

Emory University School of Medicine
Department of Psychiatry and Behavioral Sciences
Informed Consent Form
(MR Scanning)

Title: **Neurobiology of Reward and Preference in Adolescence**

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

INTRODUCTION:

Both adults (ages 30-49), and adolescents (ages of 12-17), will be asked to be in this study. If you are the parent or legal guardian of a child who is being asked to participate, the term "you" used in this consent refers to your child.

You are being asked to volunteer for a research project examining how the reward system of the brain works. The purpose of this study is to determine how the reward system of teenagers' brains is different than adults'. A total of 200 subjects (both men and women) will participate in this study. The study will require a type of brain scan called a magnetic resonance image (MRI). You will also be asked to complete a series of computer tasks to test your mental function. This study will take 2 hours to finish.

PROCEDURE:

Urine test: We will ask you to urinate in a cup. We will test your urine for the following illicit drugs: benzodiazepines (sleeping pills), methamphetamine, cocaine, THC (marijuana), and morphine. We will tell you the results immediately, and if it is positive, we will advise you on where to seek medical care. This information is confidential, and even if you are an adolescent, WE WILL NOT TELL YOUR PARENT.

If you are female, then we will also test your urine to see if you are pregnant. We will tell you the results immediately, and if it is positive, we will advise you on where to seek medical care. This information is confidential, and even if you are an adolescent, WE WILL NOT TELL YOUR PARENT.

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 (or have a positive pregnancy test), 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 (or have a positive drug test). You will be asked to complete a screening questionnaire for depression. You will not be allowed to participate in this study if the results indicate that you may be struggling with depression. In this case, we will advise you on where to seek further health evaluation.

Head Scanning: The MRI scanner uses a strong magnet and radiowaves to obtain a picture of the brain. To be scanned, you will enter a large room where a powerful magnet is located. You will be instructed to remove all jewelry and other metal-containing objects. You will then be placed on a narrow table with plastic-encased metal coil close to your head. You will then be slid into a small tunnel approximately 6 feet long and 2 feet in diameter. You will then be asked to lie still during the scan for approximately 30-50 minutes. A small mirror will be positioned above your head so you will be able to see out of the end of the scanner. After you are positioned, the table will move you into the scanner itself. During scanning, it produces a loud knocking noise. This is normal.

Task: While you lie in the scanner, a computer display will be positioned at your feet. You will be able to see this through the mirror above your head. You will be given a small box with buttons to press in response to what appears on the screen. The specific instructions will be given to you before the scan. The MRI studies will be conducted in the MRI center at Emory University Hospital. While there, you will interact with Dr. Berns and his co-investigators. You will be asked to perform one of three tasks.

In the first task, you will be given small squirts of fruit juice in your mouth. These will be given to you through tubes attached to a baby pacifier. Using the response box, you will be asked to rate its pleasantness. After the task, we will ask you several questions about how much you liked the juice. You will also be given a choice of taking some home with you, and you will also be asked how much you would be willing to pay for it.

In the second task, you will hear short clips of music through headphones. These will be chosen from the MySpace library. You will be asked to rate the appeal of the music clips, and you will be asked to choose songs to create a CD that you may take home with you, as well as how much you would be willing to pay for these songs.

In the third task, you will play a financial game. You will make choices between winning a certain amount of money for sure or you can take a chance on the probability of earning a greater amount of money. One of your choices will be picked at random at the end of the game and payment will be based on that particular choice. You can win \$0 to \$36 in addition to your base payment of \$40.

Before you do one of these tasks, you will be asked to do another test, which measures intelligence. You will also be asked to complete a questionnaire about behaviors that some people engage in. Your answers to these questions will remain confidential. We will not share your responses with anyone. Finally if you are participating in either the first or second task, you will be asked to play a game. For this you will receive \$20.00 and will be asked to make choices about whether to risk it or not. Depending on your choices you may gain up to another \$16.00 or lose \$16.00 from this.

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. However, if we observe anything unusual on your brain scan, we will tell you. If this happens, we may suggest that you consult with a doctor for further tests, which may result in other medical expenses.

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.

The lyrics and subject matter in some of the songs may be considered offensive.

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. However, the knowledge gained may result in a better understanding of how the reward system of the brain develops in adolescence. Should you want them, we will give you a picture of your brain scan.

CONFIDENTIALITY:

People other than those doing the study may look at both medical charts and study records. Agencies and Emory departments and committees that make rules and policy about how research is done have the right to review these records. So do companies and agencies that pay for the study. The government agencies and units within Emory responsible for making sure that studies are conducted and handled correctly that may look at your study records in order to do this job include: National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Clinical Trials Office (CTO), the Emory Office of Research Compliance, 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. Companies and other groups that pay for studies and that are listed in consent and authorization documents also will have the right to look at your records. In addition, records can be opened by court order or

produced in response to a subpoena or a request for production of documents. We will keep any records that we produce private to the extent we are required to do so by law. We will use a study number rather than your name on study records where we can. Your name and other facts that might point to you will not appear when we present this study or publish its results.

If you are or have been a patient at an Emory Healthcare facility, then you will have an Emory Healthcare medical record. If you are not and have never been a patient at an Emory Healthcare facility then no Emory Healthcare medical record will be created for you just because you are participating in a research study.

Results from study tests and procedures that are performed, analyzed and/or read at or for Emory Healthcare facilities that can be used for healthcare purposes will be placed in any medical record that you have with Emory Healthcare facilities. In addition, a copy of the informed consent form and HIPAA authorization form that you sign will be placed in any Emory Healthcare medical record you may have. Persons who have access to your medical record will be able to have access to all results and documents that are placed there, and the results/documents may be used by Emory Healthcare facilities to help provide you with medical care. Any results and documents that are kept as part of your medical record are not covered by certain state and federal laws and regulations that may prevent the disclosure of, research data. However, the confidentiality of the results and other documents in the medical record will be governed by laws such as HIPAA that concern medical records.

Emory University does not have any control over results from tests and procedures performed and/or analyzed or read at non-Emory Healthcare facilities. These results are NOT routinely included in medical records at Emory Healthcare facilities, and they will not necessarily be available to Emory Healthcare providers. Emory University also does not have control over any other medical records that you may have with other healthcare providers and will not send any test or procedure results from the study to these providers. It is up to you to let these healthcare providers know that you are participating in a clinical trial.

Some tests and procedures that may be performed during this study by Emory Healthcare or other facilities or persons may not be looked at or read for any healthcare treatment or diagnostic purposes. These tests and procedures will only be looked at for research purposes and the results will not be reviewed to make decisions about your personal health or treatment. The specific types of tests or procedures, if any, that fall within this category are listed below:

MR scans, pregnancy test, drug test, and psychological tests

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 completing the MRI session. This research is funded by grants from the National Institutes of Health (NIH), which pays the costs of the MRI.

In the event that injury occurs as a result of this research, medical treatment will be available. However, you will not be provided with reimbursement for medical care other than what your insurance carrier may provide, nor will you receive other compensation. Emory University Hospital,

Emory University, and the Emory Clinic have made no provisions for payment of costs associated with any injury resulting from participation in this study. For more information concerning the research and research-related risks or injuries, you can contact Dr. Berns, the investigator in charge, at (404) 727-2556.

VOLUNTARY PARTICIPATION/WITHDRAW:

Participation in this study is voluntary. You are free to withdraw from participation at any time. Your decision to participate or not participate in 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.

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, Ph.D., Chairman, Emory University Institutional Review Board at 404-712-0720 or toll free at 1-877-503-9797.

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 the consent form will be given to you. The researchers will ask you to sign and date this form. If you are willing to volunteer for this research study, please sign below. Before you sign this form, please ask any questions on any part of this study that is not clear to you. You may take as much time as you need to think this over.

PARENTS SIGNING FOR CHILDREN:

I/We certify that I/We are the parents/legal guardian of _____, a child who is under 18 years of age and who has been invited to participate in this study. I/We further certify that I/We have legal custody of the child and that I/We have full legal authority to make decisions concerning the child including decisions regarding health care information. I/We also understand that the results of the urine drug screen and pregnancy test will not be revealed to me/us.

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

Print name

Patient/Subject, Parent or legal guardian

Date

Time

Person Obtaining Consent

Date

Time

Assent to Participate (if 17 yrs of age)

Date

Time

FUTURE CONTACT:

The research team may wish to contact you in the future to invite you to participate in other studies. Therefore, we ask your permission to contact you in the future. Giving your permission for the research team to contact you does not obligate you to participate in future research – you always have the right to decline. Please indicate your preference about future contact by writing your initials in one of the spaces below:

_____ I give the research team permission to contact me in the future.

_____ I do not give the research team permission to contact me in the future.

***Note: The following must also be completed for those less than 18 years of age**

ASSENT FROM PEDIATRIC SUBJECTS

Subject age: _____years.

1. _____ WRITTEN ASSENT (ages 12-16)
2. _____ READ/SIGN MAIN CONSENT DOCUMENT WITH GUARDIAN (age 17)

Person Soliciting Assent	Date	Time

3. _____ WRITTEN ASSENT (age 17) the subject is encouraged to read the full informed consent document and sign the document on the “Assent to Participate” line

WRITTEN ASSENT DOCUMENT

We are asking you to volunteer to be in a medical research study. The study is about the pleasure centers of your brain and will take about 2 hours to finish. You will receive \$40 for completing the study. During the study you will have a brain scan done using a machine called an MRI scanner. The MRI scanner is a big machine that has a hole in it like a donut. It can take pictures of your brain while you do something. During the study you will go into the room where the MRI scanner is. You will lie down on a table that goes into the hole of the MRI scanner. To take the pictures of your brain, we will put some plastic bars around your head. The bars have a mirror on them. You will look straight up into the mirror and will see a computer screen that is in front of the hole of the MRI scanner. When we take the brain pictures, the MRI scanner will make a really loud noise. Before you go into the hole of the MRI scanner we will put plugs in your ears to make the noise not so loud. While you lie in the hole of the MRI scanner we will either give you squirts of juice in your mouth, play music clips for you, or ask you to play a game with money. In this game you will make decisions on the chances of winning more money in addition to the \$40. You can win from \$0-\$36 in addition to the \$40.

If you get nervous or scared when you are inside the hole of the MRI scanner, you can let us know and we will take you out right away. If you get cold we can give you a blanket, or if you get hot we can turn on the air conditioning.

You can refuse (say no) to be in this study. The doctor doing this study (Dr. Berns) or your parents cannot make you be in the study if you don't want to be in it. If you agree to be in the study but change your mind about it later, you can stop being in the study.

Dr. Berns will talk to you about what it means to be in a research study. You should ask Dr. Berns all of the questions you have and he will answer them. You can also talk to your parents about the study if you want to.

The researchers will ask you to sign and date this form. If you are willing to volunteer for this research study, please sign below. Before you sign this form, please ask any questions on any part of this study that is not clear to you. You may take as much time as you need to think this over.

If you agree to be in the study, sign here:

Print Participant's Name

Participant's Signature

Date

Time

Parents signing for children:

I/We certify that I/We are the parents/legal guardian of _____ , a child who is under 18 years of age and who has been invited to participate in this study. I/We further certify that I/We have legal custody of the child and that I/We have full legal authority to make decisions concerning the child including decisions regarding health care information.

_____	_____	_____
Participant, Parent or legal guardian	Date	Time

_____	_____	_____
Person obtaining	Date	Time

Rev. 03/20/08