ADDI
Alzheimer's Disease
Data Initiative

ALZHEIMER'S DISEASE DATA USE AGREEMENT TEMPLATE

INSTRUCTIONS:

This template Alzheimer's Disease Data Use Agreement is intended to be used by a data provider and a data recipient to govern the terms of their data sharing. Throughout, the fillable fields should be edited as appropriate to turn this template into a usable agreement.

UPDATED NOVEMBER 2020

Section 2.c:
Note that, if the arrangement will involve the transfer of personal data from the European Economic Area (EEA), the parties must select one of the bases for lawful transfer in the table in this section. The preferred option should be initialed by both parties to incorporate it as part of the agreement.

Section 4.c:
We have included as an option a requirement that the data recipient grant the data provider certain intellectual property rights. If desired, this provision can be retained. Otherwise, it can be edited or deleted.

Exhibit A:
The parties should attach the Research Plan to the Alzheimer's Disease Data Use Agreement as Exhibit A.

Exhibit B:
This Exhibit should be attached only if the parties are relying on the standard contractual clause option by initialing the applicable row in the table in Section 2.c. Otherwise, Exhibit B can be deleted. If standard contractual clauses will be used, the text of the available sets of standard contractual clauses can be found here: *https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/standard-contractual-clauses-scc_en.*

NOTE:

[Magenta, Bold, bracketed text] shows fields on the Data Use Agreement that will generally need to be customized to the particular study. Once edited, the **[brackets and bold]** formatting should be removed and the text color changed to black.

Customize the template as needed and then delete this page of instuctions.

For help editing and formatting text in a pdf, visit: *https://helpx.adobe.com/acrobat/using/edit-text-pdfs.html.*

The actual template is on the next page

ALZHEIMER'S DISEASE DATA USE AGREEMENT

This Alzheimer's Disease Data Use Agreement (the "Agreement") is effective as of **[_____]** (the "Effective Date") between **[Data Recipient]**, acting for and on behalf of its investigator **[Investigator Name]** with an address at **[Data Recipient Address]** and **[Data Provider]**, with an address of **[Data Provider Address]**.

WHEREAS, Data Provider has collected certain data pertaining to Alzheimer's Disease through research or clinical care;

WHEREAS, Data Recipient is an institution that desires access to certain data and associated information held by Data Provider for the purpose of carrying out research related to Alzheimer's Disease (each a "Data Set" and collectively "Data Sets");

WHEREAS, Data Recipient wishes to carry out certain analyses using the Data Sets that are described in one or more research plans (each a "Research Plan" and collectively "Research Plans"); and

WHEREAS, Data Provider desires to make available to Data Recipient certain Data Sets to carry out the Research Plan(s) under the terms set forth in this Agreement;

NOW, THEREFORE, Data Provider and Data Recipient agree as follows:

1. **Data Access**

   a) **Research Plan.** Data Provider grants to Data Recipient a royalty-free, worldwide, non-exclusive, irrevocable (except in the event of the termination of this Agreement as hereinafter provided) license to use the Data Set(s) described in the Research Plan(s) appended hereto as Exhibit A for the purpose of performing the Alzheimer's Disease-related analysis set forth in the Research Plan(s) for which the Data Set is requested (the "Analysis") subject to the terms and conditions of this Agreement. Notwithstanding the foregoing, Data Provider maintains any pre-existing ownership rights that it may have in the Data Set(s) (including all intellectual property rights therein except for the license granted pursuant to this Agreement). Additional Research Plans accepted by Data Provider may be appended to this Agreement in writing through the mutual agreement of the parties and the signature of the parties on such additional Research Plans evidencing their mutual intent to add the plans to this Agreement's Exhibit A. Such appended additional Research Plans shall carry a statement that, "The parties desire this Research Plan to be governed by the terms of the Alzheimer's Disease Data Use Agreement entered into as of **[Effective Date]**." For the avoidance of doubt, the use by Data Recipient of all Data Sets described in Research Plans appended in writing, signed by the parties hereto, including both those initially appended to this Agreement and those added at a later time, shall be subject to the terms and conditions of this Agreement.

   b) **Analysis.** Data Recipient agrees that it will restrict its use of any Data Set to the Analysis described in the Research Plan for which the Data Sets were requested. Data Recipient may share Data Sets and/or access to Data Sets with third parties who perform services on behalf of Data Recipient in its performance of the Research Plan, but only if (i) such third parties are named in the Research Plan, and (ii) Data Recipient first enters an agreement with such third parties binding the third parties to restrictions on the use of the Data Sets that are no less stringent than those placed on Data Recipient's use of the Data Sets herein.

2. **Conditions on Use of the Data**

   a) **Regulatory Approvals; Compliance with Laws.** Data Recipient shall obtain any regulatory or ethical approvals required by law or institutional policy before beginning the Analysis, including but not limited to institutional review board or research ethics committee approval. The parties shall comply with all applicable state/provincial, and local laws, regulations, codes and guidelines, including those regarding the handling, analyzing and reporting of analyses of data.

b) **Data Privacy.** Data Recipient acknowledges the importance of the data privacy of individuals to whom the Data Sets may relate and commits to comply with all applicable national, state/provincial, and local laws and regulations regarding (i) patient/research subject privacy, (ii) the collection, storage, processing, disclosure and use of personally identifiable information, and (iii) other uses and disclosures of the types of data contained in the Data Sets. Data Recipient shall not share with any third party any username, password, or other account details that Data Recipient uses to access the Data Sets on Data Provider's systems. Data Recipient shall employ and maintain reasonable technical and administrative measures to prevent unauthorized or unlawful access or use of any Data Sets or the accidental loss, destruction of, or damage to the Data Sets. In addition, Data Recipient shall not remove, bypass, circumvent, neutralize or modify any technological protection measures employed by Data Provider that are intended to protect the Data Sets. Data Provider shall notify the Data Recipient if any of the Data Sets include any "personal data," as defined in Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 (the "General Data Protection Regulation" or "GDPR"), that has been collected from persons located in the European Economic Area ("EEA Personal Data"). In the event that one or more shared Data Sets includes EEA Personal Data, the parties agree that each shall be a separate controller of such EEA Personal Data, and not joint controllers of the EEA Personal Data, under GDPR. Data Recipient hereby represents and warrants to Data Provider that Data Recipient will establish lawful bases for processing such personal data and special categories of personal data under the GDPR and otherwise comply with all requirements of the GDPR with respect to the data. Data Provider hereby represents and warrants to Data Recipient that it has obtained lawfully any such personal data and special categories of personal data and established a lawful basis for the processing of such personal data and special categories of personal data under the GDPR.

Basis for Transfer of Personal Data from the EEA (if Applicable, Choose One, Which Both Parties Should Initial)	
Option	**Initials of Both Parties' Representatitive (if Option Chosen)**
Data Provider represents and warrants that it has obtained the explicit consent of the data subjects for the transfer of their EEA Personal Data to Data Recipient.	
The parties shall enter into the standard contractual clauses attached hereto as Exhibit B concurrently with the execution of this Data Use Agreement to legitimize the transfer of EEA Personal Data from Data Provider's jurisdiction to Data Recipient's jurisdiction.	
The parties agree that the transfer of EEA Personal Data fro Data Provider's jurisdiction to Data Recipient's jurisdiction shall be legitimized through the use of the following mechanism: **[Insert Mechanism]**	

c) **Re-identification.** Data Recipient agrees not to attempt intentionally to identify any individuals who are subjects of the data contained in any Data Set or others who could be identified from the Data Sets (including but not limited to clinical research staff and relatives of participants). Data Recipient further agrees not to combine the Data Sets with other sources of data in a manner intended to lead to the identification of any individual.

d) **No Guarantee of Accuracy.** Data Provider provides the Data Set "as is" and makes no guarantee that any Data Set is accurate or complete. Data Recipient shall bear full responsibility and risk as to the accuracy, completeness, usefulness, performance and results derived from any Analysis performed using the Data Sets.

3. **Publication**

a) **Analysis Availability.** Data Recipient agrees to make the results of the Analysis (the "Analysis Results") available to Data Provider within one (1) year of completing the Analysis. Data Provider may make the Analysis Results publicly available, but only if the Data Recipient has informed Data Provider that it does not intend to pursue publication of the Analysis. If the Analysis has not been completed within one year (i) Data Recipient shall provide Data Provider with an explanation of why analysis completion was not possible, and (ii) Data Provider may, at its sole discretion, require that the Data Recipient provide Data Provider with updates on the progress of the analysis at six month intervals until the research has been completed. If Data Recipient fails to comply with the requirements of section 3(a) of this Agreement without good cause, Data Recipient shall not be eligible to receive any further Data Sets from Data Provider until Data Recipient remedies such non-compliance to the satisfaction of Data Provider.

b) **Publication of Analysis Results.** Data Recipient shall make the Analysis Results publicly available in printed form, on the internet, or in a presentation in a learned forum, and Data Recipient shall use reasonable efforts to obtain public disclosure of the Analysis Results in a peer-reviewed journal. These public disclosures of the Analysis Results shall be referred to as a "Publication." Data Recipient shall submit to Data Provider a copy of any Publication at least 30 days prior to submission of the Publication to a learned forum or journal, or if the Publication takes place other than through submission to a learned forum or journal, at least 30 days prior to public disclosure. Data Provider shall make comments on the Publication regarding the scientific accuracy of the Publication, review for patentable subject matter, and request deletion of confidential information (including, without limitation, patient-level data, research specifications or clinical trial/study protocols, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of Data Provider that is provided to or otherwise made available to Data Recipient in connection with this Agreement ("Contributor Confidential Information"). Data Recipient shall be under no obligation to implement any comments on the Publication received from Data Provider provided that Data Recipient shall not include any information that is Contributor Confidential Information for which Data Provider has requested deletion. Additionally, Data Recipient shall provide Data Provider with a reference citation upon publication which Data Provider shall share with the applicable Data Provider(s).

Data Recipient further consents that the title of the Research Proposal, name of the Lead Researcher, affiliation, funding source, potential conflicts of interest, summary of the proposed Research, and requested studies (all as provided by the Researcher in the Data Request) may be made publicly available by Data Provider after the Data Use Agreement is executed.

c) **Acknowledgment.** Data Recipient agrees to include the following acknowledgment in any publication or presentation of the Analysis Results: "This publication or presentation, as applicable is based on research using data from **[Data Provider]**. **[Data Provider]** has not contributed to or approved, and is not in any way responsible for, the contents of this publication."

4. Intellectual Property

a) **New Intellectual Property.** For the purposes of this Agreement, "New Intellectual Property" shall mean all data, discoveries, developments, inventions (whether patentable or not), improvements, methods of use or delivery, processes, know-how, or trade secrets which are generated, conceived, reduced to practice or otherwise made by or on behalf of Data Recipient as a result of the conduct of the Research Plan or as a result of the use of any Data Set provided to Data Recipient under this Agreement.

b) **Data Provider Uses.** For the purposes of this Agreement, "Data Provider Uses" shall mean any and all uses of, or related to, Data Provider's Data Set or any and all making, use, sale or importation of a compound which is owned or controlled by Data Provider, including any compound(s) used to generate the Data Set, which would otherwise be an infringement of New Intellectual Property.

c) **License to New Intellectual Property.** All New Intellectual Property shall be the sole property of Data Recipient; however, Data Recipient shall notify Data Provider of any New Intellectual Property.

[Data Recipient agrees to grant, and hereby does grant, to Data Provider a perpetual, non-exclusive, fully-paid up, royalty-free, irrevocable, worldwide, unrestricted license under any New Intellectual Property for Data Provider Uses, with the right to sublicense through multiple tiers.]

d) **Written Agreements from Researchers.** Data Recipient agrees to obtain written agreements with all of its researchers who utilize the Data Set which grant a present assignment, without additional consideration, of all rights, title and interests in New Intellectual Property to Data Recipient for subsequent licensing to Data Provider.

e) **Data Provider Obligations Regarding New Intellectual Property.** Data Recipient agrees that Data Provider(s) shall have no further obligations resulting from the assignment and/or exploitation of any New Intellectual Property.

5. Independent Contractor

The relationship of the parties is that of independent contractors. Neither party is the partner, joint venturer, or agent of the other and neither party has authority to make any statement, representation, commitment, or action of any kind that purports to bind the other without the other's prior written authorization.

6. Representations, Warranties and Covenants

a) **No Contrary Agreement.** Data Recipient represents and warrants that it does not have, and agrees that it will not enter into, any legal or contractual obligations that would prevent it from complying with its obligations under this Agreement, including without limitation, the obligations of Section 3.

b) **Authority to Enter Agreement.** Each party represents and warrants that it has the full right, power, and authority to enter into this Agreement. Each party represents and warrants that it does not have, and agrees that it will not enter into, any legal or contractual obligations that would prevent it from complying with its obligations under this Agreement.

c) **Authority to Bind.** Data Recipient represents and warrants that it has the authority to bind to the terms of this Agreement any individual proposed by Data Recipient to have access to the Data Sets and any third party provided access to the data under Section 1(b) above, and that use of the Data Sets by any such individuals shall be subject to the terms of this Agreement.

7. **Term and Termination**

a) **Term.** The term of this Agreement shall commence on the Effective Date and terminate upon the earlier of (i) that date which is three years from the Effective Date, or (ii) the termination of this Agreement in accordance with 7(b) or 7(c).

b) **Data Provider Termination.** Data Provider may terminate this Agreement immediately upon the breach by Data Recipient of any of the material terms of this Agreement or use of the Data Sets in violation of any applicable law.

c) **Termination.** Either party may terminate this Agreement by providing sixty (60) days' written notice to the other party.

d) **Effect of Termination.** Upon termination of this Agreement, Data Recipient shall promptly return or destroy (at Data Provider's sole election) all Data Sets and any copies thereof provided by Data Provider hereunder.

e) **Survival.** The obligations of Sections 3-6 of this Agreement shall survive termination of this Agreement.

8. **Entire Agreement**

This Agreement and the exhibits hereto represent the entire and integrated agreement between the parties and supersedes all prior negotiations, representations or agreements, either written or oral, regarding its subject matter.

9. **Signature**

This Agreement may be executed by a party's signature transmitted by facsimile or electronic portable document format (.pdf), and copies of this Agreement so executed and delivered shall have the same force and effect as originals.

10. **Counterparts**

This Agreement may be executed in one or more counterparts, all of which shall be considered one and the same.

11. **Notice**

All notices provided hereunder shall be made in writing to the addresses set forth below via next-day delivery service:

If to Data Provider: [Insert Provider Address]

If to Data Recipient: [Insert Recipient Address]

* * *

Signature Page Follows

* * *

IN WITNESS WHEREOF, the parties hereto execute this Agreement as of the Effective Date.

Data Provider

Data Provider Name

By

Name

Title

Date

Data Recipient

Data Provider Name

By

Name

Title

Date

Read & Acknowledged by Investigator

Name

Title

Date

EXHIBIT A
Research Plan

EXHIBIT B
Standard Contractual Clauses