AN1-V2/SGSOP 07/V3

Amendment Reporting Form (6 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	

_____

Signature of PI

Name_____ **Date**_____

AN1-V2/SGSOP 08/V3

Continuing Review Application Form/Annual status Report form
(For Interventional Study, 6 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

_____

Signature of PI

Name_____ **Date**_____

AN2-V2/SGSOP 08/V3

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:**

_____
Signature of PI

Name_____ **Date**_____

AN1-V2/SGSOP 13/V3

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

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 (http://ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.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

_____

_____

Signature of PI

Name_____ **Date**_____

AN1-V3/SGSOP 09/V3

Deviation (D)/Waiver (W)/Violation (V) Reporting Form (6 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:
Signature of PI **Name_____ Date_____**

AN1-V3/SGSOP 09/V3

Deviation (D)/Waiver (W)/Violation (V) Reporting Form (6 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:
Signature of PI **Name_____ Date_____**

AN3-V2/SGSOP 10/V3

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-V2/SGSOP 10/V3). 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:

_____
Signature of PI

Name_____ **Date**_____

AN4-V2/SGSOP 10/V3

Off Site Safety Reports Log (6 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 SGPGI: _____No. of Participants enrolled globally: _____
No. of subjects on trials at SGPGI: _____ No. of SAE at SGPGI: _____
No. of death at SGPGI: _____ 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.

_____
Signature of PI

Name_____ Date_____

AN1-V2/SGSOP 10/V3

Onsite Adverse Drug Event Reporting Form (6 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): _____ **Signature of PI** **Date _____** **Upon receipt of this report, the IEC will decide whether additional information is needed or whether further investigation of the reaction is required.**

AN1-V2/SGSOP 12/V3

Premature Termination/Suspension/Discontinuation Report (6 copies required)

<table>
<tr><td colspan="2">IEC code No.:</td></tr>
<tr><td colspan="2">Study/Protocol No. (For drug/device trials/any other):</td></tr>
<tr><td colspan="2">Protocol Title:</td></tr>
<tr><td colspan="2">PI:</td></tr>
<tr><td colspan="2">Sponsor:</td></tr>
<tr><td>IEC Approval Date:</td><td>Date of Last Progress Report Submitted to IEC:</td></tr>
<tr><td>Starting Date:</td><td>Termination Date:</td></tr>
<tr><td>No. of Participants Enrolled:</td><td>No. of Participants Completed:</td></tr>
<tr><td>No. of Ongoing Participants:</td><td>No. of Drop Outs:</td></tr>
<tr><td>SAE (Total No.):</td><td>SAE Event:</td></tr>
<tr><td colspan="2">Summary of Results (attach a separate sheet if necessary):</td></tr>
<tr><td colspan="2">Reason for Termination/Suspension/Discontinuation:
• Safety concern
• Lack of efficacy
• Others</td></tr>
<tr><td colspan="2">Storage of document for more than 5 years, Yes [ ] No [ ]
If yes, for how many years? _____</td></tr>
<tr><td colspan="2">_____
Signature of PI

Name_____ Date_____</td></tr>
</table>

AN5-V3/SGSOP01/V3

Request for Formulation of New SOP/Revision of SOP

This form is to be completed by any member of IEC, faculty of SGPGI 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:		

AN1-V2/SGSOP 05/V3

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-V3/SGSOP 03/V3)].

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/V3).

Principal Investigator's signature: _____ Date _____

Forwarded by the Head of the department:

Name: _____

Signature: _____

Date _____

AN1-V2/SGSOP 11/V3

Study Completion Report form
(For Interventional Study)

(To be Filled by PI and submit 6 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:
_____ **Signature of PI** **Name_____ Date_____**

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

AN2-V2/SGSOP 11/V3

Study Completion Report form
(For Non-Interventional Study, 6 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? _____

_____
Signature of PI

Name_____Date_____

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