

APPROVED
Consent Form Approval

JAN 04 2013

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COMIRB

Valid for Use Through: 01-03-14

Study Title: **CENTER ON ANTISOCIAL DRUG DEPENDENCE, COMPONENT 1: The Genetics Of Risk Behaviors**

Principal Investigator: **Christian J. Hopfer, M.D.**

COMIRB No: 09-0157

Version Date: 12/20/2012

Version #: 5 (Proband Consent Authorization)

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.

Why is this study being done?

This study plans to learn more about causes for teenagers' and young adults' drug, alcohol and behavior problems.

You are being asked to be in this research study because you are in evaluation or treatment for drug, alcohol or behavior problems and the researchers hope to learn more about the causes for those problems.

We will look at your DNA and the information you give to us. DNA is a chemical molecule in every person's body that shows everything that is inherited biologically. In the DNA researchers will look for genes affecting drug use, drinking, and behavior problems.

Other people in this study

Up to 1400 people from your area will participate in the study.

What happens if I join this study?

If you join the study, this is how it will go:

1. You will meet with a researcher for about 2-5 hours at their office, the treatment center, your home, or another place of your choice. During that time you will answer many questions about your thinking, personality, your school or work, and your thoughts, feelings and behaviors, including possible drug use, criminal and sexual behaviors. We will measure your blood pressure and heart rate. You will also be asked to play a very short computer game.
2. As part of your treatment you may have had interviews about medical, emotional, and drug issues. In other studies of these same researchers, you also may have had such interviews. The researchers will study the information from these treatment and research interviews.

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3. You will give us a sample of your DNA. The best way to do that is with blood. About 3 tablespoons of blood will be removed by putting a needle into your vein. This is the standard method used to take blood for tests. This takes about 15 minutes. If you do not want to give a blood sample, there is another way you can give us your DNA. You will rinse your mouth with water for 30 seconds and after waiting about a minute, spit into a small container.
- If the blood cells fail to grow in the lab, you may be asked to repeat the blood draw one more time in the future.
 - The researchers will store some of your DNA permanently at a lab on the University of Colorado at Boulder campus, and may use it for future studies.
 - The researchers may also send your blood cells and some of your information to the National Institutes of Health Repositories, but only WITHOUT YOUR NAME OR OTHER IDENTIFIERS. The National Institutes of Health (NIH) will store your information and keep cells from your blood growing permanently. They will give your information (WITHOUT YOUR NAME OR OTHER IDENTIFIERS) to leading qualified scientists around the world. Those scientists will keep your information secret. They agree never to try to find out who you are.

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?

- Some of the questions may make you feel uncomfortable. You don't have to answer those questions if you don't want to.
- A break in secrecy. You will be asked questions about very private things, like drug use or crimes and we will look at your DNA. The researchers know that it could be bad if the wrong people got that information. The researchers keep information with your name on it under lock and key, or in password-protected computers in secure rooms. Your answers 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.
- Another risk is that someone could learn about your DNA makeup if they got the information from this study. Therefore, the researchers will only release your information WITHOUT YOUR NAME OR OTHER IDENTIFIERS and only to qualified scientists.
- You will feel discomfort or pain during the blood draw. A bruise may form at the blood draw site. You may feel lightheaded, faint, or nauseous.

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- There is a small chance that you could get embarrassed or nervous about the interviews, or DNA sample. If that happens the researchers will help you find a counselor or therapist who can discuss those problems with you.
- If your blood pressure or heart rate are outside the range expected for people your age, the researchers will tell you and your parent so that you can see your doctor. Your family would be responsible for the costs of that medical care.
- If the researchers in this project find out about current child abuse, they must 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 causes for teenager's and young adult's drug, alcohol and behavior problems. 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.

Who is paying for this study?

The sponsor for this study is the National Institutes of Health (NIH), 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 \$100 for your time and inconvenience in completing this study. You will also get the chance to earn an additional \$3-\$8 from the computer game you will play as part of this study. You will be paid \$20 for your time and inconvenience if you have to repeat the blood draw.

For patients at Synergy Outpatient the \$100 payment is a money order made payable to both you and your parent, and the computer game money is cash.

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?

No. Researchers do not yet know of any gene that makes drug, alcohol, or behavior problems worse. There is no normal or abnormal result to this test. Your DNA is used for research purposes only.

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Can you get the test results?

No. Results from this study will not be available to anyone for any purpose other than research. No results of this DNA research will be used to make any medical decision or judgment about you or any member of your family. However, information might become available in the future regarding prevention or treatment of some genetic influence on drug, alcohol, or behavior problems for which you may be at risk. If so, the researchers will make a reasonable effort to contact you to ask whether you want that information from them.

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 choose to stop, the researchers will immediately call your responsible adults and arrange for you to return to them or to the treatment program. If you refuse to be in the study or decide to withdraw later, you will not lose any rights to which you are entitled. Being in the study will not change your treatment at Synergy or STEP. This research study is not part of your treatment. Whether or not you do this research, you will receive the treatment program's standard care.

If you want to withdraw at any time in the future, you have been provided with a subject withdrawal form.

If I am on commitment, diversion, probation, or parole, will this get me off?

No, it won't. Your being in this study is voluntary. If you are under supervision by a criminal justice agency, on probation or parole, participation in the study will not affect or change this status, the conditions of your suspended sentence, your release date, or your general living conditions.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the study sponsor may stop the study at any time. You can choose to be removed from this study at anytime.

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. Christian Hopfer immediately. His phone number is 303-724-3170. 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.

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Who do I call if I have questions?

The researcher carrying out this study is Dr. Christian Hopfer. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call or write Dr. Hopfer at 303-724-3170, 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. Hopfer 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 institution involved in this study is the University of Colorado Denver and they have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy.

This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

These researchers will see, use and disclose your information only as described in this form. People outside the University of Colorado Denver may not be covered by this promise.

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

The use and disclosure of your information has no time limit. You can cancel your permission for us to use and give out your information at any time by writing to the study's Primary Investigator at the name and address listed below. If you do cancel your permission for us to use and give out your information, your part in this study will end. No further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Christian Hopfer, Mail Stop F478, 12469 E 17th Pl, Aurora CO 80045.

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information:

- 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.

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- The National Institutes of Health, National Institute on Drug Abuse, who pay 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. The researchers hold all of your information in the strictest confidence. 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.
- 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 or others if information is not released.
- If you commit or threaten to commit a crime at the research program or against its employees.

You have the right to request access to your personal health information from the investigator. To ensure proper evaluation of study results, you may not be allowed to see that information until after the study has been completed.

The investigator (or staff acting on behalf of the investigator) will also make the following health information about me available to:

Our collaborating researchers at the University of Colorado at Boulder will receive all research data collected in this study except for your name, phone number, and address.

For patients at Synergy Outpatient the treatment program Director, Susan Krill-Smith, and her staff will receive a summary of drug abuse and psychiatric symptoms and diagnoses.

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Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc).
- Your social security number.
- Portions of previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies.
- Research Visit and Research Test records.
- Psychological tests.
- Alcoholism, Alcohol or Drug abuse.
- Tissue samples and the data with the samples.

What happens to Data and DNA Samples that are collected in this study?

Researchers at the University of Colorado Denver work to find the causes and cures of disease. The data and DNA samples collected from you during this study are important to this study and to future research. If you join this study:

- The data, or the DNA sample is given by you to the researchers for this research and so no longer belongs to you.
- Both the researchers and any sponsor of this research may study your data and DNA sample collected from you.
- If data or DNA sample are in a form that identifies you, these researchers at the University of Colorado Denver may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

The researchers may send your information and blood cells WITHOUT YOUR NAME OR OTHER IDENTIFIERS to the NIH repository in New Jersey. NIH will give your DNA and your information WITHOUT YOUR NAME OR OTHER IDENTIFIERS to qualified scientists around the world.

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In addition, NIH requires genetic (genotype) and clinical (phenotype) information WITHOUT YOUR NAME OR OTHER IDENTIFIERS from subjects in this study to be submitted to the NIH database of Genotypes and Phenotypes (dbGaP). Dr. Hopfer or his authorized research staff will retain the key to the code that would link data to specific individuals. NIH will never receive this code or other information that would identify you. The information at dbGaP will be used only for other research studies and will only be used by qualified research scientists who apply for access to dbGaP and are approved by NIH.

You get to choose how your DNA and information will be used by other research scientists:

Put Your Initials on only ONE line below:

_____ Scientists can use my information and DNA for any kind of genetic research.

OR

_____ Scientists can use my information and DNA only for genetic studies of substance abuse or related medical problems.

OR

_____ Only researchers associated with this study can use my information and DNA. My information and DNA will not be sent to NIH.

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 understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Study Subject Signature: _____

Date: _____

Print Name: _____

Parent Signature: _____

Date: _____

Print Name: _____

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Parent Signature: _____

Date: _____

Print Name: _____

Consent form explained by: _____

Date: _____

Print Name: _____