Informed Consent Form for Participation in a Research Study

Yale University School of Medicine

Study Title: Project Hope-Kyrgyzstan: Exploring the Feasibility of a Peer-Driven Intervention to Improve HIV Prevention among Prisoners Who Inject Drugs.

Principal Investigator: Julia Rozanova, Ph.D.

Funding Source: National Institute on Drug Abuse, USA

Invitation to Participate and Description of Project

You are invited to participate in a research study that aims to deliver a peer-driven intervention for persons at risk of HIV with a history of substance use disorders. You are being asked to participate because: (a) you are currently incarcerated in one of the 4 participating prisons in Kyrgyzstan; (b) you are ≥1 year before your scheduled date of release to the community; (c) you are HIV negative by self-report before the study (to be confirmed by HIV rapid test); (d) you have ever injected drugs; (e) you are currently not enrolled in MMT/Atlantis; and (f) you are 18 years of age or older.

To decide whether you wish to participate in this research study, you should know enough about the risks and benefits to make an informed decision. This consent form provides you 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 your status as a prisoner or the medical care you receive in or out of prison, nor will it impact your release from prison.**

Study Objective

The objective of this study is to develop and conduct a Peer-Driven Intervention to reduce HIV risk, improve health, and increase the uptake of addiction treatment among individuals incarcerated in prisons in Kyrgyzstan, and then to explore how participants experience the PDI and if it can be further improved, from the perspective of prisoners themselves. Results of this study will determine whether PDI is used countrywide in the future to deliver HIV prevention and addiction treatment services for incarcerated persons with a history of injection drug use. In this first study, we are examining a longitudinal (within prison) sample of 96 prisoners.

Procedures

If you choose to participate in this study, you will begin by receiving an HIV rapid test and urine test for opioids. If your HIV test is positive, you will not be eligible to continue to participate in this study but the blood test results will be still be made available to you if you wish to receive them. In addition to the

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blood tests, you will also receive counseling to inform you about HIV and possible treatment options. This information will help you decide if you want to share this information with others and to seek care within the prison before you leave. The results of the blood tests will not be shared with anyone in the prison unless you decide that you want the prison doctor to know so that treatment can be started. We will keep the information private unless you tell us to let the doctor know. Under no circumstances will we tell the prison guards or anyone else. If you do not want to know whether you are HIV positive or not you should not participate in the study. We can, however, still give you information about getting drug treatment after you leave the prison.

If your self-reported HIV-negative status is confirmed by the HIV rapid test you will complete a questionnaire that will ask you about your health-related habits and behaviors, and about your history of harmful substance use. Filling the questionnaire will take approximately 30 minutes. Within 2 weeks after that, you will attend a training session within prison provided by an experienced health educator from AIDS Foundation East West, on HIV risk reduction and Health Advocate (HA) and Peer (P) roles. You will be assigned to a Work-group (there will be three work-groups of eight participants in each prison) and the health educator will explain what you will do in a Peer and in a Health Advocate role (as each participant will have an opportunity to perform both these roles). You will participate in weekly meetings of your Work-group for the next 12 weeks, alternately providing Health Advocacy support to your Peer regarding HIV prevention and addiction treatment, and receiving likewise assistance from your Health Advocate. The purpose of these meetings is to support participants in initiating and adhering to a healthier lifestyle, making informed decisions and choices particularly in terms of addiction treatment (including, should a participant decide this may be right for him, initiation of MMT or Atlantis treatment), and reducing their HIV risk. Each weekly meeting will take about 1 hour. The health educator will be available during the meeting to answer any questions that may emerge among the participants; an experienced researcher will attend and observe the meetings to learn how the meetings go and if participants enjoy them, and this knowledge will be used to refine the peer-driven intervention for future use. After the Work-group meeting, the health educator will discuss with participants their progress and challenges and any goals for the next week.

After the 12-week program, some participants may be randomly invited for an interview to share their experiences in the program, how they liked it (or not) and why, what and how worked for them, and any suggestions for this program in the future. The interview will last approximately 45 minutes and time will be made available for participants to ask questions. The interview will be audio recorded; audio file of the interview will be deleted after it is transcribed and verified, deleting will be done by choosing “delete” option in the menu of the digital recording device, permanently erasing the audio file. The study materials, including forms and transcripts, will be deleted in 3 years after the close-of-study report is filed by the Principal Investigator in the U.S.

You will receive weekly urine opioids tests while participating in the 12-week intervention program, and you will also receive a urine opioid test 6 and 9 months after you have completed the program. You will complete a follow-up 30-minute survey questionnaire at the end of the 12-week program (that will include questions about your health, risk behaviors, and negative and positive experiences that may influence health, and then 3, 6, and 9 months later. 6 months after the end of the program, you will receive an HIV rapid test. In addition to the blood test, you will also receive counseling to inform you about HIV and possible treatment options. This information will help you decide if you want to share this information

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with others and to seek care within the prison before you leave. The results of the blood tests will not be shared with anyone in the prison unless you decide that you want the prison doctor to know so that treatment can be started. We will keep the information private unless you tell us to let the doctor know. Under no circumstances will we tell the prison guards or anyone else. If you do not want to know whether you are HIV positive or not you should not participate in the study. We can, however, still give you information about getting drug treatment after you leave the prison.

Risks and Inconveniences

You may feel uncomfortable answering questions about risky health behaviors, talking about HIV risks and addiction with peers during the 12-week program, or discussing health, HIV risk, and factors that shape HIV risk and health during the interview. The answers you give to the questionnaire, as well as the answers given during the interviewing containing personal information will remain strictly confidential and will not be shared without your permission. You do not have to answer any questions you are uncomfortable answering. Another inconvenience associated with the study is the time it takes to participate.

Benefits:

There may be benefits to participating in this study. First, you will receive a free medical health assessment regarding the risk of harmful substance use. With this information, you can make informed decisions about how to access care or treatment during the rest of your prison stay. We have purposely designed this study so that we are interviewing only those people who are still going to be in prison for at least another year, so that they can seek care there and make the best use of the already available programs and services. Additionally, we anticipate that as a participant in the 12-week program you will increase your sense of social support and develop knowledge about HIV risks and primary HIV prevention strategies especially in terms of addiction treatment. You may get health benefits by accessing primary HIV prevention strategies through addiction treatment programs like MMT/Atlantis. Youmay enhance your skills in navigating the HIV prevention system within prison, and get initial training and skills in how to be a peer counsellor and a peer health advocate, which may be valuable assets for gaining volunteer or employment opportunities subsequently upon release from prison.

Your participation in this study may also benefit others by allowing us to understand more about the health risk behaviors and health needs of prisoners in Kyrgyzstan, and how a 12-week peer-driven program may help prisoners manage and reduce their HIV risk. Results from this study will guide recommendations to the criminal justice system on implementing similar peer-support programs for prisoners in the future, and provide knowledge on what medical services are needed and on how to provide them. This may improve the health care other prisoners receive in the future.

Economic Considerations:

For participation in this study and in gratitude for the time you spend, you will receive compensation of will receive a small food or personal hygiene items equivalent of 300 Kyrgyz SOM (~5 USD) on the first day of the study, after the questionnaire, a urine analysis and blood for HIV. You will also receive a small food or personal hygiene items equivalent of 250 Kyrgyz SOM at the end of the 12-week program and three months after, following the questionnaire and a urine analysis; and a small food or personal hygiene items equivalent of 300 Kyrgyz SOM six months after, following the questionnaire, a urine analysis, and

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blood for HIV test. If you are invited for an additional qualitative interview after the 12-week program to share your experiences, you will receive a small food or personal hygiene items equivalent of 300 Kyrgyz SOM.

During the 12-week program, you may additionally receive weekly incentives in the form of small food or personal hygiene items equivalent of 580 Kyrgyz SOM (~10 USD) for the time you spend performing your Health Advocate and Peer roles

Confidentiality:

All information you give or tell us during the study will be identified by a participant ID number. Information that links your name to this number will be kept in a separate file that is known ONLY by the research staff. Your study information will be kept in a locked office and on a secure computer server. When the results of this study are published or discussed at conferences, aggregate information will only be used. No information will be used that reveals your identity.

Representatives from Yale University Human Investigation Committee (the committee that reviews, approves, and monitors human subjects research) may inspect study records during auditing procedures. These individuals are required to keep your information confidential.

In compliance with the policy of the funding agency, clinical trial information about this study will be posted in anonymized form at ClinicalTrials.gov.

Voluntary Participation and Withdrawal:

Participation in this study is completely voluntary and you may withdraw at any time. You can refuse to answer any question(s) you do not wish to respond to. Your health services or prisoner status will not be affected by such decisions in any way. Whether you participate or not, or whether you drop out or not, your release date or treatment as a prisoner will not be affected. Your decision to participate or not will not be reported to the prison staff.

You do not give up any rights by signing this form.

Questions:

We have used some technical terms in this form. Please feel free to ask questions about anything you do not understand about the research or what is required of you if you decide to participate. You can take as long as you like to consider this consent form before you sign it.

If you have any questions concerning participation in this study, or if at any time you feel you may have experienced a research-related injury or reaction to testing, you may contact Principal Investigator, Dr. Julia Rozanova at +011 203 824 8130, or you may contact the study research assistant and coordinator, Dr. Ainura Kurmanalieva, at +966 550 181 181.

Authorization and Permission:

I have read (or someone has read to me) this form and I have decided to participate in the project described above. Its general purposes, what is involved, and possible risks and inconveniences have been

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explained to my satisfaction. By signing this form, I give permission to the researchers to use de-

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identified information about me for the purposed described in this form. My signature also indicates that I have received a copy of this consent form.

Participant Name: _____

Participant Signature: _____

Date: _____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

I have read (or someone has read to me) this form and I have decided not to participate in the project described above.

If you are willing, please explain why you are choosing not to participate in this study. Answering this is completely voluntary. It will help us improve our research. No one in the prison will see your answer. Your name will not be included anywhere on this form.

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If you have further questions about this project or if you have a research-related problem, you may contact the AIDS Foundation East West at + 996 312 240266. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale University Human Investigation Committee at +011 203 785-4688.

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