University of Illinois at Chicago (UIC)
Research Information and Consent for Participation in Social, Behavioral, or Educational Research

"Health Education for Tajik Migrant Workers"

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About this research study
You are being asked to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

Taking part in this study is voluntary
Your participation in this research study is entirely voluntary. You can choose not to take part in this study, and you can withdraw from the study at any time without penalty. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with the Tajik Diaspora Union, any of the medical or social service organizations that you might use in Tajikistan or Moscow, or the PRIZMA Research Center and the University of Illinois at Chicago that are conducting this study.

This consent form will give you information about the research study to help you decide if you want to participate. Please read this form and ask any questions you have before agreeing to be in the study.

Why am I being asked to participate? You are being invited to participate in the study because you are from Tajikistan, report injecting drugs in the last 30 days, you see the person who gave you the project coupon about once a week, and you are 18 years of age or older.

425 participants will be enrolled in this research study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

WHY IS THIS STUDY BEING DONE?	We want to evaluate two different approaches to educating Tajik migrants who inject drugs about health risks and prevention of health problems.
WHAT WILL I BE ASKED TO DO DURING THE STUDY?	You will complete a computer-assisted personal interview at the PRISMA Research Center or a location of your choice. The interviewer will ask questions about your background your drug-using social network, and behaviors that affect your health risks, including substance use and sexual behavior. For some portions of the questionnaire the interviewer will read the questions and enter your responses, and for other portions you will be asked to read the questions and enter your responses on the tablet computer. After the interview, you will be asked to go to the Moscow HIV Prevention Center to be tested for HIV and hepatitis C (HCV). You will be given a card with a code number for the Center testing staff to report your result to us. The results will be reported by group so that your individual results will not be identifiable. We will keep this information confidential. You will be re-interviewed again at 3, 6, 9 and 12 months after your initial interview. You will be asked to retest for HCV after the 6-month interview, and for both HIV and HCV after the 12-month interview.
HOW MUCH TIME WILL I SPEND ON THE STUDY?	The initial interview visit will require 2 to 3 hours. The interview will last between 60-90 minutes. You will then go to the Moscow HIV Prevention Center for counseling and testing that will take about 20 minutes plus travel and waiting time. Each follow-up interview will require 60-90 minutes.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?	Being in this research study may not benefit you directly, but the findings from this study are expected to benefit your community by helping us to meet the health needs of Tajik male migrants working in Moscow and other places.
WHAT ARE THE MAIN RISKS OF THE STUDY?	The primary risks presented by this research study are breaches of privacy (others outside of the study may find out you are a participant) and/or confidentiality (others outside of the study may find out what you did, said, or information that was collected about you during the study). The accidental disclosure of some types of information (substance use, HIV test result) could have negative consequences. You may be uncomfortable with some of the questions you may be asked and/or asked to discuss. This research includes some items about substance use and sexual behavior. You can skip and/or not respond to any questions that make you uncomfortable. All test procedures have possible minor risks (bruising at the blood draw site, nausea, fainting). The trained phlebotomist will watch for any problems during the procedure and stop if necessary. Although we will follow precautions for preventing COVID-19 spread by requiring masks and physical distancing, there may be some risk in meeting with the interviewer.
DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?	This research study is not designed to provide treatment or therapy, and you have the option to decide not to take part at all or you may stop your participation at any time without any consequences.
QUESTIONS ABOUT THE STUDY?	For questions, concerns, or complaints about the study, please contact Dr. Mahbat Bahromov, Director of PRIZMA Research Center at +992 935676565 or email at mahbat.bahromov@akdn.org. or Dr. Mary E. Mackesy-Amiti, University of Illinois at Chicago, +1 312-355-4892, mmamiti@uic.edu. If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects (OPRS) at +1 312-996-1711 or e-mail OPRS at uicirb@uic.edu. or contact the PRISMA Research Center IRB at +992 446006469, email prismairb@mail.ru; or the Moscow NGO Scientific and Educational Center "Bridge to the Future" IRB at +7 9261363657, email selin.zurbek@gmail.com.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research. Please also feel free to ask the researchers questions at any time.

What procedures are involved?

This research will be performed at the PRIZMA Research Center.

The study procedures are:

- You will come to the PRIZMA Research Center or a location of your choice to complete the initial interview.
- After the interview, we will ask you to go to the Moscow HIV Prevention Center to be tested for HIV and HCV. We will give you 2 cards with a code number for the testing staff to report your result to us. The code number will identify a group of participants, not individuals. This code number only and no other information will be used to communicate your test results from the testing center to the researchers. Testing is voluntary. You may decline to be tested, or you may agree to be tested but decline to have your results shared with the researchers.
- If you receive a positive screening test MHPC will conduct additional confirmatory tests. MHPC staff will instruct you when to return to receive the results of these tests. If you require confirmatory testing we will ask you to use the second coded card to send these results to PRIZMA.
- You will return to PRIZMA or a location of your choice to complete follow-up interviews at 3, 6, 9, and 12 months
- You will voluntarily retest for HCV at 6 and 12 months, and HIV at the end of 12 months

During this study, Dr. Mackesy-Amiti and Dr. Bahromov and their research team will collect information about you for the purposes of this research. The data collected for study include your responses to the eligibility screening questions, a baseline questionnaire including demographics, migration history, alcohol and drug use, sexual behavior, STI diagnoses, HIV and hepatitis C risk knowledge, syringe cleaning and sharing, psychosocial measures, and your injection drug use social network. We will ask you obtain an HIV and HCV test and allow the results to be shared with us confidentially. In follow-up interviews we will again collect information on your alcohol and drug use, sexual behavior and STIs, HIV and hepatitis C risk knowledge and behavior, psychosocial measures and interactions with your injection drug use social network. We will ask you to obtain an HCV test again at the 6 and 12-month follow-up interviews, and we will ask you to obtain another HIV test at the 12-month follow-up interview. The purpose of collecting these data is to evaluate the effect of health education programs on your health-related behavior and on HIV and HCV infection rates.

What will happen with my information used in this study?

Your identifiable private information collected for this research study may be used for future research studies and/or shared with other researchers for future research. If this happens, information that could identify you will be removed before any information is shared. Once the

identifying information is removed, the information cannot be withdrawn from further use. You will not be asked for additional consent.

Will I receive the results (including any psychological and/or health results) from the study? This research will not produce any psychological or health diagnoses. The results of HIV and HCV testing will be provided directly to you by the Moscow HIV Prevention Center.

What are the potential risks and discomforts of the study?

The primary risk is associated with potential loss of confidentiality.

- It is possible that study participants who are actively injecting drugs may become known to Russian authorities or other Tajiks who were unaware of their drug use. If it becomes known that you are attending a program for people who inject drugs, this has potential legal and social consequences.
- Unintentional disclosure of HIV-positive status may have serious consequences due to stigma. If it becomes known to Russian authorities that you are HIV positive you may be subject to deportation.

Other potential risks include:

- The study's structured interviews will ask you to report on sensitive behavioral and health information that might embarrass you, make you uncomfortable, or cause difficulties in your relations with others should what they disclose become known.
- Undocumented migrants may face risks in traveling to the PRIZMA Research Center, as police may stop them to check their documents.
- HIV and HCV confirmatory testing for those who screen positive requires a blood draw which has the risk of slight discomfort from the needle stick.
- Face-to-face interviews pose a potential risk of COVID-19 transmission.

What about privacy and confidentiality?

Efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. In general, information about you or provided by you during the research study will not be disclosed to others without your written permission. However, laws and state university rules might require us to tell certain people about you. For example, study information which identifies you may be looked at and/or copied for quality assurance and data analysis by:

- Representatives of the (USA) University of Illinois at Chicago committee that reviews and approves research studies, the Institutional Review Board (IRB), and Office for the Protection of Research Subjects.
- Representatives of the PRIZMA Research Center IRB or the NGO Scientific and Educational Center "Bridge to the future" IRB.
- Other representatives of the state of Illinois, USA and university responsible for ethical, regulatory, or financial oversight of research.
- U.S. Government Regulatory Agencies, such as the Office for Human Research Protections.

- The National Institutes of Health (USA)

A possible risk of the study is that your participation in the study or information about you might become known to individuals outside the study. Your personal information, interview data, and test results will be stored in a secure data base to prevent access by unauthorized personnel. Personal information that may identify you will be kept separately from research data and linked by research ID number. Your test results will be identified by a group number only and cannot be linked to your identifiable information. Your contact information and the master code list will be destroyed within six months after data collection is completed.

If you test positive for HIV or HCV (hepatitis C), the Moscow HIV Prevention Center will refer you to a doctor for counseling and treatment. The Tajik Diaspora Union has resources to assist migrants in need of treatment.

Your individual data will be stripped of all direct and indirect identifiers when primary data analysis is complete. The de-identified research data will be deposited to a digital repository to facilitate data sharing according to NIH guidelines. Access to the data will be restricted and will require a data sharing agreement.

When the results of the study are published or discussed in conferences, no one will know that you were in the study. During the study audio recordings will be collected for quality control purposes. The audio recordings will be destroyed within 30 days after being transcribed.

For added security, your information will be protected in the U.S. by a federal Certificate of Confidentiality. This Certificate means that information the researchers have promised to protect cannot be obtained from the researchers by any means, legal or otherwise. The Certificate does not stop you or a family member from disclosing or agreeing, in writing, to allow the researchers to disclose this information. The only exceptions to the Certificate are if child, elder, and/or disabled adult abuse or neglect, or the threat of imminent self-harm or harm to others is disclosed, the researchers may inform the appropriate authorities.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What are the costs for participating in this research?
There are no costs to you for participating in this research.

Will I be reimbursed for any of my expenses or paid for my participation in this research?
You will receive 1500 RUB for your time and transportation costs for each completed interview. If you do not finish the study, you will be compensated for the visits you have completed. If you complete the study, you will receive a total of 7500 RUB. You will receive your payment in person immediately following each interview.

Can I withdraw or be removed from the study?
If you decide to participate, you have the right to withdraw your consent and leave the study at any time without penalty. If you wish to withdraw from the study you must send a written notice

in order to have your name and contact information removed from the study database. The notice should be addressed to

> Dr. Bahromov mahbat.bahromov@akdn.org or Mr. Jonbekov Jonbek@mail.ru
> PRIZMA Research Center 21 Pravda Street Moscow, Russia.

The researchers may use your information that was collected prior to your written notice.

The researchers also have the right to stop your participation in this study without your consent if they believe it is in your best interests.

What other things should I know?

Remember:
Your participation in this research is entirely voluntary. Your decision whether or not to participate will not affect your current or future relations with the Tajik Diaspora Union, other social or medical service organizations that you might use in Tajikistan or Moscow, or the PRIZMA Research Center and the University of Illinois at Chicago that are conducting this study. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

You will be given a copy of this form for your information and to keep for your records

Questions to Assess Participant Understanding

What is this study about?

What will you be asked to do?

Can you decline to participate in the study, refuse to answer any questions that you wish, or end participation at any time without penalty?

What will you receive as compensation for your time and transportation?

Are there possible risks involved in participating and if so, what are they?

Are there any direct benefits to you for participating in the study?

How will we protect your identity in the study?

Signature

I have personally explained the research to the study volunteer and answered all questions.
I believe that he understands the information described in this informed consent and freely consents to take part.

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent