

### Application form for Biobank Accreditation

For official only

CAB No. ....

Place.....

Date.....

Name of applicant .....

( ) Top management

( ) Authorized representative

Identification Number .....Age.....yrs    Nationality.....

Issued at.....Issued Date .....    Expired date.....

Address.....

.....

Telephone Number: .....Mobile Number: .....E-mail: .....

**Note:** Power of attorney:  
 # For government organization/ state enterprises, one of the following is followed:  
 1. Letter of Power of Attorney specifies the individual authorized to perform and the matter delegated clearly, signed by grantor of authorization, authorized representative and two witnesses.  
 2. Official Letter specifies the individual authorized to act and the matter delegated clearly, signed by the Top management.  
 # For private organizations, Letter of Power of Attorney affixing a 30 Baht of revenue stamp is required.

#### 1. Information for Biobank

Name of Biobank .....

.....

Address of Biobank .....

.....

Telephone .....    Fax .....

Website .....    E-mail address.....

**2. Nomination a senior staff member as a representative in all dealings with BLQS, DMSc.**

Name.....Position.....  
Telephone ..... Fax .....  
E-mail address.....

**Note:** The Authorized Representative shall be in the position of sufficient authority to ensure that the applicant organization comply with the BLQS criteria(s). Furthermore, this representative is responsible for ensuring that all of the relevant conditions for accreditation are maintained.

Name of Top management..... Position.....  
Telephone..... Fax..... Mobile..... E-mail.....  
Name of Quality manager..... Position.....  
Telephone..... Fax..... Mobile..... E-mail.....

**4. Legal status:**

- Government organization
- Public Company Limited
- others (please specify).....
- State enterprises
- Company

Date of established of Biobank: .....Registration number: .....

The trade registration or the commercial registration number: .....  
(company/ trade registration or etc. to be attached)

**Note:** For government organization/ state enterprises, please attach the information of establishment, including government act of establishment, organization, royal decree on establishment of departments, or any other documents demonstrating legal entity.

**5. Purpose of request:**

- New accreditation
- Extended scope of accreditation
- Surveillance
- Request for Pre-assessment
- Re-assessment accreditation

**6. Test item submitted for accreditation**



(1) No.	(2) Status	(3) Categories	(4) Subcategories	(5) Activities	(6) Storage conditions	(7) Methods	(8) Proficiency Testing, PT*		(9) Location** <small>(based on layout of Biobank)</small>
							Processing	Testing	
Example	New/Re/Extend /Surveillance	Human	Tissue, Body fluids	Acquisition, Collection, Preparation, Preservation, Testing, Storage, Distribution	-80 °C Freezer	SOP xxx			

Note

\* Biobank shall submit either summary report of Proficiency Testing (PT), Interlaboratory comparisons (ILC) or Biobank’s performance assessment in process or test, respectively.



\*\*Please identify a fixed physical location from where accredited activities are performed.

**7. Quality management system**

7.1 The date of current internal audit and specify the cycle (Cycle ..... / Year .....)

.....

The date of closed out of internal audit. ....

7.2 The date of current management review and specify the cycle (Cycle ..... / Year .....)

.....

7.3 The date of current risk management

.....

**8. Personnel**

Name of staff who engaged in every step of the biobanking and work history.

No.	Name	Position	Responsibility	Qualification	Experience/Year

Note\* Indicate the asterisk (\*) symbol at No. of the names who assigned to sign the test reports utilizing the accreditation symbol of BLQS.

**9. The equipment that affect the accuracy of Biological Material & Associated Data**

No.	Equipment	Lot/Model	Responsible person	Calibration frequency	Date of last calibration	Name of calibration service

**10. Reporting (compliance with ISO 20387: 2018 clause 7.12 Report requirements)**

Please indicate the issues of the report and attach an example of the report that used the accreditation logo of BLQS, DMSc.

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**11. Attach herewith quality documents apply for accreditation (Quality system documents or other name, SOP, QP WI, WS, F, etc. or other name according to the related international standard for accreditation) and master list of quality documents.**

Please specify the title, code, revision No., issued date, approved date, effective date.

No.	Name of Quality system documents	Title	Code	Revision No.	Issued date/ Approved date/ effective date

**12. Flow chart of Biobank**

Details of the flow chart of Biobank operation map to clearly understand since beginning until the end process.

**13. Structure of Biobank**

(Please provide the organization chart showing the line of authority within Biobank and if relevant, the Biobank's position in the overall structure of the parent organization. If it is available in the Biobank document, please state the relevant section of the location of the Biobank's structure)

**Enclosure: document needed are as follows:**

For laboratory (please specify)	No.	List of attachments	For official only		
			Yes	No	Remark
<input type="checkbox"/>	1)	Location maps of the Biobank and nearby landmark building			
<input type="checkbox"/>	2)	The flow chart of Biobank operation map with the whole process area of Biological Materials			
<input type="checkbox"/>	3)	The certificate of registration as a legal entity with registration purposes, and authorized personnel name of a Juristic person (signed to certify true copy)			
<input type="checkbox"/>	4)	The trade registration or the commercial registration (signed to certify true copy)			
<input type="checkbox"/>	5)	Government act of establishment or regulation (signed to certify true copy)			
<input type="checkbox"/>	6)	License to operate a sanatorium (For medical laboratory) (signed to certify true copy) (if any)			
<input type="checkbox"/>	7)	License to management of a sanatorium (For medical laboratory) (signed to certify true copy) (if any)			
<input type="checkbox"/>	8)	Power of attorney for the applicant. The evidence of authorizing representative and enclosed with 30 Baht of revenue stamp. (Original copy)			
<input type="checkbox"/>	9)	House registration and identification of the applicant (in case of foreign biobank)			
<input type="checkbox"/>	10)	Application form No. 15			
<input type="checkbox"/>	11)	Master list of quality documents			
<input type="checkbox"/>	12)	Quality system documents or other name, SOP, QP WI, WS, F, etc. or other name			
<input type="checkbox"/>	13)	Copy of all referenced documents for each requested item of accreditation			
<input type="checkbox"/>	14)	Result of method validation/ method verification for the requested scope of accreditation (if any)			
<input type="checkbox"/>	15)	Report include at least the internal quality control (IQC) and proficiency testing (PT) or interlaboratory comparison (ILC) or biobank's performance assessment in process or test (if any)			
<input type="checkbox"/>	16)	Internal audit			
<input type="checkbox"/>	17)	Management review			
<input type="checkbox"/>	18)	Summary report of risk and opportunity management			
<input type="checkbox"/>	19)	Staffs and qualifications			
<input type="checkbox"/>	20)	Major equipment calibration			
<input type="checkbox"/>	21)	Example of test report			
<input type="checkbox"/>	22)	A set of hard copy documents (separate sets of documents for each test item requested for accreditation) and electronic files in			

For laboratory (please specify)	No.	List of attachments	For official only		
			Yes	No	Remark
		Handy drive, CD/DVD, or Google drive format of all submitted documents (separate folders for each test item requested for accreditation in a readable file format shall be submitted as one set of documents and files separated by Categories/ Subcategories. Except for the BLQS form, which shall be submitted in 2 formats: MS-Word and PDF).			
	23)	The relevant ethical approvals compliance with applicable regulatory of human and/or animal scope. (signed to certify true copy)			
<b>Other attached documents</b>					
<input type="checkbox"/>	24)	.....			
<input type="checkbox"/>	25)	.....			
<input type="checkbox"/>	26)	.....			
<input type="checkbox"/>	27)	.....			

Result of document check

Document received from:  Authorized person from the CAB  Parcel post

All of documents are accepted to fulfill the requirement for accreditation.

Shall submit additional documents fulfill the requirement for accreditation which are as following:

.....

.....

Check by (BLQS staff) .....

(.....)

Position .....

Document complete date.....

 **Declaration**

- 1) I hereby commitment to follow the Policy, Requirements and Conditions for the Biobanking (R 07 15 005), Policy and Conditions for the Use of an Accreditation Symbol or a Statement to Claim Accreditation Status (N 07 15 009) and the additional requirements of the BLQS;
- 2) I shall pay all fees and costs for the accreditation process irrespective of the eventual granting of accreditation;
- 3) I shall provide access to personnel, locations, equipment, information, documents and records as necessary for the assessment and maintenance of the accreditation;
- 4) I shall provide access to the information of independence level and impartiality of the biobank from its related bodies, where applicable;
- 5) I shall arrange the witnessing of biobank services as requested;
- 6) I shall notify BLQS in writing immediately when there is a change of major issues, that affect application competency, such as change on trade regulations, change on organization status, re-organization, changes on key person on management, change on personnel or method or equipment or facility or work environment and other important resources that may have a significant impact on the scope already accredited;
- 7) I shall use the certificate and accreditation symbol according to the criteria and condition defined by BLQS without utilizing them in the way cause deterioration or misunderstanding, misleading or exaggerating the accreditation scope. Disobedience will cause BLQS to consider a reduction of accreditation scope, suspension or withdrawn of its certificate, or carry out any other appropriate means;
- 8) In the case that the certificate was suspended, cancelled, withdrawn, or did not get the certificate renewal, the applicant discontinue its use of all advising matters or referral to the accreditation;
- 9) I shall assist BLQS in the investigation and resolution of any complaints made by third parties about the accredited activities and submit such related documents to BLQS upon request.

I hereby certify that the undersigned is authorized to take any action on behalf of the Biobank and the information provided herein is correct to the best of my knowledge and belief. I have read, understand and agreed to follow the terms and condition of the agreement.


Signature of CAB .....

Name of CAB's authorized representative (.....)

Position .....

Date .....

 (Affix Company Seal Here, if any)

 Signature of BLQS staff .....

Name of BLQS designated person (.....)

Position .....

Date .....