



National Health Research Ethics Committee of Nigeria (NHREC)

Promoting Highest Ethical and Scientific Standards for Health Research in Nigeria



Federal Ministry of Health

REGISTRATION OF BIOBANK OR BIOREPOSITORY

Health care providers, research institutes, and other bodies that have decided to establish a biobank in Nigeria should use this form. The form must also be used to report changes of previously reported data.

Notification must be made within one month of the decision. Changes must be notified within one month of the change being implemented.

The notification relates to:

<input type="checkbox"/>	Newly established Biobank	Date	Day	Month	Year
<input type="checkbox"/>	Change in the information previously provided by a registered biobank	Date	Day	Month	Year
Registration if available *					

* This is the number assigned by NHREC on behalf of the Federal Ministry of Health for all newly established Bio banks

Principal Investigator responsible for the Biobank

Surname:		First name:			
Qualification(s) relevant to biobank management:					
1. <input type="text"/>					
2. <input type="text"/>					
3. <input type="text"/>					
Address:					
City:			State:		
Phone (with area code):			E-mail:		

Institution Responsible for the Biobank

<input type="checkbox"/>	State Authority	Enter name of State and responsible agency
<input type="checkbox"/>	Local Government	Enter name of LGA and responsible agency
<input type="checkbox"/>	Private	Name of company / foundation / sole proprietorship
Corporate (Tax Identification Number or Corporate Affairs Commission Company Registration Number)/ Personal identification number* (National Identification Number)		
*Personal identification number shall be indicated only if corporate missing		



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Address of the Institution Responsible for the Biobank

Delivery Address:	
City:	State:

Location where biospecimens will be stored

Type of Location of the biobank(s)		
Rural area <input type="checkbox"/>	Urban area <input type="checkbox"/>	Multiple locations <input type="checkbox"/>

Enter the name, address and contact phone number of the medical institution, research institute or equivalent where the biobank is located. If multiple biobanks are being established by the same organization or a biobank has multiple storage locations, please state all addresses.

Location 1	
Name:	
Physical Address:	
Post Code:	City:
Primary source of power	Capacity of primary source of power (in KVA)
Secondary source power	Capacity of secondary source of power (in KVA)
Phone no. 1:	Phone no. 2:

Location 2	
Name:	
Physical Address:	
Post Code:	City:
Primary source of power	Capacity of primary source of power (in KVA)
Secondary source power	Capacity of secondary source of power (in KVA)
Phone no. 1:	Phone no. 2:



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Type of Biobank (indicate one of the options)

- Biobank at Public Hospital
- Biobank at Private Hospital
- Biobank at Public Research Institute
- Biobank at Private Research Institute
- Combination of biobanks (please describe characteristics and contents):

.....

.....

- Other types of biobank, please describe characteristics and contents:

.....

.....

Biobank purposes (enter one or more of the options)

- Care and treatment
- Other medical purposes
- Quality Assurance
- Education
- Research
- Clinical trials
- Development

Other activities, please describe in detail

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Biobank scope of work (enter one or more of the options)

Type of sample	Approximate number of samples at the time of notification	Estimated number of new samples per year
<input type="checkbox"/> Organ
<input type="checkbox"/> Tissue
<input type="checkbox"/> Cell/cell lines
<input type="checkbox"/> Genomic materials
<input type="checkbox"/> Blood or blood plasma
<input type="checkbox"/> Urine
<input type="checkbox"/> Saliva

Others, please list

Type of sample	Approximate number of samples at the time of notification	Estimated number of new samples per year
.....
.....
.....
.....

Business model – how will the activities of the biobank be funded

	Funding source	Reference number
<input type="checkbox"/> Grant funding
<input type="checkbox"/> Public sources
<input type="checkbox"/> Private funding
<input type="checkbox"/> End user payment
<input type="checkbox"/> Donor payment



Additional information:

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.....
.....

Commitment to Continuing Oversight

NHREC shall carryout oversight of all established biobanks to ensure adherence to international best practices. Such oversight would include but not limited to inspection of the following:

- a. Participants’ documented consent forms;
- b. Documents describing mechanism for ensuring that research volunteers exceptions and limitations are noted and there is sufficient mechanism in place to ensure compliance;
- c. Evidence of how the materials that are taken out of the bio-bank are used only in accordance and in strict compliance with MTA guiding the stored samples;
- d. Copies of MTA relating to all samples stored and shipped out of the biobank;
- e. Copies of Researchers’, Research teams’ or Consortiums’ Guidelines, Agreements and SOPs applicable to samples stored in or shipped out of the biobank;
- f. Copies of all versions of previous documents with a summary of changes;
- g. Documents describing mechanism for removing and destroying the samples of participants who opt out of future participation. If opt-out is not possible, the operators of the bio-bank should explain why so that NHREC can satisfy itself that a good faith effort has been made;
- h. Information about the business model that the biobank is using for cost recovery;
- i. Document or statement within other policies making explicit, the role of the biobank, if any, in “Return of Results” to participants. If the biobank plays no role in return of results, a statement attesting to and the reason this should be provided;
- j. Document or statement within other policies describing the role of the biobank, if any, in all matters relating to intellectual property arising from research done on samples kept in the biobank; and
- k. Evidence of training in (a) Informed consent, (b) Biosafety and (c) the Nigerian National Code of Health Research Ethics for all bio-bank staff responsible for receipt, storage, handling and shipment of biospecimen.
- l. Re-registration of the biobank every 2 years.



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IMPORTANT NOTE

Submission of this application form is considered as a commitment from the responsible institution to abide by the provisions of the “**Policy Statement on Storage of Human Samples in Biobanks and Biorepositories in Nigeria (PS1.02013)**” including subjecting the biobank to continuing oversight by NHREC.

Person providing information

Name:	
Signature:	
Phone number including area code:	
Post Code:	e-mail:

List of additional documents being submitted with this application
Document 1:
Document 2:
Document 3:
Document 4: