Pt. Ravishankar Shukla University, Raipur (C.G.)

Institutional Ethics Committee (IEC) of
Pt. Ravishankar Shukla University, Raipur (C.G.)

Model form to be filled by the Principal Investigator (PI)/Research Scholar for submission to Institutional Ethics Committee (IEC)

(for attachment to each copy of the proposal)

Proposal Title:

	Name, Designation & Qualifications	**Address Tel & Fax Nos. Email ID**	**Signature**
PI/ Research Scholar/ Investigator			
Co-PI			
Collaborator/ Advisor			

Tick appropriately

Sponsor Information : 1. Indian a) **Government** Central State Institutional b) Private
2. International Government Private UN agencies
3. Industry National Multinational
Contact Address of Sponsor:
Total Budget :

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1.Type of Study :	Clinical	Epidemiological		
	Behavioral			
	Other	Specify: R & D:		
Whether :	Multi-centric	Single center		
2. Status of Review:	New	Revised		
3. Clinical Trials: Drug /Vaccines/Device/Herbal Remedies : **i.** Does the study involve use of :				
Drug	Devices	Vaccines		
Indian Systems of Medicine/ Alternate System of Medicine	Any other	**NA**		
ii. Is it approved and marketed: NA				
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? **If yes,** Date of permission :			YES	**NO**
iv. Is it an Investigational New Drug? **If yes,** IND No:			YES	**NO**
a). Investigator's Brochure submitted			YES	**NO**
b). *In vitro* studies data			YES	**NO**
c). Preclinical Studies done			YES	**NO**
d). Clinical Study is : **NA** Phase I	Phase II	Phase III	Phase IV	
e). Are you aware if this study/similar study is being done elsewhere? **If Yes**, attach details			YES	NO

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4. Brief description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & 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 study :		
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 Any other		
vii. Special group subjects: Yes **No** *(Tick the appropriate boxes)* Captives Institutionalized Employees Students Nurses/Dependent Armed Any other Staff Forces		
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	YES	NO
ii. Use of organs or body fluids	YES	NO
iii. Use of recombinant/gene therapy **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 Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?		
vii. Use of Infectious/bio-hazardous specimens **If Yes, justify with details of collaborators** a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	YES	NO
viii. Proper disposal of material	YES	NO
ix. Will any sample collected from the patients be sent abroad? **If Yes, justify with details of collaborators**	YES	NO
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? b) Sample will be sent abroad because (*Tick appropriate box*)	YES	NO
Facility not available in India Facility in India inaccessible Facility available but not being accessed. If so, reasons…		
8. Consent : Written/ Thumb Impression i. Consent form : (tick the included elements) Understandable language — Alternatives to participation Statement that study involves research — Confidentiality of records Sponsor of study — Contact information Purpose and procedures — Statement that consent is voluntary Risks & Discomforts — Right to withdraw Benefits — Consent for future use of biological material Compensation for participation — Benefits if any on future commercialization Compensation for study related injury — eg. Genetic basis for drug development *If written consent is not obtained, give reasons: In all cases subjects may unable to sign due to illiterate.		
ii. Who will obtain consent? PI/Co-PI Nurse/Counselor Research staff Any other		
9. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly 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	YES	NO
iii. Is there a benefit a) to the subject? Direct Indirect b) Benefit to society		
11. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	YES	NO
ii. Is there a plan for reporting of adverse events? **If Yes,** reporting is done to : Sponsor Ethics Committee DSMB	YES	NO
iii. Is there a plan for interim analysis of data?	YES	NO
iv. Are there plans for storage and maintenance of all trial databases? **If Yes, for** how long?	YES	NO
12. Is there compensation for participation? **If Yes,** Monetary In kind Specify amount and type:	YES	NO
13. Is there compensation for injury? **If Yes,** by Sponsor by Investigator by insurance company by any other	YES	NO
14. Do you have conflict of interest? (financial/nonfinancial) If Yes, specify:	YES	NO
Checklist for attached documents: Project proposal – 1 Copy Curriculum Vitae of Investigators Brief description of proposal Patient information sheet Informed Consent form Investigator's brochure for recruiting subjects Copy of advertisements/Information brochures Copy of clinical trial protocol and/or questionnaire HMSC/DCGI/DBT/BARC clearance if obtained		

Place & Date Signature of Applicant