Participant ID

Behavioral & Clinical Investigation Consent Form – PART A

Short Title: Integrated Behavioral And Biological Assessment (IBBA)

Sponsor: Bill & Melinda Gates Foundation Grant to Family Health International.
Implementing Partners: Indian Council of Medical Research (ICMR), New Delhi through;
National AIDS Research Institute (NARI), Pune, Maharashtra
National Institute of Epidemiology (NIE), Chennai, Tamil Nadu
National Institute of Nutrition (NIN), Hyderabad, Andhra Pradesh
Regional Medical Research Center (RMRC), Dibrugarh, Assam
National Institute of Medical Statistics (NIMS), New Delhi

Principal Investigator: Dr. R.S. Paranjape, Director, NARI, Pune

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Dr. J. Mahanta, Director, RMRC, Dibrugarh
Dr. Arvind Pandey, Director, NIMS, New Delhi

Date of Ethics Committee Approval:

_____

Introduction: My name is _____(name), and I work in a collaborative project with (research agency) and ….. (State-level institute). We are collecting sexual health data for a project called Integrated Behavioral and Biological Assessment (IBBA) which is supported by the Bill & Melinda Gates Foundation. The round-I of IBBA was conducted during 2005-07 and we are currently doing round-II of IBBA to evaluate and measure changes in behavioral and biological indicators. The findings of IBBA round-I have been widely disseminated to the community through the implementing agencies. You are being chosen to request participation by chance and not for any other reason. This consent form gives you information about IBBA Round-II. You are being requested to think about your participation in this study through this consent form. It is necessary for you to receive complete information about this study to participate in it. Therefore, you have to read this form or somebody will read it out to you. If you are willing to participate in this study, you will put today's date and sign this consent form. If you cannot or do not wish to sign, a witness will sign it.

Purpose of study
Comprehensive interventions to reduce the spread of HIV infection among different vulnerable population groups have been accorded high priority in India. Many non-governmental organizations are implementing comprehensive focused interventions among various 'at risk' populations in India. However, limited information is available about the impact of such programs. This study proposes to assess the impact of these interventions especially that sponsored by Avahan.

Your participation in this study

If you agree to participate in this study, we will ask you some personal questions about you, your migration history, sexual behavior, substance use and sexually transmitted infections etc. The interview is likely to last for about 45 minutes. We will also request you to permit us to collect blood and urine samples. Our study doctor will perform external physical examination and if you have certain symptoms, you will be requested to permit us to collect vaginal secretions or secretions from an ulcer on the external genitals. At the end of this form, we will request you to give consent for each of these procedures. You may participate, only if you are willing to. You may choose not to answer certain questions, if you do not want to. There is no right or wrong answer to any of the questions. After that, your 10 ml (approximately 2 teaspoonfuls) blood will be taken. Your blood sample will be tested for syphilis, HIV and HSV2 antibodies. If it is found that you are having symptoms suggestive of sexually transmitted infections, our study doctor will provide you appropriate medicines for treatment. Also, you will be referred to a clinic where you can get the result of your syphilis test and if you are found to be infected you will receive medicines against it. The results of the HIV test will not be revealed to you. If you wish to know HIV test results, you will be referred to a nearby Integrated Counseling and Confidential Testing Centers (ICCTC). This study cannot provide you with treatment for HIV, but study staff will refer you to other available sources of care.

Who is eligible

You should be above the age of 18 years and willing to participate in this survey

Risks and Benefits of Participating in the Study

You may feel discomfort when your blood is drawn. Some may feel dizzy or faint. You may have a bruise or a swelling where the needle goes into your arm. You may become embarrassed when discussing sexual behaviors. You will talk with a trained staff member who will help you deal with any feelings or questions you have.

We will make every effort to protect your privacy and confidentiality in IBBA. However, it is possible that others may learn of your participation may treat you unfairly or discriminate against you. In very rare situation your family or community may not accept you.

This study may be of no direct benefit to you. However, you and other community members may benefit in the future from information learned from this study. If you have symptoms, the doctor will offer you medicine for some STDs that are treatable. If you wish, you will be referred for pelvic exam and additional STD treatment if needed. You will also be referred for counseling and testing for HIV. This study cannot provide you with other medical care, but study staff will refer you to other available sources of care.

If you decide not to participate in this study

You may decide not to take part or to withdraw from the study at any time. You will continue to receive the services from your local intervention program, if you were receiving them and your routine medical care.

Confidentiality

The study staff will keep your personal information confidential. In all other forms beside this consent form, and on all the samples, instead of name, only a code number shall be mentioned. The forms linking your name and the assigned code number will be kept in lock and key. This information will not be given to anybody else without your permission.

Compensation for Your Participation

There is no cost to you to participate in the study. You will be compensated for your time and effort. (Rs.). Additionally, the cost of travel for going to the referred STI treatment and HIV counseling center (Rs.) will be reimbursed. No other compensation will be provided to you.

Problems about the study

If you ever have any questions about this study, or in case of research-related injuries, you should contact ……..…(Name of Co-PI), ……(Designation), …….. (State-level Institute), …….. (Address) at …….. (Phone No.), or if you have questions about your rights as a research participant, you can call …….. (Name), Chairman, Ethical Committee, …….. (State-level Institute) at ……. (Phone No.).

Statement to be Made By A Woman Willing to Participate in the Study

I have read this consent form completely / this consent form has been read out to me. All my doubts have been cleared. I can withdraw my participation anytime, if I feel so. I have understood this. I have received and understood the information about my rights and have been promised that my personal information shall be kept confidential.

I want to participate in this study myself by my own free will and am willing to (Circle number/s that are accepted);

1. Answer the questionnaire
2. Consult the study doctor
3. Provide blood, urine and if necessary, swabs from genital ulcer bases
4. All 1+2+3

I have been offered a copy of my consent form and (Circle number that is accepted);

1. I want a copy of my consent form
2. I don't want a copy of my consent form

Ethics Committee Stamp of Certification **Date of Expiry of Consent Validity**
Pl do not sign after date of expiration

Date ***Signature*** ***Signature of witness***
Participant's name ***Name of witness***

Addendum I - Consent Form: Permission to use of blood samples in future Part B

Introduction

Of the blood sample that is going to be collected, a small quantity of blood may be leftover. In such circumstances, we would request you to permit us to keep this leftover blood for future research instead of throwing it off. We may be able to use this leftover sample to undertake newer tests as the technology develops or to study genetic and immunologic factors influencing the risk of acquiring HIV infected or disease progression. It will be only used for research and not for any commercial gains. If you agree to this, it means that you also give us permission to do such studies on this blood sample. These results will not be used to identify participants individually.

Sample Identification

Your leftover blood sample will have your unique number and not name. Though we would be able to link the test result with the other data that we have collected, we will not be able to get back to you with the test results as we will not be recording your address.

Risks

There are no risks to you from future use of your specimens. Reports about research done with your sample will only be presented in publications and meetings and shall not have your name or any other personal identifier.

Freedom to Refuse

You can decide not to allow use of your samples for future research or you may change your mind at any time about allowing your samples to be used for future research. If you wish to change your mind, you can contact …… (Name of Co-PI), ……. (Designation), …….. (State level Institute), ……. (Address); Phone-…….. and let him know. To do so, if you provide the number on the paper we give you today, it will help us best. We will find your specimen and destroy it so that it will not be available for future research.

Your decision to allow us to use your specimens in future research, will not have any effect on your taking part in this assessment, or your ability to obtain services from the project. Even if you refuse to permit use of blood samples in future, you can take part in IBBA and also receive services from any intervention project.

Voluntary Consent

I certify that all my questions and concerns have been answered and I willingly agree that samples can be used for future research. I give permission for the use of my leftover blood sample in future research for the purposes described above. (Please check one)

_____ YES
_____ NO (If NO, my specimens will be destroyed)

I have been offered a copy of my consent form and (Circle number that is accepted);

1. I want a copy of my consent form
2. I don't want a copy of my consent form

Date ***Signature*** ***Signature of witness***
Participant's name ***Name of witness***