

AMENDMENT FOR DISTRIBUTION 4.0—INDUCED PLURIPOTENT STEM CELLS (iPSC) NIMH HUMAN GENETICS INITIATIVE DISTRIBUTION AGREEMENT

NOW, THEREFORE, it is mutually agreed that the National Institute of Mental Health (NIMH) Human Genetics Initiative Distribution Agreement signed by NIMH, the center for Genetic Studies, and _____ as the Receiving Institution is amended to include the following text in paragraph 14 under the section, Acknowledgement for Induced Pluripotent Stem Cells (iPSC) Sample Biomaterials and Clinical Data:

Biomaterials and phenotypic data were obtained from the following projects that participated in the NIMH Induced Pluripotent Stem Cells (iPSC) Genetics Initiative:

NIMH Study 115 – Data and biomaterials collection were supported by the National Institutes of Health. The Principal Investigator of NIH grant DP1MH099904 was Dr. Ricardo Dolmetsch and the Co-Investigator was Dr. Joachim Hallmayer. The Principal Investigators of NIH grant R33MH087898 were Dr. Joachim Hallmayer and Dr. Ricardo Dolmetsch. Additionally, Dr. Hallmayer received supplementary funding for NIH grant R33M087898 to obtain biomaterials, diagnostic assessments and other data from subjects with Phelan McDermid Syndrome Foundation and their families. Dr. Hallmayer supervised the diagnostic data collection on all projects. The collection of data and biomaterials would not have been possible without the generous help of the Phelan McDermid Syndrome Foundation. Staff of the foundation offered invaluable assistance, support and guidance. Deepest gratitude is also due to the families and individuals with Phelan McDermid Syndrome who were our partners in this research.

NIMH Study 116 – The collection of data and biomaterials comes from two studies funded by the NIMH. The first project, *Biological Correlates of Altered Brain Growth in Autism*, was supported from 2009 to 2012 by the NIMH grant R01MH089176. Co-principal investigators were Flora Vaccarino, M.D., Sherman Weissman, M.D., Mark Gerstein, Ph.D., and Elena Grigorenko, Ph.D., of Yale University. The second study, *Cellular and Genetic Correlates of Increased Head Size in Autism Spectrum Disorder*, is funded since 2009 by the NIMH grant R21/R33MH087879. Principal Investigator is Flora Vaccarino, M.D., Co-Investigators are Katarzyna Chawarska, Ph.D., and Anita Huttner, M.D.

NIMH Study 117 – We have generated induced pluripotent stem cell (iPSC) lines from patients with Fragile X Syndrome in order to study the neural development aspects of autism. Fragile X fibroblasts were obtained from Dr. Philip Schwartz who has recently launched an NIH-sponsored program to generate fibroblast and iPSC lines from patients with autism spectrum disorder as a resource for the research community.

The collection of data and biomaterials for NIMH Study 117 was supported by the National Institutes of Health grant number R33MH087925 entitled “Autism iPSCs for Studying Function and Dysfunction in Human Neural Development” to Jeanne F. Loring, Ph.D. (The Scripps Research Institute). Biospecimen collection was coordinated by Philip Schwartz, Ph.D. (Children’s Hospital of Orange County) and Randi Hagerman, M.D. (University of California – Davis). Subjects enrolled in the study were diagnosed using the Autism Diagnostic Interview-Revised (ADI-R) and the Autism Diagnostic Observation Schedule (ADOS). The induced pluripotent stem cells were generated in Jeanne Loring’s laboratory by Michael Boland, Ph.D. (RSRI).

NIMH Study 125 – Data and biomaterials generated in Study 125/Site 393 were funded by an NIMH grant to Dr. Herb Lachman (MH087840: Analysis of Glutamatergic Neurons Derived from Patient-Specific iPS Cells). The co-investigators on this grant included Dr. Deyou Zheng and Dr. Reed Carroll, both from the Albert Einstein College of Medicine. Patients and controls were recruited at the Albert Einstein College of Medicine and at the Child Psychiatry Branch, NIMH, directed by Dr. Judith L. Rapoport. We want to thank participating families and Dr. Robert J. Shprintzen, Ph.D., President and Chairman of the board of The Virtual Center for Velo-Cardio-Facial-Syndrome, Inc., for patient referrals at the Einstein site.

NIMH Study 132 – The clinical data and collection of biomaterials for the genetics of childhood-onset schizophrenia has been funded through the intramural program at the National Institute of Mental Health, NIH. The Child Psychiatry Branch/NIMH in Bethesda, Maryland recruited all patients and controls. Principal Investigator is Dr. Judith L. Rapoport. The entire team at the Child Psychiatry Branch extends our gratitude to our patients and their families for making our research possible.

NIMH Study 143 – This work was supported by grants from the California Institute for Regenerative Medicine (CIRM) TR4-06747, the National Institutes of Health through the NIH Director's New Innovator Award program (1-DP2-OD006495-01), an R21 MH093954 from NIMH; and a NARSAD Independent Investigator award. The principal investigators are Drs. Alysson R. Muotri and Vias Duvvuri at UCSD.

NIMH Study 144 – This work was supported by grants from the California Institute for Regenerative Medicine (CIRM) TR2-01814 and TR4-06747, the National Institutes of Health through the NIH Director's New Innovator Award program (1-DP2-OD006495-01), an R01 MH100175-01 from NIMH and from the International Rett Syndrome Foundation (IRSF grant # 2915); a NARSAD Independent Investigator Grant, an NIMH Autism Center of Excellence Program Project; the work was supported by the Helmsley Trust, the JPB Foundation, the Engmann Foundation, a grant from the CDMRP Autism Research Program; a KL2 CTRI (KL2TR00099) and a Postdoctoral Translational Fellowship from Autism Speaks. The principal investigators are Drs. Alysson R. Muotri (UCSD); Eric Courchesne (UCSD); Alan Percy (University of Birmingham); Fred H. Gage (Salk); Daniel Geschwind (UCLA) and Anthony Wynshaw-Boris (Case Western Reserve University).

We would also like to thank the families who have participated in and contributed to these studies.

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DATED SIGNATURES

Signature and **Date**, Principal Investigator

Signature and **Date**, Receiving Institution's Authorized Representative

Signature and **Date**, NIMH Center for Genetic Studies' Authorized Representative
Washington University in St. Louis

Signature and **Date**, NIMH Center for Genetic Studies' Authorized Representative
Rutgers University

Signature and **Date**, NIMH's Authorized Representative