

# SIMONS COLLECTION RESEARCHER DISTRIBUTION AGREEMENT

(Revised May 2017)

The purpose of this Researcher Distribution Agreement is to set forth the terms and conditions under which Principal Investigators may participate in approved Research Projects through the Institution using the Simons Foundation Autism Research Initiative (SFARI) Simons Collection made available by the Foundation.

## Part I. APPLICATION INSTRUCTIONS

Each Principal Investigator (as defined below) must apply and be approved by the Simons Foundation, in order to qualify for access to the SFARI Simons Collection for purposes of purchasing Biomaterials, accessing online data, and applying to recruit participants for additional research. Refer to the sfari.org website for additional details on resource availability for each cohort, and instructions about how to apply:

<https://sfari.org/resources/sfari-base>.

## Part II. DEFINITIONS

- A. Agreement** – This Researcher Distribution Agreement (RDA), by and among the Foundation, the Institution, and each approved Principal Investigator (as documented by a duly executed Joinder to this Agreement).
- B. Biomaterials** – Any biological or biochemical materials stored in the Repository and made available to approved researchers pursuant to this Agreement, which may include DNA, immortalized cell lines, fibroblasts, or any other material retained in the Repository, and any Progeny, Unmodified Derivatives, byproducts, or derivatives thereof. Biomaterials shall **not** include: (a) Modifications or (b) other substances created by Recipient through the use of the Biomaterials that are not Modifications, Progeny or Unmodified Derivatives.
- C. Clinical Data** – Information concerning subjects, 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 the Foundation or any of its collaborating researchers. Clinical Data shall exclude any personally identifying information about the family or its members.

- D. Data** – Collectively, Clinical Data and Genetic Analysis Data. All such Data are coded for confidentiality and stripped of personal identifiers.
- E. Effective Date** – The date indicated below when the Foundation has executed this Agreement.
- F. Foundation** – The Simons Foundation, a Delaware nonstock corporation and an organization described under Section 501(c)(3) of the Internal Revenue Code of 1986, as amended.
- G. Genetic Analysis Data** – Data derived from genotyping, mutation analysis, sequencing, karyotyping, zygosity testing, Fragile X testing, and any other genetic analyses performed on the Biomaterials.
- H. Institution** – The institution that has executed this Agreement and employs/retains each Principal Investigator (whether the Principal Investigator is in an employee/employer relationship or an independent contractor relationship with the institution) who is subject to the terms of this Agreement.
- I. Joinder to the Researcher Distribution Agreement (or Joinder)** – The written acknowledgment that a Principal Investigator has read and understood the terms and conditions of this Agreement in the conduct of his/her Research Project at or through the Institution using the SFARI Simons Collection, the form of which is attached hereto as Exhibit A.
- J. Materials** – Collectively, Data and Biomaterials.
- K. Modifications** – Substances or information created by Recipient that contain/incorporate the Materials.
- L. Person** – A natural person, corporation, partnership, trust, estate, joint venture, sole proprietorship, government (and any branch or subdivision thereof), government agency, association, cooperative, laboratory, or other entity.
- M. Principal Investigator** – Each researcher employed/retained by Institution who is conducting a Research Project (for which he/she has sole responsibility) that has been approved or exempted by the Institutional Review Board (IRB) and subject to the terms and conditions of a Joinder.
- N. Progeny** – Unmodified descendant from the Biomaterials, such as virus from virus, cell from cell, or organism from organism.
- O. Recipient** – Collectively, Institution and the Principal Investigator(s).
- P. Recruitment Services** – The process by which SFARI may help facilitate recruitment of SFARI Simons Collection participants into new research studies.
- Q. Researcher Access Application** – The online application for access to SFARI Simons Collection Materials.
- R. Researcher Generated Data** – Any and all data (including, but not limited to, Genetic Analysis Data) generated by Principal Investigator that was derived from or based upon the use of any of the Data, Biomaterials, Recruitment

Services, and/or resulted from new studies involving SFARI Simons Collection participants.

- S. Research Project** – The specific research project to be conducted at or through the Institution for which a Principal Investigator has sole responsibility, and which is explicitly described in such Principal Investigator’s Researcher Access Application.
- T. SFARI Base** – The website found at <https://base.sfari.org/ordering>, through which researchers explore SFARI Simons Collection data, make queries, and place requests for data and biomaterials.
- U. SFARI Simons Collection** – Any and all collections of data and biological samples from individuals and families that SFARI maintains for research from time to time. These may include, among others, specific cohorts such as the Simons Simplex Collection (SSC), the Twins Collection, the Ancillary Collection, the Simons Variation in Individuals Project (Simons VIP), and Simons Foundation Powering Autism Research for Knowledge (SPARK). Each cohort and respective protocol in the collection is described on sfari.org.
- V. Repository** – The facility responsible for the production Biomaterials and extraction of DNA from samples, as well as for the storage and distribution of Biomaterials.
- W. SFARI Research Liaison** – A representative of the Simons Foundation responsible for reviewing and approving researcher access applications.
- X. Unmodified Derivatives** – Substances created by Recipient that constitute an unmodified functional subunit or product expressed by the Biomaterials or Data. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the Biomaterials, proteins expressed by DNA/RNA, or monoclonal antibodies secreted by a hybridoma cell line.

### Part III. GENERAL TERMS AND CONDITIONS

Foundation and Institution (collectively, the Parties), intending to be legally bound, hereby agree as follows:

#### A. Effective Dates; Changes and New Projects

1. This Agreement becomes effective upon the Effective Date. Upon execution of this Agreement by Foundation, Foundation shall promptly provide Recipient with a copy of the executed Agreement.
2. This Agreement remains in effect for the duration of each Research Project.
3. During the term of this Agreement, if there have been any material

changes to any Research Project, the applicable Principal Investigator shall promptly provide the SFARI Research Liaison and the Institution with an updated project abstract and statement of intended use.

4. In the event that a Principal Investigator wishes to embark on a new research project using any Materials, a new online application must be filed. Similarly, if a Principal Investigator wishes to expand an existing project to include an additional SFARI Simons Collection cohort or request type, the project must be amended and/or a new online application request filed and approved. In either case, this Agreement will be deemed to be amended to include such Principal Investigator's new Research Project following the Foundation's approval of the new application for the research project.

## **B. Usage**

1. Materials and Modifications shall be used exclusively by Recipient in connection with the applicable Research Project.
2. Materials and Modifications shall be used exclusively for the advancement of biomedical science and shall be used in a manner consistent with the goals and policies of the Foundation.
3. Recipient shall not use Materials or Modifications in connection with human experimentation of any kind.

## **C. Resale, Third Party Use, and Transferability**

1. Recipient shall retain control over all Materials obtained from the SFARI Simons Collection and the Repository, and shall not provide, resell, share, or otherwise distribute them (free of charge or otherwise), directly or indirectly, to any other Person other than as provided in this Agreement.
2. If Institution or a Principal Investigator collaborates (or intends to collaborate) with any Person(s) not bound by this Agreement who will be utilizing and/or analyzing any Materials, such Party(ies) shall immediately inform the SFARI Research Liaison in writing of any and all such collaborations. All such Person(s) and their respective institutions must sign a separate Research Distribution Agreement with Foundation and a Joinder prior to their receiving or using any Materials.
3. Neither this Agreement nor any rights or obligations established hereunder are transferable to any other principal investigator, Person, facility, or institution without written consent of the Foundation. If a

Principal Investigator moves to an institution other than the Institution, any new institution shall sign a new Researcher Distribution Agreement, and the Principal Investigator shall sign a new Joinder, before such Principal Investigator may continue utilizing the Materials. Institution may not appoint a new principal investigator, conduct the Research Project at a different facility under Institution's control, or make any other substantive changes, unless Foundation agrees in writing to an appropriate amendment of this Agreement.

#### **D. Commercial Use; Rights of Third Parties**

1. Foundation arranges for the provision of Materials through the Repository for research purposes only. Nothing in this Agreement shall be construed as authorizing or prohibiting the use of Materials for any commercial purposes.

Recipient further understands and acknowledges that Foundation has made no attempt to determine outstanding rights in or to the Materials, and disclaims any knowledge relating to property interests in the Materials.

FOUNDATION DOES NOT MAKE ANY WARRANTY, EXPRESS OR IMPLIED, THAT THE MATERIALS MAY BE EXPLOITED WITHOUT INFRINGEMENT OF THE INTELLECTUAL PROPERTY OR PROPRIETARY RIGHTS OF ANY THIRD PARTIES.

#### **E. Data Sharing**

1. The Parties acknowledge that data sharing is an essential component of scientific research. Recipient grants Foundation the perpetual right to use and publish the Researcher Generated Data developed by the Principal Investigator under the Research Project, subject to the terms of this Article III.E. Therefore, Recipient shall provide Foundation with an electronic copy of all Researcher Generated Data within a reasonable time after generation or collection (not to exceed one year). In order to facilitate other research projects, subject to Section E(3) of this Article, Simons Foundation personnel may, at their discretion, release these data to other qualified investigators with the understanding that these other investigators will have agreed not to publish on these data until after an embargo period expires. The length of this embargo period will be established on a case-by-case basis in consultation with Recipient, but will generally not exceed one year after the end of the project or until publication, whichever comes first. These data may eventually be integrated with the other Foundation data collections. How,

when and if such data are made available to the wider research community will remain under the sole discretion of the Foundation. In addition, upon publication of the Project results, the Recipient shall make every effort to deposit all Researcher Generated Data into public databases (which may or may not be affiliated with Foundation) that are widely accessible, without charge, to the scientific research community. If no such databases are available that properly fit the type and content of the Researcher Generated Data, then the Recipient shall make every effort to make these data available through electronic supplementary tables and figures, which are now routinely associated with scientific publications. In all cases, Researcher Generated Data shall be in the format specified in paragraph E(2) below.

- 2 All Researcher Generated Data shall be indexed by the Foundation's official subject ID number, in the electronic format specified by the party hosting the receiving database, which may be a publicly funded repository, or the Foundation, as detailed in E(1).
- 3 Foundation may at any time distribute any or all of the Researcher Generated Data in its possession to qualified scientific investigators, subject to any patents or pending patent applications of the applicable Principal Investigator and/or Institution; provided, however, that should Recipient provide timely notice to Foundation of Recipient's intention to file a patent application related to the Researcher Generated Data, Foundation shall allow Recipient a reasonable amount of time in which to file said patent application prior to making the Researcher Generated Data available to qualified scientific investigators.
- 4 Foundation may, at its discretion, request project updates from the Recipient, including but not limited to overall project status, availability of Researcher Generated Data and publications resulting from use of the Data, Materials, and/or Recruitment Services, and summaries of new recruitment study outcomes. Recipient shall make every effort to respond to such queries within a reasonable period of time.

#### **F. Acknowledgement of Use**

1. Recipient shall acknowledge the use of any and all Materials and/or Recruitment Services as part of new research studies, pursuant to the then current acknowledgement guidelines posted on sfari.org, in any and all publications, oral and written presentations, media reports, interviews, and disclosures resulting from any and all analyses of Materials, whether during the term of this Agreement or afterwards. Recipient shall submit a list of all such publications, presentations,

media reports, interviews, and disclosures to the SFARI Research Liaison at least annually, or as requested by Foundation.

- 2 Upon publication of the results of any and all analyses of the Materials, Recipient shall forward a supplementary data table that clearly identifies the samples that were selected for analysis and the type of assays performed (i.e., genetic markers, cell culture treatments, etc.).
- 3 Recipient shall acknowledge the contributions of researchers who generated Researcher Generated Data used by Recipient in any and all publications, written and oral presentations, media reports, interviews, and disclosures resulting from any and all analyses of such Researcher Generated Data, whether during the term of this Agreement or afterwards.
- 4 As soon as Recipient has any manuscript regarding or based upon the Research Project accepted for publication (whether during the term of this Agreement or afterwards), a copy of the manuscript along with the name of the publication and expected date of publication shall be forwarded to the SFARI Research Liaison through SFARI Base. As soon as reprints are available, two copies of the reprint shall be forwarded to Foundation. In lieu of reprints, PDF files may be submitted.

### **G. Confidentiality**

For all projects except those utilizing Recruitment Services, the identities of the contributing subjects are confidential, and no identifying information is being or will be provided to Recipient. Recipient shall make no effort whatsoever to establish the identity of any contributing subject. Recipient shall notify Foundation immediately if Recipient becomes aware of any identifying information regarding any contributing subject. For projects involving recruitment of SFARI Simons Collection participants into new research studies, identifying information regarding participants may be shared with the Principal Investigator only if the participant authorizes such an exchange. Additionally, linking of participant identifying information to Data and Materials is only permitted after appropriate consent has been signed, during the course of a new research study. Principal Investigator shall notify Foundation immediately if he/she becomes aware of any improper use or disclosure of participant identifying information.

### **H. Access to Materials**

1. Foundation shall authorize the Repository to transfer to Recipient Biomaterials for exclusive use by each Principal Investigator to conduct his/her respective Research Project(s).

2. Foundation shall provide Institution and each applicable Principal Investigator with Data for all qualified participating subjects, if available, provided that it does not jeopardize the privacy or safety of the research subject. Such Data, along with periodic updates, if available, will be provided through SFARI Base, at no cost to Recipient.
3. Biomaterials will be provided to Recipient by the Repository, for a fee to be determined and collected by the Repository pursuant to such procedures as the Repository may establish from time to time. The Foundation shall pay such fees on behalf of Principal Investigators who have been designated, by separate agreement with the Foundation. A current fee schedule may be obtained on sfari.org, or by contacting the SFARI Research Liaison. This site provides a link to SFARI Base, an online tool that enables researchers to explore SFARI Simons Collection data and submit requests for Data and Biomaterials and to apply for access to contact participants for new recruitment studies.

In the event that a family or family member of the original contributor of the Materials provided to Recipient wishes to withdraw from the SFARI Simons Collection, Foundation reserves the right to request that Recipient destroy all such remaining Materials and any Progeny, Modifications or Unmodified Derivatives thereof. In such event, Recipient shall comply with such request and refrain from using such Materials and any Progeny, Modifications or Unmodified Derivatives thereof in further analyses; provided, however, that Recipient may continue to use Researcher Generated Data.

#### **I. Biohazard and Handling of Human Biomaterials**

1. All cultured animal and human cells have the potential for carrying viruses, latent viral genomes, and other infectious agents in an unapparent state. All Biomaterials shall, therefore, be treated as if they are NOT free of contamination.
2. Biomaterials shall always be handled carefully by trained personnel under laboratory conditions that afford adequate biohazard containment. By accepting Biomaterials from the Repository, Recipient accepts and assumes full responsibility, financial and otherwise, for the safe and appropriate handling of such Biomaterials. FOUNDATION ASSUMES NO RESPONSIBILITY FOR ANY PERSONAL ILLNESS OR INJURY OR PROPERTY LOSS RESULTING FROM RECIPIENT'S USE OF THE BIOMATERIALS, EXCEPT TO THE EXTENT CAUSED BY THE WILLFUL



MISCONDUCT OR GROSS NEGLIGENCE OF FOUNDATION.

3. Recipient understands that the Repository has the sole responsibility of storing and distributing the Biomaterials. Recipient shall comply with all of the Repository's and other appropriate safety and quality control procedures, including the guidelines set forth in *Biosafety in Microbiological and Biomedical Laboratories* (Fifth Edition, 2007), prepared by the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, and National Institutes of Health, which can be found online at <http://www.cdc.gov/biosafety/>.

#### **J. Institutional Review Board (IRB) Compliance**

Recipient certifies that (i) the Institution provides IRB approval or exemption for the conduct of each Research Project, and (ii) each Principal Investigator is and shall remain in full compliance with the regulations and policies of said IRB. Recipient shall report promptly to Foundation any proposed changes in any Research Project and any unanticipated problems involving risks to subjects or others. Recipient shall provide to Foundation updated IRB approval documents as needed for ongoing projects, via upload on SFARI Base or directly to the SFARI Research Liaison.

#### **K. No Warranty and Limitation of Damages**

THE MATERIALS AND RECRUITMENT SERVICES ARE PROVIDED AS A SERVICE TO THE RESEARCH COMMUNITY. THEY ARE PROVIDED "AS IS." FOUNDATION DOES NOT MAKE, AND EXPRESSLY DISCLAIMS, ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT. THIS PROVISION SHALL ALSO APPLY TO ANY BYPRODUCTS OR DERIVATIVES OF THE MATERIALS. IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY INCIDENTAL, SPECIAL, INDIRECT, PUNITIVE OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR RELATING TO THIS AGREEMENT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

#### **J. Indemnification**

Institution shall indemnify, defend and hold harmless Foundation, the original contributor of the Materials supplied to Recipient and their families, and the officers, directors, employees and agents, and the heirs, successors and assigns of them and each of them, from and against 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 Recipient's receipt, handling, storage, use, disposal, distribution or redistribution of any and all Materials supplied to and/or Recruitment Services

utilized by Recipient, except to the extent caused by the willful misconduct of Foundation.

#### **L. Termination of Agreement**

1. This Agreement shall automatically terminate with respect to a Principal Investigator upon such Principal Investigator ceasing to be employed or retained by Institution. Upon a Principal Investigator ceasing to be employed or retained by Institution, such Principal Investigator and Institution each shall provide written notice to Foundation of such fact.
2. Foundation may terminate this Agreement if Recipient is in default of any of the terms and conditions specified herein and if the default has not been remedied within thirty (30) days after the date of written notice by Foundation of such default.
3. Institution may terminate this Agreement, in whole or with respect to a specific Research Project or Principal Investigator, upon thirty (30) days written notice to Foundation.  
Upon the termination or expiration of this Agreement (in whole or in part), Recipient shall return all unused Materials to Foundation, or provide Foundation with written certification of their destruction.
4. Sections E, F, G, and L of Part III of this Agreement, and any other provisions of this Agreement that by their nature extend beyond termination or expiration hereof, shall survive such termination or expiration.

#### **M. Choice of Law and Venue**

This Agreement shall be governed by the laws of the State of New York. In the event of any controversy, claim or dispute among the Parties hereto arising out of or relating to this Agreement, such controversy, claim or dispute shall be tried exclusively in the courts of the State of New York or in the United States Federal District Court for the Southern District of New York, located in the County of New York, as the Parties may elect. The Parties hereby waive any defense of lack of in personam jurisdiction, improper venue and forum non conveniens, and agree that service of process of such court may be made upon each of them 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 hereby 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.

## N. Miscellaneous

1. The terms and conditions of this Agreement are binding upon Recipient, including the applicable Principal Investigator, any and all personnel working on a Research Project under the direct or indirect supervision of a Principal Investigator. Recipient shall ensure that the terms and conditions of this Agreement are understood and obeyed by all such research associates, graduate students, and collaborators.
2. The relationship of Recipient and Foundation is in the nature of an independent contracting arrangement. This Agreement shall not be deemed to create a partnership, joint venture or franchise, and neither party is the other's agent, partner, employee or representative.

Neither Recipient nor Foundation shall use any name, trade name, trademark, domain name, or other designation of another Party in connection with any products, promotion, marketing or advertising, except as set forth in this Agreement or otherwise with the prior written consent of the other Party.

3. The waiver or failure of a Party to exercise any right in any respect provided for herein shall not be deemed to be a waiver of any further right hereunder.
4. This Agreement shall be binding upon and inure to the benefit of each of the Parties, including their respective heirs, legal representatives, successors, and permitted assigns.
5. This Agreement, together with the applicable Joinder, constitutes the entire understanding of the Parties with respect to the matters referred to herein and supersedes all prior negotiations, commitments and understanding with respect thereto. No variation or modification of this Agreement or waiver of any terms of provisions hereof shall be deemed valid unless in writing and signed by authorized representatives of both Parties.
6. Notice made hereunder shall be 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 Foundation:**

**SFARI Simons Collection  
Simons Foundation**

**160 Fifth Avenue, 7<sup>th</sup> Floor  
New York, NY 10010  
Attention: SFARI Research Liaison**

**If to Recipient:**

**To the name and address of the Institution's designated contact as set forth  
on the signature page of this Agreement.**

{Signature Page Follows}

**ACCEPTED AND AGREED BY INSTITUTION:**

\_\_\_\_\_  
Name of Institution

\_\_\_\_\_  
Signature of Institution Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Institution Representative

\_\_\_\_\_  
Title

\_\_\_\_\_  
Printed Name of Designated Contact

\_\_\_\_\_  
Telephone

\_\_\_\_\_  
Email address of Designated Contact

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**SIMONS FOUNDATION**

\_\_\_\_\_  
Signature of Foundation Representative

\_\_\_\_\_  
Date ("Effective Date")

\_\_\_\_\_  
Printed Name of Foundation Representative

\_\_\_\_\_  
Title

**EXHIBIT A**

**JOINDER TO  
SIMONS FOUNDATION AUTISM RESEARCH INITIATIVE (SFARI)  
SIMONS COLLECTION  
RESEARCHER DISTRIBUTION AGREEMENT**

I, the undersigned, have applied for access to and use of the Simons Foundation Autism Research Initiative (SFARI) Simons Collection in the conduct of my research at **[Add Name of Institution]** (the “Institution”) under the research protocol entitled \_\_\_\_\_ (the “Research Project”).

In connection with my application to conduct the Research Project at **[Add Name of Institution]**, I have been provided a copy of the Researcher Distribution Agreement (the “RDA”) between the Simons Foundation and the Institution dated \_\_\_\_\_.

I have had the opportunity to review the RDA, and to have any questions regarding the RDA fully answered by the Foundation and Institution, as applicable.

I understand that this Joinder will apply to any modifications to the Research Project or any new research project approved by the Foundation under the RDA referenced above.

Based on the foregoing, I understand and acknowledge all of the applicable terms and conditions of the RDA and will abide by these terms in the conduct of the Research Project at or under the auspices of the Institution, and any amendments thereof that are provided to me in writing.

**READ AND UNDERSTOOD BY PRINCIPAL INVESTIGATOR:**

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Principal Investigator

\_\_\_\_\_  
Title

A copy of this Joinder will be sent to your institutional officer as identified in the applicable RDA.