

Young Adult Informed Consent for Participation in a Study
Health and Justice: A Continuum of Care for HIV and SU for
Justice-Involved Young Adults (Phase 2)
(Katherine Elkington, PhD, 646-774-6965)

CONSENT SUMMARY PAGE

Overview

Below is a summary of the study that you are asked to participate in. This outline is meant to be a guide for you to use while considering the study and reading the consent form. It is not meant to replace the consent form, which you will have to sign if you decide to participate in the study. The consent form contains detailed information about the study and about the risks which you will need to consider before making your decision. Read the consent form carefully and discuss it with others before deciding to take part. And remember that, even if you agree to participate, you can change your mind at any time

Voluntary

As with all research, this is a voluntary study, and you do not have to participate if you do not want to. Also, you may stop participating at any time.

Procedures

- Participate in 5 surveys over the course of 1 year.
- You may be asked to participate in 4 intervention sessions, depending on which group you are randomized to. Details about the intervention sessions are included in the consent form.
- You will be offered an opportunity for an HIV and STI test – it is voluntary.

Risks and Inconveniences

This study includes some risks and discomforts (please refer to the consent form for further details and explanations of these risks). These include loss of confidentiality related to your responses and possible discomfort because of the types of questions we ask.

Benefits

This research study is not meant to benefit you directly.

Questions

You may contact the study principal investigator, Dr. Kate Elkington at 646-774-6965 with any questions.

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Purpose of the Study: We are asking you to participate in MOVE UP, which is a program to reduce Human Immunodeficiency Virus (HIV) and Sexually Transmitted Infection (STI) risk and drug and alcohol use for young adults involved in the justice system. The goal of MOVE UP is to empower justice involved young adults to make safe and healthy decisions that reduces their risk of HIV and STIs and also their drug or alcohol use. Additionally, we are asking you to complete surveys 5 surveys over a 12-month period. You are being asked to participate in this study because you are 1) currently enrolled at Center for Alternative Sentencing and Employment Services (CASES), 2) Between the ages of 18-24, and 3) have a history of unprotected sex. Including you, there will be 450 young adult participants, in this study. The study is designed to see if MOVE UP works.

Alternatives to Study Participation: Your participation is voluntary. You do not have to participate in this study in order to get services that are otherwise available to you through CASES. The alternative to participating is simply not to take part; if you do not take part in this study, you will still receive all services as usual through CASES and your terms at CASES will not change. Study participation will not affect anything related to your status at CASES, either positively or negatively.

Study Procedures:

Surveys: If you agree to participate in the study, we will be asking you to complete 5 surveys, 4 of the surveys will last approximately 1.5 hours long and 1 survey (the 9 month survey) will last 45 minutes. You will be asked to complete the first survey today, and then again 3, 6, 9, and 12 months from now. We will contact you by phone, text, or email to schedule the survey appointments and to remind you about them. The surveys will take place in a confidential space at the Kings County Downtown Brooklyn Courthouse, or at a confidential space in the community such as your home or a local library. You will be asked questions about your experiences, thoughts, and feelings, including those regarding sex, drugs, and alcohol use. You do not have to answer any questions that you do not want to answer. You will receive \$50 for the completion of the first, 3-, 6-, and 12-month survey, and \$25 for the 9-month survey.

If you are placed in a secure or non-secure justice facility (including jail or prison) we will continue to make efforts to reach out to you for interviews. If we have trouble finding you, we may search non-secure justice facilities in New York State to try to find you to see if you still want to participate in the study.

Participants in this study will be assigned to one of two groups: 1) the Intervention group where you receive the MOVE UP program or 2) the Control group – which means you do everything as normal and do not receive the MOVE UP program. After you complete the survey, we will ask you to attend an appointment with a health coach. At this meeting you will be told which study group you will be part of. There is a 50:50 chance (same chance as flipping a coin) of being in the intervention or control groups.

Intervention group (MOVE UP program) If you are assigned to the Intervention group you will participate in the MOVE UP program. MOVE UP includes 4 sessions. During session 1 (approximately 1.5 hours) you will meet one-on-one with our study Health Coach in a confidential space at CASES, you will receive a brief sex questionnaire and drug and alcohol questionnaire, you will be asked to talk about risky behaviors concerning sex and drugs and alcohol, and you will be offered a rapid oral HIV test (swab gums for saliva) and a urine STI test that tests for chlamydia and gonorrhea. We are not testing for drugs with your urine specimen. You will receive your HIV results 20-30 minutes after the test is conducted, and you will receive your STI results within 14 days of the

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session. You do not have to complete the HIV or STI test to participate in the study. If you express interest in getting an HIV and/or STI test we will provide you with a consent form with more information about the testing procedures right before we do the test. The Health Coach or research staff may speak to staff at CASES as well as any treatment provider you work with that we refer you to as a part of the intervention.

During sessions 2, 3, and 4 of MOVE UP you will be attending a group session here at CASES. The group will include up to 10 individuals like yourself who are participating in the study. The group session will be about critical consciousness (a way of viewing the world through understanding how oppression impacts our health decisions), risky sex, drug and alcohol use, stress and coping, and working to change risky behaviors. You will receive \$25 for each session that you attend. After each session, we will ask you to complete a brief voluntary online questionnaire about your impressions and understanding of the intervention.

Control group: If you are assigned to the control group, you will not participate in the MOVE UP program. You will be offered a rapid oral HIV test (swab gums for saliva) and a urine STI test that tests for chlamydia and gonorrhea. We are not testing for drugs with your urine specimen. You do not have to complete the HIV or STI test to participate in the study. If you express interest in getting an HIV and/or STI test we will provide you with a consent form with more information about the testing procedures right before we do the test. After your meeting with the health coach, we will contact you via phone, text or email once a week to just check in to make sure that your contact information is still the same. At this time you will also be eligible to receive \$25 once every 3 months, for a total of \$100 over the course of 12 months of your study participation. To receive the \$25 you must respond to at least 8 of our weekly check-ins by text, phone, or email over each 3 month period. We will contact you again 3, 6, and 12 months from now and ask you to complete a survey at a confidential location in the community such as your home or a local library.

Texting: As part of the intervention sessions, you have the option of texting yourself a plan about changing a specific behavior of your choice that you will create during the intervention. Additionally, we will also be sending you brief texts to keep in contact with you as we schedule the intervention sessions. We will text you up to 20 times during the course of session 1 through 4; each texting session will comprise 3-4 texts. We will also send you a weekly text reminder about your upcoming MOVEUP sessions or survey appointment. Texting yourself the plan and receiving text messages from MOVEUP is completely optional. Similarly, receiving reminders for MOVEUP sessions or study interviews is also voluntary. You do not have to agree to utilize these texting options to participate in the study. Even if you do not agree to utilize these texting options, you can still participate in other parts of the study.

Record Data: We will also gather information from your CASES records on whether or not you were referred to a voluntary or mandated treatment program, whether you attended that program, if you finished the treatment program as well as the outcome of your mandate with CASES (e.g. successfully completed, still ongoing, violated). We will also contact any HIV/STI and substance abuse treatment providers that you may have seen to confirm your attendance at appointments.

Audio taping: For interviews that take place outside of the courthouse (such as your home or other confidential locations in the community), the survey interview read to you by the research assistant may be audio recorded with a digital recorder. Please note that audio taping is optional. You are not required to have your interview recorded in order to participate in the study. Your participation will not be affected in any way by your decision to consent to being audio taped or not.

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The audio digital files help the research team to remember exactly what was said during the survey interviews and to ensure that the survey was done correctly. If you consent to being recorded, your name will not be on the digital audio file. Instead, you will be assigned an identification number to ensure confidentiality. All audio recordings will be private and will be kept in an electronically secure database. The files will be listened to only by the people doing the study and will be destroyed after the information has been written down, no later than ten years from now.

Risks: There are no physical risks involved with participation in this study for you. Some of the interview questions ask about your experiences with sex and drugs and alcohol. They may make you feel embarrassed, worried, or upset. If this happens, the interviewer will spend time talking with you until you feel better. You may also experience distress during the HIV or STI testing and/or if you receive a reactive HIV or positive STI test result. Again, if this happens, the interviewer will spend time talking with you until you feel better, will explain the findings of the test and work with you to ensure you are linked to care. You may experience a loss of confidentiality related to your responses or use of texts; we have several procedures in place to reduce this risk (see Confidentiality section below).

Benefits: There are no direct benefits to you from participating in the study. The results of this study may improve the HIV, STI, and substance use outcomes for justice-involved young adults.

Compensation:

You will receive \$50 cash for completing each survey, except for the 9 month survey which you will receive \$25 for, for a total of \$225 over a 12-month period if you complete every survey.

If you are in the control group you will also be eligible to receive \$25 once every 3 months, for a total of \$100 if you respond to weekly texts, phone calls, or emails from the research staff.

If you are in the intervention group (MOVE UP program), you will receive a single ride metro card if you arrive on time for each of the MOVE UP group sessions (1-4). If you are in the intervention group, you will also receive \$25 for attending sessions 1-4, for a total of \$100 if you attend all 4 sessions.

If you are placed in a secure or non-secure justice facility (including jail or prison) after enrollment in the study, your compensation can be paid to your inmate account directly, or can be held for you by us until your release, or given to a family member or friend who you choose.

Confidentiality – when we can and cannot keep this private: All records and the results of the research will remain private and confidential. We will do everything we can to protect your privacy. The researchers will keep your responses private and confidential **except** in the following circumstances: 1) if we learn of threatened violence to self (e.g. thoughts of suicide) or others (e.g. thoughts of homicide) that you discuss, or 2) suspected or known physical abuse, sexual abuse or neglect of minors. If we learn of this information, we will take whatever measures are needed to protect individuals involved, and will voluntarily comply with State reporting laws on child abuse, harm to self or others, including reporting to the Administration for Children's Services (ACS) as necessary. If we learn of this information, we will do whatever is necessary to protect anyone involved, including you. Part of what we will do is let the staff at CASES know if you tell us you want to hurt yourself or someone else. Research staff may not be able to discuss this with you first.

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The information from the surveys will be collected using Sawtooth Software SSI, a software program that develops surveys to be delivered either by a computer (loaded directly onto the computer) or via the web-based survey, which can be accessed through a URL designated by the researchers. Both modes of delivery (web-based or directly on the computer) will be password protected. During online survey data collection, all data are stored directly onto a secure Columbia University Medical Center (CUMC) server. Participants' responses are de-identified since we will give each participant a unique ID number, which means identifying information like your name will be removed. Responses are encrypted under a 128-bit SSL encryption (same security used when you enter credit card numbers in online purchases) and CUMC firewall. The only textual information present is the participants' ID numbers, IP addresses, and whether participants chose to enter textual data. This survey will not be part of your record at CASES and will not be shared with any of the CASES staff or with the Court. All records and the results of the research will remain confidential to the extent permitted by law. Once you have agreed to participate in this study, you will only be identified by a code number; your name will not be connected with your information in any way so you cannot be identified. All study information including your name and other personal identifying information will be stored in an electronically secure database; all other study information will be coded and kept in locked files at the New York State Psychiatric Institute. Only research staff and institutional personnel, as part of routine audits, will have access to the files. No part of your interview will be part of your records at CASES and no part of your interview will be shared with any of the CASES or court staff. Your name will not go on any forms that will be completed as part of the study. You will be recognized by a number (code) that is specific to each participant.

Information from this research may be published but publications will not include the names of any study participants or any information that could identify you. Data stored in computers will only be available with a password. **Information from this study could also be used for future research studies or distributed to another investigator for future research studies, with or without identifiers.**

We have received a Certificate of Confidentiality, issued by the National Institute of Health, for this study. This Certificate prevents the researchers from being forced to release any identifiable research data (including under court order or subpoena) without your written consent. This Certificate does not prevent the researchers from reporting suspected or known neglect or sexual or physical abuse of a child, or threatened violence to self or others. Such information will be reported to the appropriate authorities. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

If you agree to participate in the study, you agree to keep confidential anything that you hear during the MOVE UP groups and the focus group, including overall discussion of topics. You may not disclose names or other identifying information about other group members.

The SMS text messages sent and received through the Mobile Commons SMS system (a system that allows the research team to safely and confidentially send multiple texts to all participants) will include your phone number as well as the plan that you create during the intervention. All SMS messages sent through Mobile Commons will be encrypted. To increase privacy and security of this data, the Mobile Commons SMS system will be password-protected and accessible only to specific members of the research team. We will also encourage you to place a password on your phone

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and remove any message comment from text alert banners that come up on your phone to make sure texts are kept private. Mobile Commons utilizes multiple techniques (including third party evaluation) to assess the security of their platform and keep your information safe. Mobile commons will be bound by confidentiality contracts.

We will ask your permission for our Research Staff and Health Coaches to communicate with you via phone, text or email regarding appointments for interviews, MOVE UP sessions and to send you follow-up information after MOVE UP sessions (for those in the intervention group). Receiving texts from our Research Staff and Health Coaches is entirely voluntary and will have no impact on your participation in the study.

We will also ask your permission to inform CASES staff that you are enrolled in our study, we will not share any information with them about your participation other than information related to attendance, and how to get in contact with you. If we are having trouble reaching you about interviews or MOVE UP appointments, we may ask CASES staff to share your contact information with us.

Research Standards and Rights: Your participation in this study is voluntary. You do not have to participate and can stop participation in this study at any time for any reason or for no reason at all. You can terminate participation in the study even after the study has started and can also refuse to answer any of the questions you are asked without terminating your participation. If you decide not to participate, or if you later decide to stop participation, you will not lose any benefits to which you are otherwise entitled, including services and care that are normally available to you through CASES. It will have absolutely no effect on your terms at CASES; whether you participate or not, you will still have to comply with all the terms and conditions at CASES that you did before. **The study is projected to conclude in December 2021. Results from the study may be available in future publications and conferences. If you are interested in receiving the results from the current study, including individual research results, you may contact us at 646-774-6965.**

If you are placed in a secure or non-secure justice facility after enrollment in the study, the study team will contact the proper authorities to get permission for you to take part in the interviews while placed in the justice facility. We may need to tell them that you are participating in a research study if the facility requires this information. However, we will not tell them exactly what the study is about – that is private. We will only interview you if the interview can be done in a private place (this is for both in-person and over the phone interviews). Although we will try our best to keep the interview private while you are in the facility, we cannot guarantee it.

In Case of Injury: If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator Dr. Katherine Elkington at 646-774-6965 so that you can review the matter and identify the medical resources that may be available to you.

In case of injury, New York State Psychiatric Institute will provide short term emergency medical treatment, which has been determined to be necessary by New York State Psychiatric Institute's doctors, and which is within the capability of New York State Psychiatric Institute to provide. In addition, we will provide assistance in arranging follow up care in such instances.

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New York State Psychiatric Institute does not provide compensation or payment for treatment of research related injuries. However, you should be aware that participation in this research does not waive any of your legal rights to seek such compensation through the courts.

Please be aware that:

1. The New York State Psychiatric Institute, Columbia University Medical Center, and New York Presbyterian Hospital will furnish that emergency medical care determined to be necessary to the medical staff of this hospital.
2. You will be responsible for the cost of such care, either personally or through your medical insurance or other form of medical coverage.
3. No monetary compensation for wages lost as a result of injury will be paid to you by Research Foundation for Mental Hygiene, the New York State Psychiatric Institute, Columbia University Medical Center or New York Presbyterian Hospital.
4. By agreeing to the terms of this consent form, you are not waiving any of your legal rights to seek compensation through the courts.

Questions: The research staff will answer, to the best of their knowledge, any questions concerning the procedures described above. If you have any questions about this study, you may contact Dr. Katherine Elkington at 646-774-6965. If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may call the IRB Main office at (646) 774-7155 during regular office hours. You will be given a copy of this consent form to keep.

Documentation of Consent:

I voluntarily agree to participate in the research study above.

Participant's name (print): _____

Participant's signature: _____

I voluntarily agree to have my interview audiotaped.

Participant's name (print): _____

Participant's signature: _____

Person Designated to Obtain Consent:

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions, and in my opinion, is freely consenting to participate in this research.

Print name: _____

Signature: _____

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Date: _____