# MATERIAL AND DATA TRANSFER AGREEMENT

*The Document can serve the purpose of a Material AND/OR Data transfer agreement. If human biological samples are transferred, the recent Regulation EU 2016/679 - General Data Protection Regulation (GDPR) implies that the specimen itself may contain personal and sensitive data (i.e., biological data, health data, genomic data) to which the GDPR applies.* ***THE GDPR-RELATED CLAUSES******SHALL BE DEFINED BY THE PARTIES ACCORDING TO THEIR POLICIES AND THE APPLICABLE NATIONAL IMPLEMENTATIONS OF THE GDPR****.* ***THE CLAUSES HEREBY PROVIDED ARE INTENDED AS A TRACE TO DETAIL SUCH OBLIGATIONS AND RAISE AWARENESS BETWEEN THE PARTIES– PLEASE CONTACT YOUR COMPETENT OFFICE TO DEFINE SUCH CLAUSES****.*

*Section highlighted in grey are for user guidance only – to be defined and removed from the final document that the parties negotiate.*

This agreement is entered into by and between:

**XXX *[name, legal address, legal representative authorized to sign this type of contract]***

Hereafter referred to as the **“Provider”**

**And:**

**YYY *[name, legal address, legal representative authorized to sign this type of contract]****,*

Hereafter referred to as the **“Recipient”**

**IN CASE RECIPIENT IS LOCATED OUTSIDE THE EUROPEAN UNION (EU) AND PERSONAL AND/OR SENSITIVE DATA ARE TRANSFERRED, THE GDPR IMPOSES CERTAIN STANDARD CONTRACTUAL CLAUSES – SEE ANNEX B**

The Provider and the Recipient shall hereafter be referred to individually as a “**Party**” and together as “the **Parties**”.

**PREAMBLE**

Whereas Provider has scientific and technological expertise in the field of *…To be completed….*

Whereas Recipient is active in the field of *…To be completed….*

Whereas the Parties, having considerable experience in the field concerned, have signed a Framework Consortium Agreement (The “**Consortium Agreement**”) relating to the Action entitled “**Promoting Implementation of Recommendations on Policy, Information and Material and Data for Rare Diseases”**, in short **RD ACTION**, hereinafter referred to as “**Project**”.

Whereas Recipient will access to the Material and Data defined below for research purposes as described in the Consortium Agreement and Provider agrees to transfer the Material and Data described below to Recipient, subject to the strict respect by the Parties of the conditions stated in the present agreement (hereinafter referred to as the “**Agreement**”).

|  |  |
| --- | --- |
| ***Material and Data***(Short description)  |  \_\_\_\_\_\_\_\_\_\_ |
| ***Personal Material and Data*** (If applicable) | [ ]  Yes[ ]  NoTHIS SECTION SHALL IDENTIFY IF HUMAN SAMPLES AND PERSONAL DATA and/or SENSITIVE DATA (AS PER GDPR definition) ARE TRANSFERRED. UNDER GDPR, BIOLOGICAL SAMPLES AND PERSONAL DATA SHALL BE FULLY ANONYMIZED WHENEVER POSSIBLE (i.e., no connection can be made BY ANYONE between the code assigned to the sample and the Data Subject). IF THE RESEARCH REQUIRES IT, SAMPLE CAN BE PSEUDONYMIZED (i.e., CODED) and PROTECTIVE CLAUSES IN ACCORDANCE WITH GDPR SHALL BE INCLUDED: THE FACT RECIPIENT DOES NOT HAVE THE KEY TO RE-IDENTIFY THE PATIENT FROM THE CODE DOES NOT RENDER THE SAMPLES/DATA FULLY ANONYMIZED, AS e.g., PROVIDER STILL CAN RETRACE THE PATIENT. |
| ***Intended Use of Material and Data*** | General description of the study to be performed by Recipient:      Specific purpose of the use of Material and Data by Recipient:       |
| ***Foreseen period of Use of Material and Data*** | SHALL BE IN ACCORDANCE WITH THE TERM OF THE AGREEMENT. UNDER CERTAIN NATIONAL IMPLEMENTATION OF GDPR, A DEFINED TERM SHALL BE STATED |
| ***Transfer and Mode of Transfer*** |  |
| ***Recipient Scientist*** |  |

**DEFINITIONS**

**(i) Commercial Purpose:**

shall mean he sale, lease, license, or other transfer of the Material and Data and/or Modifications (as defined below) to a for-profit organization. Commercial Purposes shall also include publication and uses of the Material and Data and Personal Data or Modifications by any organization, including the Recipient, to perform contract research or to conduct research activities that result in any sale, lease, license, or transfer of the Material and Data or Modifications to a for-profit organization.

**(ii) Effective Date:**

shall mean the date on which of the last required signature was obtained.

**(iii) Progeny:**

shall mean any descendant from the Reagent such as virus from virus, cell from cell, or organism from organism.

**(iv) Unmodified Derivatives:**

shall mean substances and genetic material created by the Recipient which constitute an unmodified functional subunit or product expressed by the Reagent. Some examples include: subclones of unmodified cell lines, recombinant constructs, subcultures, mutations, proteins expressed by DNA/RNA supplied by Provider, sub-sets of the original Reagent such as novel plasmids or vectors, monoclonal antibodies secreted by a hybridoma cell line, and/or purified or fractioned sub-sets of the original Reagent; DNA, RNA, proteins, cells, tissues and organs either directly derived from Reagent, or reproduced by any means, specifically including cloning, PCR, cell or organ culture.

**(v) Material and Data:**

Shall mean the material and data described in the Premises table above and Progeny, Unmodified Derivatives and Confidential Information

**(vi) Modification(s):**

shall mean substances created by Recipients as a result of the Research which contains and/or incorporates the Material.

**(vii)** **Personal Data:**

shall mean Material and Data that is defined and protected as personal material and data under the provisions of the General Data Protection Regulation (EU) 2016/679 (“GDPR”) and national applicable legislation(s), and that shall be subject to terms and conditions specified in article 4 of this Agreement. This term shall cover any personal data, including health and genetic data, related to the Material and Data, including the Material itself. For sake of clarity, Regulation (EU) 2016/679 define “personal data” as any information relating to an identified or identifiable natural person (“Data Subject”); 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;

**(viii)** **Research:**

shall mean the experimental, non-commercial, scientific research described in the Premises table above to be performed by Recipients.

**TERMS AND CONDITIONS OF THIS AGREEMENT**

# 1. PURPOSE

The purpose of this Agreement is to define the terms and conditions of the transfer of Material and Data between the Recipient and the Provider for the performance of the Research, as well as the rights and obligations of the Parties with regard to their use of Material and Data.

# 2. SUPPLY OF MATERIAL AND DATA

The Provider shall send the Material and Data to the attention of the Recipient, at the Recipient’s expenses, in the above specified Format and Mode of Transfer.

# 3. USE OF MATERIAL AND DATA

## Material and Data, Personal Data and their Modifications shall be used solely for purpose of the Research, in accordance with the Consortium Plan, to the exclusion of any other use of the Material and Data thereof such as a use for Commercial Purpose

## Recipients shall use the Materials only in compliance with all applicable laws, governmental regulations and guidelines, including any regulations or guidelines pertaining to research with animals or recombinant DNA that may be applicable to the Materials, in the country where the Research is carried out; The Research shall be carried out under the direct supervision and responsibility of Recipient Scientist.

## The Materials shall remain in the premises of Recipient, only in the Recipient Scientist's laboratory and under the direction of the Recipient Scientist.

## Recipients shall not transfer or otherwise make available, without Provider’s written consent, any Materials to any third party other than Recipient Scientist and the Institution’s employees who are working under the supervision of Recipient Scientist and who: (i) need to have access to Materials for the purpose of performing the Research; (ii) are apprised of the proprietary nature of the Materials and are bound to use the Materials only in the manner permitted under this Agreement

## Recipients shall refer any request received by any third parties for the Materials to Provider. To the extent the Material is available, Provider will evaluate and decide, at its own discretion and without any obligation to consent, whether to make the Materials available to third parties indicated by Recipients, on condition that a proper Material Transfer Agreement is signed by each of these third parties with Provider.

## Recipients shall use Materials only in vitro or in a laboratory for animal experiments.

## Recipients shall not use the Materials in human subjects, in clinical trials involving human subjects, or for diagnostic purposes involving human subjects without the prior written consent of Provider.

## Recipients shall acknowledge Provider in any publication and any other disclosure as the source of the Materials in accordance with scientific custom.

## Recipient may not transfer or otherwise make available Modification to third parties without Provider’s written consent.

## The Recipient agrees to apply the same degree of security in order to protect the Material and Data as it applies to its own material and data, and in any case no less than a reasonable degree of security.

## The Recipient undertakes that its use of the Material and Data shall not be subject to the terms of any research agreement according to which a third party would obtain rights to the results arising from the Research.

## The Recipient acknowledges that the Material and Data are or may be covered by intellectual property rights.

## Except as provided in this Agreement, no express or implied license or other right are provided to the Recipient under any patents, patent applications, trade secrets or other proprietary rights of the Provider, including any altered forms of the Material and Data made by the Provider.

## The Recipient acknowledges that nothing herein shall create or be construed to create any license to the Recipient or any obligation to enter into any other agreement.

## The Parties shall respect all terms and conditions under the present article 3 at their own costs and expenses.

**4. PERSONAL DATA**

The following rules apply to any transfer and use of Personal Material and Data covered by this Agreement:

4.1 The Provider and the Recipient represent and warrant that they each have previously obtained all authorizations or opinions and made all proceedings or declarations that are necessary in regards of the Transfer and the Intended Use of the Material and Data and Personal Data.

4.2 The Provider represents and warrants the Recipient that:

1. The Data Subjects (Hereinafter “Data Subjects”) who initially provided Personal Data have been duly informed and gave the written consent, to the full extent defined by the applicable law and regulations and covering the use of their Personal Material and Data for the Research.
2. Personal Data have been collected by fair means, in respect of applicable law and regulations.
3. Prior to the transfer of the Material and Data and Personal Data to Recipient, Provider will ensure that the Material and Data and Personal Data are coded, so that under no circumstances will Recipient be supplied with the identity of the Data Subjects, or any information that in Provider’s opinion could identify the Data Subjects.
4. ***THIS CLAUSE SHALL BE DEFINED BY THE PARTIES ACCORDING THE THEIR POLICIES AND THE NATIONAL IMPLEMENTATION OF THE GDPR****. Depending on the agreement between Provider and Recipient there are two options that shall be validated by the competent offices (including DPO) of both parties (see art 4.3.a) – briefly, Recipient shall be appointed as a DATA PROCESSOR or as a DATA CONTROLLER (autonomous data controller or co-controller), and an additional DATA PROCESSOR AGREEMENT shall be stipulated*

*Under GDPR, Provider has certain obligations pertaining to communication with the patients (e.g., ensuring that the Material and Data can be transferred to third parties like Recipient, that the purpose of use stated by the Recipient are in line with those agreed upon by patients in the informed consent).*

[***OPTION 1: RECIPIENT AS DATA PROCESSOR, see art 4.3.a -******THIS CLAUSE 4.2.d IS INTENDED AS A TRACE TO DETAIL SUCH OBLIGATIONS – PLEASE CONTACT YOUR COMPETENT OFFICE****]* Being the Material coded, Provider will be responsible for and manage all the interactions with the Data Subjects, included and not limited to the following. In particular, by means commonly put in place by Provider and compliant with applicable law, Provider shall be responsible for: (i) informing and making Data Subjects aware that Material and Data and related Personal Data have been communicated and transferred for the Research to Recipient; (ii) collecting the consent of Data Subjects for the abovementioned purposes under point (i), ensuring that it was freely given; (iii) promptly notifying the requests made by Data Subjects to the Recipient pursuant to Art. 15 to 22 of the Regulation (EU) 2016/679; Recipient will offer the cooperation necessary for Provider in order to fulfil its obligations towards the Data Subjects as related to Recipient’s processing of Personal Data.

***[OPTION 2: RECIPIENT AS DATA CONTROLLER, see art 4.3.a THIS CLAUSE 4.2.d IS INTENDED AS A TRACE TO DETAIL SUCH OBLIGATIONS – PLEASE CONTACT YOUR COMPETENT OFFICE]* *Recipient is required to provide patients with its privacy notice, but as the Material and Data are coded (pseudonymised), Recipient can do so only through the action of Provider. Please note that providing patients with an additional privacy notice may require to prepare and-submit a new informed consent to the Ethics Committee and re-consent patient.****]* Being the Material coded, Provider will be responsible for and manage all the interactions with the Data Subjects, included and not limited to the following. In particular, by means commonly put in place by Provider and compliant with applicable law, Provider shall be responsible for: (i) informing and making Data Subjects aware that Material and Data and related Personal Data have been communicated and transferred for the Research to Recipient; (ii) providing data protection information of Recipient to Data Subjects; (iii) collecting the consent of Data Subjects for the above mentioned purposes under point (i), ensuring that it was freely given; (iv) Provider will promptly notify the requests made by Data Subjects to the Recipient pursuant to Art. 15 to 22 of Regulation (EU) 2016/679; Recipient will offer the cooperation necessary for Provider in order to fulfil its obligations towards the Data Subjects as related to Recipient’s processing of Personal Data.

1. When required by law or regulation, the Personal Material and Data will be encrypted before Transfer.

4.3 The Recipient represents and warrants the Provider that:

1. ***THIS CLAUSE SHALL BE DEFINED BY THE PARTIES ACCORDING THE THEIR POLICIES AND THE NATIONAL IMPLEMENTATION OF THE GDPR****.* ***THIS CLAUSE 4.3.a IS INTENDED AS A TRACE TO DETAIL SUCH OBLIGATIONS AND NOT AS THE FINAL CLAUSE – PLEASE CONTACT YOUR COMPETENT OFFICE*** *Depending on the agreement between Provider and Recipient there are two options that shall be validated by the competent offices (including DPO) of both parties.*

The Material and Data and related Personal and Data, once received by the Recipient, shall be processed by Recipient in accordance with the provisions of Regulation (EU) 2016/679 as [OPTION 1: Data Processor, as per Data Processor Appointment agreement in Annex A (*Agreement defined by Provider according to applicable law and regulations*)] [OPTION2: Data Controller, *the parties shall define if they are autonomous data controller or co-controller*].

1. Notwithstanding the terms and conditions set out under section 3.2, Personal Data shall be stored with relevant degree of security in order to protect them in regards of their specific nature, and adequate maintenance procedures for the proper conservation of Personal Data shall exist, pursuant to applicable laws and regulations, in order to prevent any misuse, involuntary change, loss or modification of the Personal Data.
2. Personal Data shall only be used for the Research, which shall be legitimate and lawful.
3. Personal Data shall only be used to the strict extent that is necessary and during a reasonable period of time as regard to the Research and in any case only for the term of this agreement.
4. Personal Data shall not be used for Commercial Purpose;
5. Personal Material and Data shall not be transferred to a third party including any affiliate of the Recipient, without prior written authorization from the Provider and in accordance with the authorization/declaration necessary for the transfer.
6. Recipient undertakes not to perform any activities aimed at the identification of the Patients.
7. Any communication or publication of the results of the Research shall not allow, directly or indirectly, identification of the Patients.

4.4 At any time, following at least X business day advance written notice to Recipient, Provider shall be granted access by the Recipient to the place where Personal Data are stored (including premises, compounds, websites, servers, files, authorizations, etc.), for the only purpose and to the only extent of verifying if the terms and conditions stated in section 4.3 are respected.

4.5 At the end of the Period of Use of the said Personal Data as specified above, or upon termination of this Agreement, Recipient shall terminate any use and destroy or return such Personal Material and Data to Provider with no delay.

4.6 Parties shall respect all terms and conditions under article 4 at their own costs and expenses.

**5. OWNERSHIP OF MATERIAL AND DATA AND RESULTS**

5.1 Material and Data shall be treated as ownership of the Provider between the Parties, subject to applicable laws and regulations.

5.2 The Recipient shall not file, or have filed in the name of third parties in any country, any patent application, or intellectual property rights (including but not limited to copyrights, trademarks, …) claiming the Material and Data and the Personal Data.

5.3 Provider retains ownership and/or control of the Material and Data and related Personal Data, even where contained or incorporated in any Modifications, and shall decide, at its sole discretion, to prepare, file, prosecute and maintain in its name patent and/or patent applications covering the Material.

5.4 Subject to third parties rights on third parties materials contained and/or incorporated in the Modifications, if any Modification and/or any result of the Research stems from the collaborative efforts of both Provider and Institution, joint ownership shall be determined in good faith by Provider and Institution pursuant to the respective inventive contribution and in such a case the Parties shall negotiate an Inter-Institutional Agreement. Each party shall have the right to use any co-owned Modification and result of the Research for its internal research activity and non-commercial purposes.

**6. CONFIDENTIALITY**

6.1 Nothing in this Agreement shall be construed as conferring rights to use in advertising, publicity, or otherwise the name of the Provider or any of their marks.

6.2 The Recipient undertakes to respect and maintain strictly confidential all the Material and Data and Personal Data identified by the Provider as confidential or which is confidential by its nature.

**7. WARRANTIES**

7.1 The Recipient accepts the Material and Data "as is". Provider makes no representation and extends no warranties of any kind, either expressed or implied. No warranties expressed or implied are offered by the Provider as to the fitness for a particular purpose of the Material and Data. Provider and their directors, officers, employees, or agents assume no liability and make no representation in connection with the Material and Data use by Recipient. Recipient will defend, indemnify and hold harmless Provider, their directors, officers, employees, and agents from any damages, claims, or other liabilities which may be alleged to result or arise from its use or its storage of the Material and Data, even where included in Modifications, except to the extent caused by the gross negligence or willful misconduct of Provider.

7.2 ***THIS CLAUSE SHALL BE DEFINED BY THE PARTIES ACCORDING THE THEIR POLICIES AND THE NATIONAL IMPLEMENTATION OF THE GDPR****.* ***THIS CLAUSE IS INTENDED ONLY AS A TRACE TO DETAIL SUCH OBLIGATIONS AND NOT AS THE FINAL CLAUSE – PLEASE CONTACT YOUR COMPETENT OFFICE***Provider represents and warrants that the Material and Data and Personal Data have been collected and processed in compliance with applicable law, rules, regulations, and other requirements set by the applicable governmental authority, including without limitation those applicable to patient informed consent. Provider confirms that the Data Subjects involved have been informed according to the provisions of the Regulation (EU) 2016/679 about potential transfer to third parties of the Material/Data and related Personal Data for research purposes.

7.3 ***THIS CLAUSE SHALL BE DEFINED BY THE PARTIES ACCORDING THE THEIR POLICIES AND THE NATIONAL IMPLEMENTATION OF THE GDPR****.* ***THIS CLAUSE IS INTENDED ONLY AS A TRACE TO DETAIL SUCH OBLIGATIONS AND NOT AS THE FINAL CLAUSE – PLEASE CONTACT YOUR COMPETENT OFFICE***Provider shall indemnify, defend and hold harmless Recipient (and its employees, agents and consultants) from and against all claims, damages and liabilities that may be asserted by third parties (including Data Subjects) directly and/or indirectly related to Provider’s violation of any such laws, rules, regulations and requirements regarding collection and processing of the Material and Data and related Personal Data.

7.4 Provider makes no representation that the use of the Material and Data and Personal Data will not infringe any intellectual property right of any third party.

**8. TERMS OF CONTRACT**

8.1 This Agreement enters into force at the Effective Date and shall earlier be terminated: (a) thirty-six (36) months from the Effective Date, or (b) upon completion of the Project, unless otherwise agreed by the Parties. *PLEASE NOTE Option (b) may not be feasible under certain national implementation of GDPR*

8.2 At the expiration of this Agreement, the Recipient shall discontinue its use of the Material and Data and shall, according to the Provider’s instructions, return or destroy any remaining Material and Data.

**9. NON-TRANSFERABILITY**

This Agreement has been concluded *intuitu personae* and none of the Parties may assign all or part of the Agreement to a third party without the prior written agreement of the other Parties.

**10. MISCELLANEOUS**

10.1 Each Party will be excused for failure to fulfill its obligations and may not be held responsible or liable for damages with regard to the other Parties, if the non-performance is due to a force majeure event within the meaning of the applicable law, or such as the disruption of its services as a result in particular of strike, resignation or any other event beyond its control. The Party which finds it impossible to perform its contractual obligations due to a force majeure event shall immediately notify the other Parties in writing.

10.2 The Agreement shall in no event be interpreted as creating a partnership relationship or a company, even a *de facto* company, between the Parties which are independent contracting parties.

10.3 ***THIS CLAUSE SHALL BE DEFINED BY THE PARTIES ACCORDING THE THEIR POLICIES AND THE NATIONAL IMPLEMENTATION OF THE GDPR****.* ***THIS CLAUSE IS INTENDED AS A TRACE TO DETAIL SUCH OBLIGATION – PLEASE CONTACT YOUR COMPETENT OFFICE*** *In case of transfer of pseudonymized biological samples and/or personal and sensitive data, the GDPR recommends that the agreement is subject to the law and jurisdiction of Provider (assuming that Provider is a member of the EU). In any case, the Recipient shall comply with GDPR (and its national implementation of GDPR) even when receiving samples from outside the EU (Standard contractual clauses).* This Agreement shall be governed by the laws of Belgium. The Belgian relevant courts shall have sole jurisdiction for any litigation related to interpretation or execution of the Agreement, which parties cannot solve in an amicable way within a period of two (2) months following notification from a Party.

In witness whereof, the Recipient and Provider have executed this Agreement as of the date below written.

Signed in       original counterparts drafted in the English language, with one (1) for the Provider and the other for the Recipient.

|  |  |
| --- | --- |
| **Provider**Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Authorized signatory of the Provider) Name: Title: Date:        | **Recipient**Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Authorized signatory of the Recipient)Name: Title: Date:       |
|  |  |

READ, UNDERSTOOD AND AGREED TO BY THE SCIENTIT(S):

Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name:

Title:

Date:

**Annex A Data Processor Appointment**

**TO BE DEFINED BY PROVIDER**

**Annex B Standard Contractual Clauses**

**IN CASE RECIPIENT IS OUTSIDE THE EU, THE GDPR REQUIRES THAT CERTAIN STANDARD CONTRACTUAL CLAUSES SHALL BE IMPLEMENTED IN THE AGREEMENT. PLEASE CONTACT YOUR COMPETENT OFFICE ON THIS MATTER.**

**MORE DETAILS CAN BE FIND HERE:**

<https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/standard-contractual-clauses-scc_en>