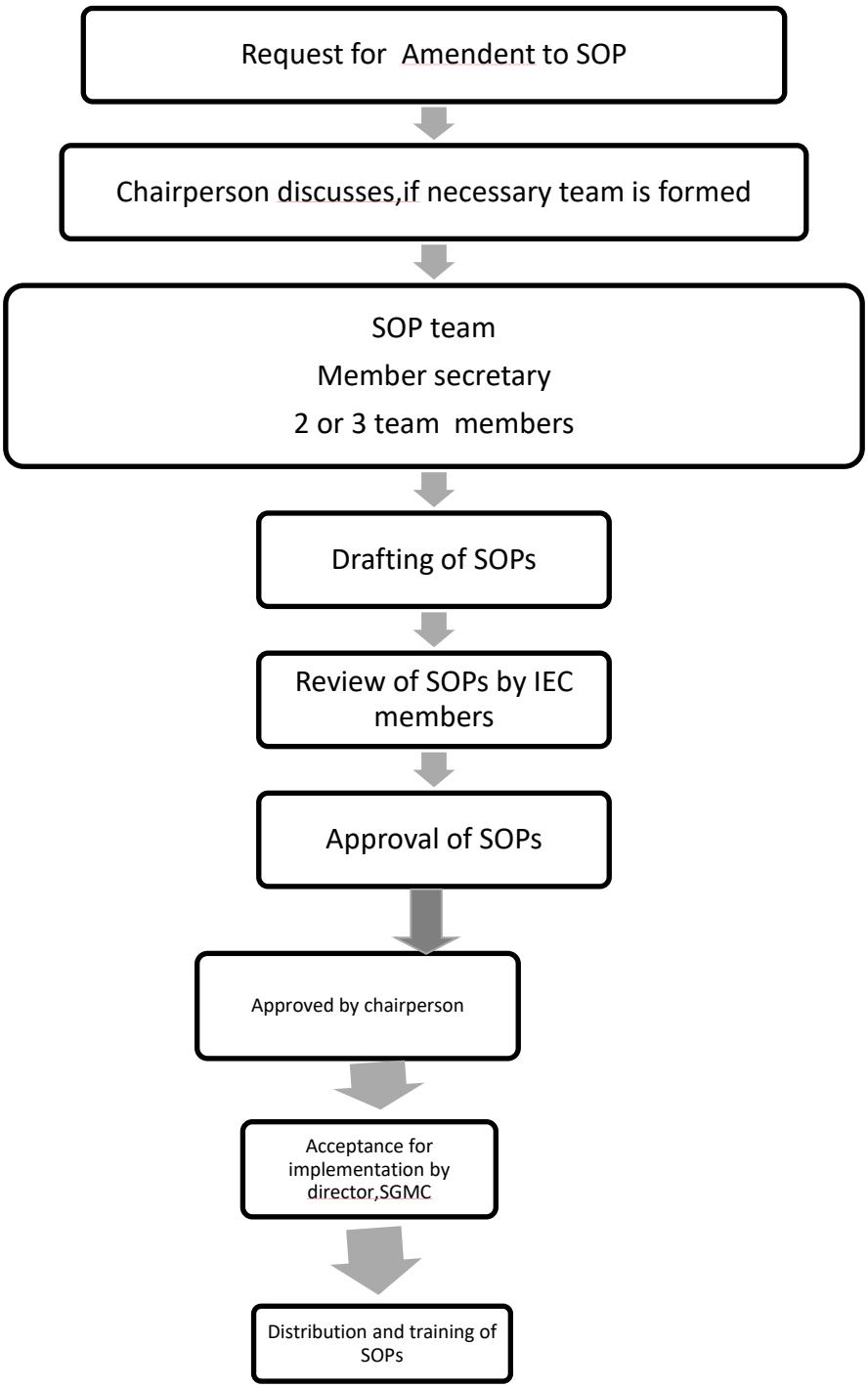
This form is to be completed by any member whenever a problem or a deficiency in an SOP is identified and maintained with the SOP until an authorized replacement is in place.

SOP No.		
Title:		
Details of problems or deficiency in the existing SOP		
Need to formulate an entirely new SOP (i.e. SOP not existing previously)		
Identified by:	Date (DD/MM/YYYY):	
SOP revision required:	□ Yes	□ No
New SOP to be formulated:	□ Yes	□ No
If yes, to be carried out by whom?		
If no, why not?		
Date SOP revised:		
Date SOP approved:		
Date SOP becomes effective:		

AX6-V1/SOP01/V1 : Log of SOP recipients

No.	Name of Recipients	Designation	SOP code number	No. of Copies	Date
1	XXXX	XXXX			
2	XXXX	XXXX			
3	XXXX	XXXX			
4	XXXX	XXXX			
5	XXXX	XXXX			
6	XXXX	XXXX			

FLOW CHART


Request for Amendent to SOP
Chairperson discusses,if necessary team is formed
SOP team
Member secretary
2 or 3 team members
Drafting of SOPs
Review of SOPs by IEC members
Approval of SOPs
Approved by chairperson
Acceptance for implementation by director,SGMC
Distribution and training of SOPs

Institutional Ethics Committee Standard Operating Procedures(SGMC-IEC:SOP:02/V3)

Title : Constitution of Institutional Ethics Committee (SGMC IEC)

SOP Code: SOP 02/V3 Date : 01/05/2020 Pages:....

The Institutional Ethics Committee is constituted by Director, Sree Gokulam Medical College (SGMC) under authority vested by Governing Council of the SGMC Institutional Ethics Committee, Sree Gokulam Medical College (SGMC-IEC) was established in 2007.

2.1 Purpose

The IEC was established to formalize and specify the Institution's commitment to promotion of high ethical standards in patient care, professional education, clinical research, and community interests.

2.2 Mandate

The IEC functions independently for maintaining consistent ethical framework in patient care and research, and in the integration of ethical values into practice, policy relationships, and organizational activities.

- The purpose of IEC is to cultivate a pluralistic and democratic exchange of ethical values, concerns and to critically analyze them looking for opportunities to enhance the ethical integrity of the Institution
- The mandate of IEC, SGMC essentially targets patient care and ethical aspects of research and education.

The terms of reference for the IEC are as follows:

- To improve the standards of ethics practiced in SGMC and to issue guidelines on dilemmas relating to patient care services at SGMC
- To ensure that all proposed research projects conform to standard ethical guidelines.
- To initiate and commission research studies on ethical aspects of practice in SGMC
- Continuing education in research bioethics and ethical aspects of clinical practice by seminars, workshops and interactive discussions for all categories of staff members including nursing and paramedical staff
- To function as a forum for redressal of complaints on ethical issues, from patients and their families
- The Ethics committee endeavors to produce guidance on a broad range of topics. Disclosures of diagnosis, diagnosis of brain death, indications for stopping resuscitation, true informed consent, etc. are some examples
- The committee does not address or interfere in matters of an administrative nature, nor does the committee function as a grievance cell for staff members.

2.3 Scope

The SOP applies to the formation of the IEC

2.4 Responsibility

IEC has responsibility within the institution with the following objectives:

- To ensure the competent review and evaluation of all ethical aspects of research projects received, to ensure compliance with the appropriate laws and safeguard welfare of subjects.
- Clinical ethics consultation
- Education of professional, administrative, and support staff about ethical issues
- Creation, developing revising and implementing ethical guidelines (SOPs)
- Initiate studies in ethics
- Continuing education and training programs to ensure that IEC members are qualified to perform their specific duties.

2.5 Ethical Basis

- The committee consists of members who collectively have the qualifications and experience to review and evaluate the scientific, medical, and ethical aspects of a proposed research project.
- The IEC recognizes that the protocols it approves may also be approved by national and / or local ethics committees prior to their implementation in specific localities.
- In evaluating protocols and ethical issues, the IEC is aware of the diversity of laws, cultures and practices governing research and medical practices in various countries around the world
- The IEC also seeks to be informed, as appropriate, by national / other local ethics committees and researchers of the impact of the research it has approved.
- The IEC is guided in its reflection, advice and decision by

    - ❖ *The ethical principles expressed in Declaration of Helsinki (Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; 35th World Medical Assembly, Venice, Italy, October 1983; 41st World Medical Assembly, Hong Kong, September 1989; 48th World Medical Assembly, Somerset West, Republic of South Africa, October 1996; and the 52nd World Medical Assembly,Edinburgh, Scotland, October 2000; Note of Clarification on Paragraph 29 added by the World Medical Assembly, Washington 2002; Note of clarification on Paragraph 30 added by the World Medical Assembly, Tokyo 2004, 59thWMA general Assembly, Seoul, October 2008)*

    - ❖ *It makes further reference to the International Ethical Guidelines for e.g. The Nuremburg Code (1945), the Council of International organizations of Medical Sciences (CIOMS), the Belmont Report 1979, the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva 2002), and the European Convention on Human Rights and Biomedicine 1977*

- The IEC establishes its own Standard Operating Procedures based on the ICMR guidelines (2006), Schedule Y (Drugs and Cosmetics Act 1940., amendment 8th Feb 2013), Operational Guidelines for Ethics Committees that Review Biomedical Research (WHO 2000), and ICH-GCP, 1996 and the local regulations
- The IEC seeks to fulfill the requirements for international assurances and is established and functions in accordance with the national law and regulations

- In view of the tremendous growth of clinical research in the institution, the Director,SGMC in 2012, constituted two committees to function as separate panels which divided the work load of Good design and ethical aspects. These two committees were renamed as Institutional Ethics Committee(IEC) and Institutional Research Committee(IRC) to expedite and maintain high standard of ethical review.

2.6 Composition

IEC will be multidisciplinary and multi-sectorial in composition.

The committee is composed of a minimum of 7, and maximum of 15 members. The members are selected to have an equitable representation of all specialties in the institution. It includes scientific and non-scientific, clinicians and non-clinicians,Clinical pharmacologist, members of the community, a lawyer/expert in ethics, a social scientist / representative of non-governmental voluntary agency,a philosopher / ethicist / theologian / lay person from the community to represent different point of view. Each committee will comprise of a Chairperson, a Member Secretary, and 7-15 active members who represent an appropriate balance of professional, ethical, legal, cultural, educational, and community interests. The committee should have adequate representation of age, gender, community, etc. to safeguard the interests and welfare of all sections of the community / society. Members are expected to be aware of local, social and cultural norms, as this is the most important social control mechanism. The member should have various backgrounds to promote complete and adequate review of research activities commonly conducted by that given institute / centre. The members should not be part of any other committee which takes decision on research activities within the institution(IRB/IRC if there is a separate body review the same protocols) so enable unbiased independent decision making.

Composition of IEC

The composition should be as follows:-

1. Chairperson (not – affiliated to SGMC)
2. Member secretary (SGMC Staff members)
3. 1-2 clinicians (affiliated to SGMC)
4. Basic medical scientists
5. Clinical Pharmacologist
6. One legal expert or retired judge or medico-legal expert
7. One social scientist / representative of non-governmental voluntary agency
8. One philosopher / ethicist / theologian / lay person from the community

2.6.1 Membership

All members will be appointed by the Director, SGMC in consultation with the Chairperson, IEC and Member Secretary.

Criteria for selection of members:

1. Members are selected on their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in domain field and profile.
2. Conflict of interest will be avoided when making appointments, but where unavoidable, there will be transparency regarding such interests.
3. New members will be identified according to the requirement i.e. as per the composition specified in Section 2.6. of this SOP and provided the potential member fulfils the conditions of appointment as defined in 2.6.2 of this SOP.

The following qualities are sought in IEC members:

- interest and motivation
- time and effort
- commitment and availability

- experience and education
- respect for divergent opinions
- integrity and diplomacy

2.6.2 Terms of Appointment

2.6.2.a Duration

- The members of the IEC, SGMC will be appointed for duration of 3 years.
- The appointment procedure for membership will be followed so that it allows for continuity, the development and maintenance of expertise within the IEC, and the regular input of fresh ideas and approaches.
- The members can be continued and there will be no limit on the number of times the membership is extended. Extension of membership will be based on the recommendation of the Chairperson & Member Secretary of IEC.
- A Member Secretary, Chairperson or member may be newly appointed before the completion of the tenure of the existing appointed committee. This appointment will be effective for the remaining tenure of the existing committee.

2.6.2.b Renewal

- The membership will be renewed after the stated term of 3 years
- The process of renewal will be as follows:
    - Selection of Member Secretary and other members should be done 6 months and 1month in advance, respectively. Member secretary designate should be inducted in the committee as a member before he/she takes on the mantle in the new IEC.
    - Other members designate may attend the board meeting as observers before starting their tenure as IEC member. Designated members of the IEC who wish to attend IEC meetings as observers should read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form (AX3 – V1/SOP02/V2) at the beginning of the IEC meeting and/or before ethical review tasks of the IEC commence
    - If a regular member resigns, or ceases to be a member due to disqualification, or death, a new member will be appointed for the remaining term as per the Conditions of appointment stated below – section 2.6.3

2.6.2.c Resignation / Replacement procedure

The members who have resigned may be replaced at the discretion of the appointing authority for the same. IEC members who decide to resign must provide the Director, SGMC and Chairperson, IEC the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting. In case of resignation, Director, SGMC would appoint a new member, falling in the same category of membership ex. NGO representative with NGO representative. The recommendations may be sought from the resigning member. Appointment may be made in the consultation with Member Secretary and /or Chairperson

2.6.2.d Termination / Disqualification procedure

A member may be relieved or terminated of his/her membership in case of

- Conduct unbecoming for a member of the Ethics Committee
- Inability to participate in the meetings on any grounds

- If a regular member fails to attend more than 3 meetings of IEC. The membership shall be reviewed by the IEC if the member is a regular defaulter. If deemed necessary, the IEC may decide to terminate the membership and recommend to the Director, SGMC, by the Chairperson IEC for necessary action
- Relocate to another city or any such matter

In all such situations/circumstances, Director, SGMC will serve a letter of termination to the member. Documentation of the termination will be recorded in the meeting minutes of the next duly constituted IEC meeting and IEC membership circular/roster will be revised.

2.6.3 Conditions of Appointment

- Name, age, gender, profession, and affiliation of IEC members will be publicised.
- Members must accept the appointment in writing.
- Submit one page CV and training certificates in Ethics and /or GCP.
- Conflict of interest, if any, must be disclosed.
- Members must apprise themselves of the relevant documents, codes, GCP, ICH guidelines and the ICMR code & IEC, SGMC SOPs Members are required to sign the confidentiality agreement (AX1-V1/SOP 02/V2) at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IEC/IRB in the course of its work.
- An investigator can be a member of the IEC; however, the investigator-as-member cannot participate in the review and approval process for any project in which he or she has presence as a PI,Co-PI or CI or potential conflict of interest.

2.6.4 Independent Consultants

- The IEC may call upon, or establish a standing list of, independent consultants who may provide special expertise to the IEC on proposed research protocols, when the Chairperson / Member secretary or the IEC members determine that a study will involve procedures or information that is not within the area of expertise of the IEC members. These consultants may be specialists in ethical or legal aspects, specific diseases, or methodologies, (e.g. genetic disorders, stem cell research etc.) or they may be representatives of communities, patients, or special interest groups. These consultants must sign the confidentiality agreement (AX2-V1/SOP02/V2) regarding meeting, deliberations, and related matters. These consultants or subject experts cannot vote for decision.

2.6.5 Honorariums

Honorarium/ consultancy to the members/ invited experts etc

Chairman : Rs.5000/-
External members travelling >20kms from the institution for the purpose: Rs.2000/-
Other external members: Rs.1000/-
Invited experts (outside institution):Rs.1000/
Institutional Members: Local hospitality
Invited experts (inside institution): Local hospitality

2.7 Office Bearers

The IEC will have the following office bearers who have the expertise and professional qualifications to review what comes in.

2.7.1 Chairperson

The IEC Chairperson should be a highly respected individual preferably from outside the Institution, fully capable of managing the IEC and the matters brought before it with fairness and impartiality. The task of making the IEC a respected part of the institutional community will fall primarily on the shoulders of this individual. The IEC must be perceived to 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 nonprofessional sources.

2.7.2 Member Secretary

The Member Secretary will be a staff member of institute, committed to the task of coordinating and managing the activities of the committee. He/she will be responsible for scheduling the meetings, describing the agenda and ensuring that the function of the committee is conducted as per the norms and policies described in this SOPs.

2.7.3 Secretariat

Secretariat is composed of Member Secretary, IEC and the administrative supporting staff. The supporting staff consists of staff members of the SGMC appointed by the Director, SGMC.
The secretariat shall have the following functions:

- Organizing an effective and efficient tracking procedure for each proposal received
- Preparation, maintenance and distribution of study files
- Organizing IEC meetings regularly
- Preparation of agenda and minutes of the meetings
- Maintaining IEC documentation and archive
- Communicating with IEC members and PIs
- Arrangement of training for personnel and IEC members
- Providing necessary administrative support for IEC related activities to the Member Secretary, IEC

The IEC Administrative Staff: Working Rules

1. There will be administrative officer/s and attendant/s /helper/s who will help the IEC Chairperson and Member Secretary in executing functions of the IEC. Additional staff may be appointed and duties assigned; as and when deemed necessary by the IEC. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile. The need for appointment of administrative staff, job profile and qualifications may be recommended by IEC members during regular IEC meeting and will be recorded in minutes; these are forwarded to the Director,SGMC.
2. The administrative staff will be appointed by conducting formal interviews (to be conducted by panel of experts appointed by Director, SGMC.
    a. Duties of the administrative officer/s/staff
    b. Correspondence with the IEC members and external experts
    c. Correspondence with the investigators
    d. Pre and post arrangements of IEC meetings
    e. Preparing agenda and minutes of the IEC meetings
    f. Answering queries of the investigators
    g. Filing study related documents
    h. Archiving and maintaining the study files
3. Duties of the attendant/s /helper/s
    a. Assisting the secretariat in arranging the IEC meetings
    b. Dispatching sets of study documents to IEC members and external experts

c. Receiving the study related documents from and dispatching the IEC letters to the investigators
d. Filing study related documents
e. Archiving and maintaining the study files
f. Correspondence with the IEC members and external experts

4. The administrative staff will report to the Chairperson and/or Member Secretary.
5. The office timing for the administrative staff will be as per SGMC rules & regulations.
6. The administrative staff will avail leave as per SGMC norms.

2.8 Roles and Responsibilities of the IEC members

- The Committee's primary responsibilities will be protection of safety, rights and confidentiality of the research subjects.
- Participate in the IEC meeting.
- Review & discuss research proposals submitted for evaluation.
- Review progress reports and monitor ongoing studies.
- Maintain confidentiality of the documents and deliberations of the IEC meetings.
- Declare conflict of interest, if any.
- To carry out work delegated by Chairperson, & Member Secretary.
- To participate in continuing education activities in biomedical ethics and biomedical research.
- To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat

2.9 Signatory Authority:

a) Member Secretary will be primary signatory authority for signing the approval letters, correspondence with the office of regulatory authorities and all correspondence on behalf of IEC, whereas for the minutes of meeting, copies of IEC Standard Operating Procedure and Membership list, will be signed by the Member Secretary and Chairperson.

b) In the absence of Chairperson, any other unaffiliated member may be designated by the Chairperson as signatory authority for the interim period. In the absence of Member Secretary, this role shall be allocated as per direction of the chairperson

c) Member Secretary or the Secretariat shall be the signatory authority for Standard Operating Procedure Formation of the IEC and Terms of Reference for Membership,correspondence to members and Principal Investigators regarding the meeting schedule and any requirements of IEC review.

d) IEC Secretariat, under the guidance of the Member Secretary will prepare the Standard Operating Procedure (SOP) and IEC Chairperson, Member Secretary and an IEC member will be the signatory authority for the SOP on behalf of all members.

2.10 Quorum Requirements

A minimum of five (5) members is required to form the quorum without which a decision regarding the project should not be taken. The quorum requirements of IEC should have the following representation:

(a) basic medical scientists (preferably one pharmacologist)
(b) clinicians
(c) legal expert
(d) social scientist or representation of non-governmental voluntary agency or philosopher or ethicist or theologian or similar person

(e) lay person from the community

In any case, the ethics committee must include at least one member whose primary area of interest/ specialization is nonscientific and at least one member who is independent of the institution / trial site. Besides, there should be appropriate gender representation on the IEC

- A quorum should include at least one member whose primary area of expertise is in a non-scientific area, a clinician and at least one member who is independent of the institution/research site
- No quorum should consist entirely of members of one profession or one gender
- In absence of the Chairperson, Chairman can designate a member who is independent of the institution if capable or a member from the institution, will chair the meeting as Acting Chairperson.

2.11 Decision making

- Decision is arrived at by consensus, if consensus not possible, voting is carried out
- Opinions of absent members that are transmitted by mail or telephone or fax may be considered by the attending members during discussion but may not be counted as votes or quorum for formally convened full board meetings
- Any committee member with a conflicting interest in a proposal will abstain from deliberations and in decision making process on that proposal, except to provide information as requested by the committee. Such abstentions will be recorded in the minutes. Decision is arrived at by consensus, if consensus not possible voting is carried out

2.12 Frequency of Meetings

6-9 IEC meetings shall be conducted in a year. In case of more submissions meetings can be convened as per requirement.

2.13 Education for IEC Members

IEC members have a need for initial and continued education regarding the ethics and science of biomedical research. All IEC members must be conversant with ICMR Guidelines for Research involving Human Subjects 2006, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines.
IEC members will receive introductory training material in research bioethics and functioning of IEC and will be exposed to ongoing opportunities for enhancing their capacity for ethical review.

Training of the IEC members in Research Bioethics

- A new member will be inducted 1 month prior and will be requested to be an 'observer' for the first board meeting. An introductory training will be imparted by the Member Secretary.
- The IEC members will be encouraged to receive ongoing training by attending workshop at least once every year.
- The IEC will conduct workshops from time to time to impart training to the IEC members and Institutional faculty members.
- The training programmes should be scheduled and spread over the year.

Glossary

Confidentiality: Prevention of disclosure, to other than authorized individuals, of information and documents related to IEC
Institutional Ethics Committee (IEC) : It is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a clinical trial and to provide public assurance of that protection

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

AX1-V1/SOP02/V2 :

Confidentiality and Conflict of Interest Agreement form for IEC Members

In recognition of the fact, that I, Dr…… herein referred to as the "Undersigned", has been appointed as a member of the Institutional Ethics Committee (IEC), would be asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;

Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC member is to independently review research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The undersigned, as a member of the IEC is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information")in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that my performance of this agreement is consistent with the Institute's policies and any contractual obligations they may have to third parties.

Conflict of Interest

It has been recognized that the potential for conflict of interest will always exist but has faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

In accordance of the policy of the IEC, I shall not participate in the review, comment or approval of any activity in which I have a conflict of interest, except to provide information as requested by the IEC.

_____ _____

Undersigned Signature Date

Edited by: Prof.Dr.Regi Jose,Member Secretary SGMC IEC

The Undersigned will immediately disclose to the Chairperson of the IEC any actual or potential conflict of interest that I may have in relation to any particular proposal submitted for review by the committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that a IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IEC member(s) in question.
The committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IEC review or approval except to provide information requested by the Committee.

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest.

In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the committee not to count me toward a quorum for consensus or voting.

I, Dr. …….. have read and I accept the aforementioned terms and conditions as explained in this Agreement.

Undersigned Signature	Date
Director of the SGMC	Date

AX2-V1/SOP02/V2 : Confidentiality Agreement Form for Independent Consultants

I, _____ (Name and Designation) as a non-member of IEC understand that thecopy (ies) given to me by the IEC is (are) confidential. I shall use the information only for the indicated purpose as described to the IEC and shall not duplicate, give or distribute these documents to any person(s) without permission from the IEC.

Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

_____ _____

Undersigned Signature Date

_____ _____

Chairperson of IEC Date

I, _____ (Enter name) acknowledge that I have received a copy of this Agreement signed by Chairperson, IEC and me.

_____ _____

Signature of the recipient Date

AX3-V1/SOP02/V2 : Confidentiality Agreement Form for Observer Attendees to IEC, SGMC Meetings

I, _____, understand that I am allowed to attend the IEC meeting scheduled on _____ at _____am/ pm as an Observer.
The meeting will be conducted in the Conference room, 5th Floor College Building, SGMC.
In the course of the meeting of the IEC some confidential information may be disclosed or discussed.
Upon signing this form, I ensure to take reasonable measures to keep the information and discussion as confidential.

_____
Signature of the Guest

_____
Date

_____
Chairperson of IEC

_____
Date

I, _____ (Enter name) acknowledge that I have received a copy of this

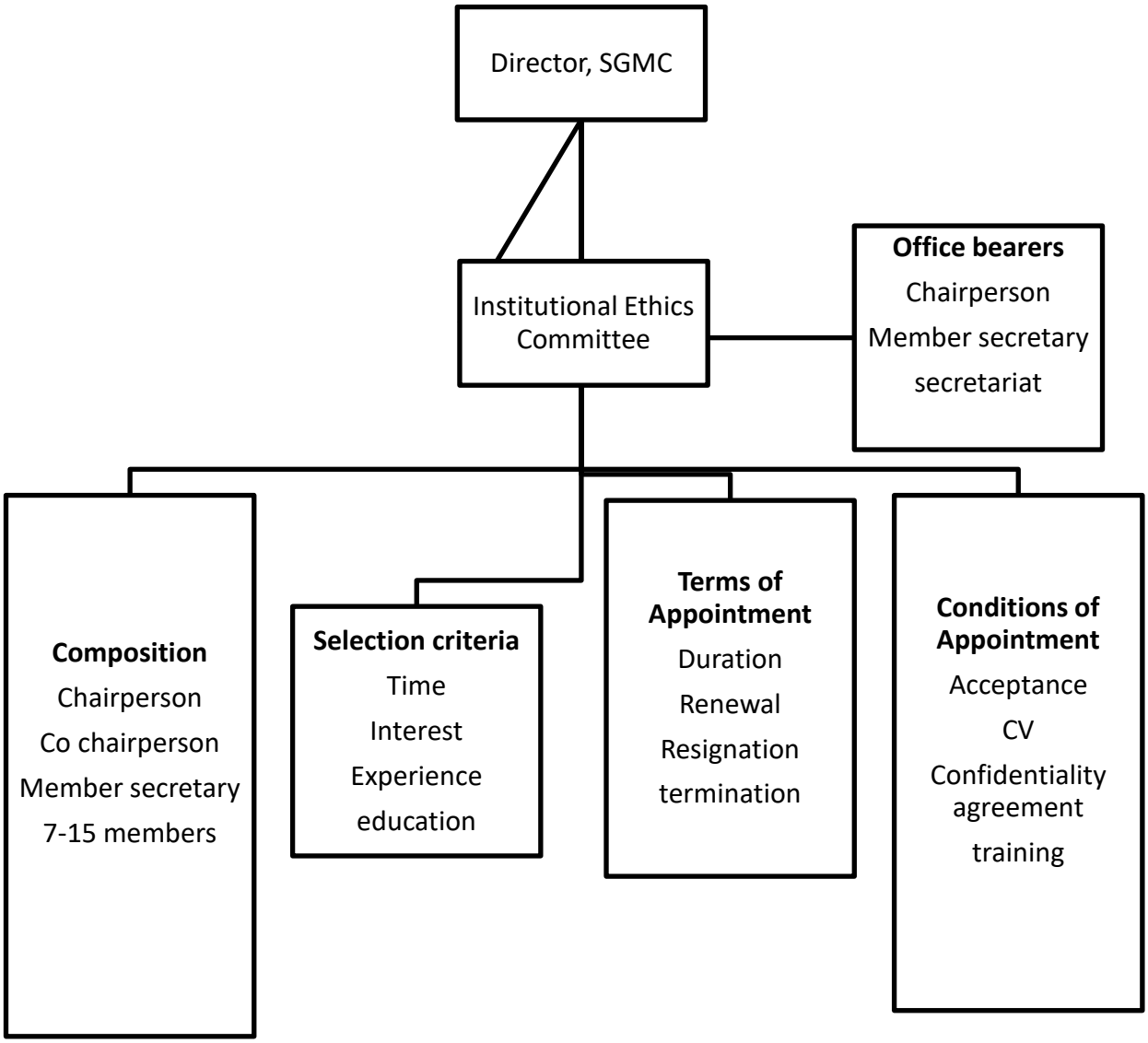
Agreement signed by Chairperson, IEC and me.

_____ _____
Undersigned Signature Date

AX1a-V1/SOP02/V2: CV for Members of the Institutional Ethics Committee of Sree Gokulam Medical College

First Name:		Middle Initial:		Last Name:
Date of Birth (mm/dd/yy):		Gender:		
Professional Mailing Address (Include institution name):				
Telephone (Office):		Mobile Number:		
Telephone (Residence):		E-Mail:		
Academic Qualifications (Most current qualification first):				
Degree/Certificate		Year	Institution	
Professional Experience:				
Duration (Month and Year)		Title	Institution/Company, Country	
Current Institution:				
Past Institution:				
Total:				
Experience in Bioethics:				
Trainings in Bioethics:				
Sr. No:	Courses/Workshops/Conferences /Meetings Attended	Organized by	Place	Duration
Members of the other Institutional Ethics Committee/Bioethics Societies with duration:				
Consent:	I hereby give my consent to be the member of the SGMCIEC		Signature &Date:	

FLOW CHART


Director, SGMC
Institutional Ethics Committee
Office bearers
Chairperson
Member secretary
secretariat
Composition
Chairperson
Co chairperson
Member secretary
7-15 members
Selection criteria
Time
Interest
Experience
education
Terms of Appointment
Duration
Renewal
Resignation
termination
Conditions of Appointment
Acceptance
CV
Confidentiality agreement
training

Institutional Ethics Committee Standard Operating Procedures(SGMC-IEC:SOP:03/V2)

Title : Management of Protocol Submissions

SOP Code: SOP 03/V1 Date : 01/04/2013 Pages:....

3.1 Purpose

This SOP is designed to describe and act as a guideline for the IRB Secretariat of the IRB to manage research protocol submissions.

3.2 Scope

The scope includes the following -

- ¸Submission for initial review
- ¸Resubmission of protocols with modifications
- ¸Protocol amendments and any other amendments
- ¸Continuing review of approved protocols
- ¸Protocol completion/termination

3.3 Responsibility

It is the responsibility of the IEC secretariat to receive record and distribute the protocols for review by the IEC and communicate the decisions to PI in a prescribed format.The projects shall be tabled for IEC review; only after obtaining approval from the research committee.
Soft copies should be mailed to sgmciec@gmail.com, and a copy should be submitted in a CD.

3.4 Detailed process

3.4.1 Receive submitted packages

The PI can submit research proposal to the IEC for review and approval under any of the 5 sections mentioned below :

- Initial Review Application
- Resubmission of Protocols with Corrections
- Protocol Amendment or any other Amendments
- Continuing Review of Approved Protocols
- Protocol Completion / Termination

3.4.2 Verify Contents of Submitted Package

- Check the applicable documents to ensure that all required forms and materials are contained within the submitted package. Checking is done as per checklist (AX2-V1/SOP 03/V2) for submissions for initial review.
- Verify contents of the submitted package which should include
    - Original Application Form for Initial Review or Project submission Form (AX1-V1/SOP 03/V2)

- Study protocol
- Other related documents necessary for initial review (AX 2-V1/SOP 03/V2)
- Check completeness of necessary information and signature at all appropriate places in the application form submitted for initial review.
- Notify the applicants, if a package is incomplete.State clearly the items missing in the package on the Protocol submission / document receipt form (AX 3-V1/SOP03/V2) along with IRC approval document.

The Secretariat will

_ Stamp, sign & date of receipt on the cover letter confirming receipt of the documents.

_ Make a photocopy of the completed document receipt form (AX 3-V1/SOP03/V2) and return the original copy of the (AX 3-V1/SOP03/V2) to the applicants for their records

_ Count for correct numbers of hard copies (Initially 13 copies for investigator-initiated studies and 13 copies for pharma-sponsored studies)

_ Store the hard copies and soft copy of the research project. The hard copies will be stored in locked cupboards in IEC office and soft copy of IRB submission form /study protocol accepted by email will be saved on IEC computer.

_ The project file is numbered as serial number / P or E or I /Year / Number e.g. 628/P/13/01 will indicate – 628 as serial no of project, P – Pharma, 13 – year, number 01 project of the year 2013. (where P = Pharma sponsored trials, E = Extramural funding, I = Intramural funding). This coding system will be maintained on the excel sheet (inventory of projects) and also labeled on each project file.

_ All correspondence for the projects, should quote only the serial number i.e 628 this unique identity number

_ Record the date of receipt, no. of copies and the name of the receiver in register.

_ Store the received packages, which include original protocol file and copies of the protocol to be distributed for review.

3.5 Detailed description of Study Project Submission

The study protocol should be accompanied with the following relevant supporting documents for scientific and ethical review. These are –

1. Checklist (Refer AX 2-V1/SOP 03/V2)
2. Project Submission Form
    A. Grouping of Project
    B. Project Fact Sheet
    C. Project Submission Overview
    D. Budget Sheet for the Proposed Study
3. Essential Documents
    a. Informed Consent Documents (Refer (AX4-V1/SOP 03/V2)
    b. Participant Information Sheet
4. Decision of other Ethics Committees (If required / asked for)

Details of Essential Documents along with protocol

1. Participant Information Sheet, Informed Consent Forms (ICFs), Assent Forms and Parentconsent forms (if children / adolescents between 7 – 18 years of age are participants in the trial) - in English, Hindi and Malayalam (Refer (AX5-V1/SOP 03/V2)
2. Investigator's Brochure
3. CRF

4. One page, recent, signed and dated curriculum vitae of the investigators indicating qualifications and relevant experience.
5. Agreement to comply with national and international GCP protocols for clinical trials
6. Details of Funding agency / Sponsors and fund allocation
7. Regulatory clearance for all types of studies from appropriate regulatory authorities i.e.DCGI approval, DGFT approval (for export of study samples), ICMR, DBT, other local government agencies (as applicable)
8. For exchange of biological material in international collaborative study a MOU / MTA between the collaborating partners and of Health Ministry Screening Committee (SGSC)
9. CTA or MOU between the collaborators
10. Insurance/Indemnity policies, indicating who are covered
11. Any other information relevant to the study

3.6 Resubmission of Protocols with corrections as per IEC suggestions

- For resubmitted protocol, the PI will submit one copy of the amended Protocol and related documents along with justification for amendment, and clearly highlighted /demarcated sections which have undergone amendment
- The IRB Secretariat will verify the completeness and reconfirm that the copy contains the modification highlighted with respect to the earlier protocol
- The IRB Secretariat will perform the steps 3.4.2 as mentioned in initial review application.The protocol related documents which do not require to be changed and are already submitted to the IEC during initial review are need not be submitted again

3.7 Research Protocol Amendments and other study related documents

- The PI will submit 15 copies of the protocol amendments or any other study related documents to the IRB Secretariat.
- The IRB Secretariat will verify the completeness as per checklist for the contents of submitted package
- The PI will highlight the modification/s in the amendment, along with a summary of changes and whether these changes would entail changes in the ICF.
- The Member Secretary in consultation with Chairperson will decide whether to:
- Carry out an expedited review in case of minor administrative amendment.
- Table for discussion at the full board meeting / or revert back for IRC review
- This is process is further elaborated in SOP 06/V2.

3.8 Annual Continuing Reviews of Approved Protocols

_ The IEC will send reminders for annual report to Individual PI, 15 days prior to the expiry date of approval, which usually is one year from the date of approval letter

_ The IEC will receive a copy of Annual Study / Continuing Review Report in the prescribed format and related documents (as per SOP 07/V2) for the approved protocol

_ The IEC Secretariat will verify the completeness of the Continuing Review Application Form (AX1-V1/SOP 07/V2) Progress report/Request letter for extension of approval of the project. The IRB Secretariat will sign and date the documents.

_ The progress or continuing review report will be tabled in the full board meeting of IEC.

3.9 Protocol Completion

- The IEC will send reminders for annual report to Individual PI, 15 days prior to the date of completion.
- The IEC will receive a copy of Study Completion Report in the prescribed format (as per SOP 12/V2).
- The IRB Secretariat will verify the completeness of the Study Completion Report Form (SOP12/V2) filled by the PI.
- The study completion report will be tabled in the full board meeting of IEC.

3.10 Payment of processing fee to the IEC for review:

Studies (P&E-- Pharma sponsored trials, E = Extramural funding): Rs.25000/-
Reviews or resubmissions:Rs:15000/-
Studies (with I = Intramural funding)): Rs.15000/-
Reviews or resubmissions:Rs: 5000/-
Studies by Post graduate students : Rs.1000/- (one time)
Studies by Undergraduate students and faculty;Rs.100/-(one time)

Glossary

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

AX1-V1/SOP 03/V2: Project Submission Form for review by IRC & IEC

A. Grouping of Project

Project No.:	
Title:	
PI:	

Please complete the questionnaire for submitting the research proposal for SGMC-IRC/IEC

Study Group
(Please circle the applicable Y/N neatly)

	Group	Detail	Yes	No
		Controlled trials		
01	A1 a	Is this a randomized controlled trial?	Y	N
02	A1 b	Is this a non-randomized controlled trial?	Y	N
03	A1 c	Is this a controlled trial that seeks new indication for establishing drug, process or a procedure?	Y	N
		Uncontrolled trials		
04	A2 a	Is this a prospective trial testing new intervention, drug, or device on patients?	Y	N
05	A2 b	Is this a prospective trial designed to test new (unproven) indication for established drug, process, procedure or device on patients?	Y	N
06	A2 c	Is this a pilot trial on new intervention, drug, and device on patients?	Y	N
		Trial involves transfer of data / material from SGMC		
07	A3 a	**Is this a multi-centre trial?**	Y	N
08	A3 b	Does this trial involves transfer of patients' data to another site including industry)?	Y	N
09	A3 c	Does this trial involves transfer of patients' blood, serum, DNA, tissue to another site?	Y	N
		Intramural Funding		
10	A4 a	Are you seeking intramural funding?	Y	N
11	A4 b	Does this trial use additional resources of SGMC beyond the usual patients' work-up (e.g. IHC, molecular profiling,MRI etc. which is not a routine part of work-up)?	Y	N

		Extramural Grants		
12	A5 a	Are you submitting application for extra-mural grant for this trial?	Y	N
13	A5 b	Is this trial partly or wholly supported by grants from sponsored industry?	Y	N
14	A5 c	Is this a phase IV / marketing trial undertaken on behalf of the industry?	Y	N
		Modification in approved trials		
15	A6	Are you seeking modification/s in the SGMC-IRC/IEC approved trial?	Y	N
		Study participants to bear the cost of trial		
16	A7 a	Will the study participants bear the cost of experimental intervention or drug therapy?	Y	N
17	A7 b	Will the study participants undergo additional blood sample collection, biopsy, endoscopy, procedure etc.?	Y	N
18	A7 c	Will the study participants bear the cost of complications arising from experimental treatment?	Y	N
19	A7 d	For the trial purpose, does the study participants have to spend Rs. 5000/- or more above the usual expenses (for any reason such as drug therapy, additional investigation, prolonged stay or repeated travel)?	Y	N
		Community or screening trials		
20	A8 a	Will this trial be undertaken in the community?	Y	N
21	A8 b	Will this trial involve the screening?	Y	N
		Trials involving genomics & proteomics	Y	N
22	A9	Does this trial involve conducting genomics or proteomics studies on study participants specimens?		
		Trials with conflict of interest	Y	N

23	A10	Will this trial involve development of a device, drug or test leading to profits or patent?	Y	N
		GROUP- B **Trials that should be notified to IRC secretariat for entry in to the "SGMC TRIAL REGISTER".**		
24	B1	Is this a prospective follow-up study (documentation of parameters only) of patients who are being offered standard treatment at SGMC?	Y	N
25	B2	Is this a phase II-IV trial restricted to standard intervention / treatments published in EBM book?	Y	N
26	B3	Is this a feasibility study for introduction of new treatment, recently shown in major international studies, to be beneficial / superior and need to be started at SGMC?	Y	N
27	B4	Is this a retrospective or prospective analysis of charts and audit of procedures / tests / treatments?	Y	N
28	B5	Is this a retrospective or prospective review of pathology specimen (may involve some additional staining techniques)?	Y	N
29	B6	Is this a retrospective or prospective review of radiology reports and their clinical correlation?	Y	N
30	B7	Is this a retrospective or prospective review of laboratory reports and their clinical correlation?	Y	N
		Procedure / demonstration at workshops etc.		
31	B8	Are you demonstrating an experimental procedure which is 'not established standards of care' at a workshop, or a public meeting?	Y	N
32	B9	Are you performing a procedure in workshop at SGMC by non-SGMC staff member? (Please check other requirements also)	Y	N

Name of PI: Signature:

A. Project Fact Sheet

Project No. (To be filled by the Secretariat)	
Date of receipt by IRB	
Project Title	
Key Words title (2-4 options)	
Principal Investigator	
Co-Principal Investigators (if any)	
Co-investigators	
Contact number Principal Investigator	
Site/sites where study is to be conducted i.e. SGMC hospital / Community / Both. (Please specify).	
Number of ongoing studies, PI is involved?	
Agency or Sponsor	
Total estimated budget	
Conflict of interest, if any	
Duration of the Project (months)	
Suggested date of starting the study	
Total number of patients to be accrued in study (including SGMC, if multi-institutional study)	
Number of patients from SGMC to be accrued	
Will biological products be sent out of the country? If yes,has ICMR/HMSC/DGFT Permission/NOC been obtained?	
Signature of PI	

Date of submission	
Project No.	
Trial Register No.	
Project Title (To be filled by PI) ..	
Revised Title if any (To be filled by IRB) ..	
Principal Investigator	

SGMC - SCIENTIFIC REVIEW COMMITTEE APPROVAL

The above titled project with all the accompanying documents listed above was reviewed by the members of the SGMC – Institutional Research Committee present on ……………………….. at SGMC&RF. The committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Human Ethics Committee for granting final approval.

Secretary …………..……………………...……………….……. Chairperson ….………..……………………

Name: ………..……..…………………………………..………. Name: ………..……..…………….………….

Date: ……………………………..…………………….…...…... Date: ……………………………….……..……...

Institutional ETHICS COMMITTEE APPROVAL

The members of the Human Ethics Committee met on …… at Sree Gokulam Medical College and reviewed the above named project with all the documents listed above. The ethics committee after careful deliberations has granted final approval to the project. The above mentioned project / study may now be undertaken at SGMC in accordance with the study protocol submitted by the investigators, subject to fulfilling other institutional regulations.

Secretary ……..…….. Chairperson ……..……

Name: ……..…….. Name: ……..……..

Date: …… Date: ……..…….....

Investigators Declaration

01	This research project (including collection of blood or tissues samples for research) will not be started until the final approval of the IEC has been obtained.
02	We agree to undertake research proposal involving human subjects in accordance with the ICH-GCP and ICMR ethical guidelines, 2006. We will not modify the research protocol, consent, etc without prior approval by the IEC.
03	The investigators agree to obtain a properly informed and understood consent for all trial subjects before their inclusion in the trial in the informed consent form that is approved by the IEC. Participants will receive an 'information sheet' which will detail the project design in simple understandable layperson's language.
04	The investigators agree to report within a week all serious adverse events (SAE) associated with the trial in the SAE form to the IEC. In the event of a death of the trial subject, the Secretary, IEC and Director SGMC , will be informed within 24 hours.
05	The investigators agree to submit periodic 6 monthly progress report of the trial in the appropriate form. A final report will be submitted at the end of the trial.
06	Full details on funding and a proposed budget are included with the trial proposal. The proposed budget is presented on the specific budget sheet of this form.
07	We understand that the IEC is concerned about transparent financial transactions during the trial. A report on how the trial funds were utilized will be presented to the EC along with the final project report at the end of the trial.

08	The investigators agree to transfer 20% of the total budget to SGMC as overhead charges. This will not apply to intramural projects.
09	The investigators agree that the grant money will be spent in accordance with the budget proposal only. The funds will not used for any other purposes without prior approval from the IEC. Thirty percent of the surplus grant if left over at the end of the study will be credited to SGMC. The remaining 70% of the surplus grant money may be used by the investigators for conducting intramural research, improving teaching facilities in the department, providing financial assistance to investigators for conferences, etc after obtaining permission from the IEC.
10	For all research proposals that are sponsored by a pharmaceutical or biomedical company, we the investigators will ensure that the Sponsor Company will underwrite all expenses such that neither the hospital nor the study participants are made to spend while participating in the trial. The investigators will also ensure that in the event of complications arising directly due to the trial or litigation, the cost of management or legal fees will be borne by the Sponsor Company totally.
11	The investigators state that they do not stand to gain financially from the commercial sponsor and don't have conflict of interest in the drug or product by way of consultations, shareholding, etc.
12	The investigators will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the Institutional Ethics Committee. SGMC, approved protocol.
13	All data collected during the research project, including those supported by commercial sponsors (e.g. pharmaceutical company), will remain the property of Sree Gokulam Medical College&RF.
14	The salaries to staff employed for the research project will be as shown in the budget sheet and at par with the prevailing SGMC salary scales.
15	The case records (source documents) will be made available to members of the IRC or IEC any time for random verification and monitoring. The case records (source documents) will be preserved in the premises of SGMC for at least 5 years after the last approval of application or publication.
16	The investigators promise to ensure that there is no falsification of data when compared to the source documents. We agree to clarify any doubts or discrepancies that may arise during the data monitoring evaluation.
17	All the findings and conclusions of the proposed project such as review of case records, analysis of forms of treatment, investigations, etc will be first presented to the staff members of SGMC before they are released or presented elsewhere. The investigators will submit a copy of the abstract to the IRC and IEC well in advance of any proposed presentation at national or international conferences or seminars.

18	The investigators will not issue any press release before the data and conclusions have been peer-reviewed by the SGMC staff or published in a peer-reviewed journal.
19	All serious injuries arising from the trial will be the responsibility of the investigators. The investigators agree to ensure that the sponsors undertake a product liability insurance to cover any expenses for injury or compensation arising from the study treatment.
20	The investigators will constantly inform the IEC about amendments in the study protocol, data collection forms, informed consent forms, budget expenses, salaries, other trial documents, etc. as and when they occur. No major changes in the treatment arms or the study protocol or randomization technique will be carried out without prior permission of the IEC.
21	The investigators realize that the IEC is particular that all aspects of the study are in accordance with the ICH-GCP and ICMR ethical guidelines, 2006. The investigators will comply with all policies and guidelines of the SGMC and affiliating/collaborating institutions where this study will be conducted, as well as with all applicable laws regarding the research.

We the investigators of the proposed trial have read all the statements listed above and agree to observe / undertake these IEC requirements while conducting our proposed project / trial.

We understand that serious protocol violations and/or non-compliance during the trial by the investigators may result in withdrawal of project approval by Institutional Ethics Committee.

	CC No. if available	**Investigator Name**	**Email**	**Status** (PI, Co-PI, CI)	**Sign & date**	**Role & responsibility**
1						
2						
3						

Role & responsibility of investigator is categorized from A to Z as follows:

A. Concept
B. Design
C. Screening of patients
D. Selection & Recruitment of patients
E. Laboratory investigations
F. Laboratory report interpretation
G. Treatment decision
H. Patient evaluation
I. SAE evaluation and reporting
J. Examination of patients on follow-up
K. Data collection and monitoring of data
L. Interpretation of data
M. Statistical analysis & Interpretation
N. Maintaining patients file and master file of project
O. Drafting final report
P. Publication
Q. Any other, please specify

Please mention the category in column of role & responsibility.
Note: Investigators may clarify any of the points in this undertaking with the IRB secretariat

To,

The Member Secretary
Institutional Ethics Committee
Sree Gokulam Medical College &Research Foundation

Project entitled: ……..
Name of PI:
Conflict of Interest
☐ I hereby declare that I have no conflict of interest in my project. ☐ I have following conflict of interest:
Signature of PI Date

Consent of Head of the PI's Department

Date:…….

I have reviewed the above project submitted by ……. Principal Investigator from my Department. I endorse the project and have 'no objection' for submission

for consideration by Scientific & Ethics committee.

I concur with the participants / investigators included in the study.

Signature & date Name Department

Consent from Working Group

Date:…….

The above project submitted by …….. ., Principal Investigator, has been discussed in the ……..working group and has been accepted to be submitted for submission for Scientific & Ethics committee consideration.

The investigators / participants included in the study are acceptable to the members.

Signature & date Name (senior member of working group)

A. Project Submission Overview

Title	
Names of all Investigators (underline principle investigator)	
Introduction / background Give the background, including human or animal research relevant to the design of the proposed study. When new techniques or procedure are to be used, provide a description of preliminary work. When an investigation drug is to be used, animal data and phase I or II data on the drug should be included. A summary of how the study may help in the future should be included in the protocol.	
Aims / Objectives Clearly state the aims or objectives of the study. Whenever possible this should be in the form of a hypothesis	
Design of the Study	
Phase-I, Phase-II, Phase-III, Phase-IV, NA	
Randomized [Double or single blind], Open [ ]	
If multicentric, is SGMC the co-coordinating centre?	
Epidemiological [ ] Survey [ ] Observational [ ]	
Case control [ ], Any other (Specify)	
Study methodology	
Explain, in sequence, the conduct of study and all data collection procedures. Describe the involvement of human subjects including initial evaluation procedures and screening tests, phases, medical/surgical procedures and sequence of the study. Separate standard and experimental aspects of the study as much as possible. Give brief account of procedures for treatment, dose adjustments, etc. Describe the randomization procedure, if applicable. Specify if procedure involves banking of biological samples. Define stop points and criteria for withdrawing subjects from the study.	

Eligibility (Explain inclusion and exclusion criteria; To be stated clearly in the summary) (specific explanation if participants will include Minor, Pregnant woman, Neonate, Person incompetent to give informed consent, Normal/ Healthy volunteer, Student, Staff of the institute).	
How many subjects will be screened? How many subjects are likely to be enrolled?	
Describe benefits to the subject/participant in this study. Also describe the benefits, if any, to the society.	
Power estimates Describe power calculations, if the study involves statistical comparisons between two or more groups. Mention evidence to support that adequate number of subjects can be enrolled during the study period by the investigators.	
Variables to be estimated (e.g. response, survival, toxicity, age, etc) Enumerate the variables, outcomes and end points that will be measured. Try to separate variables as response and explanatory variables. Describe the type and frequency of tests, admissions, outpatient visits, etc used to obtain these variables or variables.	
Analysis of the variables Describe how the variables obtained during the study will be statistically analyzed. e.g. Univariate comparison or Cox-proportional hazards model, etc	
Describe all possible risks and discomfort for subjects due to use of intervention and / or data collection methods proposed. Describe expected degree and frequency of such risks, discomfort, side effects of drug etc.	
If the procedures in the trial are invasive or potentially harmful, describe what arrangements have been made for treatment of the complications arising from the trial?	

Who will bear the cost of treating the complications arising from this trial?	
Does your study involve testing of drug/s, device/s and/or biologics?	Yes [ ] No [ ]
Are they already approved by the regulatory authorities and available in the market or are they new ones?	Already approved [ ] New one [ ]
Who has prepared and /or is manufacturing the drug/s, device/s and biologics under investigation?	
Who holds the patent or IND/IDE of the drug/s, device/s and biologics under investigation?	
What are the reasonable possibilities of the availability after the study of the investigational drug(s), device(s) and biologics for the study participants/subjects if it is found to be effective?	
Does your study require permission from regulatory authorities?	Yes [ ] No [ ]
If yes,	
(i) from DCGI	Yes [ ] No [ ]
(ii) from the ICMR	Yes [ ] No [ ]
(iii) From other govt. departments	Yes [ ] No [ ]
If yes, specify the department Whether permission is obtained	Yes [ ] No [ ]
Does your study require you to send human biological material outside India?	Yes [ ] No [ ]
If yes, have you obtained permission of the director, SGMC & DGFT?	Yes [ ] No [ ]
Has SGMC and the foreign party signed agreement/MOU for that? If yes, attach a copy of agreement/MOU	Yes [ ] No [ ]
If study will be conducted fully or partially outside the SGMC, please describe the need for permission from institution(s), health centre(s), local government/administrative bodies, etc.	

Describe how you define adverse events in your study, how and to whom you propose to report them, and what rules you will use for stopping the study due to adverse events.	
In what way will you ensure the confidentiality and privacy of the subjects?	
If some procedures in this trial are emotionally upsetting describe what arrangements have been made for psychological counseling?	
Describe (i) How, where, when and by whom the Informed Consent will be obtained. (ii) how much time the subject/ participant will be given to consider participation and decide, (iii) describe additional plans/needs for informed consent in case the study involves special population such as minors, pregnant mothers, neonates, etc. (iv) Describe how you will assess that information is correctly understood by the participant.	
Who will be maintaining the trial records and where? For how long will the data be stored? Give details of where they will be stored, who will access	
Describe briefly, if any, the financial and other interests of any of the investigators and /or close relative/s, with the sponsor/s and outcome of the study.	
Have you made provision for insuring yourself, and SGMC against any legal action that may arise out of this project?	
Have you made provision for insuring trial subjects for any accidental unforeseen trial related injury?	
How is it intended the results of the study reviewed will be reported and disseminated?	- Peer reviewed scientific journals - Other publication - Conference presentation - Internal report - Submission to regulatory authorities - Access to raw data and right to publish freely by all the investigators in study or by independent steering committee on behalf of all investigators - Other ……..

Name of PI: Signature: Date:

D. Budget Sheet for the Proposed Study

1. Title of the Project:	
2. Principal Investigator	
3. Designation and address of the PI	
4. Co-investigators	
5. Source of funding	
Government	Central [ ], State [ ], Local [ ]
Intramural	
Private Foundation	Indian [ ], Foreign [ ]
Industry	Private [ ], Public [ ], Other [ ]
Other	
No funding required	
Address, phone, fax. E-mail of sponsor with the name of the contact person	
6. Total Budget for the entire project	
7. Duration of the Project	
8. Proposed date of starting the project	
9. Direct payments to investigators, if any	
10. Any other benefits to the investigators	
11. Conflict of Interests, if any	
12. Type of project funding Intramural from SGMC	
Non profit agency / trust funded Pharma / industry sponsored	
Others – specify	

Name of PI: Signature: Date:

Detailed Budget for the Proposed Study

1.	Source of funding				
	Items	1st Year	2nd Year	3rd Year	Total
2.	Salaries-personnel (Numbers)				
	Research Nurse				
	Doctor (Research Fellow)				
	Data operator				
	Any other specify				
3.	Equipment and Hardware				
	-				
	-				
	-				
	-				
4.	Drugs and Consumables				
	-				
	-				
	-				
	-				
5.	Clinical Investigations				
	-				
	-				
	-				
	-				
6.	Hospitalization				
	-				
	-				
	-				
7.	Travel expenditure for investigators				
	-				

8.	Travel expenditure for trial subject and one attendant				
9.	Honorarium to doctors/technicians				
10.	Insurance				
	i. for investigators				
	ii. any unforeseen, accidental trial related injury				
11.	Any other expenditures				
12.	Miscellaneous (<5% of budget)				
13.	Total				
14.	SGMC Service Charge (10% of total) (SGMC, DAE, ICMR, DBT, DST, IAEA,WHO, IARC etc. funded project are exempted)				
15.	Estimated Investigator fees (15% at the end of the study on actuals)				
	Grand Total				

Name of PI: Signature: Date:

Note:

- PI should devise incremental budget whenever necessary.
- Please provide the complete break-up of item nos. 3, 4 & 5 on separate sheet.

Instructions:

- This form must be printed and not handwritten.
- Fill the form completely (If there are any questions/queries, please contact the IRB office (022-24177262).
- Make sure to include the e-mail address and contact numbers of the PI, Co-investigators.
- Please submit the documents as per the checklist (AX2-V1/SOP03/V2) to ensure all requirements for submission are fulfilled so that the IRB review is not delayed.
- Submit this application (submission form) and appendices along with the supporting
  documentation to the IRB office.

AX2-V1/SOP03/V2 Checklist of Documents

Item No.	Mandatory Documents	Yes	No	NA
1	IRB processing fee (applicable for sponsored trials) PG Students(Rs.1000/-) to be paid at accounts department			
2	Project Submission Form (both hard and soft copies) duly signed by the Principal Investigator			
	A. Grouping of Project			
	B. Project Fact Sheet			
	Investigators Declaration			
	Conflict of Interest Statement			
	Consent of Head of the PI's Department			
	Consent from Working Group			
	C. Project Submission Overview			
	D. Budget Sheet for the Proposed Study Detailed Budget for the Proposed Study			
3	Study Protocol			
4	Participant Information Sheet & Informed consent forms			
	(ICFs) in English, Malayalam & Hindi			
	(and if required any other language)			
5	Back translations of ICFs			
	(not mandatory for Hindi and Malayalam)			
6	Case Record Form			
7	Investigator Brochure			
8	Insurance policy			
9	DCGI approval letter / DCGI submission letter			
10	NOC from DCGI / DGFT/ICMR			
11	Appendix VII (Schedule Y) Undertaking by the Investigator			
12	Clinical Trial Agreement (CTA) / Memorandum of Understanding (MOU) / Material Transfer Agreement (MTA) if applicable			
13	Brief resume of PI and Co-investigators (1 Page each)			

AX3-V1/SOP 03/V2 Institutional Review Board Document Receipt Form

SGMC Study Number :	
Submitted date:	
Type of Submission:	□ Initial Review □ Continuing Review of Approved Protocols
Protocol Title:	
Principal Investigator:	
Mode of submission: □ Post □ E-submission □ in Person	
Type of document:	

Checklist to assess the projects before they are submitted to IRC & IEC review

Item No.	Mandatory Documents	Yes	No	NA
1	IRB processing fee (applicable for sponsored trials)			
2	Project Submission Form (both hard and soft copies) duly signed by the Principal Investigator			
	A. Grouping of Project			
	B. Project Fact Sheet			
	Investigators Declaration			
	Conflict of Interest Statement			
	Consent of Head of the PI's Department			
	Consent from Working Group			
	C. Project Submission Overview			

	D. Budget Sheet for the Proposed Study Detailed Budget for the Proposed Study			
3	Study Protocol			
4	Participant Information Sheet & Informed consent forms			
	(ICFs) in English, Marathi & Hindi			
	(and if required any other language)			
5	Back translations of ICFs			
	(not mandatory for Hindi and Marathi)			
6	Case Record Form			
7	Investigator Brochure			
8	Insurance policy			
9	DCGI approval letter / DCGI submission letter			
10	NOC from DCGI / DGFT/ICMR			
11	Appendix VII (Schedule Y) Undertaking by the Investigator			
12	Clinical Trial Agreement (CTA) / Memorandum of Understanding (MOU) / Material Transfer Agreement (MTA) if applicable			
13	Brief resume of PI and Co-investigators (1 Page each)			

Documents submitted:

- ☐ Complete
- ☐ Incomplete; will submit on……..

Comments:

Receiver Name, Sign & Date
(IRB Secretariat)

Secretary, IRC
Sign & Date

Project submitted by Name & Sign
(Project or study team member)

AX4-V1/SOP03/V2 Guidelines for devising ICF and Sample format of an Informed Consent Document.

Guideline for preparation of the informed consent form	
While submitting your project report to the Human Ethics Committee, ensure that you have included an informed consent form that is prepared as per the guidelines for ICH – GCP,ICMR ethical guidelines 2006, and the Declaration of Helsinki. The consent form must necessarily include the following points listed below. Any further information you wish to add, is your choice.	
The following are instructions for devising Informed Consent Form:	
-	Informed consent forms in English, Marathi, and Hindi
-	Font: Arial
-	Size: 12
-	All the consent forms must have Version No, Date, Page no in the footer
-	Separate forms should be prepared when minors (children) are study participants; assent form for the mature minors (teenagers) and consent form for the parents
The consent form must necessarily include the following points listed below and any further information you wish to add.	

"Template for devising an "Informed Consent Form"
(Include or exclude information, as applicable)

Informed Consent Form
[The title of the project here exactly as it is in the project design with names of Principal Investigator and all other investigators.]
Introduction:
You are invited to participate in a study/research/experiment. This document gives you a description of the study/trial in which you are being asked to participate. Your participation in this study is voluntary, and you can enquire about all details before giving your written consent to participate in the study.
Purpose:
The purpose of this study is to ……

Information:

List all procedures, which will be employed in the study. Point out any that are considered experimental/or otherwise, and explain technical and medical terminology in simple, non-technical & direct language.

Graphics could be used if helpful in making the text meaningful to the research subject.

If this is a randomized trial, details of both arms of the trial must be explained in writing to the subject being enrolled.

State the amount of time required of the subject per session, for the total duration of study and the expected duration of the study.

If applicable to your study, list:

i. The number of participants who will be participating in the research.
ii. Information concerning taping or filming.
iii. If tissues or biological samples are being retained for research, describe what will be done to the tissues in simple lay person's terms.

Alternative treatments:

Disclose appropriate alternative treatments available, if any.

Risks:

List the foreseeable risks, if any, of each of the procedures to be used in the study, and any measures which will be used to minimize the risks, or treat them should they occur. Explanation of anticipated side effects, and even rare side effects, or known idiosyncratic reactions.

Costs:

Describe the cost for participating in the study to the subject/participant. The information must be written in clear terms regarding the cost which will be borne by sponsors/Principal Investigator/s of the project, and study participant.

Reimbursement for Participation:

Describe plan to reimburse or compensate participant for the inconvenience, time spent and for expenses incurred. If yes, the amount of payment proposed. Discuss travel details for trial subjects &/or attendant who need to come for follow-up, and spell out methodology for the reimbursement for travel.

Emergency Medical Treatment:

(If applicable, add here)

If physical injury is suffered in the course of research, or for more information, please notify the investigator in charge (list PI name and phone number).

Describe available medical treatment in case of complications.

Benefits:

List the benefits you anticipate will be achieved from this research, either to the participants, others, or the body of knowledge.

Also mention that the many of the most effective treatments used today are the result of clinical trials done in the past.

Confidentiality:

The information in the study records will be kept confidential and the clinical charts will be housed in the TMH/CRS. Data will be stored securely and will be made available only to persons conducting the study and to the regulatory authorities. The data will not be made available to another individual unless you specifically give permission in writing. No reference will be made in oral or written reports which could link you to the study. Result of the project will not be communicated to the subject unless deemed necessary

Compensation for protocol Related Injury:

Describe the details of compensation or insurance for protocol related injury to the trial subject. Explain who will bear the cost in case of trial related injury?

Contact:

If you have questions at any time about the study or the procedures, (or you experience adverse effects as a result of participating in this study,) you may contact the researcher, [Name], at [Office Address], and [Office Phone Number]. If you have questions about your rights as a participant, contact the member secretary, IEC [Name], at [Office Address], and [Office Phone Number].

Participation:

Your participation in this study is voluntary; you may decline to participate at anytime without penalty and without loss of benefits to which you are otherwise entitled.

If you withdraw from the study prior to its completion, you will receive the usual standard of care for your disease, and your non participation will not have any adverse effects on your subsequent medical treatment or relationship with the treating physician

If you withdraw from the study before data collection is completed, your data will not be entered in the project report. Your legal rights will not be affected by signing this documents.

Consent I have read the above information and agree to participate in this study. I have received a copy of this form.	
Participant's name (print):	
Participant's signature:	
Address (capital letters):	
Phone Nos.:	
Legal Representative name:	
Legal Representative signature & date:	
Witness's name (Print):	
Witness's signature & date:	
Name of PI or the person administering the consent (Print):	
PI or person's Signature & date:	

Note to Investigators Regarding the Process of Administering Informed and Understood Consent
(The templates for Participant Information Sheet have been provided herewith):

The prospective participant should be given Participant Information Sheet first.
The participant should then be encouraged to read the Information Sheet and think over, preferably for a period of 24 hours. Following which, the participant should be served a questionnaire to ensure that he/she is aware of his/her own rights as a participant in the clinical trial. The informed consent form should be served to the participant only after ensuring that the participant is now prepared for informed decision making. The PIs are urged by the IEC to download and use the wording in the glossary available on the SGMC website and follow the sample format of Informed Consent Form, unless the PI support reasons for alternative wording.

Use of alternative wording or different format may slow down the review process. The form should be written in second person ("You are invited..."). Use of first person ("I") can be interpreted as suggestive and coercive.

The study participant should be explained all the details in a language she/he understands.
The Informed Consent Form must have the name and Telephone No. of the Principal Investigator or of any other co-investigator, as the subject must know who to contact in case of an emergency, or even to seek answers to their queries.

The consent form must be dated.
If the prospective participant so desires, a Xerox copy of the Informed Consent Form must be given to him/her.
Copies of the consent form must be available in English & vernacular languages .
Please tailor your ICF to suit the needs of our Indian population, and if this is a multinational Pharma based project, an additional ICF specifically designed for us may be used.
Separate forms should be prepared when minors are used; one for the mature minors (teenagers) and one for the parents.

If your form is more than one page, there should be a line at the bottom of each page for the subject's initials, except for the last page where the signature is obtained.

Be sure to include any elements of informed consent that are appropriate to your study. If they apply to your study, they must be included. If informed consent form requires more than one page, print the informed consent form front to back.

Please make provision for the assent of the child to the extent of the child's capabilities such as in the case of mature minors and adolescents.

Please make provision on the form for signatures/thumb impression of the participant/parent or legal guardian, if minor and of the investigator, or person administrating the consent form, and of a witness.

AX5-V1/SOP 03/V2: Child Information Sheet and Assent Form

Study title: "……"

Introduction

You have come to meet the doctor as you are suffering from …..... You may be having symptoms……..

Describe briefly the purpose of this study

If this is a randomized trial, details of both arms of the trial must be explained in writing to the subject being enrolled.

Disclose appropriate alternative treatments available, if any.

We invite you to participate in this study.

What will you have to do?

To participate in this research study, you will be examined by your doctor and if found to fulfill pre-specified criteria, you will be eligible to be enrolled in this research study.

Since you are in the age group of 8-12 years we ask you to sign this assent form if you agree to participate. The assent form describes the research study and states that you have been explained the purpose and the nature of the study to your satisfaction by the attending doctor and you are ready to abide by the trial procedures. Your accompanying parent / guardian will also sign a similar form called as the Parent Informed Consent Form.

List all procedures, which will be employed in the study. Point out any that are considered experimental/or otherwise, and explain technical and medical terminology in simple, nontechnical & direct language.

In addition, to record the same parameters daily your parent / guardian will also be provided with a diary where they will enter the same findings accordingly. You will have to tell them about your symptom and they will mark accordingly in the diary

Side effects

All medicines/procedures produce some side effects – the medicine you will take/the procedure you will undergo can produce (Describe the side effects). Your Physician will take due precautions so that you do not experience these side-effects. If you experience any of these listed effects or any other unlisted effects do contact your study doctor immediately. The study doctor will treat you accordingly.

Your parents will not have to bear the cost of the medical treatment / hospitalization as a

result of these side effects.

In addition, during the trial period if you suffer from any other diseases, if you consider some of the side effects as serious or you undergo hospitalization during the study period, please immediately contact the study doctor:

Dr. **Phone:**

The occurrence of any of the side effects (known / unknown) and concomitant diseases will be noted by the physician at every visit. The assessment of acceptability of the formulation/procedure will be performed by the treating physician at the end of the study.

Risks and discomforts

There is no foreseen significant risk / hazard to your health, if you wish to participate in the study. You will not bear the expenses regarding the therapy. If you follow the directions of the doctors in charge of this study and you are injured due to any substance or procedure given under the study plan, the Sponsor will pay for the medical expenses for the treatment of that injury.

Benefits

If you participate in the study you will receive ……If you appear to have any acute illness ……you will be offered free treatment for those visits in accordance with local standard medical care. You will not be offered free treatment for chronic diseases or conditions not related to study procedures. Your participation in the study may help others, because this participation will help us determine if the study drug/procedure is safe.

Confidentiality

Your existing medical records may be accessed; personal health information about you may be collected and processed by study investigators for the purpose of performing the study. Information about you will be collected and stored in files with an assigned number, and not directly with your name. All documents related to the study will only be accessed by the study investigator, sponsor, the Ethics Committee and the Regulatory authority.

Your parent / guardian will have the right to access personal information about you at any time with the study doctor and the right to correct this personal information. Your parent /guardian can take away your authorization to collect process and disclose data about you at any time.

Right to refuse or withdraw

You do not have to take part in this research if you do not wish to do so. Refusing to participate will not affect your treatment. You will still have all the benefits that you would otherwise have got at this clinic/hospital. You may stop participating in the research at any time you wish without losing any of your rights. Your treatment will not be affected in any way.

The study doctor may decide to withdraw you from the study if he/she considers it is in your best interest

You will be informed of important new findings developed during the course of the study so you will be able to consider your participation in the study in light of new information

Whom to contact

If you have any questions, please ask them now. You may also ask questions later. If you wish to ask questions later, contact

Dr. **Phone:**

If you have any queries regarding your rights as a study participant, you may contact, the Chairperson of the Institutional Ethics committee

Dr. **Phone:**

Your responsibilities

It is the responsibility of your parent / guardian to come along with you to the hospital during the study period for all the visits unless you withdraw or are prematurely discontinued from the study. It is also your responsibility and your parent / guardian to report any expected or unexpected reactions (side effects) that you notice during the study period.

It is also the responsibility of your parent / guardian to inform the doctor if you consume any other medication apart from the study treatment.

We expect your co-operation throughout the study.

Child Assent Form

I_____, exercising my free power of choice,
hereby give my consent for participation in the study entitled:
"……"
I have been informed, to my satisfaction, by the attending physician, about the purpose of the study and the nature of the procedure to be done. I am aware that my parents/guardians do not have to bear the expenses of the treatment if I suffer from any trial related injury, which has causal relationship with the said trial drug

I am also aware of right to opt out of the trial, at any time during the course of the trial, without having to give reasons for doing so

_____

Name and Signature of the study participant Date:

_____

Name and Signature of the attending Physician Date:

AX6-V1/SOP 03/V1 Information regarding appropriateness of investigator

Modified on 28th December 2017

1. Qualifications and affiliation:
   (a) Principal investigator (PI) should have a medical degree recognized by the Medical Council of India (MCI) (or equivalent regulatory body in India) and be registered with the State Medical Council. He/she should provide the evidence of his/her qualification using Curriculum Vitae (CV) form.
   (b) PI must be a qualified faculty member who is currently employed in the institution. Qualified faculty members attached to other institutions **can only be listed as the co-investigators for the clinical trials submitted to this IEC.**
   (c) If PI leaves the institution, he should inform the IEC at least one month in advance (unless circumstances mandate otherwise) and either make arrangement to close the trial or nominate another qualified employee of the institution to act as PI with proper procedure.
2. Prior to Trial:
   (a) PI must start the trial only after obtaining the permission from the Licensing authority and the IEC and registering with the Clinical Trials Registry of India (www.ctri.nic.in).
   (b) PI must inform the IEC about the sponsor or any other funding body for his trial through his protocol.
   (c) PI should have scientific knowledge to conduct the trial and it is desirable if the PI has had prior experience of conducting a clinical trial.
   (d) PI should submit the Informed consent document for the approval of IEC (as per Appendix V of Schedule Y (amended version) of Drugs and Cosmetics Rules, 1945), should have knowledge of procedure of the Informed consent, and ensure that the benefits and risks of participating in the study are explained and understood by the patients prior to participation in the study.
3. During the Trial:
   (a) PI should be regularly seeing the patients requiring the type of drug or device under trial.
   (b) PI should be thoroughly familiar with the appropriate use of product under trial.
   (c) PI should have clear understanding of the ethical issues involved in the trial, be aware of confidentiality policies and participants' rights including the right to withdrawal from the trial.
   (d) PI should have knowledge about Good Clinical Practice.
   (e) PI should prioritize patients' safety and well-being.
   (f) PI should promptly respond to all the requests for information by the IEC, including reviews, timely submission of requests for renewal of the trial or protocol deviation or change in PI if any, or information regarding closure of the trial.
   (g) PI should have adequate staff, resources and facilities to carry out the proposed research study properly and safely.

(h) PI is responsible for conducting the clinical trial at the trial site and to ensure that the test article/substance is dispensed/administered under his immediate direction. In case there is an investigating team, PI acts as a responsible leader.
(i) PI is responsible for protocol compliance, clinical trial documentation, safekeeping of drugs/device under trial and training of the staff in the team. PI should seek permission from IEC and Licensing Authority before any protocol amendments.
(j) PI is responsible for reporting of SAEs and attending to the patients' medical and emergency care during the trial and during any SAEs.
(k) PI is responsible for ensuring that compensation is provided to the participants in case of SAEs.
(l) In case a PI of a clinical trial receives queries regarding SAEs (trial-related death or injuries), a Compensation Committee is constituted that includes IEC members, clinicians, clinical pharmacologist, legal and financial experts, to discuss the recommended compensation. The committee shall convene a meeting in the presence of PI along with reports of SAEs and participants' case reports. The committee shall examine the reports to ascertain causality and send its report and recommendations regarding compensation to Expert Committee and/or DCGI within 21 days of the reported SAEs.

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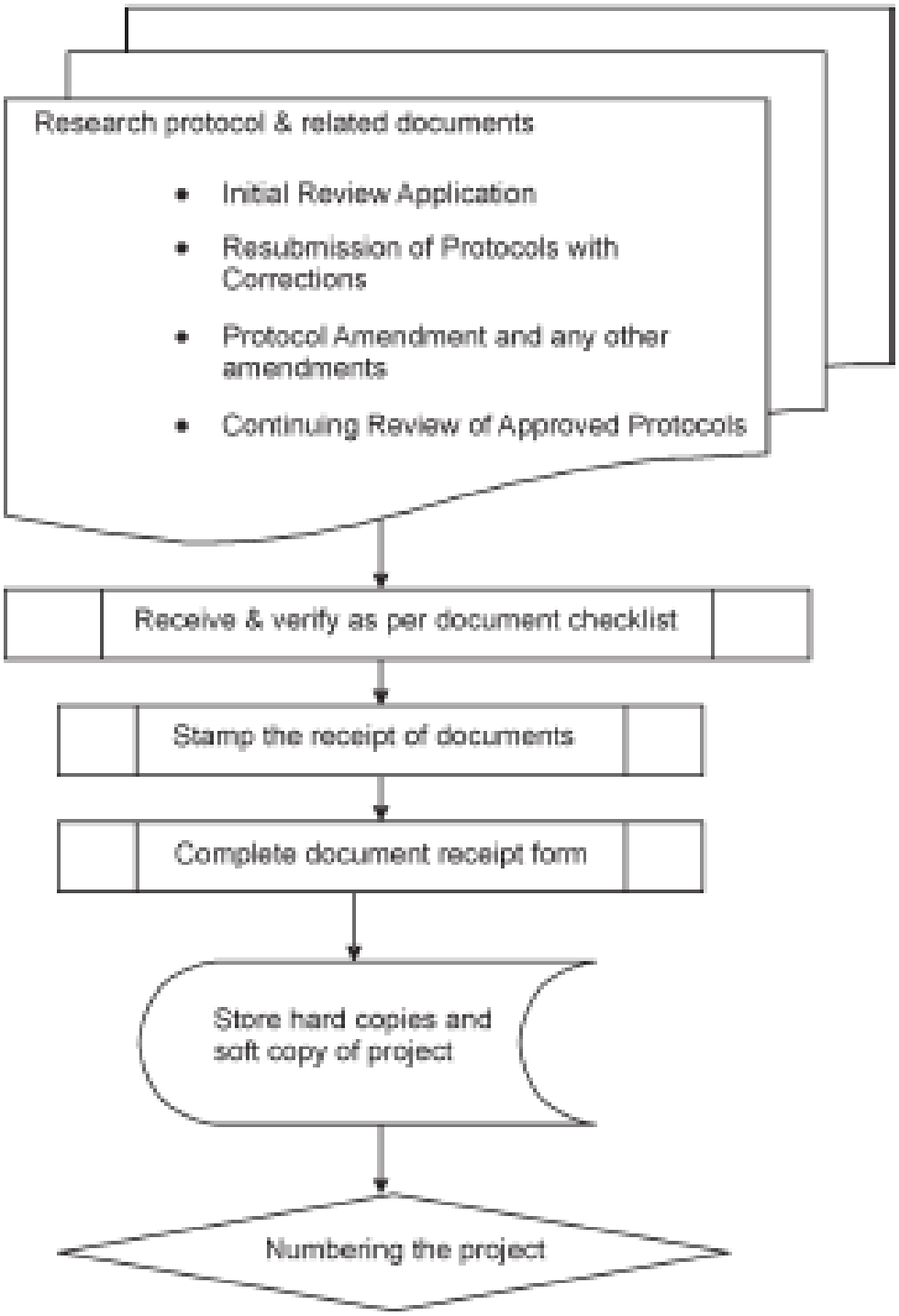
Research protocol & related documents
Initial Review Application
Resubmission of Protocols with Corrections
Protocol Amendment and any other amendments
Continuing Review of Approved Protocols
Receive & verify as per document checklist
Stamp the receipt of documents
Complete document receipt form
Store hard copies and soft copy of project
Numbering the project

Institutional Ethics Committee Standard Operating Procedures(SGMC-IEC:SOP:04/V2)

Title :Review Procedures

SOP Code: SOP 04/V1 Date : 01/04/2013 Pages:....

4.1 Purpose

The IEC should review every research proposal on human participants and must approve the proposal before the research is initiated. IEC should ensure that scientific evaluation has been completed and approved by IRC before ethical review is taken up. The committee should evaluate the possible risks to the participants with proper justification, the expected benefits to participants/community and adequacy of documentation for ensuring privacy & confidentiality.

The purpose of this Standard Operating Procedure (SOP) is to describe how the IEC members will review an initially submitted protocol for approval using the Assessment Form for initial review.The Assessment Form AX1-V1/SOP04a/V2 is designed to standardize the review process and to facilitate reporting, recommendations, and comments offered to each individual protocol.

4.2 Scope

This SOP applies to the review and assessment of all protocols submitted for initial review and approval from the IEC. The specific points in the guidelines attached to the Assessment Form for initial review must be adequately addressed in the protocol itself and/or protocol-related documents under review. Relevant comments made during discussion and deliberation about a specific protocol should be recorded in the minutes of the meeting. The decision reached by the IEC will be communicated to the PI.

4.3 Categorization of protocols

The Member Secretary, IEC or secretariat shall screen the proposals for their completeness and depending on the risk involved in the research proposals categorise them into three types, viz. Exemption from review, Expedited review, and Full review. An investigator cannot categorize his/her protocol in to the above three types. This SOP describes the review process.

Chapter 4A: Full review of Submitted Protocol

SOP Code: SOP 04a/V2 Date :01/04/2013 Pages:

4a.1 Full Review

All research presenting with more than minimal risk, research protocols which do not qualify for exemption or expedited review and projects that involve vulnerable population and special groups should be subjected to full review by all the members.
While reviewing the research protocols, the following situations should be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

a. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture from (Refer APP6/V1) :-

- Healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8 week period and frequency of collection is not more than 2 times per week
- ii. From other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg whichever is lesser, is drawn in an 8 week period and not more than 2 times per week
- iii. From neonates depending on the hemodynamic, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 – 72 hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion
- iv. Prospective collection of biological specimens for research purposes by noninvasive means.

For instance:

- skin appendages like hair and nail clippings in a non-disfiguring manner
- dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and subgingival dental plaque and calculus, provided the collection
- procedure is not more invasive than routine prophylactic scaling of the teeth
- excreta and external secretions (including sweat)
- uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue
- mucosal and skin cells collected by buccal scraping or swab, skin swab,or mouth washings
- sputum collected after saline mist nebulization and bronchial lavages.

b. Collection of data through noninvasive procedures routinely employed in clinical practice. Where medical devices are employed, they must be cleared/ approved for marketing, for instance –

- Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy

- Weighing or Testing Sensory Acuity
- Magnetic Resonance Imaging
  Electrocardiography, Echocardiography Electroencephalography,Thermography, detection of naturally occurring radioactivity,Electroretinography, Ultrasound, Diagnostic Infrared Imaging, Doppler Blood Flow and such alike
- Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

c. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes

d. Collection of data from voice, video, digital, or image recordings made for research purposes

e. Research on individual or group characteristics or behaviour not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

f. Research involving collection and storage of genetic materials (Refer APP10/V1)

g. Research involving gene therapy and gene transfer protocols (Refer APP11/V1)

4a.2 Elements of Review

The primary task of the IEC is to review of research proposals and their supporting documents with special attention given to the informed consent process, documentation, and the suitability and feasibility of the protocol. IEC will take into account prior scientific review by the IRC, and the requirements of applicable laws and regulations.

The following will be considered, as applicable:

4a.2.1 Scientific Design and Conduct of the Study

- The appropriateness of the study design in relation to the objectives of the study _ The statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants
- The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities
- The justification for the use of control arms; criteria for prematurely withdrawing research participants
- Criteria for suspending or terminating the research as a whole
- The adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a DSMB, the adequacy of the site, including the supporting staff, available facilities, and emergency procedures
- The manner in which the results of the research will be reported and published

4a.2.2 Care and Protection of Research Participants

- Suitability of the investigators' qualifications and experience for the proposed study
- Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action

- Medical care to be provided to research participants during and after the course of the research
- Adequacy of medical supervision and psycho-social support for the research participants
- Steps to be taken if research participants voluntarily withdraw during the course of the research
- Criteria for extended access to, the emergency use of, and/or the compassionate use of study products
- Arrangements, if appropriate, for informing the research participant's general practitioner or family doctor, including procedures for seeking the participant's consent to do so
- Description of any plans to make the study product available to the research participants following the research; a description of any financial costs to research participants (Refer APP3/V1)
- Rewards and compensations for research participants (including money, services, and/or gifts)
- Provisions for compensation/treatment in the case of the injury/disability/death of a research participant attributable to participation in the research (Refer APP4/V3, See Also ICMR website for Draft Guidelines on compensation)
- Insurance and indemnity arrangements

4a.2.3 Protection of Research Participant Confidentiality

- A description of the persons who will have access to personal data of the research participants, including medical records and biological samples
- The measures taken to ensure the confidentiality and security of personal information concerning research participants

4a.2.4 Informed Consent Process

- A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent (Refer APP7/V1 & APP8/V1)
- Adequacy, completeness, and comprehension of written and oral information to be given to the research participants, and, when appropriate, their Legally Acceptable Representative(s) (LAR) (Refer APP5/V1)
- Clear justification for the intention to include research participants who cannot consent ,and a full account of arrangements made to obtain their consent /authorization
- Assurances that research participants will receive information that becomes available during the course of the research relevant to their participation including their rights, safety, and well-being
- Provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project

4a.2.5 Community Considerations

- Impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn
- Steps taken to consult with the concerned communities during the course of designing the research
- Influence of the community on the consent of individuals
- Proposed community consultation during the course of the research
- Extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs
- A description of the availability and affordability of any successful study product to the concerned communities following the research
- The manner in which the results of the research will be made available to the research participants and the concerned communities

4a.2.6 Recruitment of Research Participants

- The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, and ethnicity) (Refer APP2/V1)
- The means by which initial contact and recruitment is to be conducted
- The means by which full information is to be conveyed to potential research participants or their representatives
- Inclusion criteria for research participants
- Exclusion criteria for research participants
- Students or staff recruitment in research (Ref. APP1/V1)

4a.3 Responsibility

The IRB Secretariat is responsible for receiving, verifying, and managing the hard copies of the received packages. In addition, the Secretariat should create a protocol specific file, distribute the packages to the IEC members for review by IEC and communicate the review results to the investigators.IEC members are responsible for receiving, verifying, and reviewing the research protocols.

4a.4 Detailed instructions

Distribution of the project documents

- The distribution of the project documents for IEC review will be as follows:
- Chairperson, Member Secretary, and the lead discussant/s will get complete project proposal while all other members should be given only the duly filled SGMC Project Submission form and informed consent forms.

Assigning Lead discussants

- Member Secretary, IEC assigns 1 or 2 lead discussants to each research protocol. A lead discussant is the member of IEC responsible for a detailed review of the assigned protocol

- The lead discussant is informed preferably 10 days prior to the meeting through the agenda. In case, the lead discussant is not in a position to review due to some reason; he/she should inform the Member Secretary, IEC at the earliest,so that the research protocols can be assigned to other member.
- In the event of his/her absence, a lead discussant can send written comments on the research protocols to the Member Secretary, which will be tabled and discussed during meeting. However, a final decision on the research protocol will be arrived at, by a broad consensus at the end of discussion among attending members and not solely based on written comments.
- It is the responsibility of the assigned lead discussant/s to review the research protocols assigned to them thoroughly, offer their observations, comments,and decisions to the IEC during the meeting and return all research protocols to the secretariat on the day of the meeting

Responsibilities of IEC members

- Check the contents of the package
- Sign and date an acknowledgement form / receipt upon receiving the package
- Return the acknowledgement form/ receipt back to the delivery person /IRB Secretariat
- Check the meeting date to see if he/she is available to attend the meeting.
- Identify the project assigned for review
- Notify the IRB Secretariat 3 days prior to the convened IEC meeting regarding the missing documents, if any
- The members must return the packages to the IRB Secretariat on the day of the scheduled meeting. In case, IEC member is not in a position to attend the scheduled meeting, the responsibility of returning of packages would that be of the respective IEC member.

4a.5 Review the Protocol:

Review all elements as per section 4.3. The protocol will be reviewed by each member as per guidelines to review a study protocol described in AX1-V1/SOP04/V2

4a.6 Use of study assessment forms

It is the responsibility of the IEC members to use assessment form as a checklist while reviewing each research protocol. The duly filled, signed and dated assessment forms should be returned along with the research protocols to the Secretariat at the end of the meeting. The assessment form is designed to standardize the review process. The study assessment form helps to ensure that all elements of research protocol are reviewed and are accordingly documented during the discussion / meeting Study Assessment Form Template (AX1-V1/SOP04aV2)

Note: The completed assessment form is the official record of the decision reached by the IEC for the specific protocol

4a.6.1 Gather the assessment reports

The IEC Secretariat will collect the Assessment Forms AX1-V1/SOP04a/V2, the comments from each reviewer and file in the original set of the study file.

4a.7 IEC meeting

The details of review procedures and communication of decision is described in detail in SOP05/V2

Glossary

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

Expedited review/meeting: A review process by only member secretary of the IECs or IEC subcommittee, who then report the decision to the full board in a formal meeting. An expedited review is an accelerated review for minor changes to the approved protocol, for research proposal with minimal risk and documents of minor nature.

Full Board/ Regular Review: Review of initial, resubmitted, continuing review, amendments of protocols and or ICFs and any other documents which are tabled in a formally convened meeting of the full IEC committee for detailed discussion and decisions.

Initial Review: The first time review of the protocol done by one or two individual reviewers/lead discussants (IEC members) during the formally convened full board IEC meeting.

Pre-clinical study: Animal and in vitro studies provide information on possible toxicities and mechanisms of action, and starting doses for human studies.

Phase I studies: Initial introduction of an investigational new drug (IND) into humans, studies designed to determine the metabolism and pharmacological actions of drugs in humans, and studies designed to assess the side effects associated with increasing doses.

Phase II study: A study of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.

Phase III study: A study expands controlled and uncontrolled trials performed after preliminary evidence suggesting effectiveness of the drug has been obtained. They are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.

Phase IV study: A study that seeks to expand an approved medication's use into a new population, new indication, or new dose.

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

Vulnerable subjects: A vulnerable category of subjects 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.

AX1-V1/SOP04a/V2

Protocol Number : Date (DD/MM/YY):	Protocol Number : Date (DD/MM/YY):					
Protocol Title						
Principal Investigators:	TCMC Registration No.					
INSTITUTE	Contact No. /website/E-mail					
Co – investigator(s):	Contact No. /website/E-mail					
Delineation of responsibilities of investigators:						
Total No. of Participants:	No. of Study site/s:					
Funding Agency	Contact No. /website/E-mail					
Duration of the Study:	Status:	□New		□Revised		□Amended
Reviewer's name :	Contact No.					
Type of the Study :	Intervention	Epidemiology	Social Survey	Others specify	Genetic	Document based
Review Status	□Regular		□Expedited		□Emergency	

Description of the Study in brief: Mark whatever applied to the study.

- □ Descriptive
- □ Screening
- □ Case control Study
- □ Cohort Study
- □ Clincal trials
- ▪ Randomized
- ▪ Stratified Randomized
- ▪ Open-labeled
- ▪ Double blinded
- ▪ Placebo controlled
- ▪ Treatment controlled
- ▪ Cross-over
- ▪ Parallel Interim Analysis
- □ Multicenter study
- □ Use of Tissue samples
- □ Use of Blood samples
- □ Use of genetic materials

Brief the study design and the statistic used:
Study Objectives:

Mark and comment on whatever items applicable to the study

Assessment Criteria	Comment
1 Objectives of the Study. What should be improved?	☐ Clear ☐ Unclear
2 Need for Human Participation	☐ Yes ☐ No
3 Methodology: What should be improved?	☐ Clear ☐ Unclear
4 Background Information and Data	☐ Sufficient ☐ Insufficient
5 Risks and Benefits Assessment	☐ Acceptable ☐ Unacceptable
6 Inclusion Criteria	☐ Appropriate ☐ Inappropriate
7 Exclusion Criteria	☐ Appropriate ☐ Inappropriate
8 Discontinuation and Withdrawal Criteria	☐ sufficient ☐ insufficient
10 Voluntary, Non-Coercive Recruitment of Participants	☐ Yes ☐ No
11 Sufficient number of participants?	☐ Yes ☐ No
12 Control Arms (placebo, if any)	☐ Yes ☐ No
13 Are qualification and experience of the Participating Investigators appropriate?	☐ Yes ☐ No
14 Disclosure or Declaration of Potential Conflicts of Interest	☐ Yes ☐ No
15 Facilities and infrastructure of Participating Sites	☐ Appropriate ☐ Inappropriate
16 Community Consultation	☐ Yes ☐ No
17 Involvement of Local Researchers and Institution in the Protocol Design,Analysis and Publication of Results	☐ Yes ☐ No
18 Contribution to Development Local Capacity for Research and Treatment	☐ Yes ☐ No
19 Benefit to Local Communities	☐ Yes ☐ No
20 Availability of similar Study / Results	☐ Yes ☐ No
21 Are blood/tissue samples sent abroad?	☐ Yes ☐ No
22 Are procedures for obtaining Informed consent appropriate	☐ Yes ☐ No
23 Contents of the Informed Consent Document	☐ Clear ☐ Unclear

24 Language of the Informed Consent Document	□ Clear □ Unclear
25 Contact Persons for Participants	□ Yes □ No
26 Privacy & Confidentiality	□ Yes □ No
27 Inducement for Participation	□ Unlikely □ Likely
28 Provision for Medical Psychosocial Support	□ Appropriate □ Inappropriate
29 Provision for Treatment of Study-Related Injuries	□ Appropriate □ Inappropriate
30 Provision for Compensation	□ Appropriate □ Inappropriate
31 Provision for post-trial access	□ Appropriate □ Inappropriate

Assessment Report

Review Date (DD/MM/YYYY):	Protocol number:	
Protocol Title :		
Elements Reviewed	Attached	Not attached
Review of Revised Application □ Yes □ No	Date of Previous review:	
DECISION	□ Approved □ Approved with Recommendation □ Resubmission □ Disapproved	
Comment:		
Signature	: Date	

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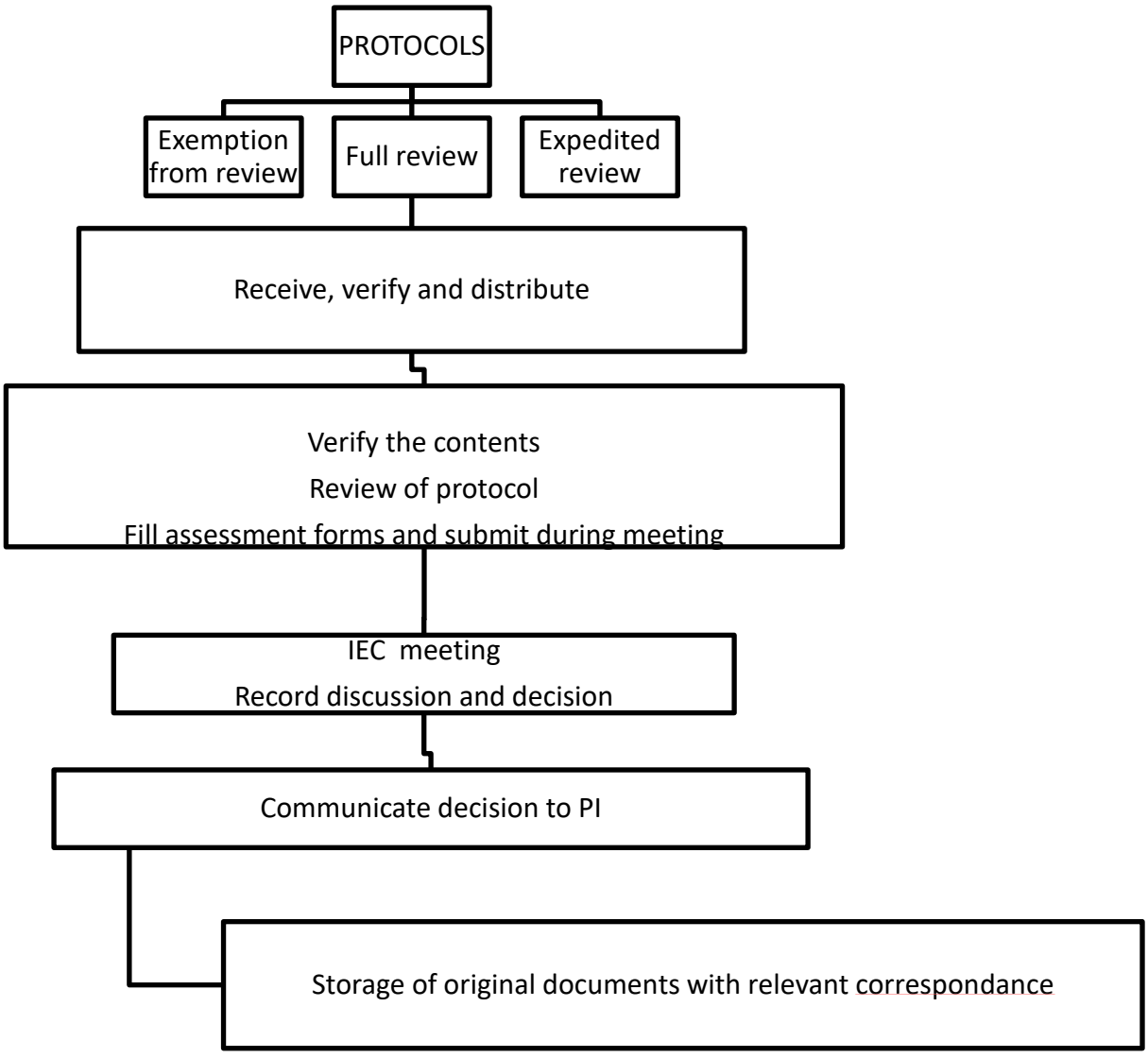
PROTOCOLS
Exemption from review
Full review
Expedited review
Receive, verify and distribute
Verify the contents
Review of protocol
Fill assessment forms and submit during meeting
IEC meeting
Record discussion and decision
Communicate decision to PI
Storage of original documents with relevant correspondance

4B: Expedited Review of Submitted Protocol

SOP Code: SOP 04b/V2 Date :01.04.2013 Pages:

4b.1 Purpose

The purpose of this SOP is to provide criteria for categorisation of research protocols which can be reviewed through expedited process as well as instructions on management, review, and decision of the expedited review.

4b.2 Categorization of protocols

The Member Secretary, IEC or secretariat shall screen the proposals for their completeness and depending on the risk involved in the research proposals categorise them into three types, viz., Exemption from review, Expedited review, and Full review. An investigator cannot categorize his/her protocol in to the above three types. This SOP describes expedited review in detail.

4b.3 Expedited Review

The proposals involving no more than minimal risk to research participants may be subjected to expedited review

An expedited review may be conducted, only if the protocols involve -

1. Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis or health record research (Refer APP9/V1)
2. Anonymous surveys and retrospective chart reviews
3. Analysis of discarded pathological specimens / stored paraffin blocks without personal identifiers
4. Proposals involving previously banked materials and/or tissues as per policies of respective authorities like – tumour tissue repository, following scientific approval by IRC
5. Research activities that involve only procedures listed in one or more of the following categories:
   a.Clinical studies of drugs and medical devices only when -
   i. Research is on already approved drugs except when,
      a. Study of drug interaction
      b. Conducting trial on vulnerable population OR
   ii. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported
   b.Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes
6. Other documents which would be considered for expedited review are as follows but may not restrict to:
   i. Minor deviations from originally approved research during the period of approval (usually of one year duration
   ii. Change in the name, address of sponsor
   iii. Change in contact details of PI and IEC
   iv. Change in PI or hand over of trials or projects
   v. Inclusion or deletion of name/s of co-investigator/s
   vi. Request for change in PI , Co-I, change in any member involved in the research

vii. Minor amendments in the protocol, CRF
viii. Minor corrections in budget
ix. Other administrative changes in the IB, ICF, etc.

4b.4 Scope

This SOP applies to the review and approval of research protocols and documents with not more than minimal risk to participants

4b.5 Responsibility

It is the responsibility of the Member Secretary to identify (as per section 4b.3) which research protocols or documents should be reviewed through expedited process.

4b.6 Detailed instructions to the IRB secretariat:

4b.6.1 Receive the submitted documents

_ Receive the application documents submitted by investigators as per the check list
_ Acknowledge the submitted documents
_ Hand over the received documents to the Member Secretary, IEC

4b.6.2 Expedited Process

- The subcommittee comprising of Member Secretaries of both the IECs will review the documents which qualify for expedited review (refer section no. 4b.3-point 6).
- After determining that the Protocol/ Project or documents qualify for an expedited review, Member Secretary informs the Chairperson and Chairperson nominates one or two IEC members to review the protocol. In this case, the subcommittee comprising of Member Secretary, an external IEC member from the committee and a IEC member from the institution will be formed. The external member will chair the meeting.
- Review may be made either by circulation of comments, telephone discussion, or meeting
- The expedited review should not take longer than 2 weeks, from the date of receipt of the research protocol approved by IRC.
- The minutes of the expedited review subcommittee meeting should be ratified in the next regular full board meeting.
- If consensus cannot be reached, the Chairperson will revert the proposal or the documents back to the IEC for a full board review.

4b.6.3 Communication between the IEC and the investigator

- The decision of subcommittee, IEC, will be communicated to the PI immediately after minutes of subcommittee are finalized.
- If project is disapproved or requires resubmission after certain modifications, this will be informed to the PI in writing. The reasons for disapproval of a project will be specified in the letter sent to PI.

Glossary

Document: Document may be of any forms, e.g., paper, electronic mail (e-mail),faxes, audio or video tape, etc.**Expedited review/meeting:** A review process by only member secretaries of both the IECs and IEC subcommittee, who then report the decision to the full board in a formal meeting. An expedited review is an accelerated review for minor changes to the approved protocol, for research proposal with minimal risk and documents of minor nature.

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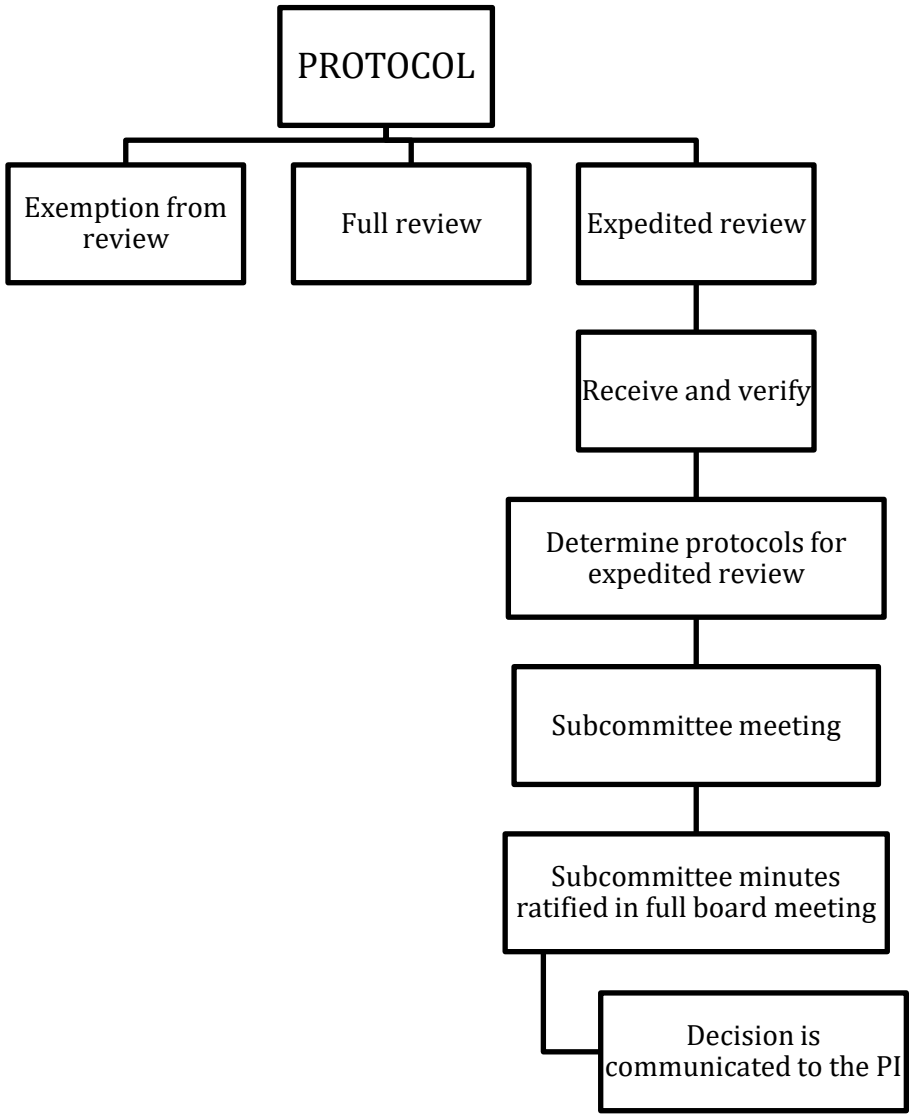

4C: Exemption from the Ethical Review for Research Projects

SOP Code: SOP 04c/V2 Date : 01/04/2013 Pages:

4c.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe which research projects can be exempted from ethics review and do not require the approval of the IEC. The Exemption Form AX1-V1/SOP04c/V2 is designed to standardize the process of exemption.

4c.2 Categorization of protocols

The Member Secretary, IEC or secretariat shall screen the proposals for their completeness and depending on the risk involved in the research proposals categorise them into three types, viz., Exemption from review, Expedited review, and Full review. An investigator cannot categorize his/her protocol in to the above three types. This SOP describes exemption from ethics review in detail.

4c.3 Exemption from review

Proposals which involve less than minimal risk fall under this category. **Minimal risk would be defined as one which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of 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 undergoing these interventions since it would be undertaken as part of current every day life (ICMR 2006).
The exemption from review may be seen in following situations:

i. Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

Exceptions:

a. *When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm*
b. *When interviews involve direct approach or access to private papers*

ii. The research proposals which do not involve live human participants or data derived from them are exempt from ethics review. For example,

- ✓ Audits of educational practices
- ✓ Research on microbes cultured in the laboratory
- ✓ Research on immortalized cell lines
- ✓ Research on cadavers or death certificates provided such research reveals no identifying personal data

- ✓ Analysis of data freely available in public domain In some circumstances research which appears to meet low risk criteria may need to be reviewed by the IEC. This might be because of requirements of:
- ✓ The publisher of the research
- ✓ An organization which is providing funding resources, existing data, access to participants etc.

Exceptions:

a. *When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.*
b. *When interviews involve direct approach or access to private papers.*

4c. Scope

This SOP applies to the all protocols submitted for exemption from review by the IEC. The specific points in the Exemption Form should guide the Member Secretary to determine whether the protocol qualifies for exemption from review. The decision should be taken by the Member Secretary in consultation with the Chairperson and should be informed to the members in the forthcoming IEC meeting.

4c.5 Responsibility

It is the responsibility of the Member Secretary to record the decision in the Exemption Form with reasons. The IEC Secretariat is responsible for recording and filing the decision including the reasons for that decision. The Chairperson must sign and date letter conveying the decision AX1-V1/SOP04c/V2.

4c.6 Detailed instructions to the IRB Secretariat:

4c.6.1 Receive the submitted documents

- The Secretariat will receive the Exemption from review Application Form AX1-V1/SOP04c/V2, Protocol and other documents submitted by the investigators.
- Acknowledge the submitted documents
- Hand over the received documents to the Member Secretary, IEC

4c.6.2 Determine protocols eligible for exemption from review

The Member Secretary, IEC will determine whether a protocol qualifies for exemption from review based on criteria explained in (section 4c.3).

4c.6.3 Exemption Process

- If the protocol and related documents satisfy the criteria as listed in 4c.3, the Member Secretary in consultation with the Chairperson will review the brief summary of the project and the Exemption Form.

- The Member Secretary records the decision on the Exemption Form.
- The Secretariat communicates the decision to the investigator.
- The Member Secretary informs the IEC members about the decision at the next full board meeting.
- In case the protocol does not fit in any of the above stated criteria, the Member Secretary / Chairperson may keep the application for review and discussion at the full board meeting.

4c.6.4 Communication between the IEC and the investigator

The decision regarding request for Exemption from review, signed by the IEC Chairperson, will be forwarded by the Secretariat to the PI within 14 days after the decision regarding the exemption is taken.

The Member Secretary will inform the IEC members of the decision at the forthcoming regular meeting and minute it in the meeting notes.

AX1-V1/SOP04c/V2: Review Exemption Application Form

SGMC Project No. : _____ (To be filled by IEC Secretariat)

1 Principal Investigator's Name:

2 Department:

3 Title of Project:

4 Names of other participating staff and students:

5 Brief description of the project:

Please give a brief summary (approx. 300 words) of the nature of the proposal, including the aims/objectives/hypotheses of the project, rationale, participants' description, and procedures/methods to be used in the project:-

6 State reasons why exemption from ethics review is requested?

- ✓ Audits of educational practices
- ✓ Research on microbes cultured in the laboratory
- ✓ Research on immortalized cell lines
- ✓ Research on cadavers or death certificates provided such research reveals no identifying personal data
- ✓ Analysis of data freely available in public domain
- ✓ Any other

*(This should include justification for exemption e.g. study does not involve human participants. If exemption is being requested on the basis of low risk involved in the study please refer to **Note** of this annexure.)*

7 Investigational New Drug (IND) APPLICATION EXEMPTION CHECKLIST

This checklist is intended to be used by the investigator as a preliminary test of whether an IND application needs to be submitted to the DCGI for studies involving DCGI/RA-approved drugs. If any question is answered "yes", an IND application must be submitted to the DCGI. If the answers to all questions are "no", then the study may meet the criteria for an exemption from an IND.

1. Name of drug
   Dosage
   Route
2. Does the study involve a different route of administration of the marketed drug than already approved?
   □ YES □NO
3. Does the study involve the administration of different drug dosage levels that significantly increase risk or decrease the acceptability of risk to study subjects?
   □ YES □NO

4. Does the study involve the administration of the drug to a different patient population for whom there may be increased risk or decreased acceptability of risk?
   □ YES □NO
5. Does the study entail any other factor that significantly increases the risk or decreases the acceptability of risk to study subjects?
   □ YES □NO
6. Are the results of the study intended to be reported to the DCGI/RA in support of any significant change in labeling or advertising for the drug (only for corporate sponsored studies)?
   □ YES □NO

Signature of Investigator: Date:

Principal Investigator's signature: _____ Date:

Forwarded by the Head of the department:

Name:_____Signature:_____ Date:

Recommendations by the IEC Member Secretary:

□ Exemption
□ Cannot be exempted, Reasons……
□ Discussion at full board

Signature of the Member Secretary: _____ Date _____

Final Decision:

□ Exemption
□ Cannot be exempted, Reasons……

Signature of the Chairperson: _____ Date _____

Final Decision at Full Board meeting held on _____

Signature of the Chairperson: _____ Date _____

NOTE:

No research can be counted as low risk if it involves:

1. Invasive physical procedures or potential for physical harm
2. Procedures which might cause mental/emotional stress or distress, moral or cultural offence
3. Personal or sensitive issues
4. Vulnerable groups
5. Cross cultural research
6. Investigation of illegal behavior(s)
7. Invasion of privacy
8. Collection of information that might be disadvantageous to the participant
9. Use of information already collected that is not in the public arena which might be disadvantageous to the participant
10. Use of information already collected which was collected under agreement of confidentiality
11. Participants who are unable to give informed consent
12. Conflict of interest e.g. the researcher is also the lecturer, teacher, treatment-provider colleague or employer of the research participants, or there is any other power relationship between the researcher and the research participants.
13. Deception
14. Audio or visual recording without consent
15. Withholding benefits from "control" groups
16. Inducements
17. Risks to the researcher

This list is not definitive but is intended to sensitize the researcher to the types of issues to be considered. Low risk research would involve the same risk as might be encountered in normal daily life.

Please check that your application / summary has discussed:

- Procedures for voluntary, informed consent
- Privacy & confidentiality
- Risk to participants
- Needs of dependent persons
- Conflict of interest
- Permission for access to participants from other institutions or bodies
- Inducements

In some circumstances research which appears to meet low risk criteria may need to be reviewed by the IEC. This might be because of requirements of:

_ The publisher of the research

_ An organisation which is providing funding resources, existing data, access to participants

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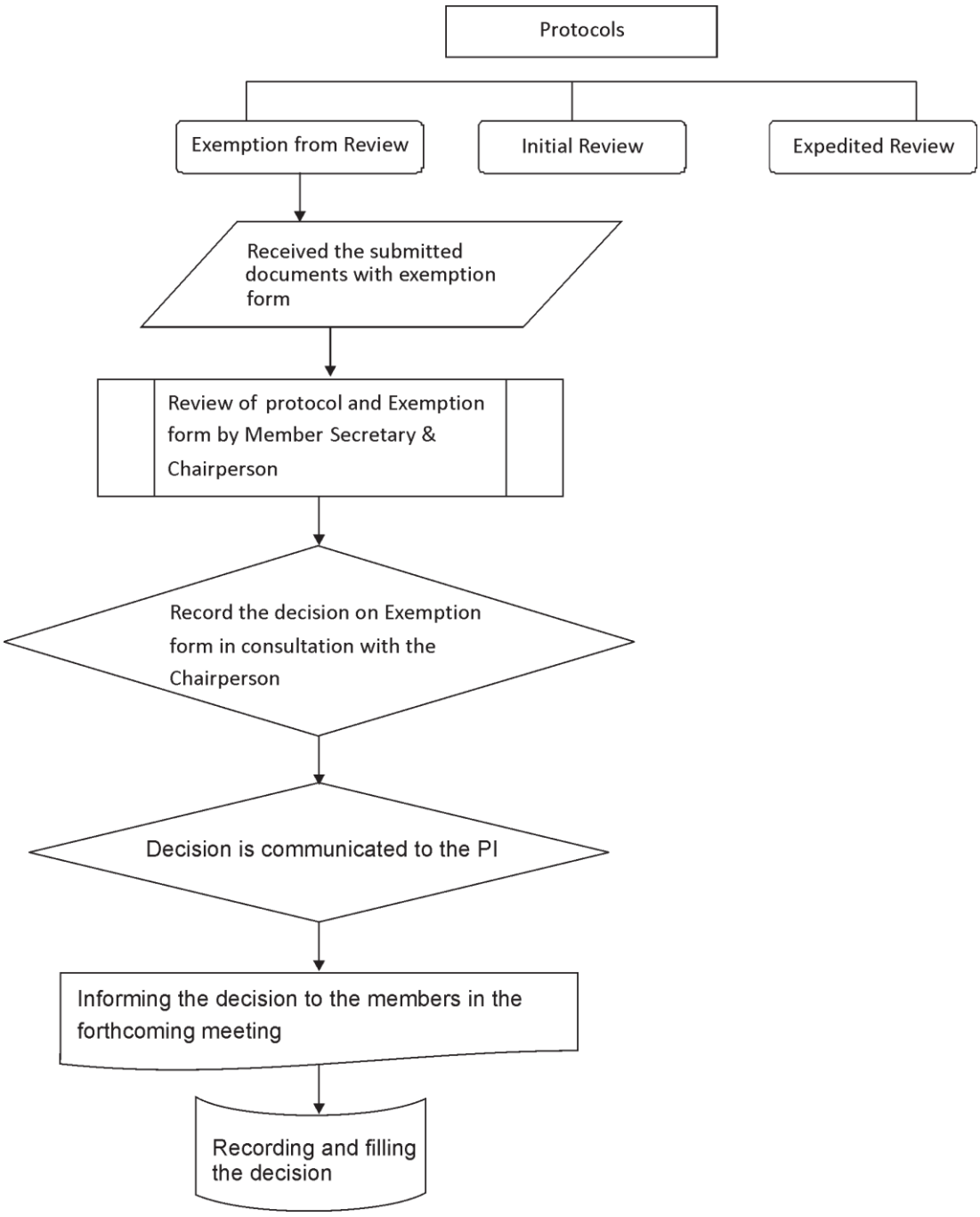
Protocols
Exemption from Review
Initial Review
Expedited Review
Received the submitted documents with exemption form
Review of protocol and Exemption form by Member Secretary & Chairperson
Record the decision on Exemption form in consultation with the Chairperson
Decision is communicated to the PI
Informing the decision to the members in the forthcoming meeting
Recording and filling the decision

Institutional Ethics Committee Standard Operating Procedures(SGMC-IEC:SOP:05/V2)

Title: Agenda Preparation, Meeting Procedures and Recording of Minutes

SOP Code: SOP 05/V2 Date : 01/04/2013 Pages:

5.1 Purpose

The purpose of this procedure is to elaborate administrative process and provide instructions for preparation, review, approval, and distribution of meeting agenda, minutes, and notification letters of IEC, SGMC meetings.
The day, time, and venue of IEC meetings for both committees are specified as follows:
IEC meets at 8.30 am on the last Thursday of every month unless otherwise specified. Maximum interval between 2 regular meetings shall not be more than 8 weeks.
Venue: Council Room 5th Floor, College Building Sree Gokulam Medical College &RF

5.2 Scope

This SOP applies to administrative processes concerning the conduct of the meeting.

5.3 Responsibility

It is the responsibility of the Secretary, and IRB staff to prepare for the respective IEC meeting.

5.4 Detailed instructions

5.4.1 Before full board IEC meeting

- Prepare the agenda of the IEC meeting (AX1-V1/SOP05/V2)
- Schedule protocols on the agenda on a first come first serve basis.

5.4.2 Distribution of Protocol/Documents Packages to the IEC Members

- Distribute copies of the protocols to the IEC members by either electronic mail (in case of electronic submission of protocols) or by courier preferably 10 days in advance of the scheduled meeting
- Verify (verbally, by e-mail, by fax or by mail) with the members whether the protocol packages are received
- It is the responsibility of the IEC member to verify items of the parcel on receipt and in the event of any missing items, intimate the IRB office immediately so that the relevant documents could be made available to the members before the meeting.

5.4.3 Preparation for the meeting

- Reserve the conference room on the scheduled meeting date and time. The meeting will be held in the conference room of Principal, unless otherwise specified.
- Ensure that the room, equipment (projectors, recorder, etc) and facilities are available in good housekeeping conditions on the day of the meeting.
- On the previous day of the meeting keep all original files of protocols on the agenda in the meeting room for ready reference during the meeting.

5.4.4 Conduct of Meeting

- The members should gather in conference room on scheduled time.
- The Chairperson should determine that the quorum (SOP 02/V2 section no. 2.9)requirements are met.
- The Chairperson should ask for declaration of conflict of interest either verbally or written on any protocol for discussion.
- If a IEC member has conflict of interest involving a project then he / she should declare the same, before the meeting commences and leave the meeting room before the discussion on the same. This should be recorded in the minutes
- The Member Secretary should table the minutes of the previous meeting and present the agenda for discussion
- The IEC may invite investigators to attend the full board meeting related to their studies,and clarify doubts, if any
- The meeting proceeds in the sequential order of the agenda; however the Chairperson may change the order, if the situation so demands
- The Member Secretary will request the lead discussant to discuss the research protocol. The lead discussant will submit the duly filled study assessment form at the end of the discussion or at the conclusion of IEC meeting.
- Amendment will be reviewed by previously assigned lead scientific discussant.
- In case the lead discussant cannot attend the meeting, secretary, IEC or any other IEC member may brief the IEC about the research protocol and also discuss the written comments/duly filled study assessment form, if provided by the lead discussant.
- The Member Secretary, IEC / IRB administrative officer minutes/records the proceedings of the IEC meeting.

5.4.5 Decision Making Process

IECs provide complete and adequate review of the research proposals submitted to them. The committees will review new project proposals, amendments, annual progress of ongoing projects, SAE reports, and assess final reports of all research activities through a scheduled agenda.

- A IEC member will withdraw from the meeting for the decision procedure concerning an application where a conflict of interest exists.
- If IEC member has her/his own proposal for IEC review he/she will not participate in the IEC discussion on that particular project.

- Decision may only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g., the investigator, representatives of the sponsor, independent consultants) from the meeting, with the exception of IRB staff.
- Decisions will only be made at meetings where a quorum (SOP 02/V2 section no. 2.9) is present.
- The documents required for a full review of the application should be complete and the relevant elements considered before a decision is made.
- Only IEC members who attend the meeting will participate in the decision.
- Decisions will be arrived at through consensus. When a consensus is not possible, the IEC will vote.
- If the full board approves a research proposal in principle subject to minor modifications, the revised project proposal submitted by the PI will be reviewed and approved by the Member Secretary, IEC or in some cases by the primary reviewer on behalf of the full board. Such revised proposals will not be taken up for the full board review. However, in case of major changes, the revised documents will be discussed in full board meeting.
- An IEC may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk/ benefit ratio.
- Any advice that is non-binding will be appended to the decision.
- In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed will be specified.
- A negative decision on an application will be supported by clearly stated reasons. If the investigator wishes to appeal to the decision, he/she may do so by contacting the IRB Secretariat.
- The discontinuation of a trial will be recommended if the IEC finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.
- If necessary, the investigator may be invited to present the protocol or offer clarifications in the meeting. Representative of the patient groups or community can be invited during deliberations to offer their viewpoint.
- Subject expert/s may be invited to offer their views, but expert/s should not participate in the decision making process. However, his / her opinion must be recorded.
- The proceedings of the IEC meetings will be documented and signed by the Member Secretary.

5.4.6 After the IEC meeting

5.4.6.a Preparing the minutes and the decision letters

- The Member Secretary will compile the proceedings of IEC meeting in a concise and easy-to-read style and will check spelling, grammar and context of the written minutes.
- The minutes of the meeting will be compiled within a week.

5.4.6.b Approval of the minutes and the decision

- The minutes of the IEC meeting will be signed by Member Secretary, IEC.
- The minutes of the IEC meeting will be ratified in the subsequent IEC meeting.
- The IEC decisions will be communicated to the PIs.

5.4.6.c Filing of the minutes of the meeting

- Place the original version of the minutes in the minutes file and copy of the minutes are filed in the corresponding research protocol file.

5.4.7 Communicating Decision

- The decision will be communicated in writing to the PI, preferably within a period of 10 days of the IEC meeting at which the decision was made.
- The communication of the decision will include, but is not limited to, the following,
- SGMC Project No. and title of the research proposal reviewed
- The clear identification of the protocol of the proposed research or amendment, date and version number (if applicable).
- The names and specific identification number version numbers/dates of the documents reviewed, including the potential research participant information sheet/material and informed consent form
- The name and title of the Principal Investigator
- The name of the site(s)
- The date and place of the decision
- A clear statement of the decision reached
- Validity of approval usually will be yearly for multiyear projects, however may change on case to case basis.
- Any suggestions by the IEC
- A conditional decision (i.e. approval with recommendations or modifications, suggestions for revision and the procedure, any other requirements by the IEC), will be valid only for six months from the date of issue of letter. If the PI does not comply with the IEC suggestions during these three months, a reminder will be issued. The modifications will be re-reviewed by Member Secretary, IEC or primary reviewer/s and /or may be referred for full board review (AX3-V1/SOP05/V2).
- In the case of a positive decision, the PI is notified of the following requirements through an approval letter (AX2-V1/SOP05/V2)
  - a statement of the responsibilities of the PI; for example, confirmation of the acceptance of any requirements recommended by the IEC

- submission of progress report(s) decided on case to case basis, usually yearly.
- the need to notify the IEC in cases of protocol amendments (other than amendments involving only logistical or administrative aspects of the study)
- the need to notify the IEC in the case of amendments to the recruitment material like the potential research participant information, or the informed consent form
- the need to report serious and unexpected adverse events related to the conduct of the study
- the need to report unforeseen circumstances, the termination of the study, or significant decisions by other IEC
- the information the IEC expects to receive in order to perform ongoing review
- the final summary or final report
- the schedule/plan of ongoing review by the DSMB of sponsored trials
- _ In the case of a negative decision, the reasons should be clearly stated in the communication to the PI
- _ The PI will also be notified of the duration of the approval, which will not exceed one year
- _ All decision and approval letters will be signed by the Member Secretary, IEC
- _ Every page of consent forms (English, Hindi, Malayalam) of investigator initiated trials and first page of ICFs of sponsored trials (English, Hindi, Malayalam) will be signed and dated by Member Secretary, IEC. These approved ICFs will be sent to the PI along with the approval letter.
- _ The Chairperson / Member Secretary, IEC, will sign and date the approval letter and approval certificate in the original research protocol.

Glossary

Agenda: A list of things to be done; a program of business for the meeting
Minutes: An official record of proceedings at a meeting
Quorum: Number of IEC members required to act on any proposal presented to the committee
for action.

AX1 –V1/SOP05/V2: AGENDA FORMAT

I) Minutes
II) Projects for Initial Review
III) Amendments
IV) Letters
V) Minutes of DSMSC & SAEs

AX2 –V1/SOP05/V2: FORMAT FOR APPROVAL LETTER OF ETHICS COMMITTEE

To

Dr._____
Principal Investigator,
Sree Gokulam Medical College

Ref: Project No.

Dear Dr.----------,

Ethics Committee of Sree Gokulam Medical College & RF reviewed and discussed your application (dated) to conduct the research study entitled "_____" during the IEC meeting held on (date).

The following documents were reviewed and approved:

1. Project Submission form.
2. Study protocol (including protocol amendments), dated_____, version no(s).
3. SGMC- Institutional Research Committee approval letter dated _____
4. Patient information sheet and informed consent form (including updates if any) in English and/Vernacular language.
5. Investigator's brochure, dated_____, version no._____
6. Proposed methods for patient accrual including advertisement(s) etc. proposed to be used for the purpose.
7. Current CVs of Principal investigator, Co-investigators
8. Package inserts
9. Insurance policy/compensation for participation and for serious adverse events occurring during the study participation.
10. Investigator's Agreement with the sponsor
11. Investigator's undertaking
12. DCGI/DGFT approval
13. Clinical Trial Agreement (CTA)/Memorandum of Understanding (MOU)/Material Transfer Agreement (MTA), if applicable

The following members of the Institutional Ethics committee (IEC) were present at the meeting held on Date _____ Place _____

Name of member/Position on IEC/Affiliation/Gender

_____ Chairman of the Ethics committee
_____ Member secretary of the ethics committee
_____ Name of each member with designation

The trial is approved in its presented form. The approval is valid until one year from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of annual status report.

Following points must be noted:

1. IEC should be informed of the yearly progress of the study.
2. IEC has approved recruitment of ____ patients on this study.
3. PI and other investigators should co-operate fully with DSMSC, who will monitor the trial from time to time.
4. The decision was arrived at through consensus. Neither PI nor any of proposed study team members was present during the decision making of the IEC.
5. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to colleague after obtaining clearance from HOD, Status report, including accounts details should be submitted to HOD, DSMSC and extramural sponsors.
6. The IEC functions in accordance with the ICH-GCP/ICMR/Schedule Y guidelines.
7. In case of any new information or any SAE, which could affect any study, must be informed to IEC, DSMSC and sponsors. The PI should report SAEs occurred for IEC approved studies within 7 days of the occurrence of the SAE. If the SAE is 'Death', the IRB Secretariat will receive the SAE reporting form within 24 hours of the occurrence.
8. In the events of any protocol amendments, IEC must be informed and the amendments should be highlighted in clear terms as follows:
a. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)
b. Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted
c. If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval.
d. If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented.
e. If there are any amendments in the trial design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the IRC and IEC, only then can they be implemented.
f. Approval for amendment changes must be obtained prior to implementation of changes. Without including all the above points, the amendment is unlikely to be approved by the Ethics committee.
g. Any deviation/violation/waiver in the protocol must be informed to the IEC.

Thanking You,

Yours Sincerely,

Member Secretary,
Institutional Ethics Committee

SGMC- IEC No:--/--/--/YEAR Date:dd/mm/Year

Communication of the decision of Institutional Ethical Committee (SGMC -IEC)

Protocol Title:
Principal Investigator:
Name& Address of Institution:
☐ **New review** ☐ Revised review ☐ Expedited review
Date of review(D/M/Y): Date of previous review, if revised application:
Decision of the IEC: ☐ **Recommended** ☐ Recommended with Suggestion ☐ Revision ☐ Rejected
Suggestions/Reasons/Remarks:
Recommended for period of study:1 year

Please note*

-Inform IEC immediately in case of any Adverse events and serious adverse events
-Inform IEC in case of any change of study procedure, site and investigator
-This permission is only for a period mentioned above Annual report to be submitted to IEC
-Members of IEC have right to monitor the trial with prior intimation

Signature of Member Secretary
Institutional Ethical Committee

AX3–V1/SOP05/V2: FORMAT FOR CONDITIONAL APPROVAL FOR PROJECT/AMENDMENTS

Conditional approval.

Dr…
Principal Investigator,
SGMC&RF
Ref: Project No.

Dear Dr…

The above referenced project was tabled, reviewed and discussed during the Institutional Ethics Committee meeting held on date/time/place
List of documents reviewed.

The following members attended the meeting.

The committee suggested the following:
a.
b.
c.

The approval will be granted subject to the compliance with all the above suggestions of the IEC. Kindly resubmit the two copies of revised proposal or documents within three months for re-review.
This conditional approval is valid only for six months from the date of issue of letter.

Thanking you,

Yours sincerely,

Secretary, IEC

SOP 05 /V2 IEC SGMC
Effective Date:

Institutional Ethics Committee Standard Operating Procedures(SGMC-IEC:SOP:06/V2)

Title: Review of Amended protocol/ Protocol related documents

SOP Code: SOP 06/V2 Date : 01/04/2013 Pages: 6

6.1 Purpose

The purpose of this procedure is to describe how protocol amendments or any other amendments/letters are reviewed by the IEC.

6.2 Scope

This SOP applies to amended study protocols/ documents and letters that are submitted for IEC approval. Amendments made to protocols or any other amendments related to the study may not be implemented until reviewed and approved by the IEC.

6.3 Responsibility

It is the responsibility of the IEC secretariat to manage protocol amendments, documents and letters.

Receipt of the Amendment Package

_ The amendment package forwarded by the PI is received by the secretariat. The amendment package along with the covering letter should be accompanied by Amendment Reporting Form (AX2-V1/SOP06/V2).

_ The secretariat of the IEC should follow the procedures as in SOP03/V2 (Procedures for Management of protocol submission).

Upon receipt of the amendment package the IRB, Secretariat should follow the following procedure

The Member Secretary, IEC, classifies the amendments into minor or major and tables the major amendments on the agenda of the subsequent scheduled meeting (for Minor amendments refer to 6.4.3). The amendments and other documents which need full board review are processed as per the SOP 04a/V2

6.4. Review amended protocols/documents/letters:

Review as per Section 4.3 SOP 04a/V2

6.4.1 Decision

_ If the IEC approves the amendments, the secretariat staff communicates this decision to the PI (AX1-V1/SOP06/V2).

_ If the IEC does not approve the amendments, the secretary should immediately notify the investigator in writing of the decision and the reason for not approving the amendment.

_ If the IEC recommends or suggests modifications to any of the documents, or the amendments, the secretariat sends a written communication to the investigator about the specific changes asking him or her to make the necessary changes and resubmit the documents to IEC.

6.4.2 Storage of Documents:

File the amendments in the corresponding research protocol file, as per the SOP 10/01 on documentation and archival.

6.4.3 Minor amendments and notifications

Minor amendments (those that do not increase the risk or decrease the potential benefit to subjects) may be approved by the Member Secretaries, IEC in the expedited review subcommittee meeting (Refer SOP no. 04b/V2.)
Minor notifications may be noted by the Member Secretary, IEC and not tabled in IEC Meeting. This may include but may not restrict to:
_ Renewed insurance policy
_ DCGI and DGFT approvals
_ Administrative notes

Glossary

Amendment protocol package: A package of the amended parts and related documents of the protocol, previously approved by the IEC/IRB, SGMC. In the course of the study, the PI may decide to make changes in the protocol

AX1-V1/SOP06/V2: Format for Project Amendment/Document Amendment Approval letter

To

XXXXX (PI)
Department

Ref: - Project title

Dear Dr. ——

We have received the following document/s on (date)

At the IEC meeting held on —— date/time/place, the above mentioned documents were reviewed. After deliberation, the committee has decided to approve the aforementioned study-related documents.

The members who attended this meeting held on —— date and place of meeting —— at which the above mentioned document was discussed, are listed below.
1.
2.
3.

It is to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the IEC.

Yours truly,

Signature with Date
Member Secretary IEC

AX2-V1/SOP06/V2 : IRB Secretariat Amendment Reporting Form

Project No. :	
Title :	
Principal Investigator :	
Have you highlighted the amended portion in the document or tabulated details of changes?	
Does this amendment entail any changes in ICFs	Yes / No
If yes, whether amended ICFs are submitted pl. specify Version No & Date	
Please mention version no. and date of amended Protocol / Investigators brochure / Addendum	
No. of active trial participants	

Signature of the Principal Investigator & Date:

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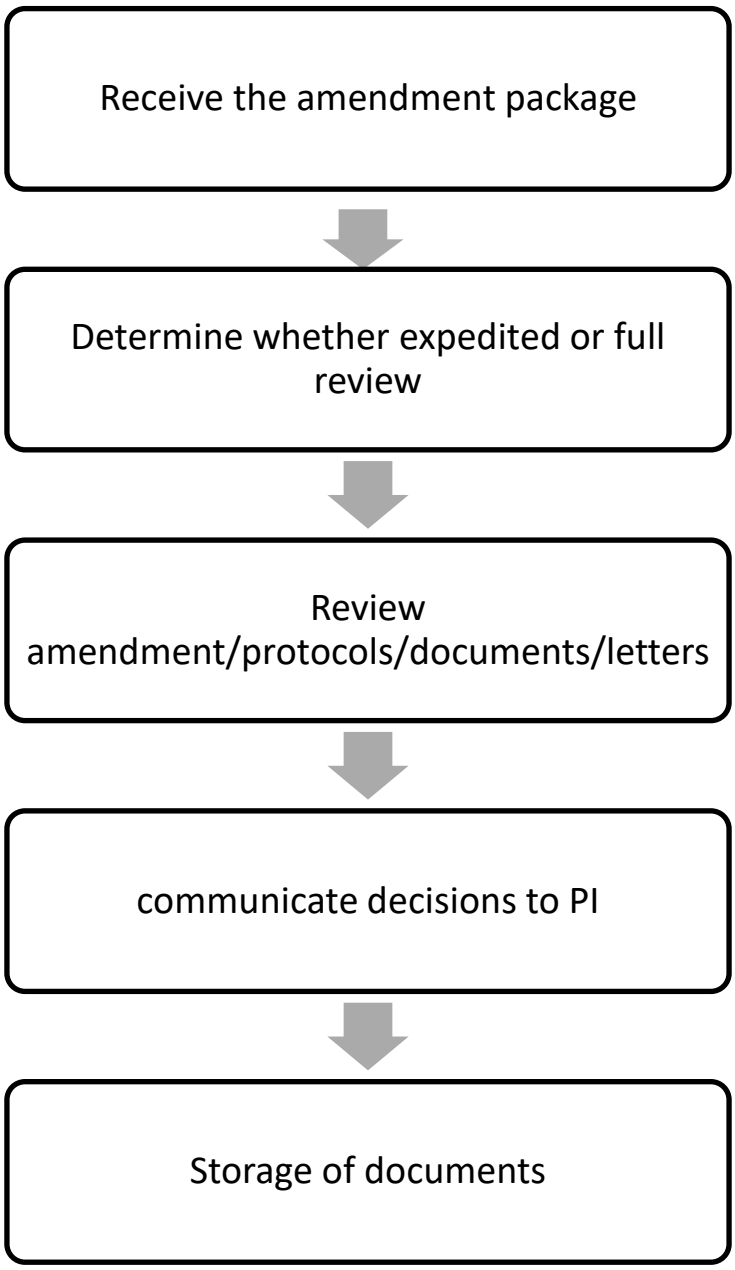
Receive the amendment package
Determine whether expedited or full review
Review amendment/protocols/documents/letters
communicate decisions to PI
Storage of documents

Institutional Ethics Committee
Standard Operating Procedures

(SGMC-IEC:SOP:07/V2)

Title: Continuing review of study Protocols

SOP Code: SOP 07/V2 Date : 01/04/2013 Pages:

7.1 Purpose

The purpose of continuing review is to monitor the progress of the entire study which was previously approved; not just the changes in it but to ensure continued protection of the rights and welfare of research subjects. Continuing review of the study may not be conducted through an expedited review procedure, unless

1) The study was eligible for, and initially reviewed by, an expedited review procedure; or 2) the study has changed such that the activities remaining are eligible for expedited review.

7.2 Scope

This SOP applies to conducting continuing review of study protocols involving human subjects at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participants, the nature of the studies and the vulnerability of the study participants and duration of the study, the IEC may choose to review the studies more frequently.

7.3 Responsibility

It is the responsibility of the secretary, IEC to determine the date of continuing review and to remind the IEC and the PIs.

All the approved protocols will be reviewed annually. The Chairperson is responsible for determining the date of continuing review if the project will be reviewed more frequently in the year. This decision is taken during the IEC meeting wherein the project is finally approved. The IEC is responsible for reviewing the progress made in the protocol, the occurrence of unexpected events or problems, and the rate of accrual of participants. The protocol, informed consent documents and assent documents are examined to ensure that the information remains accurate. The IEC has the same options for decision making on a continuing review package as for an initial review package. The decision is made as, approval to continue the study; approval with recommendations; or disapproval. All Principal Investigators along with the submission of the annual project progress report will also apply for extension of approval of the project.

7.4 Detailed Instructions

7.4.1 Determine the date of continuing review

- The Secretariat will look through the master file of projects approved by the IEC for the due date of continuing reviews.
- The Secretariat will plan for continuing review of annual progress reports to be reviewed at least one month ahead and as close as possible to the due date (i.e. one year after the date of original approval) of the protocol.
- The Member Secretary will consult the Chairperson whether to include the annual project report/s in the forthcoming IEC meeting for discussion or to review by Member Secretary/Chairperson and inform the members at the full board meeting or to send to two IEC members nominated by Chairperson for review.

7.4.2 Notify the PI or the study team

- The Secretariat will inform the PI at least two months of the due date for the continuing review in writing, (AX2-V1/SOP 07/V2) requesting for 2 copies of the annual / periodic progress report to allow the Study Team sufficient time to collate the information and to prepare a report package required for the continuing review.
- The Secretariat will provide a Continuing Review Application Form (AX1-V1/SOP 07/V2) (available at the IRB Secretariat) to the Study Team and file the acknowledgement in the master file of the research protocol.
- Any PI who fails to submit the report for review within the stipulated time, will have to clarify the delay in writing, this will be forwarded to the Chairperson, IEC.

7.4.3 Manage continuing review package upon receipt

- The Secretariat will receive a package submitted by the Study Team of continuing review for each approved protocol.
- Upon receipt of the package, the Secretariat of the IEC will perform the following (as per instructions in SOP03/V2 for procedures on receipt of submitted packages).

7.4.4 Verify the contents of the package

- The Secretariat will verify that the contents of the package include the following documents:
- Continuing Review Application Form (AX1-V1/SOP 07/V2)
- The Progress Report with:
- Information about the number of participants enrolled to date and since the time of the last review, an explanation for any “yes” (ticked on the Continuing Review Application Form AX1-V1/SOP7/V2)answers on the application form and a discussion of scientific development, either through the conduct of this study or similar research that may alter risks to research participants.
- The progress report summary of the protocol since the time of the last review (1 copy).
- Request letter for extension of approval of the project, if the project is ongoing.
- The Secretariat will check for complete information and for the presence of the required signatures of the Principal Investigator in the Continuing Review Application Form.

7.4.5 Filing the continuing review package

The Administrative Officer will file the continuing review package in master file of the research protocol.

7.4.6 Notify the Members of the IEC

The Secretariat will distribute the protocol progress report to IEC members prior to the meeting.

7.4.7 Prepare meeting agenda

The Secretariat will follow for procedures on the preparation of meeting agenda and place the forwarded Annual Progress Report on the agenda for the meeting of the IEC, if deemed necessary by the Chairperson/ Member Secretary, on the date which is as close as possible to the due date (i.e. one year after the date of original approval) of the protocol.

7.4.8 Protocol Review Process

- The IEC Chairperson/ Member Secretary/ members will use the Continuing Review Application Form (AX1-V1/SOP07/V2) to guide the review and deliberation process. The IEC members could arrive at any one of the following decisions at the IEC meeting:

1) Noted and the project can be continued without any modifications
2) Modifications recommended - Protocols for which modifications have been suggested by the IEC may not proceed until the conditions set by the IEC in the decision have been met. Protocols should be amended and submitted to the IEC within one month for re-review. Protocols that have been approved with recommendations by the IEC may not proceed until the conditions set by the IEC in the decision have been met.
3) Disapproved.
    - This decision is recorded by the Member Secretary on AX3-V1/SOP07/V2
    - The IEC Chairperson will sign and date the IEC decision on Continuing Review Report after a decision has been reached.
    - The completed IEC decision on Continuing Review Report is the official record of the decision reached by the IEC for the protocol.
    - The IEC Secretariat will maintain and keep the IEC decision forms and minutes of the meeting relevant to the continuing review as part of the official record of the review process.

7.4.9 Store original documents

Place the original completed documents with the other documents in the Continuing Review Package in the protocol file.

7.4.10 Communicate the IEC Decision to the PI

The Secretariat will notify the PI of the decision (AX4-V1/SOP 07/V2). If the decision is to recommend modifications, the recommendations will be notified to the PI and he/she will be requested to resubmit the protocol/protocol related documents as amendment within 1 month for approval. Till then the project is suspended. These letters must be sent to the PI within 14 days.

AX1-V1/SOP 07/V2: Continuing Review Application Form

SGMC STUDY No.:
PROTOCOL TITLE:
PI : Institute: Date of IEC approval : Start Date of study: Duration of study:

HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW? ☐ NO ☐ YES (Describe briefly in attached narrative) WERE THESE PROTOCOL AMENDMENTS APPROVED BY IEC ☐ NO ☐ YES If no mention the amendments not approved Which protocol amendment is the site following at this date SUMMARY OF PROTOCOL PARTICIPANTS: Accrual ceiling set by IEC New participants accrued since last review Total participants accrued since protocol began _____ Number of active patients	WERE THE ICD AMENDMENTS APPROVED BY IEC ☐ NO ☐ YES If no mention the amendments not approved _____ _____ Which ICF amendment is the site following at this date _____ Has any information appeared in the literature, or Evolved from this or similar research that might affect the IEC evaluation of the Risk/Benefit analysis of human subjects involved in this protocol?

_____ Number of patients who have completed the study IMPAIRED PARTICIPANTS □ None □ Physically □ Cognitively □ Both HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW? □ NO □ YES (Explain changes in attached narrative) HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY DURING THE LAST ONE YEAR? □ NO □ YES (Discuss in the attached narrative, state reasons for drop-outs) HAVE ANY PARTICIPATING INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW? □ NO □ YES (Identify all changes in the attached narrative) HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR DELETED SINCE THE LAST REVIEW? IS REPORT OF INTERIM DATA ANALYSIS AVAILABLE?	□ NO □ YES (Discuss in the attached narrative) Have any unexpected complications, AEs Or SAE been noted since last review at our site? □ NO □ YES (Discuss in the attached narrative no. of patients at our site who had SAEs, whether reports of SAEs at our site have been submitted to the IEC, whether reports of SAEs at other sites have been submitted to the IEC, types of adverse events. This should be tabulated with complete details) IS REPORT OF THE DATA SAFETY AND MONITORING BOARD AVAILABLE? □ NO □ YES (submit as an attachment) When was study last monitored? _____ Did the monitoring team have any adverse comments regarding the study? (If, Yes, please attach a copy of their comments) Attach a copy of current statement from accounts showing utilization of funds.

□ NO □ YES (submit as an attachment)	Status of project □ Ongoing □ Not started/Not initiated - If not started, state reasons- _____ □ Completed Accrual completed Follow-up □ Suspended □ Terminated □ Closed
HAVE ANY INVESTIGATORS DEVELOPED AN EQUITY OR CONSULTATIVE RELATIONSHIP WITH A SOURCE RELATED TO THIS PROTOCOL WHICH MIGHT BE CONSIDERED AS CONFLICT OF INTEREST? CONFLICT Of INTEREST □ NO □ **YES (Append a statement of disclosure)**	

SIGNATURES:
Date: ……..

Principal Investigator

AX2-V1/SOP 07/V2: Reminder letter by the IEC to PI

Name of Principal Investigator:-
Address of Principal Investigator:-
Ref: - Project Title: XXXXXX

The above referenced project was approved by the IEC on XXXXXXX and is due for continuing annual review by the IEC. You are requested to submit an annual status report in the prescribed format AX1-V1/SOP 07/V2 on or before XXXXX.

Signature with date
Secretary

AX3-V1/SOP 07/V2: IEC Decision on Continuing Review Report

Project Title:
PI:
Review a) Annual Progress Report
b) Other
Date of IEC meeting:
Further the review and approval of resubmitted protocol is subjected to:

- Reviewed by Chairperson / Member Secretary only. IEC members were informed at Full Board/ Expedited meeting.
- Reviewed in Full Board
- Reviewed by any 2 IEC members in Full Board /Expedited meeting

1. Name of IEC member: Sign:
2. Name of IEC member: Sign:

Decision

- Noted and the project can be continued without any modifications
- Modifications recommended, requiring protocol resubmission
- Protocol discontinued

State the recommendations:

Member – Secretary Signature with date

Chairperson Signature with date

AX4-V1/SOP 07/V2: Project Report Approval Letter

PI Name:

PI address:

Ref: Project Title

This is with reference to your letter dated _____ regarding the annual status report of the above mentioned project. The Annual Study Status Report was discussed and noted in the IEC meeting held on _____. The IEC has noted the progress report. The following recommendations are suggested (wherever applicable)

Signature with date
Member Secretary
IEC

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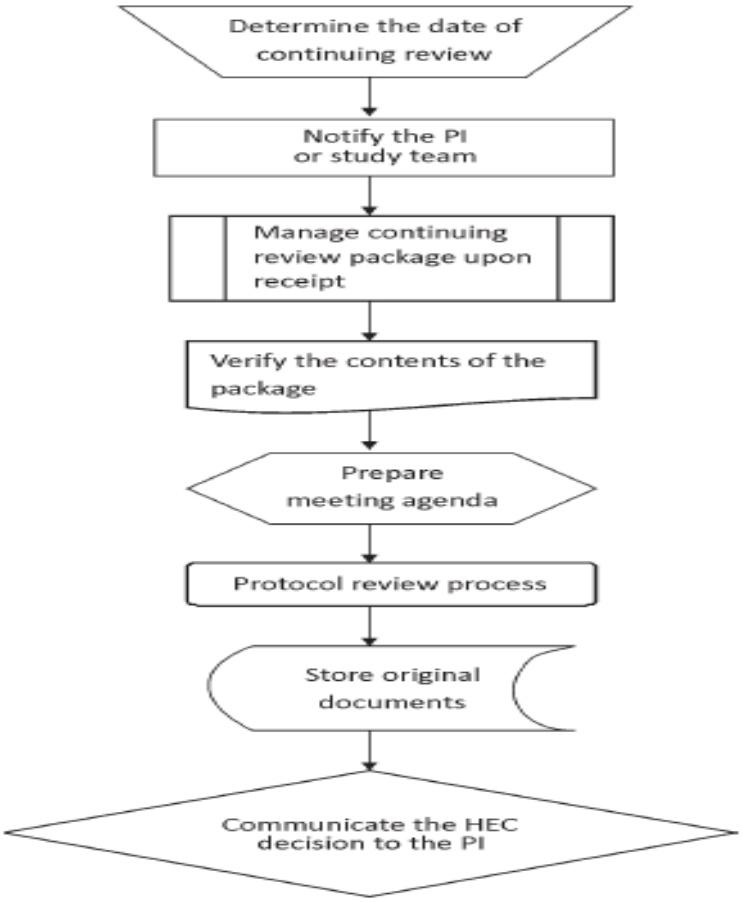

Institutional Ethics Committee
Standard Operating Procedures

(SGMC-IEC: SOP: 08/V2)

Title: Reporting of Protocol Deviation/ Noncompliance/ Violation/ Waiver

SOP Code: SOP 08/V2 Date: 01/04/2013 Pages: 8

8.1 Purpose

To provide instructions for taking action and maintaining records, when investigators/ trial sites, fail to -

- follow the procedures written in the approved protocol
- comply with national / international guidelines for the conduct of human research, including those who fail to respond to the IEC requests

8.2 Scope

This SOP applies to all IEC approved research protocols involving human subjects.

8.3 Responsibility

1. IEC secretariat is responsible for receiving deviations /violations/waiver reports as per (AX1– V1/SOP08/V2) submitted by the PI and placing it on agenda of the meeting. Reporting of deviation/ non-compliance/violation/waiver in any other reporting format will not be accepted.
2. IEC members should review and take action on such reports.

8.4 Detailed instruction

8.4.1 Detection of Protocol deviation/ non-compliance/ violation/waiver

8.4.1. a The IEC members performing monitoring of the project at trial site can detect protocol deviation/non-compliance / violation, if the project is –

- not conducted as per protocol / national / international regulations
- when scrutinizing annual / periodic reports / SAE reports
- any other communication received from the Investigator / trial site / sponsor /study monitor / CRO

8.4.1. b The Secretariat can detect protocol deviation / non-compliance / violation from failure to

- comply with statutory requirements
- respond to requests from IEC within reasonable time limit
- respond to communication made by IEC

8.4.1. c The PI himself / herself may forward protocol deviation / non- compliance /violation /

waiver reports to inform the IEC. Protocol Waiver is analogous to a Protocol Deviation, except that prior IRB approval must be obtained before implementing the necessary departures from the protocol. Therefore, Protocol Waivers are anticipatory, while Protocol Deviations are not.

E.g. Protocol Waiver means a prospective decision by a sponsor or investigator to permit accrual of a subject who does not satisfy the approved inclusion /exclusion criteria for enrollment.

8.4.1. d Communication / complaint / information received from research participant who has been enrolled or any individual who has been approached for enrollment

8.4.1. e Any report / communication brought to the notice of member secretary /Chairperson of IEC

8.4.1.f Communication received from the Director, SGMC informing IEC about an alleged protocol violation / non-compliance / protocol deviation

8.4.2 Noting protocol deviation / non-compliance / violation / waiver by the Secretariat

- The IEC members who have performed monitoring of a particular trial site and detect protocol deviation / non-compliance / violation will inform the Secretariat in writing within 24 hours [one working day].
- Whenever protocol deviation / non-compliance / violation have been observed, the Secretariat will ensure that the issues as well as the details of non-compliance involving research investigators are included in the agenda of the IEC meeting.
  The deviations / violations will be scrutinized for gravity and implications in the formal full board. IEC meeting. The IEC decision will be communicated to PI.

8.4.3 Board discussion, Decision and Action

- If the protocol deviation / non-compliance / violation are detected by IEC member during monitoring visit he/she will present the protocol deviation / noncompliance /violation information.
- If detected by Secretariat / forwarded by PI, the Secretary will present the protocol deviation / non-compliance / violation / waiver information.
- The Chairperson / IEC members will review the information available and take a decision depending on the seriousness of the violation.
- The decision will be taken to ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by consensus and if no consensus is arrived at, voting will be conducted.

The **actions taken by IEC** could include one or more of the following:

- Inform the PI that IEC has noted the violation / noncompliance / deviation and direct the PI to ensure that deviations / noncompliance / violations do not occur in future and follow IEC recommendations.
- Enlist measures that the PI would undertake to ensure that deviations / noncompliance /violations do not occur in future.
- Reprimand the PI
- Call for additional information
- Suspend the study till additional information is made available and is scrutinized

- Suspend the study till recommendations made by the IEC are implemented by the PI and found to be satisfactory by the IEC
- Suspend the study for a fixed duration of time
- Inform the Director, SGMC
- Revoke approval of the current study
- Inform DCGI / Other relevant regulatory authorities
- Keep other research proposals from the PI/ Co-PI under abeyance
- Review and / or inspect other studies undertaken by PI/Co-PI

8.4.4 Notify the investigator

- The IRB secretariat records the IEC decision Drafts and types a notification letter.
- The Chairperson / Secretary signs and dates the letter.
- The IRB Secretariat makes four copies of the notification letter.
- The IRB Secretariat sends the original copy of the notification to the investigator.
- The IRB Secretariat sends a copy of the notification to the relevant national authorities and other trial sites, in case of multi-centric trial.
- The IRB Secretariat sends the fourth copy to the sponsor or the CRO of the study.

8.4.5 Records and follow up to be kept by IRB Secretariat

- Keeps the last copy of the notification letter in the "non-compliance' file.
- Stores the file on the shelf with an appropriate label.
- Follows up the action after a reasonable time.
- Maintains a file that identifies investigators who are found to be non-compliant with national / international regulations or who fail to follow protocol approval stipulations or fail to respond to the IEC request for information/action

Glossary

Deviation / on-compliance / Violation: The IEC monitors whether investigators do not perform the study in compliance with the approved protocol, ICH GCP, FDA regulations and/or fail to respond to the IEC request for information/action.
Waiver: Protocol Waiver is analogous to a Protocol Deviation, except that prior IRB approval must be obtained before implementing the necessary departures from the protocol

AX 1-V1/SOP08/V2: Deviation (D)/Waiver (W)/Violation (V) Reporting Form

Specify if D/W/V
Nature : □ Minor □ Major □ Other (Tick whichever applicable) If other, please specify:
Date of occurrence: dd/mm/yyyy (Not applicable in case of Waiver)
No of similar D/W/V occurred for the same trial:
Patient No.
IRB Project No: Project Title:
Complete Details of D/W/V:
Action taken by PI/Co-PI/Co-I : (Not applicable in case of Waiver)
Impact on trial subject (if any) : (Not applicable in case of Waiver)
Name of PI: Sign of PI: Date :

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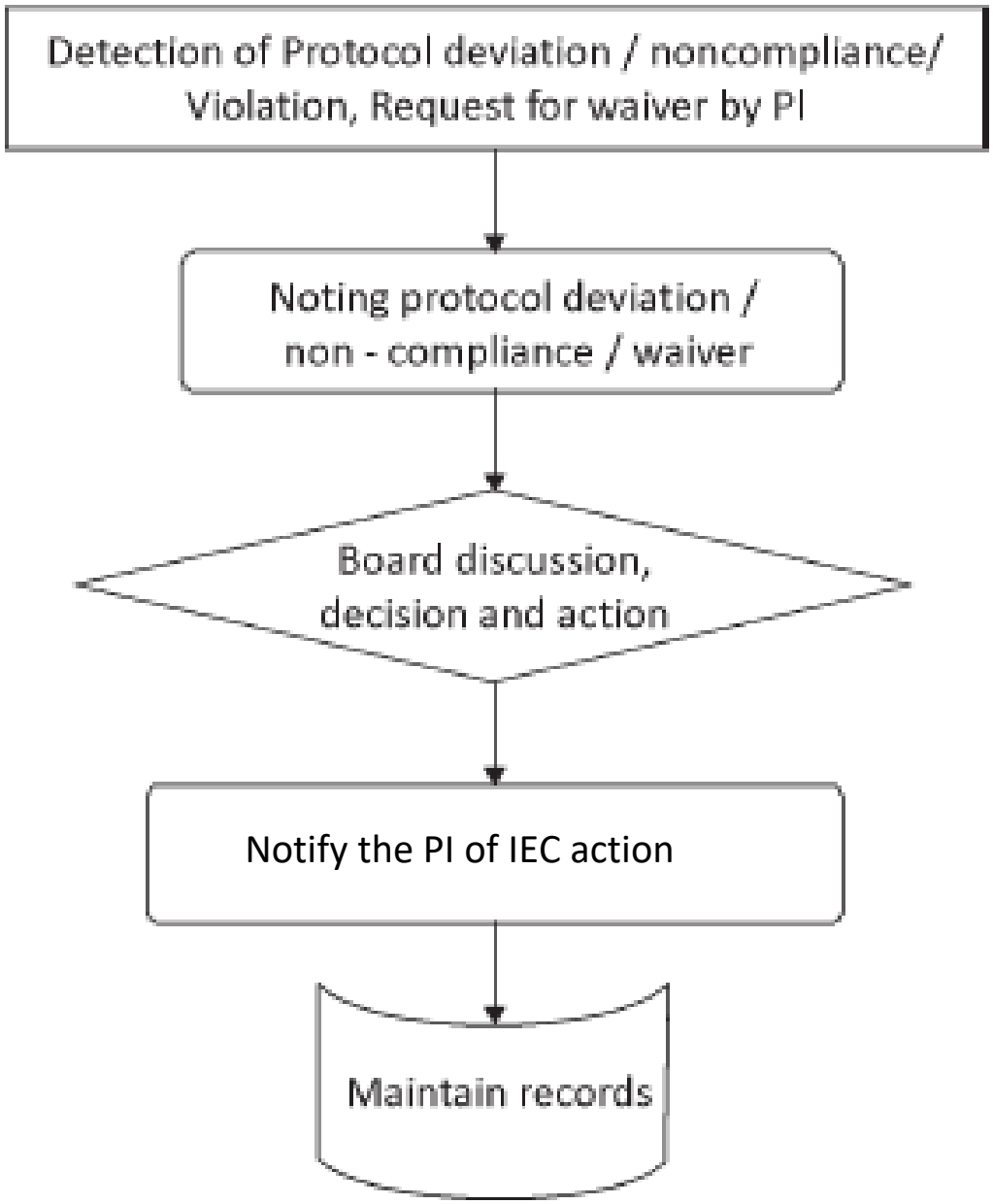

Detection of Protocol deviation / noncompliance/ Violation, Request for waiver by PI
Noting protocol deviation / non - compliance / waiver
Board discussion, decision and action
Notify the PI of IEC action
Maintain records

Institutional Ethics Committee
Standard Operating Procedures

(SGMC-IEC: SOP: 09/V2s)

Title: Review of Serious Adverse Events (SAE) Reports

SOP Code: SOP 09/V2 Date: 01/04/2013 Pages: 14

9.1 Purpose

The purpose of this SOP is to provide instructions on the review and follow-up reports of serious adverse events (SAEs) and unexpected events for any active study approved by the IEC. Unanticipated risks are sometimes discovered during the course of studies. Information that may impact on the risk/benefit ratio should be promptly reported to and reviewed by the IEC to ensure adequate protection of the welfare of the study participants. The unanticipated risks may as well include any event that in the investigator's opinion, may adversely affect the rights, 22222welfare or safety of subjects in the study.

9.2 Scope

This SOP applies to the IEC review of SAE and unexpected events reports, both on site and off site, including follow up reports submitted by investigators. The detailed instructions regarding on site and off site SAE review are described in the following section 9.4

9.3 Responsibility

The primary responsibility of the IEC is to review and address SAE and unexpected events involving risks to research participants. In addition, the committee is authorized to offer mediation under appropriate circumstances.

IEC should also make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements.

The IRB Secretariat is responsible for receiving the complete SAE / unexpected events reports and directing them to DSMSC for detailed review as described in the DSMSC - Policy and Procedures manual (2003). Following the DSMSC meeting, the Secretary, DSMSC will then submit the report to the Member Secretary, IEC. The Member Secretary, IEC will then table the DSMSC minutes in the subsequent IEC meeting.

Notifying the IRB Secretariat, DSMSC, or Secretary, IEC does not relieve the PI from his/her responsibility to notify the sponsor and regulatory authorities.

9.4. Detailed instructions

A. On site SAEs

9.4.1 SAE related activities before IEC meeting

- The IRB Secretariat will verify that the reports are complete, signed and dated by the PI. In case the IRB Secretariat notes that the report is incomplete, it will be forwarded to Member Secretary, IEC for decision and also revert back to PI.
- The IRB secretariat should receive the reports of SAEs occurred for IEC approved studies within 7 days of the occurrence of the SAE.
- If the SAE is 'Death', the IRB Secretariat should receive the SAE reporting form (AX1-V1/SOP 09/V2) within 24 hours of the occurrence.
- If the PI has not adhered to the above stipulated time period, the IRB Secretariat will notify the discrepancies in the reporting time and time of occurrence of SAE to the PI.

9.4.2 Actions to be taken by Member Secretary, IEC

- The Member Secretary will review the SAE Report, write comments and forward it to the Secretary, DSMSC, immediately.
- If the SAE reported is 'death', the Member Secretary, IEC, will review the SAE report and forward it to member Secretary, DSMSC within 1 working day for immediate action. If deemed necessary, Member Secretary of IEC and Member Secretary, DSMSC will review the SAE, death, either in person, by e-mail or telephone and inform the Chairperson, IEC.
- The Member Secretary will table the DSMSC minutes which includes SAE review, at the next scheduled IEC full board meeting.

9.4.3 Actions to be taken by Chairperson

The Chairperson, IEC on basis of the information and comments received from the Member Secretary, IEC and DSMSC, and applying his/ her judgment will direct the IRB Secretariat to any one or more actions listed below, but are not limited to.

- suspending enrolment of new research participants till further review by the IEC
- suspending all trial related procedures (except those intended for safety and wellbeing of the participant) till further review by the IEC
- suspend some trial-related procedures (listed by the secretariat).
- **calling for an emergency review by full board.**

✓ This review should be initiated within 48 working hours (2 working days) of receipt of information.

✓ This review could be done through a meeting, teleconference, email or telephonic conversation.

✓ The IRB Secretariat will take appropriate steps to ensure that IEC members are informed about this full board meeting.

✓ Depending upon the complexity of the issue(s) involved, the chairperson could direct the Member Secretary, IEC, to invite one or more experts whose opinion would be valuable. These experts could participate after they agree to the confidentiality clause and abide by the rules and regulations of IEC.

- soliciting opinion of one or more expert in writing. The information can be provided to expert after he/ she/ they agree(s) to the confidentiality clause and abide by the rules and regulations of IEC. The expert would be requested to provide an opinion in writing within 2-14 working days, depending upon the gravity and seriousness of the matter.

B. Off Site SAEs

- Off Site SAEs where adverse event reports that are serious, unexpected and related (definitely, probably and possibly) to the drug need prompt reporting to the IEC.
- The SAEs that are expected (if listed in the informed consent) or unexpected but unrelated to the drug (classified as per the Offsite Safety Report Classification form– AX2-V1/SOP09/V2) have to be logged (AX3-V1/SOP09/V2) by the PI and to be submitted every 3 months and/or submitted along with continuing review report. The log has to be maintained continuously until the end of the study.
- Those off site SAEs which qualify for prompt reporting, (classified as per the Offsite Safety Report Classification form – AX2-V1/SOP09/V1) will be reported to IRB Secretariat, and forwarded to Member Secretary, IEC and Secretary, DSMSC for further action.
- If the IEC and DSMSC need to review the offsite SAE reports, the committee will request copies of SAE reports at any time, as and when necessary.
- If a trend is observed in SAEs by PI, such a trend will be reported to IRB Secretariat, action on such reports will be taken by the Member Secretary, IEC and Secretary DSMSC, as per 9.3-9.4
- The IRB Secretariat will not accept the complete set of "Off site Safety Reports" and/or the log. However, the IRB will accept the log of (AX3-V1/SOP09/V2) the SAEs every 3 months and/or at the time of continuing review/submission of annual status report.

9.5 During the IEC meeting

On site SAEs

- The Secretary, DSMSC will inform all the IEC members about the SAEs and actions taken. The minutes of DSMSC meeting will be discussed.
- If appropriate, specific action or combination of actions will be taken, based on the consensus decision of the IEC discussion. Some of which are listed below:

✓ Terminate the study;
✓ Suspend the study till review is completed;
✓ Suspend the study till additional information is obtained;
✓ Suspend the study for a fixed duration of time;
✓ Suspend the study till amendments requested for by the IEC are accepted;
✓ Suspend enrolment of new research participants;
✓ Suspend certain activities under the protocol (while going on with activities intended to protect the safety, well-being of participants who have already been enrolled);
✓ Recommend an amendment to the protocol, the ICD, Participant information sheet, investigator brochure and/ or any other document.
✓ Request additional details
✓ Request further follow up information

- ✓ Direct the PI to inform participants already enrolled in the study about the SAE and obtain their consent regarding continuation in the research trial, if necessary.
- ✓ Direct the PI to inform participants already enrolled in the study about the SAE and request them to undertake additional visits, additional procedures, additional investigations, etc. as prescribed in the amendment.
- ✓ Note the SAE report in the IEC records if information submitted is found to be adequate
- ✓ Any other action

Off site SAEs

- The Secretary, DSMSC will inform all the IEC members about those off site SAEs which qualify for prompt reporting, (classified as per the Offsite Safety Report Classification form – AX2-V1/SOP09/V) and were reviewed in DSMSC meeting. The minutes of DSMSC meeting will be discussed.
- If appropriate, specific action or combination of actions will be taken, based on the consensus decision of the IEC discussion. Some of which are listed below:

- ✓ Terminate the study;
- ✓ Suspend the study till review is completed;
- ✓ Suspend the study till additional information is obtained;
- ✓ Suspend the study for a fixed duration of time;
- ✓ Suspend the study till amendments requested for by the IEC are accepted;
- ✓ Suspend enrolment of new research participants;
- ✓ Suspend certain activities under the protocol (while going on with activities intended to protect the safety, well-being of participants who have already been enrolled);
- ✓ Recommend an amendment to the protocol, the ICD, Participant information sheet, investigator brochure and/ or any other document.
- ✓ Request additional details;
- ✓ Request further follow up information;
- ✓ Direct the PI to inform participants already enrolled in the study about the SAE and obtain their consent regarding continuation in the research trial, if necessary.
- ✓ Direct the PI to inform participants already enrolled in the study about the SAE and request them to undertake additional visits, additional procedures, additional investigations, etc. as prescribed in the amendment.
- ✓ Any other action

9.6 After the review of SAE

- The IRB secretariat will send a formal letter to the investigator/s with instructions for specific actions as per the IEC decision.
- The IEC will instruct the PI to forward follow-up reports of the SAE to the IRB.
- The IEC will instruct the PI regarding compliance to actions recommended by the IEC within 14 days of receipt of the IEC letter.
- In case a PI fails to respond to the IEC letter, the matter will be discussed at the next full board meeting and a decision will be taken for specific action by simple majority.
- The Member Secretary / Chairperson will sign and date the letter.
- The IRB Secretariat will send the letter and file a copy of the letter in the master file of the research protocol.

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 unfavorable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.

Adverse Drug Reaction: In the pre-clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not established all noxious or unintended responses to the product related to any dose should be considered adverse drug reactions. The phrase "responses to a medicinal product" means that a causal relationship between the product and the adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out. Regarding marketed products, a response to a product which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function.

IND: Investigational New Drugs means substances with potential therapeutic actions during the process of scientific studies in human in order to verify their potential effects and safety for human use and to get approval for marketing.

AX1-V1/SOP09/V2: Serious Adverse Event Review Report for SAE

As per ICH-GCP:
Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR)
Any untoward medical occurrence (due to the participation in the concerned trial) that at any dose:

- results in death,
- is life-threatening,
- requires inpatient hospitalization or prolongation of existing hospitalization,
- results in persistent or significant disability / incapacity,

Or

- is a congenital anomaly/birth defect

Investigator(s) shall report all SAE (as above) to the Sponsor within 24 hours and to the Ethics Committee that accorded approval to the study protocol within 7 working days of their occurrence and within 24 hours in the event of death.

Does the Principal Investigator feel this SAE is related to participation in the trial? ☐ Yes ☐ No ☐ Possibly
Does the protocol have an inbuilt data monitoring plan? ☐ Yes ☐ No

1. Title of project and Project No:		
2. Principal Investigator:		
3. Report date		
Report type ☐ initial ☐ follow up		
4. Patient case no:	5 a. Age	5 b. Gender
6. Mention the total number of SAE (prior) occurred at our site_____ other site(s)_____		
7. Mention number of similar SAEs (prior) occurred for same study at our site_____ other site(s)_____		

Suspect drug /device/intervention information

8. Suspect drug (include generic name)/device/intervention	
9. Dose:	10. Route(s) of administration:
11. Therapy dates (from/ to)	12. Therapy duration:
13. Did the reaction decline after stopping the drug/procedure □ YES □ NO □ NA	
Concomitant drugs and history	
14. Concomitant drug(s) and date of administration	
15. Patient relevant history (e.g. diagnosis, allergies)	
Reaction information	
16. Description of adverse event (indicate if this is follow-up report and if so, include follow-up information only) Underline the adverse event	
17.Tick whichever is applicable for specific adverse event	
A] □ expected event □ unexpected event (this refers to trial being conducted and not disease process)	
B] □ hospitalization □ increased hospital stay □ death □ others (If others, please specify)	
C] □ No permanent significant functional/ cosmetic impairment □ Permanent significant functional/ cosmetic impairment □ Not applicable 18. Describe the medical treatment provided(if any) to the research subject:	
19. Outcome was □ resolved □ ongoing □ death	
20. Was the research subject continued on the research protocol □ Yes □ No	

21. In your opinion, does this report require any alteration in trial protocol?

□ Yes □ No

if yes then please specify.

Signature of Principal Investigator _____ date: _____

Upon receipt of this report , the IEC/DSMSC will decide whether additional information is needed or whether further investigation of the incident is required

For IEC use only

I _____ agree _____ disagree with the assessment of the Principal Investigator.

DSMSC Reviewer _____ date: _____

Explanation:

AX2-V1/SOP09/V2: Offsite Safety Reports Classification Form

NOTE to PI:

The following questions will act as a guide for submission of the "Safety Reports". This form is merely providing guidance for reporting / logging of Offsite Safety Reports.

If the answer to all three questions is **"Yes", prompt reporting is required and such off site Safety Reports need to be reported to IEC along with the log.**

If any one answer is "No", it needs to be logged as prescribed format. (AX3-V1/SOP 09/V2).
This log should be submitted to the IRB Secretariat every 3 months and/or along with Continuing
Review report.

Project No.

Project Title:

Questions	Yes	No
Is adverse event serious?		
Is adverse event related?		
Is adverse event unexpected?		

Date of reporting

Signature of PI

Name of PI

AX3-V1/SOP09/V2: Off Site Safety Reports Log

NOTE to PI:

1. Please log in details of Off Site Safety Report.
2. The following log has to be maintained continuously until the end of the study.
3. This log should be submitted to the IRB Secretariat every 3 months and/or along with Continuing Review report.
4. The log must be submitted to the IRB Secretariat immediately, if prompt reporting is required and/or if a trend related to the occurrence of SAE is observed.
5. Please note the complete set of Offsite Safety Reports need not be sent to IRB Secretariat as and when received. If the IRB needs to review the reports, they can request copies at any time.

Project No.:

Project Title:

No. of Participants already enrolled in SGMC:

S. No.	Country	Date of Onset	Adverse event	Out Come	Remarks

Name and Signature of PI: Date:

AX4-V1/SOP09/V2: Reporting of SAEs

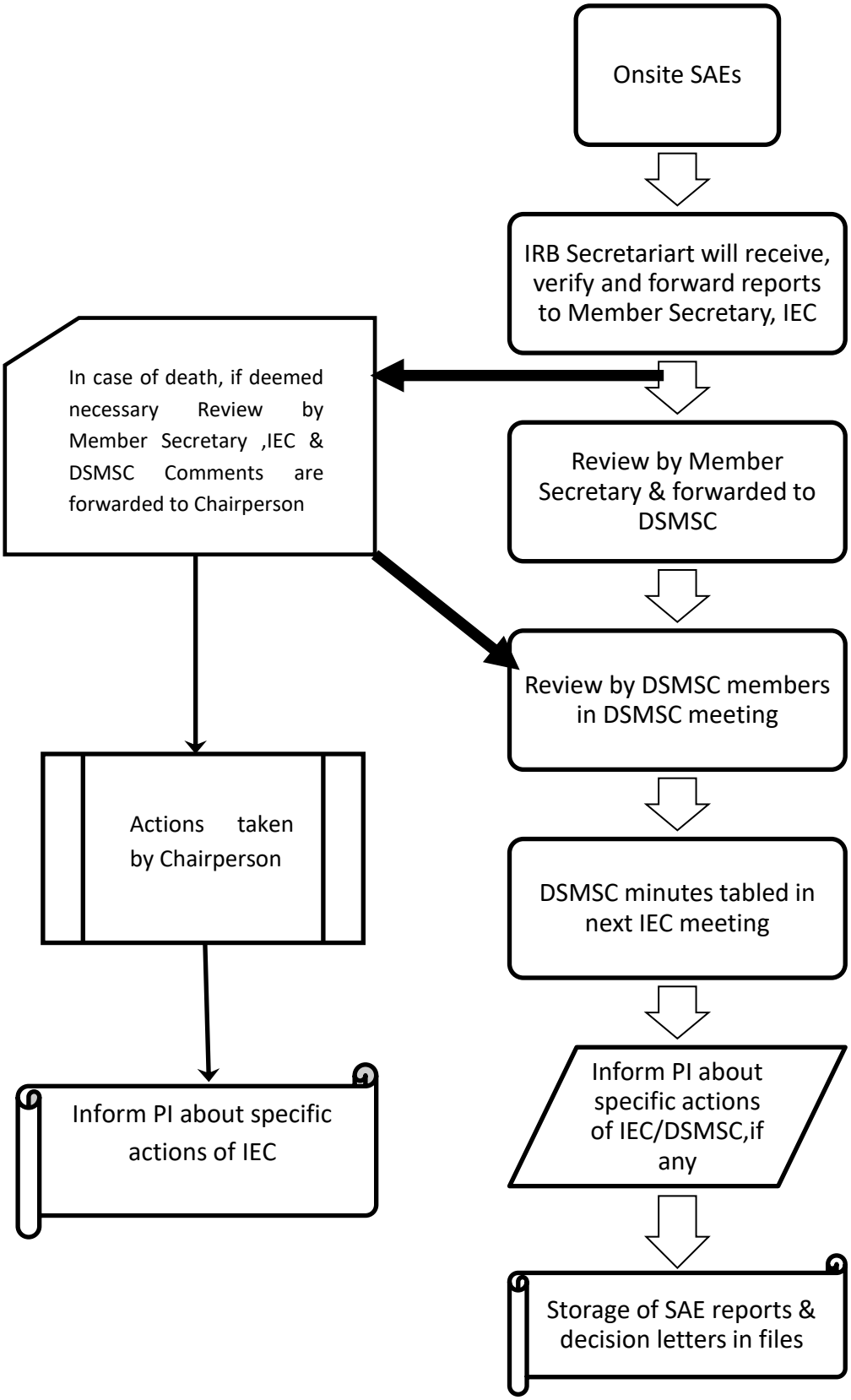
1. IEC shall regularly review the trials through the progress reports submitted by the PI and periodically conducted site visits, especially to ascertain the protocol compliance.

2. PI is responsible for notifying the DCGI about the SAEs within 24 hours of their occurrence and the report shall also be forwarded to IEC. A completed report after analysis is submitted to the Chairman of IEC within 10 days in addition to sending the report to Expert Committee, DCGI and to Head of the Institution in case of Death.

3. In case a PI of a clinical trial receives queries regarding SAEs (trial-related death or injuries), a Compensation Committee is constituted that includes IEC members, clinicians, clinical pharmacologist, legal and financial experts, to discuss the recommended compensation. The committee shall convene a meeting in the presence of PI along with reports of SAEs and participants' case reports. The committee shall examine the reports to ascertain causality and send its report and recommendations regarding compensation to Expert Committee and/or DCGI within 21 days of the reported SAEs.

4. IEC shall facilitate inspection of the trial site by DCGI officials in case of SAEs and other necessary actions as per the guidelines.

FLOWCHART



Edited by: Prof.Dr.Regi Jose,Member Secretary SGMC IEC

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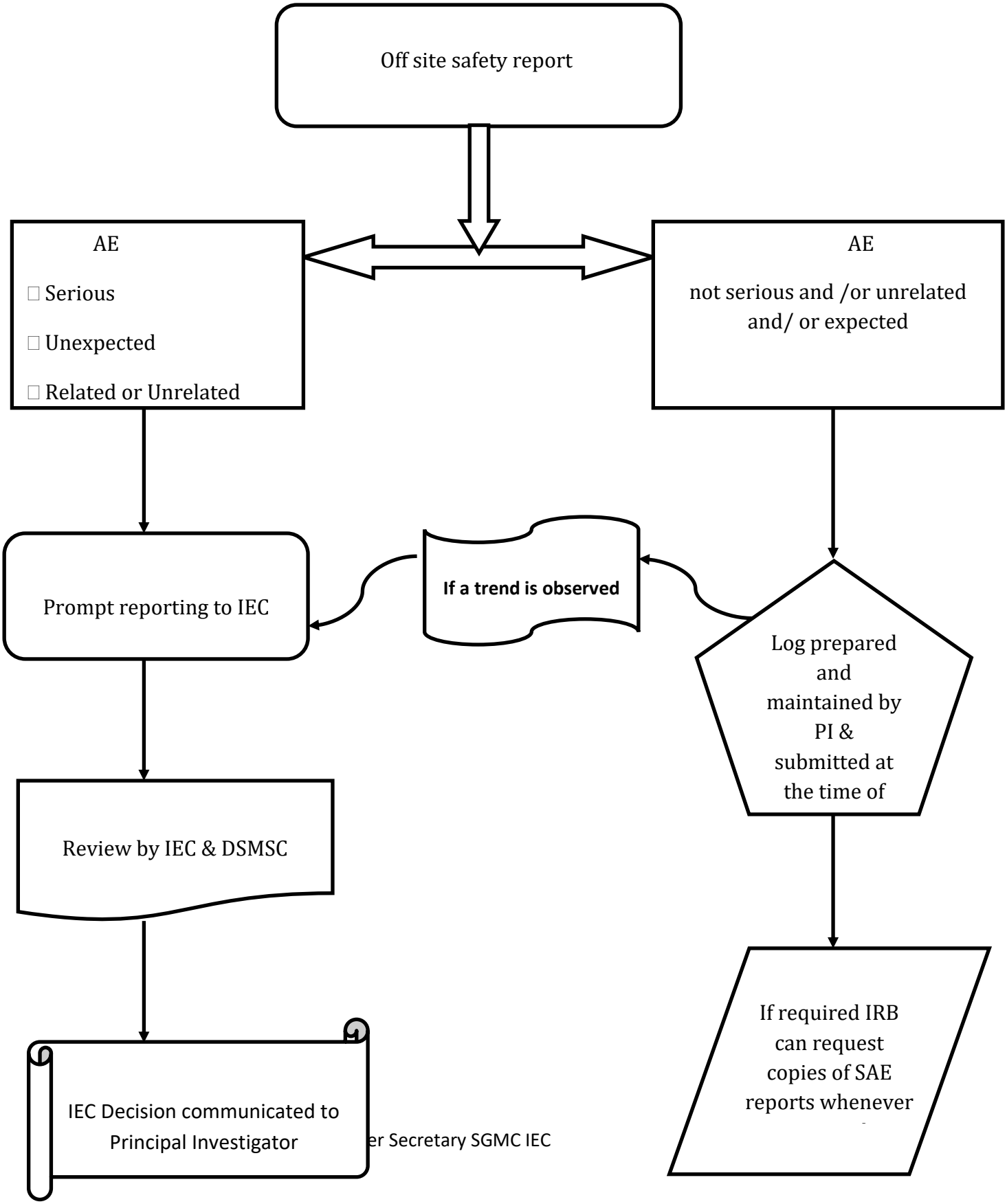

er Secretary SGMC IEC

Institutional Ethics Committee
Standard Operating Procedures

(SGMC-IEC: SOP: 10/V3)

Title: Maintenance of Active Project Files, Archival of Closed Files and Retrieval of Documents

SOP Code: SOP 10/V2 Date: 01/04/2013
SOP Code: SOP 10/V3 Date:28/12/2017

10.1 Purpose

To provide instructions for preparation and maintenance of active study files and other related documents approved by the IEC, SGMC, and storing of closed files and retrieval of documents.

10.2 Scope

This SOP applies to all protocol/study files and their related documents that are maintained in the
IRB office and closed files.

10.3 Responsibility

It is the responsibility of IRB staff to ensure that all study files are prepared, maintained, and kept securely for a period of three years after the closure of the project (under a proper system that ensures confidentiality and facilitates retrieval at any time).

10.4 Maintain the active study files

- Master file is the file comprising of all essential documents and correspondence related to the study/protocol. Trial master files should be established at the beginning of the trial, in the IRB secretariat.
- The approved study files are assigned unique identifiers (serial project no.).
- Gather, classify and combine all related documents together of the approved study files appropriately.
- Keep all active files in a secured file cabinet with controlled access. A log book of authorized individuals accessing the files will be maintained.
- Maintain the study files in an easily accessible and secure place for at least **five years** after the study closure.
- All closed study files will be separately archived.
- Final disposal of study/master files on completion of archival period.

10.5 Disposal of closed files and copies of protocols and documents submitted for IEC review.

The trial master file will be maintained in the IRB office for a period of three years following closure of the study. After completion of archival period the closed files will be shredded and disposed off. However, all the copies of research projects and documents submitted for IEC review will be shredded off by the authorized IRB personnel after the IEC meeting without any notification to PI. A log book of disposed documents will be maintained.

10.6 Accessibility / Retrieval

Master files will be made available for inspection and copying by authorized representatives of regulatory authorities after receiving the request in writing.
In case, any investigator needs a copy of any document from the master file, he/she should make a written request. (AX1 –V1/SOP10/V2). The IRB staff will furnish a copy of the required document within a week with IEC Secretary's consent. The IRB will issue a copy of the following documents on formal written request:

10.7 Final Disposal of Master files

The master files will be disposed off after archival period of 3 years. A formal written off register (AX2- V1/SOP 10/V2) will be maintained, providing details of documents being written off /disposed off.

Glossary

Active Study File: Any approved protocol, supporting documents, records containing communications and reports that correspond to each currently approved study
Closed Study File: The study which is completed or terminated or discontinued or suspended or not initiated is considered to be closed.

AX1–V1/SOP10/V2: Document Request Form

Project No.:	Project Title :
Name of PI:	Requested by:
Documents requested:	
Purpose of the request:	
Principal Investigator's Signature:	
Signature of the requesting person:	
Permission of Secretariat YES/NO Member Secretary , IEC	

AX2 –V1/SOP10/V2: Format of written off register

Project No	Title	PI	No of files	Ec Approval	Study initiation date	Study closure date	Name & Sign of authorized individual

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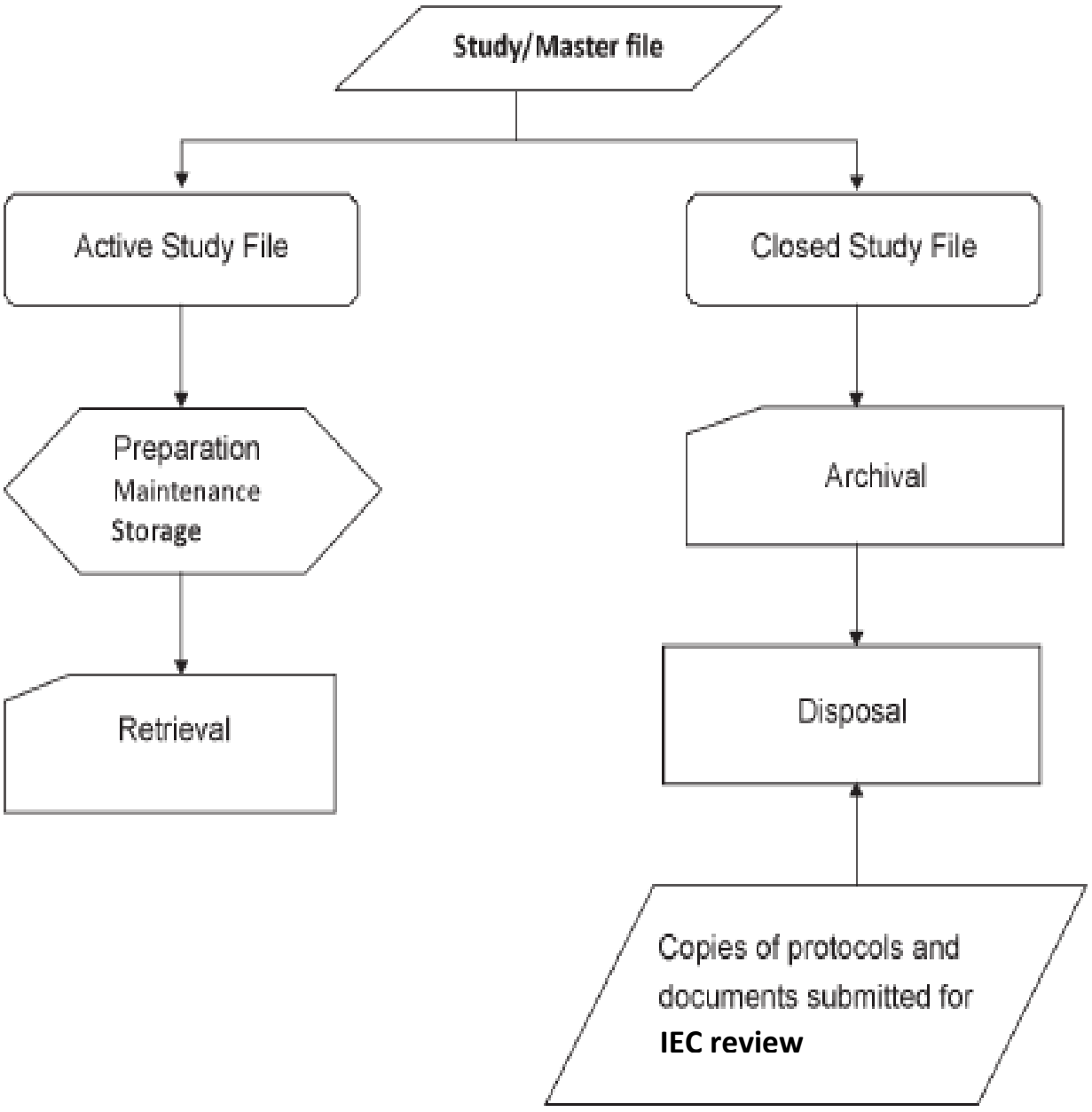
Study/Master file
Active Study File
Closed Study File
Preparation
Maintenance
Storage
Archival
Retrieval
Disposal
Copies of protocols and documents submitted for **IEC review**

Institutional Ethics Committee
Standard Operating Procedures

(SGMC-IEC: SOP: 11/V2)

Title: Documentation of the IEC activities

SOP Code: SOP 11/V2 Date: 01/09/2009 Pages: 4

11.1 Purpose

To describe the procedures for documenting the IEC activities.

11.2 Scope

This SOP will apply to all research activity involving human subjects, without regard to the source type of funding.

11.3 Responsibility

It is the responsibility of IRB staff to maintain IEC files at IRB office.

11.4 Detailed Instructions

11.4.1 IEC records will include the following

1. IEC members' records
a. Acceptance letters of each member
b. signed and dated recent Curriculum vitae and confidentiality agreement letters of each member
c. Training records for each IEC member
d. Documentation of resignation/termination
2. IEC membership roster
3. IEC attendance roster
4. IEC meeting agenda and minutes
5. Standard Operating Procedures
6. Annual reports

11.4.2 Access to IEC records

IEC records will be made available for inspection by authorized representatives of regulatory authorities after receiving the request in writing.

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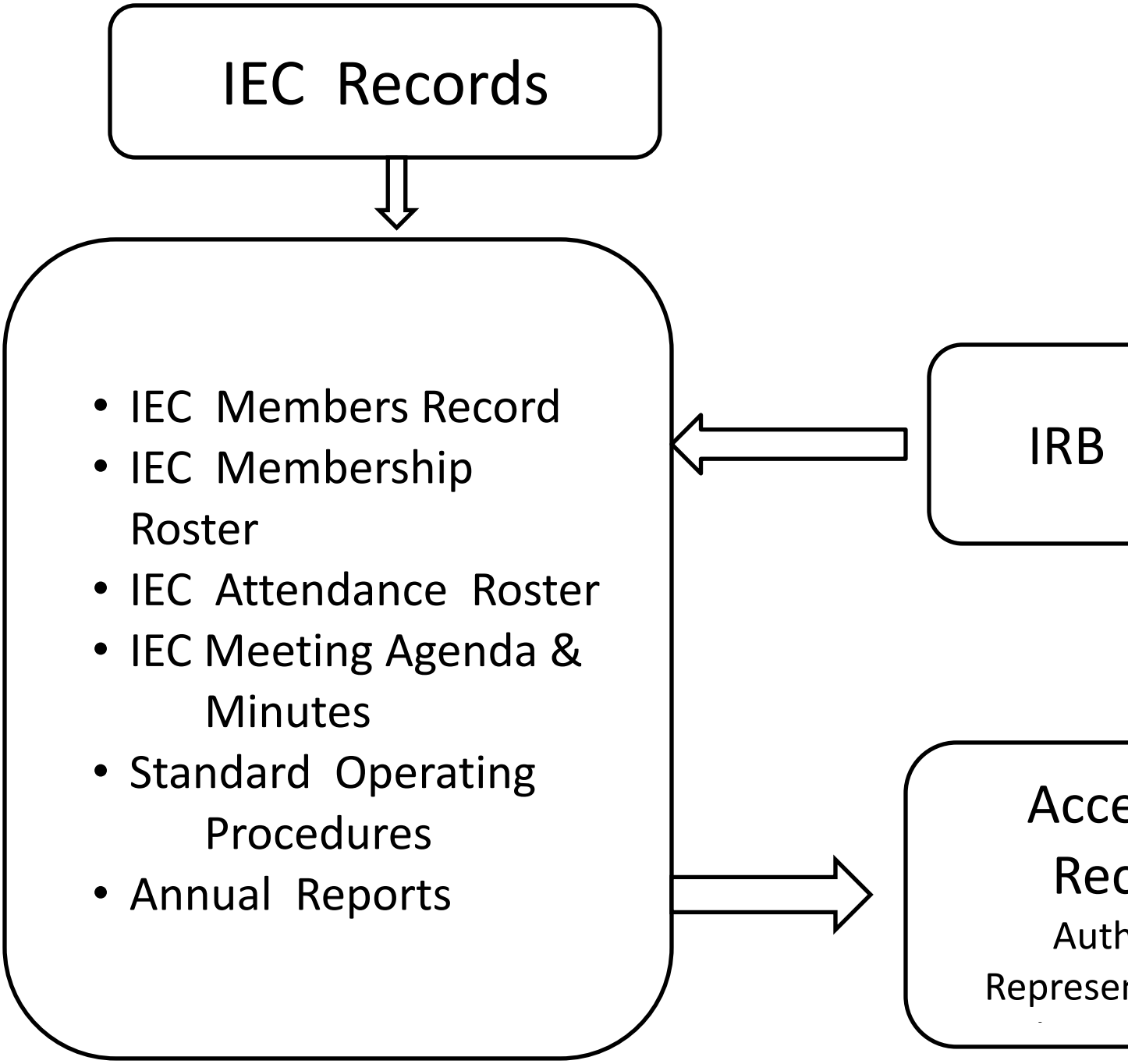

IEC Records
IEC Members Record
IEC Membership Roster
IEC Attendance Roster
IEC Meeting Agenda & Minutes
Standard Operating Procedures
Annual Reports
IRB
Acce
Rec
Auth
Represer

Institutional Ethics Committee
Standard Operating Procedures

(SGMC-IEC: SOP: 12/V2)

Title: Review of study completion reports

SOP Code: SOP 12/V2 Date: 01/09/2009 Pages:

12.1 Purpose

The purpose of this SOP is to provide instructions on the review of Study Completion Report for every study previously approved by the IEC.

12.2 Scope

This SOP applies to the review of the Study Completion Report which is an obligatory review of each investigator's activities presented to the IEC as a written report of study completed. Although IEC provides a Study Completion Report Form (AX1-V1/SOP12/V2) to the investigator, any mechanism (letter format, form provided by the Sponsor, etc.) may be used, provided that the information submitted is sufficient.

12.3 Responsibility

It is the responsibility of the IEC members to review the study completion report and notify it or request for further information, if necessary.

12.4 Detailed instructions

12.4.1 Before each board meeting

- The secretariat will receive 15 copies / as per strength of IEC membership, of Study Completion Reports from the PI.
- The Secretariat will follow instructions as in SOP 03/V2 (Management of Protocol Submission) for receiving and checking the report packages.
- It is the responsibility of the IRB Secretariat to review the report for completeness before submission for the Board meeting.
- The IRB Secretariat should keep the study completion reports on the agenda for IEC meeting. (Procedures for Agenda preparation, Meeting procedures and recording of Minutes- SOP 05/V2)

12.4.2 Before and during board meeting

- IEC member(s) should review a copy of the Final Report.
- The members will discuss the report in the IEC meeting.
- If appropriate to the discussions, the Chairperson may call for consensus to accept it or request further information or take any other action as suggested by IEC.

12.4.3 After the board meeting

- The Secretariat will note the decision in the meeting minutes and the study will be considered as closed if the document is accepted.
- The IEC decision is communicated to the investigator. In case further information /action is requested, the same should be followed by the PI and communicated to the IRB office within 30 days. This update will be tabled in the full board meeting of IEC.
- The Secretariat will accept and file the Final Report in the project master file.
- The IRB secretariat will archive the entire study protocol and the report for a period of 3 years from the date of completion of the project, if the report is accepted.

Institutional Ethics Committee
Standard Operating Procedures

(SGMC-IEC: SOP: 13/V2)

Title: Management of Premature Termination / Suspension /Discontinuation of the Study

SOP Code: SOP 13/V2 Date: 01/04/2013 Pages: 6

13.1 Purpose

The purpose of this SOP is to describe how the IEC proceeds and manages the premature termination / suspension / discontinuation of a research study. Protocols are usually terminated at the recommendation of the IEC, DSMSC, PI, sponsor or other authorized bodies wherein subject enrollment and subject follow-up are discontinued before the scheduled end of the study.

13.2 Scope

This SOP applies to any study approved by IEC that is being recommended for termination/ suspension/discontinuation before its scheduled completion.

13.3 Responsibility

It is the responsibility of the Chairperson, IEC to terminate any study that the IEC has previously approved when the safety or benefit of the study participants is doubtful or at risk. The Secretariat is responsible for management of the premature termination / suspension /discontinuation process.

13.4 Detailed instructions

13.4.1 Receive recommendation for study Termination / Suspension / Discontinuation

_ The Secretariat will receive recommendation and comments from DSMSC, PI, Sponsor or other authorized bodies for premature termination of study protocol.
_ The IEC members /Chairperson can prematurely terminate the study if protocol non-compliance /violation is detected and IEC decision is to terminate the study.
_ SAE occurring at trial site may require the study to be prematurely terminated for the safety of the patients.
_ The Secretariat will inform the PI to prepare and submit a protocol termination package along with Premature Termination Report (available at IRB office)
_ The Secretariat will receive the study protocol termination package prepared and submitted by the PI and verify the contents of the package for inclusion of:
o Premature Termination Report (AX1- V1/SOP13/V2) signed and dated by the PI

should contain a brief written summary of the protocol, its results, and accrual data.
o The Secretariat will check the completeness of the information, including accrual data since the time of the last continuing review.
o The Secretariat will initial and date the package upon receipt.

13.4.2 Review and discuss the Termination / Suspension / Discontinuation Package

- IEC will review the termination package at regular full board meeting to discuss about the recommendation.
- The Secretary in the meeting will inform of the premature termination of the project and the IEC members will review the Premature Termination Report (AX1- V1/SOP13/V2)
- If the Premature Termination Report is unclear/more information is required from the PI, the Secretariat is instructed to send a query to the PI.

13.4.3 Notify the PI

- The Secretariat will make notification letter acknowledging the approval of termination or query letter to request information regarding the premature termination.
- The Secretariat will send the notification letter to the PI for their records within 14 days after the meeting.

13.4.4 Store the protocol documents

- The Secretariat will keep the original version of the Premature Termination Report in the Protocol file and send the file to archive.
- The protocol documents will be stored for a period of 3 years from the date of project Termination.
- If a query is sent to PI, on receipt of the reply letter, it is reviewed in the forthcoming full board meeting and steps in 13.4.2 will be performed by the Secretariat.

References

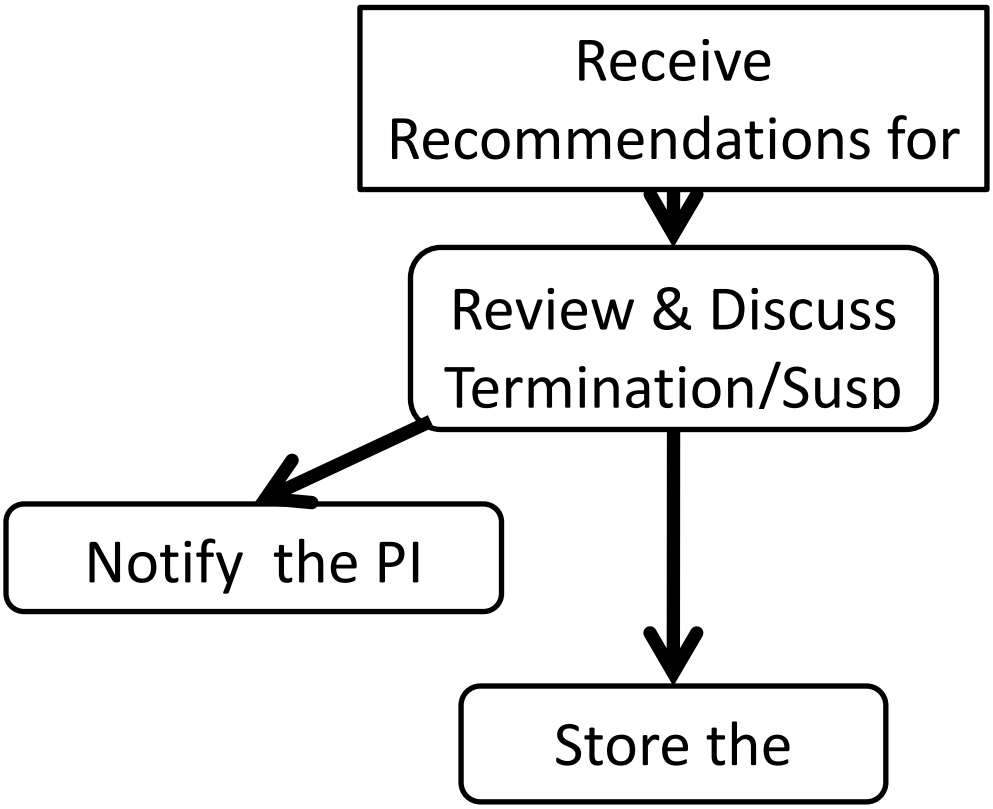
1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000) - www.who.int/tdr/publications/publications/ (accessed 24 March 2008).
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996 - http://www.ich.org/LOB/media/MEDIA482.pdf (accessed 24 March 2008)

AX1- V1/SOP13/V2: Premature Termination/ Suspension/ Discontinuation Report

SGMC Project No.:	
Protocol Title:	
PI:	
Phone :	E-Mail:
Trial Site:	
Sponsor:	
IEC Approval Date:	Date of Last Progress Report Submitted to IEC:

Starting Date:	Termination Date:
No. of Participants Enrolled:	No. of Participants Completed:
No. of Ongoing Participants:	No. of Drop Outs:
SAE (Total No.):	SAE Event:
Summary of Results:	
Reason for Termination/Suspension/Discontinuation:	
PI Signature:	Date:

Flow Chart


Receive
Recommendations for
Review & Discuss
Termination/Susp
Notify the PI
Store the

Institutional Ethics Committee
Standard Operating Procedures

(SGMC-IEC: SOP: 14/V2)

Title: Request for Waiver of Written Informed Consent

SOP Code: SOP 14/V2 Date: 01/04/2013 Pages:

14.1 Purpose

The purpose of this SOP is to describe the type of research projects for which the IEC may grant waiver for requirement of obtaining written informed consent and the format of the application form to be used by the investigators for requesting waiver of consent. The Application Form AX1-V1/SOP 14/V2 is designed to standardize the process of applying for consent waiver.

14.2 Scope

This SOP applies to the all protocols with a request of granting consent waiver submitted for review by the IEC. The decision should be taken by the IEC members at the expedited subcommittee meeting or in some cases during full board meeting.

14.3 Responsibility

It is the responsibility of the Member Secretary to table the request in the expedited subcommittee meeting or in some cases, during full board meeting.

14.4 Detailed instructions

_ When a request for waiver of consent is submitted by the PI along with the study documents to the IEC secretariat, in the given format AX1-V1/SOP 14/V2 stating the reasons for the consent waiver; the following steps are taken:

_ The IEC Secretariat will check if the concerned documents are filled completely and the required list of documents is enclosed.

_ The IEC members will review the request taking into consideration the types of studies for which waiver of consent may be granted.

_ The IEC will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining confidentiality of the study data. This is necessary as the participant cannot be assured directly about confidentiality of health data through a formal informed consent process, when consent waiver is granted.

_ The decision whether to grant the waiver is taken in expedited subcommittee meeting or in some cases during full board meeting.

_ The decision regarding approval/disapproval of waiver is informed to the PI in writing. If the waiver is not granted, the IEC will provide reasons for the same.

14.5 Type of research projects which may qualify for consent waiver:

A request to waive written informed consent must be accompanied by a detailed explanation. The investigator is also required to provide assurance regarding protection of identity of research participants and maintenance of confidentiality about the data of the research participants. The following criteria (ICMR 2006 guidelines) must be met for a research project so that it can qualify for granting a waiver of both written and verbal consent.

1) The proposed research presents no more than minimal risk to subjects. (ICMR guidelines, 45CFR 46) e.g. a retrospective review of patient case records to determine the incidence of disease/ recurrence of disease. [Minimal risk would be defined as that which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of 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 undergoing these interventions since it would be undertaken as part of current everyday life].

2) When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout research as may be required by the sensitivity of the research objective. (ICMR 2006 guidelines)
   E.g. *conducting interviews with citizens about their religious beliefs/ people with HIV and AIDS / conducting phone interviews with homosexuals.*
   The only record linking the participant and the research would be the consent document and when there is a possible legal, social or economic risk to the participant entailed in signing the consent form as they might be identified as such by signing the consent form, the requirement for obtaining consent can be waived of by the IEC.

   [In case of telephonic interviews, waiver of written informed consent may be requested but this does not mean that verbal consent cannot be utilized].

   a) The following points need to be considered.
      The following documents need to be submitted for the IEC review
      - A script for verbal consent - a verbal consent script provides all of the elements of consent in a more informal style. In addition, each subject should be provided with an information sheet that describes the study and gives contact names and numbers.
      - The interview schedule (questions to be asked???) will confirm that the interview is a simple 5 minute call and that no questions are asked that compromise a person's confidentiality or position.

   b) Normally, investigators will be asked to keep a log of those who were approached about the study, and offered verbal consent. A simple chart can indicate the subjects as participant 1, participant 2, and participant 3. A column can indicate that verbal consent was given and a date. Since a specific number of study participants are to be recruited. It is important that investigators keep some record to indicate that they are not enrolling more subjects than they originally requested.

3) Research on publicly available information, documents, records, work performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies. (ICMR 2006 guidelines)

4) Research on anonymised biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognized institutions or qualified investigators, samples or data from repositories or registries etc. (ICMR 2006 guidelines)

5) In emergency situations when no surrogate consents can be taken. (ICMR 2006 guidelines) when consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible, the IEC can allow waiver of consent for recruiting participant in a research study. However, information about the intervention should be given to the patients whenever he/she gains consciousness or to relative/ legal guardian when available later.

AX1-V1/SOP 14/V2: Application form for requesting waiver of consent

1. Principal Investigator's name: _____

2. Department: _____

3. Title

_____

_____

4. Names of other participating staff and students:

_____

_____

_____

_____

5. Request for waiver of informed consent:

- Please check the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by IEC consider waiver of consent).

    1. Research involves 'not more than minimal risk'
    2. There is no direct contact between the researcher and participant
    3. Emergency situations as described in ICMR Guidelines (ICMR 2006 Guidelines- http://www.icmr.nic.in/ethical_guidelines.pdf)
    4. Any other (please specify)

- Statement assuring that the rights of the participants are not violated

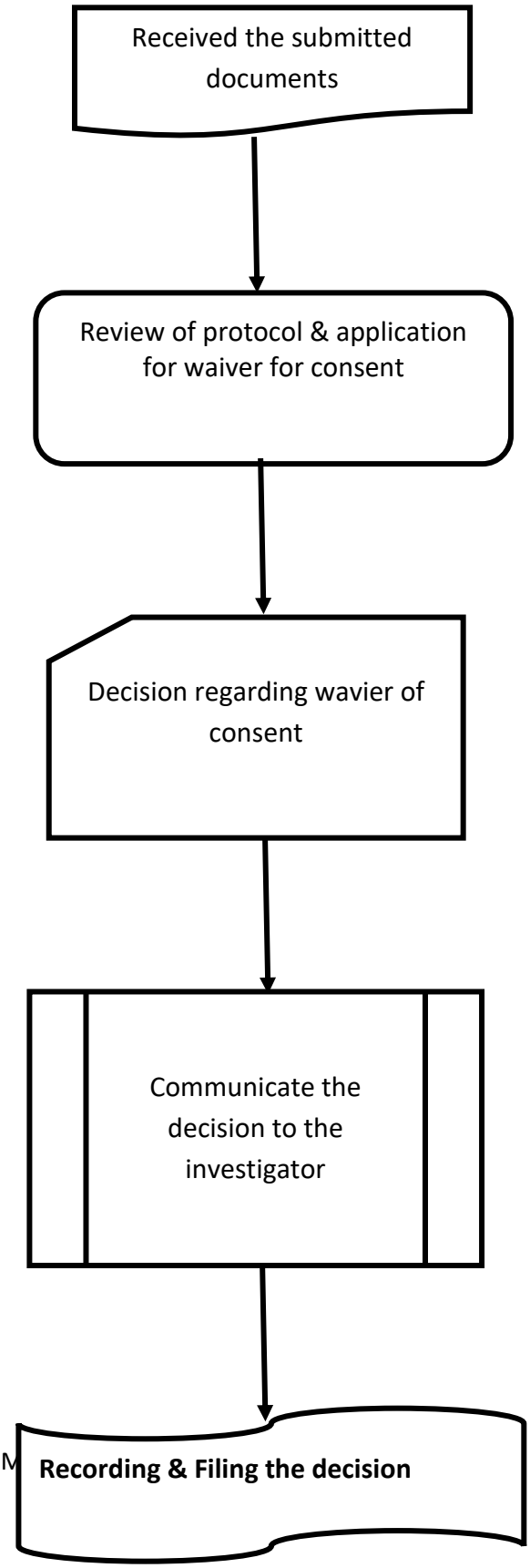
    _____

- State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant

    _____

Principal Investigator's signature with date: _____

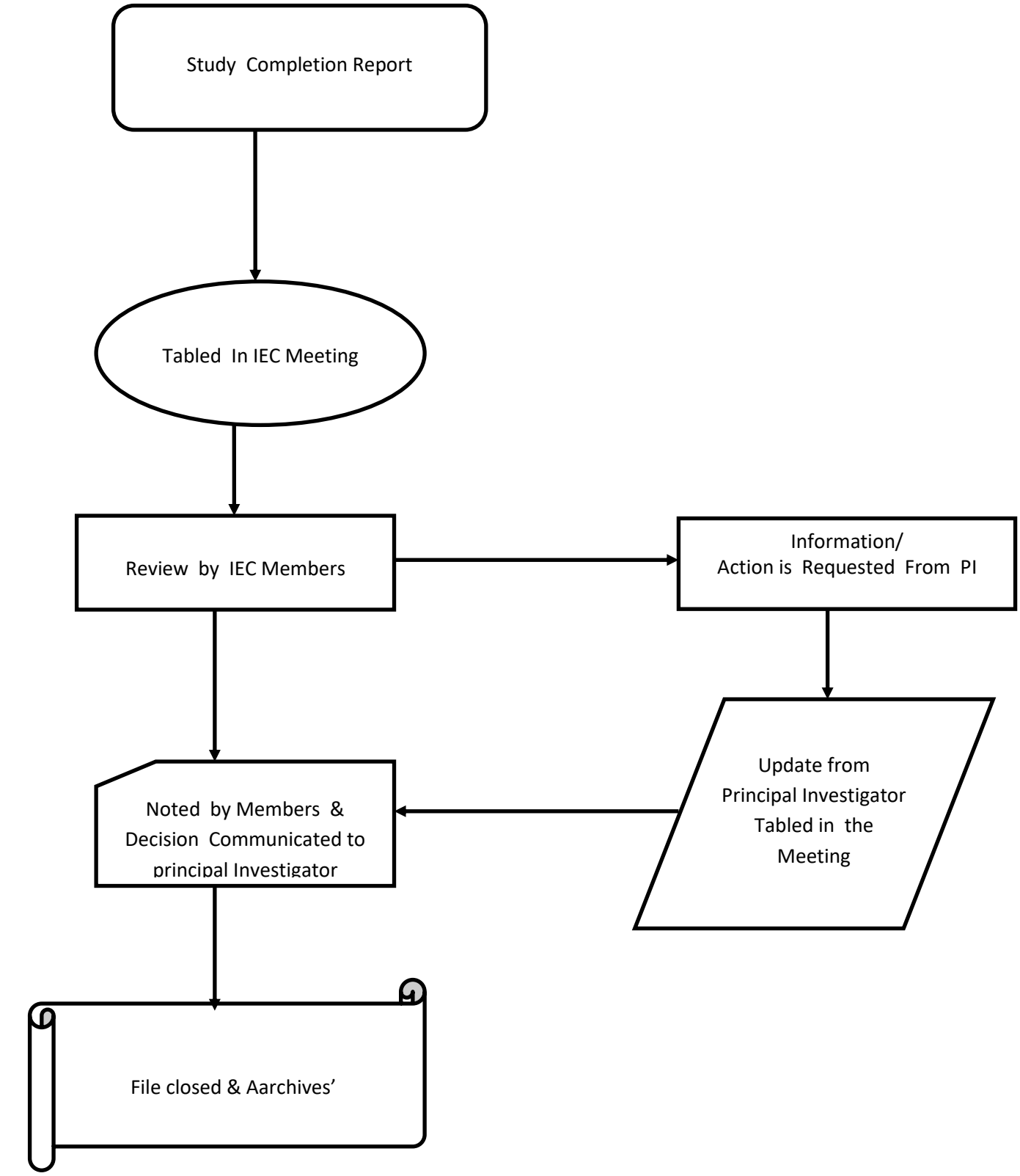
FLOWCHART


Received the submitted documents
Review of protocol & application for waiver for consent
Decision regarding wavier of consent
Communicate the decision to the investigator
Recording & Filing the decision

AX1-V1/SOP 12/V2: Study Completion Report Form

(To be Filled by PI)	
SGMC Project No. Protocol Title: Principal Investigator:	
Phone number, email address	
Sponsor	
Address	
Phone, E mail	
Total no. of study participants recruited	
Study Initiation Date	
Total no. of study participants approved by the IEC for recruitment	
No. of study arms	
Duration of the study	
Objectives	
Results (brief) (use extra blank sheets, if more space is required)	
SAEs at our center (Total number and type)	
Whether all SAEs intimated to the IEC (Yes/No)	
No. of patients withdrawn	
Reasons for withdrawal	
Protocol deviations/violations (Number and nature)	
Conclusion	
Signature of PI Date:	

FLOW CHART



Edited by: Prof.Dr.Regi Jose,Member Secretary SGMC IEC

Institutional Ethics Committee
Standard Operating Procedures

(SGMC-IEC: SOP: 15/V2)

Title: Site Monitoring

SOP Code: SOP 15/V1 Date: 01/04/2013 Pages: 8

15.1 Purpose

The purpose of this SOP is to provide the procedures to select a site for monitoring and how the site will be monitored.

15.2 Scope

This SOP applies to any visit and /or monitoring of any study sites of IEC approved study protocols.

15.3 Responsibility

It is the responsibility of the IEC members to perform or designate some qualified agents to perform on its behalf on-site inspection of selected study sites of relevant projects it has approved. The IEC members or Secretariat in consultation with the Chairperson may initiate an on-site evaluation of a study site for cause or for a routine audit.

15.4 Detailed instructions

15.4.1 Selection of study sites

- Sites will be identified for routine monitoring at the time of approval of the project by the Full Board which will be recorded in the minutes.
- "For cause" monitoring will be performed at sites for reasons identified by any member of IEC, approved by Chairperson. For cause monitoring could be initiated, in any of the following conditions: for high number of protocol violations, large number of studies carried out at the study sites, remarkable SAE reports, high recruitment rate, Non-compliance or suspicious conduct and any other cause as decided by IEC.

15.4.2 Before the visit

- If the site was identified for routine monitoring, the Secretariat will inform the IEC members in the Full Board meeting, 1 month prior to the stipulated date of monitoring.
- For cause / routine monitoring of the project, the IEC Chairperson will designate an IEC member or appoint an independent monitor to perform the task of monitoring.
- The Secretariat will inform the PI in writing about the date / time of monitoring visit and request for confirmation letter from the PI to be available for the monitoring visit.
- The IEC member / Independent monitor will also:

o Contact the site to notify them that they will be visiting them. At that time, the monitor and the site will coordinate the time for the site evaluation visit.
o The Secretariat will make the appropriate travel arrangements for the IEC member / Independent monitor.
o The IEC member / Independent monitor will review the IEC project files for the study and site profile and make appropriate notes.
o The IEC member / Independent monitor may copy some parts of the IEC project files for comparison with the site files and collect the Site Monitoring Visit Report Form (AX1-V1/SOP15/V1) from the Secretariat.

15.4.3 During the visit

The IEC member/Independent monitor will

- Review the informed consent document to make sure that the site is using the most recent version,
- Review randomly the subject files to ensure that subjects are signing the correct informed consent,
- Observe the informed consent process, if possible,
- Observe laboratory and other facilities necessary for the study at the site, if possible.
- Review the project files for the study to ensure that documentation is filed appropriately.
- Verifying that the investigator follows the approved protocol and all approved amendment(s), if any.
- Ensuring that the investigator and the investigator's trial staff are adequately informed about the trial
- Verifying that the investigator and the investigator's trial staff are performing the specified trial functions, in accordance with the protocol and any other written agreement between
  the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals.
- Verifying that the investigator is enrolling only eligible subjects.
- Verifying that source documents and other trial records are accurate, complete, kept up-to date and maintained.
- Checking the accuracy and completeness of the CRF entries, source documents and other trial-related records against each other.
- Determining whether all adverse events (AEs) are appropriately reported within the time periods required by GCP, the protocol, the IRB/IEC, the sponsor, and the applicable regulatory requirement(s).
- Collect views of the study participants, if possible.
- Fill the Site Monitoring Visit Report Form AX1-V1/SOP15/V1and write the comments.

15.4.4 After the visit

- The IEC member / Independent monitor will complete the report (use the form AX1-V1/ SOP15/V1) within 14 days describing the findings of the monitoring visit and during the Full Board meeting present them. If the Independent monitor is unable to attend the IEC meeting he / she can courier the Monitoring Visit Report with comments and the IEC Secretary can present the same.
- The Secretariat will place the report in the correct files.
- Full board recommendations to change the study / premature termination / continuation of

the project will go to the PI in writing within 14 days of the meeting.

Glossary

Independent Consultants
Many Ethics Committees rarely find time to perform monitoring visit themselves. They may ask outside experts or the staff of Ethics Committees to perform the tasks on their behalf and later report their findings to IEC.
Monitoring visit
An action that IEC or its representatives visit study sites to assess how well the selected investigators and the institutes are conducting researches, taking care of subjects, recording data and reporting their observations, especially SAEs found during the studies. Normally monitoring visit will be arranged in advance with the PI.
Monitoring Report
Reports should include a summary of what the monitor reviewed and the monitor's statements concerning the significant findings / facts, deviations and deficiencies, conclusions, actions taken or to be taken and / or actions recommended to secure compliance.

AX1-V1/SOP15/V1: Site Monitoring Visit Report

Site Monitoring Visit Report IEC project-	Date of the Visit:
Study Title:	
Principal Investigators:	Phone:
Institute:	Site:
Sponsor:	
Total number of subjects enrolled:	Total subjects ongoing:
No. of subjects completed:	No. of drop outs:
Are site facilities appropriate? □Yes □ No	Comment:
Are Informed Consents of recent version Used? ☐ YES ☐ No	Comment:
Is it approved by the IEC? ☐ Yes ☐ No	Comment:
Whether consent has been taken from all patients? ☐ Yes □ No	Comment:
Whether appropriate vernacular consent have been taken? □Yes □ No	Comment:
Are Protocols of recent version used? □Yes □No	Comment:
Is it approved by the IEC? □ Yes □ No	Comment:
Any adverse events found? □ Yes □ No	Comment:
Any SAEs found?	Comment:

Were the SAEs informed to IEC within 7 working days & SAE death within 24 hrs.? □ Yes □ No	Comment:
Any protocol non-compliance / violation? □ Yes □ No	Comment:
Are all Case Record Forms up to date? □ Yes □ No	Comment:
Are storage of data and investigating Products locked? □ Yes □ No	Comment:
How well are participants protected? ☐ Good ☐Fair □ Not good	Comment:
Any outstanding tasks or results of visit? □ Yes □ No	Give details:

Duration of visiting….hours	Starting from: Finish:
Name of IEC/ representatives:	
Completed by: Signature:	Date:
Name of study team member (PI/Co-I): Signature:	

AX2-V1/SOP15/V1: Clinical trial site for conduct of trial

1. Clinical trial site shall ensure compliance with the regulations of IEC.
2. Clinical trial site shall have adequate infrastructure including the drug/device storage location, documents storage location, computer(s) with required accessories for proper documentation and any other requirements dictated by the protocol thereof.
3. Clinical trial site shall have adequate facilities for collection and safe storage of biological samples, diagnostic facilities, preparation for shipment if needed and documentation for all these activities.
4. Clinical trial site should have facilities to provide regular medical care during the trial and emergency medical care when needed.
5. There shall be an inventory management system in place for the drug/device under trial and the equipment.
6. The trial site shall maintain adequate documentation (as per Annexure VII of Schedule Y – amended version of Drugs and Cosmetics Rules, 1945) about the SOP for the clinical trial, qualifications and experience of the team, documents about training of the staff, relevant policies and procedures, protocols for medical care in case of SAEs.
7. The trial site should maintain record of the informed consent documents, documents about patient/subject's rights, fair selection of subjects, confidentiality policies, procedure for withdrawal of the participant from the trial, documents about SAE reporting and handling procedures, compensation policies, and clinical trial related documentation.
8. Clinical trial site shall have a plan in place for quality control & management, addressing the grievances and conflict of interest management.

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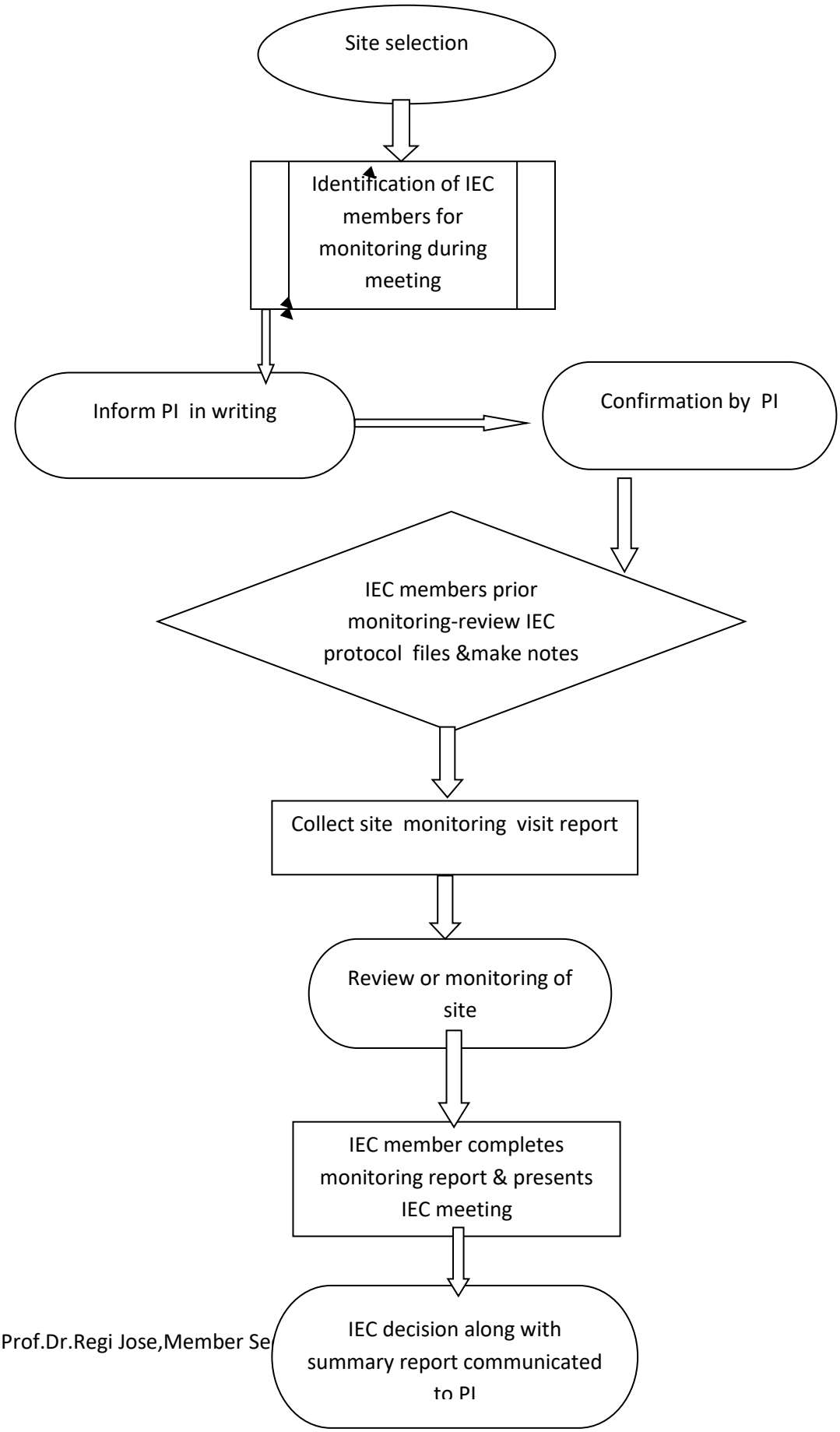

Site selection
Identification of IEC members for monitoring during meeting
Inform PI in writing
Confirmation by PI
IEC members prior monitoring-review IEC protocol files &make notes
Collect site monitoring visit report
Review or monitoring of site
IEC member completes monitoring report & presents IEC meeting
IEC decision along with summary report communicated to PI

Institutional Ethics Committee
Standard Operating Procedures
(SGMC-IEC: SOP: 16/V2)

Title: Dealing with participants / patients requests and complaints

SOP Code: SOP 16/V1 Date: 01/04/2013 Pages: 6

16.1 Purpose

The IEC considers protection of the rights and welfare of the human subjects participating in a clinical research approved by the IEC as its primary responsibility, Informed Consent documents reviewed by the IEC contains the statement, "Questions regarding the queries regarding rights of a participant/patient may be addressed to the IEC, Member secretary, with the IEC address and phone number.

This procedure provides guidelines for dealing with and accommodating requests by participants/patients regarding their rights as a participant or to resolve their complaints in any approved research study.

16.2 Scope

This SOP applies to all requests concerning the rights and well-being of the research participants participating in studies approved by the IEC.

16.3 Responsibility

It is the responsibility of the IEC Secretariat for providing required information to the research participants in case of queries received from research participants.

It is the responsibility of the Chairperson to initiate a process to give information to the participants or to identify and address any injustice that has occurred, if complaints are received from research participants.

16.4 Detailed instructions

- The IEC member/ administrative staff receive an inquiry or request from research participant / patient.
- The request and information is recorded in the request record form (Form AX1-V1/SOP16/V1)
- The Secretariat will inform the Chairperson about the query / complaint received from the research participant.
- The Chairperson / Members designated by the Chairperson will provide information required by the research participant.
- In case of complaint received from a research participant, the Chairperson initiates a process to identify and address any injustice that may have occurred.
- The Chairperson will direct the Member Secretary to consider the matter for discussion at a full board meeting or to call an emergency meeting of 2 or more IEC members for discussion or to appoint a subcommittee of 2 or more IEC members for enquiry in order to resolve the matter.

- The Chairperson / Member Secretary / designated IEC members will assess the situation and mediate a dialogue between the research participant and the investigator in an attempt to resolve the matter.
- The IEC will insist on factual details to determine reality between truth and individual perception.
- The final decision will be informed to the research participant by the Secretariat.
- The information including any action taken or follow-up will be recorded in the form AX1- V1/SOP 16/V1 and the form is signed and dated.
- The IEC members are informed about the action taken and the outcomes in the forthcoming IEC meeting.

16.5 Filing the request document

_ The record form is filed in the "response" file by the Member Secretary / administrative staff.
_ A copy of the same is kept in the study file.
_ The file is stored in a secured place.

AX1- V1/SOP 16/V1: Request Record Form

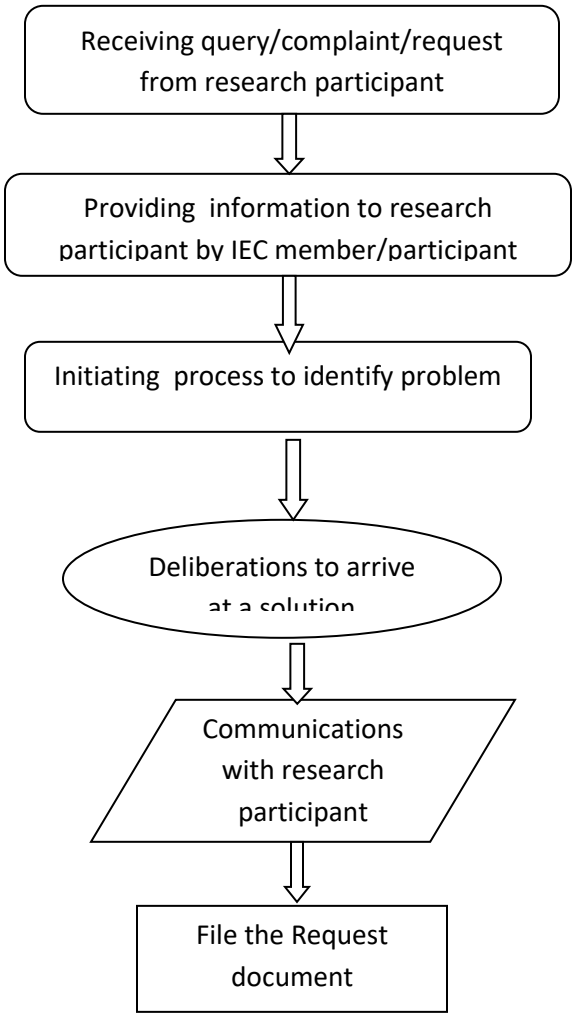
Date Received:	
Received by	□ Telephone call No □ Fax No □ letter / Date □ E-mail / Date □ Walk-in: Date / Time □ Other, specify
Request from	
Participant's Name	
Contact address Phone:	
Title of the Participating Study	
Starting date of participation :	
What is requested?	
Action taken:	
Outcome:	

Name of the Chairperson / Member Secretary

_____

Signature of the Chairperson / Member Secretary _____ Date- _____

FLOW CHART


Receiving query/complaint/request from research participant
Providing information to research participant by IEC member/participant
Initiating process to identify problem
Deliberations to arrive at a solution
Communications with research participant
File the Request document

Institutional Ethics Committee
Standard Operating Procedures
(SGMC-IEC: SOP: 17/V1)

Title: Standard operating procedures to be followed by the committee for research among vulnerable population

SOP Code: SOP 17/V1 Date: 01/05/2020 Pages: 4

17.1 Purpose

The IEC considers protection of the rights and welfare of the human subjects participating in a clinical research approved by the IEC as its primary responsibility.
This procedure provides guidelines for dealing with research involving vulnerable subjects regarding their rights as a participant or to resolve their complaints in any approved research study.
VULNERABILITY Individuals/ groups/ populations are considered vulnerable if they are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power, understanding or ability to communicate or other reasons.

17.2 Scope

This SOP applies to all requests concerning the rights and well-being of the research participants participating in studies approved by the IEC.

- Equitable distribution of burdens and benefits in the selection of participants/groups: Groups/communities to be invited to participate in research should be selected in such a way that the burdens and benefits of research will be equitably distributed.

- The exclusion of certain groups or communities that might benefit from study participation must be justified.

- Overuse of certain groups, such as the poor, is unjust as they may be more easily induced to participate in exchange for small payments.

17.2.1 Research involving vulnerable individuals

Individuals are considered to be vulnerable if they are:

• Socially, economically or politically disadvantaged and susceptible to exploitation
• Incapable of making a voluntary informed decision for themselves or if their autonomy is compromised temporarily or permanently (e.g., people who are unconscious, differently abled)
• Able to give consent, but their voluntariness or understanding is compromised due to their situational conditions
• Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate, which may lead them to give consent

17.2.2 Research involving children

Before undertaking research involving children the investigators must ensure that:

17.2.2.1. the research might not equally well be carried out with adults;

17.2.2.2. the purpose of the research is to obtain knowledge relevant to the health needs of children;

17.2.2.3. a parent or guardian has given permission;

17.2.2.4. the consent of each child has been obtained after the child has been informed to the extent that the child's maturity and intelligence permits;

17.2.2.5. a child's refusal to participate or continue in research will be respected;

17.2.2.6. the research is conducted in a setting in which the child and parent can obtain adequate medical and psychological support; and

17.2.2.7. the parent or guardian is given the opportunity to observe the research as it proceeds, so as to be able to withdraw the child if they decide that it is in the child's best interest to do so (see 3.3.5). 3.3.10.

17.2.3 Research involving pregnant women

Before undertaking research on pregnant women the investigators must ensure that:

17.2.3.1. prospective participants are adequately informed about the risks and benefits to themselves, their pregnancies, the fetus and their subsequent offspring and their fertility;

17.2.3.2. the purpose of the research is to obtain knowledge relevant to the particular health needs of pregnant women, their fetuses or to the health needs of pregnant women in general; and

17.2.3.3. where appropriate, such research is supported by reliable evidence from animal experiments regarding risks of teratogenicity and mutagenicity.

17.3 Responsibility

It is the responsibility of the IEC Secretariat for providing required information to the research participants in case of queries received from research participants.
It is the responsibility of the Chairperson to initiate a process to give information to the participants or to identify and address any injustice that has occurred, if complaints are received from research participants.
17.3.1. Researchers must justify the inclusion/exclusion of a vulnerable population.

17.3.2. A community representative may be invited to EC meetings to make sure the research is responsive to their needs and the informed consent process is appropriate.

17.3.3. Additional precautions should be taken by all stakeholders such as researchers, ECs and sponsors to avoid exploitation of vulnerable participants.

17.3.4. Informed consent process should be well documented and additional measures adopted if required, such as audiovisual/audio recording of assent/consent/reconsent.

17.3.5. Research proposals should undergo review in a full committee meeting.

17.3.6. Protection of privacy and dignity as well as provision of quality health care is required in dealing with vulnerable people, especially the minorities.

17.3.7. Research involving children, in addition, should follow the National Ethical Guidelines for Biomedical Research Involving Children, ICMR, 2017.

17.3.8. Due approvals are needed from competent authorities before entering tribal areas.

17.3.9. Research involving cognitively impaired individuals or those with mental illness must be done carefully, especially if there is risk to themselves, to others or suicidal ideation.

17.3.10. The EC should carry out the benefit–risk analysis and examine risk minimization strategies.

17.4 Detailed instructions

Specific protections are focal at SGMC IEC meetings when studies involve minority groups, particularly those enrolling under-represented minority populations, such that culturally sensitive values and the trust of minority ethnic communities are respected and maintained.

The principles usually recorded in EC meeting reports for referral to investigators for clarification/revision include:

(a) ensure no exploitation, coercion, or pressure to participate among the minority, which is regarded as a vulnerable population;

(b) ensure that the research methodology does not affect the legal status of the minority;

(c) consider the necessary educational level and competency of the minority research subjects to participate in the study;

(d) understand and consider the ethnicity and cultural issues of the minority communities being studied;

(e) ensure that the research methodology and instruments are accepted and understood by minority ethnic participants; and

(f) provide appropriate compensation for the contributions of the minority participants residing in under-served and limited-resource environments.

After the EC had made its decision on a proposal, the reasons for clarification/revision or deferment/not approval were clearly explained to the investigators.

Institutional Ethics Committee Standard Operating Procedures (SGMC-IEC: SOP:18/V1)

Title: **Handling Conflict of Interest Among Ethics Committee Members**

SOP Code: SOP 18/V1 Date: 01/05/2020 Pages: 5

18.1 Purpose: It has been recognized that the potential for conflict of interest will always exist but has faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects. The purpose of this SOP is to describe the process to identify and manage conflict of interest among SGMC IEC members.

18.2 Scope: This SOP covers the policy related to identification, declaration, and management of conflict of interest and is applicable to all IEC members.

18.3 Responsibility:

All SGMCIEC members are responsible for self-identifying and disclosing the conflict of interest. The Chairperson of IEC is finally responsible for ensuring that all members of IEC self-declare conflict of interest during review of research proposals

18.4 Procedure:

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the HEC review or approval except to provide information requested by the Committee.

If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson.

The request must contain evidence that substantiates the claim that a conflict exists with the IHEC member(s) in question.

The committee may elect to investigate the applicant's claim of the potential conflict. Examples of conflict of interest cases may be any of the following: _ A member is involved in a potentially competing research program. _ Access to funding or intellectual information may provide an unfair competitive advantage. _ A member's personal biases may interfere with his or her impartial judgment.

18.4.1 Information to members on conflict of interest:

A. During the appointment of members, one of the conditions is "To read, understand, accept and follow the conflict of interest policy of ethics committee, and declare conflict of interest if any at appropriate time".

B. The member will be signing the consent letter after going through the terms and conditions in the appointment letter.

C. The conflict of interest policy of the SGMCIEC will be explained to the members on induction. It will be a part of the trainings imparted to the members

18.4.2 Types of Conflict of Interest (COI):

Personal COI:

If the investigator of a research proposal has close and immediate family relationship with the member of SGMCIEC (spouse, son/daughter, parents, sibling, dependent) ; If the SGMCIEC member is a collaborator, Principal investigator, co-investigator, financer, research staff, consultant for a research proposal which has come for review in SGMCIEC.

If a research proposal is submitted by a departmental colleague with whom the member has conflict of interest (dispute, bias, any benefits, etc..,) –if applicable and if the member feels there is a conflict of interest.

Professional COI:

If the IEC member or his/her immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research.

Financial COI:

If the IEC member or the spouse or dependent of a member receives monetary benefits including, but not limited to, salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests) and intellectual property rights (e.g., patents, copyrights, product or service being evaluated).

18.4.3 Procedure for Declaring COI:

- The IEC member should identify the COI whenever a research proposal is assigned to him/her for the review. The COI should be declared in the format provided in SOP of SGMCIEC and submitted to the member secretary.

- The IEC members should not participate in discussing, or decision making on research proposals' applications reviewed at any level (exempt, expedited, or full-board) when they have conflicts of interest except to provide information requested by the IEC.

- If an IEC member has a COI for review outside a meeting (e.g., the expedited procedure/ amendments), he or she should notify the IEC Secretariat and return the documents.

- If an IEC member has a COI for a study for which he or she has been assigned as a primary reviewer, he or she will inform the IEC secretariat so that the review is reassigned to other members.
- If an IEC member has a COI for review of research study at a meeting, he or she will inform the Chairperson and leave the meeting room while discussion of the study takes place. He/she may stay in the meeting room only to answer questions about the research. This is applicable also for IEC meetings at which discussion on serious adverse events, deviations/violations, amendments/ continuing review reports related to studies are discussed

- The IEC member who declares COI and leaves the meeting does not count towards the quorum for the vote. The member's absence under these circumstances is called a recusal, not an abstention or an absence.

- If an IEC member finds that he/she has a COI during the conduct of a research project approved by IEC, he/she shall report the conflict to the IEC at the next IEC meeting.

- At the beginning of each meeting, the SGMCIEC Chairperson asks the members to disclose any COI concerning any of the items on the agenda. During the meeting, IEC member having conflict discloses the existence of the conflict just before the review of the relevant item begins.

- If the Chairperson has a conflict of interest for a project, this should be so declared and handled like any other member's conflict is handled. An acting Chairperson should be appointed for discussion on such a project.

- When determination regarding existence of COI is uncertain, more information is gathered from relevant sources and determination is done by the IEC member with the help of the IEC Chairperson / Member Secretary or by IEC Chairperson / Member Secretary (as applicable)

- The IEC Chairperson has the final authority to determine whether a COI has been managed or eliminated appropriately for research participant protection. The IEC shall not approve a research study proposal where a COI is not managed or eliminated

- The declaration and management of COI should be recorded in the proceedings

of the SGMCIEC meetings.

18.5Annexure:

AX1-V1/SOP02/V2:
Confidentiality and Conflict of Interest Agreement form for IEC Members

In recognition of the fact, that I, Dr…… herein referred to as the "Undersigned", has been appointed as a member of the Institutional Ethics Committee (IEC), would be asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;

Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest.

Whereas, the fundamental duty of an IEC member is to independently review research protocols involving human subjects and decide and the best possible objective recommendations, based on the merits of the submissions under review.

Whereas, the IEC must meet the highest ethical standards to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects.

The undersigned, as a member of the IEC is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information")in trust or confidence and agrees that it shall be used only for contemplated

purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that my performance of this agreement is consistent with the Institute's policies and any contractual obligations they may have to third parties.

Conflict of Interest

It has been recognized that the potential for conflict of interest will always exist but has faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

In accordance with the policy of the IEC, I shall not participate in the review, comment, or approval of any activity in which I have a conflict of interest, except to provide information as

requested by the IEC.

_____ _____

Undersigned Signature Date

The Undersigned will immediately disclose to the Chairperson of the IEC any actual or potential conflict of interest that I may have in relation to any particular proposal submitted for review by the committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IEC member(s) in question.

The committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may

not participate in the IEC review or approval except to provide information requested by the Committee.

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest.

During my activities as a member of the IEC, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the committee not to count me toward a quorum for consensus or voting.

I, Dr. ……. have read and I accept the terms and conditions as explained in this Agreement.

_____	_____
Undersigned Signature	Date
_____	_____
Director of the SGMC	Date

Institutional Ethics Committee
Standard Operating Procedures
(SGMC-IEC: SOP: 19/V1)

Title: Standard operating procedures for Review of Biomedical and Health Research during COVID-19 Pandemic

SOP Code: SOP 18/V1 Date: 25/05/2020 Pages: 4

1. Purpose: The purpose of this Standard Operating Procedure (SOP) is to describe how the EC will function and conduct ethics review in an emergency situation with restrictions as imposed by social distancing requirements during the COVID-19 outbreak.

2. Procedures & Responsibilities:

Institute Logo	SOP for Review of Biomedical and Health Research during COVID-19 Pandemic	SOP No: __/ V01 Effective Date: *dd/mm/yyyy*

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe how the EC will function and conduct ethics review in an emergency situation with restrictions as imposed by social distancing requirements during the COVID-19 outbreak.

2. Procedures & Responsibilities:

SN	Procedure	Responsibility
	Submission and initial review	
a.	Submit research proposal (electronically)	Researchers
b.	Receive, record, verify completeness and allot reference no.	Secretariat/ Member Secretary
c.	Categorize depending on risk (Exempt/ Expedited, Full committee), identify need for review by experts/ independent consultants/ patient /others, designate reviewers	Member Secretary in consultation with Chairperson
d.	Perform Initial review of documents as described in *Table 4.3 of ICMR National Ethical Guidelines*, fill study evaluation form	Primary/ secondary Reviewers
e.	Schedule virtual Meeting, Prepare Agenda, invite members (*Independent Consultants/Subject Experts/ PI/ Member secretary of local EC/ in consultation with Chairperson*).	Secretariat / Member Secretary
	Virtual EC meeting	
f.	Open the meeting, determine quorum (*Section 4.8.4 of ICMR National Ethical Guidelines), COI declaration, Summaries* Agenda	Chairperson
g.	Brief presentation and/or address queries on the research proposal and leave meeting prior to decision	Researchers/ subject experts (optional)
h.	Present observations on item reviewed	Primary/ secondary Reviewers
i.	Discuss further on the item and reach consensus	EC members
j.	Record Decision and rejoin member who had declared COI before moving on to subsequent item on agenda	Secretariat / Member Secretary
k.	Record minutes of meeting, ratify approved decisions of exemption/expedited review before closing meeting	Member Secretary/ Chairperson
	Post meeting activities	
l.	Communication of decision and maintaining records.	Secretariat/ Member Secretary
m.	Follow up/monitoring/ analysis of SAE/ handling of issues related to non-compliance, violation, complaints etc.	Member Secretary in consultation with Chairperson

3. Detailed Instructions:

- The Research Proposal should be submitted electronically in ICMR Common Forms for Ethics Review (http://ethics.ncdirindia.org/Common_forms_for_Ethics_Committee.aspx) with supporting documents (Informed Consent, Brief CV of PI/ Co PIs, Questionnaire/ Case report form, Approval/ Comments of scientific committee, CTRI/ CDSCO/ HMSC/ MTA/ MoU/ insurance coverage) as applicable.
- Once received, the secretariat will verify protocol for completeness (if not ask PI) and number.
- Member Secretary to categorise research into full review, expedited review or exemption from review.
- Member Secretary (in consultation with Chairperson) will identify need for review by subject experts, independent consultants, special invitees, patient representatives, others for prior review or to present views during the meeting.
- The project for full review will be included in agenda of virtual full-committee meeting to be scheduled at the earliest (48 hrs) by the Member Secretary in consultation with the Chairperson.
- The members will be briefed about the technological requirements and virtual platform used for the conduct of the meeting.
- Quorum requirements for review will be applicable as per Section 4.8.4 ICMR National Ethical Guidelines, 2017.
- Review procedures as per ICMR National Ethical Guidelines will also hold good for the virtual web ethics meeting.

4. Annexures: *if any*

5. References: ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants

Prepared by	Reviewed by	Page _ of _	Approved by	Accepted by
Signature with date	*Signature with date*		*Signature with date*	*Signature with date*

Institutional Ethics Committee, Sree Gokulam Medical College (IEC, SGMC)

APPENDICES

APP1/V1 Policy on Recruitment of SGMC Students and Staff

APP2/V1 Policy on the Recruitment of Research Subjects

APP3/V1 Policy on Research Costs to Subjects

APP4/V1 Guidelines on Compensation for Research Subjects

APP5/V1 Policy on the Use of Third Party/Surrogate Consent in Research at SGMC

APP6/V1 Policy on Blood Withdrawal for Research Purposes

APP7/V1 Guidelines and Policy on Informed Consent

APP8/V1 Policy for Documentation of Informed Consent

APP9/V1 Health Record Research

APP10/V1 Guidelines for Research Protocols That Require Collection and /or Storage of Genetic Materials

APP11/V1 Guidelines for Submission and EC Review of Gene Therapy / Gene Transfer Protocols

APP12/V1 Recommended Terms for Use in Consent Forms

APP1/V1

Policy on Recruitment of SGMC Students and Staff for Research

DEFINITIONS

"Student" means any individual who is enrolled at SGMC and those individuals who are in training as, Residents, Fellows, or Postdoctoral trainees, including individuals enrolled at a training facility other than SGMC training or work program. "Staff" mean all other SGMC employees, including faculty.

POLICY GUIDELINES

SGMC students and staff have the same rights as any other potential subject to participate in research project, irrespective of the degree of risk, provided all of the following conditions exist:

- The research must not bestow upon participating SGMC subjects any competitive academic or occupational advantage over other SGMC students or staff who do not volunteer, and the researchers must not impose any academic or occupational penalty on those SGMC students or staff who do not volunteer.

- SGMC students and staff must not be systematically treated differently from non-SGMC subjects as part of the project.

- Due to the potential for perceived or real coercion to participate, SGMC students and staff who desire to participate in the research (especially those under the direct supervision of the PI or listed research collaborators) must be reviewed by Director SGMC.

APP2/V1

Policy on the Recruitment of Research Subjects

SPECIFIC RECRUITMENT GUIDELINES

(1) In addition to its review for scientific merit and protection of subjects from unnecessary research risks, the IEC will evaluate all protocols for subject recruitment especially with respect to women with childbearing potential, minority groups and children. Exclusion of minorities, women or children will be recommended or approved when inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

(2) **SGMC PATIENTS** - Patients may be identified as potential research subjects through Direct contact of the PI with his or her patients, collaboration with physicians of other medical specialties, contact with individual attending physicians, posted written notices, radio announcements, or other IEC approved methods.

a. **Inpatients** - May be recruited by the investigator or other member of the research team only after consultation with the patient's attending physician.

b. **Outpatients** -

(i) For minimal risk research which does not bear directly upon a specific continuing therapeutic relationship between the individual and a SGMC physician, outpatients may be recruited* without prior notification of their personal physicians. However, when possible, each subject's personal physician should be notified of the study and informed that the patient has been entered into a minimal risk study.

(ii) For more than minimal risk research or any research bearing directly upon a specific diagnosis or treatment, the subject's personal physician should be notified before enrolling* the subject.

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* If the potential research subject is a minor, then contact must be via a parent or legal guardian.

APP3/V1

Policy on Research Costs to Subjects

If a research participant may have to bear any costs, which would be unnecessary if the subject had declined to participate in the research, all potential subjects must be fully informed of the nature and estimated extent of these costs when obtaining consent. Examples of additional research costs include:

1) Prolongation of treatment or hospitalization.
2) Extra diagnostic tests necessary for the research.
3) Extra clinical or laboratory assessments to evaluate research treatment outcome.
4) A research treatment (whether randomly assigned or not) which may be more costly than a standard treatment.
5) Other substantial costs associated with extra visits to SGMC.

APP4/V1

Guidelines on Compensation for Research Subjects

COMPENSATION FOR PARTICIPATION (ICMR Code 2000)

Subjects may be paid for the inconvenience and time spent, and should be reimbursed for expenses incurred, in connection with their participation in research. They may also receive free medical services. However, payments should not be so large or the medical services so extensive as to induce prospective subjects to consent to participate in research against their better judgment (inducement). All payments, reimbursement and medical services to be provided to research subjects should be approved by the IEC.

Care should be taken:

1) when a guardian is asked to give consent on behalf of an incompetent person, no remuneration should be offered except a refund of out of pocket expenses;
2) when a subject is withdrawn from research for medical reasons related to the study the subject should get the benefit for full participation;
3) when a subject withdraws for any other reasons he/she should be compensated in proportion to the amount of participation.

Prospective participants in research should also be informed of the sponsorship of research, so that they can be aware of the potential for conflicts of interest and commercial aspects of the research.

During the initial review of a research protocol, the IEC is required to review both the amount of compensation proposed and the method and timing of disbursement to assure that neither are coercive or present undue influence. The following are some additional guidelines:

1) Any compensation should not be contingent upon the subject completing the study, but should accrue as the study progresses.
2) Unless it creates undue inconvenience or a coercive practice, compensation to subjects who withdraw from the study should be made at the time they would have completed the study, had they not withdrawn.
3) Compensation given as a “bonus” or incentive for completing the study is acceptable, providing that the amount is not coercive. The IEC is responsible for determining if the incentive amount is not so large as to be coercive or represent undue influence.
4) The amount of compensation should be clearly set forth in the informed consent document

APP4/V1 AX1 – V1/APP4/V1 :

Guidelines on Compensation for Research Subjects information regarding effective compensation mechanism to be provided.

1. IEC shall ascertain the inclusion of compensation clause in the informed consent document at the time of protocol submission with documented information about the complete medical care and compensation to be given to the participant in case of SAEs.

2. IEC shall receive from the PI a copy of insurance policy or the compensation for the participants in case of SAEs and/or a copy of agreement between the PI and the sponsor before the approval of the trial.

3. In case of ant CT related injury, the participant shall receive free medical treatment as long as required. The participant is also entitled for additional financial compensation as per the rules laid out by the Licensing authority.

4. In case of CT related death of the participant, his/her nominee shall receive the compensation as per the rules of the Licensing authority.

5. PI is responsible for ensuring that compensation is provided to the participants in case of SAEs.

6. In case a PI of a clinical trial receives queries regarding SAEs (trial-related death or injuries), a Compensation Committee is constituted that includes IEC members, clinicians, clinical pharmacologist, legal and financial experts, to discuss the recommended compensation. The committee shall convene a meeting in the presence of PI along with reports of SAEs and participants' case reports. The committee shall examine the reports to ascertain causality and send its report and recommendations regarding compensation to Expert Committee and/or DCGI within 21 days of the reported SAEs.

7. The Licensing authority shall decide the quantum of compensation to be paid by the sponsor or his representative and the compensation shall be paid to the participant or the nominee (as applicable) within thirty days of receipt of the order.

APP5/V1

Policy on the Use of Third Party / Surrogate Consent in Research at SGMC

APPLICABILITY

When a SGMC investigator proposes to conduct a research project utilizing adult subjects who by virtue of age, physical impairment, mental impairment, language barrier or any other reason may not be able to personally execute legally effective informed consent, the IEC shall review the project on the basis of "risk" and "benefit" and shall determine that each project be assigned to one of the categories below. **This policy does not mean to imply that the requirement for written documentation of consent is waived. Rather, it applies to those studies in which third party/surrogate consent is obtained from a legally authorized representative.** Investigators must complete and submit an IEC Form for review and approval of inclusion of subjects who are decisionally impaired.

Category I - Risks to subjects are minimal, direct benefits may or will accrue to subjects.

Category II - Risks to subjects are minimal, direct benefits will not, or are unlikely, to accrue to subjects but potential societal benefits are inherent in research.

Category III - Risks to subject are greater than minimal, direct benefits may or will accrue to subjects.

Category IV - Risks to subjects are greater than minimal, direct benefits will not, or are unlikely, to accrue to subjects but potential societal benefits are inherent in the research.

IEC RECOMMENDATIONS TO THE ADMINISTRATION

When categorization has been accomplished, the IEC will recommend to the SGMC Administration to consider implementation or non-implementation of the project based upon the level of benefit to be gained by the individual or society from this project as compared to the level of risk involved.

It is the intent of the IEC to cause to recommend Category I projects to be initiated.

It is the intent of the IEC not to recommend initiation of any Category IV projects.

APP6/V1

Policy on Blood Withdrawal for Research Purposes

APPLICABILITY

For many studies where the only research intervention is the collection of blood for analysis, the IEC categorizes the following procedures for obtaining blood from children and adults as **minimal risk**:

A. General Requirements

1. There are no special health reasons (e.g., anemia) to contraindicate blood withdrawal.
2. In patients from whom blood is already being drawn for clinical purposes, there are no other health reasons to preclude additional blood collection.
3. In subjects from whom blood is not already being drawn for clinical purposes, the withdrawal method is by cutaneous sticks (e.g., heel or finger) or by standard venipuncture in a reasonably accessible peripheral vein, and the frequency of punctures does not exceed two per week.
4. The volume of blood drawn from lactating or known pregnant subjects does not exceed 20 ml per week.
5. All blood withdrawals and collections are carried out by experienced professional or technical personnel.

B. Additional Requirements for Adults (Subjects over 18 years of age)

1. If less than 50 ml is being collected, there are no additional restrictions with regard To hemoglobin or hematocrit.
2. If a volume greater than 50 but less than 200 ml is being collected for "no-benefit" studies, hemoglobin levels should be >11.0 g/dl for males and >9.5 g/dl for females with MCVs >85 fl (These restrictions would not apply if iron deficiency anemia or other forms of anemia were critical for inclusion in the study.).
3. The cumulative volume withdrawn or collected may not exceed 450 ml per twelve-week period (this maximum includes blood being drawn for clinical purposes) from patients 18 years of age or older in good health and not pregnant.

C. Additional Requirements for Children (Subjects under 18 years of age

1. No more than three (3) skin punctures are to be made in any single attempt to draw blood, and the frequency of punctures does not exceed twice per week.
2. The volume of blood withdrawn, including blood for clinical purposes, does not exceed the lesser of 50 ml or 3 ml/kg in an eight week period and collection may not occur more frequently than 2 times per week.
3. The cumulative volume of clinical and research blood withdrawn per eight-week

period does not exceed six per cent (6.0%) of the child's total blood volume.

4. In patients from whom blood is already being drawn for clinical purposes and when the research is directly related to the child's condition, there is no maximum number of extra volume specimens which can be collected as long as the preceding requirements are met.
5. In subjects from whom blood is not already being drawn for clinical purposes, the maximum number of allowable separate specimens (again, within the limits of the preceding restrictions) depends upon the child's age and whether the research is directly related to the child's condition.

D. Cord Blood

Cord blood from newborns can be used without restrictions when blood is extracted from the placental side of the cord, after it has been clamped and severed.

E. Consent

Oral consent is generally sufficient to collect additional volume (within the limits specified above for minimal risk) from patients in whom blood is being drawn for clinical purposes.

APP7/V1

Guidelines and Policy on Informed Consent

A. General Requirements

Except as described below, investigators may not enroll human subjects in research unless they have obtained the legally effective, written, informed consent of the subject or the subject's legally authorized representative, prior to enrollment of the subject in the research. Investigators are responsible for ensuring that subjects, or their representatives, are given sufficient opportunity to consider whether or not to participate and must seek to avoid coercion or undue influence. Information given to potential subjects or their representatives must be in language that is understandable to the subject or representative. No process of obtaining consent may include language through which the subject waives any of their legal rights or releases or appears to release the investigator, sponsor, or institution or its agents from liability for negligence.

B. Elements of Informed Consent

A current sample informed consent document with required phraseology may be found in Appendix B-2. The sample consent form contains all the required elements of consent. The IEC requires that all consent forms be written in the first person, e.g., "I understand that…" The following are the basic required elements:

1. A statement that the study involves research, an explanation of the purpose of the proposed research, the duration of the subject's participation, a description of the procedures, and which procedures are experimental;
2. The number of subjects that will be involved with the study, totally and at SGMC;
3. A description of reasonably foreseeable risks or discomforts that the subjects may encounter, and, if appropriate, a statement that some risks are currently unforeseeable;
4. A description of possible benefits, if any, to the subject and others which may be reasonably expected. It should be stated that since it is an experimental treatment or procedure, no benefits can be guaranteed;
5. A discussion of possible alternative procedures or treatments, if any, which are available to the subject. One alternative might be to choose not to participate in the research and this will not affect the usual standard of care;
6. A discussion of how confidentiality of records associated with the subject will be maintained;
7. A description of any compensation or reimbursement for time, inconvenience, travel, parking, and other similar costs to the subject;
8. A description of any provisions for treatment of or compensation for research related injury;
9. A statement of whom to contact for answers about the research and in the event there is a research related injury. (This is generally the PI or another staff member

closely associated with the study.) A separate contact must be named for questions concerning the subject's rights;

10. A statement that the subjects' participation is voluntary, that refusal to participate will not involve penalty or loss of benefits to which the subject is entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits;
11. If appropriate, any circumstances under which the subject's participation may be terminated, with or without the subjects consent; and
12. A description of additional costs for which the subject will be responsible, that is likely to result from participation in the research study.

C. WAIVER OF INFORMED CONSENT

The IEC may waive the requirements for obtaining informed consent or approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent listed above, provided that:

1. The research involves no more than minimal risk to the subjects
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

D. DOCUMENTATION OF INFORMED CONSENT

Informed consent must be documented by the use of a written consent form reviewed and approved by the IEC and signed by the subject or subject's legally authorized representative.

A copy must be given to the subject or person signing the form. For SGMC patients, a copy of the signed consent form should also be placed in the subject's medical record. It is assumed that the consent form is only part of the total consent process in which the investigator, perhaps using the written consent form as an outline, describes all facets of the study and answers the subject's questions. **The investigator is responsible for ensuring that research subjects understand the research procedures and risks. Failure of the subjects to ask questions should not be construed as understanding on the part of the subject.**

E. RECORD RETENTION REQUIREMENTS FOR SUBJECT CONSENT FORMS

1. The PI or project director shall maintain, in a designated location, all executed subject consents. These consent forms are to be available for inspection by authorized officials of the IEC, DSMSC, regulatory agencies and sponsors. For DCGI/RA regulated test article studies, all signed subject consent forms shall be retained by the principal investigator for the appropriate period(s) specified below.

Drugs: Two (2) years following the date a marketing application is approved or the study is discontinued.

Devices: Two (2) years after a study is terminated or completed and the records are needed to support DCGI/ RA approval.

APP8/V1

Policy for Documentation of Informed Consent

I. INFORMED CONSENT PROCESS

1. **Informed Consent of Subject:** For all biomedical research involving human subjects, the investigator must obtain the informed consent of the prospective subject or in the case of an individual who is not capable of giving informed consent, the consent of a legal guardian.
   Informed consent is based on the principle that competent individuals are entitled to choose freely whether to participate in research or not. Informed consent protects the individual's freedom of choice and respect for individual's autonomy.
   When research design involves not more than minimal risk (for example, where the research involves only collecting data from subject's records) the IEC may waive off some of the elements of informed consent.
   Waiver of informed consent could also be considered during conditions of emergency.
   However, this would be permissible only if IEC has already approved the study or use of drug. However, the patient or the legal guardian should be informed after she/he regains consciousness or is able to understand the study.

2. Obligations of investigators regarding informed consent: The investigator has the duty to –

i. Communicate to prospective subjects all the information necessary for informed consent. There should not be any restriction on subject's right to ask any questions related to the study as any restriction on this undermines the validity of informed consent.

ii. Exclude the possibility of unjustified deception, undue influence and intimidation. Deception of the subject is not permissible. However, sometimes information can be withheld till the completion of study, if such information would jeopardize the validity of research.

iii. Seek consent only after the prospective subject is adequately informed. Investigator should not give any unjustifiable assurances to prospective subject, which may influence the subject's decision to participate in the study.

iv. As a general rule obtain from each prospective subject a signed form as an evidence of informed consent (written informed consent) preferably witnessed by a person not related to the trial and in case of incompetence to do so, a legal guardian or other duly authorized representative.

v. Renew the informed consent of each subject, if there are material changes in the conditions or procedures of the research or new information become available during the ongoing trial.

vi. Not use intimidation in any form which invalidates informed consent. The investigator must assure prospective subjects that their decision to participate or not will not affect the patient - clinician relationship or any other benefits to which they are entitled.

3. **Essential information for prospective research subjects**: Before requesting an individual's consent to participate in research, the investigator must provide the individual with the following information in the language he or she is able to understand which should not only be scientifically accurate but should also be sensitive to their social and cultural context:
   i. the aims and methods of the research;
   ii. the expected duration of the subject participation;
   iii. the benefits that might reasonably be expected as an outcome of research to the subject or to others;
   iv. any alternative procedures or courses of treatment that might be as advantageous to the subject as the procedure or treatment to which she / he is being subjected;
   v. any foreseeable risk or discomfort to the subject resulting from participation in the study;
   vi. right to prevent use of his / her biological sample (DNA, cell-line, etc.) at any time during the conduct of the research;
   vii. the extent to which confidentiality of records could be maintained i.e., the limits to which the investigator would be able to safeguard confidentiality and the anticipated consequences of breach of confidentiality;
   viii. responsibility of investigators;
   ix. free treatment for research related injury by the investigator / institution;
   x. compensation of subjects for disability or death resulting from such injury;
   xi. freedom of individual / family to participate and to withdraw from research anytime without penalty or loss of benefits which the subject would otherwise be entitled to;
   xii. the identity of the research teams and contact persons with address and phone numbers;
   xiii. foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, clear mention of the same;
   xiv. risk of discovery of biologically sensitive information;
   xv. publication, if any, including photographs and pedigree charts.

The quality of the consent of certain social groups requires careful consideration as their agreement to volunteer may be unduly influenced by the Investigator.

This is accomplished as part of the total consent process by using a consent form that has been reviewed and approved by the IEC. Confusion sometimes arises as to who can obtain consent and who can be designated to sign the consent form. The following are the acceptable methods for documentation of informed consent of human research subjects at SGMC:

1. The IEC must be made aware of the person (s) who will be conducting the consent interviews. These faculty/staff members should be the only personnel allowed to obtain consent unless indicated otherwise. The IEC requires that the person obtaining consent is medically trained.
2. Each subject (or their legally authorized representative) must be provided adequate time to read and review the consent form, in addition to being advised of the procedures, risks, potential benefit, alternatives to participation, etc. This is frequently accomplished using the consent form as an outline for the interview process.
3. After completing the consent interview and assuring that the subject (or their representative) has no further questions and agrees to participate in the research activity, the interviewer should instruct the subject to sign and date the consent form in the appropriate spaces.
4. A witness must sign and date in the appropriate spaces. The witness cannot be the person conducting the consent interview, but is not further restricted.
5. The person conducting the consent interview must then sign and date the consent form in the appropriate spaces (PI or designee). It is assumed that in most cases, all persons signing the consent form will do so at the conclusion of the consent interview.
6. Each subject (or their representative) must be given a copy of the signed consent form. The original consent form should be filed in such a manner as to insure immediate retrieval when required by auditing entities, IEC, or sponsor monitors.
7. The regulations are clear that written documentation informed consent is required. Therefore, obtaining consent from an authorized third party via the telephone is not acceptable.
8. The regulations also include provisions for approval of a waiver or alteration of part or all of the consent process. The IEC will consider written requests for waiver or alteration of the process when accompanied by sufficient justification.
9. Obtaining informed consent from subjects must be accomplished prior to performing the research activity and using only an IEC approved consent form. Written requests for amendments to an existing consent form must be approved by the IEC prior to implementation.
10. Upon receipt of an IEC approved consent form, all old versions should be discarded to prevent inadvertent use of an outdated consent form. Copies of the most recently approved consent form may be made and should be used until superseded by an amended consent form. The consent form must be reviewed at least annually as part of the continuing review process.

APP9/V1

Health Record Research

The following is the IEC policy concerning research involving the study of medical records or other forms of health information.
Research projects may involve the study of Patient case files with the stipulations described below. Such studies raise issues of confidentiality that must be carefully addressed by the investigator and the official custodian of the records. If it is anticipated that an individual's records or specimens will likely be used for research purposes, the potential subject should be informed of the potential use of such materials upon entry into the institution or program in which the materials will be developed or collected and be given an opportunity to either provide or refuse consent to such research. Patient case files may always be used or disclosed for research purposes if it has been de-identified and linkage back to a specific patient would not be possible.

To use or disclose identifiable Patient case files without authorization of the research participant, the investigator must accomplish one of the following:

1) complete and submit an IEC Form to request waiver of the requirements for obtaining informed consent;
2) provide written documentation that the use of disclosure of patient case files is solely used to design a research protocol or to assess feasibility of conducting a study, or;
3) Document that the use or disclosure is solely for research on the patient case files of decedents.

Investigators must maintain in their files a letter from the IEC identifying the date on which the waiver or alteration of the requirements to obtain informed consent was approved by the IEC, and a statement that the IEC has determined that the waiver or alteration satisfies the following criteria:

1) The use or disclosure of patient case files involves no more than minimal risk to the research participants;
2) The alteration or waiver will not adversely affect the privacy rights and welfare of the subjects;
3) The research cannot practicably be conducted without the alteration or waiver;
4) The research could not practicably be conducted without access to or the use of the patient case files;
5) The privacy risks to individuals whose Patient case files is to be used or disclosed are reasonable in relation to the anticipated benefits, if any, to the individuals, and the importance of the knowledge that may reasonable be expected to result from the research;
6) There is an adequate plan to protect the identifiers from improper use and disclosure;

7) There is an adequate plan to destroy the identifiers at the earliest possible opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers, and;
8) There are adequate written assurances that the Patient case files will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of Patient case files would be permitted by this policy.

The IEC letter should also contain a brief description of the Patient case files for which use or access has been determined by the IEC to be necessary, a statement that the waiver or alteration was approved by Expedited Review or at a convened meeting, and the letter should be signed by the IEC Chair or the Chair's designee.

Research use or disclosure of identifiable Patient case files with authorization of the research participant is permitted providing that use or disclosure is for only the Patient case files that were originally authorized. In order to use or disclose additional information, the investigator would either have to obtain consent or request a waiver of the requirements to obtain consent.

APP10/V1

Guidelines for Research Protocols which require Collection and Storage of Genetics Materials

For the purpose of these guidelines, "Genetic Materials" are defined as human tissue samples (blood, serum, tumor, etc.) on which genetic related research, such as biochemical studies of inherited human traits or identification of DNA mutations, may be performed.

A. Previously acquired samples

i. Previously acquired genetic material may be used if identifiers are stripped irrevocably from samples.
ii. If identifiers are present, experiments not described in present protocols must be submitted for IEC review.

B. Prospectively acquired samples

1. Anonymous samples (further identification made impossible)

i. Ownership of genetic material will generally remain with the institution. This must be stated in the consent form.
ii. The general scope of the investigations must be explained in the consent form, but new avenues of investigation in the future are permissible if this possibility is explained in the consent form.
iii. Whether the genetic material will be shared by other investigators should be explicit in the consent form.
iv. The consent form should make clear that no specific information relative to the individual donor will be forthcoming; however, information that accrues from the study that is valuable to society may be shared with the individual.

2. Identified samples

i. if genetic material is linked to the donor by specific identifiers, ownership of the material will generally remain with the institution. If a commercial use is anticipated for the genetic material, the individual must be notified. The general policy of ownership should be stated in the consent form using the following wording:
"I understand that additional or "leftover" (blood, serum, tumor, etc.) tissue may be used for future research which may result in financial gain for SGMC and the researchers. I also understand that my donated tissue will be one of many that are used in the research and it will be virtually impossible to attribute findings to any one sample. I understand, however, that I am not otherwise waiving any of my legal rights by participating in this study."
ii. If identifiers are present, new experiments must be reviewed by the EC and new consent obtained from the research participant regardless of the details of ownership.
iii. The investigator may include a provision in the consent form for new experiments not requiring new consent if identifiers are irrevocably removed from the samples. If the investigator anticipates future experiments without identifiers, this possibility should be present in the original consent form. The methods for removal of identifiers must be approved by the EC. Removal of identifiers must not be employed as a method of avoiding ownership issues.

iv. A satisfactory method for sharing or withholding information gained by the research must be in the research protocol and clearly indicated in the consent form.
v. Details for sharing or not sharing the genetic material with other investigators must be present in the protocol and clearly indicated in the consent form.
vi. The length of time the genetic material will be maintained must be indicated in the consent form.

C. Donation of genetic material as a requirement for participation in a research protocol.

i. Donation of genetic material may be required for participation in a protocol only if the presence of the genetic material is necessary to satisfy the central question of the research.
ii. The investigator will be required to make a clear case in the research protocol for the necessity of the genetic material, if donation of genetic material is mandatory.
iii. This policy applies to genetic material with or without identifiers.APP11/V1

APP11/V1

Guidelines for Submission and IEC review of Gene Therapy /Gene Transfer Protocols

As of October 10, 2000 the ICMR formulated Ethical Guidelines for Biomedical Research on Human Subjects. ICMRs goal is to insure that no research participant is enrolled in a human gene therapy/gene transfer research protocol before the local IEC have the benefit of the broad perspective and experience in protocol review and risk assessment.

In November 2001, the Department of Biotechnology also finalized the Ethical Policies on the Human Genome, Genetic Research and Services.

Guidelines are available at the Office of Biotechnology Activities Internet site http://dbtindia.nic.in/ethical.html

The following items are required to be addressed in the protocol to provide the necessary information for IEC review:

A. Background and justification

i. Why is this disease a good candidate for gene transfer or gene therapy?
ii. What previous work has been done, including studies of animals and cultured cell models?
iii. Does the work demonstrate effective gene delivery? How does the proposed study relate to previous work?
iv. Is the disease course sufficiently predictable to allow for meaningful assessment of the results of the treatment proposed?
v. What level of gene expression is presumed to be required to achieve the desired effect?
vi. Given responses to the above questions, is there a sufficient justification for the investigator to proceed at this point to a clinical trial?

B. Research design

i. What are the objectives of the proposed study (e.g., establishing feasibility or relative safety of the gene transfer, determining therapeutic effectiveness, establishing a safe dose range, demonstrating proof of principle, etc.)?
ii. Is the goal of the study to ameliorate or cure disease or to enhance healthy individuals?
iii. What is the target tissue for gene transfer (e.g., bone marrow cells, skeletal muscle cells, respiratory epithelial cells, central nervous system tissue, etc.)?
iv. What method(s) (e.g., direct injection, inhalation, ex vivo genetic modification with injection of modified cells) and reagent(s) (e.g., vectors based on retroviruses, adenoviruses, adenoassociated viruses, herpes viruses) will be employed for gene delivery? What is the rationale for their

use? Are other methods or reagents known that are more appropriate with regard to efficacy, safety, and stability?

v. How will the investigator determine the proportion of cells that acquires and expresses the added DNA?
vi. How will the investigator determine if the product is biologically active?
vii. Is the planned statistical treatment appropriate: i.e., is it likely to provide valid answers to the study question?
viii. Is it reasonable to expect that the research design proposed will meet the investigator's objectives?

C. Procedures

i. What research-specific procedures and research-specific investigations are required by the study over and above those that would be required for patients receiving standard clinical care (e.g., physical examinations, venous or arterial blood tests, collection of target cells, imaging procedures, irradiation, chemotherapy, direct injection of vector, re-injection of genetically modified cells, organ or tissue transplantation, surgery, tissue/tumor donation, questionnaires, interviews)?
ii. Is long term follow-up appropriate or essential for this protocol? If long term follow-up is proposed, is there justification for the number of visits and the length of time required? Is such follow-up feasible in the case of this protocol (e.g., have provisions been made for subjects who move? Is adequate funding available for such follow-up?)?
iii. What are the procedures for obtaining or maintaining information in a data/DNA bank (e.g., use of identifiers, limitation on access, need for consent, sharing with other investigators, duration of storage, future subject contact)?
iv. Are all of the research-specific procedures necessary? In combination with data collected in the course of clinical care, is it reasonable to expect that the information produced by this study will be sufficient to answer the research question?

D. Confidentiality

i. Are the practical steps for maintaining confidentiality of data/records/database information clearly specified and adequate (e.g., encryption, use of unique identifiers, sequestering of records, security measures)?

E. Subject selection

i. How has the study population been defined?
ii. Has an adequate rationale been provided for each eligibility criterion (e.g., safety considerations, definition of disease, avoidance of additional concurrent therapies, administrative considerations)? Do they strike a defensible balance between scientific validity and generalizability (i.e., is the study population sufficiently, but not unduly, restricted so as to yield interpretable results)?

iii. How will subjects be recruited? If a cohort of eligible patients exists, how will selection be made amongst them? If several trials exist for which the same patients are eligible, how will this be presented to prospective subjects?
iv. Does the definition of the research population reflect appropriate scientific, clinical, and ethical norms? In recruiting and negotiating with potential subjects, have the norms of nondiscrimination been respected?

F. Risks, discomforts, and benefits

i. What risks and discomforts are associated with the research-specific procedures and investigations (e.g., surgery, chemotherapy, radiation, bone marrow transplantation)? Have they been minimized?
ii. If a virus-mediated gene transfer is proposed, what is the potential for the presence of a replication-competent or pathological virus or other form of contaminants? How sensitive are the tests to detect such viruses or contaminants? What level of viral presence or other form of contamination would be tolerable in this protocol?
iii. Has the possibility of vertical transmission (i.e., gene insertion into germ cells or a fetus) or horizontal transmission (e.g., to family members or health care staff) been considered? What measures have been taken to minimize the risks of transmission? Are other measures possible? If transmission were to occur, what would be the consequences?
iv. What are the risks for the vector to activate an oncogene or inactivate a tumor suppressor gene leading to vector-related malignancy?
v. Are the risks and discomforts of the study justified given the potential benefit to subjects and the scientific importance of the research?

G. Information to subjects

- Have prospective participants been adequately informed of the following:
  1. What is being studied and why, giving details about study procedures, known or potential risks, discomforts and benefits, and alternatives to participation;
  2. Their rights: (a) to information on an ongoing basis, confidentiality with regard to their participation and handling of their data, and the right to consult with others before making a decision whether to participate; and (b) to withdraw from the study without penalty or loss of benefits, as well as of any health consequences of withdrawal for themselves or their immediate contacts, or limitations on withdrawal, if any;
  3. Any special issues related to this gene therapy trial, such as uncertainty associated with short and long term risks and benefits or the possibility of media attention; and
  4. Any commercial or financial interests in the research.
- Have prospective participants been provided this information in simple language, using translation where necessary, with answers to their questions, referral to other sources of information, and adequate time to make up their minds whether to participate?
- If there is no individual benefit from participation in the research, has this been appropriately disclosed?
- Will the general study results be made available to subjects?

- Do all of the elements of the consent process combine to allow subjects a full opportunity to make an informed choice?

Reference: Ethical Guidelines for Biomedical Research on Human Subjects ICMR 2000

APP12/V1

Recommended Terms for use in Consent Forms

To facilitate understanding of consent forms by the subject, it is recommended that the language used is at a reading level of a 12 year old. The following lay terms, definitions and suggestions are recommended to help investigators in this process.

Abdominal	the body cavity containing the stomach, intestines, liver, and other organs
acute	new; recent; sudden
adjuvant	helpful; assisting; aiding
adverse effect	bad side effect
agitation	Upset
allergic reaction	itching and swelling; rash; trouble breathing
ambulate (-ation –ory)	walk; able to walk; ability to walk
ameliorate	make smaller or less, reduce
analgesia	pain relief
anaphylactic reaction	a severe and sometimes dangerous reaction which may cause problems breathing, fainting, itching and skin rash
anemia	low red blood cell count
anesthetic (local)	a drug used to decrease the feeling of pain by numbing an area of the body, without putting you to sleep
anesthetic (general)	a drug used to decrease the feeling of pain or eliminate the feeling of pain by putting you to sleep.
anorexia	lack of appetite
arrhythmia	abnormal heartbeat
aspiration	removal by using a sucking machine; fluid entering the lungs
asymptomatic	without symptoms; having no symptoms
barrier method	diaphragm and condom (with spermicide), cervical cap, or sponge
benign	not malignant; usually without serious consequences
bolus	an amount given all at once
bradycardia	slow heartbeat
carcinogenic	capable of causing cancer
carcinoma	a type of cancer
cardiac	heart
catheter	a tube in a vein for withdrawing or putting fluids into my blood
central nervous system	the brain and spinal cord
cerebral	the brain; of the brain
cessation	stopping
CHD	coronary heart disease; heart disease

chemotherapy	treatment of a disease, usually cancer, with chemical agents
chronic	continuing for a long time
clinical status	state of health, how you are doing and feeling
Clinical trial	an experiment in patients
completed	done
congenital	occurring prior to birth, due to parent's genetic input
conjunctivitis	irritation and redness of the thin covering of the eye
Consequences	result or effects
controlled trial	study in which the experimental treatment is compared to a standard treatment
conventional therapy	standard treatment
coronary	pertaining to the blood vessels that supply the heart
CT (CAT) scan	computerized series of x-rays
cutaneous	relating to the skin
culture	take a sample of blood, fluid, or tissue to see if bacteria or viruses can be found in it
dehydration	loss of fluids
dermatologic	pertaining to the skin
diastolic	the lower number in a blood pressure reading
dilation	expansion or stretching
discomfort	pain; uncomfortable feeling
disseminated	widely-spread, all through the body
distal	toward the end; away from the center of the body
diuretic	water pill; drug that causes an increase in urination
double-blind	neither the subject nor physician can know what is being given
dysfunction	improper function
dysplasia	abnormal cells
echocardiogram	sound wave test of the heart
edema	fluid in the tissues; puffiness; swelling
efficacy	producing a positive result
electrocardiogram	heart test; tracing of heartbeat or heart rhythm
emesis	vomiting
endoscopic	examination of the inside of the body with a lighted tube
epidural	outside the spinal cord
eradicate	get rid of
Erythrocyte	red blood cell
FDA	Food and Drug Administration; the branch of the government that approves new drugs
fibrillation	irregular heartbeat
fibrous	like scar tissue
gastrointestinal	stomach and intestines
granulocyte	white blood cell
hematocrit	number of red blood cells

hematoma	bruise; black and blue mark
Holter monitor	portable machine for recording heartbeats
hormonal therapy	treatment with hormones
hypertension	high blood pressure
hypotension	low blood pressure
hypoxia	low oxygen level in the blood
immunosuppressive	a drug or therapy that reduces the body's ability to fight infection; helps prevent rejection of a transplanted organ
incidence	number of times it happens
infarct	death of tissue due to loss of blood flow
infectious	occurrences infections
inflammation	swelling which is usually painful, red and warm
infusion	putting a substance into the body, usually into the blood
intravenous	putting it into the vein
intubate	the placement of a tube into the airway
ischemia	decrease in oxygen in a tissue, usually because of decreased blood flow
lactating	producing milk
laparotomy	a procedure where an incision is made in the abdominal wall to enable a physician to look at the organs
lethargy	sleepiness; lack of energy
lumen	cavity of an organ; inside a blood vessel
lymphocyte	a type of white blood cell important for defense against infections
malaise	feeling bad; a feeling of bodily discomfort
malignancy	cancer which usually spreads and may be fatal if not successfully treated
marrow suppression	decreased growth of the bone marrow
metastasis	spread of cancer cells from one part of the body to another
monoclonal antibody	very specific, purified antibody
morbidity	sickness/illness
mortality	death
motility	the ability to move
MRI	pictures of the body created using magnetic rather than x-ray energy
murine	obtained from mice
myalgia	muscle aches
myocardial infarction	heart attack
nasogastric tube	a tube from the nose to the stomach
necrosis	death of tissue
neoplasia	a tumor that may be cancerous or non-cancerous
neural	brain or nerves
neutropenia	decrease in white blood cells

non-invasive	not breaking, cutting or entering the skin
obviate	to prevent
occlusion	closing; obstruction
occult blood test	testing a stool sample for trace amounts of blood
Oncology	the study of tumors or cancer
Ophthalmic	pertaining to the eye
orthopedic	pertaining to bones
osteoporosis	bone disorder resulting from loss of bone leading to increased risk of fracture
ovaries	female sex glands that release the egg cells
pancytopenia	low number of blood cells
percutaneous	through the skin
perforation	puncture, tear or hole
phlebitis	irritation or inflammation of a vein
placebo	inactive medication; dummy pill; sugar tablet; containing no medication
platelets	blood cells that help the blood clot normally
post-	after
prenatal	before birth
probability	chance
prognosis	outlook, probably outcomes
prophylaxis	A drug given to prevent disease or infection
prosthesis	artificial body parts, such as arms, legs, hips
proximal	closer to the center of the body, away from the end
psychosis	major psychiatric problem
pulmonary	pertaining to the lungs
QID	four times a day
Radiotherapy	treatment with radiation
randomly assigned	similar to the toss of a coin; assignment to a treatment group by chance
recur	happen again
refractory	not responding to treatment
regimen	pattern of giving treatment
relapse	return or reappearance of a disease
remission	disappearance of evidence of cancer or other disease
renal	kidney
resect	remove or cut out surgically
respiratory failure	lung failure; stop breathing
somnolence	sleepiness
staging	a determination of the extent of the disease
stenosis	narrowing of a duct, tube, or blood vessel
stratify	arrange in groups by age, sex, etc., for analysis
subcutaneous	under the skin
subsequent	another, next
supine	lying on the back

symptomatic	having symptoms
syndrome	a condition with a certain set of symptoms
systolic	the top number in blood pressure
tachycardia	fast heart beat
taper	decrease; reduce
therapy	treatment
thrombosis	to get or have a blood clot in a blood vessel
titration	gradual alteration of a drug dose to get the desired effect
topical	applied to the skin
toxicity	harm; problem; poisoning; unwanted side effect
transdermal	through the skin
transient	short-term; brief
trauma	injury; wound
trial	study
uptake	taking a substance into the body and the cells
uremia	kidney failure
varices	enlarged veins, usually in the legs
vasodilation	widening of the blood vessels
vasospasm	narrowing of blood vessels due to a spasm of the vessel walls
vehicle	preparation placebo cream; inactive preparation
venipuncture	taking blood from the vein
via	by
waive	give up

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