COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY
YALE UNIVERSITY SCHOOL OF MEDICINE

Study Title: Improving Antiretroviral Adherence and Persistence using mHealth Tools in HIV-infected Cocaine Users
Principal Investigator: Frederick L. Altice, MD
135 College Street, Suite 323, New Haven, CT
Funding Source: National Institutes of Health (NIH)
Purpose: To determine whether cellular-enabled smart pill boxes and feedback through cell phones will help increase antiretroviral treatment adherence among persons with cocaine use disorders and HIV in the community.

Invitation to Participate and Description of the Study

You are invited to participate in a research study that uses blister packs and feedback using cell phones to help increase antiretroviral treatment (ART) adherence among persons with cocaine use disorders and HIV. You are being asked to participate because: a) you have been diagnosed with HIV; b) you meet the criteria for self-reported cocaine use; c) you are 18 years or older; d) you are currently prescribed ART; and e) you currently have insurance coverage.

In order to decide if you want to be part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form provides detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed and any risks of the procedures, possible alternatives, and possible benefits. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form. This process is known as informed consent. Agreement to meet with us and to participate further will not in any way, positively or negatively, affect the medical care you receive in or out of Yale University or Yale New Haven Hospital. If you wish to be part of this study, we will ask you not to participate in any other study for the duration of your participation with us. Also, if you are currently part of another study you may not be eligible to participate in this study.

Study Purpose

The purpose of this study is to determine whether using dosage reminders received through cell phones and from people in your social network can help increase ART adherence among persons with HIV who use cocaine, thus improving their health outcomes. In order to see if there is an effect, the study researchers will follow all participants and schedule regular interviews and blood draws. This will enable them to look at the amount of virus in the participant's blood. You will receive a medication blister pack and a cell phone (if you do not have access to one already). The study will last for 16 weeks and interviews will be conducted at the beginning of the study (baseline) and then once monthly till the end of the study.

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Procedures

If you think you would like to participate in this study, you will need to give us your consent to continue. If you decide to take part in this research study, you will be required to give us information about your substance use and HIV status. As part of the screening process, you will be asked some questions to determine if you are competent to participate. You will also be asked to allow a research assistant to review your medical records, including all medications prescribed and laboratory results. If you are eligible to participate in this study, the research assistant (RA) will conduct a baseline interview that will ask you questions about your drug and alcohol use history, HIV history and your experiences with medical and mental health care. You will be interviewed at the beginning of the study (baseline interview) and then every month until the study is finished. The entire study will last for 16 weeks. The baseline interview and month 3 interviews will be more extensive. You will also undergo blood draws at baseline and at weeks 12 and 16 to find out your HIV viral load.

At the beginning of the study, you will receive blister pack and a smartphone. You may choose to use your cell phone for this study if you wish as long as it is an Android smartphone device. You will be taught how to use your blister medication pack. Once a week for 16 weeks, you will receive a text message asking you to take a picture of your blister pack and text it to a study phone. The RA will provide detailed instructions on how to take a picture with your Andriod phone and send it via text message. You will also will receive a text message reminding you to open a survey app on your smartphone. This survey will ask you a few brief questions. You will be able to use the smartphone's touchscreen to answer the questions. You will be reminded to open the survey app and take the survey on the day and time of your choosing. If you are unable to understand or perform the necessary minimal requirements to use the blister pack or answer the cell phone, then you will not be able to participate in the study. You also agree to use the services offered through this study that are appropriate for you. These services are described below.

After you have completed the baseline interview and given the blister pack and cell phone, you will receive a text message reminding you to take your medication at your dosage times every day. Once a week, you will also receive a text reminder to open the survey app on your smartphone and take the survey. Additionally, your social network designee will send you a text message on your cell phone to remind you to take your medication regularly and to stay healthy.

You agree to be interviewed by Research Assistants and Clinical Nurses from the Yale School of Medicine. The interviews will be about your physical and mental health, use of medical care, and alcohol and drug use. We will also obtain some locating information like your house address and telephone number in order to keep in touch with you. This information will only be shared with the study team. We will also ask you to provide names and cell phone information of three people in your social network (family, friends or case workers) who will be willing help you stay healthy during this study. We will contact one person to be your "social network designee" out of the three names you provide. This social network designee will be asked to send you one text message per week to remind you to take your medication or help you stay healthy in general. We will contact your social network and explain their role in the study and seek their verbal consent. We will also download your text messages every month to a secure and password protected location to study the content and the frequency of your communication with your social network designee for the period of this study (12 weeks). Your social network designee will be compensated for his/her participation in the study. We will also take a blood sample from you in order to take a look at

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your CD4 count and HIV virus level.

As part of your participation in this study, you will be asked to sign a Release of Medical Information form (ROI) including specific authorization for release of HIV, ART regimen, drug treatment and mental health treatment. These authorizations will allow our study researchers to review your medical records at your facility, including information on your lab tests, diagnoses and medications prescribed. You will also be asked to sign a release form to allow us to talk with other agencies, such as the Department of Social Services or AIDS Service Organization, which will allow us to help coordinate your care. You decide which organizations we can talk with. Signing this second release is optional. We will not talk with any agency that you have not given us permission to speak with.

Risks and Inconveniences

There is a risk that you may feel uncomfortable talking about certain topics such as cocaine use and your medical history. You may choose to answer only those questions you feel comfortable with. The research staff members will make every effort to keep the information that you give to

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us safe and confidential. However, there is a minimal possibility that confidentiality may be breached unintentionally both within our laboratory and within our study site. There is also the inconvenience and time spent traveling to and from the focus group.

Benefits

You will receive a smart pill box and a cell phone for the duration of the study. Additionally, if you are in Group B or C, you will receive automated feedback through the smart pill box which might improve your medication adherence. From a broader perspective, you will be contributing to the science on how to best improve adherence of HIV+ persons with cocaine use disorders and thus may help to improve health care and quality of life for other people with HIV and cocaine use disorders in the near future.

Economic Considerations

There is no cost to you for participating in this study. You will be given gift cards for your time and participation. The payments will be disbursed in the following amounts at the following time points:
You will be given a $30 gift card at baseline and at the follow-up interviews at week 4 and 12, and a $20 gift card for follow-up interviews at weeks 8 and 16.

If you choose to use your own Android smartphone you will receive a $10 gift card for a period of 3 months to compensate you for use of minutes and/or instant messages. If you receive a study phone, you will receive a $40 gift card at the end of the study when the phone is returned. You will also receive a $5 gift card for every phone survey you complete in the 16 weeks for a total of $80.

Therefore, the maximum total amount you can receive during your participation in this study over a 16-week period will be $230.

Treatment Alternatives/Alternatives

You are free to drop out of this study at any time. You may obtain healthcare, treatment for cocaine use disorders and case management services through standard means in the community.

Confidentiality and Privacy

You will be given a study number. All information we collect from study interviews will identify you only by this study number. Information linking your name to the study number will be kept in a file that is separate from files with your study information. Your study information will be kept on a secure server and in a locked file in a locked office. All computers and files are encrypted

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as per Yale ITS requirement and password protected. Your data will only be used for this study unless you give us permission to use it in other ways. Only people working on this study will have access to your information.

Any identifiable information that we get for this study will remain confidential. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained. Some of the information you provide will be shared anonymously with other researchers. None of your personal information that may identify you, however, will be shared with these researchers.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. Any information you give to your medical providers during this study may be entered into your medical record and could be available to insurers. If you decide to be in this study, the study researchers will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and address. This information will be kept for a period of 7 years. After that time, it will be destroyed or de-identified, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. The research team will only give this coded information to others to carry out this research study.

The information about your health that will be collected in this study includes:

- Research study records
- Medical records of only those services provided in connection with this study and community providers.
- HIV / AIDS
- Drug use
- Alcohol use
- Diagnosis and treatment of a mental health condition
- Use and abuse of alcohol and drugs

Information about you and your health which might identify you may be used by or given to:

- Representatives from Yale University and the Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for insuring research compliance. These individuals are required to keep all information confidential.
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The Principal Investigator: Frederick L. Altice, MD
- The study sponsor: NIH
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information

in connection with this study, according to the study plan.

- Co-Investigators and other investigators
- Dr. Yerina Ranjit, Assistant Professor in the Department of Communication at the University of Missouri Columbia. University of Missouri, Columbia is a site that will be relying on Yale IRB review for the limited engagement of Dr. Ranjit for obtaining identifiable data.
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the study

Certificate of Confidentiality

To help us protect your privacy, we have obtained Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of events associated with child abuse and neglect, or harm to self or others.

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine is required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

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The sponsor will see the research information we collect about you when they come to Yale to monitor the conduct of this research study. The "Sponsor" includes any persons that work for or are hired by the sponsor to conduct research activities related to this study. For this study the

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sponsor includes NIH. Yale researchers will also send the sponsor your health information during the study or at the end of the study. When Yale researchers send information about you to the sponsor, they will not send information that directly identifies you such as your name, address, phone number or social security number.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies.

This authorization to use and disclose your health information will never expire unless and until you change your mind and revoke it.

In Case of Injury

If you are injured as a result of your participation in this study, clinical care will be provided. However, you or your insurance carrier will be billed for any clinical services that are provided **outside** of the Community Health Care Van. You do not give up any legal rights by signing this form.

Voluntary Participation and Withdrawal

Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). Your health care at your primary care facility will not be affected by your decision to participate or not participate in this study. You will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

If you do choose to withdraw, you may either simply decline any further contact, or if you request so, we will destroy all records in our research files connecting your name, so that it would only be studied anonymously from that at point forward.

If you do become a study participant, you are free to stop and withdraw from this study at any time during its course. You may also return to the study if you have left if it is within 4 months of your start date. To withdraw, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any appointments in the future.

The researchers may withdraw you from participating in the research if necessary. Reasons would include violent or inappropriate behavior or not following study rules.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you choose not to participate or if you withdraw it will not harm your relationship with your own doctors, Yale University or Yale New Haven Hospital.

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Withdrawing Your Authorization to Use and Disclose Your Health Information

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to the principal investigator: ***Frederick Altice, MD.; 135 College St. Suite 323 New Haven, CT.***

If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision

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Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, what is involved, and possible risks and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to participate in this research.

Name of Subject:_____

Signature:_____

Date:_____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator Frederick Altice, MD at (203) 737-2883. If you have any questions concerning your rights as a research subject, you may contact the Human Investigation Committee at (203) 785-4688. If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 436-3650.

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