You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

College of Global Public Health, New York University and North-West District AIDS Prevention and Control Center, Ministry of Health of Russia

Consent to be a Research Subject

Title: Computer-Based Alcohol Reduction Intervention for Alcohol-Using HIV/HCV Co-Infected Russian Women in Clinical Care

Principal Investigator: Ralph J. DiClemente, PhD and Dr. S. Plavinsky

Sponsor: RFBR (Russian Federation) and National Institutes of Health (USA)

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

What is the purpose of this study?

The purpose of the study is to test a computer intervention to reduce problem alcohol use of our female patients. Another focus of our study is to identify risks in young Human Immunodeficiency Virus (HIV)/Hepatitis C Virus (HCV)-infected women's' behaviors that could be related to infecting other people. This information will help to improve practice of social and medical care provision for the patients in our Center. In addition, we are planning to use some new methods to estimate health conditions of HIV/HCV-infected people that have not been used before in our country, so that this study will allow us to better understand perspectives of their use in further Russian practice.

The study will enroll 250 adult female patients from four sites affiliated with the North-West District AIDS Center.

What will I be asked to do?

If you are eligible to participate, decide to participate in the study, and sign an informed consent form, you will be asked to complete the study procedures, which are listed below. Study procedures will not start until you sign the consent form.

When you enroll in the study you will:

1) Take a survey. The survey will not involve the participation of anybody else – it will be taken via paper-and-pencil and may take from 30 to 60 minutes. The survey will ask you questions and you will need to check the most right one answer for each question. The survey will cover a wide range of questions: social-demographic characteristics (age, education, place of birth etc.), experience of alcohol use, sexual behaviors, knowledge on HIV, HCV and experience of receiving medical and social care related to HIV-status, and specifics of treatment with HAART- Highly Active Antiretroviral Therapy. All of it is important information, needed to improve medical and social care for patients with HIV and HCV.

Some of the questions may look quite personal, so that sometimes people may feel embarrassed to respond. In particular, we would like to ask you some questions related to your sexual contacts with some of your sex partners. Some people may feel uncomfortable or experience emotional tension while answering such questions. If for some reason you feel that you are not comfortable to respond on any of our questions, you do not have to answer. Also you will be able to stop answering our questions at any time. All of your answers will go to a general dataset, with no identifying information None of the information provided by you will be shared with anybody (including your doctor) in relation to your name.

2) Fibroscan: a clinician will perform a Fibroscan of your liver. A Fibroscan is a noninvasive test, with no pain, and sedation is not required. The test takes only 5 to 7 minutes to perform and has not been associated with any side effects.

3) Blood draw: we will take a blood sample to test for indirect serum markers of HCV infection.

4) **Blood spot:** we will take a blood spot sample on a card to test for alcohol in your blood.

5) Medical chart data: we will abstract your medical charts to obtain your HIV viral load (VL), CD4 levels and HCV antibody status. Research staff will also record whether you had documented chronic HCV.

After you have finished your medical procedures and survey, you will be selected by random to either receive materials about drug and alcohol problems OR take a computer program about drug and alcohol problems. The computer program will last 1 hour the same day and you will then meet with a clinician to further discuss information covered in the computer program.

All participants will be asked to return to the clinic to complete the survey and medical procedures (blood spot, blood draw) at 3-, 6-, and 9- months after enrollment. The Fibroscan will be conducted only at the initial study visit and visit 9-months after enrollment. Participants who are in the control group will be able, if they wish, to complete a computer program after the end of participation in the study

Who owns my study information and samples?

If you join this study, you will be donating your samples and study information. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?

There may be effects from the study procedures that are not known at this time. **The most common risks and discomforts expected in this study are:**

Puncture of a vein (blood draw) in the study may be accompanied by unpleasant sensations. There is a risk of complications during the procedure cubital vein puncture. In the puncture site may occur hematoma (bruise) and infiltration (swelling). Dizziness and/or weakness can occur during or shortly after taking blood. However, the procedure will be performed by highly qualified personnel, which brings this risk to a minimum.

Puncture of a fingertip (blood spot) may be accompanied by unpleasant sensations. The procedure will be performed by highly qualified personnel, which brings this risk to a minimum.

Fibroscan is a minimally invasive procedure and therefore confers minimal risk.

If, during the course of the study, the tests reveal concerning health findings, the physicians at the North West AIDS Center and affiliated clinical sites will meet with you to discuss these findings and possible treatments available to you.

Will I benefit directly from the study?

This study is not designed to benefit you directly. The study results may be used to help others in the future. You may receive a computer intervention that helps you lead a healthier life.

Will I be compensated for my time and effort?

You will get 1000 rubles for the initial study visit and the 9-month study visit. You will get 500 rubles for the visits at 3 and 6 months, to compensate you for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. You will receive a gift card in these amounts.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. There is alcohol and substance use counseling available at the clinic as part of your routine care.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Certain offices and people other than the researchers may look at study records, for example, The Ethical Committee of St. Petersburg State University IRB and the New York University offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the IRB, Compliance Offices, and the Office for Clinical Research. Government agencies and study funders may also look at your study records.

New York University will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Medical Record

The results of the routinely provided tests (Fibroscan, indirect serum markers of HCV, HIV viral load (VL), CD4 levels and HCV antibody status) will become part of your medical record at the clinic in order to provide care to you.

What will happen in the event of any problems?

If you get ill or injured from being in the study, the North-West District AIDS Center and its affiliated sites will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this research, you should contact Dr. Ekaterina Boeva at telephone number ***+7 (911) 792-91-94***.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave this study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Contact Information Contact Dr. Ekaterina Boeva, project coordinator, at +7 (911) 792 91 94.

- if you have any questions about this study or your part in it, or
- if you have questions, concerns or complaints about the research

Contact the Ethical Committee of St. Petersburg State University Institutional Review Board at 8 (812) 327-79-69 or irb@spbu.ru

- if you have questions about your rights as a research participant.
- If you have questions, concerns or complaints about the research.

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**