

## **BROAD DATA USE OVERSIGHT SYSTEM (DUOS)** **DATA SUBMITTER AGREEMENT**

The undersigned (“Data Submitter”) registers to submit Data to the DUOS Dataset Catalog as of the date of Data Submitter’s electronic agreement to these term and conditions (“Registration Date”).

**Introduction.** The Broad Institute, Inc. (“**Broad**”) seeks to improve human health and use science and genomics to advance the understanding of human disease. Enabling widespread access and analysis of scientific data is essential to Broad’s mission and consistent with its tax-exempt status. Through its Data Use Oversight System (“**DUOS**”) Broad registers and enables widespread access to various types of data and materials, including genomic and imaging data to promote global scientific and genomic research. Per these terms and conditions (this “Agreement”), Broad allows the Data Submitter, an institution, to register Data in DUOS and issue permissions to the Data Submitter’s Authorized Submission Representatives (defined below) to register and submit datasets in the DUOS Dataset Catalog (see [https://duos.broadinstitute.org/dataset\\_catalog](https://duos.broadinstitute.org/dataset_catalog), the “Application”) at such Authorized Submission Representatives’ discretion and provided further, the Data Submitter is and remains responsible for its compliance with this Agreement and for compliance herewith by its Authorized Submission Representatives.

To implement DUOS, Broad has entered into, and may in the future enter into, certain “**Library Card Agreements**” with various institutions (each, a “**Requestor**”). The Library Card Agreement (“**LCA**”) enables Requestors to request access to Data through DUOS. A link to the form of LCA and, from time to time, as applicable, any updates thereto, is available via DUOS.<sup>1</sup> Each LCA enables multiple investigators at a Requestor institution (“**Requestor Investigators**”) to request access to Data registered on DUOS. Requestor Investigators are issued Library Cards and are then able to apply for access to Data identified as available on DUOS. Access to any Data registered on DUOS is subject to Requestor’s LCA, review and approval by the data access committee (“**DAC**,” as further defined in Section 15 below) and Data Submitter’s terms and conditions of use coded into DUOS, as more fully provided in Section 1 below.

Data Submitter, from time to time may register Data under its control in DUOS to be matched and made available for access and use by Requestors and their respective Requestor Investigators. Upon DAC approval to grant access to certain specified Data to a Requestor or Requestor Investigator (and the Requestor Investigator’s signed attestation in the data access request, “**DAR**,” see Section 15), that Data’s conditions and terms of use restrictions coded in DUOS bind the authorized user of the Data under the Requestor’s LCA without any further action or documentation by and between Data Submitter and Requestor.

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<sup>1</sup>Broad will not materially change the LCA to accommodate individual Requestors. Broad may modify the form of LCA from time to time, in its sole discretion, including due to modifications or improvements to DUOS.

See Section 15 below for the meaning of certain capitalized terms that are not otherwise defined in the text of this Agreement.

1. **Data Registration.** Data Submitter may register one or more specified datasets to be listed in and managed under DUOS by submitting a Data Registration Form (“**DRF**”) through a live link on DUOS.

Data Submitter shall complete a DRF for each dataset that it seeks to make available through DUOS for matching with Requestor Investigators’ research requests submitted via DUOS. The DRF shall be submitted by an authorized representative of the Data Submitter and include all access criteria and use restrictions applicable to such Data, all in a form and format suitable and compatible for inclusion and coding into DUOS. Broad shall include and code such description(s), access criteria and use restrictions into DUOS, enabling Library Card Holders to request access to such Data through DUOS.

Data Submitter may, at its option, authorize multiple investigators or representatives to submit DRFs for registration of Data on DUOS through the corresponding digital interfaces in the DUOS Application (“Authorized Submission Representatives”). For the avoidance of doubt, Data Submitter (i) is not required to list or register all or any of its Data in DUOS, but may select which Data to register on a dataset by dataset basis; and (ii) may identify multiple Authorized Submission Representatives. Data Submitter shall also be permitted, at its option, to grant access outside of the DUOS system to any Data included in DUOS, it being understood and agreed that Broad shall have no responsibility with respect thereto.

2. **Access to Data.** Data Submitter may establish and maintain a DAC to review, and approve access to its Data registered on DUOS during the Term. Each DAR under a LCA must be submitted directly to a DAC registered in DUOS. Data Submitter shall include the name of the contact person(s) and contact information for the DAC through the DRF, and shall be responsible for updating such information as necessary through the DUOS Application interface. The DAC and not Broad, is responsible for determining whether to grant or deny access to each applicable Data requested under a DAR. Broad shall have no input or decision making responsibility or authority as to any grant or denial of access to any specific Data, which decision shall be in Data Submitter’s DAC’s sole discretion.

Only in the event that such Data access is granted by the DAC, the Data or access to the Data shall be provided to the Library Card Holder.

Broad and Data Submitter expect that Requestors, Library Card Holders, and Authorized Users of Data will recognize and comply with all restrictions on access and use of Data, requirements for confidentiality, security and publication of Data, restrictions on the sharing of Data, all other terms and conditions contained in the applicable LCAs and DARs, any restrictions on such Data use as specified by Data Submitter for inclusion in DUOS and all Applicable Laws. However, Broad shall have no responsibility or liability for any such compliance or non-compliance, or for monitoring or confirming any such compliance by Requestors, Library Card Holders, and Authorized Users of Data. Subject to the provisions of Section 14 (Term and Termination) below and as provided in LCAs, access to any requested Data shall be granted for a renewable period of one (1) year.

3. **Library Cards.** Requestor Investigators granted Library Card permission by each Requestor will be named in such Requestor’s 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 registered on DUOS. Data Submitter understands and agrees that a Library Card issued to a particular Requestor Investigator permits that Requestor Investigator to apply for use of available Data and, once approved by the DAC, permits use of the specified Data, by: (i) any person at the same Requestor who reports to that Library Card Holder; and (ii) the Internal Collaborators (see Section 15) of the Library Card Holder who are employees of Requestor and listed as Internal Collaborators on the DAR for access and use of the specified Data (as provided in the LCA).

**4. Requestor Responsibilities.** Under its LCA each Requestor agrees that, by issuing Library Cards to Requestor Investigators, the Requestor is pre-authorizing its Requestor Investigators to submit DARs directly to the DAC using a live link in DUOS, without further Requestor review. By issuing a Library Card to a Requestor Investigator, each Requestor certifies that the Requestor Investigator is (i) in good standing (*e.g.*, no known sanctions) with the Requestor, relevant funding agencies and relevant regulatory agencies, and (ii) eligible to conduct independent research. In addition, each 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. Data Submitter understands that (i) DUOS identifies Data as available for access upon approval by the DAC, and (ii) under no circumstances does Broad have any responsibility or liability for performance or compliance by any Requestor of its LCA obligations, any of the foregoing certifications or confirming compliance therewith, or for any obligations of a Requestor or its Requestor Investigators to Data Submitter.

**5. Representations and Warranties.** Broad represents and warrants to the Data Submitter that the Data use restrictions furnished by the Data Submitter to Broad via DUOS at the time of coding will be coded in DUOS in accordance with the instructions of Data Submitter. Data Submitter represents and warrants to Broad that (a) its Data's *use restrictions* as coded in DUOS are consistent and sufficient to comply with the Applicable Law and applicable consents under which such Data was collected, and (b) Data Submitter owns or otherwise has the legal right to control access to the Data and has the legal right to grant and provide access to the Data through DUOS subject to the Data use restrictions provided by Data Submitter to Broad via DUOS.

**6. No Other Representations or Warranties; Disclaimer.**

6.1 Except as specifically provided in Section 5 above, DUOS and all Data registered and made available for access, accessed and/or used pursuant to this Agreement and any LCA are provided "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY. WITHOUT LIMITING THE FOREGOING, EXCEPT AS SPECIFICALLY PROVIDED IN SECTION 5 ABOVE, BROAD AND DATA SUBMITTER 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.

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

7. MONETARY LIMITATION OF LIABILITY. EXCEPT AS TO “ASSUMPTION OF LIABILITY AND INDEMNIFICATION” IN SECTION 8 BELOW, THE MAXIMUM LIABILITY OF EITHER PARTY TO THE OTHER PARTY FOR CLAIMS ARISING FROM OR RELATING TO THIS AGREEMENT SHALL BE THE GREATER OF THE MONETARY AMOUNT RECEIVED BY BROAD FROM DATA SUBMITTER UNDER THIS AGREEMENT, IF ANY, OR THE TOTAL SUM OF ONE THOUSAND U.S. DOLLARS (\$1000).

THE FOREGOING LIMITATIONS APPLY REGARDLESS OF WHETHER THE CLAIM IS BROUGHT UNDER CONTRACT, TORT, WARRANTY OR OTHERWISE.

8. **Assumption of Liability and Indemnification.**

***If the Data Submitter is a Federal or State entity or non-profit organization:***

Except to the extent prohibited by law, Data Submitter assumes all liability for damages which may arise from any Requestor's or its Authorized Users' access, use, storage or disposal of the Data and that under no circumstances will Broad, and its respective affiliates, and their respective directors, officers, employees, investigators and personnel, and their respective successors, heirs and assigns, be liable to Data Submitter for any loss, claim or demand made by Requestor, or made against Requestor by any other Party, due to or arising from access, use, storage, transfer or disposal of the Data by Requestor or any Authorized User, except to the extent permitted by law when caused by the gross negligence or willful misconduct of Broad.

***If the Data Submitter is a for-profit organization:***

Data Submitter hereby indemnifies and holds harmless Broad and each of its affiliates, and their respective directors, officers, employees, investigators and personnel, and successors, heirs and assigns, against all claims, losses, expenses and damages (including reasonable attorney's fees) arising out of or relating to this Agreement or the access, use, storage, transfer or disposal of any Data by any Requestor, its Authorized Users or any third party, or any breach of a material provision of this Agreement by the Data Submitter, except to the extent that any such claim arises out of Broad's gross negligence or willful misconduct.

## **9. Notices.**

9.1 Data Submitter will promptly update the DUOS Application interfaces, according to any changes or departures of Authorized Submission Representative(s).

**10. Amendment of Use Restrictions by Data Submitter.** Broad acknowledges that it may be necessary for Data Submitter 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 Data Submitter. In the event that changes are required, Data Submitter, by an Authorized Submission Representative, will contact the Library Card Holder directly to inform it of the changes in writing and the Library Card Holder may elect to accept the changes or terminate the applicable DAR and access to such Data.

**11. Data Submitter Rights.** Pursuant to each LCA, each Requestor agrees that Data Submitter under an approved DAR is an express third party beneficiary of the LCA. Data Submitter has the right to enforce the DAR, the data access and use restrictions of a LCA and all restrictions in an approved DAR, directly against each Requestor, without any obligation, intervention or involvement of any nature from Broad. Broad has no responsibility for any data access and use restrictions of a LCA or DAR breach or enforcement thereof, all of which are the sole rights and obligations of the Data Submitter.

Notwithstanding the foregoing, Data Submitter shall promptly notify Broad in writing in the event of any LCA or DAR enforcement action or activity, or any claim or dispute with respect thereto, and of any termination by Data Submitter of any DAR approval and/or access rights to any Data due to non-compliance or breach by any Requestor, Library Card Holder or other Authorized User, of any DAR or any data access and use restrictions. In the event of termination of an approved DAR, Data Submitter may, independently and in its sole discretion, remove access permissions granted by the DAC in the applicable repository for such Data outside of DUOS.

**12. Non-Use of Names.** Neither Party will use the other Party's (or any Requestor'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 Requestor, such Requestor). In the case of Broad, such approval can only be granted by Broad's Office of Communications which may be contacted at [communications@broadinstitute.org](mailto:communications@broadinstitute.org) or as otherwise specified on Broad's website. Each Party may disclose factual information regarding the existence and purpose of this Agreement without written permission from the other Party, provided that any such statement accurately and appropriately describes 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.

**13. Ownership.** As amongst Broad, the Requestor and a Data Submitter, Data is owned by the Data Submitter, 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.

## **14. Termination.**

14.1 This Agreement shall commence as of the Registration Date and continue in full force and effect until terminated by a Party as provided in this Section 14 ("Term").

14.2 Either Party may terminate this Agreement upon ninety (90) days' prior written notice to the other Party. Any such termination of this Agreement will not terminate any outstanding approved DARs with respect to any Data under any LCA, which will, so long as Broad continues to use and manage DUOS as contemplated by this Agreement, continue until the end of the applicable access period then in effect under an approved DAR.

14.3 Either Party may terminate this Agreement upon written notice if the other Party materially breaches this Agreement 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 not terminate any outstanding approved DARs with respect to any Data under any LCA, which will, so long as Broad continues to use and manage DUOS as contemplated by this Agreement, continue until the end of the applicable access period then in effect under an approved DAR.

## **15. Certain Definitions.**

15.1 ***Applicable Laws:*** All Federal, state, local and foreign statutes, ordinances, regulations, rules, laws, codes, and other legal requirements of any type of any governmental authority (collectively, "***Laws***"), including, without limitation, all applicable Laws concerning the privacy, protection, processing, storage, access, use, exchange, disclosure, transfer, disposal and/or security of personal information or other data, including without limitation, (i) the Health Insurance Portability and Accountability Act of 1996, PL 104-191 (HIPAA), as modified by the Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of the American Recovery and Reinvestment Act of 2009, PL 1105; (ii) the Patient Protection and Affordable Care Act, Public Law 111-148; and (iii) the European General Data Protection Regulation (GDPR), EU Directive 95/46/EC, and EU Directive 2002/58/EC.

15.2 ***Authorized User(s):*** The individuals at Requestor who are under the supervision of the Library Card Holder or their Internal Collaborators at Requestor listed on the applicable DAR to whom the 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.

15.3 ***Data:*** The data and materials, including genomic and imaging datasets owned (or to which access is otherwise controlled) by Data Submitter, which are listed on DUOS for managed access and to which a Library Card Holder has requested access.

15.4 ***DAC:*** A data access committee established by Data Submitter that grants or denies access to Data contributed by the Data Submitter and registered on DUOS on behalf of the Data Submitter.

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

15.6 ***Institutional Signing Official:*** The individual that has institutional authority to legally bind the Requestor in matters relating to such Requestor's LCA, as named from time to time pursuant to the terms thereof.

15.7 ***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.

15.8 ***Library Card:*** A status which can be issued to a Requestor Investigator by the Requestor through a signed LCA 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.

15.9 ***Library Card Holder:*** A Requestor Investigator who has been issued a Library Card pursuant to the terms of a LCA.

15.10 ***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.

15.11 ***Project Close-Out:*** Termination of a Project that used Data from DUOS and confirmation of Data destruction, as applicable.

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

15.13 ***Requestor Investigator:*** The principal investigator (or other person specifically approved by the applicable 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.

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

**16. Entire Agreement.** This Agreement constitutes the entire agreement of the parties with respect to the subject matter hereof and supersedes all prior oral or written agreements, arrangements or understandings between them relating to such subject matter.

[SIGNATURE PAGE FOLLOWS]

[SIGNATURE PAGE TO DATA SUBMITTER AGREEMENT]

**Agreed for Data Submitter:**

<b>Name of Institution:</b>	
<b>Signature:</b>	
<b>Name:</b>	
<b>Title:</b>	
<b>Date:</b>	

Data Submitter represents that the above signature is by a signatory authorized to legally bind the Data Submitter.

**Agreed for The Broad Institute, Inc.:**

<b>Signature:</b>	
<b>Name:</b>	
<b>Title:</b>	
<b>Date:</b>	

**Data Submitter's Authorized Submission Representative(s):**

<b>Name:</b>	
<b>Title:</b>	
<b>Email:</b>	
<b>Telephone:</b>	

<b>Name:</b>	
<b>Title:</b>	
<b>Email:</b>	
<b>Telephone:</b>	