IRB USE ONLY
Approval Date: September 26, 2012
Expiration Date: January 11, 2013

Please print your name: _____

Are you participating in any other research studies? _____ Yes _____No

INTRODUCTION TO RESEARCH STUDIES

A research study is designed to answer specific questions, sometimes about a drug's or device's safety and effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your doctor have a great deal of freedom in making decisions about your health care. When you are a research participant, the Protocol Director and the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

PURPOSE OF RESEARCH

You are invited to participate in a research study of human brain function. We hope to learn, using magnetic resonance imaging, which parts of the brain are responsible for cognitive functions, such as perception, reading, and thinking, and how that changes through development.

This study uses new technology in magnetic resonance imaging (MRI) to measure brain activity in human volunteers. This MRI technology uses a strong magnet and radiofrequency magnetic field to make images of the inside of the body. This includes new imaging software, sequencing, and radiofrequency imaging coils used in scanning at the Stanford center for Cognitive and Neurobiological Imaging and the Lucas Center that are not approved by the FDA.

You were selected as a possible participant in this study because you are an adult subject with either healthy vision or with a specific visual impairment, such as color blindness or macular degeneration.

Your participation in this study is entirely voluntary.

Your decision whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are free to withdraw your consent, and to discontinue participation at any time without prejudice to you or effect on your medical care. If you decide to terminate your participation in this study, you should notify Dr. Brian A. Wandell at (650) 725-2466 or the research team at (650) 725-1255.

This research study is looking for 40 to 120 participants. We will enroll participants with healthy vision as well as those with visual impairments such as color-blindness or macular degeneration. Enrollment will occur throughout the United States. Stanford University expects to enroll 120 research study participants.

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DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 12 years. You will be asked to participate in at least one hour long scan. You may be asked to return for additional hour long scans.

PROCEDURES

If you choose to participate, Dr. Brian A. Wandell at (650) 725-2466 and his research study staff at (650) 725-1255 will describe the procedure to you. This MRI machine uses a strong magnet and radiowaves to make images of the body interior. The scanning procedure is very much like an x-ray CT scan. You may be asked to participate in up to 6 scanning sessions of 1-2 hours each. For each scanning session, you will be asked to lie on a long narrow couch for a certain amount of time (up to two hours per scanning session) while the machine gathers information.

During this time you will not be exposed to x-rays, but rather a magnetic field and radiowaves. You will not feel either. The space within the large magnet in which you lie is somewhat confined, although we have taken many steps to relieve the "claustrophobic" feeling. You will be asked to either passively attend to or actively respond in one or more of the following experimental conditions during each scanning session:

1. Watching words or pictures presented on a TV-like screen in the scanner, or listening to words or other sounds presented through headphones (for example, seeing pictures of geometric patterns, hearing words or tones);
2. Watching or listening to words, pictures or sounds and actively making a response (for example, pressing a button or saying a word or phrase) about the type of pictures or sounds seen or heard;
3. Moving specific regions of your body (for example, tapping your fingers);
4. Performing cognitive activities (for example, adding two numbers, imagining faces).

MRI (Magnetic Resonance Imaging)

MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the body interior. The scanning procedure is very much like an X-ray or CT scan. You will be asked to lie on a long narrow couch for up to two hours while the machine gathers data. During this time you will not be exposed to x-rays, but rather a strong magnetic field and radiofrequency magnetic fields, which you will not feel. You will, however, hear repetitive tapping noises that arise from the Magnetic Resonance scanner. We will provide earplugs or headphones that you will be required to wear. The space within the large magnet in which you lie is somewhat confined, although we have taken many steps to relieve the "claustrophobic" feeling.

Genetic Testing

You may be asked to spit into a small vial so that a sample of your saliva can be collected. As part of the analysis on your samples the investigators will do genetic testing. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises

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certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

The results of the study of your samples will be used for research purposes only and you will not be told the results of the tests.

By conducting this aspect of our research we hope to learn how specific genes contribute to the neural representation of color appearance.

Do you consent to genetic testing? (Initial)

Yes _____ No _____

Risks:
Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MR scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you have a cardiac pacemaker or any other biomedical device in or on your body, it is very important that you tell the operator/investigator immediately. As metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your body before entering the magnet room. All such objects must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed. In addition, watches and credit cards should also be removed as these could be damaged. You will be provided a way to secure these items. If you have any history of head or eye injury involving metal fragments, if you have ever worked in a metal shop, or if you could be pregnant, you should notify the operator/investigator.

There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is expected and should not be painful. Some of the radio frequency imaging coils, imaging software and devices being used in your scan are not approved by the FDA but are similar to counterparts that have been approved by the FDA. There is a small risk of heating from the cables associated with these devices. Please report any heating sensation immediately. Dizziness or nausea may occur if you move your head rapidly within the magnet.

IF YOU FEEL DISCOMFORT AT ANY TIME, NOTIFY THE OPERATOR AND YOU CAN DISCONTINUE THE EXAM AT ANY TIME.

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The scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project may not be trained to perform medical diagnosis. The investigators and Stanford are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. When this occurs, a physician will be consulted as to whether the findings merit further investigation, in which case the investigator will contact you and your primary care physician and inform you of the finding. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators, the consulting physician, and Stanford are not responsible for any examination or treatment that you undertake based on these findings. Because the images collected in this study may not comprise a proper clinical MRI scan, these images will not be made available for diagnostic purposes.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without approval from the Protocol Directors of each study. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, the possible interaction(s) of research drugs, or other similar hazards.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

You can indicate at any time that you would like to discontinue participation. In the MRI scanner a button is provided for this purpose, when pressed, we will immediately terminate the experiments.

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There are no consequences if you withdraw from the study for any reason,

The Protocol Director may also withdraw you from the study and the study medication may be stopped without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances

If you have any questions, we expect you to ask us. If you have any additional questions later, Dr. Wandell at (650) 725-2466 or the research team at (650) 725-1255 will be happy to answer them.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

There are no known significant risks with this procedure at this time since the radiofrequency magnetic fields and the main magnetic field, at the strengths used, are felt to be without harm. There are conservative Federal and Stanford guidelines for radiofrequency magnetic field exposure. Our examinations fall within those guidelines. We feel these are safe levels and less hazardous than a comparable x-ray computed tomography examination.

Exceptions include if a person has a cardiac pacemaker or a certain type of metallic clip in their body (i.e., an aneurysm clip in the brain); if a person has worked with metal or had a head or eye injury involving a piece of metal; or if a person has shrapnel, bullets, or buckshot in their body. As metallic objects may experience a strong attraction to the magnet, it is very important that you notify the researcher of any metal objects, devices or implants that are in or on your body before entering the magnet room. This includes biomedical devices such as pacemakers and aneurysm clips, prostheses, and other metallic objects embedded in the body such as bullets, buckshot, shrapnel, and any metal fragments from working around metal. All other metallic objects must also be removed from your person prior to entering the magnet room or approaching the magnet to prevent them from becoming a projectile or being pulled by the magnet. This includes keys, jewelry, pocket knives, money clips, paper clips, safety pins, hair pins, and barrettes. In addition, objects such as watches, credit cards, and hearing aids could be damaged in the presence of the magnetic field. A locker will be provided for you to secure all your items and valuables.

If you are or are trying to get pregnant, the effects of the scan on a fetus are unknown and, therefore, we will not perform the examination at this time. Some of the radiofrequency imaging coils and the imaging

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software and sequencing being used to perform scans at the Stanford center for Cognitive and Neurobiological Imaging and the Lucas Center are not approved by the FDA. There is a risk of heating from radiofrequency imaging coils, the cables of radiofrequency imaging coils, the cables from monitoring devices such as those that record physiologic processes by way of an electrocardiogram, pulse oximeter, and/or plethysmograph, and/or cables from response boxes and other accessories. Please report any heating/burning sensation immediately. You may have the scan stopped at any time if this occurs. There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, you may have the scan stopped at any time if this occurs. Please take note that some subjects have experienced claustrophobia**;** you may discontinue the scan at anytime. Dizziness and nausea may occur if the head is moved within the bore of the magnet.

POTENTIAL BENEFITS

There are no direct benefits to you for participating in this study. You will contribute to the development and testing of new noninvasive imaging technology (i.e., technology that does not rely on either surgery or on the use of drugs), which will contribute to the understanding of brain function and may help patients with various mental and neurologic disorders.

WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

ALTERNATIVES

The alternative is not to participate.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

If you have any questions, we expect you to ask. Dr. Wandell (650) 725-2466 or his associates will be happy to answer them.

If you decide not to participate, tell the Protocol Director. You will still receive care for your disease and will not lose any benefits to which you would otherwise be entitled.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

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CONFIDENTIALITY

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

Your research records, including neuroimaging data and the results of behavioral testing, may be shared with other researchers both within Stanford and at other institutions outside of Stanford. In this case you will be identified only by a unique code number and no personally identifying information will be shared. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed**.**

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

FINANCIAL CONSIDERATIONS

Payment

As compensation for your participation, you may be paid $30 at the end of the testing session. Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa.

Costs

There is no cost to you for participating in this study.

If you participate in this study, there may be additional costs to you. These include the personal time it will take to come to all of the study visits.

The study will pay for those services, supplies, procedures, and care associated with this study that are not a part of your routine medical care. If you would like to review the list of such covered services, supplies, procedures and care, please tell us now or at any time during the study.

Participation in this study is not a substitute for health insurance. You and/or your health insurance must pay for those services, supplies, procedures, and care that you require during this study for routine medical care. **You will be responsible for any co-payments and/or deductibles as required by your insurance.**

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Sponsor
The National Institutes of Health is providing financial support and/or material for this study.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

Additionally, Stanford is not responsible for research and medical care by other institutions or personnel participating in this study. You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Brian Wandell at (650) 725-2466. You should also contact him at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, MC 5579, Palo Alto, CA 94304.

Appointment Contact: If you need to change your appointment, please contact the research team at (650) 725-1255.

Alternate Contact: If you cannot reach the Protocol Director, please contact the research team at (650) 725-1255.

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- 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.

May we contact you about future studies that may be of interest to you?
____Yes ____ No

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YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

_____ _____

Signature of Adult Participant **Date**

Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the subject has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

_____ _____

Signature of Person Obtaining Consent Date

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Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

You are invited to participate in a study of human brain function investigating the regions of the brain involved in vision. This study uses new technology in magnetic resonance imaging (MRI) to measure brain activity in human volunteers. The data collected from you will be analyzed by the research team (see below). Resulting publications will not disclose any identifying information.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to:

Brian Wandell, Ph.D.
Department of Psychology, Stanford University
Jordan Hall, Bldg 420, 450 Serra Mall
Stanford, CA 94305-2130
Phone: 650-725-2466

What Personal Information Will Be Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, MRI's.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director: Brian Wandell, Ph.D.
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- The Research Team and Coordinators.

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The National Institutes of Health
- The Machiah Foundation

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will expire on December 31, 2100.

Name of Participant (print)	Signature of Participant
Date	Description of Representative's Authority to Act for Subject