MEDICAL RECORD	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • Adult Patient or • Parent, for Minor Patient

INSTITUTE:

STUDY NUMBER:

PRINCIPAL INVESTIGATOR:

STUDY TITLE: EFFECTS OF INFUSIONRATEON PHYSIOLOGICAL AND BEHAVIORAL RESPONSE TO IV COCAINE

Latest IRB Review:
Latest Amendment Approved:

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

Purpose of the study: The response to the same dose of cocaine can vary from person to person and in the same person from time to time. One factor that might cause these differences is how fast the cocaine is given. One study in rats has shown that how fast an intravenous (IV) injection of cocaine was given changed some of the initial effects on heart rate. This effect has never been systematically studied in people. The goal of this study is to evaluate whether how fast an IV dose of cocaine is given influences the effect of that dose.

You have been asked to volunteer for this research study because you have used IV cocaine in the past, have used cocaine in the past 30 days, and are not currently seeking or participating in treatment for cocaine abuse. (If you are seeking treatment, we will provide a referral for you.)

Procedures: After a medical and psychological evaluation to determine your eligibility, you will be admitted to the research residential unit for about four weeks. During this time, you will receive 10 test sessions on 10 different days. At some of these test sessions you will receive an injection of saline (sterile water with salt) through a vein in your hand or arm. At other test sessions you will receive an injection of cocaine. You will not be told what injection you are receiving. At the end of the study you will receive another medical and psychological evaluation to make sure it is safe to discharge you.

Each test session will last about 2 hours. At the start, a needle will be placed into a vein in your hand or arm. Several electrodes will be placed on your chest to record your heart activity, breathing rate, and skin temperature. Several electrodes will also be placed on your scalp to record your brain wave activity. A monitoring device like a small wristwatch will be placed on your wrist and ankle. You will then sit still in a small room or chamber for the rest of the session. From time to time, questions about how you feel will appear on a computer screen, which you will answer by pressing keys on the keyboard. Your blood pressure and pulse will be checked and your body temperature measured by shining a light beam into your ear. Twice each session you will also have a small rod with gel on the end placed on your neck for several minutes to record the movement of blood through the arteries carrying blood from your heart to your brain. This device measures blood flow by reflecting high frequency sound waves off the blood vessels. Also, for the day before and the day of each test session you will have your heart activity continuously recorded by wearing several electrodes on your chest connected to a small recorder hanging from a belt around your waist.

At the start of this study you will be given the chance to have the blood test for the HIV antibody (indicating whether you have the AIDS virus in your body). This test is not required for study participation, and the results of the test will not affect your eligibility.

While you are living on the residential unit, you are expected to abide by all rules. These include giving a urine sample under observation by staff whenever asked to do so. This urine sample is tested for drugs, to help ensure that no unauthorized drugs or medications are used.

Risks and discomforts: The major risks to you from study participation are the risks from getting cocaine. Cocaine can cause damaging effects ranging from agitation, a fast heart rate, palpitations, and high blood pressure to psychosis, paranoia, heart attack, stroke, seizures, and death. To minimize these risks, the doses of cocaine used in this study are limited to those used in previous research studies without having caused life-threatening or permanent damaging effects. As added safety measures, you will receive a thorough medical evaluation to make sure that you have no health problems which could increase your chances of having a bad reaction to the cocaine, a physician and nurse will be present when cocaine is given to you, and your heart and brain wave activity will be monitored during each session. In the event of any emergency, basic life support (CPR) can be provided on the residential unit and if necessary, you will be transferred to the emergency room.

As part of the thorough medical evaluation, you will receive an electrocardiogram (ECG), an echocardiogram, and an exercise stress test. These tests assess whether your heart is in good health. The electrocardiograms and exercise stress test involve placing electrodes on your chest which may cause some skin discomfort. In the exercise stress test you will be walking on a treadmill for several minutes which may make you temporarily short of breath. The echocardiogram involves using sound waves to take a picture of your heart. It requires you to lie still for several minutes while a rod with gel on the end is placed on your chest. As a further part of the medical evaluation, you will also receive a very detailed neurological examination which assesses whether your brain and nervous system are in good health. You will also receive an EEG in which sixteen electrodes will be placed on your scalp and measure your brain activity while you are at rest, watching a fast-blinking light, and breathing rapidly. This measures your brain activity and gives an indication of whether you may be prone to seizures. The electrodes may cause some skin discomfort. In addition you will have a doppler ultra sound done of your carotid arteries (blood vessels in your neck) and a transcranial ultrasound, which uses sound waves to take a picture of the blood vessels supplying blood to your brain. Like the echocardiogram, it requires you to lie still for approximately 20 minutes while a rod with gel on the end is placed on your head. If any of these tests indicate that you have a physical condition which could cause problems if you were to use cocaine, you will be disqualified from the study and referred to medical professionals who will talk to you about what tests and/or treatment might be recommended.

You should not participate in this study if you have previously had a serious bad effect from taking cocaine. Cocaine can have bad effects on unborn fetuses, so you should not participate in this study if you are or think you might be pregnant. To help avoid this, you must have used a medically acceptable form of birth control (or abstained from sexual intercourse) for one month before entering this study and throughout the study. Also, a serum pregnancy test will be done before you start to determine that you are not pregnant.

The other research procedures may cause minor, temporary discomfort. Placement of the needles in your vein may cause temporary pain, bruising, or swelling, but there is little risk of infection, since standard aseptic methods will be used. Placement of the heart and brain wave electrodes on your chest and scalp may cause temporary skin irritation and discomfort. Giving a urine sample under observation may cause embarrassment, but is necessary to ensure a valid sample.

Benefits: There are no direct treatment benefits to you from participating in this research study. The free medical and psychological evaluation may reveal some problem of which you were previously unaware. Should this occur, you will be told about the problem and referred for appropriate treatment. If, at the end of this study, you want treatment for drug abuse, we will refer you to appropriate treatment in the community. Knowledge gained from this study could help scientists design safer research studies using IV cocaine administration.

You will be compensated $50 on admission to the residential unit and $20 per day (about $560) for each day spent on the unit and $10 per day (up to $100) for each day an indwelling needle is placed in a vein in your hand or arm and one-time $25 for hair shaving involved in ECG lead placement. For successful completion of the entire study, you will receive a bonus of $50 per week ($200 total). The maximum amount of money you could earn from successful completion of the entire study is about $1375. Partial payments,

based on how many days you have completed, will be made if you are disqualified for medical, scientific, or behavioral reason, with no weekly completion bonus. If you leave AMA without medical clearance, you will receive only 50% of this partial payment, in accordance with IRP requirements. All compensation will be paid in three equal installments with the first payment received upon study completion. If you show evidence of being impaired by recent drug or alcohol use when you attempt to collect payment, that payment will be held until a later date.

Alternatives to participation: There are other research protocols for which you may be eligible if you are, ineligible for or do not wish to participate in this study.

Confidentiality: All subject records generated here will be accessible only to authorized research staff and will be kept in locked files. All forms with information about you will be identified by code number. The key linking code numbers with subjects' names will be kept by the principal investigator under lock-and -key. We will not release any information about you to outsiders without your explicit consent, except that, in the event of a medical emergency, pertinent medical information will be provided to the medical personnel caring for you. Your records may also be reviewed by authorized representatives of the U.S. Food and Drug Administration.

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OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or other authorized people.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, ; Building , Room , Telephone: . Other researchers you may call are:

You may also call the Clinical Center Patient Representative at 301-496-2626.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Patient's Consent

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

Signature of Adult Patient/Legal Representative _____ Date _____

B. Parent's Permission for Minor Patient.

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study. (Attach NIH 2514-2, Minor's Assent, if applicable.)

Signature of Parent(s)/Guardian _____ Date _____

C. Child's Verbal Assent (If Applicable)

The information in the above consent was described to my child and my child agrees to participate in the study.

Signature of Parent(s)/Guardian _____ Date _____

THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM MAY XX, 1998 THROUGH MAY XX, 1999.

Signature of Investigator _____ Date _____ Signature of Witness _____ Date _____

PATIENT IDENTIFICATION	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY (Continuation Sheet) • Adult Patient or • Parent, for Minor Patient NIH-2514-1 (5-98) P.A.: 09-25-0099 File in Section 4: Protocol Consent