

**SBP
SERVICE LEVEL
AGREEMENT
TEMPLATE**

* **Version 1.0**

**Background[[1]](#footnote-2)**

Biobanks often collaborate with service subcontractors who indirectly contribute to the successful implementation of their activities. These services typically include maintenance, cleaning, informatics (IT), human resources or purchase, or can be related to a specific biobanking process (e.g.: sample transport or storage). The biobank shall document its cooperation with these service subcontractors, in particular if the service provided can have a critical impact on the sample quality. In this case, the biobank shall implement measures to ensure that services are monitored and evaluated over time. The implemented measures shall be proportional to the degree of risk impacting the quality of the biobank related activities or samples (see Risk Management SOP by SBP).

This Service Level Agreement (SLA) template details in the format of a written contract the services provided and the expectations between the service provider and the biobank. Records of the service assessment shall be maintained and could be used as part of a regular review of the suppliers.

In a nutshell, this agreement specifies the parties’ mutual obligations and communication aspects. The document describes the scope, the procedure for modification, the service controls and audits, the responsibilities, the duration and termination terms of the contract, and the expectations in terms of quality for all services covered by the agreement.

SLAs are developed to satisfy a requirement from the ISO 20387 standard (“Biotechnology – Biobanking – General requirements for biobanking”) regarding subcontractors. Fulfilling this requirement is mandatory to obtain the SBP Optima label when subcontractors are outside the host Institution and recommended as good practice if service providers belong to the same institution.

Any use of this template is exclusive responsibility of the respective user. Marked fields are to be completed. In certain settings, modifications will be necessary. In case of need, specific legal advice should be sought.

In the event of additional questions, please contact SBP at info@swissbiobanking.ch

Swiss Biobanking Platform

**SERVICE
LEVEL
AGREEMENT**

FOR OUTSOURCED [SERVICE]

This agreement (hereinafter referred to as the “Agreement”) is made and entered into by and between:

[Name of Service Organization] (“Service Organization”)

[Address of Service Organization]

and

[Name of the Biobank] (“Biobank”)

[Name of Biobank Organization]

[Registration number]

[Address of the Biobank]

Hereinafter jointly referred to as the “Parties” and individually as a “Party”/”Counterparty”

|  |  |
| --- | --- |
| **Service Organization Authorized Signature(s)**(Duly Authorized Representative) | **Biobank Authorized Signature(s)**(Biobank Operational manager) |
| Signature | Signature |
| Name & Title[YYYY/MM/DD] | Name & Title[YYYY/MM/DD] |
| Date  | Date  |
| **Service Organization Authorized Signature(s)**(Responsible Person of Organization) | **Biobank Authorized Signature(s)**(Biobank Responsible person) |
| Signature | Signature |
| Name & Title[YYYY/MM/DD] | Name & Title[YYYY/MM/DD] |
| Date  | Date  |

Document details and change history

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Date** | **Change Description** | **Biobank responsible person authorization** |
| [version] | [Date] | [Description] | [Name] |

Agreement Overview

INTRODUCTION

This Service Level Agreement (SLA) between [Name of the biobank] and [Name of service Organization] describes the obligations and the expectations related to the service of [list of services] outsourced by the Biobank for the period between [MM/DD/YYYY] to [MM/DD/YYYY].

DEFINITIONS, ABBREVIATIONS AND ACRONYMS

Definitions

The terms « Biological Material », « Personal Data », « Health-related Personal Data » used in this Agreement shall have the meanings specified in the Federal Act on Research Involving Human Beings. The term “Personal Data” used in this Agreement shall have the meanings specified in the Federal Act on Data Protection.

**Confidential information**

For the purposes of this Agreement, Confidential Information is defined as any data or information to which either Party have access within the service provision, and which is neither publicly known nor generally accessible, regardless of its form (e.g. in verbal, written or electronic form), and irrespective of whether such data and/or information was designated as confidential.

Confidential Information of a Party might include, but not be limited to that Party’s: (i) methods, reports, standard operating procedures, practices and know-how; (ii) personnel’s data, or patients’/ research participants’ data and samples; (iii) inventions, processes, methods, products, patent applications, and other proprietary rights; or (iv) specifications, drawings, sketches, models, tools, computer programs, technical information, or other related information.

In particular, the Parties acknowledge that any Personal Data, including Health-related Data, accessed to within the service provision is Confidential Information.

**Biological Resources**

For the purposes of this Agreement, Biological Resources are defined as Biological Material and Associated Data.

**Associated Data**

Personal and/or Preanalytical Data.

**Preanalytical Data**

Data related to the collecting, processing, storage and usage of Biological Material.

**Shared Personal Data**

Personal Data shared between the Parties in the frame of the service described in this Agreement.

[ **Intellectual Property Rights**

All legal rights granted with the aim to protect the creations of the intellect, registered or unregistered, now or hereafter in force or recognized, including trade secrets and know-how.

**Background Intellectual Property (Background IP) and Foreground Intellectual Property (Foreground IP)** shall have the meaning set forth in Chapter 5 of this Agreement.]

[Term] [Definition]

Abbreviations and acronyms

SLA Service Level Agreement

[Term] [Description]

PURPOSE

The purpose of this Agreement is to specify the requirements linked to the service of [list of services] outsourced by the [name of the biobank]:

1. Scope and definition of the services outsourced by the Biobank.
2. Roles and responsibilities including communication aspects.
3. Agreed service performance parameters, metrics and service targets.
4. Contractual parameters of this agreement.
5. Intellectual Property Rights.
6. Liability and Indemnification.
7. Service management details.
8. Exceptions and limitations to the contract.
9. Applicable law and jurisdiction.
10. Appendices.

SERVICE AGREEMENT

1. SCOPE AND REQUIREMENTS
	1. Scope

The following services are covered by this agreement:

[Summary of the services outsourced by the biobank. e.g.: equipment maintenance/reparation/calibration, room cleaning, IT services (user account maintenance for database, server backup, BIMS maintenance), personnel training, reagents purchase, genomic sequencing, proteomics analysis, immunohistochemistry, …]

* 1. Service to be covered

[The biobank shall fulfill ISO 20387:2018 requirements and requires every aspect mentioned below to be compliant with this standard]

[Define all requirements of the services as required by the biobank, related to its specific processes, specifications and procedures]:

* [ E.g.: The mentioned equipment is in good operations with regular maintenance (minimum every … )
* E.g.: When needed, additional maintenance check is performed when unusual event is reported by the biobank
* E.g.: The personnel is trained on the tasks (e.g. maintenance) with the mentioned equipment
* E.g.: The maintenance process and its frequency are conformed to the manufacturer’s instructions
* E.g: Any planned task related to the maintenance of the mentioned equipment is communicated and documented in the corresponding logbook
* E.g.: Any unusual event occurring when using the mentioned equipment is documented and communicated
* E.g.: The mentioned BIMS frequency of updates or new versions is every […] years maximum; onsite support is proposed in case of obsolete version; intervention delay is shorter than 24h
* E.g.: Adequate quality controls are performed during the sample analysis and are communicated to the biobank
* E.g.: Maximum sample and data retention period are [duration]
* ….]

[If applicable, define all requirements of the service as required by the service organization, related to its specific processes, specifications and procedures]:

* [ E.g.: Use the mentioned equipment according to the manufacturer’s instructions
* E.g.: Maintain a logbook for the mentioned equipment
* E.g.: Train the personnel on the tasks performed with the mentioned equipment
* E.g.: Communicate any unusual event occurring when using the mentioned equipment and document it in the corresponding logbook
* E.g: Make sure that equipment is available for maintenance task when required
* E.g: A dedicated personnel shall be allocated for the service. The specified personnel are considered to be essential to the task being performed. Prior to replacing any of the specified individuals, the service provider shall notify the biobank and submit written justification allowing evaluation of the impact on the task. No replacement shall be made by the service provider without the written consent of the biobank.
* ….]
1. ROLES AND RESPONSIBILITIES
	1. Roles
* [Name of biobank] will act as the services user herein identified.

[…]

* [Name of service Organization] will act as the primary support provider of the services herein identified except when third-party vendors are employed who shall assume appropriate service support responsibilities accordingly.

[…]

* 1. Responsibilities
* Biobank responsibilities

[Name of biobank] should provide all necessary information and assistance related to service performance that allows the [name of service Organization] to meet the performance standards as outlined in this document.

[Name of biobank] shall inform [name of service Organization] regarding changing requirements that may necessitate a review, modification, or amendment of this Agreement.

[Name of biobank] shall communicate to [name of service Organization] all non-conformities related to the service.

[Name of biobank] shall approve the reports describing all activities related to the mentioned services and store a paper or electronic copy of these reports.

[…]

* Service Organization responsibilities

[Name of service Organization] will inform [name of biobank] regarding scheduled and unscheduled service outages due to maintenance, troubleshooting, disruptions or as otherwise necessary.

[Name of service Organization] will document all activities related to the mentioned services in reports that shall be approved by [Name of biobank]. [Name of service Organization] should store a paper version or electronic copy of these reports.

[Name of service Organization] will perform regular validation of its processes related to the mentioned services.

[Name of service Organization] will plan and document regular internal controls or audits of its processes related to the mentioned services, using a risk-based approach.

[When applicable, Name of service Organization] should monitor performance parameters detailed below and communicate to the Biobank if the targeted value is not achieved.

[…]

1. SERVICE PERFORMANCE
	1. Performance parameters, metrics and targets

The table below lists the parameters, metrics and targets that will be used to evaluate if the services meet the Biobank expectations. When applicable, these parameters will be monitored. It should be used as a basis to improve the service.

[Requirements should be translated into qualitative and quantitative quality parameters, metrics and targets that are understandable for service provider and could be easily monitored. Examples of parameters, metrics and targets to evaluate the service are listed below.]

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter | Description | Metrics | SLA Target [value or range] |
| [Exception handling] | [measure the handling and the recurrence of exceptional circumstances] | [number of related non-conformities, number of recurrent non-conformities] | [max n/year] |
| [Accessibility] | [measure the capability to serve a biobank request] | [success rate] | [min x %]  |
| [Availability] | [measure the duration time a service is present for immediate use under normal circumstances] | [percentage of availability, mean up/down time, Response time, execution time, mean time to provision] | [min x %] |
| [Reliability] | [measure the degree to which a service can be expected to be accurate] | [mean Time between Failure, number of failures over time] | [min n years, max n / year] |
| [Capacity] | [measure the maximum service utilization by the biobank] | [batch size, database size, files per database] | [n of samples, bytes, n] |
| [Scalability] | [measure of the capability to handle a growing amount of work by adding human or structural resources] | [resources usage] | [n of users, CPU usage, network usage, number of requests, …] |
| [Robustness and flexibility] | [measure if the service work correctly despite failing inputs] | [presence of error trapping mechanisms] | [Present for …] |
| [Consistency] | [measure of the degree to which a service is able to produce data from different source following the same definition] | [number of data fulfilling the consistency rule] | [n] |
| [Traceability] | [measure of how the service allows to follow the origin of an action] | [presence of log files, presence of audit trail, presence of certificates/statements] | [present for …] |
| [Integrity, authentication] | [measure of how the service maintains the correctness of the interaction regarding the source] | [presence of data encryption, digital signatures] | [present for …] |
| [Authorization] | [measure of how the service allows access to granted resources] | [presence of authorization tokens] | [present for …] |
| [Legal requirements /regulation / standards] | [measure the service conformance with the law or rules or standards] | [compliant or not] | [compliant to …] |
| [Confidentiality] | [measure how the service provides information only to users who are granted] | [presence of confidentiality agreement] | [present for …] |
| […] | […] | [….] | […] |

1. CONTRACTUAL PARAMETERS
	1. General

This section specifies the contractual parameters of this agreement:

* [Contract renewal must be requested by [name of biobank] at least [30 days] prior to expiration date of this agreement]

or

* [[Automatic Renewal](https://www.lawinsider.com/clause/automatic-renewal). This Agreement shall be renewed automatically for succeeding terms of 3 years each unless either party gives written notice to the other at least 30 days prior to the expiration of any term of its intention not to renew the agreement.]
* Modifications, amendments, extension and early termination of this Agreement must be agreed by both signatory parties.
* The Biobank may terminate the Service Level Agreement at any time giving a [60 days] prior written notice to the other Party, in case the Service Organization is in breach of this Service Level Agreement, in particular related to SLA targets described in ch. 3.1 and has not remedied such a breach by the end of the notice period.
* [Name of biobank] requires a minimum of [60 days] notice for early termination of this Agreement.
* […]
	1. Duty of Confidentiality

Each Party shall keep strictly confidential any Confidential Information disclosed by the Counterparty within the service provision.

Each Party shall use Confidential Information only for the intended purpose and shall not divulge it directly or indirectly to any third parties, except as approved in writing by the Counterparty.

Each Party shall only permit access to Confidential Information of the Counterparty to those of its employees or authorized third parties bound by confidentiality obligations at least as restrictive as those contained herein.

* 1. Warranty

The Parties shall warrant that all activities related to the mentioned service are performed in accordance with the requirements set forth in all applicable law, rules and regulation.

[In particular, the Parties undertake to comply with the following organisational measures: e.g: ISO 20387 / 9001 certification maintenance]

[**Service Organization Insurance**

Unless otherwise agreed in writing between the parties, and for a period of two years following the effective date of termination, the Service Organization will, at its own expense, ensure that it maintains adequate insurance in respect of its potential liability for loss or damage under this Agreement, including: e.g: liability insurance, …]

[Subject to the terms of this agreement, risk and title in the Biological Material shall pass to Service Organization upon its or its agent's or carrier’s collection of the Material from Biobank's facility. Service Organization is responsible for obtaining all transportation insurances, import and export clearances and licenses and arranging itself for the import of the Material to its local jurisdiction and facility.]

* 1. Security Measures

The Parties shall ensure that Confidential Information is adequately protected.

To this end, the Parties shall take appropriate technical and organisational measures (i) to guarantee the confidentiality and integrity of the Confidential Information received at all times, and (ii) to prevent any unauthorized access, disclosure, use and/or reproduction, of any of the Confidential Information.

In particular, the Parties undertake to comply with the following security measures:

* The parties shall adequately protect unauthorized or unlawful access or processing and accidental loss, destruction or damage of biological resources through appropriate organizational and technical measures.
[Related to the processing and protection of personal data[[2]](#footnote-3), including health-related personal data, these measures specifically include: e.g. the use of firewalls; the use of personal data in a coded form; the means to ensure the ongoing confidentiality, integrity, availability and resiliency of processing systems and services; the means to limit access to the Shared Personal Data to personnel who need to access it in the course of providing or using the service; the means to restore the availability of and access to the Shared Personal Data within an appropriate time frame in the event of a Security Incident; and a procedure to regularly test, analyze and evaluate the effectiveness of technical and organizational measures to ensure the security of the processing.]
* The Parties shall adequately protect the IT resources used against viruses, malware and other threats;
* Only the communication means that have been authorized by the Parties may be used;
* The storage of Confidential Information is hosted in [country];
* Each Party shall comply with all instructions and safety guidelines notified by the Counterparty.
	1. Notice of breach

Each Party shall notify the Counterparty immediately upon discovery of, or suspicion of, any unauthorized access, disclosure, use and/or reproduction, of Confidential Information, and/or any breach of data protection security.

Such notification must be in writing and must include a detailed description of the circumstances and people involved.

1. [Intellectual Property Rights[[3]](#footnote-4)
	1. Background IP

The Parties agree that each Party shall retain all the right, title and interest in and to its respective Intellectual Property Rights, as of the Effective Date (referred to as the “Background IP”). Unless otherwise agreed, nothing in this Agreement shall be construed as a transfer, license, and/ or assignment by a Party to the other Party of ownership of, right, title and interest in and to its respective Background IP.

* 1. Foreground IP

The Biobank and the Service Organization agree to opt for the following option:

The service organization is the owner of the output

Foreground IP. All the right, Intellectual Property Rights, title and interest in and to the output (referred to as the “Foreground

IP”), shall be owned and vest in the Service Organization.

[OR]

The Service Organization is the owner of the output but the Biobank is granted a license on the output and/or receives a portion of the revenues from the commercialization.

Foreground IP. All the right, Intellectual Property Rights, title and interest in and to the ouput (referred to as the “Foreground

IP”), shall be owned and vest in the Service Organization.

License on Foreground IP. The Service Organization hereby grants to the Biobank a royalty-free, worldwide, non-transferrable, non-exclusive, irrevocable license to access and use Foreground IP for purpose of internal scientific research only.

[and/or] Royalties. The Service Organization will pay to the Biobank [a fair share of or [...]% on] any net revenues received by the Service Organization for the commercialization of the Foreground IP.

[OR]

The intellectual property is jointly owned by both the Biobank and the service Organization.

Joint Foreground IP. All right, Intellectual Property Rights, title and interest in and to the output shall be owned jointly by the

Service Organization and the Biobank (referred to as the “Joint Foreground IP”). The Service Organization and the Biobank will set forth, by separate mutual agreement, their respective rights, duties and responsibility relating to the Joint Foreground IP.]

1. LIABILITY AND INDEMNIFICATION

Each Party shall be liable to, and indemnify, the other Party for actual costs, charges, damages, expenses or losses suffered by the other Party resulting from any of the first Party’s violation of this Agreement provided such damage was caused by gross negligence or willful misconduct.

The Biobank shall assume all and any liability and shall hold harmless the Service Organization for any loss, claim, damage of whatsoever kind or nature, which could be raised by the Biobank, or made against the Biobank by any third party, due to, or in connection with, the Biobank’s use of the services, except to the extent caused by the Service Organizer gross negligence or willful misconduct.

No Party shall be responsible to any other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts, loss of turnover, income, business, goodwill and opportunity or loss of or damage to reputation or to data, no matter how arising provided such damage was not caused by a willful act or by gross negligence.

1. SERVICE MANAGEMENT

The contact person for the service provided by the [name of service organization] is [first and last name, email, phone number].

Service provided by the [name of service organization] as outlined in this agreement follows the schedule specified below:

* On-site support: [hour]. to [hour], Monday to Friday between [date] to [date].
* Phone Support: [9:00 A.M. to 5:00 P.M. Monday - Friday].
* Email Support: [9:00 A.M. to 5:00 P.M. Monday - Friday].
* Delay of intervention: […]
1. EXCEPTIONS AND LIMITATIONS

This Agreement is subject to the following exceptions and special conditions:

[Include any exceptions to the SLA scope and application. For example, describe the conditions when the service provider shall not be responsible for the failure of not meeting the targets (e.g.: service misuse by the biobank)]

1. APPLICABLE LAW AND JURISDICTION

This Agreement shall be governed by and construed in accordance with the laws of Switzerland [town], canton of [name of canton]. Switzerland shall be the place of jurisdiction.

1. APPENDICES

Copy of relevant documents is provided in Appendices [x, y, z].

[Include reference agreements, policy documents, glossary and relevant details in this section. This might include terms and conditions for both the service organization and the biobank, and any additional reference material, like third-party vendor contracts]

Appendix 1: [Pricing models and charges]

Appendix [x]: […]

APPENDIX 1
PRICING MODELS AND CHARGES

|  |  |  |
| --- | --- | --- |
| **Service** | Description | Price |
| [Service 1] |  |  |

1. This introductory Background page is not part of the template. [↑](#footnote-ref-2)
2. Legal services or technology transfer office should be consulted regarding this clause. [↑](#footnote-ref-3)
3. Legal services or technology transfer office should be consulted regarding this clause. [↑](#footnote-ref-4)