



Answer ALS Foundation

## Data Use Agreement

I request access to data available through the Answer ALS Foundation Data Portal, also known as Neuromine, for scientific investigation, teaching, or the planning of clinical research studies and agree to the following terms:

1. I acknowledge and agree that this ANSWER ALS Data Use Agreement (“Agreement”) grants me permission, as set forth below, to use the ANSWER ALS Data Portal and the data contained within and describes my obligations concerning the ANSWER ALS Data Portal.
2. I will have access to a limited data set as described in attachment A. I will maintain the ANSWER ALS Data and will not attempt to re-identify the data in any way or establish the identity of any of the subjects who are or may be the sources of the ANSWER ALS Data. If I am in possession of any data that can be used, either alone or in combination with any other information, to re-identify any subjects, I will immediately notify the ANSWER ALS Data Approval Committee ([DAC](mailto:data@answerals.org)) [data@answerals.org](mailto:data@answerals.org). Such notification must occur within 24 business hours.
3. I will not attempt to directly contact the cohort Principal Investigators (PIs) or staff associated with the studies that are part of the ANSWER ALS program, the data from which are added to the ANSWER ALS Data Portal, concerning additional information regarding individual subjects, provided that, for clarity, contacts that are not specifically related to individual subjects are permitted.
4. Approved Users who may have access to personal identifying information for research participants in the original study at their institution or through their collaborators may be required to have IRB approval. By approving and submitting the associated Data Access Request, the Institutional Signing Official provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including IRB approval if required. The Institutional Signing Official also assures through the approval of the Data Access Request that other organizations within the institution with relevant authorities have reviewed the relevant sections of the AALS Data Sharing Policy and the associated procedures and are in agreement with the principles defined.
5. It is anticipated that, at least in some cases, these datasets will be updated with additional information. Unless otherwise indicated, all statements herein are presumed to be true and applicable to the access and use of all versions of these datasets.
6. I will use the ANSWER ALS Data Portal solely to access and analyze the ANSWER ALS Data in accordance with this Agreement.

7. I will not disclose or use ANSWER ALS Data beyond the permitted disclosures and uses outlined in this Agreement. I will not sell, rent, lease, loan, or license the ANSWER ALS Data to any third party.

8. I will require anyone with whom I will share relevant ANSWER ALS Data, including others on my team and within my institution, to comply with this Agreement by having them become an approved data and register user of the ANSWER ALS Data Portal and agreeing to these terms through signature on or acceptance of this Agreement, as applicable, prior to my sharing of the data. The Requester and Approved Users agree to retain control over the data and further agree not to distribute data obtained through this Data Access Request to any entity or individual not covered in the submitted Data Access Request.

9. I may disclose ANSWER ALS Data only to individuals who are registered users of the ANSWER ALS Data Portal and have the appropriate data access approval for the data I am sharing. I will respond promptly and accurately to annual requests by the ANSWER ALS DAC to update my application information.

10. I agree that if access is approved, I, the Principal Investigator and the designated individuals named in the Data Access Request (DAR) shall become Approved Users of the requested dataset(s). Research use will occur solely in connection with the research project described in the DAR, which includes a description of the research objectives and design. New uses of these data outside those described in the DAR will require submission of a new DAR; modifications to the research project will require submission of an amendment to this application.

11. I will respond promptly and accurately to any request by the Answer ALS DAC to update my request information.

12. Should I choose to download any Answer ALS Data, my host institution accepts responsibility for the security of the downloaded data through the institutional signature on this Agreement for as long as the downloaded data is in existence.

13. I will retain control over the ANSWER ALS Data and will use appropriate administrative, physical, and technical security safeguards to prevent the use or disclosure of the ANSWER ALS Data other than as provided for by this Agreement.

14. Approved Users agree that if they change institutions during the access period, they will submit a new Data Access Request in which the new institution agrees to the AALS data use policy before data access resumes. Any versions of data stored at the prior institution for the approved use will be destroyed and documented through a final Data Use Report as described below. However, if advance written notice and approval by the AALS Data Access Committee is obtained to transfer responsibility for the approved research project to another Approved User within the same institution, the data may not need to be destroyed.

15. I will immediately report any inadvertent data release, including breach of data security or other data management incidents, to ANSWER ALS DAC. Such reports must occur within 24 business hours.

16. I will contact ANSWER ALS DAC without undue delay if I suspect that ANSWER ALS Data are improperly shared on the ANSWER ALS Data Portal or if I suspect unauthorized use of ANSWER ALS Data. Such contact shall occur within 24 business hours.

17. I will comply with any rules imposed by my institution and its institutional review board, as well as any federal, state, and local laws and regulations, in each case, that apply to my use of ANSWER ALS Data, provided such institutional rules do not conflict with the obligations owed by me under this Agreement. In the presence of such an unresolved conflict, I will cease to use the ANSWER ALS Data until a suitable resolution is identified and implemented and the obligations of this Agreement continue to prevail without hindrance.

18. I acknowledge that the ANSWER ALS program the intellectual property (IP) policies and agree as follows:

By requesting access to AALS dataset(s), the Requester and Approved Users acknowledge the intent of the AALS Program that anyone authorized for research access through the attached Data Access Request follows the intellectual property principles within the AALS Policy for Data Sharing as summarized below:

Achieving maximum benefit is the ultimate goal of data distribution through the Answer ALS data repositories. The AALS Program believes that these data should be considered as pre- competitive, and requests Approved Users not to make IP claims derived directly from the Answer ALS dataset(s). However, the AALS Program also recognizes the importance of the subsequent development of IP on downstream discoveries, especially in therapeutics, which will be necessary to support full investment in products to benefit the public. The AALS Program requests that the Requestor and all Approved Users acknowledge that they will not claim IP on any of the datasets made available through the data portal, however, it does support IP development based on derivative discoveries made from these data.

It is expected that these AALS-provided data, and conclusions derived from the data, will remain freely available without requirement for licensing. The AALS Consortium encourages the broad use of Answer ALS datasets and a responsible approach to the management of intellectual property derived from downstream discoveries in a manner consistent with the NIH Best Practices.

19. I understand that other individuals or entities might share or upload their data to the Answer ALS Data Portal in the spirit of discovery. Therefore, I agree that I will not seek any right, title, or interest in the clinical data, analysis results, or any other intellectual property uploaded into the Answer ALS Data Portal that is owned by other individuals or entities without the expressed written consent of the individuals or entities that uploaded to the Answer ALS Data Portal or shared the data to the Answer ALS Program.

20. I agree, subject to Sections 18 and 19 above, that all data and discoveries generated by me from analyses of ANSWER ALS Data (collectively, the "Study Materials Results") may become and be deemed part of the public domain through the ANSWER ALS Data Portal.

21. By accessing the ANSWER ALS Data Portal, I waive any and all claims against the

ANSWER ALS program, the Answer ALS Foundation, the ANSWER ALS funding and research partners with respect to or arising from my use of the ANSWER ALS Data Portal or the ANSWER ALS Data. This data is considered for research purposes and should not be used directly to care for patients.

22. It is the policy of the ANSWER ALS program to make analyzed data available to investigators as quickly as possible. Data analysis for the ANSWER ALS program is expected to take years as methods for data analysis evolve. Therefore, I understand that any data and/or results that I access might be preliminary. Finally, because “preliminary data” will be posted on the database, in the event that I use or download ANSWER ALS Data for the purposes of analysis and future publication in the form of abstracts, manuscripts, or other publications, I will: (a) note in such abstracts, manuscripts, or other publications the defined version of the data used in my analysis and the date of download (ex. Answer ALS DOI Tool), (b) prior to my submission of any material for publication, check the ANSWER ALS Data Portal to determine if updated data is available, and (c) if the data is updated, note in such material for publication that the data has been updated in the ANSWER ALS Data Portal.

23. The Principal Investigator agrees that, if they become an Approved User, information about the PI and the approved research use, including the submitted research description (abstract) and citations to all resultant publications may be posted on a public website. The information may include the Approved User’s name and institution, project name, Research Use Statement, and a Non-technical Summary of the Research Use Statement. In addition, citations resulting from the use of AALS biological samples and datasets may be posted on other data repository websites.

24. If I seek to publish manuscripts incorporating ANSWER ALS Data or Study Materials Results, I agree to comply with the ANSWER ALS Publications Policy guidelines, listed in section 25, as applicable, including sharing manuscripts with the ANSWER ALS Publications Committee for administrative review prior to publication of a final manuscript. The administrative review is conducted to ensure compliance with this Agreement and does not constitute editorial control by the ANSWER ALS Publications Committee.

25. The general ANSWER ALS Publications Policy guidelines are as follows:

- You may not publish or claim the original data, however, you are free to do so with any derivatives or findings from the data.
- In your manuscripts and presentations incorporating ANSWER ALS Data or Study Materials Results, you agree to acknowledge the ANSWER ALS program, ANSWER ALS funders, and the relevant cohorts who provided data to the ANSWER ALS program by including language similar to the following:

ANSWER ALS Acknowledgement:

"Data used in the preparation of this article were obtained from the ANSWER ALS Data Portal (**AALS-01184**). For up-to-date information on the study, visit <https://dataportal.answerals.org>.

CITE ANSWER ALS DESCRIPTION PAPER

Baxi, E. G. *et al.* [Answer ALS, a large-scale resource for sporadic and familial ALS combining clinical and multi-omics data from induced pluripotent cell lines](#). Nat Neurosci 1-12 (2022) doi:10.1038/s41593-021-01006-0.

ANSWER ALS Cohort Acknowledgements:

“Clinical data and biosamples used in the preparation of this article were obtained from the Answer ALS Foundation Program, ‘Answer ALS’. For up-to-date information on the program, [visit https://www.answerals.org](https://www.answerals.org).

26. I will provide either (i) a copy of the manuscript upon its acceptance for publication or (ii) the full citation of all published manuscripts to the ANSWER ALS Publications Committee. Citations will be listed on the ANSWER ALS websites and available to the public through PubMed.

27. Access to the ANSWER ALS data components is managed solely by the ANSWER ALS DAC, which may notify users of additional ANSWER ALS-specific data usage requirements from time to time. I agree to comply with all such ANSWER ALS-specific requirements immediately upon notification by the ANSWER ALS DAC representative. I agree that continued use of ANSWER ALS data components after receipt of additional terms constitutes acceptance of those terms.

28. I ACKNOWLEDGE AND AGREE THAT THE ANSWER ALS DATA ARE PROVIDED AS IS AND NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE ANSWER ALS DATA PROVIDED UNDER THIS AGREEMENT. THERE ARE NO WARRANTIES OR REPRESENTATIONS AS TO THE PURITY, ACCURACY, SAFETY OR USEFULNESS OF THE ANSWER ALS DATA OR THAT THE USE OF THE ANSWER ALS DATA WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHT.

29. I acknowledge and agree that this Agreement will remain in effect for a period of four (4) years from the Effective Date and will automatically expire at the end of this period unless terminated earlier or renewed. For renewals requiring a signature from an Authorized Institution Business Official, I understand that the renewal process will be initiated by communications from ANSWER ALS DAC approximately one (1) month prior to the expiration date of this Agreement, and I agree to respond promptly to communications from ANSWER ALS DAC. For other renewals, I understand that investigators should sign, date, and submit a new agreement electronically at <https://dataportal.answerals.org/> within one year of the Effective Date of this Agreement. I agree that, at the time the agreement expires or is terminated, I will return all copies of the data set to Answer ALS or destroy them and certify to the destruction; or, if the if neither return nor destruction is feasible, and Answer ALS agrees, then the protections of this Agreement will be extended.

30. I acknowledge and agree that this Agreement may be terminated by the ANSWER ALS program without cause by providing thirty (30) days written notice to me or the institutional official identified below at the email address(es) provided below. I also understand that the Agreement may be terminated by me or the institutional official identified below by providing thirty (30) days written notice to ANSWER ALS DAC.

31. I understand that failure to abide by the terms of this Agreement will result in the immediate termination of my privileges to access the ANSWER ALS Data through the ANSWER ALS Data Portal and to use ANSWER ALS Data that has been downloaded in accordance with Section 11 above.

32. Sections 2, 3, 4, 7, 8, 9, 10, 12, 13, 14, 15, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28 and 31 of this Agreement will survive expiration or termination of this Agreement.

**Individual Applicant**

Signature:

Name:

Title:

Date:

Email:

**Authorized Institutional Business Official**

Signature:

Name:

Title:

Date:

Email:

**Answer ALS Foundation Representative**

Signature:

Name:

Title:

Date:

Email:

## ATTACHMENT A

### DEFINITION OF De-identified data set” and “Limited data set”

De-identified data set means Protected Health Information that excludes the following direct identifiers of the patient or of relatives, employers, or household members of the patient:

The following identifiers must be removed prior to disclosure to Recipient:

- Names;
- All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes (except that the initial three digits of a zip code may be used if, according to the current publicly available data from the Bureau of the Census, the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people AND the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000)
- All elements of dates (*except* the year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (*including* the year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints;
- Full face photographic images and any comparable images; and
- Any other unique identifying number, characteristic, or code, except for the sole purpose of re-identification as permitted below:

A code or other means of record identification may be assigned to allow the de-identified information to be re-identified, provided that such code or record identification:

- is not derived from or related to information about the individual;
- is not otherwise capable of being translated so as to identify the individual;
- is not used or disclosed for any other purpose; and
- does not disclose the mechanism for re- identification.

### Limited Data Set

The de-identified clinical data in combination with genomic data (whole genome sequencing) is now considered to be a limited data set.