

## CONSENT TO PARTICIPATE IN BIOMEDICAL RESEARCH

### An investigation of the relationship among cognition, brain function and genetic variation

You are asked to participate in a research study conducted by Nancy Kanwisher, from the Department of Brain & Cognitive Sciences at the Massachusetts Institute of Technology (M.I.T.). You have been asked to participate in this study because you are a typical adult or an adult with Autism Spectrum Disorder (ASD) and because you have previously participated in a behavioral and/or a brain imaging study in the Kanwisher lab (and agreed to be contacted for follow-up studies), or because you are scheduled to participate in a behavioral and/or a brain imaging study. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

#### • PARTICIPATION AND WITHDRAWAL

Your participation in this research is completely VOLUNTARY. If you choose to participate you may subsequently withdraw from the study at any time without penalty or consequences of any kind. If you choose not to participate, that will not affect your relationship with M.I.T. or your right to health care or other services to which you are otherwise entitled.

#### • PURPOSE OF THE STUDY

The purpose of the study is to investigate the relationship among i) mental abilities, ii) structural and functional images of the brain, and iii) genes. Research that attempts to relate differences in genes to differences in mental abilities has only just begun. Our brain imaging research gives us good images of each individual subject's brain (in contrast to many other labs, who primarily look at data averaged across many individuals). As a result, we would like to explore the relationship between differences across individuals in mental abilities, brain activations, and genes. The particular mental abilities we study include visual and auditory processing, language, and thinking about other people.

#### • PROCEDURES

If you volunteer to participate in this study, we will obtain a small sample of saliva from you. You will spit into the cup designed to collect DNA from saliva. You will then place the cup into the biological sample bag.

The sample will be de-identified (labeled with an alphanumeric code) and temporarily stored in the Kanwisher lab. Then, it will be mailed to our collaborator Dr. Simon Fischer, expert in neurogenetics, at the Max Planck Institute for Psycholinguistics in Nijmegen. The DNA, which contains the genetic material, will be removed from the saliva and analyzed for genes that may play a role in mental abilities. The results from the genetic analysis will be sent back to the Kanwisher lab to be combined with the results from the brain activations and behavioral tests. We will use this information to determine whether certain patterns of behavioral and/or brain activity are related to certain genes.

After the initial analysis of genes, we would like to save any remaining DNA obtained from you for future testing of the hypotheses relating genes to mental abilities (to be stored indefinitely, at the Max Plank Institute in the de-identified form) in case new genes are implicated in cognition. Dr. Kanwisher will have control over the DNA samples, and Drs. Kanwisher, Fedorenko and Fischer will be the ones who have access to the samples.

- **POTENTIAL RISKS AND DISCOMFORTS**

There are no known discomforts associated with providing a saliva sample. Because of the sensitive nature of the DNA data, special care will be taken to make it impossible to link your identifying information to your saliva sample. As mentioned above, saliva samples will be stored with alphanumeric codes (i.e., a combination of letters and numbers not related to your name), and the only way to link these codes with the brain/behavioral data (which are also stored with alphanumeric codes, as per the relevant protocols) is through a log sheet that will be stored securely by one of the investigators (Fedorenko).

The genetic analysis being done is designed to answer research questions, not examine your genes medically. The genetic testing we carry out is not a substitute for one a doctor would order. In particular, we will not be examining medically relevant genes. As a result, you will not be informed of any results concerning your individual DNA data. If you ask the investigator obtaining consent to be informed of the general outcomes of the study as a whole, we would be happy to contact you and share any relevant publications.

- **ANTICIPATED BENEFITS TO SUBJECTS**

There will be no direct benefit for you for participating in this study.

- **ANTICIPATED BENEFITS TO SOCIETY**

Society will benefit from the increased understanding of the relationship between genetic variation and cognitive abilities. To the extent that certain genes can be reliably linked to mental abilities, this knowledge can be used to identify individuals who are at risk for developmental and acquired disorders, and potentially to develop more efficient diagnosis/treatment methods.

- **ALTERNATIVES TO PARTICIPATION**

You are free to participate in this study. If you choose not to participate, your medical and treatment at the hospital(s) will be unaffected.

- **PAYMENT FOR PARTICIPATION**

You will be paid at the rate of \$10/hour for participation in this study.

- **FINANCIAL OBLIGATION**

Neither you nor your insurance company will be billed for your participation in this research.

- **PRIVACY AND CONFIDENTIALITY**

The only people who will know that you are a research subject are members of the research team and, if appropriate, your physicians and nurses. No information about you, or provided by you during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare, or if required by law.

When the results of the research are published or discussed at conferences, no information will be included that would reveal your identity.

Authorized representatives of the Food and Drug Administration (FDA) or a funding agency, such as the National Institutes of Health may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

Subjects are identified in the log book and on the consenting forms. Both of these items are kept in a secure location in the Kanwisher lab. Subjects are not identified in the scientific reporting of the data. The importance of privacy and confidentiality is impressed on all research staff who have also all completed HIPAA training.

- **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The investigator may withdraw you from participating in this research in certain cases. If you experience any of the following side effects – discomfort, inattentiveness, excessive sleepiness – or if you become ill during the research, you may have to be dropped from the study, even if you would like to continue. The investigator, Nancy Kanwisher, will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

If you must drop out because the investigator asks you to or because you have decided on your own to withdraw, you will receive the same payment as if you completed the study. You may choose to withdraw your data. In this event, your data will be discarded and no further analyses will be performed on your data.

- **NEW FINDINGS**

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

- **EMERGENCY CARE AND COMPENSATION FOR INJURY**

If you feel you have suffered an injury, which may include emotional trauma, as a result of participating in this study, please contact the person in charge of the study as soon as possible.

In the event you suffer such an injury, M.I.T. may provide itself, or arrange for the provision of, emergency transport or medical treatment, including emergency treatment and follow-up care, as needed, or reimbursement for such medical services. M.I.T. does not provide any other form of compensation for injury. In any case, neither the offer to provide medical assistance, nor the actual provision of medical services shall be considered an admission of fault or acceptance of liability. Questions regarding this policy may be directed to MIT's Insurance Office, (617) 253-2823. Your insurance carrier may be billed for the cost of emergency transport or medical treatment, if such services are determined not to be directly related to your participation in this study.

- **IDENTIFICATION OF INVESTIGATORS**

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact Nancy Kanwisher (Principal Investigator, 617-258-0721, 46-4133 MIT).

- **RIGHTS OF RESEARCH SUBJECTS**

You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you feel you have been treated unfairly, or you have questions regarding your rights as a research subject, you may contact the Chairman of the Committee on the Use of Humans as Experimental Subjects, M.I.T., Room E25-143B, 77 Massachusetts Ave, Cambridge, MA 02139, phone 1-617-253 6787.

<b>SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE</b>
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I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form.

**BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.**

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Name of Subject

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Name of Legal Representative (if applicable)

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Signature of Subject or Legal Representative

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Date

**SIGNATURE OF INVESTIGATOR**

I have explained the research to the subject or his/her legal representative, and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

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Name of Investigator

Signature of Investigator

Date (must be the same as subject's)

**SIGNATURE OF WITNESS (If required by COUHES)**

My signature as witness certified that the subject or his/her legal representative signed this consent form in my presence as his/her voluntary act and deed.

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Name of Witness

We are asked by NIH, the federal agency that supports this research, to collect information on the ethnicity of our participants, in order to provide aggregate data to include whether our participants come from a diverse population. If you are willing to indicate your ethnicity, please do so here. If you would rather not provide that information, just leave this space blank.

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**ETHNICITY**

We may in the future run a follow-up to this study, for which we would want to include the same participants. Do you agree to being recontacted at a future date and invited to participate in such a follow-up study?

Yes \_\_\_\_\_

No \_\_\_\_\_