Official Title: Medication Enhanced CM for Cocaine Dependence

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If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Medication Enhanced CM for Cocaine Dependence**

Application No.: **NA_00090062**

Sponsor: **National Institute on Drug Abuse**

Principal Investigator: **Kelly Dunn, Ph.D.**
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1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

This research is being done to find out whether a particular medication called bupropion can help participants when they try to reduce or stop cocaine use. The results may identify new strategies for helping people stop using cocaine.

Bupropion is approved by the Food and Drug Administration (FDA) for the treatment of Major Depressive Disorder. It is not approved for use in the treatment of cocaine dependence and is still being tested in research studies.

Some methadone maintenance patients from participating methadone clinics as well as community members willing to enter methadone treatment who qualify for the study may join.

How many people will be in this study?

A total of 150 people are expected to participate.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you first to complete a screening visit. Signing the consent does NOT mean that you are automatically invited to participate in the whole study. This will depend on whether you are eligible based on information from the screening visit.

Screening Visit

If you agree to participate in the screening session after signing this consent form, you will be asked to do the things listed below. The screening visit usually takes about 1 1/2 to 2 hours.

- We will ask you questions about your medical history, medication use, current and past drug use, and your mood.

- We will measure your blood pressure. We will take a blood sample from your arm for laboratory analyses that tell us how well your liver and kidneys are working.

- We will ask you to give us a sample of your urine that will tell us whether you have recently used illicit drugs. If these tests suggest that this study may not be right for you, we may ask you to come back a second time for urine testing to make sure.

- If you are a woman, we will do a urine pregnancy test. Women who are pregnant will not be able to participate in the study.

Your participation in this screening is voluntary, which means that you can leave at any time if you lose interest or are uncomfortable.

After we finish the screening and get the laboratory results, we will decide whether you are eligible for the study. If you are eligible, a research assistant will contact you and schedule your first (baseline) study visit. In the event that the Principal Investigator and/or medical staff decide later that this study is

not right for you, the research assistant will contact you to tell you about this.

You will receive up to $50 in gift cards for completing this screening session, even if you are not eligible for the study or decide that you do not want to participate.

Daily visits to the methadone clinic
If you are eligible and join the study, you will be expected to visit your methadone clinic daily as usual to swallow your regular methadone dose, unless you have a take-home privilege.

Study medication
After the study starts, you will also be given a capsule to swallow daily. You will not know what is in the capsule; it will be either active study medication or placebo. A placebo is an inactive substance that looks like the study drug, but contains no active drug. The daily capsules will continue for the entire 30-week study and may be swallowed at the methadone clinic along with your methadone dose, at the BPRU research office or at home.

Study Visits: 3 times per week brief visits
You will be asked to make a brief visit to the research staff office located at your methadone clinic for ATS, REACH, Glenwood Life Center or at the BPRU for others 3 times per week for 6-7 months to leave a urine sample and report about your recent drug use.

Study visits: 6 longer visits
You will also be scheduled for 6 longer assessment sessions at study weeks 1 (baseline), 6, 12, 18, 24, and 30. At these sessions, you will give urine samples, complete questionnaires and interviews and take a series of cognitive tests on a computer. These longer visits may take up to 3 hours. You can earn up to $210 for completing all study assessments.

Abstinence incentives
Throughout this study you will have the chance to earn points worth money for giving cocaine-negative urine samples. The total amount that you could earn during the study for cocaine negative urines is $688. We will explain later the details of how points are earned. Maximum earnings depend on giving all requested urine samples and achieving continuous abstinence from cocaine; the longer you are abstinent, the more money you will earn.

The money you earn for cocaine negative urines can be used to buy goods at local stores of your choosing. Money can be used as soon as it is earned or saved for larger purchases later.

How long will you be in the study?
You will be in this study for 30 weeks (a little over 6 months).

4. What are the risks or discomforts of the study?

1) Screening and Baseline Procedures. The screening and baseline interviews will include questions about your medical and psychiatric histories, drug and alcohol use, urine tests of drug use and pregnancy, and questionnaires about your mood. Answering personal questions could make you uncomfortable. You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer. There is no discomfort from the urine tests. The cognitive tests could make you feel frustrated if you find them difficult to accomplish.

2) Blood Pressure and Blood Draws. The blood pressure cuff and/or the needle stick needed to draw

blood may cause a small amount of discomfort. The medical tests could reveal that you have abnormal blood pressure or something abnormal with your heart, liver, or kidney function. In this case, you may not be eligible to continue in the study and we would ask that you see your doctor.

3) Medication side effects. The most serious potential side-effect from the study medication is an allergic reaction. If you get a rash, itching, swelling in your face, mouth, or throat, or have trouble breathing you should tell the research staff right away and stop taking the study medicine. There is also a small risk that the research medicine could cause a seizure or convulsion. Again, if anything like this happens to you, you should tell the research staff immediately and stop taking the medicine. You will not be allowed to take any other anti-depressants while you are in the study. If your doctor wants you to start an anti-depressant, you should discuss this with the research medical staff.

There are many other side-effects that could happen from taking study medications. These are listed below along with the percent of people who may experience each one.

Common

- Hypertension (high blood pressure) (2.5% to 4.3%)
- Tachyarrhythmia (abnormal heart rate) (10.8%)
- Pruritus (itching) (2% to 4%)
- Rash (3% to 5%)
- Urticaria (hives) (1% to 2%)
- Constipation (5% to 26%)
- Nausea (9% to 24%)
- Arthralgia (joint pain) (1% to 5%)
- Myalgia (muscle pain) (2% to 6%)
- Confusion (8.4%)
- Dizziness (6% to 22.3%)
- Headache (about 25%)
- Insomnia (sleeplessness) (11% to 40%)
- Tremor (2% to 21.1%)
- Tinnitus (hearing noises) (3%)
- Agitation (2% to 31.9%)
- Anxiety (3.1% to 8%)
- Hostile behavior (6%)
- Disorder of menstruation (5%)
- Pharyngitis (sore throat) (3% to 11%)
- Xerostomia (dry mouth) (10% to 27.6%)

Serious

- Cardiac dysrhythmia (irregular heartbeat) (5.3%)
- Seizure (0.1% to 0.4%)

Other rare, but serious reactions include:

- Anaphylaxis (severe allergic reaction)
- Stevens-Johnson Syndrome (life-threatening skin condition)
- Depression
- Exacerbation (worsening of symptoms)

- Mania
- Psychotic disorder
- Suicidal thoughts

Additional Risks while taking the study **drug:**
There have been reported increases in the risk of seizures when drinking alcohol while taking the study drug. Additionally, taking the study drug with a history of an eating disorder (such as anorexia or bulimia) can also place you at increased risk of seizures.

4) Stopping cocaine use. You may experience temporary discomfort from stopping cocaine use with symptoms including lethargy, disturbed sleep, and poor appetite. These symptoms should be gone in a week or two.

5) Risk of placebo. There is the risk that you may not receive any benefit from the medication and that your cocaine use may worsen.

6) Breach of Confidentiality. One risk of the study is your loss of privacy if other people find out about interview answers, health information, or urine test results. We do everything we can to protect your research information, as described in the Confidentiality section below.

5. Are there risks related to pregnancy?

Pregnant women will not be recruited at part of this study. Pregnancy tests will be given before a woman is allowed to be in the study and while she is in the study. If a woman becomes pregnant during the study, she will be excused from participation and referred to services at their methadone clinic or elsewhere.

6. Are there benefits to being in the study?

You will continue to receive standard methadone maintenance during this study, but your methadone treatment is controlled by your methadone clinic policies and is not part of the study. You may benefit from the study by stopping or reducing your cocaine use.

7. What are your options if you do not want to be in the study?

If you decide not to join this study, other options are available. You do not have to join this study to get treatment. Other treatments include standard drug abuse treatment and counseling

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

No. But if you don't have Medicaid or insurance, you may be asked to pay for your methadone treatment according to the policies of your methadone clinic. Any up-front fees associated with new participants entering ATS methadone treatment will be covered by the study.

9. Will you be paid if you join this study?

The total possible amount of money that you can earn for this study is $948. This includes $50 in gift cards for the screening session, $210 for completing the baseline and 5 other longer assessment sessions, and up to $688 for giving cocaine negative urines. If you start but do not finish the study, you will be paid for the sessions that you have completed and for any incentive earnings. You may also earn bus tokens or other incentives for completing a scheduled study visit.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

11. Why might we take you out of the study early?

The Principal Investigator also reserves the right to remove you from the study at any time.
You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

12. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

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

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

13. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

14. What if there is a Certificate of Confidentiality for this study?

The National Institutes of Health has given us a Certificate of Confidentiality for this study. This Certificate provides some additional protection for research information that identifies you. The Certificate allows us, in some circumstances, to refuse to give out information that could identify you as a research subject without your consent, when such information is sought in a federal, state, or local court or public agency action. Still, we may disclose identifying information about you if, for example, you need medical help.

We may also disclose identifiable information about you as described in Section 12 of this form or in other cases. For example, the government may see your information if it audits us, and the research team will voluntarily comply with reporting requirements to the appropriate local or state authorities:

- if they suspect abuse, neglect or abandonment of a child or vulnerable or dependent adult;
- if certain diseases are present; and
- if the team learns that you plan to harm someone. In this case, the team also may warn the person who is at risk.

Even with this Certificate in place, you and your family members must continue to protect your own privacy. If you voluntarily give your written consent for an insurer, employer, or lawyer to receive information about your participation in the research, then we may not use the Certificate to withhold this information.

This Certificate does not mean the government approves or disapproves of this research project.

15. What treatment costs will be paid if you are injured in this study?

Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.
The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

16. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?
The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?
Call the principal investigator, Dr. Kelly Dunn at 410-550-2254. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?
If you think you are injured or ill because of this study, call Dr. Annie Umbricht, MD at 410 550-1917 during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call the BPRU emergency line at 410- 550-0052 which is available at any time.

d. What happens to Data and Biospecimens that are collected in the study?
Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your biospecimens and information with our research sponsors and partners.

17. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.