

# LIBRARY CARD AGREEMENT

*(November 17, 2022, version)*

## INTRODUCTION

This Agreement outlines the terms and conditions pertaining to the issuance by a requesting institution (the Requester) of Library Cards to specific investigators employed by that institution for the purpose of accessing controlled-access data through the National Human Genome Research Institute (NHGRI) Analysis, Visualization, and Informatics Lab-space (AnVIL) platform, an NIH-designated data repository. Controlled-access datasets are maintained in AnVIL per the expectations of the [NIH Genomic Data Sharing Policy](#). All terms set forth in the [NIH Data Use Certification \(DUC\) Agreement](#) (except to the extent expressly modified herein) are hereby incorporated herein by reference and apply to future data access requests for datasets by Library Card Holders under this Agreement.

## STATEMENT OF POLICY

This Agreement contains the terms of access to controlled-access datasets maintained in AnVIL under the NIH Genomic Data Sharing Policy. This Agreement allows Requester to pre-authorize Principal Investigators (PIs) to submit a Project directly in DUOS without requiring additional individual institutional review and signature. NHGRI maintains the expectation that Approved Users of controlled-access datasets will abide by their responsibilities under the NIH Genomic Data Sharing Policy.

Underlined terms in this document are defined in the DUC Agreement. Modifications to terms as they pertain to this Agreement as well as new terms are listed below.

## AGREEMENT

The parties to this Agreement are: (1) the Requester that will be granting Library Card access to PIs seeking access to genomic datasets (a Library Card Holder as further defined below), as represented by the Institutional Signing Official designated through the eRA Commons system (or equivalent authentication system), and (2) NHGRI, an institute within the NIH. The effective date of this Agreement will be the date specified in the notification of approval of this Agreement. This Agreement has a one-year term and may be renewed annually, as needed. The Requester will remain responsible and liable to NIH for any acts or omissions as outlined below and as specified in the DUC Agreement of any of its Library Card Holders.

## TERMS OF ACCESS

- Requesters issuing Library Cards to PIs acknowledge they are pre-authorizing PIs to submit a Project (made up of one or more Data Access Requests (DARs)) directly to in DUOS without Requester review of individual Projects for controlled-access datasets in AnVIL under the NIH Genomic Data Sharing Policy.
- Library Card Holders can submit DARs for controlled access datasets maintained in AnVIL under the NIH Genomic Data Sharing Policy, without requiring the approval of the Institutional Signing Official for each Project.
- By signing this Agreement, the Requester agrees to their responsibilities as outlined in the DUC Agreement, including any dataset-specific restrictions (e.g., Data Use Limitations) of a particular DAR. Library Card Holders will continue to sign a DUC Agreement, including the study specific

Addendum to the DUC Agreement, for each individual DAR in order to acknowledge their responsibilities under the DUC Agreement. Though Projects will not be individually signed by the Institutional Signing Official, the Requester acknowledges that the references to “this DAR” in the DUC Agreement is applicable to all future DARs submitted by a Library Card Holder to which they have issued a Library Card.

- Upon issuing a Library Card the Requester will list the Information Technology (IT) Director (e.g., the Chief Information Officer, Information System Security Officer, or equivalent for the Institution) that will be associated with any future DARs made by the Library Card Holder. The IT Director will fulfill the role as outlined in the DUC Agreement, as needed, upon any egress of data from AnVIL.
- The Requester is responsible for ensuring its Library Card Holders use the dataset(s) only in accordance with the parameters described in the DUC Agreement, the study specific Addendum to the DUC Agreement, and on the repository study page, for the approved research use as described in the DAR, and as required by law.
- The Requester agrees that the PIs to which they issue a Library Card will be named on the list of approved Library Card Holders, which is maintained in the Data Use Oversight System (DUOS) maintained and operated by The Broad Institute, Inc. or one of its affiliates.
- External Collaborators must independently be approved for the Project, either as a Library Card Holder in DUOS or via dbGaP.
- The Requester agrees that, like the initiation of a DAR, Library Card Holders are pre-approved to renew DARs (Project Renewal).
- Project Close-Out of approved Projects or individual DARs made by a Library Card Holder will require Institutional Signing Official review and approval.
- The Requester agrees that if a Library Card Holder changes institutions during the access period, they will notify the NIH and ensure that the PI completes the Project Close-out process (See the DUC Agreement for more details) before moving to their new institution.
- The Requester will be notified if a Data Management Incident involving a Library Card Holder is found by or reported to the NIH.
- The Requester acknowledges that the NIH may terminate a Library Card and immediately revoke or suspend access to all controlled-access datasets subject to the NIH Genomic Data Sharing Policy at any time if the Requester, PI, or Approved User is found to be no longer in agreement with the principles outlined in the NIH Genomic Data Sharing Policy, the terms described in this Agreement, the DUC Agreement, or the “Genomic Data User Code of Conduct.”

## **ORDER OF PRECEDENCE**

In the event of any inconsistency between the terms of the DUC Agreement and this Agreement, the inconsistency shall be resolved by giving precedence in the following order: (1) the DUC Agreement and any other data use attestations specific to the datasets requested (e.g., study specific Addendum to the DUC Agreement), (2) this Agreement.

## **DEFINITIONS**

**Data Use Certification (DUC) Agreement:** An agreement between the Approved User, the Requester via the Library Card Agreement, and NIH regarding the terms associated with access to controlled-access datasets subject to the NIH Genomic Data Sharing Policy and the expectations for use of these

datasets.

**Institutional Signing Official:** The label, “Signing Official,” is used in conjunction with the [NIH eRA Commons](#) and refers to an individual who has institutional authority to legally bind the institution in grants administration matters. The individual fulfilling this role may have any number of titles in the institution, but is typically located in its Office of Sponsored Research or equivalent. The Signing Official for the Requester issues Library Cards and reviews Project and DAR Close-out applications submitted by Principal Investigators and legally binds the Requester to agree to adhere to the terms described in this Agreement if the application is submitted to NIH. The Institutional Signing Official for the Submitting Institution enters into the Institutional Certification and signs on behalf of the Submitting Investigator(s) who has submitted data.

**Library Card:** A status which can be issued to PIs by their Requester, as represented by the Institutional Signing Official, that allows approved PIs to make future DARs for controlled-access datasets maintained in AnVIL under the NIH Genomic Data Sharing Policy, without requiring the signature of the Institutional Signing Official on each Project, for a period of one (1) year.

**Library Card Holder:** A PI who has been issued a Library Card by their Requester, as represented by the Institutional Signing Official.

**Project Close-out:** Termination of a research project that used controlled-access data from an NIH-designated data repository (e.g., dbGaP or AnVIL), final reporting of all research uses of the data and any resulting publications or presentations using the data, and confirmation of data destruction when the research is completed and/or discontinued. The Project close-out process is completed in DUOS and requires certification by the Institutional Signing Official.