BABASAHEB BHIMRAO AMBEDKAR UNIVERSITY, LUCKNOW
(A Central University)

(***Form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC)***

(for attachment to each copy of the proposal)

***IEC Code No.** (To be filled by the Bioethics cell):   **Study/Protocol No.** (For drug/device trials/any other, to be filled by PI):
Type of project: Intramural [ ] Extramural [ ] Drug trial/devise [ ] Independent [ ]   MD/DM/PhD/SRF/M.Sc Project [ ] Collaborative [ ] Other [ ]   **Status of review**: New [ ] Revised [ ]   **Proposal Title:……..**   **……**

	Name, Designation & Qualifications	**Address, Tel & Fax Nos.** Email ID	**Signature**
PI			
Co-PI / Collaborators			
1.			

Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years) not working at B.B.A.U. The investigators should sign their CV.

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

1**. Study Type** :
2. **Status of Review** New [ ] Revised [ ]
3. **Clinical Trials**: **Drug/Vaccines/Device/Herbal Remedies**: i. study involves use of Drugs [ ] Device [ ] Vaccines [ ] Indian system of medicine/ alternate system of medicine [ ] NA [ ]
II.is it approved and marketed Yes [ ] No [ ]
iii. Does it involve a change in use, dosage, route of administration? Yes [ ] No [ ] **If Yes**, weather DCGI's/ any other Regulatory Authority's permission obtained? Yes [ ] No [ ] **If Yes**, date of permission attached.
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 [ ]
e) DGCI's permission obtained (if yes, copy of letter enclosed) Yes [ ] No [ ]
4. **Brief summary of proposal** (Annexure-II) attached Yes [ ] No [ ]

5. **Subject Selection** : i. Number of Subjects:
ii. Duration of a)Study: b) Subject participation:
iii. Type of Subjects: Volunteers [ ] Patients [ ]
iv. Inclusion and Exclusion Criteria given Yes [ ] No [ ]
v. Sex of the subjects for study Male [ ] Female [ ] Both [ ] Transgender [ ]
vi. Vulnerable Subjects Yes [ ] No [ ] If Yes, Tick Apt Pregnant women [ ] Children [ ] Elderly [ ] Foetus [ ] Terminally Ill [ ] Illiterate [ ] Mentally challenged [ ] Economically & socially Backward [ ] Any Other [ ]
vii. Special group subjects Yes [ ] No [ ] If yes, specify
6. **Privacy and Confidentiality** i. Study involves: Direct Identifiers [ ] Indirect Identifiers/ Coded [ ] Completely anonymous/delinked [ ]
ii. Confidential handling of data by staff Yes [ ] No [ ]

7. Details of Sample Collection

A. ***Regarding sample collection***

1. **Collection of organs or body fluids or blood. If yes, please specify** Yes ☐ No ☐

   Type:_____

   Amount each time_____ml Total_____ml

   No. of time in 2 week_____ Total (in 2 weeks)_____ml

2. **Collection of fetal tissue or abortus. If yes, please specify** Yes ☐ No ☐

   _____

3. Use of pre-existing/stored/left over samples. If yes, please specify Yes ☐ No ☐

_____

4. Proper disposal of material Yes ☐ No ☐

B. Special situation

1. 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 ☐

2. Collection for banking/future research Yes ☐ No ☐

8. **Use of Biological/ hazardous materials**		
i. Use of fetal tissue or aborts (if yes provide detail)	Yes [ ]	No [ ]
ii. Use of body organs/ fluids (if yes, provide detail)	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 ionising radiation/ radioisotopes If Yes, has Bhabha Atomic Research centre (BARC) approval for radioactive isotopes have been obtained? Yes/No	Yes [ ]	No [ ]
vii. Use of Infectious/ biohazardous specimens	Yes [ ]	No [ ]
viii. Proper disposal of material	Yes [ ]	No [ ]

9. Participant Information Document (PID) and Consent form:

1. Consent *Written ☐ Oral ☐ Audio-Visual ☐

Patient Information documents and consent form attached : (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	☐	Benefits if any on future	☐

Consent for future use of material biological ☐

Free supply of drug till it is not marketed in country if necessary ☐

Compensation for study related injury ☐

Translation of Participant Information Document (PID) in local Language ☐

2. **If healthy volunteers, PID for them** Yes ☐ No ☐

3. **If participant is child, PID for parent** Yes ☐ No ☐

4. **PID and Assent Form for child 8-18 yrs** Yes ☐ No ☐

5. **Consent form** in English ☐ Local Languages ☐

(For participant/healthy volunteer/parent/legal guardian)

6. **Who will obtain consent?** PI-Co-PI ☐ Nurse/Counselor ☐

Research Staff ☐ Any Other ☐

If written consent is not obtained, give reasons……..

10. Will any advertising be done for recruitment of Subjects? Yes ☐ No ☐

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

11. For archival of record by Bioethics cell for more Yes ☐ No ☐ Not applicable ☐

than 5 years required

If yes, for how many years……

J. Do you have conflict of interest? Yes ☐ No ☐

(Financial/Nonfinancial)

If yes, specify_____

_____

Place:

Date: Signature & designation of PI/ Co-PI/Collaborators