ADDI
Alzheimer's Disease
Data Initiative

ADDITIONAL CONSENT REQUEST TEMPLATE

INSTRUCTIONS:

This template Additional Consent Request is intended to be attached to a consent form from a primary study to enable the data collected in the primary study to be shared and used for additional future research on Alzheimer's Disease and related dementias.

UPDATED MARCH 2020

Throughout, the fillable fields should be revised as appropriate to turn this template into an Additional Consent Request tailored for the study and the desired future uses of the data.

[Magenta, Bold, bracketed text] shows fields on the additional consent form that will generally need to be customized to the particular study, On the signature page, the term **"legally acceptable representative"** should be replaced with any alternate term required to be used under the laws of the jurisdiction in which the Additional Consent is obtained. Once edited, the **[brackets and bold]** formatting should be removed and the text color changed to black.

NOTE:

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

ADDITIONAL CONSENT REQUEST

The **[Sponsor/Institution]** would like your permission to use and share some or all of your data collected in the **[insert study name]** (the "Main Study") for additional research with researchers, institutions or companies (collectively, "Researchers") who are conducting research on Alzheimer's Disease and related dementias. This additional use of your data is called "Additional Research."

If you decide to participate in this Additional Research, you do not have to provide any additional data. Researchers will use data that already have been collected during the Main Study, **[which may include information from your medical record and new information about you generated during the Main Study, including the results or findings from study-related tests and study-specific procedures, including genetic tests and tests of your mental health status].**

There is no penalty or change to your regular medical care or participation in the study if you decide not to take part in this Additional Research.

1. What is the purpose of this Additional Research?

The aim of the Additional Research is to use the data collected in this study to increase our understanding of Alzheimer's Disease and related dementias and to advance science, which may include the development of other medicines or treatments. The Additional Research may use and bring together data from around the world so that Researchers can better understand Alzheimer's Disease and related dementias.

The Additional Research might include exploratory research of Alzheimer's Disease and related dementias. At this time, it is not possible to know all specific research projects that may be undertaken as part of the Additional Research.

2. What are the possible benefits of this Additional Research?

This Additional Research will not have any direct benefit to you. However, information learned from the Additional Research may help other people in the future who have Alzheimer's Disease, as well as other diseases and conditions, and may help in the development of new medicines or treatments.

3. What are the possible risks of this Additional Research?

No additional procedures are performed for the Additional Research, and thus the main risks of the Additional Research include a loss of privacy and confidentiality. Researchers accessing your data will put measures in place to minimize the possibility that results from this Additional Research could be linked to you, such as replacing your name and other directly identifying information with a unique code, as described in more detail below under the heading "What will happen to my personal information?" However, there is a possibility that information from your participation in the Additional Research may be accessed by unauthorized persons not participating in the Additional Research, which could lead to a loss of your privacy and a loss of the confidentiality of your information.

4. What if I agree to this Additional Research and then change my mind?

You can change your mind at any time about allowing your data to be used for this Additional Research. Tell **[Study Doctor's Name]** if you would like to end your participation in the Additional Research. Your decision will not affect your regular medical care or any benefits to which you are entitled.

If you end your participation in the Additional Research, no new information about you will be shared with Researchers who wish to conduct Additional Research. However, information that has been shared prior to your withdrawal will continue to be used and shared for research purposes as described in this form.

5. What will I have to pay for if I take part in this Additional Research?

There will be no charge to you for allowing your data to be used for this Additional Research.

6. Will I be paid if I consent to this Additional Research?

You will not be paid for taking part in this Additional Research. Researchers may use information from this Additional Research to develop products or processes, from which they or others could make a profit. There are no plans to pay you or provide you with any products developed from this Additional Research. The Researchers engaged in the Additional Research will own or have rights to all products or processes that are developed using your information for the Additional Research.

7. What will happen to my personal information?

The study will gather information about you as part of your participation in the research study. The information that gathered may include personal information, such as your name, address, and birth date; information from your medical record; and new information about you, such as the results or findings from study-related tests and study-specific procedures.

To advance science, medicine, and public health, the **[Sponsor/Institution]** will share information about you from this research study with Researchers engaged in Additional Research, but only after personal information that may identify you has been removed. Your name, address, and medical record number, as well as other data that could identify you will be removed. The data that lack these identifiers are known as “Your Coded Data.” The remaining information can be combined with other people’s data to help Researchers’ understanding of Alzheimer’s Disease and other diseases, how to best diagnose and treat diseases, and how to develop new medicines or medical devices.

Your Coded Data may be transferred to other countries than your own, including the United States. If you are located in the European Economic Area (“EEA”), it is important that you know that the United States and other countries to which your data may be transferred have not been found by the European Commission to offer the same degree of protection of personal information as those of the European Union. Your Information could be subject to disclosure to government agencies and law enforcement under the laws of another country, such as the United States. Researchers engaged in the Additional Research will take the steps outlined in this form to protect your information. By signing the consent form to participate in this Additional Research, you agree to the transfer of your personal information outside of the EEA.

8. Where can I find additional information about this Additional Research or the results of this Additional Research?

It may not be possible to link the results of the Additional Research to individuals, including you. Researchers engaged in Additional Research do not plan to give any information generated during the Additional Research to you, the **[Study Doctor]**, your personal doctor (if your personal doctor is different from the study doctor), your family, your employer or any insurance company.

The study team will answer your questions or concerns regarding the Additional Research. The consent document for the study provides contact information if you need to reach the study team or wish to speak with someone not involved with the Additional Research.

* * *

If you agree to participate in the Additional Research, please sign below.

* * *

PARTICIPANT OR **[LEGALLY ACEPTABLE REPRESENTATIVE]**

Printed Name of Participant

Signature of Participant or **[Legally Acceptable Representative]**

Date of Signature

Printed Name of **[Legally Acceptable Representative]**

Relationship