Standard Operating Procedure (SOP) for Institutional Ethics Committee for Human Research at Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow

1. Objective

The objective of Standard Operating Procedure (SOP) is to ensure quality and consistency in review of clinical research proposals and to follow the ICMR and national ethical guidelines for biomedical research on human subjects.

2. Functions of Institutional Ethics Committee (IEC)

IEC should provide independent, competent and timely review of the ethics of proposed studies before the commencement of a study and regularly monitor the ongoing studies.

IEC will review and approve all research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of research participants irrespective of the source of funding. The goals of research, however important, should never be permitted to override the health and well being of the research subjects.

The IEC will ensure that all the cardinal principles of research ethics viz, autonomy, beneficence, non–maleficence and justice are taken care of in planning, conduct and reporting of a proposed study. It will look into the aspects of informed consent process, risk benefit ratio, distribution of burden/benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through periodic reports, final report and site visits etc. The committee will also ensure compliance with all regulatory requirements, applicable guidelines and laws.

3. Composition of IEC

IECs shall be multidisciplinary and multisectorial in composition.

The number of members in the committee shall be kept small (7-11 members) as a large committee makes it difficult in reaching consensus and in having the presence of all the members. The external members shall be in majority to ensure the independence of the committee.

The Chairperson of the committee shall be from outside the Institution and not Head/former Head of SGPGI. The Member Secretary, drawn from SGPGI itself, shall conduct the business of the Committee. Other members will be a mix of medical and non-medical scientific and non-scientific persons including general public to reflect the differed viewpoints.

The composition may be as follows:-

1. Chairperson
2. Basic medical scientists
3. Clinicians
4. Legal expert
5. Social scientist/representative of non-governmental voluntary agency
6. Educated person from the community  
7. Member-Secretary

IEC shall have majority of its members from other institutions. They could be drawn from any public or private institute from anywhere in the country. There shall be adequate representation of age, gender, community etc. in the Committee to safeguard the interests and welfare of all sections of the society. The Committee can not consist entirely of men or entirely of women.

4. Constitution of IEC

The Director, SGPGI, Lucknow shall constitute the IEC, in consultation with the Academic Board in the following pattern:

1. Chairperson  
2. Member Secretary from Institute  
3. Dean  
4. 5-7 members from different specialties as specified above, some of them should be from the Faculty of the Institute.

The committee will be normally reconstituted every 3 years

5. Membership Duration and Responsibilities

1. The duration of the membership will be 3 years  
2. There will be no bar on the members serving for more than one term but it is desirable to have around one third fresh members.  
3. A member can be replaced in the event of long-term non-availability (three consecutive meetings). Authority to replace the member shall be with the Director.  
4. Members should maintain confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term. Each member of the committee will submit a declaration to maintain the confidentiality of the documents submitted to them during their membership period.  
5. Conflict of interest if any shall be declared by members of the IEC at the beginning of every meeting.

6. Quorum Requirements

A minimum of 5 members including at least three outside members is required for quorum. All decisions should be taken in meetings and not by circulation of project proposals.

7. Offices/Conduct of the Meeting

The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available, an alternate Chairperson will be elected by the members present from among themselves. The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get them approved by the Chairperson before communicating to the PI.
8. Independent Consultants

IEC may call upon subject experts as consultants for review of selected research protocols. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups e.g. cancer patients, HIV/AIDS positive persons or ethnic minorities. They will not take part in the decision making process.

9. Application Procedure

1. All proposals should be submitted in the prescribed application form, copies of which will be available with the Member Secretary.
2. All relevant documents should be enclosed with application.
3. The required number of copies of the proposal along with the application and documents in prescribed format duly signed by the PI and Co-investigators/Collaborators should be forwarded by the Head of the Department.
4. The Member Secretary will acknowledge the receipt and indicate any lacunae. Missing information should be supplied within two weeks.
5. The date of meeting will be intimated to the PI who should be available to offer clarifications if necessary.
6. The decision of IEC will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication.

10. Documentation

All research proposals should be submitted with the following documents:

1. Title of the project
2. Names of the PI and Co-investigators with designation.
3. Name of any other Institute/Hospital/Field area where research will be conducted.
4. Approval of the Head of the Department.
5. Protocol of the proposed research.
6. Ethical issues in the study and plans to address these issues.
7. Proposal should be submitted with all relevant annexure like proforma, case report forms, questionnaires, follow-up cards, etc. to be used in the study.
8. Patient information sheet and informed consent form in English/Hindi and local language(s) should be enclosed. The patient information sheet should provide adequate and complete information in understandable language. It should also assure that any new information that becomes relevant during the trial and is related to their participation will be given to them. The consent form should be as per schedule Y published in Gazette of India (2005).
9. For any drug/device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country/other countries, if available.
10. Any regulatory clearances required. Copy of clearances if obtained. This is necessary for new drug/device not approved for marketing in India, justification for sending of biological samples outside India and use of radioactive pharmaceuticals in clinical studies.
11. Source of funding and Budget along with the supporting documents.
12. Indemnity issues including insurance for the compensation to the participants etc.
13. An undertaking to immediately report Serious Adverse Events (SAE) to IEC.
14. Statement of conflicts of interest, if any.
15. Plans for publication of results—positive or negative—while maintaining the privacy and confidentiality of the study participants.
16. Any other information relevant to the study.
17. Agreement to submit annual progress report and final report at the end of study.
18. The PI should provide the details of other ongoing research projects (Title of the project, Date of starting and duration, source and amount of funding).

11. Review Procedure

1. Meetings of IEC shall be held on scheduled intervals as prescribed (once in 3 months, for which the dates will be decided at the end of previous meeting). Additional meetings will be held as and when necessary.
2. The proposals will be sent to members at least 2 weeks in advance.
3. Decisions will be taken by consensus after discussions, and voting will be done if necessary.
4. PI should be available during the meeting and may be invited to offer clarifications.
5. Independent consultants/Experts may be invited to offer their opinion on specific research proposals.
6. The decisions of the meeting shall be recorded in the minutes book and shall be confirmed during the next meeting with signature of Chairperson at each page.

12. Element of Review

1. Scientific design and conduct of the study.
2. Approval of scientific review committee and regulatory agencies.
3. Assessment of predictable risks/harms and potential benefits.
4. Procedure for selection of subjects including inclusion/exclusion, withdrawal criteria and other issues like sample size and advertisement details.
5. Management of research related injuries, adverse events and compensation provisions.
6. Justification for placebo in control arm, if any.
7. Availability of products to the trial subjects after the study, if applicable.
8. Patient information sheet and informed consent form in English/Hindi and local language.
10. Involvement of the community, wherever necessary.
11. Protocol and proforma of the study including the consent form.
12. Plans for data analysis and reporting.
13. Adherence to all regulatory requirements and applicable guidelines.
14. Competence of investigators, research and supporting staff.
15. Facilities and infrastructure.

13. Expedited Review

Proposals which are recommended for minor revisions will be reviewed by a sub committee appointed by the IEC for clearance and approved by the Chairperson. The approvals will be reported in the next IEC meeting by Member Secretary. The revised form of proposals requiring major changes will be reviewed at the next ethics committee meeting. Rejected proposals may be reconsidered only if a very strong background is there.
14. Decisions Making

1. A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises. This shall be indicated to the chairperson prior to the review of the application and recorded in the minutes.

2. Only members will make the decision. The decisions shall be taken in the absence of investigators, representatives of sponsors, consultants.

3. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.

4. Revised proposals may be subjected to an expedited review.

5. All approved proposals will be subject to the following standard conditions. Additional conditions may be added by the IEC.

   i) PI should submit annual report of the ongoing project on format prescribed by the Institute, to the IEC.
   ii) The final report of the completed study should be submitted by PI.
   iii) The PI should highlight the changes in the protocols/brochures/informed consent form etc. being amended from the previous documents while submitting amended documents to IEC.

15. Communicating the Decision

1. Decision will be communicated to PI by the Member Secretary in writing.

2. Suggestions for modifications and reasons for rejection shall be communicated to the PI.

16. Memorandum of Understanding and Indemnity Agreement for Sponsored Drug/Device/Collaborative Trials

After the approval from IEC, the sponsor/CRO will submit the clinical trial agreement/Memorandum of Understanding and Indemnity Agreement document on Rs. 100 stamp paper separately (two copies) to the Institute which will be signed by sponsor and the Dean, SGPGI with the counter signature of PI. As per existing policy of the Institute, there will be 25% overhead charges 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 as well as DCGI and required regulatory approvals are available for the concerned trial.

17. Follow up Procedures

1. Annual report should be submitted by the PI on prescribed format along with comments.

2. Final report should be submitted at the end of study on prescribed format including a copy of the report which has been sent to sponsoring agency.

3. All SAEs and the interventions undertaken should be intimated immediately to IEC. The PI should submit the SAEs reported by other centers from time to time to the Member Secretary for information to IEC along with comments if any action is required in the current study.

4. Protocol deviation, if any, should be informed with adequate justifications.

5. Any amendment to the protocol should be submitted for approval.

6. Any new information related to the study should be communicated to IEC.

7. Premature termination of study should be notified with reasons along with summary of the data obtained so far.

8. Change of investigators should be done with the approval of IEC.
18. Record Keeping and Archiving

1. Curriculum Vitae (CV) of all members of IEC.
2. Minutes of all meetings duly signed by the Chairperson. Copy of all correspondence with members, researchers and other regulatory bodies.
3. Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.
4. All study related documents (study protocols with enclosed documents, progress reports, and SAEs.) should be archived for minimum of ten years after the completion of study. A copy of filled CRF shall remain with the PI for minimum of fifteen years.
5. Final report of the approved projects.

19. Updating IEC Members

1. All relevant information on ethics will be brought to the attention of the members of IEC by the Member Secretary.
2. Institute Members will be encouraged to attend national and international training programs/conferences/seminars in the field of research ethics to help in improving the quality of research protocols/ethics committee submissions and review.
**SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW**

*Form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC)*

(for attachment to each copy of the proposal)

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*Code No. of IEC:*

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*To be filled by IEC Member Secretary*

**Proposal Title:**

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<tr>
<th></th>
<th>Name, Designation &amp; Qualifications</th>
<th>Departmental Tel Nos. Email ID</th>
<th>Signature</th>
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<td>PI</td>
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**Co-PI/ Collaborators**

1. 

2. 

3. 

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Please attach Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years) not working at SGPGI. The investigators should sign their CV.

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### Sponsor Information

| 1. Indian         | a) Government [ ]  Central [ ]  State [ ]  Institutional [ ]  
|                  | b) Private [ ]  
| 2. International | Government [ ]  Private [ ]  UN Agencies [ ]  
| 3. Industry      | National [ ]  Multinational [ ]  
| 4. Contact address of sponsor |  
| 5. Budget        |  

| 1. Type of study | Epidemiological [ ]  Basic Sciences [ ]  Behavioral [ ]  
|                 | Clinical [ ]  Single Centre [ ]  Multicentric [ ]  
| 2. Status of review | New [ ]  Revised [ ]  
| 3. Clinical trials | Drug/Vaccines/Device/Herbal Remedies  
|                   | i. Does the study involve use of  
|                   |   Drugs [ ]  Devices [ ]  Vaccines [ ]  
|                   |   Indian Systems [ ]  Any Other [ ]  None [ ]  
|                   |   Alternate systems of Medicine  
|                   | ii. Is it approved and marketed  
|                   |   In India [ ]  UK & Europe [ ]  USA [ ]  
|                   |   Other Countries, Specify  
|                   | iii. Does it involve a change in use, dosage, route of administration?  
|                   |   If yes, whether DCGI’s/Any other Regulatory Authority’s Permission is obtained?  
|                   |   If yes, copy of permission attached  
|                   | iv. Is it an Investigational New Drug?  
|                   |   If yes  
|                   |   a. Investigator’s Brochure enclosed  
|                   |   b. Preclinical studies data available (If yes, provide summary)  
|                   |   c. Clinical studies data available (If yes, provide summary)  
|                   |   d. Clinical study is Phase I [ ]  Phase II [ ]  Phase III [ ]  Phase IV [ ]  
|                   |   e. DCGI’s permission obtained  
|                   |   If yes, copy of letter enclosed  
|                   |   Yes [ ]  No [ ]  
|                   |   Yes [ ]  No [ ]  
|                   |   Yes [ ]  No [ ]  
|                   |   Yes [ ]  No [ ]  
|                   |   Yes [ ]  No [ ]  
|                   |   Yes [ ]  No [ ]  
|                   |   Yes [ ]  No [ ]  
|                   |   Yes [ ]  No [ ]  
|                   |   Yes [ ]  No [ ]  

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8
4. Brief description of the proposal-aim(s) and objectives, justification for study, methodology describing the potential risks and benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words)

5. Subject selection
   i. Number of subjects
   ii. Duration of (a) Study: (b) Subject participation:
   iii. Will subjects from both sexes be recruited  Yes ☐  No ☐
   iv. Inclusion/exclusion criteria given  Yes ☐  No ☐
   v. Type of subjects  Volunteers ☐  Patients ☐
   vi. Vulnerable subjects  Yes ☐  No ☐
      (Tick the appropriate boxes)
      Pregnant Women ☐  Children ☐  Elderly ☐
      Fetus ☐  Illiterate ☐  Handicapped ☐
      Terminally ill ☐  Seriously ill ☐  Mentally Challenged ☐
      Economically & socially backward ☐
   vii. Special group subjects  Yes ☐  No ☐
      (Tick the appropriate boxes)
      Captives ☐  Institutionalized ☐  Employees ☐
      Students ☐  Nurses/Dependent ☐  Armed Forces ☐
      Any Other ☐  Staff ☐

6. Privacy and confidentiality
   i. Study Involves Direct Identifiers ☐
      Indirect Identifiers/Coded ☐
      Completely Anonymised/ Delinked ☐
   ii. Confidential handling of data by staff  Yes ☐  No ☐

7. Use of biological/hazardous materials
   i. Use of fetal tissue or abortus. If yes provide details  Yes ☐  No ☐
   ii. Use of organs or body fluids. If yes provide details  Yes ☐  No ☐
   iii. Use of recombinant/gene therapy products  Yes ☐  No ☐
      If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained?  Yes ☐  No ☐
   iv. Use of pre-existing/stored/left over samples  Yes ☐  No ☐
   v. Collection for banking/future research  Yes ☐  No ☐
   vi. Use of ionizing radiation/radioisotopes  Yes ☐  No ☐
      If yes, has Bhabha Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?  Yes ☐  No ☐
   vii. Use of Infectious/biohazardous specimens  Yes ☐  No ☐
   viii. Proper disposal of material  Yes ☐  No ☐
ix. 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**

8. Consent  
   *Written*  **Oral**  **Audio-Visual**
   i. Patient Information Sheet attached : (Tick the included elements)  
      **Yes**  **No**  
      - Understandable language
      - Statement that study involves research
      - Sponsor of study
      - Purpose and procedures
      - Risks & discomforts
      - Benefits
      - Compensation for participation
      - Compensation for study related injury
      - Translation of information sheet in local Language
      *If written consent is not obtained, give reasons*
   ii. If healthy volunteers will be included, information sheet for them attached  
      **Yes**  **No**
   iii. Consent form in English  
      Local Languages
   iv. Who will obtain consent? PI-Co-PI  
      Nurse/Counsellor
      Research Staff
      Any Other
   *If written consent is not obtained, give reasons*

9. Will any advertising be done for recruitment of Subjects?  
   (Posters, flyers, brochure, websites – if so attach a copy)  
   **Yes**  **No**

10. Risks & benefits
   i. Is the risk reasonable compared to the anticipated benefits to subjects/community/country?  
      **Yes**  **No**
   ii. Is there physical/social/psychological risk/discomfort?  
      *If yes, Minimal or no risk*  
      More than minimum risk
      High risk
### iii. Is there benefit

- **a) to the subject?**
  - [ ] Direct
  - [ ] Indirect

- **b) to the society**
  - [ ] Yes
  - [ ] No

### 11. Data monitoring

- **i. Is there a data & safety monitoring committee/Board (DSMB)?**
  - [ ] Yes
  - [ ] No

- **If yes, reporting will be done to**
  - Sponsor [ ]
  - IEC [ ]
  - DSMB [ ]

- **ii. Is there a plan for reporting of adverse events?**
  - [ ] Yes
  - [ ] No

- **iii. Is there a plan for interim analysis of data?**
  - [ ] Yes
  - [ ] No

### 12. Is there compensation for injury?

- [ ] Yes
  - [ ] No

- **If yes, by**
  - Sponsor [ ]
  - Investigator [ ]
  - Insurance Company [ ]
  - Any Other [ ]

### 13. Do you have conflict of interest?

- [ ] Yes
  - [ ] No

  *(Financial/Non financial)*

  **If yes, specify**

### Check list for attached documents:

- **Project proposal-11 copies**
- Curriculum Vitae of non SGPGI Investigators
- Brief description of proposal/summary
- Copy of the Protocol/Project and questionnaire (if any)
- Investigator’s Brochure
- Copy of Patient information sheet & Consent form in local language
- Copy of Advertisements/Information brochures
- DCGI/DBT/BARC clearance if obtained
- Copy of Insurance Policy
- Copy of Clinical trial agreement
- Copy of IEC proforma
- Copy of PI undertaking
- Copy of Case Report Form

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**Signature of PI**

**Date**

**Signature of HOD**

11
UNDERTAKING BY THE PRINCIPAL INVESTIGATOR

1. NAME AND CODE NUMBER 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.

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 ICMR and National Regulatory 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 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 Principal Investigator

Date
**ONE PAGE CV**

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<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Middle Initial</th>
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Date of Birth (dd/mm/yy):  
Sex

**Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordinator)**

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<tr>
<th>Professional Mailing Address (Include institution name)</th>
<th>Study Sited Address (Include institution name)</th>
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**Telephone (Office):**  
**Mobile Number:**

**Telephone (Residence):**  
**E-Mail:**

**Academic Qualifications (Most current qualification first)**

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<th>Degree/Certificate</th>
<th>Year</th>
<th>Institution, Country</th>
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**Current and Previous 4 Relevant Positions Including Academic Appointments (Most current position first)**

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<th>Title</th>
<th>Institution/Company, Country</th>
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**Brief Summary of Relevant Clinical Research Experience:**

**Signature:**  
**Date:**

(Signature Required)

*For Non-SGPGI Investigator*
To,

Prof./Dr. ________________________________

Dear Prof./Dr. ________________________________

The Institutional Ethics Committee in its meeting held on ________________, has reviewed and discussed your application to conduct the clinical trial/project entitled

"__________________________________________________

__________________________________________________

__________________________________________________

"

_________________ sponsored by _________________ Code no.______________________________

The following documents were reviewed:

a. Trial Protocol (including protocol amendments)/project, dated _______. Version no (s).

b. Investigator’s Brochure, dated ________________, Version no. ________________

c. Patient Information Sheet and Informed Consent Form (including updates if any) in Hindi, English and/or vernacular language.

d. Proposed methods for patient accrual including advertisement(s) etc. proposed to be used for the purpose.

e. Current CV of investigator from outside SGPGI.

f. Insurance Policy/Compensation for participation and for serious adverse events occurring during the study participation.

g. Investigator’s Agreement with the Sponsor.

h. Investigator’s Undertaking.

i. Ethics Committee Proforma.

j. DCGI approval letter/submission letter.

k. Case Report Form

l. Any other/additional documents

Decision of Committee: Institutional Ethics Committee Member Secretary
1. Project/Trial Code Number
2. Title of the drug/multicentric trial
3. Principal Investigator (Name & Department)
4. Sponsor
5. Contract Research Organization (CRO) if any
6. Date of sanction by IEC
7. Date of start

Date:  
(Signature of Principal Investigator)
SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

PROGRESS REPORT (Annual)/FINAL REPORT

1. Project/Trial Code Number

2. Title of the drug/multicentric trial

3. Principal Investigator (Name & Department)

4. Sponsor

5. Contract Research Organization (CRO) if any

6. Date of sanction by IEC

7. Date of start

8. Objectives of the study

9. Progress report as per objectives (attach separate sheet)

10. Serious Adverse Events if any with details (in summary form)

11. Protocol deviation if any with reasons/justifications

12. Report/publications/conference presentation

13. Awards/recognition

Date:  

(Signature of Principal Investigator)

(Signature of Head of the Department)
GUIDELINES FOR PATIENT INFORMATION SHEET

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. An Information Sheet should contain information under the headings given below where appropriate, 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.

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. The following is an example:

“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 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. You could use the following paragraph:-

“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/fastimg. You should explain simply and briefly the research/trial methods you intend to use – the following simple definitions may help:-

**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.

**Placebo:** A placebo is a dummy treatment such as a pill, which looks like the real thing but is not. It contains no active drug, chemical or ingredient.

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 appropriate) that the patient should take the medication regularly.

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, the following (or similar) should be said:

“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 women 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. This could be seen as coercive. It would be reasonable to say something similar to:
“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. You could use the following:

“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 should 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 redress 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.

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. A suggested form of words for drug company sponsored research/trial is:

“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 answer 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 the doctor conducting the research/trial is being paid for including and looking after the patient in the study. This means payment other than that to cover necessary expenses such as laboratory tests arranged locally by the researcher, or the costs of a research nurse.

19. Who has reviewed the study?

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

20. 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 Patient Information Sheet should state that the patient will be given a copy of the information sheet and the signed consent form.

Date ___________________ Signature of PI ___________________
SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

INFORMED CONSENT FORM

Study Title______________________________________________________________

Study Number___________________________________________________________

Subject’s Full Name _______________________________________________________

Date of Birth/Age_________________________________________________________

Address ___________________________________________________________________

____________________________________________________________________________

1. I confirm that I have read and understood the information sheet 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 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 ________________________________
Lakt; xkj/kh LukrdksRrj vk;qfoZKku lALFkkku] y[kuÅ

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5- mi;qZDr v/;u esa Hkx ysus ds fy;eSa lger gwaA

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A. INTRODUCTION

1. The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.

2. It is the duty of the physician to promote and safeguard the health of the people. The physician’s knowledge and conscience are dedicated to the fulfillment of this duty.

3. The Declaration of Geneva of the World Medical Association binds the physician with the words, “The health of my patient will be my first consideration,” and the International Code of Medical Ethics declares that, “A physician shall act only in the patient’s interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient.”

4. Medical progress is based on research, which ultimately must rest in part on experimentation involving human subjects.

5. In medical research on human subjects, considerations related to the well being of the human subject should take precedence over the interests of science and society.

6. The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best-proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.

7. In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.

8. Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.
9. Research Investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

10. It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.

11. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.

12. Appropriate caution must be exercised in the conduct of research, which may affect the environment, and the welfare of animals used for research must be respected.

13. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.

14. The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.

15. Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.

16. Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.

17. Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.

18. Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.

19. Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.
20. The subjects must be volunteers and informed participants in the research project.

21. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient’s information and to minimize the impact of the study on the subject’s physical and mental integrity and on the personality of the subject.

22. In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject’s freely given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

23. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.

24. For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.

25. When a subject deemed legally incompetent, such as a minor child, is able to given assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.

26. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.

27. Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

28. The physician may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value. When medical
research is combined with medical care, additional standards apply to protect the patients who are research subjects.

29. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists. See footnote

30. At the conclusion of the study, every patient entered into the study should be assured of access to the best-proven prophylactic, diagnostic and therapeutic methods identified by the study. See footnote

31. The physician should fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship.

32. In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician’s judgment it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.

Note of clarification on paragraph 29 of the WMA Declaration of Helsinki

The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:

- Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or

- Where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm. All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review.

Note of clarification on paragraph 30 of the WMA Declaration of Helsinki

The WMA hereby reaffirms its position that it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or access to other appropriate care. Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review.

The Declaration of Helsinki (Document 17.C) is an official policy document of the World Medical Association, the global representative body for physicians.

9.10.2004
## ONE PAGE CV FOR MEMBERS OF THE INSTITUTIONAL ETHICS COMMITTEE

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### Date of Birth (mm/dd/yy):

### Professional Mailing Address
(Include institution name)

### Telephone (Office):

### Mobile Number:

### Telephone (Residence):

### E-Mail:

### Academic Qualifications (Most current qualification first)

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### Professional Experience

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### Signature:

(Signature Required)

### Date:
SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW.

SECRECY UNDERTAKING BY MEMBER OF INSTITUTIONAL ETHICS COMMITTEE

Name:

Designation:

Address:

I understand that as a Member of the Institutional Ethics Committee I may receive documents containing confidential or privileged information about patients, volunteers or commercial products.

I agree not to disclose or discuss such information or minutes of the meeting with persons not entitled to have them. I also agree either to return all documents marked CONFIDENTIAL/PRIVILEGED to Member Secretary or destroy them after perusal.

Date

Signature
SANJAY GANDHI POSTGRADAUTE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

LIST OF MEMBERS OF ETHICS COMMITTEE (2005-2007)

1. Prof. B.N.Dhawan, Ex-Director, CDRI, Lucknow
   3 Ram Krishna Marg, Lucknow-226007
   Chairman

2. Prof. A.K. Mahapatra, Director & Chairman, Research Committee, SGPGI, Lucknow
   Member

3. Prof. R.K. Sharma, Dean, SGPGI, Lucknow
   Member

4. Prof. G. Choudhuri, HOD, Gastroenterology, SGPGI, Lucknow
   Member

5. Prof. Sunil Pradhan, Dept. of Neurology, SGPGI, Lucknow
   Member

6. Dr. E. Charles, Principal, IT College, Lucknow
   Member

7. Dr. J. S. Srivastava, Dy. Director/Scientist F, Division of Clinical & Experimental Medicine, Central Drug Research Institute (CDRI), Lucknow
   Member

8. Justice K.L. Sharma, Ex-Judge, Allahabad High Court & Ex-Chairman, State Public Service Tribunal, Lucknow
   12, Avas Vikas Colony, Mall Avenue, Lucknow
   Member

9. Dr. Shanta Mehrotra, Emeritus Scientist, NBRI, Lucknow
   Member

10. Dr. S. Srivastava, Senior Research Officer, SGPGI, Lucknow
    Member Secretary