Emory University School of Medicine
Department of Psychiatry and Behavioral Sciences
Informed Consent Form
(MRI Version)

Title: **The Neurobiology of Uncertainty**

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Source of Funding: National Institute on Drug Abuse (NIDA)

INTRODUCTION:

You are being asked to take part in a research study looking at how the brain reacts to new information. The purpose of this study is to understand which parts of the human brain respond to unexpected events and the effect this has on emotional well-being. The study will require a type of brain scan called functional magnetic resonance imaging (fMRI) that is able to take pictures of the brain and determine which parts become active when you do or feel different things. We will also measure your heart rate, temperature, breathing, and changes in sweating while you lie in the scanner in order to connect how your body responds to the way you feel. The study will also require you to fill out a form describing how you felt before and during the scan. This study will take about 1 to 2 hours to complete.

A total of 300 subjects (both men and women) will participate in this study at the Emory University Hospital Center for MRI. In order to participate in this study, you must be between the ages of 18 and 45 and you must be able to see the computer display clearly without eyeglasses.

PROCEDURE:

Pregnancy certification: Women who could be pregnant or sexually active and not using a contraceptive method should not participate in this study. If you are a female who is sexually active, you must have had a menstrual period within the last 30 days to participate.

Glucose-6-Phosphate Dehydrogenase (G6PD) Deficiency certification: If you have ever been diagnosed with and enzyme deficiency called G6PD deficiency or have ever had hemolytic anemia you cannot participate in this study. Hemolytic anemia is a condition where red blood cells are destroyed and because of this there are not enough of them in the blood. You may have had this if you have experienced chills, fatigue, pale or yellow skin color, shortness of breath, rapid heart rate, dark urine, or an enlarged spleen.

Metal Implants certification: If you have any metal implanted in your body you will not be able to participate in this study. Examples of metal implants are: pacemakers, aneurysm clips, shrapnel, metal fragments, IUD's, piercings that you cannot remove, orthopedic pins, screws, or plates, cochlear implants, or if you are a steel worker (tooth fillings are fine).

Exclusion Criteria: This consent form will be reviewed with you by a member of the research team. If you agree to participate, you will be asked to sign this consent form. You will not be able to participate in this study if you are nursing or pregnant, if you have a diagnosed mental illness (including depression and schizophrenia) other than nicotine dependence, if you are taking medications other than contraceptives, or if you have a history of alcohol or drug dependence.

Head Scanning: To be scanned, you will be asked to remove all jewelry and other metal-containing objects (including credit cards) and then you will enter a large room where a powerful magnet is located. You will be asked to lie down on a narrow table and then you will be put into a small tunnel approximately 6 feet long and 25 inches in diameter. You will then be asked to lie as still as possible during the scan for approximately 30-50 minutes. You will have headphones and a microphone through which you will be able to communicate with the members of our team running the experiment. A small mirror will be positioned above your head so you will be able to see out of the end of the scanner. During scanning, you will hear a loud banging noise while the fMRI machine takes pictures of your brain. This is normal. You will be given earplugs to make you more comfortable.

Computer Task: While you lie in the scanner, a computer display will be placed at one end of the tunnel. You will be able to see this through the mirror in front of your face. In some cases, we will need you to respond to things you see on the screen, and for this you will be given a small box with buttons that will be put under your hand when you are placed into the scanner. Things you will be shown may include colored geometric shapes that will be explained to you before the scan, or images of cards that will require you to make choices depending on the particular study you are doing. In other cases, you will be asked to just lie still and look at the screen without doing anything. One of the research team personnel will clearly explain what you will need to do and you will have a chance to practice before you go into the scanner.

Stimuli: Since this is a study of how your brain responds to unexpected events, it may require you to receive pleasant and/or unpleasant stimulation. If this is the case, you will be told beforehand and offered the chance to withdraw from the study. The pleasant stimulation would be fruit juice squirted into your mouth through a plastic tube while you are in the scanner. The unpleasant stimulus could be one of two things: quinine solution or a mild electric shock. The member of the research team working with you will tell you which stimulus you will receive. Quinine is a bitter flavoring used in tonic water; if this is what is used, it will also be squirted into your mouth through a plastic tube while you are in the scanner. If shock is what is used, it will be given to you through two small electrodes attached with Velcro or medical tape to the back of your foot or the ankle while you are in the scanner. The shocks are very short and feel like mild stings. In either case, you will be allowed to feel or taste whatever will be used before going into the scanner. You will be asked to rate different strengths of the stimulation on how pleasant or unpleasant they are in order to determine which one will be used. You will have a chance to experience all the stimuli as they will be used in the experiment before being put into the scanner.

Psychophysiological Assessment: Some of your body's responses may be measured while you perform the computer task, including heart rate, temperature, breathing, and changes in sweating.

This requires wires or belts to be attached with stickers or Velcro to your fingers, hand, arm, chest, or leg. The wires and belts are not harmful and should give you a minimum of discomfort.

Self-Report Questionnaire: *At the end of the scan you may be asked to answer some questions about how you felt while doing the computer task inside the scanner. This should take no more than 10 minutes.* Finally, you will be asked to do a gambling task. For this you will receive $20.00 and will be asked to make choices about whether to gamble it or not. Depending on your choices you may gain up to another $16.00 or lose $16.00 from this. You will also be asked to fill out personality questionnaires.

RISKS:

There are minimal risks involved with this procedure, although it may at times be unpleasant.

Although the scanner at Emory University Hospital is twice the strength of many MRI machines, it is approved by the Food and Drug Administration (FDA) for diagnostic purposes and is becoming the standard in hospitals. There is no evidence that it is harmful. This type of brain scan is not for diagnostic purposes, and a radiologist will not be reading the scan.

Because of the investigative nature of this study and the unknown effects of the magnetic field on human development, you should not participate if there is the possibility that you are pregnant.

Because the magnetic field will affect any metallic object, you should not participate if you have any type of metallic implant in your body, including pacemakers, aneurysm clips, shrapnel, metal fragments, orthopedic pins, screws, or plates, IUD's, or piercings that you cannot remove. If you have any of these, there is a risk that the magnetic field could cause them to move or heat up.

You may experience some muscle discomfort while lying in the scanner. You may also become too hot or too cold, in which case you may ask for an adjustment of room temperature or a blanket. Some people become nervous or claustrophobic (anxious in or afraid of closed-in spaces) in the scanner. If this happens to you, you may ask to be withdrawn immediately. You may also experience a sense of dizziness in the magnet. This is due to the strong magnetic field, and if it disturbs you, you may ask to be withdrawn.

The MRI machine is as loud as riding in a loud train—you will be given earplugs and headphones to lessen the noise.

Measuring your heart rate, temperature, respiration, and changes in sweating should not have any risks. Sometimes there is some discomfort when we remove the stickers holding the recording wires in place, but this is small. The wires are grounded and are only measuring your body's responses, so there is no danger of electric shock.

There is a degree of risk of acute hemolytic anemia (a condition where red blood cells are destroyed and because of this there are not enough of them in the blood) with the use of quinine in people who have glucose-6-phosphate dehydrogenase (G6PD) deficiency. Although the amount of quinine used in this study is approved by the FDA as a food additive (it is the same flavoring and amount used to make tonic water bitter) and should therefore be safe, it is possible that you may have a hemolytic reaction if you do have G6PD deficiency that you do not know about. In case this should happen, you will be given emergency care. Generally, however, the amounts used are so small that there is minimal risk to this procedure.

Quinine has a bitter taste and even though it will not be used in a strength that would cause any damage, it could become unpleasant. It will taste like strong and flat tonic water without the sweetener.

The electric shock is mildly unpleasant and will be adjusted so it is tolerable to you. Although the machine that makes the shocks is not approved by the FDA for use on humans and is therefore considered experimental, it has been used extensively for purposes similar to this study and has a long record of safety. Under some conditions the machine may have the potential to cause minor burns, but the procedure used in this study minimizes any such risk. The shocks will last less than 1 second each, and will feel mildly unpleasant like small stings.

Due to the investigative nature of this study there may be other risks that are currently unknown.

BENEFITS:

There is no direct benefit to you for participating in this study. The knowledge gained, however, may result in a better understanding of how the brain reacts to new information and how this becomes altered in mental illness. Should you want them, pictures of your brain will be sent to you via email at some point after your scan.

CONFIDENTIALITY:

All information concerning your participation in this study will be kept private. Research records may be obtained by court order, however. If information obtained from you for this study leads to published data, it will be written so that your identity will remain confidential.

People other than those doing the study may look at both medical charts and study records. Agencies that make rules and policy about how research is done have the right to review these records, as do agencies that pay for the study. By signing this consent form, you are giving permission for your physician to allow representatives from the National Institutes of Health (NIH), the Food and Drug Administration (FDA), or the Emory University Institutional Review Board, its agents or contractors, and any legally entitled regulatory body to review the information regarding your participation in this study and your medical records. All data and medical records associated with your participation will be kept confidential except where noted, and as may be required by law. You will be identified by your initials and not your name whenever possible, including to the University and any regulatory body.

COMPENSATION/COSTS:

You will not be charged for your participation in this study. Any medical or hospital care you may require independent of this study will be your responsibility. You will receive $40 for your participation in this study. This research is funded by grants from the National Institutes of Health (NIH), which pays the costs of the MRI.

In the event that you are injured as a result of this research, you will be given medical treatment. You will not receive reimbursement for medical care other than what your insurance carrier may provide, however, nor will you be given other compensation. Emory University Hospital, Emory University, and the Emory Clinic have not set aside funds to compensate you in case you are injured by participating in this study. For more information concerning the research and research-related risks or injuries, or if you believe you have been injured by this study, you can contact Dr. Berns, the investigator in charge, at (404) 727-2556.

VOLUNTARY PARTICIPATION/WITHDRAW:

Your participation in this study is completely voluntary and you have the right to refuse to participate at any time. Your decision to participate or not participate will in no way affect your current or future treatment. There are no medical consequences for withdrawing. You may be withdrawn from the study if at any time you no longer meet the requirements for participation or you are found to violate one of the listed exclusion criteria.

CONTACT PERSONS:

* To make inquires concerning this study, contact Dr. Berns at (404) 727-2556.

* If you have any questions or concerns about your rights as a participant in this research study, you may contact Colleen DiIorio, PhD, Chairman, Emory University Institutional Review Board at (404) 712-0720.

NEW FINDINGS:

In the event that any significant new findings are developed during the course of research, this information will be provided to you.

A copy of this consent form will be given to you.

Your signature below indicates that you consent to volunteer for this study.

_____	_____	_____
Patient/Subject	Date	Time
_____	_____	_____
Person obtaining consent	Date	Time

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