**CONSORTIUM AGREEMENT including**

**DATA TRANSFER AND USE AGREEMENT and DATA TRANSFER AND PROCESSING AGREEMENT**

**Colour code:**

Grey background = To be completed;

Yellow background = the internal references to the contract (to be completed or deleted if necessary)

Green background = Guidance through the document, to be deleted at the end.

**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 |  | DTUA III.3 (Security measures amended) and III.9 (limitation of download from BioMedIT Node); Annex II (minimal security requirements) deleted (replaced by security measures in DTUA III.3).DTPA III. 2 (Scope adapted), III.5 (Payment of fees adapted), IV.3.1 (Security requirements adapted), IX.5 (Further needs after termination of DTPA added); Annex II (minimal security requirements) deleted and replaced by security measures in DTPA IV.3.1. | FE/JM/MH |

✂ **….. Please remove the ‘Colour code instructions’, the green guidance text**

**and the table ‘Change history’ …..** ✂

dated [date]

To [form a multicenter research consortium to conduct a project entitled] “[InsertProjectName]” (the **Project**).

*The Consortium Agreement (CA) regulates the general principles of a collaboration between the parties to a research project, such as rules for publications and intellectual property, financial conditions, governance. 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). The Provider and the Recipient jointly determine the purpose and means of the processing within the framework of the research project. They both assume the role of "Data Controller" (as opposed to the role of "Data Processor").*

*If the Controllers 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 has to be regulated in a specific agreement: a Data Transfer and Processing Agreement (DTPA), as provided in Annex III.*

*Note that this agreement should be approved by your legal department, in accordance with the internal rules of your institution.*

among

|  |  |
| --- | --- |
| **[#Name, Address]** | (**Party01**) |
| **[#Name, Address]** | (**Party02**) |
| **[#Name, Address]** | (**Party03**) |
| **[#Name, Address]** | (**Party04**) |
| **[#Name, Address]** | (**Party05**) |
| **[#Name, Address]** | (**Party06**) |
| **[#Name, Address]** | (**Party07**) |
| **[#Name, Address]** | (**Party08**) |
| **[#Name, Address]** | (**Party09**) |
| **[#Name, Address]** | (**Partynn**) |

(together with any other entity accessing to this Consortium Agreement, the **Parties**)

*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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1. Scope
	1. **Scope**. This agreement together with its Schedules (the **Consortium Agreement**) specifies 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 (the **Project Description**).
	2. **Hierarchy**. In case of contradiction between the terms of the main body of this Consortium Agreement and the terms of any Schedule, the terms of the main body of this Consortium Agreement shall prevail, unless the relevant Schedule makes an explicit reference to the provision of this Consortium Agreement that shall be amended.
	3. **No Agency**. This Consortium Agreement does not establish any principal-agent or similar relationship between the Parties, and nothing in this Consortium Agreement shall be interpreted as allowing either Party to represent or act in the name or for the account of the other Party. The Parties shall act in all aspects as independent contractors.
2. General Undertakings of The Parties
	1. **In General**. Each Party undertakes to use reasonable endeavours to perform and fulfil, promptly, actively and on time, all of its obligations under this Consortium Agreement – including the tasks specifically allotted to it in the Project Description (the **Allocated Work**) – in accordance with:
		* 1. its institutions’ policies;
			2. the Project Description;
			3. [the rules of the Swiss Personalized Health Network (**SPHN**) and in particular the “Funding Regulations” including “General implementation regulations for the Funding Regulation“ referenced in the Project Description];
			4. The study protocols specified in the Project Description and other study protocols as may be approved by the Scientific Board (the **Study Protocols**); and
			5. all applicable laws and regulations, including data protection and human research laws, and ethical guidelines.

*Adapt accordingly, if the rules of the SPHN do not apply or if there is no scientific board.*

* 1. **Resources**. Each Party shall maintain and allocate sufficient resources required to carry out such tasks in a timely manner.
	2. **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.
	3. **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 Human Samples shall be governed by Section 6.4.

*Adapt if human samples are not used in this project.*

1. Governance
	1. **Governance Structure**
		1. In General. The Parties shall implement a governance structure for the Project as specified in Schedule 2, composed of:
			1. the project leader (**Project Leader**) and the legal sponsor (**Sponsor**) of any study or human research project study in relation to the Project (each a **Study**), as specified in Schedule 1 for the initial Study or in the relevant Study Protocol of any subsequent Study;
			2. the investigators of the Project referenced in Schedule 1 (the **Investigators**);
			3. the executive board of the Consortium (the **Executive Board**);
			4. the scientific board of the Consortium (the **Scientific Board**);
			5. the other bodies as specified in Schedule 2 or as set up by the Executive Board; and
			6. the authorized representative of each Party listed in Schedule 2 (**Authorized Representative**).
		2. Project Leader.The Project Leader is responsible for the overall management of the Study and has the responsibilities specified in this Consortium Agreement and in the Project Description.
		3. Sponsor(s). The Sponsor(s) of each Study shall take the overall responsibility for the organization and management of the Study, in accordance with this Consortium Agreement, clinical practice guidelines, the Human Research Act and its related Ordinances.
		4. Investigators.The Investigators shall be responsible for the day-to-day supervision of the Project in accordance with the work packages and tasks defined by the Project Description, with assistance from associates and colleagues as required. They shall regularly meet or hold telephone conferences together with the Sponsor and Project Leader to discuss the progress of the Project. Face-to-face project meetings will take place as required.
		5. Executive Board.TheExecutive Board is the ultimate decision-making body that takes on behalf of the Parties all strategic decisions and that supervises activities carried out by the consortium formed hereunder and the finding of amicable solutions for any unresolved disputes between the Parties relating to the execution of the Project. Its composition, organization, and responsibilities are specified in Schedule 2. The Executive Board may delegate part of its responsibilities to other boards or subcommittees.
		6. Scientific Board.The Scientific Board is responsible for decision-making in relation to the scientific direction of the Project and to implement the coordination of the Study. Its composition, organization, and responsibilities are defined specified in Schedule 2.
	2. **Compliance**. Each Party shall procure that all governance bodies set up within the Project shall abide by the terms of this Consortium Agreement in any and all of their decisions and actions.
	3. **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 any scheduled meeting of a governance body. If a representative can permanently no longer participate, either Party may replace such representative at any time, upon written notice to the other Parties in accordance with Section 11.6.
	4. **Binding Effect**. The Parties agree to abide by all decisions of the Executive Board, which shall be binding on the Parties. The Parties shall ensure that decisions taken by the Executive Board are adequately communicated to personnel within each Party’s organization who have a need to know such Executive Board decisions in order to implement them. [Decisions taken by other governance bodies shall only be binding if they are ratified by the Executive Board or the Authorised Representatives.]
	5. **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 [simple majority] approval of the Executive Board and the relevant ethics committees to be implemented, provided always that a Party whose Allocated Work, time for performance, allocation of funds are impacted, may veto such decisions of the Executive Board, provided such veto is duly justified. In such a case, the concerned Party and the Executive Board shall discuss in good faith possible solutions to enable the continuation of the Project within 3 months.
2. Financial Conditions
	1. **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, or in the absence of a Project Leader, by the Executive Board, always in accordance with Project Description.
	2. **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.
3. Confidentiality
	1. **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.
	2. **Exclusions**. Section 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.
	3. **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.
4. Data and Human Samples
	1. **In General**. The Parties must process personal data and Human Samples under the Consortium Agreement in compliance with applicable data protection laws. Each Party represents and warrants that any personal data and/or Human Samples required for use in the Project that are obtained, handled or used by it will be obtained, handled or used in accordance with all relevant laws and regulations (and where applicable, ethical guidelines) regarding their collection, use, transport and subsequent disposal and that any ethics committee approvals and, as the case may be, informed patient consents required for performing the Project and for Study will be obtained prior to the commencement of the respective part of the Allocated Work as described in detail in the Project Description.

*Delete the part for Human Samples under section 6.3, 6.4, 7.6, 8.3 and 9.5 if not applicable or regulated in a separate Material Transfer Agreement (MTA).*

* 1. **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, including its annexes (**DTPA and Minimal Security Requirement**).
	2. **Human Samples**. “**Human Samples”** means human biological material, including any portion of any tissue, blood, cerebrospinal fluid, cells or sub-cellular structures such as DNA, or any derivative of such human biological material such as pathogens (bacteria, viruses, fungi, parasites), serum, stem cells, cell lines and any human biological product. Access to, provision and exchange of Human Samples under the Project shall be carried out pursuant to the terms of this Consortium Agreement, any Study Protocols and the following principles:
		+ 1. only Parties that are [hospitals **//or//** university/university hospital] shall be allowed to permanently store Human Samples. Collected Human Samples will be aliquoted (split) into fragments of the original sample at the microbiology institutions of each Party that is a [university/university hospital]. One aliquot will be shipped to the Party/ies performing examinations such as sequencing and metabolomics as described in the Project Description and/or the respective Study Protocol. Leftover aliquots will be stored at each microbiology institution for at least 5 years;
			2. Human Samples shall not be disposed of or acquired as such for research purposes in return for payment or other non-cash advantage. However, the foregoing shall not apply to operations such as preparation, transport, storage etc. of Human Samples;
			3. The Parties may only use the Human Samples received under this Consortium Agreement for the Project and shall either return or destroy the Human Samples after the related activities to the providing Party, or if requested by the patient.
	3. **Access**. Parties can use and may share Data and Human Samples under their custodianship with any third party providing analyses within the Project, if and to the extent required for the Project, provided that the Data and Human Samples: (i) are disposed in accordance with all necessary patient consents, regulatory approvals and the purpose of the Project, under terms at least equivalent to those of this Consortium Agreement and the DTUA and (ii) remain confidential and are published only after the publication of the Results from the Project by the Executive Board pursuant to Section 8.
1. Intellectual Property
	1. **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 Human Samples; “**Results**”meansanyresults 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.
	2. **Duty to Inform.** Each Party generating Results shall promptly inform the Sponsor or Project Leader and all Parties having contributed to such Results.
	3. **Background IP**. Each Party shall retain all title, right and interest in and to its respective Intellectual Property Rights existing as of the date of this Consortium Agreement or which is later developed independently from the Project (the “**Background IP**”). Unless otherwise agreed herein, 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.

*Background IP means all Intellectual Property Rights owned by or licensed to a Party at the start of the Project.*

* 1. **Foreground IP**

Choose the appropriate regulation regarding the foreground IP.

Foreground IP means all Intellectual Property Rights made in the performance of work under this agreement.

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

* + 1. 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 Section 7.7. Such an agreement shall not cause a delay of publication of the Results any longer than defined in Section 8.2.
		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.

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 Section 8.2.

* 1. **Licences 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.
	2. **Licence to Foreground IP.** Each Party generating Foreground IP by using Data, Human Samples, 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.
	3. **IP Exploitation**
		1. 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, Human Sample). The owners of Foreground IP shall pay to Parties having contributed to generating the Foreground IP [a fair share of *or* [...]% on] any net revenues received by Recipient for the commercialization of the Foreground IP].
		2. Patent Protection. [To adapt to Section 7.4: If an owner of Sole Foreground IP or 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.

*Please adapt according to Section 7.4.*

* 1. **Open Source**. Notwithstanding anything to the contrary in this Section 7, the Parties agree to make software implementations necessary for making the Results available to the public upon publication by means of open source software release. In order to do so, the Parties shall consult with each other and agree on the strategy and use of any open source software and its respective licensing terms and possible effects (such as but not limited to viral effects also known as copy left effects), before the first publication of the Results. The use of open source software in the Project shall be in accordance with its respective licenses and all relevant notices retained.
1. Publications
	1. **In General**. The Parties agree that the Results shall be made public as soon as possible by the Party having generated it, unless publication goes against its legitimate interests (for instance, because the Results have not yet been protected, the Results concern trade secrets, or disclosing the Results would infringe on applicable personal data protection, security related, or other applicable obligations). Published information shall be deposited in an open access data repository to the extent reasonably possible.
	2. **Right to object**. Prior to the publication of its Results, the publishing Party shall submit to the other Parties for review a draft of the publication. Each other Party shall have [60] days to request the disclosing Party to:
		* 1. withdraw any Confidential Information provided by it, in which the affected Party 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 affected Party wishes to file a patent application (as the case may be, pursuant to Section 7.7.2).

*Adapt the period of time accordingly.*

* 1. **Authorship Guidelines and Acknowledgment**. All publications of the Results must be compliant with the authorship guidelines specified in Schedule 4 (Authorship Guidelines)and shall acknowledge the role and contribution of the consortium formed hereunder and of the Parties that provided the Data and Human Sample, in accordance with best scientific practice.
1. Duration, Entry and Exit of Parties
	1. **Duration**. This Consortium Agreement will enter into force once signed by all Parties and will continue in force until [date **// or //** completion of the Project], subject to early termination decided by the Executive Board with a [two third] majority of the votes cast.
	2. **Accession**. The Executive Board shall be entitled to accept submissions of entities to become party of the consortium formed hereunder. The new entity shall execute this Consortium Agreement or an adapted version of it, or a deed of adherence in a form acceptable to the Execution Board, upon which it shall become a new Party and be subject to all the terms and conditions of this Consortium Agreement. The Parties unconditionally accept any such entity as a Party.
	3. **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.
	4. **Eviction**. In the event of a material breach of the Consortium Agreement or of other agreements for the implementation of the Project, such as the DTUA, by a Party, [the Executive Board] shall give written notice to the breaching Party to allow the latter to remedy the breach within thirty [30] days. If the breach has not been rectified within said period, the other Parties may terminate the breaching Party’s participation [through a decision of the Executive Board requiring at least two third of the votes cast in which the representative of the breaching Party shall not participate], in which case the breaching Party’s participation and all rights granted to the breaching Party according to this Consortium Agreement will cease immediately.

*Adapt this part accordingly.*

* 1. **Effects of termination of expiry**. Upon termination or expiry of this Consortium Agreement (respectively in case of an exit or eviction of a Party, for that Party only), all Confidential Information, Data and Human Samples, if any, shall immediately be returned or destroyed, as per request of the providing or disclosing Party. Expiration or termination of 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.
1. Warranties and Indemnification
	1. **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. There is no duty to conduct searches with regard to registered intellectual property rights.]
	2. **No liability**. Subject to Sections 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 wilful 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.
	3. **Use of Results**. The Parties use the Results at their own risk. A Party using any of 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.

*[Optional: to be discussed according to the configuration of the project and the will of the parties:]*

* 1. **Sponsor's liability**. The Sponsor shall defend and indemnify a Party, its directors, agents, employees and all Study personnel from any liability or loss resulting from judgments or claims against them arising out of the activities to be carried out pursuant to the obligations of this Consortium Agreement; provided, however, that Sponsor shall not defend and indemnify a Party from liability resulting from wilful misconduct or gross negligence of such Party, its directors, agents, or employees.

*Adapt according to the configuration of the project and the will of the parties.*

1. Miscellaneous
	1. **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**). 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. In order to avail itself of the relief provided in this Section 10.4, the affected Party shall act with due diligence to remedy the cause of, or to mitigate or overcome, such delay or failure.
	2. **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.
	3. **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.
	4. **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 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.
	5. **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.
	6. **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 Authorized Representative's addresses listed in Schedule 2. Such addresses may be changed, from time to time, by means of a notice given to the other Parties in the manner provided in this Section 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.
	7. **No Waiver and Enforceability**. No delay or failure by a Party to exercise any of its powers, rights or remedies under the Consortium Agreement will operate as a waiver of them nor will any single or partial exercise of any such powers, rights or remedies preclude any other or further exercise of them. Any waiver to be effective must be in writing.
	8. **Amendment**. The Consortium Agreement (including this Clause) may be amended only by (i) a written instrument duly signed by the Parties or (ii) a resolution of the Executive Board in accordance with Section 3.4, within the limits of the Executive Board’s competences as specified in Schedule 2.
	9. **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. The provisions of the United Nations Convention on Contracts for the International Sale of Goods dated 11 April 1980 are excluded.
	10. **Jurisdiction**. Dispute in relation to this Consortium Agreement shall be submitted to the exclusive jurisdiction of the competent courts [at the defendant's registered office in Switzerland], subject to the right to appeal to the Swiss Federal Tribunal.

[signatures on the following page]

|  |  |
| --- | --- |
| **[#Entity1Name]****[#RepresentativeName]** |  |
| **[#Entity2Name]****[#RepresentativeName]** |  |
| **[#Entity3Name]****[#RepresentativeName]** |  |
| **[#RepresentativeName]****[#Entity4Name]** |  |
| **[#Entity5Name]****[#RepresentativeName]** |  |
| **[#Entity6Name]****[#RepresentativeName]** |  |

Schedule 1 – Project Description

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

**Exhibit A** Project Application ref. [#InsertReference] dated [#InsertDate].

**Exhibit B** Ethical proposal application [#InsertSponsorName] dated [#InsertDate].

**Exhibit C** Study protocol [#InsertName] dated [#InsertDate].

[**Exhibit D**] [#InsertDescription].

|  |
| --- |
| **Summary Table** |
| **Sponsor** | [#InsertSponsorName] |
| **Project Leader** | [#InsertProjectLeaderName] |
| **Investigators** | [#InsertInvestigatorsName] |
| **Title** | [#InsertProjectName] |
| **Short Title** | [#InsertShortProjectName] |
| **Description**  | See Exhibit A and Exhibit B. |
| **[Study Protocols]** | See Exhibit C |
| **Allocated Works and deliverables** | See Exhibit A. |
| **Timeline** | See Exhibit A. |
| **Financing** | See Exhibit A. |
| **[other]** | [#Insertdescription] |
| **Applicable guidelines**  | SPHN “Funding Regulations” including “General implementation regulations for the Funding Regulation“  |

*Adapt this table accordingly.*

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

Schedule 2 – Governance

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

1. Authorized Representative

For all matters which do not fall under the remit of a specific body, each Party shall act through its Authorized Representative listed below, which shall have the power to represent and bind the Parties, and which shall act as is the contact point within their organization.

|  |  |  |
| --- | --- | --- |
| **Name of Party** | **Authorized Representative** | **Postal Address and email address** |
| [#Entity1Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |
| [#Entity2Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |
| [#Entity3Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |
| [#Entity4Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |
| [#Entity5Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |
| [#Entity6Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |
| [#Entity7Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |
| [#Entity8Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |
| [#Entity9Name] | [#RepresentativeName] | [#PostalAdress][#EmailAdress] |

1. Executive Board

|  |  |
| --- | --- |
| **Members** | The Executive Board shall consist of one representative of each Party. The Composition of the Executive Board as of the time of signature of the Consortium Agreement is as follows:[#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party] |
| **Chairperson** | Members of Executive Board shall appoint a person who will chair the meetings (as defined below) on a rotating basis (**EB** **Chairperson**).The initial EB Chairperson is [#Name(First Name Last Name), #Party] |
| **Responsibilities** | The Executive Board shall decide on, including but not limited to, the following matters:* + - 1. manage, oversee and coordinate the Parties’ relationship under the Consortium Agreement;
			2. evaluate the progress and activities towards achievement of the targets and results of the Project;
			3. amend the Project Description;
			4. review and determine extension of time or re-formulation of the Project;
			5. define the organization, composition and the *modus operandi* of the Project;
			6. identify and seek to resolve any issues that arise between the Parties, which cannot otherwise be resolved between the Parties;
			7. decide on the admission of new Parties;
			8. discuss other subject matters related to this Consortium Agreement;
			9. terminate this Consortium Agreement.
 |
| **Board Meetings** | The Executive Board shall meet at least [quarterly], at venues to be agreed, or at any other time [as agreed by the Parties]. 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. Agenda items may be addressed by any 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 in advance of the meeting. |
| **Voting Rules** | Each member shall have one vote. The members shall act in good faith to cooperate with one another and seek agreement with respect to issues to be decided. The members shall first try to reach consensus. However, if consensus cannot be reached, decisions of the Board will require simple majority, unless another majority is specified in the Consortium Agreement. |
| **Minutes** | The Parties shall agree upon which member acts as secretary and prepare the minutes of a particular meeting at such meeting. The assigned Party shall send the minutes to each of the Executive Board members within [15] days after the meeting. Any member that was present to that meeting may object to the minutes, within [2] weeks of receipt, if they are incorrect by notice to the EB Chairperson. In case of objection, the EB Chairperson shall try to resolve the objection in a telephone conference, in which case the adapted minutes shall be sent a new [2]-week objection period shall start. |

1. Scientific Board

*Section to be kept only if a Scientific Board has been established under section 3.1.6.*

|  |  |
| --- | --- |
| **Members** | The Scientific Board shall consist of [●]. The composition of the Scientific Board as of the time of signature of the Consortium Agreement is as follows:[#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party] |
| **Chairperson** | The Executive Board shall appoint the chairperson of the Scientific Board (**SB** **Chairperson**).The initial SB Chairperson is [#Name(First Name Last Name), #Party]. |
| **Responsibilities** | Matters pertaining to the scientific direction of the Project and to implement the coordination of the Study, such as:* + - 1. Approval of further Study Protocols;
			2. Secondary data analysis;
			3. Follow-up studies;
			4. Studies analysing new data.
 |
| **Board Meetings** | [*Same as the Executive Board.*] |
| **Voting Rules** | [*Same as the Executive Board.*] |
| **Minutes** | [*Same as the Executive Board.*] |

1. [Other]

|  |  |
| --- | --- |
| **Members** | The [name] shall consist of [●]. The composition of the [name] as of the time of signature of the Consortium Agreement is as follows:[#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party][#Name(First Name Last Name), #Party] |
| **Chairperson** | The Executive Board shall appoint the chairperson of the [name] (**[xx]** **Chairperson**).The initial [xx] Chairperson is [#Name(First Name Last Name), #Party] |
| **Responsibilities** | [#Insertdescription]. |
| **Board Meetings** | [*Same as the Executive Board.*] |
| **Voting Rules** | [*Same as the Executive Board.*] |
| **Minutes** | [*Same as the Executive Board.*] |

**Schedule [3] | Data Transfer and Use Agreement (DTUA)**

*The DTUA regulates the conditions under which a data "Provider" (e.g. a hospital) agrees to disclose personal data to a data "Recipient" (e.g. a university). The Provider and the Recipient jointly determine the purpose and means of the processing within the framework of the research project. They both assume the role of "Data Controller" (as opposed to the role of "Data Processor").*

*If the Controllers 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 has to be regulated in a specific agreement: a Data Transfer and Processing Agreement (DTPA), as provided in Annex I.*

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 [and PHRT] 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.

*Choose the appropriate granted support.*

1. The Provider is the controller of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ data (**Data** as set forth in **Annex I** of this DTUA and its exhibit I;
2. The Recipient wishes to conduct the [#ProjectName] research 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.

**I. Definitions**

Unless defined below, terms shall have the meaning described in the applicable law; in case there is no definition in the law, the SPHN Glossary

 (<https://sphn.ch/document/sphn-glossary/>)

definition shall apply.

For the purpose of this DTUA, capitalized terms which are not defined herein shall have the meaning given to them in the Consortium Agreement.

**II. Data Provision**

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

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

1. **Form.** The Data shall be provided to the Recipient by the Provider in a coded form and in a format to be agreed upon by the Parties as perexhibit Iof **Annex I.** The Recipient shall not have the key.

*Specify in which form data is provided (uncoded, coded or anonymized).* As a reminder, coded or pseudonymized data is not considered as anonymous 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.

*Make sure data provision is made in accordance with the law (e.g. Human Research Act) and your institutional governance processes.*

1. **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.
2. **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.

**III. Data Processing**

1. **Purpose**. The Recipient and the Recipient’s Authorized Representative agree that the Data: (a) is to be used only for the academic purposes as described in the Project Description; (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.

*Note that the purpose may be adapted depending on the project, within the limits of the law.*

1. **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.
2. **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 research 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 protection 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” and the “SPHN Information Security Policy”, as both updated occasionally, accessible at:

<https://sphn.ch/document/ethical-framework/>

<https://sphn.ch/document/information-security-policy/>

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 according to section III.6. below.
2. **Rights of the data subject.** 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. The Parties shall respond to requests from the data subject within one month after having received the notification. Moreover, the Parties will provide any data subject with a copy or the content of this DTUA upon their request or if required by law. In case of a production request by a data subject, 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 raise damages and 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 provided both by Swiss law and the GDPR.*

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 delay depending on the consent signed by the data subject and must provide the pseudo-identifier of the data subject that revoked access to his/her Data. 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.
2. **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.
3. **Data transfer via the BioMedIT Node.** The Parties agree that the Data transfer will be performed as agreed in writing by the technical representatives of the BioMedIT Node, as set forth in **Annex I** of this DTUA and in accordance with all applicable laws.
4. **Download of Data from the BioMedIT Node.** Except with the prior written agreement of the Data Provider, the Recipient is not allowed to download or extract from the BioMedIT node 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 and pseudonymized data.

**IV. 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.

**V. Liability and Third-Party Rights**

1. **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.
2. **Data Subject 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 (the Provider shall have the burden to prove that it took reasonable efforts).

**VI. Miscellaneous**

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

**VII. Annexes**

**Annex I:** BioMedIT infrastructureData Transfer and Processing Agreement

**ANNEX I: BIOMEDIT INFRASTRUCTURE DATA TRANSFER AND PROCESSING DTUA**

[One Node Only]

(the "**DTPA**")

between

[name], [(registration number if any)],[address]

[name], [(registration number if any)],[address]

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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

and

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

OR

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

OR

**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 a BioMedIT node, 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, as specified in the Appendix 1. Choose the node relevant for the project.*

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

(the **BioMedIT Node**)

(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 Node provides *inter alia* a secured IT infrastructure, consisting of high performance compute and storage infrastructure, in order to support computational biomedical research and clinical bioinformatics.
3. Within the framework of their access and use of the Data, the Principals wish to benefit from the BioMedIT Node’s services to *inter alia* store and transfer Data from Provider to Recipient.
4. The BioMedIT Node agrees to provide such services under the terms and conditions of this DTPA.
5. Definitions

Except as otherwise defined in this DTPA, capitalized terms, whether used in singular or plural form, shall have the same meaning as set forth in the DTUA.

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 Node 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, the BioMedIT Node undertakes to provide to the Principals the services specified in Section 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 Node 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 Node;
		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 Node that fall out of the scope of this DTPA according to this Section III.2 (standard services provided by the BioMedIT Node) are regulated by separate service agreement between the BioMedIT Node 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 Section IV.3.1 below.
2. **Power**. The Provider’s Authorized Representative and the Recipient’s Authorized Representative shall have the individual power to give instructions to, and receive notification from, the BioMedIT Node, on behalf of, respectively, the Provider and the Recipient, for all actions relating to the Data.
3. **Payment of Fees**. Costs associated to the Services to be provided by Regional Node shall be determined by mutual agreement between the Parties once the project for which Provider needs the BioMedIT Node has been validated by the competent ethics committee.

[Or]

The Services are part of the SPHN initiative and are provided without any associated costs, unless it surpassed 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 BioMedIT 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:

the subject matter and details of the processing are specified in this DTPA and its **Exhibit 1**;

the BioMedIT Node is a processor of the Data;

the Principals are joint controllers of the Data; and

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).

* 1. Nature and Purpose of Processing. The BioMedIT Node 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 Authorised Representative and the Recipient’s Authorised Representative. For the sake of clarity, the BioMedIT Node shall have no obligation to carry out any instruction which it considers, at its 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).
	2. Restrictions. The BioMedIT Node shall not, without the prior written consent of Provider:

subcontract any of its processing operations of the Data; and

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).

* 1. Return of Data. Upon termination of the DTPA, or earlier as requested by the Provider, the BioMedIT Node shall, within reasonable time following a written request by Provider, provides 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 Node shall be allowed to permanently delete the Data 60 days after termination of the DTPA.
1. **Security**
2. 1. Security Requirements. The BioMedIT Node 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 Node 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 Project Leader to the BioMedIT Node, provided that the BioMedIT Node personnel have the right to access the Data to the extent necessary for providing the Services.

The BioMedIT Node shall adopt adequate organizational measures ensuring that the BioMedIT Node 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 Node 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 Node measures shall be regularly assessed, and corrective measures shall be immediately implemented in case of suspected data security breach.

The BioMedIT Node processes the Data in accordance with the “Ethical Framework for Responsible Data Processing in Personalized Health Research” and the “SPHN Information Security Policy”, as both updated occasionally, accessible at:

<https://sphn.ch/document/ethical-framework/>

<https://sphn.ch/document/information-security-policy/>

3.2 Security Incidents. The BioMedIT Node shall, if it becomes aware of any accidental or unauthorized access to the Data, inform the Principals as soon as possible 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 Node 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 Node acts 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 Node with all information reasonably necessary for the BioMedIT Node to meet its obligations.
2. Representations and Warranties
	* + 1. The Principals represent and warrant that:
		1. the Data to be transferred to and processed by the BioMedIT Node 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 Node and the processing of the Data by the BioMedIT Node (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 provided to the concerned data subjects all required information (including in relation to any processing activity contemplated under this DTPA) and complied with any notification and registration obligations under any applicable laws and regulations;
		4. the Principals will not require the BioMedIT Node 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 Node, in particular with those specified in Section 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 Section III.3 of the DTUA are sufficient in this regard.
3. Information, Assistance and Notifications
4. **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.
5. **Rights of the Concerned data subjects.** The Principals are responsible that the concerned data subjects are provided with their right of access, rectification, deletion or objection. The BioMedIT Node will fully and in a timely fashion cooperate with the Principals in, and when applicable provide to the Principals the necessary services for, fulfilling such requests or inquiries of the concerned data subjects.
6. **Impact assessments and prior consultation**. The BioMedIT Node undertakes, to the extent it 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).
7. **Notification and Assistance**. The BioMedIT Node shall promptly inform, and cooperate with, the Principals if it believes that it may no longer be able, or are no longer able, to comply with this DTPA, particularly in case it receives 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.
8. **Audits.** The provisions of Exhibit 2 shall apply regarding audits.
9. Data ownership, Intellectual Property, Confidentiality
10. **Data Ownership and Right to Use**
	* 1. Ownership. As between the Principals and the BioMedIT Node, 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 Section VII.1.b) below, nothing in this DTPA is intended to assign or grant the BioMedIT Node any Intellectual Property Rights or other rights in the Data.
		2. Use of Data. The Principals grant to the BioMedIT Node 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.
11. **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.
12. **IP in BioMedIT Node**. As between the Principals and the BioMedIT Node, the BioMedIT Node shall be and remain the sole owner of all Intellectual Property Rights in and to the BioMedIT Node, 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 Node.
13. Liability
14. 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.
15. 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.
16. Term
17. **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 of IX of the DTPA.
18. **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.
19. **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 is not diligently pursuing a cure, within 30 days after written notice of breach.
20. **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.
21. **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. Principals wishing to benefit from such further services shall notify the BioMedIT Node 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 Node 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.
22. Miscellaneous
23. **Amendment**. This DTPA may be modified only by a written instrument duly executed by each Party.
24. **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.
25. **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.
26. **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.
27. **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.
28. **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.
29. **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.
30. **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.
31. **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.
32. Governing Law and Jurisdiction
33. **Governing Law.** This DTPA shall be governed by and construed in accordance with Swiss substantive law, without reference to its conflict of laws provisions.
34. **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 the Principals**

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:

OR

**University of Basel** (sciCORE, Basel BioMed-IT Node)

Torsten Schwede

Vice President for Research, University of Basel
Date:

Thierry Sengstag

Deputy director - sciCORE computing center

Date:

OR

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

Bernd Rinn

Head of SIS

Date:

Rui Brandao

Head of IT-Services

Date:

Choose the relevant node

**Exhibit 1 to the DTPA – Description of Data and Service**

1. **Description and format of DATA**

The following DATA and meta data shall be provided from PROVIDER to RECIPIENT:

[•]

*Specify the data used in the project and the applicable transfer process, e.g.*

*The XX registry, built by 4 University Hospitals, will comprise digital information about*

* *clinical data*
* *laboratory variables*
* *drugs*
* *electrocardiograms*
* *imaging data (TTEs, MRIs)*
* *outcomes*

*Number of patients/site:*

*Duration of project:*

1. **Supply of Data to the BioMedIT Node**

[●]

# Transfer of Data

Data will be transferred to the BioMedIT Node 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 Lead [ ] 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 node is access-controlled.

Specify who defines the access rules and who has explicitly access to the data.

1. **Services**

As specified in the Agreement.

[ ] 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.,

**D. Main Project Leader**

[Name, address, email]

**Exhibit 2 to the DTPA – Information and Audits of Security Measures**

1. Scope. The provisions of this Exhibit apply to personal data contained in the Data.
2. Information. The BioMedIT Node shall make available to the Principals, all documents and information reasonably necessary to demonstrate its respective compliance with the applicable data protection law and their obligations arising therefrom.
3. Right of audit. The BioMedIT Node shall allow the Principals or an independent auditor appointed by the Principals to conduct audits (including inspections) to verify the BioMedIT Node’s compliance with its obligations under the applicable data protection law. Any audit shall be constrained to infrastructure needed to perform the Services and related measures. The BioMedIT Node 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 Node, free of charge.
4. Request. Any request under clause 2 (Information) or clause 3 (Audits) must be communicated to the BioMedIT Node 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 Node to be audited, and (iv) that the Principals expressly undertake to use the information collected only to ensure that the BioMedIT Node is in compliance with its 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 Node shall comply with the request as follows:
6. the BioMedIT Node 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 Node, the Principals shall not be authorised to make copies of the documents consulted. Alternatively, the BioMedIT Node may decide to provide the documents electronically;
7. the BioMedIT Node 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 Node’s compliance with its 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 Node may invoice the Principals for its own costs associated with the preparation for and execution of the audit based on the costs incurred by the BioMedIT Node. The BioMedIT Node may object to any independent auditor appointed by the Principals if, in its opinion, the auditor is not sufficiently qualified, is a competitor of the BioMedIT Node, 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 Node.
8. Confidential information. The provisions contained in this clause 2 shall not be interpreted as requiring the BioMedIT Node to provide the Principals with (i) any information relating to trade secrets of the BioMedIT Node or any information of a confidential nature or (ii) any information concerning other users of the BioMedIT Node’s services. The BioMedIT Node 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.

**\* \* \* \***

Schedule 4 – Authorship Guidelines

All publications of the Results must be compliant with the authorship guidelines of the Swiss Academies of Arts and Sciences, as updated from time to time, accessible at:

<https://api.swiss-academies.ch/site/assets/files/4413/akademien_autorschaft_en.pdf>