

## **Informed Consent for Participation in Research Activities**

### **Project Title: Localization of Neural Response to Vision and Audition in Normal Subjects with 3.0-Tesla MRI System**

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1. **Purpose of this Research Study:** You have been asked to participate in this research study because you are a healthy, normal adult. The purpose of this study is to localize the brain areas that underlie visual and/or auditory perception.
2. **Background:** MRI is a non-invasive imaging method that uses a strong magnetic field and radio waves to make pictures of your body. No X-rays or ionizing radiation is used in MRI. Functional MRI is a safe and non-invasive method for studying human brain activity. Your brain is active when you see or sense something, think, or even do nothing. We know that different parts of brain specialize in different computations. When some part of the brain becomes more active, the blood flow changes and this can be studied by looking at small changes in the contrast of the image of the brain. We are interested in studying how different aspects of sensory information and cognitive tasks are processed by different areas of the brain and how people are similar or different with regards to their brain activity. Therefore, we will ask you to do simple sensory and cognitive tasks at the same time that we scan your brain. We use a 3 Tesla MR scanner, which has a stronger magnetic field than most MR systems in hospitals. Today there are many 3 Tesla or stronger magnets around the world used for research and they have been as safe as conventional clinical MR scanners. Because the quality of the signal increases with magnetic field strength, we hope that studying your brain in our 3-Tesla MRI scanner results in a better understanding of how the brain works and the nature of the relationship between the pattern of activation of different brain regions and structures and your perceptual /cognitive experience.

### **YOU WILL NOT BE GIVEN MRI CONTRAST AGENT OR ANY OTHER DRUGS IN THIS STUDY.**

3. **What will be done:** If you decide to volunteer to participate in this study, you will be asked to fill out a questionnaire, so that we can make sure that the experiments are safe for you. We will scan your brain to get a high resolution anatomical image. Then, in the same session or in separate sessions we will do functional imaging, i.e. we will ask you to look, listen, press buttons, etc. while your head is scanned. We may ask you to do the same tasks before putting you inside the scanner to make sure that your performance is good.

When you enter the imaging center, we will ask you to remove any metallic item or magnetic material that you may have on your person. This includes jewelry, coins, keys, belt, watches, credit cards or other cards containing magnetic strips, etc. Bringing a metallic object close to the magnet can be extremely dangerous. Furthermore, the magnetic field can permanently damage watches and clear magnetic media such as your credit card or Caltech ID. An operator may check you before you enter the MR room.

After you entered the room, you will be asked to put on protective earphones or ear-plugs. We will ask you to lie on your back on the table and put your head on or inside a head coil. We may fix your head using foam pads or ask you to hold a bite-bar with your teeth. This procedure is extremely important

because if your head moves during the scan it might change the location we are scanning and degrade the signal. We may also ask you to wear goggles that deliver high-quality, colored images to both of your eyes and that can also track your eye movements. Depending on the study, the earphone might deliver sound stimuli. We will usually place a simple switch/button in one or into both of your hands that will allow you to signal what you are seeing or hearing. We may also attach a monitoring device to your finger to record your pulse.

You will be asked to lie within the magnetic resonance imager for between 30 and 120 minutes at a time with short breaks if you require them. Your total time in the imager will be less than two hours. While in the magnet, you can relax until each block is started. You must try to avoid movement during the scan. We will ask you before each block if you are ready. If you have any problem you should let us know. You may also terminate the experiment if you are tired or don't want to continue. After we know you are ready, we will start scanning and you should start performing your task (the tasks will have been fully described to you before you enter the magnet). Remember, we cannot read your mind. So it is very important that you cooperate with us in performing the task correctly. If you feel drowsy or sleepy or if you cannot perform the task please let us know after the block. If for any reason you feel uncomfortable and want to terminate the block you may interrupt the scan by notifying the operator. Otherwise we expect that you will run continuously for 5 minutes or so. Before each block we will let you know how long it will take. You may take breaks between blocks if you wish.

Because in extremely rare cases, flashing lights and flickering computer monitors can trigger seizures in those with epilepsy, previous stroke, or head trauma, you will be asked about your neurological and mental history in the questionnaire. For your own protection, you would not be allowed to participate if your medical history suggests risk of complications. All questionnaires will be treated as confidential and stored in a locked place to which only principal investigators or their research associates have access. After a year, they will be shredded and discarded.

4. **Possible Benefits:** You are not expected to benefit directly from participation in this research study. Potential benefit to others may result from the knowledge gained from your participation in this research study. **THE MRI SCAN YOU WILL RECEIVE IS NOT INTENDED TO BE DIAGNOSTIC AND DOES NOT REPLACE A CLINICAL MRI SCAN REVIEWED BY A QUALIFIED RADIOLOGIST.**

You are entitled to compensation for participating in this experiment at the rate of \$\_\_\_\_\_ per hour for the MR experiments and \$\_\_\_\_\_ per hour for any required psychophysical training outside the scanner. You can quit the experiment at any time. If you quit in the middle of a session, you will still be paid for the blocks you completed. Because the payments for financial compensation are arranged via Caltech, it may take about one month before you receive a check.

By writing my initials in the box here, I waive my right to receive compensation.

5. **Possible Risks and Discomforts:** You have been informed that the possible risks and discomforts of this study are as follows:

- **Very slight warming of the body.** This effect is rare and unlikely to cause you any harm.
- **Tingling or small involuntary muscle twitches.** This effect is rare and unlikely to cause you any harm.
- **Claustrophobia.** Some people experience claustrophobia (fear of confined spaces) within the MRI magnet. If you are severely claustrophobic you should not volunteer for this study. **Sedation will not be used in this study.** If you become claustrophobic within the magnet, you must communicate this to the MRI operator immediately via the intercom or hand-held signaling switch. You will be removed from the magnet bore immediately and the study will be terminated.

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- **Metallic Implants.** It is extremely important that you do not participate in this study if you have, or believe that you may have certain metallic implants in your body. Please read and fill out the accompanying MRI screening questionnaire very carefully.
  - **Unknown risk to a fetus.** Do not participate in this study if you are, or believe that you may be pregnant.
  - **Acoustic Noise.** You will be provided with and required to wear earplugs or protective earphones that reduce the level of noise in the imager to a comfortable level.
6. **Alternatives:** Your alternative is to choose not to participate in this study.
  7. **Confidentiality of Records:** Any information from this study in which you might be identified will be confidential and disclosed only with your permission. (By signing this form, however, you allow the study investigators to make your records available to the Caltech Institutional Review Board Office and Regulatory Agencies as required by law). If information generated by this study is published, you will not be identified by name.
  8. **Offer to Answer Questions and Research Injury Notification:** One of the principal investigators or their research associates has offered to and has answered any and all questions regarding your participation in this research study. If you have any further questions or in the event of a research related injury, you can contact the principal investigators or one of the following persons:

Farshad Moradi, M.D.	Melissa Saenz, Ph.D.	Patrick Wilken, Ph.D.
Phone: 626 395 2873	Phone: 626 395 2879	Phone: 626 395 2881
Email: <a href="mailto:farshadm@caltech.edu">farshadm@caltech.edu</a>	Email: <a href="mailto:saenz@klab.caltech.edu">saenz@klab.caltech.edu</a>	Email: <a href="mailto:patrickw@klab.caltech.edu">patrickw@klab.caltech.edu</a>
  9. **Explanation of Treatment and Compensation for Injury:** In the unlikely event of illness or physical injury resulting from participation in this research, medical treatment will be available through Caltech according to the Institute's policy regarding human subjects, as follows:

**For minor injuries:** Monday through Friday, 7:30 a.m. to 6:00 p.m. – subjects will be taken to the Huntington Occupational Health Center at 800 S. Fairmont Avenue, Suite 312, in Pasadena. After 6:00 p.m. and on the weekends and holidays – subjects will be taken to the Huntington Memorial Hospital Emergency Room (711 S. Fairmont Avenue, Pasadena).

**For serious injuries:** Paramedics would be summoned by calling campus security (x5000) and the subject would be transported to the nearest hospital emergency room. In most cases, this would be Huntington Memorial Hospital in Pasadena. The insurance carrier of the subject may be billed for the cost of such treatment depending upon the circumstances. Making such medical treatment available, or providing it, does not imply that such injury is the Investigator's fault. Further information may be obtained by calling the Institute's Insurance Office (626) 395-6878, or the Office of the General Counsel (818) 354-5710.
  10. **Voluntary Participation with Right of Refusal:** You have been informed that your participation in this research study is voluntary. You are free to withdraw your consent for participation in this study without any penalty.
  11. **IRB Review and Impartial Third Party:** This study has been reviewed and approved by the Institutional Review Board (IRB) of the California Institute of Technology. A representative of that board, from the IRB Office, is available to discuss the review process or your rights as a research subject. The telephone number of the IRB office is 626-395-4571.
  12. **Findings Relating to Your Willingness to Continue Participation:** The principal investigator has explained that you will be informed of any significant new findings related to this study that might affect your willingness to continue to participate.
  13. **Sponsor of this Research:** The California Institute of Technology is the sponsor of this research study.

14. **Experimental Subjects Bill of Rights:**

You have been asked to participate as a subject in an experimental research procedure. Before you decide whether you want to participate in the experimental procedure, you have a right to:

- a. Be informed of the nature and purpose of the experiment;
- b. Be given an explanation of the procedures to be followed in the research experiment, and any drug or device to be utilized;
- c. Be given a description of any attendant discomforts and risks reasonably to be expected from your participation in the experiment;
- d. Be given an explanation of any benefits reasonably to be expected from your participation in the experiment;
- e. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to you and their relative risks and benefits;
- f. (Be informed of the avenues of medical treatment, if any, available to you after the experimental procedure if complications should arise;)
- g. Be given an opportunity to ask any questions concerning the research experiment or the procedures involved;
- h. Be instructed that consent to participate in the experimental procedure may be withdrawn at any time and that you may discontinue participation in the research experiment without prejudice;
- i. Be given a copy of this form and the signed and dated consent form; and
- j. Be given the opportunity to decide to consent or not to consent to the research experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on your decision.

15. **Signature for Consent:** The above-named investigator has answered your questions and you agree to be a research subject in this study. You have carefully read the information contained above in the “Experimental Subject’s Bill of Rights” and understand fully your rights as a potential subject in a research experiment involving people as subjects.

Print Subject’s Name: \_\_\_\_\_ Date: \_\_\_\_\_

Subject’s Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Witness’ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Investigator’s Signature: \_\_\_\_\_ Date: \_\_\_\_\_

(If applicable) I have translated this form into the \_\_\_\_\_ language.

Translator’s signature: \_\_\_\_\_ Date: \_\_\_\_\_

Parent/Legal Guardian: \_\_\_\_\_ Date: \_\_\_\_\_

If signed by other than subject, indicate relationship: \_\_\_\_\_