

MSSNG
A Program of Autism Speaks Inc.
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MSSNG RETURN OF RESEARCH RESULTS POLICY
(VERSION 1.3)

1. Description of MSSNG and Statement of Policy

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. “**Research Data**” means information concerning Participants (defined below), 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. “**Researcher Provided Data**” means any and all data provided by Researchers to the Sponsor for inclusion in the MSSNG Database. “**WGS Data**” means whole genome sequencing data derived from the biological materials of Participants collected by or on behalf of a Sponsor.

This MSSNG Return of Research Results Policy (this “**Policy**”) describes (1) how a Participant will be informed about Research Results (defined below) during the informed consent process; (2) the circumstances in which the Researchers (defined below) shall report Research Results to the Sponsor; and (3) the obligation of the Sponsor to report to any Research Results of which it is made aware by a Researcher to Contributor (defined below).

2. Definitions

“**AS**” means Autism Speaks Inc.

“Contributor” means the contributing organization that made the Participant’s biomaterials available for sequencing by MSSNG and the associated Research Data available for deposit into the MSSNG Database.

“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.

“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.

“Participant Consent” means a consent form signed by a Participant in connection with his/her provision of biological materials and/or Research Data for use as part of MSSNG and/or another program established by Sponsor or by a third party research organization.

“Policy” means this MSSNG Return of Research Results Policy.

“Research Data” means information concerning Participants (defined below), 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.

“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 Results” means results that arise in the conduct of the Research Project, whether or not the results are related to the original purpose for which a Research Project was conducted.

“Researcher” means a person seeking access to the 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 Researchers to the Sponsor for inclusion in the MSSNG Database.

“**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. The Informed Consent Process

During the informed consent process, Participants will be told they may be contacted by the Contributor to discuss Research Results. However, for certain types of Research Results, a Participant must affirmatively request to be notified of such results.

4. Reporting of Research Results by Researchers to Sponsor

Not all Research Results must be reported to the Sponsor. Researchers shall report to the Sponsor Research Results that are discovered in the course of his or her access and use of MSSNG Data obtained through the MSSNG Database *if such Research Results are analytically valid, have clinical significance and/or are medically actionable.*

The following category of Research Results shall be deemed to meet the criteria above and shall be reported by Researchers to the Sponsor without need for additional evaluation: a mutation in a gene known to cause a medically actionable disease or condition. Without limiting the generality of the foregoing, where a mutation in gene known to cause a medically actionable disease or conditions with onset in childhood, such finding shall immediately be returned to the Sponsor, in all cases.

Research Results that are required to be reported to the Sponsor shall be reported on an annual basis and in any event upon the termination of the Database Access Agreement executed by the Researcher; provided however, that any reportable Research Results that relate to (a) a life-threatening disease or condition or (b) a medically actionable disease or condition with onset in childhood shall be reported immediately.

5. Reporting of Research Results by Sponsor to Contributor

Upon receipt of a report of Research Results by a Researcher, the Sponsor shall provide such results to the Contributor that made available the underlying biomaterials and associated Research Data that resulted in the applicable Research Results. Each Contributor that receives a report of Research Results from the Sponsor shall then be responsible, in its sole discretion, for evaluating and reporting the results to the affected Participants in accordance with the terms of the Participant’s consent, the Contributor’s internal policies and procedures, and any applicable laws and regulations.

6. 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.

References: Presidential Commission for the Study of Bioethical Issues. Anticipate, And Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research and Direct-to-Consumer Contexts. December 2013. Available at http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PC_SBI_0.pdf

Bartha Maria Knoppers, Ma'n H. Zawati and Karine Sénécal, Return of genetic testing results in the era of whole-genome sequencing. Nature. September 2015. Volume 16. Available at www.nature.com/reviews/genetics

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