

**DATA SHARING AGREEMENT**

This DATA SHARING AGREEMENT (hereinafter **AGREEMENT**) is dated [effective date].

**BETWEEN**

**[LEGAL NAME OF THE DATA HOLDER/CONTROLLER]**, a [organization corporate form] having its registered office at [legal address], duly represented by [name of legal representative] (hereinafter **DHC**)

**AND**

**[LEGAL NAME OF THE USER INSTITUTION]**, a [organization corporate form] having its registered office at [legal address], duly represented by [name of legal representative] (hereinafter **USER INSTITUTION**)

**AND**

**[LEGAL NAME OF THE DP]** a [organization corporate form] having its registered office at [legal address], duly represented by [name of legal representative], which processes data on behalf of the DHC (hereinafter **DATA PROCESSOR** or **DP**),

[AND] OR [IN THE PRESENCE OF]

**[NAME OF THE MAIN APPLICANT]**, an [individual researcher] employed at the USER INSTITUTION and in charge of the research project detailed in ANNEX 1, with professional address at [address], [country] (hereinafter **DATA USER**),

Hereinafter jointly referred to as the “**PARTIES**”

**WHEREAS**

- (A) the **PARTIES** hereby agree to conclude the AGREEMENT within the framework of the valorisation and exploitation of the ORCHESTRA Portal of the research project “Connecting European Cohorts to Increase Common and Effective Response to SARS-CoV-2 Pandemic: ORCHESTRA” (hereinafter **ORCHESTRA**);
- (B) ORCHESTRA is an international research project aimed at tackling the Coronavirus pandemic, coordinated by UNIVR and involving 26 partners from 15 countries. The project, funded by the European Union’s Horizon 2020 Research and Innovation Programme under the ERAvsCORONA Action, Grant Agreement 101016167, started in December 2020 and finished on November 2024;
  - each partner contributed to the elaboration of the prospective datasets to varying degrees in the following way: protocol elaboration; design of the database (including data harmonisation); data collection; data storage; sample analysis; data analysis;
- (C) this AGREEMENT regulates the methods of sharing and use of the data accessed through the ORCHESTRA Portal (hereinafter **ORCHESTRA DATA PORTAL**);
  - the DHC grants the right of access its cohort prospective data (hereinafter **DATA**, as defined below);
  - the DATA USER access request was approved by the ORCHESTRA Governing Board and access to data authorized by the DHC on [insert date] (protocol no. [enter protocol number] of

[insert date]);

- (D) the DP is prepared to provide access, though the ORCHESTRA DATA PORTAL, to the DATA USER under the conditions listed in this AGREEMENT;
- the USER INSTITUTION is [description of type of institution and activity] and is the home institution of the DATA USER who wish to access to the DATA under the conditions listed in this AGREEMENT and subject to additional terms and conditions referred to herein, where applicable;
  - each of the PARTIES recognises as a priority the need to respect the fundamental interests and rights of data subjects, including the need to preserve the security and confidentiality of the data, given in particular their extreme sensitivity.

## STIPULATE AND AGREE AS FOLLOWS

### ART. 1 - DEFINITIONS

#### 1.1 For the purposes of this AGREEMENT:

- **ACCESS** means controlled access to DATA through the ORCHESTRA DATA PORTAL via the established mechanisms (FLDA, QODE) as described in the MoU on behalf of the DHC.
- **DATA** means data, including personal, biomedical, technical and any other data provided by the DP to the DATA USER and described in ANNEX 2.
- **ORCHESTRA Governing Board** means a committee that reviews the application of access from the USER INSTITUTION/DATA USER and approve it subject to approval of the DHC.
- **DHC** means the Data Holder/Controller that grants/declines individual access rights for USER INSTITUTION/DATA USER based on its data access policy.
- **FLDA** means “Federated Learning Data Analysis” that is a set of techniques to analyse or learn from distributed datasets without loading them into a common database. Instead, analyses or learning processes are performed by only accessing the datasets locally and transforming aggregated data (e.g. analysis results, model parameters) to the central level. This approach guarantees that no personal data is exchanged, making it easier to share DATA in some contexts (e.g. when no consent has been informed) and implementing a privacy-by-design approach. FLDA provides DATA in an aggregated form so that no individual data (or means to access, infer or reconstruct such individual data) is disclosed.
- **QODE** means Question Oriented Data Export.
- **DATA ACCESS POLICY** means the methods of sharing determined by the DHC that grants the rights of access to its cohort prospective data and described in ANNEX 2:
  - in the case the DATA will be provided to the user through FLDA the DHC keeps the DATA in their local storage place, and do not physically transfer data
  - in the case the DATA will be provided to the user through a QODE, there is a physical transfer of DATA through a secure channel made directly by the DHC.
- **DATA PROTECTION LAW** means the applicable data protection laws, such as the GDPR (General Data Protection Regulation), as well as its implementing and successors texts.
- **DATA PROCESSOR** or **DP** means, where foreseen, the individual(s) or entity(ies) who/which processe(s)/store(s) data on behalf of the DHC, on the ORCHESTRA DATA PORTAL and who is authorized by the DHC to share the DATA under this AGREEMENT.
- **DATA USERS** means the PI (Principal Investigator) and any other individual researcher or investigator or group of researchers or investigators to whom access to the DATA has been granted by the DHC and who access, process or use DATA; DATA USERS’ access to the DATA

as well as use and processing thereof is performed exclusively under the PI's and USER INSTITUTION's joint liability. DATA USERS and USER INSTITUTION are recipients of the DATA.

- **GDPR** means the EU Regulation 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such DATA.
- **PERSONAL DATA** means 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.
- **RESEARCH PROJECT** means the research project described in ANNEX 1 and for the purpose of which access to DATA is granted to DATA USERS hereunder.
- **PUBLICATIONS** means, without limitation, articles published in a printed or electronic form on the press, reviews, books, public display and other written and verbal presentations (including private or publicly accessible conferences, meetings and similar events) of research and/or research results.
- **RECIPIENT** means a natural or legal person, public authority, agency or another body, to which the personal data are disclosed.

1.2 The terms 'controller', 'processor', 'recipient', 'data subject', 'processing' and 'personal data breach' have the same meaning in this AGREEMENT as in the DATA PROTECTION LAW.

## ART. 2 - OBJECT OF THE AGREEMENT

2.1 The purpose of the AGREEMENT is to define the terms on which access to DATA is granted to DATA USERS, and the further use of such DATA by the DATA USER and USER INSTITUTION.

2.2 Access to DATA is provided by DP to the DATA USER under the conditions determined in the AGREEMENT.

2.3 The USER INSTITUTION (either directly or through the DATA USER):

- a) provides to DHC and ORCHESTRA Governing Board a list of individuals to be approved as DATA USERS, and
- b) undertakes to update constantly the list of DATA USERS with DHC and ORCHESTRA Governing Board, as necessary to reflect changes or departures in affiliated researchers and personnel in good time to allow DHC to revoke related access rights at the effective date of such change. These updates are made by email to: [insert e-mail] and other secure transmission channels.

2.4 DP makes no particular commitment as regards the constant availability, continued operation and performance of the ORCHESTRA DATA PORTAL, or the uninterrupted access to data. DP will endeavour to inform the USER INSTITUTION and/or (at DHC's choice) the DATA USERS in advance in case of planned interruption of such access.

2.5 The USER INSTITUTION is liable for ensuring that DATA is used solely:

- a) in connection with the RESEARCH PROJECT as described in ANNEX 1; and
- b) in compliance with DATA PROTECTION LAW.

2.6 Any use of the DATA outside the strict scope of the RESEARCH PROJECT, or any modification of the RESEARCH PROJECT will require:

- a) the prior submission of a separate DATA access request to ORCHESTRA Governing Board that reviews and approve it;
- b) the prior written authorization thereof by the DHC (subject to potential restrictions or conditions set out therein).

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2.7 DATA USERS will use the DATA and the ORCHESTRA DATA PORTAL exclusively in accordance with the terms of this AGREEMENT.

2.8 Commercial use of the DATA is not permitted.

2.9 The USER INSTITUTION is liable for ensuring that DATA USERS will not:

- a) attempt to link DATA to/with other information or DATA, including DATA to which access has been granted hereunder, or which is freely available without restriction, unless specifically authorised by the DHC, or
- b) analyse or make any use of the DATA in such a way that has the potential to:
  - I. circumvent pseudonymisation (or anonymisation) or similar measures taken to protect the confidentiality of data subjects' identity; or
  - II. lead to the identification of any data subject; or
  - III. otherwise compromise the confidentiality of any data subject's identity in any way.

### **ART. 3 - NON-TRANSFERABILITY**

3.1 The USER INSTITUTION will not, and procures that DATA USERS will not, transfer or disclose the DATA, in whole or part, or any material derived from the DATA to any third party (including employees, agents, representatives, director and contractors of the USER INSTITUTION who are not DATA USERS) except:

- a) in an aggregated form so that no individual data (or means to access, infer or reconstruct such individual data) is disclosed, or
- b) if a separate data access request has been filed with, and approved in writing beforehand by the DHC.

### **ART. 4 - INFORMATION OF DATA USERS**

4.1 The USER INSTITUTION undertakes:

- a) to distribute a copy of this AGREEMENT and explain its contents to each DATA USER, including any subsequent amendments or additions;
- b) to implement and distribute any such guidelines, policies, procedures and instructions as necessary to ensure DATA USERS' compliance with the obligations contained in this AGREEMENT and DATA PROTECTION LAW; and
- c) to ensure that the DATA USERS have reviewed and understand the principles for responsible research use and DATA handling as defined in this AGREEMENT

### **ART. 5 - PUBLICATION, DISSEMINATION AND ACKNOWLEDGEMENT**

5.1 The USER INSTITUTION ensures that the PI agrees that his/her personal data (at least his/her name, contact details, title and home institution), information on the RESEARCH PROJECT (comprising its abstract and the PUBLICATIONS) may be posted on the ORCHESTRA website.

5.2 The USER INSTITUTION :

- a) agrees that the valorisation and exploitation of the ORCHESTRA DATA PORTAL (as indicated in the preamble) requires the dissemination of the research results obtained from any analyses of the DATA, as widely as possible, through scientific publications or other appropriate public dissemination mechanisms, and adheres to and intends to contribute to this objective; consequently, it undertakes to publish the results of its research in PUBLICATIONS;
- b) undertakes to acknowledge the DHC's and ORCHESTRA's role and contribution to the RESEARCH PROJECT in all PUBLICATIONS resulting from any analyses of the DATA and quote the DP and ORCHESTRA as authors in all PUBLICATIONS resulting from any analyses of the DATA;

- c) agrees to protect the confidentiality of DATA (and the identity of data subjects) in any PUBLICATION by taking all possible care to limit the possibility of identification;
- d) agrees that DHC contributing only DATA to new studies are to be recognised as co-authors (1 to 3 names) in the final manuscript, according to the numerosity of the data/samples provided. These provisions for the authorship are defined before DATA access and included in ANNEX 3 to this AGREEMENT. The authorship for authors contributing to the study follows the Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in medical Journals (ICMJE Recommendations);
- e) agrees that the ORCHESTRA funding (and, where appropriate, the relevant cohort funding), must be acknowledged with the following **Funding Statement**: *«This study/report/paper is based on data from ORCHESTRA and <name of the cohort, reference year(s), release date, version and DOI reference if available>. ORCHESTRA has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101016167. <Name of the cohort> has received funding from [...] The responsibility for all conclusions drawn from the data lies entirely with the author(s).»*

5.3 With a view to ensuring that DHC's policies and procedures applicable to the access to and use of DATA are respected, the USER INSTITUTION (either directly or through the PI) undertakes to provide, at least once a year (or upon completion of the research) , to the ORCHESTRA Governing Board a report detailing how the DATA have been used and any results generated as a result of the use of the DATA, including a status on patent (or similar) applications and PUBLICATIONS (with a copy thereof).

## ART. 6 - INTELLECTUAL PROPERTY

6.1 DHC recognises the importance of the subsequent development of intellectual property (IP) and associated protection rights (IPR) on downstream discoveries, especially in therapeutics, which will be necessary to support full investment in products to benefit the public.

6.2 However, by requesting access to the DATA, the USER INSTITUTION and DATA USERS acknowledge and support the objective of ORCHESTRA's policy on IP, that is:

- a) achieving maximum public benefit of the DATA distributed through the ORCHESTRA DATA PORTAL; and
- b) treating the DATA as 'pre-competitive' assets.

6.3 Consequently, USER INSTITUTION and DATA USERS will refrain from making IP claims derived directly from the DATA and which may result in restrictions, conditions or otherwise create obstacles to the distribution and use of the DATA (hereinafter the "Generated IP").

6.4 Without prejudice to the above provisions and to the control of the DATA by the data controller, the USER INSTITUTION or the DATA USERS, as the case may be, shall obtain ownership of those results and inventions and any intellectual property therein developed or created through the use of the DATA, pursuant to articles 2.5 -2.9 of the present AGREEMENT, either (i) independently of or (ii) not being Generated IP. The USER INSTITUTION and the DATA USERS commit and ensure that their use of such Generated IP shall not prejudice to ORCHESTRA's policy on IP, as defined above, and shall not restrict the use of the DATA by DHC, or any other USER INSTITUTION and DATA USERS.

## ART. 7 - RESPONSIBILITY

7.1 DP, on behalf DHC, undertakes to provide access only to DATA for which:

- a) technical and organizational measures have been adopted, including pseudonymisation, to guarantee compliance with the principle of data minimisation (art. 89, par. 1, GDPR); and/or
- b) documented, valid and informed consents have been obtained from data subjects (or their legal representatives), as confirmed by the DHC; and/or
- c) it is documented that prior consent of data subject was not necessary and the DATA is processed under another valid legal ground in accordance with DATA PROTECTION LAW, as confirmed by the DHC; alternatively
- d) preventive anonymisation will be carried out, where possible (exceptional measure); and
- e) when applicable, required ethical committees' or authorities' approval has been obtained to distribute and allow DATA USERS to process the DATA for the RESEARCH PROJECT's purposes, as confirmed by the DHC; alternatively.

7.2 In the event DATA are anonymized by the DHC before the sharing, the PARTIES are aware that the qualification of DATA as anonymous from a legal perspective is associated with the residual risk of different legal interpretations. In the event that the legal framework changes or new relevant case laws, decisions or guidelines are published, new (technical) data or technical means become available that affect the possibility of anonymizing data, DHC may modify the provision of the DATA and can require in last resort the immediate deletion of the data already provided. Nevertheless, the PARTIES may decide to amend the AGREEMENT accordingly.

7.3 The DHC with this AGREEMENT provides the DP with the instructions and authorization necessary to allow access to the data to the USER through FLDA or to transfer the requested data through a QODE, as established in ANNEX 2.

7.4 The DHC authorises the physical transfer of DATA (QODE) subject to approval of its Data Protection Officer (DPO).

7.5 The USER INSTITUTION undertakes and procures that DATA USERS will:

- a) only access, use and process the DATA as strictly necessary for the RESEARCH PROJECT in accordance with the data minimisation principle; and
- b) ensure that DATA is completely deleted (backup copies included) at the end of the term of this AGREEMENT.

## **ART. 8 DATA PROTECTION**

8.1 The PARTIES will duly observe all their obligations under DATA PROTECTION LAW which arise in connection with this AGREEMENT and the processing of the DATA.

8.2 The parties acknowledge that:

- a) the DHC is the controller as regards the collection and processing of the DATA until and including the access through the ORCHESTRA DATA PORTAL for subsequent use for research projects, and
- b) the DP is the DHC's processor as regards the storage of DATA and making such DATA available through the ORCHESTRA DATA PORTAL for subsequent use for research projects, and
- c) Members of ORCHESTRA Governing Board and DHC act as joint controllers with respect to the decision to grant access to the DATA.
- d) The USER INSTITUTION and DATA USERS are recipients and independent controllers as regards the access to DATA from the ORCHESTRA DATA PORTAL and the subsequent use and processing of the DATA for the RESEARCH PROJECT's purposes.
- e) Each PARTY is solely liable for ensuring its own compliance with the applicable DATA PROTECTION LAW as regards the acts of processing of the DATA it carries out (or which are carried out on its behalf).



8.3 The PARTIES undertake to co-operate in the event of and the USER INSTITUTION shall comply with any request made by DP and/or DHC with respect to:

- a) a DATA subject's claim, request or exercise of statutory rights on his/her DATA; or
- b) in case of any request by supervisory authorities.

8.4 The USER INSTITUTION will, and procures that DATA USERS will:

- a) notify DP of any errors detected in the DATA; and
- b) accept that DATA be reissued from time to time, with suitable versioning and, if DATA is reissued at the request of data subjects and/or as the result of ethical scrutiny, remove earlier versions of the DATA from subsequent analysis and publication and destroy/discard all earlier versions of DATA.

8.5 If the USER INSTITUTION or DATA USERS are located outside of (i) the European Union, (ii) the European Economic Area, or (iii) countries providing an adequate level of protection within the meaning of article 45.1 of the GDPR, the access to and transfer of DATA to the concerned DATA USERS will be subject to the entry by the USER INSTITUTION and DHC into a data transfer agreement based on the contractual clauses in ANNEX 4.

#### **ART. 9 - DATA SECURITY**

9.1 DP provides access to DATA through secure communication channels.

9.2 The USER INSTITUTION undertakes to implement and maintain at all times, throughout the duration of this AGREEMENT, an adequate technical infrastructure and environment with technical and organisational measures appropriate with respect to the nature of the DATA, their extreme sensitivity, volumes exchanged and associated risks, in order to ensure the ongoing confidentiality, integrity, availability and resilience of the systems used by DATA USERS for the processing of DATA. The USER INSTITUTION is in particular liable for:

- a) any access to the DATA or the ORCHESTRA DATA PORTAL by DATA USERS or through the latter's access accounts or credentials (including by third parties impersonating DATA USERS);
- b) implementing, testing, reviewing, regularly training DATA USERS on, and enforcing rules (including good practices in terms of information security, such as, clean desk policy, credentials management including non-sharing of credentials -including with other DATA USERS-, revocation of compromised credentials) applicable to all DATA USERS on the use of the DATA, access thereto and relevant credentials to ensure that DATA USERS comply at all times with the terms of the AGREEMENT and DATA PROTECTION LAW;
- c) revoking immediately compromised (lost, stolen or shared) credentials with DP in writing (email accepted); and
- d) any access to and use of the DATA or the ORCHESTRA DATA PORTAL by a DATA USER or a third party impersonating a DATA USER.

9.3 Upon request of DP, the USER INSTITUTION will make available to DP all information necessary to demonstrate compliance with the obligations laid down in this AGREEMENT and allow for and contribute to audits conducted by DHC or any independent inspections by DHC's representatives, auditors or competent authorities, to ascertain compliance with this AGREEMENT, with reasonable notice and during regular business hours.

9.4 DP, having consulted DHC, reserves the right to suspend the access or account of DATA USERS whose credentials have been compromised or revoked, or who have acted in breach of this AGREEMENT or the terms of use of the ORCHESTRA DATA PORTAL, without prejudice to the right to terminate the AGREEMENT pursuant to clause 15 of this AGREEMENT.

#### **ART. 10 - CONFIDENTIALITY**

10.1 The USER INSTITUTION will, and procures that DATA USERS will:

- a) treat the DATA as confidential information and keep it in strict confidence;
- b) to only use, make/keep copies of the DATA for the sole purpose of the RESEARCH PROJECT or as strictly required by DATA PROTECTION LAW;
- c) to protect the DATA, whether in storage, in process or in use, with the same degree of care as the USER INSTITUTION uses to protect its own sensitive/confidential information, but in no circumstances with less than reasonable care; and
- d) ensure traceability and document any action of dissemination, retention and destruction of the DATA, and communicate such documentation to DHC upon request.

10.2 During the performance of this Agreement, USER INSTITUTION or DATA USERS may disclose to DHC and/or DP certain information relating to their business or research operations, policies, or procedures. DHC and/or DP will keep such information in strict confidence and only use it for the sole purpose of this Agreement.

#### **ART. 11 - PERSONAL DATA BREACH**

11.1 The USER INSTITUTION undertakes to, and procures that DATA USERS will, notify to DHC or DP any personal data breach without undue delay, not later than 48 hours, after becoming aware of such data breach.

11.2 All notifications and reports of data breaches should be submitted through [insert e-mail]

11.3 Notifications under clause 11.1 should include:

- a) a description of the nature of the data breaches as well as all factual details and any other useful information available regarding the data breach,
- b) a general description of the measures deployed by the USER INSTITUTION and/or DATA USERS to remediate the situation, including, where appropriate, measures to mitigate its possible adverse effects,
- c) where possible, the categories and approximate number of DATA subjects concerned and the categories and approximate number of DATA records concerned,
- d) a description of the likely consequences of the data breach,
- e) the name and contact details of the USER INSTITUTION's data protection officer or other contact point where more information can be obtained.

11.4 The USER INSTITUTION will continue to keep DHC or DP apprised on any subsequent development and, until complete resolution of the case, provide at least weekly reporting on the personal data breach, countermeasures, risk assessments and other useful information (including competent authorities requests, decisions or injunctions).

#### **ART. 12 - LIABILITY**

12.1 The DHC, the DP, copyright holders, and all other parties make no warranty express or implied as to the accuracy, quality or comprehensiveness of DATA to the USER INSTITUTION and the DATA USER.

12.2 USER INSTITUTION shall hold DHC and DP harmless against any claim from the DATA USERS:

- a) the DHC, the DP, and copyright holders exclude to the fullest extent permitted by law all liability for actions, claims, proceedings, demands, losses (including but not limited to loss of profit), costs, awards damages and payments made by the USER INSTITUTION or DATA USERS that may arise (whether directly or indirectly) in any way whatsoever from the use by the DATA USERS of DATA or from the unavailability of, or interruption in access to, DATA or the ORCHESTRA DATA PORTAL for whatever reason; and



- b) the DHC and the DP bear no responsibility for the further analysis or interpretation of the DATA.

12.3 USER INSTITUTION shall be liable for keeping copies of the DATA by its DATA USERS, and DHC shall not be liable for damages incurred to the USER INSTITUTION by reason of the destruction or alteration of any sort of the DATA on the account of a DATA USER.

#### **ART. 13 - STORAGE DURATION**

13.1 DATA will be destroyed by USER INSTITUTION or DATA USERS, at the sooner of (1) the DATA being no longer used or strictly necessary for the research project or (2) the termination of the AGREEMENT for whatever reason.

13.2 Archiving of the DATA will be provided by DP exclusively.

13.3 Where this AGREEMENT provides that the USER INSTITUTION or DATA USERS should destroy the DATA (regardless of the cause), any such destruction should be carried out in a secure manner so as to avoid any potential restoration or reconstruction of the DATA, and the USER INSTITUTION will issue to DP (or DHC) without undue delay after such destruction a written certificate of secure destruction of the DATA, including a commitment to have destroyed all copies (including backups) of the DATA.

#### **ART. 14 - FINANCIAL PROVISIONS**

14.1 The services are provided free of charge.

#### **ART. 15 - TERM AND TERMINATION**

15.1 This AGREEMENT will be effective for a period of one (1) year from the date of the DHC granting access to the DATA to the (first) DATA USERS.

15.2 The PARTIES may, but will not be obliged to, decide to extend this AGREEMENT after its term. If advance written notice and approval by the DHC is obtained to allow USERS to finish their RESEARCH PROJECTS when they are using the DATA, the DATA will not need to be destroyed, unless if there is a compelling legal reason to do so; Section 13.1 remains unaffected. In any other case, the USER INSTITUTION (either directly or through the PI) will be required to file a new DATA access request with the ORCHESTRA Governing Board and DHC, which may take a decision in its own discretion. Should the PARTIES decide to renew this AGREEMENT, the ORCHESTRA Governing Board and DHC will solely determine the conditions in which the DATA may be retained by the USER INSTITUTION during the transition between the two contractual periods. In the absence of such prior written decision, the USER INSTITUTION will, and procures that DATA USERS will destroy the DATA at the initial AGREEMENT's termination date.

15.3 DP, having consulted DHC, may terminate this AGREEMENT and immediately revoke access to DATA and the ORCHESTRA DATA PORTAL upon any breach of this AGREEMENT (including without limitation in case of personal data breach) or rules identified herein or DATA PROTECTION LAW by the USER INSTITUTION or any DATA USER. The USER INSTITUTION should be solely liable for the consequences of such termination and revocation.

15.4 In case of termination or non-renewal of this AGREEMENT for whichever cause, the USER INSTITUTION shall, and procures that DATA USERS shall destroy the DATA at the date of termination, using endeavours conform to clause 13.3.

15.5 Any termination under this clause 15 will be automatic ('de plein droit'), without recourse to the courts and without compensation for the other party.

15.6 The breach of any of the terms outlined in AGREEMENT will result in a withdrawal of approval to access and/or use of the DATA.

### ART. 16 - GOVERNING LAW, JURISDICTION

16.1 The AGREEMENT will be governed by [insert jurisdiction] law.

16.2 Any disputes, claims or litigation in connection with the AGREEMENT, which cannot be solved amicably, will be brought exclusively before the courts of the judicial district of [insert city].

**THE AGREEMENT IS DRAWN UP IN AS MANY ORIGINALS AS THERE ARE PARTIES, EACH PARTY ACKNOWLEDGING RECEPTION OF ONE ORIGINAL.**

### SIGNATORIES:

<p><b>FOR DHC</b></p>          <p>Name : Function :</p>	<p><b>FOR THE USER INSTITUTION</b></p>          <p>Name : Function :</p>
<p><b>FOR DP</b></p>          <p>Name : Function :</p>	<p><b>Read and understood: THE PI</b></p>          <p>Name: Function:</p>

**ANNEX 1 – RESEARCH PROJECT DESCRIPTION**

*The compilation is carried out by the Secretariat and the data of the access request completed online where possible is reported*

**A. CONTACT INFORMATION:**

Main applicant:

Position:

Mailing Address:

Institutional E-mail:

**B. NAMES OF AUTHORIZED PERSONNEL**

*Include the names of all investigators, collaborators, post-doctoral researchers, research staff, and students who will have access to the controlled data in order to work on the Research Project. Please ensure that a valid institutional e-mail address for each name is included, along with a proper job title.*

*\*Note that co-investigators or collaborators at other institutions must submit a separate Data Access Request.*

Name:

Position:

Affiliation:

Institutional E-mail:

Name:

Position:

Affiliation:

Institutional E-mail:

**C. PROJECT INFORMATION:**

Research Ethics Approval Number (if exists):

Project Title:

Project Website:

Project Purpose and Aims:

**ANNEX 2 – DATA & DATA ACCESS POLICY**

*The compilation is carried out by the DHC in agreement with the DP*

**Title:**

**Data Use Restrictions:**

**Data access policy:**

☐ FLDA

☐ QODE

### **ANNEX 3 - AUTHORS**

*The compilation is carried out by the DHC*

**Numerosity of data/sample provided:**

**author 1:**

**author 2:**

**author 3:**

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#### **ANNEX 4 – STANDARD CONTRACTUAL CLAUSES**

Commission Implementing Decision (EU) 2021/914 of 4 June 2021 on standard contractual clauses for the transfer of personal data to third countries pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council (Text with EEA relevance)

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021D0914>