AN1-V1/SGSOP 03/V1

Project Submission Form for Review by IEC
(6 copies and a CD required)

A. Identification details:

***IEC Code No. (** To be filled by the Bioethics cell**):** **Study/Protocol No.** (For drug/device trials/any other, to be filled by PI):
Type of project: Intramural [ ] Extramural [ ] Drug trial/devise [ ] Independent [ ] MD/DM/MCh/PhD/SRF Project [ ] Collaborative [ ] Other [ ] **Status of review**: New [ ] Revised [ ] **Proposal Title:……..** **……**

B. Investigator details:

	Name, Designation & Qualifications	**Departmental Tel Nos. & Email ID**	**Signature**
****PI/Guide**			
1. Co-PI/Co-Guide /Collaborators			
2.			
3.			
****4. Student**			

One page recent, signed and dated curriculum vitae of the investigators indicating qualifications and relevant experience for **new or investigator outside SGPGI or of the **student (MD/MS/DM/MCh/PhD)** who has submitted thesis/project

C. Sponsor Information: **Applicable [ ]** **Not applicable [ ]**

1. Name of sponsor/CRO:
2. Indian: **a) Government** ☐ Central ☐ State ☐ Institutional ☐ **b) Private** ☐
3. International: Government ☐ Private ☐ UN Agencies ☐
4. Industry: National ☐ Multinational ☐
5. Contact address of sponsor/CRO:
6. Budget: Rs._____ **7. Details of allocation of budget in Clinical Trial Agreement:** Yes [ ] No [ ]

D. Study related Information:

1. Design of study: Epidemiological ☐ Basic Sciences ☐ Behavioral ☐ Clinical ☐ Interventional ☐ Single Centre ☐ Multicentre ☐		
2. No. of participants:	**SGPGI**	**Total (if multicentre)**
Patient*	_____	_____
Control*	_____	_____
3. Duration of study:_____		
4. Duration of subject participation (no. of visit by a participant in study):_____ **Please mention sample size calculation and source of control in methodology*		

E. Interventional study: Yes [ ] No [ ] If No, move to next section i.e. F

1. Does the study involve use of

Drugs ☐ Devices ☐ Vaccines ☐ Radiopharmaceutical ☐

Recombinant DNA/Gene therapy ☐ Stem cell ☐ *(need BARC approval)*

(need DBT- GEAC approval (NAC-SCRT registration and approval)

Indian Systems of Medicines/ Alternate systems of Medicine ☐

Any Other ☐ None ☐

2. Is it approved and marketed

In India ☐ UK & Europe ☐ USA ☐ Other Countries, Specify_____

3. Does it involve a change in use, dosage, route of administration? Yes ☐ No ☐

If yes, whether DCGI's/Any other Regulatory Authority's Permission is obtained?

Yes ☐ No ☐

If yes, copy of permission attached. Yes ☐ No ☐

4. 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 is Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ NA ☐

If phase I-III will the drug/device be provided free? Yes ☐ No ☐

If phase IV will the drug/device be 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 a plan for reporting of adverse events? Yes ☐ No ☐

If yes, reporting will be done to Sponsor ☐ IEC ☐

b. Is there a plan for interim analysis of data? Yes ☐ No ☐

6. Provision for travel/treatment due to injury out of study	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 ☐

F. Details of participant of study:

1. Will subjects from both sexes be recruited: Yes [ ] No [ ]			
2. Inclusion/exclusion criteria given: Yes [ ] No [ ]			
3. Type of subjects: Volunteers [ ] Patients [ ]			
4. **Vulnerable subjects** Yes [ ] No [ ]			
(if **Yes** tick the appropriate boxes)			
Pregnant Women [ ]	Children [ ]	Elderly [ ]	Fetus [ ]
Illiterate [ ]	Handicapped [ ]	Terminally ill [ ]	Seriously ill [ ]
Mentally challenged [ ]	Economically & socially backward [ ]	Any other [ ]	
5. **Special group subjects:** Yes [ ] No [ ]			
(if **Yes** tick the appropriate boxes)			
Captives [ ]	Institutionalized [ ]	Employees [ ]	Students [ ]
Nurses/Dependent [ ]	Staff [ ]	Armed Forces [ ]	Any Other [ ]

G. **Privacy and confidentiality:**

1. **Study Involves**	Direct Identifiers (Pt. identified by name/Cr. no.)	☐
	Indirect Identifiers/Coded (Pt. identified after break of code)	☐
	Completely Anonymised /Delinked (Pt. cannot identified)	☐
2. **Confidential handling of data by staff**	Yes ☐	No ☐

H. Detail of sample collection (If no sample being collected, move to next section i.e. I):

A. ***Regarding sample collection***

1. Collection of organs or body fluids or blood. If yes, please specify Yes ☐ No ☐

Type:_____

Amount each time_____ml Total_____ml

No. of time in 2 week_____ Total (in 2 weeks)_____ml

2. Collection of fetal tissue or abortus. If yes, please specify Yes ☐ No ☐

_____

_____

_____

3. Use of pre-existing/stored/left over samples. If yes, please specify Yes ☐ No ☐

_____

_____

_____

4. Proper disposal of material Yes ☐ No ☐

B. Special situation

1. Will any sample collected from the patients be sent abroad? Yes ☐ No ☐

If yes, give details and address of collaborators

_____

_____

_____

a. ***Sample will be sent abroad because (Tick appropriate box)***

Facility not available in India ☐

Facility in India inaccessible ☐

Facility available but not being accessed ☐

If so, reasons_____

b. ***Has necessary clearance been obtained*** Yes ☐ No ☐

2. Collection for banking/future research Yes ☐ No ☐

I. Participant Information Document (PID) and Consent Form:

1. Consent *Written ☐ Oral ☐ Audio-Visual ☐

Patient Information documents and consent form attached : (Tick the included elements)

Understandable language	☐	Alternatives to participation	☐
Statement that study involves research	☐	Confidentiality of records	☐
Sponsor of study	☐	Contact information	☐
Purpose and procedures	☐	Statement that consent is voluntary	☐
Risks & discomforts	☐	Right to withdraw	☐
Benefits	☐	Benefits if any on future	☐

Consent for future use of material biological ☐

Free supply of drug till it is not marketed in country if necessary ☐

Compensation for study related injury ☐

Translation of Participant Information Document (PID) in local Language ☐

2. **If healthy volunteers, PID for them** Yes ☐ No ☐

3. **If participant is child, PID for parent** Yes ☐ No ☐

4. **PID and Assent Form for child 8-18 yrs** Yes ☐ No ☐

5. **Consent form** in English ☐ Local Languages ☐

(For participant/healthy volunteer/parent/legal guardian)

6. **Who will obtain consent?** PI-Co-PI ☐ Nurse/Counselor ☐

Research Staff ☐ Any Other ☐

If written consent is not obtained, give reasons……....

J. Will any advertising be done for recruitment of Subjects? Yes ☐ No ☐

(Posters, flyers, brochure, websites – if so attach a copy)

K. For archival of record by Bioethics cell for more Yes ☐ No ☐ Not applicable ☐

than 5 years required

If yes, for how many years……

L. Risk and benefits:

1. **Is there physical/social/psychological risk/discomfort?** Yes ☐ No ☐

If yes, Minimal or no risk ☐

More than minimum risk ☐

High risk ☐

2. **Is there benefit** a) to the subject? Yes ☐ No ☐

Direct ☐ Indirect ☐

b) to the society Yes ☐ No ☐

3. **Do you think that the risk is in commensurate with the benefits to be accrued subjects/community/country?** Yes ☐ No ☐

4. **Please identify the ethical issues involved in your study**._____

_____

M. Do you have conflict of interest? Yes ☐ No ☐

(Financial/Non financial)

If yes, specify_____

N. Brief proposal summary

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

_____

Signature of PI

Name_____ **Date_____**

******* Please **<u>also</u>** submit detail **Study/Project Protocol** separately (Short review of literature, justification for study, aim, methodology, inclusion, exclusion criteria, statistical analysis).

AN2-V1/SGSOP 03/V1

Consent of Head of the PI's Department

Date:…….

I have reviewed the project "……." 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**

AN3-V1/SGSOP 03/V2

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

The project titled "……" with all the accompanying documents listed above was reviewed by the Research committee/department committee /doctoral committee/scientific committee/ Protocol Committee present on ……..at SGPGI. 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/**Secretary (Research Committee) /***In charge of doctoral committee or scientific committee/Dean (Protocol Committee)****

Name: ……..……..…….…….

Date: ……..…...…

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

****In case of intramural**

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

****** In case student (MD/MS)**

*******Not applicable to sponsor/CRO initiated drug/device trials**

The PI should also attach a copy of minutes of **"Research committee/department committee /doctoral committee/scientific committee"**.

AN4-V1/SGSOP 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 clinical trials with active enrolments:** _____
    b. **Number of 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.

_____

Signature of PI

Name_____ **Date_____**

AN5-V1/SGSOP 03/V1

Conflict of Interest Declaration by PI

To,

The Member Secretary

Institutional Ethics Committee

SGPGI, Lucknow.

Project entitled: …….

Name of PI:

Conflict of Interest

[ ] I hereby declare that I have no conflict of interest in my project.

[ ] I have following conflict of interest:

_____

Signature of PI

Name_____ **Date_____**

AN6-V1/SGSOP 03/V1

CV* of New or Investigator outside SGPGI 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 SGPGI** or of the **student (MD/MS/DM/MCh/PhD)** who has submitted thesis/project

AN7-V1/SGSOP 03/V1

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

Guideline for preparation of the participant information document	
While submitting your project report to the Institutional Ethics Committee, ensure that you have included participant information document and an informed consent form that is prepared as per the guidelines for GCP-CDCO 2001, ICH – GCP, ICMR ethical guidelines 2006, and the Declaration of Helsinki. The document is important because it enables the participants to make an informed choice. It also has got to be unique because no two research projects are identical. **The participant information document (PID should include only those headings listed below which are relevant to that study. Any further information you wish to add, is your choice.**	
1.	Participant information document and an consent form **in English and Hindi** (other languages if required)
2.	Font: Arial
3.	Size: 12
4	All the consent forms must have Version No, Date, Page no **in the footer**
5.	**Separate participant information document and consent form for <u>patient/patient's guardian (when patient not able to give consent)/volunteer/parents of children (minor) and information document and assent form for children (minor)</u>**

Potential recruits to your research/trial study must be given sufficient information to allow them to decide whether or not they want to take part. The Information Document should contain information under the headings given below, and preferably in the order specified. It should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs. PID should mention about Audio Visual recording after taking consent for drug and device trials.

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. States: "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 fetal 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. States:

"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.

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 avaibility 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 patient information sheet should be dated and given a version number.
The Participant Information document should state that the participant will be given a copy of the information sheet and the signed consent form.

_____

Signature of PI

Name_____ **Date**_____

****Please see AP6/V1: page-217** of SOPs**,** Guideline to prepare Patient Information Document for study with only sample collection and no intervention.

AN8-V1/SGSOP 03/V2

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/project, 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 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/SGSOP 03/V1

(आप हिंदी में लिखने के लिए "http://www.google.com/transliterate" के लिंक का सहयोग ले सकतें हैं)

PDF में देखने के लिए यहाँ क्लिक करे

प्रतिभागी **के लिए सूचना पत्र**

1. अध्ययन शीर्षक

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

2. निमंत्रण अनुच्छेद

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

आप को एक अध्ययन / शोध परीक्षण में भाग लेने के लिए आमंत्रित किया जा रहा हैं | इससे पहले आपके लिए यह समझना ज़रूरी है की यह अध्ययन क्यो किया जा रहा है और उसमे क्या चीज़े शामिल है | कृपया आप अपना समय निकालकर इस सूचना को पढ़े तथा अपनी इच्छानुसार अपने मित्रो, परिजनो तथा अपने चिकित्सक के साथ चर्चा करें | अगर आप को कोई जानकारी समझ मे नही आती है या और चाहिए तो हमे बताए | आप अपना समय निकालकर इस सूचना को पढ़े और बताए की आप अध्यन मे भाग लेना चाहते है की नही |

3. अध्ययन का उद्देश्य क्या है?

पृष्ठभूमि और अध्ययन के उद्देश्य की जानकारी सरल शब्दो में यहाँ देनी चाहिए |

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

कृपया आप प्रतिभागी को यह बताए की उसे क्यों चुना गया है और इस अध्ययन और कितने लोगो 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 की आप को भाग लेना चाहिए की नही | 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 आप ने भाग लेने का फैसला किया फिर भी किसी भी समय बिना कारण वापस भाग न लेने के लिए स्वतंत्र हैं | इस कारण आप के इलाज मे कोई फरक नही पड़ेगा |"

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

आप को यह बताना चाहिए की प्रतिभागी को कितने समय के लिए अध्यन में भाग लेना है और यह अध्यन कितने समय चलेगा | आपको यह भी बताना होगा की भागी को कितनी बार और कितने दिनो के लिए परीक्षण के लिए अस्पताल में आना होगा | आप प्रतिभागी को यह भी बताए की उसे अस्पताल में नियमित विज़िट के अलावा आना होगा और आप बताए की आने जाने का खर्च किसे देगा होगा ? आप भागी को यह भी बताए की उसे आने पर हर बार कौन से जाँच करना होगा |आप प्रतिभागी को यह भी बताए की उसकी क्या ज़िम्मेदारी होगी | प्रतिभागी को हे लिखकर यह दीजिए की उसे क्या सावधानी बरतकर आना चाहिए | आप प्रतिभागी को अध्ययन के विभिन पहलूए के बारे में जानकारी दीजिए |

7. मुझे क्या करना है?

क्या अध्ययन में भाग लेने जीवन शैली पर किसी तरह का फ़र्क पड़ेगा? आप भागी को यह भी बताए की उसे आहार में कोई सावधानी बरतनी होगी | आप प्रतिभागी को यह भी बताए की क्या वह रोज की तरह गाड़ी चला सकता है? क्या वह खेलकूद में भाग ले सकता है? क्या वह अपनी रोज की दवाए ले सकता है? क्या उसे रक्त देने से बचना चाहिए? आप यह भी बताए की 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 | आप को उनके विकास के बारे में जानकारी देना चाहिए | आप को 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 की उसके उपचार के अन्य कौन से विकल्प उपलब्ध हैं |

10. इस अध्यन 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 | आप भी उन्हें अपना नाम और फोन नंबर देना चाहिए ताकि यदि वे किसी भी आपातकालीन स्थिति में आप से संपर्क कर सके | ज्ञात दुष्प्रभाव को भागी को सरल भाषा में समझकर तथा लिखकर देना चाहिए | किसी भी नई दवा के लिए अज्ञात दुष्प्रभाव के बारे में रोगी को पता होना चाहिए |

11. इस अध्यन 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 की संभानवा है उन्हे भी इस अध्ययन में भाग नहीं लेना चाहिए | जिन महिलाओ को गर्भावस्था की संभावना है ऐसे भागी का पहले एक गर्भावस्था परीक्षण के लिए कहा जा सकता है | यदि संभव है है तो उन्हे 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 |

आपको 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 की जाँच करनी चाहिए कि उनकी भागीदारी उनकी चिकित्सा बीमा को प्रभावित नहीं करेगा |

आपको यह स्पष्ट बताना होगा क़ि 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 नही है तो?

12. अध्यन 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 बढ़ाचढ़ाकर 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 हमें 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 आपके चिकित्सक आपको इसके 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 का फ़ैसला करते हैं तो आपका चिकित्सक आपके इलाज को जारी रखने के की व्यवस्था करगें | यदि आप अध्ययन में जारी रखने का निर्णय लेते हैं, तो आपको एक अपडेटेड सहमति फार्म पर हस्ताक्षर करने के लिए कहा जा सकता है | इसके अलावा, नई जानकारी प्राप्त होने पर आपका चिकित्सक आपके हित 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 की अध्ययन समाप्त होने के बाद उस दवा से इलाज हो पाएगा कि नही ? आप यह भी बताए की 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 प्रतिभागी को को सूचित करना चाहिए की उसकी शिकायतों का निवारण कैसे होगा और जिनके पास शिकायत करनी है, उनके पते क्या है? आपको शिकायत करने की प्रक्रिया की जानकारी देनी होगी | आप को प्रतिभागी को यह भी बताना होगा की 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 की 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 की सहमति देते है तो परीक्षण के लिए आपके 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 की नही इसे देखने के लिए किया जाता है | आपका नाम का अस्पताल/क्लिनिक और प्रयोगशाला के बाहर खुलासा नहीं किया जाएगा "

"सभी अनुसंधान / परीक्षण के दौरान आप के बारे में एकत्र जानकारी कड़ाई से गोपनीय रखी जाएगी | कोई भी जानकारी है जो अस्पताल / क्लिनिक और प्रयोगशाला से बाहर जाएगी, तो उसके उपर से आपका 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 की आगे उसका क्या होगा| आप को यह भी समझाना होगा की 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 की कौन इसे करा रहा है और इस अध्ययन के लिए कहाँ से धन आ रहा है | आपको यहाँ बताना चाहिए की चिकित्सक जो प्रतिभागी की देखभाल कर रहा है तथा और लोग जो उसमे शामिल है उन्हें इसके लिए धन दिया जा रहा है की नहीं | ***आप प्रतिभागी को यह बताये की उसे अध्ययन में शामिल होने पर उसमें शामिल जाँच और दवा के लिए पैसे अलग से नहीं देना होगा |***

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 पुर्नानिरिक्षण किसने किया है ?

आप यह बताये की इसका पुर्नानिरिक्षण या पुर्नावलोकन हमारे संस्थान की नैतिकता/आचार समिति ने किया है तथा अध्ययन करने की सहमति दी है |

21. अधिक जानकारी के लिए निम्न लोगो से संपर्क करे

आप को 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 आप नें जानकारी पत्रक और सहमति फार्म पर हस्ताक्षर किए की एक प्रतिलिपि आप नें प्रतिभागी को दिया है |

_____

प्रमुख अन्वेषक के हस्ताक्षर _____

प्रमुख अन्वेषक का नाम_____ **दिन्नांक**

AN10-V1/SGSOP 03/V2

सहमति पत्र

अध्ययन शीर्षक_____

अध्ययन संख्या_____

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

जन्म तिथि / आयु _____

पता _____

अर्हता_____

व्यवसाय : विद्यार्थी/स्वतः नियोजित/सेवा/गृहणी/अन्य (कृपया समुचित पर निशान लगाये)

व्यक्ति की वार्षिक आय_____

नाम निर्दिशिती का नाम एंव पता उनका व्यक्ति से सम्बन्ध

_____

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

2. मैं यहाँ समझा लिया की अध्ययन मे मेरी भागीदारी पूर्णतः 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. मैं 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 की 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 इससे 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 | **हाँ [ ]** **नहीं [ ]**

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

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

हस्ताक्षरकर्ता 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/SGSOP 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 must be explained in writing to the subject being enrolled.

Disclose appropriate alternative treatments available, if any.

We invite you to participate in this study.

What will you have to do?

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

Since you are in the age group of 8-18 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.

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

AN12-V1/SGSOP 03/V2

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

Signature of the study participant _____Date:_____
Name of the study participant_____

Signature of the Witness _____Date_____
Name of the Witness _____

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

AN15-V1/SGSOP 03/V2

शिशु सहमति पत्र

अध्ययन शीर्षक_____

अध्ययन संख्या_____

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

जन्म तिथि / 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 चिकिस्तक द्वारा बता दिया गया है। मुझे पता है की परीक्षण सम्बन्धी किसी छति जिसका की परीक्षण की दवाई से हेतुक सम्बन्ध है उसका खर्च मेरे माता पिता/ अभिभावकों को वहन नहीं करना है। मुझे यह भी पता है की 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 _____

AN13-V1/SGSOP 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)

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 project/extramural/student project/investigator initiated/drug trial

Item No.	Mandatory Documents (*with version and date)	Yes	No	NA	Page No. ⬇
1.	Document Receipt Form (to be submitted in duplicate, AN14-V1/SGSOP 03/V1)				
2.	Project Submission Form (AN1-V1/SGSOP 03/V1)				
3.	Study Protocol (Review of literature, aim, methodology, inclusion, exclusion criteria)				
4.	Case Report Form (form to capture data)				
5.	Consent of Head of the PI's Department (AN2-V1/SGSOP 03/V1)				
6.	Research committee/department committee /doctoral committee/scientific committee approval (AN3-V1/SGSOP 03/V1)				
7.	Undertaking by the PI (AN4-V1/SGSOP 03/V1)				
8.	Conflict of Interest Statement by PI (AN5-V1/SGSOP 03/V1)				
9.	CV of new or investigator outside SGPGI or of the student (AN6-V1/SGSOP 03/V1)				
10.	Participant Information document (PID) & consent forms CF) in English and Hindi (and if required in any other language) (AN **7to 10** -V1/SGSOP 03/V1) * Include guardian and parents				
11.	Child Information Document and assent form in English and Hindi (and if required in any other				

	language) (AN11-12-15V1/SGSOP 03/V1)				
12.	Ethics Committee clearance of other centers (in case of collaborative project)				
1**3**.	Clinical Trials Registry- India (CTRI) is a pre-requisite for clinical trials. In other case this must be done after approval by IEC				
14.	Investigator Brochure				
15.	Advertisement/Information brochure				
16.	Insurance policy and certificate				
17.	DCGI approval letter/DCGI submission letter				
18.	NOC from DCGI /ICMR/DBT				
19.	Director General of Foreign Trade (DGFT) approval in case study samples are to be sent abroad for analysis				
20.	Genetic Engineering Advisory Committee (GEAC) approval in case study involves use of gene therapy/recombinant DNA				
21.	Bhabha Atomic Research Centre (BARC) approval in case study involves use of radioisotopes/ionizing radiations				
22.	Stem cell (NAC-SCRT registration and approval)				
23.	DCGI marketing/manufacturing license for herbal formulations/nutraceutics				
24.	Clinical Trial Agreement (CTA)/Memorandum of Understanding (MOU)				
25.	Material Transfer Agreement (MTA)- Health Ministry Screening Committee (HMSC) approval in case the study involves collaboration with any foreign laboratory/clinic/institution				
26.	IEC processing fee (applicable for sponsored trials)				
27.	Any other documents				

AN14-V1/SGSOP 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 review

Item No.	Mandatory Documents (*with version and date)	Yes	No	NA	Page No. ⬇
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2.	Project Submission Form (AN1-V1/SGSOP 03/V1)				
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4.	Case Report Form (form to capture data)				
5.	Consent of Head of the PI's Department (AN2-V1/SGSOP 03/V1)				
6.	Research committee/department committee/doctoral committee/scientific committee approval (AN3-V1/SGSOP 03/V1)				
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8.	Conflict of Interest Statement by PI (AN5-V1/SGSOP 03/V1)				

9.	CV of new or investigator outside SGPGI or of the student (AN6-V1/SGSOP 03/V1)				
10.	Participant Information document (PID) & consent forms CF) in English and Hindi (and if required in any other language) (AN **7to 10** -V1/SGSOP 03/V1) * Include guardian and parents				
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27.	Any other documents				

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)