AUTISM RESEARCH RESOURCE

Material Transfer Agreement (Assurance Form)

This Material Transfer Agreement (MTA) pertains to Sample(s) that are part of the Autism Research Resource and which are administered by the Coriell Institute for Medical Research, Camden, New Jersey 08103 (Coriell).

To ensure compliance with the Office for Protection from Research Risks (OPRR), Department of Health and Human Services (DHHS) regulations for the protection of human subjects (45 CFR Part 46), prior to the shipment of Sample(s) from the Autism Research Resource, the Principal Investigator receiving the Sample(s) (Principal Investigator) must provide the Autism Research Resource with a **Statement of Research Intent**, describing the purpose of the research to be done using the Sample(s).

Both the Principal Investigator and the Institutional Official (legal representative authorized to make legally binding agreements for the institution receiving the Sample(s)) must sign this MTA, agreeing to adhere to the following conditions.

WARRANTY AND LIABILITY:

Warranty: THE AUTISM RESEARCH RESOURCE AND CORIELL MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

Liability Statement for State Institutions: The recipient Institution agrees to be responsible for any claims, costs, damages, or expenses resulting from any injury (including death), damage, or loss that may arise from the use of the Sample(s) to the extent permitted under the laws of the Institution's state. This provision shall also apply to any byproducts or derivatives of the Sample(s).

Liability Statement for U.S. Government Laboratories: The United States assumes the liability for any claims, damages, injuries, or expenses arising from the use of the Sample(s) or any byproduct or derivative, but only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171).

Liability Statement for All Other Institutions: The recipient Institution agrees to indemnify and hold harmless the United States government, Coriell and the submitter of the Sample(s)

from any claims, costs, damages, or expenses resulting from any injury (including death), damage, or loss that may arise from the use of the Sample(s). This provision shall also apply to any byproducts or derivatives of the Sample(s).

HUMAN EXPERIMENTATION:

Human experimentation utilizing the Sample(s) is **strictly prohibited**.

RESEARCH USE, COMMERCIAL USE, AND RESTRICTIONS ON REDISTRIBUTION AND PROHIBITIONS ON RESALE:

The Autism Research Resource provides biomaterials as a service to the research community. The purpose of the Autism Research Resource is to stimulate and facilitate research in genetics and related fields, leading to a better understanding of normal genetic and cellular processes, to the identification and function of disease-related genes, and to the diagnosis and treatment of genetic disorders.

It is expressly understood that the Sample(s) delivered pursuant to this MTA are experimental in nature and are for use in research, in teaching, and as reference materials in clinical genetics laboratories. Institutions using Sample(s) for use as reference materials or controls are responsible for complying with all laws and regulations applicable to the intended use of the Sample(s), including any requirements for FDA approval.

The identification number(s) of the sample(s) must be cited as follows in publications or presentations that are based on the use of these materials: "The following samples were obtained from the Autism Research Resource at the Coriell Institute for Medical Research: [list Autism Research Resource ID numbers here]."

There is no restriction on development of commercial products resulting from the **knowledge** gained from studies using the Sample(s). However, Sample(s) may not themselves be used in the manufacture of commercial products.

SECONDARY DISTRIBUTION AND SHARED USE OF SAMPLE(S):

Genetic research often involves collaborations among several investigators or several laboratories that share materials toward a common goal. Also, as a result of new genomic technologies, data are often generated by multi-user core facilities. Many laboratories benefit from using common biological reference materials for research or clinical purposes. Thus, consistent with the mission to facilitate genetic research, the Autism Research Resource will permit secondary distribution to accommodate certain situations if it can be established that protection of human subjects and quality control of the samples can be ensured. **Secondary distribution, defined as the sharing of Sample(s) with members of laboratories other than the Principal Investigator's, is prohibited except under special circumstances. The Principal Investigator must contact**

Coriell before proceeding with a secondary distribution.

SHARED USE AND POSTING OF PERSONALLY IDENTIFYING GENETIC INFORMATION:

Sample(s) have the potential to generate data that could be used to identify an individual (e.g.: Combined DNA Index System (CODIS) reports, whole-genome microarray genotyping data, whole-exome or whole-genome DNA sequencing data). Investigators are **strictly prohibited** from posting or making available through open-access public websites and/or databases genetic data that might identify an individual. Investigators may, however, submit such datasets to the Database of Genotypes and Phenotypes (dbGaP), which requires users of the data to abide by a Code of Conduct. Investigators must agree not to identify or contact the submitter of the Sample(s) or the donor subject from whom the Sample(s) was derived for any reason.

BIOHAZARD:

All cultured animal and human cells have the potential for carrying viruses, latent viral genomes and other infectious agents in a latent or inactive state. Sample(s) shipped by the Autism Research Resource should therefore not be treated as if they are free of contamination. These Sample(s) should always be handled carefully by trained persons under laboratory conditions which afford adequate biohazard containment following MINIMUM SAFETY GUIDELINES RECOMMENDED FOR WORKING WITH BIOHAZARDS. By accepting these Sample(s), the undersigned assume full responsibility for their safe and appropriate handling.

We, the undersigned, have read and understand this document and agree to adhere to the restrictions and warnings stated herein.

Name of Institution

Name of Institutional Official who can make legal commitments on behalf of the Institution (typed or printed)

Title of Institutional Official

Signature of Institutional Official Date

Read and Understood the terms and conditions of this Agreement:

Name of Principal Investigator (typed or printed)

Signature of Principal Investigator Date

To contact the CORIELL CELL REPOSITORIES:

Write: 403 Haddon Avenue, Camden, New Jersey 08103 USA

Call: 800-752-3805 in the United States; 856-757-4848 from other countries

E-mail: **customerservice@coriell.org**