Standard Operating Procedures of Institutional Ethics Committee of SSPHPGTI

July, 2019

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute, Noida

(An Autonomous Institute under Govt. of Uttar Pradesh)

Preface

Phone: +91-120-2455552
Fax: +91-120-2455561
E-mail: sspginoida@gmail.com
Website: www.sspginoida.ac.in

Prof. D.K. Gupta
M.S, M.Ch, FAMS, FRCS (Glas. &Edin.) FCS, D.Sc (H.C.)
Director, SSPHPGTI, Noida

It gives me immense pleasure to write preface for the first edition of SOPs (Standard Operating Procedures) for Institutional Ethical Committee, SSPHPGTI, Noida.

The Super Specialty Pediatric Hospital and Postgraduate Teaching have irreplaceable capability to provide high quality pediatric health care, postgraduate and postdoctoral teaching, training and research in various branches of pediatrics and pediatric surgery i.e., Developmental Disorder, Inborn errors, infectious diseases, and pediatric tumors etc.

"Ethics" are fretful with the difference between true and erroneous, with right choice, duty and obligation. Looking into the olden times, ethics in remedial practice were addressed in Charaka Samhita in 1600 BC which also point out the code of ethical conduct. As per the WHO definition also, a clinical research study that prospectively assign human participant to one or more health related interventions to evaluate the effects on health outcome.

So, to maintain the welfare and the human rights of the participants it is compulsory that all proposals on biomedical research involving human participants/intervention should be cleared by an appropriately constituted Institutional Ethics Committee (IEC) for an effective & biasness ethical review mechanism.

I would like to thanks the Chairman and Members of the Institutional Ethics Committee, for their enormous effortfor preparing the user friendly Standard Operating Procedure (SOP) of Institutional Ethical Committee, SSPHPGTI.

(Prof. D.K. Gupta)
Director, SSPHPGTI, Noida

Foreword

Prof. T. P. Singh
Emeritus Scientist, Biophysics
AIIMS, New Delhi

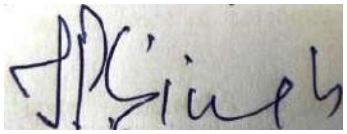
Phone: +91-120-2455552
Fax: +91-120-2455561
E-mail sspginoida@gmail.com
Website: www.sspginoida.ac.in

It gives me an immense pleasure to announce that we have successfully finalised the Standard Operating Procedures (SOP's) for the Institutional Ethics Committee for Intramural and Extramural Projects for the Principal Investigators.

The Super Specialty Pediatric Hospital and Postgraduate Teaching Institute (an autonomous Institute under the Govt. of UP), located in Sector 30, Noida, is a unique facility conceptualized at par with the western children hospitals to provide high quality pediatric health care, postgraduate and postdoctoral teaching, training and research.Hence, there is a need to constitute anInstitutional Ethics Committee for high end translational research in the area of Pediatricdiseases. So, the objective of the Standard Operating Procedure (SOP) of IEC is to put in place an effective ethical review mechanism for approval of health and Biomedical Research for all the proposals submitted by the Principal Investigators of this Institute.

The primary responsibility is to ensure that the standard of Research performed at this Institute within the existing frame work is ethically acceptable or not. This document will help the investigators to prepare the proposals for ethical clearance. However, the SOPs should be revised and up dated as and when such a need arises.

I would like to thank the Members of the Institutional Ethics Committee, for their help in preparing the Standard Operating Procedure (SOP) with the hope that, Principal Investigators & Researchers will find them user friendly.



Prof. T. P. Singh
Chairman IEC, SSPHPGTI, Noida

Acknowledgement

Dr. Mukesh Kumawat
Associate Prof., CTVS
SSPHPGTI, Noida

Phone: +91-120-2455552
Fax: +91-120-2455561
E-mail sspginoida@gmail.com
Website: www.sspginoida.ac.in

The research activities has been started for more than two years in this Institute, therefore, there was a need to form "**Standard Operating Procedures**" ofIEC for Principal Investigators to maintained the standard and quality of the research of the Institute.

Herewith, I express my gratitude & sincere thanks to the **PatronProf. D. K. Gupta**, **Director, SSPHPGTI, Noida-30**, for giving us the opportunity & constant motivation to frame the SOP's of Institutional Ethics Committee- SSPHPGTI. The development of the SOP documents started in the January 2019 and just within six months, it has been prepared & approved by the IEC members in first meeting of IEC held on 20 July 2019 for its implementations.

I wish to thanks, all the IEC members of this Institute for their valuable contributions, without which this great achievement would not have been achieved.Special thanks to **Chairman**, IEC, **Prof. T. P. Singh** for his guidance and valuable inputs in finalization of SOPs. We are also grateful to Prof. Jyotsna Madan, Dean, SSPH&PGTI for her immense support and contribution. We appreciate & acknowledge the special contributionat the outset by Dr Ruchi Rai and Dr Ankur Agrawal in framing of SOPs.

We hope that these new SOPs for the functioning of IEC would be useful for upholding the procedures for conduct of ethical practices in research at our Institute.

(**Dr Mukesh Kumawat**)
Member Secretary IEC, SSPHPGTI,Noida

Institutional Ethics Committee

Super Specialty Pediatric Hospital & Postgraduate Teaching Institute
(IEC, SPHPGTI)

SOPs Approved by:

Name	Position In the IEC	Signatures with date
Prof. T. P. Singh Biophysics [Emeritus Scientist], AIIMS, New Delhi.	Chairperson	20/7/2019
Dr. Mukesh Kumawat Associate Professor, CTVS, SSPH&PGTI, Noida	Member Secretary	20/7/19
Mr. P. N. Aggarwal IPS Retd. ~~Additional~~ Special Commissioner	Member [NGO Representative]	20/7/19
Mr. Mukesh Chandra Ret. Chief Engineer, UP Government	Member [Representative from Society]	
Dr. Satendra Kumar HOD Surgery Dept. GIMS, Kasna, GN	Member	
Dr. Shilpa Sharma Associate Professor, Dept. of Paediatric ~~Cardiac~~ Surgery, AIIMS, New Delhi.	Member	20/7/19
Miss. Ruchira Gupta Advocate High Court, New Delhi.	Member [Legal Advisor]	20/7/19
Dr. Bhanu K. Bhakhri Associate Professor, Paediatric Medicine, SSPH&PGTI, Noida	Member	
Dr. Usha Bindal Assistant Professor, Biochemistry, SSPH&PGTI, Noida	Member	
Dr. Ankur Agrawal Assistant Professor, Dept. of Orthopedics, SSPH&PGTI, Noida	Faculty from Institute-SSPH&PGTI	

SOP's Accepted by: **Director**
SSPH&PGTI, Noida-30

Contents

Sr. No.	Titles	Page. No
	List of Abbreviations	x
	Bibliography	xii
	Glossary	xiii
1.	**Chapter 1**	**SOP 01/V1**
	Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing & Amending SOPs for the Institutional Ethics Committee	01
1.1	Responsibilities	01
1.2	Detailed Instructions	03
1.2.1	Identifying the need for new or amendment to SOP	03
1.2.2	List of relevant SOPs	03
1.2.3	Designing a format and layout	04
1.2.4	Review by consultation	04
1.2.5	Preparation and submission of final draft	04
1.2.6	Final approval of new and revised SOP	04
1.2.7	Implementation, distribution and filing all SOPs	05
1.2.8	Management and archiving of superseded SOPs	05
	Annexures	
	AN1-V1/SOP-01/V1 List of SOPs of Institutional Ethics Committee	06
	AN2-V1/SOP-01/V1 Template for SOP	07
	AN3-V1/SOP-01/V1 Document History of the SOPs	08
	AN4-V1/SOP-01/V1 Log of the IEC Members Receiving Printed Copy of SOPs	09
	AN5-V1/SOP-01/V1 Request for Formulation of New SOP/Revision of SOP	10
	AN6-V1/SOP-01/V1 Log of Printed Copy of SOP Recipients	12
	Flow Chart	12
2.	**Chapter 2**	**SOP 02/V1**
	Constitution of Institutional Ethics Committee	13
2.1	Mandate	13
2.2	Responsibility	14
2.3	Ethical basis	14
2.4	Composition	15
2.5	Terms of appointment	16
2.5.1	Duration and renewal	16
2.5.2.	Condition of appointment	16
2.5.3	Resignation/replacement procedure	17
2.5.4	Termination/disqualification	17
2.6	Independent consultants	17
2.7	Office bearers	17
2.7.1	Chairperson	18

Sr. No.	Titles	Page. No
2.7.2	Member Secretary	18
2.7.3	The Bioethics cell	18
2.8	Roles and responsibilities of the IEC members	19
2.9	Quorum requirements	19
2.10	Decision making	19
2.11	Education and training for IEC members	20
2.12	IEC Subcommittees'	20
2.12.1	Expedite review committee	20
2.12.2	Three-member subcommittee	20
2.12.3	SAE Subcommittee	20
	Annexures	
	AN1-V1/SOP-02/V1 Confidentiality and Conflict of Interest Document Form for IEC Members	21
	AN2-V1/SOP-02/V1 Confidentiality Document Form for Independent Consultants	23
	AN3-V1/SOP-02/V1 Invitation to Attend a Meeting as Independent Consultant	24
	AN4-V1/SOP-02/V1 Invitation to Attend a Meeting as Observer	25
	AN5-V1/SOP-02/V1 Confidentiality Document form for Observer Attendees	26
	AN6-V1/SOP-02/V1 Confidentiality Document Form for Non-members Requesting Copies of IEC/Documents	27
	AN7-V1/SOP-02/V1 CV for Members of the Institutional Ethics Committee	28
	AN8-V1/SOP-02/V1 List of Members of Institutional Ethics Committee	29
	AN9-V1/SOP-02/V1 Confidentiality Document Form for Faculty/Observer visiting Bioethics Cell	30
	AN10-V1/SOP-02/V1Conflict of Interest Declaration for IEC Members (During IEC meeting)	31
	Flow Chart	32
3.	**Chapter 3**	**SOP 03/V1**
	Management of Protocol Submissions	33
3.1	Type of protocols	33
3.2	Detailed process	33
3.2.1	Receiving Protocols	33
3.2.2	Bioethics Cell	33
3.2.3	Documents to be submitted for initial review	34
3.3	Informed consent process	36
3.4	Information of change in funding agency/status of approved project	37
3.5	Resubmission of protocols with corrections as per IEC suggestions	37
3.6	Research protocol amendments and other study related documents	37
3.7	Annual continuing review of approved protocols	37
3.8	Protocol completion	38
3.9	CTA / other agreements for sponsored Drug/ Device /Collaborative trials/ studies	38
3.10	Charges	38

Sr. No.	Titles	Page. No
3.11	reporting of SAE / Protocol violation/amendment	38
3.12	Site Monitoring Procedures	38
	Annexures	
	AN1-V1/SOP-03/V1 Project Submission Application Form for Review by IEC	39
	AN2-V1/SOP-03/V1 Consent of Head of the PI's Department	46
	AN3-V1/SOP-03/V1 Research Committee/Department/Doctoral Committee/ Scientific Committee /M. D Protocol Committee Approval	47
	AN4-V1/SOP-03/V1 Undertaking by the Principal Investigator	48
	AN5-V1/SOP-03/V1 Conflict of Interest Declaration by PI	50
	AN6-V1/SOP-03/V1 CV of new or investigator outside SSPHPGTI or of the student	51
	AN7-V1/SOP-03/V1 Guidelines for devising a Participant / Legally acceptable representative Information Document (PID) in English	52
	AN8-V1/SOP-03/V1 Consent Form (English)	57
	AN9-V1/SOP-03/V1 Guidelines for devising a Participant / legally acceptable representative Information Document (PID) in Hindi	58
	AN10-V1/SOP-03/V1 Consent Form (Hindi)	61
	AN11-V1/SOP-03/V1 Child Information Document	62
	AN12-V1/SOP-03/V1 Child Assent Form	64
	AN13-V1/SOP-03/V1 Child Assent Form (Hindi)	65
	AN14-V1/SOP-03/V1 Checklist of Documents	66
	AN15-V1/SOP-03/V1 IEC Document Receipt form	68
	Flow Chart	70
4	**Chapter 4**	**SOP 04/V1**
	Initial Review of Submitted Protocol	71
4.1	Purpose	71
4.2	Scope	71
4.3	Categorization of protocols	72
4.3.1	Exemption from review	72
4.3.2	Expedited review	72
4.3.3	Full committee review	72
4.4	Elements of review	73
4.4.1	Scientific design and conduct of the study	73
4.4.2	Care and protection of research participants	74
4.4.3	Protection of research participant confidentiality	74
4.4.4	Participant information document and consent process	74
4.4.5	Community considerations	74
4.4.6	Recruitment of research participants	74
4.4.7	Risk - Benefit Analysis	74
4.5	Responsibility	76
4.6	Detailed instructions	76
4.7	Review of protocol	77

Sr. No.	Titles	Page. No
4.8	Study assessment forms	77
4.9	Collection of assessment reports	77
4.10	At IEC meeting	77
	Annexures	
	AN1-V1/SOP-04/V1 Letter to IEC Members Requesting Initial Review with Study Assessment Form	78
	AN2-V1/SOP-04/V1 Study Assessment Form	79
	Flow charts	82
5.	**Chapter 5**	**SOP 05/V1**
	Exemption from Ethical Review for Research Projects	83
5.1	Purpose and scope	83
5.2	Type of protocol for exemption from review	83
5.3	Responsibility	84
5.4	Detailed instructions	84
5.4.1	Receive the submitted documents	84
5.4.2	Exemption process	84
	Annexures	
	AN1-V1/SOP-05/V1 Review Exemption Application form	85
	AN2-V1/SOP-05/V1 Decision of IEC Regarding Exemption from the Ethical Review	86
	Flow Chart	87
6.	**Chapter 6**	**SOP 06/V1**
	Agenda Preparation, Meeting Procedures and Recording of Minutes	88
6.1	Responsibility	88
6.2	Detailed instruction	88
6.2.1	Agenda for full board IEC meeting	88
6.2.2	Distribution of protocol/ documents to the IEC members	88
6.2.3	Preparation for the meeting	88
6.2.4	Conduct of meeting	88
6.2.5	Decision making process	89
6.2.6	After the IEC meeting	90
6.2.6 A	Preparing the minutes and the decision letters	90
6.2.6 B	Approval of the minutes and the decision	90
6.2.6 C	Filing of the minutes of the meeting	90
6.2.7	Communicating decision	90
	Annexures	
	AN1-V1/SOP-06/V1 Agenda Format	92
	AN2-V1/SOP-06/V1 Format for Approval Letter of Ethics Committee	93
	AN3-V1/SOP-06/V1 Format for Communication of IEC decisions	96

Sr. No.	Titles	Page. No
	AN4-V1/SOP-06/V1 Format for Three-Member subcommittee of IEC Approval for Project	97
	AN5-V1/SOP-06/V1 Intimation of Start of Study	98
	Flow Chart	99
7.	**Chapter 7**	**SOP 07/V1**
	Review of Amendments/Notification	100
7.1	Procedures	100
7.1.1	Receipt of amended protocol	100
7.1.2	Review of amended protocols/documents/letters	100
7.1.3	Minor amendment and notification	100
7.2	Decision	100
7.3	Storage of documents	101
	Annexures	
	AN1-V1/SOP-07/V13 Amendment Reporting Form	102
	AN2-V1/SOP-07/V1 Project Amendment/Document Amendment Approval Letter	103
	AN3-V1/SOP-07/V1 Format for Project Amendment/ Approval letter	104
	Flow Chart	105
8.	**Chapter 8**	**SOP 08/V1**
	Continuing Review of Study Protocols	106
8.1	Responsibility	106
8.2	Procedures	106
8.3	Decision making	106
8.4	Communicate the IEC decision to the Principal Investigator	107
	Annexures	
	AN1-V1/SOP-08/V1 Continuing Review Application Form/Annual Status Report Form (For Interventional Study)	108
	AN2-V1/SOP-08/V1 Continuing Review Application Form/Annual Status Report Form (For Non-Interventional Study)	112
	AN3-V1/SOP-08/V1 Reminder Letter by the IEC to PI	113
	AN4-V1/SOP-08/V1 IEC Decision on Continuing Review Report	114
	AN5-V1/SOP-08/V1 Project Annual Report Approval Letter	115
	Flow Chart	116
9.	**Chapter 9**	**SOP 09/V1**
	Reporting of Protocol Deviation/Non-Compliance/Violation/Waiver	117
9.1	Responsibility	117
9.2	Detailed instructions	117
9.2.1	Detection of protocol deviation/non-compliance/violation /waiver	117
9.2.2	Noting protocol deviation/non-compliance/violation/waiver by the Bioethics cell	118
9.2.3	Board discussion, decision, and action	118

Sr. No.	Titles	Page. No
9.3	Notifying the investigator	119
9.4	Records and follow up by the Bioethics cell	119
	Annexures	
	AN1-V1/SOP-09/V1 Deviation/Non-Compliance/Violation/Waiver Reporting Form	120
	AN2-V1/SOP-09/V1 Form for communicating decision of Deviation/Non-Compliance /Violation / Waiver to PI	121
	Flow Chart	122
10.	**Chapter 10**	**SOP 10/V1**
	Review of Adverse Events (AE) Reports	123
10.1	Purpose	123
10.2	Scope	123
10.3	Responsibility	123
10.4	Detailed instructions	124
A.	*On site SAEs*	124
10.4.1	SAE related activities before IEC meeting	124
10.4.2	Actions to be taken by Member Secretary, IEC	124
10.4.3	Actions to be taken by SAE subcommittee	124
10.4.4	Actions to be taken by Chairperson, IEC	124
B.	*Off site SAEs*	125
10.5	During the IEC meeting	125
10.6	After the review of SAE	126
10.7	Timelines	126
	Annexures	
	AN1-V1/SOP-10/V1 Adverse Drug Event Reporting Form	128
	AN2-V1/SOP-10/V1 Form to Record Recommendations by IEC	131
	AN3-V1/SOP-10/V1 Off Site Safety Reports Classification Form	132
	AN4-V1/SOP-10/V1 Off Site Safety Reports Log	133
	AN5-V1/SOP-10/V1 Form to Record SAE assessment by SAE monitoring subcommittee	134
	Flow Charts	135
11.	**Chapter 11**	**SOP 11/V1**
	Review of Study Completion Reports	137
11.1	Responsibility	137
11.2	Detailed instructions	137
11.2.1	Before board meeting	137
11.2.2	During board meeting	137
11.2.3	After board meeting	137
	Annexures	
	AN1-V1/SOP-11/V1 Study Completion Report Form (For Interventional Study)	138
	AN2-V1/SOP-11/V1 Study Completion Report Form (For Non-Interventional	140

Sr. No.	Titles	Page. No
	Study)	
	AN3-V1/SOP-11/V1 Notification for Acceptance of Study Completion Reports	141
	Flow Chart	142
12.	**Chapter 12**	**SOP 12/V1**
	Management of Premature Termination/Suspension/Discontinuation of the Study	143
12.1	Responsibility	143
12.2	Detailed instructions	143
12.2.1	Receiving recommendation for study termination/suspension/discontinuation	143
12.2.2	Review and discussion of termination / suspension/discontinuation report	143
12.2.3	Notifying the PI	144
	Annexures	
	AN1-V1/SOP-12/V1 Premature Termination/Suspension/Discontinuation Report	145
	AN2-V1/SOP-12/V1 Notification from IEC for Premature Termination/Suspension/ Discontinuation of the Study	146
	Flow Chart	147
13.	**Chapter 13**	**SOP 13/V1**
	Request for Waiver of Written Informed Consent	148
13.1	Type of research projects which may qualify for consent waiver	148
13.2	Detailed instructions	149
	Annexures	
	AN1-V1/SOP-13/V1 Application Form for requesting Waiver of Consent	150
	AN2-V1/SOP-13/V1 Decision of IEC Regarding Waiver of Consent	151
	Flow Chart	152
14.	**Chapter 14**	**SOP 14/V1**
	Maintenance of Active Project Files, Archival of Closed Files and Retrieval of Documents	153
14.1	Responsibility	153
14.2	Maintenance of the active study files	153
14.3	Accessibility/retrieval	153
14.4	Disposal of closed files and copies of protocols and documents	153
	Annexures	
	AN1-V1/SOP-14/V1 Document Request Form	154
	AN2-V1/SOP-14/V1 Format of Written Off Register	155
	Flow Chart	156
15.	**Chapter 15**	**SOP 15/V1**
	Documentation of the IEC Activities	157
15.1	Responsibility	157
15.2	Detailed instructions	157
15.2.1	IEC records	157

Sr. No.	Titles	Page. No
15.2.2	Access to IEC records	157
	Annexures	
	AN1-V1/SOP-15/V1 Request /Compliance Form	158
	AN2-V1/SOP-15/V1 Log of Requests for Copies of IEC Documents	159
	Flow Chart	160
16.	**Chapter 16**	**SOP 16/V1**
	Dealing with Research Participants' Requests and Complaints	161
16.1	Responsibility	161
16.2	Detailed instructions	161
16.3	Filling the request document	162
	Annexures	
	AN1-V1/SOP-16/V1 Request Record Form	163
	Flow Chart	164
17.	**Chapter 17**	**SOP 17/V1**
	Site Monitoring and Post- Monitoring activities	165
17.1	Purpose	165
17.2	Scope	165
17.3	Responsibility	165
17.4	Detailed instructions	165
17.4.1	Selection of study sites	165
17.4.2	Before the visit	166
17.4.3	During the visit	166
17.4.4	After the visit	167
	Annexures	
	AN1-V1/SOP/7/V1 Site Monitoring visit report.	169
	AN2-V1/SOP17/V1 Monitoring of audio-visual recording of AV consent process	175
	Flow Chart	177
	Appendices	178
AP1/V1	Policy on the Recruitment of Research Participants	179
AP2/V1	Policy on Research Costs to Participants	181
AP3/V1	Guidelines on Compensation for Research Participants	182
AP4/V1	Policy on the Use of Third Party/Surrogate Consent in Research at SSPHPGTI	183
AP5/V1	Guidelines on Blood Withdrawal for Research Purposes	184
AP6/V1	Guidelines and Policy on Participant Information Documents and Consent Form	186
AP7/V1	Examples of PID (Hindi and English in Non-interventional studies)	187
AP8/V1	Health Record Research	188

Sr. No.	Titles	Page. No
AP9/V1	Guidelines for Research Protocols That Require Collection and /or Storage of Genetic Material	190
AP10/V1	Guidelines for Submission and EC Review of Gene Therapy/Gene Transfer Protocols	192
AP11/V1	Ethical Policies on the Human Genome, Genetic Research and services, DBT, Ministry of Science and Technology, Govt. of India.	193
AP12/V1	Recommended Terms for Use in Informed Consent Documents	194
AP13/V1	Good Clinical Practices for Clinical Research in India (Essential documents for the conduct of a clinical trial) by Central Drugs Standard Control Organization, Directorate General of Health Services, New Delhi, 2001	197
AP14/V1	Declaration of Helsinki Seoul, October 2013	198
AP15/V1	IND Application Exemption Checklist	199
AP16/V1	Clinical Trial Registry-India	200
AP17/V1	Guidelines for Stem Cell Research and Therapy	201
AP18/V1	Guideline for Medical Device Related Studies	202

LIST OF ABBREVIATIONS

Acronym	Full Title/Description
AAHRPP	Association for the Accreditation of Institutional Research Protection Programs
ADR	Adverse Drug Reaction
AE	Adverse Event
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
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
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
CTRI	Clinical Trial Registry India
GMP	Good Manufacturing Practices
IEC	Institutional Ethics Committee
HIPAA	Health Insurance Portability and Accountability Act
HMSC	Health Ministry Screening Committee
IAEA	International Atomic Energy Agency
IB	Investigator's Brochure
CF	Consent Form
ICH	International Committee on Harmonization
ICMR	Indian Council of Medical Research
IDE	Investigational Device Exemption
IMDRA	Indian Medical Devices Regulatory Authority

IND	Investigational New Drug
IRB	Institutional Review Board
ISI	Indian Standards Institute
MOU	Memorandum of Understanding
MTA	Material Transfer Agreement
NAC-SCRT	National Apex Committee for Stem Cell Research and Therapy
NDA	New Drug Application
NIH	National Institutes of Health
NOC	No-objection Certificate
OHRP	Office for Institutional Research Protections
PI	Principal Investigator
PID	Participant Information Document
RCT	Randomized Controlled Trial
SAE	Serious Adverse Event
SOPs	Standard Operating Procedures
SRC	Scientific Review Committee
SSPHPGTI	Super Specialty Pediatric Hospital & Post Graduate Teaching Institute
WHO	World Health Organization
WMA	World Medical Assembly

BIBLIOGRAPHY

1. Good Clinical Practices for Clinical Research in India by Central Drugs Standard Control Organization, New Delhi, (Available at: http://www.cdsco.nic.in/html/GCP1.html)
2. National Ethical guidelines for biomedical and health research involving human participants. Indian Council of Medical Research 2017. (Available at:http://ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.pdf)
3. National ethical guidelines for bio-medical research involving children, Indian Council of Medical Research, 2017. (Available at: http://www.icmr.nic.in/guidelines/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf)
4. Ethical guidelines for biomedical research on human subjects. New Delhi: Indian Council of Medical Research; 2000.
5. Ethical guidelines for biomedical research on human participants. New Delhi: Indian Council of Medical Research; 2006.
6. Schedule Y, Drugs And Cosmetics act 1940; amendment 20th January 2005, Ministry Of Health and Family Welfare, Govt. of India.
7. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
8. CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, 1993.
9. European Convention on Human rights and Biomedicine, 1997
10. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
11. Declaration of Helsinki: ethical principles for medical research involving human subjects. Fortaleza: World Medical Association. 2013 (Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethicalprinciples-for-medical-research-involving-human-subjects/)
12. Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10", Vol. 2, pp. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949.
13. The Belmont Report, Ethical Principles and Guidelines for the protection of human subjects of research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research April 18, 1979, Department of Health, Education, and Welfare.
14. Schedule M III, Drugs and Cosmetics act 1940; amendment 20th January 2005, Ministry of Health and Family Welfare, Govt. of India.
15. NABH Guidebook to standards for accreditation of Ethical Committees (1st ed., 2015).

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.

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

Assent: To agree or approve after thoughtful consideration an idea or suggestion to participate in research by a young person below the age of 18 years who is old enough to understand the implications of any proposed research but not legally eligible to give consent. The assent has to be corroborated with informed consent of parent/LAR.

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

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

Clinical trial: As per amended Schedule Y (2005) of the Drugs and Cosmetics Rules, 1945, a clinical trial refers to a systematic study of new drugs in human subjects to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and /or adverse effect with the objectives determining safety and/or efficacy of a new drug. The academic clinical trial as per GSR 313 (e) dated 16 March 2016 is a clinical trial intended for academic purposes in respect of approved drug formulations for any new indication or new route of administration or new dose or new dosage form.

Confidentiality: Keeping information confidential which an individual has disclosed in a relationship of trust and with the expectation that it shall not be divulged to others without permission.

Also- prevention of disclosure, to other than authorized individuals, of information and documents related to IEC.

Compensation: Provision of financial payment to the research participants or their legal heirs when temporary or permanent injury or death occurs due to participation in biomedical and health research.

CRF: Case Report Form (CRF); in a clinical trial, the document showing all the evaluated patient data.

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

Exemption from review: A research study is said to be exempt from review when it does not require the Ethics Committee approval for its conduct

Expedited review/meeting: A review process for a revised document not needing major alteration by 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 by the Member Secretary/committee as decided by IEC.

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

IEC members: Individuals serving as regular members of the Institutional Ethics Committee, SSPHPGTI.

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

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

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

Institutional Ethics Committee (IEC): It is an independent body whose responsibility is to ensure the protection of the rights, safety, dignity and well-being of human subjects involved in a clinical trial and to provide public assurance of that protection

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

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

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

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

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

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

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

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

Master SOP files: An official collection of the Standard Operating Procedures (SOP) of IEC, SSPHPGTI 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 on first page.

Minimal risk: means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (US-FDA 2014).

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

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

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.

Post-marketing surveillance: The practice of monitoring the safety of a pharmaceutical drug or medical device after it has been released on the market. This is an important part of the science of pharmacovigilance.

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

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

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

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

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

Revision date: Date/year on 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.

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

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

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

SOP Effective date: The date of approval of the SOPs signed and dated by the Chairperson, IEC, acceptance by the Director, SSPHPGTI, and subsequently the SOP is implemented after 2 weeks of that date.

SOP Team: A team of members including the Member Secretary, administrative staff, and any other member of IEC as identified by the chairperson which oversees the creation, preparation, review, or revision of the designated IEC, SSPHPGTI SOP.

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

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

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.

Violation: The act of doing something that is not allowed by approved study protocol.

The IEC monitors whether investigators do not perform the study in compliance with the approved protocol, national regulations and/or fail to respond to the IEC request for information/action

Standard Operating Procedures of Institutional Ethics Committee;

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SOPs, IEC, SSPHPGTI)

Title : Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing and Amending SOPs for the Institutional Ethics Committee

SOP Code: SOP-01/V1 : Date: 20/07/2019

- Responsibilities of IEC for preparing/revising SOPs
- Instructions for amendment, approval and implementation of SOPs

These Standard Operating Procedures (SOPs) define the process for writing, reviewing, distributing, and amending SOPs of the Institutional Ethics Committee (IEC), SSPHPGTI. This SOP covers the procedures of writing, reviewing, distributing, and amending SOPs within SSPHPGTI.

1.1 Responsibilities

It is the responsibility of Chairperson of the IEC to appoint a **SOP team (Bioethics Cell)** to formulate the SOP. SOP team drafts SOP, gets it reviewed and approved by the IEC members and amends it as and when required. All members of IEC will review the SOP and approval will be given by **Chairperson of IEC**. The SOPs shall then be accepted by the **Director, SSPHPGTI.**

Bioethics cell will:

- Co-ordinate activities of writing, reviewing, distributing, and amending SOPs.
- Maintain on file all current and past SOPs and the list of SOPs.
- Maintain 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 requisition.
- Ensure all IEC members and involved administrative staffs have access to the SOPs.
- Ensure the IEC members and involved staffs are working according to current version of SOPs.
- Assist in the formulation of SOP procedures.
- Ensure availability of current SOPs on Institute website.

SOP team

A team of members including the Member Secretary, administrative staff, and any other member of IEC as identified by the chairperson which oversees the creation, preparation, review, or revision of the designated IEC, SSPHPGTI SOP.

The Chairperson will constitute an SOP team consisting of the Member Secretary and one or more members of the IEC and/or the Bioethics cell. The SOP team will carry out the subsequent steps.

- Assesses the request(s) for SOP revision in consultation with the Bioethics cell and Chairperson.
- Proposes new/modified SOPs as and when required.
- 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 (AN -).
- Selects the format and coding system for SOPs.

These Standard Operating Procedures (SOPs) define the process for writing, reviewing, distributing, and amending SOPs of the Institutional Ethics Committee (IEC), SSPHPGTI. This SOP covers the procedures of writing, reviewing, distributing, and amending SOPs within SSPHPGTI.

1.2 Responsibilities

It is the responsibility of Chairperson of the IEC to appoint a **SOP team (Bioethics Cell)** to formulate the SOP. SOP team drafts SOP, gets it reviewed and approved by the IEC members and amends it as and when required. All members of IEC will review the SOP and approval will be given by **Chairperson of IEC**. The SOPs shall then be accepted by the **Director, SSPHPGTI.**

Bioethics cell will:

- Co-ordinate activities of writing, reviewing, distributing, and amending SOPs.
- Maintain on file all current and past SOPs and the list of SOPs.
- Maintain 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 requisition.
- Ensure all IEC members and involved administrative staffs have access to the SOPs.
- Ensure the IEC members and involved staffs are working according to current version of SOPs.
- Assist in the formulation of SOP procedures.
- Ensure availability of current SOPs on Institute website.

SOP team

A team of members including the Member Secretary, administrative staff, and any other

member of IEC as identified by the chairperson which oversees the creation, preparation, review, or revision of the designated IEC, SSPHPGTI SOP.

The Chairperson will constitute an SOP team consisting of the Member Secretary and one or more members of the IEC and/or the Bioethics cell. The SOP team will carry out the subsequent steps.

- Assesses the request(s) for SOP revision in consultation with the Bioethics cell and Chairperson.
- Proposes new/modified SOPs as and when required.
- 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 (AN -).
- Selects the format and coding system for SOPs.
- Drafts the SOP in consultation with the IEC members and involved administrative staff.
- Review of draft SOP by IEC.
- Submit the draft for approval to Chairperson.

Chairperson of the ethics committee:

- Appoints 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 Bioethics cell.

1.3 Detailed instructions

1.3.1 Identifying the need for new or amendment to SOP

Any member of the IEC, faculty members, or investigators, can make a request for revision or renewal of an inconsistency/discrepancy in the existing SOPs or requests to design new SOP through a request form (AN-). This form is submitted to the Member Secretary, IEC. If IEC members agree to the request, the Chairperson will appoint SOP team to revise/formulate the SOP. If IEC members do not agree to the request, no further action will be taken. The IEC member who made the request for modification of the SOP will be informed in writing by the Member Secretary about the decision.

1.3.2 List of relevant SOPs

The SOP team will:

- 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 (AN - ……).

1.3.3 Designing a format and layout

- Each SOP should be given a number and a title that is self-explanatory and is easily understood. Each SOP will be prepared according to the template for Standard Operating Procedures in AN - . Each page of the SOP will bear a header with the effective date. 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. A unique code number with the format SOP xx/Vy will be assigned to each SOP by the Bioethics cell. xx will be a two-digit number assigned specifically to a SOP. "V" refers to version of the SOP and "y" will be a number identifying the version e.g. SOP -01/V1 is SOP number 01 with V=version no.1.
- Each Annexure (AN) will be given unique code number with the format ANn-Vp/SOP xx/Vy. e.g. AN1–V1/SOP01/V1 indicates AN is Annexure; n is Annexure no.1, V1 is version no. 2, belonging to the SOP 01/V1.
- Each Appendix (AP) will be given unique code number with the format APn/Vy e.g. AP1/V1indicates AP is Appendix, n is Appendix no 1, V1 is version no.2.
- The first page of SOP document will be signed and dated by the SOP team members, the IEC members who have reviewed the SOPs, IEC Chairperson who has approved and Director, SSPHPGTI who has accepted the SOPs. The SOP will be implemented within 2 weeks after acceptance by the Director.

1.3.4 Review by consultation

- The draft SOP will be discussed with members of IEC, administrative staff and relevant faculty members.
- The final draft version will be forwarded to the Chairperson for review and approval by IEC.

1.3.5 Preparation and submission of final draft

- All the members of IEC will review the draft/revised SOP.
- During the IEC meeting, 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 dissolved once the IEC takes final decision regarding the SOP.

1.3.6 Final Approval of new/revised SOP

- The final version of SOP duly approved by the IEC will be signed by the chairperson and

accepted by the Director, SSPHPGTI.

- Two weeks after the date of acceptance by the Director is declared as the effective date for implementing the SOP.

13.7 Implementation, distribution, and filing all SOPs

- Approved SOPs will be implemented from the effective date and will be distributed to IEC members and IEC staff according to the distribution list (AN4-V1/SOP 01/V1).
- One complete original set of current SOPs will be archived in the SOP master file, by the Bioethics cell and maintained in the IEC Office (Bioethics cell). Photocopies made from the 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 (AN6-V1/SOP 01/V1).
- SOPs are made available to all Investigators on Institute website.

13.8 Management and archiving of superseded SOPs

Old SOPs should be retained and clearly marked "superseded" and archived in a file by the Bioethics cell. The process of evolution of previous SOPs of the IEC will be documented in defined format (AN3-V1/SOP01/V1)

AN1-V1/SOP 01/V1

List of SOPs of Institutional Ethics Committee

Sr. No.	SOP Title	SOP CODE
	Preparing Standard Operating Procedures (SOPs):	
1.	Writing, Reviewing, Distributing, & Amending SOPs for the Institutional Ethics Committee	SOP 01/V1
2.	Constitution of Institutional Ethics Committee	SOP 02/V1
3.	Management of Protocol Submissions	SOP 03/V1
4.	Initial Review of Submitted Protocol	SOP 04/V1
5.	Exemption from the Ethical Review for Research Projects	SOP 05/V1
6.	Agenda Preparation, Meeting Procedures and Recording of Minutes	SOP 06/V1
7.	Review of Amendments/Notifications	SOP 07/V1
8.	Continuing review of Study Protocols	SOP 08/V1
9.	Reporting of Protocol Deviation/Non-Compliance/Violation/Waiver	SOP 09/V1
10.	Review of Adverse Events (AE) Reports	SOP 10/V1
11.	Review of Study Completion Reports	SOP 11/V1
12.	Management of Premature Termination/Suspension/Discontinuation of the Study	SOP 12/V1
13.	Request for Waiver of Written Informed Consent	SOP 13/V1
14.	Maintenance of Active Project Files, Archival of Closed Files and Retrieval of Documents	SOP 14/V1
15.	Documentation of the IEC Activities	SOP 15/V1
16.	Dealing with Research Participants Requests and Complaints	SOP 16/V1
17.	Site Monitoring and Post-monitoring activities	SOP 17/V1
	Appendices	AP1-AP18

AN2-V1/SOP01/V1

Template for SOP

Institutional Ethics Committee

Title: *Title which is self-explanatory and is easily understood*

SOP No: SOPxx/Vy **Page:** a of b

Code : SOP xx/Vy

Effective date: DD/MM/YYYY

Authors: xxxxxxxxx

Reviewed by: xxxxxxxx

Approved by: xxxxxxxxx

Accepted by: xxxxxxxxx

AN3-V1/SOP01/V1

Document History of the SOPs

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

AN4-V1/SOP 01/V1

Log of the IEC Members Receiving Printed Copy of SOPs

No.	Name of recipients	Designation	SOP code number	No. of copies	Signature	Date
1		Chairperson				
2		Member Secretary				
3		Dean, SSPHPGTI				
4		Member				
5		Member				
6		Member				
7		Member				
8		Member				
9		Member				
10		Member				
11		Member				
12		Member				
13		Member				

AN5-V1/SOP01/V1

Request for Formulation of New SOP/Revision of SOP

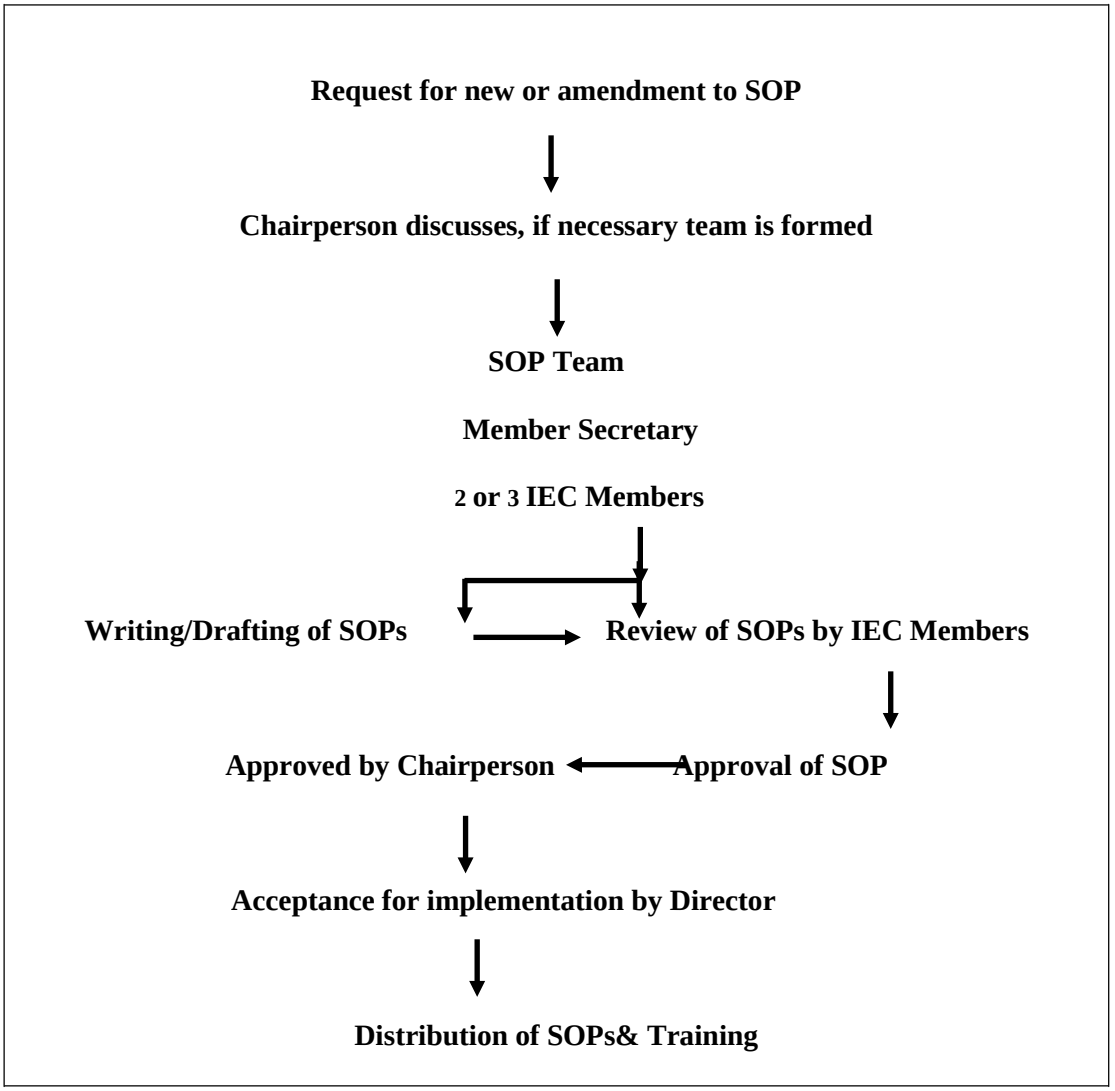
This form is to be completed by any member of IEC, faculty of SSPHPGTI or investigators, whenever a problem or a deficiency in an SOP is identified or a new SOP is considered necessary.

Need to formulate new SOP (i.e. SOP not existing previously), justification should be provided:			
Details of problems or deficiency in the existing SOP:			
SOP No.			
Title:			
Identified by:		**Date (DD/MM/YYYY)**	
Discussed in IEC meeting held on:			
New SOP to be formulated:	**Yes**	**No**	
SOP revision required:	**Yes**	**No**	
a. If yes, members of SOP team:			
b. If no, why?			
Date SOP revised/formulated:			
Date SOP approved:			
Date SOP becomes effective:			

AN6-V1/SOP 01/V1

Log of Printed Copy of SOP Recipients

No.	Name of Recipients	Designation	SOP code number	No. of Copies	Date
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					


Request for new or amendment to SOP
Chairperson discusses, if necessary team is formed
SOP Team
Member Secretary
2 or 3 IEC Members
Writing/Drafting of SOPs
Review of SOPs by IEC Members
Approved by Chairperson
Approval of SOP
Acceptance for implementation by Director
Distribution of SOPs& Training

Flow Chart

Standard Operating Procedures of Institutional Ethics Committee;

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SOPs, IEC, SSPHPGTI)

Title : Constitution of Institutional Ethics Committee

SOP Code: SOP 02/V1 : Date: 20/07/2019

- IEC constitution, composition and terms of appointment
- Independent Consultants: roles
- Office Bearers and IEC Members: roles and responsibilities
- IEC sub-committees

The IEC has been established to formalize and specify the Institution's commitment to promotion of high ethical standards in clinical research, and teaching. This SOP applies to the formation of the IEC.

The Institutional Ethics Committee (IEC) is constituted by Director, Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SSPHPGTI) in consultation with the Dean, SSPHPGTI, in accordance with the By-Laws, and notified by the Governing Body of SSPHPGTI.

2.1 Mandate

The IEC through its delegated sub-committee's functions independently for maintaining consistent ethical framework in 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, SSPHPGTI essentially targets ethical aspects of research and education.

The terms of reference for the IEC are as follows:

- To ensure that all proposed research projects conform to standard national and international ethical guidelines and that dignity, right and wellbeing of research participants is protected.
- Continuing education in research bioethics and ethical aspects of clinical practice by seminars, workshops and interactive discussions for IEC members, investigators, study coordinators, research staff, and officials of Bioethics cell.
- 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.

2.2 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 participants.
- Continuing education and training programs to ensure that IEC members are qualified to perform their specific duties, by education of professional, administrative, and support staff about ethical issues and current ethical standards and guidelines.
- Creation, developing revising and implementing ethical guidelines (SOPs).

2.3 Ethical basis

- The committee consists of members who collectively have the qualifications and experience to review and evaluate the scientific, medical, ethical and legal aspects of a proposed research project/Clinical Trials.
- In collaborative research, the IEC recognizes that the protocol it approves has to be approved by national and/or institutional ethics committees prior to implementation/start of study.
- 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 WMA Declaration of Helsinki (Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and finally amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013).
- It makes further reference to the International Ethical Guidelines like. The Nuremburg Code (1945), the Belmont Report 1979, the CIOM International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva 1993), European Convention on Human Rights and Biomedicine 1997, Standard and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (WHO 2011), International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use - Good Clinical Practice (ICH-GCP 2016).
- The IEC establishes its own Standard Operating Procedures taking recognition of Indian Good Clinical Practice Guidelines (2001) by Central Drugs Standard Control Organization (CDSCO) for clinical trials (and revised Schedule Y of the Drugs and Cosmetics Act, 1940, in the year 2005 with several amendments in the Rules under Drugs and Cosmetics Act in the year 2013), National Ethical Guideline for Biomedical and Health Research Involving Human Participants by the Indian Council of Medical Research (ICMR 2017) National Ethical Guideline for Biomedical Research Involving Children (ICMR 2017),NABH Guidebook to standards for accreditation of Ethical Committees (1st ed.,

2015) and Helsinki Declaration (Oct., 2015).

- 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, SSPHPGTI has accepted a SOP prepared by IEC to facilitate the work of IEC and maintain high standard of ethical review in 2019.

2.4 Composition

The Ethics Committee will be multidisciplinary and shall consist of not less than seven members and a maximum of 15 members. One among its members, who is from outside the Institute, shall be appointed as Chairperson, one member (faculty member of the Institute) as Member Secretary, and rest of the members shall be from Medical, Scientific, Non-medical and Non-scientific fields including lay public and clinical pharmacologist, persons of the community, a legal expert, a social worker/layperson/patient representative to represent different point of view. There shall be an appropriate balance of professional, ethical, legal, cultural, educational, and community interests with an equitable representation of all specialties and gender. The external members shall be in majority to ensure independence of the committee.

Members shall be conversant with the provisions of clinical trials and Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial participants. Members are expected to be aware of local, social and cultural norms, as this is the most important social control mechanism.

The composition of IEC, SSPHPGTI would be as follows:

1. Chairperson (Not affiliated to SSPHPGTI)
2. Member secretary (SSPHPGTI faculty member)
3. Two faculty members of SSPHPGTI
4. Dean, SSPHPGTI
5. One to two clinicians (Not affiliated to SSPHPGTI)
6. Basic medical scientists
7. Clinical pharmacologist(s).
8. One or two legal experts or retired judge or medico-legal expert
9. One social scientist/representative of non-governmental voluntary agency
10. One philosopher/ethicist/theologian
11. Lay person from the community

Criteria for selection of members:

- Members are selected on their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in domain field and profile.
- Conflict of interest will be avoided when making appointments, but where unavoidable, there will be transparency with regard to such interests.

- The members representing medical scientist and clinicians should have postgraduate qualifications and adequate experience in their respective fields and be aware of their role and responsibilities as committee members.
- New members will be identified according to the requirement i.e. as per the composition specified in Section 2.5 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
-

2.5 Terms of appointment

2.5.1 Duration and renewal

- The IEC Members will be appointed by the Director, SSPHPGTI in consultation with Dean for a duration of 3 years. The Head of the Institute will issue letters of appointment to the Chairman, Member Secretary and IEC members.
- 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 is no limit on the number of times the membership is extended. Extension of membership will be decided by the Director, SSPHPGTI in consultation with the Dean, SSPHPGTI.
- Chairperson, Member Secretary and an IEC member may be appointed before the completion of the tenure of the existing appointed committee.

2.5.2 Conditions of appointment

- Name, gender, profession, and affiliation of IEC members will be publicized.
- Members must accept the appointment in writing.
- Submit CV (AN7-V1/SOP 02/V1).
- Members must apprise themselves of the relevant documents, codes, GCP, ICH guidelines and the ICMR code & IEC, SSPHPGTI SOP. Copies of these documents will be provided by the Bioethics Cell on written request.
- 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 the member is PI, Co-PI or has any other potential conflict of interest.
- The designated member of the IEC who accepts the membership should sign the Conflict of interest, if any, must be disclosed (AN5-V1/SOP 02/V1) and the Confidentiality Document (AN1-V1/SOP 02/V1).

2.5.3 Resignation/replacement procedure

- 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 above.
- IEC member who decides to resign should send a written notification of resignation to the Director, SSPHPGTI.
- Director, SSPHPGTI would appoint a new member, falling in the same category of membership (ex. NGO representative with NGO representative) in consultation with the Dean, SSPHPGTI.
- Similarly, if internal faculty member proceeds on leave for more than 6 months, the Director may replace with another faculty member in consultation with the Dean, SSPHPGTI.

2.5.4 Termination/disqualification procedure

A member may be relieved or terminated of membership in case of:

- Conduct unbecoming for a member of the Ethics Committee.
- If a member fails to attend more than 3 consecutive meetings of IEC, the matter shall be reviewed by the IEC. If deemed necessary, the IEC may decide to terminate the membership and recommend to the Director, SSPHPGTI, through the Chairperson IEC for necessary replacement.
- In all such situations/circumstances, Director, SSPHPGTI in consultation with the Dean, will send a letter of termination to the member. Documentation of the termination will be recorded in the meeting minutes of the next IEC meeting and IEC membership circular will be revised.

2.6 Independent consultants

- The IEC may call upon, or establish a standing list of, independent consultants/ experts who may provide special expertise to the IEC on proposed research protocols, when the Chairperson 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 Document (AN2-V1/SOP 02/V1) regarding meeting, deliberations, and related matters.
- These consultants or subject experts cannot vote for decision. They may attend the IEC meeting as special invitee as per the requirement for the research protocol only.

2.7 Office bearers

The IEC will have the following office bearers who have the expertise and professional qualifications to review the submitted documents.

2.7.1 Chairperson

The IEC Chairperson should be from outside the institution, capable of managing the IEC and the matters brought before it with fairness and impartiality. He/she should not be a former faculty member of SSPHPGTI. 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.

The Chairperson will conduct all meetings of the IEC. If the chairperson is not available for reasons beyond control, then his/her designee will act as alternate Chairperson In case, designee is not available, then an alternate Chairperson will be elected by the members present from among themselves.

2.7.2 Member Secretary

The Member Secretary will be a staff member of institute, responsible for coordinating and managing the activities of the committee including 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 SOP.

In absence of Member Secretary of IEC, a SSPHPGTI member of IEC may perform the function of the Member Secretary if necessary.

2.7.3 Bioethics cell

Bioethics cell is composed of In-charge Bioethics Cell (Member Secretary, IEC) and the administrative supporting staff. The supporting staff consists of staff members of the SSPHPGTI appointed by the Director, SSPHPGTI or contractual staff approved by the Director, SSPHPGTI.

The Bioethics cell shall have the following functions:

- SOP operations.
- Organizing an effective and efficient tracking procedure for each proposal received.
- Preparation, maintenance and distribution of study files.
- Organizing IEC meetings.
- Preparation of agenda and minutes of the meetings.
- Maintaining IEC documentation and archive.
- To receive IEC processing fees as prescribed by the institute time to time and issue official receipts for the same.
- Communicating with IEC members and principal investigators (PIs).
- Providing necessary administrative support for IEC related activities to the Member Secretary, IEC.
- Arrangement of training for personnel and IEC members.
- The IEC may conduct workshops from time to time for institutional faculty members.

- Prepare an annual activity report of the IEC for submission to the Director, SSPHPGTI for its reporting to Academic Board which should include:
- A quantitative evaluation of the activities of the committee in a year.
- List of the research proposals reviewed in a year.

2.8 Roles and responsibilities of the IEC members

The Committee's primary responsibilities will be protection of safety, rights, dignity and confidentiality of the research participants.

- Review and discuss research proposals submitted for evaluation.
- Review progress reports and monitor ongoing studies.
- Monitor SAEs and recommend appropriate action(s).
- Maintain confidentiality of the documents and deliberations of the IEC meetings.
- Declare conflict of interest, if any.
- To carry out work delegated by Chairperson and Member Secretary.
- To participate in continuing education activities in biomedical ethics and research.
- To provide information and documents related to training obtained in biomedical ethics and research to the Bioethics cell.

2.9 Quorum requirements

For review of each protocol the quorum of Ethics Committee shall be at least five members with the following representation:

1. Basic medical scientist (preferably one pharmacologist)
2. Clinician
3. Legal expert
4. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person
5. Lay person from community

2.10 Decision making

- Decision is arrived at by consensus. In exceptional case, 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.
- In case of a tie the chairperson can have a casting vote.

2.11 Education and training for IEC members

- IEC members should become conversant with all national and international ethics guidelines like, Indian GCP Guidelines by CDSCO, National Ethical Guideline for Biomedical and Health Research Involving Human Participants and National Ethical Guideline for Biomedical Research Involving Children by ICMR, Standard and Operational Guidance for Ethics Review of Health-Related Research with Human Participants by WHO, ICH-GCP guidelines.
- The institute shall support participation of IEC members in bioethics workshop/conference once a year, for capacity building. The request should be recommended by Chairperson, IEC.

2.12 IEC subcommittees

Subcommittees of IEC may be formed as when required for expedited review of new or revised proposal where major changes not required and SAE reporting. The decisions of all the subcommittees will be reported to the next meeting of IEC by the Member Secretary.

2.12.1 Expedite review committee

It will consist of the Member secretary and two members designated by the chairperson. At least one member should be from outside the Institute. The subcommittee should report to the main IEC. The approval granted through expedited review must be ratified at the next Full committee meeting.

2.12.2. Three -member subcommittee

The subcommittee will consist of the Member Secretary (convener) and two outside IEC members designated by the chairperson. It will take decisions regarding revised proposals/clarifications in proposals where major changes are not required. The subcommittee should report to the IEC.

2.12.3 SAE subcommittee

The subcommittee will consist of the Member Secretary, one senior faculty member of the Institute (Chairman of SAE subcommittee) and 3-4 other members from inside the Institute. The SAE subcommittee will review SAE reports with assessment of causality, compensation and regulatory compliance. The decisions of the SAE subcommittee must be approved at the next Full committee meeting.

AN1-V1/SOP 02/V1

Confidentiality and Conflict of Interest Document for IEC Members

In recognition of the fact, that I, (name and designation ……
…….....…….
....……
herein referred to as the "Undersigned", have 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 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.

That, 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. All Confidential information (and any copies and notes thereof) shall not be copied and retained by member, and 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.

Conflict of Interest

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

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.

I will 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 abstain from participation in discussions or recommendations in respect of such proposals.

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.

If an applicant submitting a protocol identifies a potential conflict of interest with the undersigned, then the investigator may request in writing to the Chairman; and the undersigned may be excluded from the review of the project.

In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation ("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 agenda items) to the Bioethics cell 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, ……..... have read and I accept the aforementioned terms and conditions as explained in this Agreement.

Name:

Date: **Signature**

AN2-V1/SOP 02/V1

Confidentiality Document Form for Independent Consultants

I,……
……...(name and designation) as a non-member of IEC understand that the copy (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.

Name:
Date: **Signature**

AN3-V1/SOP 02/V1

Invitation to Attend a Meeting as Independent Consultant

To,

_____

_____

_____

Sub: Invitation to attend Institutional Ethics Committee meeting

Sir/Madam,

The Chairman IEC has nominated you as an independent consultant/observer to evaluate a research protocol submitted to the Institutional Ethics Committee for approval.

You are requested to attend the meeting of IEC on …….at…….and to provide written opinion regarding the assigned research proposal (IEC code no:…… ……. and title of project.....). You will not have any voting right during the meeting and you will have to sign confidentiality document, which is enclosed for your kind perusal.

Kindly note that all the documents submitted to you are confidential. These should not be disclosed to anyone and should be returned to the Bio-Ethics Cell, SSPHPGTI after the meeting.

Yours faithfully,

Name of the Member Secretary:
Date: **Signature of the Member Secretary**

Enclosures:

1. Research protocol
2. Confidentiality document

AN4-V1/SOP 02/V1

Invitation to Attend a Meeting as Observer

To,

_____

_____

_____

Sub: Invitation to attend Institutional Ethics Committee meeting

Sir/Madam,

The Chairman IEC has invited you as an independent observer to see functioning of the Institutional Ethics Committee meeting.

..... You are requested to attend the meeting of IEC on …….at..... You will not have any voting right during the meeting and you will have to sign confidentiality document, which is enclosed for your kind perusal.

Yours faithfully,

Name of the Member Secretary:
Date: **Signature of the Member Secretary**

Enclosures:

1. Confidentiality document

AN5-V1/SOP 02/V1

Confidentiality Document Form for Observer Attendees to IEC, SSPHPGTI Meetings

I,…… (name and designation) understand that I am invited to attend the IEC meeting scheduled on……..at…… am/pm as an Observer. 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.

Name:
Date: **Signature**

AN6-V1/SOP 02/V1

Confidentiality Document Form for Non-members Requesting Copies of IEC/Documents

I,…..,..,., as a non-member of IEC, understand that the copy (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.
I have received copies of the following IEC documents:

……

……

……

……

Name:
Date:
Designation and address: **Signature of the recipient**

AN7-V1/SOP 02/V1

CV for Members of the Institutional Ethics Committee

First Name	Middle Initial	Last Name
Date of Birth (mm/dd/yy):		**Sex**
Professional Mailing Address (Include institution name):		
Telephone (Office):		**Mobile Number:**
Telephone (Residence):		**E-Mail:**

Academic Qualifications (Most current qualification first):		
Degree/Certificate	**Year**	**Institution, Country**

Professional Experience:		
Month and Year	**Title**	**Institution/Company, Country**

Experience in Bioethics:
A.

Sr. No.	Courses/Workshops/Conferences/Meetings Attended	Organized by	Place	Duration
1				
2				
3				
4				

B. Members of the other Institutional Ethics Committee/Bioethics Societies with duration:

Signature: **(Signature Required)**	**Date:**

AN8-V1/SOP 02/V1

List of Members of Institutional Ethics Committee (2019 onwards)
]
(w.e.f 01.06.2019)

Sr. No.	Name	Affiliation	Roles
1.	Dr T. P. Singh	Clinical Scientist	Chairman
2.	Dr Mukesh Kumawat	Clinician / Faculty SSPHPGTI	Member Secretary
3.	Dr Shilpa Sharma	Clinician	Member
4.	Dr Bhanu K. Bhakri	Clinician / Faculty SSPHPGTI	Member
5.	Ms Ruchira Gupta	Legal Expert	Member
6.	Mr Mukesh Chandra	Educated Person from the society	Member
7.	Mr P. N. Agarwal	Representative of NGO	Member
8.	Dr Usha Dudeja Bindal	Clinician / Faculty SSPHPGTI	Member
9.			Member
10.			Member
11.			Member
12.			Member
13.			Member
14.			Member
15.			Member

AN9-V1/SOP 02/V1

Confidentiality Document Form for Faculty/Observer visiting Bioethics Cell

I,……(name and designation) understand that I visited Bioethics Cell on…….at…..am/pm. In the course of the meeting in the Bioethics Cell 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.

Name:
Date: **Signature**

AN10-V1/SOP 02/V1

Conflict of Interest Declaration for IEC Members (During IEC meeting)

To,

The Chairperson

Institutional Ethics Committee

SSPHPGTI, Noida.

IEC Meeting Number: _____

Conflict of Interest

I hereby declare that I have conflict of interest in the following Agenda:

1.

2.

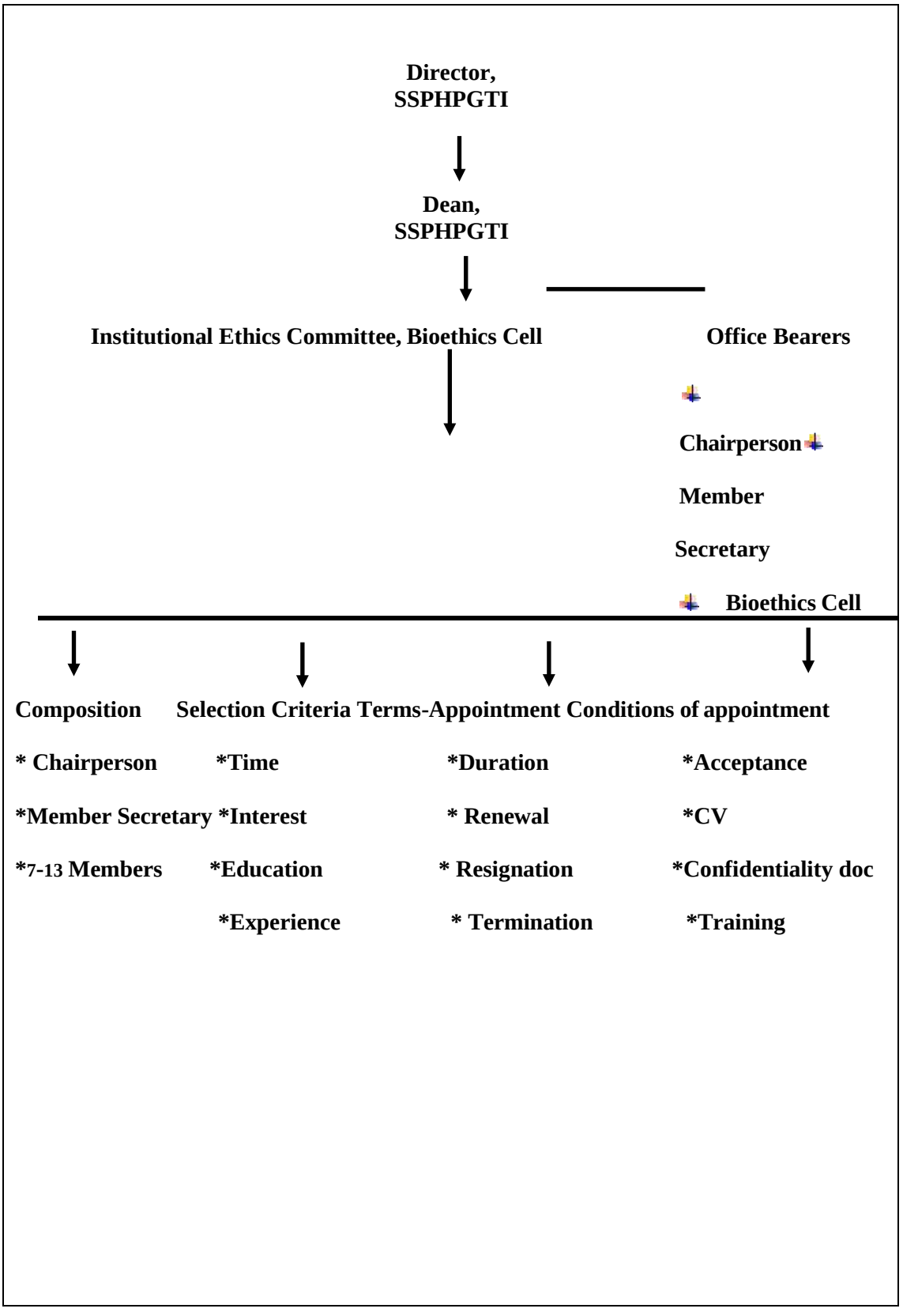
3.

4.

Name:

Date: **Signature of member**

Flow Chart


Director, SSPHPGTI
Dean, SSPHPGTI
Institutional Ethics Committee, Bioethics Cell
Office Bearers
Chairperson
Member
Secretary
Bioethics Cell
Composition
* Chairperson
*Member Secretary
*7-13 Members
Selection Criteria
*Time
*Interest
*Education
*Experience
Terms-Appointment
*Duration
* Renewal
* Resignation
* Termination
Conditions of appointment
*Acceptance
*CV
*Confidentiality doc
*Training

Standard Operating Procedures of Institutional Ethics Committee;

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SOPs, IEC, SSPHPGTI)

Title : Management of Protocol Submissions

SOP Code: SOP 03/V1 : Date: 20/07/2019

- Type of protocols
- Process of submitting and receiving protocols
- Documents to be submitted for Initial review
- Reports/amendments/termination/revision of protocols
- CTA/MTA/Agreements and charges in sponsored studies

This SOP is designed to describe and act as a guideline for the Bioethics cell of the IEC to manage research protocol submissions.

3.1 Type of Protocols

The type of protocols includes:

I. Submission of protocols for initial review.
II. Resubmission of protocols with modifications.
III. Protocol amendments and any other amendments.
IV. Continuing review of approved protocols.
V. Protocol completion/termination.

3.2 Detailed Process

It is the responsibility of the Bioethics cell to receive, record and distribute the protocols for review by the IEC and communicate the decisions to PI in a prescribed format.

3.2.1 Receiving protocols

The PI can submit research proposal to the IEC for review and approval under any of the 5 sections mentioned above (see section 3.1). Before submitting to the Bioethics cell for initial review, all projects/proposals (intramural/extramural/student/investigator initiated study) should be first scientifically reviewed by Departmental Research Committee/Doctoral committee/M. D Protocol Committee and a copy of approval letter/document should be submitted to the Bioethics cell.

3.2.2 Bioethics Cell

The Bioethics cell will:

- Check the application documents to ensure that all required forms and documents are submitted as per checklist (AN14-V1/SOP 03/V1). Refer to **Table 3.1 (section 3.2.3).** Include**:**
  - Original Application form/Project submission form (AN1-V1/ SOP 03/V1)
  - Study protocol

- Case Record Form
- Other documents necessary for initial review (AN2 to13-V1/SOP 03/V1)

- Check completeness of necessary information and signature at all appropriate places in the application form submitted for initial review.
- Notify the applicants, if incomplete.
- State clearly the missing documents in the document receipt Form (AN15- V1/SOP03/V1).
- Stamp, sign and put date of receipt on the cover letter confirming receipt of the documents.
- Return one copy of the document receipt form (AN15-V1/SOP 03/V1) to the applicant for their records
- Count number of copies (Initially 6 hard copies and one soft copy accepted by email/CD/pen drive).
- Store the hard copies and soft copy of the research project. The hard copies will be archived in the office of the Bioethics cell and soft copy will be saved on Bioethics cell computer and external hard disc drive/CD.
- The project file is uniquely numbered as "A-x-y-z" where "A" will indicate years, e.g. 2012 "x" is abbreviation for serial no. of project, "y" will be type of project such as EMP for extramural, IM for intramural, IP for independent, MD for MD thesis, DT for drug trial and so on, "z" will denote IEC meeting number.
- All correspondence for the project, should quote the complete project number assigned to it.

Table 3.1 Documents to be submitted for Initial review

	Document	**Annexure**	**Remarks**
1.	Original Application form/Project submission form	AN1-V1/ SOP 03/V1	Attach copy of protocol and case report form
2.	Consent of Head of the PI's Department	AN2-V1/SOP 03/V1	
3.	Departmental Research Committee/Doctoral Committee/ M.D Protocol Committee approval	AN3-V1/ SOP 03/V1	
4.	Undertaking by PI	AN4-V1/ SOP 03/V1	
5.	Conflict of Interest Declaration by PI	AN5-V1/ SOP 03/V1	
6	Recent signed and dated curriculum vitae (CV) of the student (MD/MS/DM/MCh/PhD)/ investigator from outside	AN6-V1/SOP 03/V1	
7.	Participant /volunteer /control /child information documents, consent forms [legally accepted guardian in case of patient incapable of giving consent e.g. unconscious, mentally deranged and parent consent forms if participant is a child/ adolescent between 7–18 years of age] and assent form (child 7-18 yrs)	AN7-V1/SOP 03/V1 to AN13-V1/SOP 03/V1	English and Hindi and any other language if necessary

8	Investigator Brochure and advertisement/information brochure	For drug/device trials
9	CTRI (Clinical Trial Registry of India) registration	Prerequisite for sponsored clinical trials. In other trials, it can be done after IEC approval
10	DCGI approval letter with list of approved Institutes	For sponsored drug/device trials§
10	Details of funding agency/sponsors and fund allocation (patient care/staff/contingency/travel etc.)	In project submission form and CTA
11	Clinical Trial Agreement (CTA) (as per SSPHPGTI format)	For drug/device trials
12	Insurance policy and certificate	For drug/device trials
13	For international export/import of Biological materials: Material Transfer Agreement (MTA) and Health Ministry's screening committee (HMSC) clearance	In collaborative projects. Copy of HMSC clearance should be submitted to IEC before start of study
14	For export of study samples: Director General Foreign and Trade (DGFAT) approval	In clinical trials
15	Clinical trials with stem cells*	
16	Recombinant DNA/Gene therapy: DST-GEAC (Genetic Engineering Advisory Committee) approval	
17	Study involving radioisotopes/ionizing radiations: Bhabha Atomic Research Centre (BARC) approval	
18	Decision of other concerned Ethics Committees	In collaborative studies
19	IEC Processing Fees	For sponsored clinical/drug trials
20	Any other MOU/Agreement in International collaboration	
21	Any other document	

- Please see guidelines for device based studies in Appendices (AP18/V1).

§ In investigator initiated drug trials for academic purposes: the trial can be approved by the IEC and information sent to DCGI (as per recent guidelines)

* All clinical trials with any stem cells shall have prior approval of Institutional Committee for Stem Cell Research and Therapy (IC-SCRT)

3.3 Informed consent process

For biomedical and health research involving human participants, the investigator must obtain voluntary written informed consent of the prospective participant. It is based on the principle that competent individuals are entitled to choose freely whether to participate in research or not. Informed consent is a process that provides opportunity to the individual to accept or refuse to participate in the study. It protects the individual's freedom of choice and respects the individual's autonomy.

Table 3.2 Essential elements of an informed consent document

1. Statement mentioning that it is research
2. Purpose and methods of the research in simple language
3. Expected duration of the participation and frequency of contact with estimated number of participants to be enrolled, types of data collection and methods
4. Benefits that might reasonably be expected as an outcome of research to the participant or community or to others
5. Any foreseeable risk, discomfort or inconvenience to the participant resulting from participation in the study
6. 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
7. Freedom of individual to participate and to withdraw from research any time without penalty or loss of benefits which the participant would otherwise be entitled to
8. Free treatment and/ or compensation of participants for research related injury and harms.
9. The identity of the research teams and contact persons with address and phone numbers (PI/ Co-PI for queries related to the research and Chairperson/member secretary or helpline for appeal against violations of ethical principles and human rights.

In addition, the following elements may also be required depending on the type of Study;

1. Any alternative procedures or courses of treatment that might be as advantageous to the participant as the ones to which she/he is going to be subjected to.
2. Payment/ reimbursement for participation and incidental expenses may be required depending on the type of study.

3.4 Information of change in funding agency/status of approved project:

If there is change in funding status/agency of approved project; PI should inform same to IEC through the Bioethics cell stating the title of project, IEC code and date of approval and PI should also state that there are no changes in title, design, methodology. The Bioethics cell will notify to the IEC and PI will be given fresh approval letter for administrative purpose (if requested by PI).

3.5 Resubmission of protocols with corrections as per IEC suggestions

- For minor corrections as per the suggestions of the IEC, the PI will submit cover letter stating the changes along with one copy of the amended Protocol and related documents with clearly highlighted/demarcated sections which have undergone correction.
- For resubmitted/major changes in the protocol, the PI will submit 3 copies of the amende Protocol and related documents along with justification for amendment, and clearly highlighted/demarcated sections which have undergone amendment.
- When the protocol has been revised and is being submitted for review as a new study, the PI will submit 6 copies with related documents as per the checklist for initial review.
- The Bioethics cell will verify the completeness and confirm that the copy contains the modification highlighted with respect to the earlier protocol.
- The Bioethics cell will perform the steps 3.2.2 as mentioned in initial review application.

3.6 Research protocol amendments and other study related documents

- The PI will submit 6 copies of the protocol amendments or any other study related documents to the Bioethics cell.
- DCGI approval letter is required for amended protocol in drug/device trials.
- The PI must highlight the modification/s in the amendment, along with a summary of changes and whether these changes would entail changes in the ICF. If yes, details of changes should be summarized.
- The Member Secretary in consultation with Chairperson will decide whether to:
    a) Carry out an expedited review
    b) Table for discussion at the full board meeting
    c) This process is further elaborated in SOP 06/V1.

3.7 Annual continuing reviews of approved protocols

The Bioethics cell 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 Bioethics cell will receive 6 copies of Annual Study/Continuing Review Report/ progress report/request letter for extension of approval and related documents of the project in the prescribed format (as per SOP 08/V1) for each approved protocol.
- The Bioethics cell will verify for completeness of the documents and sign and date the

documents. These will be tabled in the next full board meeting of IEC.

3.8 Project completion

- It is the responsibility of the PI to submit the final report within 6 months of completion of the project along with a copy of abstract/publication.
- The Bioethics cell will receive 6 copies of Study Completion Report in the prescribed format (as per SOP 11/V1).
- The Bioethics cell will send reminders for completion report to PI, 15 days prior to the date of completion.
- The Bioethics cell will verify the completeness of the Study Completion Report Form (SOP 11/V1) filled by the PI and the study completion report will be tabled in the next full board meeting of IEC.

3.9 Clinical Trial Agreement (CTA) or Other Agreement for Sponsored Drug/ Device/ Collaborative Trials/ Study

After the approval from IEC, the sponsor/ principal investigator (PI) will submit the duly signed copies by the sponsor/ CRO of CTA/ other agreement on Rs. 100 quasi-judicial stamp papers (three copies) to the institute with counter signature by PI, for signature of the Director, SSPHPGTI. CTA/ other agreement and indemnity will safeguard the interest and right of the research participant, investigator and institute. It should contain the main constituents of the CTA draft (Available at Institute website under Bioethics cell SOPs). As per existing policy of the institute, there would be 25% overhead charges in the financial part to the total cost of the trial/per patient cost.

The drug trial shall be started by the PI after the agreement is signed by both the parties. Also, DCGI and other required regulatory approvals should be obtained for the concerned trial, and copy of the same should be submitted to Bioethics Cell before starting the trial.

After approval of the CTA by the CTA screening committee (appointed by the Institute), a copy of the approved and duly signed CTA should be submitted to the Bioethics Cell before starting the trial.

Material transfer agreement (MTA): For any study, where there is exchange of biological samples, by import or export from abroad, there has to be an MTA as per ICMR format; and it should be submitted along with the study protocol to the IEC. After the approval from IEC, PI has to obtain endorsement from HSMC, ICMR before starting the study.

3.10 Charges

The Institute will charge a minimum Rs. 25000/+GST (as per rules) as an administrative charge from the Sponsor/CRO of clinical drug/device/Intervention trial for IEC submission. This may be exempted in case of Academic institution or Academic Society by the Director SSPHPGTI.

3.11 **Reporting of SAE/protocol violation/protocol amendment** is detailed in chapter 7, 9 and 10.

3.12 **Site Monitoring procedures** are detailed in Chapter 17 (SOP 17/V1).

AN1-V1/SOP 03/V1

Project Submission Form for Review by IEC

(02 hard copies and a softcopy required)

To be filled by Bioethics cell:

Project ID:_____Date of Submission of completed form: _____

A. Identification:

Project Title:				
Principal Investigator (PI)		**Department and designation**	**Tel. no./E-mail**	**Signature**
Co-PI/ Collaborator*/Student*				
1.				
2.				
3.				
4.				
5.				
Project funded	☐No ☐Yes	Funding Agency: ☐Intramural ☐Extramural ☐Clinical Trial	Sponsor/CRO/Funding agency: ……. Budget: …….	
Student project	☐No ☐Yes*	MD ☐DM ☐MCh ☐PhD ☐SRF ☐		
Collaborative	☐No ☐Yes	☐National ☐International	Name of Institute/'s:	
Study duration				

*See instructions/notes

B. Project Details§

I. Study Design	☐Interventional ☐Others …….. ☐Observational		☐Single Centre ☐Multicentre
II. Participants			
1. From SSPHPGTI* Controls Patients	Numbers ……..... …….....	Source …… …….	Total (if multicentre) …… …… …… ……
2. Gender	☐Both ☐Males only ☐Females only		
3. Clearly defined inclusion/ exclusion criteria: ☐Yes ☐No			
4. Vulnerable subjects	☐No ☐Yes	☐Pregnancy☐Children☐Elderly ☐Illiterate ☐Handicapped ☐Terminally/seriously ill ☐Mentally challenged ☐Economically/socially backward ☐Others	
5. Special group subjects:	☐No ☐Yes	☐Captives ☐Employees ☐Students ☐Nurses ☐Armed Forces ☐Healthcare workers ☐Any other	
6. Advertising for recruitment of subjects	☐No ☐Yes	If yes, please attach copies of posters, flyers, brochures, websites etc.	
III. Specimen collection	☐No ☐Yes	If yes, complete section B.III	
IV. Interventional Study	☐No ☐Yes	If yes, complete section B. IV	

<table>
<tr><td>V. Risk and Benefits</td><td colspan="2">a. Does this study qualify for ☐ Minimal risk'*
☐More than minimum risk
☐High risk
b. Is there benefit a) to the subject? ☐Yes ☐No; ☐Direct
☐Indirect
b) to the society? ☐Yes ☐No
c. Is the risk commensurate to the benefits to be accrued by the subjects/ community/country? ☐Yes ☐No</td></tr>
<tr><td>VI. Privacy and Confidentiality</td><td colspan="2">Study Involves: ☐Direct Identifier (Subject identified by name/ Cr. No) ☐ Indirect identifiers (Patient identified by study ID)
☐ Completely Anonymized (Subject cannot be identified)
Confidential handling of data by staff: ☐Yes ☐No</td></tr>
<tr><td rowspan="4">VII. Informed Consent Documents: a. Participant Information Document (PID)*
b. Informed Consent Forms (ICF's)</td><td colspan="2">☐ None (Waiver of consent form)</td></tr>
<tr><td>☐Written
☐Verbal
☐Audiovisual</td><td>-Language: ☐Hindi ☐English ☐Others
-Study includes children: ☐Yes ☐No
If yes, Age group …….</td></tr>
<tr><td colspan="2">PID and ICF for: ☐Patient ☐Controls/volunteers ☐Parents/LAR
LAR-Legally acceptable/authorized representative/guardian</td></tr>
<tr><td colspan="2">PID and Assent form (children 7-18yrs): ☐Child</td></tr>
<tr><td colspan="3">Consent will be taken by: ☐PI/Co-PI ☐Nurse ☐Counselor
☐Research Staff ☐Student ☐Any Other</td></tr>
<tr><td colspan="3">VIII. Archival of records by Bioethics cell for more than 3years (5years for clinical trials) after termination/completion of study: ☐Yes ☐No
If yes, for how many years……
Reasons for Archival ……</td></tr>
</table>

*See instructions/notes

C. Identify the ethical Issues (if any) related with the study:

……

……

……

……

D. Brief proposal summary

Aim(s) and objectives, methodology describing the potential risks and benefits, outcome measures (maximum 500 words).

Name:
Date: **Signature of PI**

Section B.III (Specimen collection)

1. Type	Nature	Amount	Frequency	Total amount	Comment
Blood					
Body fluid					
Tissue					
Others					

2. Collection of fetal tissue or abortus: ☐No ☐Yes

Specify……

3. Use of pre-existing/stored/left over samples: ☐No ☐Yes

Provide details……

……

4. Proper disposal of material: ☐Yes ☐No

5. **Storage for banking/future research:** ☐Yes ☐No

6. Will any sample collected from the patients be sent abroad? ☐Yes ☐No If yes, give details and address of collaborators:

_____

_____

Sample will be sent abroad because: ☐Facility not available in India

☐Facility in India is inaccessible

☐Facility available but not being accessed

If so, reasons_____

***Has necessary clearance been obtained*:** ☐Yes ☐No

Section B.IV (For Interventional studies only)

1. Study involves use of: ☐Drugs* ☐Devices* ☐Vaccines* ☐Radiopharmaceutical ☐Recombinant DNA/Gene therapy ☐Stem cell ☐Indian/Alternate system of Medicine ☐Any other ……. *(need approval from *DCGI; BARC for radioactive substances and from DBT for gene therapy. Research in alternate system of medicine in accordance to AYUSH-GCP guidelines)* **2. Is it approved and marketed in:** ☐India ☐UK & Europe ☐USA ☐Other Countries Approved Indication, specify…….
3. Is it an Investigational New Drug? ☐Yes ☐No. **If yes:** a. Investigator's Brochure enclosed ☐Yes ☐No b. Preclinical studies data available (If yes, provide summary ☐Yes ☐No c. Clinical studies data available (If yes, provide summary ☐Yes ☐No d. Clinical study in Phase: ☐I ☐II ☐III ☐IV☐NA **If phase I-III** will the drug/device provided free? ☐Yes ☐No **If phase IV** will drug/device provided at cost less than Hospital pharmacy? ☐Yes ☐No e. DCGI's permission obtained: ☐Yes ☐No, **if yes,** copy of letter enclosed ☐Yes ☐No
5. Data monitoring a. Is there plan for reporting of adverse events? ☐Yes ☐No **If yes**, reporting will be done to: ☐Sponsor ☐ IEC ☐ DCGI b. Is there a plan for interim analysis of data? ☐Yes ☐No **Mention Date Monitoring Plan** **……** **…..……**
6. **Provision for travel/treatment due to injury from study funds:** ☐Yes ☐No **If yes**, by: ☐Sponsor ☐Investigator ☐Insurance Company ☐Any Other
7. Registered with Clinical Trial Registry – India: ☐Yes ☐No **If yes**, copy of certificate enclosed: ☐Yes ☐No

Instructions/ Notes:

1. Submit six copies and one C.D of form and all documents as per checklist.
2. Submit ddetailed Study/Project Protocol (Short review of literature, justification for study, aim, methodology, inclusion, exclusion criteria, statistical analysis).
3. Submit case report form
4. Submit a page of recent, signed and dated curriculum vitae for **PI or investigator outside SSPHPGTI** or of the **student (MD/MS/DM/MCh/PhD)** who has submitted thesis/project.
5. Mention sample size calculation in protocol
6. Mention source of controls/healthy volunteers.
7. PID should be in simple language avoiding technical terms
8. 'More than minimal risk': *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (US-FDA 2014).
9. Consider the following while framing Participant Information Sheet/Document (PIS/PID):

- Understandable language
- Alternatives to participation
- Statement that study involves research
- Confidentiality of records
- Sponsor of study
- Contact information
- Statement that consent is voluntary
- Purpose and procedures
- Risks & discomforts
- Consent for future use of biological sample
- Benefits if any in future
- Right to withdraw
- Free supply of drug, as applicable
- Compensation for study related injury

AN2-V1/SOP 03/V1

Consent of Head of the Department

Date: …….

I have reviewed the project entiled "……" submitted by

…… Principal Investigator from my department. I endorse the project and have 'no objection' for submission for consideration by Ethics committee.

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

……	……..	……..
Signature & date	**Name**	**Department**

Note: To avoid conflict of interest, if the Head of the Department is himself/herself the PI, this form is not to be submitted.

AN3-V1/SOP 03/V1

Research Committee/Department Research committee /Doctoral Committee/Scientific Committee/MD Protocol Committee Approval

The project titled "……" with all the accompanying documents listed above was reviewed by the Research committee/Department Research Committee /Doctoral committee/M. D Protocol Committee present on..... at SSPHPGTI. The committee has granted approval on the scientific content of the project.

The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

……

Signature of *HOD or Chairperson**Doctoral/Scientific Committee

Name: ……..…….……..…….

Date: ……..…...…

***In case of student (MD/DM/MCh) or independent project/extramural/intramural**

****In case of PhD or any other project**

Not applicable to sponsor/CRO initiated drug/device trials

Kindly attach a copy of minutes of 'Research committee/Department Research Committee /Doctoral committee/scientific committee/ MD Protocol Committee'.

AN4-V1/SOP 03/V1

Undertaking by the Principal Investigator

1. **Name of the project:**

2. **Name, designation and department of the principal investigator:**

3. **Other members of the research team:**

4. **Name and address of any other medical college, hospital or institution where parts of the study will be done:**

5. **Number of ongoing projects/clinical trials in which you are PI:**

a. **Number of sponsored clinical trials with active enrolments:**

b. **Number of sponsored clinical trials with follow up only:**

c. **Total number of ongoing projects (any) (Projects+a+b):**

1. I confirm that I will initiate the study only after obtaining all regulatory clearances.
2. I will not implement any deviation from the approved protocol without prior consent of the sponsor nature and it will be intimated to the IEC at the earliest.
3. I confirm that the Co-PI and other members of the study team have been informed about their obligations and are qualified to meet them.
4. I will personally supervise the study and ensure that requirements of obtaining informed consent and other ethical requirements under national regulatory and ICMR guidelines are adhered to.
5. I will maintain accurate and complete record of all cases in accordance with GCP provisions and make them available for audit/inspection by IEC, regulatory authorities, sponsors or their authorized representatives.
6. I will inform the IEC and the sponsors of any unexpected or serious adverse event at the earliest and definitely within seven days of its occurrence.
7. I will maintain confidentiality of the identity of all participating subjects and assure security and confidentiality of study data.

8. I and my colleagues will comply with statutory obligations, requirements and guidelines applicable to such clinical studies.
9. I will inform IEC if there is change in funding agency/status.
10. I will inform IEC of the date of starting the study within 2 weeks of initiation of the trial and submit annual progress reports and final report to Member Secretary, IEC within 4 weeks of the due date.

Name:
Date: **Signature of PI**

AN5-V1/SOP 03/V1

Conflict of Interest Declaration by PI

To,

The Member Secretary

Institutional Ethics Committee

SSPHPGTI, Noida.

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:

Name:
Date: **Signature of PI**

AN6-V1/SOP 03/V1

CV* of PI or Investigator outside SSPHPGTI or of the Student

Name:		
Date of Birth (dd/mm/yy):		**Sex: Male [ ] Female [ ]**
Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordinator):		
Professional Mailing Address: **(Include institution name)**	**Study Sited Address:** **(Include institution name)**	
Telephone (Office):	**Mobile Number:**	
Telephone (Residence):	**E-Mail:**	
Academic Qualifications (Most current qualification first):		
Degree/Certificate	**Year**	**Institution, Country**
Current and Previous 3 Relevant Positions Including Academic Appointments (Most current position first):		
Month and Year	**Title**	**Institution/Company, Country**
Brief Summary of Relevant Clinical Research Experience:		
Signature:		**Date:**

*Signed and dated curriculum vitae of the investigators indicating qualifications and relevant experience for **new or investigator outside SSPHPGTI** or of the **student (MD/MS/DM/MCh/PhD)** who has submitted thesis/project

AN7-V1/SOP 03/V1

Guidelines for Devising a Participant / Legally Acceptable Guardian Information Document (PID) in English

Kindly refer to Table 3.2 for the essential elements of an informed consent document. For example, of PID in non-interventional studies, see appendix (AP7/V1). For 'Recommended Terms for use in Informed Consent Document', see appendix (AP12/V1).

1. **Study Title**
   Is the title self-explanatory to a lay person? If not, an additional simplified title may also be included.
2. **Invitation Paragraph**
   You should explain that the patient is being asked to take part in a research/trial study. "You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part."
3. **What is the purpose of the study?**
   The background and aim of the study should be given here.
4. **Why have I been chosen?**
   You should explain how and why the patient/volunteer was chosen and how many other patients will be studied.
5. **Do I have to take part?**
   You should explain that taking part in the research/trial is entirely voluntary. States:
   "It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive."
6. **What will happen to me if I take part?**
   You should say how long the patient will be involved in the research/trial, how long the research/trial will last (if this is different), how often they will need to visit the hospital/lab or a clinic (if this is appropriate) and how long these visits will be. You should explain if the patient will need to visit the doctor (or clinic) more often than for the usual treatment and if travel expenses are available. What exactly will happen e.g. blood tests, x-rays, interviews etc.? Whenever possible you should draw a simple flow chart or plan indicating what will happen at each visit. What are the patient's responsibilities? Set down clearly what you expect of them in the form of simple instructions, for example asking them to come to the clinic at 8.00 am without having eaten anything/on an empty stomach/fasting. You should explain simply and briefly the research/trial methods you intend to use States:

Randomized Trial: Sometimes, because we do not know which way of treating patients is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer, which has no information about the individual – i.e. by chance. Patients in each group then have a different treatment and these are compared. This way, the chances of something happening as a result of our choosing to put you in a specific group or bias is reduced. You should tell the patients what chance they have of getting the study drug/treatment: e.g. a one in four chance.

Blind Trial: In a blind trial you will not know which treatment group you are in. If the trial is a double-blind trial, neither you nor your doctor will know in which treatment group you are (although, if your doctor needs to find out he/she can do so). This is done to ensure that the trial is carried out without a bias that may result from knowing which group you are in, which can adversely affect the results.

Cross-over Trial: In a cross-over trial both the groups have the different treatments in turn. There may be a break between treatments, a washout period, so that the effects of the first drug or treatment are cleared from your body before you start the new treatment.

7. **What do I have to do?**

   Are there any lifestyle restrictions? You should tell the patient if there are any dietary restrictions. Can the patient drive? Drink? Take part in sport? Can the patient continue to take his/her regular medication? Should the patient refrain from giving blood? What happens if the patient becomes pregnant? Explain (if necessary) that the patient should take the medication regularly and dangers of non-compliance.

8. **What is the drug or procedure that is being tested?**

   You should include a short description of the drug or device and give the stage of development. You should also state the dosage of the drug and method of administration. Patients entered into drug trials should preferably be given a card (similar to an identify card) with details of the trial they are in. They should be asked to carry it at all times.

9. **What are the alternatives for diagnosis or treatment?**

   For therapeutic research/trial the patient should be told what other treatment options are available.

10. **What are the side effects of taking part?**

    For any new drug or procedure you should explain to the patients the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned or in case of emergency. The known side effects should be listed in terms the patient will clearly understand (e.g. ‘damage to the heart’ rather than ‘cardiotoxicity’; ‘abnormalities of liver tests’ rather than ‘raised liver enzymes’). For any relatively new drug it should be explained that there may be unknown side effects.

11. **What are the possible disadvantages and risks of taking part?**

    For studies where there could be harm to an unborn child if the patient were pregnant or became pregnant during the study, States:

"It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should woman who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the investigator.

Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.

There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of foetal damage.

If future insurance status, e.g. for life insurance or private medical insurance, could be affected by taking part this should be stated (if e.g. high blood pressure is detected). If the patients have private medical insurance you should ask them to check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance.

You should clearly state what will happen if you detect or find a condition of which the patient was unaware. It is treatable? What are you going to do with this information? What might be uncovered (e.g. high blood pressure, HIV status)?

12. What are the possible benefits of taking part?

Where there is no intended clinical benefit to the patient from taking part in the trial this should be stated clearly.

It is important not to exaggerate the possible benefits to the patient during the course of the study, e.g. saying they will be given extra attention. States:

"We hope that both (all) the treatments will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future patients with (name of condition) better".

13. What if new information becomes available?

If additional information becomes available during the course of the research/trial you will need to tell the patient about this. States:

"Sometimes during the course of a research project/trial, new information becomes available about the treatment/drug that is being studied. If this happens, your research/trial doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research/trial doctor will make arrangements for your care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form.

Also, on receiving new information your research/trial doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue."

14. What happens when the research/trial study stops?

If the treatment will not be available after the research/trial finishes this should be explained to the patient. You would also explain to them what treatment will be available instead. Occasionally the company sponsoring the research/trial may stop it. If this is the case the reasons should be explained to the patient.

15. What if something goes wrong?

You should inform patients how complaints will be handled and what addresses may be available. Is there a procedure in place? You will need to distinguish between complaints from patients as to their treatment by members of staff (doctors, nurses etc.) and something serious happening during or following their participation in the trial, i.e. a reportable serious adverse event. You should incorporate following line in PID "In case of study related injury or death, (name of CRO/ company), will provide the complete medical care as well as compensation for the injuries or deaths".

16. Will my taking part in this study be kept confidential?

You will need to obtain the patient's permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential. "If you consent to take part in the research/trial any of your medical records may be inspected by the company sponsoring (and/or the company organizing) the research/trial for purposes of analyzing the results. They may also be looked at by people from the company and from regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital/clinic/laboratory"

"All information collected about you during the course of the research/trial will be kept strictly confidential. Any information which leaves the hospital/clinic/laboratory will have your name and address removed so that you cannot be recognized from it."

17. What will happen to the results of the research/trial study?

You should be able to tell the patients what will happen to the results of the research/trial. You might add that they will not be identified in any report/publication.

18. Who is organizing and funding the research/trial?

The information should include the organization or company sponsoring or funding the research/trial (e.g. Govt. agency, pharmaceutical company, NGO, academic institution).

The patient should be told whether he has to pay for drugs/tests, the doctor conducting the research/trial is being paid for including and looking after the patient in the study. The information regarding payment and compensation should be included in PID.

19. Will the drug be made available after trial is over? (new drug requires continued use, till it is marketed in India)

Please explain to participant regarding the query of availability of study drug.

20. Who has reviewed the study?

You may should mention that IEC has reviewed and approved the study (you should not however list the members of the Committee).

21. Contact for further information

You should give the patient a contact address for further information. This can be your name or that of another doctor/nurse involved in the study. **Name of the PI, Address, Telephone Numbers and Name of the Member Secretary of Ethics Committee and address with telephone numbers.**

Remember to thank your patient for taking part in the study!

The PID should be dated and given a version number. It should state that the participant will be given a copy of the information sheet and the signed consent form.

Name:

Date: **Signature of PI**

AN8-V1/SOP 03/V1

Consent Form (English)

Study Title_____
Study Number _____
Subject's Full Name (with father's name) _____
Date of Birth/Age_____
Address of subject _____
_____
Qualification_____

Occupation: Student/self-employed/service/housewife/other (please tick as appropriate)
Annual income of subjects_____
Name and address of nominee(s) and his relation to subject_____
_____

1. I confirm that I have read and understood the information document dated_____ for the above study and have had the opportunity to ask questions.
   OR I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3. I understand that the sponsor of the clinical trial/study, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study/ trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
5. I permit the use of stored sample (tissue/blood) for future research. **Yes** ☐ **No** ☐
6. I agree to take part in the above study.

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:

_____
Signatory's Name_____Date_____

Signature of the Investigator_____Date_____
Study Investigator's Name _____

Signature of the Witness_____Date_____
Name of the Witness _____

Received a signed copy of Participant Information Document and Consent Form.

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:
_____ Date_____

AN9-V1/SOP 03/V1

प्रतिभागी के लिए सूचना-पत्र

हिंदी में प्रतिभागी के लिए सूचना पत्र के नमूने के लिए, अपेंडिक्स (परिशिष्ट) AP7/V3 (देखें)

1. अध्ययन शीर्षक

क्या आपका अध्ययन शीर्षक एक आम आदमी के समझने योग्य है? यदि नहीं, तो आप एक अतिरिक्त सरल शीर्षक शामिल कर सकते हैं।

2. निमंत्रण अनुच्छेद

आपको समझना चाहिए कि मरीज को एक अध्ययन/शोध परीक्षण में भाग लेने के लिए कहा जा रहा है. निम्नलिखित एक उदाहरण है:

आपको एक अध्ययन/शोध परीक्षण में भाग लेने के लिए आमंत्रित किया जा रहा है। इससे पहले आपके लिए यह समझना ज़रूरी है कि यह अध्ययन क्यों किया जा रहा है और उसमें क्या चीज़ें शामिल है। कृपया आप अपना समय निकाल कर इस सूचना को पढ़े तथा अपनी इच्छानुसार अपने मित्रों, परिजनों तथा अपने चिकित्सक के साथ चर्चा करें। अगर आपको कोई जानकारी समझ मे नहीं आती है या और चाहिए तो हमें बताएं । आप अपना समय निकाल कर इस सूचना को पढ़ें और बताए कि आप अध्ययन मे भाग लेना चाहते हैं कि नहीं।

3. अध्ययन का उद्देश्य क्या है?

पृष्ठभूमि और अध्ययन के उद्देश्य कि जानकारी सरल शब्दो में यहाँ देनी चाहिए।

4. मुझे इस अध्ययन के लिए क्यों चुना गया है?

कृपया आप प्रतिभागी को यह बताए कि उसे क्यों चुना गया है और इस अध्ययन और कितने लोगों का चुनाव किया जाना है।

5. क्या इसमे मुझे भाग लेना चाहिए?

कृपया आप भागी को समझाए कि अनुसंधान/परीक्षण में भाग लेने के पूरी तरह स्वैच्छिकता है। आप निम्नलिखित पैराग्राफ का इस्तेमाल कर सकते हैं:-

" यह आप पर निर्भर है कि आप को भाग लेना चाहिए कि नहीं । यदि आप भाग लेने का फैसला करते हैं तो आप को अपने पास रखने के लिए एक सूचना पत्र दिया जाएगा और एक सहमति फार्म पर हस्ताक्षर करने के लिए कहा जाएगा । यदि आपने भाग लेने का फैसला किया फिर भी किसी भी समय बिना कारण वापस भाग न लेने के लिए स्वतंत्र हैं। इस कारण आपके इलाज मे कोई फरक नही पड़ेगा। "

6. मुझे क्या होगा यदि मैं इस अध्ययन में भाग लेता हूँ?

आपको यह बताना चाहिए कि प्रतिभागी को कितने समय के लिए अध्य यन में भाग लेना है और यह अध्य यन कितने समय चलेगा। आपको यह भी बताना होगा कि भागी को कितनी बार और कितने दिनों के लिए परीक्षण के लिए अस्पताल में आना होगा । आप प्रतिभागी को यह भी बताए कि उसे अस्पताल में नियमित विज़िट के अलावा आना होगा और आप बताए कि आने जाने का खर्च किसे देगा होगा ? आप भागी को यह भी बताए कि उसे आने पर हर बार कौन-कौन सी जाँचें करना होगा । आप प्रतिभागी को यह भी बताए कि उसकी क्या ज़िम्मेदारी होगी। प्रतिभागी को लिखकर यह दीजिए कि उसे क्या सावधानी बरत कर आना चाहिए। आप प्रतिभागी को अध्ययन के विभिन पहलुओं के बारे में जानकारी दीजिए।

7. मुझे क्या करना है ?

क्या अध्ययन में भाग लेने से जीवन शैली पर किसी तरह का फ़र्क पड़ेगा ? आप भागी को यह भी बताए कि उसे आहार में कोई सावधानी बरतनी होगी। आप प्रतिभागी को यह भी बताए कि क्या वह रोज की तरह गाड़ी चला सकता है ? क्या वह खेलकूद में भाग ले सकता है ? क्या वह अपनी रोज कि दवायें ले सकता है ? क्या उसे रक्त देने से बचना चाहिए ? आप यह भी बताए कि उसे गर्भवती हो जाने पर क्या करना चाहिए। भागी को नियमित रूप से दवा लेने के बारे में बताए और उसे न लेने के नुकसान के बारे में बताए।

8. दवा या प्रक्रिया का परीक्षण किया जा रहा है ?

आप को दवा या प्रक्रिया या डिवाइस का एक संक्षिप्त विवरण देना चाहिए। आपको उनके विकास के बारे में जानकारी देना चाहिए। आपको दवा की खुराक और उसे देने की विधि के बारे में जानकारी देना चाहिए । यदि मरीज को दवा के परीक्षणों में शामिल किया जाता है तो उसे अध्ययन की जानकारी का एक पहचान पत्र जैसा कार्ड देना चाहिए।

9. निदान या उपचार के लिए और विकल्प क्या हैं ?

चिकित्सकीय शोध/परीक्षण के लिए रोगी को आप यह बताए कि उसके उपचार के अन्य कौन से विकल्प उपलब्ध हैं।

10. इस अध्ययन भाग लेने के क्या दुष्प्रभाव हैं ?

किसी भी नई दवा या प्रक्रिया के लिए आप प्रतिभागी को उसके संभव दुष्प्रभाव को समझा जाना चाहिए । यदि वे इन या किसी भी अन्य लक्षण से पीड़ित हैं तो उन्हें अगली बार जब आप से मिलने आए तो बताना चाहिए । आपको भी उन्हें अपना नाम और फोन नंबर देना चाहिए ताकि यदि वे

E किसी भी आपातकालीन स्थिति में आप से संपर्क कर सकें। ज्ञात दुष्प्रभाव को भागी को सरल भाषा में समझकर लिख कर देना चाहिए। किसी भी नई दवा के लिए अज्ञात दुष्प्रभाव के बारे में रोगी को पता होना चाहिए।

11. इस अध्ययन भाग लेने के सम्भावित जोखिम और नुकसान क्या हैं ?

अध्ययन के पहले या उसके दौरान महिला यदि गर्भवती हो जाती है तो बच्चे पर नुकसान हो सकता है, उसे आप को इन शब्दो में बताना होगा :

" यह संभव है कि अगर एक गर्भवती महिला को उपचार के लिए दिया जाता है तो अजन्मे बच्चे को नुकसान होगा। इसलिए गर्भवती महिलाओं को इस अध्ययन में भाग नहीं लेना चाहिए , जो औरत अध्ययन के दौरान गर्भवती होने कि संभानवा है उन्हे भी इस अध्ययन में भाग नहीं लेना चाहिए। जिन महिलाओ को गर्भावस्था कि संभावना है ऐसे भागी का पहले एक गर्भावस्था परीक्षण के लिए कहा जा सकता है। यदि संभव है तो उन्हें इस अध्ययन के दौरान एक प्रभावी गर्भनिरोधक का उपयोग करना चाहिए। किसी भी औरत को यदि पता चलता है कि वह गर्भवती बन गयी है , तो उसे तुरंत अन्वेषक को सूचित करना चाहिए। गर्भावस्था के बयान को सावधानी से करें।

आप को प्रतिभागी को एक उपयुक्त चेतावनी देनी होगी जिसमे पुरुषों के शुक्राणु खराब होने का डर है। परीक्षण में भाग लेने के लिए सहमत होने से पहले बीमा कंपनी के साथ जाँच करनी चाहिए कि उनकी भागीदारी उनकी चिकित्सा बीमा को प्रभावित नहीं करेगा।

आप को यह स्पष्ट बताना होगा कि अध्ययन के दौरान आप को ऐसी जानकारी मिलती है जिसे भागी को पहले से नही मालूम है। आप उसे क्या करेंगे, आप उसकी जानकारी को क्या करेंगे, अगर वह ठीक होने लायक नहीं है तो?

12. अध्ययन में भाग लेने के संभावित लाभ क्या हैं ?

क्या प्रतिभागी को अध्ययन में भाग लेने से उसकी बीमारी में सहायक होगा ? यह स्पष्ट रूप से कहा जाना चाहिए। यह महत्वपूर्ण है अध्ययन के बारे में प्रतिभागी को बढ़ा-चढ़ा कर नही बताना चाहिए। बल्कि उसे इस भाषा में समझना चाहिए :

"हमें आशा है कि दोनों (सभी) उपचार से आपको मदद मिलेगी। हालांकि, यह गारंटी नहीं हो सकती, इस अध्ययन से प्राप्त जानकारी में भविष्य में लोगों का इलाज करने के लिए मदद मिल सकती है। "

13. क्या होगा यदि कोई नई जानकारी उपलब्ध हो जाती है ?

यदि अनुसंधान/परीक्षण के दौरान अतिरिक्त जानकारी उपलब्ध हो जाती है आप इस बारे में प्रतिभागी को बताएँ। आप निम्न शब्द इस्तेमाल कर सकते हैं:

"कभी कभी एक अनुसंधान परियोजना/ परीक्षण के दौरान इलाज/ दवा के बारे में नई जानकारी उपलब्ध हो जाती है। आगे यदि ऐसा होता है तो आप के चिकित्सक आप को इस के बारे में बताएँगे और आप के साथ चर्चा करेंगे कि क्या आप इस अध्ययन में भाग लेना जारी रखना चाहते हैं या नही। यदि आप वापस लेने का फैसला करते हैं तो आपका चिकित्सक आप के इलाज को जारी रखने की व्यवस्था करगें। यदि आप अध्ययन में जारी रखने का निर्णय लेते हैं , तो आप को एक अपडेटेड सहमति फार्म पर हस्ताक्षर करने के लिए कहा जा सकता है। इसके अलावा, नई जानकारी प्राप्त होने पर आपका चिकित्सक आपके हित के लिए अध्ययन से वापस लेने के लिए कह सकता है। वह इन कारणों को आपको बताएगें और इलाज जारी रखने की व्यवस्था करेंगे। "

14. क्या होता है जब अध्ययन/शोध परीक्षण बंद हो जाता है ?

आप प्रतिभागी को यह समझाए कि अध्ययन समाप्त होने के बाद उस दवा से इलाज हो पाएगा कि नही ? आप यह भी बताए कि उसकी जगह पर कौन सी दवा दी जाएगी। अगर कभी अध्ययन बीच में बंद हो जाता है तो आप उसका कारण प्रतिभागी को बताएँगे।

15. क्या होगा अगर कुछ गलत हो जाता है ?

आप को प्रतिभागी को सूचित करना चाहिए कि उसकी शिकायतों का निवारण कैसे होगा और जिनके पास शिकायत करनी है, उनके पते क्या है ? आप को शिकायत करने की प्रक्रिया की जानकारी देनी होगी। आप को प्रतिभागी को यह भी बताना होगा कि दवा के अध्ययन के दौरान यदि कोई शारीरिक हानि या मृत्यु होती है (दवा की कंपनी का नाम) तो आप तो दवा का खर्च और समुचित मुवावजा दिया जायेगा।

16. क्या मेरे इस अध्ययन में भाग लेने को गोपनीय रखा जाएगा ?

आप को अध्ययन के दौरान मेडिकल रिकॉर्ड प्राप्त करने के लिए रोगी कि अनुमति लेना ज़रूरी होगा। आप को स्पष्ट करना चाहिए कि उनके बारे में एकत्र सभी जानकारी को कड़ाई से गोपनीय रखा जाएगा। दवा शोध/परीक्षण प्रायोजित कंपनी के लिए एक फार्म का सुझाव दिया है :

"यदि आप शोध में भाग लेने कि सहमति देते है तो परीक्षण के लिए आप के मेडिकल रिकॉर्ड/परिणामों का विश्लेषण जाँच प्रायोजित कंपनी द्वारा किया जा सकता है। यह कंपनी और नियामक अधिकारियों द्वारा अध्ययन सही ढंग से किया जा रहा है कि नही इसे देखने के लिए किया जाता है। आपका नाम का, अस्पताल/क्लिनिक और प्रयोगशाला के बाहर खुलासा नहीं किया जाएगा। "

E "सभी अनुसंधान/परीक्षण के दौरान आप के बारे में एकत्र जानकारी कड़ाई से गोपनीय रखी जाएगी । कोई भी जानकारी है जो अस्पताल/क्लीनिक और प्रयोगशाला से बाहर जाएगी, तो उसके ऊपर से आप का नाम और पता हटा दिया जायगा । "

17. अध्ययन / शोध परीक्षण के परिणाम का क्या होगा ?

आप को रोगी के अनुसंधान/परीक्षण के परिणाम को यह बताना होगा कि आगे उसका क्या होगा । आपको यह भी समझाना होगा कि उसकी पहचान किसी भी रिपोर्ट/प्रकाशन में नहीं की जायेगी ।

18. इस अध्ययन को कौन आयोजित कर रहा है और इस परीक्षण के लिए धन कहाँ से आयेगा?

आपको प्रतिभागी को यह जानकारी देनी होगी कि कौन इसे करा रहा है और इस अध्ययन के लिए कहाँ से धन आ रहा है । आपको यहाँ बताना चाहिए कि चिकित्सक जो प्रतिभागी कि देखभाल कर रहा है तथा और लोग जो उसमे शामिल है उन्हें इसके लिए धन दिया जा रहा है कि नहीं । *आप प्रतिभागी को यह बताये कि उसे अध्ययन में शामिल होने पर उसमें शामिल जाँच और दवा के लिए पैसे अलग से नहीं देना होगा / अगर इस अध्ययन में क्षतिपूर्ति देने का प्रावधान नहीं तो उसकी जानकारी प्रतिभागी को दी जानी चाहिए* /

19. क्या अध्ययन या शोध की दवा परीक्षण खत्म होने के बाद भी उपलब्ध रहेगी?

इस जानकारी को कृपया आप सूचना पत्र में शामिल करे ।

20. इस अध्ययन का पुर्न-निरीक्षण किसने किया है ?

आप यह बताये कि इसका पुर्न-निरीक्षण या पुर्न-अवलोकन हमारे संस्थान कि नैतिकता/आचार समिति ने किया है तथा अध्ययन करने की सहमति दी है।

21. अधिक जानकारी के लिए निम्न लोगों से संपर्क करे

आपको रोगी अधिक जानकारी के लिए संपर्क का नाम तथा पता देना चाहिए । यह आपका या अध्ययन में शामिल एक और चिकित्सक/नर्स का नाम पता हो सकता है ।

(प्रमुख अन्वेषक का नाम, पता तथा टेलीफोन नंबर और आचार समिति के सदस्य सचिव का नाम, पता और टेलीफोन नंबर)

अध्ययन में भाग लेने के लिए अपने मरीज को धन्यवाद करने के लिए याद रखना चाहिए !

प्रतिभागी के सूचना पत्र को दिनांकित और संस्करण संख्या दी जानी चाहिए ।

सूचना पत्र में आप यह लिखिए आपने जानकारी पत्रक और सहमति फार्म पर हस्ताक्षर किए तथा एक प्रतिलिपि आपने प्रतिभागी को दिया है ।

_____

प्रमुख अन्वेषक के हस्ताक्षर _____

प्रमुख अन्वेषक का नाम _____ दिनांक _____

AN10-V1/SOP 03/V1

सहमति पत्र

अध्ययन शीर्षक_____

अध्ययन संख्या_____

प्रतिभागी का पूर्ण नाम (पिता के नाम के साथ)_____

जन्मतिथि / आयु _____

पता_____

अर्हता_____

व्यवसाय : विद्यार्थी/स्वत:नियोजित/सेवा/गृहणी/अन्य (कृपया समुचित पर निशान लगायें)

व्यक्ति की वार्षिक आय_____

नाम निर्दिशिती का नाम एंव पता उनका व्यक्ति से सम्बन्ध _____

1. मेरी पुष्टि है कि मैंने अध्ययन हेतु सूचना पत्र दिनांक _____ को पढ़ व समझ लिया तथा मुझे प्रश्न पूछने या मुझे अध्ययन अन्वेषक ने सभी तत्थो को समझा दिया है तथा मुझे प्रश्न पूछने के समान अवसर प्रदान किये गए ।

2. मैंनें यहाँ समझ लिया कि अध्ययन मे मेरी भागीदारी पूर्णत: स्वैच्छिक है और मैं किसी भी समय किसी भी कारण के बिना, मेरे इलाज या कानूनी अधिकारों को प्रभावित किये बिना, अध्ययन में भाग न लेने के लिए स्वतंत्र हूँ ।

3. मैंने यह समझ लिया है कि अध्ययन के प्रायोजक, प्रायोजक की तरफ से काम करने वाले लोग, आचार समिति और नियामक अधिकारियों को मेरे स्वास्थ्य रिकॉर्ड को वर्तमान अध्ययन या आगे के अध्ययन के सन्दर्भ देखने के लिए मेरी अनुमति कि जरूरत नहीं है , चाहे मैंने इस अध्ययन से अपना नाम वापस ले लिया हो । हालांकि, मैं यह समझता हूँ कि मेरी पहचान को किसी भी तीसरे पक्ष या प्रकाशित माध्यम में नहीं दी जायेगी ।

4. मैं इस से सहमत हूँ कि कोई भी डेटा या परिणाम जो इस अध्ययन से प्राप्त होता है उसका वैज्ञानिक उद्देश्य (ओं) के उपयोग के लिए मेरी तरफ से कोई प्रतिबन्ध नहीं है ।

5. मैं भविष्य के अनुसंधान के लिए भंडारित नमूना (ऊतक /रक्त) पर अध्ययन के लिए अपनी सहमति देता हूँ ।

हां☐ नहीं ☐

6. मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूँ ।

प्रतिभागी/कानूनी तौर पर स्वीकार्य प्रतिनिधि का हस्ताक्षर (या अंगूठे का निशान)_____

हस्ताक्षर कर्ता का नाम_____ दिनांक _____

अन्वेषक के हस्ताक्षर _____ दिनांक _____

अध्ययन अन्वेषक का नाम_____

गवाह के हस्ताक्षर_____दिनांक _____

गवाह का नाम_____

मैंने हस्ताक्षर युक्त सूचना तथा सहमति पत्र प्राप्त किया ।

प्रतिभागी/कानूनी तौर पर प्रतिनिधि का हस्ताक्षर/अंगूठे का निशान)_____दिनांक_____

A11-V1/SOP 03/V1

***Child Information Document**

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/study 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 7-18 years we ask 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.

Risks and discomforts

There is no foreseen significant risk/hazard to your health, if you wish to participate in the study. 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 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.

Parents 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.

Contact for further information

You should give the patient a contact address for further information. This can be your name or that of another doctor/nurse involved in the study. **Name of the PI, Address, Telephone Numbers and Name of the Member Secretary of Ethics Committee and address with telephone numbers**

***(please translate in Hindi also)**

AN12-V1/SOP 03/V1

Child Assent Form

Study Title_____
Study Number_____
Subject's Full Name (with father's name) _____
Date of Birth/Age_____
_____
Address of subject
_____
_____

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 study/trial related injury, which has causal relationship with the said study/trial drug. I am also aware of right to opt out of the study/trial, at any time during the course of the study/trial, without having to give reasons for doing so.

_____ Date: _____
Signature of the study participant

Name of the study participant: _____

_____ Date_____
Signature of the Witness
Name of the Witness: _____

_____ Date: _____
Signature of the attending Physician
Name of the attending Physician: _____

AN13-V1/SOP 03/V1

शिशु स्वीकृति पत्र

अध्ययन शीर्षक _____

अध्ययन संख्या _____

प्रतिभागी का पूर्ण नाम (पिता के नाम के साथ) _____

जन्मतिथि/आयु _____

पता _____

मैं _____ में भाग लेने के लिए अपनी सहमति प्रदान करता हूँ। मुझे इस अध्ययन के उद्देश्य एंव किये जाने वाली प्रक्रिया के बारे में चिकित्सक द्वारा बता दिया गया है। मुझे पता है कि परीक्षण सम्बन्धी किसी क्षति जिसका परीक्षण की दवाई से हेतुक सम्बन्ध है उसका खर्च मेरे माता-पिता/अभिभावकों को वहन नहीं करना है। मुझे यह भी पता है कि मैं इस परीक्षण से किसी समय बिना कोई कारण बताये बहार हो सकता हूँ।

प्रतिभागी का हस्ताक्षर _____

प्रतिभागी का नाम _____ दिनांक _____

गवाह के हस्ताक्षर _____ दिनांक _____

गवाह का नाम _____

अन्वेषक के हस्ताक्षर _____ दिनांक _____

अध्ययन अन्वेषक का नाम _____

AN14-V1/SOP 03/V1

Checklist of Documents (6 copies and a CD of all documents listed below)
(Non-Interventional trial require documents listed in Item no. 1 to 13 and 27)

Please give page no. to all documents (start from 1, 2, 3..... 40 and so on.)

****Please provide version no. and date of each document* (for drug/device trial)**

Protocol Title:
Principal Investigator:
Type of document: Intramural/extramural/student project/investigator initiated/drug trial

As per **Table 3.1, Section 3.2.3** in SOP

Item No.	Mandatory Documents (*with version and date)	Yes	No	NA	Page No.
1.	Project Submission Form (AN1-V1/SOP 03/V1)	☐	☐	☐	
2.	Study Protocol	☐	☐	☐	
3.	Case Report Form (form to enter data)	☐	☐	☐	
4.	Consent of Head of the PI's Department (AN2-V1/SOP 03/V1)	☐	☐	☐	
5.	Research/Department research/Doctoral/M. D Protocol committee's approval (AN3-V1/SOP 03/V1)	☐	☐	☐	
6.	Undertaking by the PI (AN4-V1/SOP 03/V1)	☐	☐	☐	
7.	Conflict of Interest Statement by PI (AN5-V1/SOP 03/V1)	☐	☐	☐	
8.	CV of investigator outside SSPHPGTI or of the student (AN6-V1/SOP 03/V1)	☐	☐	☐	
9.	Participant Information document (PID) and consent forms CF) in English and Hindi (and if required in any other language) (For participants/controls/volunteers/guardian/parents) (AN7 to 10 -V1/SOP 03/V1)	☐	☐	☐	
10.	Child Information Document and assent form in English and Hindi (and if required in any other language) (AN11-13V1/SOP 03/V1)	☐	☐	☐	
11.	Ethics Committee clearance of other centers	☐	☐	☐	
12.	Clinical Trials Registry- India (CTRI)	☐	☐	☐	
13.	Investigator Brochure	☐	☐	☐	

14.	Advertisement/Information brochure	☐	☐	☐	
15.	Insurance policy and certificate	☐	☐	☐	
16.	DCGI approval letter	☐	☐	☐	
17.	Director General of Foreign Trade (DGFAT) approval	☐	☐	☐	
18.	Genetic Engineering Advisory Committee (GEAC) approval	☐	☐	☐	
20.	Bhabha Atomic Research Centre (BARC) approval	☐	☐	☐	
21.	Stem cell (NAC-SCRT) registration and approval	☐	☐	☐	
22.	DCGI marketing/manufacturing license for herbal formulations/nutraceutics	☐	☐	☐	
23.	Clinical Trial Agreement (CTA)	☐	☐	☐	
24.	Material Transfer Agreement (MTA)/MOU/Health Ministry Screening Committee (HMSC) approval	☐	☐	☐	
25.	IEC processing fee (applicable for sponsored trials)	☐	☐	☐	
26.	Any other Agreements/documents	☐	☐	☐	
27.	Document Receipt Form (AN15-V1/SOP 03/V1, in duplicate)	☐	☐	☐	

AN15-V1/SOP 03/V1

IEC Document Receipt Form (to be submitted in duplicate)

Type of Submission:	○ **New** ○ **Revised**
Protocol Title:	
Principal Investigator:	
Type of document: Intramural project/extramural/student project/investigator initiated/drug trial	

Checklist to assess the projects before they are submitted to IEC for review

Item No.	Mandatory Documents (*with version and date)	Yes	No	NA	Page No.
1.	Project Submission Form (AN1-V1/SOP 03/V1)	☐	☐	☐	
2.	Study Protocol	☐	☐	☐	
3.	Case Report Form (form to enter data)	☐	☐	☐	
4.	Consent of Head of the PI's Department (AN2-V1/SOP 03/V1)	☐	☐	☐	
5.	Research/Department research/Doctoral/M. D Protocol committee's approval (AN3-V1/SOP 03/V1)	☐	☐	☐	
6.	Undertaking by the PI (AN4-V1/SOP 03/V1)	☐	☐	☐	
7.	Conflict of Interest Statement by PI (AN5-V1/SOP 03/V1)	☐	☐	☐	
8.	CV of investigator outside SSPHPGTI or of the student (AN6-V1/SOP 03/V1)	☐	☐	☐	
9.	Participant Information document (PID) and consent forms CF) in English and Hindi (and if required in any other language) (For participants/ controls/ volunteers/ guardian/ parents) (AN7to 10 -V1/SOP 03/V1)	☐	☐	☐	
10.	Child Information Document and assent form in English and Hindi (and if required in any other language) (AN11-13V1/SOP 03/V1)	☐	☐	☐	
11.	Ethics Committee clearance of other centers	☐	☐	☐	
12.	Clinical Trials Registry- India (CTRI)	☐	☐	☐	
13.	Investigator Brochure	☐	☐	☐	

14.	Advertisement/Information brochure	☐	☐	☐	
15.	Insurance policy and certificate	☐	☐	☐	
16.	DCGI approval letter	☐	☐	☐	
17.	Director General of Foreign Trade (DGFAT) approval	☐	☐	☐	
18.	Genetic Engineering Advisory Committee (GEAC) approval	☐	☐	☐	
20.	Bhabha Atomic Research Centre (BARC) approval	☐	☐	☐	
21.	Stem cell (NAC-SCRT) registration and approval	☐	☐	☐	
22.	DCGI marketing/manufacturing license for herbal formulations/nutraceutics	☐	☐	☐	
23.	Clinical Trial Agreement (CTA)	☐	☐	☐	
24.	Material Transfer Agreement (MTA)/MOU/Health Ministry Screening Committee (HMSC) approval	☐	☐	☐	
25.	IEC processing fee (applicable for sponsored trials)	☐	☐	☐	
26.	Any other Agreements/documents	☐	☐	☐	
27.	Document Receipt Form (AN15-V1/SOP 03/V1, in duplicate)	☐	☐	☐	

Note: Please provide version no. and date of each document (for drug/device trial)

Documents submitted:

( ) Complete

( ) Incomplete; will submit on……...

Comments:

Receiver Name, Sign & Date: _____

(Bioethics cell)

Project submitted by Name & sign: _____

(Project or study team member)

Flow Chart

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

Standard Operating Procedures of Institutional Ethics Committee;

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SOPs, IEC, SSPHPGTI)

Title : Initial Review of Submitted Protocol

SOP Code: SOP04/V1 : Date: 29/07/2019

- Responsibilities of IEC for preparing/revising SOPs
- Instructions for amendment, approval and implementation of SOPs

- Purpose and scope
- Categorization of protocols
- Elements of review
- Responsibility and detailed instructions for review of protocols

4.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the IEC members will review an initially submitted protocol for approval.

The IEC must review every research proposal on human participants and approve it before the research is initiated. IEC should ensure that scientific evaluation has been completed and approved by Departmental Review/Research committee/ Doctoral Committee/ MD Protocol Committee 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.

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 Bioethics cell shall screen the proposals for their completeness before putting at the IEC meeting for review. It is categorized as exempt, full review or expedited. In case of an emergency proposal needing immediate approval; an adhoc meeting will be called by the Chairperson.

Types of Review

4.3.1 Exemption from review

Proposals that can be exempt from review include those with less than minimal risk where there are no linked identifiers, e.g.

- Research conducted on data that is in the public domain for systematic reviews or meta-analyses. • Observation of public behavior when information is recorded without linked identifiers and disclosure would not harm the interests of the observed person.
- Quality control and quality assurance audits in the institution.
- Comparison among instructional techniques, curricula, or classroom management methods.
- Consumer acceptance studies related to taste and food quality.
- Public health programmes including programme evaluation where the sole purpose of the exercise is refinement and improvement of the program or monitoring.

4.3.2. Expedited review

Proposals that pose no more than minimal risk may undergo expedited review, e.g.

• Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks, left over clinical samples.

• Research involving clinical documentation materials which are non-identifiable (data, documents, records)

• Modifications or amendment to approved protocol including administrative changes or correction of typographical errors and change in investigator(s).

• Revised proposals previously approved through expedited review, full review or continuing review of approved proposals.

• Minor deviations from originally approved research causing no risk or minimal risk.

• Progress/ Annual reports where there is no additional risk e.g. activity limited to data analysis.

• Expedited Review will be conducted by Chairperson, Member Secretary and 1-2 designated members.

• Expedited review of SAEs/ unexpected AEs will be conducted by SAE subcommittee.

• The approval granted through expedited review and the decisions of the SAE subcommittee must be ratified at the next Full committee meeting.

• Research during emergencies and disasters.

4.3.3. Full Committee Review

All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, e.g.

• Studies involving vulnerable population even if the risk is minimal.
• Studies involving deception of participants (Refer Informed Consent Process for further detail).
• Research proposals that have received exemption from review, or have undergone expedited review/ undergone subcommittee review should be ratified by the full committee. Full committee has a right to reverse/or modify any decision taken by the subcommittee or expedited committee.
• Amendments of proposals/related documents (including but not limited to informed consent documents, Investigators Brochure, advertisements, recruitment methods etc.) involving an increase in risk.
• Major deviations and violations.
• Any new information that has emerged during the course of the research must also be reviewed and decisions taken if necessary to terminate the study or not in view of altered benefit–risk assessment.

• Research during emergencies and disasters through unscheduled meetings.
• Program evaluation research activities other than those mentioned in the exempt category.

4.4 Elements of review

The primary task of the IEC is 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 consider the prior scientific review by the Research committee/department/funding agency/doctoral committee/scientific committee, and the requirements of applicable laws and regulations. Primary reviewer assigned by the Member Secretary will review and present the project in the meeting.
The IEC Member receives the letter for review (AN1-V1/SOP 04/V1) and assessment Form (AN2-V1/SOP 04/V1). The assessment form is designed to standardize the review process and to facilitate reporting, recommendations, and comments offered on each individual protocol.

The following will be considered (as applicable):

4.4.1 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, the adequacy of the site, including the supporting staff, available facilities, and emergency procedures.
- The way the results of the research will be reported and published.

4.4.2 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 AP6/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 as per Gazette of India (2013).
- Valid Insurance policy for the participant and indemnity arrangements.

4.4.3 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.

4.4.4 Participant information document and consent process

- A full description of the process for obtaining consent, including the identification of those responsible for obtaining consent (Refer AP6/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).
- 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 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 a research project.

- In clinical trials of new chemical entity or new molecular entity, audio-visual recording of informed consent process is required when vulnerable participants are enrolled.

4.4.5 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 designing the research.
- Influence of the community on the consent of individuals.
- Proposed community consultation during 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 way the results of the research will be made available to the research participants and the concerned communities.

4.4.6 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 AP1/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. AP1/V1).

4.4.7 Risk-Benefit Analysis

While reviewing the research protocols, the following points should be carefully assessed for risk/benefit analysis:

a. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture (Refer AP5/V1).
b. Prospective collection of biological specimens for research purposes by noninvasive means. E.g. skin, saliva, sputum, other body fluids etc.
c. Collection of data through noninvasive procedures routinely employed in clinical practice. E.g. Magnetic Resonance Imaging, sensory acuity, Electrocardiography, Echocardiography, Electroencephalography, Ultrasound, Doppler Blood Flow and other similar procedures.
d. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.
e. Collection of data from voice, video, digital, or image recordings made for research

purposes.

f. Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, focus group, or quality assurance methodologies
g. Research involving collection and storage of genetic materials (Refer AP9/V1)
h. Research involving gene therapy and gene transfer protocols (Refer AP10/V1)

Where medical devices are employed, they must be cleared/ approved for marketing (Refer for detailed guidelines, Medical Device Rules 2016 & 2017: www.cdsco.nic.in/)

4.5 Responsibility

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

4.6 Detailed instructions

Distribution of the project documents

- The distribution of the project documents for IEC review will be as follows: Chairperson, Member Secretary, and all members will get complete project proposal as hard/soft copy.

Assigning Primary reviewer

- Member Secretary, IEC assigns 1 or 2 Primary reviewersfor each research protocol. A Primary reviewer is the member of IEC responsible for an initial detailed review of the assigned protocol.
- The Primary reviewer is informed preferably 10 days prior to the meeting through the agenda. A project evaluation form will also be sent along with the necessary document for each project assigned to the IEC Member. In case, the lead discussant is not in a position to review due to some reason including conflict of interest; 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 Primary reviewer 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 consensus at the end of discussion among attending members and not solely based on written comments.
- The assigned lead discussant/s shall review the assigned research protocols offer their observations, comments, and decisions to the IEC during the meeting and return all the documents including a completed evaluation form to the Bioethics cell on the day of the meeting.

Responsibilities of IEC members

- Check the contents of the documents received and acknowledge receipt.
- Return the acknowledgement form/receipt back to the delivery person /Bioethics cell.
- Check the meeting date and inform the Bioethics cell immediately if unable to attend the meeting.
- Identify the project assigned for review.
- Notify the Bioethics cell immediately regarding the missing documents, if any.
- The members must return the documents to the IEC Bioethics cell on the day of the scheduled meeting. In case, IEC member is not able to attend the scheduled meeting, the proposals should be returned at the next meeting.

4.7 Review of protocol

Review all elements as per section 4.4. The Chairperson will invite comments from IEC members following the presentation of Primary reviewer covering the element mentioned in AN2-V1/SOP 04/V1.

4.8 Study assessment forms

The primary reviewer for a particular project should 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 Bioethics cell 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 (AN2- V1/SOP 04/V1).

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

4.9 Collection of assessment reports

The IEC Bioethics cell will collect the Study Assessment Forms AN2-V1/SOP 04/V1, the comments from each reviewer and file in the original set of the study file.

4.10 At IEC meeting

The details of review procedures and communication of decision is described in detail in SOP 06/V1.

AN1-V1/SOP 04/V1

Letter to IEC Members Requesting Initial Review with Study Assessment Form

Dear member,

The next meeting of the IEC will be held on……at……..in……..... You are requested to review the below mentioned proposals before the IEC meeting. Please review the protocol and related documents as per the guidelines and provide your comments on the form provided with the package (AN2-V1/SOP 04/V1). Please also confirm your availability for the meeting

IEC code no.:

Project Title:

Name of the Principal Investigator:

Name of the Reviewer:

Name of Member	Date of Receipt	Signature	Attending meeting Y/N

Name of the Member Secretary:

Date: **Signature of the Member Secretary**

AN2-V1/SOP 04/V1

Study Assessment Form

IEC Code:	**Date of IEC meeting:**	**Date (DD/MM/YY):**
Protocol Title:		
Principal Investigators:		
Primary reviewer's name:		

Mark and comment on whatever items applicable to the study

Items	**Comments**
1 Objectives of the Study ( ) Clear ( ) Unclear	
2 Need for Human Participants ( )Yes ( ) No	
3 Methodology: ( ) Clear ( ) Need changes	
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 ( ) Appropriate ( ) Inappropriate	
9 Involvement of Vulnerable Participants ( ) Yes ( ) No	
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 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 Researchers and Institution in the Protocol Design, Analysis and Publication of Results ( ) Yes ( ) No	
18 Contribution to Development of Local Capacity for Research and Treatment ( ) Yes ( ) No	
19 Benefit to Local Communities ( ) Yes ( ) No	
20 Are blood/tissue samples being sent abroad? ( ) Yes ( ) No	
21 Are procedures for obtaining Informed Consent appropriate? ( ) Yes ( ) No	
22 Contents of the Informed Consent Document ( ) Clear ( ) Unclear	
23 Language of the Informed Consent Document ( ) Clear ( ) Unclear	
24 Contact Persons for Participants ( ) Yes ( ) No	
25 Privacy & Confidentiality	

( ) Yes ( ) No	
26 Provision for Medical / Psychosocial Support ( ) Appropriate ( ) Inappropriate	
27 Provision for Treatment of Study-Related Injuries ( ) Appropriate ( ) Inappropriate	
28 Provision for Compensation ( ) Appropriate ( ) Inappropriate	

Comments: _____

_____

_____

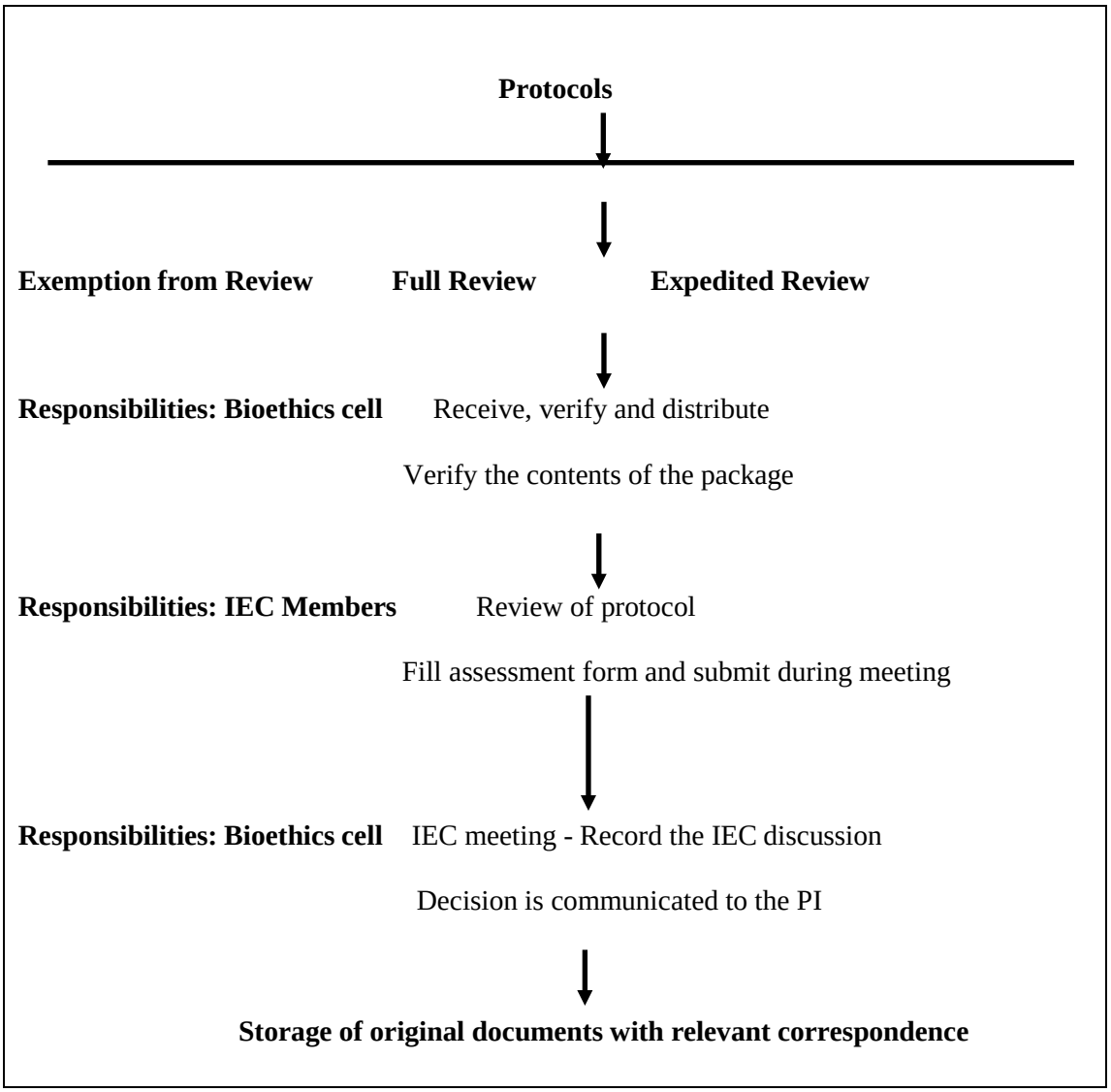
_____

If revision/rejection of project is recommended Yes [ ] No [ ]

Signature of Primary reviewer

Date: _____

Flow Chart


Protocols
Exemption from Review
Full Review
Expedited Review
Responsibilities: Bioethics cell
Receive, verify and distribute
Verify the contents of the package
Responsibilities: IEC Members
Review of protocol
Fill assessment form and submit during meeting
Responsibilities: Bioethics cell
IEC meeting - Record the IEC discussion
Decision is communicated to the PI
Storage of original documents with relevant correspondence

Standard Operating Procedures of Institutional Ethics Committee;

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SOPs, IEC, SSPHPGTI)

Title : Exemption from Ethical Review for Research Projects

SOP Code: SOP 05/V1 : Date: 20/07/2019

- Purpose and scope
- Categorization of protocols as exemption from review
- Responsibility and detailed instructions

5.1 Purpose and scope

This SOP applies to the all protocols submitted for exemption from review by the IEC.

The purpose of this 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 AN1-V1/SOP 05/V1 is designed to standardize the process of exemption.

5.2 Type of Protocol for Exemption from review

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:

1. 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.
2. When interviews involve direct approach or access to private papers.

ii. 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 meets above 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.

5.3 Responsibility

The Member Secretary will record the decision in the Exemption Form with reasons. The Bioethics cell is responsible for recording and filing the decision including the reasons for that decision (AN2-V1/ SOP 05/V1).

5.4 Detailed instructions for Bioethics cell

5.4.1 Receive the submitted documents

- The Bioethics cell will receive the Exemption from Review Application Form AN1-V1/SOP 05/V1, Project Submission Form for Review by IEC (AN1-V1/SOP 03/V1) Protocol and other documents submitted by the investigators.
- Acknowledge the submitted documents
- Put it at the full board meeting of the IEC.

5.4.2 Exemption process

IEC may exempt a proposal from ethical review.

- The Member Secretary records the decision on the Exemption Form.

AN1-V1/SOP 05/V0

Review Exemption Application Form

IEC Code no.: _____ (To be filled by the Bioethics cell)

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 [Please fill Project Submission Form for Review (AN1-V1/SOP 03/V1)].

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 AP15/V1).

Principal Investigator's signature:_____Date _____

Forwarded by the Head of the department:

Name:
Date: **Signature**

AN2-V1/SOP 05/V1

Decision of IEC Regarding Exemption from the Ethical Review

To,

Dr._____
Principal Investigator,
SSPHPGTI.

Ref: IEC code.
Title of project:

Dear Dr.
Institutional Ethics Committee reviewed and discussed your application (dated) for waiver to exemption from the ethical review during the IEC (number of meeting) meeting held on (date).

Exemption granted: Yes [ ] No [ ]
Cannot be exempted, Reasons, reasons

_____

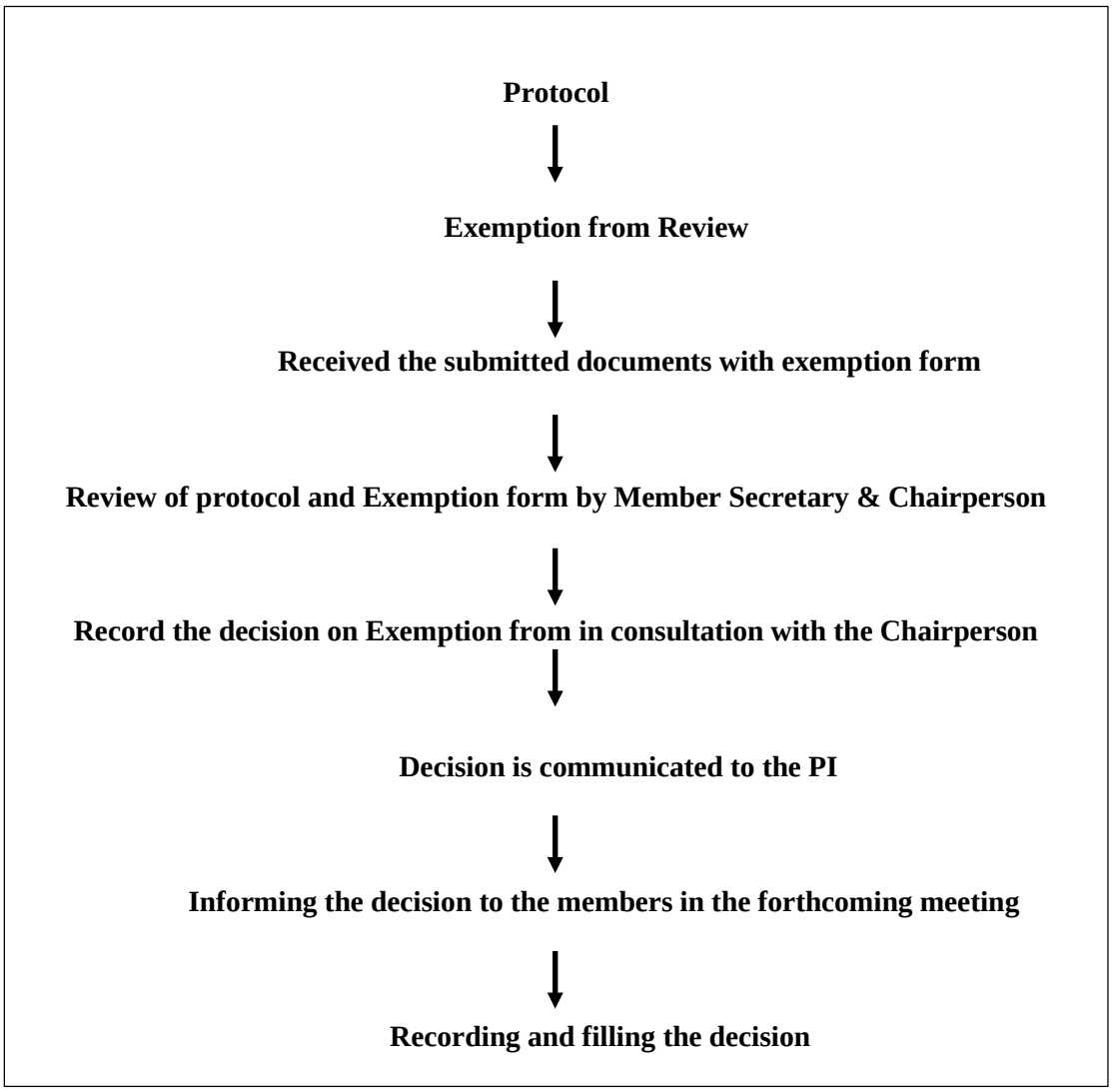
_____

Thanking You,

Yours Sincerely,

Name of the Member Secretary
Date: **Signature of the Member Secretary**

Flow Chart


Protocol
Exemption from Review
Received the submitted documents with exemption form
Review of protocol and Exemption form by Member Secretary & Chairperson
Record the decision on Exemption from 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

Standard Operating Procedures of Institutional Ethics Committee;

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SOPs, IEC, SSPHPGTI)

Title : Agenda Preparation, IEC Meeting Procedures and Recording of Minutes

SOP Code: SOP 06/V1 : Date: 20/07/2019

- Responsibility and instructions for conduct of IEC meetings
- Process of decision making
- Preparation of minutes and communicating decisions

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

The day, time, and venue of IEC meetings will be communicated at least 10-14 days in advance.

6.1 Responsibility

It is the responsibility of the Bioethics cell to prepare for the respective IEC meeting.

6.2 Detailed instructions

6.2.1 Agenda for full board IEC meeting

- Prepare the agenda of the IEC meeting (AN1-V1/SOP 06/V1)
- Schedule protocols on the agenda on a first come first serve basis.

6.2.2 Distribution of Protocol/Documents to the IEC Members

- Circulate meeting agenda with date, time, venue, and submitted documents to the IEC members preferably 10-14 days in advance of the scheduled meeting.
- Verify (verbally, by e-mail, or by phone) with the members whether all relevant documents are received.
- It is the responsibility of the IEC member to verify items on receipt and in the event of any missing items, intimate the Bioethics cell immediately so that the relevant documents could be made available to the members before the meeting.

6.2.3 Preparation for the meeting

- Circulate meeting notice with agenda to investigators by email, with request to be available on meeting date.

- All relevant guidelines and SOPs should be available at venue on the day of meeting.

6.2.4 Conduct of meeting

- The members should reach IEC meeting room on scheduled time
- The Chairperson should determine that the quorum (SOP 02/V1 section no. 2.9) requirements are met.
- The Chairperson should ask for declaration of conflict of interest either verbal or written on any protocol for discussion.
- If an 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 which should be confirmed.
- 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 (primary reviewer) to discuss the research protocol. The primary reviewer will submit the duly filled study assessment form at the end of the discussion or at the conclusion of IEC meeting.
- In case the primary reviewer cannot attend the meeting, Member 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 primary reviewer.
- The Member Secretary, IEC/the Bioethics cell staff minutes/records the proceeding of the IEC meeting.

6.1.1 Decision Making Process

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

- If IEC member has her/his own proposal for IEC review he/she will not participate in the IEC discussion on that particular project.
- The documents required for a full review of the application should be complete and the relevant elements considered before a decision is made.
- Decisions will only be made at meetings where a quorum (SOP 02/V1 section no. 2.9) is present.
- Decisions will be arrived at through consensus. When a consensus is not possible, the IEC will vote. In case of tie the Chairperson can have a casting 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 subcommittee of IEC on behalf of the full board, Member Secretary will report the decisions to the next IEC meeting. 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 by 3-member subcommittee or 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 against the decision, he/she may do so.
- The discontinuation of a trial will be recommended if the IEC finds that the goals of the trial have already been achieved midway, unequivocal results are obtained or SAE have been observed.
- 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 as consultant to offer their views, but 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 and the Chairperson.

6.1.2 After the IEC meeting

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.

B Approval of the minutes and the decision

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

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.

6.1.3 Communicating decisions

The decision will be communicated in writing by the Member Secretary to the PI, preferably within a period of 2 weeks of the IEC meeting at which the decision was made.

The communication of the decision will include, but is not limited to, the following,

- IEC code of project 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 date and place of the decision.
- A clear statement of the decision reached.
- Validity of approval usually will be yearly; for multiyear projects, however changing on case to case basis.
- Any suggestions by the IEC.
- A dead line of 4 week will be given to PI. If Clarification is received after dead line, the project may not be put up in next meeting for approval. Conditional approval pending clarification will not be given. If PI fails to provide clarification, reminder will be send by Bioethics cell stating that failure to respond will lead to closure of the file. (AN3-V1/SOP 06/V1).
- In the case of a positive decision, the PI is notified of the following requirements through an approval letter (AN2-V1/SOP 06/V1).
- A statement of the responsibilities of the PI; for example, confirmation of the acceptance of any requirements recommended by the IEC.
- Registration with CTRI if applicable.
- Communicate date of start of study to IEC (AN5-V1/SOP 06/V1).
- Submission of annual progress report.
- 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 recruitments like the potential research participant information, the informed consent form or participant numbers.
- The need to report serious and unexpected adverse events related to the conduct of the study.
- The need to report unforeseen circumstances, the withdrawn/ termination of the study, or significant decisions by another 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 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 normally will not exceed one year or duration of project whichever is later.
- All decision and approval letters will be signed by the Member Secretary, IEC
- The Member Secretary, IEC, will sign and date the approval letter and approval certificate in the original research protocol.

AN1-V1/SOP 06/V1

Agenda Format

I) Minutes

II) New Projects for Review

III) Report of approved clarification/revision by of 3 Member Committee/Member Secretary

IV) Amendments/Addendum

V) Letters/General notification

VI) SAEs

VII) Protocol violation

VIII) Progress report

IX) Closed out notification

X) Any other matter

AN2-V1/SOP 06/V1

Format for Approval Letter of Ethics Committee

To,

Dr._____

Principal Investigator,

SSPHPGTI.

Ref: IEC code & Project title:

Study/Protocol No.

Dear Dr.

Institutional Ethics Committee 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 (IEC Proforma).
2. Study protocol (including protocol amendments), dated_____,version no(s)_____.
3. Research committee/department/funding agency/doctoral committee/scientific committee approval
4. Patient information document and 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. One page, recent, signed and dated curriculum vitae of a new investigator or investigator outside SSPHPGTI or of the student (MD/MS/DM/MCh/PhD) who has submitted thesis/project.
8. Insurance policy/compensation for participation and for serious adverse events occurring during the study participation.
9. Investigator's Agreement with the sponsor
10. Investigator's undertaking

11. DCGI/DGFT approval
12. Clinical Trial Agreement (CTA)/Memorandum of Understanding (MOU)/Material Transfer Agreement (MTA), if applicable
13. Clinical Trials Registry-India (CTRI), in case of drug trial require at time of submission but in other case this must be done after approval of the study but before initiation

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 or duration of project whichever is later 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 date of commencement of study (AN5-V1/SOP 06/V1) and annual progress.
2. **IEC has approved recruitment of____patients on this study.**
3. PI and other investigators should co-operate with IEC, which may 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 a colleague after obtaining clearance from HOD and getting IEC concurrence and submitting status report, including accounts details should be submitted to HOD, IEC and extramural sponsors.

6. The IEC functions in accordance with the GCP-CDSCO/ICMR/Schedule Y guidelines/ICH-GCP.
7. New information or any SAE, which could affect any study, must be communicated to IEC 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 Bioethics cell should 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. **The PI must comment how proposed amendment will affect the ongoing trial.**
   c. Alteration in the budgetary status, staff requirement should be clearly indicated and the revised budget form should be submitted.
   d. If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval.
   e. If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented.
   f. 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 IEC, only then can they be implemented.
   g. Approval for amendment changes must be obtained prior to implementation of changes. The amendment is unlikely to be approved by the IEC unless all the above information is provided.
9. Any deviation/violation/waiver in the protocol must be informed to the IEC as detailed in SOP 09/V1.
10. If project/drug/device trial initiation not done in next 6 months from date of approval from IEC, further extension will not be granted and it will require resubmission to IEC.

Thanking You,

Yours Sincerely,

Name of the Member Secretary
Date: **Signature of the Member Secretary**

AN3-V1/SOP 06/V1

Format for Communication of IEC decisions project/trials

To,

Dr._____

Principal Investigator,

SSPHPGTI.

IEC code and Project title:

Study/Protocol No.:

Dear Dr.

The above referenced project was tabled, reviewed and discussed during the Institutional Ethics Committee meeting held on (date)_____

List of documents reviewed.

The following members attended the meeting.

The committee suggested the following changes or additional information in project proposal:

a.

b.

c.

The approval will be granted subject to the compliance with all the above suggestions of the IEC.

PI advised to submit above clarifications within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.

Kindly resubmit the 1 copy of revised proposal or documents within 4 weeks for re-review by the Member Secretary/three Member Sub-committee.

Thanking you, Yours Sincerely,

Name of the Member Secretary
Date: **Signature of the Member Secretary**

AN4-V1/SOP 06/V1

Format for Three-Member Subcommittee of IEC Approval for Project

Deliberation by the 3 members committee for the review of the clarification made by the PI regarding the objections raised about the research protocol presented during IEC meeting held on in the Committee Room of guest house, SSPHPGTI, on_____

IEC code:

Title of projects:

The clarification made by the Principal Investigator was reviewed by the 3Members Committee comprising of:

1

2.

3.

After due deliberation the committee made the following decisions regarding the clarifications presented by the PI.

---------- ----------

Signature and date **Signature and date**

(Member) **(Member)**

Signature and date

(Member Secretary)

AN5-V1/SOP 06/V1

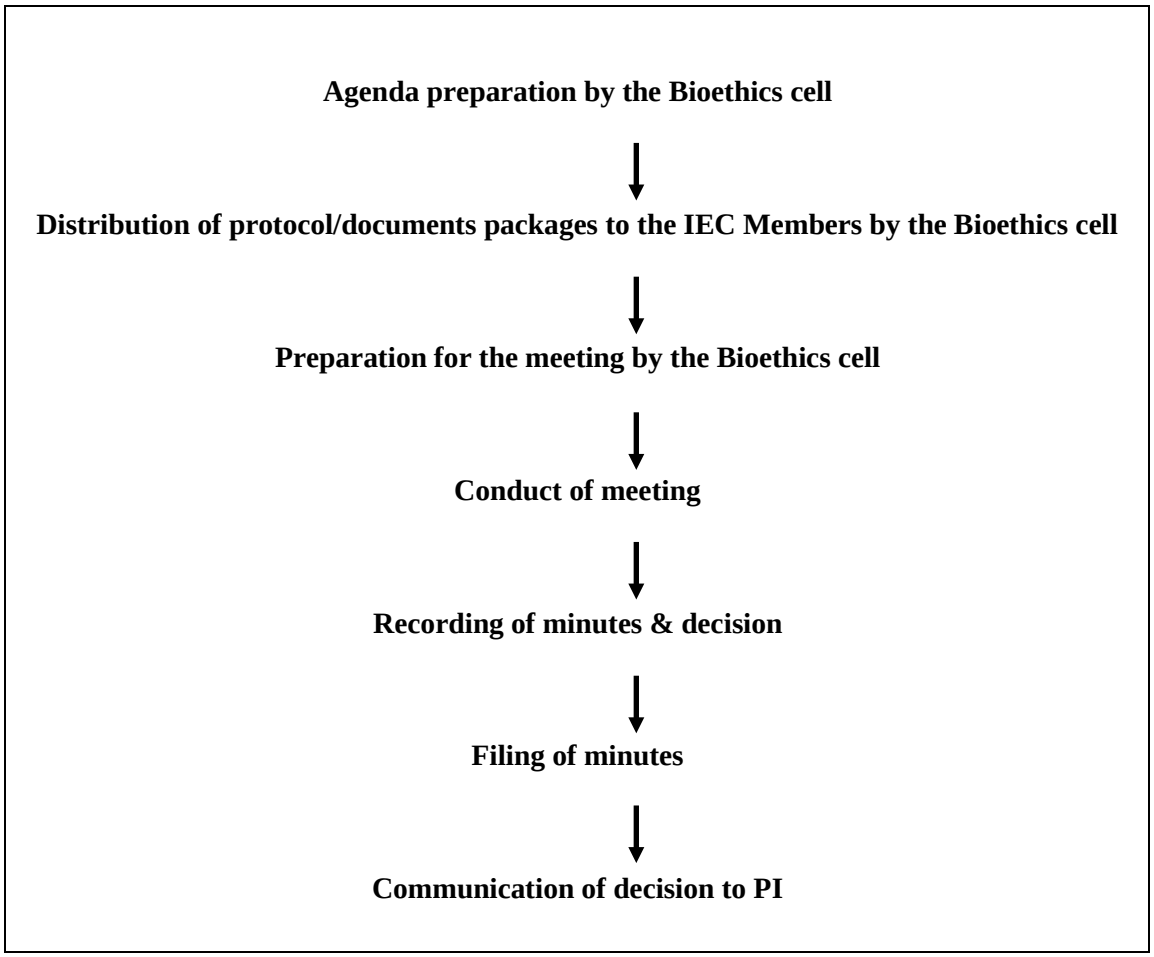
Intimation of Start of Study

1. **IEC code Number:**
2. **Study/Protocol No. (For drug/device trials/any other):**
3. **Title of the drug/multicentre trial:**
4. **Principal Investigator (Name & Department):**
5. **Sponsor:**
6. **Contract Research Organization (CRO) if any:**
7. **Date of sanction by IEC:**
8. **Date of start**:

_____

Name of the PI
Date: **Signature of the PI**

Flow Chart


Agenda preparation by the Bioethics cell
Distribution of protocol/documents packages to the IEC Members by the Bioethics cell
Preparation for the meeting by the Bioethics cell
Conduct of meeting
Recording of minutes & decision
Filing of minutes
Communication of decision to PI

Standard Operating Procedures of Institutional Ethics Committee;

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SOPs, IEC, SSPHPGTI)

Title : Review of Amendments/Notifications

SOP Code: SOP 07/V1 : Date: 20/07/2019

- Procedure for amendments/notifications
- Decision making
- Storage of documents

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

7.1 Procedures

7.1.1 Receipt of the amended protocol

- The amendment forwarded by the PI is received by the Bioethics cell. The amendment along with the covering letter should be accompanied by Amendment Reporting Form (AN1-V1/SOP 07/V1).
- It is the responsibility of the Bioethics cell to manage protocol amendments, documents and letters.
- The Bioethics cell should follow the procedures as in SOP 03/V1 (Procedures for Management of protocol submission).

7.1.2 Review of amended protocols/documents/letters: Review as per SOP 04/V1

7.1.3 Minor amendments and notifications

Minor amendments (those that do not increase the risk or decrease the potential benefit to subjects) may be approved in the 3-member subcommittee meeting.

Minor notifications may be noted by the Member Secretary, IEC and reported in IEC meeting. This may include but may not restrict to: Renewed insurance policy, DCGI and DGFT approvals, Administrative notes, etc.

7.2 Decision

- If the IEC approves the amendments, the Bioethics cell staff communicates this decision to the PI (AN2-V1/SOP 07/V1 or AN3-V1/SOP 07/V1).
- If the IEC does not approve the amendments, the Member Secretary should 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 Bioethics cell 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.

7.3 Storage of documents

File the amendments in the corresponding research protocol file, as per the SOP 14/V1 on documentation and archival.

AN1-V1/SOP 07/V1

Amendment Reporting Form (2 copies required)

1. IEC code No.:	
2. Study/Protocol No. (For drug/device trials/any other):	
3. Title:	
4. Principal Investigator:	
5. Please mention version no. and date of amended Protocol/Investigators brochure/Addendum	
6. Have you highlighted the amended portion in the document or tabulated details of changes?	
7. Do you wish to extend the approval for your study? If so, please provide details of date of completion, how long you require and the justification for the extra time:	**Yes/No**
8. Does this amendment lead to any change in trial protocol? If yes: please specify the changes	**Yes/No**
9. Does this amendment entail any changes in Participant information documents (PID)?	**Yes / No**
10. If yes, is the amended PIDs is enclosed	**Yes / No** **If No, reasons for not submitting**
11. Does it require signing of new consent form by participant already on trial	**Yes/No**
12. No. of active trial participants	
13. Any other additional comment including changes to budgetary or staff requirement: Yes/No	

Name of the PI

Date: **Signature of the PI**

AN2-V1/SOP 07/V1

Format for Project Amendment/Document Amendment Approval letter

To,

Dr._____
Principal Investigator,
SSPHPGTI
IEC code no. and project title:
Study/Protocol No. (For drug/device trials/any other):

Dear Dr.
We have received the following document/s on (date)_____

1.
2.

At the IEC meeting held on (date) ——, 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.

Yours Sincerely,

Signature of the Member Secretary_____Date _____

Name of the Member Secretary _____

Name of the Member Secretary
Date: **Signature of the Member Secretary**

AN3-V1/SOP 07/V1

Format for Project Amendment/Approval letter

To,

Dr._____
Principal Investigator,
SSPHPGTI.

IEC code and Project title:
Study/Protocol No. (For drug/device trials/any other):

Dear Dr.
We have received the following document/s on (date)_____

1.
2.

At the IEC meeting held on (date) ——, 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. The following members attended the meeting.

The committee suggested the following:

a.
b.
c.

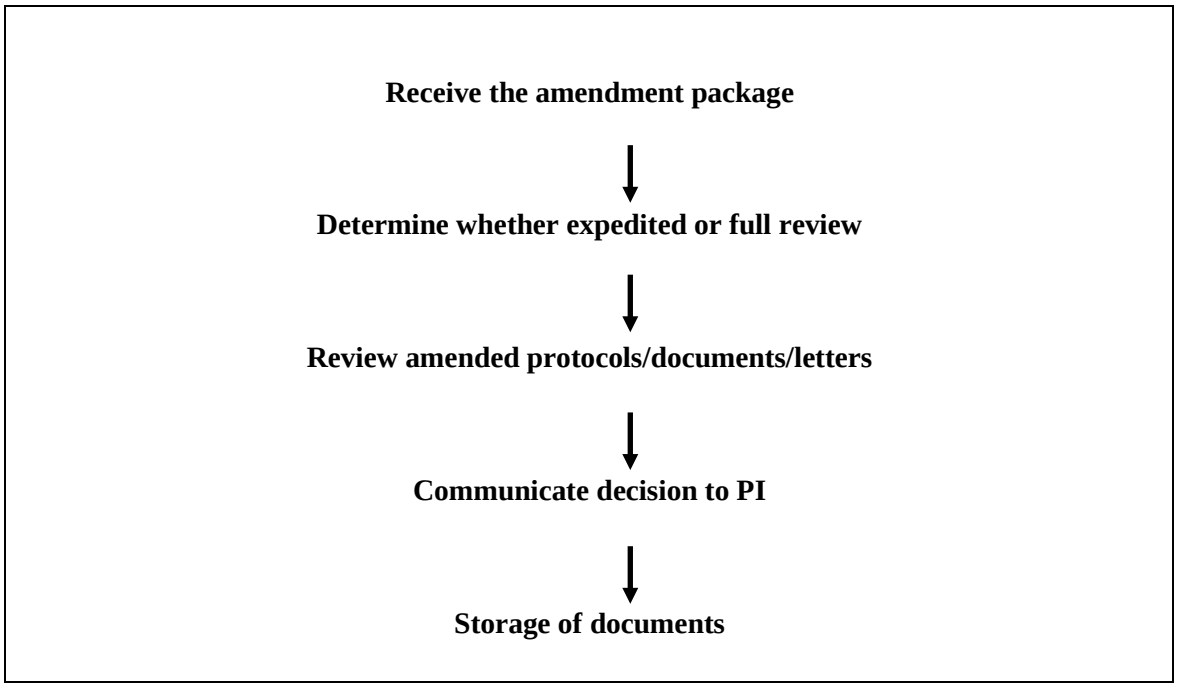
The approval will be granted subject to the compliance with all the above suggestions of the IEC. Kindly resubmit one of revised proposal or documents within 4 weeks for re-review by the Member Secretary/three Member Sub-committee/IEC.

Thanking you,

Yours Sincerely,

Name of the Member Secretary
Date: **Signature of the Member Secretary**

Flow Chart


Receive the amendment package
Determine whether expedited or full review
Review amended protocols/documents/letters
Communicate decision to PI
Storage of documents

Standard Operating Procedures of Institutional Ethics Committee;

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SOPs, IEC, SSPHPGTI)

Title : Continuing Review of study Protocols

SOP Code: SOP 08/V1 : Date: 20/07/2019

- Responsibility and procedures for Continuing review
- Decision making
- Communication to PI

The purpose of continuing review is to monitor the progress of the study which was previously approved; not just the changes in it to ensure continued protection of the right and welfare of research participants.

This SOP applies to continuing review of study protocols involving human participants, 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 a study more frequently.

8.1 Responsibility

- It is the responsibility of principal investigator (PI) to submit the periodic/annual progress report of the approved ongoing studies.
- The Chairperson is responsible for determining the date of continuing review if the project will be reviewed more frequently. 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.
- PI will also apply for extension of approval of the project if necessary along with the submission of the annual project progress report.
- 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.

8.2 Procedures

The Bioethics cell will:

- Check the master file of projects approved by the IEC for the due date of continuing reviews.

- It will inform the PI well in advance (one to two months) before the due date for the continuing review in writing, (AN3-V1/SOP 08/V1) requesting for 6 copies of the annual/periodic progress report to allow the study team sufficient time to collate the information and to prepare a report required for the continuing review.
- It will verify that the following documents are submitted:

1. Continuing Review Application Form (AN1-V1/SOP08/V1 or AN2-V1/SOP 08/V1) with signature of PI.
2. 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 AN1-V1/SOP 08/V1 or AN2-V1/SOP 08/V1) answers on the application form and a discussion of scientific development, either through the result of this study or similar research elsewhere that may alter risks to research participants.
3. Summary of the progress since the time of the last review.
4. Request letter for extension of approval of the project, if requested by PI.

- The IEC follows the procedure for review and decision making same as for an initial review.
- The Member Secretary will consult the Chairperson whether to include the annual project report/s in the forthcoming IEC meeting for discussion. After consultation with Chairperson, it can be reviewed by Member Secretary/Chairperson and informed in the full board meeting or sent to two more IEC members nominated by Chairperson for review.

8.3 Decision making

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 four weeks for re-review.
3. Disapproved further continuation.

- This decision is recorded by the Member Secretary on AN4-V1/SOP 08/V1.
- The IEC Chairperson will sign and date the IEC decision on Continuing Review Report after a decision has been reached.
- The Bioethics cell 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.

8.4 Communicate the IEC decision to the PI

The Member Secretary IEC will notify the PI of the decision (AN5-V1/SOP 08/V1) within 14 days.

AN1-V1/SOP 08/V1

Continuing Review Application Form/Annual status Report form
(For Interventional Study, 2 copies required)

IEC code No.: **Study/Protocol No. (For drug/device trials/any other):**
Protocol Title:
PI: **Institute:** **Date of IEC approval:** **Start Date of study:** **Duration of study:**

1. Project Status

[ ] Ongoing

[ ] Completed

[ ] Accrual completed

[ ] Follow-up

[ ] Suspended

[ ] Terminated

[ ] Closed

[ ] Not started/Not initiated

If 'Not started' state reasons:

2. Provide the date of last status review report submitted to IEC for this project

3. Have there been any amendments since the last status report?

[ ] YES

[ ] NO

If 'Yes', Were these Protocol amendments approved by IEC

- YES, if 'YES', please provide date of approval_____
- No

Note: Kindly attach a sheet with the list of amendments to be approved / approved by the IEC in a tabular column with details of amendment no. with date, date of submission to IEC and date of approval by IEC.

4. Have there been any Participant Information Document (PID) amendments since

the last status report?

[ ] YES

[ ] NO

If 'Yes', Were these PID amendment approved by IEC

- YES, if 'YES', please provide date of approval_____
- No

Note: Kindly attach a sheet with the list of amendments to be approved / approved by the IEC in a tabular column with details of amendment no. with date, date of submission to IEC and date of approval by IEC.

5. 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_____
- Number of patients who have completed the study_____
- Impaired participants:
  - None_____
  - Physically_____
  - Cognitively_____
  - Both_____

6. Is the recruitment on schedule?

[ ] YES

[ ] NO

(If 'NO', please attaché a sheet giving reason and your plans to improve accrual)

7. Have there been any changes in the participant population, recruitment or selection criteria since the last status report was submitted to IEC review?

[ ] YES (If 'YES', kindly attach a sheet explaining the changes)

[ ] NO

8. **Have any participants withdrawn from this study during the last one year?**

   [ ] YES (If 'YES', kindly attach a sheet stating reasons for drop-outs)

   [ ] NO

9. **Have any participating Investigators been added or deleted since last status report was submitted to IEC?**

   [ ] YES (If 'YES', kindly attach a sheet with details regarding the changes)

   [ ] NO

10. **Have any new collaborating sites (institutions) been added or deleted since the last status report was submitted to IEC?**

    [ ] YES (If 'YES', kindly attach a sheet with details)

    [ ] NO

11. **Does the Protocol have an inbuilt monitoring plan?**

    [ ] YES

    [ ] NO

12. **Is interim data analysis report available?**

    [ ] YES (If 'YES', kindly submit as an attachment)

    [ ] NO

13. **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?**

    [ ] YES (If 'YES', kindly attach a sheet with details)

    [ ] NO

14. **Have any unexpected complications, AEs or SAE been noted since last status report?**

    [ ] YES

[ ] NO

(If 'YES', please attach a sheet giving complete details regarding number of SAEs occurred, whether reports of SAEs have been submitted to IEC, type of adverse events in a tabular format.)

15. **When was study last monitored?**

    Date of monitoring_____

    Monitored by_____

    Number of subjects monitored_____

16. **Is report of the data safety and monitoring board report available?**

    [ ] YES (If 'YES', submit as an attachment)

    [ ] NO

17. **Did the monitoring team have any adverse comments regarding the study?**

    [ ] YES (If 'YES', please attach a copy of their comments)

    [ ] NO

18. **Has there been any presentation/publication related to the data generated in this trial?**

    [ ] YES (If 'YES', kindly attach a sheet with details)

    [ ] NO

19. **Have any investigators developed an equity or consultative relationship with a source related to this protocol which might be considered as conflict of interest?**

    [ ] YES (If 'YES', kindly append a statement of disclosure for the same)

    [ ] NO

Name of the PI

Date: **Signature of the PI**

AN2-V1/SOP 08/V1

Continuing Review Application Form/Annual status Report form
(For Non-Interventional Study, 6 copies required)

1. **IEC code no.**
2. **Title of the project:**
3. **Principal Investigator (Name & Department):**
4. **Sponsor:**
5. **Date of sanction by IEC**
6. **Date of start:**
7. **Duration of project:**
8. **Objectives of the study:**
9. **Total number of patients to be recruited for the study:**
10. **Progress report as per objectives (summary in 250 word):**

_____

_____

_____

_____

_____

_____

11. **Protocol deviation if any with reasons/justifications:**

Name of the PI
Date: **Signature of the PI**

AN3-V1/SOP 08/V1

Reminder Letter by the IEC to PI

Name of Principal Investigator: -

Address of Principal Investigator: -

IEC code no. & Project Title:

Study/Protocol No. (For drug/device trials/any other):

The above referenced project was approved by the IEC on… .....and is due for continuing annual review by the IEC. You are requested to submit an annual status report in the prescribed format AN1-V1/SOP 08/V1 or AN2-V1/SOP 08/V1 on or before…….

Name of the Member Secretary
Date: **Signature of the Member Secretary**

AN4-V1/SOP 08/V1

IEC Decision on Continuing Review Report

IEC code no:

Project Title:

PI:

Review: Annual Progress Report

Date of IEC meeting:

Further the review and approval of resubmitted protocol is subjected to:

- Reviewed in Full Board

Decision:

- Noted and the project can be continued without any modifications
- Modifications recommended, requiring protocol resubmission
- Protocol discontinued
- Extension of project (if extension necessary, Yes/No, if Yes, period of extension)

State the recommendations:

Name of the Member Secretary
Date: **Signature of the Member Secretary**

AN5-V1/SOP 08/V1

Project Annual Report Approval Letter

PI Name:

PI address:

Project Title:

IEC code no.

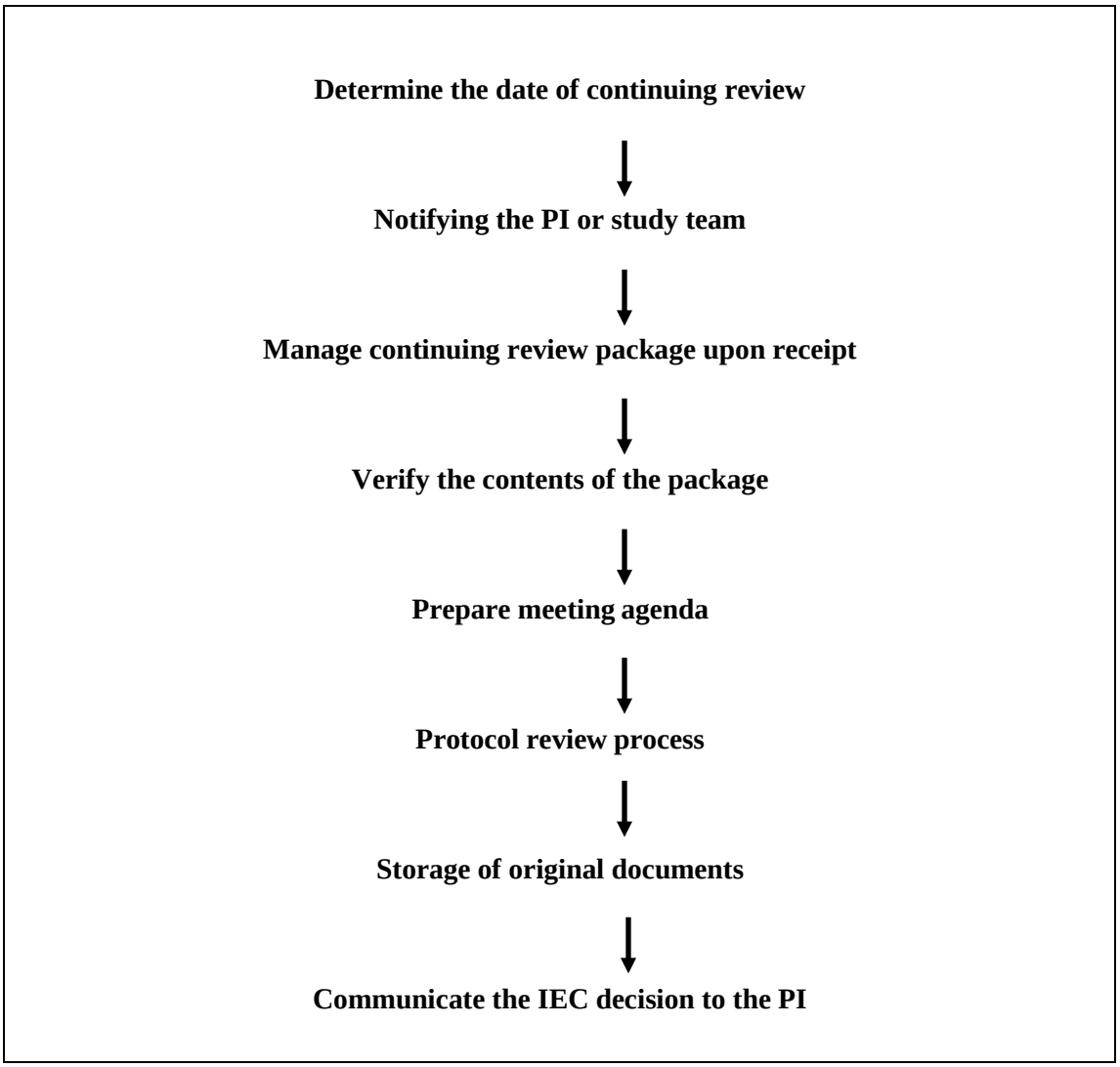
Study/Protocol No. (For drug/device trials/any other):

This is with reference to your letter 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);

Name of the Member Secretary

Date: **Signature of the Member Secretary**

Flow Chart


Determine the date of continuing review
Notifying the PI or study team
Manage continuing review package upon receipt
Verify the contents of the package
Prepare meeting agenda
Protocol review process
Storage of original documents
Communicate the IEC decision to the PI

Standard Operating Procedures of Institutional Ethics Committee;

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SOPs, IEC, SSPHPGTI)

Title : Reporting of Protocol Deviation/Non-Compliance/Violation/Waiver

SOP Code: SOP 09/V1 : Date: 20/07/2019

- Responsibility
- Detailed Instructions, decisions and actions
- Notifying the investigator
- Records and follow-up

These SOPs 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.
- Respond to the IEC requests.

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

9.1 Responsibility

- The PI should forward protocol deviation/non-compliance/violation/waiver reports to the IEC. Protocol Waiver is analogous to a Protocol Deviation, except that prior IEC 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.
- The Bioethics cell will receive deviations /violations/waiver reports as per (AN1- V1/SOP 09/V1) submitted by the PI. Reporting of deviation/non- compliance/violation/waiver in any other reporting format will not be accepted. It will be placed in the meeting agenda.
- IEC members should review and take action on such reports.

9.2 Detailed instructions

9.2.1 Detection of protocol deviation/non-compliance/violation/waiver

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

B. Bioethics cell 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

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

E. Any report/communication brought to the notice of the Member Secretary/Chairperson of IEC

F. Communication received from the Director, SSPHPGTI informing IEC about an alleged protocol violation/non-compliance/protocol deviation

9.2.2 Noting protocol deviation/non-compliance/violation/waiver by the Bioethics cell

- The members of site monitoring committee who have performed monitoring of a particular trial site and detect protocol deviation/non-compliance/violation will inform the Bioethics cell in writing within 24 hours [one working day].
- Whenever protocol deviation/non-compliance/violation have been observed, the Bioethics cell 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.

9.2.3 Board discussion, decision and action

- If the protocol deviation/non-compliance/violation is detected by IEC member during monitoring visit he/she will present the protocol deviation/noncompliance/violation information.
- If detected by the Bioethics cell forwarded by PI, the Member Secretary will present the protocol deviation/non-compliance/violation/waiver information.
- The deviations/violations will be scrutinized for gravity and implications in the formal full board IEC meeting. The 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 IEC decision will be communicated to PI.

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 inform 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, SSPHPGTI for suitable action.
- Revoke approval of the current study.
- Keep other research proposals from the PI/ Co-PI under abeyance.
- Review and / or inspect other studies undertaken by PI/Co-PI.

9.3 Notifying the investigator

- The Bioethics cell records the IEC decision and prepares a notification letter (AN2-V1/SOP 09/V1).
- The Member Secretary signs and dates the letter.
- The Bioethics cell sends a copy of the notification to the investigator.
- The Bioethics cell sends a copy of the notification to the relevant national authorities, the sponsor or the CRO of the study and other trial sites, in case of multi-centric trial, if so recommended by IEC.

9.4 Records and follow up by Bioethics cell

- Keeps the original 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.

AN1-V1/SOP 09/V1

Deviation (D)/Waiver (W)/Violation (V) Reporting Form (2 copies required)

IEC Code No: **Study/Protocol No. (For drug/device trials/any other):** **Project Title:** **PI:**
Specify if D/W/V-
Date of occurrence: dd/mm/yyyy (Not applicable in case of Waiver)
No of similar D/W/V occurred the same trial:
Patient No. and name:
Complete Details of D/W/V (attach separate sheet if necessary):
Action taken by PI/Co-PI/guide: (Not applicable in case of Waiver)
Impact on trial subject (if any): (Not applicable in case of Waiver)
Whether D/W/V informed to sponsor/CRO:
Name of the PI **Date:** **Signature of the PI**

AN2-V1/SOP 09/V1

Form for communicating decision of Deviation (D)/Waiver (W)/Violation (V) to PI

IEC Code No:
Study/Protocol No. (For drug/device trials/any other):
Project Title:
PI:

Sub:

Reviewed by the IEC

Final decision at the full board meeting held on _____

Action taken:

[ ] Noted

[ ] Request the Principal Investigator to take immediate action to prevent such deviations/non compliances/violations in future

[ ] Specific recommendations stated below to be followed

_____

_____

_____

[ ] Suspend the study till the IEC recommendations are implemented [ ]

Suspend the study till information available

[ ] Terminate approval of the current study

Reasons for termination:

_____

_____

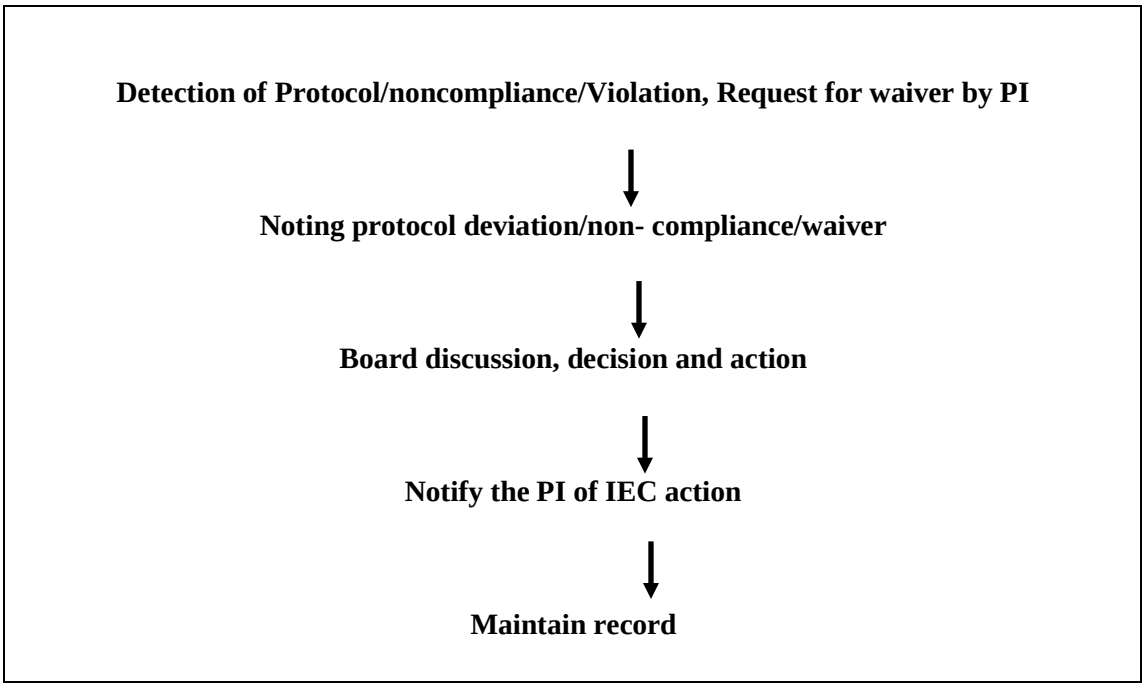
_____

Any other comment _____

Name of the Member Secretary

Date: **Signature of the Member Secretary**

Flow Chart


Detection of Protocol/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 record

Standard Operating Procedures of Institutional Ethics Committee;

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SOPs, IEC, SSPHPGTI)

Title : Review of Adverse Events (AE) Reports

SOP Code: SOP 10/V1 : Date: 20/07/2019

- Purpose and scope
- Categorization of protocols as exemption from review
- Responsibility and detailed instructions
  - Onsite SAE
  - Offsite SAE

10.1 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 study approved by the IEC. The reporting is in accordance to the Gazette, Govt. of India.

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 or SAE monitoring sub-committee (formed by 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, welfare or safety of participants in the study.

10.2 Scope

This SOP applies to the IEC and SAE monitoring sub-committee review of SAE and unexpected events reports, both on site and off site, including follow up reports submitted by investigators.

10.3 Responsibility

It is the responsibility of the PI to report any AE/SAE (onsite or offsite) in the enrolled participants as per rules of Govt. of India.

The primary responsibility of the IEC or SAE monitoring sub-committee is to review and address SAE and unexpected events involving risks to research participants. IEC should also make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements for SAE.

In case, the investigator fails to report any SAE within the stipulated period, he shall have to furnish the reason for the delay to the satisfaction of DCGI along with the report of the SAE.

10.4. Detailed instructions

A. On site SAEs

10.4.1 SAE related activities before IEC meeting

- The Bioethics cell will verify that the reports are complete, signed and dated by the PI. In case the Bioethics cell notes that the report is incomplete, it will be forwarded to Member Secretary, IEC for decision and also revert back to PI.
- The Bioethics cell should receive the reports of SAEs occurred for IEC approved studies within the stipulated time of the occurrence of the SAE.
- If the SAE is 'Death', the Bioethics cell should receive the SAE reporting form (AN1-V1/SOP 10/V1) within the stipulated time of its occurrence.
- If the PI has not adhered to the above stipulated time period, the Bioethics cell will notify the discrepancies in the reporting time and time of occurrence of SAE to the PI.

10.4.2 Actions to be taken by Member Secretary, IEC

- If the SAE reported is 'death', the Member Secretary will send to SAE monitoring sub-committee, and it will report to the Chairperson, IEC for further action.
- The Member Secretary will table SAE report (as submitted by SAE monitoring sub-committee) at the next scheduled IEC full board meeting.

10.4.3 Actions to be taken by SAE subcommittee

The SAE subcommittee will look at the report of SAEs submitted by PI (on site) and will report to the Chairperson, IEC. Decision of subcommittee will be reported in the next IEC meeting (AN5-V1/SOP 10/V1).

10.4.4 Actions to be taken by Chairperson

The Chairperson, IEC on basis of the information and comments received from the Member Secretary, IEC, and SAE monitoring sub-committee and applying his/ her judgment will direct the Bioethics cell 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 (to be listed).
- 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 Bioethics cell will take appropriate steps to ensure that IEC members are informed about this full board emergency review.
  - The chairperson could direct the Member Secretary, IEC, to invite one or more experts if necessary. 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 mandate of IEC. The expert would be requested to provide an opinion in writing within 14 working days, depending upon the gravity and seriousness of the matter.
- Report at the next IEC meeting for discussion.

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 with reporting of centre-wise SAE's.
- 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 (AN3-V1/SOP 10/V1) have to be logged (AN4-V1/SOP 10/V1) 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 AN3-V1/SOP 10/V1) will be reported to the Bioethics cell, and forwarded to Member Secretary, IEC for further action.
- If a trend is observed in SAEs by PI, such a trend will be reported to the Bioethics cell, action on such reports will be taken by the Member Secretary, IEC as per 10.3-10.4.
- The Bioethics cell will require complete set of "Off site Safety Reports" and/or the log. The IEC will review the log of (AN4-V1/SOP 10/V1) the SAEs every 3 months and at the time of continuing review/submission of annual status report.
- **The PI must comment possible effect of previously reported and current SAE reports on ongoing study while submitting the documents.**

10.5 During the IEC meeting (On site or off site SAEs)

- If appropriate, specific action or combination of actions will be taken, based on the consensus decision of the IEC discussion. Some of these 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.
- Recommend for compensation and send to DCGI.
- Any other action (as per schedule Y).

10.6 After the review of SAE

- The Bioethics cell will send a formal letter signed by the Member Secretary to the investigator/s with instructions for specific actions as per the IEC decision and compliance to actions recommended by the IEC within 14 days of receipt of the IEC letter.
- The IEC will instruct the PI to forward follow-up reports of the SAE to the IEC.
- The Bioethics cell keep a copy of the letter in the master file of the research protocol.
- 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.
- Inform the DCGI (within 30 days) of IEC decision in case of drug trials.
- IEC will decide if it is necessary to suspend recruitment/modify protocol/PID.

10.7 Time line for reporting of SAE('s)/SAE for 'death' (as per Gazette, Govt. of India, 2013 and 2014

Responsibility of PI

The researcher is responsible for reporting all SAEs to the IEC within 24 hours of knowledge. Reporting of SAE may be done through email or fax communication (including on non-working days).

A report (after due analysis) has to be submitted by the PI to DCGI, Chairman of IEC and the Head of Institution where the trial is being conducted, within 14 days of the occurrence of SAE**.**

Responsibility of IEC

The IEC shall forward its report on the SAE, after due analysis, along with opinion on the financial compensation, if any to be paid by the sponsor, to DCGI **within 30 days of the occurrence of the SAE**

Responsibility of DCGI

DCGI shall forward the report of the Investigator, sponsor and the IEC to the chairman of the independent Expert Committee of DCGI.

The Expert Committee of DCGI shall examine the report of SAE and give its recommendations to DCGI for the purpose of arriving at the cause of SAE **within 105 days of occurrence of the SAE.** In case of clinical trial related death, the Expert Committee shall also recommend the quantum of compensation to be paid by the sponsor/representative.

DCGI, after considering the recommendations of Expert committee, shall decide the quantum of compensation to be paid by the sponsor/representative and pass orders **within 150 days of occurrence of the SAE.**

Responsibility of sponsor/PI

The sponsor/representative, shall pay the compensation in case of clinical trial related injury or death as per the order of the DCGI **within 30 days of the receipt of such order**.

AN1-V1/SOP 10/V1

Onsite Adverse Drug Event Reporting Form (2 copies required)

1. IEC code no.:

2. Study/Protocol No. (For drug/device trials/any other):

3. Title of project:

4. Principal Investigator:

5. Suspected Adverse Reaction (diagnosis):

6. Report date:

7. Date of onset of SAE:

8. Report type:

a. Initial:

b. Follow up---------- If Follow-up report, state date of Initial report----------

c. Final:

9. Patient information:

a. Patient Initial and Case No./Subject ID.

b. Age: c. Gender:

d. Height: e. Weight:

10. Information related to no. of recruitment/prior SAE and death

	Total number of recruitment at	Total number of SAE (prior) occurred at	Number of similar SAEs (prior) occurred for same study at	Total number of death at
This site				
Other site (s)				

11. Tick which eve is applicable for serious adverse event

A] Expected event [ ] Unexpected event [ ]

B] Hospitalization [ ] Increased hospital stay [ ] Death [ ] Others [ ]

In case of Death, state probable cause of death…….

(If other, please specify: …….

C] No permanent significant functional/cosmetic impairment [ ]

Permanent significant functional/cosmetic impairment [ ]

Not applicable [ ]

12. If there was a research related injury/hospitalization, the cost of treatment/

hospitalization was borne by: Patient [ ] Institute [ ] Sponsor/CRO [ ]
13. Suspect drug information a. Suspect drug (include generic name) device/intervention: b. Indication(s) for which suspect drug was prescribed or tested: c. Daily dose and regimen : d. Route(s) of administration: e. Dosage Form and Strength: f. Therapy dates (start and stopped date):
14. Did the reaction decline after stopping the drug/procedure (Dechallenge & Rechallenge information): YES [ ] NO [ ] NA [ ]
Concomitant drugs history and lab investigations
15. Concomitant drug (s) and date of administration:
16. Relevant test/laboratory data with dates:
17. Patient relevant history (e.g. diagnosis, allergies):
Reaction information
18. Description of adverse event a. Start date (and time) of onset of reaction: b. Stop date (and time) or duration of reaction: c. Setting (e.g. hospital, out-patient clinic, home, nursing home): d. [Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction, indicate if this is follow-up report and if so, include follow-up information only]:
19. Describe the medical treatment provided for adverse reaction (if any) to the research subject. This is an update on treatment given during hospitalization:
20. Outcome: Resolved [ ] Ongoing [ ] Death [ ]

21. Was the research subject continued on the research protocol? Yes [ ] No [ ] NA (Mark 'NA' in case of death) [ ]
22. Has this information been communicated to sponsor/CRO/regulatory agencies? Yes [ ] No [ ] Provide details if communicated (including date):
23. In your opinion, does this reaction require any alteration in trial protocol? Yes [ ] No [ ] **If yes then please specify:**
24. Causality Assessment:
25. Details about the Investigator Name: Address: Telephone number/email: Profession (specialty): **Name of the PI** **Date:** **Signature of the PI** **Upon receipt of this report, the IEC will decide whether additional information is needed or whether further investigation of the reaction is required.**

AN2-V1/SOP 10/V1

Form to Record Recommendations by IEC

• Noted and follow up report requested (if applicable) No [ ] Yes [ ]

• Changes to the protocol recommended? No [ ] Yes [ ] If yes then recommendations:

_____

_____

• Changes to the informed consent form recommended? No [ ] Yes [ ] If yes then recommendations:

_____

_____

• Request for additional information [ ]

Additional Information needed:

_____

_____

(Till additional information is received, new recruitment should be withheld)

• Terminate the project [ ]

Reasons for termination:

_____

_____

_____

• Any other including communicated of information to sponsor/CRO/regulatory agencies

_____

_____

Name of the Member Secretary

Date: **Signature of the Member Secretary**

AN3-V1/SOP 10/V1

Off-site 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 initial three questions (1-3) 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 (AN4-V1/SOP 10/V1). This log should be submitted to the Bioethics cell every 3 months and/or along with Continuing Review report.

IEC Code No.:
Project No.
Project Title:
Subject ID.:
Type of SAE (initial/follow up/any other):

Sr. No.	Questions	
1.	**Is adverse event serious? Yes/No**	
2.	**Is adverse event related to the trial medication/procedure? Yes/No**	
3.	**Is adverse event unexpected? Yes/No**	
4.	**Does warrant any change in protocol, PID? Yes/No**	**If yes, please provide details**

Date of reporting:

Name of the PI

Date: **Signature of the PI**

AN4-V1/SOP 10/V1

Off Site Safety Reports Log (2 copies required)

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 Bioethics cell every 3 months and/or along with Continuing Review report.
4. The log must be submitted to the Bioethics cell immediately, if prompt reporting is required and/or if a trend related to the occurrence of SAE is observed.
5. Please note the complete sets of Offsite Safety Reports need to be sent to Bioethics cell as and when received.

IEC Code No.:
Study/Protocol No. (For drug/device trials/any other):
Project Title:
PI:

No. of Participants enrolled in SSPHPGTI:____No. of Participants enrolled globally:
_____
No. of subjects on trials at SSPHPGTI: ____ No. of SAE at SSPHPGTI: ____
No. of death at SSPHPGTI: ____ No. of death globally:
_____

S. No.	Subject ID/SAE No.	Country	Date of Onset	Adverse event	Out Come	Remarks

Is any change in protocol, PID required on the basis these and of previously reported SAE? Yes/No, if yes, please provide details.

Name of the PI

Date: **Signature of the PI**

AN5-V1/SOP 10/V1

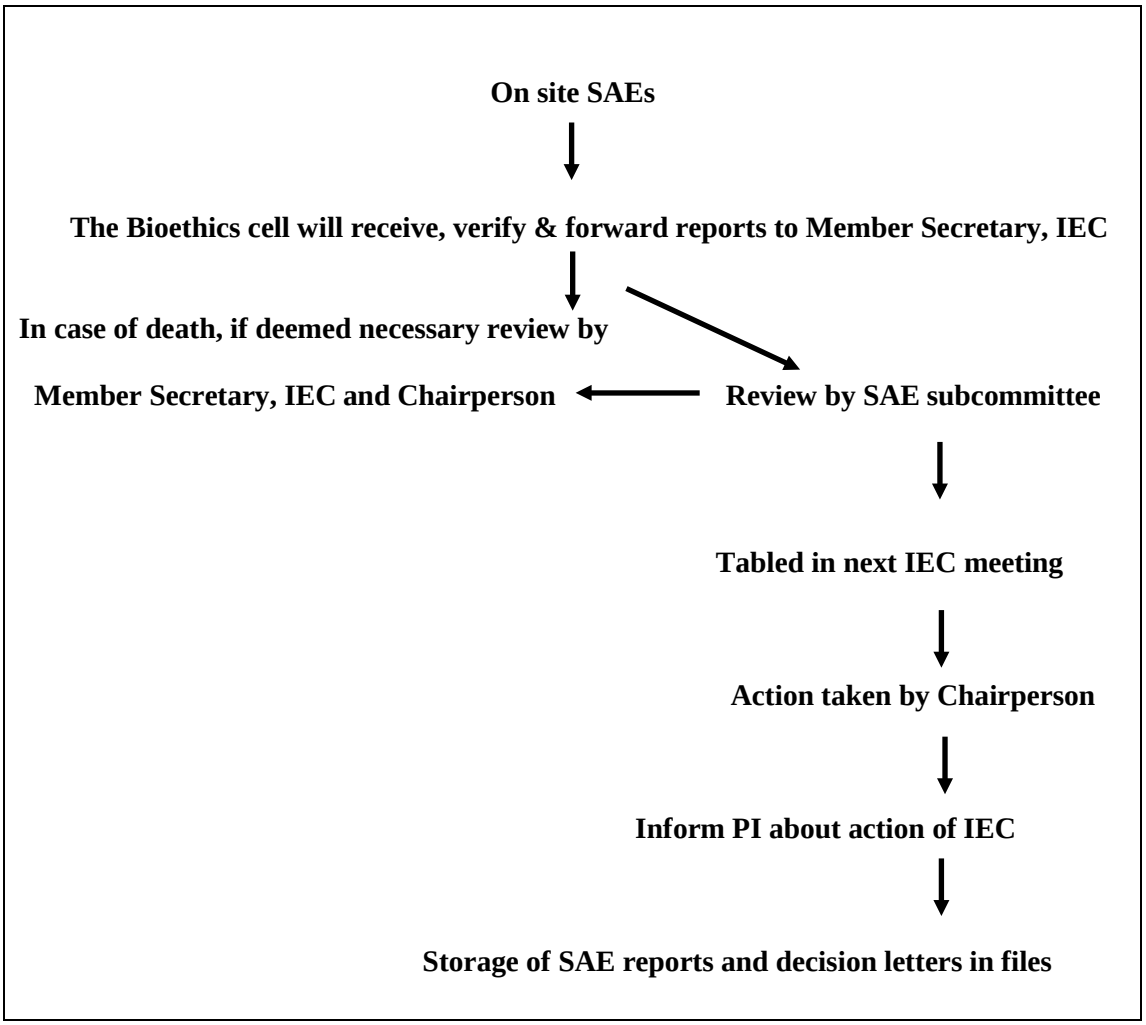
Form to Record SAE assessment by SAE monitoring subcommittee

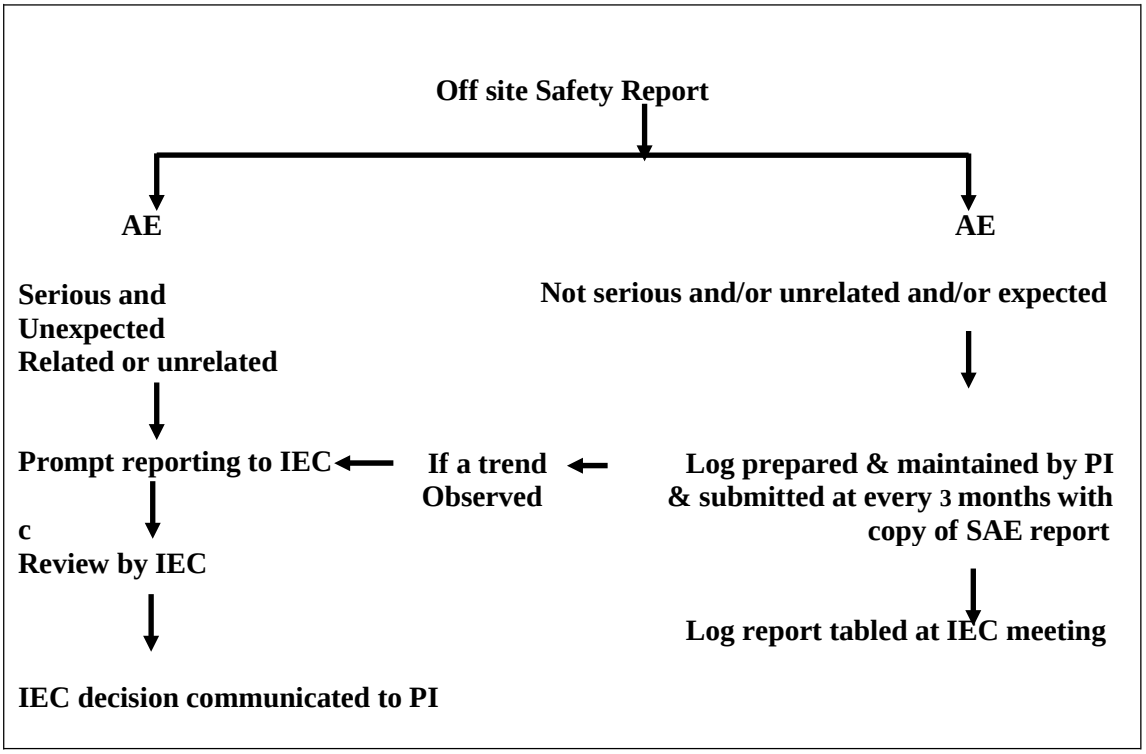
1. Details of the communication between you & Investigator along with other details etc. with regard to the event.
2. Details of examination of event by the SAE monitoring subcommittee, minutes of meeting including cause of death & recommendation on compensation, if any.
3. Details of the documents considered during the assessment of the SAE.
4. Indicate with justification and documentary evidence to as whether the SAE (death) is related/no related to each of the following criteria mentioned under GSR 53 (E) dated 30.01.2013 and rule 122 DAB of the Drugs and Cosmetics Rules.
   (a) Adverse effects of investigational product(S);
   (b) Violation of the approved protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator;
   (c) Failure of investigational product to provide intended therapeutic effect;
   (d) Use of placebo in a placebo-controlled trial;
   (e) Adverse effect due to concomitant medication excluding standard care necessitated as part of approved protocol;
   (f) For injury to a child in-utero because of the participation of parent in clinical trial;
   (g) Any clinical trial procedures involved in the study.
5. Inform the risk Factor depending on the Seriousness and severity of disease, presence of co-morbidity and duration of disease the subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as per the compensation formula decided by IEC (available on website: cdsco.nic.in).
   (a) 0.50 terminally ill patients (expected survival not more than (NMT) 6 month).
   (b) 1.0 Patient with high (expected survival between 6 to 27 months)
   (c) 2.0 Patient with moderate risk.
   (d) 3.0 Patient with mild risk.
   (e) 4.0 Healthy Volunteers or subject of no risk.

Name of the PI

Date: **Signature of the PI**

Flow Chart


On site SAEs
The Bioethics cell will receive, verify & forward reports to Member Secretary, IEC
In case of death, if deemed necessary review by
Member Secretary, IEC and Chairperson
Review by SAE subcommittee
Tabled in next IEC meeting
Action taken by Chairperson
Inform PI about action of IEC
Storage of SAE reports and decision letters in files


Off site Safety Report
AE
AE
Serious and
Unexpected
Related or unrelated
Not serious and/or unrelated and/or expected
Prompt reporting to IEC
If a trend
Observed
Log prepared & maintained by PI
& submitted at every 3 months with
copy of SAE report
c
Review by IEC
Log report tabled at IEC meeting
IEC decision communicated to PI

Flow Chart

Standard Operating Procedures of Institutional Ethics Committee;

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SOPs, IEC, SSPHPGTI)

Title : Review of Study Completion Reports

SOP Code: SOP 11/V1 : Date: 20/07/2019

- Responsibility
- Detailed Instructions/procedures

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

11.1 Responsibility

- It is the responsibility of the PI to submit Study Completion Report for the concerning project to the Bioethics cell within 6 weeks of completion of the study as per the Study Completion Report form (AN1-V1/SOP 11/V1 or AN2-V1/SOP 11/V1). Any alternate form for Pharma company driven trials (provided by the Sponsor, etc.) may be used, provided that the information submitted covers all the points mentioned in Study Completion Report forms. Site closure information Pharma company driven trials should also be submitted.
- It is the responsibility of the IEC members to review the study completion report and notify its approval or request for further information, if necessary.

11.2 Detailed instructions

11.2.1 Before board meeting

- The Bioethics cell will receive 6 copiesof Study Completion Reports from the PI and check for completeness before submission for the Board meeting.

11.2.2 During board meeting

- IEC member(s) should review and discuss the Final 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.

11.2.3 After board meeting

- The Bioethics cell 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 are requested, the same should be followed by the PI and communicated to the IEC office within 4 weeks. This update will be tabled in the full board meeting of IEC (AN3- V1/SOP 11/V1).
- The Bioethics cell will archive the entire study protocol and the report for a period of 5 years or longer as per the requirement of the study.

AN1-V1/SOP 11/V1

Study Completion Report form
(For Interventional Study)

(To be Filled by PI and submit 2 copies)	
IEC code No. **Study/Protocol No. (For drug/device trials/any other):** **Protocol Title:** **Principal Investigator:** **Phone number, email ID:**	
Sponsor: **Address:** **Phone, E mail:**	
Study Initiation Date:	
Study Completion Date:	
Number Screened: **Number Enrolled:** **Target Number:**	
Date of first Subject enrolled: **Date of last Subject enrolled:** **Date of first Subject completed study:** **Date of last Subject completed study:**	
No. of study arms:	
Duration of the study:	
Objectives:	
SAEs at the center: **(Total number and type)**	
Whether all SAEs intimated **to the IEC (Yes/No):**	
No. of patients withdrawn/lost to follow up **(drop out):**	
Reasons for withdrawal: **Protocol deviations/violations:** **(Number and nature)**	

Storage of document for more than 5 years, Yes [ ] No [ ] **If yes, for how many years? _____**
Results please attach a separate sheet if necessary):
Conclusion:
Name of the PI **Date:** **Signature of the PI**

**Please submit thesis summary/manuscript (if applicable)*

AN2-V1/SOP 11/V1

Study Completion Report form
(For Non-Interventional Study, 2 copies required)

IEC code no.

Title of the project:

Principal Investigator (Name & Department):

Sponsor:

Date of sanction by IEC:_____Date of start: _____

Date of termination: _____

Duration of project:

Objectives of the study:

Total number of patients to be recruited for the study: _____

Number actually recruited: _____

Protocol deviation/violation (number): _____

Result:_____

_____

_____

Conclusion:

Storage of document for more than 5 years, Yes [ ] No [ ]

If yes, for how many years? _____

Name of the PI

Date: **Signature of the PI**

**Please submit thesis summary/manuscript (if applicable)*

AN3-V1/SOP 11/V1

Notification for Acceptance of Study Completion Reports

Reviewed by the IEC

• Full Board meeting held on (date)_____

Comments (if any):

_____

_____

Action taken:

Noted [ ]

Requires more information/ action as follows [ ]:

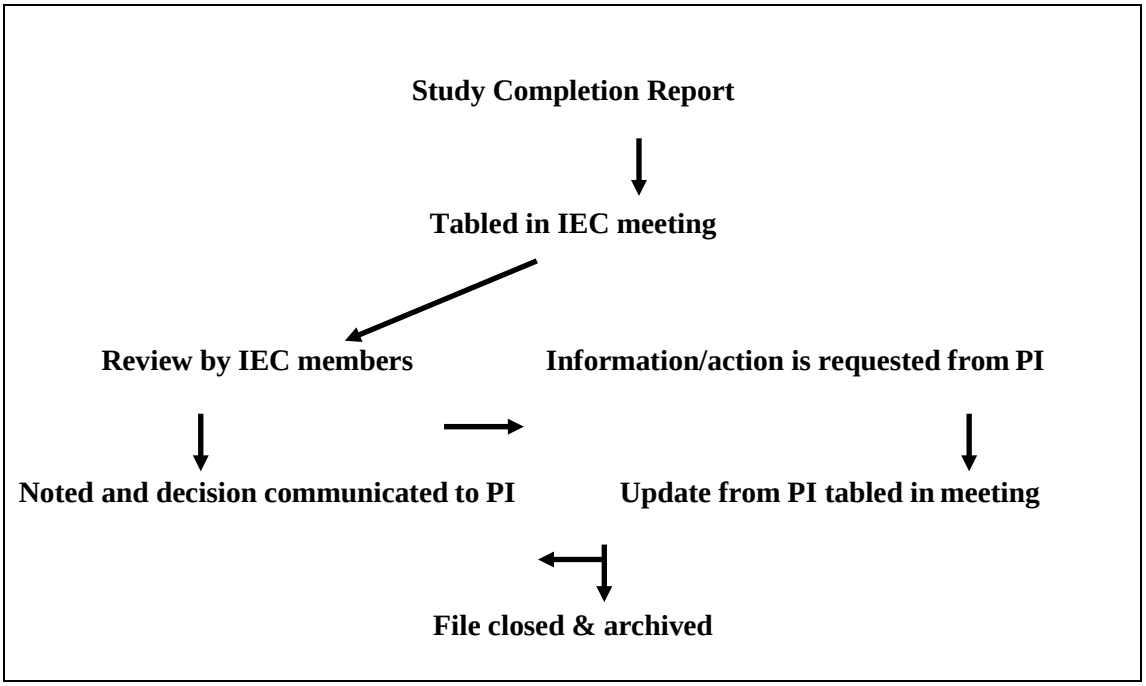
_____

_____

Name of the Member Secretary

Date: **Signature of the Member Secretary**

Flow Chart


Study Completion Report
Tabled in IEC meeting
Review by IEC members
Information/action is requested from PI
Noted and decision communicated to PI
Update from PI tabled in meeting
File closed & archived

Standard Operating Procedures of Institutional Ethics Committee;

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SOPs, IEC, SSPHPGTI)

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

SOP Code: SOP 12/V1 : Date: 20/07/2019

- Responsibility
- Detailed Instructions
  - Receipt and decision making
  - Communication to PI

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, PI, sponsor or other authorized bodies wherein subject enrollment and subject follow-up are discontinued before the scheduled end of the study.
This SOP applies to any study approved by IEC that is being recommended for termination/ suspension/discontinuation before its scheduled completion.

12.1 Responsibility

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

12.2 Detailed instructions

12.2.1 Receiving recommendation for study termination/suspension/discontinuation

- The Bioethics cell will receive recommendation and comments from PI, sponsor or other authorized bodies for premature termination of study protocol and place them before the board.
- The IEC members /Chairperson can prematurely terminate study if protocol non-compliance /violation are 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 Bioethics cell will inform the PI to prepare and submit a protocol termination report.
- The Bioethics cell will receive the Premature Termination Report (AN1-V1/SOP 12/V1) submitted by the PI and check for completeness. It should contain a brief written summary of the protocol, its results, and accrual data. The Bioethics cell will initial and date it upon receipt.

12.2.2 Review and decision on termination/suspension/discontinuation report

- IEC will review the Premature Termination Report (AN1- V1/SOP 12/V1) at regular full board meeting and make appropriate recommendation(s).
- If the report is unclear, a query can be sent to the PI for more information.

12.2.3 Notifying the PI

- The Bioethics cell will make notification letter acknowledging the approval of termination or query letter to request additional information regarding the premature termination within 14 days after the meeting (AN2- V1/SOP 12/V1).
- If a query is sent to PI, the reply letter will be reviewed in the next full board meeting and steps in 12.4.2 will be performed by the Bioethics cell.

AN1-V1/SOP 12/V1

Premature Termination/Suspension/Discontinuation Report (2 copies required)

IEC code No.:	
Study/Protocol No. (For drug/device trials/any other):	
Protocol Title:	
PI:	
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 (attach a separate sheet if necessary):	
Reason for Termination/Suspension/Discontinuation: • **Safety concern** • **Lack of efficacy** • **Others**	
Storage of document for more than 5 years, Yes [ ] No [ ] **If yes, for how many years? _____**	
Name of the PI **Date:** **Signature of the PI**	

AN2-V1/SOP 12/V1

Notification from IEC for Premature Termination/Suspension/Discontinuation of the Study

IEC code no.

Study/Protocol No. (For drug/device trials/any other):

Title of the project:

PI:

Reviewed by the IEC

• Full Board meeting held on (date)_____

Action taken:

Approval of the Premature Termination of the project [ ]

Requires more information/ action as follows [ ]:

_____

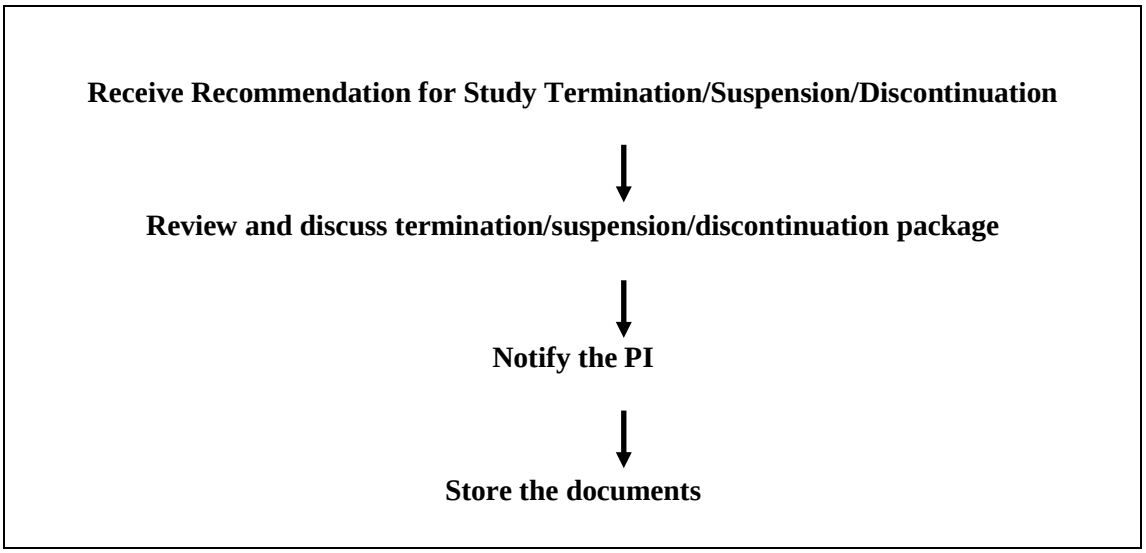
_____

_____

Name of the Member Secretary

Date: **Signature of the Member Secretary**

Flow Chart


Receive Recommendation for Study Termination/Suspension/Discontinuation
Review and discuss termination/suspension/discontinuation package
Notify the PI
Store the documents

Standard Operating Procedures of Institutional Ethics Committee;

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SOPs, IEC, SSPHPGTI)

Title : Request for Waiver of Written Informed Consent

SOP Code: SOP 13/V1 : Date: 20/07/2019

- Projects which may qualify for consent waiver
- Detailed instruction/procedures

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.
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/full board meeting.

13.1 Type of research projects which may qualify for consent waiver

The investigator can apply to the EC for waiver of consent if the ***proposed research should present no more than minimal risk to the participants and the waiver will not adversely affect the rights and welfare of the participants***. 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. As per the ICMR 2017 guidelines (http://ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.pdf) in the following conditions consent waiver may be granted by IEC:

1	Research cannot practically be carried out without the waiver and the waiver is Scientifically justified (e.g. disease burden estimation in HIV, genetic studies etc.).
2	Retrospective studies, where the participants are de-identified or cannot be contacted. e.g. a retrospective review of patient case records
3	Research on anonymized biological samples/ data.
4	Surveillance programmes/ programme evaluation studies
5	Research on data available in public domain.
6	Research on humanitarian emergencies and disasters, when the participant may not be in a position to give consent. However, information about the study should be given to the patients whenever he/she gains consciousness, or to relative/ legal guardian when available later.

The requirement for obtaining consent can be waived of by the IEC, if 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,

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

For verbal consent/telephonic interviews, the following documents need to be submitted by the PI:

- 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 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.
- 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 1,2,3. 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.

13.2 Detailed instructions

- The PI will submit request for waiver of consent along with the study documents to the Bioethics cell, in the given format AN1-V1/SOP 13/V1 stating the reasons for the consent waiver
- 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.
- 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 in the given format AN2-V1/SOP 13/V1.

AN1-V1/SOP 13/V1

Application Form for requesting Waiver of Consent

1. **Principal Investigator's name**: _____

2. **Department**: _____

3. **Title of project**: _____

_____

_____

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 to 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 is not violated

_____

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

_____

Name of the PI

Date: **Signature of the PI**

AN2-V1/SOP 13/V1

Decision of IEC Regarding Waiver of Consent

To,

Dr._____

Principal Investigator,

SSPHPGTI.

Ref: IEC code.

Title of project:

Dear Dr.

Institutional Ethics Committee reviewed and discussed your application (dated……..) for waiver to written informed consent during the IEC (number of meeting) meeting held on (date……..).

Waiver granted: Yes [ ] No [ ]

If not granted, reasons

_____

_____

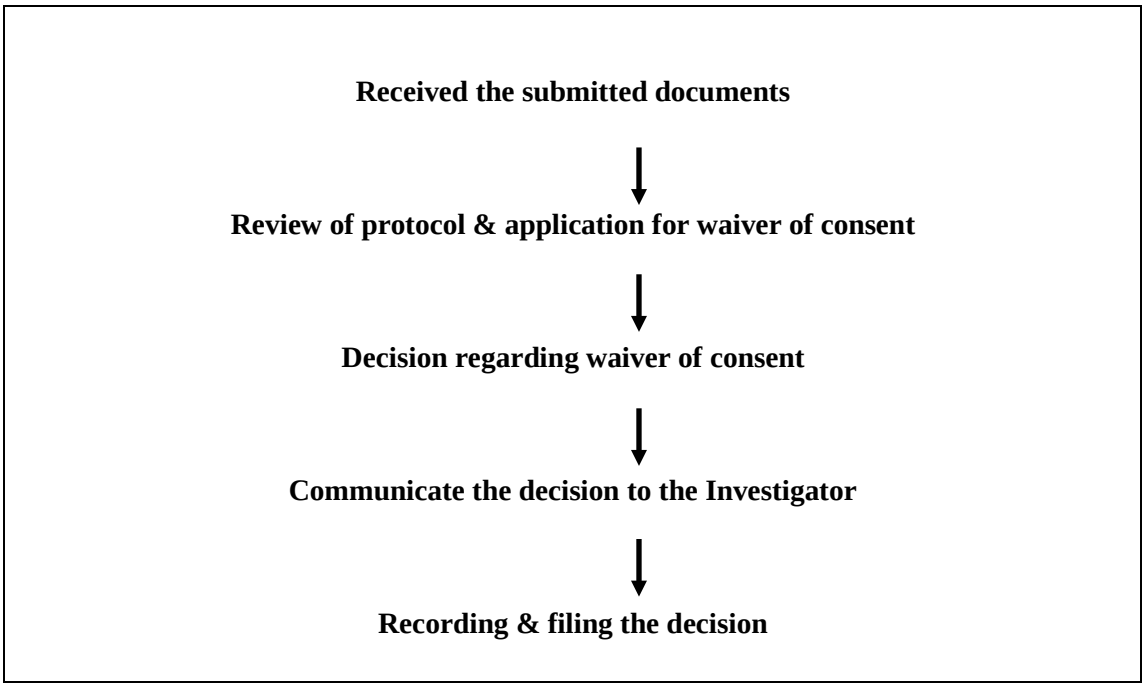
Thanking You,

Yours Sincerely,

Name of the Member Secretary

Date: **Signature of the Member Secretary**

Flow Chart


Received the submitted documents
Review of protocol & application for waiver of consent
Decision regarding waiver of consent
Communicate the decision to the Investigator
Recording & filing the decision

Standard Operating Procedures of Institutional Ethics Committee;

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SOPs, IEC, SSPHPGTI)

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

SOP Code: SOP 14/V1 : Date: 20/07/2019

- Responsibility
- Maintenance of active study file
- Accessibility/retrieval
- Disposal of closed files and related documents

This SOP provides instructions for maintenance of active study files and other related documents approved by the IEC, SSPHPGTI, and storing of closed files and retrieval of documents.

Responsibility

It is the responsibility of Bioethics Cell staff to ensure that all study files are prepared, maintained, and kept securely for a period of five years after the closure of the project (under a proper system that ensures confidentiality and facilitates retrieval at any time) or till the time stipulated in the project whichever is later.

Maintenance of the active study files

- Master file is the file comprising of all essential documents and correspondence related to the study/protocol. Trial master files shall be established at the beginning of the trial, in the Bioethics Cell.
- The approved study files will assign unique identifiers (serial IEC code no.).
- All related documents together of the approved study files appropriately should be collected together.
- All active files will be kept in a secured file cabinet with controlled access. A log book of authorized individuals accessing the files will be maintained.
- All closed study files will be separately archived.
- Final disposal of study/master files, on completion of archival period, will be done by a committee constituted by Chairperson, IEC.

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 (AN1-V1/SOP 14/V1). The staff of the Bioethics Cell will furnish a copy of the required document within a week with IEC Member Secretary's approval.

Disposal of closed files and copies of protocols and documents

The records for any study in master file will be maintained in the Bioethics Cell for a period of 5 years or longer if required in the protocol following closure of the study. After completion of archival period, the records for closed files will be shredded by the Bioethics cell and disposed off, without any notification to PI. This will be done preferably within 1 year of completion of archival period. A log book of disposed documents will be maintained (AN2-V1/SOP 14/V1).

AN1-V1/SOP 14/V1

Document Request Form

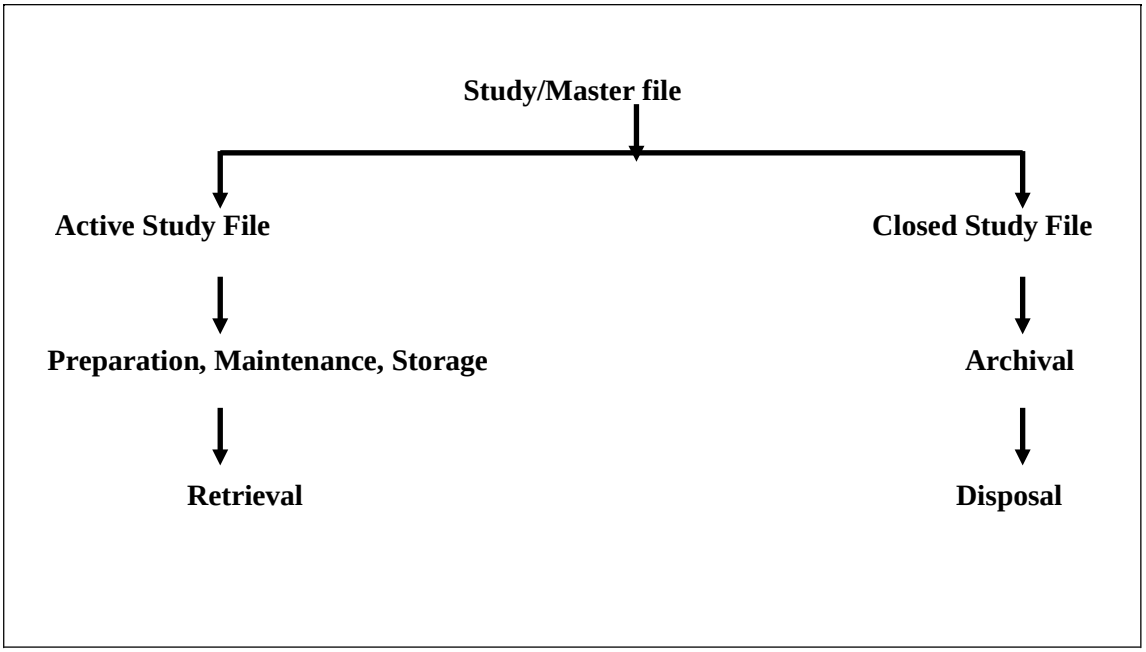
IEC code no.:	**Project Title:**
Name of PI:	**Requested by:**
Documents requested:	
Purpose of the request:	
Principal Investigator's Signature:	
Signature of the requesting person:	
Permission of Member Secretary, IECYES/NO **Name of the Member Secretary** **Date:** **Signature of the Member Secretary**	

AN2-V1/SOP 14/V1

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

Flow Chart


Study/Master file
Active Study File
Closed Study File
Preparation, Maintenance, Storage
Archival
Retrieval
Disposal

Standard Operating Procedures of Institutional Ethics Committee;

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SOPs, IEC, SSPHPGTI)

Title : Documentation of the IEC Activities

SOP Code: SOP 15/V1 : Date: 20/07/2019

- Responsibility
- Detailed Instructions
  - List of IEC records
  - Access to IEC records

This SOP describes the procedures for documenting all IEC activities.

15.1 Responsibility

It is the responsibility of the Bioethics Cell staff to maintain all records.

15.2 Detailed instructions

15.2.1 IEC records. It 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) Records for each IEC member's participation in National/International Bioethics related activities
   d) Documentation of resignation/termination.
2. IEC members list
3. IEC attendance roster.
4. IEC meeting agenda and minutes.
5. Standard Operating Procedures.
6. Archival of current and completed/terminate study files.
7. Annual/ continuing/ completion reports.

15.2.2 Access to IEC records

IEC records will be made available for inspection by authorized representatives of regulatory authorities/funding agency after receiving the request (AN1-V1/SOP 15/V1) in writing and log will be maintained (AN2-V1/SOP 15/V1).

AN1-V1/SOP 15/V1

Request/Compliance Form

To,

The Member Secretary,
IEC, SSPHPGTI,

Dear Sir,

I would like to inform you that I want to take documents for following purpose. I will ensure you I will not divulge any information from the documents to anyone without your written authorization.

Purpose_____

List of documents,

_____

_____

_____

_____

You're faithfully,

Name and Designation

Date: **Signature**

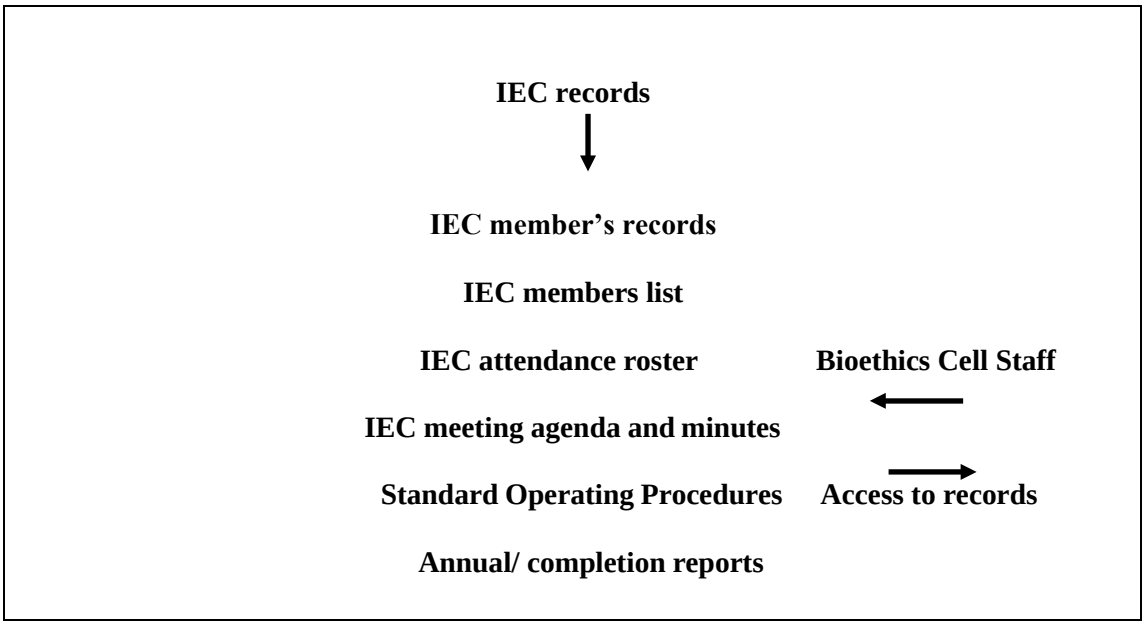
Address:

AN2-V1/SOP 15/V1

Log of Requests for Copies of IEC Documents

No./ date of request	Documents requested (including file number if relevant)	No. of Copies	Name address of the individual requesting copies	Reason for request	Signature of the individual receiving the copy and date	Name and Signature of the IEC staff providing the copy and date

Flow Chart


IEC records
IEC member's records
IEC members list
IEC attendance roster
IEC meeting agenda and minutes
Standard Operating Procedures
Annual/ completion reports
Bioethics Cell Staff
Access to records

Standard Operating Procedures of Institutional Ethics Committee;

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SOPs, IEC, SSPHPGTI)

Title :Dealing with Research Participant's Requests and Complaints

SOP Code: SOP 16/V1 : Date: 20/07/2019

- Responsibility
- Detailed Instructions
  - List of IEC records
  - Access to IEC records

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

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 contain the statement, "The queries related to the study and rights of participants may be addressed to the IEC, Member secretary (with the IEC address and phone number)".

16.1 Responsibility

It is the responsibility of the Bioethics cell for providing required information to the research participants in case of queries received from research participants as per the guidelines/ regulation of Right to Information (RTI) Act.

It is the responsibility of the IEC 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.

16.2 Detailed instructions

- The Member Secretary/the Bioethics cell receive an inquiry or request from research participant /patient.
- The request and information are recorded in the request record form (AN1-V1/SOP 16/V1)
- The Bioethics cell 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 as per RTI Act.
- 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 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 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 Bioethics cell. The information including any action taken or follow-up will be recorded in the form AN1-V1/SOP 16/V1 and the form is signed and dated.
- The IEC members shall be informed about the action taken and the outcomes in the forthcoming IEC meeting.

16.3 Filing the request document

The request details and copy of response by Bioethics cell will be kept in the study file.

AN1-V1/SOP 16/V1

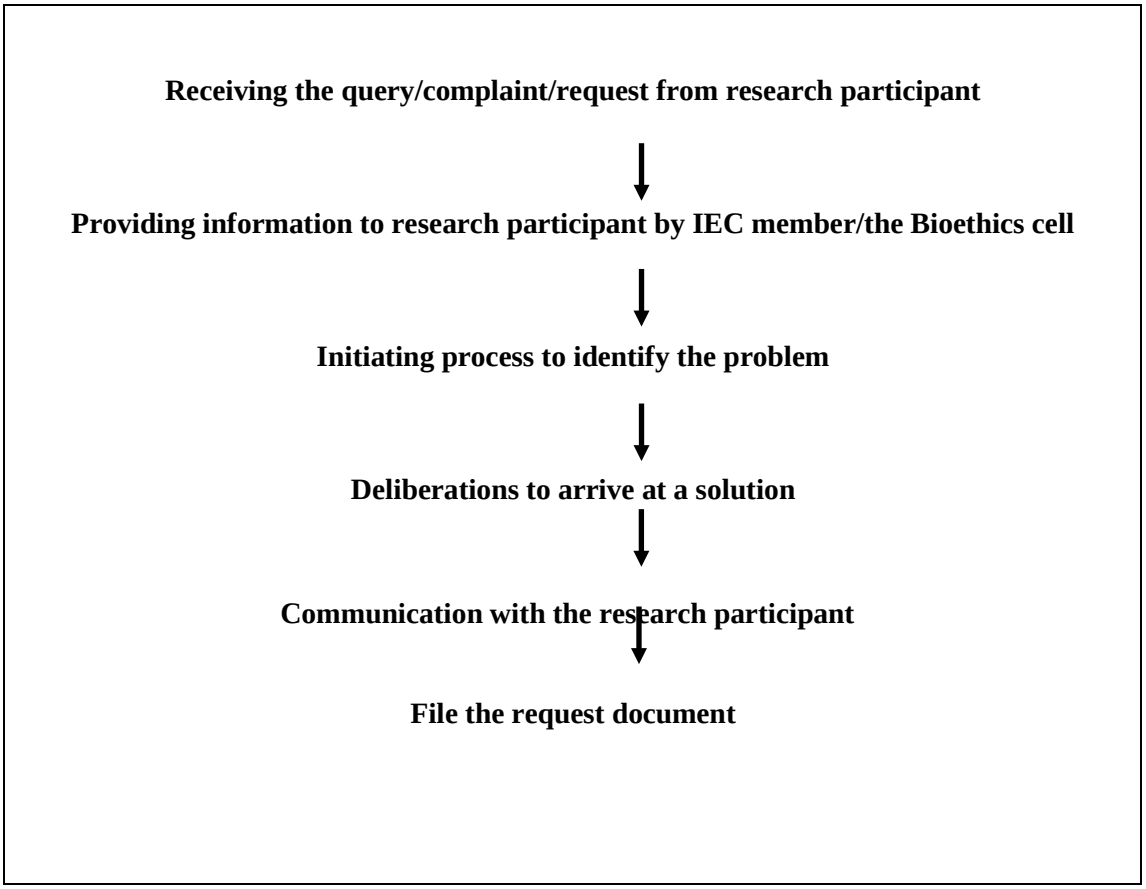
Request Record Form

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

Name of the Member Secretary

Date: **Signature of the Member Secretary**

Flow Chart


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

Standard Operating Procedures of Institutional Ethics Committee;

Super Specialty Pediatric Hospital & Post Graduate Teaching Institute (SOPs, IEC, SSPHPGTI)

Title : Site Monitoring and Post-Monitoring Activities

SOP Code: SOP 17/V1 : Date: 20/07/2019

- Purpose and scope
- Responsibility
- Detailed Instructions
  - Selection of study sites
  - Before the visit
  - During the visit
  - After the visit

17.1 Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedures for site monitoring of an Institutional Ethics Committees (IEC) approved protocol to ensure participant rights, safety and well being.

17.2 Scope

This SOP applies to all IEC approved studies for which a **routine or for-cause on-site** monitoring may be undertaken by the IEC.

17.3 Responsibility

It is the responsibility of the IEC to decide for conduct on-site monitoring. It is further the responsibility of the designated IEC member(s) to perform on-site monitoring of selected study site(s).

17.4 Detailed instructions

17.4.1 Selection of study sites

- Routine monitoring for a site may be decided at the time of approval of the project by the Full Board.
- This is recorded in the IEC minutes.
- *"For-cause monitoring"* will be performed at sites for reasons identified by any member of the IEC, after approval by the Chairperson.
- The reasons for identifying a particular site for "*for-cause monitoring*" could include any one or more of the following:
  - High number of protocol violations,
  - Large number of studies carried out at the study site or by the investigator,
  - Large number of Serious Adverse Events (SAE) reports,

- High recruitment rate,
- Large number of Protocol deviations,
- Complaints received from participants or any other person,
- Frequent failure to submit the required documents
- Any other cause as decided by IEC.

17.4.2 Before the visit

Irrespective of the cause for conducting monitoring the following procedure will be followed

- The IEC will identify and select one or more IEC members (henceforth referred to as monitors) to conduct monitoring of a site.
- The selected member/members will be given a letter in this regard.
- The agenda of monitoring will be decided by the identified monitors in consultation with the Member Secretary and Chairperson.
- The Bio-Ethics Cell will decide the date of the monitoring in consultation with the monitors and the PI.
- The final date will be communicated to the PI (with a request to be available) and monitors.
- The monitor/monitors will receive documents from Bio-Ethics Cell and review the relevant project documents and make appropriate notes.
- Monitors will carry with them Site Monitoring Visit Report Forms- AN-1/SOP 17/V1 and AN-2/SOP 17/V1 (if applicable) collected from the Bio-Ethics Cell.

17.4.3 During the visit

- The Monitor will follow the check list and:
  - check the log of delegation of responsibilities of study team.
  - check if the site is using latest IEC approved current versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc.
  - observe the informed consent process, if possible.
  - review randomly selected participants files to ensure that participants are signing the correct informed consent.
  - check investigational product accountability is adequately controlled and documented throughout the product flow at the study site (arrival, dispensing, use, return from the subject and return/destruction after the study).
  - check for storage times, conditions and expiry dates to be acceptable and sufficient supplies available, wherever applicable.
  - verify that the investigator follows the approved protocol and all approved amendment(s), if any.

- ensure that the investigator and the investigator's trial staff are adequately informed about the trial.
- verify that the investigator and the investigator's trial staff are performing the specified study functions, in accordance with the approved protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals.
- verify that the investigator is enrolling only eligible subjects.
- determine whether all SAEs are appropriately reported within the time as per the applicable regulatory requirement(s). Case record forms would be checked to review the safety data i.e. Adverse Events (AEs) and SAEs for the volume or severity of adverse events.
- review the project files of the study to ensure that documentation is filed appropriately.
- review the source documents for their completeness.
- collect views of the study participants, if possible.

- The Monitor will fill the Site Monitoring Visit Report Form- AN-1/SOP 17/V1 and AN-2/SOP 17/V1 (if applicable), sign and date it.

17.4.4 After the visit

- The Monitor will submit the completed Site Monitoring Visit Report Form- AN-01/SOP 17/V1and AN-02/SOP 17/V1(if applicable) to the IEC Bio-Ethics Cell within 7 working days of conducting a site monitoring visit or at the time of full board meeting (whichever is earlier).

- The report should describe the findings of the monitoring visit.

- The Member-Secretary will present the monitoring report at the next full board IEC meeting and the concerned Monitor will provide additional details/ clarifications to members, as required.

- The IEC will discuss the findings of the monitoring process and take appropriate specific action by voting or combination of actions, some of which are listed below:
  - Continuation of the project with or without changes,
  - Restrictions on enrollment,
  - Recommendations for additional training,
  - Recruiting additional members in the study team,
  - Revising/ providing qualifications/ experience criteria for members of the study team, termination of the study,

- Suspension of the study, etc.

- If the Monitor has findings that impact on safety of the participant the Monitor will inform the Member Secretary on the same day. The Member Secretary will discuss with the Chairperson and any one of the actions described above will be taken.
- The final decision taken at the full board IEC meeting by the Chairperson will be recorded in the Site Monitoring Visit Report Form- AN-01/SOP 17/V1.
- The Bio-Ethics Cell will convey the decision to the Principal Investigator in writing within 14 working days of the meeting.
- The Bio-Ethics Cell will place the copy of the report in the protocol file.

AN-1/SOP 17/V1
Site Monitoring Visit Report
(Please tick the box corresponding to the answer)

IEC project no.	Date of Visit:
Study Title:	
Principal Investigator and Department:	
Type of study: □Investigator initiated □Pharma □Thesis	
□ Government agency □ Others _____	

Date of IEC approval: **Date of Initiation of the study:** **Duration of study:**
Reason for monitoring: □ Routine □For-cause (State reason/s) □ Protocol Violations/Deviations □ SAE reporting □ Recruitment rate □ Other _____
Last monitoring done, if any, □Yes Date of last monitoring _____ □ No
Project Status: 1. Ongoing □ 2. Completed □ 3. Recruitment Completed □ 4. Follow-up, extension study □ 5. Suspended □ 6. Terminated □ In case of the response to the above question is option 5 or 6, kindly provide reason/s: _____ _____
Recruitment Status: □ Total patients to be recruited: _____ □ Screened: _____ □ Screen failures: _____ □ Enrolled: _____ □ Withdrawn: _____ Reason: _____ _____ □ Discontinued: _____ Reason: _____ _____ □ Completed: _____ □ Active: _____

Are the present study team members as per the list approved by the IEC ☐ Yes ☐ No	Comment:
Are site facilities appropriate? ☐ Yes ☐ No	Comment:
Is the recent version of Informed Consent Document (ICD), after IEC approval, used? ☐ Yes ☐ No	Comment:
Whether appropriate vernacular consent has been taken from all patients? ☐ Yes ☐ No	Comment:
Any other findings noted about the ICDs? ☐ Yes ☐ No	Comment:
Is recent IEC approved version of protocol used? ☐ Yes ☐ No	Comment:
Have the eligibility, inclusion exclusion criteria been adhered to? ☐ Yes ☐ No	Comment:
Any adverse events found? ☐ Yes ☐ No	Comment:

Any SAEs found? ☐ Yes ☐ No	Comment:
Were the SAEs informed to IEC within timelines specified by CDSCO? ☐ Yes ☐ No	Comment:
No. of deaths reported: ☐ Deaths unrelated to participation in the trial: ☐ Deaths related to participation in the trial Any other non-death study related injury	_____ _____ _____ ☐ Yes ☐ No ☐ NA Comments (If Any) _____ _____
Compensation paid for study related injury or death	☐ Yes ☐ No ☐ NA Comments (If Any)
Are there any protocol non-compliance deviations/violations? ☐ Yes ☐ No	Comment:
Have the protocol non-compliance deviations/violations been informed to IEC? ☐ 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 the participants protected? ☐ Good ☐ Fair ☐ Not good	Comment:
Any other remarks ☐ Yes ☐ No	Give details:
Duration of visit:_____ hours	Starting from: Finish:
Name of the study team member/s present: Signature _____	Date:
Name of IEC members and representatives who attended monitoring visit:	
Completed by: Signature:_____	Date:

Final Decision at the IEC meeting held on _____

_____

_____

_____

Date: **Signature of the Chairperson, IEC**

AN2-V1/SOP 17/V1
Monitoring of Audiovisual recording of AV consent Process

1. Facility where informed consent process should be carried out - (well lit, free from noise, privacy ensured):
   - Yes_____No_____
   - Remarks: _____

2. The consent is taken in language the participant/LAR understands best and is literate in.
   - Yes_____No_____
   - Remarks: _____

3. Introduction of each person (person conducting the informed consent discussion participant/ legally acceptable representative (LAR) / impartial witness) involved during informed consent process and information about necessity for audiovisual recording
   - Yes_____No_____
   - Remarks: _____

4. Information to the participant/ LAR and impartial witness (as applicable) that the process of taking the consent is being recorded for the purpose of documentation as required by the government rules.
   - Yes_____No_____
   - Remarks: _____

5. Information to the participant/ LAR and impartial witness (as applicable) that the confidentiality of information and privacy of participants is assured.
   - Yes_____No_____
   - Remarks: _____

6. Information to the participant/ LAR and impartial witness (as applicable) that the recording may be shown to government agencies or members from the IEC.
   - Yes_____No_____
   - Remarks: _____

7. Explanation or narration by the person conducting the informed consent discussion.
   - Yes_____No_____
   - Remarks: _____

8. Questions asked by the potential participant/LAR are answered satisfactorily.
   - Yes_____No_____
   - Remarks: _____

9. Allowing ample time and opportunity to read/understand the information in the informed consent document or discuss the same with family members.

- Yes_____No_____
- Remarks: _____

10. Reading out by the participant/LAR (or having read out by impartial witness) the statements mentioned in Informed Consent and stating whether participant agrees or not for each statement.

- Yes_____No_____
- Remarks: _____

11. Documentation of signatures of all those involved in the Informed Consent Process.

- Yes_____No_____
- Remarks: _____

12. Clarity and completeness of AV recording

- Yes_____No_____
- Remarks: _____

13. Storage of recording in password protected laptop/ desktop computer and/ or hard drive and labelled CD with access allowed only to the principal investigator and designated members of the study team.

- Yes_____No_____
- Remarks: _____

Flow chart

Activity		**Responsibility**
1. Selection of Study Sites	→	IEC Member Secretary/Chairperson
2. Identification of IEC Members for Monitoring during meeting	→	Chairperson
3. Inform Principal Investigator in Writing	→	Bioethics Cell
4. Review of IEC Protocol file prior to Visit and collect site Monitoring Visit report from IEC office	→	IEC Member
5. Review of monitoring of site	→	IEC Member (Monitor)
6. Complete the monitoring	→	IEC Member (Monitor)
7. Communication of IEC decision to PI	→	Bioethics Cell

Institutional Ethics Committee
Super Specialty Pediatric Hospital & Post Graduate Teaching Institute
(IEC, SSPHPGTI)

Appendices

SOP AP1/V1: Policy on the Recruitment of Research Participants

SOP AP2/V1: Policy on Research Costs to Participants

SOP AP3/V1: Guidelines on Compensation for Research Participants

SOP AP4/V1: Policy on the Use of Third Party/Surrogate Consent in Research at SSPHPGTI

SOP AP5/V1: Guidelines on Blood Withdrawal for Research Purposes

SOP AP6/V1: Guidelines for obtaining Informed consent

SOP AP7/V1: Examples of PID (Hindi and English in Non-interventional studies)

SOP AP8/V1: Health Record Research

SOP AP9/V1: Guidelines for Research Protocols That Require Collection and/or Storage of Genetic Material

SOP AP10/V1: Guidelines: Submission and EC Review of Gene Therapy/Gene Transfer Protocols

SOP AP11/V1: Ethical Policies on the Human Genome, Genetic Research and services, DBT, 2002

SOP AP12/V1: Recommended Terms for Use in Informed Consent Documents

SOP AP13/V1: Good Clinical Practices for Clinical Research in India (Essential documents for the conduct of a clinical trial) by CDSCO, DGHS, New Delhi, 2001

SOP AP14/V1: Declaration of Helsinki Fortaleza, Brazil, October2013

SOP AP15/V1: IND Application Exemption Checklist AP16/V1 Clinical Trial Registry – India

SOP AP17/VI: Guidelines for Stem Cell Research and Therapy AP18/V1 Guideline for Medical Device Related Studies

SOP AP1/V1
Policy on the Recruitment of Research Participants

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, children and normal volunteers as controls. Exclusion of women of child bearing age 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. SSPHPGTI patients - Patients may be identified as potential research subjects through direct contact of the PI with the 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**

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

c. **Community studies**

Epidemiology is defined as the study of the distribution and determinants of health- related states or events in specified populations and the application of this study to control health problems. Epidemiological studies are of primary importance in a large developing country like ours where the natural history, incidence, prevalence and impact on morbidity and mortality of a variety of diseases are not known. Such studies are on large scale and assist in improving the public health, which includes both patients and healthy people and communities.

In most epidemiological research it would be necessary to have the consent of the community, which can be done through the Village Leaders, the Panchayat head, the tribal leaders etc. who are considered to be gate keepers of the society/ community. Particularly in a country like India, with the level of poverty that is prevalent it is easy to use inducements, especially financial inducements, to get individuals and communities to consent. Such inducements are not permissible. However, it is necessary to provide for adequate compensation for loss of wages and travel / other expenses incurred for participating in the study.

Benefits: When epidemiological studies (like those on mortality and morbidity as a result of exposure to an agent) lead to long associations with the community, the results if released in timely manner could give improved health care facilities or educate the community to reduce the impact of adverse environment on health and tackle the problem at their end in time.

A community can be defined as a group of people sharing the same location, beliefs, culture, ideals, goals, age, gender, profession, lifestyle, common interests, geographical locations or settings or disease. When research participants are drawn from a specific community, members of that community can be involved to discuss any concerns it may have regarding the research. In different ways such a dialogue can be facilitated.

If an ethics committee does not have a member from the community, it may ask a local community representative to be the voice for all participants. On the other hand, community representatives can formally join together to form a group termed as Community Advisory Board, Community Working Group, or Community

Advisory Group, which takes part in the research at all stages of the study. In international studies, particularly on issues involving communities, representation from this body ensures that the community's health needs and expectations are addressed, informed consent is appropriate, and access to research benefits is provided through research that is designed and implemented in the best interests of science and community. Community representation should be involved before, during and after the study.

Before the study is initiated the community is informed to see if it agrees that the research addresses a need or problem relevant to that community and to confirm that the design is culture specific and brings some benefits to research participants or the community. Since some risk may be associated the community representation is needed to assist in developing appropriate ways to protect the participants. During the study, the association with community representatives continues to educate others about the research and to alert the researcher to ethical issues related to the research. After the study is completed, community representatives can help in making the results known to the entire community. However, application of research findings may take a long time, which the community representatives should be made to understand. The benefits may be participants' and community's access to intervention. Whose responsibility and conditions under which this would be done, duration of availability of intervention, methods of improving the quality of health care in the community and any expected desirable behavioral change in the community should be clearly explained to community by the Ethics Committee or community representatives.

SOP AP2/V1
Policy on Research Costs to Participants

If a research participant has to bear any costs, all potential participants 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 costlier than a standard treatment.
5. Other substantial costs associated with extra visits to SSPHPGTI.

SOP AP3/V1

Guidelines on Compensation for Research Participants

1. http://ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.pdf (pg 8-9)
2. www.cdsco.nic.in **Formula to Determine the quantum of compensation in the cases of Clinical Trial related serious Adverse Events(SAEs) of Injury other than Deaths Occurring During Clinical Trials**

We will also follow guideline issued by DCGI time to time (Gazette notification).

SOP AP4/V1

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

Applicability

When a SSPHPGTI 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 decisional 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 subjects are greater than minimal, direct benefits may or may not 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 SSPHPGTI 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.

IEC will recommend normally Category I projects to be initiated.

IEC will not recommend normally initiation of any Category IV projects.

IEC recommendation on Category II and III projects will depend on case to case assessment of risk/benefit ratio to subject and community.

SOP AP5/V1

Guidelines 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 having minimal risk:

A. General Requirements

1. There are no special health reasons (e.g., anemia) to contraindicate blood withdrawal.

2. Participants in whom blood is already being drawn for clinical purposes, there are no other health reasons to preclude additional blood collection provided the amount is limited to as mentioned in B and C.

3. In subjects from whom blood is not already being drawn for clinical purposes, the withdrawal method is by cutaneous pricks (e.g., heel or finger) or by standard venipuncture in a reasonably accessible peripheral vein, and the frequency of punctures should not exceed two per week except in pharmacokinetic study.

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 should be 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 limit 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.

SOP AP6/V1

Guidelines for obtaining Informed consent [Participant Information Document and (PID) and Consent Form (CF)]

Available: http://ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.pdf (Page 50-68)

SOP AP7/V1

Examples of PID (Hindi and English in Non-interventional studies)

Available at www.ssphpgti.ac.in

SOP AP8/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 if an individual's records or specimens are 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 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 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 Member Secretary.

   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.

SOP AP9/V1

Guidelines for Research Protocols which require Collection and Storage of Genetic 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 fresh 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 and agreed upon by the participant.

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 SSPHPGTI 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 IEC 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.

SOP AP10/V1

Guidelines for Submission and IEC review of Gene Therapy/Gene Transfer Protocols

Available at:
http://ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.pdf (pg 122)

SOP AP11/V1

Ethical Policies on the Human Genome, Genetic Research and services, Department of Biotechnology, Ministry of Science and Technology, Govt. of India, 2002

Available at: **https://www.india.gov.in/ethical-policies-human-genome-genetic-research-and- services-department-biotechnology**

SOP AP12/V1

Recommended Terms for Use in Informed Consent Document

To facilitate understanding of informed consent document by the participant, it is recommended that the language used is at a reading level of a12-year-old. The following lay terms, definitions and suggestions are recommended to help investigators in this process.

For	Use
Adjuvant	helpful; assisting; aiding ambulate (-action –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
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
Cardiac	heart
Cerebral	the brain; of the brain
CHD	coronary heart disease; heart disease
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
DCGI	Drug Controller General of India
Diastolic	the lower number in a blood pressure reading
Disseminated	widely-spread, all through the body
Distal	toward the end; away from the center of the body
Diuretic	drug that causes an increase in urine secretion
Double-blind	neither the subject nor physician knows what is being given
Dysfunction	improper function
Dysplasia	abnormal cells
Echocardiogram	sound wave test of the heart
Edema	fluid in the tissues; puffiness; swelling
Emesis	vomiting
Endoscopic	examination of the inside of the body with a lighted tube
Epidural	outside the spinal cord
Erythrocyte	red blood cell
Fibrillation	irregular heartbeat
Fibrous	like scar tissue
Granulocyte	white blood cell

Hematocrit	concentration of red blood cells
Holter monitor	portable machine for recording heartbeats
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
Infarct	death of tissue due to loss of blood flow
Intubate	the placement of a tube into the airway
	decrease in oxygen in a tissue, usually because of decreased blood flow a procedure where an incision is made in the abdominal wall to enable a physician to look at the organs
Lumen	cavity of an organ; inside a blood vessel a type of white blood cell important for defense against infections
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
	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
Occult blood test	testing a stool sample for invisible amounts of blood
Oncology	the study of tumors or cancer
Pancytopenia	low number of blood cells
Percutaneous	through the skin
Phlebitis	irritation or inflammation of a vein inactive medication; dummy pill; sugar tablet; containing no medication
Platelets	blood cells that help the blood clot normally
Prenatal	before birth
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
Radiotherapy	treatment with radiation
Randomly assigned	similar to the toss of a coin; assignment to a treatment group by chance
Refractory	not responding to treatment
Regimen	pattern of giving treatment
Renal	kidney
Resect	remove or cut out surgically
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
Supine	lying on the back
Syndrome	a condition with a certain set of symptoms
Systolic	the top number in blood pressure
Tachycardia	fast heart beat
Taper	decrease; reduce
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
Transdermal	through the skin
Uremia	kidney failure
Varices	enlarged veins
Vasodilation	widening of the blood vessels
Vasospasm	narrowing of blood vessels due to a spasm of the vessel walls
Venipuncture	taking blood from the vein

SOP AP13/V1

From Essential documents for the Conduct of a Clinical Trial Good Clinical Practices for Clinical Research in India by Central Drugs Standard Control Organization, Directorate General of Health Services, New Delhi, 2001

Available at: http://www.cdsco.nic.in/html/GCP1.html;
Good Clinical Practice Guidelines

SOP AP14/V1

WMA Declaration of Helsinki
Ethical Principles for Medical Research Involving Human Participants

Adopted by the18th WMA General Assembly, Helsinki, F inland, June1964 and amended by the:

29th WMA General Assembly, Tokyo, Japan, October 1975

8th WMA General Assembly, Somerset West, Republic of South Africa, October1996,
35th WMA General Assembly, Venice, Italy, October1983

41st WMA General Assembly, Hong Kong, September 1989

52nd WMA General Assembly, Edinburgh, Scotland, October 2000

53rd WMA General Assembly, Washington DC, USA, October 2002(Note of Clarification added)

5th WMA General Assembly, Tokyo, Japan, October 2004(Note of Clarification added)

59th WMA General Assembly, Seoul, Republic of Korea, October 2008 64th WMA General Assembly, Fortaleza, Brazil, October 2013

Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki- ethical-principles-for-medical-research-involving-human-subjects/

SOP AP15/V1

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

Name of the PI

Date: **Signature of the PI**

SOP AP16/V1

Clinical Trial Registry – India

The Clinical Trials Registry- India (CTRI), hosted at the ICMR's National Institute of Medical Statistics (NIMS), is a free and online public record system for registration of clinical trials being conducted in India that was launched on 20th July 2007 (www.ctri.nic.in). Initiated as a voluntary measure, since 15th June 2009, trial registration in the CTRI has been made mandatory by the Drugs Controller General (India) (DCGI) (www.cdsco.nic.in). Moreover, Editors of Biomedical Journals of India declared that only registered trials would be considered for publication.

Today, any researcher who plans to conduct a trial involving human participants, of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies as well as trials being conducted in the purview of the Department of AYUSH (http://indianmedicine.nic.in/) is expected to register the trial in the CTRI before enrollment of the first participant. Trial registration involves public declaration and identification of trial investigators, sponsors, interventions, patient population etc before the enrollment of the first patient. Submission of Ethics approval and DCGI approval (if applicable) is essential for trial registration in the CTRI. Multi-country trials, where India is a participating country, which have been registered in an international registry, are also expected to be registered in the CTRI. In the CTRI, details of Indian investigators, trial sites, Indian target sample size and date of enrollment are captured. After a trial is registered, trial lists are expected to regularly update the trial status or other aspects as the case may be. After a trial is registered, all updates and changes will be recorded and available for public display.

Being a Primary Register of the International Clinical Trials Registry Platform (ICTRP) (http://www.who.int/ictrp/search/en/), registered trials are freely searchable both from the WHO's search portal, the ICTRP as well as from the CTRI (www.ctri.nic.in).

SOP AP17/V1

National Guidelines for Stem Cell Research (ICMR, 2017).

Available at: www.dbtindia.nic.in/wp-content/uploads/National_Guidelines_StemCellResearch-2017.pdf;
http://www.dbtindia.nic.in/guidelines/

SOP AP18/V1

Guideline for Medical Device Related Studies

As per Medical Device Rules 2016 and 2017 (Available at: www.cdsco.nic.in/)

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which are to commence from 01.01.2018.

Institutional Ethics Cell, Room No. , 1st Floor, Administrative Block,
Super Specialty Pediatric Hospital & Post Graduate Teaching Institute, Sector 30,
Noida, UP, India. Pin-201303.

***Tel: 0120-2455552**
***Fax: +91-120-2455552**
Email: ethics.sspgi@gmail.com
iec@ssphpgti.ac.in
Website: www.ssphpgti.ac.in