Template CONSORTIUM AGREEMENT

INCLUDING DATA TRANSFER AND USE AGREEMENT AND DATA TRANSFER AND PROCESSING AGREEMENT [if applicable: AND MATERIAL TRANSFER AGREEMENT]

**Colour code:**

Grey highlight = to be completed according to the specifics of the project

Yellow highlight = options to be selected, deleted or amended as preferred by the Parties

Green highlight = guidance information, to be deleted at the end

*The Consortium Agreement (CA) regulates the general principles of a collaboration between the parties to a research project, such as governance, publications, intellectual property, financial conditions It constitutes a framework research agreement for multicentre research projects.*

*The Data Transfer and Use Agreement (DTUA) completes the conditions under which a data "Provider" (e.g. a hospital) agrees to disclose personal data to a data "Recipient" (e.g. a university), as provided in Schedule 3. The Provider and the Recipient jointly determine the purpose and means of the processing within the framework of the research project. They both act as "Data Controller" (as opposed to "Data Processor").*

*The Controllers might decide to subcontract the secure transfer and hosting of the data to a third party (the “Processor”), for example to one or more BioMedIT node(s). The relationship between Controllers and Processor must be regulated in a specific agreement: a Data Transfer and Processing Agreement (DTPA), as provided in Annex III. More information about BioMedIT is available on the webpage* [*BioMedIT.ch*](https://www.biomedit.ch/)

*Applicable law may include the requirements of the Human Research Act (such as ethical approval and data reuse conditions such as consent) and the data protection legislation (federal/cantonal).*

*The Swiss Biobanking Platform (****SBP****) provides MTA templates for the Swiss research community compatible with the SPHN legal agreements:* [*https://swissbiobanking.ch/documents/.Delete*](https://swissbiobanking.ch/documents/.Delete) *MTA in the header if no biological material is used in this project.*

***Please note that this template should be reviewed and approved by your legal department, in accordance with the internal rules of your institution.***

Change history

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Version Nr | Version date | Modified without version change | Description, comments | Control |
| 1.0 | 29.03.2019 |  | Initial DTUA version published | NA |
| 2.0 | 20.11.2021 |  | DTUA V2.0 with included DTPA incorporated as Schedule 3 in the Consortium Agreement; Minimal security requirements included, GDPR compliance considered | JM |
| 3.0 | 01.06.2021 |  | Colour code instructions added; Change history added; 11.4. and X.3 ‘Counterparts and Electronic form’ wording adapted; 11.8 Amendment wording adapted; V.2 ‘Third party rights’ renamed in ‘Data subject rights’, DTPAVII.1c Regional Node’s policies changed; DTPAVIII.1 Liability wording changed; links updated | JM |
| 3.1 | 23.01.2023 |  | Security measures amendedDTUA III.3 (Security) and III.9 (Download of data) amended; Annex II (minimal security requirements) deleted.DTPA III. 2 (Scope), III.5 (Payment of fees), IV.3.1 (Security), IX.5 (Further needs) amended; Annex II (minimal security requirements) deleted. | FE/JM/MH |
| 4.0 | 01.12.2025 |  | Overall revision 1 Scope; 3 Governance; 6 Data and Biological Material; 7 Intellectual Property; 8 Publication; 10 Warranties and Indemnification; Schedule 3 DTUA; Schedule 5 and 6 added | MH/AS/JM/JK/ME |

**Please remove the ‘Colour code instructions’, the green guidance text**

**and the table ‘Change history’** 

CONSORTIUM AGREEMENT

INCLUDING DATA TRANSFER AND USE AGREEMENT AND DATA TRANSFER AND PROCESSING AGREEMENT [if applicable: AND MATERIAL TRANSFER AGREEMENT]

dated [date]

To form a multicenter research consortium for the “[Project Name]” Project (the **Project**).

among

|  |  |
| --- | --- |
| [Name, abbreviation, address] | (**Party01**) |
| [Name, abbreviation, address] | (**Party02**) |
| [Name, abbreviation, address] | (**Party03**) |
| [Name, abbreviation, address] | (**Party04**) |
| [Name, abbreviation, address] | (**Party05**) |
| [Name, abbreviation, address] | (**Party06**) |
| [Name, abbreviation, address] | (**Party07**) |
| [Name, abbreviation, address] | (**Party08**) |

(each a **Party**, together with any other entity accessing to this Consortium Agreement, the **Parties** and/or the **Consortium**)

Add all parties involved: Principal Investigators’ home institutions and institutions required to exchange data for the project (e.g. University Hospital Basel (USB), Spitalstrasse 21, Petersgraben 4, CH - 4031 Basel)

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Schedule 5 and 6 are optional. Delete if not relevant for this project.

# Scope

## **Scope**. This agreement together with its schedules (the **Consortium Agreement**) governs the Parties’ collaboration and their rights and obligations in relation to the Project, in accordance with the project application, description and funding decision referenced in [Schedule 1](#Schedule1) (the **Project Description**). Unless defined in this Consortium Agreement, capitalized terms shall have the meaning described in the applicable law.

## **Hierarchy**. In the event of any inconsistency or contradiction between the terms and conditions set forth in this Consortium Agreement and those outlined in any schedule, the terms and conditions of this Consortium Agreement shall prevail, unless a specific provision within the relevant schedule expressly provides for an exception to a particular clause of this Consortium Agreement.

## **No Agency**. Except for 3.2.3 letter […] and […], this Consortium Agreement does not create any agency or similar relationship between the Parties. Nothing in this Consortium Agreement shall be construed as authorizing any Party to represent or act on behalf of the other Party or Parties.

# General Undertakings of the Parties

## **In General**. Each Party commits to making reasonable efforts to promptly, actively and punctually fulfill all its obligations under this Consortium Agreement – including the tasks assigned to it in the Project Description (the **Allocated Work**) – in compliance with:

* + 1. its institutions’ policies, including internal data governance rules and processes;
		2. the Project Description;
		3. the rules of the Swiss Personalized Health Network (**SPHN**) and in particular the “Funding Regulations” including the “General implementation regulations for the Funding Regulation“ referenced in the Project Description;
		4. the ethical approval or waiver, delivered by the competent ethics committee for the purpose of the Project, and
		5. all applicable laws and regulations, including data protection and human research laws, and ethical guidelines.

*Delete the highlighted clauses if not applicable.*

## **Resources**. Each Party shall ensure the availability and appropriate allocation of adequate resources necessary to carry out such tasks in a timely manner.

## **Collaboration**. The Parties shall promptly provide each other with all documents, objects, technical aids, and resources required to carry out the Project. The Parties will coordinate the performance of the Project and will support each other to the best of their abilities.

## **Subcontracting**. If necessary to implement the Project, the Parties may engage subcontractors to carry out limited parts of their Allocated Works (**Subcontractors**). The subcontracting Party shall enter with the Subcontractor into a written agreement containing terms which, at a minimum, are consistent with the terms of this Consortium Agreement and shall not conflict with the terms of this Consortium Agreement. The subcontracting Party shall be liable for the acts and omissions of its Subcontractors as if those acts and omissions had been performed by such Party and, as such, shall remain responsible for the implementation of this Consortium Agreement. Access by Subcontractors to Data and Biological Material shall be governed by Clause 6.4 below.

*Delete the highlighted text if biological material is not used in this project. Note that the same text has to be deleted throughout the template.*

# Governance

## **Governance Structure. The governance structure for the Project is as follows**:

* + 1. The project leader (**Project Leader**), referenced in [Schedule 1](#Schedule1), is responsible for the practical implementation of the Project and has the responsibilities specified in this Consortium Agreement and in the Project Description.
		2. The sponsor(s) (**Sponsor**), referenced in [Schedule 1](#Schedule1), is responsible for the Project’s initiation, management and funding, in accordance with this Consortium Agreement, and to the extend applicable, the Human Research Act and its Ordinances. The Sponsor is also liable towards the participants (within the meaning of the Human Research Act) for any damage suffered by them in connection with the Project.
		3. The investigators of the Project (**Investigators**), referenced in [Schedule 1](#Schedule1), are responsible for the day-to-day supervision of the Project in accordance with the work packages and tasks defined by the Project Description. They shall regularly meet, in person or virtually with the Sponsor and Project Leader to discuss the progress of the Project.
		4. The executive board of the Consortium (**Executive Board**) is the highest decision-making body which takes all strategic decisions on behalf of the Parties, supervises activities carried out by the Consortium, and oversees the resolution of any disputes between the Parties relating to the execution of the Project.
		5. The scientific board of the Consortium (**Scientific Board**) serves as an advisory group providing scientific support for the Project.

*Delete letter e) if no scientific board is established. Note, you should also delete the corresponding clauses below regarding members, quorums, voting rules, meetings and minutes and composition in Schedule 2.*

* + 1. Other bodies, if any, as set up by the Executive Board.

*Delete letter f) if no other bodies are established. Note that the corresponding clauses below regarding members, quorums, voting rules, meetings and minutes should be added, if other bodies are formed.*

## **Executive Board Rules**

### Members (EB Members). The Executive Board consists of one representative of each Party. The composition of the Executive Board at the time of signature of the Consortium Agreement is described in [Schedule 2](#Schedule2). EB Members shall appoint one person to chair the meetings (**EB Chairperson**) for a [year] renewable mandate, with a vote pursuant to Clause 3.2.3. The initial EB Chairperson is indicated in Schedule 2. Each Party designates its EB Member and may change its EB Member by informing the Executive Board. The list of EB Members set out in [Schedule 2](#Schedule2) shall be updated accordingly, it being specified that it does not require any formal amendment of this Consortium Agreement within the meaning of Clause 11.8.

*Delete highlighted text if the mandate should not be renewable.*

### Quorum and participation. The quorum for any Executive Board meeting shall be [two-thirds] of its membership, including the EB Chairperson at the time of the meeting. Investigators of the Project (who are not EB Members) may attend EB meetings in an advisory capacity, providing expertise and insights, but shall not have any voting rights.

*Delete the highlighted text if no-EB Members are not allowed to participate in the meetings.*

### Voting Rules. Each EB Member shall have one vote. The EB Members shall act in good faith to cooperate and seek consensus with respect to issues to be decided. Decisions of the Executive Board, depending on the subject matter, are governed by the following voting rules:

* In principle, decisions are taken by a simple majority vote.
* If the number of votes for and against a proposal are equal, the EB Chairperson has a casting vote;
* For certain specific decisions, a unanimous vote is required, it being specified that any Party that failed to attend the Executive Board meeting is set a [two weeks] deadline to communicate its decision on the amendment, failing which it will be deemed to have accepted the decision of the Executive Board.
* All Executive Board decisions may be taken via videoconference, telephone conference, or electronic mail. The subject of the decision must be submitted to the EB Chairperson, who will handle the decision-making procedure. Decisions taken in this way must then be recorded in the minutes of the next Executive Board Meeting, indicating their subject, the result of the vote and their effective date.

*Delete or adapt the highlighted text if you wish to specify different rules.*

### In application of the above voting rules, the following chart presents a non-exhaustive list of matters on which the Executive Board must decide, **in principle by a simple majority vote and, when expressly indicated, by a two-third or unanimous vote**.

*The SPHN Initiative encourages collaborative decision-making and consensus-seeking among parties to the consortium. While a qualified majority or unanimous voting rule may be chosen for certain decisions, opting for unanimity should be weighed against potential challenges, particularly in larger projects where it could hinder progress. In the table below, you can choose the option that best suits your preferences as the voting rule (simple majority, 2/3rd majority, or unanimity).*

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Responsibility** | **Voting Rule***Select an option in this column for each responsibility* | **CA Clause** |
|  | manage, supervise, and coordinate relations between the Parties under this Consortium Agreement | Simple majority/2/3rd *majority/unanimity*  | 3.1 let. d) |
|  | evaluate the progress and activities to achieve project objectives and results | Simple majority/2/3rd majority/unanimity | 3.1 let. d) |
|  | define the organization, structure and operating mode of the Project | Simple majority/2/3rd majority/unanimity | 3.1 let. d) |
|  | identify and resolve issues arising between the Parties that cannot be resolved by the Parties themselves | Simple majority/2/3rd majority/unanimity | 3.1 let. d) |
|  | appoint the Chairperson of the Executive Board  | Simple majority/2/3rd majority/unanimity | 3.2.1 |
|  | *Delete this letter if there is no Non-disclosure Agreement (NDA) clause for SB Members* issue a template NDA for members of the Scientific Board | simple majority/2/3rd majority/unanimity | 3.3.3 |
|  | amend the list of SB Members | Simple majority/2/3rd majority/unanimity | 3.3.1 |
|  | amend the Project Description  | Simple majority/2/3rd majority/unanimity | 3.7 |
|  | decide on requests for Reuse of Data during the Consortium Agreement and enter into a Data sharing agreement, acting through the EB Chairperson | Simple majority/2/3rd majority/unanimity | 6.4 |
|  | establish a strategy for the Reuse of Data after the expiration of the Consortium Agreement and decide on the fate of the Data after the expiration of the Consortium Agreement | Simple majority/2/3rd majority/unanimity | 6.5 |
|  | *Delete this letter if there is no Background IP List* decide on the Parties’ requests for modification of Background IP from the Background IP list ([Schedule 6](#Schedule6)) | Simple majority/2/3rd majority/unanimity | 7.3.2 |
|  | decide on an extension of the duration of this Consortium Agreement | Simple majority/2/3rd majority/unanimity | 9.1 |
|  | terminate this Consortium Agreement | Simple majority/2/3rd majority/unanimity | 9.1 |
|  | decide on the admission of new Parties | Simple majority/2/3rd majority/unanimity | 9.2 |
|  | decide on the exclusion of a Party  | Simple majority/2/3rd majority/unanimity | 9.4 |

### Executive Board meetings. The Executive Board shall meet at least [quarterly]. Meetings may be held in person, by telephone, or by video conference. Meetings will be convened with at least [one month] written notice in advance by the EB Chairperson. Any item may be added to the agenda at the request of any EB Member to the EB Chairperson no later than [15 days] prior to the meeting date. An agenda will be provided by the EB Chairperson [10 days] before the meeting.

### Minutes of Executive Board meetings. The Parties shall agree upon which EB Member acts as secretary and prepares the minutes of a particular meeting at such meeting. The designated EB Member shall send the minutes to the EB members within [5 days] after the meeting. Any EB Member that was present to that meeting may object to the minutes, within [10 days] of receipt of the minutes, by notice to the EB Chairperson. In case of objection, the EB Chairperson shall try to resolve the objection, preferably by telephone or videoconference. Once the objection resolved and if the minutes have been amended, they shall be circulated to the Parties and a new [10 days] objection period shall start.

## **Scientific Board Rules**

### Members. The Scientific Board consists of investigators involved in the Project and selected experts in the relevant fields (**SB Members**). The composition of the Scientific Board at the time of signature of this Consortium Agreement is described in [Schedule 2.](#Schedule2) The list of SB Members set out in [Schedule 2](#Schedule2) may be amended by a simple majority vote of the Executive Board and does not require any formal amendment of this Consortium Agreement within the meaning of Clause 11.8.

### Scientific Board meetings. The Scientific Board shall meet at least [quarterly]. Meetings may be held in person, by telephone, or by video conference. Meetings will be convened with at least [one month] written notice in advance by the SB Chairperson(s).

### Non-disclosure agreements. Within [1 month] following the entry into force of this Consortium Agreement, all members of the Scientific Board shall sign a Non-Disclosure Agreement (NDA) to ensure that any confidential information shared within the Scientific Board is not disclosed. A template NDA will be issued by the Executive Board.

*Delete entire Section 3.3 and composition in Schedule 2 if you do not wish to have a Scientific Board.*

*Delete only 3.3.3 if you wish to have a Scientific Board but if there are no external members to it (i.e. not employees of a party to this Consortium Agreement).*

## **Compliance**. Each Party shall ensure that all governance bodies set up within the Project comply with the provisions of this Consortium Agreement in all their decisions and actions.

## **Replacement**. Each Party shall use reasonable efforts to keep an appropriate level of continuity in representation. Each Party shall nominate a replacement upon advance notice to the other Parties in the event that the original representative is unable to attend a scheduled meeting of a governance body. If a representative is permanently unable to participate the Party may replace him or her at any time, subject to written notification to the other Parties in accordance with Clause 11.6.

## **Binding Effect**. Decisions of the Executive Board are binding on all Parties, unless expressly provided otherwise. The Parties agree to abide by all decisions of the Executive Board. The Parties shall ensure that decisions taken by the Executive Board are adequately communicated within their institution, in order to implement such decisions.

## **Changes and amendments to the Project**. Changes and amendments to the Project Description may be proposed to the Executive Board by any Party and require approval of the Executive Board pursuant to Clause 3.2.3 and, if applicable, approval from the relevant ethics committees to be implemented.

# Financial Conditions

## **Allocation**. The financial conditions and grants allocated to the Parties for the completion of the Project are specified in the Project Description. Grants shall be distributed by the Project Leader specified in [Schedule 1](#Schedule1), or in the absence of a Project Leader, by the Executive Board, always in accordance with Project Description.

## **Costs and Expenses**. Except as expressly stated otherwise in the Project Description, each Party shall bear its own costs and expenses incurred in relation with this Consortium Agreement.

# Confidentiality

## **In General**. Without prejudice to special provisions (in particular Section 6 below) or laws with regard to the processing of personal data, each Party shall at any time for the duration of this Consortium Agreement, including any extension thereof, and thereafter for a period of 5 years following the termination or expiry of this Consortium Agreement, keep confidential all proprietary and/or non-public information which is marked as being confidential at the time it is disclosed hereunder or which may reasonably be regarded as confidential, including trade secrets or know-how or other related proprietary business information and data (collectively, **Confidential Information**) and shall not use such Confidential Information for any other purpose than completing the Project.

## **Exclusions**. Clause 5.1 shall not apply to (i) any Confidential Information which one Party can reasonably demonstrate that it (a) was previously lawfully known to it, or (b) is, and/or becomes publicly available through no fault of a Party, or (c) is independently and lawfully developed by it; (ii) any disclosure required by law, provided that the receiving Party shall notify the disclosing Parties of any disclosure required by law in sufficient time so that each disclosing Party may contest such requirement, if any disclosing Party so chooses.

## **Return of Confidential Information**. Subject to mandatory law, upon the expiration or termination of this Consortium Agreement for whatever reason, or at the earlier request of a Party, the other Party shall, at its own costs, return or destroy all originals and copies of Confidential Information, or, in case of Confidential Information stored in electronic, magnetic or digital media, shall erase or render unreadable all materials furnished (including without limitation, working papers containing any Confidential Information or extracts therefrom) which contain Confidential Information.

# Data and Biological Material

## In **General**. The Parties shall ensure that the processing of personal data and Biological Material under the Consortium Agreement complies with applicable data protection laws. Each Party represents and warrants that any personal data and/or Biological Material required for the Project will be processed in compliance with all relevant laws, regulations and, where applicable, ethical guidelines. Additionally, any necessary ethics approvals and informed consents will be secured before commencing the respective task detailed in the Project Description.

## **Data**. Access to, provision and exchange of data, including the metadata, between the Parties under the Project (**Data**) shall be carried out pursuant to the Data Transfer and Use Agreement (**DTUA**) substantially in the form as specified in [Schedule 3](#Schedule3), including its annexes (**DTPA and Minimal Security Requirements**).

*As data is being processed along the project life cycle, the scientific value of data, the legal framework applicable to such data or governance requirements and decision rules can change. It might be necessary to use specific terms of data in clauses 6.1-6.5, in addition to those provided in the applicable laws (Federal Act of Data Protection (FADP) and Human Research Act (HRA).*

*The* [*SPHN Glossary*](https://sphn.ch/document/sphn-glossary/) *(*[*https://sphn.ch/document/sphn-glossary/*](https://sphn.ch/document/sphn-glossary/)*) provides definitions of subcategories of data along the project lifecycle to assist users of this template in selecting appropriate subcategories of data as needed. The main distinctions made are between primary data, curated data, combined data and analyzed data. If different decision rules are required for different sub-categories of data, this should also be reflected in the voting rules in the Executive Board in Section 3.2.3.*

## **Biological Material**. Biological Material shall have the meaning ascribed to it in the Material Transfer Agreement (**MTA**) set in Schedule 5, which shall be based on the Swiss Biobanking Platform templates. Access to, provision and exchange of Biological Material under the Project shall be carried out in compliance with the MTA in Schedule 5.

## **Further Use of Data during the term of the Consortium Agreement.** During the term of the Consortium Agreement, Data may be shared (provided access to or received) with a Party or a third party for a research purpose unrelated to the Project (**Further Use**), provided that the following conditions are met:

1. Further Use complies with applicable law.
2. Further Use is approved by a decision of the Executive Board pursuant to Clause 3.2.3.
3. To the extent personal data is concerned, each Party or third party who supplies data has given prior written approval.
4. A data sharing agreement, the terms of which are at least as strict as those provided by the DTUA (Schedule 3) is concluded between the Party or third party wishing to share or access data and all Parties to this Consortium, it being understood that the data sharing agreement shall be signed by the Chairperson of the Executive Board on behalf of all Parties to this Consortium pursuant to Clause 3.2.3 above.

*Note that the use of data within the framework of the Project constitutes a form or “reuse” under the Human Research Act. What is covered by clauses 6.4 and 6.5 are scenarios of reusing these already reused data, which we designate “further use”.*

## **Further Use of Data after the Termination of the Consortium Agreement.** The Parties hereby commit to making the Data available for Further Use on the [REPOSITORY NAME], provided that at the Termination of this Consortium Agreement, such repository continues to offer sufficient legal guarantees, particularly regarding the protection and security of data. No later than six months prior to the end of this Consortium Agreement, the Executive Board shall establish a strategy for data reuse after termination of this Consortium Agreement. This strategy shall comply with applicable law, ethical requirements, and open science principles.

*To the extent possible, data should be made available for research purposes in public repositories (with or without controlled access). This should be done provided that such public repositories adhere to the principles of open science and all relevant laws, especially those concerning the protection of personal data and data security.*

*Note that the repository name might also be a registry, a dataset or a data platform hosted by the department of an institution or on a BioMedIT node. Please refer to the SPHN Glossary to specify the subcategory data along the research life cycle that should be made available on such a repository. From a scientific point of view, it is generally recommended that data that has been combined by the project team into a richer and more scientifically valuable set of data be made available for further use.*

# Intellectual Property

## **Definitions**.

### “**Intellectual Property Rights”** means all present and future rights and prerogatives, registered or not, arising from Swiss or any other national or international legislation, in copyright, rights to software, databases, trademark protection, corporate names, trade and business names, domain names, designs and patents of invention, semiconductor topography rights, know-how, confidentiality and business secrets, and rights in the nature of unfair competition right, and all other intellectual property or similar proprietary rights of whatever nature (including, without limitation, applications to register or rights to apply for registration). For the sake of clarity, Intellectual Property Rights do not include Data and/or Biological Material.

### “**Results**” means any results generated by a Party from its participation in the Project – such as invention, data, software, algorithms, knowledge, know-how or information, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including Intellectual Property Rights.

### “**Know-How**” means a set of non-published knowledge and processes of technical nature which are reduced in writing, derives independent economic value, actual or potential, from not being generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question.

## **Duty to Inform**. Each Party generating Results in the performance of the Project shall report regularly, at least [quarterly] to the Sponsor / Project Leader and all Parties having contributed to such Results.

*Choose the applicable option*

## **Background IP.**

### “Background IP”means any Intellectual Property Rights existing before the effective date of this Consortium Agreement or which is later developed or otherwise acquired independently from the Project. The term Background IP includes any and all developments and improvements made to such Background IP within and outside the Project.

### Background IP List. In [Schedule 6](#Schedule6), the Parties have identified and agreed on the Background IP for the Project. The Party introducing any Intellectual Property to the Background IP List in [Schedule 6](#Schedule6) shall state, whether or not the existence and/or details of the Background IP entered by it is confidential or not and, if confidential, shall label the listed Background IP as “confidential”.

Anything not identified as Background IP in [Schedule 6](#Schedule6) shall not be the object of the access rights granted in this Consortium Agreement.

Any Party may add further own Background IP to [Schedule 6](#Schedule6) during the Project by written notice to the other Parties. However, approval of the Executive Board is needed should a Party wish to modify or withdraw its Background IP in [Schedule 6](#Schedule6). In such cases, the Party wishing to do so shall submit a request to the Chairperson of the Board to add this to the agenda of the next Executive Board meeting. The Executive Board decides on the modification or withdrawal of Background IP by a majority vote, in accordance with [Schedule 2](#Schedule2).

*Delete clause 7.3.2 if no background IP List is created. Adapt the list of voting rules in section 3.2.3 accordingly.*

### Background IP Rights. Each Party shall retain all title, right and interest in and to its respective Background IP. The Parties agree that any and all developments and/or improvements made to such Background IP within and outside of the Project shall be owned solely by the Party that brought the Background IP into the Project. Subject to any rights conferred between Parties under the following paragraph, nothing in this Consortium Agreement shall be construed as a transfer, license, and/or assignment by a Party to the other Party of ownership of, title, right or interest in and to its respective Background IP or further developments thereof and/or improvements. If a Party needs Background IP of one or more of the other Party(/-ies) for the implementation of the Project, the Party owning or providing such Background IP grants to such requesting Party a non-exclusive right of use of such Background IP free of charge and limited to the duration and the purpose of the performance of its tasks in the Project provided that there are no conflicting third party rights. The request for such access rights to another Party’s Background IP shall be made in writing and specify for what purpose the Background IP will be used. The granting of any additional rights to Background IP is at the Background IP owning Party’s sole discretion and subject to a separate written agreement.

## **Foreground IP.**

Choose between alternative 1 or alternative 2 for 7.4.1(and 7.4.2) regarding foreground IP**.**

**Alternative 1**: Joint IP only for common works, otherwise IP owned solely by the party generating it.

### Joint Foreground IP. If two or more Parties have jointly generated Intellectual Property Rights, and where it is not possible to separate from each other their individual contributions, all right, title and interest in and to Intellectual Property Rights generated within the Project shall be owned jointly by the Parties who have contributed to it (**Joint Foreground IP**). The involved Parties shall set forth, by separate mutual agreement, their respective rights, duties and responsibility relating to the Joint Foreground IP, subject to the terms of Clause 7.7. Such an agreement shall not cause a delay of publication of the Results any longer than defined in Clause 8.2.

### Sole Foreground IP. All Intellectual Property Rights in Results which are neither Background IP nor Joint Foreground IP shall be owned and vest solely in the Party generating them (**Sole Foreground IP**), and together with the Joint Foreground IP, the **Foreground IP**). Such Party shall be free to use such Sole Foreground IP in any form whatsoever, subject to Section 7.7.

**Alternative 2**: The IP is jointly owned by the Parties.

### 7.4.1 All right, Intellectual Property Rights, title and interest in and to the Results shall be owned jointly by the Parties (the **Foreground IP**). The Parties shall set forth, by separate mutual agreement, their respective rights, duties and responsibility relating to the Joint Foreground IP. Such an agreement shall not cause a delay of publication of the Results any longer than as defined in Clause 8.2.

## *If your project requires a more sophisticated IP section, covering in particular the case where all parties do not agree on the filing of a patent application, do not hesitate to contact your institution’s legal department or the SPHN legal support team so that we can propose one more suited to this type of project.*

## **License to use Results**. Each Party generating Results hereby grants to all other Parties a royalty-free, worldwide, non-transferable, non-exclusive, irrevocable license, with the right to grant sublicences only to Subcontractors, to access and use such Results (including any Background IP and Foreground IP therein) solely for the purpose and to the extent necessary for undertaking and completing the Project.

## **License to use Foreground IP**. Each Party generating Foreground IP by using Data, Biological Material, Confidential Information or Background IP of another Party hereby grant to that Party a royalty-free, worldwide, non-transferrable, non-exclusive, irrevocable license, with the right to grant sublicenses, to access and use that Foreground IP for purposes of internal scientific research.

## **IP Exploitation.**

### Exploitations of Foreground IP. With respect to the exploitation of Foreground IP (e.g. granting of licenses to third parties), the Parties shall mutually consult each other and agree upon the conditions and sharing of revenues, if any, whereby appropriate account is taken of significant non-inventive contributions (such as providing know-how, Data, Biological Material). The owners of Foreground IP shall pay to Parties having contributed to generating the Foreground IP a fair share of / [...]% on any net revenues received by Recipient for the commercialization of the Foreground IP.

*Delete the highlighted text if you do not want to specify the distribution of the revenue payments at this point. You can choose between the options fair share of or specify a specific percentage.*

### Patent Protection. If an owner of Sole Foreground IP/the owners of Joint Foreground IP decide not to pursue or maintain a patent application based on the Results, the Executive Board may decide to protect or commercialize the Results in the name of all Parties. If the Executive Board decides not to pursue or maintain a patent application based on a Project Invention, any Party or group of Parties may negotiate with the Parties owning the Project Invention terms and conditions for transferring the rights to protect or commercialize the respective Project Invention.

Delete 7.7.2 if the EB is not allowed to decide to protect the Results in the name of all Parties. You may choose between the options Sole or Joint Foreground IP according to Clause 7.4.

## **Open-Source Software.** Subject to any contrary provisions of this Agreement and the applicable funding conditions, the Parties agree to use their best efforts to release under an Open-Source license any software code generated *ab initio* in this Project which constitutes Foreground IP (**Open-Source Software**). For the purpose of this Agreement, Open-Source Software means any licenses that comply with the internationally recognized definition for Open Source, that can be found on the website of the Open-Source Initiative (https://opensource.org/osd-annotated).

# Publications

## **In General**. The Parties agree that the Results shall be publicly disclosed as soon as possible by the Party generating them, unless such publication goes against its legitimate interests (for instance, if the Results have not yet been protected, the Results involve trade secrets, or disclosing the Results would violate applicable obligations regarding personal data protection, security, or other legal requirements). Published information shall be deposited in an open access data repository to the extent reasonably possible.

## **Right to object**. Prior to the publication of its Results, any Party intending to publish some Results (the **Publishing Party**) shall provide the draft publication for review to the other Parties. Each other Party shall have [60] days to request the Publishing Party to:

* + 1. remove any Confidential Information provided by it, in which case the other Party/-ies shall use their best efforts to provide scientifically meaningful equivalent information for such deleted Confidential Information.
		2. postpone, for no more than [6] months, the publication of the Results for which the other Party/-ies wishes to file a patent application (as the case may be, pursuant to Clause 7.7.2).

## **Authorship Guidelines and Acknowledgment**. All publications of the Results must be compliant with the authorship guidelines specified in [Schedule 4](#Schedule4) (Authorship Guidelines) and shall acknowledge the role and contribution of this Consortium and of the Parties that provided the Data and Biological Material, in accordance with best scientific practice.

# Duration, Entry and Exit of Parties

## **Duration termination and extension**. This Consortium Agreement will enter into force once signed by all Parties and will continue to be in force until [date // or // completion of the Project], subject to termination decided by a [vote of the Executive Board pursuant to Clause 3.2.3]. This Consortium Agreement may be extended, provided that the Executive Board decides so pursuant to Clause 3.2.3 above.

## **Admission.** Any legal entity wishing to become a party to this Consortium must apply in writing to the Executive Board. Admission is subject to a [vote from the Executive Board pursuant to Clause 3.2.3] and the condition that the entity adheres to this Consortium Agreement in its entirety unless an exception is expressly described in a deed of admission and validated by the Executive Board. Once admitted, the entity becomes a party to this Consortium Agreement, by which it is legally bound.

## **Exit**. Each Party may exit from the Consortium Agreement by giving [60] days advance written notice to the other Parties. The withdrawal of a Party from the Consortium Agreement shall not affect the rights and responsibilities of the other Parties.

## **Exclusion**. In the event of a material breach of the Consortium Agreement by a Party, the Executive Board shall notify the Party in writing and set it a deadline within which to remedy the breach. If the breach is not remedied within this deadline, the Executive Board may decide to exclude that Party, by a [vote pursuant to Clause 3.2.3]. The Party breaching the Consortium Agreement does not participate in this vote.

## **Effects of termination, exit or expiry**. Upon exclusion, exit or expiry of this Consortium Agreement, all Confidential Information, Data and Biological Material shall immediately be returned or destroyed, as per request of the providing or disclosing Party. Expiration or exclusion of a Party from this Consortium Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Provisions which by their nature are intended to survive expiration or termination of the Consortium Agreement, shall survive. In case of exclusion or exit, the Party leaving the Consortium Agreement shall refund to the [Executive Board or // to be discussed] any funding it has received under the Project except the amount of eligible costs approved by the Executive Board.

# Warranties and Indemnification

## **In General**. The Parties shall perform the Project and their respective Allocated Work to the best of their scientific knowledge, exercising due care, taking into account recognized scientific standards and shall endeavour to achieve the goals of the Project aimed for in the Project Description. By its nature, research involves the risk of unforeseen consequences. The Parties therefore do not make any representation that the intended goals and results of the Project will be reached, nor that their Allocated Work will lead to any particular result. The Parties make no warranties, neither express nor implied, regarding the Results, including but not limited to warranties of originality, accuracy, non-infringement of third-party rights, merchantability, completeness or fitness for a particular purpose.

*Delete the highlighted text if not applicable.*

## **No liability**. Subject to Clauses 10.3 and 10.4 and the DTUA, the Parties assume no liability for any damages, including but not limited to any indirect or consequential loss or similar damage (e.g. loss of profit, loss of revenue or loss of contracts inter alia due to a shutdown; other costs and expenses) suffered in connection with this Consortium Agreement, provided such damage was not caused by a willful intent or act of gross negligence. This limitation of liability shall also apply to the Parties' auxiliary persons (including but not limited to consultants and students), agents and subcontractors.

## **Use of Results**. The Parties use the Results at their own risk. A Party who generated the Results shall, to the fullest extent permitted by the applicable law, defend, indemnify and hold the other Parties harmless against third party claims which are based on the Party’s use of the Results.

*Adapt 10.3 according to the configuration of the project and the intent of the parties, if needed.*

## **Liability for Data processing activities**. Without prejudice to the Sponsor’s liability pursuant to the Federal Human Research Act (HRA) and the Federal Human Research Ordinance (HRO), the Parties’ liability towards each other with respect to Data processing activities is governed by the DTUA ([Schedule 3](#Schedule3)).

Adapt 10.4 according to the Project and the common intent of the parties, if needed.

# Miscellaneous

## **Force Majeure**. A Party will not be in breach of its contractual obligations in case of delay in performing, or failure to perform, its obligations to the extent such delay or failure is caused by the occurrence of any contingency beyond the reasonable control, and without any fault, of such Party, which contingencies include natural disasters of a particular intensity, war, epidemics, riot, strike, hacking, power failure or Internet network failure (**Force Majeure Event**). If a Party is prevented or delayed in the manner previously described, it shall notify the Project Leader without delay, who must then inform all Parties. The Party faced with a Force Majeure event must immediately take all necessary measures to limit any damage and use its best efforts to resume performance of this Consortium Agreement as soon as possible. In such event, the time limits for performance will be extended for a period of time equivalent to the time lost due to the Force Majeure Event. The affected Party shall act with due diligence to remedy the cause of, or to mitigate or overcome, such delay or failure.

## **Assignment**. Neither Party may transfer this Consortium Agreement, or assign in whole or in part its rights or obligations under this Consortium Agreement, without the prior written consent of the other Parties. Any transfer or assignment made without such consent shall be null.

## **Severability**. If any provision of this Consortium Agreement is held to be invalid or unenforceable for any reason, the Parties shall replace it by a substitute provision that achieves to the fullest extent possible the same legal and economic purposes as those of the invalid or unenforceable provision. In any event, the remainder of this Consortium Agreement shall remain in full force and effect between the Parties.

## **Counterparts and Electronic Form**. This Consortium Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which shall together be deemed to constitute one and the same Agreement. Each Party acknowledges that a handwritten signature or a copy thereof, including a "portable document format" or PDF copy, or a signature generated by industry standard electronic signature software (e.g. Docusign), which is transmitted by email shall constitute a handwritten signature for purposes of this Agreement and shall have the same legal force and effect as the exchange of handwritten signatures; while the term "in writing" shall include communications by email or other electronic forms.

## **Further Actions**. The Parties shall communicate, sign and deliver any information or document, and shall take any action or decision required to effect or implement this Agreement.

## **Notices**. Any notice made under this Agreement shall be in writing, in English, and shall be either personally delivered or mailed by registered mail or emailed to the Parties’ addresses listed in the preamble of this Consortium Agreement. Such addresses may be changed by means of a notice pursuant to this Clause 11.6. In the event that notification has to be made within a certain period of time, the relevant Party should have complied with such requirement if it has at the last day of such period (i) mailed, transmitted or initiated delivery procedure per registered mail, or (ii) received delivery confirmation of the electronic communication, as the case may be.

## **Waiver**. Failure by a Party to exercise any of its powers, rights or remedies under this Consortium Agreement shall not be construed as a waiver of such power, rights or remedies. To be effective, any waiver must be recorded in writing.

## **Amendment**. Amendment. Except for [Clauses 3.2.1 and 3.3.1], this Consortium Agreement (including this Clause) may be amended only by (i) a written instrument duly signed by the Parties or (ii) a decision of the Executive Board in accordance with Clause 3.7 above, within the limits of the Executive Board’s responsibilities as specified in [Clause 3.2.3].

## **Governing Law**. This Consortium Agreement and the respective rights and obligations of the Parties shall be governed exclusively by Swiss law, without regard to its conflict of laws provisions.

## **Jurisdiction**. Dispute in relation to this Consortium Agreement shall be submitted to the exclusive jurisdiction of the competent courts [indicate competent court e.g. at the registered seat of the defending Party], subject to the right to appeal to the Swiss Federal Tribunal.

[signatures on the following page]

|  |  |
| --- | --- |
| 1. **[Full name and abbreviation of Party 1]**

**[Name(s) and of Party 1 representative(s)]****[Date and Signature]** |  |
| 1. **[Full name and abbreviation of Party 2]**

**[Name(s) and of Party 2 representative(s)]****[Date and Signature]** |  |
| 1. **[Full name and abbreviation of Party 3]**

**[Name(s) and of Party 3 representative(s)]****[Date and Signature]** |  |
| 1. **[Full name and abbreviation of Party 4]**

**[Name(s) and of Party 4 representative(s)]****[Date and Signature]** |  |
| 1. **[Full name and abbreviation of Party 5]**

**[Name(s) and of Party 5 representative(s)]****[Date and Signature]** |  |
| 1. **[Full name and abbreviation of Party 6]**

**[Name(s) and of Party 6 representative(s)]****[Date and Signature]** |  |
| 1. **[Full name and abbreviation of Party 7]**

**[Name(s) and of Party 7 representative(s)]****[Date and Signature]** |  |

Schedule 1 – Project Description

This Schedule 1 (Project Description) is composed of the summary table below and of the following annexes:

***Annex I*** *Project Description, reference number […] dated […].*

***Annex II*** *Ethical approval dated […].*

***[Annex III]*** *[…].*

|  |
| --- |
| **Summary Table** |
| **Sponsor** | [Name of Sponsor] |
| **Project Leader** | [Name of Project Leader] |
| **Investigators** | [Name of Investigator] |
| **Title** | [Project Name] |
| **Short Title** | […] |
| **Description**  | See Annex I and Annex II |
| **Allocated Works and deliverables** | See Annex I |
| **Timeline** | See Annex I |
| **Financing** | See Annex I |
| **[other]** | […] |
| **Applicable guidelines**  | SPHN “Funding Regulations” including “General implementation regulations for the Funding Regulation“ [or any other applicable guideline]  |

*Delete highlighted text or choose between the options provided on this and the following pages, as needed.*

Annex I        Project Description, reference number […] dated […]

Annex II        Ethical Approval dated […]

[Annex III      […]]

SCHEDULE 2 - GOVERNANCE

This Schedule 2 (Governance) lists the governance bodies for the Project.

1. Executive Board

|  |  |
| --- | --- |
| **Members** | The composition of the Executive Board is governed by Clause [3.2.1] of the Consortium Agreement. The Composition of the Executive Board at the time of signature of the Consortium Agreement is as follows:Party 1 : [Full Name of EB Member]Party 2 : [Full Name of EB Member]Party 3 : [Full Name of EB Member]Party 4 : [Full Name of EB Member]Party 5 : [Full Name of EB Member]Party 6 : [Full Name of EB Member]Party 7 : [Full Name of EB Member] |
| **Chairperson** | Pursuant to Clause [3.2.3] of the Consortium Agreement, EB Members shall appoint one/two Chairperson(s).The initial EB Chairperson(s) is/are [Full Name and Party Number]. |

1. [Scientific Board]

|  |  |
| --- | --- |
| **Members** | The composition of the Scientific Board is governed by Clause […] of the Consortium Agreement. The composition of the [Scientific Board] at the time of signature of the Consortium Agreement is as follows:Party 1 : [Full Name of xx Member]Party 2 : [Full Name of xx Member]Party 3 : [Full Name of xx Member]Party 4 : [Full Name of xx Member]Party 5 : [Full Name of xx Member]Party 6 : [Full Name of xx Member]Party 7 : [Full Name of xx Member] |

*Delete Section II above and corresponding clauses in Sections 3.1 letter e) and 3.3 of the Consortium Agreement if you do not wish to have a Scientific Board.*

1. [OTHER]

|  |  |
| --- | --- |
| **Members** | The composition of the [name] is governed by Clause […] of the Consortium Agreement. The composition of the [name] at the of signature of the Consortium Agreement is as follows:Party 1 : [Full Name of xx Member]Party 2 : [Full Name of xx Member]Party 3 : [Full Name of xx Member]Party 4 : [Full Name of xx Member]Party 5 : [Full Name of xx Member]Party 6 : [Full Name of xx Member]Party 7 : [Full Name of xx Member] |
| **Chairperson** | The Executive Board shall appoint the chairperson of the [name] ([**xx**] **Chairperson**).The initial [xx] Chairperson is [Full Name and Party Number]. |

SCHEDULE 3 – DATA TRANSFER AND USE AGREEMENT (DTUA)

For the project "[ProjectName]"

This Schedule [3] reflects the agreement between the Parties regarding the terms governing the processing, security and sharing of Data under the Consortium Agreement, to which it forms an integral part.

By entering into the Consortium Agreement, each Party providing Data to another Party (the **Provider**) and each Party receiving such Data (the **Recipient**, and together with the Provider, the **Parties**) automatically enter into the Data Transfer and Use Agreement formed pursuant to this Schedule [3] (**DTUA**) for as long as they are each a Party to the Consortium Agreement.

**WHEREAS**

1. The Parties have been granted support by [SPHN] for their joint research project [CompleteProjectName] (hereinafter referred to as “[ProjectName]”). A Party providing Data to another Party under this Agreement shall be considered a Provider for the purposes of this Agreement. A Party receiving Data from another Party under this Agreement shall be considered a Recipient for the purposes of this Agreement;
2. The Provider is the controller of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ data (Data), as set forth in Annex I of this DTUA and its **Exhibit 1**;
3. The Recipient wishes to conduct the [ProjectName] research project (**Project**) with the Data made available by the Provider. The Provider is willing to provide such Data to the Recipient under the terms and conditions as follows hereafter.
4. Definitions

Unless defined below, or in the Consortium Agreement, capitalized terms shall have the meaning described in the applicable law.

1. Data provision
2. **DTPA**. The Data shall be made available to Recipient subject to the Parties entering into a Data Transfer and Processing Agreement with the BioMedIT Nodes substantially in the form as specified in Annex II (DTPA).

This template has been established for data exchange using BioMedIT nodes. To be adapted according to the specificities of the project.

1. **Form**. The Data shall be provided to the Recipient by the Provider in a uncoded/coded/anonymized form and in a format to be agreed upon by the Parties as per **Exhibit 1** of Annex II. The Recipient shall not have the key.

Specify in which form data is provided (uncoded, coded or anonymized). As a reminder, coded (= pseudonymized data) is not considered anonymized data under the Human Research Act.

1. **Provider’s Warranties about Data Provision**. The Provider warrants that it is entitled to supply the Data and that all necessary consents and/or authorizations for the transfer and/or use of the Data to/by the Recipient have been obtained.
2. **No Provider’s Warranties about Data**. It is expressly understood that the Provider does not warrant or guarantee that the Data will be accurate, complete, or useful for any particular purpose.
3. **No Provider’s Warranties about Third Parties’ Intellectual Property Rights**. The Provider offers no warranty that the use of Data and/or Confidential Information will not infringe or violate any patent or other proprietary rights of any third party.
4. Data Processing
5. **Purpose**. The Recipient agrees that the Data: (a) is to be used only for the purposes described in the Project Description and in accordance with the rules applicable or the reuse of Data (Clause 6.4 and 6.5 of the Consortium Agreement); (b) may not itself be commercialized and (c) shall not be transferred to or accessed by any third party, for any purposes whatsoever, without the prior written agreement of the Provider and in compliance with the informed consent of the Data Subjects.
6. **Right of use**. The Data Subject retains her/his right to decide on the use of the Data provided. The Confidential Information provided is and remains the property of the Provider.
7. **Security**. The Recipient shall process the Data in a manner that ensures appropriate confidentiality, integrity, availability and resilience of the systems with regard to processing of the Data. The Recipient must in particular ensure appropriate protection against unauthorized or unlawful Data access or processing in any form (e.g., reading, copying, altering) and against accidental loss, destruction or damage, using appropriate technical or organizational measures. The effectiveness of such measures shall be regularly assessed, and corrective measures shall be immediately implemented in case of suspected Data Security Breach.

The Recipient shall have in place procedures so that access to the Data is only granted to identifiable persons who require it to conduct the specified Project. The Recipient shall adopt adequate organizational measures ensuring that any person authorized to access the Data:

* is diligently and appropriately selected, instructed and supervised, in particular through the availability of adequate confidentiality and data protection guidelines, regular data protection and privacy trainings, documentation of all organizational measures;
* respects and maintains the confidentiality and security of the Data;
* processes the Data only on instructions from the Recipient’s Project Leader;
* does not combine the Data with other data unless explicitly authorized by the competent ethics commission for the specific research project and to the extent necessary to conduct the specific research project.

The technical and organizational measures adopted by the Recipient must ensure that it is possible to examine and verify if, when and by whom Data was processed.

The Recipient agrees to immediately report to the Provider (i) any actual or suspected Data Security Breach, including a breach against applicable data protection regulation, data protection section of this DTUA, (ii) any actual or suspected impairment or inadequacy of the Recipient in fulfilling data protection section of this DTUA, and (iii) any application to receive or any actual access to data by an authority, unless such reporting is not admissible under statutory provisions.

The Recipient and the Recipient’s authorized users shall not (i) provide any output or Results of the Data to any third party, except as expressly permitted in the Consortium Agreement or this DTUA; or (ii) sell, lease, sublicense, copy or provide the Data to any third party, except as expressly permitted in the Consortium Agreement or this DTUA.

Except as provided above, the Recipient processes the Data in accordance with the “Ethical Framework for Responsible Data Processing in Personalized Health Research” (accessible at: <https://sphn.ch/document/ethical-framework/>) and the SPHN Information Security Policy attached as Annex III to this DTUA, as both updated occasionally.

*The SPHN/BioMedIT Information and Security Policy is accessible upon request at* *dcc@sib.swiss**.*

1. **No Re-Identification**. The Recipient shall not carry out any procedures with the Data (linking, comparison, processing) with the intention to identify the Data Subject, unless requested by a Data Subject.
2. **Rights of the Data Subjects**. The Provider shall secure the exercise of the Data Subject’s rights, including access rights, the right to rectification and erasure, and the right to object. Each Party shall respond to requests from the Data Subject concerning Data for which it is the Data Controller within one month after having received the notification. Moreover, each Party will provide any Data Subject with a copy or the content of this DTUA upon their request or if required by law. If a Data Subject requests a copy of this DTUA, either Party may summarize any part of this DTUA (including its Annexes) to the extent necessary for confidentiality and data protection reasons. Finally, any Data Subject may claim damages and raise other claims pursuant to the applicable law relating to the transfer and/or processing of their Data under this DTUA against either Party.

Note that those Data Subject rights are established both by Swiss law and the General Data Protection Regulation of the European Union.

1. **Revocation of Consent**. In case of Data Subject’s total or partial revocation of consent, the Provider must inform the Recipient of this revocation without undue delay and must provide the pseudo-identifier of the Data Subject that revoked access to Data of the data subject. In such case, if applicable, the Recipient shall comply with Provider’s requests to anonymize their Data according to the HRO, unless one of the exceptions listed in Article 10 of the HRO applies. A written notification shall be sent to the Provider upon receipt and after completion of the request.

*Adapt 6. if the process of revocation is different.*

1. **Data Storage and Processing**. The Data should not be kept by the Recipient longer than necessary for the purpose of the Research, and the Data processing must be limited to the purpose pursued, provided that the Data Subject does not decide otherwise. In accordance with Art. 36d of the Federal Act on the Federal Institutes of Technology (ETH Act), if anonymization is not possible due to the purpose of the Project, personal data used in research may be stored for a maximum of 20 years. At the end of the 20 years retention perod provided by the ETH Act, the Parties will assess whether such maximum retention period is still applicable and act in accordance with all applicable laws.

*The highlighted text only applies if a Party is subject to the ETH Act and should be deleted otherwise.*

1. **Data transfer via the BioMedIT Nodes**. The Parties agree that the Data transfer will be performed as agreed in writing by the technical representatives of the BioMedIT Nodes, as set forth in Annex I of this DTUA and in accordance with all applicable laws.
2. **Download of Data from the BioMedIT Nodes**. Except with the prior written agreement of the Data Provider, the Recipient is not allowed to download or extract from the BioMedIT nodes Data related to identified or identifiable Data Subjects. For the sake of clarity, Data related to identified or identifiable Data Subjects includes “coded data” within the meaning of the Human Research Act, which equal pseudonymized data.
3. **Responsibilities**. When they act as Joint Controllers for the purpose of the Project, the Parties agree that the responsibilities described below are assumed by the Parties designated hereafter:

|  |  |
| --- | --- |
| Approval of personal data processing or sub-processing activity for the purpose of shared Allocated Work | According to Clause 6.4 of the CA |
| Approval and legal compliance of international personal data transfer | [name of the Party + specify if Sponsor] |
| Notification of a Data Security Breach to a supervisory authority, according to applicable law | [name of the Party + specify if Sponsor] |
| Notification of a Data Security Breach to Data Subjects, according to applicable law | Respective Data Providers |
| Conducting a data protection impact assessment, if imposed by and according to applicable law | [name of the Party + specify if Sponsor] |
| Consultation of a supervisory authority, if imposed by and according to applicable law | [name of the Party + specify if Sponsor] |
| Appointment of a data protection office for the purpose of the Project | [name of the Party + specify if Sponsor] |

1. Compliance with Law

Each Party undertakes to comply at all time with all applicable Swiss laws, applicable international statutes, regulations and guidelines, especially all laws, statutes and regulations concerning human research and personal data protection, including any necessary regulatory approvals.

1. Liability and Third-Party Rights
2. **Liability**. Each Party shall be liable to 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 DTUA.
3. **Data Subjects Rights**. The Parties agree that a Data Subject shall have the right to enforce, as a third-party beneficiary, this Agreement against the Recipient or the Provider, for their respective breach of their contractual obligations, with regard to their Data. In cases involving allegations of breach by the Recipient, the Parties agree that the Provider may take appropriate action to enforce their rights against the Recipient. A Data Subject is entitled to proceed directly against the Provider that has failed to use reasonable efforts to determine that the Recipient is able to satisfy its legal obligations under this Agreement.
4. Miscellaneous

The provisions of Section 11 of the Consortium Agreement shall apply *mutatis mutandis*.

1. Annexes and Exhibits

**Annex I:** List of transferred Data (including metadata)

**Annex II:**  BioMedIT infrastructure Data Transfer and Processing Agreement (DTPA)

[**Annex III**](#Annex3): SPHN BioMedIT Information and Security Policy

Annex I – LIST OF TRANSFERRED DATA (INCLUDING METADATA)

*[please insert description of data and metadata to be transferred]*

Annex II - BIOMEDIT INFRASTRUCTURE DATA TRANSFER AND PROCESSING AGREEMENT

[MULTIPLE NODES]

(the "DTPA")

between

[name], [address]

[name], [address]

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

(the “**Provider**” and “**Recipient**”, together the “**Principals**”)

and

**University of Lausanne**, (SENSA, BioMedIT Node Romandie) Quartier UNIL-Centre, Unicentre, 1015 Lausanne, Switzerland

and

**University of Basel** (SciCORE, Basel BioMedIT Node) Petersplatz 1, Postfach, 4001 Basel, Switzerland.

and

**ETH Zurich** (Scientific IT Services - SIS, Zurich Node), Hauptgebäude, Rämistrasse 101, 8092 Zürich, Switzerland

If the parties to the DTUA decide to subcontract the secure transfer and hosting of the data to a third party, in this case to the BioMedIT nodes, the relationship between Controllers (parties to the DTUA) and Processor (BioMedIT) is regulated in a DTPA.

Add all parties involved:

* + The institutions that are providing data for the project (e.g. University Hospital Basel (USB), Spitalstrasse 21 / Petersgraben 4, CH - 4031 Basel) to the processor as well as the data recipients.
	+ The institutions hosting the BioMedIT node as a processor and providing project related services. Choose the respective nodes relevant for the project. Note that at least two nodes have to be chosen, since this template is created for multiple nodes.

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

(each a **Regional Node** and together the **BioMedIT Nodes**)

(for the purposes of this DTPA, each Provider, Recipient and Regional Node a **Party**, and together the **Parties**)

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

**WHEREAS**

1. The Principals have signed a consortium agreement for the [ProjectName], containing a Data Transfer and Use Agreement (the DTUA).
2. The BioMedIT Nodes form together a coordinated Swiss nationwide network of secured IT network, consisting of high performance compute and storage infrastructure, in order to support computational biomedical research and clinical bioinformatics. For the sake of clarity, and subject to the provisions of this Agreement, the Regional Nodes are independent legal entities and act as independent contractors.
3. Within the framework of their access and use of the Data, the Principals wish to benefit from the BioMedIT Nodes services to inter alia store and transfer Data from Provider to Recipient.
4. The BioMedIT Nodes agree to provide such services under the terms and conditions of this DTPA.
5. DEFINITIONS

Unless defined in the DTUA or in the Consortium Agreement, capitalized terms shall have the meaning described in the applicable law.

1. SCOPE

This DTPA applies to all Data, including personal data relating to any concerned Data Subjects, that are transferred to and processed by the BioMedIT Nodes in the name and on behalf of the Principals under the Study and the DTUA.

1. SERVICES
2. **In General**. Subject to, and in accordance with, the terms of this DTPA, each Regional Node undertakes to provide to the Principals the services specified in Clause III.2 (the Services) to the best of its ability using all reasonable skill and care, and always subject to the Principals’ compliance with all its obligations under this DTPA.
3. **Scope**. The Services consist of the standard services provided by the BioMedIT Nodes as described in the BioMedIT Base Package (accessible at: https://sphn.ch/document/biomedit-base-package) which include the following:
	* 1. hosting of the Data on the BioMedIT Nodes;
		2. transferring Data from the Provider to the Recipient in accordance with this DTPA; and
		3. other processing activities as required under this DTPA or as reasonably requested by the Principals, and as agreed on with the BioMedIT node.

Computational and storage resources that exceed the limits set for the BioMedIT base package, will incur a service fee to the project. Services provided by the BioMedIT Nodes that fall out of the scope of this DTPA according to this Clause III.2 (standard services provided by the BioMedIT Nodes) are regulated by separate service agreement between the BioMedIT nodes and the Party of the Consortium Agreement needing more capacity.

1. **Means of Transfer**. Except as otherwise agreed in writing, Data shall be transferred by providing to the Recipient remote secured access to the Data in accordance with the security standards specified in Clause IV.3.1 below. The Parties shall decide on a case by case basis from which Regional Node the Data shall be made available.
2. **Collaboration with and between Regional Nodes**. Services are provided by the Regional Nodes as described in Exhibit 1. The Parties shall specify in **Exhibit 1** which Regional Node shall be primarily responsible for providing the Services. Each Regional Node undertakes to collaborate with the other Regional Nodes, and to assist them, as may be required for the proper providing of the Services.
3. **Power**. The Provider’s Investigator and the Recipient’s Investigator shall have the individual power to give instructions to, and receive notification from, the BioMedIT Nodes, on behalf of, respectively, the Provider and the Recipient, for all actions relating to the Data.
4. **Payment of Fees**. Costs associated with the Services to be provided by Regional Nodes are detailed in Exhibit 1 and shall be due only once the Project for which Provider needs the BioMedIT Nodes has been validated by the competent ethics committee as applicable.

[Or]

Services falling under the scope of this DTPA according to Clause III.2 of this DTPA are part of the SPHN initiative and are provided without any associated costs, unless they surpass a specifically defined upper limit of compute, storage or human resources. Services provided by the main BioMedIT node that exceed the limits set by BioMedIT or fall out of the scope of this DTPA and their associated costs are regulated by a separate agreement.

*Choose or adapt the appropriate terms of payment.*

1. DATA PROCESSING TERMS
2. **Supply of Data**. Provider shall provide the Data to the selected Regional Node, or make the Data available to it, in the form and as specified in **Exhibit 1**.
3. **Scope of Processing**
	1. In General. The Parties acknowledge and agree that:
		1. the subject matter and details of the processing are specified in this DTPA and its Exhibit 1;
		2. the BioMedIT Nodes are joint processors of the Data;
		3. the Principals are joint controllers of the Data; and
		4. each Party shall comply with its obligations under any applicable laws with regard to the processing of the Data (including data protection laws, as well as laws, statutes and regulations concerning human research and personal data protection).
	2. Nature and Purpose of Processing. The BioMedIT Nodes shall process the Data on behalf of the Principals and solely for the purpose of providing the Services or as otherwise expressly instructed jointly by the Provider’s Investigator and the Recipient’s Investigator. For the sake of clarity, the BioMedIT Nodes shall have no obligation to carry out any instruction which they consider, at their sole discretion, to be unlawful, ambiguous, doubtful or unclear (in which case the Parties shall collaborate in good faith to find a solution agreeable to all).
	3. Restrictions. The BioMedIT Nodes shall not, without the prior written consent of Provider:
		1. subcontract any of their processing operations of the Data (except to another Regional Node); and
		2. transfer the Data in any country outside Switzerland (it being agreed that the Data may be accessed and processed by the Principals outside Switzerland, in which case they shall be responsible for compliance with any applicable data protection obligation).
	4. Return of Data. Upon termination of the DTPA, or earlier as requested by the Provider, the BioMedIT Nodes shall, within reasonable time following a written request by Provider, provide Provider with a final extract of the Data and permanently delete all copies of such Data still under its control. In any case, the BioMedIT Nodes shall be allowed to permanently delete the Data 60 days after termination of the DTPA.
4. **Security**
	1. Security Requirements. The BioMedIT Nodes shall process the Data in a manner that ensures appropriate confidentiality, integrity, availability and resilience of the systems with regard to processing of the Data. The BioMedIT Nodes must in particular ensure appropriate protection against unauthorized or unlawful Data access or processing in any form (e.g., reading, copying, altering) and against accidental loss, destruction or damage, using appropriate technical or organizational measures.

The scope of persons authorized to access the Data is determined according to the instructions given by the Recipient’s Investigator to the BioMedIT Nodes. Such BioMedIT Nodes personnel has the right to access the Data only to the extent necessary for providing the Services.

The BioMedIT Nodes shall adopt adequate organizational measures ensuring that the BioMedIT Nodes personnel:

* + respects and maintains the Confidentiality and security of the Data;
	+ processes the Data only on instructions from the Principals;
	+ is diligently and appropriately selected, instructed and supervised, in particular through the availability of adequate confidentiality and data protection guidelines, regular data protection and privacy trainings, documentation of all organizational measures.

The BioMedIT Nodes must ensure that logging mechanisms exist which allow authorized personnel to inspect which Data was accessible by whom and when.

The effectiveness of security technical and organizational adopted by the BioMedIT Nodes measures shall be regularly assessed, and corrective measures shall be immediately implemented in case of suspected Data Security Breach.

The BioMedIT Nodes process the Data in accordance with the “Ethical Framework for Responsible Data Processing in Personalized Health Research” (available at : <https://sphn.ch/document/ethical-framework/>) and the “SPHN Information Security Policy” attached as Annex III to the DTUA, as both updated occasionally.

*The SPHN/BioMedIT information and security policy is accessible upon request to: dcc@sib.swiss.*

* 1. Security Incidents. Each Regional Node processing Data shall, if it becomes aware of any Data Security Breach, immediately inform the Principals by any useful means (in particular via the Provider’s Authorised Representative). The Regional Node shall, to the extent possible, describe the nature of the security incident, as well as any measures taken by it to mitigate potential risks and the measures that it recommends the Principals to take. The Principals shall be responsible for complying with the legal provisions applicable to them, in particular any obligations of the Principals to provide a notification of the incident to any competent authority and/or the Data Subjects. In this context, the Regional Node shall provide the Principals with any assistance reasonably required by them in order to comply with their obligations.
1. **Register of Processing Activities**
	1. The Principals acknowledge that the BioMedIT Nodes may be required by the law to:
		1. collect and store certain information, including the name and contact details of each Processor and/or Controller with whom the BioMedIT Nodes act and, where applicable, the local representative of the controller and/or the data protection officer as well as the categories of processing carried out; and
		2. make such information available to any competent authority.
	2. The Principals undertake to provide the BioMedIT Nodes with all information reasonably necessary for the BioMedIT Nodes to meet their obligations.
2. REPRESENTATIONS AND WARRANTIES
3. The Principals represent and warrant that:
	* 1. the Data to be transferred to and processed by the BioMedIT Nodes has been collected, transferred and processed in accordance with the requirements of all applicable laws, rules and regulations, including all applicable data protection laws and regulations;
		2. the transfer to the BioMedIT Nodes and the processing of the Data by the BioMedIT Nodes (including any further transfer to the Recipient) as set forth in this DTPA is (i) admissible under all applicable laws, rules and regulations and (ii) is not prohibited by a statutory or contractual duty of confidentiality;
		3. prior to any collection, transfer, or processing of personal data, the Principals have obtained consent of the concerned Data Subjects (if required), provided to the Data Subjects all information required by the applicable law and complied with any notification and registration obligations under any applicable laws and regulations;
		4. the Principals will not require the BioMedIT Nodes to undertake a Processing of Data that they would not be permitted to carry out themselves; and
		5. they have and will verify that the technical and organizational measures, as required by all applicable laws, rules and regulations, undertaken by the BioMedIT Nodes, in particular with those specified in Clause III.3 of the DTUA, are sufficient to protect the transferred and processed Data from any unauthorized processing. The Principals warrant that the technical and organizational measures set forth in Clause III.3 of the DTUA are sufficient in this regard.
4. The BioMedIT Nodes represent and warrant that they will process the Data only according to this DTPA and the applicable law and implement all agreed security measures.
5. INFORMATION; ASSISTANCE AND NOTIFICATIONS
6. **Compliance**. Each Party shall provide the other Parties with all the necessary information so that they can demonstrate compliance with their obligations under the applicable data protection legislation.
7. **Rights of the Concerned Data Subjects**. The Principals are responsible for ensuring that the concerned Data Subjects are provided with their right of access, rectification, deletion or objection. The BioMedIT Nodes will fully and in a timely fashion cooperate with the Principals, and when applicable provide to the Principals the necessary services for, fulfilling such requests or inquiries of the concerned Data Subjects.
8. **Impact assessments and prior consultation**. The BioMedIT Nodes undertake, to the extent they can reasonably be expected to do so in light of the nature of the processing and the information available to them, to assist the Principals in ensuring its compliance with its impact assessment, prior consultation and records of processing activities obligations (if any).
9. **Notification and Assistance**. The BioMedIT Nodes shall promptly inform, and cooperate with, the Principals if they believe that they may no longer be able, or are no longer able, to comply with this DTPA, particularly in case they receive or must reasonably expect to receive a request or order of a competent authority requiring them to disclose, or refrain from further processing, some or all Personal Data to which this DTPA applies.
10. **Audits**. The provisions of Exhibit 2 shall apply regarding audits.
11. DATA OWNERSHIP, INTELLECTUAL PROPERTY, CONFIDENTIALITY
12. Data Ownership and Right to Use
	* 1. Ownership. As between the Principals and the BioMedIT Nodes, and without prejudice to the Data Subjects' rights to the Data pursuant to applicable laws on data protection and on Human research, all rights to the Data are and remain the property of the Principals and all right, title, and interest in the same (including any Intellectual Property Right) is reserved by the Principals. Subject to Clause VII.1.b) below, nothing in this DTPA is intended to assign or grant the BioMedIT Nodes any Intellectual Property Rights or other rights in the Data.
		2. Use of Data. The Principals grant to the BioMedIT Nodes a right to access and use the Data for the sole purpose of, and only to the extent necessary for, providing the Services, including a license to collect, process, store, generate, and display the Data.
		3. Regional Node’s Policies. Principals undertake to comply with the Acceptable Use Policy and other internal policies (e.g., service level agreement) specific to each Regional Node. Provider also undertakes, within the framework of its agreements with the Recipient, to require the Recipient to comply with such regulations.
13. **Confidentiality.** For the purpose of this DTPA, Confidential Information means any data, documents or other material (in any form) that is identified as confidential in writing at the time it is disclosed hereunder by a Party to its counterpart. Without prejudice to special provisions or laws with regard to the processing of personal data, each Party shall treat the Confidential Information confidential for the duration of this Agreement, including any extension thereof, and thereafter for a period of five (5) years following termination or expiry of this Agreement. Excluded from this obligation of confidentiality shall be any Confidential Information of which one Party can reasonably demonstrate that it (a) was previously known to them, or (b) is, and/or becomes, publicly available during said five (5) year period through no fault of a Party, or (c) is independently and lawfully developed by one Party. This obligation of confidentiality shall not apply to any disclosure required by law, provided that a Party shall notify its counterpart of any disclosure required by law in sufficient time so that the counterpart may contest such requirement, if it so chooses. Subject to mandatory law, upon the expiration or termination of this Agreement for whatever reason, or at the earlier request of a Party, the other Party shall, at its own costs, return or destroy all originals and copies of Confidential Information, or, in case of Confidential Information stored in electronic, magnetic or digital media, shall erase or render unreadable all materials furnished (including without limitation, working papers containing any Confidential Information or extracts therefrom) which contain Confidential Information.
14. **IP in BioMedIT Nodes.** As between the Principals and the BioMedIT Nodes, the BioMedIT Nodes shall be and remain the sole owner of all Intellectual Property Rights in and to the BioMedIT Nodes, as well as any other infrastructure used to provide the Services. Nothing in this DTPA is intended to assign or grant the Principals or any other party any Intellectual Property Rights or other rights of the BioMedIT Nodes.
15. LIABILITY
16. The Parties agree to each be solely responsible for all acts or omissions in the performance of their respective duties hereunder, and shall be financially and legally responsible for all liabilities, costs, damages, expenses and attorney fees resulting from, or attributable to any and all such acts or omissions.
17. Each Party disclaims any liability for any indirect damages or losses, whether foreseen or foreseeable, related to the loss of use, interruption of business, loss of actual or anticipated profit, loss of revenue, loss of anticipated savings, loss of opportunity, loss of goodwill, loss of reputation, loss of, damage to or corruption of assets or data, or any other indirect, incidental, exemplary, or consequential damages or losses of any kind, regardless of the form of action, whether in contract, tort or otherwise.
18. TERM
19. **Term**. This DTPA shall become effective on the date when it is signed by the duly authorized representatives of one BioMedIT Node, and then for each additional BioMedIT Node, on the date when the duly authorized representatives of each additional BioMedIT Node adhere and sign this DTPA. This DTPA shall remain in effect until expiration or termination of the DTUA, unless terminated earlier in accordance with this Section IX of the DTPA.
20. **Termination for Convenience**. Each Party may terminate this DTPA for any reason at any time upon 3 months prior written notice to the other Parties. A termination by a Party shall have the effect of terminating the DTPA for all Parties, except as otherwise agreed in writing by the non-terminating Parties.
21. **Termination for Cause**. Each Party may terminate the DTPA with immediate effect, if another Party has materially breached or is in material breach of its obligations and such breach is not cured, or the breaching Party does not make sufficient efforts to remedy the breach, within 30 days after written notice of breach.
22. **Survival**. All terms which are expressed or intended to survive, and any provisions of the DTPA necessary for its interpretation or enforcement will continue to apply regardless of the reason for termination of the DTPA.
23. **Further Needs after the termination of the DTPA**. Data hosting needs after the termination of the DTPA such as for long-term archiving or for making Data available for other research projects, shall be regulated by separate agreement as specified in Clause 6.5 of the Consortium Agreement. Principals wishing to benefit from such further services shall notify the BioMedIT Nodes at least three (3) months before the termination of this DTPA. In any case, such a notification does not affect this DTPA, including its termination clauses (Section IX). The BioMedIT Nodes have no obligation to enter into a new agreement and shall in no event be held responsible for any interruption of the Services, in particular the Data hosting activity.
24. MISCELLANEOUS
25. **Amendment**. This DTPA may be modified only by a written instrument duly executed by each Party.
26. **Independent Contractors**. Nothing in this DTPA is intended to, or shall be deemed to, establish any partnership or joint venture between the Parties, constitute any Party the agent of any other Party, nor authorize any Party to make or enter into any commitments for or on behalf of another Party. No Party shall have the power to incur any obligations in the name of, or on behalf of, or pledge credit of, the other Parties in any manner whatsoever.
27. **Counterparts and Electronic Form**. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which shall together be deemed to constitute one and the same Agreement. Each Party acknowledges that an original signature or a copy thereof, including a "portable document format" or PDF copy, or a signature generated by industry standard electronic signature software (e.g. Docusign), which is transmitted by email shall constitute an original signature for purposes of this Agreement and shall have the same legal force and effect as the exchange of original signatures; while the term "in writing" shall include communications by email or other electronic forms.
28. **Assignment**. No Party may transfer this DTPA, or assign in whole or in part its rights or obligations under this DTPA, without the prior written consent of all other Parties. Any transfer or assignment made without such consent shall be null.
29. **Force Majeure**. No Party shall be considered in default under this DTPA if all or any of its obligations are delayed or prevented as a result of a situation of force majeure, such as natural disasters of a particular intensity, war, epidemics, riot, strike, power failure or Internet network failure, or any other cause that is reasonably beyond the control of the affected Party.
30. **Entire DTPA**. This DTPA contains all of the terms and conditions agreed upon by the Parties relating to its subject matter and supersedes all prior agreements, negotiations, correspondence, undertakings and communications of the Parties, whether oral or written, with respect to such subject matter.
31. **Hierarchy**. In the event of conflict with an exhibit to this DTPA, this main body of this DTPA will govern, unless the exhibit specifically states its intent to do so and cites the section or sections amended.
32. **Severability**. If any provision of this DTPA is held to be invalid or unenforceable for any reason, the Parties shall replace it by a substitute provision that achieves to the fullest extent possible the same legal and economic purposes as those of the invalid or unenforceable provision. In any event, the remainder of this DTPA shall remain in full force and effect between the Parties.
33. **No Waiver**. The failure of any of the Parties to enforce any of the provisions of this DTPA or any rights with respect thereto shall in no way be considered as a waiver of such provisions or rights or in any way affect the validity of this DTPA. The waiver of any breach of this DTPA by any Party shall not be construed as a waiver of any other prior or subsequent breach.
34. GOVERNING LAW AND JURISDICTION
35. **Governing Law**. This DTPA shall be governed by and construed in accordance with Swiss substantive law, without reference to its conflict of laws provisions.
36. **Jurisdiction**. Any dispute or difference arising out of or in relation to this DTPA shall be subject to the exclusive jurisdiction of the Swiss courts at the registered seat of the defending Party, subject to the right of appeal to the Federal Tribunal.

Acknowledged and approved by

**University of Lausanne** (SENSA BioMedIT Node Romandie) Quartier UNIL-Centre, Bâtiment Unicentre, 1015 Lausanne, Switzerland

Adriano Barenco

Head of IT Department

Date:

Roberto Fabbretti

Head of SENSA BiomedIT Node Romandie

Date:

**University of Basel** (sciCORE, Basel BioMedIT Node)

Marco Gersbacher

Deputy Head of IT-Services, University of Basel

Date:

Thierry Sengstag

Deputy director - sciCORE computing center

Date:

**ETH Zurich** (Scientific IT Services - SIS, Zurich Node)

Bernd Rinn

Head of SIS

Date:

Rui Brandao

Head of IT-Services

Date:

*Choose the relevant nodes.*

Exhibit 1 to the DTPA – Description of Data and Service

1. Supply of DATA to the BIOMEDIT NODES

[●]

Transfer of Data

Data will be transferred to the BioMedIT Nodes within a standardized and secure way, i.e. using the network-internal Data Transfer Tool. Data is stored and processed in compliance with the SPHN Information Security Policy.

*Adapt the information given for the transfer of data, if needed.*

Data access

The Project Leader [ ] defines who will be authorized to access the Data. Only authorized users can access and process the data. Login to the secure BioMedIT Node requires two-factor authentication and access to data is only possible via trusted networks (either from within Swiss university and university hospital networks or via VPN). For this project access will be provided to [ ]. Access to the Internet is strictly controlled, limited to trusted and explicitly whitelisted web resources. Contractual and technical measures prevent that data is shared and/or combined without the appropriate authorization. Transfer, access and processing operations are logged. Physical access to server rooms of BioMedIT nodes is access-controlled.

*Specify the names of the people defining the access rules and having access to the data.*

1. Services

As specified in the Agreement.

All three BIOMEDIT NODES provide services to the PROVIDER.

Specifically:

* [ ] is the main BIOMEDIT NODE for this project. It is providing the processing services mandated by the PROVIDER to fulfill the project goals, including data storage (hosting), computational resources for data analyses, transfer of data, etc.,
* [ ] will provide services related to transfer of data,
* [ ] will provide services related to transfer of data.

*Delete or specify the applicable nodes.*

Exhibit 2 to the DTPA – Information and Audits of Security Measure

1. Scope. The provisions of this Exhibit apply to personal data contained in the Data.
2. Information. The BioMedIT Nodes shall make available to the Principals, all documents and information reasonably necessary to demonstrate their respective compliance with the applicable data protection law and their obligations arising therefrom.
3. Right of audit. The BioMedIT Nodes shall allow the Principals or an independent auditor appointed by the Principals to conduct audits (including inspections) to verify the BioMedIT Nodes' compliance with their obligations under the applicable data protection law. Any audit shall be constrained to infrastructure needed to perform the SERVICES and related measures. The BioMedIT Nodes shall provide reasonable assistance with respect to the audits described in this clause 3. Upon conclusion of the audit, the Principals shall forward the complete audit report to the BioMedIT Nodes, free of charge.
4. Request. Any request under clause 2 (Information) or clause 3 (Audits) must be communicated to the BioMedIT Nodes in writing and indicate (i) the Data concerned, (ii) the reasons for which the conditions referred to in clause 2 (Information), respectively clause 3 (Audits) apply to these Data, (iii) the specific documents to be reviewed, respectively the specific obligations of the BioMedIT Nodes to be audited, and (iv) that the Principals expressly undertake to use the information collected only to ensure that the BioMedIT Nodes are in compliance with their obligations with regard to the concerned Data. Unless there are exceptional circumstances, the Principals may not make more than one request per year.
5. Exercise of rights. Upon receiving a request in accordance with the preceding clause, and provided that all conditions are met, the BioMedIT Nodes shall comply with the request as follows.

the BioMedIT Nodes shall inform the Principals, with regard to the review of documents (clause 2 [Information] above), of the period during which they may consult the documents at the BioMedIT Node's offices. Unless otherwise expressly agreed by the BioMedIT Nodes, the Principals shall not be authorised to make copies of the documents consulted. Alternatively, the BioMedIT Nodes may decide to provide the documents electronically;

1. the BioMedIT Nodes shall inform the Principals with regard to audits (clause 3 [Audit] above) of (i) the date or dates on which the audits may take place and (ii) the scope of the audit, in particular the inspections that may be carried out, in order to check the BioMedIT Nodes' compliance with their obligations under the DTPA. The Principals' internal costs or the costs of the independent auditor appointed by them shall be borne entirely by the Principals. The BioMedIT Nodes may invoice the Principals for their own costs associated with the preparation for and execution of the audit based on the costs incurred by the BioMedIT Nodes. The BioMedIT Nodes may object to any independent auditor appointed by the Principals if, in their opinion, the auditor is not sufficiently qualified, is a competitor of the BioMedIT Nodes, or in any other way would not be able to perform its duties properly. In this case, the Principals may either carry out the audit itself or propose another auditor to the BioMedIT Nodes.
2. Confidential information. The provisions contained in this clause 2 shall not be interpreted as requiring the BioMedIT Nodes to provide the Principals with (i) any information relating to trade secrets of the BioMedIT Nodes or any information of a confidential nature or (ii) any information concerning other users of the BioMedIT Nodes' services. The BioMedIT Nodes may make the review of documents (clause 2 [Information] above) or the conduct of an audit (clause 3 [Audits] above) subject to the conclusion of a specific confidentiality agreement.

Annex III – SPHN BIOMEDIT INFORMATION AND SECURITY POLICY

*[PLEASE INSERT THE LATEST VERSION OF THE SPHN/BIOMEDIT INFORMATION AND SECURITY POLICY]*

*The SPHN/BioMedIT information and security policy is accessible upon request to:* *dcc@sib.swiss**.*

SCHEDULE 4 – AUTHORSHIP GUIDELINES

**Authorship Guidelines**. All publications of the Results must be compliant with the Authorship Guidelines of the Swiss Academies of Arts and Sciences accessible at : <https://api.swiss-academies.ch/site/assets/files/4413/akademien_autorschaft_en.pdf>

*These guidelines may be updated. Please make sure you refer to the latest version.*

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

OPTIONAL - SCHEDULE 5 – MATERIAL TRANSFER AGREEMENT (MTA)

*The Swiss Biobanking Platform (****SBP****) provides MTA templates for the Swiss research community that are compatible with the SPHN Templates. This SPHN template therefore refers to the SBP MTA templates to manage questions relating to the transfer of biological material in this agreement. Please note that at the date of the last update of this SPHN template, the SBP MTA templates consist of two parts (the master legal agreement (****MLI****) and the project agreement (****PA****). Please ensure to include both documents in Schedule 5 and not just the PA. Templates are available here:* [*https://swissbiobanking.ch/documents/*](https://swissbiobanking.ch/documents/)

OPTIONAL – SCHEDULE 6 – LIST OF BACKGROUND IP