**Yenepoya Ethics Committee-1**

**Ann01/SOP15/v4**

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

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|  | Protocol No |  | | |
|  | Title of the project: |  | | |
|  | Name of the Principal investigator: |  | | |
|  | Department: |  | | |
|  | Names of the Co-investigators and departments *(add rows if necessary)*: |  | | |
| 6. | Reason for request for waiver of informed consent | Please tick the reason | | |
|  | A. Research involves ‘less than minimal risk’ |  | | |
|  | 1. Research involves anonymized human tissue samples/data and does not collect personal identifiers like name, contact details, address, MRD number |  | | |
|  | 1. There is/will be no direct contact between the researcher and participant |  | | |
|  | 1. Emergency situations as described in ICMR Guidelines |  | | |
|  | 1. Any other (please specify) |  | | |
|  | Nature/source of data collection (anonymized) | Applicable/not applicable | Source of data | Permission obtained Yes/No |
|  | Medical records/ investigation reports |  |  |  |
|  | Clinic/ Hospital Registers |  |  |  |
|  | Radiological/ ultrasound/ other imaging films AV recordings |  |  |  |
|  | Blood samples collected for diagnostic tests |  |  |  |
|  | Tissues/ body fluids collected for diagnostic purposes |  |  |  |
|  | Tissues/ body parts removed surgically for therapy |  |  |  |
|  | Tissues/blood removed surgically for donation |  |  |  |
|  | Samples collected for previous research (provide details of the research, EC approval and consent form as attachment) |  |  |  |
|  | Microorganisms cultured in the laboratory from samples obtained for diagnosis/treatment |  |  |  |
|  | Data (including protographs, soft copies stored on computers) collected for previous research, healthcare, academic or therapeutic purposes |  |  |  |
|  | Medical education technology studies and feedback analysis |  |  |  |
|  | Medical or academic audit reports or hospital administrative policies/procedures |  |  |  |
|  | Any other (Specify with details) |  |  |  |
|  | Commercially available cell lines/ tissue |  | | |
|  | Data in public domain |  | | |
| **Anonymization of the data/samples** | | | | |
|  | Describe the method of anonymization |  | | |
|  | Name, designation and department of the individual who will carry out the anonymization/coding |  | | |
| c. | Signature of the person carrying out the anonymization/coding |  | | |
| **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 participants by not collecting any personal information like name, phone number, address or other identifying data from MRD files/images/samples/ other data sources mentioned above collected for the purpose of research and related publications. * I will not 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 will not take photocopies/ photographs/ scans of MRD files/images/other sources of data for the purpose of this study * I will maintain the confidentiality of data collected from the MRD files/images /samples/ other sources of data during and after the study. \ * I will access files/images/samples/other sources of data only after the approval from YEC-1. * Only research team members will access the MRD files/images/samples/other sources of data and will not be accessed by any other person. * I will collect only that data which is relevant to meet the objectives of the study as per the data collection form approved by YEC-1. * I will restrict to the approved sample size as approved by the YEC-1. * 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 YEC-1. * The MRD files/images/samples/ other sources of data accessed for the purpose of this research will be anonymized as described above | | | | |
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| Signature of the Principal investigator with date: | | | | |
| Signature of the Guide (if applicable) with date: | |  | | |
| Signature of the HOD with date: | |  | | |

Please submit a copy of this declaration to the MRD/ concerned department which holds custody of the samples after the EC approval is given.