

Consent Form Approval

Date:

Valid for Use Through:

**Study Title: CENTER ON ANTISOCIAL DRUG DEPENDENCE, COMPONENT 3: A
Neurogenetic Basis for Risky Decisions**

Principal Investigator: Thomas J. Crowley, M.D.

COMIRB No: 09-0211

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Version #: 2

You are being asked to be in a research study. This form tells you about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part in this study.

Why is this study being done?

This study focuses on decision-making and brain functioning. This study plans to learn more about what parts of the brain make risky decisions.

You are being asked to be in this research study because you have been in other studies of these investigators.

Other people in this study

Up to 144 people from your area will participate in the study.

What happens if I join this study?

If you join the study, the researchers will access information and DNA from your participation in earlier research studies done by these investigators.

The researchers will ask you to make choices about whether to puff up a balloon on a computer. While you do that, they will take special pictures of your brain to see what parts of the brain are working. They do this with a special research machine called an fMRI. That stands for functional magnetic resonance imager.

You will go to the University of Colorado Denver Brain Imaging Center on the Anschutz Medical Campus, where the fMRI machine is located. The researchers will help you lay down in a long tube inside the machine, which has a big magnet in it. While you are in the tube, the machine will take pictures of your brain.

The researchers will show you balloons on a computer and will ask you to make decisions about whether to puff up the balloon. You will press a button to puff it up, and if it does puff up you will win some money, but if it pops, you will lose some money. You will be given \$5 to play the game, and you probably will end up with between \$5 and \$10, depending on how you play the game. You will practice the balloon game outside the fMRI machine before you play it in the machine.

Consent Form Approval

You will be in the tube for about 50-60 minutes. There will be some rest periods while you are in it. The whole study will last about 2-3 hours from the time you get there until you leave.

If you agree to participate in this research study, this is how it will go:

1. You will answer some questions about drugs you may have used. Those questions take about 5 minutes.
2. You will be asked questions about whether you have any metal inside your body. That is because the fMRI machine is not safe for people who have some kinds of metal in their bodies. Those questions take about 5 minutes.
3. If you are a female, before the study the researchers will ask you to do a urine pregnancy test to make sure that you are not pregnant. You cannot do the study if you are pregnant.
4. You will give a urine and saliva sample just before the fMRI test. You cannot do the study if the urine or saliva tests show drugs or alcohol.
5. Before you go into the tube, you will be told more about the researchers' balloon game and you will practice the balloon game on a computer in a practice tube that looks like the fMRI machine. You also will practice holding your head very, very still.
6. Before you go into the tube you will store away any metal things you have with you, like a watch or eyeglasses. You will then change into hospital scrubs and be scanned with a metal detector.
7. Then you will lie on your back, very still, inside the tube on a padded mat. Spongey pillows will help hold your head still. The first brain picture takes about 5-10 minutes. When the machine works it makes loud banging noises.
8. Then, for about 35 minutes you will play the balloon game while lying very still inside the tube. There will be some rest periods. After the balloon game, another brain picture will be taken. That takes about 5-10 minutes.
9. If you feel that you must get out of the tube during the experiment, you can tell or signal the researcher to take you out. Then you cannot go back in.
10. After you get out of the tube, the researchers will ask you a few questions about the balloon game. This takes about 5 minutes. Your answers help the researchers make the game better. They will tape record what you say with a small voice recorder so it is easier to write down your answers. Once your answers are written down on paper, the tape will be erased. Until the tape is erased it is kept safe in a locked room.
11. If you want to know the results of the study, the researchers can send you a picture of your own brain, or a copy of scientific reports that they might publish, or they can

Consent Form Approval

discuss the results at the end of the study. To get your results you must make a written request to Dr. Crowley (address: Mail Stop F478, 12469 E. 17th Pl. Aurora, CO 80045). No member of a family can get information on any relative, so your family members and others cannot get your information.

12. You may be re-contacted in the future to ask if you want to be in other studies. However, you do not have to do more research studies in the future.

What are the possible discomforts or risks?

- In this study we will take fMRI's of your brain. The fMRI machine uses powerful magnetic waves to take pictures inside the body. The waves themselves are not harmful, but they can cause metal on your body to heat up and electronics to stop working.
- You should NOT have an fMRI if you have metal or electronic devices inside your body. Heart pacemakers and insulin pumps are examples of electronic devices. The fMRI machine's big magnet can make some metal things fly around, and they could cause injury or even death. That is why the researchers will make sure that you do not have any metal on or in your body when you go into the machine.
- The most common side effect of having an fMRI is flashing lights in the eyes. This is caused by the magnetic waves and is not harmful. Some people also experience warmth and reddening of the skin. This usually goes away after a few minutes.
- There is some risk of a break in secrecy. The researchers try hard to keep your information secret. The researchers keep information with your name on it under lock and key, or in password-protected computers in secure rooms. Your information will be identified by code numbers and not by your name. That way you cannot be identified and your information stays secret. The researchers got a Certificate of Confidentiality from the U.S. Government. This Certificate is not an endorsement by the government, but it protects the researchers from being forced to release information that identifies you, even under a court order or subpoena.
- The researchers do not know of any fMRI risks during pregnancy, but to be careful they do not study pregnant women. That is why they do pregnancy tests on females before the study.
- The fMRI machine is a small round tube. It might make you uncomfortable if you do not like tight spaces.
- You might get tired or bored from the balloon game on the computer and in the tube, and feel mild discomfort from lying flat in the same position for about 50 minutes.
- You will hear a number of sounds during the test. Some are pretty soft; they sound like a hammer tapping a piece of wood. Some other sounds are much louder; they sound like a car with a hole in its muffler, or the "ping" sounds of submarines in movies. These sounds may be repeated several times. They may be unpleasant, but they will not be loud enough to harm you. For comfort, the researchers will give you special earplugs and headphones to cut down the noise.

Consent Form Approval

- Researchers will not ask about child abuse but if such information comes up by accident, they will report it to state agencies.
- The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about decision-making. This study is not designed to treat any illness or to improve your health. There are no benefits to you from participating in this research study, and there are the risks just mentioned.

This study is not designed to find or treat any illness or to improve your health. But if your brain pictures show any possible health problems the researchers will tell you so that you can see your doctor. You would be responsible for the costs of that medical care.

Who is paying for this study?

The sponsor for this study is the National Institute on Drug Abuse, a federal agency. They encourage everyone in their studies to get more information about HIV/AIDS. If you would like more information about HIV/AIDS, go to: www.aids.gov.

Will I be paid for being in the study?

You will be paid \$200 for your time and inconvenience in completing this study. You can keep whatever money you earn playing the balloon game, which probably will be between \$5 and \$10. You will also be paid \$3 extra if you hold very, very still in the fMRI machine.

If you leave the study early, or if we have to take you out of the study, you will be paid only for the part of the study you completed.

It is important to know that a payment for participation in a study is taxable income.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is this a test for a genetic disease?

Researchers will access your information and DNA samples from the earlier research studies you have participated in with these researchers. DNA is a chemical molecule in every person's body that shows everything that is inherited biologically. In previous studies, you provided a sample of your DNA. You answered many personal questions about your thinking, feelings, moods, behavior, and drugs that you may have used. With your permission we will look at how your genes relate to your decision making ability. If you do not want the researchers to study your genes and DNA, you should not sign this consent to participate in this study.

Consent Form Approval

There is no normal or abnormal result to this test. Your DNA is used for research purposes only.

Is my participation voluntary?

Being in this study is voluntary. You have the right to choose not to be in this study. If you choose to take part, you have the right to stop at any time. If you refuse to be in the study or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?

The researcher or his research staff may decide to stop your participation without your permission if he or she thinks that being in the study may cause you harm, or for any other reason. If you move too much in the tube, or if you cannot stay in the tube for the whole time, the information obtained may not be used for the study. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. Thomas Crowley immediately. His phone number is 303-724-3181. We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Thomas Crowley. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call or write Dr. Crowley at 303-724-3181, or Mail Stop F478, 12469 E. 17th Pl., Aurora CO 80045. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Crowley with questions. You can also call the Colorado Multiple Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Who will see my research information?

The researchers hold all of your information in the strictest confidence. To keep everything secret the information is kept under lock and key and the researchers' computers are protected by passwords and burglar alarms. Your researcher will treat your identity with professional standards of confidentiality.

However, there are some things that the researchers WOULD tell about:

- Information about current child abuse or neglect.
- Any serious threat of future physical violence against another person.

Consent Form Approval

- If you tell the researchers in writing to release information.
- If information is needed by medical personnel treating you in an emergency.
- If the researchers believe that you may harm yourself.
- If you commit or threaten to commit a crime at the research program or against its employees.

The researchers have a Certificate of Confidentiality from the Federal Government. That Certificate keeps courts or police agencies from getting information that you give the researchers.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

Both the records that identify you and the consent form signed by you may be looked at by others. They are:

- Federal offices that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB).
- The study doctor and his team of researchers.
- National Institute on Drug Abuse, who pays for this research study.
- Officials at the University of Colorado Denver who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

We will ask you to sign a different form that talks about who can see your research records. That form is called a HIPAA form. It will mention companies and universities who will see your research records.

You can ask the researchers for your personal health information from this study, but you may not be allowed to see that information until after the study has been completed.

Your HIPAA form agreement continues unless you make it stop by asking the investigator. If you ask him to make it stop, the Institution, the Investigator, the research staff, and the research Sponsor will no longer be able to use or disclose your personal health information from this study, except for what they have already done.

Consent Form Approval

Agreement to be in this study

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be in this study. I will get a copy of this consent form.

Subject Signature: _____

Date: _____

Print Name: _____

Consent form explained by: _____

Date: _____

Print Name: _____

Investigator: _____

Date: _____