

Colour code:

Grey background = To be completed;

Yellow background = the internal references to the contract (to be updated if necessary) or Optional text.

DATA TRANSFER AND USE AGREEMENT

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

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

(the “PROVIDER”)

and

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

(the “RECIPIENT”)

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

WHEREAS

- a) The PROVIDER is the controller of data on _____ (hereinafter referred to as the “DATA”), as set forth in **Annex I** of this Agreement;
- b) The RECIPIENT wishes to conduct a 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://www.sphn.ch/dam/jcr:d3b6d609-1075-4f5a-b56c-dfe633aaa8f5/Glossary_20180530_SPHN.pdf) 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 metadata, 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 of last signing of 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 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. **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.
2. **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.
3. **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.
4. **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.
2. **Ownership.** The DATA provided is and remains the property of the DATA SUBJECT. The CONFIDENTIAL INFORMATION provided is and remains the property of the PROVIDER.
3. **Security.** The RECIPIENT shall process the DATA in a manner that ensures appropriate security of the DATA, including protection against unauthorized or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organizational measures ('integrity and confidentiality'). DATA processing shall comply with the "*Ethical Framework for Responsible Data Processing in Personalized Health Research*" and with the "*SPHN Information Security Policy*", as both updated occasionally, accessible at:

https://www.sphn.ch/dam/jcr:6fb78ffa-95c8-4372-bfb1-5c9b1e2cb53d/Ethical_Framework_20180507_SPHN.pdf

https://dcc.sib.swiss/media/filer_public/a5/7b/a57b4ad4-c741-4be9-aefb-b0256be150c4/sphn_information_security_policy_v1.pdf

The RECIPIENT shall have in place procedures so that any person it authorizes to have access to the DATA, including the RECIPIENT'S PROJECT LEADER and their authorized users, will respect and maintain the confidentiality and security of the DATA. Any person acting under the authority of the RECIPIENT shall be obligated to process the DATA only on instructions from the RECIPIENT'S PROJECT LEADER.

In case the RECIPIENT'S PROJECT LEADER or the PROVIDER'S PROJECT LEADER is replaced, the other PARTY must be notified without delay. 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 Agreement; or (ii) sell, lease, sublicense, copy or provide the DATA to any third party, except as expressly permitted in this Agreement.

4. **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.
5. **Confidentiality.** Either 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.

6. **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.
7. **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. If applicable, the RECIPIENT ought to anonymize their DATA according to the Human Research Ordinance as per the PROVIDER's request, unless one of the exceptions listed in Article 10 of the Human Research Ordinance applies. A written notification shall be sent to the PROVIDER upon receipt and after completion of the request.
8. **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 minimum required for the purpose pursued, provided that the DATA SUBJECT does not decide otherwise.

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 (**reference to swissethics/ELSIag upcoming document**), the RECIPIENT'S PROJECT LEADER shall inform the PROVIDER.

2. **Publication.**

Option to use in case of unpublished data (e.g. ongoing clinical study), when the PROVIDER wants to secure that their research results can be published first:

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) _____ [date].

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.

3. **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:

http://www.akademien-schweiz.ch/en/dms/E/Publications/Guidelines-and-Recommendations/integrity/Academies_Authorship.pdf.

4. **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.

Alternatives to be chosen by the PARTIES during the negotiation:

2. **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.** This Agreement shall become effective on the EFFECTIVE DATE, and it shall automatically expire at the completion of the RESEARCH (according to the project 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 [] months prior written notice, unless a material breach of this Agreement by (one of) the other PARTY(IES) 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 [] days' notice from such breach.
3. **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, Indemnification and Third Party Rights

1. **Liability and Indemnification.** Each PARTY shall be liable to, and indemnify, 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. **Third Party 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. **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.
4. **Contact Point:** The RECIPIENT'S PROJECT LEADER is the contact point within its organisation, 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: Data Transfer Specifications

IN WITNESS WHEREOF, the PARTIES have executed this Agreement, in duplicate originals, as of the EFFECTIVE DATE.

PROVIDER
[NAME]

RECIPIENT
[NAME]

Duly Authorized Representative
[Name]
[Title]

Duly Authorized Representative
[Name]
[Title]

PROVIDER'S PROJECT LEADER
[Name]
[Title]

RECIPIENT'S PROJECT LEADER
[Name]
[Title]

ANNEX I: DATA AND META DATA TO BE TRANSFERRED

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

[]

ANNEX II: RESEARCH PROJECT

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



ANNEX III: DATA TRANSFER SPECIFICATIONS

The DATA and meta data to be transferred as described in Annex I shall be transferred according to the following conditions:

[• e.g. standards, formats, protocols, schedule, transfer costs, etc.]