

MSSNG
A Program of Autism Speaks Inc.
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DATA SHARING POLICY AND PROCEDURES
(VERSION 10.0)

1. Introduction

MSSNG is a groundbreaking program sponsored by Autism Speaks Inc. (“**AS**”) to create the world’s largest genomic database on autism; AS and any other organizations that AS elects to collaborate with as co-sponsors of MSSNG are referred to herein as the “**Sponsor**” of MSSNG.

The goal of MSSNG is to sequence the DNA of over 10,000 individuals from families affected by autism and provide the whole genome sequencing results and associated phenotype data to the researcher community in a cloud environment for research and analysis (the “**MSSNG Database**”). Through MSSNG, authorized researchers will have access to a large database of whole genome sequenced data on thousands of autism cases, which should speed discovery of autism etiology, treatments, and ultimately cures. It is the policy and objective of MSSNG to make the MSSNG Database available to the broadest possible research community, as quickly as possible.

The MSSNG Database contains Research Data, WGS Data, Researcher Provided Data and other data or information that the Sponsor elects to make available through MSSNG (collectively, “**MSSNG Data**”). MSSNG Data will be obtained from (or derived from biomaterials provided by) retrospectively and prospectively recruited cohorts of Participants (defined below), where appropriate Review Board (defined below) waivers are obtained..

This MSSNG Data Sharing Policy and Procedures (this “**Policy**”) (1) states the policy of MSSNG with respect to access by researchers to the MSSNG Database and the downloading by researchers of copies of MSSNG Data from the MSSNG Database; and (2) addresses the procedures for approval of individual researchers to access the MSSNG Database. This controlled access is to be offered to researchers from around the world who are conducting research on autism spectrum and related conditions. The accessible data will include whole genome sequencing data as well as coded phenotype information.

2. Definitions

“**Access Authorization Letter**” means the formal letter sent by the Coordinating Center to the Researcher to advise him/her of the decision of the DACO in connection with the Researcher’s Research Application.

“**AS**” means Autism Speaks Inc.

“**Access Renewal Letter**” means the formal letter sent by the Coordinating Center to the Researcher to advise him/her of the decision of the DACO in connection with the Researcher’s Renewal Form.

“**Consultant**” means Public Population Project in Genomics and Society (P3G) or such other independent consultant as Sponsor may appoint from time to time.

“**Coordinating Center**” means the Sponsor’s MSSNG Coordinating Center.

“**DACO**” means MSSNG’s independent Data Access Compliance Office.

“**Database Access Agreement**” or “**DAA**” means the database access agreement between Researcher, the Institution (if any) and the Sponsor that sets forth the terms and conditions regarding access by a Researcher to the MSSNG Database. The form of DAA that is in effect at any given time is available on the MSSNG Website.

“**Genomic Discovery Operating Committee**” or “**GDOC**” means an expert committee appointed by the Sponsor that oversees the MSSNG Database.

“**Institution**” means the organization at which the Researcher is employed, affiliated or enrolled.

“**MSSNG Data**” means Research Data, WGS Data and Researcher Provided Data and other data or information that the Sponsor elects to make available through MSSNG.

“**MSSNG Database**” means the cloud based data environment maintained by the Sponsor as part of MSSNG that stores MSSNG Data.

“**MSSNG Website**” means the MSSNG website at research.mss.ng.

“**Participant**” means a provider of biological materials and/or Research Data that is used as part of MSSNG whether contributed by a Sponsor or a third party organization.

“**Policy**” means this MSSNG Data Sharing Policy and Procedures.

“**Research Data**” means information concerning Participants, which may include family configuration, age at time of testing, sex, psychopathology, diagnosis, cognitive functioning, family and medical history, and any other clinically relevant information collected by or on behalf of the Sponsor or by a third party research organization. Research Data will not include any personally identifying information about the Participant, his/her family or its members.

“**Renewal Form**” means the form submitted by Researcher to renew access to the MSSNG Database, which will be reviewed and approved in accordance with this Policy. The form of Renewal Form that is in effect at any given time is available on the MSSNG Website.

“Research Project” means the research project that a Researcher intends to conduct using MSSNG Data accessed through the MSSNG Database as described in the Researcher Application.

“Research Team” means the individuals who will assist the Researcher on the Research Project.

“Researcher” means a person seeking access to MSSNG Database in accordance with this Policy.

“Researcher Application” means the application submitted by Researcher to obtain access to the MSSNG Database, which will be reviewed and approved in accordance with this Policy. The form of Researcher Application that is in effect at any given time is available on the MSSNG Website.

“Researcher Provided Data” means any and all data provided by another researcher other than you or your Research Team (defined below) to the Sponsor for inclusion in the MSSNG Database.

“Review Board” means the Institutional Review Board (“**IRB**”), Research Ethics Committee (“**REC**”), Research Ethics Board (“**REB**”) or another equivalent body under the laws or regulations governing a Researcher and a Research Project.

“Sponsor” means AS and any other organizations that AS elects to collaborate with as co-sponsors of MSSNG.

“WGS Data” means whole genome sequencing data derived from the biological materials of Participants collected by or on behalf of a Sponsor.

3. Governance

The MSSNG Database is subject to oversight by an expert committee appointed by the Sponsor (the “**Genomic Discovery Operating Committee**” or “**GDOC**”).

The Sponsor’s MSSNG Coordinating Center (the “**Coordinating Center**”) and MSSNG’s independent Data Access Compliance Office (the “**DACO**”) will have the responsibility for implementing this Policy as set forth herein. The Coordinating Center and the DACO will provide reports to the GDOC regarding implementation of this Policy.

The independent DACO will be composed of a minimum of 5 members: one autism research expert, one legal/ethical expert, one expert on the legal/ethical aspects of pediatric research, one bioinformatics/privacy expert, and one member of the autism community, in each case appointed by the Public Population Project in Genomics and Society or such other independent consultant as Sponsor may appoint from time to time (“**Consultant**”), and one individual from Consultant.

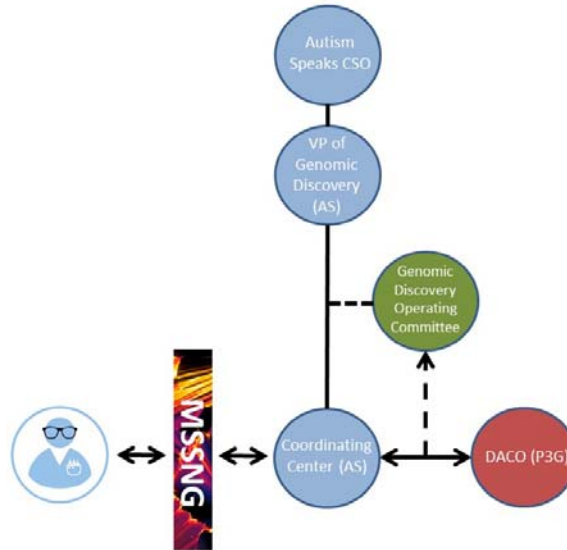


Figure 1: MSSNG Database Governance

4. Application Procedure

In order to access the MSSNG Database, a Researcher must apply for and receive approval for access to the MSSNG Database in accordance with the following procedures.

Step 1: Completion of Researcher Application

A Researcher must complete a Researcher Application and sign and submit a DAA. The Researcher Application will require the Researcher to provide:

- Name and credentials of the Researcher for the proposed Research Project;
- Institutional affiliation (if applicable);
- List of all individuals who will assist the Researcher on the Research Project (the “**Research Team**”), with their respective job titles, institutional affiliations and institutional e-mail addresses;
- Title of the Research Project;
- Research question proposed to be answered by the Research Project (as it relates to autism spectrum disorder or related conditions) in no more than 500 words;
- Summary of Research Project suitable for a lay audience in no more than 200 words);
- Country(ies) where the Research Project will be conducted and downloaded copies of MSSNG Data will be held;
- Description of MSSNG Data proposed to be downloaded from the MSSNG Database;
- Confirmation that the Researcher and Institution, if any, has implemented the minimum data security safeguards described in Section 7;

- Confirmation that a Review Board has approved the Researcher's use of MSSNG Data, including the name of the approved protocol, the date of approval and the name, address and email address of the Review Board, or, if the Research Project does not require approval of a Review Board, an explanation as to why Review Board approval is not required;
- List of up to 5 peer reviewed publications by the Researcher; and
- If the Researcher is not affiliated with an Institution, an up-to-date curriculum vitae and names and addresses of two references who have agreed to be contacted.

The DAA must be signed by the Researcher and by an authorized representative of the Institution (if any).

Step 2: Submission of the Researcher Application

The completed Researcher Application and signed DAA must be sent to the Coordinating Center by e-mail or mail as follows:

Email: coordinatingcenter@mss.ng

Mail: MSSNG
Autism Speaks Inc.
85 Devonshire St, 9th Floor
Boston, MA 02109
Attention: Jenna Whooley

Step 3: Review by the Coordinating Center

Once the Researcher Application and DAA are received, the Coordinating Center will review the Researcher Application to confirm the following:

- The Researcher Application is complete and the DAA has been properly completed and signed;
- The Researcher is not on a debarment list (USA);
- The Research Project is feasible given the resources in the MSSNG Database; and
- The Research Project has scientific validity, including whether the research question proposed to be answered is relevant to the objectives of MSSNG and the scope of the Research Project is relevant to autism spectrum or related conditions.

Step 4: Review by the Data Access Compliance Office

Once the Coordinating Center has confirmed the matters described in Step 3 above, the Researcher Application and the DAA will be submitted by the Coordinating Center to the independent DACO for review. The DACO will have the discretion to approve or decline a Researcher Application based on ethical, scientific, programmatic or other relevant considerations. Among other things, the DACO may consider the following criteria:

- The Researcher is qualified to conduct the Research Project and undertake the proposed analysis;
- The Researcher has confirmed that the minimum data security safeguards described in Section 7 have been implemented;
- The Researcher has confirmed that Review Board approval has been obtained, or, if no confirmation of Review Board approval is provided, whether the explanation as to why Review Board approval is not required is adequate; and
- The lay summary of the Research Project is comprehensible to the general public.

For Researcher Applications from Researchers who are affiliated with known institutions, the DACO will endeavor to render its decision within 5 business days after receipt by the DACO of the Researcher Application. For the avoidance of doubt, Researcher Applications will be considered from Researchers who do not have an institutional affiliation, but review of such Researcher Applications is likely to take more time.

Step 5: Notification of Decision

The DACO will submit to the Coordinating Center its decision as to whether a Researcher Application is approved, declined or conditionally approved. The Coordinating Center will then send a formal letter (the “**Access Authorization Letter**”) to the Researcher to advise him/her of the decision. A copy of the Access Authorization Letter will also be provided to the DACO.

If the DACO has approved a Researcher Application, the Access Authorization Letter will assign access to the email address provided by the researcher(s) in the application. This account will be owned by the researcher and all costs associated with work undertaken in that account will be the responsibility of the researcher.

The Access Authorization Letter will also be accompanied with a copy of the DAA executed by the Sponsor. The DAA will govern the Researcher’s access to the MSSNG Database. The terms of the DAA will prevail over any inconsistent terms of this Policy, the MSSNG Website or elsewhere, and over any oral or written statement made by the staff of the Coordinating Center or of the DACO or any other representative of the Sponsor.

If the DACO has conditionally approved a Researcher Application, the Access Authorization Letter will set forth the additional information required to be submitted to the Coordinating Office. Upon receipt of such additional information, the Coordinating Office and the DACO will review the Researcher Application, together with the additional information in accordance with Steps 3 and 4 above, and a notification of the decision of the DACO will be provided in accordance with this Step 5.

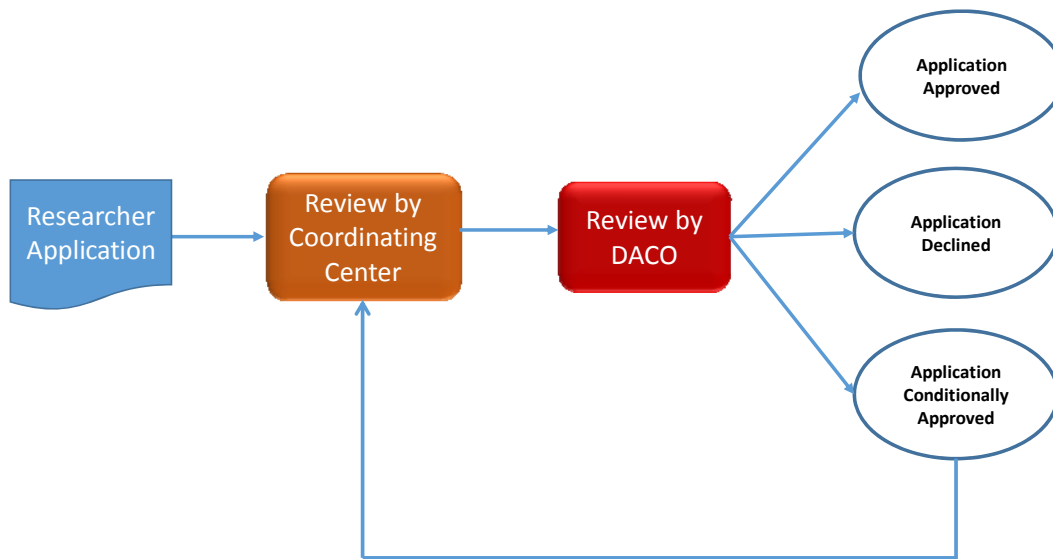


Figure 2: Overview of Application Procedure

5. Duration of Access and Renewal Procedure

Each DAA will have a term of one year from the date of execution of the DAA by the Sponsor. Notification will be given by the Coordinating Center to the Researcher prior to the annual expiration of the DAA.

To renew a DAA and continue access to the MSSNG Database after termination of the then-existing DAA, the Researcher will be required to submit a Renewal Form. The Renewal Form will require a Researcher to provide:

- An updated Researcher Application, or confirmation that the content of the Researcher Application originally submitted remains correct and complete;
- An updated list of and contact information for the members of the Research Team, or confirmation that the list of and contact information for the members of the Research Team remains correct and complete;
- Report on all publications prepared using the results of the Research Project; and
- Report on research results that are required to be reported to the Sponsor in accordance with the MSSNG Return of Research Results Policy promulgated by the Sponsor as may be amended from time to time and in effect as of the date of reference thereto.

Upon completion, a Researcher must send the completed Renewal Form to the Coordinating Center by e-mail or mail using the information set forth in Step 2 of the Application Procedure. It is recommended that Researchers send the Renewal Form within 10 days prior to expiration of a DAA.

The Coordinating Center will submit the Renewal Form to the DACO for review, together with any additional information related to the Researcher, including a summary of reports of unauthorized use or security breaches received by the Coordinating Center related to the Researcher.

Upon approval of the Renewal Form by the DACO, the Coordinating Center will send a formal letter (“**Access Renewal Letter**”) to the Researcher to advise him/her of the renewal. A copy of the Access Renewal Letter will also be provided to the DACO. The Access Renewal Letter will renew the DAA and the Researcher and the Research Team can continue access of the MSSNG Database using the existing log-on credentials.

If a DAA expires without being renewed, the log-on credentials of the Researcher and the Research Team will expire simultaneously, but the obligations of the Researcher and the Institution that survive termination of the DAA will remain in effect, including, without limitation, the obligation to provide the Final Report (as defined in the DAA).

6. MSSNG Researcher Application Registry

The DACO will create a registry of the names, affiliated institutions and Research Project summaries for all Researchers who have been approved for access to the MSSNG Database. This registry will be available for public access. Other aspects of the Researcher Application will not be disclosed to the public by MSSNG.

7. Data Security Assessment

In order to avoid, among other things, inadvertent disclosure of the data of Participants to unauthorized individuals, the DAA requires that Researchers implement data security safeguards. Minimum data security safeguards are as follows:

- *Physical Security* – Downloaded copies of MSSNG Data must be maintained on physically secure computer systems, such as a locked office. If downloaded copies of MSSNG Data are stored on a portable device (*e.g.*, laptop, tablet, USB thumb drive, external drives), the portable device must be encrypted to avoid its disclosure in case of loss or theft.
- *Access Security* – Only the Researcher and Research Team should have access to MSSNG Data. If downloaded copies of MSSNG Data are stored locally on a shared computer system or a file server, then the downloaded data must be password or encryption protected so that only the Researcher and the Research Team have access to the downloaded copies. Any backup media must either be encrypted or stored in a physically secure location.
- *Network Security* – If downloaded copies of MSSNG Data are stored on a network-accessible computer, some combination of network firewalls, network

intrusion monitoring and virus scanning software must be implemented. If MSSNG Data is used on multiple systems, the Researcher must ensure that the data access security policies are retained throughout the processing of MSSNG Data on all other systems.

- *Destruction of Data* – Upon completion of the Research Project (or the earlier expiration or termination of the DAA), the Researcher must delete and destroy all copies of MSSNG Data in accordance with the DAA.
- *Data Security Policies* – The Researcher and the Researcher’s Institution (where applicable) must have an information technology (IT) policy in place that addresses at a minimum the following items:
 - Logging and auditing of access to data and the computer network;
 - Password protection of the computer network;
 - Virus and malware protection of the computer network;
 - Auditable data destruction procedure;
 - Secure data backup procedure; and
 - Strong encryption on any portable device which may store or provide access to MSSNG Data.

8. Amendment of this Policy

The Sponsor may at any time and without notice amend this Policy in any manner in which the Sponsor determines to be in the best interest of MSSNG. The Policy that is current at any given time will be the Policy that is posted on the MSSNG Website.

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