



GREGoR Consortium Data Sharing Agreement

For use by and among
Members of the GREGoR Consortium

Date Approved: April 20, 2022

Date of Last Update: May 9, 2022

Version: 1.0

Terms and Definitions

The [GREGoR Consortium \(Genomics Research to Elucidate the Genetics of Rare diseases\)](#) seeks to develop new methods and approaches to understand the genetic cause of rare conditions. The Consortium includes five Research Centers, a Data Coordinating Center (DCC), NIH/ NHGRI program staff, and other collaborators and research groups studying the genomics of rare diseases who wish to become Partner Members.

GREGoR members (“GREGoR Members” or “Members”) include the institutions funded through the primary GREGoR grant mechanisms (Research Centers and the DCC). GREGoR Partner Members are investigators not funded by the primary NHGRI awards to the GREGoR Consortium but who have applied and have been approved to join the program as non-voting Partner Members, as described in the “GREGoR Consortium Partner Membership Policy”. In this agreement, MEMBERS is used to refer to the signatories of this GREGoR Data Sharing Agreement, who can be either GREGoR Members or GREGoR Partner Members. “MEMBER Representatives” include the investigators, fellows, students, research staff directly involved in GREGoR-related projects, and GREGoR Grant Sub Contract recipients. This Agreement is intended to establish operating principles to promote collaboration and facilitate Data sharing between MEMBERS to enable successful analyses of the GREGoR Data and to generate the outcomes and resources discussed in the original NIH Funding Opportunity Announcements for GREGoR (RFA-HG-20-007, RFA-HG-20-008). “GREGoR Data” (or “Data”) is defined as follows: phenotypic data, genotyping data, nucleic acid sequence data, multi-omic, biomarker, “Scientific Data” as defined in the [Final NIH Policy for Data Management and Sharing](#) (see section ‘Definition of “Scientific Data”’), preliminary analyses, re-processed, derived, and associated metadata generated from samples collected and/or sequenced under the primary GREGoR grant mechanisms outlined above and that is shared under this Agreement. It is the expectation and intent of the parties that all Data will be de-identified and no Protected Health Information (as defined by applicable Federal law) will be shared or transmitted under this Agreement. MEMBERS shall share GREGoR Data with other MEMBERS who have signed this

Agreement and with any future MEMBERS who sign this Agreement. In addition, GREGoR Members have direct collaborative relationships with investigators who provide samples and who may participate in analyses. Such collaborative relationships should be established according to the requirements of the associated institutions and may include separate agreements (i.e., GREGoR Investigator collaboration agreement) with terms consistent with this Agreement.

Data Sharing Guiding Principles

All data sharing under this Agreement will adhere to 1) the terms of consent agreed to by research participants and/or NIH Institutional Certifications; 2) applicable laws and regulations; 3) NIH data security policies and guidelines. These principles are intended to maximize sharing of the Data generated by MEMBERS among and between other MEMBERS as well as with the wider scientific community, and to do this without compromising data security or the confidentiality of information about individuals whose Data and/or samples are used for research. Prior to sharing any Data, MEMBERS sharing the Data (both the originating MEMBER and the receiving MEMBER) shall agree to reasonable terms on the transmission and use of the Data and shall adhere to all Federal and State laws, regulations and requirements when sharing and transmitting the Data. For clarification, the DCC may assist the other MEMBERS in sharing Data, but shall not comment on or validate whether the Data sharing meets all standards or requirements.

Data Sharing Responsibilities

Each MEMBER may collaborate in GREGoR research studies by sharing Data as follows: (1) distribution through the NIH database of Genotypes and Phenotypes (dbGaP) or other NIH-designated repository (e.g. NHGRI Analysis Visualization and Informatics Lab-space, [AnVIL](#)); (2) distribution within the GREGoR Consortium to the MEMBERS who have a need for such Data and who adhere to the Data Sharing Guiding Principles (preceding paragraph); and/or (3) distribution to the DCC. Each MEMBER is obliged to deposit the Data they produce into dbGaP or other NHGRI-designated archive either directly or via an intermediary and to adhere to the NIH Genomic Data Sharing Policy. With prior approval, MEMBERS may aggregate GREGoR Data from any MEMBER and, may submit said aggregate GREGoR Data to dbGaP and/or other databases administered by the NIH. Prior to sharing any GREGoR Data externally, the MEMBER wishing to share the Data must receive written permission from the originating MEMBER. MEMBERS sharing GREGoR Data externally must also ensure that each external GREGoR Data recipient agrees to the same restrictions and conditions applicable to MEMBERS and MEMBER Representatives regarding the use and disclosure of the GREGoR Data or as may be required by law. GREGoR Data may be shared by Members with their Supporting Organizations (e.g., organizations that provide direct services such as sequencing on Member-provided samples, site-initiated subcontracted services and/or other services required for GREGoR sanctioned studies), provided that said Supporting Organizations are held to all applicable and stated standards herein.

Nature of Information

By signing this Agreement, the MEMBER certifies that its MEMBER Representatives are aware of the sensitive nature of the data on research participants maintained by the MEMBER and of the necessity for maintaining its security and privacy. The MEMBER agrees not to attempt to personally identify any GREGoR participant based on GREGoR Data and agrees not to attempt to contact any GREGoR participant of a center other than their own. The MEMBER agrees not to transfer or disclose any confidential data or any information about individual GREGoR participants, except as permitted by this Agreement or as required by law, either during or after the conclusion of the affiliation with GREGoR. The MEMBER agrees to provide adequate security for the GREGoR Data, including but not limited to safeguards intended to prevent unauthorized use or disclosure of such information. In addition each MEMBER agrees to report in writing to the other MEMBERS any use or disclosure of any portion of the Data of which it becomes aware that is not permitted by this Agreement including disclosures that are required by law. The MEMBER agrees to ensure that its MEMBER Representatives do not use, disclose or transfer any GREGoR Data to anyone except as permitted by this Agreement, permitted by the originating MEMBER in writing, or as required by law. Further, if/when the MEMBER terminates its affiliation with the GREGoR Consortium, the MEMBER agrees to either delete/destroy all received shared electronic GREGoR Data and to notify the DCC when it has done so or to separately negotiate single-party agreements in order to continue Data sharing.

Limitations of Data Use

The MEMBER agrees to ensure that MEMBER Representatives will only use GREGoR data in a manner that is consistent with any limitations that have been specified for individual studies by the disclosing MEMBER. Each MEMBER shall ensure compliance with all applicable state and federal laws, regulations and requirements governing the use of such Data.

Disclaimer

MEMBERS MAKE NO WARRANTIES, EXPRESSED OR IMPLIED, AS TO ANY MATTER WHATSOEVER, INCLUDING WITHOUT LIMITATION, THE ACCURACY, AUTHENTICITY, COMPLETENESS, OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE DATA PROVIDED. MEMBERS SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, CONSEQUENTIAL, OR OTHER DAMAGES SUFFERED BY OTHER GREGoR MEMBERS OR ANY OTHERS RESULTING FROM SHARING DATA UNDER THIS AGREEMENT.

Electronic Execution

Each MEMBER intends that an electronic copy of its signature stored in a PDF software application format shall be regarded as an original signature and agrees that this Agreement may be executed in any number of counterparts, each of which shall be effective upon delivery and thereafter shall be deemed an original, and all of which shall be taken to be one and the

same instrument.

Miscellaneous

This Agreement shall be for a term of one (1) year from the last date of signature below and shall automatically renew for an additional one (1) year term each year until the GREGoR Consortium terminates. A MEMBER may terminate this Agreement, with respect to the MEMBER's participation in GREGoR, with thirty (30) days written notice to the DCC. The MEMBER agrees to comply with all established policies of GREGoR governing the acquisition, analysis, reporting, publication, use and distribution of GREGoR Data. This Agreement supersedes and replaces any conflicting agreements made between MEMBERS regarding the sharing and confidentiality of GREGoR Data.

[Signature Page to Follow]

Signatures

The MEMBER (GREGoR Member or GREGoR Partner Member) has received authorization for the MEMBER's Institution to sign on their behalf. Each MEMBER certifies that it has the authority to distribute the GREGoR Data to other MEMBERS. The party below has caused this Agreement to be executed by their duly authorized representatives and effective as of the date below.

Electronic signatures may count as originals.

Name of MEMBER Institution

MEMBER Institution's Authorized Official's name and title (printed)

MEMBER Institution's Authorized Official's signature

Date

Read and understood by:

MEMBER PI name and title


MEMBER PI signature

Date

Glossary

- **GREGoR Member:** Institutions funded through the primary GREGoR grant mechanisms (i.e., Research Centers and the DCC) and whose PIs and institutions are signatories of this GREGoR Data Sharing Agreement.
- **GREGoR Partner Member:** GREGoR Partner Members are investigators not funded by the primary NHGRI awards to the GREGoR Consortium but who have applied and have been approved to join the program as non-voting Partner Members. The terms of the Partner Membership and the process for becoming a Partner Member are described in the “GREGoR Consortium Partner Membership Policy” (see [GREGoR Policies](#)). Partner Members can be signatories of this GREGoR Data Sharing Agreement.
- **MEMBERS:** In this agreement, MEMBERS is used to refer to the signatories of this GREGoR Data Sharing Agreement, who can be either GREGoR Members or GREGoR Partner Members.
- **MEMBER Representatives:** The investigators, fellows, students, research staff directly involved in GREGoR-related projects, and GREGoR Grant Sub Contract recipients. The MEMBER agrees to ensure that its MEMBER Representatives do not use, disclose or transfer any GREGoR Data to anyone except as permitted by this Agreement. MEMBER Representatives are held to all applicable and stated standards herein.
- **GREGoR Investigator Collaborator:** Investigators who provide samples for and who may participate in analyses who have direct collaborative relationships with GREGoR Members. The terms of the collaboration are detailed in the “GREGoR Investigator collaboration agreement”.
- **GREGoR Supporting Organization:** GREGoR Supporting Organizations provide direct services to GREGoR Members, such as, sequencing on Member-provided samples, site-initiated subcontracted services and/or other services required for GREGoR sanctioned studies. GREGoR Data may be shared by GREGoR Members with their Supporting Organizations, provided that Supporting Organizations are held to all applicable and stated standards herein.
- **GREGoR Data:** phenotypic data, genotyping data, nucleic acid sequence data, multi-omic, biomarker, "Scientific Data" as defined in the [Final NIH Policy for Data Management and Sharing](#) (see section 'Definition of “Scientific Data”'), preliminary analyses, re-processed, derived, and associated metadata generated from samples collected and/or sequenced under the primary GREGoR grant mechanisms.

Change Log

- V1.0 - Initial Policy approved by GREGoR Steering Committee on April 20, 2022 with minor updates implemented on May 9, 2022.
- V0.1 - Based on  [GSP example DSA 2016-07-25.pdf](#)