**DATA TRANSFER AND USE AGREEMENT including 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 published; Minimal security requirements included, GDPR compliance considered | | | JM | |
| 3.0 | 01.06.2021 |  | Colour code instructions added; Change history added; I.6 ‘Effective date’ wording changed;IX.3 and DTPA X.3 ‘Counterparts and Electronic form’ wording adapted, III.7 ‘Third party rights’ renamed in ‘Rights of data subjects’, DTPA IX.I ‘Term’ wording changed; DTPA VII.1c BioMedIT Nodes Intern Policies wording changed; DTPA VIII.1 Liability wording changed; links updated | | | JM | |
| 3.1 | 23.01.2023 |  | | IDTUA III.3 (Security measures amended), III. 11 (Limitation of download from the BioMedIT Nodes); Annex IV deleted (replaced by security measures in DTUA III.3)  DTPA III.2 (scope adapted), IV 3.1 (Security requirements adapted); IX 5 (Further needs after termination of DTPA added); Annex IV deleted (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’ …..** 

for the project [#CompleteProjectName]

*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 III.*

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

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

[name], [address]

and

[name], [address]

and

[name], [address]

*Add all parties involved: The institutions that are required to exchange data for the project (e.g. University Hospital Basel (USB), Spitalstrasse 21 / Petersgraben 4, CH - 4031 Basel*)

Hereinafter jointly referred to as the “PARTIES” and individually as a “PARTY”;

**WHEREAS**

1. The PARTIES have been granted support by SPHN [and PHRT] for their joint research project \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. 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 support.*

1. The PROVIDER is the controller of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ data (hereinafter referred to as the “DATA”), as set forth in **Annex I** of this Agreement;
2. The RECIPIENT wishes to conduct the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ research project (hereinafter referred to as the “RESEARCH”), as set forth in **Annex II** of this Agreement, 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 Agreement, capitalized terms, whether used in singular or plural form, shall have the following meaning:

1. **BACKGROUND INTELLECTUAL PROPERTY (BACKGROUND IP)**: shall have the meaning set forth in Section V below.
2. **CODED DATA** or **DATA IN CODED FORM**: means the data linked to a specific person via a code.
3. **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.
4. **DATA**: means all the data, including the meta data, being transferred (or if not transferred, the data given access to) under this Agreement, as set forth in **Annex I** of this Agreement.
5. **DATA SUBJECT**: means the natural person whose data is processed*.*
6. **EFFECTIVE DATE**: means the date when this Agreement is signed by the duly authorized representatives of two PARTIES, and then for each additional PARTY, the date when the authorized representatives of such PARTY adhere and sign this Agreement.
7. **FOREGROUND INTELLECTUAL PROPERTY (FOREGROUND IP)**: shall have the meaning set forth in Section V below.
8. **INTELLECTUAL PROPERTY RIGHTS:** means all intellectual property rights throughout the world, whether existing under statute, at common law or equity, registered or unregistered, now or hereafter in force or recognized, including trade secrets and know-how.
9. **PROVIDER’S PROJECT LEADER:** means the PROVIDER’s person who takes responsibility for the project as described in the Ordinance on Human Research (**HRO**).
10. **RECIPIENT’S PROJECT LEADER:** means the RECIPIENT’s person who takes responsibility for the project as described in the HRO.
11. **RESEARCH**: means the research project as set forth in **Annex II** of this Agreement, as approved by the Ethics Committee, and for which the DATA will be used;
12. **RESULTS**: means without limitation any output of the RESEARCH such as invention, data, software, algorithms, knowledge, know-how or information that is generated in the RESEARCH, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including INTELLECTUAL PROPERTY RIGHTS.

**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 Nodes substantially in the form as specified in Annex III (DTPA).
2. **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 per **Annex III.** 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 PROJECT LEADER agree that the DATA: (a) is to be used only for the academic purposes as described in the plan on the RESEARCH; (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 SUBJECT.

*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 this DTUA; or (ii) sell, lease, sublicense, copy or provide the DATA to any third party, except as expressly permitted in 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. **Confidentiality.** Without prejudice to provisions (in particular section III.6-9 below) 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 the RECIPIENT shall notify the PROVIDER of any disclosure required by law in sufficient time so that the PROVIDER may contest such requirement, if the PROVIDER 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.
3. **Personal data.** Each PARTY must process personal data under this Agreement in compliance with applicable data protection laws. Each PARTY represents and warrants that any personal data of DATA SUBJECTS required for use in the RESEARCH 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, and subsequent disposal and that any ethics committee approvals and, as the case may be, informed DATA SUBJECTS consents required for performing the RESEARCH will be obtained prior to the use in the RESEARCH.

*Section III 6.-8. needs to be adapted respectively deleted, if anonymous data (within the meaning of applicable law) is used.*

1. **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 Agreement 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 Agreement (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 Agreement 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 BioMed-IT infrastructure.** 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 III** of this Agreement and in accordance with all applicable laws.
4. **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 and pseudonymized data.

**IV**. **Information about RESULTS and Publication**

1. **Information about RESULTS**. Upon the PROVIDER’s request, the RECIPIENT’S PROJECT LEADER shall keep the PROVIDER informed of the RESULTS. In case clinical actionable findings are identified according to good practice RECIPIENT’S PROJECT LEADER shall inform the PROVIDER.
2. **Publication**.

The RECIPIENT shall refrain from publishing the RESULTS until the earlier of i) publication by the PROVIDER of the results of the RESARCH in which DATA was gained or ii) \_\_\_\_\_\_\_\_\_\_[date].

*Use this part (IV.2. and 3.) in case of unpublished data (e.g. ongoing clinical study), when the PROVIDERS wants to secure that their research results can be published first. Note: these aspects can also be addressed in a separate research consortium or collaboration agreement. If this relates to an already existing agreement, make sure there is no conflict.*

1. Thereafter, the RECIPIENT shall be free to publish and disclose the RESULTS but agrees to submit the proposed disclosure to the PROVIDER for review at least thirty (30) days prior to the scheduled submission for publication or disclosure. If the PROVIDER believes that the publication or disclosure contains CONFIDENTIAL INFORMATION of the PROVIDER, the PROVIDER has the right, within a maximum of a further one (1) month from the time of receipt, to request that any such CONFIDENTIAL INFORMATION be removed from the publication or disclosure. The PROVIDER also has the right to provide comments on the manuscript and both PARTIES shall discuss in good faith to incorporate such comments into the publication or disclosure. Failure to respond within the above mentioned thirty (30) day period is considered as approval of the publication by the PROVIDER.
2. **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>

1. **Acknowledgements**. The RECIPIENT agrees to acknowledge the PROVIDER as the source of the DATA in all written publications, posters or oral presentations.

**V. INTELLECTUAL PROPERTY RIGHTS**

1. **BACKGROUND IP**. The PARTIES agree that each PARTY shall retain all title, right and interest in and to its respective INTELLECTUAL PROPERTY RIGHTS, as of the date of entry into force of this Agreement (the “**BACKGROUND IP**”). Unless otherwise agreed herein, nothing in this 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.

*Choose the appropriate regulation regarding the foreground IP.*

*Background IP means all INTELLECTUAL PROPERTY RIGHTS owned by or licensed to a Party at the start of the Project. Foreground IP* means all *INTELLECTUAL PROPERTY RIGHTS made in the performance of work under this agreement.*

1. ***Alternative 1:*** *The RECIPIENT is the owner of the RESULTS.*

**FOREGROUND IP.** All right, INTELLECTUAL PROPERTY RIGHTS, title and interest in and to the RESULTS (the “FOREGROUND IP”), shall be owned and vest in the RECIPIENT.

***Alternative 2:*** *The RECIPIENT only is the owner of the Result but the PROVIDER is granted a license on the Result and/or receives a portion of the revenues from the commercialization.*

**FOREGROUND IP.** All right, INTELLECTUAL PROPERTY RIGHTS, title and interest in and to the RESULTS (the “FOREGROUND IP”), shall be owned and vest in the RECIPIENT.

**License on FOREGROUND IP.** RECIPIENT hereby grants to PROVIDER a royalty-free, worldwide, non-transferrable, non-exclusive, irrevocable license to access and use the FOREGROUND IP for purpose of internal scientific RESEARCH only.

and*/or*

**Royalties.** RECIPIENT will pay to PROVIDER [a fair share of *or* [...]% on] any net revenues received by RECIPIENT for the commercialization of the FOREGROUND IP.

***Alternative 3:*** *The IP is jointly owned by the PARTIES.*

**FOREGROUND IP.** All right, INTELLECTUAL PROPERTY RIGHTS, title and interest in and to the RESULTS shall be owned jointly by the PARTIES (the “JOINT FOREGROUND IP”). The PARTIES will 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 IV.2.

**VI. Compliance**

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.

**VII. Expiration and Termination**

1. **Expiration**. Subject to the approval of the appropriate ethics committee(s) if any, this Agreement shall become effective on the EFFECTIVE DATE, and it shall automatically expire at the completion of the RESEARCH (according to the research plan as described in **Annex II**) or at the termination of the RESEARCH for any reason.
2. **Termination**. Each PARTY may terminate this Agreement at any time by giving a three months prior written notice, unless a material breach of this Agreement by the other PARTY occurs. In such case, the PARTY that suffers the material breach may terminate this Agreement by written notice to the other PARTY, which is either incapable of remedy or has not been remedied within 30 days’ notice from such breach. If the breach has not been rectified within said period, the other PARTY can terminate the breaching PARTY’s participation with immediate effect and all rights granted to the breaching PARTY according to this Agreement, will cease immediately upon receipt of the formal termination notice. If the breaching PARTY is the PROVIDER, the PROVIDER shall continue to grant access to its DATA as if it had remained a PARTY for the whole duration of the PROJECT. However, it shall have no rights whatsoever to the RESULTS subsequently generated by the RECIPIENT after effective termination.

*Adapt the appropriate time-limit if needed.*

1. **Survival Clauses**. The provisions concerning CONFIDENTIAL INFORMATION, publications, INTELLECTUAL PROPERTY RIGHTS, warranty and liability as well as those intended to protect the rights of participants / DATA SUBJECTS shall survive the Agreement’s expiration.

**VIII. 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 Agreement.
2. **DATA SUBJECT’S 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).
3. **FOREGROUND IP**. The PARTIES use the FOREGROUND IP at their own risk. A PARTY using any of the FOREGROUND IP shall, to the fullest extent permitted by the applicable law, defend, indemnify and hold the other PARTY harmless against third party claims (including but not limited to claims based on mandatory product liability law) which are based on the PARTY’s use of the FOREGROUND IP.

**IX. General Provisions**

1. **Entire Agreement.** This AGREEMENT represents this entire Agreement among the PARTIES with respect to the subject matter hereof, and may only be altered or amended by an instrument in writing signed by all of the PARTIES.
2. **Severability and No Waiver**. If any portion of this AGREEMENT is in violation of any applicable regulation, or is unenforceable or void for any reason whatsoever, it should be put in writing and discussed by the PARTIES. Such portion will be inoperative and the remainder of this Agreement will be binding upon the PARTIES.
3. **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.
4. **Governing Law and Jurisdiction**. This AGREEMENT will be construed, governed, interpreted and enforced according to the laws of Switzerland. All disputes arising out of or in relation to this Agreement will be brought before the competent court at the seat of the defending PARTY. In case of disputes, the PARTIES will consult each other before taking any legal action.
5. **Contact Point:** The RECIPIENT’S PROJECT LEADER is the contact point within its organization, authorized to respond to enquiries concerning this Agreement, and will cooperate in good faith with the PROVIDER within a reasonable time.

**X. Annexes**

**Annex I:** Data and Meta Data to be Transferred

**Annex II:** Research Project

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

**IN WITNESS WHEREOF**, the PARTIES have executed this AGREEMENTas of the EFFECTIVE DATE.

*Add all responsible project leaders per institution/hospital and, if applicable, the duly authorized representative of the institution/hospital. The duly authorized representative is a person who is entitled to sign the institutional data sharing in accordance with signatures rules of the institution (e.g. director of research department, member of the institution’s executive board). Add an additional signature line, if you need for example to add the CEO.*

*To facilitate and accelerate the signature process, add one new page (separate page) per institution/hospital.*

*Note that the electronic unqualified signatures (e.g. using Docusign) might be allowed, but, depending on the institutional process, a wet ink signature on paper might be required. Please contact your legal department to clarify the respective process, if needed.*

**[PARTY’S NAME]**

**Project Leader Duly Authorized Representative**

[Name] [Name]

[Title] [Title]

**IN WITNESS WHEREOF**, the PARTIES have executed this Agreement as of the EFFECTIVE DATE.

**[PARTY’S NAME]**

**Project Leader Duly Authorized Representative**

[Name] [Name]

[Title] [Title]

**ANNEX I: DATA AND META DATA TO BE TRANSFERRED**

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:*

**ANNEX II: RESEARCH PROJECT**

The RESEARCH shall be limited to use of the DATA in connection with the following activities:

[•]

*Please add the research protocol and if applicable the ethics approval.*

**ANNEX III: 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, as specified in the Appendix 1. 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 a **PARTY**, and the **PARTIES**)

WHEREAS

1. The PRINCIPALS have signed a Data Transfer and Use Agreement for the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Project (the **DTUA**).
2. The BIOMEDIT NODES form together a coordinated Swiss nationwide network of secured IT network (the BioMedIT NODES), 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

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 NODES in the name and on behalf of the PRINCIPALS under the RESEARCH 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 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 NODES as described in the BIOMEDIT Base Package (accessible at: https://sphn.ch/document/biomedit-base-package) which include the following:

a) hosting of the DATA on the BIOMEDIT NODES;

b) transferring DATA from the Provider to the Recipient in accordance with this DTPA; and

c) other processing activities as required under this DTPA or as reasonably requested by the PRINCIPALS, and as agreed on with the BIOMEDIT NODES.

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 Section III.2 (standard services provided by the BIOMEDIT NODES) are regulated by separate service agreement between the BIOMEDIT NODES and the PARTY 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. 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 **Appendix 1**. The Parties shall specify in **Appendix 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 PROJECT LEADER and the RECIPIENT’S PROJECT LEADER 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 to the SERVICES to be provided by REGIONAL NODES shall be determined by mutual agreement between the PARTIES once the project for which PROVIDER needs the BIOMEDITNODES 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 payment regulation.

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 **Appendix 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 **Appendix 1**;

the BIOMEDIT NODES are joint processors 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).

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 PROJECT LEADER and the RECIPIENT’S PROJECT LEADER. 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).

* 1. Restrictions. The BIOMEDIT NODES shall not, without the prior written consent of PROVIDER:

subcontract any of their processing operations of the DATA (except to another Regional Node); 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).

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.

1. **Security**
2. 1. Security Requirements. Each PARTY shall comply with the security requirements set forth in Section III.3 of the DTUA. 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 PROJECT LEADER to the BIOMEDIT NODES, provided that the BIOMEDIT NODES personnel have the right to access the DATA 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” 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

Security Incidents. Each Regional Node processing DATA 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 PROJECT LEADER). 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:

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

make such information available to any competent authority.

The PRINCIPALS undertake to provide the BioMedIT Nodes with all information reasonably necessary for the BioMedIT Nodes to meet their obligations.

1. Representations and Warranties

The PRINCIPALS represent and warrant that:

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;

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;

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;

the PRINCIPALS will not require the BioMedIT Nodes to undertake a processing of Data that they would not be permitted to carry out themselves.

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 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 III3 of the DTUA are sufficient in this regard.

1. Information, Assistance and Notifications
2. **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.
3. **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 NODES 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.
4. **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 their compliance with their impact assessment, prior consultation and records of processing activities obligations (if any).
5. **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.
6. **Audits**. The provisions of **Appendix 2** shall apply regarding audits.
7. Data ownership, Intellectual Property, Confidentiality
8. **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 Section 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.

b)  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.

c) 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.

1. **Confidentiality.** 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.
2. **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.
3. Liability
4. 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.
5. 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.
6. Term
7. **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.
8. **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.
9. **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.
10. **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.
11. **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 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.
12. Miscellaneous
13. **Amendment**. This DTPA may be modified only by a written instrument duly executed by each PARTY.
14. **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.
15. **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.
16. **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.
17. **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.
18. **Entire Agreement**. 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.
19. **Hierarchy**. In the event of conflict with a schedule to this DTPA, this main body of this DTPA will govern, unless the schedule specifically states its intent to do so and cites the section or sections amended.
20. **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.
21. **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.
22. Governing Law and Jurisdiction
23. **Governing Law.** This DTPA shall be governed by and construed in accordance with Swiss substantive law, without reference to its conflict of laws provisions.
24. **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**

**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)

Torsten Schwede

Vice President for Research, 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 respective nodes.

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

*This Exhibit 1 should in particular include the information provided for in Sections I./1.2, II./2.2-3, II./4.1 and III./6 of the DTPA.*

1. **Description and format of DATA**

*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 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 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 nodes is access-controlled.

Specify who defines the access rules and who has explicitly 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.

Specify who acts as main node and provide additional services, if applicable.

**D. Main Project Leader**

[Name, address, email]

**Appendix 2 to the DTPA – Information And Audits of Security Measures**

1. Scope. The provisions of this Appendix 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:
6. 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;
7. 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.
8. 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.

**\* \* \***