All India Institute of Medical Sciences
Jodhpur, Rajasthan

Format of submission of Research Project to Institution Ethics Committee (HR)

Note: Fill all columns neatly. Use additional sheets, if required

S.No.		
1.	Title of the Research Project	
2.	Name, designation & address of Principal Investigator/Supervisor	Signature of Principal Investigator/Supervisor
3.	Name, designation & address of Co-investigators (AIIMS) a. b. c. (Expand, if needed)	Signature of Co-Investigators a. b. c. (Expand, if needed)
4.	Name, designation & address of Co-investigators (Other than AIIMS) a. b. c. (Expand, if needed)	Signature of Co-Investigators a. b. c. (Expand, if needed)
5.	Name of the department(s) where research/study will be carried out	
6.	Name of the institutions (Other than AIIMS) collaborating in the study (MoU duly signed by the Principal Investigator & Head of the Institution should also be submitted)	
7.	Details of the centres involved in multicentre study (applicable to multicentric studies only).	
8.	Name & address of Funding Agency	
9.	Details of the budget	
10.	Objective(s) of the study	

11.	Rationale of conducting the study	
12.	Methodology	
13.	Does the project involve : a. Clinical trial with new drug(s)/device(s) approved by DCGI. b. Clinical trial with existing drug(s)/device(s) approved by DCGI. c. Traditional medicine(s) (Ayurvedic/Unani/Homeopathic /Tribal System). d. Animals will be used. (if YES, refer to IEC-A) e. None of the above. (if "a" is yes, kindly provide details/evidence of experimental & clinical safety of the drug(s)/device(s))	YES/NO YES/NO YES/NO YES/NO YES/NO
14.	Permission from DGFT if applicable:	1. Required 2. Not required 3. Received 4. Applied (When…..)
15.	Will human material be collected: a. If "yes" please specify the tissue b. Mode of collection of tissue (operation / biopsy / autopsy / abortion/others) specify. c. Is the procedure to obtain the tissue indicated for the management of the patient. (Give details of the procedure with justification if the answer of "c" is yes. d. Will the tissue be collected by a method otherwise not required for the management of the patient. (If "yes", specify the method with justification) e. Please also see S.No 6.	YES/NO YES/NO YES/NO

16.	Are there any anticipated risk(s) during the course of the study (procedural/adverse drug reaction or any other). (If"yes", please provide details along with management/compensation of the risk factors).	YES/NO
17.	Details of fees/honorarium payable to investigators/collaborator/volunteers/ patients, if any.	
18.	Is clearance required from any other agency. (If "yes", kindly furnish the details)	YES/NO
19.	Is there any provision to compensate the volunteers/patients in case of mishap? (If "yes", please provide details.	YES/NO
20.	Conflict of interest of any investigator (If "yes", please furnish details.	YES/NO

Date : ……. **Signature of Principal Investigator/Supervisor**

Date : ……. **Signature of Head of concerned Department**

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Informed Consent Form

Title of the project : _____

Name of the Principal Investigator : _____Tel. No. _____

Patient/Volunteer Identification No. : _____

I, _____ S/o or D/o _____
R/o _____
give my full, free, voluntary consent to be a part of the study "_____", the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by responsible individual from _____(Company Name) or from regulatory authorities. I give permission for these individuals to have access to my records.

Date : _____ _____

Place : _____ Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date : _____ _____

Place : _____ Signature of Principal Investigator

1. Witness 1

_____
Signature
Name: _____
Address : _____
_____

2. Witness 2

_____
Signature
Name: _____
Address : _____
_____

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Check List for submitting research proposals to Institute Ethical Committee

1. Title of the project : ----------
2. Name, Designation : ----------
   & Address of Principal : ----------
   Investigator : ----------

S.No.	Particulars	Yes	No	If No, Give reasons
1.	Research project (16 copies)			
2.	Proforma for IEC (duly filled)			
3.	Informed consent form a. English b. Hindi/Vernacular			
4.	Patient Information Sheet a. English b. Hindi/Vernacular			
5.	Declaration by Principal Investigator			
6.	Case record form			
7.	Any other document for consideration by IEC			
8.	Permission to use copyrighted questionnaire and proforma			
9.	Brief CV of Principal Investigator			

Date: Signature of Principal Investigator

For office use only

Date of receiving : ----------

Office No. : ----------

Signature
(On behalf of IEC)

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Declaration by the Principal Investigator

I hereby declare that:

1. The study will be done as per ICMR/ GCP guidelines.
2. The study has not been initiated and shall be initiated only after ethical clearance
3. Voluntary written consent of the volunteers/patients will be obtained.
4. In case of children and mentally handicapped volunteers/patients, voluntary written informed consent of the parents/guardians will be obtained.
5. The probable risks involved in the study will be explained in full to the subjects/parents/guardians in their own language.
6. Volunteers/patients/parents/guardians will be at liberty to opt out of the study at any time without assigning reason.
7. I will terminate the study at any stage, if I have probable cause to believe, in the exercise of the good faith, skill and careful judgement required for me that continuation of the study/experiment is likely to result in injury/disability/death to the volunteers/subject.

Date : _____ **(Signature of Principal Investigator)**

Department _____