

## ADNI Data Use Agreement (DUA):

I request access to data collected by the Alzheimer's Disease Neuroimaging Initiative (ADNI) for the purpose of scientific investigation, teaching, or the planning of clinical research studies.

### **I agree to the following terms:**

1. I will receive access to de-identified data and will not attempt to establish the identity of, or attempt to contact any of the ADNI participants.
2. I will not attempt to make direct contact with ADNI PIs or staff at sites concerning the specific results of individual subjects.
3. I will not further disclose these data beyond the uses outlined in this agreement and my data use application. **I understand that redistribution of individual participant-level data in any manner is prohibited.** Reports and publication of summary (not participant-level) data are allowed.
4. I will not utilize AI tools, especially (but not exclusively) those with public-facing interfaces that do not offer guarantees regarding the containment of data inputs for ADNI data, recognizing that the use of AI tools, including generative and analytical models, poses a **potential risk of inadvertent data sharing** due to the nature of how these tools process information and may lead to data being sent, saved, viewed, or used in unforeseen ways by parties not covered by the DUA, which is a direct violation of this agreement. See Appendix A for additional AI tool concerns, restrictions, and guidance.
5. I will not disclose any participant-level raw or derived datasets beyond the uses outlined in this agreement. Derived datasets containing participant-level data that I create and that I anticipate will benefit the scientific community, will be submitted to the ADNI study PI (Dr. Michael Weiner) using the format described in *Derived Data Submission Form* (available in the ADNI repository). The study PI will determine whether my data may be distributed through the ADNI-LONI and/or other NIA-designated data repository. I understand derived datasets should only be shared through the ADNI-LONI and/or other NIA-designated data repository.
6. I will require anyone on my team (i.e. in my lab or company) who utilizes these data to comply with this Data Use Agreement. I understand that I am not allowed to distribute ADNI data outside of my team, only the ADNI study website operated by LONI-IDA can distribute data.
7. I will accurately provide the requested information for persons who will use these data and the analyses that are planned using these data.
8. I will respond promptly and accurately to annual requests to update information about my use of ADNI data.
9. I will comply with any rules and regulations imposed by my institution and its institutional review board in requesting these data.

### **If I publish abstracts using data from ADNI, I agree to the following:**

1. I will cite ADNI as the source of data and the ADNI funding sources in the abstract as space allows.
2. For abstracts, you are *not* required to cite ADNI in the authorship line.

### **If I publish manuscripts using data from ADNI, I agree to the following:**

1. On the by-line of the manuscript, after the named authors, I will include ADNI as an author by using the phrase "for the Alzheimer's Disease Neuroimaging Initiative\*" with the asterisk referring to the following statement and list of names:

\*Data used in preparation of this article were obtained from the Alzheimer's Disease Neuroimaging Initiative (ADNI) database (adni.loni.usc.edu). As such, the investigators

within the ADNI contributed to the design and implementation of ADNI and/or provided data but did not participate in the analysis or writing of this report. A complete listing of ADNI investigators can be found

at: [http://adni.loni.usc.edu/wp-content/uploads/how\\_to\\_apply/ADNI\\_Acknowledgement\\_List.pdf](http://adni.loni.usc.edu/wp-content/uploads/how_to_apply/ADNI_Acknowledgement_List.pdf)

[*Note:* For manuscripts that use metabolomics data generated by the Alzheimer's Disease Metabolomics Consortium (ADMC) in the by-line of the manuscript, after the named authors, I will include the phrase "for the Alzheimer's Disease Metabolomics Consortium\*\*" with the double asterisk referring to the following statement and list of names:

**\*\*Data used in preparation of this article were generated by the Alzheimer's Disease Metabolomics Consortium (ADMC). As such, the investigators within the ADCM provided data but did not participate in the analysis or writing of this report. A complete listing of ADCM investigators can be found at: <https://sites.duke.edu/adnimetab/team/>**

2. I will include language similar to the following in the Methods section of my manuscripts in order to accurately acknowledge data gathering by the ADNI personnel. Depending upon the length and focus of the article, it may be appropriate to include more or less than the example below. However, inclusion of some variation of the language shown below is mandatory.

*Data used in the preparation of this article were obtained from the Alzheimer's Disease Neuroimaging Initiative (ADNI) database ([adni.loni.usc.edu](http://adni.loni.usc.edu)). The ADNI was launched in 2003 as a public-private partnership, led by Principal Investigator Michael W. Weiner, MD. The original goal of ADNI was to test whether serial magnetic resonance imaging (MRI), positron emission tomography (PET), other biological markers, and clinical and neuropsychological assessment can be combined to measure the progression of mild cognitive impairment (MCI) and early Alzheimer's disease (AD). The current goals include validating biomarkers for clinical trials, improving the generalizability of ADNI data by increasing diversity in the participant cohort, and to provide data concerning the diagnosis and progression of Alzheimer's disease to the scientific community. For up-to-date information, see [adni.loni.usc.edu](http://adni.loni.usc.edu).*

3. I will acknowledge funding by the ADNI in the support acknowledgement section of the manuscript using language similar to the following:

*Data collection and sharing for the Alzheimer's Disease Neuroimaging Initiative (ADNI) is funded by the National Institute on Aging (National Institutes of Health Grant U19AG024904). The grantee organization is the Northern California Institute for Research and Education. In the past, ADNI has also received funding from the National Institute of Biomedical Imaging and Bioengineering, the Canadian Institutes of Health Research, and private sector contributions through the Foundation for the National Institutes of Health (FNIH) including generous contributions from the following: AbbVie, Alzheimer's Association; Alzheimer's Drug Discovery Foundation; Araclon Biotech; BioClinica, Inc.; Biogen; Bristol-Myers Squibb Company; CereSpir, Inc.; Cogstate; Eisai Inc.; Elan Pharmaceuticals, Inc.; Eli Lilly and Company; EuroImmun; F. Hoffmann-La Roche Ltd and its affiliated company Genentech, Inc.; Fujirebio; GE Healthcare; IXICO Ltd.; Janssen Alzheimer Immunotherapy Research & Development, LLC.; Johnson & Johnson Pharmaceutical Research & Development, LLC.; Lumosity; Lundbeck; Merck & Co., Inc.; Meso Scale Diagnostics, LLC.; NeuroRx Research; Neurotrack Technologies; Novartis Pharmaceuticals Corporation; Pfizer Inc.; Piramal Imaging; Servier; Takeda Pharmaceutical Company; and Transition Therapeutics.*

[*Note:* For manuscripts that use metabolomics data generated by the Alzheimer's Disease Metabolomics Consortium (ADMC) I will include the following language:

*Data collection and sharing for this project was funded by the Alzheimer's Disease Metabolomics Consortium (National Institute on Aging R01AG046171, RF1AG051550 and 3U01AG024904-09S4).*

[Note: For manuscripts that use ADNI whole genome sequencing data generated by the ADSP, I will include the following language: *Data generation and sharing for this project was funded, in part, by the Alzheimer's Disease Sequencing Project.* For details on how to acknowledge ADSP Data Sets including ADNI see:

<https://dss.niagads.org/datasets/ng00067/#dataset-acknowledgement> ]

[Note: For manuscripts that use multiomics data generated by CLEAR-AD, I will include the following language: *Data generation and sharing for this project was funded, in part, by "Centrally-linked longitudinal peripheral biomarkers of AD in multi-ethnic populations" (National Institute on Aging U19 AG074879).* See CLEAR-AD.org for further details. ]

4. I will submit all manuscripts to the ADNI Data and Publications Committee (DPC) **prior** to submitting them to a journal. This review will not be a scientific review, but it is intended to ensure that the items above are correctly implemented. The DPC will maintain confidentiality of the manuscript and will complete its review within 2 weeks. The DPC can be reached by logging into your LONI-IDA account: 1) click "My Account" in the upper right corner 2) click the "Update" button in the Project line for ADNI; 3) On the ADNI User Account Update page, select "Publication Update" tab; 4) Enter and upload your publication information; 5) Email your manuscript to the DPC at: [EDRAKE@BWH.HARVARD.EDU](mailto:EDRAKE@BWH.HARVARD.EDU).

*Note:* in the event that a journal requires a Conflict of Interest form because ADNI is listed on the author line of the manuscript, the DPC will provide one on request.

5. I will ensure that Investigators who utilize ADNI data use appropriate administrative, physical, and technical safeguards to prevent the use or disclosure of the data other than as provided for by this Agreement.
6. I will report any use or disclosure of the data not provided for by this Agreement of which I become aware within 15 days of becoming aware of such use or disclosure.

*IMPORTANT NOTE: It is the policy of the Alzheimer's Disease Neuroimaging Initiative to make analyzed data available to investigators as quickly as possible. However, data analysis for this project is expected to take years as methods for analysis of these datasets evolve. Therefore, I understand that any processed data that I download might be preliminary and that results may change as new methods of analysis are implemented. I will familiarize myself with the analysis methods so that I am aware of the limitations of these data prior to using them for scientific purposes.*

*Finally, because "preliminary data" will be posted on the database, in the event that I download data from the ADNI database for the purposes of analysis and future presentation/publication in the form of abstracts and/or manuscripts, I will note the version (download date) of the data I download and provide this information in any Methods section (if publishing), and I will check the database to determine if updated data has been provided prior to submission of any material for publication.*

ADNI maintains the right to modify terms of this agreement and may do so by posting notice of such modifications on this page: <https://adni.loni.usc.edu/news-publications/> . Any modification made is effective immediately upon posting the modification (unless otherwise stated). You should visit this page periodically to review the current use agreement terms.

## APPENDIX A ADNI DUA: Use and Requirements of AI tools

**Prohibited use of AI Tools:** This ADNI Data Use Agreement explicitly prohibits any individual who has obtained ADNI data from sharing raw data, specifically participant-specific data, with any other individual or entity, in any forum, in any medium. For a variety of reasons, including the important need to protect the privacy of research participants, all data must be directly released to requesting individuals from our ADNI LONI website.

The use of AI tools, including generative and analytical models, pose a **genuine risk of inadvertent data sharing** due to the nature of how AI tools process, store, and regenerate information. AI tools, including but not limited to those with public-facing interfaces, such as OpenAI's ChatGPT, usually do not offer guarantees regarding the containment of data inputs. Any data input into a prompt or output generated from a prompt could result with proprietary data infringed, sent, saved, viewed, misinterpreted, or used in unforeseen public ways. **As a result, the use of such AI tools which may release ADNI participant level data to others, is in direct violation of ADNI Data Use Agreement policies.**

However, an important exception to the above stated prohibition would be AI tools, including generative and analytical models, which **explicitly prevent sharing data** with others. Such AI tools may be developed and internally trained by individual research groups or academic institutions, and strictly used for the individual research group or academic institution provided that "sharing" data beyond the tool is strictly prohibited. Therefore, ADNI data may be analyzed using AI tools which provide guarantees that all data is safeguarded, contained, and will not be released to others.

Note that this amendment does not impose any new restrictions on the use of ADNI data, but is intended for clarification on item #3 in the DUA (above): "I will not further disclose these data beyond the uses outlined in this agreement and my data use application and understand that redistribution of data in any manner is prohibited."

As of the writing of this Appendix the term "Artificial Intelligence" or "AI" means a broad range of technologies and tools that can generate and regenerate content in various mediums including text, images, videos, and audio, based on the content or data input to generate output in any medium response. The recent commercialization of these AI tools represents a significant challenge in maintaining the privacy of participants in the ADNI study, and of participants in human subjects' research in general. Uploading ADNI data to a third-party platform that is not explicitly in compliance with the prohibition and restrictions on redistribution of ADNI data set forth herein is a clear violation of this Agreement.

ADNI requires investigators to adhere to the following terms when deciding whether a project utilizing these tools is in compliance with the terms of this Agreement:

- Computational resources
  - The application of any statistical or other analytic methods to ADNI data - whether branded as 'AI' and "AI Tool" or otherwise - should not be performed using computational or AI resources owned by third parties who engage in the long-term retention of user content that is either shared with other parties or used in the training of public-facing models, such activity could include the contents of the ADNI data set. This includes the use of third-party platforms for inference (e.g. the inclusion of ADNI data as part of an input or 'prompt' for a generative language model), training (including both the training of foundations model and the fine-tuning of pre-trained models via transfer learning or some other process),

prediction, or any other task that could result in ADNI data being retained, shared, regenerated or otherwise by entities that are not in compliance with the DUA.

- Some commercial entities may offer an 'opt-out' clause in the terms of use for their models, allowing users to decline the right of the entity to retain the data for training and other purposes. This does not constitute sufficient protection, and under no circumstances should this be viewed as an acceptable safeguard for sharing ADNI data with these third parties.
- Investigators making use of remote computational resources such as Microsoft Azure, Google Cloud, Amazon Web Services, Runpod, or other computational services for the purposes of training AI models must take care to review the terms of use for the service to ensure that their workflow is secure.
- Public release of models trained using ADNI data
  - The use of ADNI data in training models is both permitted and encouraged, provided that the process is carried out in compliance with the DUA as outlined above. However, investigators who intend on making the weights of a trained model publicly available should consider whether the model could be used to easily reconstruct parts of the ADNI data set. ADNI prohibits release of participant level data, even if it is sufficiently processed or altered and lack ADNI subject codes. See Term (3) above “**I understand that redistribution of individual participant-level data in any manner is prohibited**”. All participant level data generated by ADNI can only be released by the LONI-IDA website. Individual investigators who have generated participant level data based on ADNI data can request for their data to be shared by contacting Dr. Weiner at michael.weiner@ucsf.edu
  - This precaution is particularly important in the case of large language models and other highly overparameterized generative models. Numerous studies have demonstrated that it is possible to extract training examples from these large and complex models, and investigators should keep this fact in mind.

**I understand that failure to abide by these guidelines will result in the termination of my privileges to access ADNI data. Furthermore, ADNI reserves the right to pursue damages for actions which violate ADNI guidelines.**