

Broad Data Use Oversight System (DUOS) – LIBRARY CARD AGREEMENT

1. **Introduction.** The Broad Institute, Inc. (“**Broad**”) seeks to improve human health by using genomics to advance the understanding of human disease. The production, storage, access management and analysis of genomic data is a key aspect of this mission. Broad manages access to certain of this genomic data via its Data Use Oversight System (“**DUOS**”). By executing and delivering this Library Card Agreement (this “**Agreement**”), Broad agrees to grant access to and use of certain genomic data to the undersigned requesting institution (the “**Requestor**”) on the terms and conditions contained herein; and the Requestor hereby agrees to such terms and conditions. The effective date of this Agreement will be the date this Agreement is fully executed by Requestor and Broad.

See Section 21 below for the meanings of certain terms that are not otherwise defined in the text of this Agreement.

The Requestor will enter this Agreement once, and multiple approvals of this Agreement will not be required for each Library Card Holder so long as this Agreement is in effect. An Institutional Signing Official will be required to execute this Agreement on behalf of the Requestor.

2. **Library Card Program.** From time to time during the term of this Agreement, the Requestor may issue one or more Library Cards to specific Requestor Investigators for the purpose of accessing and using certain Data (details of which will be set out in the applicable DAR) managed by DUOS. Broad expects (and the Requestor acknowledges and agrees) that Authorized Users of Data recognize any restrictions on such Data use established by Broad and/or the applicable Data Providers as specified in the information provided in connection with such Data. New uses of the Data outside those described in the DAR will require submission of a new DAR. Subject to the provisions of Section 18 of this Agreement, access to any requested Data is granted for a period of one (1) year, with the option to renew access and use beyond such one (1) year period or close-out a Project prior to or at the end of such one (1) year period. Similarly, Library Card Holders will need to be re-confirmed by the Requestor annually to continue using their Library Card privileges when requesting Data under a new DAR.

3. **Issuance of a Library Card.** The Requestor agrees that if it approves Library Card access to a Requestor Investigator, then such Requestor Investigator will be named in the Requestor’s “white list” of approved Library Card Holders on DUOS in the manner indicated in DUOS. Once a Requestor Investigator has been approved as a Library Card Holder, and so long as such Library Card is in effect, such Requestor Investigator may make DARs for Data managed by DUOS. A Library Card issued to a particular Library Card Holder also covers access to and use of the specified Data by any person at the same Requestor who reports to the Library Card Holder and by the Internal Collaborators of the Library Card Holder who are employees of Requestor and listed as Internal Collaborators on the specific DAR for access and use of such Data. If a Library Card Holder plans to collaborate with individuals not at the Requestor, the individuals at each such external site must submit an independent DAR. If such a collaborator is not also a Library Card Holder, then such investigator’s DAR will also require such investigator’s Institutional Signing Official’s approval, using the same project title and research use statement. Library Card Holders may be required to have IRB approval if they have access to personal identifying information for Research Participants. The Requestor hereby assures Broad that, when issuing a Requestor Investigator a Library Card, other institutional departments at the Requestor with relevant authorities (*e.g.*, those overseeing

human subjects research, information technology, technology transfer) have also approved such issuance of a Library Card to such Requestor Investigator. Library Cards are not transferable.

The Requestor agrees that if a Library Card Holder changes institutions or leaves the Requestor for any reason during the particular Library Card access period, then the Requestor will notify Broad and ensure that the Requestor Investigator completes the Project Close-Out process before leaving the Requestor. Before the Data covered by such Requestor Investigator's Library Card may be re-accessed, a new DAR with Institutional Signing Official of the new institution's approval (either via submitting such DAR through DUOS or by such new institution agreeing to its own Library Card Agreement and issuing a Library Card thereunder to such Requestor Investigator) must be approved by the applicable DAC.

4. Requestor Responsibilities. The Requestor acknowledges and agrees that, by issuing Library Cards to Requestor Investigators, the Requestor is pre-authorizing such Requestor Investigators to submit DARs directly to one or more DACs managing Data using DUOS, without further Requestor review. By issuing a Library Card to a Requestor Investigator, the Requestor certifies to Broad that the Requestor Investigator is in good standing (*e.g.*, no known sanctions) with the Requestor, relevant funding agencies and relevant regulatory agencies and is eligible to conduct independent research. The Requestor is responsible for ensuring its Library Card Holders submit a Project Renewal or Project Close-Out prior to the expiration date of the one (1) year data access period.

5. Use of Data. The Requestor agrees that Data will only be used for the Project (described in the applicable DAR), only by Authorized Users, and only after such Authorized Users have been informed of and agreed to the provisions and restrictions stated in this Agreement. The Requestor is responsible for ensuring that each Authorized User's access and use of the Data is in accordance with (a) the parameters of the applicable internal research use, as well as any limitations on such use, as described in the DAR and DUOS, (b) all applicable national, tribal, state and other laws, rules and regulations, (c) all professional standards applicable to the use, confidentiality, security and disclosure of such Data, and (c) all applicable institutional policies and procedures for managing sensitive genomic data. Without limiting the generality of the foregoing provisions of this Section 5, the Requestor agrees that the Data will not be sold or offered as the basis for or in conjunction with any service.

6. No Third Party Data Sharing. The Requestor and its Authorized Users will not share Data with any third parties. Any collaborator involved in a Project who works for an institution other than the Requestor must be granted access by the applicable DAC pursuant to an independent DAR submitted to such DAC as described in Section 3 above.

7. Confidentiality. The Requestor agrees that it and all Authorized Users will preserve at all times the confidentiality of the Data and, without limitation, will not use or attempt to use the Data to contact or identify any Research Participant. The Requestor confirms that all Authorized Users receiving access to the Data will have completed all required training (whether on-line or classroom-based) on appropriate handling and protection of human subjects data.

8. Data Security. The Requestor represents and warrants that it has enacted appropriate administrative, technical and physical safeguards to prevent unauthorized use of or access to the Data and will comply with any specific terms included in the data use limitations for specific Data provided by Broad and/or the Data Provider relating to safeguarding of such Data.

9. DUOS. Broad hereby represents and warrants to the Requestor that:

9.1 the Data's *data use restrictions* have been coded in DUOS in accordance with the instructions of the applicable Data Provider;

9.2 each Data Provider has represented to Broad that its Data's *data use restrictions* as coded in DUOS are consistent with the applicable law and applicable consents under which such Data was collected; and

9.3 if Broad is the Data Provider, its Data's *data use restrictions* as coded in DUOS are consistent with the applicable law and applicable consents under which such Data was collected.

10. No Other Representations or Warranties; Disclaimer.

10.1 Except as specifically provided in Section 9 above, DUOS and all Data managed by, made available, accessed and/or used pursuant to this Agreement are provided "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY. WITHOUT LIMITING THE FOREGOING, EXCEPT AS SPECIFICALLY PROVIDED IN SECTION 9 ABOVE, BROAD AND ANY DATA PROVIDERS MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY REPRESENTATION OR WARRANTY (A) REGARDING THE ACCURACY, COMPLETENESS OR CURRENCY OF THE DATA, (B) REGARDING THE ACCESSIBILITY OF THE DATA AND/OR THE CONTINUED OPERATION OF DUOS IN THE MANNER FOR WHICH IT IS INTENDED, (C) THAT THE DATA AND DUOS DO NOT CONTAIN ANY "VIRUS" OR OTHER CODE OR OTHER ITEM OF ANY KIND THAT MAY DISABLE, DISRUPT OR OTHERWISE HARM OR IMPAIR ANY INFORMATION, SOFTWARE, HARDWARE OR OTHER COMPUTER OR NETWORK COMPONENT, (D) REGARDING MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR (E) THAT THE ACCESS TO OR USE OF THE DATA AND/OR DUOS WILL NOT INFRINGE, MISAPPROPRIATE OR OTHERWISE VIOLATE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER INTELLECTUAL OR PROPRIETARY RIGHTS OF ANY PERSON OR ENTITY.

10.2 EXCEPT TO THE EXTENT PROHIBITED BY LAW, IN NO EVENT WILL BROAD OR ANY DATA PROVIDERS BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY OR PUNITIVE DAMAGES ARISING OUT OF OR RELATED TO DUOS AND/OR THIS AGREEMENT, WHETHER OR NOT THE POSSIBILITY OF SUCH DAMAGES WAS REASONABLY FORESEEABLE OR DISCLOSED.

11. Assumption of Liability.

If the Requestor is a Federal or State entity or non-profit organization:

Except to the extent prohibited by law, the Requestor assumes all liability for damages which may arise from its or its Authorized Users' access, use, storage or disposal of the Data. Broad and each Data Provider, and their respective affiliates, and their respective directors, officers, employees, investigators and personnel, and their respective successors, heirs and assigns, will not be liable to the Requestor for any loss, claim or demand made by the Requestor, or made against the Requestor by any other party, due to or arising from

the access, use, storage or disposal of the Data by the Requestor or any Authorized User, except to the extent permitted by law when caused by the gross negligence or willful misconduct of Broad or such Data Provider, as applicable.

If the Requestor is a for-profit organization:

The Requestor agrees to indemnify and hold harmless Broad and each Data Provider, and their respective affiliates, and their respective directors, officers, employees, investigators and personnel, and their respective successors, heirs and assigns, against all claims, losses, expenses and damages (including reasonable attorney's fees) arising out of or relating to the access, use, storage or disposal of the Data by the Requestor or any Authorized User, or any breach of a material provision of this Agreement by the Requestor or any Authorized User, provided that the Requestor's liability to Broad or a given Data Provider, as applicable, will be limited to the extent that any such claim arises out of Broad's or such Data Provider's, as applicable, gross negligence or willful misconduct.

12. Publications. The Requestor and its Authorized Users will acknowledge the contribution of the applicable Data Providers in all Publications resulting from the use of Data.

13. Required Notices. The Requestor will notify Broad in writing:

13.1 of any changes or departures of Authorized Users within thirty (30) days of such event;

13.2 of any change or departure of an Institutional Signing Official within thirty (30) days of such event; provided that until Broad is notified of such change or departure, Broad and the applicable Data Providers may rely on instructions or decisions of the existing Institutional Signing Official;

13.3 immediately in the event of any material change to the protocol for any Project;
and

13.4 immediately upon discovery of a breach of the terms of this Agreement or any DAR.

14. Amendment by Data Provider. The Requestor acknowledges that it may be necessary for a Data Provider to alter the terms of the data use restrictions for its Data from time to time. As an example, this may include specific provisions relating to the Data required by a Data Provider. In the event that changes are required, the Data Provider or its appointed agent will contact the Library Card Holder to inform it of the changes and the Library Card Holder may elect to accept the changes or terminate the applicable DAR and access to such Data.

15. Inspections. If requested, the Requestor will allow data security and management documentation to be inspected by Broad to verify that it and its Authorized Users are in compliance with the terms of this Agreement.

16. Data Provider Rights. The Requestor acknowledges and agrees that the Data Provider of Data made available pursuant to an approved DAR, is an express third party beneficiary of this Agreement and will have the right to enforce the DAR, and the data access and use restrictions of this Agreement, directly against Requestor, without intervention or involvement of any nature from Broad.

17. Non-Use of Names. Neither party will use the other party's (or, except as provided in Section 12, any Data Provider's) name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of such other party (or, in the case of a Data Provider, such Data Provider). In the case of Broad, such approval can only be granted by the Broad's Office of Communications which may be contacted at communications@broadinstitute.org or as otherwise specified on Broad's website. The parties agree that each party may disclose factual information regarding the existence and purpose of the relationship that is the subject of this Agreement for other purposes without written permission from the other party provided that any such statement will accurately and appropriately describe the relationship of the parties and will not in any manner imply endorsement by the other party whose name is being used, and will not violate any confidentiality obligation imposed by any applicable law or regulation or this Agreement.

18. Ownership. As amongst Broad, the Requestor and a Data Provider, Data is owned by the applicable Data Provider, the DUOS system is owned by Broad, and the results of the use of the Data by the Requestor in connection with the Project are owned by the Requestor.

19. Termination.

19.1 Either party may terminate this Agreement upon ninety (90) days' prior written notice to the other party. Any such termination of this Agreement by Broad will not terminate any outstanding DARs hereunder, which will continue until the end of the applicable access period then in effect with respect thereto.

19.2 Either party may terminate this Agreement or any DAR upon written notice if the other party materially breaches this Agreement or such DAR and fails to cure such breach within thirty (30) days following receipt of written notice specifying the breach. Any such termination of this Agreement will automatically terminate all outstanding DARs hereunder, whether pending or approved.

19.3 Broad may terminate any Library Card held by any Requestor Investigator and/or access to Data by any Authorized User immediately upon written notice to the Requestor and such Requestor Investigator or Authorized User, as applicable, if such Requestor Investigator or Authorized User materially breaches this Agreement or any DAR under which it has access to Data. Any such termination will automatically terminate all outstanding DARs submitted by any such Requestor Investigator, whether pending or approved.

19.4 Upon termination of this Agreement or any particular DAR, the Requestor will destroy, or cause any Library Card Holder(s) to destroy, Data downloaded or otherwise held by an Authorized User, including copies and any then-accessible backup copies, under this Agreement and the outstanding DARs or the particular terminated DAR, as applicable. This clause does not prevent the Requestor from retaining Data to the extent necessary to comply with the records retention requirements under any law, and for the purposes of research integrity and verification to the extent such use and purpose is consistent with the terms of this Agreement.

20. Authorized Users. The Requestor agrees to distribute a copy of these terms to the Authorized Users. The Requestor will ensure that all Authorized Users comply with the terms of this Agreement. The Requestor will be responsible and liable to Broad for any acts or omissions of its Authorized Users.

21. Certain Definitions.

21.1 ***Authorized User(s)***: The individuals at the Requestor who are under the supervision of the Library Card Holder or their Internal Collaborators at the Requestor listed on the applicable DAR to whom the applicable DAC grants access to specified Data for a specified period of time and only for the purposes outlined in the Library Card Holder's approved research use statement contained in the applicable DAR. This includes the Library Card Holder.

21.2 ***Data***: The managed access datasets to which a Library Card Holder has requested access.

21.3 ***DAC***: A data access committee that oversees access to Data managed by DUOS on behalf of a Data Provider.

21.4 ***DAR***: A data access request submitted to a DAC for access by one or more specified individuals specifying the Data to which access is sought, and the planned research use. The form of DAR will be as provided in DUOS, and each DAR will be submitted through DUOS. The DAR is signed by the Requestor Investigator requesting the Data. Except to the extent specifically provided in this Agreement, Requestor collaborators and Project team members must be from the same organization.

21.5 ***Data Providers***: The person or entity granting access to the applicable Data managed by DUOS.

21.6 ***Institutional Signing Official***: The individual that has institutional authority to legally bind the Requestor in matters relating to this Agreement. The initial Institutional Signing Official will be as set forth on the signature page to this Agreement. Requestor may change its Institutional Signing Official by providing written notice to Broad. Upon request from time to time, Requestor agrees to confirm to Broad that its Institutional Signing Official is authorized to sign on behalf of Requestor.

21.7 ***Internal Collaborator***: Employees of Requestor not under the supervision of the applicable Library Card Holder but who assist with the Library Card Holder's Project involving the Data as specified in the applicable DAR.

21.8 ***Library Card***: A status which can be issued to a Requestor Investigator by the Requestor through a signed Library Card Agreement and by adding the Requestor Investigator to the Library Card "whitelist" in DUOS in the manner indicated in DUOS, which allows the Requestor Investigator to make future DARs for Data managed by DUOS, without requiring the signature of the Institutional Signing Official on each DAR, for a period of one (1) year.

21.9 ***Library Card Holder***: A Requestor Investigator who has been issued a Library Card.

21.10 ***Project***: A project for which a Library Card Holder has requested access to Data. A description of the applicable Project will be set out in the applicable DAR.

21.11 ***Project Close-Out***: Termination of a Project that used Data from DUOS and confirmation of Data destruction.

21.12 ***Project Renewal***: Renewal of a Requestor Investigator's access to Data for a previously-approved Project.

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

21.14 ***Requestor Investigator***: The principal investigator (or other person specifically approved by the Requestor) for the applicable Project, who prepares DARs, Project Renewals and Project Close-Outs for such Project. To be able to submit a DAR, a Requestor Investigator must be a permanent employee of the Requestor.

21.15 ***Research Participant***: An individual whose data form part of the Data.

22. Entire Agreement. This Agreement and the DARs constitute the entire agreement of the parties with respect to the subject matter hereof and thereof and supersedes all prior oral or written agreements, arrangements or understandings between them relating to such subject matter; provided that neither this Agreement nor any DAR will supersede or replace any agreements between the parties in effect at the time of execution of this Agreement that provide access to particular Data through DUOS.

[SIGNATURE PAGE FOLLOWS]

[SIGNATURE PAGE TO LIBRARY CARD AGREEMENT]

Agreed for Requestor:

Name of Institution:	
Signature:	
Name:	
Title:	
Date:	

Agreed for The Broad Institute, Inc.:

Signature:	
Name:	
Title:	
Date:	

Initial Institutional Signing Official if different from the signatory:

(This space may be left blank, in which case the initial Institutional Signing Official is the signatory of this Agreement)

[illegible]