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:

<table>
<thead>
<tr>
<th>Name, Designation &amp; Qualifications</th>
<th>Address Tel &amp; Fax Nos. Email ID</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI/ Research Scholar/ Investigator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co-PI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Collaborator/ Advisor</td>
<td></td>
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</tr>
</tbody>
</table>

**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:
**Type of Study:**
- Clinical
- Epidemiological
- Behavioral
- Other (Specify: R & D:)
- Multi-centric
- Single center

**Status of Review:**
- New
- Revised

### Clinical Trials:

**Drug/Vaccines/Device/Herbal Remedies:**

1. **Does the study involve use of:**
   - Drug
   - Devices
   - Vaccines
   - Indian Systems of Medicine/Alternate System of Medicine
   - Any other (NA)

2. **Is it approved and marketed:** (NA)
   - In India
   - UK & Europe
   - USA
   - Other countries, specify

3. **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, Date of permission:

4. **Is it an Investigational New Drug?**
   - If yes, IND No:
     - a). Investigator’s Brochure submitted (YES/NO)
     - b). In vitro studies data (YES/NO)
     - c). Preclinical Studies done (YES/NO)

5. **Clinical Study is:**
   - NA
   - Phase I
   - Phase II
   - Phase III
   - Phase IV

6. **Are you aware if this study/similar study is being done elsewhere?**
   - If Yes, attach details (YES/NO)
Pt. Ravishankar Shukla University, Raipur (C.G.)
Institutional Ethics Committee (IEC) of
Pt. Ravishankar Shukla University, Raipur (C.G.)

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
      YES NO
      (Tick the appropriate boxes)
      Pregnant women Children Elderly
      Fetus Illiterate Handicapped
      Terminally ill Seriously ill Mentally challenged
      Economically & socially backward Any other
   vi. Vulnerable subjects
      Yes No
      (Tick the appropriate boxes)
      Captives Institutionalized Employees
      Students Nurses/Dependent Armed
      Any other Staff Forces
   vii. Special group subjects
      Yes No
      (Tick the appropriate boxes)
      Any other

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
      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 Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?

<table>
<thead>
<tr>
<th>vii. Use of Infectious/bio-hazardous specimens</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>

If Yes, justify with details of collaborators

<table>
<thead>
<tr>
<th>a) Is the proposal being submitted for clearance from Health Ministry’s Screening Committee (HMSC) for International collaboration?</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>viii. Proper disposal of material</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>ix. Will any sample collected from the patients be sent abroad?</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

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 |
| b) 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…

8. Consent: Written/Thumb Impression

i. Consent form: (tick the included elements)

<table>
<thead>
<tr>
<th>Understandable language</th>
<th>Alternatives to participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statement that study involves research</td>
<td>Confidentiality of records</td>
</tr>
<tr>
<td>Sponsor of study</td>
<td>Contact information</td>
</tr>
<tr>
<td>Purpose and procedures</td>
<td>Statement that consent is voluntary</td>
</tr>
<tr>
<td>Risks &amp; Discomforts</td>
<td>Right to withdraw</td>
</tr>
<tr>
<td>Benefits</td>
<td>Consent for future use of biological material</td>
</tr>
<tr>
<td>Compensation for participation</td>
<td>Benefits if any on future commercialization</td>
</tr>
<tr>
<td>Compensation for study related injury</td>
<td>eg. Genetic basis for drug development</td>
</tr>
</tbody>
</table>

*If written consent is not obtained, give reasons: In all cases subjects may unable to sign due to illiterate.*

<table>
<thead>
<tr>
<th>ii. Who will obtain consent?</th>
<th>PI/Co-PI</th>
<th>Nurse/Counselor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research staff</td>
<td></td>
<td>Any other</td>
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</table>

9. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly attach a copy)

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
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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?

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>If Yes,</td>
<td>Minimal or no risk</td>
<td>More than minimum risk</td>
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### iii. Is there a benefit

a) to the subject?

- Direct
- Indirect

b) Benefit to society

### 11. Data Monitoring

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>i. Is there a data &amp; safety monitoring committee/ Board (DSMB)?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>ii. Is there a plan for reporting of adverse events?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>If Yes, reporting is done to:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sponsor</td>
<td>Ethics</td>
<td>Committee</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
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<tbody>
<tr>
<td>iii. Is there a plan for interim analysis of data?</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
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<tbody>
<tr>
<td>iv. Are there plans for storage and maintenance of all trial databases?</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

### 12. Is there compensation for participation?

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>If Yes, Monetary</td>
<td>In kind</td>
<td></td>
</tr>
<tr>
<td>Specify amount and type:</td>
<td></td>
<td></td>
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</table>

### 13. Is there compensation for injury?

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>If Yes, by Sponsor</td>
<td>by Investigator</td>
<td></td>
</tr>
<tr>
<td>by insurance company</td>
<td>by any other</td>
<td></td>
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</table>

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

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
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<tbody>
<tr>
<td>(financial/nonfinancial) If Yes, specify:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### 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