Autism Science Foundation Grant Funding Agreement Grant number: XXX

This Agreement is made and entered into as of the date affixed with signatures below, between and among Autism Science Foundation, Inc. ("ASF"), a not-for-profit corporation with an address of 3 Continental Road, Scarsdale, NY 10583 ("Grantor") and INSTITUTION NAME, a university with an address of INSTITUTION'S ADDRESS ("Grantee").

TERMS

A. Grant Period, Use of Funds and Payments

The total TYPE OF GRANT Grant (the "Grant") is AMOUNT (\$X,000) to provide support to the project entitled "TITLE" (the "Project") as specified in the grant application. No Grant funds may be used to pay for indirect costs or university overhead costs. The Project is to be conducted by APPLICANT ("Researcher") under the mentorship of their faculty advisor, MENTOR ("Mentor").

The funding period for the Project will be one year starting on START DATE and ending on END DATE.

Funds will be disbursed to Grantee in one single payment upon receipt of a fully executed Agreement and proof of IRB approval (see Section B). Date of delivery of the payment shall not affect the funding period.

B. Termination, Transfer or Retirement of the Grantee

If the Researcher's affiliation with the Grantee is suspended, terminated or otherwise disrupted, whether by the Researcher or the Grantee or both, or if the Researcher stops conducting the Project, the Agreement is terminated and the unspent grant funds must be returned to ASF. Upon termination, Grantee releases Autism Science Foundation from any further obligation hereunder except that such termination shall not operate to release Grantee with respect to any duties or obligations hereunder accruing prior to the date of such termination.

C. Human Subjects Certifications

For research involving human subjects, the Grantee shall certify that the proposed research project has been reviewed and approved in writing by an accredited university or medical school Institutional Review Board ("IRB") constituted in accordance with current regulations promulgated by the United States Department of Health and Human Services ("HHS"), or by the Association for the Accreditation of Human Research Protection Programs (in the absence of an HHS-approved university or medical school IRB). In accordance with HHS regulations, the Grantee shall secure informed consent of all human subjects taking part in research funded in whole or in part by ASF. IRB certification must be documented by submitting to ASF a copy of the institutional approval letter identifying the Grantee, the Project, Autism Science Foundation as a funding agency and date of approval. This letter must be signed by the IRB Chair or equivalent responsible institutional official. Prior IRB certification for another project is not a sufficient substitute, unless it is officially amended to include the proposed project, the Grantee, and ASF as the funding agent. Funds will NOT be released unless and until proof of IRB certification is received by ASF.

D. Intellectual Property

Grantee and Researcher shall notify Autism Science Foundation of any discovery that may be patentable or otherwise protectable under applicable law and is discovered in the course of the research funded by ASF (an "Invention"). Grantee and Researcher shall be responsible for obtaining patent or other legal protection for each Invention that Grantee or Researcher believe to have commercial potential, and for paying all costs associated with obtaining such protection. Grantee and Researcher shall be solely responsible for all commercial exploitation of any Invention and Autism Science Foundation will have no responsibility therefore.

Grantee and Researcher shall notify Autism Science Foundation of the granting of each patent or other legal protection and of all commercial exploitation of any Invention (including the terms of any sales or licenses and the amount of fees or other receipts received by Grantee or Researcher as a result thereof).

Title to any Invention shall be retained by the Grantee or the Researcher (as specified in the policies and procedures of the Grantee)

E. Acknowledgement of Support

ASF depends upon private support to meet its goals and to fund research grants. Therefore, your help and support are very important in the efforts to educate the general public and the scientific community about autism and ASF. To this end, any publications, presentations or Inventions arising from work **supported in whole or in part by** the Grantor shall acknowledge Grantor's support using the following words: "This work was supported by a grant from the Autism Science Foundation [and any other co-funding sources]."

If Researcher or Mentor has a manuscript accepted for publication based on work supported in whole or in part by the Grantor, Researcher must send ASF the name of the publication, the name of the article, the expected date of publication and any other relevant information. Following publication, an electronic version of the final manuscript shall be forwarded (in PDF format) to ASF.

In addition, during the term of the grant and afterwards, Researcher shall reference Grantor's support on any publicity or communications (external or internal) resulting from research supported in whole or in part by the Grantor, including research papers, patent announcements, press releases, media reports, interviews, conference talks and poster presentations of data. ASF hereby grants Grantee and Researcher the right to use the ASF trademarked logo for this purpose.

F. Reports

Researcher shall provide the Autism Science Foundation with a six-month Progress Report in [DATE]. The Progress Report must include a description of the findings of the Project to date as well as any unanticipated problems or substantial deviations from the research aims outlined in the original application. A financial report signed by the responsible administrative official at the Grantee must accompany the progress report. The Researcher shall be responsible for notifying ASF of any significant problems that will delay the progress of the project for more than six (6) months.

In addition, Researcher shall provide the Autism Science Foundation with a Final Report by [DATE]. The Final Report (the template will be provided by ASF) must include a description of

the findings of the Project to date as well as any unanticipated problems or substantial deviations from the research aims outlined in the original application. A financial report signed by the responsible administrative official at the Grantee must accompany the report. The Autism Science Foundation may contact the Researcher in the years following the project end to track his/her career trajectory and progress.

G. Data Sharing:

All data resulting from ASF-funded research *involving human subjects* must be submitted to the National Database for Autism Research (NDAR), along with appropriate supporting documentation to enable efficient use of the data. Our data sharing policy is attached as Exhibit A. The goal of this data sharing policy is to facilitate autism spectrum disorder research and foster collaboration by giving the broader research community access to publicly available high-quality data. Grantee and Researcher agree to abide by the terms of Exhibit A and agree to work with the National Institutes of Health and NDAR staff to ensure efficient sharing of data gathered through this project.

Within 1 month of the start of the contract period, Researcher will send their ORCID ID (www.orcid.org) to the Autism Science Foundation. If no previous account with ORCID exists, Researcher shall register and upload their information.

H. Ownership of Equipment

Title to any equipment purchased with Autism Science Foundation funds belongs to Grantee, or, if consistent with the policies of Grantee and at the sole discretion of Grantee, to Researcher.

I. Right to Audit

In accordance with generally accepted accounting principles, Grantee shall maintain reasonably full and complete records of the cost and completion of services performed under this Agreement. During the term of this Agreement, and for a period of two years after its termination or completion, ASF shall have the right to inspect and/or audit Grantee's records as they pertain to the performance of the Agreement. Upon five business days written notice from ASF, Grantee agrees to make available all records for inspection or audit at its offices during normal business hours (Monday through Friday, 9 a.m. - 5 p.m. local time).

J. Indemnification

To the extent allowed by United States federal, state and trust law, Grantee agrees to defend, indemnify and hold Autism Science Foundation, its officers, trustees, employees and agents harmless from and against any and all damages, claims, liabilities or demands which may be made or asserted by reason of: (a) any injury or loss to persons or property sustained for whatever reason whatsoever by Researcher or Grantee, or its or their officers, employees, agents, subcontractors, patients, subjects, visitors or other individuals who may be involved in the Project or in any research conducted in connection with the Project, and (b) any injury or loss to persons or property sustained for any reason whatsoever by any person caused by or otherwise attributable to acts of omission or commission of persons performing work pursuant to the research project. In no circumstance will ASF be liable to an extent that exceeds the Grant amount.

Grantee and Researcher are responsible for notifying Autism Science Foundation immediately

in writing of any institutional investigation into the conduct of Researcher or any member of his/her research team, including, in the case of research involving human subjects, any suspension or termination of IRB approval, and for keeping Autism Science Foundation informed on a timely basis of the progress and outcome of any investigation.

K. Force Majeure

Neither party shall be liable in damages or have the right to terminate this Agreement for any delay or default in performing hereunder if such delay or default is caused by conditions beyond its control including, but not limited to Acts of God, Government restrictions (including the denial or cancellation of any export or other necessary license), wars, insurrections and/or any other cause beyond the reasonable control of the party whose performance is affected.

L. Jurisdiction

This Agreement shall be governed and construed in accordance with the laws of the State of New York. Any and all controversies, disputes or claims arising out of or relating to this Agreement shall be determined by arbitration in the County of New York, State of New York.

BY SIGNATURE AND DATE BELOW, THE PARTIES HEREBY AGREE TO THE TERMS OUTLINED ABOVE:

Grantor: Autism Science Foundation	
Alison Singer, President	
Dated:	
Grantee: INSTITUTION	
Authorized Official	
Name:	
Title:	
Dated:	

Addendum to the Grant Funding Agreement

By signing below, APPLICANT ("Researcher") and MENTOR ("Mentor"), as the Researcher and Mentor identified in Autism Science Foundation Grant Funding Agreement number GRANT NUMBER (the "Agreement") entered into by Autism Science Foundation ("Grantor") and INSTITUTION ("Grantee"), acknowledge and agree to the following:

- 1. Researcher and Mentor accept all rights and obligations conferred on them by the Agreement and agree to be subject to the terms and conditions of the Agreement insofar as they apply.
- 2. If Researcher's affiliation with Grantee ends prior to completion of the Project and Researcher wishes to continue the Project in affiliation with a new research institution, Grantor may, at its sole discretion, enter into a separate grant funding agreement with the new research institution to fund the remainder of the Project. In order to request such continuation of the Project, Researcher shall submit to Grantor: (i) a request for such continuation; and (ii) sufficient information with respect to Researcher's new research institution to enable Grantor to conclude whether such institution is eligible to enter into a grant agreement.

Researcher: APPLICANT	
Name:	
Title:	
Dated:	
Mentor: MENTOR	
Name:	
Title:	
Dated:	

Payment Information Form

Please type or print the requested information below.

Grantee:	
Researcher:	
Grantee EIN:	
Grants and Contracts Officer Name: (note: please designate a contact person to whom future questions can be addressed, note general OSP email address)	ot a
Officer Title:	
Officer's E-mail:	
Mailing Address for Grant Payments:	
Address:	
City: State: Zip:	
Country: Phone:	
Grantee's Website:	
Researcher's Permanent Mailing Address (not a university based address):	
Address:	
City: State: Zip:	
Researcher's Permanent Email Address (not a university affiliated email):	
Researcher's Phone:	

Please return this form with the signed contract

Exhibit A: Data Sharing Policy

I. Data Sharing Overview

All data resulting from this ASF-funded research involving human subjects are expected to be submitted to the National Database for Autism Research (NDAR), along with appropriate supporting documentation to enable efficient use of the data. The goal of this data sharing policy is to facilitate autism spectrum disorder research and foster collaboration by giving the broader research community access to publicly available high-quality data.

Outlined below is the two-tiered approach for data submission to, and sharing through, NDAR. The first tier is for descriptive/raw data, and the second for analyzed data (see Definitions). The objective of this two-tiered approach is to make data available to the research community as soon as possible without compromising the ability of the authors to interpret and communicate formally their findings.

II. Submission Schedule for Descriptive/Raw Data

Descriptive/raw data are data used to characterize a research subject (see Definitions), including data from standard diagnostic assessments, standard clinical measures, family/subject medical history, demographic data, raw unprocessed images, -omics (e.g. proteomics, genomics, metabolomics) data, and genetic test results (karyotype, Fragile X, MeCP2, etc.) that are being collected in the course of the supported research. Not included as descriptive/raw data are analyzed data, clinical observations, outcome variables, laboratory measures, etc. These are considered analyzed data.

Descriptive/raw data are expected to be submitted to NDAR on a semi-annual basis (on or before January 15 and July 15). NDAR support staff will be following up with you within the next 3 months to plan an appropriate data submission schedule for the raw/descriptive data. Cumulative submission of clinical data is expected during each submission cycle accommodating any changes. Raw -omic, EEG, and neuroimaging data are expected to be submitted only once.

III. Submission Schedule for Analyzed Data

Analyzed data (see Definitions) are expected to be submitted at the time of publication. Even if a publication focuses on only part of an analyzed dataset, the entire analyzed dataset should be submitted when the first paper is published. The data that are not part of the paper will not be shared immediately with the research community, but rather along the timeline described in the Data Sharing section below.

Analyzed data include:

- Results.
- Data from custom or proprietary clinical assessments/measures that support the aims of the proposed research or are otherwise not included in the semi-annual submissions.
- Final data and/or images derived from processed images (see Definitions).

- Sufficient supporting documentation to enable efficient and appropriate use of the data by the broader research community (see Definitions).
- All other de-identified research data acquired through the supported research but not explicitly listed here.

Additionally, Researchers are **expected** to associate the data deposited in NDAR with their publications using the NDAR Study feature (see http://ndar.nih.gov/ndarpublicweb/access.html#ndar_study). Study definitions from hypotheses that generate negative results are encouraged.

IV. Provisions for Data Submission

- All human subject data provided must include an NDAR Global Unique Identifier (GUID) and must not include personally identifiable information (PII).
- All data collected on all human subjects involved in the NIH-supported research are
 expected to be provided. These include data from control subjects and related family
 members. The total number of subjects for which data are provided should be
 consistent with the total number of subjects reported on the <u>2590 Inclusion Enrollment</u>
 Report. It is understood that gaps in data will exist in the event that not all participants
 agree to share their data, or do not complete the entire protocol for other reasons.
- Custom or proprietary measures not currently defined in the NDAR Data Dictionary will require the investigator to define the data measures, data structures, and discrete data elements using the NDAR Data Dictionary Tool, allowing those data to be made available for sharing.
- Individual subject-level data rather than summary/aggregate data are expected.
- Item-level detail on core autism measures such as ADOS, ADI, Vineland, and a research participant's medical/family history are expected.
- Due to the challenges inherent in de-identifying video footage, video material should not be submitted.

V. Data Sharing Schedule

All submitted data (both descriptive/raw and analyzed data) will be made available for access by members of the research community according to the provisions defined in the <u>NDAR Data</u> <u>Sharing Policy</u>. The data sharing policy is intended to allow investigators sufficient time for data verification, and for submission of primary publications based on the collected data.

Descriptive/raw research data are made available for access to other researchers within **four (4) months after submission**, allowing the Principal Investigator and their team sufficient time to complete appropriate quality assurance/quality control (QA/QC) procedures. Thus, there would be between five (5) and eleven (11) months from collection to sharing of descriptive/raw data. Descriptive data on banked biospecimens are expected to be shared when the sample is banked.

Analyzed research data are expected to be submitted to NDAR at the time a publication is accepted and shared when the publication is released. Unpublished data are expected prior to project completion and will be shared one year after the original project completion, or the data are published, whichever comes first.

It is expected that any deviations from the above in terms of timelines or types of data to be shared may be negotiated with the NIH program officer for the grant (or other award

mechanism) before the award is made. If circumstances arise during the course of the research that might cause deviations from these terms, such deviations must receive approval as defined in <u>NDAR SOP-10</u> Request Time Extension for Sharing or <u>NDAR SOP-11</u> Deviations in <u>Data Sharing Terms</u>.

V. Privacy

All data (see Definitions) made available for public use via NDAR will be de-identified data, such that the identities of participants cannot be readily ascertained or otherwise associated with the data by the repository staff or secondary data users. Submissions of data to NDAR must be accompanied by the NDAR Data Submission Agreement, which is expected within 6 months of award.

VI. Data Access for Research Purposes

Access to data for research purposes will be provided through the NDAR <u>Data Access</u> <u>Committee (DAC)</u>. Investigators and institutions seeking data from NDAR will be expected to meet data security measures and will be asked to submit a data access request, including a Data Use Certification, which is co-signed by the investigator and the designated Institutional Official(s) at the NIH-recognized sponsoring institution with a current Federal Wide Assurance (FWA). The procedures associated with data access are described at http://ndar.nih.gov/ndarpublicweb/policies.go#SOP.

VII. Definitions

Cumulative data: A dataset that includes all data collected from the beginning of the study to designated time point; each submission replaces previously submitted datasets in order to avoid the challenges of tracking interim changes or corrections in the database. Data containing references to large files (e.g., genomic, imaging, and other rich data types), may be provided incrementally for efficiency reasons.

Data: For human subjects, data include all research and clinical assessments and information obtained via interviews, direct observations, laboratory tasks and procedures, records reviews, genetic and genomic data, neuroimaging data, psychophysiological assessments, data from physical examinations, etc. The following are not included as data: laboratory notebooks, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens.

Descriptive/raw data: Descriptive/raw data include family/medical history, demographic data, data from standard diagnostic instruments, or custom measures supporting a categorization of a subject's phenotype. Examples include but are not limited to ADOS, ADI-R, IQ, Vineland, M-CHAT, Medical History, etc. Additionally, raw unprocessed images and genomic submissions are also categorized as descriptive/raw data. For longitudinal neuroimaging studies, where images at different time points are considered outcome measures, only baseline raw images are expected as descriptive/raw data.

Genomic data:

Descriptive/raw genomic data are defined as the raw or primary data specific to the technology platform used for the research study. If a microarray technology is used, an example of descriptive/raw data is the intensity data such as an Affymetrix CEL file. Descriptive/raw data submissions from research studies using the next generation of sequencing technology should include the read data, the second most frequent base and the quality data. Formats for these submissions include fastq, AB SOLiD Native, AB SOLiD SRF, Illumina Native, Illumina SRF, and Roche 454 SFF.

Analyzed genomic data are defined as data derived from the primary or raw data. For the example of the next generation of sequencing technology, analyzed data would be alignments or mapped data in the BAM (Binary Alignment/Map) format or the Sequence Alignment/Map (SAM) Format. Examples of analyzed data from the SNP microarray technology would include copy number and/or genotype. For the gene expression microarray technology, an example of analyzed data would be normalized gene expression levels.

The investigator is required to provide enough information to allow other researchers to repeat the experiment. Information provided using NDAR's Experiment Definition Tool includes the experimental molecule, used technology and experimental platform, protocols used for molecule and experiment preparation and kits used for these purposes, as well as names of analysis software, experimental equipment and description of analysis protocols.

Raw unprocessed images: Data acquired from a scanner in a standard medical imaging format. DICOM format is preferred.

Processed images: Derived data generated as the final result of image analysis applications in any standard medical research format (e.g. NIFTI, AFNI, etc.). If applicable, supporting de-identified video and imaging materials that define the experiment (e.g. timing sequences in fMRI) should accompany processed images. Intermediate image datasets should not be submitted unless the investigator feels that they are pertinent.

Analyzed Data: Data specific to the primary aims of the research being conducted (e.g. outcome measures, other dependent variables, observations, laboratory results, analyzed images, volumetric data, etc.)

Supporting documentation: Clear documentation expected in order to enable an investigator unfamiliar with the dataset to understand and use the data. For example, supporting documentation may include non copyrighted data collection forms, study procedures and protocols, data dictionary rationale, exclusion criteria, website references, a listing of major study publications, and the definition of a genomic experiment using the NDAR Experiment Definition Tool.