

MSSNG
A Program of Autism Speaks Inc.
85 Devonshire St
Boston, MA 02109, USA
(617) 726-1515

MSSNG DATABASE ACCESS AGREEMENT (DAA)
(VERSION 2.0) [USA]

THIS MSSNG DATABASE ACCESS AGREEMENT (“this DAA”) is entered into as of _____, 2018 (the “Effective Date”), by and between AUTISM SPEAKS INC. (“AS”), with principal offices at 1 East 33rd Street, 4th Floor, New York, NY 10016, and _____ (“Institution”), with an address of _____ (individually a “Party” and collectively the “Parties”).

I. INTRODUCTION

1. MSSNG is a groundbreaking program established and sponsored by AS pursuant to which AS proposes to conduct the whole genome sequencing (“WGS”) of more than 10,000 human genomes using genetic samples donated by individuals with autism spectrum disorders (“ASDs”) and neurotypical family members.
2. MSSNG has been established for storing WGS data and other data generated in the course of the operation of MSSNG in a cloud-based data environment for the purpose of providing access to researchers to the MSSNG Database.
3. Institution desires to enter into this DAA with AS in order to obtain access to the MSSNG Database for the purpose of conducting a research project.

II. DEFINITIONS

1. “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.
2. “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.
3. “Consultant” means McGill University or such other independent consultant as AS may appoint from time to time.

4. “Commercial” means income-generating.
5. “Contributor” means the contributing organization that made the Participant’s biological materials available for sequencing by MSSNG and the associated Research Data available for deposit into the MSSNG Database.
6. “Coordinating Center” means AS’s MSSNG Coordinating Center.
7. “DACO” means MSSNG’s independent Data Access Compliance Office.
8. “Data Security Safeguards” shall mean the requirements set forth in Section IV(F) of this DAA.
9. “Final Report” means the report from Institution to AS upon termination of this DAA describing (i) all publications of Researcher Generated Data as of the Final Report date and (ii) Research Results that are required to be reported to AS in accordance with this DAA.
10. “Genomic Discovery Operating Committee” or “GDOC” means an expert committee appointed by AS that oversees the MSSNG Database.
11. “MSSNG Data” means the Research Data, WGS Data and Researcher Provided Data, and all other data or information that AS elects to make available through MSSNG.
12. “MSSNG Database” means the cloud-based data storage environment for MSSNG Data.
13. “MSSNG Program” the program pursuant to which AS conducts the whole genome sequencing of more than 10,000 human genomes using genetic samples donated by individuals with autism spectrum disorders (“ASDs”) and neurotypical family members.
14. “MSSNG Website” means the MSSNG website at <https://research.mss.ng>.
15. “Participant” means a provider of biological materials and/or Research Data that is used as part of MSSNG, whether contributed by AS or a third-party organization.
16. “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 research program established by AS or a third-party organization.
17. “Person” means any individual, company or other entity, including governmental and quasi-governmental agencies, associations, cooperatives and laboratories.
18. “Program Data Access Protocol” or “Protocol” means the protocol established by AS for access by Researchers to the data resulting from the WGS of genetic materials and associated Research Data contributed to the MSSNG Program, which protocol is set forth in Section III of this DAA.
19. “Renewal Form” means the MSSNG form submitted by Researcher to renew access to the MSSNG Database, which will be reviewed and approved in accordance with this DAA.

20. “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 AS or a third-party organization and contributed to the MSSNG Database. Research Data shall not include any personally identifying information about the Participant, his/her family or its members.
21. “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 submitted by Researcher in accordance with the MSSNG Website.
22. “Research Results” means the data, analyses and conclusions generated through Institution’s use of the MSSNG Data in the course of the Research Project, including but not limited to any Researcher Generated Data.
23. “Research Team” means the research staff employed by Institution and assisting the Researcher in the conduct of the Research Project, all of whom have signed this DAA to indicate that they have read and acknowledge its terms.
24. “Researcher” means the researcher employed by Institution and approved by the Review Board as the principal investigator of the Research Project, for which Institution has sole responsibility, and who is has signed this DAA.
25. “Researcher Application” means the application submitted by Researcher to obtain access to the MSSNG Database, which will be reviewed and approved in accordance with the MSSNG Data Sharing Policy and Procedures. The form of Researcher Application that is in effect at any given time is available on the MSSNG Website.
26. “Researcher Generated Data” means any and all data generated by Institution, Researcher or the Research Team that was derived in the course of the Research Project and from or based upon the MSSNG Data. For the avoidance of doubt, “Researcher Generated Data” does not include the MSSNG Data.
27. “Researcher Provided Data” means any and all data provided by another approved MSSNG Database researcher other than Institution, the Researcher or the Research Team to AS for inclusion in the MSSNG Database.
28. “Review Board” means the Institutional Review Board, Research Ethics Committee, Research Ethics Board or such other equivalent body under the laws governing the Institution, the Researcher and the Research Project for the conduct of the Research Project.
29. “Term” means the term of one (1) years from the Effective Date, plus any renewal term, unless terminated earlier pursuant to this DAA.

30. “Third Party Providers” means contracting and consulting parties of AS that provide services in connection with the MSSNG Database and collaborating partners with other data sets.
31. “Third Party Terms” means the terms and conditions connected with the services provided by Third Party Providers in relation to the MSSNG Database, including but not limited to acceptable use policies of providers of cloud computing platforms or other technologies, that are either posted on the MSSNG Website or are otherwise communicated to Institution.
32. “WGS Data” means whole genome sequencing data derived from the biological materials of Participants collected by or on behalf of AS.

III. MSSNG PROGRAM DATA ACCESS PROTOCOL

1. Approved Access to MSSNG Data. Access to MSSNG Data is in accordance with the Program Access Data Protocol set forth below.
2. Program Data Access Protocol

(a) Introduction.

This Protocol describes (i) the governance structure of the MSSNG Database; and (ii) 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 ASDs and related conditions.

(b) Governance of MSSNG Database.

The GDOC is an ad hoc committee that is convened as needed to advise the Coordinating Center and DACO upon request. The GDOC is composed of a minimum of three (3) individuals appointed by McGill University or such other Consultant as AS may appoint from time to time, drawing from the following communities: research (academia, governmental, and/or industry), healthcare, bioinformatics, Information Technology, software engineering, experimental design, regulatory, statistics, legal, and ethics, as well as the autism community at large.

AS’s Coordinating Center and the DACO have the responsibility for implementing this Protocol and provide reports to the GDOC regarding such implementation.

The independent DACO is composed of a minimum of five (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 McGill University or such other Consultant as AS may appoint from time to time, and one representative from Consultant.

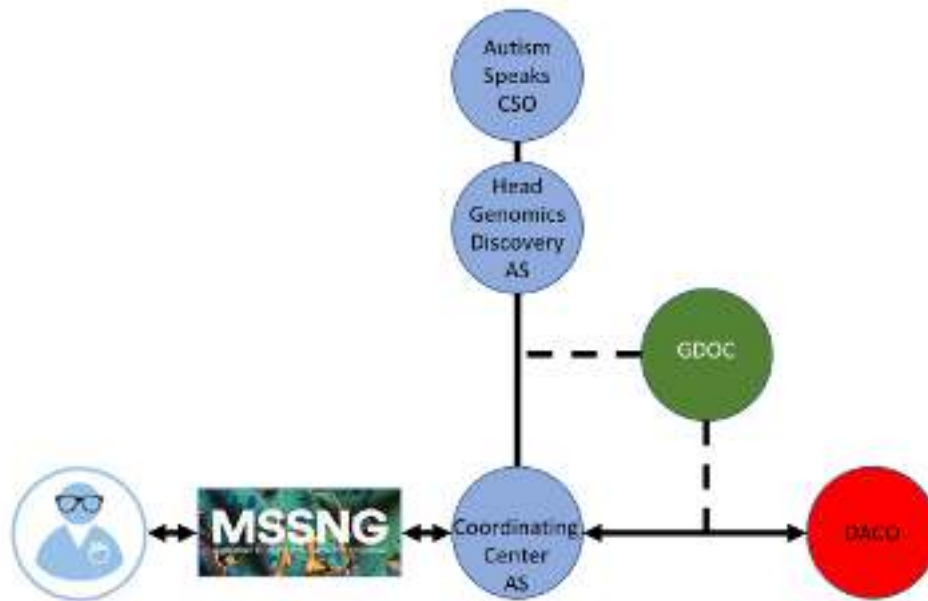


Figure 1: MSSNG Database Governance

(c) Access 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 the DAA online to the Autism Speaks Genetics Application System: <https://science.grants.autismspeaks.org/genetics/login.php>. 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 on 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 required by this DAA;
 - 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 five (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 (2) 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 uploaded and submitted to the Coordinating Center via the Autism Speaks Genetics Application System.

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 ASDs 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 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 ten (10) business days after receipt by the DACO of the Researcher Application. 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 an 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 Researcher 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 AS. The DAA will govern the Researcher's access to the MSSNG Database. The terms of the DAA will prevail over any inconsistent terms of 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 AS.

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.

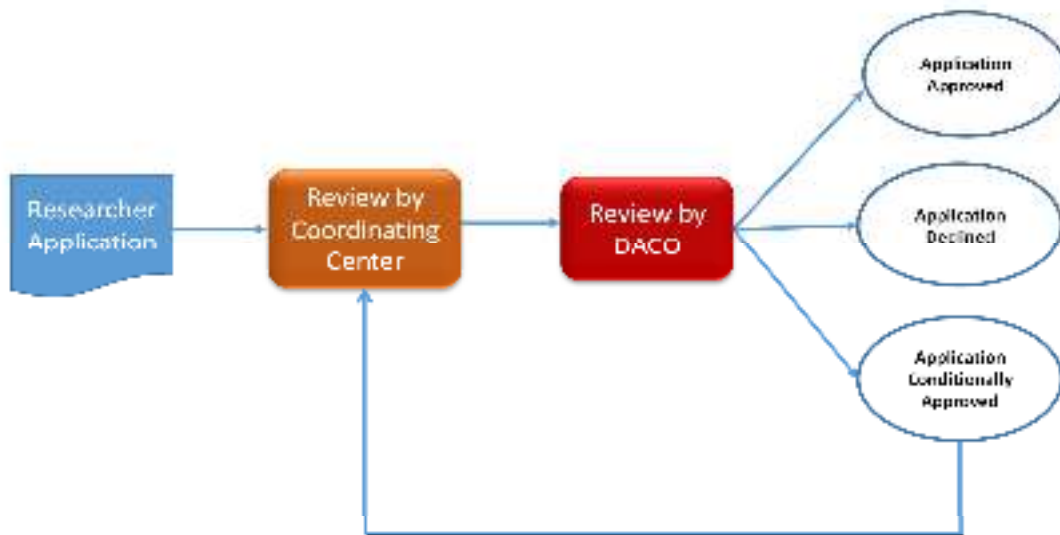


Figure 2: Overview of Application Procedure

(d) Duration of Access and Renewal Procedure.

Each DAA will have a term of one (1) year from the Effective Date of the DAA. Notification will be given by the Coordinating Center to the Researcher prior to the expiration of the DAA.

To renew a DAA and continue access to the MSSNG Database after expiration 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 AS in accordance with this DAA.

Upon completion, a Researcher must send the completed Renewal Form 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: Morgan Quirbach

It is recommended that Researchers send the Renewal Form at least thirty (30) 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 an 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.

- (e) 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.

IV. DATA ACCESS AGREEMENT

1. Preliminary Conditions.

- (a) Review Board Compliance. Institution represents and warrants that (i) Researcher has obtained Review Board approval or an exemption from such approval for the conduct of the Research Project as required by applicable laws, and (ii) Institution, Researcher and the Research Team are and at all times during the term of this DAA (and thereafter as

applicable) shall be in full compliance with the any and all applicable Review Board regulations and policies.

- (b) Researcher/Research Team Acknowledgment of DAA Terms. Before any MSSNG Data may be transferred to Institution, Researcher shall sign a copy of this DAA to indicate that the Researcher has read this DAA and acknowledges its terms. In addition, no individual may become a member of the Research Team or perform services in connection with this DAA until he or she signs a copy of this DAA to indicate that he or she has read this DAA and acknowledges its terms.
- (c) Data Security. Before any MSSNG Data may be transferred to Institution, Institution shall implement and adhere to the minimum data security safeguard requirements set forth in this DAA, and such other safeguards as Institution deems necessary or appropriate, in order to protect the security of the MSSNG Data.

2. **Compliance with DAA; Research Project.**

- (a) Compliance with DAA. As a condition of being granted access to the MSSNG Database, Institution agrees to the terms and conditions set forth in this DAA. Institution shall be fully responsible for the acts and omissions of the Researcher and all members of the Research Team and shall ensure compliance with the terms and conditions of this DAA by the Researcher and all members of the Research Team.
- (b) No Material Change to Research Project. Institution agrees that there will be no material changes to the Research Project during the Term of this DAA. Should Researcher wish to embark on a new research project using MSSNG Data, a new application must be filed in accordance with the MSSNG Data Sharing Policy and Procedures and a new database access agreement must be signed prior to any such access.
- (c) Reporting Research Project Issues. Institution shall report promptly to AS any issues or problems with the Research Project, including without limitation those involving risks to Participants or others.

3. **Access to MSSNG Data.**

- (a) Right to Access MSSNG Data. Upon satisfaction of all Preliminary Conditions contained in this DAA, AS grants to Institution the non-exclusive right to access MSSNG Data, which shall be used exclusively by Institution, Researcher and the Research Team solely in the conduct of the Research Project in the advancement of medical science, and only during the Term of this DAA and in accordance with the terms and conditions of this DAA.
- (b) Log-on Credentials. Institution, Researcher and each member of the Research Team will access the MSSNG Database using only the log-on credentials assigned by AS. Institution will maintain the privacy of the log-on credentials assigned to them by AS and will be solely responsible for all activities that occur under such log-on credentials.

(c) Third Party Providers. Institution acknowledges and agrees that access to the MSSNG Database involves services provided by Third Party Providers. Institution shall comply with all Third Party Terms, as may be modified by AS from time to time. Institution shall take such actions as may be reasonably requested in writing by AS in connection with the services provided by such Third Party Providers.

4. **Withdrawal by Participant.**

In the event that a Participant wishes to withdraw from MSSNG, AS reserves the right to remove the MSSNG Data related to such Participant from the MSSNG Database. AS reserves the right to request that Institution destroy all copies (including backup copies) of MSSNG Data archived, copied, downloaded or otherwise extracted by Institution, Researcher or the Research Team from the MSSNG Database related to such Participant. In such event, Institution shall comply with such request and certify in writing to AS the destruction of, and refrain from using in further analyses, any such copies of MSSNG Data; provided, however, that Institution may retain copies of MSSNG Data to the extent required by law. Notwithstanding the foregoing, Institution may continue to use Researcher Generated Data in accordance with this DAA.

5. **Use and Transferability of MSSNG Data.**

(a) No Access to Others. Institution agrees not to allow access to the MSSNG Database or use of MSSNG Data (free of charge or otherwise), directly or indirectly, to any other Person for any purpose whatsoever other than to Researcher and the Research Team solely for the purposes of the conduct of the Research Project during the Term of this DAA and in accordance with this DAA.

(b) Departure of Research Team Member. Institution will notify AS of a departure of any member of the Research Team.

(c) Control over Copies of MSSNG Data. Institution agrees to retain control over all copies of MSSNG Data archived, copied, downloaded or otherwise extracted by Institution, Researcher and the Research Team from the MSSNG Database, and further agrees not to transfer, provide, resell, share, publish or otherwise distribute such copies of MSSNG Data (free of charge or otherwise), directly or indirectly, to any other Person for any purpose whatsoever other than to Researcher or the Research Team as permitted by this DAA.

(d) Proposed Collaborations. If Institution proposes to collaborate with any Person (including, without limitation, with vendors or service providers in connection with the Research Project), other than the Researcher and the Research Team, who proposes to access the MSSNG Database or use MSSNG Data, Institution will not initiate such collaboration or provide access to MSSNG to such Person unless and until such Person and, if applicable, their respective institutions, have signed a separate database access agreement with AS or AS otherwise agrees in writing, in which event such Person will be assigned individual log-on credentials.

- (e) Commercial Use. Should Institution reasonably believe that its activities under the Research Project have led to the development of a commercial product, Institution shall notify AS within sixty (60) days of such development. If Institution desires to use or license the MSSNG Data for commercial purposes, Institution agrees, in advance of such use, to negotiate in good faith with AS to establish the terms of a commercial use license to be granted from AS to Institution. It is agreed that any such commercial use license shall include provisions for an initial license fee in a minimum amount of Twenty-Five Thousand Dollars (\$25,000), earned royalties and minimum annual royalties payable by Institution to AS, as determined by that which is reasonable and acceptable in the industry, plus usual and customary provisions relating to records-keeping by Institution and audit rights of AS. It is understood by Institution that AS shall have no obligation to grant such a license to Institution, and may grant exclusive or non-exclusive commercial use licenses to others, or sell or assign all or part of the rights in the MSSNG Data to any third party or parties, subject to any pre-existing rights held by Institution or others and any pre-existing obligations to the Federal Government.

6. **Research Results, including Researcher Generated Data.**

- (a) Use and Transfer of Researcher Generated Data. Researcher will retain the right to use all Researcher Generated Data for the purposes of scientific or medical research subject to the license of such Researcher Generated Data to AS and other researchers pursuant to this DAA; provided, however, that any provision, transfer or distribution of any Researcher Generated Data to any Person other than AS will be subject to the prior written confirmation by AS that AS has determined that such provision, transfer or distribution does not violate the terms of the applicable Participant Consents or Review Board approvals or regulations.
- (b) Copy of Researcher Generated Data to AS. Within thirty (30) days after publication of Researcher Generated Data in a Peer Reviewed Publication, Institution shall provide AS with an electronic copy of the Researcher Generated Data, including a supplementary data table in the format in accordance with the instructions of AS. The form of data table may be obtained by contacting MSSNG (coordinatingcenter@mss.ng).
- (c) License to AS. Institution grants to AS a nonexclusive, royalty-free, worldwide, perpetual license, for research and educational purposes only and not for any commercial purposes, to any and all Researcher Generated Data. Such Researcher Generated Data shall be in the format and shall contain the content specified in the current guidelines for providing Researcher Generated Data that are posted on the MSSNG Website. In the event that AS identifies a potential commercial use of the Researcher Generated Data that was not identified by Institution, then AS and Institution will engage in good faith negotiations regarding licensing the right to commercialize the use to a third party, with AS and Institution as co-licensors.
- (d) Availability to Researchers. AS has the right to make any or all of the Researcher Generated Data available to authorized researchers through the MSSNG Database or otherwise and subject to such terms and conditions as AS shall specify; provided, however, that should

Institution desire to file a patent application related to any Researcher Generated Data and Institution so notifies AS when it provides such Researcher Generated Data pursuant to this DAA, AS will allow Institution a reasonable amount of time in which to file the application prior to making the Researcher Generated Data available pursuant to this DAA.

7. **Distribution to Governmental /Quasi-Governmental Agencies/NGOs.**

AS may at any time distribute any or all of the Researcher Generated Data to governmental or quasi-governmental agencies and/or non-governmental organizations, subject to the qualifications related to patent and patent applications in this Section.

8. **Access by Third Party Providers.**

AS may at any time allow access to any or all of the Researcher Generated Data by Third Party Providers.

9. **Reporting of Research Results to AS.**

(a) Not all Research Results must be reported to AS. Researchers shall report to AS Research Results that are discovered in the course of their 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: a mutation in a gene known to cause a medically actionable disease or condition.*

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

10. **Data Security Safeguards.**

(a) **Implementation of Safeguards.**

Institution agrees to implement and maintain at all times during the Term of this DAA, and thereafter while maintaining copies of MSSNG Data, the minimum data security safeguards described in this DAA, and such other safeguards as Institution deems necessary or appropriate to protect the security of the MSSNG Data. The minimum data security safeguards are as follows:

Physical Security – Institution shall obtain prior approval from AS in order to download copies of MSSNG Data. If Downloaded copies of MSSNG Data are maintained locally on a personal computer or laptop, related equipment must be stored in a locked room or office. Any laptop or personal computer must have encryption enabled to protect the hard drive and data stored within it.

Access Security – Only the Researcher and Research Team should have access to MSSNG Data. MSSNG Data must not be stored on any removeable media, such as a USB thumb drive or external hard drive at any time.

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, with the inability for data users to delete logs;
- Password protection of the personal computer or laptop with minimum password requirements as follows:
 - Policy must be updated every 90 days
 - Be at least seven characters
 - Must contain both alpha and numeric characters
 - must contain one capital letter
 - May not be the same as an of an individual’s previous four passwords
- Virus and malware protection of the computer network;
- Proper firewalls in place;
- Auditable data destruction procedure;
- Secure data backup procedure; and
- Strong encryption on any portable device which may store or provide access to MSSNG Data.

(b) Notice of Unauthorized Use. Institution shall immediately notify AS of any unauthorized use of the MSSNG Database or any other breach of security that may have affected the MSSNG Data (or copies thereof archived, copied, downloaded or otherwise extracted by Institution, Researcher or the Research Team from the MSSNG Database) or the MSSNG Database.

11. **Intellectual Property.**

(a) Institution’s IP. As between Institution and AS, AS retains ownership of the MSSNG Data. Institution retains its rights to intellectual property created or discovered by Institution, Researcher or the Researcher Team in the course of the Research Project, subject to the terms of this Section.

- (b) Patents. Institution is free to file patent applications claiming inventions made or discovered by Institution through the use of MSSNG Data or access to the MSSNG Database. However, Institution agrees to notify AS within ninety (90) days after any of the following events: (a) when a decision to file an application for patent is made by Institution; (b) when an invention disclosure (or similar document) is prepared by or for Institution; (d) when any divisional, continuation or continuation-in-part application is filed; (e) when a provisional or other application for patent is filed; (f) when any application is abandoned; and (g) when any patent is issued. Institution will include with its notice of an event, any related document, such as the invention disclosure, patent application or patent.
- (c) License Granted to AS. Institution grants to AS a nonexclusive, royalty-free, worldwide, perpetual license, for research and educational purposes only and not for any commercial purposes, to any patents and patent applications owned or filed by Institution based upon or arising out of the use of the MSSNG Database or access to MSSNG. Such license shall include AS's right to grant sublicenses without fee to nonprofit organizations for research and educational purposes only and not for any commercial purposes.
- (d) Disclaimer – Third Party Rights in MSSNG Data. Institution understands that AS has made no attempt to determine whether any third parties have any rights in the MSSNG Data and disclaims any knowledge relating to any property interest in such MSSNG Data. AS does not make any warranty, express or implied, that the MSSNG Data may be exploited without infringement of the intellectual property or proprietary rights of any third parties. The responsibility for determining any rights in the MSSNG Data for purposes of commercialization rests exclusively with Institution.

12. Acknowledgement of Use.

- (a) Acknowledge Use of MSSNG Data. Institution and Researcher shall acknowledge the use of any and all MSSNG Data and the MSSNG Database in any and all publications, oral and written presentations, media reports, interviews, and disclosures that are permitted hereunder and that result from any and all analyses of MSSNG Data or use of the MSSNG Database that are permitted hereunder, whether the same occur during the term of this DAA or afterwards, in accordance with the guidelines in this DAA and the MSSNG Website. Such acknowledgment shall state:

“The authors wish to acknowledge the resources of MSSNG (www.mss.ng), Autism Speaks and The Centre for Applied Genomics at The Hospital for Sick Children, Toronto, Canada. We also thank the participating families for their time and contributions to this database, as well as the generosity of the donors who supported this program.”
- (b) Institution shall submit a list of all such publications, presentations, media reports, interviews, and disclosures to MSSNG coordinatingcenter@mss.ng.
- (c) Acknowledge Contribution of other Researchers. Institution and Researcher shall acknowledge the contribution of researchers who generated Researcher Provided Data used by Institution in any and all publications, written and oral presentations, media reports,

interviews and disclosures that are permitted hereunder and that result from any and all analyses of such Researcher Provided Data, whether the same occur during the term of this DAA or afterwards, in accordance with guidelines in this DAA and the MSSNG Website.

13. **Use of AS's Name/Marks.**

Institution may not use any name, trade name, trademark, logotype, domain name, or other designation of AS, except in accordance with the terms of this DAA or with the prior written consent of AS in each instance.

14. **Confidentiality.**

Institution understands that the identities of the contributing Participants are confidential. Institution agrees to make no intentional attempt to link individual-level Data from the MSSNG Database with any other data or database without prior explicit approval from the DACO and not to re-identify Research Participants through linkage of Data, or otherwise. Institution shall ensure that, should Institution, Researcher, a member of the Research Team, or a Person under Institution's control discover the identities of any Participants, such identities of the Participants or their corresponding family and Participant ID numbers shall not be revealed to any Person. **Under no circumstances may Institution reveal any family or Participant ID numbers of which it becomes aware.**

15. **No Warranty; Limitation of Damages; Release.**

(a) **No Warranty.** INSTITUTION ACKNOWLEDGES THAT THE MSSNG DATA MAY BE THE SUBJECT OF A PATENT APPLICATION OR COVERED BY PATENT OR OTHER RIGHTS IN ONE OR MORE COUNTRIES. NO EXPRESS OR IMPLIED LICENSES TO SUCH PATENT RIGHTS ARE PROVIDED TO INSTITUTION BY AUTISM SPEAKS. THE MSSNG DATA ARE PROVIDED AS A SERVICE TO THE RESEARCH COMMUNITY. THEY ARE PROVIDED "AS IS." AUTISM SPEAKS IS NOT RESPONSIBLE FOR THE ACCURACY OF MSSNG DATA. AUTISM SPEAKS DOES NOT MAKE, AND EXPRESSLY DISCLAIMS, ANY EXPRESS OR IMPLIED WARRANTIES WITH RESPECT TO THE MSSNG DATA, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, OR NON-INFRINGEMENT OF INTELLECTUAL PROPERTY OR PROPRIETARY RIGHTS OF THIRD PARTIES.

(b) **Limitation of Damages.** To the fullest extent permitted by law, In no event shall AS be liable for any incidental, special, indirect, punitive or consequential damages arising out of or relating to this DAA, even if it has been advised of the possibility of such damages.

(c) **Release.** Institution hereby releases Verily Life Sciences LLC, all other Third Party

Providers and AS from any and all liabilities, damages, costs and expenses arising out of Institution's and/or Principal Investigator's use of the MSSNG Data and access to the MSSNG Database. Institution acknowledges and agrees that the Third Party Providers are an intended beneficiary of the provisions of this Section and, without limiting the scope of the persons who may have standing to enforce this Section, shall be entitled to enforce this Section.

16. Term and Termination of DAA.

- (a) Term and Renewal Terms. This DAA shall be effective for the Term, including any renewal terms, unless terminated earlier pursuant to this Section. This DAA may be renewed at the end of the Term or any renewal term for an additional one (1) year term upon compliance prior to the expiration of the then-current term with the procedure set forth in this DAA and signing of a written agreement between AS and Institution, with Researcher and the members of the Research Team signing the DAA to indicate they have read and acknowledged the terms of this DAA.
- (b) Termination Prior to Expiration of Term or Renewal Term. This DAA may be terminated prior to the expiration of the Term (including any renewal term) upon the occurrence of either of the following:
 - i. AS may terminate this DAA if Institution is in breach of any of the terms and conditions specified in this DAA, provided that AS in its sole discretion may accord to Institution a thirty (30) day cure period within which to remedy the breach.
 - ii. Institution may terminate this DAA upon thirty (30) days' written notice to AS.
- (c) Effect of Termination or Expiration of DAA. Upon termination or expiration of this DAA, Institution shall:
 - i. cease all use of the MSSNG Data (including copies thereof archived, copied, downloaded or otherwise extracted by Institution Researcher and the Research Team from the MSSNG Database) and MSSNG Data Downloads and all access to the MSSNG Database;
 - ii. destroy all copies (including backup copies) of MSSNG Data archived, copied, downloaded or otherwise extracted by Institution, Researcher and the Research Team from the MSSNG Database, provided, however, that Institution may retain copies of MSSNG Data to the extent required by law;
 - iii. certify in writing to AS the destruction (in accordance with this DAA) of all copies of MSSNG Data archived, copied, downloaded or otherwise extracted by Institution, Researcher and the Research Team from the MSSNG Database;

- iv. and provide to AS the Final Report within thirty (30) days of the termination or expiration of this DAA.

17. Remedies for Breach.

- (a) Consequences of Breach. In the event that Institution fails to comply with any of the terms and conditions specified in this DAA including, without limitation, the requirement to obtain AS's agreement to change in the scope of a Research Project, in addition to any other remedies available to AS, such failure may result in (i) your disqualification from further use of MSSNG Data or access to the MSSNG Database; (ii) AS withholding support for Institution's or Researcher's future research; (iii) AS terminating previously approved use of MSSNG Data or access to the MSSNG Database; (iv) the denial by AS of future requests for use of MSSNG Data or access to the MSSNG Database; and/or (v) AS reporting such failure to any relevant public databases and debarment lists. Notwithstanding the remedies provided for in (i)-(v) above, nothing in this Section shall be construed to limit any other remedy available to AS under this DAA or applicable law.
- (b) Equitable Relief. Institution acknowledges that because of the necessity of ensuring adherence to the terms of the Participant Consents, a remedy at law will be inadequate in the event of Institution's breach or default under the terms of this DAA. Therefore, in the event of any such breach or default, Institution consents, without the necessity of AS posting a bond, to the entry against Institution of an injunction by a court of competent jurisdiction prohibiting Institution from any further use of any kind of the MSSNG Data or the MSSNG Database.

18. Indemnification.

To the fullest extent permitted by law, Institution agrees to indemnify, defend and hold harmless each of AS, the officers, directors, employees and agents of AS, the Participants and their families and the heirs, successors and assigns of each of them, from and against (i) any and all claims, demands, suits, liabilities, damages, costs and expenses (including reasonable attorneys' fees) that arise out of or in any way relate to (A) Institution's use, storage, disposal or distribution of the MSSNG Data and access to the MSSNG Database; and (B) any use, publication or exploitation of any and all Researcher Generated Data, except in each case to the extent caused by the willful misconduct or gross negligence of AS; and (ii) any and all claims, demands, suits, liabilities, damages, costs and expenses (including reasonable attorneys' fees) that arise out of or in any way relate to Institution's breach of its obligations under this DAA. The acts and omissions of Researcher and the members of the Research Team shall be attributed to Institution.

19. Choice of Law and Venue.

The Parties acknowledge that the principal place of business of AS is located at 1 East 33rd Street, New York, New York 10016. This DAA shall be governed by the laws of the State of

New York, without giving effect to the principles of the conflict of laws. In the event of any controversy, claim or dispute between the Parties arising out of or relating to this DAA, such controversy, claim or dispute shall be tried exclusively in the courts of the State of New York, located in the County of New York, or in the United States Federal District Court for the Southern District of New York, as the Parties may elect. Institution waives any defense of lack of in personam jurisdiction, improper venue and forum non conveniens, and agrees that service of process of such court may be made upon Institution by personal delivery or by mailing certified or registered mail, return receipt requested, to the other at the address indicated herein or as otherwise agreed to by the Parties. The Parties submit to the jurisdiction of the court so selected, to the exclusion of any other courts which may have had jurisdiction apart from this paragraph. The Parties waive any right to a trial by jury in any action arising from this DAA or the breach hereof.

20. Miscellaneous.

- a. Conflicting Terms. If the terms of this DAA contradict any applicable Third Party Terms, the Third Party Terms shall apply to the extent such Third Party Terms are more restrictive.
- b. Amendments. AS reserves the right to modify and amend this DAA upon thirty (30) days' notice to Institution and, after such 30-day period, Institution's continued access to the MSSNG Database will constitute assent to such modification or amendment. Upon written notice to AS in such 30-day time period, Institution may terminate this DAA effective as of the effective date of any such modification or amendment.
- c. No Partnership, Joint Venture, Franchise, Agency. Institution's relationship to AS is in the nature of an independent contractor. This DAA shall not be deemed to create a partnership, joint venture or franchise, and neither Party is the other's agent, partner, employee or representative.
- d. No Endorsement. Institution shall not claim, infer, or imply endorsement by AS of the Research Project, the Institution, the Researcher, the Research Team or any Research Results.
- e. Waiver. The waiver or failure of either Party to exercise any right in any respect provided for in this DAA shall not be deemed to be a waiver of any further right hereunder.
- f. Assignment. This DAA shall be binding upon and inure to the benefit of each of the Parties, including their respective successors and permitted assigns. Institution may not assign this DAA or any of its rights or obligations hereunder without the prior written consent of AS. Any such assignment without prior written consent shall be void. AS may assign this DAA to any successor on notice to Institution, whereupon AS will be released from any further obligation.
- g. Entire Agreement. This DAA, plus the Researcher Application and the Third Party Terms, which are hereby incorporated into this DAA by reference, constitute the entire

understanding of the Parties with respect to the matters referred to herein and supersede all prior negotiations, commitments and understanding with respect thereto. No variation or modification of this DAA or waiver of any terms of provisions hereof shall be deemed valid unless in writing and signed by each of the Parties.

- h. Survival. All provisions of this DAA that by their nature extend beyond termination hereof, shall survive the expiration or termination of this DAA for any reason.
- i. Notices. Notices, invoices, and communications hereunder shall be deemed made if given by overnight courier or by registered or certified envelope, post prepaid, and addressed to the party to receive such notice, invoice, or communication at the address given below or such other address as may hereafter be designated by notice in writing:

If to AS:

MSSNG
Autism Speaks Inc.
85 Devonshire St, 9th Floor
Boston, MA 02109
Attention: Morgan Quirbach
Email: coordinatingcenter@mss.ng

If to Institution:

[Signature Page to Follow]

READ AND ACKNOWLEDGED BY RESEARCH TEAM MEMBER:

Signature of Research Team Member

Name:

Title:

Date

READ AND ACKNOWLEDGED BY RESEARCHER:

Signature of Researcher
Name:
Title:

Date

ACCEPTED AND AGREED BY INSTITUTION:

Name of Researcher's Institution

Signature of Institution Official
Name:
Title:

Date

**THE COMPLETED RESEARCHER APPLICATION AND SIGNED DAA MUST BE
UPLOADED AND SUBMITTED TO THE COORDINATING CENTER VIA THE
AUTISM SPEAKS GENETICS APPLICATION SYSTEM.**

MSSNG
Autism Speaks Inc. (AS)
85 Devonshire St, 9th Floor
Boston, MA 02109
Attention: Morgan Quirbach
Email: coordinatingcenter@mss.ng

AUTISM SPEAKS INC.:

Signature
Name: Dean M. Hartley, PhD
Title: Senior Director

Date

