TIRUNELVELI MEDICAL COLLEGE
TIRUNELVELI,
STATE OF TAMILNADU, INDIA
PIN CODE:627011
Tel: 91-462-2572733, 2572734 Fax: 91-462-2572944
Under the Directorate of Medical Education, Government of Tamilnadu.
Estd:1965

Application Form to be submitted to the Institutional Ethical Committee for Approval of Research Proposals

IEC CODE NUMBER						DATE							

Applications Accepted Secretary IEC Date

Proposal Approved Secretary IEC Date

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

IEC CODE NUMBER						DATE							

	TITLE OF THE RESEARCH PROPOSAL*No changes to the title will be entertained once the process of approvals are complete		
1	**DETAILS OF PRINCIPAL INVESTIGATOR**		
1.a	**NAME OF THE PRINCIPAL INVESTIGATOR**		
1.b	**BASIC QUALIFICATION**		
1.c	**DESIGNATION**		
1.d	**DEPARTMENT**		
1.e	**ADDRESS FOR COMMUNICATION**		
1.f	**PHONE NUMBERS**	**LANDLINE(OFFICE)**	
		LANDLINE(RES)	
		MOBILE	
1.g	**EMAIL**		
2	**DETAILS OF CO- INVESTIGATOR**		
2.a	**NAME OF THE CO- INVESTIGATOR**		
2.b	**BASIC QUALIFICATION**		
2.c	**DESIGNATION**		
2.d	**DEPARTMENT**		
2.e	**ADDRESS FOR COMMUNICATION**		
2.f	**PHONE NUMBERS**	**LANDLINE(OFFICE)**	
		LANDLINE(RES)	
		MOBILE	
2.g	**EMAIL**		

ADD ADDITIONAL PAGES IF REQUIRED….

3. PLEASE ATTACH CURRICULUM VITAE OF ALL INVESTIGATORS. THE INVESTIGATORS SHOULD SIGN THEIR CV.

4. TYPE OF STUDY

- **EPIDEMIOLOGY** ☐
- **BASIC MEDICAL SCIENCES** ☐
- **CLINICAL STUDY** ☐
- **CLINICAL TRIAL** ☐

4.a. IF CLINICAL TRIAL, THEN IS THIS STUDY ASSOCIATED WITH USE OF

- **DRUGS** ☐
- **VACCINES** ☐
- **DEVICES** ☐
- **HERBAL REMEDIES** ☐
- **OTHERS** ☐

4.b. NAME THE PRODUCT OR PRODUCTS TO BE USED

4.c. IS THE PRODUCT APPROVED FOR HUMAN USE

- **WORLD-WIDE** ☐
- **USA / FDA APPROVED** ☐
- **USA / FDA UNAPPROVED** ☐
- **EUROPE & UK** ☐
- **INDIA** ☐

4. d. DOES THE STUDY INVOLVE CHANGE IN USE, DOSAGE OR ROUTE OF ADMINISTRATION?

☐ **YES** ☐ **NO**

4.e. IF YES, WHETHER ANY REGULATORY AUTHORITY PERMISSION HAS BEEN OBTAINED?

☐ **YES** ☐ **NO**

4.f . IS IT AN INVESTIGATIONAL NEW DRUG? IF YES ATTACH THE INVESTIGATOR BROCHURE, PRECLINICAL AND CLINICAL DATA IF ANY AVAILABLE

☐ **YES** ☐ **NO**

4.k. CLINICAL STUDY IS

☐ **PHASE I** ☐ **PHASE II** ☐ **PHASE III** ☐ **PHASE IV** ☐ **N.A**

4.n. MODE OF STUDY

☐ **Single Centre** ☐ **Multi Centre**

5.a. BUDGET FOR STUDY

☐ **SPONSORED** ☐ **SELF**

5.b. IF SPONSORED, BY WHOM

(ATTACH DETAILS OF THE SPONSORSHIP)

6. DETAILS OF THE PROPOSED STUDY

6.a. Brief description of the proposal-aim(s) and objectives, justification for study, methodology describing the potential risks and benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach a separate sheet with maximum 500 words)

6.b. SUBJECT SELECTION & PARTICIPATION

NUMBER OF SUBJECTS				
DURATION OF STUDY				
SUBJECT SELECTION	☐ **RANDOM** ☐ **CRITERIA BASED** ☐ **VOLUNTEER** ☐ **PATIENT**			
SUBJECT SELECTION INCLUDES	Pregnant Women	☐	Captives/Prisoners	☐
	Fetus	☐	Students	☐
	Terminally ill	☐	Forces	☐
	Physically / Mentally Challenged	☐	Doctors/Nurses/ Paramedics	☐
	Economically & socially backward	☐	Any Other	☐
INCLUSION CRITERIA GIVEN				

EXCLUSION CRITERIA GIVEN	
SUBJECT PARTICIPATION	☐ **CONFIDENTIAL** ☐ **IDENTIFIABLE**
SUBJECT CONSENT REQUIRED	☐ **YES** ☐ **NO**
SUBJECT MATERIAL	☐ **ADDRESS** ☐ **PERSONAL DETAILS** ☐ **DETAILS OF SPOUSE AND FAMILY** ☐ **DETAILS OF CLINICAL EXAMINATIONS** ☐ **DETAILS OF TREATMENT** ☐ **PATIENT PHOTOGRAPHY / VIDEO** ☐ **RADIOLOGY** ☐ **INTERVENTIONAL STUDY** ☐ **BLOOD & BODY FLUIDS** ☐ **FNAC & BIOPSIES** ☐ **BONE MARROW**
DOES THE STUDY INVOLVE BIOHAZARDOUS MATERIAL, IF YES GIVE DETAILS	☐ **YES** ☐ **NO**
WILL SAMPLES/BIOMATERIAL COLLECTED FROM THE PATIENTS BE TRANPORTED OUTSIDE INSTITUTE	☐ **YES** ☐ **NO**
IF YES, GIVE DETAILS OF NECESSARY CLEARANCE & METHODS	
ARE SAMPLES/BIOMATERIAL COLLECTED FROM THE PATIENTS BE TRANPORTED OUTSIDE INDIA	☐ **YES** ☐ **NO**
SAMPLES/BIOMATERIAL COLLECTED FROM THE PATIENTS ARE TRANPORTED OUTSIDE THE INSTITUTE BECAUSE	☐ **FACILITY NOT AVAILABLE IN THE INSTITUTE** ☐ **FACILITY NOT AVAILABLE IN INDIA** ☐ **FACILITY AVAILABLE BUT NOT ACCESSIBLE** ☐ **FACILITY AVAILABLE BUT NOT DEPENDABLE**

DOES YOUR STYUDY INVOLVE **If yes provide details**	☐ Use of fetal tissue or abortus ☐ Use of organs ☐ Use of recombinant/gene therapy products ☐ Use of pre-existing/stored/left over samples ☐ Collection for banking/future research ☐ Use of ionizing radiation/radioisotopes ☐ Use of Infectious/biohazardous specimens
SUBJECT RECORDS - CONSENT / PATIENT INFORMATION SHEET	☐ **ORAL** ☐ **WRITTEN**
CONSENT / PATIENT INFORMATION SHEET HAS THE FOLLOWING DETAILS ATTACH COPY OF THE CONSENT FORM	
Risks & discomforts ☐ **Right to withdraw** ☐ **Benefits** ☐ **Consent for future use of material biological** ☐ **Compensation for participation** ☐ **Benefits / Risk of future commercialization** ☐ **Genetic basis for drug development** ☐ **Compensation for study related injury** ☐ **Data Monitoring and Safety Protocols** ☐	**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** ☐ **Translation in Local Language** ☐

CHECK LIST FOR ATTACHED DOCUMENTS:

1. **CURRICULUM VITAE OF PRINCIPAL INVESTIGATOR (PI) & CO-INVESTIGATOR**
2. **DESCRIPTION OF STUDY / PROTOCOL / PROJECT QUESTIONNAIRE**
3. **MOU OF THE CO-OPERATING DEPARTMENTS**
4. **COPY OF PATIENT INFORMATION SHEET / CONSENT FORM IN LOCAL LANGUAGE**
5. **COPY OF PI UNDERTAKING**
6. **COPY OF ADVERTISEMENTS / INFORMATION BROCHURES (if applicable)**
7. **INVESTIGATOR'S BROCHURE (if applicable)**
8. **REGULATORY CLEARANCE IF OBTAINED (if applicable)**
9. **COPY OF INSURANCE POLICY COPY OF CLINICAL TRIAL AGREEMENT (if applicable)**

Certification

I Dr……certify that the information given in the application form are correct.

Signature of the Principal Investigator

Certification

I Dr……certify that I have verified the information given in the application form are correct.

Signature of the Guide

Forwarded & Recommended

Signature of the HOD

UNDERTAKING BY THE PRINCIPAL INVESTIGATOR

1	**NAME OF THE PROJECT**	
2	**NAME, DESIGNATION AND DEPARTMENT OF THE PRINCIPAL INVESTIGATOR**	
3	**OTHER MEMBERS OF THE RESEARCH TEAM**	
4	**NAME AND ADDRESS OF ANY OTHER MEDICAL COLLEGE / HOSPITAL / LABORATORY / INSTITUTION WHERE PARTS OF THE STUDY WILL BE DONE**	
5	**NUMBER OF ONGOING PROJECTS/CLINICAL TRIALS IN WHICH YOU ARE PI**	
	1. I confirm that I will initiate the study only after obtaining all regulatory clearances. 2. I will not implement any deviation from the approved protocol without prior consent of the sponsor nature and it will be intimated to the IEC at the earliest. 3. I confirm that the CO PI and other members of the study team have been informed about their obligations and are qualified to meet them 4. I will personally supervise the study and ensure that requirements of obtaining informed consent and other ethical requirements under ICMR and National Regulatory Guidelines are adhered to. 5. I will maintain accurate and complete record of all cases in accordance with GCP provisions and make them available for audit/inspection by IEC, Regulatory authorities, Sponsors or their authorized representatives. 6. I will inform the IEC and the Sponsors of any unexpected or serious adverse event at the earliest and definitely within seven days of its occurrence. 7. I will maintain confidentiality of the identity of all participating subjects and assure security and confidentiality of study data. 8. I and my colleagues will comply with statutory obligations, requirements and guidelines applicable to such clinical studies. 9. I will inform IEC of the date of starting the study within 2 weeks of initiation of the trial and submit annual progress reports and final report to Member Secretary, IEC within 4 weeks of the due date.	

Signature of Principal Investigator

Date

CURRICULUM VITAE OF THE PRINCIPAL/Co- INVESTIGATOR

Name with Full Expansion of Initials (in Block Letters)		
Age / Sex / Date of Birth		
Department & Institute		
Mailing Address		
Mobile Number		
Telephone (Residence):		
E-Mail:		
Academic Qualifications		
Degree	**Year**	**Institute / University**
Current and Last 4 Academic Appointments if any		
Month and Year	**Designation**	**Institution**
Publications & Presentations		

Signature:

MEMORANDUM OF UNDERSTANDING WITH CO-OPERATING DEPARTMENTS.

(Separate undertaking is to be submitted for each co-operating department involved)

1	TITLE OF PROJECT	
2	NAME, DESIGNATION AND DEPARTMENT OF THE PRINCIPAL INVESTIGATOR	
3	NAME OF CO-OPERATING DEPARMENT	
4	TYPE OF CO-OPERATION EXTENDED	☐ SHARING OF EXISTING CLINICAL MATERIAL ONLY ☐ CONDUCT OF SPECIFIC PROCESS / PROCEDURES ☐ NEW DRUG TRIALS ☐ NEW PROCEDURES ☐ ALTERATIONS IN METHOD OF EXISITNG PROCEDURES
5	NUMBER OF ONGOING PROJECTS/CLINICAL TRIALS IN WHICH YOU ARE CO-OPERATING DEPARTMENT	
6	REMARKS	

Signature of Head of the

Co-operating Department

Date&Seal

INFORMED CONSENT FORM

Study Title _____

Study Number _____

Subject's Full Name _____

Date of Birth/Age_____

Address _____

1. I confirm that I have read and understood the information sheet dated for the above study and have had the opportunity to ask questions.
   OR I have been explained the nature of the study by the Investigator and had the opportunity to ask questions

2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

3. I understand that the sponsor of the clinical trial/project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.

4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)

5. I agree to take part in the above study

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative: _____

Signatory's Name _____ Date _____

Signature of the Investigator _____ Date _____

Study Investigator's Name _____

Signature of the Witness _____ Date _____

Name of the Witness