|  |  |
| --- | --- |
|  | **NABL 227** |
|  | **National Accreditation Board for Testing**  **and Calibration Laboratories (NABL)** |

|  |
| --- |
| **Application Form for** **Accreditation of**  **Biobanks** |

|  |  |
| --- | --- |
| **ISSUE NO.: 01**  **ISSUE DATE: 26-Sep-2024** | **AMENDMENT NO.: --**  **AMENDMENT DATE: --** |

**AMENDMENT SHEET**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **S. No.** | **Amendment no.** | **Page No.** | **Clause No.** | **Date of Amendment** | **Amendment** | **Reasons** | **Signature**  **of**  **QA Team** | **Signature of**  **Competent Authority** |
| 1 |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |  |  |
| 6 |  |  |  |  |  |  |  |  |
| 7 |  |  |  |  |  |  |  |  |
| 8 |  |  |  |  |  |  |  |  |
| 9 |  |  |  |  |  |  |  |  |
| 10 |  |  |  |  |  |  |  |  |

### CONTENTS

|  |  |  |
| --- | --- | --- |
| S. No. | **Title** | Page No. |
|  | Amendment Sheet | 1 |
|  | Contents | 2 |
| 1. | Requirements to be fulfilled and Instructions to be followed by the Biobanks, while applying for NABL Accreditation | 3 |
| 2. | Information for Biobanks | 4 |
| 3. | Application Form for Accreditation of Biobanks | 5 |

**Information & Instructions for completing an Application Form**

1. Application shall be made in the prescribed form (NABL 227) only. The application shall consists of the following:

* Completed application form
* Management System Document / Quality Manual
* Application fees
* Duly signed NABL 131: Terms & Conditions for Obtaining and Maintaining NABL Accreditation

Incomplete application, fraudulent behavior, false information and concealing the information may lead to rejection of application or termination of the assessment process.

1. Biobanks are required to undertake biobanking activities in such a way as to meet the requirement of ISO 20387: 2018, NABL specific criteria, other relevant requirements of NABL and the regulatory authorities, as applicable at all times.

*Note: Other relevant requirements of NABL are mentioned in documents such as NABL 133, NABL 142 & NABL 163 etc. The list of documents is available on NABL website under publications section.*

1. Biobanks are required to follow the current version of NABL documents available on NABL website.
2. Biobanks are advised to familiarize themselves with NABL 100A ‘General Information Brochure’ NABL 100B ‘Accreditation Process & Procedure’, NABL 216 ‘Procedures for Dealing with Adverse Decisions’, NABL 131 ‘Terms and Conditions for Obtaining and Maintaining NABL Accreditation’ and NABL 133 ‘Policy for Use of NABL Symbol and/or Claim of Accreditation by Accredited Conformity Assessment Bodies (CAB) & NABL Accredited CAB Combined ILAC MRA Mark’ before filling up this form.
3. Biobanks shall provide/upload copy of following appropriate document(s) in support of the legal entity status claimed:

|  |  |
| --- | --- |
| **Type of Legal Entity** | **Document(s) to be submitted** |
| One Person Company | Registration certificate under The Companies Act, 2013 |
| Limited Liability Partnership | Registration certificate under The Limited Liability Partnership Act, 2008 |
| Company | Registration certificate under The Companies Act, 1956 or 2013 |
| Societies/ Trust | Registration certificate under Societies Registration Act, 1860/ Registration under The Indian Trusts Act, 1882 |
| Government | Gazette or Government Notification or self-Declaration on Letter head by Head of the organization |

1. Biobanks are required to satisfactorily participate in Proficiency Testing (PT) program conducted by accredited PT provider as per ISO/IEC 17043 before submission of application where available. For participation in PT, refer NABL document NABL 163: Policy for Participation in Proficiency Testing Activities.

**Information for Biobanks**

1. ISO 20387 does not apply to biological material intended for food/feed production, laboratories undertaking analysis for food/feed production, and/or therapeutic use. Such Biobank shall not apply for NABL accreditation of Biobanks.
2. The application must be filled up by the authorized representative of the Biobank.
3. Incomplete application will be rejected by NABL.
4. If the Biobank has provided false information and/ or conceals any information, then, NABL will reject the application and/ or terminate the assessment process.
5. NABL may refuse the services (not accepting the application and/ or not conducting the assessment) to a Biobanks, in case of proven evidence of fraudulent behavior, falsification of information and/ or deliberate violation of accreditation requirement.
6. The application fee and other necessary charges related to accreditation process is given in NABL document NABL 100A ‘General Information Brochure’, is available on NABL website.
7. Biobanks are required to pay due attention while providing information to NABL in application form. After submission of application, Biobanks will not be able to make changes in the application form.
8. Biobanks are required not to request for any changes in applied scope of accreditation and/ or personnel to report, review and authorize the results during ongoing on-site assessment.
9. Biobanks are required to implement changes related to NABL accreditation criteria/ policies within stipulated time.
10. Biobanks are required to inform their affected clients whenever any adverse action is taken against the Biobanks by NABL (such as suspension, scope reduction or withdrawal of accreditation etc.) and the associated consequences without undue delay.
11. The application will be kept confidential (unless required by law) by NABL and information obtained during the processing of application, assessment visit and decision on accreditation will be safeguarded and confidentiality and impartiality will be maintained. The procedure for processing of application for accreditation is given in NABL 100B ‘Accreditation Process & Procedure’,

### Application Form for Accreditation of Biobanks

We apply for NABL accreditation of our Biobank as per details given below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | First Accreditation |  | Renewal of Accreditation |  |

|  |  |
| --- | --- |
|  | Extension of Scope (Apart from scheduled assessment) |

If earlier accredited by NABL, please provide the following:

Accreditation Certificate No.:\_\_\_\_\_\_\_\_\_\_\_\_ Accreditation Certificate valid until:\_\_\_\_\_\_\_\_\_\_\_ Biobank ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Any adverse action has been initiated/ taken against the Biobank in the past.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Yes |  | No |  |  |

If yes, provide the details with present status

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_

1. **Biobank Details**
   1. **Name/ Identification of the Biobank**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Note: Accreditation is granted to the registered Legal Entity (Ref. Cl. No. 5 mentioned under “Information & Instructions for completing an Application Form” above), hence the same may be clearly stated above. If the Biobank is a defined part of a legal entity, having a defined name/division, the same may also be stated. In case it is defined part of the legal entity separated through location, then it shall be identified accordingly in unique terms.*

**Address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*Note: (Indicate if the premise is owned or is acquired on lease, as applicable. Copy of proof of ownership or registered lease agreement shall be enclosed as evidence). Large institutions/government entities may be exempted from providing proof.*

**Telephone No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Fax No. \_\_\_\_\_\_\_\_\_\_\_E-mail ID**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Note: The email id will be used to provide official information and notices by NABL and hence an official email id shall be provided which is checked by the biobank on a regular basis. Any changes in this regard shall also be informed without delay*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **1.2** | **Does the Biobank wish to take accreditation for different locations/dedicated area having same legal entity within the city?** | |  | **Yes** |  | **No** |  |
|  |  |  |  |  |  |
|  |  | |  |  |  |  |  |
|  | a. | If yes, please provide the complete details for each location/dedicated area with respect to Clause 1.1, 2.1, 2.2, 3.2, 3.4, 4 & 6 of the application form. |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

**1.3 *Legal entity of the Biobank and date of establishment* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*(Please give Registration No. and name of authority who granted the registration. Copy of the certificate shall be enclosed. Refer Cl. No. 5 mentioned under “Information & Instructions for completing an Application Form” above)*

**1.4 *Has adverse action been initiated/taken against the Biobank in the past? YES/NO***

*(If yes, please provide the details with present status)*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**1.5 Goods and Services Tax (GST) Number along with PAN/ TAN Number**

GST Registration No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PAN No.:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

TAN No.:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**1.6 Type of Biobanks by service:**

(please tick in appropriate box)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Open to others |  | Partly open to others |  | In-house Biobanks |  |

**1.7 Other accreditations** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**1.8 *Indicate exactly how the name and address of the Biobank are to appear on the certificate*** *(In English)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

1. **Accreditation Details**
   1. ***Category for which accreditation is sought*** (Please tick the appropriate box)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Human |  |  |
|  |  |  |  |
|  | Veterinary |  |  |
|  |  |  |  |
|  | Plant Material |  |  |
|  |  |  |  |
|  | Microorganisms |  |  |
|  |  |  |  |
|  | Fungi |  |  |

* 1. **Scope of Accreditation**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| S. No. | Category of biological material | Type of biological Material | Activities \* | Storage Conditions | Methods |
|  |  |  |  |  |  |

*Examples of Activities: Collection, Acquisition, Transport, Preparation, Testing & Analysis Preservation, Storage, Distribution, etc.*

*\* Acquisition and Storage must be a performed activity along with one other activity.*

1. **Organization** 
   1. **Senior Management**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Person | Name | Designation | Contact Number | | E-mail ID |
| Landline | Mobile |
| Head of the Biobank |  |  |  |  |  |
| Person responsible for management system |  |  |  |  |  |
| Person responsible for technical operations |  |  |  |  |  |
| Governance Body/ Advisory Board Details |  |  |  |  |  |
| Contact person for NABL (Biobank’s staff only) |  |  |  |  |  |

* 1. **Proposed personnel to authorize the report**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| S. No | Name & Designation | Qualification with Specialization | Experience in years related to present work | Relevant Training | Part time / Full time (timings if part time) | Authorized for which specific area of Biobanking | Specimen Signature |
|  |  |  |  |  |  |  |  |

* 1. **Organization Chart**
     1. Detailed organization chart of the Biobank for which accreditation is being sought (please append).
     2. Indicate how the Biobank is placed in the parent organization (where applicable, please append).
  2. **Employees** 
     1. **Details of staff**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| S. No. | Name | Designation | Academic and Professional Qualifications\* | Experience related to present work (in years) |
|  |  |  |  |  |

\* Please clearly indicate the field of specialization

Note: Biobanks operating in shifts shall clearly identify the staff working in shifts.

1. **EQUIPMENT AND REFERENCE MATERIALS/REFERENCE STANDARDS**
   1. **List of test equipment**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| S. No. | Name of equipment | Model/ type/ year of make | Receipt date & date placed in service | Range and accuracy | Date of last calibration | Calibration due on \* | Calibrated by\*\* |
|  |  |  |  |  |  |  |  |

\* The Biobank to decide the calibration interval based on ISO 10012 or ILAC-G24

\*\* Please mention name of calibration agency along with its accreditation certificate number and validity.

* 1. **List of Reference Biological materials available for use**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| S. No. | Name of Reference Biological material | Source | Date of expiry/ validity | Metrological Traceability |
|  |  |  |  |  |

1. **Internal Audit and Management Review**
   1. **Date of last Internal Audit**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
      1. Whether all requirements of ISO 20387: 2018 covering all activities of Biobank has been audited at least once in last one year

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Yes |  | No |  |  |

* + 1. Whether all locations were covered in the internal audit

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Yes |  | No |  |  |

* 1. **Date of last Management Review Meeting \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
     1. Whether Biobank has reviewed its management system as per the requirements of ISO 20387: 2018 at least once in last one year

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Yes |  | No |  |  |

1. **Quality Control approaches used by Biobank**
2. Use of certified reference materials, where available, produced by a reference material producer fulfilling the requirements of ISO 17034;

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Yes |  | No |  |  |

1. Samples previously examined;

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Yes |  | No |  |  |

1. Samples previously shared with other biobanks;

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Yes |  | No |  |  |

1. Participation in PT program

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Yes |  | No |  |  |

**6.1 Details of PT Participation**

Participation in PT / Inter Laboratory Comparison any other approach(for details and requirements refer to ISO 20387: 2018)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Sl. No.** | **Material** | **Details of activity/ procedure/ examination** | **Date of participation** | **Organizing body** | **Performance in terms of z score or any other criteria** | **Corrective action taken (if required)** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

1. **Application Fees**
   1. Application fees (Rs).\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
   2. Transaction number\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note:

1. *Kindly make all kind of payments preferably through portal (*[*https://nablwp.qci.org.in/Account/Login*](https://nablwp.qci.org.in/Account/Login)*) or as defined in NABL 100A.*
2. **Declaration by the Biobank**
   1. We declare that this application is submitted for accreditation of biobanking of biological material which are not intended for food/feed production, laboratories undertaking analysis for food/feed production, and/or therapeutic use.
   2. We are familiar with the terms and conditions for obtaining and maintaining accreditation (NABL 131), which is enclosed and will abide by it. We have understood the requirements given in NABL 133
   3. We have declared and submitted accurate and complete information in the enclosed “Declaration Form”
   4. We will maintain strict confidentiality of personal sensitive data. This information will not be shared with any other person, agency or organization (unless required by law).
   5. We agree to comply fully with ISO 20387: 2018 for the accreditation of Biobank.
   6. We abide by the National/ Regional/ State/ Local regulatory requirements/ Acts/ Rules/ Legal orders/ Court Decisions/ Orders issued by Government/ Statutory Bodies as applicable and effective from time to time.
   7. We agree to comply with accreditation procedures, pay all costs for assessments, supplementary visit (if any), surveillance and reassessment irrespective of the result.
   8. We agree to co-operate with the assessment team appointed by NABL for examination of all relevant documents by them and their visits to those parts of the Biobank that are part of the scope of accreditation.
   9. We comply with all national, regional and local regulatory requirements for operating a Biobank.
   10. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_has provided consultancy / advise for preparing towards NABL accreditation. (Information regarding any individual or organization who provided consultancy (if any) for NABL accreditation shall be declared).
   11. No adverse action has been initiated / taken against the Biobank in the past. (If yes, please provide the details with present status ………………………………………….). Biobank is also required to provide the information if they (including family members) have obtained NABL accreditation and adverse action has been taken by NABL.
   12. All information provided in this application is true.

Signature of Head of the organization\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Head of the organization\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Designation of Head of the organization\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Application Form - Check List**

|  |  |  |
| --- | --- | --- |
| **S. No.** | **Information / details provided as part of application** | **Availability** |
|  | Application Form |  |
|  | Management System Document/ Quality Manual (latest version) according to ISO 20387: 2018 |  |
|  | Application fee |  |
|  | Copy of Legal Identity (Registration Details of the Biobank) |  |
|  | Details of adverse action initiated/taken against the Biobank in the past, if applicable |  |
|  | Goods and Service Tax (GST) Number along with PAN/TAN Number |  |
|  | Scope of Accreditation with category, subcategory, activities, storage conditions and methods |  |
|  | Details of Senior Management with Designation and Contact Details |  |
|  | List of Staff and proposed personal for key activities |  |
|  | Organization Chart |  |
|  | List of Equipment’s / Reference Material used with details of traceability |  |
|  | Details of PT and ILC |  |
|  | Dates of Internal Audit and Management Review |  |
|  | Information/Declaration about the Consultant (if any) |  |
|  | The declarations on the “Declaration Form” enclosed with the “Application Form” |  |
|  | Signed copy of NABL 131 (latest issue) which includes the policy mentioned in NABL 133 |  |

Verified the above details and confirmed the availability of all required documents/ details as part of application form.

Signature of Head of the Organization\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Head of the Organization\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Designation of Head of the Organization\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Declaration Form***

**Declarations by the Biobanks Shareholders and Directors**

1. **Details of Owners, Partners, Shareholder(s) and/or the Board of Director(s) as the case may be:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SI.** | **Name of Shareholders/ Directors** | **% of Shareholding, if applicable\*** | **Relations, if any, with other director(s)/shareholder (s)** | **Remarks** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*\*The total of % shareholding shall add up to 100%, as the case may be.*

*Please add additional rows if necessary*

1. **How many other biobanks are operational with the same name as yours, with one or more common owners or with different owners and related to you. Please give details about the address, shareholders and Directors, etc.:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SI.** | **Other related labs – Name (s)\*** | **Address** | **Relationship**   1. **Same legal entity** 2. **Group Company** 3. **Common Owners**   **(Shareholders/Director)** | **Accredited/ Non-Accredited** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*Please add additional rows if necessary*

1. **List of the contracts (including MoUs, B2B agreements, etc.) the biobank has with other organizations/laboratories for the purpose of testing business, franchisee arrangements, marketing, subcontracting/outsourcing of activity on your behalf as well as carrying out of activities on their behalf. Please give details:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SI.** | **Name of the organization with whom the lab has MOU/Contract\*** | **Nature of Contract** | ***Enclose copy of contract***  ***(optional)*** | ***Remarks*** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*Please add additional rows if necessary*

1. ***In case the biobank intends to use or carry out its reporting under a specific trade mark/brand, then the details of the same shall be provided with the application along with the proof of registration and ownership or permission.***

*Note: This declaration form is to be filled giving accurate, complete and latest information. As and when changes occur in the information provided, the laboratory to provide the updated “Declaration”, within 15 days of the changes taking place, failing which lab may be subject to adverse decisions as described in NABL 216.*

It is declared that we shall re-submit the declaration as and when there is any change in the information provided above.

Signature of Shareholder/Director \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name & Designation\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date & Place\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

National Accreditation Board for Testing and Calibration Laboratories (NABL)

**NABL House,**

Plot No. 45, Sector- 44,

Gurugram – 122003, Haryana

Tel.: +91-124 4679700

###### Fax: +91-124 4679799

Website: [www.nabl-india.org](http://www.nabl-india.org)