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

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

|  |  |  |
| --- | --- | --- |
| 1. | Title of the Research Project |  |
| 2. | Name, Designation & Address of Guide: | Signature of Guide |
| 3. | Name of Student:  MBBS Batch: | Signature of Student |
| 4. | STS Registration No. |  |
| 5. | Name of the department(s) where research/study will be carried out: |  |
| 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 |

**Please attach following documents along with this form:**

**1. Complete PROFORMA FOR PROJECT PROPOSAL (as required by ICMR – STS Project).**

**2. Informed Consent Form**

**3. Declaration by Guide**

**4. Check List**

**Date: ……………………. Name & Signature of Student**

**Date: ……………………. Name & Signature of Guide**

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