

**UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG**

Division of the Deputy Registrar (Research and Innovation)

**HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)**

**Biobanks Ethics Committee (BEC) – Application Form 1 - 2025**

**APPLICATION FORM 1:** Application for registration of a Biobank/ Biorepository /Databank

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| Please refer to the Biobanks/Databanks Policy documents and checklist before filling in this application form. BEC 1 applications must be submitted in hard copy (1 x copy of an application form and all the required/supporting documents) at our offices and via e-mail: HREC-Medical.BEC@wits.ac.za **\*BEC 1 applications are subject to the published monthly closing dates.** |

1. **APPLICANT DETAILS** (Biobank/Databank Applicant to be the South African-Based)

**Title: Prof [ ]  Dr [ ]  Mr [ ]  Ms [ ]  Other** [ ]

**Full Name:**

**Department/Research Unit/Entity:**

**Name of Institution/School:**

**Position:**

**Qualification/s:**

 **HPCSA or Other Statutory Council No:**

 **Contact Details:**

 **(*Telephone)***

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 ***(Country Code) (Telephone Number)***

**Contact Details:**

 ***(Mobile)***

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***(Country Code) (Mobile Number)***

 **Contact Details:**

***(Fax)***

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***(Country Code) (Fax number)***

**Email:**

**APPLICANT'S SIGNATURE:**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:**

1. **APPROVAL OF A BIOBANK/DATABANK**
2. **BIOBANK/DATABANK DETAILS:**

**a) Proposed name**

**b) Location**

**c) Affiliated to an existing approved Biobank/Databank**

**d) Public/Private**

**e) Affiliated Institute (Laboratory) (University)**

**f) Approximate sample capacity**

**h) Specify type of Human Biological Samples (HBM) to be stored**

**i) Specify the kind of data that will be stored**

1. **OBJECTIVES OF THE BIOBANK/DATABANK** (Please note this is not objectives of a study)
2. **OVERARCHING PRINCIPLES OF THE BIOBANK/DATABANK**
3. **GOVERNANCE** (please attach relevant documents at the end – see section 9)
4. **Country level registration**
5. **Management of Biobank/Databank**
6. **Organogram**
7. **Oversight**
8. **Back-up systems**
9. **REGULATORY APPROVALS** (please attach relevant documents at the end)
10. **Ethics**
11. **Institutional**
12. **Other**
13. **COMPLIANCE/ACCREDITATION/CERTIFICATION** (please attach relevant documents at the end – ensure documents are updated)
14. **ISO**
15. **GCLP Compliance; and**
16. **IATA; and / or**
17. **Other**
18. **PROTECTION OF SAMPLE/DATA DONORS**
19. **Procedure for ensuring sample and data have been obtained with consent**
20. **Procedure for consent withdrawal**
21. **Procedure for transfer/destruction of samples/data**
22. **Procedure for protection of privacy of samples/data**
23. **Community consultation where relevant e.g. Population Genetic Studies**
24. **Process for community consultation**
25. **Ongoing information sharing**
26. **Other**
27. **SAMPLE / DATA MANAGEMENT**
	1. **Details of management systems**
	2. **Audit trail (proof of internal/external audits)**
	3. **Anonymization of donor identifiers**
	4. **Back-up system**
	5. **Compliance of IT system, e.g., 21 CFR part 11 Compliance**
	6. **Import and export of samples and data**
	7. **Links with other Biobanks and Databanks**
	8. **Sample and data security safeguards**
	9. **Sample and data access controls**
28. **RISK MANAGEMENT**

**a) Risk management policy**

**b) Overall insurance**

 **c) Health and safety for staff**

 **d) Staff capacity**

1. **PROCEDURES FOR CLOSURE**
2. **Process for notification of HREC (Medical) prior to closure**
3. **Process for transfer and acceptance of samples and data to an HREC approved recipient organisation**
4. **FUNDING**
5. **Funding sources**
6. **Sustainability**
7. **Private/Public**
8. **SAMPLES**
9. **Type of samples stored**
10. **Type of storage conditions**

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| --- | --- | --- |
| **STORAGE CONDITIONS** | **CAPACITY** | **COMMENT** |
| **Ambient** |  |  |
| **Minus 20 degrees C** |  |  |
| **Minus 80 degrees C** |  |  |
| **Liquid Nitrogen** |  |  |
| **Other** |  |  |

1. **List key storage equipment**
2. **Sample flow from collection to submission to Biobank/Databank**
3. **Sample flow from release of samples from Biobank/Databank**
4. **Sample destruction process**
5. **Storage Backup Capacity**
6. **SUPPORTING DOCUMENTATION**

Please attach the following to your application:

|  |  |  |
| --- | --- | --- |
| **Document** | **ATTACHED: Yes/No** | **Comment** |
| **Proof of country level registration** |  |  |
| **Proof of Registration with the Company’s Act no 71 of 2008 where applicable**  |  |  |
| **Organogram** |  |  |
| **Material Transfer Agreement (MTA) Template** |  |  |
| **Data Transfer Agreement (DTA) Template** |  |  |
| **List of policies and/or SOP’s** |  |  |
| **Certifications** |  |  |
| **Other** |  |  |