*This box has to be deleted at the end.*

**Colour code:**

Grey background = To be completed

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

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

*If the Controllers decide to subcontract the secure transfer and hosting of the data to a third party (the “Processor”), the relationship between Controllers and Processor has to be regulated in a specific agreement: a Data Transfer and Processing Agreement (DTPA).*

**DATA TRANSFER AND USE AGREEMENT**

for the project [#CompleteProjectName]

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

**Université de Fribourg**

Avenue Europe 20

1700 Fribourg

Switzerland

represented by

Prof. Dr. Katharina Fromm

and

[Name and Address Academic Partner]

represented by

[Name and Title of signatories]

*Add all parties involved: The institutions that are required to exchange data for the project.*

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

**WHEREAS**

Choose one option and delete the other one.

***Option 1:***

a)The PARTIES wish to conduct the joint research project [to complete], as set forth in **Annex II** of this Agreement, with the DATA made available by the PROVIDER.

***Option 2:***

a) The RECIPIENT wishes to conduct the [to complete] 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.

b) 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, the following 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**: [to complete with the date]

*It may be the date on which this AGREEMENT is signed by the duly authorized representatives of two PARTIES or a specific (including retroactive) date.*

1. **FOREGROUND INTELLECTUAL PROPERTY (FOREGROUND IP)**: shall have the meaning set forth in Section V below.
2. **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.
3. **PROVIDER:** means a PARTY providing DATA to another PARTY for the purposes of this Agreement.
4. **PROVIDER’S PROJECT LEADER:** means the PROVIDER’s person who takes responsibility for the project as described in the Ordinance on Human Research (**HRO**).

*Delete the last part of the sentence if the RESEARCH is not subject to the Human Research Act or if it’s an international collaboration.*

1. **RECIPIENT:** means a PARTY receiving DATA from another PARTY for the purposes of this Agreement.
2. **RECIPIENT’S PROJECT LEADER:** means the RECIPIENT’s person who takes responsibility for the project as described in the HRO.

*Delete the last part of the sentence if the RESEARCH is not subject to the Human Research Act or if it’s an international collaboration.*

1. **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.

*If the project hasn’t yet been approved by the Ethics Committee, please delete the precision.*

1. **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. **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 I.** The RECIPIENT shall not have the key.

*If data are not provided in a CODED FORM, specify in which other form data is provided (uncoded, 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.
2. **No PROVIDER’s Warranties about DATA.** It is expressly understood that the PROVIDER does not warrant or guarantee that the DATA will be accurate, complete, or useful for any particular purpose.
3. **No PROVIDER’s Warranties about Third Parties’ INTELLECTUAL PROPERTY RIGHTS.** The PROVIDER offers no warranty that the use of DATA and/or CONFIDENTIAL INFORMATION will not infringe or violate any patent or other proprietary rights of any third party.

**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 RESEARCH plan, as set forth in Annex II of this Agreement;

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

(b) may not itself be commercialized;

(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 and

(d) is only accessed according to the rules as further described in Annex I.

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 shall 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.

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.7. 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. **DATA Processing.** 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.
4. **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.

*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.

*Delete the last two sentences if the Project is not subject to the Human Research Act*

1. **DATA Storage and Processing**. The DATA processing must be limited to the purpose pursued, provided that the DATA SUBJECT does not decide otherwise. The DATA should not be kept by the RECIPIENT longer than necessary for the purpose of the RESEARCH.

**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 research in which DATA was gained or ii) [to complete with the date].

*Use this part IV.2 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.*

*Delete this part IV.2 if not necessary.*

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 fifteen (15) days 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 fifteen (15) days period is considered as approval of the publication by the PROVIDER.

*Delete the word “Thereafter” in the beginning of the part IV.3 if you have deleted part IV.2.*

1. **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**

*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. **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.

***2.*** *Choose the appropriate regulation’s option regarding the foreground IP. Delete the other two.*

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

1. **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. Any copyrights of RECIPIENT’ employees and/or collaborators on publications are reserved.

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

1. **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 and teaching only.

Any copyrights of PARTIES’ employees and/or collaborators on publications are reserved.

**Royalties.** In consideration of PROVIDER’s contribution to the FOREGROUND IP and the exclusive rights assigned to the RECIPIENT thereon, in the event of commercialize of FOREGROUND IP by the RECIPIENT, the RECIPIENT hereby agrees to pay the PROVIDER a fair share of the revenues generated with such commercialization of Foreground IP. The decision to commercialize the FOREGROUND IP shall be left to RECIPIENT’s discretion.

*Delete this part on Royalties if not necessary.*

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

**2. 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”). Any copyrights of PARTIES’ employees and/or collaborators on publications are reserved. The PARTIES shall be entitled to use the JOINT FOREGROUND IP for non-commercial research and teaching activities on a royalty-free basis, and without re-quiring the prior consent of the other PARTY. 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**

**Compliance with Law**. Each PARTY undertakes to comply at all times 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 month 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**

1. **Liability**. Without prejudice to the Sponsor’s liability pursuant to the Federal Human Research Act (HRA) and the Federal Human Research Ordinance (HRO), 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) suffered in connection with the Agreement, provided such damage was not caused by a willful intent or act of gross negligence.

*Delete the first part of the sentence if the RESEARCH is not subject to the Human Research Act*

1. **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” (PDF copy), or a signature generated by industry standard electronic signature software (e.g. Docusign, Switchsign), 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.
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 exclusive competence of the courts of Fribourg, Switzerland, unless otherwise agreed between the Parties. 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:** Transfer and Access Rules for Data and Meta Data

**Annex II:** Research Project

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

*Add all responsible project leaders per institution and, if applicable, the duly authorized representative of the institution. 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. rector, 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.*

**Université de Fribourg**

**Duly Authorized Representative Project Leader**

**Prof. Dr. Katharina Fromm** [Name]

Rector [Title]

**Date Date**

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

**[PARTY’S NAME]**

**Duly Authorized Representative Project Leader**

[Name] [Name]

[Title] [Title]

**Date Date**

**ANNEX I: TRANSFER AND ACCESS RULES FOR DATA AND META DATA**

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

[to complete]

*Specify here the data used in the project. Specify which party is the PROVIDER and which party is the RECIPIENT for each type of data. You can e.g. use this box.*

|  |  |
| --- | --- |
| Provider |  |
| Recipients |  |
| Categories of Personal Data |  |
| Categories of Data Subjects |  |
| Form of Personal Data | Coded  The source data, the consent forms and the key are stored by the Provider and not communicated to the Recipients |

**The following applicable transfer and access process for DATA and meta data shall be used:**

[to complete]

*Specify here:*

* *the measures of data protection transfer and access;*
* *the flow of data between PROVIDER and RECIPIENT;*
* *all processing operations which are essential to ensure traceability;*

**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.*