THE SMITH-KETTLEWELL EYE RESEARCH INSTITUTE CONSENT FORM

Study Title: Tactile Object Understanding and Characterization

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

The Institutional Review Board at The Smith-Kettlewell Eye Research Institute wishes you to know: Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of both the procedures to be followed in the medical experiment, as well as any drug to be used in the experiment.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of the signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

If you have questions regarding this research project, the researcher or his/her mentor will be glad to answer them. You may also seek information from the Institutional Review Board--established for the protection of volunteers in research projects--by calling (415) 345-2075 Monday through Friday, between 9:00 a.m. and 4:00 p.m.

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Participant's Name

_____ _____

Participant's Signature or Legal Representative (if appropriate) Date

Study Title: Tactile Object Understanding and Characterization

Investigator: Rezaul Karim, Ph.D., Postdoctoral Fellow at ERI (316) 440-1519
and SKERI (415) 345-2065

Mentor: Lora Likova, Ph.D., Scientist at SKERI (415) 345-2066

Research Team: Christopher W. Tyler, Ph.D., D.Sc., Senior Scientist at SKERI; Donald Fletcher, M.D., Clinical Scientist at SKERI, Medical Director of the EVRC at ERI; Laura Walker, Ph.D., Associated Scientist at SKERI, Executive Director of ERI; Laura Cacciamani, Ph.D., Postdoctoral Fellow; Spero Nicholas, M.S., Systems Programmer; Kristyo Mineff, M.S.; Shannon Riley, M.A.

You are invited to participate in this research project conducted by Dr. Rezaul Karim, Postdoctoral Fellow, Envision Research Institute (ERI) and The Smith-Kettlewell Eye Research Institute (SKERI) under the supervision of Dr. Lora Likova, Scientist, The Smith-Kettlewell Eye Research Institute (SKERI). You are eligible to participate if you are over the age of 18 and have normal (or corrected to normal) vision OR if you are congenitally OR late-onset blind. You can participate in the behavioral experiments and/or in the fMRI experiments. The behavioral study will take place at ERI, SKERI, and remotely at any other locations, such as schools, institutions, or residences, if necessary. The fMRI study will take place exclusively at UCSF.

Purpose

The general purpose of this research is to understand how people perceive tactile objects, how they characterize them, and whether the perception of tactile object properties is affected by early visual experience through the study of congenitally blind, late-onset blind and blindfolded (sighted) participants. To this end, we will employ innovative behavioral measures in combination with brain imaging techniques, i.e., functional Magnetic Resonance Imaging (fMRI), to study the functionality of the tactile modality and tactile aesthetics, and the underlying brain mechanisms.

Duration and procedures

If you decide to participate, the following will occur:

Subject Information:

You will first be asked a brief series of general questions about your age, health, handedness, whether you have any metal in the body or are pregnant (for fMRI study only), whether you have previous experience with abstract 2D tactile shapes, 3D tactile shapes and tactile textured objects, any formal training in art, training in Braille, or whether you are sighted or congenitally blind or late-onset blind.

Behavioral Tests:

You will be presented with abstract 2D or 3D tactile shapes and tactile textured objects. A standard rating scale and/or a questionnaire will be administered to measure your stimulus preference, appreciation of tactile beauty, and ability to recognize basic object properties. You will be asked to perform tactile tests that evaluate processes such as tactile appreciation, sensory discrimination, tactile

memory, etc. There will be four behavioral tests, the first two with 2D or 3D tactile shapes and the last two with tactile textured objects, which will take approximately 3 hours in total.

MRI Exams:

1. MRI exam for brain anatomy. If you choose to participate, MRI scans will be performed of the anatomy of your brain. You will first be asked a number of questions concerning your health, lack of metal implants and absence of claustrophobia. You will lie down on a narrow bed, which will then be moved into a tunnel that is 6 feet by 2.5 feet. Communication with the researchers and technologists will be possible at all times by a microphone and loudspeaker. During the MRI exam, you will hear machine-like banging noises. However, earplugs will be provided to reduce the sound level. During the exam, you will be asked to relax, breathe normally and hold your head as still as possible. The scanning session will last about 10-15 min.

2. Functional MRI exam. If you agree to participate, you will be presented with abstract 2D or 3D tactile shapes and tactile textured objects as in behavioral tests, asking to perform a series of tactile tasks while in the scanner to measure your brain functions. The procedure is the same as for the anatomical MRI exam above and is typically performed in the same session, with the following additions:
   Before the testing session you will be given some practice. Each fMRI trial will begin with an audio cue signal indicating the start of the exploration period, and another cue signal will indicate the end of the exploration period. In each session, the trials will be pseudo-randomly presented, interspersed with the baseline condition. You will be able to ask the researchers any questions that you may have about the tasks. You may be instructed to make decisions about these stimuli, and give your responses by pressing buttons on a small keyboard with your fingers. Each of these tasks will last approximately five minutes. The entire fMRI exam will last about 1 hour per session. You will be asked to keep confidential any information about the tactile objects per se or the experiments as a whole, and regard them as a privileged intellectual property.

Photo Release:

Each participant may be asked if he/she is willing to be photographed, audioed and/or videoed during the behavioral tests. The audios/videos are necessary for data collection, data checking and data analysis. In particular, the audio recording will prevent the loss of any important information of the participant's responses to the *open-ended* questions, as it will allow subsequently to double check and complete the experimenter's notes (taking complete notes while at the same time running the experiment is not realistic). Video recording is necessary, for example, during tactile exploration in order to provide information for the analysis of strategies for tactile-exploration of 2D vs 3D objects. This will equip the experimenter with valid data crucial for an accurate analysis. The recordings may also be used in presentations, publications and grant submissions. However, the participant will be ensured that his/her face will not be visible in the photos/videos or will be digitally obscured. Compliance with this request is entirely optional and is not a requirement for participation in the study. If the participant agrees, he/she will be given a photo/audio/video release consent form to check and sign on.

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Risks or Discomforts

Participation in the behavioral study involves no medical risk. There are also not known health risks associated with MRI or fMRI scans. These procedures are entirely non-invasive and do not involve injections or ionizing radiation exposure. However, in the case of MRI/fMRI procedures there could be some risks or discomforts from participating in this study, including the following:

1. Because the MRI machine attracts certain metals, it could move metallic objects within the MRI room during examination, which could in the process possibly harm you. Precautions have therefore been made to prevent such an occurrence.
2. Your participation may mean some added discomfort for you. During an MRI exam, you may be bothered by the loud noise and feelings of claustrophobia during the exam.
3. Participation in this research may result in a loss of privacy. However, your records will be kept as confidential as possible. No individual identities will be used in any reports or publications resulting from this study. Study information will be coded and kept in locked files at all times. Only the researcher(s) or study personnel will have access to the files.

It is possible, although very unlikely, that you have a preexisting abnormality in your brain that you are not aware of. Such abnormalities may be detected in these MRI scans. If you give your prior consent on this consent form, the researcher(s) will automatically show parts of your MRI scans to a neuroradiologist at UCSF (without any of your identifying information). If the neuroradiologist finds an abnormality of potential clinical importance in those scans, you will be alerted by the researcher(s), and notified that you have the option to call the neuroradiologist or your own physician (a copy of your scans will be made available).

If the researchers notice an anomaly of potential clinical importance in my MRI scans:

☐ I authorize the researcher(s) to show my MRI scans to a neuroradiologist at UCSF who can evaluate any clinical relevance of the anomaly.

☐ I DO NOT authorize the researcher(s) to show my MRI scans to a neuroradiologist.

If you are injured as a result of participation in this study, treatment will be available. The costs of such treatment may be covered by the University of California, San Francisco, depending on a number of factors. The University does not normally provide any form of compensation for injury. For further information about this matter, you may call the Office of the Committee on Human Research at (415) 476-1814.

Benefits to you or others

You will not directly benefit from this research study, but the knowledge gained may be of a great value to humanity. In particular, the study may provide transformative insights into the basic tactile processing and tactile aesthetic processing in the blind and the sighted, and into the commonality and specificities of the neural process for perception through the tactile modality. The results may significantly enhance the understanding of the neural mechanisms underlying tactile information processing in blindness that are of major importance for blindness rehabilitation strategies and devices.

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Alternatives
If you elect not to participate in this study, it will not affect your medical care or your status with the University of California, San Francisco, in any way, now or in the future.

Confidentiality
Any information that is obtained in connection with this study that can be identified with you will remain confidential and will be disclosed only with your permission. Subject's identity will be kept confidential by masking the name and coding with numbers and/or alphabets.

The research team, authorized members of the Institutional Review Board (a committee that reviews and approves the involvement of humans in research), and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare. Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed by these entities without your prior consent, except as specifically required by law. Publications and/or presentations that result from this study will not include identifiable information about you.

Compensation
If you participate in this research, you will be paid $30 per hour (or part thereof) for the MRI/fMRI sessions and $20 per hour (or part thereof) for the behavioral testing session outside the MRI scanner at SKERI/UCSF, or a payment in the form of gift cards at ERI. You will be reimbursed for travel to SKERI/UCSF or other out-of-pocket expenses up to $20. If you should choose to withdraw before completion of the study session you will be given a pro-rated amount based on the amount of time that you participated. The payment mechanism requires the submission of your social security number and mailing address on the check request form.

Investigator Financial Conflict of Interest
No one of the research team has a significant financial interest related to this research project.

IF YOU HAVE QUESTIONS
If you have any comments, concerns, or questions regarding the conduct of this research please contact the research team listed at the top of this form.
If you are unable to reach a member of the research team listed at the top of the form and have general questions, or you have concerns or complaints about the research project, research team, or questions about your rights as a research subject, please contact Smith-Kettlewell's Human Subject Coordinator, Margaret McGovern, by phone, **(415) 345-2075** or by e-mail at **margaret@ski.org** or in person at 2318 Fillmore Street, San Francisco, CA 94115.

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VOLUNTARY PARTICIPATION STATEMENT

Participation in this study is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with ERI, SKERI or UCSF. The Consent Form should have been either emailed to you to preview it in advance electronically, or/and a hard copy of the same should have been provided and read to you in the experimental lab, covering all the important aspects prior to signing it. Your signature below indicates that you have read (or someone has read to you) all the information in this consent form and have had a chance to ask any questions that you have about the study.

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 consent form and the Experimental Subject's Bill of Rights.

I agree to participate in the study.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____ _____
Name and Signature of Legally Authorized Representative (if appropriate) Date

_____ _____
Name and Signature of the Person Conducting Consent Discussion Date

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CONSENT FOR SUBJECT TO BE PHOTOGRAPHED, AUDIOED AND/OR VIDEOED

The experimenter may ask you if you are willing to be photographed, audioed and/or videoed during experiments. The photos/audios/videos would be used for data completion, data checking, data analysis or in grant submissions, publications, or presentations related to the study. Compliance with this request is entirely optional and is not a requirement for participation in the study. In addition, you are free to grant permission to be photographed or videoed conditional on reasonable requirements you wish to impose on the experimenter, such as ensuring that your face is not visible in the photos/videos (or is digitally obscured before inclusion in a publication or presentation).

Please check one of the following two boxes:

- ☐ **Yes, I provide consent to be photographed, audioed or videoed.**
- ☐ **No, I do not provide consent to be photographed, audioed or videoed.**

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Participant's Signature Date