National Eye Institute / National Institutes of Health

AMD Integrative Biology Initiative

DATA USE AGREEMENT
For Access to NEI AMD Integrative Biology Initiative Data

This Data Use Agreement ("Agreement") is between the National Eye Institute ("Provider or "NEI") part of the National Institutes of Health ("NIH"), an agency of the U.S. Government, and _____ ("Recipient"), located at _____, for access to data from the NEI AMD Integrative Biology Initiative ("Initiative") for research purposes. Provider and Recipient are each a "Party" and collectively, the "Parties." This Agreement will become effective on the date of the last signature below ("Effective Date").

Recipient Investigator:

Recipient and Provider agree as follows:

Section 1. ***Data***

Provider will grant Recipient access to de-identified data from the NEI AMD Integrative Biology Initiative that is available through the NEI BRICS (Biomedical Research Informatics Computing System) platform ("Data").

Section 2. ***Research Use, Collaborations, and Data Sharing***

Use. Recipient will use the Data only for the research described in the NEI AMD Integrative Biology Initiative Access Application ("Research Project") for , which is attached as Appendix A and made a part of this Agreement. The Research Project is reviewed for completeness, intuitional ethics review, data management and sharing plans, and consistency with participant consent by the NEI AMD Integrative Biology Initiative Access Subcommittee. If approved the Recipient will be provided log-in credentials to the NEI Biomedical Research Computing System (BRICS) to access available Data. The Data may be used for research purposes but may not be transferred to or accessed by third parties without the permission of the NEI. If in any progress reports NEI discovers a use of the Data inconsistent with the uses proposed in Appendix A, the NEI AMD Integrative Biology Initiative Access Subcommittee will review the inconsistent use and either (1) approve the use and require modification of Appendix A to state the permitted use or (2) deny the use and terminate this Agreement as a breach subject to Section 12. RECIPIENT AGREES THAT THE DATA MAY NOT BE USED FOR ANY HUMAN DIAGNOSTIC, PROGNOSTIC, OR TREATMENT PURPOSES. Recipient will comply with all laws, rules, and regulations applicable to the handling and use of the Data.

Recipient may only transfer the Data to Recipient Investigator and his/her research team that are under the direct supervision of Recipient Investigator (the "Research Team"). Before transfer of the Data, Recipient Investigator and members of the Research Team must receive the Agreement and agree to be bound to the terms of this Agreement.

Any transfer of the Data from the Recipient to anyone other than Recipient Investigator and the Research Team requires the advanced written approval of the Provider, except as required by law or regulation. If Provider agrees to the transfer of the Data to other Recipient staff, Recipient agrees it must provide the Agreement to the approved staff members and obtain each staff member's agreement to be bound by the terms of the Agreement. No secondary distribution of the Data is permitted except as specifically described within the approved Research Project.

Collaborations. For single purpose collaborations where the Recipient Investigator and at least one additional investigator at a separate entity will engage in collaborative research utilizing the same Data, each entity must sign a separate Data Use Agreement. The Research Project should include the names of any collaborating investigator(s) and their respective entities. If more than one investigator located at Recipient will be collaborating, only one Data Use Agreement is needed but all investigators must be named within the Data Use Agreement.

Sharing Generated Data. Because a main objective of the Initiative is to develop a robust database, Provider requires that summary results, code(s) used for analysis, and final scientific data generated during the Research Project shall be provided to NEI for inclusion within NEI BRICS, as applicable. Scientific data for this purpose is defined as the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data do not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens. The Recipient will provide a Data Management and Sharing Plan as part of the Research Plan outlining the details of the data to be contributed to the Initiative and any plans to share generated data with third party sources (ex. dbGaP, GitHub, Figshare).

Section 3. ***De-identification***

Recipient will not receive any Identifiable Private Information ("IPI") as defined by 45 CFR 46 or Protected Health Information as defined by the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder at 45 CFR Parts 160 and 164 ("HIPAA"). Instead, the Data will be fully de-identified. A unique code for research purposes without a key to decipher the code will be available, but without the key, re-identification is not possible. In the event that Recipient receives IPI or the code key in error, Recipient agrees to:

(a) Abide by all applicable human subjects and other regulations and guidance and NIH policies, which may include:

  (i) The Privacy Act of 1974, as amended, at 5 U.S.C. §552a ("Privacy Act"), HIPAA or other equivalent privacy regulations; and

  (ii) 45 C.F.R. Part 46, the Food and Drug Administration ("FDA") human research regulations at 21 C.F.R. Parts 50 and 56, and FDA Good Clinical Practice Guidelines (ICH E6 Good Clinical Practice: Consolidated Guidance, 62 FR 25692 (1997)); and

  (iii) A certificate of confidentiality issued by NIH in accordance with 42 U.S.C 241(d) of the Public Health Service Act and the NIH Policy on Certificates of Confidentiality.

  (iv) NIH Genomic Data Sharing Policy

(b) Maintain any transferred information in a secure manner and location that restricts access by any individual not involved in the Research Project (e.g., for paper records – locked file cabinets or continual physical presence in a room that locks, or for electronic records – encryption and password protection); and

(c) Remove or destroy any information that may be used to identify the Human Subject at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the Research Project; and

(d) Make no further use or disclosure of the information unless approved by the Provider or required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments). Notwithstanding the foregoing, IPI is immune from the legal process, and will not, without the consent of the Human Subject, be admissible as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding.

Section 4. ***Non-identification***

Recipient will not contact or make any effort to identify individuals who are or may be the sources of the Data

Section 5. ***Non-transferability and Change of Institution***

Recipient agrees Recipient Investigator will only use the Data while associated with the Recipient. Recipient Investigator is prohibited from using the Data at any other institution or entity. If Recipient Investigator moves to a new institution or entity, the Data will not be transferred from the Recipient until after a new Data Use Agreement with the new institution or entity has been signed and Provider grants written permission.

Section 6. ***Annual Reports and Final Report***

Progress Reports. Recipient will provide Recipient Investigator's brief progress report summarizing the progress of the Research Project after one year, and annually thereafter until completion of the research or termination of this Agreement; the progress report should be sent to: *NEI Office of Data Science and Health Informatics, NEIODSHI@nei.nih.gov*. The progress will include a brief update on the research, including the potential significance of any findings and plans for future research; any resulting scientific presentations and publications with the name, bibliographic citation (if any) and submission date. Late or missed reports will result in disabling of user accounts in NEI BRICS and a letter to Institutional Signatory.

The NEI will maintain annual progress reports internally but will list bibliographic citations on the https://eyepsc.nei.nih.gov public website.

Final Report. Recipient will send Provider a Final Report upon completion of the Research Project or termination of the Agreement. The Final Report should include a final brief update on the research accomplishments, including the potential significance of any findings; any resulting scientific presentations and publications with the name, bibliographic citation (if any) and submission date, and an abstract of findings to be use in reporting and for posting on the https://eyepsc.nei.nih.gov public website. Final Reports should be sent to *NEI Office of Data Science and Health Informatics, NEIODSHI@nei.nih.gov*

Section 7. ***Intellectual Property***

The ownership of all intellectual property generated by activities under the Research Project will be governed by applicable patent law. Provider recognizes the importance of intellectual property in promoting the development of new therapies and products; as such, there is no restriction on development of commercial products resulting from the knowledge gained from the Research Project. However, in order for the Initiative to achieve maximum public benefit, Provider expects the Recipient and Recipient Investigator to adhere to the intellectual property guidelines outlined below:

Provider encourages licensing practices consistent with the recommendations cited in NIH's Best Practices for the Licensing of Genomic Inventions (https://www.govinfo.gov/content/pkg/FR-2005-04-11/pdf/05-7247.pdf. NIH Sharing Policy and in the NIH Research Tools Policy (http://grants.nih.gov/grants/sharing.htm)

Section 8. ***Publication and Acknowledgement of Initiative***

The Initiative wants to promote the dissemination of analyses of Initiative data and resources as widely as possible. To further this goal, Recipient Investigator is strongly encouraged to publish his/her results in peer-reviewed journals. Recipient agrees that the Recipient Investigator must refer to the NEI BRICS GUID in corresponding manuscripts and will acknowledge the Initiative in all oral and written presentations, disclosures, and publications resulting from the Research Project. An example of a possible acknowledgment is:

> *"The data used for the analyses described in this manuscript were obtained from the National Eye Institute –AREDS2 Study (NCT 00345176) and the AMD Integrative Biology Initiative which has been funded in part from the National Institutes of Health/National Eye Institute, under Contract No. HHSN263201800007C. We would like to thank the AREDS2 participants and the AREDS2 Research Group for their valuable contribution to this research."*

Section 9. ***Disclaimer***

Data is provided as a service to the research community. IT IS BEING SUPPLIED TO THE RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Provider makes no representations that use of the Data will not infringe any patent or proprietary rights of third parties.

Section 10. ***Indemnification***

No indemnification for any loss, claim, damage, or liability is intended or provided by either Party under this Agreement. Each Party shall be liable for any loss, claim, damage, or liability that it incurs as a result of its activities under this Agreement, except that Provider, as an agency of the U.S. Government, may be liable only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171). No indemnification for third party claims is intended or implied by either Party.

Section 11. ***Public Posting of Investigator Information and Privacy Act Notification***

Recipient understands that information about the Research Project may be posted on a public website that describes the projects of approved users of Data from the Initiative. The information may include Recipient Investigator's name, institution or organization, project name, a description of the research objectives, design and analysis plan, and a non-technical summary of the planned research. Recipient will provide the information requested herein and on the attached Research Project. Recipient agrees that information collected regarding the Research Project may be made public in part or in whole for tracking and reporting purposes. This Privacy Act Notification is provided pursuant to the Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested below from the Recipient comes from the authorities regarding the general authority of the NIH to conduct and fund research, and its general authority to maintain records in connection with these and its other functions (5 U.S.C. 301 and 302, 42 U.S.C. 241, 44 U.S.C. 3101 and 3102. Completing the form is voluntary, however, declining to provide any or all the requested information may delay or nullify your request. The information you provide will be included in a Privacy Act system of records, and will be used and may be disclosed for the purposes and routine uses described and published in the Privacy Act System of Record Notice 09-90-1401 covering "Records About Restricted Dataset Requesters, HHS/PHS/NIH/OD." The primary uses of this information are to document, track, and monitor and evaluate utilization of the Initiative, as well as to notify recipients of updates, corrections, or other changes to the database.

Section 12. ***Term and Termination***

This Agreement will become effective upon final signature below and will terminate when the Research Project is completed or if the Agreement is terminated by a Party. Upon termination of this Agreement, Recipient will no longer have access to the Data through BRICS.

Either Party may terminate this Agreement without cause with thirty (30) days written notice to the other Party, except, in the case of breach by Recipient, Provider may terminate the Agreement immediately.

Recipient Investigator will notify Provider upon completion of the Research Project and Recipient's obligations under this Agreement will survive termination and Recipient will remain bound by the terms of this Agreement until the Final Report (see Section 6) has been received by Provider.

SIGNATURES

RECIPIENT SIGNATURE INSTRUCTIONS -- This Agreement must be executed by an official (president, vice-president, director, dean, granting official or the equivalent) with responsibility for scientific and technological research and development or legal affairs. **This individual is likely to be the person authorized to sign grant applications or contract proposals on behalf of the Recipient**. It is unlikely that staff of a purchasing department would be authorized to make assurances about the scientific use of data. Please include a sufficiently relevant "title" used by the signatory on this Agreement so that the level and scope of responsibility of the authorized representative is clear and unambiguous (for example: the title of "Dr." or "Professor" does not in itself provide sufficient information about the responsibilities of the signer; however, the title "Director of Research" or "Deputy Director of Ethics" are examples of sufficiently relevant titles).

Recipient acknowledges that it has shared this Agreement with any research staff who will use the Data and other appropriate institutional or entity staff and officials as necessary.

Any communication or notice to be given by either party shall be forwarded in writing to the respective addresses listed below.

For the Recipient:

Name of Recipient Institution: _____

Recipient's Authorized Representative:
Name (typed or printed): _____
Title of Institutional Official: _____

Signature of Institutional Official: _____

Date: _____

Mailing Address for Notices:

_____

Recipient Investigator – *I have read and understood and terms of this Data Use Agreement*

Signature: _____
[*insert name and title*]

For the Provider:

_____ Date: _____
Santa Tumminia, Ph.D., Deputy Director, NEI

_____ Date: _____
Mala Dutta, Ph.D., Technology Development Coordinator, NEI

_____ Date: _____
Amberlynn Reed, M.P.H., Acting Chair of the Initiative Committee

Mailing Address for Notices or to contact the Initiative:

NIH/NEI
31 Center Drive, Room 6A03
Bethesda, MD 20892

APPENDIX A

RESEARCH PROJECT