INDIRA GANDHI INSTITUTE OF MEDICAL SCIENCES, SHEIKHPURA, PATNA-14.

Form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC)
(for attachment to each copy of the proposal)

***Code No. of IEC:**

* To be filled by IEC Member Secretary

Proposal Title:

PI	**Name, Designation & Qualifications**	**Departmental Tel Nos. Email ID**	**Signature**
Co-PI/ Collaborators			
1. **2.**			
3.			
Please attach Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years) not working at IGIMS. The investigators should sign their CV.			

Sponsor Information

1. Indian	a) Government	☐	Central	☐	State ☐	Institutional	☐
	b) Private	☐					
2. International	a) Government	☐	Private	☐		UN Agencies	☐
3. Industry	b) 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 of Medicines/ Alternate systems of Medicine	☐	Any Other	☐		None	☐
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?						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 ☐
iv. 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 ☐		
e. DCGI's permission obtained						Yes ☐	No ☐
If yes, copy of letter enclosed						Yes ☐	No ☐

4. Objectives of the study	4.1_____ 4.2_____ 4.3_____ 4.4_____ 4.5_____
5. Justification for conduct of this study	
6. Methodology	6.1. Number of Patients: 6.2. Inclusion criteria a)_____ b)_____ c)_____ d)_____ 6.3. Exclusion criteria a)_____ b)_____ c)_____ d)_____ 6.4. Control(s) _____ 6.5. Study design _____
	6.6. Dosages of drug _____ 6.7. Duration of treatment _____ 6.8. Investigation specifically related to projects_____ 6.9 Permission to use copyrighted Questionnaire/proforma 6.10. Others _____

7. Subject selection

i. Duration of (a) Study: (b) Subject participation:

ii. Will subjects from both sexes be recruited Yes ☐ No ☐

iii. Inclusion/exclusion criteria given Yes ☐ No ☐

iv. Type of subjects Volunteers ☐☐ Patients ☐

v. Vulnerable subjects Yes No ☐
(Tick the appropriate boxes)

Pregnant Women ☐ Children ☐ Elderly ☐

Fetus	☐	Illiterate	☐	Handicapped	☐
Terminally ill	☐	Seriously ill	☐	Mentally	☐
Economically & socially backward	☐	Any other	☐	Challenged	

vi. Special group subjects (Tick the appropriate boxes) Yes ☐ No ☐

Captives	☐	Institutionalized	☐	Employees	☐
Students	☐	Nurses/Dependent	☐	Armed	☐
Any Other	☐	Staff	☐	Forces	

8. Privacy and confidentiality

i. Study Involves

Direct Identifiers ☐

Indirect Identifiers/Coded ☐

Completely Anonymised /Delinked ☐

ii. Confidential handling of data by staff Yes ☐ No ☐

9. 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 r DNA 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 ☐

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

i. Patient Information Sheet attached : (Tick the included elements) Yes ☐ No ☐

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	☐	Consent for future use of material biological	☐
Compensation for participation	☐	Benefits if any on future commercialization e.g. Genetic basis for drug development	☐
Compensation for study related injury	☐	Cost of Management of Adverse Effects will be borne by sponsor	
Translation of information sheet in local Language	☐		

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

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

12. 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? Yes ☐ No ☐

If yes, Minimal or no risk ☐

More than minimum risk ☐

High risk ☐

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

Direct ☐ Indirect ☐

13. Data monitoring b) to the society Yes ☐ No ☐

i. Is there a data & safety monitoring committee/Board (DSMB)? Yes ☐ No ☐

ii. Is there a plan for reporting of adverse events? Yes ☐ No ☐

If yes, reporting will be done to

Sponsor ☐ IEC ☐ DSMB ☐

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

14. Is there compensation for injury? Yes ☐ No ☐

If yes, by

Sponsor ☐ Investigator ☐

Insurance Company ☐ Any Other ☐ Yes ☐ No ☐

15. Do you have conflict of interest?

(Financial/Non financial)

If yes, specify

16. Insurance Policy for the following is available?

Patient/Participant Yes ☐ No ☐ Company/Sponsor Yes ☐ No ☐

Investigator/s & Team Yes ☐ No ☐ Institute/Committees Yes ☐ No ☐

Check list for attached documents:

Project proposal-15 copies

CHECK LIST

Curriculum Vitae of 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 ☐

Signature of
P/I Signature of HOD

ONE PAGE CV

Last Name Date of Birth (dd/mm/yy):	First Name	Middle Initial
		Sex
Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordinator)		
Professional Mailing Address (Include institution name) Telephone (Office):	Study Sited Address (Include institution name) Mobile Number:	
Telephone (Residence):	E-Mail:	
Academic Qualifications (Most current qualification first)	Institution, Country	

Degree/Certificate	Year	

Current and Previous 4 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:	
(Signature Required)	

INDIRA GANDHI INSTITUTE OF MEDICAL SCIENCES, SHEIKHPURA, PATNA-14.

FORMAT FOR COMMUNICATION TO THE PRINCIPAL INVESTIGATOR BY THE MEMBER SECRETARY, INSTITUTIONAL ETHICS COMMITTEE

/20

To,

Prof./Dr. _____
_____
_____
_____

Dear Prof./Dr. _____IGI/Acad./

Dated:

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 IGIMS
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

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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/fasting. 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 ablind trial you will not know which treatment group you are in. If the trial is a double blind trial, neither you not 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 identity 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 woman who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the investigator.

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

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

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

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

19. 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**

INDIRA GANDHI INSTITUTE OF MEDICAL SCIENCES, SHEIKHPURA, PATNA-14.

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 _____

इन्दिरा गांधी आयुर्विज्ञान संस्थान, शेखपूरा, पटना-१४.

सूचित सहमति पत्र

अध्ययन का विषय ----------

अध्ययन नम्बर----------

सहभागी का पूरा नाम ----------

जन्मतिथि/उम्र ----------

पता----------

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१. मेरी पुष्टि है कि मैने उपरोक्त परिक्षण हेतु जानकारी पत्र दिनांक-------को पढ़ व समझ लिया है, तथा मुझे प्रश्न पूछने के अवसर प्रदान किये गये।

अथवा

मुझे अध्ययन अन्वे क ने विस्तार से सब तथ्यों को समझा दिया है तथा मुझे प्रश्न पूछने का अवसर प्रदान किया।

२. मैंने समझ लिया है कि इस अध्ययन में मेरी तिभागिता स्वैच्छिक है, तथा यह कि मै बिना कोई कारण बताए किसी भी समय अपनी चिकित्सीय देखभाल या कानूनी अधिकारों पर भाव पडे बिना हट जाने के लिए स्वतंत्र हूं।

३. मैंने समझ लिया है कि चिकित्सीय संयोजक की ओर से काम करने वाले अन्य, नैतिकता समिति तथा विनियामक आधिकारियों का चालू अध्ययन तथा इससे सम्बन्धित हो सकने वाले किसी अनुसंधान से सम्बन्धित मेरे स्वास्थ्य अभिलेखों को देखने के लिए मेरी अनुमति की आवश्यकता नही होगी, भले ही मैं इस परीक्षण से हट ही क्यों न जाउँ। तथापि मैंने समझ लिया है कि त तीय पक्ष को दी गई काशित की गई किसी या जानकारी में मेरी पहचान को उजागर नही किया जाएगा।

४. इस अध्ययन में प्राप्त किन्ही आकडों या परिक्षाणों के प्रयोग पर पाबंदी न लगाने के लिये मै सहमत हूं बशर्ते कि ऐसे योग मात्र वैज्ञानिक प्रयोजन/नों के लिये ही हों।

५. उपर्युक्त अध्ययन में भाग लेने के लिये मैं सहमत हूं।

सहभागी के हस्ताक्षर या अगूंठे का निशान/कानूनी रूप से स्वीकार्य प्रतिनिधि ----------

हस्ताक्षर करने वाले का नाम---------- दिनांक ----------

अध्ययन अन्वे क के हस्ताक्षर ---------- दिनांक ----------

अध्ययन अन्वे क का नाम ----------

गवाह के हस्ताक्षर---------- दिनांक ----------

गवाह का नाम----------

INDIRA GANDHII INSTITUTE OF MEDICAL SCIENCES, SHEIKHPURA, PATNA-14.

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 YOY 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

INDIRA GANDHI INSTITUTE OF MEDICAL SCIENCES, SHEIKHPURA, PATNA-14.

INTIMATION OF START OF STUDY

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)**

INDIRA GANDHI INSTITUTE OF MEDICAL SCIENCES, SHEIKHPURA, PATNA-14.

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)

INDIRA GANDHI INSTITUTE OF MEDICAL SCIENCES, SHEIKHPURA, PATNA-14.

ONE PAGE CV FOR MEMBERS OF THE INSTITUTIONAL ETHICS COMMITTEE		

Last Name **First Name** **Middle Initial**

Date of Birth (mm/dd/yy):

Professional Mailing Address (Include institution name)

Sex

Telephone (Office):

Telephone (Residence):

	Mobile Number:

	E-Mail:	
Academic Qualifications (Most current qualification first)		
Degree/Certificate	**Year**	
	Title	
Professional Experience		
Month and Year		
Signature: Institution/Company, Country (Signature Required)		
Date:		
Institution, Country		

INDIRA GANDHI INSTITUTE OF MEDICAL SCIENCES, SHEIKHPURA, PATNA-14.

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

Declaration of Helsinki

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964

And amended by the

29th WMA General Assembly, Tokyo, Japan, October 1975

35th WMA General Assembly, Venice, Italy, October 1983

41st WMA General Assembly, Hong Kong, September 1989

48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996

and the

52nd WMA General Assembly, Edinburgh, Scotland, October 2000

Note of Clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002 Note of Clarification on Paragraph 30 added by the WMA General Assembly, Tokyo 2004

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' 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 valve. 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

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.