

**CENTER FOR ADHERENCE SUPPORT EVALUATION (CASE)  
CLIENT CONSENT FORM**

**Purpose of Study**

The Center for Adherence Support Evaluation (CASE) is conducting an evaluation of eleven programs throughout the country to learn how best to help people living with HIV to take their HIV medications as prescribed. You have been asked to be in this study because you have enrolled in a medication adherence support program at [NAME OF INSTITUTION]. This national evaluation study is a separate from the study that you are participating in at [NAME OF INSTITUTION].

**Study Procedures**

Your participation in this study is totally voluntary. If you agree to participate, you will talk to a trained research interviewer about your health, what you know about taking HIV medications, and how you feel about taking them. You also may be asked questions about your mental health, drug use, and information about your personal background.

If you decide to participate, you will be interviewed by a *trained research* interviewer at the time of your intake visit to the adherence support treatment program, and four more times after that over a 12-month period. The interviewer who talks to you on your first visit may not be the same person you speak with at your follow-up interviews. If you decide to participate, you may choose not to answer any question that makes you uncomfortable and can stop the interview at any time. The interviews will last about 25 to 30 minutes *depending on the length of the interview form your site chooses to use*. You understand that some of the information needed for this study, including how and when you became associated with [NAME OF INSTITUTION], the kind of other services you use, your laboratory results, and your taking the HIV medications prescribed by your doctor, will be collected from your medical record. This will help to keep the interview as short as possible.

**Alternative to Study Participation**

If you decide NOT to participate in this study, you can continue to receive services at [NAME OF INSTITUTION]. Your refusal to participate will have no effect on your ability to receive services at our clinic/agency.

**Benefits and Risks**

You understand that you may not personally get any direct benefits from being in this study. However, the answers you give will be used to identify the needs of other persons living with HIV at [NAME OF INSTITUTION] and other centers across the country.

To protect your confidentiality, your name or other identifying data about you will not be recorded on the interview. Research records will be kept in a locked file and will be available only for research staff involved in this study. Your answers will remain confidential; answers will not be shared directly with non-research staff at any time at [NAME OF INSTITUTION]. To protect you, the staff will not give your name to anyone. Some of the questions you are going to be asked by the interviewer may be the same questions that you will be asked by your HIV providers during your scheduled appointments. You understand that the information that you give to the interviewer will not be shared with your HIV providers. The information for this evaluation study is completely separate from your scheduled medical and other service visits.

There is a slight possibility that the kind of questions you will be asked may be upsetting. If you become upset, you may ask to be referred to a staff member at [NAME OF INSTITUTION] who will attend to you. You understand that this study has been designed to keep information confidential but there is a small risk that the information you provide may become known by other people.

**Compensation**

There is no compensation for clients to participate in the cross-site evaluation, although a number of sites have defined incentives for participation in their local studies.

**Questions**

If you have any questions about this study at any time, you can call Dr. Ruth Finkelstein, Principal Investigator, New York Academy of Medicine, at (212) 822-7237. If you have any questions about your rights as a research participant, you may call Dr. Alan Fleischman, Chairman, Institutional Review Board at the New York Academy of Medicine at (212) 822-7219.

The New York Academy of Medicine’s Institutional Review Board for the Protection of Human Subjects has approved this study and the recruitment of subjects.

**Refusal or Withdrawal of Participation**

**You agree to participate in this study. You understand that your participation is totally voluntary. You can choose not to be in the study, and can refuse to answer a particular question or withdraw your consent at any time. You understand that anything said in the interviews is confidential.**

**Consent to Participate in the Study**

You hereby agree to participate in the New York Academy of Medicine’s Center for Adherence Support Evaluation Cross-Site Evaluation Study. You have been given a copy of this consent form to keep.

\_\_\_\_\_  
**Signature of Participant**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Signature of Person Obtaining Consent**

\_\_\_\_\_  
**Date**