BIOBANK SQAN

FAQ

VERSION 1.1

1. GENERAL INFORMATION

In which language should I answer the Biobank SQAN?

It is recommended to enter the answers in English to allow for a uniform directory and summary for all biobanks.

Who do I contact if I need help?

For any questions regarding the Biobank SQAN, there is a contact link in the navigation bar, or you can send an email to bbsqan@swissbiobanking.ch
In order to improve, feedback is always welcome. Do not hesitate to contact us.

How can I access the Biobank SQAN?

Each user can access the Biobank SQAN via the link: www.biobanksqan.ch
Before starting, the user must register in the upper right corner. Once the user has her own access, she can log in in the upper right corner.

Does the Biobank SQAN work on any Internet browser?

For the Biobank SQAN to work optimally, the user shall use a browser such as Chrome, Firefox or Safari (avoid using a version prior to 11 for Internet explorer).

How much time do I need to answer all the questions?

The pilot tests indicated that it takes less than two hours to complete the entire questionnaire, if all the required information is available at the time of completing the questionnaire.

Do I have to answer all the questions at once?

The 250 questions can be answered in one or more sessions. Your data are securely stored under your profile. You can access and modify your answers at any time.

Do I need to inform my current practice or the one I plan to implement?

Your answers should reflect your current practice that is already in place, not the one you plan to implement in the future. At any time, once the new practice is implemented, it is possible to update the information in the Biobank SQAN. It is recommended to update the information at least once a year.

Are there different access rights?

The first «creator» of the biobank/infrastructure automatically becomes «administrator» of the facility. She can therefore manage her access to her biobank/infrastructure alone. She can invite other users to have the role of editor (read & write) or guest (read-only). She may also propose to assign the role of administrator to another person via the admin tab.

What are the use cases of the Biobank SQAN?

When entering in the Biobank SQAN, the user can choose from the following actions:
a. **FIND** a biobank or a biobank infrastructure
   This browser allows the user to search for a biobank, a sample type or a biobank infrastructure and services. Several filters can be applied to facilitate the search.

b. **REGISTER** a new biobank or a new biobank infrastructure.
   If "**Register a new biobank / new biobank infrastructure**" has been selected, the registration process begins. The user

can access a form of 250 questions to complete the registration process.

c. **VIEW** my biobank(s) or my biobank infrastructure(s)
If "**View my biobank(s) / my biobank infrastructure(s)**" has been selected, the user is directed to the profile of his biobanks/biobank infrastructures, which have already been registered.

Three tabs are available in your biobank / biobank infrastructure profile:

> **Summary**: this is a summary of the characteristics of the biobank/biobank infrastructure
> **Dashboard**: this shows key features reflecting the practice of the biobanks registered in the Biobank SQAN and where your biobank stands regarding these aspects.
> **Quality indicators**: this is the score of the biobank/biobank infrastructure, according to SBP's minimum criteria.
> **Admin**: this tab appears if you are the administrator of the selected biobank or biobank infrastructure.

For a simple visitor (accessible to the public), only the summary is visible.

How can I change my data?

There are two options:
1) Click on «view my biobank/infrastructure» and select your biobank/infrastructure. Once you are in your summary, you will find a «Edit» button in the right corner. Click on it, you will be redirected to the questionnaire.

2) Click on "find a biobank/infrastructure". In the right corner, you can select «Show only my affiliations», select the biobank/infrastructure of your choice and edit the questionnaire by clicking the "edit" button in the right corner.

How can I save my data?

It is not mandatory to complete the entire questionnaire at once and there is no imposed order. The user must save the data each time she leaves the page by clicking on the «save» button in the upper right corner. We recommend that the user wait for a «message in a green box» indicating that the data have been correctly saved. Due to the calculation of the score, it may take a few seconds.

Do I have to answer all the questions?

No, there is no obligation and only few fields are required. Mandatory fields are marked with a red star and the field is framed in red.

What do the different colored symbols in the questionnaire represent?

The following symbols are used throughout the questionnaire, indicating the purpose for which the question will be used or considered:

R Questions used for generating the biobank regulation

V Questions used for the legal and ethical scoring (governance) corresponding to SBP Vita label

N Questions used for the process management scoring, corresponding to SBP Norma label

O Questions used for the quality assurance management scoring, corresponding to SBP Optima label

If you are interested in one of these reviews, you must at least answer the questions with the corresponding symbols.

2. QUALITY INDICATORS

On which criteria are the Biobank SQAN scores based?

The assessment of a biobank or a biobank infrastructure is based on criteria following ethical and legal requirements and Good Biobanking Practices.

The Governance scoring is based on four legal and ethical documents:
> Human Research Act (HRA), 30 September 2011
> Human Research Ordinance (HRO), 20 September 2013
> Declaration of Taipei (WMA), October 2016
> European Recommendation on research on biological materials of human origin (CM/Rec(2016)6) of 16 May 2016

The Quality scoring is based on the following guidelines and standards:
> OECD guidelines for biological resources centres, 2007
> IARC guidelines for biobanks, 2017
> ISBER recommendations for repositories, 2018
> NF S 96-900 standard for the management of biological resources centres, 2011
> ISO 9001 standard for the management of quality management system, 2015

How is the review structured?

The questions assessed by the Biobank SQAN correspond to 47 mandatory requirements divided into four categories:
> Governance management
> Process management
> Resource management
> Quality assurance management

Can any type of biobank be evaluated by the Biobank SQAN?

While any type of biobanks can evaluate their practice by completing the Biobank SQAN, the scoring on «ethical and legal requirements» has been designed to evaluate human biobanks established for research purposes, regulated by the Swiss Federal Law: the Human Research Act (HRA). Therefore, the scoring for ethical and legal requirements (Vita Label) will not appear for biobanks and biobank infrastructures that are not

regulated by the HRA. To support these biobanks, the specific requirements for diagnostic biobanks or animal biobanks are explained in the quality indicators tab.

How is the global score calculated?

The Governance management category assesses the degree of compliance with the law and the respect of biobank ethical considerations. It ensures a good management of regulatory affairs, a strong governance, including transparent informed consent documents, an ethical biobank regulation, a harmonised Material Transfer Agreement (MTA), and the training of staff.

Process and resource management categories assesses the degree of conformity of IT infrastructure, equipment monitoring, and premises control. It ensures a good management of processes, from the consent presentation to the shipment of samples, as well as the quality controls, and the validation of methods.

Quality assurance management category assesses the degree of effectiveness of a Quality Management System, including efficient documentation management system, non-conformities management, the risk management, and the implementation of appropriate preventive/corrective actions.

Is the evaluation publicly available?

No, the evaluation is confidential and is intended to help biobanks strengthen their practices by identifying areas for improvement. A personal scoring is issued with an explanation of the requirements.

Can I follow the improvement of my biobank/infrastructure over time?

Yes, through an audit trail, profile updates and changes to the Biobank SQAN questionnaire can be traced over time (QMS improvement, biobank activities). You can view it graphically in the quality indicators globally or specifically.

3. DATA SECURITY

Are my data securely archived?

The results of the questionnaires will be archived securely at Vital-IT. Upon request, SBP will be able to compile statistics on the data obtained from respondents. The confidentiality of respondents' individual responses will be strictly respected.
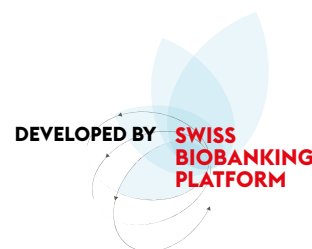
Which data are personal?

The personal login ensures confidentiality and data protection. The full questionnaire, dashboard and quality indicators (scoring related to Governance issues and Quality issues) are personal. Directory and summary of biobanks or biobank infrastructures are public data that other users can visualize.

Once my biobank is registered, which data are publicly available?

If you register your biobank/biobank infrastructure, you agree to be publicly available in SBP directory. Any users can search for your biobank/biobank infrastructure and see your details in the summary.

The summary data includes the following information:
> Biobank/biobank infrastructure details (address, responsible person contact…)
> Organisation (type of biobank, purpose, multicentricity, QMS …)
> Associated data (inclusion criteria, preanalytical and personal data collected, type and number of collected samples…)
> Sample access (access policy, sharing criteria and conditions)

DEVELOPED BY **SWISS BIOBANKING PLATFORM**

If you have any questions, you can contact us at
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