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.

3. **Sponsor Details:**

Contact address of Sponsor:

Budget:

Type of study:

4. **Clinical Trial:**

i. Does the study involve use of Drugs ( ), Devices ( ), Vaccines ( ),Any Other ( )
(If any another specify _____)

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 ( )

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

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

5. 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)

6. Subject Selection:

i. Number of subjects_____

ii. Duration of (a) Study _____, (b) Subject participation: _____

iii. Will subjects from both sexes be recruited? Yes ( ) No ( ), If No specify_____

iv. Inclusion/exclusion criteria given Yes ( ) No ( )

v. Type of subjects: Volunteers ( ) Patients ( )

vi. 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 (_)

vii. Special group subjects Yes ( ) No( )

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

7. 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/bio hazardous 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 ( )

8. 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 ( )

9. Will any advertising be done for recruitment of Subjects? Yes ( ) No ( )

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

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? 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 ( )

11. Is there compensation for injury? Yes( ) No( )

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

If any other, specify

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

If yes, specify_____

(Finanacial/Non-Financial)

Date: **Signature of Principal Investigator**