Institutional Ethics Committee (IEC)

Raipur Institute of Medical Sciences
Off NH-6, Bhansoj Road, Godhi, Raipur-492101, Chhattisgarh

Ethics Committee Registration No. ECR/969/Inst/CG/2017

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

PROPOSAL TITLE:

	Name Designation and qualification	Contact number And Email id.	Signature
Principle Investigator (PI)			
Co-PI 1.			
Co-PI 2.			
Co-PI 3.			

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 ☐ Multi-centric ☐
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. 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 (Tick the appropriate boxes) Pregnant Women ☐ Children ☐ Elderly ☐ Fetus ☐ Illiterate ☐ Handicapped ☐ Terminally ill ☐ Seriously ill ☐ Mentally Challenged ☐ Economically & socially backward vii. Special group subjects (Tick the appropriate boxes) Captives ☐ Institutionalized ☐ Employees ☐ Staff ☐ Students ☐ Nurses/ Dependent ☐ Armed force ☐ Any Other ☐	

5. Privacy and confidentiality

i. Study Involves Direct Identifiers ☐ Indirect Identifiers/Coded ☐
Completely Anonymised /Delinked ☐

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

6. 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 ☐

7. 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 ☐
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

8. Will any advertising be done for recruitment of Subjects?

(Posters, flyers, brochure, websites – if so attach a copy) Yes ☐ No ☐

9. 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 ☐

b) to the society Yes ☐ No ☐

10. Data monitoring

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 ☐

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

If yes, by

Sponsor ☐ Investigator ☐

Insurance Company ☐ Any Other ☐

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

(Financial/Non financial)

If yes, specify

Check list for attached documents:

- ☐ **Project proposal-03 copies**
- ☐ 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

Signature of PI

Signature of HOD
Date:

Institutional Ethics Committee (IEC)

Raipur Institute of Medical Sciences

Off NH-6, Bhansoj Road, Godhi, Raipur-492101, Chhattisgarh

Ethics Committee Registration No. ECR/969/Inst/CG/2017

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 PI **Date:**

Institutional Ethics Committee (IEC)

Raipur Institute of Medical Sciences
Off NH-6, Bhansoj Road, Godhi, Raipur-492101, Chhattisgarh

Ethics Committee Registration No. ECR/969/Inst/CG/2017

Information 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)

Institutional Ethics Committee (IEC)

Raipur Institute of Medical Sciences

Off NH-6, Bhansoj Road, Godhi, Raipur-492101, Chhattisgarh

Ethics Committee Registration No. ECR/969/Inst/CG/2017

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)