UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

Patient
RESEARCH CONSENT FORM

Protocol Title: The CASA Study: Care and Support Access Study for implementation of a palliative approach with HIV treatment

Study No.: HP-00058180

Principal Investigator: Carla S Alexander MD (410) 328 7129

Sponsor: Patient Centered Outcomes Research Institute (PCORI)

What you should know about this study:
You are being asked to join a research study. You do not have to join this study, participation is voluntary. This consent form explains the study and what is required. Please read it carefully and take as much time as you need. Please ask questions at any time about anything you do not understand.
The principal investigator for this study is Dr. Alexander. You should ask her, or a member of the study team, to explain any information in this informed consent that you do not understand. Once you understand the study, you can decide if you want to take part in it. Your decision to participate, or not to participate, is entirely voluntary. If you choose to take part, we will ask you to sign this form. We will give you a signed and dated copy of the consent form for your records. If you are an employee or student, your employment status or academic standing at UMB will not be affected by your participation or non-participation in this study.

PURPOSE OF STUDY

Why is this research being done?
Since the identification of the HIV virus, much has been learned about the disease caused by this virus and, for people who are able to take their antiretroviral medications on a regular basis, the life expectancy is now what it would be for that person based upon his current age.

In this study we are referring to young men who have sex with men as YMSM. In Baltimore and other US cities, HIV positive YMSM have not stayed in outpatient care or taken care of their HIV/AIDS the best way. HIV/AIDS clinics have tried a number of ways to keep YMSM coming to treatment, but we are going to try a new method.

This research is evaluating the response of both YMSM and HIV clinic staff when the staff members of the clinic are taught new skills.

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Do Not Sign this Form after this Date 2/28/2017

The staff will learn to look at things from your point of view. We are doing this research to better understand how to care for YMSM, a group that has been hard to get to come to clinic for treatment and take care of their health. We want to study how your relationships with the staff might make a difference in your mental health or quality of life.

If you participate, you will be 1 of about 102 YMSM participants at this site; there are two sites for a total of approximately 204 YMSM participants.

PROCEDURES

What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

Baseline Visit

The baseline visit will take place at the University of Maryland, Baltimore (UMB) Institute of Human Virology Jacques Initiative Clinic or at the UMB Evelyn Jordan Center depending upon where you usually receive your healthcare. We will ask you to fill out a survey on a touchpad. The questions will be about your current health and medical history. Your name will not be connected with the answers. We will review your clinical medical chart to get laboratory results and diagnoses that will allow us to look for possible associations between this information and your answers to the survey.

Questionnaires:

You will be asked a series of questions about your health status and symptoms. These questions will be given to you on a touch-pad screen; you will be able to listen to the questions read to you as well. A member of the study team will be present to answer any questions you might have. We will ask you questions about your symptoms that you might have experienced such as pain, tiredness, depression (sad mood), anxiety, sleep problems; also about your current daily activity level and about your sexual history.

Follow-up Visits

We will ask you to complete the same survey 1 more time over a 6-month period. This visit will be at the time of your regular appointment or at a time that is most convenient for you and will be about 4 to 6 months after your baseline visit. A member of the study team will be present to answer any questions you might have. We will review your clinic records just after your visit to obtain laboratory results and medications to compare with your study information. Other forms to be updated will include: your contact information, medication and medical history, and a

variety of questions about your symptoms and quality of life. Total time for the follow-up visit is approximately 30-60 minutes.

How long will you be in the study?
You will be in this study for 6 months or until 1 follow-up survey is completed.

	Baseline Visit	Additional Baseline Visit	Month 6 ±3mo
Informed Consent	X		
Inclusion/Exclusion Criteria	X		
Demographic information	X		X
Hospitalizations			X
Contact Info	X		X
Medical History	x	*x	X
Height, Weight	X	*x	X
Blood pressure	X	*x	X
Lab Studies	X	*x	X
Questionnaires	X	*x	X
Medications	X	*x	X
Adverse Events	X	*x	X

*** These pieces of information will only be collected if not collected on the initial baseline visit.**

POTENTIAL RISKS/DISCOMFORTS:
What are the risks or discomforts of the study?

When filling out Questions or Questionnaires
You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.
If the test of mental function indicates that you may have a medical condition related to difficulty thinking or forgetfulness (such as HIV associated neurocognitive disorder), you will be notified of this result and, with your permission, we will contact your physician and/or healthcare provider for further testing and treatment. That follow-up healthcare will not be part of this research study.
If your answers to the questions about depressed mood suggest severe depression, you will be notified of this result and, with your permission, we will contact your physician and/or healthcare provider for further testing and treatment. This follow-up healthcare will not be part of this research study.

If you indicate in your questionnaire answers that you are planning to hurt yourself, you will be referred for emergency medical care.

Another risk is that something you read or discuss in relationship to this study may cause you to worry. If this happens the staff is trained in methods for recognizing distress this might cause you and there is a "safety protocol" in place that will allow us to get you to an appropriate staff member or counselor experienced with this type of issue. You are also free to contact Dr. Alexander directly relative to this occurrence. Her telephone number is at the top of the consent form.
In any study, there may be risks that are not yet known.

Loss of Confidentiality

There is always a potential for the loss of confidentiality. This risk will be minimized by keeping all study data stored and secured in a locked cabinet in a locked office. Electronic data will be password protected and will not have your name on it. Private information will only be given out as listed in the HIPAA form and only if necessary. We have also obtained a Certificate of Confidentiality from the National Institutes of Health (see "Confidentiality and Access to Records" section below).

Although we believe that good research strategies for privacy make this unlikely, there is a risk that your identity could become re-connected with your health information. If this happened - information could be revealed that could lead to denial of employment or insurance for you or a relative, or law enforcement agencies might be able to demand information about you in connection with an investigation. Our staff is trained to take steps to protect your confidentiality.

There may be risks in this study that are not known.

POTENTIAL BENEFITS

Are there benefits to being in the study?

It is not known whether you will benefit directly from your participation in this study. You may have no benefit from being in this study or you may benefit by having an improved treatment outcome, but there is no guarantee. You will talk with one extra person, the data collector at your study visit and this may assist you in remembering to address issues with your health team. Even if there is no direct benefit to you, the information collected in this study will help the research

staff to understand if there are factors that might be addressed in the future to improve the care for other YMSM.

ALTERNATIVES TO PARTICIPATION

What are your options if you do not want to be in the study?

This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at University of Maryland, Baltimore will not be affected.

COSTS TO PARTICIPANTS

Will it cost you anything to be in this study?

It will not cost you anything to take part in this study

PAYMENT TO PARTICIPANTS

Will you be paid if you join this study?

You will be paid $20 cash for your time and effort with each completion of the CASA survey; this means you may receive up to $40 over the 6 months of the study. In the final year of the study, selected participants will be asked to complete an in-depth interview regarding your experience of receiving care at the clinic. This would be voluntary and if you choose to participate, you will be paid an additional $25 cash for your time and effort.

What treatment costs will be paid if you are injured in this study?

- There are no funds to pay you if you are hurt or if you have other bad results from taking part in this study.
- If you have health insurance: the costs for any treatment or hospital care you receive as the result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you.
- If you do not have health insurance: You will be billed for the costs of any treatment or hospital care you receive as the result of a study-related injury.

CONFIDENTIALITY AND ACCESS TO RECORDS

How will your privacy be protected?

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the

Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: suspected child abuse or intent to hurt yourself or others.

The University of Maryland, Baltimore has rules to protect information about you. Federal and State laws also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

Generally, only people on the research team will know that you are in the research study and will see your confidential information. The people working on the study will collect information about you. They may collect other information including your name, address, date of birth, and medical details related to your HIV disease.
Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the University of Maryland Institutional Review Board (IRB) that oversees the safety of this research, other representatives of the University of Maryland Medical System, and the sponsor of the study the Patient Centered Outcomes Research Institute (PCORI), its monitors, auditors or representatives. More information about the sponsor can be found on the website www.pcori.org.

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

The data from the study may be published. However, you will not be identified by name. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

RIGHT TO WITHDRAW

Can you leave the study early?

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. There will be no adverse consequences for you if you decide to withdraw from this study.

There are no adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research.

If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator **Carla Alexander, MD at 410-328-7129.**

If you withdraw from this study, already collected data may not be removed from the study database. You may be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study. If you are an employee or student, your employment status or academic standing at UMB will not be affected by your participation or non-participation in this study.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. The possible reasons for removal include:

- Staying in the study would be harmful.
- You fail to follow instructions.

The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

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UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

Date: _____

_____
Investigator or Designee Obtaining Consent Signature

Date: _____