APPLICATION FORM TO BE FILLED FOR PROTOCOL SUBMISSION (INTRAMURAL)

To,

The Member Secretary,

Parul University – Institutional Ethics Committee for Human Research (PU-IECHR),

Parul Seva Shram Hospital, Limda,

Waghodia, District Vadodara

Study Title			
Research Type	[ ] Student (Dissertation/Other)	[ ] Faculty-led (sponsored)	[ ] Faculty-led (non-sponsored)
Name of Principal Investigator			
Room No.			
Department			
Institute			
Mobile Contact			
Application Submission Date			
Submission Status	[ ] New	[ ] Revised	
Sign of Member Secretary / Receiving Officer (with date)			

Instructions:

- Form to be filled digitally or manually and printed/copied before submission by the Principle Investigator.
- Application format regularly updated according to suggestions of committee members. So always use latest version of form.
- Persons from other disciplines than medicine like ayurved, physiotherapy, homeopathy, pharmacy may have additional information to put. They can add/elaborate the information more than require to justify their objective, which can satisfy committee members.
- Consult member secretary, if finding any difficulty in filling out this application form.

INVESTIGATORS' UNDERTAKING

1. We certify that, we have determined that the proposal here in is not unnecessarily duplicative of previously reported research.
2. We certify that, we are qualified by education, training and have enough experience to do such a study.
3. For procedures listed under proposal, we certify that we have reviewed the pertinent scientific literature and have found no valid alternative to any procedure described here in which may cause less pain or distress to the patient.
4. We certified that, study will be initiated only upon review and approval of scientific intent by PU IECHR and getting a certificate from PU IECHR.
5. We will do necessary changes in our study protocol as per the suggestions given by respected PU IECHR members during meeting before getting approval letter and bound to submit the changes to PU IECHR. We will obtain approval from the PU IECHR before making any significant changes in this study Institutional Biosafety Committee's (IBC) certification of review and concurrence will be taken (Required for studies utilizing DNA agent so human pathogens), if apply.
6. We will do our study according to ICH-GCP guidelines and maintain all the study related records. Whenever asked,we are bound to produce to PU IECHR.
7. We will report adverse drug reaction to Pharmaco vigilance Cell & PU IECHR whenever, we come across the adverse drug reaction while doing research work. (If Applicable)
8. We certify that, we will follow the recommendations of PU IECHR and Govt.of Gujarat rules and regulation issued from time to time.
9. We certify that, record of all premature termination of a study with a summary of the reasons/final report after completion of the study including microfilms, CDs and Video recordings; will submit to the PU IECHR.

Study Title:	
Name	**Sign**
HOD:	
PI:	
Co-I:	
Co-I:	
Co-I:	

Copy this table and repeat for each ***Investigator***

Name	
Designation	
Department	
Institution	
Mobile	
Email	
Role in this research as PI/Co-I	
Include a brief summary of relevant experience for this project	

Name	
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Mobile	
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Type of Study	[ ] Animal Study		[ ] Clinical Research
	[ ] Basic/Applied Sciences		[ ] Epidemiological
Study Sites	[ ] Single		[ ] Multicenter
Collaborator(s) (Institute, Address, Name of Nodal Person & Contact Details)			
Is this a funded study?	[ ] Yes		[ ] No
Total study budget	(in Indian Rupees)		
Sponsor Information [Indian]	[ ] State Government	[ ] Center Government	[ ] Private
Sponsor Information [International]	[ ] Bilateral Agency or NGO	[ ] Government	[ ] Private
Sponsor Information [Industrial / CSR]	[ ] National		[ ] Multinational
Sponsor(s) (Institute, Address, Name of Nodal Person & Contact Details)			

CLINICAL TRIALS (Drug / Vaccines / Device / Herbal Remedies)

1. What does this clinical trial involve?	[ ] Drug [ ] Devices [ ] Vaccines [ ] Indian system of medicine [ ] Alternative system of medicine [ ] Any other: _____ [ ] Not Applicable	
2. Is it approved and marketed?	[ ] In India [ ] In UK and Europe [ ] In USA [ ] Other Country: _____	
3. Does it involve a change in use, dosage, route of Administration?	[ ] Yes [ ] No	
3.1. If yes, whether DCGI's / any other regulatory authority's permission is obtained?	[ ] Yes [ ] No	
3.1.1. If yes, date of permission:	[Date]	
4. Is it an Investigational New Drug?	[ ] Yes [ ] No	
4.1. If Yes, IND No.:		
4.2. Investigator's Brochure submitted	[ ] Yes [ ] No	
4.3. In vitro studies data	[ ] Yes [ ] No	
4.4. Preclinical Studies done	[ ] Yes [ ] No	
5. Phase of clinical trial	[ ] Phase I [ ] Phase II	[ ] Phase III [ ] Phase IV
6. Are you aware if this/similar study is being done elsewhere?	[ ] Yes [ ] No	
6.1. If 'Yes' Please **attach details** for other studies or other study sites		

Study Details

1. Number of Subjects		
2. Study duration	(in months)	
3. Will participants from both sexes included?	[ ] Yes [ ] No	
4. Inclusion & Exclusion criteria defined?	[ ] Yes [ ] No	
5. Recruitment of vulnerable participants?	[ ] Yes [ ] No	
5.1. If 'Yes' who will be recruited?	[ ] Children [ ] Pregnant Women [ ] Seriously ill [ ] Terminally ill [ ] Handicapped	[ ] Mentally challenged [ ] Illiterate [ ] Socio-economically backward [ ] Other _____
6. Recruitment of special group participants?	[ ] Yes [ ] No	
6.1. If 'Yes' who will be recruited?	[ ] Dependent [ ] Employees [ ] Staff [ ] Armed forces personnel	[ ] Students [ ] Institutionalized [ ] Captives [ ] Other _____
7. Study involves:	[ ] Direct Identifiers [ ] Coded / Indirect Identifiers [ ] Delinked / Completely anonymized data	
7.1. Confidential handling of data by study staff?	[ ] Yes [ ] No	

Study Substance (Biological/ Hazardous Materials) and International Collaboration(s)

1. Use of Fetel Tissue or aborts	[ ] Yes	[ ] No
2. Use of organ or Body fluids	[ ] Yes	[ ] No
3. Use of recombinant/gene therapy	[ ] Yes	[ ] No
3.1. If 'YES' has the Department of Biotechnology (DBT) approval for rDNA products been obtained?	[ ] Yes	[ ] No
4. Use of pre existing/ stored/ left over samples	[ ] Yes	[ ] No
5. Collection for banking/ future research	[ ] Yes	[ ] No
6. Use of ionizing radiation/ radio isotopes	[ ] Yes	[ ] No
6.1. If 'YES' has Bhabha Atomic Research Centre (BARC) approval for radioactive isotopes been obtained?	[ ] Yes	[ ] No
7. Use of Infectious/ bio Hazardous specimens	[ ] Yes	[ ] No
8. Protocol for proper disposal of material	[ ] Yes	[ ] No
9. Will any sample collected from the patient be sent abroad?	[ ] Yes	[ ] No
9.1. If 'YES' justify with details of collaborators?		
9.2. Justify the need for sending sample abroad:	[ ] Facility not available in India [ ] Facility available but inaccessible [ ] Other reason _____	
9.3. Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	[ ] Yes	[ ] No

Consent and Participant Rights

1. How are you going to obtain consent?	[ ] Written [ ] Oral [ ] Audio-visual	
1.1. If 'WRITTEN' consent is not obtained, give justification		
2. Who will obtain consent?	[ ] PI or Co-I [ ] Nurse / Counselor	[ ] Research Staff [ ] Other _____
3. Which of these are mentioned in PIS and/or ICF	[ ] Understandable Language [ ] Statement that study involves research [ ] Sponsor of Study [ ] Purpose and Procedures [ ] Risks & Discomforts [ ] Benefits [ ] Compensations for participation [ ] Compensations for study related injury	[ ] Alternative to participation [ ] Confidentiality of records [ ] Statement that consent is voluntary [ ] Right to withdraw [ ] Consent for future use of biological material [ ] Benefits if any on future commercialization eg. Genetic basis for drug development [ ] Contact information
4. Will any advertising be done for recruitment of Subjects? if so kindly **attach** a copy	[ ] Poster [ ] Brochure [ ] Flyer	[ ] Website [ ] SMS / WHATSAPP [ ] Other _____

5. Risks and Benefits		
5.1. Is the risk reasonable compared to anticipated benefits to participants/community/country?	[ ] Yes	[ ] No
5.2. Is there physical / social / psychological risk / discomfort?	[ ] Yes	[ ] No
5.2.1. If 'YES' what possible risks:	[ ] No or Minimum Risk [ ] More than Minimum Risk [ ] High Risk	

6.1. Is there any benefits to participants:	[ ] Direct (free treatment etc) [ ] Indirect [ ] Other _____	
6.2. Is there any benefits to the society:	[ ] Treatment will be marketed once approved [ ] Other _____	
Data Monitoring		
7.1. Is there a Data Monitoring and safety Committee/Board (DSMB)?	[ ] Yes	[ ] No
7.2. Is there a plan to reporting of adverse events?	[ ] Yes	[ ] No
7.3. Are there plan for storage and maintenance of all trial databases?	[ ] Yes	[ ] No
7.3.1. If 'YES' for how long	(in years)	
8. Is there compensation for Participation?	[ ] Yes	[ ] No
8.1. If 'YES' please **specify** details	[ ] Monetary Amount: _____ Disbursal:_____	[ ] In Kind _____ _____
9. Is there compensation for injury?	[ ] Yes	[ ] No
9.1. If 'YES' who is going to compensate:	[ ] Sponsor [ ] Investigator	[ ] Other _____
10. Do you have any conflict of Interest? (Financial/Non- Financial)	[ ] Yes	[ ] No
10.1. If 'YES' give details		

CHECKLIST for Documents to be Submitted [10 copies; tick whatever is submitted]

1. Duly filled Ethics Committee Review application form	
2. Investigator's Undertaking	
3. Brief description of proposal (font: Times New Roman; size: 12; double Spacing) a. Introduction b. Review of literature - submit hard copy of few published papers. c. Aim(s) & objectives d. Justification for study e. Methodology describing the potential risks & benefits with Inclusion and Exclusion Criteria f. Outcome measures g. Statistical analysis h. Whether it is of national / State of Gujarat significance with rationale i. Budgetary details (copy of sanction letter/budget approval attached) • Contingencies • Recurring (Drugs, devices) • Non recurring (equipment, stationary, books) • Travel (To attend the conference for research work) • Expenditure on dissertation preparation (If applicable) • Overhead charges (Miscellaneous)	
4. Copy of Clinical Trial Protocol	
5. Study Questionnaire and/or Case Record Form	
6. If any clearance is obtained, attach copy [HMSC / DCGI / DBT / BARC / Local Health Authorities]	
7. Agreements between PI and Sponsor or Collaborating Institutions	
8. Copy of Insurance Policy obtained for the present research work	
9. Investigator Brochure for Subjects	
10. Copy of Advertisements (online/offline) and/or Information Brochures, if any	
11. Informed Consent Form [in English]	
12. Informed Consent Form [in Gujarati/Vernacular]	
13. Participant Information Sheet [in English]	
14. Participant Information Sheet [in Gujarati/Vernacular]	
15. Attendance sheet of departmental scientific meeting	
16. Copy of power point presentation done in scientific meeting	
17. Curriculum Vitae of all the Investigators	