पंजाब केन्द्रीय विश्वविद्यालय/ਪੰਜਾਬ ਕੇਂਦਰੀ ਯੂਨੀਵਰਸਿਟੀ

Central University of Punjab

A Central University established by an Act of Parliament

Form: To be filled by the Principal Investigator (PI) for submission to Research Cell (RC)

Please fill the form completely. Incomplete forms are liable to rejection.

Reference No. (*To be entered by RC)* -

Proposal Title:

	Name, Designation & Qualifications	**Address Tel & Fax Nos. Email ID**	**Signature**
PI			
Co-PI / Collaborators 1.			
2.			
3.			
Please attach brief Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years).			

Tick appropriately

Sponsor Information:

1. Indian a) Government Central ☐ State ☐ Institutional ☐
   b) Private ☐

2. International Government ☐ Private ☐ UN agencies ☐

3. Industry National ☐ Multinational ☐

Name and Contact Address of Sponsor:

Total Budget:

A. Does the budget reflect a) Institutional overheads Y/N Please give details _____

B. Any payments / benefits to the investigator's Y/N If Yes, please give details_____

1.Type of Study: Epidemiological ☐ Basic Sciences ☐ Animal Studies ☐

Clinical: Single center ☐ Multicentric ☐ Behavioral ☐

2. Status of Review: New ☐ Revised ☐

i. **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):

3. 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 (Tick)

Pregnant women ☐ Children ☐ Fetus ☐ Handicapped ☐

Elderly ☐ Terminally ill ☐ Seriously ill ☐ Mentally Challenged ☐

Economically & Socially Backward ☐ any other (specify) ☐

4. Privacy and confidentiality

i. Study involves - Direct Identifiers ☐
Indirect Identifiers/coded ☐
Completely anonymized/ delinked ☐

ii. Confidential handling of data by staff	Yes	No
5.Use of biological/ hazardous materials i. Use of fetal tissue or abortus	Yes	No
iii. Use of organs or body fluids	Yes	No
iii. Use of recombinant/gene therapy **If yes,** has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes Yes	No 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 Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes Yes	No No
vii. Use of Infectious/biohazardous specimens	Yes	No
viii. Proper disposal of material	Yes	No
ix. Will any sample collected from the patients be sent abroad? **If Yes, justify with details of collaborators**	Yes	No
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): If so, reasons…

Facility not available in India ☐
Facility in India inaccessible ☐
Facility available but not being accessed. ☐

6. Consent: *Written ☐ Oral ☐ Audio-visual ☐

Consent form: (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	☐	Consent for future use of biological material	☐
Compensation for participation	☐	Benefits if any on future commercialization	
Compensation for study related injury			

*If written consent is not obtained, give reasons:

ii. Who will obtain consent? PI/Co-PI ☐ Nurse/Counsellor ☐
Research staff ☐ Any other ☐

7. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so, kindly attach a copy)	Yes	No

8.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? **If Yes,** Less than Minimal risk ☐ Minimal Risk ☐ Minor increase over minimal risk or Low risk ☐ More than minor increase or High risk ☐	Yes	No
iii.Is there a benefit a) to the subject? Direct ☐ Indirect ☐ b) Benefit to society ☐		
9. Do you have conflict of interest? (financial/nonfinancial) **If Yes, specify:** **In case the investigator(s) are receiving any payment or direct benefit due to the project, it may be considered a conflict of interest and should be detailed here. NOTE: It shall be the responsibility of the investigator(s) to take Appropriate administrative permissions for the pecuniary benefits *a priori*.**	Yes Noted	No

Place:
Date:

Signature & Designation of PI/Co-PI/Collaborator

Form-3

UNDERTAKING BY THE INVESTIGATOR

1. Full name, address and title of the Principal investigator (or investigator (S) when there is no principal investigator)
2. Protocol Title and study number (if any) of the clinical trial to be conducted by the investigator
3. Commitments:

A. I have reviewed the clinical protocol and agree that it contains all the necessary\information to conduct the study. I will not begin the study until all necessary Ethics committee and regulatory approvals have been obtained

B. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Funding agency/Sponsor and prior review and documented approval) and favorable opinion from the RC and Ethics Committee of the amendment, except where necessaryto eliminate an immediate hazard(s) to the trial Subjects or when changers involved are any logistical or administrative in nature.

C. I agree to personally conduct and / or supervise the clinical trial at my site.

D. I agree to inform all Subjects; that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the OCP guidelines are met.

E. I agree to report to the IEC all adverse experiences that occur in the course of the investigation(s) in accordance with regulatory and GCP guidelines.

F. I have read and understood the information in the investigator's brochure, including the potential risks and side effects of the intervention.

G. I agree to maintain adequate and accurate records and t make those records available for adult / inspection by the Sponsor, Ethics Committee, Licensing Authority or Their authorized representatives, in accordance with regulatory and GCP provisions, I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

H. I ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trials

I. I agree to inform all unexpected serious adverse events to the Funding agency/Sponsor as well as the Ethics Committee within 24 hours of their occurrence.

J. I agree to promptly report the ethics Committee all changes in the clinical trial activates and all unanticipated problems involving risks to human Subjects or others

K. I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.

L. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical investigators participating in clinical trials.

Signature of PI with date