# DATA SHARING AGREEMENT

The parties identified below hereby agree to be bound by the terms set forth hereunder.

Detailed guidance for filling out this agreement is provided in [Appendix 1](#Appendix_1).

 **Definitions Meaning**

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| **\*** | **Supplier***Party supplying the Data* | **Stichting Amsterdam UMC**, with registered address at De Boelelaan 1117, 1081 HV Amsterdam, the Netherlands, legally represented by the managing director Division 5 |
| **\*** | **Recipient***Party receiving the Data* | <Institution name>, having its office at <office address>, legally represented by <name of legally authorised representative> |
|  | **Whereas***Reasons why this agreement is concluded, context* | To collaborate with NESDA around the topic <state topic> |
| **\*** | **Term***After what term should the (Personal) Data be irreversibly deleted?*  | <max=5> years |
| **\*** | **Data***Please describe which data is provided, focusing on non-personal data (type, amount, format, etc.). Personal data is described below.* | No data other than (pseudonymized) personal data.  |
| **\*** | **Personal data***Which categories of Personal data are provided?* | Pseudonymized personal data, as described in detail in [Appendix 2](#_APPENDIX_2:_Data), Data Analysis Plan DAP XX-XX, "<DAP title>" (tentatively approved by the NESDA Board). |
| **\*** | **Special Categories of Personal data** *Does the Data contain any of the following types of personal data? Check all that apply.* | [ ]  racial or ethnic origin [ ]  political opinions [ ]  religious or philosophical beliefs [ ]  trade union membership [ ]  genetic data | [ ]  biometric data for the purpose of uniquely identifying a natural person [x]  data concerning health [ ]  data concerning a natural person's sex life or sexual orientation |
| **\*** | **Data subjects***From which categories of data subjects is the Data derived? (e.g. students, athletes, patients, researchers, etc)* | Research participants from the NESDA cohort (psychiatric patients as well as controls). |
| **\*** | **Purposes**  *Why is the (Personal) Data provided to Recipient? Please explain for which purposes the (Personal) Data will be used.* | A detailed analysis plan is attached in [Appendix 2](#_APPENDIX_2:_Data). |

 **Other information**

|  |  |  |
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| **\*** | **Does the Personal data only contain Pseudonymised data?***If the Personal data contains data which is not pseudonymised or coded, check “no”* | [ ]  yes[ ]  no |
|  | **Additional useful information**  |  |
| **\*** | **Will the Data be transferred outside the EU?***If “yes” is checked, additional approval from the Privacy Officer is required.* | [ ]  yes[ ]  no |
| **\*** | **Contact points for data protection enquiries** | **Suppliers**Privacy Office Amsterdam UMC (Research)Telephone: 020-4441717E-mail: privacy@amsterdamumc.nlName: M. EikelenboomJob title: Head of Operations E-mail: m.eikelenboom11@amsterdamumc.nl | **Recipient**Name: E-mail: |

All fields with a **\*** are mandatory and must be filled in.

|  |  |
| --- | --- |
| **Signature authorized representative Supplier**Stichting Amsterdam UMC | **Signature authorized representative Recipient**<Institution’s name> |
| Name: Title: Managing Director Division 5Signature:Date: | Name: Title: Signature:Date: |

Supplier and Recipient are solely referred to as “**Party**” and collectively referred to as “**Parties**”.

Now, therefore, in consideration of their mutual promises to each other, hereinafter stated, the Parties agree as follows:

## Definitions

1. “**Data**” means the data as identified on page one above which the Supplier will transfer to the Recipient. The Data will contain Personal data as identified on page one.
2. “**Confidential Information**” means any proprietary information, know-how, data, or procedure related to the Data and disclosed by Supplier to Recipient pursuant to its rights or obligation under this Agreement.
3. “**Controller**”, “**Data subject**”, “**Personal data**”, “**Processing**”, “**Processor**”, “**Personal data breach**” and “**Supervisory authority**” shall have the meaning as in the General Data Protection Regulation (EU) 2016/679 (hereinafter: “**GDPR**”).
4. “**Pseudonymised data**” means Personal data which can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the Personal data are not attributed to an identified or identifiable natural person.

## Clause 1. The Processing of Personal data

* 1. The Supplier will provide the Recipient with the Data in accordance with the terms of this Agreement, for the Purposes.
	2. Insofar Personal data within the meaning of the GDPR are provided by the Supplier to the Recipient and/or Processed by the Recipient, both the Supplier and the Recipient qualify as independent Controllers for such Processing. For the avoidance of doubt, this data sharing agreement is not an agreement as meant in article 26.1 nor article 28.3 of the GDPR. Descriptions of the Data subjects, the Purpose of the transfer and the Special Categories of Personal data are included on page one.
	3. The Supplier warrants and undertakes that:
1. the Personal data have been collected, processed and transferred in accordance with the GDPR and any other applicable data protection laws;
2. it has obtained any regulatory or ethics approvals necessary to collect the Data and transfer the Data to the Recipient.

1.4 The Recipient warrants and undertakes to:

1. process the Personal data in accordance with the GDPR and any other applicable data protection laws;
2. only use the Data for the Purposes;
3. not carry out any procedures with the Personal data (such as linking and comparing) through which the identity of the Data subject could be derived;
4. have in place appropriate technical and organisational measures to protect the Personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, and which provide a level of security appropriate to the risk represented by the processing and the nature of the data to be protected;
5. without prejudice to any other contractual obligation to confidentiality that applies, treat all Personal data as strictly confidential and inform all of its employees, representatives and/or (sub)Processors who are involved in the Processing of the Personal data of the confidential nature of such information and of the Personal data. The Recipient will ensure that such persons and the Parties have signed an adequate confidentiality agreement;
6. immediately notify the Supplier after it has reported a Personal data breach to a Supervisory authority and/or the Data subjects in connection with Personal data that it has received from the Supplier. In such case, the Recipient will contact the Contact point of the Supplier as specified on page one;
7. not process or transfer the Personal data in or to countries outside of the European Economic Area (EEA), unless parties have agreed on page one above that Recipient may process or transfer the Personal data in or to countries outside of the EEA. In case of such processing or transfer outside EEA, Parties will attach additional required documentation in an annex to this data sharing agreement.

## Clause 2. Confidentiality

2.1 Confidential Information shall be used by the Recipient solely for the Purposes. The Recipient agrees not to disclose Confidential Information to third parties without the consent of the Supplier and under an agreement by the third party to be bound by the obligations of this clause 2. The Recipient shall safeguard Confidential Information with the same standard of care that is used with Recipient’s own confidential information, but in no event less than reasonable care.

 The Data is not considered to be Confidential Information as clause 1.4 section e already obliges the Recipient to keep the Data confidential. This clause 2 concerns other information which may be shared between the Parties and the obligation to keep such information confidential.

* 1. The obligations under this clause 2 shall not extend to any information:
* which is or becomes publicly available through no breach of this Agreement;
* which Recipient can demonstrate that it possessed free of any obligation of confidence prior to, or developed independently from, disclosure under this Agreement;
* which Recipient receives from a third party which is not legally prohibited from disclosing such information; or
* which Recipient is required by law to disclose.

2.3 The obligations of this clause 2 shall survive this Agreement for a period of three (3) years after termination or expiration of this Agreement. Upon the request of the Supplier, the Recipient agrees to return the Confidential Information to the Supplier or destroy, at the option of the Supplier, all copies of Confidential Information; provided, however, that Recipient shall be entitled to retain one copy of Confidential Information solely to ensure compliance with its rights and obligations hereunder.

## Clause 3. Results

3.1 All discoveries, developments, databases, inventions (whether patentable or not), methods, reports, know-how, or trade secrets which are made by the Recipient as a result of the conduct of the Purposes (hereinafter: “**Results**”) shall be the solely property of the Recipient.

3.2 The Recipient shall grant the Supplier a non-exclusive and non-sublicensable license to utilize all such Results for all non-commercial research and educational purposes.

## Clause 4. Publication

4.1 Parties will jointly publish the Results in one or more articles in peer reviewed journals. Parties will not publish the Results independently.

4.2. Recipient will credit Supplier appropriately in the publication as the supplier of the Data.

## Clause 5. Representations and warranties

5.1 Other than the warranties set out in section 1.3, the Data is provided by the Supplier to the Recipient without any warranties whatsoever, express or implied, including any warranties for merchantability or fitness for a particular purpose.

5.2 The Recipient represents and warrants that the Data shall be used and the Purposes shall be performed in accordance with this Agreement, Consent and all applicable local and international laws and regulations.

5.3 Nothing in this Agreement shall be construed as granting to Recipient, either expressly or by implication, any right or licence to the Data, under any patent, patent application, trade secret, know how, confidential information, trade or service mark, copyright, or other intellectual and/or industrial property rights Supplier possesses or may possess, nor any option to any such right or license.

## Clause 6. Liabilities and indemnification

6.1 The Recipient assumes the risk of any damage, loss, or expense associated with or resulting from the conduct of the Purposes or Recipient’s use of the Data, unless such damage or loss is caused by the gross negligence or wilful misconduct of the Supplier.

6.2 The Recipient will indemnify and hold the Supplier, its directors or employees harmless against all claims of any kind whatsoever that may arise or result from the use of the Data.

6.3 The Supplier shall not be liable toward the Recipient for any claims, costs or damages that may result, directly or indirectly, out of Recipient’s use of the Data and/or Results, unless and to the extent that damage is caused by gross negligence and/or due to wilful misconduct by the Supplier.

6.4 The Parties shall in no case be liable for any indirect, incidental or consequential damages (including without limitation, lost business or profits, or loss of use of equipment) suffered by another Party.

## Clause 7. Duration and termination of the Agreement

7.1 This Agreement shall become effective on the date of the last Party’s signature below, and shall remain for the duration of the Term as identified on page one above, unless terminated earlier in accordance with section 7.2. The Parties agree that the term may be extended by mutual written agreement.

7.2 This Agreement can be terminated earlier by either Party with immediate effect by receipt of written notice:

a. Upon a material breach of this Agreement by the other Party, if it is not cured within thirty (30) days after the breaching Party has received written notice of such material breach.

b. in the event the other Party is in state of bankruptcy or suspension of payment or a petition to that effect is filed by or against that Party;

c. in the event the business of the other Party will be winded up or closed down;

d. in case of force majeure - as determined in clause 11 below - if the force majeure situation will last over ninety (90) days.

7.3 The Recipient agrees, on termination of this Agreement (whether as a result of its breach or otherwise) to cease all use of the Data and shall within fifteen (15) days return all Data to Supplier or destroy all Data at the sole discretion of Supplier, or to deal immediately with the Data in accordance with Supplier’s written instructions.

7.4 Clauses 1, 3 -6, 8 and sections 7.4 shall survive expiration or early termination of this Agreement, as well as any terms that by their nature would be expected to survive expiration or early termination of this Agreement shall survive such expiration or early termination. Clause 2 will survive expiration or early termination of this Agreement for the term specified in clause 2.

## Clause 8. Publicity

Neither Party will use the logo or name of the other Party or the name of an employee of the other Party, for promotional purposes, in any publicity, advertising or news release, without prior written approval of the Party whose name is to be used.

## Clause 9. Modifications

Modifications, changes and extensions to this Agreement are only binding after these have been agreed upon in writing between the Parties.

## Clause 10. Assignment

 The rights and obligations as determined in the Agreement may not be assigned by a Party without the prior written consent of the other Party, which consent shall not be unreasonably with­held or delayed.

## Clause 11. Force Majeure

In case of force majeure the concerning Party is entitled to suspend the obligations for the duration and extent of the force majeure, provided that the other Party has been notified in writing of the force majeure. Force majeure situations will concern those situations which prevent the execution of the Agreement and which are not imputable to the concerning Party pursuant to law, Agreement or according to generally accepted standards and as a result will not be attributable to that Party.

## Clause 12. Severability

 The invalidity or unenforceability of any particular provision of this Agreement shall not affect any other provisions therein. The Agreement shall be construed in all respects as if such invalid or unen­forceable provision were omitted.

## Clause 13. Governing law

 13.1 This Agreement will be governed by Dutch law.

 13.2 In the event a disputes may arise from the Agreement, or from the execution of the Agreement, Parties will first try to settle such dispute amicably. If the dispute cannot be settled amicably, it will be submitted to the competent court in the district of Amsterdam, the Netherlands.

## Clause 14. General Terms and conditions

 No general conditions will apply to this Agreement.

**IN WITNESS WHEREOF**, the Parties hereto have by their authorized represen­tative duly caused this

Agreement to be executed. Signatures are placed on page 2.

# APPENDIX 1: Guidance for filling in this Data Sharing Agreement

|  |  |
| --- | --- |
| **Topic** | **Guidance** |
| **Supplier***Party supplying the Data* | **Mandatory** field. For the NESDA study, this field comes pre-filled with the information for the data Supplier, Stichting Amsterdam UMC. |
| **Recipient***Party receiving the Data* | **Mandatory** field. Please fill in the information for the institution receiving the data, including its authorized legal representative in the context of this agreement. The legal representative could be, for example, a (department) manager or a senior researcher who is authorized by the institution to sign data sharing agreements as the receiver of data.  |
| **Whereas***Reasons why this agreement is concluded, context* | **Optional** field. Please summarize any relevant context for the sharing of the data, e.g. the topic of research.  |
| **Term***After what term should the (Personal) Data be irreversibly deleted?*  | **Mandatory** field. Please fill in the time period after which you agree to irreversibly delete the data. The time period is counted from the most recent signature date on page 2 of this DSA. The maximum term usually allowed is 5 years. |
| **Data***Please describe which data is provided, focusing on non-personal data (type, amount, format, etc.). Personal data is described below.* | **Mandatory** field (pre-filled). For the NESDA study, (almost) all datasets are personal (pseudonymised) data.  |
| **Personal data***Which categories of Personal data are provided?* | **Mandatory** field. You **must** refer to the data analysis plan (DAP XX-XX) where the data is described in detail. This DAP will be added as Appendix 2 by the Data Management team at a later time point. If the DAP is amended after this DSA is signed, any additional datasets can still be provided as long as all newly requested personal data falls within the “Special Categories of Personal Data” boxes checked in the original DSA; otherwise, the DSA must be amended and re-signed. |
| **Special Categories of Personal data** *Does the Data contain any of the following types of personal data? Check all that apply.* | **Mandatory** field. Please check all boxes that correspond to the categories of personal data found within the data requested. Please do not uncheck the “data concerning health” checkbox. |
| **Data subjects***From which categories of data subjects is the Data derived? (e.g. students, athletes, patients, researchers, etc)* | **Mandatory** field. Please provide a short description of the study sample, i.e. the subjects whose data is to be shared. For the NESDA study, this is “Research participants from the NESDA cohort (psychiatric patients as well as controls)”.  |
| **Purposes**  *Why is the (Personal) Data provided to Recipient? Please explain for which purposes the (Personal) Data will be used.* | **Mandatory** field. Please explain the purposes for which the (Personal) Data will be used. You may mention the topic(s) and goal(s) of the planned analyses, but a reference to the data analysis plan (DAP XX-XX) where these are described in detail is sufficient. |
| **Does the Personal data only contain Pseudonymised data?***If the Personal data contains data which is not pseudonymised or coded, check “no”* | **Mandatory** field. For the NESDA study, all personal data are pseudonymised, except, for example, genetic data or fine-grained address data.  |
| **Additional useful information**  | **Optional** field. |
| **Will the Data be transferred outside the EU?***If “yes” is checked, additional approval from the Privacy Officer is required.* | **Mandatory** field. Additional approval may not be necessary for [certain countries](https://commission.europa.eu/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions_en) outside the EU, if the European Commission has determined, on the basis of article 45 of Regulation (EU) 2016/679 that a country outside the EU offers an adequate level of data protection.  |
| **Contact points for data protection enquiries** | **Mandatory** field. Please fill in the contact details of the person(s) in your (Recipient) institution to whom enquiries regarding data protection can be sent. For the NESDA study, the Supplier side of this field comes pre-filled with the contact points for the NESDA study. |

# APPENDIX 2: Data Analysis Plan tentatively approved by the NESDA Board