Informed Consent Form to Participate in a Research Study

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Yale University *School of Medicine*

Ukrainian Institute on Public Health Policy (UIPHP)

Title: Integrating Addiction Treatment and HIV Services into Primary Care Clinics in Ukraine.

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Project Director: Sergii Dvoriak **(UIPHP)**

Source of Funding: This research study is funded by the National Institutes of Health, National Institute on Drug Abuse (USA).

Introduction:

Dr. Frederick Altice from the Yale University School of Medicine, New Haven, Connecticut, USA, in collaboration with Mr. Sergii Dvoriak from the Ukrainian Institute on Public Health Policy, are conducting a research study in Ukraine, which you are being invited to join. The following information describes the purpose of the study, what you are asked to do, as well as the potential risks and benefits of participating in the study. You can ask questions both before deciding to participate in the research study and at any time during the course of the study.

Purpose:

The aim of this research study is to determine how methadone maintenance treatment (MMT) in a primary health care setting (outpatient hospitals) will improve health outcomes among opioid-dependent people who inject drugs (PWIDs) as compared to specialty drug addiction clinics. In particular, we would like to compare HIV, tuberculosis, addiction levels, quality of life, and stigma outcomes in MMT patients in Ukraine. You are being invited to participate in this study due to the fact that you are or are about to become a participant in a drug addiction treatment or a harm reduction program in Ukraine.

APPROVED BY THE YALE UNIVERSITY IRB 1/10/2024

Procedures:

If you participate in this study, you will need to give your consent to the fact that the **clinic in which you will receive OST will be determined randomly.**

If you are already receiving MMT, you will either stay in your addiction clinic (33% chance) or you will be transferred to a new MMT clinic based on the outpatient hospitals in your city (66% chance). If you are referred to an outpatient hospital, you can choose either of the two outpatient hospitals that participate in the study (the most convenient one for you).

If you are going to start MMT now, you will be diagnosed for addiction and will start receiving MMT in this drug addiction clinic. After that, you will either stay in narcology (addiction medicine) (33% chance), or you will be referred to either of the two outpatient clinics of your choice (66% chance).

In both cases, if you get to the selected outpatient clinic, the transfer must take place within a week after signing this consent.

Each clinic will have certified doctors and nurses for carrying out MMT in accordance with the required legislation.

Regardless of where you receive MMT, you will be asked to fill out a series of questionnaires that will take 45 minutes and more. These questionnaires will ask you about your medical history, deprivation of liberty and drug use, your interest in treatment and experience in receiving MMT, HIV risk, quality of life, stigma and obtaining medical services.

We will ask you to complete these questionnaires at the initial stage, before you start participating in the study, and every 6 months for the next two years (a total of 5 times). The research staff will contact you to ensure that you complete these surveys. You will fill out the questionnaires on a computer, and the research staff will answer any questions you many have in the course of the study. Your name and contact information will only be available to the research staff.

We will also collect some data from your medical record card. Throughout your participation in the study, we will collect data from your medical examinations, appointments and consultations and enter them into the research database. In addition, you will be asked to provide the types of healthcare services received within the past six months,

and the location of the clinic where the service was received. At each follow-up interview, you will be given a medical record release form where you may list the types of services provided and specify the individual research staff to whom you are giving permission to verify this data.Research staff will then call the listed clinics to verify the type and date of each service.

Your responses to the questionnaires and a database with information from the card will be stored on a secure UIPHP server, access to which is only available to members of the research team. Your personal information (names, full date of birth, contact information, address) will be known to the research assistants so that they can communicate with you, but will NOT be recorded directly in the questionnaire or the enrollment card in order to protect your confidentiality. This contact information will be maintained only by this research staff member and will not be given to anyone or shared in the database. That is, your information is entirely confidential and your personal information will not be combined with your responses.

In case of unforeseen circumstances, in the future, another employee may contact you and conduct the interview, and not just the one who will sign this consent form.

Payment for Participation

You will be given 250 UAH for filling out one form, a total of 1250 UAH if you complete all the 5 questionnaires.

Risks and Inconveniences

Risks associated with participating in this study are minimal since such data collection is part of the routine patient care. To help minimize any emotional risks you may experience, you will be provided with counseling from research assistants and referrals for medical and/or mental health services.

There is a slight risk of a breach of confidentiality regarding your participation in this study in case information about your participation becomes known to people outside this study. We will ask you and all other study participants not to tell anyone outside the research site whom you may have seen on the site. However, the researchers cannot guarantee that all the participants will keep this information private. The researchers are required to keep

your study information confidential, and they have been trained on this matter, so the risk of breach of confidentiality is very low. Also, there is a slight probability that you may experience emotional discomfort while filling out the questionnaire, in case some questions seem too frank to you. You have the right to refuse to answer any questions.

Potential Benefits

As part of this study, you will receive standard drug addiction treatment that supports methadone maintenance treatment. You will also be referred to the treatment of co-morbidities such as HIV, tuberculosis, hepatitis B and/or C and others, **on a general basis**.

Alternative Therapies

You can receive methadone or buprenorphine treatment in this or other institutions **on a general basis** without participating in this study.

Privacy / Confidentiality

To ensure confidentiality, your name and other personal information will not be transferred from medical records and will not be listed in any research document where you provide data. You will be assigned an individual code, and no information that can be used to track your name will be recorded. We will collect only the information that we need for the study. Only the person responsible for the questionnaire will have access to the contact information you choose to provide.

Voluntary Participation and Refusal to Participate in the Study

Your participation in this study is completely voluntary. You can choose freely whether to agree to participate or not, and you can also withdraw from the study at any time for any reason, or refuse to answer any question without any penalties. If you decide not to participate or if you decide to withdraw from the study, this will in no way affect your ability to receive therapy or your relationship with the staff of this site or any other medical institutions. Your consent to participate in the study does not deprive you of any legal rights.

Authorization and Permission

I have read this form (or someone has read it to me) and have decided to participate in the project described above. Its general purposes, all the procedures, as well as possible risks and inconveniences have been explained to my satisfaction. My signature also indicates that I was offered a copy of this consent form.

For participants: By signing this form, I give permission to researchers to use 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 study.

Participant's Code	Name or Initials	Signature	Date and Time

For staff: I have explained the purpose of the study and all the procedures to the potential participant and answered all his/her questions. To the best of my knowledge, he/she understands the purpose, procedures, and all the risks and benefits of this study.

Name or Initials	Signature	Date and Time

Questions

If you have any questions about this study, you can contact the investigator, Mr. Sergii Dvoriak at UIPHP in Kiev, Ukraine at tel.: +38-044-279-3586. If you would like to talk to 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 participant, you can contact Victor Shtengelov, Head of the UIPHP Ethics Committee by tel.+38 044 222 62 71.