**FORMAT FOR SUBMISSION OF RESEARCH PROJECT TO INSTITUTION ETHICS COMMITTEE**

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

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| --- | --- | --- |
| 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, Rajkot)  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, Rajkot)  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, Rajkot) collaborating in the study |  |
| 7. | Details of the centres involved in multicentre study (applicable to multicentric studies only). |  |
| 8. | Name & address of Funding Agency (if any) |  |
| 9. | Does the project involve:   1. Clinical trial with new drug(s)/device(s) approved by DCGI. 2. Clinical trial with existing drug(s)/device(s) approved by DCGI. 3. Traditional medicine(s) (Ayurvedic/Unani/Homeopathic/Tribal System). 4. Animals will be used. (if YES, refer to IEC-A) 5. 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 |
| 10. | Permission from DGFT if applicable: | 1. Required 2. Not required 3. Received 4. Applied   (if “1” is yes, kindly provide status; if “3 or 4” is yes, kindly provide details) |
| 11. | Will human material be collected?   1. If “yes” please specify the tissue 2. Mode of collection of tissue (operation / biopsy / autopsy / abortion/others) specify. 3. 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.   1. Will the tissue be collected by a method otherwise not required for the management of the patient? (If “yes”, specify the method with justification) 2. Please also see S.No 6. | YES/NO  YES/NO  YES/NO |
| 12. | 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 |
| 13. | Details of fees/honorarium payable to investigators/collaborator/volunteers/ patients, if any. |  |
| 14. | Is clearance required from any other agency.  (If “yes”, kindly furnish the details) | YES/NO |
| 15. | Is there any provision to compensate the volunteers/patients in case of mishap?  (If “yes”, please provide details) | YES/NO |
| 16. | Conflict of interest of any investigator (If “yes”, please furnish details) | YES/NO |
| 17. | Provide details of project:  (Is it Non-funded, Intramural or Extramural?)  (Note: Fill the relevant Proforma for Project Proposal for Submission) |  |

**Please attach the complete PROFORMA FOR PROJECT PROPOSAL along with this form and statement of budget (If applicable).**

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

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