ALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY
MONTEFIORE MEDICAL CENTER OF YESHIVA UNIVERSITY

Individual Information and Consent Form

You are being asked to join this research study.
The title of the study is: *A trial of Positively Smoke Free group therapy for HIV-infected smokers*

The study is being done under the supervision of:

Principal Investigator (Researcher Conducting the Study): Jonathan Shuter, MD
Office Address: Montefiore Medical Center/AIDS Center/111 E 210th St., Bronx, NY 10467
Telephone #: 718-920-7845
Protocol #: 2013-260-000

DO I HAVE TO TAKE PART IN THIS RESEARCH STUDY?

- Your participation is voluntary. This means that you decide whether or not you want to join the study after speaking with the researcher, or other member of the research team.
- If you decide to take part you will be asked to sign this consent form. Your signature means that you agree to be a subject in this research.
- After reading this form and having a discussion about what it says, you should ask all the questions you want to ask. You should take as much time as you need to make a decision.
- If you do not understand some of the terms used in this form, ask the person who is discussing the study with you to give any additional information that may make this easier to understand.
- You do not have to consent to participate in the study immediately, or ever. Take time to decide whether or not you wish to join. You may take home a copy of this consent form to think about it or discuss the information with family or friends before you decide.
- If you decide not to participate the care providers it will not affect any of the care that you receive at this facility. You will be given a copy of this form whether or not you agree to participate in this study. Do not sign the form unless you have had all your questions answered and understand exactly what is involved.
- If you decide to take part you are still free to withdraw at any time without giving a reason. This will not affect any care that you receive at this facility.

STUDY SPECIFICS

This is a study of a group therapy program that was designed to help HIV-infected cigarette smokers quit smoking.

WHY HAVE I BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You have been asked to take part in this study because you have HIV infection and you smoke cigarettes. If you agree to take part in this study you will have to answer some questions to make sure that you qualify for the study.

WHY IS THIS RESEARCH STUDY BEING DONE?

- Cigarette smoking increases the risk of heart disease, lung disease, cancer, pneumonia, many other illnesses, and death. These risks are even higher in smokers living with HIV.
- Many treatments are known to help smokers to quit, but little is known about whether they can help HIV-infected smokers to quit.
- Group therapy programs have helped many smokers to quit, but programs designed specifically for HIV-infected smokers have not been available until now.
- This study will look at whether HIV-infected smokers who participate in the Positively Smoke Free group therapy program quit at higher rates than those who receive brief advice to quit.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

If you qualify for this study, you will be assigned by chance (like flipping a coin) to one of two treatment groups. You will have an equal (1 to 1) chance of being assigned to either of the two groups. These are the groups:

- The intervention group. This group will be asked to participate in the Positively Smoke Free group therapy. At the first visit, they will be given a choice of a day or evening group to join and they will be given a date for the first group meeting. Each group will include approximately 6 to 8 HIV-infected smokers, and the groups will be led by trained smoking cessation counselors, one of whom is an HIV-infected ex-smoker. 8 group sessions will be scheduled over 7 weeks (approximately one session per week). Study staff will call you before each session to remind you to come. The groups will last approximately 90 minutes each. A meal will be served for free before each session. A prescription for a 3 month supply of nicotine patches will be offered to all persons who enter the study.
- The control group. This group will receive "standard care" for their smoking, including advice to quit and a quit-smoking brochure. A prescription for a 3 month supply of nicotine patches will be offered to all persons who enter the study.
- Everyone in the study will be asked to complete 4 study visits. The first visit will take place on the day that you sign-up for the study, the second about 4 weeks after that, the third about 4 months after signing up for the study, and the final visit about 7 months after signing up for the study. At the end of the 4th visit, you will have completed the study. At each of the study visits, you will be asked to complete a questionnaire on a computer containing questions about your medical history as well as a number of questions about parts of your life that may affect your cigarette use. Study staff will be nearby to help in case you have trouble reading the questions or using the computer. At each study visit, you will be asked to breath into a machine that measures your exhaled

carbon monoxide. This is a chemical in the breath that increases with cigarette smoking. Each study visit will take approximately 60 minutes.
- At enrollment, medical records including CD4 counts and HIV viral loads will be collected by the investigators for analysis.

WHAT ARE THE POSSIBLE DISCOMFORTS, RISKS OR INCONVENIENCES I CAN EXPECT FROM BEING IN THIS RESEARCH STUDY?

- If you quit smoking when you are in this research study, you may experience withdrawal symptoms such as headache, fatigue, craving for cigarettes, sweating, sleep problems, and other minor physical complaints. These symptoms usually clear up within 14 days of not smoking.
- Some people experience worsening of psychiatric conditions, such as depression or anxiety, while they are quitting. If this happens to you, you are expected to call your medical care provider, one of the clinic's mental health workers, or proceed immediately to the emergency department.
- If you use the nicotine patch, you may have some skin problems, such as a rash where the patch is in contact with your skin. You may also experience stomach upset if the dose of the patch is too high or if you smoke while you are using the patch. You may experience disturbed or restless sleep and vivid dreams. You could have an allergic skin reaction to the patch, but this is not as likely to happen. You can decrease any skin irritation from the patch by changing the site you apply the patch to on your body each day. You cannot use a nicotine patch while you are still smoking or if you are pregnant or planning to become pregnant.
- If you experience any of the symptoms described above or you have any questions about the patch, you are expected to call your health educator as soon as possible. In the event of any unexpected, potentially harmful effects of the nicotine patch used in this study, we will watch your condition closely and start appropriate treatment.
- Anytime that a study collects personal information about you, there is a risk to your privacy. We will take measures to protect your privacy, but there is always a risk that your personal information will be seen by a person or persons whom you didn't give permission to. Since this study includes a group therapy program the other members of your group will know that you are HIV-infected and that you smoke. The thoughts, feelings, and opinions that you share at the group sessions will also be heard by the other group members. We will advise everyone in the group that they should respect the privacy of all other members, but we cannot guarantee the privacy of what you share at the group sessions. All of the computer information gathered in the study will be stored on password-protected computers in order to protect the privacy of study participants.

<u>Certificate of Confidentiality</u>

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study was requested or subpoenaed by government agencies or the courts, we will use the Certificate to legally refuse to provide it. This is rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of

situations that the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for a review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, 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.

ARE THERE LIKELY TO BE ANY BENEFITS TO TAKING PART IN THIS RESEARCH STUDY?

There may or may not be direct medical benefit to you from being in this research study.

- Possible benefits are receiving help in your attempt to quit smoking.
- In addition, the information learned from this study may, in the future, benefit other people with the same medical condition.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS RESEARCH STUDY?

If you choose not to take part in this study, you are free to discuss quitting smoking with your primary care provider.

- You may choose not to participate in this study.
- You may continue smoking, although many studies have shown that this is harmful to your health.

WILL I BE PAID FOR BEING IN THE STUDY?

- You will receive $30 and one roundtrip public transportation fare at the end of each study visit.
- If you are in the intervention group, you will receive one roundtrip transportation at the end of each group session. You will be provided a free meal before each group session. You will not be otherwise paid for attending group sessions.

WHO MAY SEE MY RECORDS?

- The research records will be kept private and your name will not be used in any written or verbal reports.
- Your research records and medical records may be inspected by members of the research team, the sponsor(s), and other institutions that participate in this study. These are: Georgetown University, the National Institutes of Health (NIH), and/or Department of Health and Human Services (DHHS).
- Support for this study is provided by: The National Institutes of Health.
- The researcher and research staff will review your medical records and will keep the information private.

- The research records will be kept in a secured manner and computer records will be password protected.
- The people who reviewed this research study as members of the Einstein Institutional Review Board (IRB) may also review your research and medical records.
- The Office of Human Research Protections (OHRP) may also review your research study records.
- All of these groups have been requested to keep your name private.

WILL THERE BE ANY COSTS TO ME?

- There will be no costs to you for participating in this study.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

Researcher's Name: Jonathan Shuter, MD; Montefiore Medical Center, Schiff 2; 111 E 210th St.; Bronx, NY 10467; 718-920-7845.

If any questions arise related to this research project, or you believe you have any injury related to this study, you can call the researcher above.

- You may also call: Ms. Carol Rosario at 718-920-2129 .
- If you have questions regarding your rights as a research subject, you may also call the Manager of Einstein IRB at (718) 430-2253, Monday through Friday between 9 AM and 5 PM.

CAN I BE ASKED TO STOP PARTICIPATING IN THIS STUDY BEFORE THE STUDY IS FINISHED?

Yes, you can be asked to stop if:

- The National Institutes of Health (NIH), Montefiore Medical Center, or Georgetown University cancels the study.
- You are unwilling or unable to complete the study questionnaires or exhaled carbon monoxide measurements.

MAY I STOP THE STUDY AT ANY TIME?

- Your participation in this study is voluntary and you may withdraw from the study at any time without giving a reason.
- If you agree to participate and withdraw at a later time, some of your information may have already been entered into the study and that will not be removed.
- Your treatment by doctors and staff at the institution(s) involved in this study, now and in the future, will not be affected in any way if you agree to participate and withdraw later.
- Your decision not to be in this research study will not result in any loss of benefits to which you are otherwise entitled.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS RESEARCH STUDY?

- Your participation in this study is voluntary.
- You do not waive any of your legal rights by participating in this research study.
- Your treatment by doctors and staff at the institution(s) involved in this study, now and in the future, will not be affected in any way if you refuse to participate or if you enter the study and withdraw later.

Informed Consent Signature Page

The following is a list of items we discussed about this research study. If you have any questions about any of these items, please ask the person who is discussing the study with you for more information before agreeing to participate.

- What the study is about.
- What I must do when I am in the study.
- The possible risks and benefits to me.
- Who to contact if I have questions or if there is a research related injury.
- Any costs and payments.
- I can discontinue participating in the study at any time without penalty.
- Other choices.
- All written and published information will be reported as group data with no reference to my name.
- I have been given the name of the researcher and others to contact.
- I have the right to ask any questions.

_____	_____	_____
Printed Name of Participant	Signature of Participant	Date

_____	_____	_____
Printed Name of Person Conducting the Informed Consent Process	Signature of Person Conducting the Informed Consent Process	Date