CONSENT TO PARTICIPATE IN BIOMEDICAL RESEARCH

fMRI investigations of concept representation

You are asked to participate in a federally funded 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 healthy adult. 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 proposed studies is to investigate the neural basis of concept representation. We are pursuing answers to the following questions: (1) How are individual concepts represented in the brain? (2) How are complex (composite) concepts constructed out of their constituents? (3) Can we decode complex concepts from brain activity?

- **PROCEDURES**

If you volunteer to participate in this study, we would ask you to do the following things:

In these study, you will be presented with linguistic stimuli (letter strings, words, phrases, sentences or short texts) auditorily or visually and asked to either passively listen to / read these stimuli, or to perform a task on these stimuli by pressing some buttons (e.g., answering a yes/no comprehension question about a sentence, or deciding whether a phrase or a sentence is well-formed). The details of each task will be provided by the experimenter. This study will allow us to investigate which brain regions are involved in different aspects of language. Furthermore, you may also be asked to perform some non-linguistic tasks, such as listening to musical stimuli and making some judgments about them, performing working memory tasks, or viewing pictures of objects or events and answering questions about these pictures. The details of each task will be provided by the experimenter. By combining a linguistic task with non-linguistic tasks, we can investigate whether the same brain regions are engaged in concept representation and other cognitive processes.

You will lie on a table, which will slide into a large horizontal cylinder located inside a large magnet. You will be asked to lie still during the imaging time. In order to help immobilize your head, a foam head holder and/or individually formed plastic mask may be placed around your head.

Anatomical images will be obtained during the first 10 minutes of scanning. During this time, you will lie quietly in the magnet. The scanner will make a loud thumping sound. After these scans are conducted, additional scans will be conducted that investigate brain function. During these scans, you will be presented with stimuli and asked to perform some task on these stimuli, as will be described to you by the experimenter. Visual stimulation will be provided either by goggles or a projection screen. Auditory stimulation will be provided by a stereo headset. Each scan will last from 3 to 10 minutes, and a typical scanning session will consist of about ten-fifteen of these scans. The entire scanning session will last between 1.5 and 2.5 hours, with an additional 15-20 minutes being needed both prior to and after the scan for preparation and post-experiment debriefing.

A 3T (tesla) magnetic resonance (MR) brain scanning machine will be used.

- **POTENTIAL RISKS AND DISCOMFORTS**

The known risks or side effects associated with conventional MRI procedures are minimal, except for those people who have electrically, magnetically or mechanically activated implants (such as cardiac pacemakers) or those who have intracerebral vascular clips. The greatest risk is of a metallic object flying through the air toward the magnet and hitting you. To reduce this risk we require that all people involved with the study remove all ferrous metal from their clothing and pockets before entering the magnet room. No metal objects are allowed to be brought into the magnet room at any time, unless they are permanently installed. There are no other known risks associated with high-speed MRI. Both the conventional and the high-speed MRI systems have been approved by the FDA and will be operated within the operating parameters reviewed and accepted by the FDA.

A magnetic resonance scan is not uncomfortable but if you are prone to claustrophobia (fear of enclosed spaces) you should notify the researcher in charge of the scan. You can expect to hear a knocking sound during the imaging; ear plugs or headphones will be provided so the sound should not be bothersome.

It is important in these studies that you remain motionless. The head holder is reasonably comfortable, and is designed to keep your head immobilized and in a relaxed position. If the head holder is uncomfortable, you should notify the researcher in charge of the scan. You are free to stop the study at any point if for any reason you do not wish to continue.

The MRI scan being done is designed to answer research questions, not examine your brain medically. This MRI scan is not a substitute for one a doctor would order. It may not show problems that would be picked up by a medical MRI scan. However, if we believe that we have found a medical problem in your MRI scan, we will ask a doctor who is trained in their reading of MRI scans, a radiologist, to help us review the scan. If the radiologist thinks that there may be an abnormality in your MRI scan, we will contact you and will help you get medical follow-up for the problem. If you have a primary care doctor, we can contact your doctor, with your permission, and help him or her get the right follow-up for you. No information generated in this study will become part of a hospital record routinely. However, if the study detects an abnormality in your MRI scan, then this information may become part of the MGH hospital record. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found.

The treatment or procedure may involve risks that are currently unforeseeable.

- **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 collection of data needed to understand the neural basis of concept representation. This research will provide a roadmap of the functional organization of the concept representation system, including a characterization of the domain specificity of each of the regions involved, and it will establish the methods to identify components of this system anatomically in individual subjects as needed for pre-operative localization in conditions, such as epilepsy and brain tumors.

- **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 $60 for participation in this study. You will not lose payment if you develop side effects or illness.

- **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 in conferences, no information will be included that would reveal your identity. If photographs, videos, or audio-tape recordings of you will be used for educational purposes, your identity will be protected or disguised.

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.

U.S. Department of Defense personnel will also have access to research records to ensure the protection of human subjects.

Subjects are identified in the scanning 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 if circumstances arise which warrant doing so. If you experience any of the following side effects – discomfort, excessive motion, 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.

- **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.

SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE

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.

_____
Name of Subject

_____
Name of Legal Representative (if applicable)

_____ _____
Signature of Subject or Legal Representative Date

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.

_____
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 _____

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.

_____
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.

_____
Name of Witness

_____ _____