ADDI
Alzheimer's Disease
Data Initiative

DATA SHARING MODEL EDITS TO AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

INSTRUCTIONS:

U.S. informed consent forms generally include a HIPAA authorization either as part of the consent form itself or as a separate document accompanying the consent form. To enable sharing and using data for future research on Alzheimer's Disease and related dementias under an additional consent request, it is necessary to align the HIPAA authorization contained in the consent form for the primary study with the desired future research purposes.

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

UPDATED MARCH 2020

The following Data Sharing Model Edits demonstrate how the standard HIPAA authorization section contained within a consent form or presented to study subjects as a separate form can be revised to ensure that it is consistent with sharing and using data for future research on Alzheimer's Disease and related dementias.**This document demonstrates model edits to the HIPAA authorization used in the primary study. This document is not intended to be a separate, stand-alone form. Each authorization will need to be evaluated to determine appropriate edits.**

[Magenta, Bold, bracketed text] shows fields on the HIPAA authorization for the primary study that will generally need to be customized to the particular study, and to which changes are not typically needed to permit onward data sharing. Once edited, the **[brackets and bold]** formatting should be removed and the text color changed to black.

Purple, Bold italics designate language that should be included in the HIPAA authorization used in the primary study. When inserted to the HIPAA authorization for the primary study, the ***bold italic*** formatting should be removed and the text color changed to black.

Authorization to Use and Disclose Information for Research Purposes

By signing this authorization, I, the undersigned individual, authorize and direct my health care provider, **[Name of Health Care Provider]**, to use and disclose my protected health information, as defined under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the federal regulations issued thereunder, as described in more detail below.

1. I authorize disclosure of the following specific information:
   - **[e.g. Past, present, and future medical records]**
   - **[e.g. Biological samples]**
   - **[e.g. Research records]**

2. I authorize disclosure of the above-described information to **[Sponsor and companies working with or for the sponsor, contractors working with the sponsor, the institutional review board/research ethics committee, and regulatory authorities]** for use in the study entitled "**[Title of study]**" (the "Study").

3. *If I agree to participate in the additional research described in the Additional Consent Request, I authorize disclosure of the above-described information to the researchers, institutions and companies researching Alzheimer's Disease and related dementias, as described more fully in the informed consent form and additional consent request that I signed upon enrolling in the study.*

4. I understand that once my information has been disclosed, it may no longer be protected by HIPAA and may be subject to re-disclosure.

5. I understand that I may withdraw or take away this authorization at any time, and I can do so by contacting the health care provider named above. I further understand that if I withdraw my authorization, my health care provider will no longer be able to disclose my protected health information for use in the Study, but that information that has already been disclosed will be retained for use in the research as described in the informed consent form that I signed upon entering the Study.

6. I understand that I have the right not to sign this authorization and that my refusal to sign this authorization will not affect
   the health care I receive from my health care provider or the payment for such care.

7. I understand that this authorization expires 100 years after the date on which it is signed and that I have a right to receive a copy of this authorization.

SIGNATURE OF RESEARCH SUBJECT

By signing this authorization, I direct the above-named health care provider to release the protected health information described above to the persons and groups listed above, and I willingly agree to permit my protected health information to be obtained, used and disclosed as described above.

_____

Subject Name (printed)

_____

Signature of Subject

_____

Date