

DATA ACCESS AGREEMENT for EGA Study

This Data Access Agreement (“Agreement” or “DAA”), including its appendices, is to allow a researcher’s institution (“User Institution”) to seek approval from the Board of Trustees of the Leland Stanford Junior University, on behalf of its School of Medicine, Biochemistry Division (collectively, “Stanford” or “Data Producer”) to allow Approved Personnel at User Institution to access certain data and information available in a cloud-based data environment for the purpose of conducting [REDACTED] research. Prior to Stanford giving final approval for access to said data, an application must be reviewed and approved by the Data Access Committee (DAC).

These terms and conditions govern access to the managed access datasets (details of which are set out in Appendix I) to which the User Institution has requested access. The User Institution agrees to be bound by these terms and conditions.

Definitions

Applicable Law: All U.S. Federal, state and local laws and regulations to the extent applicable to the terms of this Agreement, including without limitation the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), Title XIII of the American Recovery and Reinvestment Act of 2009 (Public Law 111-5), and the General Data Protection Regulation (EU) 2016/679 (GDPR), in each case as the same may be amended or supplemented from time to time.

Authorized Personnel: The individual(s) at the User Institution to whom the DAC grants access to the Data. This includes the User, and may include additional individuals as listed in Appendix II, and any other individuals for whom the User Institution subsequently requests access to the Data and for whom DAC has issued written approval. Details of the initial Authorized Personnel are set out in Appendix II.

Data: The managed access datasets to which the User Institution has requested access.

DAC: The data access committee for Stanford University related to the research in Appendix 1 and Appendix 2 attached to this Agreement. The DAC includes the Stanford Principal Investigator for such research, and any other personnel that Stanford may deem appropriate in its sole discretion (e.g., experts in research, ethics, privacy and/or legal matters).

Data Producers: The DAC and any other Stanford personnel responsible for the development, organization, and oversight of access to these Data.

External Collaborator: A collaborator of the User, working for an institution other than the User Institution.

Institutional Review Board (IRB): The independent ethics committee (IEC), ethical review board (ERB), or research ethics board (REB), which is/are committee(s) designated to safeguard ethical conduct of studies using human subjects by monitoring and reviewing biomedical and behavioral research under certain national and international laws, regulations, codes and/or norms.

Protected Health Information (PHI): Individually Identifiable Health Information that is transmitted by electronic media; maintained in any medium described in the definition of the term electronic media in the HIPAA regulations; or transmitted or maintained in any other form or medium as defined in 45 C.F.R. § 164.501. Protected Health Information excludes Individually Identifiable Health Information in education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. § 1232g, and records described at 20 U.S.C. § 1232g(a)(4)(B)(iv).

Personally Identifiable Information (PII): Information or data that (i) identifies an individual, including by name, signature, address, telephone number or other unique identifier, (ii) can be used to identify or authenticate an individual, including passwords, PINs, biometric data, unique identification numbers (e.g., social security numbers), answers to security questions or other personal identifiers, (iii) PHI under HIPAA and the HITECH Act and/or (iv) can be used in combination with other information or data to identify an individual, including but not limited to the individual's gender, race, income, date of birth, geographic location, school or workplace name, group affiliations, mental, emotional or physical characteristics, or other indirect identifiers.

Project: The project for which the User Institution has requested access to these Data. A description of the Project is set out in Appendix II.

Publications: Includes, without limitation, articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research.

Research Participant: An individual whose data form part of these Data.

Research Purposes: The purpose for which these Data are being sought and where such research seeks to advance the understanding of [REDACTED], including the treatment of disorders, and work on statistical methods that may be applied to such research.

User: The principal investigator for the Project at User Institution.

User Institution(s): The Institution that has requested access to the Data. Please include your Institution legal name and address here:

[NAME]
[LEGAL ADDRESS 1]
[LEGAL ADDRESS 2]
[PHONE]
[FAX]
[ATTN:]

Terms and Conditions

1. The User Institution agrees to only use these Data for the purpose of the Project (described in Appendix II) and only for non-commercial research purposes. The User Institution further agrees that it will only use these Data for research purposes which are within the limitations (if any) set out in Appendix I, II, and III, attached hereto at Appendix IV and hereby incorporated by reference.

2. The process for accessing these Data in accordance with this DAA is as set forth below:

- The process of the application review by the Data Access Committee (DAC) is being managed by the Stanford Principal Investigator, in coordination with the Stanford University Privacy Office where appropriate; but the authority for final approval to grant access and to oversee data usage is under the responsibility and control of the Stanford. The organization entering into this Agreement with Stanford is referred to as the "User Institution." User Institution's agreement with Stanford through the DAA is to obtain access to the Stanford Data stored in The European Genome-phenome Archive at the European Bioinformatics Institute Database for the stated purpose of conducting the Research Purposes as detailed in the Project and this DAA.
- User Institution will apply for EGA Database access via [REDACTED], which will see that applications are reviewed by the DAC. Final responsibility for access to Data will be governed by Stanford; however, oversight of its usage and compliance with applicable laws will be the responsibility of User Institution.
- In order to access the Data, the User and User Institution must apply for and receive approval from both the DAC and the Data Producer for access to the Data in the EGA Database in accordance with the terms and conditions hereunder.
- Once the application and DAA are received, the DAC will review the application to confirm the following: the application is complete and the DAA has been properly completed and signed; the User or User Institution is not on any type of debarment list; the User is from a recognized institution that has the appropriate research, legal and financial means to support the project; the Project is feasible given the resources in the EGA Database; and the Project aims to advance scientific exploration and principles of openness in research.
- The DAC will have the discretion to approve or decline an application or DAA based on ethical, scientific, programmatic or other relevant considerations. Among other things, the DAC may consider the following criteria: the User is qualified to conduct the Project and undertake the proposed analysis; the User Institution has confirmed that the minimum data security safeguards described at Section 6, below, have been implemented; the User has confirmed that IRB approval has been obtained, or, if no confirmation of IRB approval is provided, documentation explaining why the Institutional Review Board is not requiring approval.

- The DAC will submit to the User Institution its decision as to whether a User's application and/or DAA is approved, declined or conditionally approved. If the DAC has approved the User application, the DAC will then determine if access is appropriate and sign the DAA. An Access Authorization Letter with directions for accessing the EGA database and Data will be emailed to the address provided by the User in the application. Even though the Data is provided by the Data Producer at no cost to the User Institution, access to the Data will require the Institution to establish an account on the EGA Website and cover all costs associated with access, storage, egress charges, compute costs, and/or maintenance to service the User's account. This account will be owned by [REDACTED] and all costs associated with work undertaken in that account will be the responsibility of the Institution.
- The Access Authorization Letter will also be accompanied with a copy of the DAA executed by the Data Producer and User Institution. This DAA will govern the User's and User Institution's access to the EGA Database and Data. The terms of this DAA will prevail over any inconsistent terms of the EGA Website or elsewhere, and over any oral or written statement made by the staff of the DAC.
- If the DAC has conditionally approved an Institution's application, the Access Authorization Letter will set forth the additional information required to be submitted to the DAC, which may include additional data access and use terms to which User and User Institution must assent. Upon receipt of such additional information, the DAC will review User Institution's revised application, should one be submitted, together with the additional required information in accordance with the above steps and a notification of the decision of the DAC will be provided in accordance with this step.
- Each DAA will have a term of one (1) year from the date of last signature ("Effective Date") of the DAA. To renew a DAA and continue access to the EGA Database after expiration of the then-existing DAA, the User will be required to submit a renewal request. The Renewal Request will require User to provide: an updated User application or confirmation that the content of the User application originally submitted remains correct and complete; an updated list of and contact information for the Authorized Personnel, or confirmation that the list of and contact information for the original Authorized Personnel remains correct and complete; and all Publications prepared using the results of the Project in accordance with the Publication Policy at Appendix III.

3. Data may be used only for an IRB-approved Project as mutually agreed upon by both the DAC and the User Institution and only for the purposes of advancing science, deriving outcomes, and generating research results. The User Institution acknowledges and understands that the Data is/are valuable and that except as expressly permitted only User, Authorized Personnel, and External Collaborators agreeing to abide by the protections set forth herein are the only persons permitted to

use the Data under this Agreement. Confirmation that an Institutional Review Board (IRB) and ethics committee has approved the User's use of these Data, including the name of the approved protocol, the date of approval and the name, address and email address of the IRB, and a letter from the IRB approving the Project subject to annual oversight and approval or stating that approval is not required due to the type of data being accessed, must be received by the DAC prior to approval.

4. The User Institution will notify the DAC prior to any significant changes to the protocol for the Project or the Project itself.

5. The User Institution will notify the DAC within thirty (30) days of any changes or departures of Authorized Personnel. The User Institution agrees to distribute a copy of these terms to the Authorized Personnel. The User Institution shall ensure that the Authorized Personnel comply with the terms of this agreement.

6. User Institution agrees to use the Data only in connection with this Agreement and to hold the Data in strict confidence. The User Institution agrees not to disclose, share, sell or allow access to any of the Data except as expressly permitted by this Agreement. Furthermore, with regard to PII/PHI received in connection with the Data, the User represents and warrants that it shall comply with all Applicable Law and ensure that all computer systems and devices used to access or process these Data meet Data Producers' minimum security standards for high risk data, found at <https://uit.stanford.edu/guide/securitystandards> in order to protect these Data.

7. If requested, the User Institution will allow data security and management documentation to be inspected to verify that it is complying with the terms of this agreement.

8. The User Institution agrees only to transfer or disclose these Data, in whole or part, or any material derived from these Data, only to the Authorized Personnel. Should the User Institution wish to share these Data with an External Collaborator, the External Collaborator must complete a separate Data Access Agreement for access to these Data.

9. The User Institution agrees not to link, attempt to link, combine, or attempt to combine these Data to any other information or archived data available in a way that could reasonably be used to re-identify the Research Participants, even if access to that data has been formally granted to the User Institution or is freely available without restriction. Should User Institution inadvertently receive identifiable information or otherwise identify a subject, Recipient shall immediately notify the Data Producers and follow Data Producers' reasonable written instructions, which may include return or destruction of the identifiable information.

10. The User Institution agrees to protect the confidentiality of Research Participants in any research papers or Publications that they prepare by taking all reasonable care to limit the possibility of identification.

11. The User Institution will notify the DAC immediately upon becoming aware a breach of the terms or conditions of this agreement or upon User Institution's discovery of any unauthorized use or disclosure of these Data.

12. The parties will promptly confer and agree on legally required steps the User Institution shall take to minimize the harm (if any) resulting from such breach. The User Institution will cooperate with the Data Producer in complying with such steps. In the event of actual or suspected unauthorized disclosure of, access to, or other breach of these Data, the User Institution will comply with all Applicable Law and regulations related to such breach, and will cooperate with the Data Producer in assisting it to fulfill its legal obligations.

13. The User Institution agrees that the Data Producers, and all other parties involved in the creation, funding or protection of these Data: a) make no warranty or representation, express or implied, of any kind as to the accuracy, quality, or comprehensiveness of these Data; b) exclude to the fullest extent permitted by law all liability for actions, claims, proceedings, demands, losses (including but not limited to loss of profit), costs, awards damages and payments made by the User Institution that may arise (whether directly or indirectly) in any way whatsoever from the User Institution's use of these Data or from the unavailability of, or break in access to, these Data for whatever reason and; c) bear no responsibility for the further analysis or interpretation of these Data.

14. The User Institution shall defend, indemnify and hold the Data Producer and its directors, officers, employees, students, agents, successors and assigns harmless, to the full extent permitted in law or equity, from and against any and all losses, claims, actions, damages, regulatory actions or investigations, liabilities, costs and expenses (including reasonable attorneys' fees and expenses), fines, penalties, judgments, and costs (including but not limited to the costs of providing appropriate notice to all parties and credit monitoring, credit rehabilitation, or other credit support services to individuals with information impacted by the actual or suspected breach, to the extent procured by the User Institution (each a "Claim" or, collectively, "Claims") to the extent that a Claim or Claims: (i) arise out of a breach of the User Institution's obligations hereunder; (ii) arise out of the User Institution's use, handling or storage of these Data in a manner not permitted by this Agreement or Protocol; or (iii) relate to User Institution's gross negligence or intentional acts under this Agreement, except to the extent a Claim or Claims is/are caused by the Data Producer's own gross negligence or intentional misconduct.

15. THE DATA PRODUCER WILL NOT BE LIABLE FOR ANY INDIRECT, INCIDENTAL, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES OF THE OTHER ARISING OUT OF OR IN CONNECTION TO ANY PERFORMANCE OF THIS AGREEMENT OR IN FURTHERANCE OF THE PROVISIONS OR OBJECTIVES OF THIS AGREEMENT, REGARDLESS OF WHETHER SUCH DAMAGES ARE BASED ON TORT, WARRANTY, CONTRACT OR ANY OTHER LEGAL THEORY, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

16. The User Institution agrees to follow the *Publication Policy* in Appendix III. This includes respecting the moratorium period for the Data Producers to publish the first peer-reviewed report describing and analyzing these Data.

17. The User Institution agrees that all Data shall be owned exclusively by the Data Producer. To the extent the User Institution has or acquires any rights in or to the Data, the User and User Institution each hereby irrevocably assigns, transfers and conveys to the Data Producer all of its right, title and interest in and to the Data, excluding any modifications, enhancements or derivative works developed by the User Institution using the Data. For clarity, summaries, analyses and interpretations of the Data generated by the User pursuant to this Agreement shall not be considered "Data" and rights with respect to such summaries, analyses and interpretations shall be the property of the User or User Institution, as the case may be. Furthermore, and notwithstanding

anything to the contrary herein, to the extent Data cannot be segregated from the User's research results generated under the Project, the User and User Institution hereby grants to the Data Producer perpetual unrestricted right and license in and to that subset of Data necessary to fully exploit its rights in the Data and research results generated therefrom.

18. The User Institution can elect to perform further research that would add intellectual and resource capital to these Data and decide to obtain intellectual property rights on these downstream discoveries. In this case, the User Institution agrees to implement licensing policies that will not obstruct further research and to follow the U.S. National Institutes of Health *Best Practices for the Licensing of Genomic Inventions (2005)* (https://www.icgc.org/files/daco/NIH_BestPracticesLicensingGenomicInventions_2005_en.pdf) in conformity with the Organisation for Economic Co-operation and Development *Guidelines for the Licensing of the Genetic Inventions (2006)* (<http://www.oecd.org/science/biotech/36198812.pdf>). The User Institution hereby grants to the Data Producer a perpetual unrestricted right and license use these intellectual property rights on these downstream discoveries.

19. The User Institution agrees to certify the destruction or, if destruction is not feasible, the return of the Data held once it is no longer used for the Project, unless obliged to retain the Data for archival purposes in conformity with audit or legal requirements.

20. The Data Producer may terminate this agreement at any time and at its sole discretion by written notice to the User Institution. If this agreement terminates for any reason, the User Institution will be required to destroy any Data held, including copies and backup copies. This clause does not prevent the User Institution from retaining these data for archival purpose in conformity with audit or legal requirements.

21. The User Institution accepts that it may be necessary for the Data Producers to alter the terms of this agreement from time to time. As an example, this may include specific provisions relating to the Data required by Data Producers other than the DAC. In the event that changes are required, the Data Producers or their appointed agent will contact the User Institution to inform it of the changes and the User Institution may elect to accept the changes by written amendment to this Agreement, or terminate the agreement.

22. The validity, construction and performance of this Agreement and the legal relations among the parties hereto shall be governed by and construed in accordance with the laws of the State of California, excluding that body of law applicable to choice of law and the parties consent to the jurisdiction of the courts of California State in connection with the resolution of any dispute among them arising from the validity, construction or performance hereof. If any provision of this Agreement or the application of any such provision shall be held by a tribunal of competent jurisdiction to be unenforceable or contrary to law, the remaining provisions of this Agreement shall continue in full force and effect.

23. In the event of a dispute arising out of or relating to this Agreement, the parties shall first attempt in good faith to resolve such dispute by negotiation and consultation between themselves. Either party may, by written notice to the other party, refer the dispute to the other party for attempted resolution by formal good faith negotiation within thirty (30) days after such notice is received. If the dispute remains unresolved after the good faith negotiation period provided in the

previous sentence, either party by written notice to the other party may have such issue referred for resolution to the parties' respective executive officers or senior legal counsel. The executive officers or senior legal counsel shall meet promptly to discuss the matter submitted and to determine a resolution. If the executive officers or senior legal counsel fail to resolve the dispute within thirty (30) days after it is referred to them, each party shall have the right to pursue any other remedies legally available to resolve the dispute and the matter may be brought by a party as a suit in a court of competent jurisdiction in accordance with Section 22, above.

24. The User Institution shall not use the name, symbol, logo, likeness, service mark or trademark of the Data Producer without the prior written consent of the Data Producer.

25. All Notices. All notices under this Agreement are deemed fully given when written, addressed, and sent as follows:

All notices to User Institution:

[NAME]
[ADDRESS 1]
[ADDRESS 2]
[Attention:]
[Phone:]
[Fax:]
[Email:]

All notices to Data Producer:

Office of Sponsored Research
Stanford University
485 Broadway, Floor 3
Redwood City, California USA
94063-3136
Attention: OSR Intake (PI: Krasnow)
Phone: (650) 725-2525
Email: osr_intake@stanford.edu
cc: murphyjd@stanford.edu
cc: krasnow@stanford.edu

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[signatures continue on next page]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed below by their duly authorized signatories.

Agreed for User Institution

Signature:	
Name:	
Title:	
Date:	

I confirm that I have read and understood this Agreement.

User

Signature:	
Name:	
Title:	
Date:	

Agreed for the Data Producer

Signature:	
Name:	
Title:	
Date:	

As reviewed by the Data Access Committee

Signature:	
Name:	
Title:	
Date:	

APPENDIX I
DATASET DETAILS

Dataset reference (EGA Study ID and Dataset Details)

EGA study accession: _____.

Description: _____.

EGA dataset for study: _____.

Description: _____.

Name of project that created the dataset

EGA study accession: _____.

Description: _____.

Names of other data producers/collaborators

Specific limitations on areas of research

The User Institution agrees that it will only use these Data for Research Purposes.

APPENDIX II
PROJECT DETAILS

[to be completed by the User Institution]

Details of dataset requested (i.e., EGA Study and Dataset Accession Number):

Title of the Research Project:

Research question proposed to be answered by the Project (500 words max):

Summary of Project suitable for a lay audience (200 words max):

Country(ies) where the Project will be conducted and downloaded copies of Data will be held:

All Individuals who the User Institution to be named as registered users:

<i>Name of Registered User</i>	<i>Email</i>	<i>Job Title</i>	<i>Supervisor*</i>

All Individuals that should have an account created at the EGA:

Name of Registered User	Email	Job Title

APPENDIX III PUBLICATION POLICY

The DAC and/or Data Producer intend to publish the results of their analysis of this dataset(s) and do not consider its deposition into the European Genome-phenome Archive or any public databases to be the equivalent of such publications. The DAC and/or Data Producer anticipates that the Data could be useful to other qualified researchers for a variety of purposes. However, some areas of work are subject to a publication moratorium. The publication moratorium covers any publications (including oral communications) that describe the use of the Data.

For research papers or Publications, submission for publication should not occur until one (1) year after these Data were first made available on the relevant hosting database, unless the DAC has provided written consent to earlier submission. Without limiting the foregoing, the User Institution shall inform the Data Producers at least thirty (30) days prior to its intent to publish the results of their analysis of this Data. A shorter review time is permissible by mutual agreement. The User Institution agrees that if the Data Producers reasonably determine that the proposed publication contains confidential, proprietary, or sensitive information belonging to the Data Producers or Research Participant(s), then the User Institution shall remove any such confidential, proprietary or sensitive Information if requested to do so before publishing. If the Data Producers determine that the proposed publication contains patentable subject matter and desires to have such subject matter protected by a patent application, the User Institution agrees to delay publication for up to an additional ninety (90) days after the one-year publication moratorium in order for a patent application to be filed. For the avoidance of doubt, no right of manuscript approval is implied by this section.

In Publications based on these Data, please describe how the Data can be accessed, including the name of the hosting database (e.g., The European Genome-phenome Archive at the European Bioinformatics Institute) and its accession numbers (e.g., EGAS000000000XX), and acknowledge Stanford and the Stanford Principal Investigator in each use of the Data or analysis or research results derived therefrom in a form agreed by the User Institution with the approval of the DAC.

The User Institution agrees to follow the *Fort Lauderdale Guidelines* (http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/welb_document/wtd003207.pdf) and the *Toronto Statement* (<http://www.nature.com/nature/journal/v461/n7261/full/461168a.html>). This includes but is not limited to recognizing the contribution of the Data Producers and including a proper acknowledgement in all reports or Publications resulting from the use of these Data.

Nothing herein shall authorize the User Institution to use or further disclose the Data in a manner that would violate the requirements of Data Producers under any Applicable Law.