Informed Consent for Participation

Project name: Community Treatment Liaison Pilot Project

Project Lead: Toronto People With AIDS Foundation

You are being asked to participate in a pilot project involving one-to-one consultations on treatment support, doctor-patient communication, and service navigation being conducted by The Toronto People With AIDS Foundation. The project is financially supported by Janssen, Inc. Your participation is entirely voluntary. You are free to refuse to participate or withdraw from the project at any time without this changing in any way the quality of care that you receive. Feel free to ask questions at any time throughout the project.

1) Purpose & Design

HIV is a virus that can involve complicated treatment options. The purpose of this project is to determine whether providing on-site treatment information support through written materials and one-to-one consultations can help people living with HIV/AIDS (PHAs) to make decisions around their health and treatment. Recognizing that making the best personal choices around health also requires being able to communicate your health needs to your doctor and being able to connect with other services in the community that may be of help, the project also aims to provide support in these areas.

To participate in this project you must be a person living with HIV/AIDS and be 18 years of age or older. You must also be able to understand this form in English.

2) Procedures

This pilot project is intended to run until December 2012. If you agree to participate in the project one-to-one consultations are available to you before or after your doctor's visit over the course of the project. Consultations may range from a few minutes to 30 minutes, based on your need. You will be able to schedule the appointment ahead of time, or access it on a first come, first served basis on the day of your appointment.

During the course of the consultation you will be provided with any information you require regarding HIV and its treatment, referral to community services, and the opportunity to complete a worksheet to help plan for your doctors visit. You will be able to choose any or all of the services that you feel are useful to you.

3) Evaluation

The project will be evaluated by collecting information in several ways. First, general topics discussed in the course of the consultations will be recorded along with the types of resources given out, including referrals. You will also be asked to complete a survey regarding your experience participating in the project. In all instances the information collected will be anonymous and you will not be identified. **You have a right to participate in the project without participating in the evaluation survey or interview**. With your consent, you may be contacted and asked to provide additional feedback through an interview. This interview will occur at a later date **and should take no more than 1 hour of your time**. You will have to provide project staff with your contact information. Your information and identity will be kept confidential and will only be known by the interviewer. You have the right to change your mind about participating in the interview at any time during the project. Your contact information will be destroyed once the interview has occurred **as will the original recording. Only a transcript of the interview will be kept and any information that might identify you will be removed from the transcript.**

4) Participant Withdrawal

Participating in this project is voluntary. If you decide to participate you have the right to leave at any time. You can with draw at any time without it affecting the health care services you receive at the clinic or any services you receive at PWA if you are, or choose to become a client in the future. During the course of the project you will be kept informed of any changes in the project that might influence your participation.

5) Risks, Side Effects, and Harms

There are no foreseeable risks associated with participating in this project. The individuals conducting the consultations are not medical professionals and cannot provide medical advice. The information that you are provided over the course of the consultation, however, will be from sources judged to be medically reliable. You are in no way obligated to use the information provided to you and the information is not intended to replace your doctor's advice. Every effort will be made to explain the information and how to use it appropriately in a way that is easy to understand. How you choose to use the information is your decision alone. By participating in the project you are disclosing your HIV status to the project staff. Your HIV status will remain completely confidential and will not be disclosed to anyone for any reason. We will make every effort to address any negative impacts that may arise from participating in the project.

6) Continued Access

At the end of the pilot project, you can continue to access treatment support services at The Toronto People With AIDS Foundation, through the Treatment Resources Program. In order to continue to receive services you will have to become a client of the agency which requires that you live in an area with a postal code beginning with "M" (i.e. the city of Toronto) and provide verification of HIV status (through a doctor's letter). If you do not live in the city of Toronto and wish to continue to access treatment information services, every effort will be made to connect you with an appropriate agency in your area.

7) Potential Benefits

This project is in the pilot stage. This means that there is no guarantee that the services you receive will benefit you. Other people living with HIV may benefit from your participation in this project in the future.

Possible benefits to participating in this project may include:

- Access to medically sound treatment information, in addition to what your doctor has time to provide, and a chance to discuss the information with someone knowledgeable about HIV treatment

- Access to information to help you to connect with other services in the community related to your health
- Access to a worksheet to help you plan for your doctor's visit, with the intention of helping you to communicate your needs to your physician.

8) Reimbursement and Compensation

There will be no financial costs to you for participating in this project. You will not be charged for any of the materials or information provided to you in your consultations. You will not be paid for participating in the project, however, you will be reimbursed for travel and child care expenses at the time of the consultation:

a) two TTC tokens or reimbursement of parking expenses up to $10 with a parking receipt
b) child-care reimbursement of $20 ($10 for travel time, $10 for consultation time) if you have dependent children under the age of 14 with verification. If you are asked to participate in an interview, you will be reimbursed for childcare expenses at $10/hour for up to 5 hours.

The reimbursement is specifically for this pilot project. If you continue to access services at The Toronto People With AIDS Foundation after the project ends, the foundation's regular travel and child-care reimbursement policies will apply.

9) Communication of Results

Project staff will make the pilot project evaluation results available when they are known. If you would like to receive the evaluation results either by telephone or mail, project staff will collect your contact information. Your information will be kept confidential and will only be known by project staff for the purpose of providing the results to you. Your contact information will be destroyed (shredded) once we provide you with the results and will not be retained. You will also be able to access a plain language summary of the project evaluation on The Toronto People With AIDS' website (www.pwatoronto.org) without providing your contact information.

10) Confidentiality

All information about participants collected during the course of the project will be kept confidential unless required by law (if you reveal information that you are likely to harm yourself or someone else, or that a child is being harmed). Data collected during the pilot project is owned and will only be seen by The Toronto People With AIDS Foundation. The Ontario HIV Treatment Network and the funder (Janssen, Inc), may have access to data from the project, but that data will be made anonymous before they see it. At no time will your name be associated with any data collected. The results of the evaluation may be published in a journal or be presented at a conference but your identity will not be revealed. The evaluation results may be shared with other community agencies, without providing direct access to data.

11) Future Research

The data collected from this pilot project may be used to guide future projects or be used to answer additional questions related to HIV treatment information delivery.

12) Contact Person

If you have any questions during the project please contact Jennifer Grochocinski, Treatment Resources Coordinator at The Toronto People With AIDS Foundation at 416-506-1400 x237 or jagrochocinski@pwatoronto.org or Suzanne Paddock, Director of Programs and Services at The Toronto People With AIDS Foundation at 416-506-1400 x204 or spaddock@pwatoronto.org. For information on your rights as a participant in this project contact the University of Toronto HIV Research Ethics Board at 416-946-3608.

13) Incentives and conflicts of Interest

The Toronto People With AIDS Foundation is receiving funding from Janssen, Inc. for the development, implementation, and evaluation of this pilot project. Physicians involved are not being paid for referring their patients to the project. The project staff are employees of The Toronto People With AIDS Foundation.

Informed Consent Form

Community Treatment Liaison Pilot Project

I am aware that by initializing each page of the Consent Form and signing the signature page:

- ☐ I have read the entire document and all my questions have been answered to my satisfaction. I am free to ask further questions at any time during the project, and I will receive a copy of this Consent Form for my records
- ☐ All personal data collected will remain confidential and that any resulting publication will maintain my anonymity
- ☐ My participation in the project is voluntary and that I am completely free to refuse to participate or to withdraw from this project at any time without this changing in any way the quality of care that I will receive
- ☐ I am not waiving any of my legal rights nor am I freeing the investigators, sponsors or the health establishment from their legal and professional responsibilities
- ☐ There is no guarantee that this project will provide any benefit to me

☐ I consent to be contacted to provide additional feedback through an interview

____________________________	___________________________	_____________
Name of Participant	Signature of participant	Date
____________________________	___________________________	_____________
Name of participant's legally Acceptable representative (if applicable)	Signature of participant's legally acceptable representative (if applicable)	Date

The potential benefits, risks, and procedures associated with this project have been fully explained to the participant and he or she has had ample time and opportunity to ask questions and to decide whether or not to participate in this project.

____________________________	___________________________	_____________
Name of person obtaining Consent	Signature of person obtaining consent	Date