**FACULTY OF MEDICINE & HEALTH SCIENCES**

**RESEARCH ETHICS COMMITTEE**

*(Adapted from Stellenbosch university)*

**Databases, Registries and Repositories**

(Kindly type in all the information)

**APPLICATION FORM: REGISTRATION OF A DATABASE, REGISTRY OR REPOSITORY**

Project identification number/ Clearance number……………………………….

*N.B. This application is only for the registration of your database, registry or repository. Separate applications should be made for any research which plans to use the contents of this database, registry or repository.*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **DATABASE** | Databases are collections of information, i.e. data, arranged for ease of search and retrieval. Databases may be maintained electronically or as paper-based systems. | | | | | | |  | | |
| **REGISTRY** | Registries or data banks are collections of information or databases whose organisers: Receive information from multiple sources; maintain the information over time; control access to and use of the information by multiple users or for multiple purposes which may change over time. | | | | | | |  | | |
| **REPOSITORY** | Repositories collect, store and distribute human materials for research purposes e.g. blood, urine, faeces, bone marrow and cell aspirates. | | | | | | |  | | |
| **SECTION 1: Please provide the following information** | | | | | | | | | | |
| **1.1. Name of Database/Registry/Repository** (Please provide a descriptive name that indicates the nature of the contents) | | | | | | | | | | |
|  | | | | | | | | | | |
| **1.2. Site of Database/Registry/Repository** | | | | | | | | | | |
|  | | | | | | | | | | |
| **2. Type of data/specimens** **to be stored** (including description of identifying details, whether routine clinical data or data collected specifically for a specific research project, whether data is collected retrospectively or whether it is known at time of data collection that data will be included in a research database). **Note: Please provide a data sheet or a specific list indicating specific data to be included**. | | | | | | | | | | |
|  | | | | | | | | | | |
| **3. Is it a private or public database, registry or repository:** | | | | | | | | | | |
|  | | | | | | | | | | |
| **4. Please briefly describe the source of specimens and how and how participants will be recruited to donate their specimens to the database/registry/repository. For example:**   * Patient folders requested and data transposed on to datasheet by research assistant before being entered into Excel spreadsheet. * Data extracted from Clinicom into spreadsheet by front desk clerk. * Data entered into database after each patient seen in the clinic. * Surgical specimens collected from theatre and sent to laboratory for processing and storage in freezer situated at location. * Biological samples collected by nurse at routine hospital visit and stored at location or specifically for research. | | | | | | | | | | |
|  | | | | | | | | | | |
| **5. Objectives of the database, registry or repository. Explain how it will it benefit scientific research and development.** | | | | | | | | | | |
|  | | | | | | | | | | |
| **6. Location of the database, registry or repository** | | | | | | | | | | |
|  | | | | | | | | | | |
| **7. Will informed consent be obtained?** In the interest of respect for participants, if data or samples are to be collected prospectively (even if entered at the end of each visit) for future research purposes, then consent (at least simple consent) should be taken. | | Yes | |  | | No | | |  | |
| Please attach informed consent documents and list below (if applicable)  Donor/participants’ informed consent guidelines can be | | | | | | | | | | |
|  | | | | | | | | | | |
| **8. Please justify if informed consent will not be obtained and why a waiver of informed consent should be granted.**  Important: Even if Data is being collected for routine purposes, this is not a reason to waive consent if data is being collected prospectively. | | | | | | | | | | |
|  | | | | | | | | | | |
| Note: Obtaining informed consent to use data or specimens stored in a repository created for non-research purposes may be problematic since research was not intended at the time of collection. Where feasible, the Committee may require a researcher to obtain informed consent. However, the Committee may approve a waiver of consent requirements if:   * The research involves no more than minimal risk (e.g. anonymous use of samples); *and* * The waiver will not adversely affect participants’ rights and welfare; *and* * The research could not practically be carried out without the waiver   If routine clinical data is to be collected prospectively, it would generally be expected, in the interests of respect for participants, that at least simple informed consent be obtained. | | | | | | | | | | |
| **9. Please briefly describe how participant’s privacy and confidentiality will be protected.** | | | | | | | | | | |
|  | | | | | | | | | | |
| **10. Briefly specify who will have access to the database, registry or repository? How access will be obtained** | | | | | | | | | | |
|  | | | | | | | | | | |
| **11. Briefly describe conditions under which data/ specimens may be shared with or released to researchers.** | | | | | | | | | | |
|  | | | | | | | | | | |
| **12. For what period will data/specimens be maintained in the database/registry/repository?** | | | | | | | | | | |
|  | | | | | | | | | | |
| **13. If you anticipate exporting samples/ specimens (locally or internationally) how will you do this. *Note: Maternal transfer agreement (MTA) SOP.*** | | | | | | | | | | |
|  | | | | | | | | | | |
| **14.** **Participant’s benefits:** **Explain how it will the information benefit the participating community** | | | | | | | | | | |
|  | | | | | | | | | | |
| **15. How will data/specimens be destroyed?** | | | | | | | | | | |
|  | | | | | | | | | | |
| **16. Will participants be able to withdraw their data/specimens?** | | | Yes | |  | | No | | |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **SECTION 2: DETAILS OF APPLICANT/PRINCIPAL INVESTIGATOR** | | | |
| **Title:** | **First name:** | | **Surname:** |
|  |  | |  |
| **Professional Status:** | | | |
| **Department/D:** | | | |
| **University Department:** | | | |
| **Signature:** My signature certify that I will maintain the database, registry and repository according to the guidelines in the SOP. If at any time I want to share or reuse the information for purposes other than those indicated in the approval, I will seek further approval from the REC prior commencement of research | | | |
| **Sign…………………………………………………. Date……………………………………….** | | | |
| **Telephone No:** | | **E-mail address:** | |

|  |  |  |
| --- | --- | --- |
| **SECTION 3: DETAILS OF COLLABORATING INVESTIGATORS and SUB-INVESTIGATORS** | | |
| **Name and Title** | **Position and role** | **Division & Department** |
|  |  |  |
|  |  |  |
|  |  |  |
| **SECTION 4: Head of Department or Division (HOD) Signature** | | |
| **Date:** | **Signature:** | **Name (print):** |
|  |  |  |