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**Material and Data Transfer Agreement (MTA/DTA)**

**for human biological materials**

*This template governs the transfer and use of human biological materials and its associated coded personal data made available by a provider to recipient for analysis in a research project.*

*The template is both agreement on transfer of human biological materials and personal data processing agreement according to Article 28 of GDPR (General Data Protection Regulation 2016/679)*

*This template assumes that the personal data to be transferred is being transferred in pseudonymized and not fully anonymized[[1]](#footnote-1)*

 *This template assumes transfer within EEA but also contains clause suitable for transfer outside EEA or transfer to an international organization.*

This Material and Data Transfer Agreement (hereinafter “MTA/DTA Agreement”) is signed and executed as of Effective Date by and between:

**\_\_\_\_\_\_\_\_\_\_\_\_**(*official name of legal entity*), located at **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**(address, city, state), represented by \_\_\_\_\_\_\_\_ (*name of legal representative*),hereinafter “**Provider**”

and

**\_\_\_\_\_\_\_\_\_\_\_\_**(*official name of legal entity*), located at **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**(address, city, state), represented by \_\_\_\_\_\_\_\_ *(name of legal representative),*hereinafter “**Recipient**”

**PREAMBLE**

Whereas, **Provider** is a \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ established with the aim to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_;

WHEREAS, **Provider** is in possession of certain human biological material (“Samples”) with associated Personal Data, needed by **Recipient** for the purposes of conducting research analysis;

 WHEREAS, **Recipient** is a\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, willing to conduct research analysis on certain Samples from the **Provider;**

WHEREAS, **Provider** is willing to transfer certain Samples and associated Personal Data to the Recipient;

WHEREAS, **Parties** have agreed to be bound by the provisions set out in this Agreement;

WHEREAS, **Parties** undertake to comply with the applicable sections of the GDPR and other relevant data protection legislation;

 **1. Definitions**

1.1. **Data Subject**

Data Subject means an identified or identifiable natural person, including Donors. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

1.2. **Donor**

Donor shall mean a natural person from which Samples are taken.

1.3. **Effective Date**

Effective Date shall mean date of signature of this Agreement by the second Party to it.

1.4. **GDPR**

 GDPR means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the Processing of Personal Data and on the free movement of such data, and repealing Directive 95/46/EC.

1.5. **Human Biological Materials/Samples**

Human Biological Materials/Samples shall mean any human tissue or human biological material of a natural person, including any portion of an organ, any tissue, skin, bone, muscle, connective tissue, blood, cerebrospinal fluid, cells, gametes, or sub-cellular structures such as DNA, or any derivative of such human biological material such as stem cells, cell lines or xenograft tissues; and any human biological product, including, but not limited to, hair, nail clippings, teeth, urine, feces, breast milk, and sweat.

1.6. **Party/ies**

Party shall mean Provider and Recipient.

1.7. **Personal Data**

Personal Data means any information relating to a Data Subject (including also any data extracted from Samples if and to the extent such data refers or can be referred to an identified or identifiable Donor).

**2. Scope of TRANSFER**

The **Provider** provides to the **Recipient** Samples and associated Personal Data as specified in *Attachment 1* to this Agreement.

**Provider** confirms that for the purposes of this MTA/DTA it is entitled to supply the Samples/and or Personal Data to the Recipient and that consent covering the intended use has been obtained from the relevant Donors/Data Subjects.

**Recipient** agrees to use Samples and/or personal Data only for the purpose/s as described in Attachment 2 to this Agreement (“Permitted Use”) and not for any other purpose. Recipient confirms that all work using the Samples/Personal Data will be carried out in compliance and in accordance with applicable laws, regulations, policies, ethical requirements and approvals applicable to the research under the Project and handling and protection of samples and/or Personal data.

In the event of a withdrawal of Donor consent, **Provider** shall immediately inform **Recipient**.

**Recipient** shall take reasonable steps to destroy Samples for a given Data Subject when the **Provider** informs of such Data Subject has withdrawn his or her consent. **Recipient** confirms that it will deal promptly and appropriately with any withdrawals by Donors/Data Subjects which **Provider** notify to the **Recipient**.

**3. Provison of Samples**

**Recipient** acknowledges that the Samples and linked Personal Data are provided on an “*as is”* basis without any warranty of satisfactory quality or fitness for a particular purpose or use or any other warranty, express or implied.

**Recipient** agrees to ensure that only those persons involved in the Project shall have access to and use Samples/Personal Data provided by **Provider**. Recipient agrees that only authorized laboratory personnel in the Recipient’s institution performs analysis of Samples and processes coded Personal Data.

**Recipient** acknowledges that the Samples may have unknown and/or hazardous characteristics and therefore agrees to use prudence and reasonable care in the use, handling, storage, transportation, disposition and containment thereof. Recipient shall store the Samples promptly in [*a frozen?]* state and in compliance with all applicable regulations. **Recipient** shall give the **Provider** written notice of the transfer of Samples to any facility of **Recipient**, other than the facility to which they are initially delivered.

**Recipient** acknowledges that the Samples provided may contain viruses, latent viral genomes or other infectious agents. **Recipient** undertakes to treat such Samples as if they are not free from contamination and to ensure that all Samples are handled by appropriately trained personnel under laboratory conditions that incorporate adequate biohazard containment.

From the time of receipt, **Recipient** is fully responsible for the safe and appropriate handling of the Samples.

**Recipient** may not use the Samples in human subjects. **Recipient** agrees not to transform the Samples. **Recipient** shall refrain from performing any tests on the samples for any purpose except for Permitted Use.

**Recipient** confirms that the Samples will be kept on the premises of the **Recipient** as specifiedand not transferred (in whole or part) to any other location without the prior written approval of the **Provider.**

**Recipient** shall refer any request for the Samples to the **Provider**.

**Recipient** confirms that he has obtained all necessary import licenses for receiving the Samples in his country for purposes of this Agreement.

**Recipient** will retain Samples in a secure location as regards Samples or a secure network system as regards Personal Data at such standard as would be reasonably expected for the storage of valuable and proprietary samples and/or sensitive/confidential data.

**4. Data Protection**

*Attachment 1* specifies Samples/Personal Data that **Provider** will make available to the **Recipient**.

Samples and associated Personal Data are provided in a pseudonymized form, i.e. coded Samples and coded Personal data so that individual Donor from whom the Samples were obtained can be only identified with the key for the code.

**Provider** shall keep the key code to the Personal data during the term of this Agreement.

**Provider** is the controller of the Personal Data.

**Recipient** acknowledges that **Provider** will not provide any information to the Recipient about the Samples or Personal Data that can directly identify or be used to identify the Donor.

**Recipient** acknowledges that it shall not in any circumstances try to trace, identify or make contact with the Donors who provided the Samples. If **Recipient** becomes aware of any unauthorized use or disclosure of the use of pseudonymized personal Data, **Recipient** undertakes to promptly contact **Provider**.

**Recipient** acknowledges that coded and encrypted (pseudonymized) data for which **Provider** is responsible for, is Personal Data as long as the code or encryption key still exists.

**Recipient** agrees to preserve, at all times, the confidentiality of information pertaining to identifiable Donors. **Recipient** agrees not to give access to Samples/Personal Data, in whole or part, or any identifiable data derived from the Samples, to any third party. **Recipient** shall limit access to and processing of the Samples/Personal Data to those employees or other authorized representatives of **Recipient** who: (i) need to process such Samples in order to conduct their work in connection with the Samples/Personal Data and the Project and (ii) have signed agreements with the Recipient obligating them to maintain the confidentiality of the Samples/Personal Data and any information to be derived thereof or disclosed to them.

**Recipient** agrees to protect the integrity and security of Samples and associated Personal Data from unauthorized access, use or theft in accordance with applicable data protection or human biological material legislation.

**Recipient** agrees to meet the requirements for data processor (under Article 28 GDPR) and instructions on IT security from **Provider** in *Attachment 3 (optional).*

**5. TRANSFER OF PERSONAL DATA TO THIRD COUNTRIES AND INTERNATIONAL ORGANIZATIONS**

To the extent that the transfer of Personal Data involves transfer of such Personal Data to a country outside the EEA or to international organization (*Chapter V GDPR*), other than (i) a country or international organization ensuring an adequate level of protection for the rights and freedoms of Data Subjects in relation to the Processing of Personal Data as determined by the European Commission such as EU-US Privacy shield, or (ii) where the recipient is a member of a compliance scheme recognised as offering adequate protection for the rights and freedoms of Data Subjects as determined by the European Commissionbased on *Article 45 of GDPR,* such transfer shall be governed by the *Standard Contractual Clauses*[[2]](#footnote-2) and **Provider** and **Recipient** shall enter into an unamended version of the *Standard Contractual Clauses* ). In the event of any conflict between any terms and conditions of the *Standard Contractual Clauses* and terms of this MTA/DTA, the Standard Contractual Clauses shall prevail. If **Recipient** is pleading to be part of EU-US Privacy Shield scheme, **Recipient** shall demonstrate so via enclosure of Attachment 4 to this MTA/DTA.

**6. INSPECTIONS/AUDITS**

On reasonable notice to **Recipient**, and in order to confirm or investigate compliance with the provisions of this MTA/DTA, **Provider** may itself or via appropriate third parties:

• choose to inspect the premises and other relevant facilities of the Recipient, in order to review the security, storage or other arrangements for the Samples;

• request such additional information about the Project and/or its progress

**Provider** will bear the costs of such inspections/audits unless a default within the procedures and processes of **Recipient** is discovered, in which case **Recipient** will be obliged to reimburse the reasonable costs of **Provider** and any relevant third parties.

**7. PAYMENT/FEES**

In consideration for the transfer of Samples, Recipient shall pay to Provider an amount of EUR\_\_\_\_\_ (and VAT if applicable) to the following account:

…………………………………….

**8. Intellectual Property**

Title to the Samples/Personal Data is and remains in the ownership of the **Provider**.

**Recipient** acknowledges and agrees that nothing contained in this Agreement is deemed to grant to **Recipient** any intellectual property rights in any of the Samples and Personal Data provided hereunder.

Except as expressly set forth in this Agreement, nothing herein shall be deemed to grant to either the **Provider** or **Recipient** any rights under the other Party’s patents, patent applications, trademarks, copyrights, trade secrets, know how (whether patentable or unpatentable) or other intellectual property rights.

Parties agree that the ownership of any intellectual property rights in the results that may arise out of the Project will be subject to provisions of Grant and Consortium Agreement for EATRIS Plus Project under Grant Agreement No 871096.

**9. Results and Publication**

Results and publications of data processed in accordance with this Agreement may be subject to separate agreements between the Parties.

**10. Notices**

Notices required under this MTA/DTA will be in writing and will be delivered by email to the addresses set out below or (in the event of a failure to deliver an email) by post to the Provider or the Recipient and will be deemed to be given, in the case of delivery by email, upon receipt at the Recipient ’s email server (unless an automatic response indicating an undeliverable message is received) and, in the case of delivery by post, on the date of delivery (or, if not a business day, on the first business day thereafter).

The contact persons designated for this purpose by the Parties are:

On behalf of **Provider** On behalf of **Recipient**

Name: Name:

Email: Email:

Tel. no: Tel no.

**11. Duration and Termination of Agreement**

This Agreement shall come into force as of Effective Date and shall remain in force for X year/s [*fill in*] or until research under the project has been completed.

The Agreement may be terminated by either Party for any reason, by giving other Party thirty (30) day’s written notice.

**Provider** will be entitled to terminate this MTA/DTA with immediate effect by written notice to the **Recipient** if **Recipient** is in breach of its obligations under this Agreement (and fails to remedy the same within 20 days after receipt of a written notice giving particulars of the breach and requiring it to be remedied) or becomes bankrupt, liquidated or otherwise becomes insolvent or ceases carrying on business.

The rights to terminate this MTA/DTA given by this clause will be without prejudice to any other right or remedy of either Party in respect of the breach concerned, if any, or any other breach.

**12. TERMINATION OF TREATMENT OF SAMPLES AND PERSONAL DATA**

**Recipient** is responsible for the destruction or the return of Samples and Personal Data.

Within thirty (30) days after expiry or termination of this Agreement or completion of the Project, the grant of rights to the **Recipient** will be automatically terminated and Recipient shall return Samples to **Provider** or destroy Samples and confirm to the **Provider** (in writing) that this has taken place.

Samples will be:

* Completely consumed during analysis
* Destroyed after analysis
* Returned after analysis
* Other:

**Recipient** agrees to destroy the Personal Data or otherwise render it inaccessible.

Any provisions of this agreement intended to protect the rights of human Donors/Data Subjects shall survive the expiry or termination of this agreement.

 **13. Subcontracting**

**Recipient** will not subcontract the performance of any of its obligations under the MTA/DTA or any part thereof without having first obtained the prior written consent of the **Provider**, such consent not to be unreasonably withheld.

In the event that consent is granted, **Recipient** shall ensure that any subcontractor or third-party provider shall handle Samples and/or Personal Data in accordance with this Agreement. **Recipient** shall be responsible for the acts, defaults and omissions of its subcontractors as if they were the Recipient’s own, and any consent given will not relieve the Recipient of any of its obligations under this MTA/DTA.

**Recipient** agrees that **Provider** shall retain title to Samples and Personal Data in the **Recipient**’s or any subcontractor’s possession.

**14. Liability and Indemnity**

In case of compensation for indemnity and sanctions due to incorrect handling of Personal Data, *Articles 82* and *83* shall of GDPR shall apply.

Otherwise, **Recipient** shall indemnify and hold **Provider** harmless from any third party claim, including reasonable legal fees, due to or arising out of: (i) the use, handling, storage or disposal of Samples/Personal Data by the Recipient; or (ii) any negligence or willful misconduct of the Recipient;

Both Parties acknowledge and agree that Samples and associated Personal Data are being supplied with no warranties, expressed or implied or fitness for a particular purpose or non-infringement of third parties’ proprietary rights.

In no event shall either Party be liable for any indirect, incidental or consequential damages, loss of profits, lost savings, reduced goodwill, loss due to business interruption, arising out of or in connection with this Agreement.

**15. Applicable law and jurisdiction**

This MTA/DTA will be governed by and construed in accordance with the laws of Belgium.

Parties shall attempt to resolve any dispute arising in relation hereto amicably through negotiations.

Any suit, action, proceedings or dispute arising out of, or in connection with, this Agreement which cannot be resolved in amicable way will be referred by the Parties to the Belgian courts having exclusive jurisdiction.

 **16. Miscellaneous**

This Agreement incorporates attachments which constitute the integral part of this Agreement.

No provision of this Agreement may be amended or modified, except by the written amendment to this Agreement duly authorized and executed by both Parties.

A waiver by either party, whether express or implied, in enforcing or exercising any of its rights or remedies hereunder will not constitute a waiver of such right or remedy.

Neither Party will be entitled to assign this MTA/DTA or any of its rights or obligations hereunder without first having received the written approval of the other party, which approval not to be unreasonably withheld or delayed.

**Signatures**

 This Agreement is issued in 2 originals, one for each Party.

For and on behalf of **Provider institution**: For and on behalf of **Recipient institution**

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

Name and title Name and title

 Date: Date:

**Attachment 1**

**HUMAN BIOLOGICAL MATERIAL/SAMPLES**

*To be attached by the responsible researcher (researcher responsible for the Project in Czech Republic)*

**Specification of Biological Material to be transferred**

*(describe the content and extent, i.e. type of tissue, cells…)*

|  |  |  |
| --- | --- | --- |
| **Human Biological Materials/Samples** | Number of individuals | Number of samples |
|  |  |  |
|  |  |  |
|  |  |  |

**Description of Personal Data to be transferred**

Samples and associated Personal Data for analysis is provided in pseudonomyzed form.

Description of Personal Data:

* ………………………………………………………………….
* ………………………………………………………………….
* …………………………………………………………………..

**Attachment 2**

**RESEARCH TO BE CONDUCTED ON SAMPLES**

*\*To be attached by the responsible researcher (researcher responsible for the Project in Czech Republic)*

**Specification and description of purpose/s for which Samples and Personal Data may be used**

*Detailed description of the purposes for which Samples and Personal Data may be used*

**Attachment 3**

**IT security instructions**

**Attachment 4**

*Proof of affiliation to the Privacy Shield (registration in US Department of Commerce)*

*(in case of transfer to US)*

1. Fully anonymized data is not considered as personal data falling under the requirements of GDPR [↑](#footnote-ref-1)
2. *COMMISSION DECISION of 5 February 2010 on standard contractual clauses for the transfer of personal data to processors established in third countries under Directive 95/46/EC of the European Parliament and of the Council (notified under document C(2010) 593) (Text with EEA relevance) (2010/87/EU)* [↑](#footnote-ref-2)