

Total Budget :

(✓ as applicable)

1. **Type of study :** Epidemiological Basic Sciences Animal studies
Clinical Single center Multicentric Behavioral

2. **Status of review :** New Revised

3. **Clinical Trials : Drug / Vaccines / Device / Herbal Remedies :** NA

(i) Does the study involve use of Drug Devices Vaccines
Indian Systems or Alternate System of Medicine Any other (Specify)

(ii) Is it approved and marketed in India UK and Europe USA
Other countries (Specification required)

(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? Yes No
If YES, provide the IND 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 : Phase I Phase II Phase III Phase IV

(e) Are you aware of this study / similar study is being done elsewhere? (If YES, attach details) Yes No

4. **Brief description of the proposal** (Attach sheet with maximum 500 words)

(a) Introduction, (b) Review of literature, (c) Aim(s) and objectives, (d) Justification for study, (e) Methodology describing the potential risks and benefits, (f) Outcome measures, (g) Statistical analysis and (h) Whether it is of national significance with rationale

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

If YES,

Pregnant women Children Elderly

Fetus Illiterate Handicapped

Terminally ill Seriously ill Mentally challenged

Economically and socially backward Any other (specify)

(vii) Special group of subjects Yes No

If yes,

Captives Institutionalized Employees

Students Nurses / Dependent staff Armed forces

Any other (specify)

6. Privacy and confidentiality :

- (i) Study involves : (a) Direct Identifiers
 (b) Indirect Identifiers / coded
 (c) 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 Bhava Atomic Research Center (BARC) approval for radioactive isotopes been obtained? Yes No
- (vii) Use of Infectious / biohazardous specimens Yes No
- (viii) Proper disposal of material (*Provide information*) Yes No
- (ix) Will any sample collected from the patients be sent abroad Yes No
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*
Facility is not available in India
Facility in India is inaccessible
Facility is available but not being accessed (give reason)

8. Consent :

* Written Oral Audio-Visual

- (i) Consent form (Tick the included elements and provide sample copy)
- | | |
|---|--|
| Understandable language <input type="checkbox"/> | Alternatives of participation <input type="checkbox"/> |
| Statement that study involves research <input type="checkbox"/> | Confidentiality of records <input type="checkbox"/> |
| Sponsor of the study <input type="checkbox"/> | Contact information <input type="checkbox"/> |
| Purpose and procedures <input type="checkbox"/> | Statement that consent is voluntary <input type="checkbox"/> |
| Risks and discomforts <input type="checkbox"/> | Right to withdraw <input type="checkbox"/> |
| Benefits <input type="checkbox"/> | Consent for future use of biological material <input type="checkbox"/> |
| Compensation for participation <input type="checkbox"/> | Benefits if any on future commercialization <input type="checkbox"/> |
| Compensation for study related injury <input type="checkbox"/> | <i>e.g. genetic basis for drug development</i> |

* *If written consent is not obtained, give reason*

- (ii) Who will obtain the consent ? PI / CoI Nurse / Counsellor
 Research staff Any other (specify)

9. Will any advertising be done for recruitment of subjects?

Yes No

*If YES, Posters Flyers
 Brochure Websites Any Other Attach Copy*

10. Risks and Benefits :

- (i) Is there physical / social / psychological risk / discomfort? Yes No
If YES, risk is Minimal More than minimum High
- (ii) Is there any (a) Benefit to the subject? Yes No
If YES, benefit is Direct Indirect
(b) Benefit to the society Yes No
- (iii) Is the risk reasonable compared to the anticipated benefits to
Subjects / Community / Country ? Yes No NA

11. Data Monitoring :

- (i) Is there a Data and 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
- (iv) Is there plans for storage and maintenance of all trial database? Yes No
If YES, state the duration and mode of storage.

12. Is there any compensation for participation?Yes No *If YES, Monetary In kind (Specify the amount and type)***13. Is there any compensation for injury?**Yes No *If YES, by Sponsor by Investigator
by Insurance Company by any other (Specify the amount and type)***14. Do you have conflict of interest?**Yes No *If YES, Financial Nonfinancial (Specify)***Checklist for attached documents :**

- (a) Project proposal in the prescribed format Yes No
- (b) CV of investigators Yes No
- (c) Patient information sheet (if applicable) Yes No
- (d) Informed consent form (sample copy) Yes No NA
- (e) Copy of advertisement or Investigator's brochure
for recruiting subject (if applicable) Yes No NA
- (f) Copy of clinical trial protocol and / or
questionnaire (as applicable) Yes No NA
- (g) Special clearance(s) as applicable Yes No NA
- (h) Permission letter from the Head of the Department Yes No

Place :

Date :

Signature of the PI
with Designation & Department