Name (please print):_____

Are you participating in any other research studies? _____ yes _____no

INFORMED CONSENT FORM

Protocol Title: A neurobehavioral probe of human reward function (Meeting Date) 06/11/02
Principal Investigator: Brian Knutson, Ph.D.

INTRODUCTION

You are invited to participate in a study of the brain and emotion. We hope to learn about how brain activity is related to emotional experience and behavior. You were selected as a possible participant because you have passed the inclusion requirements of the study. We anticipate that up to 100 people total will participate. The National Institute of Health is providing financial support and materials for a portion of this study.

Your **participation** in this study **is** entirely **voluntary**. The alternative is not to participate. 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.

PROCEDURE

If you decide to participate and sign the consent form, Dr. Knutson or a designated representative will describe the procedure to you.

Before the scan, we may ask you to fill out some questionnaires about daily mood and habits (taking less than 30 minutes). We may also train you on the videogame task (typically, 10-20 minutes).

The scanning procedure is very much like an x-ray CT scan, but no x-rays are involved. You will be asked to lie on a long narrow couch for a certain amount of time (no longer than three hours) while the machine gathers data. During this time you will be exposed to a magnetic field, which you will not be able to feel. You will, however, hear repetitive tapping noises that arise from the magnetic coils surrounding your body. We will provide earplugs or ear phones 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.

You may also be fitted for a bite bar in order to keep your head from moving during the scans. A bite bar is a mouthpiece specifically molded to fit one's mouth and securely attached to a positioning device, which you will be asked to bite during the scans.

During scanning, you will be asked to either passively attend to or actively respond in one or more of the following experimental conditions:

1. You will be asked to passively view or make a response (e.g., tapping fingers) to neutral visual stimuli (e.g., checkerboard patterns);

2. You will play a simple reaction time task in which you attempt to earn or avoid losing money;

3. You will view positive, negative, or neutral emotional pictures;

4. You will view faces with emotional expressions;

5. You will rate your reactions to the visual stimuli presented.

RISKS

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 guidelines for radiofrequency magnetic fields and main magnetic field exposure and 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 piece of metal removed from the eye(s); 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 of 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, you will not be eligible to participate.

Some of the radiofrequency imaging coils, imaging software, and other devices being used to perform scans at 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, and/or the cables from monitoring devices such as those that record physiological processes by way of an electrocardiogram, pulse oximeter, and/or plethysmograph. 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 shouldn't be painful. However, you may have the scan stopped at any time if this occurs. With the stronger magnet (3.0 Tesla), dizziness and nausea may also occur if you move your head within the magnet bore.

Some subjects have experienced claustrophobia in the scanner. If you feel uncomfortable, you can choose to discontinue at any time.

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 researchers will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for additional medical or other costs. You do not waive any liability rights for personal injury by signing this form. For further information, please call (650) 723-5244 or write the Administrative Panel on Human Subjects in Medical Research, Administrative Panels Office, Stanford University, Stanford, CA 94305-5401. In addition, if you are not satisfied with the manner in which this study is being conducted or if you have any questions concerning your rights as a study participant, please contact the Human Subjects Office at the same address and telephone number.

BENEFITS

You will be paid $20.00 per hour for your participation. In addition, you will receive whatever money you make on the experimental tasks (typically from $10.00-$50.00, depending on your performance) immediately at the conclusion of the experiment. Legally, you can be paid only if you are a US citizen, a legal resident alien (i.e, possess a "green" card), or have a work eligible visa sponsored by the paying institution. **However**, **we cannot and do not guarantee or promise that you will receive any benefits from this study.**

INCIDENTAL FINDINGS

The **investigators** for this project are **not trained** to **perform radiological diagnosis**, and the scans performed in this study are not optimized to find abnormalities. Thus, the investigators or Stanford cannot be held responsible for failing to find existing abnormalities in your MRI scan. However, on occasion, an investigator may notice something on the MRI scan that seems abnormal. If this occurs, a neuroradiologist will be consulted as to whether the finding warrants 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 proceed with further examination or treatment lies solely with you and your physician — the investigators, consulting neuroradiologist, and Stanford are not responsible for further action that you take. Because the images collected in this study do not comprise a standard clinical MRI series, they will not be made available for diagnostic purposes.

CONFIDENTIALITY

Any **data that may be published** in scientific journals **will not reveal** your **identity.** Patient information may be provided to Federal and regulatory agencies as required. The Food and Drug Administration, for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

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

RIGHTS
If you have any questions, we expect you to ask us. If you have any additional questions later, feel free to call Dr. Knutson at (650)724-2965.

At the discretion of the protocol director, **you may be withdrawn from this study** due to unanticipated circumstances. Some **possible reasons for withdrawal** from the study include:

- failure to follow instructions
- the investigator decides that continuation could be harmful to you
- you need treatment not allowed in the study
- the study is canceled
- other administrative reasons

Human Subjects Bill of Rights

As a human subject you have the following rights. These rights include but are not limited to your right to:

(1) be informed of the nature and purpose of the experiment;
(2) be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
(3) be given a description of any attendant discomforts and risks reasonably to be expected;
(4) be given an explanation of any benefits reasonably to be expected, if applicable;
(5) be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to you, their relative risks and benefits;
(6) be informed of the avenues of medical treatment, if any available to you after the experiment if complications should rise;
(7) be given an opportunity to ask 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 that you may discontinue participation without prejudice;
(9) be given a copy of the signed and dated consent form;
(10) 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 your decision.

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 Participant Date

_____
Social Security #

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 participant has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the participant and explained to him or her in nontechnical 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 participant to ask questions and that all questions asked were answered.

_____ _____
Signature of Person Obtaining Consent Date

Approval Date: 06/11/02 Expiration Date: 01/07/03