REGISTRY REGULATION [SMO]

Version: January 2022

In agreement with this Regulation, the registry commits itself to protecting the fundamental rights of participants, in particular, their dignity, autonomy, privacy, the confidentiality of their data as well as their personality rights. The registry commits itself to respecting legal requirements and ethical/professional standards and to conforming to the governance principles described in this Regulation.

SPHN Swiss Personalized Health Network
An SPHN funded project

Fondation Asile des aveugles

swissethics
This document is endorsed by Swissethics

TEMPLATE DEVELOPED BY SWISS BIOBANKING PLATFORM

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Note for users:
Proposals that may not apply to your registry are marked with an asterisk (*).
You can erase the sentence whenever applicable.

1 GENERAL PROVISIONS

1.1 SCOPE

This Regulation defines the purpose, the operational processes, and the organisation of the registry [SMO]. It describes the requirements for collecting, storing, and distributing medical images and their associated data (*i.e. imaging resources*).

1.2 APPLICABLE LAW

This Regulation relies on the applicable legal framework; in particular, the legislation on Research involving Human Beings, the cantonal legislation and the one relative to Data Protection. It follows established ethical / professional principles, including the Declaration of Taipei on ethical considerations regarding health-related databases and registries (2016).

1.3 DEFINITIONS

The terms used in this Regulation are derived from the SBP glossary, which can be found in Appendix I.

1.4 GLOSSARY

Cst	Federal Constitution of the Swiss Confederation of 18 April 1999; RS 101
CC	Swiss Civil Code of 10 December 1907; RS 210
DCC	Data Coordination Centre
DPA	Data Processing Agreement
ExCo	Executive committee
FAA	Fondation Asile des Aveugles
KISANO	Certified workflow software solution for the secure transfer of health data
HRA	Federal Act on Research involving Human Beings of 30 September 2011; RS 810.30
HRO	Ordinance on Human Research with the Exception of Clinical Trials of 20 September 2013; RS 810.301
MIDATA	A secure platform for citizens to improve traceability and accessibility to their health related data
NMT	Network management team
PACS	Picture Archiving and Communication System
RMT	Registry management team
SAB	Scientific Advisory Board
SIB	Swiss Institute of Bioinformatics
SBP	Swiss Biobanking Platform
SOIN	Swiss Ophthalmic Imaging Network
SPHN	Swiss Personalized Health Network

2 DESCRIPTION OF THE REGISTRY

2.1 REGISTRY PURPOSE

1. This registry is a repository of medical images, primarily pertaining to ocular diseases.

2. The registry is currently monocentric and its primary site is FAA with secondary sites currently being developed at Hôpital Universitaire de Genève (HUG) and Luzerner Kantonsspital (LUKS). The tele-expertise plateforme creates an additional data flow from 3rd parties (*i.e. private ophthlamology practices*).

2.2 REGISTRY SCOPE

1. This registry was established for research purposes, in particular, improving diagnostics, developing decision support tools and assessing therapeutic interventions.

2. This registry is intended for the SOIN project group, an SPHN funded project of which the main users are from the named 3 collaborating hospitals.

2.3 NATURE OF THE IMAGING RESOURCES

1. Information related to imaging resources stored in the registry is given in Appendix II.

2. These imaging resources are collected from outpatients, inpatients, volunteers and vulnerable persons.

2.4 STORAGE DURATION

The imaging resources stored in the registry are kept for a period of at least the lifetime of the project (project funded until 31.08.2023). There is no fixed duration, subsequent funding will established in due course.

3 GOVERNANCE

3.1 ESTABLISHMENT OF THE REGISTRY

The registry SOIN was founded on the 01.06.2020.

3.2 LEGAL STATUS

The registry is bound to Fondation Asile des Aveugles (FAA) and has no independent legal personality.

3.3 STRUCTURE

1. The responsible person(s) of the registry are identified and listed in Appendix III.

3.4 CONSENT

1. The processing of imaging resources, including their collection, storage, transfer and use, are based on a general consent including a dynamic consent management system that assures the rapid and automated processes to ensure the proper use of these imaging resources, with respect to participants' wishes.
   Such consent must be freely given, and be preceded by appropriate information. The consent status given by the participant has to be documented and the consent form has to be archived. The consent template is provided in Appendix IV.

2. Consent can be revoked at any time and without justification by the participant. Such a revocation does not entail any prejudice especially regarding the medical care of the participant. Revocation modalities have been described in the consent form. Should the participants require any further information, they may contact the registry as per the provisions of Chapter 7 « Communication ».

3. Upon revocation, all images and medical data of the participant stored in the registry for research purposes could not be used from this point onwards. In this case, these data will be made anonymous or deleted and inaccessible to further studies.
   Note: Revocation is only applicable to future use of the imaging resources for research purposes. Revocation will not affect the lawfulness of processing based on Consent before its withdrawal. Accordingly, results obtained prior the revocation and their evaluations are not affected by this decision.

4. In the cases of no response from the patient after a period of 3 months following the 2nd invitation to manifest the position on the reuse of their data, researchers may use this basis to apply to the responsible ethics committee, for the authorization of the use of these data for research purposes under the conditions provided in article 34 let. b of the HRA.
5. In the case that the person has died prior to consent being requested/ provided the researchers may use this basis to

apply to the responsible ethics committee, for the authorization of the use of these data for research purposes under the conditions provided in article 34 let. b of the HRA.

3.5 MINORS AND ADULTS INCAPABLE OF JUDGEMENT

1. In the case of a legal minor consent is obtained from his/her legal representative up to 14 years old. For minors from 14 to 17 years old, consent can be obtained directly from the minor. An oral information will be provided by a health professional, as well as an adapted written information. In both cases, a new consent form will be sent after the minor reaches adulthood. In the case of no response, the consent status from minors who signed the form themselves remains valid.

2. In the case of an adult participant who is incapable of judgment or in a state of health that makes him/her incapable of judgment (and in the absence of a document attesting to his/her consent before his/her loss of judgment), consent is obtained from his/her legal representative. A patient in emergency situation as described in the HRA (art. 30) will not be included.

3. In all cases, the status of a legal minor or adult incapable of judgment is documented to facilitate the recollection of his/her consent when acquiring or recovering his/her capacity to consent.

3.6 CONFIDENTIALITY MEASURES

1. Imaging resources are stored as coded.

2. Coding is performed according to an automated secured process within the hospital infrastructure by the KISANO software (cf Appendix IX). The key is kept in a secure location on an encrypted hospital server, accessible by an unidirectional automated, logged process
    1. by this software during encryption process to store new encoded key entry.
    2. by this software following the modification of consent status in order to allow the dynamic patient consent management.
    3. by the key keeper in the case of fortuitous discoveries.

    The key keeper is not involved in any research project using the imaging resources of the registry.

3. When images and/or associated data are transferred to the research environment which fulfils the access conditions to the registry resources (*cf. section 5.1 – Terms of access*), no identifying information from the participant is given (*i.e. all data and images are coded*).

3.7 ACCESS AND TRANSFER

The registry follows clear rules governing the access and the transfer of imaging resources in agreement with the consent of the participant. These rules are described in Chapter 5 « Granting access to imaging resources ».

3.8 PARTICIPANT'S RIGHT TO INFORMATION

3.8.1 Right to consult

The participant can consult all information concerning him/her stored in the registry to correct or remove them as necessary. He/she can also be informed of what has been done with his/her imaging resources. The participant can contact the registry as per the provisions of Chapter 7 « Communication ».

3.8.2 Return of results

1. A participant has the right to be informed about research results pertaining to his/her health in accordance with his/her consent and the applicable ethical standards. If returned, these results should meet at least the following criteria: analytical validity[1], clinical significance[2], and be actionable[3].

2. A participant is informed of the return of results policy, which includes the type of results that will be returned to participants (see Appendix V).

3. The decision to return individual research results has to be taken by an expert committee on a case-by-case basis. In all cases, the right of not to know shall be preserved.

3.8.3 Registry activities

1. The registry communicates relevant information concerning its organisation, operational processes, and activities via its webpage of the FAA website.
2. A follow-up table of research projects carried out with the imaging resources of the registry is available in Appendix VI.

3.9 FINANCE

The registry is funded by public and private funds from SPHN and FAA for an initial duration of 2 years. After this period funds will most likely be provided primarily by the FAA and by the different collaborating institutions. Funding covers the lifetime of the imaging resources stored in the registry.

3.10 DISSOLUTION OF THE REGISTRY

1. In compliance with the consent of the participant, in the event of the end of its activities and/or dissolution of the registry, the imaging resources stored in the registry are either transferred and integrated into another registry with an equivalent level of protection or destroyed.

2. The destruction rules of imaging data are described in Appendix VII.

4 OPERATIONAL PROCEDURES

4.1 GENERAL PRINCIPLE

The collection, storage, and use of images and related data are carried out according to the applicable legislation and ethical/professional standards and according to the provisions of the given consent.

4.2 RECRUITEMENT

All persons involved in the recruitment process will undergo mandatory training on how to / who will present and explain the general consent form.

All adults who solicit the services of the FAA (or the parents or caregivers) will receive in written format the information sheet and general consent form via post before their visit when feasible or up to 6 months after their visit when it was not possible to send prior to their consultation.

The signed consent form can be returned via post or can handed over at the time of admission, or with the secretary of the concerned unit or the care provider.

If no signed consent form has been received after 6 weeks and up to six months after, a reminder will be sent by post.

All persons can speak directly to their care provider about these documents and research projects performed at the

[1] They accurately and reliably identify a particular clinical characteristic.

[2] They identify a significant risk of a potentially serious health problem.

[3] There is a therapeutic or preventive intervention or other possible actions that have the potential to change the course of this disease or condition.

FAA during their visit at the unit where the services of the FAA will be dispensed.

A telephone service will be available to participants. The members of the management committee of the clinical investigation centre will assure this service during office hours. A communication form will also be available on the FAA website.

4.3 IMAGES AND CLINICAL DATA COLLECTION AND THEIR MANAGEMENT

All data captured during the deliverance of these services of consenting persons will be added to the SMO registry for the reutilisation in the defined and authorised projects listed in annexe VI.

1. The registry is responsible for ensuring that medical images and/or data are associated with a valid consent.

2. The collection of images and data will not give rise to any financial compensation or any other material advantage.

4.4 STORAGE OF IMAGES & ASSOCIATED CLINICAL DATA

Access to the facilities where images and clinical data are kept is secured and controlled with the following measures: Dedicated double identification of preapproved research user account to the SIB/BiomedIT SOIN research space. Within this research space researchers have only access to data preapproved by the data management committee and as described in the CER-VD (or other responsible ethics committees) approved research protocol.

4.4.1 Images

Images are stored in a PACS system in the SIB/BiomedIT SOIN research space. Access to specific images is governed by the data management software (Slims)

4.4.2 Associated Data

Personal data including health-related data are automatically extracted from the clinical data warehouses and encoded with the hospital infrastructure and transported and imported into the SIB/BiomedIT SOIN research space by the ISO certified KISANO workflow manager.

4.5 UNFORESEEN DISCOVERIES

In case of unforeseen discovery, the RMT will be notified by the researcher. This notification will include the relevant information on the type of discovery and the unique patient identifier in the SIB SOIN dedicated space. This information will be communicated to the medical director, who will determine if the discovery justifies communication to the patient/treating clinician. In the case where this action is deemed necessary by the medical director; the unique identifier, with instruction on the action to be taken, will be communicated to the key holder (*i.e. the Lead of the Clinical Investigation Centre at the FAA*), who will perform this action within 30 days of receiving the communication. The security system set up does not allow routine access to the key and this process can only be done manually by the key keeper. The participant will then be contacted and asked if they wish to be informed.

5 GRANTING ACCESS TO SOIN RESEARCH SPACE

5.1 AVAILABILITY REQUESTS

1. FAA data manager is granted access to anonymized data in order to inform researchers of data availability before engaging in a research protocol according to specific criteria.

2. Researchers have access to the code book describing the available data via the federal storage infrastructure (BioMedIT). Process for accessing and consolidating at a federal level is governed by the DCC. The de-identified, encoded and encrypted data are provided to a linked node accessible by authorized project researchers located anywhere in Switzerland, who are granted an access to a secure computing environment.

5.2 TERMS OF ACCESS

1. The access of imaging resources is validated by the data management committee according to the following criteria:
    a. Origin of the request (public/private)
    b. Scientific merit of the proposed study
    c. Eligibility of the collaborator
    d. Acceptance of FAIR principles
    e. Open-access publication

   The detailed process for requesting and obtaining imaging resources is described in Appendix VIII.

2. The researcher, who has been authorized to access the registry data, agrees not to attempt to re-identify the participants, except under the conditions outlined in Article 27 of the HRO[4].

3. The registry will only grant access to its resources for projects that have been approved by the responsible ethics committee or equivalent authority.

5.3 PROCESSING AND TRANSFERING OF DATA

1. The only transfer of images and associated clinical data are regulated and documented in the attached data processing agreement (DPA), which follows the DPA template of Data Coordination Centre of the SPHN governing body.

2. The DPA establishes the obligations and responsibilities of both parties concerning the processing of a registry data before transfer. Personal data will remain exclusively in SIB/BiomedIT SOIN research space, and are never transferred to third parties. The obligations, which have not been expressly attributed to the SIB by the DPA, remain under the responsibility and the management of the registry. In all cases, the registry remains responsible towards participants within the limits of its accountability.

3. For research projects carried out outside of Switzerland, the recipient will have access to the secure SIB/BiomedIT SOIN research space, which guarantees that the same standards concerning the data protection and the rights of participants have been fulfilled.

4. If a financial contribution is foreseen for access to registry resources, the fees cover registry activities, data management and infrastructure costs.

6 QUALITY

1. To access the project space the researchers must have completed the security training of the SIB. In addition, they must be recognised by the SOIN RMT and access must be granted to this space per user. Within this space, the access to data is regulated via the Slims interface and a login system which ensure proper control of access rights per user (*i.e. role and study*). Access rights are attributed based on the criteria described in associated research protocol. Combined, these 3 levels of security minimise the risk of any unauthorized person accessing the registry data.

[4] a) breaking the code is necessary to avert an immediate risk to the health of the person concerned; b) a legal basis exists for breaking the code; or c) breaking the code is necessary to guarantee the rights of the person concerned, and in particular the right to revoke consent.

2. All data are coded, encrypted and saved in a purpose built secure storage space at the BiomedIT. Researchers are only granted the right to process and analyse data but are not able to copy, modify or delete any patient information.

3. The Slims application logs all data utilisation undertaken by the user.

4. The registry collaborates with the MIDATA, KISANO & the SIB for the management of its activities.
Note: Copy of relevant DPAs are in appendix

7 COMMUNICATION

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8 APPENDICES

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REVISION HISTORY

Version	Effective Date	Details of revision
1.0	20.06.2020	Initial Release
1.1	09.04.2021	Text addition
1.2	02.07.2021	Text addition
1.3	21.01.2022	Text addition

APPENDIX I
Definitions

ASSOCIATED DATA

Personal and/or preanalytical data.

ANONYMIZATION

The irreversible removal of the link between the imaging material and/or associated data and the participant, so that no specific participant can be reidentified.

CODING

The reversible removal of the link between the images and/or associated data and the participant, so that a specific participant can only be reidentified through a key.

DATABASE

An organized collection of data.

DATA PROCESSING AGREEMENT

A legally binding agreement that governs the transfer of data between two parties, intended for research purpose. It defines the rights and obligations of the provider (FAA) and recipient (SIB) with respect to the processing of the data in the SIB/BiomedIT SOIN research space and other related issues.

DYNAMIC CONSENT

A consent mechanism where consent is modifiable by the participant independently via a dedicated mobile application that induces a cascade of access right modifications that immediately implements the request of the participant.

GENERAL CONSENT

A form of informed consent given by a participant to allow collection, storage, further use and transfer of his/her images and/or associated data collected for future not yet defined research projects.

GOVERNANCE

Registry Governance includes the structures and the management rules set in accordance with the registry purpose(s) to ensure its compliance with the applicable legal and ethical requirements.

HEALTH-RELATED DATA

Data related to the health or disease of a participant, including genetic data (e.g. clinical, epidemiological, socio-economic data, etc.).

IMAGES

Any images obtained or derived from a consenting participant.

IMAGING RESOURCES

Images and associated data.

INFORMED CONSENT

Voluntary and informed expression of the free will of a participant or his/her legal representative to allow the collection, storage, use and transfer of his/her images and/or associated data for research purposes.

KEY

The information which allows the coding to be undone, so that the images and/or associated data can be linked back to a specific participant.

PARTICIPANT

Living or deceased person who provides his/her images and/or associated data to the registry.

PREANALYTICAL DATA

Data related to the imaging, processing, storage and usage of images (e.g. image date /time, scan pattern, resolution, device, etc.).

PERSONAL DATA

All information relating to an identified or identifiable person, including health-related data.

REGISTRY

An organized entity responsible for the governance and the management of images and associated clinical data.

REGISTRY INFRASTRUCTURE

SIB/BiomedIT SOIN research space that offers services to the registry.

SPECIFIC CONSENT

A form of informed consent given by a participant concerning the collection and storage of his/her images and/or associated data as well as their use and transfer for a defined/specific research project.

WITHDRAWAL

Withdrawal of previously given consent.

(Consequences of withdrawal are defined in consent form and should be disclosed with the concerned participant during the consent process.)

APPENDIX II
Imaging Resources of the registry

Data flow

Images

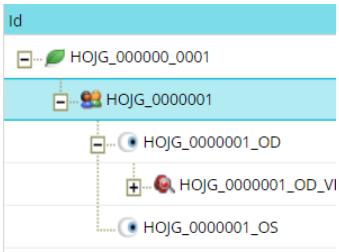
- Image type 1: Fundus photo; origin: human
- Image type 2: Ocular Coherence tomography; origin: human
- Image type 3: Ocular Coherence tomography angiography; origin: human
- Image type 4: Ocular fluorescein angiography; origin: human
- Image type 5: Ocular ICG angiography; origin: human
- Image type 6: Retinal Topography; origin: human
- Image type 7: Corneal Topography; origin: human
- Image type 8: Corneal Aberometry; origin: human
- Image type 9: Slit lamp photo; origin: human
- Image type 10: Visual field; origin: human
- Image type 11: Ocular UBM; origin: human
- Image type 12: Endothelial microscope photo: origin: human
- Image type 13: Adaptive optics enhanced scanning laser ophthalmoscope: origin: human
- Image type 14: FMRI; origin: human
- Image type 15: MRI; origin : human
- Image type 16: CT scan; origin: human
- Image type 17: PET scan; origin: human
- Image type 18: Hybrid PET/CT scan; origin: human
- Image type 19: Hybrid PET/MRI; origin: human
- Image type 20: SPECT; origin: human

Inclusion criteria: all patients that visit a participating center and have given consent for the reutilization of their data

Patient data: age, gender, ethnic origin, code*

Consent status: Active/Withdrawn but conserved

Health related data (list is not exhaustive)



Per patient

Systemic diseases, current vital status, date of death.

Per eye

Iris color, corneal curvature, biometry of eye, retinal pigmentation.

Per Visit:

Date of visit, available image locations, visual acuity measures, intraocular pressure, biomarkers for retinal, corneal, iridien, choroidal, conjunctival or other related diseases, treatments received.

Per study

Enrolled study status: Y/N

These images resources are collected from outpatients, inpatients, volunteers & vulnerable persons.

* For images stored in the registry in a coded form, the key is held by coordinator of the clinical investigation center at the local institution.

APPENDIX III
Governance structures

The setup of this registry support the running of the SPHN driver project SOIN, as such the governance of the registry is currently a reflection of the governance structure of the SOIN project

The Registry Management Team (RMT) is composed of the Medical Director of FAA (Pr. T. J. Wolfensberger), the Research director HOJG (Pr. R Schlingemann) and SOIN project lead (Dr C Bergin), the deputy CEO of the HOJG/FAA (Mr J-P. Klumpp). The RMT will meet on a quarterly basis to discuss the current progress of SOIN project and registry and to address and solve putative problems encountered.

The Executive Committee (ExCo). Twice a year, an extended RMT will convene with the directors of each participating ophthalmological service (University of Geneva, the Cantonal Hospital of Lucerne and Jules-Gonin Eye Hospital).

A Scientific Advisory Board (SAB), a multi-disciplinary international board of specialists with expertise in broad areas of research and technology will be constituted to review and advise on progress and further research proposals, as well as on the management of R&D highlighting critical issues and emerging global trends in additional basic and investigator-led research.

The ExCo will then cooperate at network level with respect to the management of all matters relating to the protection and exploitation of all knowledge arising from the Project and of the intellectual property rights pertaining to such knowledge, with the view to promote innovation. The ExCo will provide: advice, expertise and support for:

- the assessment of intellectual property arising from the network,
- Intellectual property law and regulation,
- Developing and exploiting the intellectual property, and the best strategy for exploitation and innovation (licensing, start-up).

Further, the RMT will develop and propose to the partner's guidelines to establish an integrated support infrastructure to scientists of the Network with regard to intellectual property matters and a policy for licensing and commercialization of all knowledge, with the view to foster innovation.

The operational direction of the registry is assured by:
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APPENDIX IV
Consent Template(s)

Please see attached information and consent form

APPENDIX V
Return of research results to participants

The registry informs the participants of the following results: general outcome of the research project(s), incidental findings according to the following conditions and procedures:

General outcome of the research project are published on the SOIN webpage via the news section.

Incidental findings that follow the criteria given in the information sheet and as described under point 3.8.2 of the registry regulation shall be returned to the patient, to achieve this key holder will have access to the secure location with the necessary information to re-identify the participant.

The SOIN webpage will provide to the general public an overview of the general results of the registry including the publication list.

APPENDIX VI
Follow-up table of research projects carried out with the images & clinical information

Approval Date	BASEC ID	Project Title	Multi/ monocentric	Involved Sites	Principal Investigator	Type of used resources	Risk Cat.	Project Status
13.12.2021	21021-01612	Impact of Covid-19 pandemic on retinal diseases' incidence and management	Monocentric	HOJG	Prof. Chiara Eandi	Health data, including eye imaging	A	En cours

APPENDIX VII
Rules on the destruction of images in the registry

When a participant decides to revoke consent for the reutilization of their health data and medical images via the patient portal (soin.health), a cascade of status events is triggered.

The cascade of status modifications passes from the SOIN mobile application to login manager MiDATA.coop, whom transmit this information securely to the KISANO workflow manager which resides in the clinical environment. Within the clinical environment, it follows the identical encoding pathway as the original data package, in order to have the same identifiers as the original dataset and finally is transmitted in to the Biomed IT infrastructure. Once within the infrastructure, the consent status will be transferred from the KISANO connector to the SLIMs software.

In the case that the data has not previously been used for research, the data set will be queued for deletion, these imaging files and related health data will be systematically deleted from the registry no later than 1 week after the consent status modification.

In the case where the dataset has been previously used in research, it will be conserved but the status will not permit its further utilization.

APPENDIX VIII
Detailed process for requesting and obtaining access to imaging resources

The SOIN health registry is administered by a data management team who has access to all data and whom are responsible for the configuration of access right in this research space. The Slims software installed in the SOIN registry space at the SIB, allows a fine grade control over access rights (by user, groups or administrator only) and role (level of access and available modules). Encoded data will be available to researchers via a reliable and protected process (see section 5). Researchers can ask for information about available data to the data manager (see 5.1). If the available data fills the requirements and the SOIN registry governance committee grants access (as described below), researchers will be required to obtain approbation from the CER-VD. Once obtained, the approved protocol will be provided to the SOIN registry data management team. In the protocol, each researchers role is described, thus the required user accounts will be created with the appropriate access rights (see 6.1). The inclusion and exclusion criteria will be used to dynamically filter available data and permit the researcher to access only the data within the predefined study criteria. The user accounts will remain active for the duration of study as described in the study protocol. Once research is published, a link will be displayed on the SOIN health registry website, along news and feedback updates.

Step 1: Submission of request:

The project request form can be downloaded from the SOIN webpage; this document requires the following information:

a. Project description
b. Partner list and letter of collaboration
c. Requested users list
d. Institute specific or network-wide

Step 2: Review by PMT of network-wide

a. Verification of completion
b. Verification of accuracy de content
c. Organisation of review by SAB
d. Shared with ExCo member
    i. Non contested→ approved status
    ii. Contested → Agenda on the ExCo meeting

Step 2: Review by ExCo members + SOIN responsible of Institute project

a. Verification of completion
b. Verification of veracity de content
c. Organisation of review by SAB
d. Shared with ExCo member
    i. Non contested→ approved status
    ii. Contested → Agenda on the ExCo meeting

Step 3: Review by ExCo

a. Discussion
    i. Approved status
    ii. Rejected status

Step 4: informing the project applicant

a. Rejected → Letter of rejection
b. Approved → Inform application of success, request CER-VD approbation to be established

Step 5: Reception of approved protocol (swiss ethics) from project applicant

i. Configure Study in SLIMs within research space according to study design of the study protocol
ii. Configure User account: including Type, Role and Group according to Data Management Plan (DMP) of the study protocol
iii. Validate SOIN project space ID with BiomedID/SIB
iv. Send letter confirmation of completion & invitation to create EduID account/login
v. Update APPENDIX VI

APPENDIX IX
DPA SIB (in PDF attachement)