

# **SFARI Base External Cohorts Autism Inpatient Collection (AIC) Researcher Welcome Packet**

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# Table of Contents

<b><u>AIC Participation Criteria</u></b>	<b>3</b>
Participants in the Autism Inpatient Collection	3
Inclusion Criteria	3
Exclusion Criteria	4
Other Considerations	4
AIC Available Instruments by Family Role Table	6
<b><u>Prerequisites for Access to SFARI Base</u></b>	<b>10</b>
Required Institutional Documents	10
Online SFARI Application Instructions	10
<b><u>Sample Consent Forms</u></b>	<b>10</b>

## AIC Participation Criteria

Participants enrolled in the AIC were recruited upon admission to one of six specialized child psychiatric inpatient units exclusively serving youth with autism and other developmental disorders. Variation in family composition is reflective of families in the broader community, including biological nuclear families, adoptive, step, foster, and single-parent families, as well as related caregiver and non-kin caregiver families. Each family includes a child with autism (the proband) and at least one parent/caregiver. The parent/caregiver completed phenotypic data measures. Direct assessments were conducted with the proband. The proband and biological parents were asked to provide a blood or saliva sample.

## Participants in the Autism Inpatient Collection

**Proband:** The affected child.

**Biological Parents:** Biological mother and father of the proband, living at the time of participant admission.

**Biological Relative Caregiver:** Biological grandparent, aunt or uncle, or adult sibling.

**Nonbiological Caregiver:** Adoptive, step or foster parent or non-kin caregiver.

**Blood samples, or saliva when blood could not be obtained,** were collected from the proband, biological mother and biological father and sent to a central repository ([RUCDR Infinite Biologics](#)), where biospecimens were generated.

## Inclusion Criteria

### Age

The proband was between 4 years and 20 years 11 months of age at time of enrollment.

### Screening Criteria

The proband was between the ages of 4 years and 20 years 11 months at day of admission to the inpatient unit.

- At least one parent/caregiver could speak and read proficient English and participate in the study.
- The proband, if a minor or adult without capacity, had a legal guardian who could sign consent for the proband to participate in the study.
- The proband did not have prisoner status, e.g., not on probation or house arrest.

- The proband met screening criteria to enter the study based on a:
  - score of 12 or higher on the Social Communication Questionnaire (SCQ), Lifetime, completed by a caregiver who knew the child since age 4–5

OR

- referral by the specialized unit physician based on clinical concern for ASD.

## Inclusion

Probands in the AIC data set include only those participants with confirmed autism based on meeting all of the following criteria:

- Administered ADOS-2 by a research-reliable ADOS-2 examiner
- Met ADOS-2 cutoffs for autistic disorder or autism spectrum disorder
  - The newest ADOS algorithms were used for Modules 1–3.
  - Original cutoff algorithms were used for Module 4.
- Received a final diagnosis of autism spectrum disorder according to the *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)*. The final diagnosis was made by the research-reliable ADOS-2 examiner based on ADOS-2 findings, clinical observation and chart review.

## Exclusion Criteria

Families meeting one or more of the following were excluded from the study:

- Proband had impairments that would preclude valid administration of the ADOS-2 (blind, deaf, or vision or hearing impaired to a degree that would impact ADOS-2)
- No parent/caregiver available that was fluent in English
- Consent not obtained within 10 days of proband admission to the specialized psychiatric inpatient unit
- No parent/caregiver surveys completed within 10 days of proband admission to the specialized inpatient unit (see AIC Available Measures by Family Role Table for measures required within 10 days and measures without this requirement)

## Other Considerations

### Description of AIC Data Set

The AIC data set contains prospectively collected data from children and adolescents aged 4–21 years, with a research-reliable Autism Diagnostic Observation Schedule, Second Edition (ADOS-2) supported ASD diagnosis, admitted to one of six specialized inpatient child psychiatry units in the United States. The AIC was designed to produce a collection of phenotypic, behavioral and genetic data on a sample of children with ASD that included those

who are minimally verbal, have very low adaptive functioning and/or engage in challenging behaviors. A parent/caregiver completed a study demographic questionnaire and a series of measures examining the child's behavior, communication, emotion regulation, adaptive functioning and other domains, and measures of parenting stress and self-efficacy (see full details in the AIC Instruments by Family Role Table in this packet). Data was also collected on the child's behavior, communication, cognition, sleep and other dimensions by clinical and research staff throughout their inpatient stay. Blood or saliva samples were collected from the proband and biological parents.

At the start of the third year of data collection, several changes were made in the assessment battery and data collection time points. Details regarding the measures can be found in the AIC Instruments by Family Role Table in this packet. Data sets are available that include the first 350 subjects.

This study was approved by the Institutional Review Board (IRB) at all participating sites, and all families gave written permission for their data to be used in publications related to this study. The AIC data set has been cleaned, and missing data was handled per instructions of the authors of each measure (details in the data reference). Data collection for the AIC is ongoing and the data set is updated periodically.

### **Data Management**

Data Quality Checks were carried out before transfer of data to the Simons Foundation.

Data Validation — Validation was implemented within the electronic data entry form (REDCap), which limited data entry to a specific data range or format. Categorical fields and/or data validations were created wherever possible to avoid inconsistencies, typically found with open text fields.

Missingness — All data underwent comprehensive missing data checks, which were executed within the electronic data entry form and addressed by each of the site's research assistants. Missing data codes and Not Applicable data codes were entered when indicated. Items were sometimes missed by parent/caregiver participants completing survey measures, and when applicable, imputation techniques recommended by the measure authors were used to assign a score in place of a null value.

Logic checks — Checks were executed within the database. See Release Notes for logic check examples.

Spot Checks — Ten percent of each of the six data collection sites' sample were randomly chosen for spot checks of entered data and compared with hard copy data forms. Checks included recalculation of hand-scored measures, such as the Leiter-3, and the frequencies of data errors by instrument and event were calculated. Spot checks identified an error rate of <1 percent in the examined sample and no systematic errors were identified.

Detailed information regarding Imputation and Data Quality Checks are provided in the accompanying Data Reference and Data Manager Release Notes.

## AIC Available Instruments by Family Role Table

Note: All measures listed as 'Admission' were completed within 10 days of admission to the hospital unit. Measures listed as 'During hospital stay' were completed during the hospital stay when feasible for a parent/caregiver and/or when a proband was clinically stable for the assessment to be conducted.

Instrument / Activity	Proband	Parent/Caregiver
<p><b>Social Communication Questionnaire – Lifetime (SCQ)</b></p> <p>Measure of: Screen for ASD and study inclusion            Format: Questionnaire            Administered when: Admission            Completed by: Parent/caregiver            Publisher: WPS</p>	X	
<p><b>AIC Intake Demographic and Medical Form</b></p> <p>Measure of: Proband demographics, family composition, medical and psychiatric history            Format: Questionnaire            Administered when: Admission            Completed by: Parent/caregiver            Publisher: N/A</p>	X	X
<p><b>AIC Augmentative and Alternative Communication (AAC) Survey</b></p> <p>Measure of: Communication methods and ability            Format: Questionnaire            Administered when: Admission            Completed by: Parent/caregiver            Publisher: N/A</p>	X~	
<p><b>Autism Diagnostic Observation Schedule, Second Edition (ADOS-2)</b></p> <p>Measure of: Observational measure of autism phenotype            Format: Direct examiner observation            Administered when: During hospital stay            Completed by: Research reliable ADOS examiner            Publisher: WPS</p>	X	

Instrument / Activity	Proband	Parent/Caregiver
<p><b>Aberrant Behavior Checklist (ABC) at admission</b></p> <p>Measure of: Aberrant behaviors  Format: Questionnaire  Administered when: Admission  Completed by: Parent/caregiver  Publisher: Slosson</p>	X	
<p><b>Aberrant Behavior Checklist – Irritability &amp; Hyperactivity Subscales only, at discharge and two-month follow-up</b></p> <p>Measure of: Aberrant behaviors  Format: Questionnaire  Administered when: Discharge and two-month follow-up  Completed by: Parent/caregiver (by phone at two-month follow-up)  Publisher: Slosson</p>	X*	
<p><b>Child &amp; Adolescent Symptom Inventory 5 (CASI-5)</b></p> <p>Measure of: Psychiatric symptoms and co-morbid diagnoses  Format: Questionnaire  Administered when: During hospital stay  Completed by: Parent/caregiver  Publisher: Checkmate Plus</p>	X*	
<p><b>Child Behavior Checklist for Ages 6-18 (CBCL)</b></p> <p>Measure of: Problem behavior and psychiatric symptoms  Format: Questionnaire  Administered when: During hospital stay  Completed by: Parent/Caregiver  Publisher: ASEBA</p>	X~	
<p><b>Repetitive Behavior Scale – Revised (RBS-R) Self-injury subscale only</b></p> <p>Measure of: Occurrence and severity of SIB  Format: Questionnaire  Administered when: Admission (parent/caregiver) or during hospital stay (clinical staff member)  Completed by: Parent/caregiver and clinical staff member (e.g., teacher)  Publisher: Bodfish</p>	X#	

Instrument / Activity	Proband	Parent/Caregiver
<p><b>Functional Assessment Screening Tool (FAST)</b></p> <p>Measure of: Function of behaviors            Format: Questionnaire            Administered when: Admission (parent/caregiver) or during stay (by clinical staff member)            Completed by: Parent/caregiver and by clinical staff member most familiar with probands' daily behavior in hospital            Publisher: Iwata</p>	X <sup>#</sup>	
<p><b>Difficulty Behavioral Self-Efficacy Scale (DBSS)</b></p> <p>Measure of: Parent/caregiver self-efficacy            Format: Questionnaire            Administered when: Admission, discharge, and two-month follow-up            Completed by: Primary parent/caregiver who is directly involved in caregiving for proband            Publisher: Hastings and Brown</p>		X
<p><b>Parenting Stress Index-4-Short Form (PSI-4-SF)</b></p> <p>Measure of: Parent/caregiver stress            Format: Questionnaire            Administered when: Admission            Completed by: Primary parent/caregiver who is directly involved in caregiving for proband            Publisher: PAR</p>		X
<p><b>Leiter International Performance Scale-3</b></p> <p>Measure of: Nonverbal intelligence (NVIQ)            Format: Direct assessment            Administered when: During stay, when behavior is stable            Completed by: Examiner            Publisher: Stoelting</p>	X	
<p><b>Peabody Picture Vocabulary Test, Fourth Edition (PPVT-4)</b></p> <p>Measure of: Receptive vocabulary            Format: Direct assessment            Administered when: During stay, when behavior is stable            Completed by: Examiner            Publisher: Pearson</p>	X <sup>~</sup>	



Instrument / Activity	Proband	Parent/Caregiver
<p><b>Vineland Adaptive Behavior Scales-II (VABS-II)</b></p> <p>Measure of: Adaptive behavior            Format: Questionnaire            Administered when: During hospital stay            Completed by: Parent/caregiver            Publisher: Pearson</p>	X	
<p><b>AIC Diagnostic and Behavioral Summary Form</b></p> <p>Measure of: ASD diagnosis, co-morbid diagnoses and function determination for self-injurious behavior if present            Format: Clinician evaluation summary form            Administered when: Discharge            Completed by: ADOS examiner, treating child psychiatrist and behavior specialist/unit clinician            Publisher: N/A</p>	X	
<p><b>AIC Inpatient Data Form</b></p> <p>Measure of: Inpatient data including length of stay, admission and discharge medications, discharge disposition and nightly sleep* data            Format: Chart abstraction form            Administered when: After discharge            Completed by: Research assistant            Publisher: N/A</p>	X	
<p><b>AIC Two-Month Follow-Up Form</b></p> <p>Measure of: Medications and current setting at two-month follow-up, services utilized in the two months since discharge            Format: Questionnaire            Administered when: two-month follow-up            Completed by: Research assistant by phone interview            Publisher: N/A</p>	X*	
<p>KEY            * = Stopped collecting following year two of study</p>		
<p>~ = Started collecting in year three of study</p>		
<p># = Change in who/when completed following year two</p>		

## Prerequisites for Access to SFARI Base Required Institutional Documents

Please note that each principal investigator (PI) who wishes to conduct one or more research projects using SFARI data or materials must obtain the following from their institution before applying:

- An electronically signed [Researcher Distribution Agreement \(eRDA\)](#). The RDA specifies the legal issues pertaining to research data and specimens, and requires approval from the PI's institution. Each PI and collaborator must sign the joinder agreement to the eRDA. Instructions for signing the eRDA will be emailed to the institutional officer directly from [collections@sfari.org](mailto:collections@sfari.org).
- For researchers at for-profit institutions, please email [collections@sfari.org](mailto:collections@sfari.org) to get the modified, corporate RDA.
- A letter from an institutional review board (IRB). Each SFARI project led by a PI must be governed by a protocol approved or exempted by an IRB. A protocol specifies the regulatory issues pertaining to the research and may include co-investigators at multiple institutions. You will need to obtain a PDF copy of the letter from your IRB approving or exempting your protocol.

## Online SFARI Application Instructions

1. Create a SF I.D. at <https://id.simonsfoundation.org>.
2. After creating an SF I.D., sign in to SFARI Base (<https://base.sfari.org/ordering>).
3. Affiliate with an institution. If your institution is not already on the list, email [collections@sfari.org](mailto:collections@sfari.org) to request that your institution be added.

*In this email, you must include institution name and the name and email address for the PI and institutional officer in charge of contracts and agreements.*

4. Once the eRDA and joinder agreements are signed, you will be able to submit an application for phenotype data, genetic data, biospecimens or to recontact families.

## Sample Consent Forms

The Autism Inpatient Collection Sample Consent Form is available on request

*If you have additional questions, email [collections@sfari.org](mailto:collections@sfari.org).*