

INSTITUTIONAL ETHICS COMMITTEE, NDCH

Application form requesting waiver of consent and declaration of maintenance of data anonymity for samples/data collected after waiver of consent

| 1. | Protocol No.: | |
|----|---|--|
| 2. | Title of the project: | THICA |
| 3. | Name of the Principal investigator: | |
| 4. | Department | |
| 5. | Names of the Co-investigators and departments: | MM |
| 6. | Reason for request for waiver of informed consent | Please tick the reason (vide infra more details) |
| a. | Research involves 'less than minimal risk' | |
| b. | There is no direct contact between the researcher and participant | CH |
| c. | Emergency situations as described in ICMR Guidelines | |
| d | Any other (please specify) | |
| 7. | Nature/source of data collection (anonymized) | Tick whichever applicable and mention the department or source from where this will be collected |
| a | Medical records/ investigation reports | |
| b | Clinic/ Hospital Registers | |
| с | Radiological/ ultrasound/ other imaging films AV recordings | |
| d | Blood samples collected for | |

| | diagnostic tests | | | |
|--|---|--------|--|--|
| e | Tissues/ body fluids collected for diagnostic purposes | | | |
| f | Tissues/ body parts removed surgically for therapy | | | |
| g | Tissues/blood removed surgically for donation | | | |
| h | Samples collected for previous research | | | |
| i | Microorganisms cultured in the laboratory from samples obtained for diagnosis/treatment | | | |
| j | Data (including photographs, soft copies stored on computers) collected for previous research, healthcare, academic or therapeutic purposes | THICAL | | |
| k | Medical education technology studies and feedback analysis | Z MI | | |
| 1 | Medical or academic audit reports or hospital administrative policies/procedures | | | |
| m | Commercially available cell lines/ tissue | | | |
| n | Data in public domain | CH | | |
| 0 | Any other (Specify with details) | | | |
| 1. Declaration of confidentiality of participants for anonymized data from the MRD files/images/samples/ other sources of data | | | | |
| | I declare that I shall maintain the privacy of the participants by not collecting any personal information like name, phone number, address or other identifying data from the MRD files/images/samples/ other sources of data mentioned above collected for the purpose of this research and related publications. | | | |
| | I declare that I will not use any of the personal information like name, phone number, address or other identifying data in order to contact the patient for any details which are not available in the MRD files/images/samples/ other sources of data for the purpose of this research. | | | |

| | I declare that I will not take photocopies/ photographs/ scans of MRD files/images/samples/ other sources of data for the purpose of this study |
|---|---|
| | I declare that I will maintain the confidentiality of data collected from the MRD files/images/samples/ other sources of data during and after the study. |
| | I declare that I will access the files/images/samples/other sources of data only after the approval from IEC, NDCH. |
| | I declare that only one of the research team members will access the MRD files/images/samples/other sources of data and will not be accessed by any other person. |
| | I declare that I will collect only that data which is relevant to meet the objectives of the study as per the data collection form approved by IEC, NDCH. |
| | I declare that I will access only those numbers of MRD files/images/samples/ other sources of data as is approved by the IEC, NDCH. |
| | I declare that I will access only those MRD files/images/samples/ other sources of data that fit in the inclusion and exclusion criteria as per the protocol approved by IEC, NDCH. |
| | I declare that the MRD files/images/samples/ other sources of data accessed for the purpose of this research will be anonymized using the following method: |
| | I declare that the above method of anonymization will be carried out by Dr./Mr./Ms who is not part of the research team. |
| | Signature of the Principal investigator with date: |
| | Signature of the Guide (if applicable) with date: |
| | Signature of the HOD with date: |
| L | |

Copy to MRD/ concerned department with the custody of the samples. (after the EC approval is given for information):

COO/ Dean