**Appendix E**

**APPLICATION TO IERB**

**(Form to be filled by the Principal Investigator PI) for submission to Institutional Ethic Review Board for attachment to each copy of the proposal)**

**IERB No: Status of review:** New ( ) Revised ( )

1. **Proposal Title:**
2. **Name, Designation and Qualification of Principal Investigators**

**Contact No – Office: Mobile:**

**Email ID:**

**Signature:**

**Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Co-Principal Investigator/Collaborators: 1. ­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Kindly attach Curriculum Vitae of all investigators (with subject specific publications limited to previous 5 year) with their signatures in CV.**

1. **Sponsor Details:**

**Contact address of Sponsor:**

**Budget:**

**Type of study:**

1. **Clinical Trial:**
2. Does the study involve use of Drugs ( ), Devices ( ), Vaccines ( ),Any Other ( )

(If any another specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

1. Is it approved and marketed In India ( ), UK & Europe, ( ), USA ( ) Other Countries, Specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. 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 ( )

1. Is it an Investigational New Drug? Yes ( ) No ( )

**If yes,**

1. Investigator’s Brochure enclosed: Yes ( ) No ( )
2. Preclinical studies data available (If yes, provide summary): Yes ( ) No ( )
3. Clinical studies data available (If yes, provide summary) : Yes ( ) No ( )
4. Clinical study is Phase I( ) Phase II( ) Phase III( ) Phase IV( ) NA ( )
5. DCGI’s permission obtained Yes ( ) No ( )

**If yes**, copy of letter enclosed Yes ( ) No ( )

1. Whether the insurance is covered? Yes ( ) No ( )

**If yes**, copy of letter enclosed Yes ( ) No ( )

1. **Brief description of the proposal - Aim(s) and objectives, Review of literature, justification for study, methodology describing the potential risks and benefits, outcome measures, statistical analysis and References (Enclose separate sheet with maximum 1500 words)**
2. **Subject Selection:**
3. Number of subjects\_\_\_\_\_\_\_\_\_
4. Duration of (a) Study \_\_\_\_\_\_\_\_\_\_, (b) Subject participation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. Will subjects from both sexes be recruited? Yes ( ) No ( ), If No specify\_\_\_\_\_\_\_
6. Inclusion/exclusion criteria given Yes ( ) No ( )
7. Type of subjects: Volunteers ( ) Patients ( )
8. Vulnerable subjects: Yes ( ) No ( )

If yes (Tick the appropriate boxes): Pregnant Women ( ) Children ( )

Elderly ( ) Fetus ( ) Illiterate ( ) Handicapped ( ) Terminally ill ( )

Seriously ill (\_) mentally (\_) Challenged economically (\_) Any other (\_)

1. Special group subjects Yes ( ) No( )

(Tick the appropriate boxes): Captives ( ) Institutionalized ( ) Employees ( ) Students ( ) Nurses/Dependent( ) Armed Forces ( ) Any other ( )

1. **Use of biological/hazardous materials**
2. Use of fetal tissue or abortus. If yes provide details Yes( ) No( )
3. Use of organs or body fluids. If yes provide details Yes ( ) No ( )
4. Use of recombinant/gene therapy products Yes ( ) No ( )

**If yes**, has Department of Biotechnology (DBT) approval for rDNA products been obtained? Yes ( ) No ( )

1. Use of pre-existing/stored/left over samples Yes( ) No( )
2. Collection for banking/future research Yes( ) No( )
3. Use of ionizing radiation/radioisotopes Yes( ) No( )

**If yes**, has Bhabha Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained? Yes ( ) No ( )

1. Use of Infectious/bio hazardous specimens Yes ( ) No ( )
2. Proper disposal of material Yes ( ) No ( )
3. Will any sample collected from the patients be sent abroad? Yes( ) No( )

**If yes**, give details and address of collaborators

1. 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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Has necessary clearance been obtained Yes( ) No ( )
2. **Consent: Written( ) Oral ( ) Audio-Visual ( )**
3. **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 ( )

1. If healthy volunteers will be included, information sheet for them attached?

Yes ( ) No ( )

1. Consent form in English( ) Local Languages( )
2. Who will obtain consent? PI-Co-PI ( ) Nurse/Counsellor ( ) Research Staff ( )
3. **Will any advertising be done for recruitment of Subjects? Yes ( ) No ( )**

 (Posters, flyers, brochure, websites – if so attach a copy)

1. **Risks & benefits**
2. Is the risk reasonable compared to the anticipated benefits to subjects/community/country? Yes ( ) No ( )
3. Is there physical/social/psychological risk/discomfort? Yes ( ) No ( )

**If yes**, Minimal or no risk ( ) More than minimum risk ( ) High risk ( )

1. Is there benefit a) to the subject? Yes ( ) No ( ) Direct ( ) Indirect ( )

 b) to the society Yes ( ) No ( )

1. **Is there compensation for injury? Yes( ) No( )**

 **If yes, by** Sponsor ( ) Investigator ( ) Insurance Company ( )

 **If any other,** specify

1. **Do you have conflict of interest?** Yes ( ) No ( )

**If yes**, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**(Finanacial/Non-Financial)**

**Date: Signature of Principal Investigator**