QALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called **Self-Control and Adult Cigarette Smokers.** Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." Her name is Dr. Andrea Weinberger.

You can reach Dr. Weinberger at:
1165 Morris Park Ave
Bronx, NY 10461
(718) 430-3946

For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research participant you may contact the IRB office at 718-430-2253 or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Support for this research study is provided by department funds.

Why is this study being done?

The purpose of this study is to learn more about self-control and adults who smoke cigarettes. It has been suggested that people can improve self-control by practicing tasks that require the use of self-control (such as delaying cigarettes or sitting up as straight as possible). The goal of this study is to learn about whether scores on self-control and other measures will change after one week of practicing self-control tasks at home. We believe that adults who smoke cigarettes will show better self-control after practicing tasks for a week.

Why am I being asked to participate?

You are being asked to participate in this study because you are an adult who is 18 years old or older, you currently smoke cigarettes every day, and you are not currently trying to quit smoking and you are not using medications or other treatments to stop smoking. This is a single site study (meaning that the study takes place at one location) and we plan to include 150 people in the study.

How many people will take part in the research study?

You will be one of about **150** people who will be participating in this study.

How long will I take part in this research?

It will take you about one week to complete this research study. During this time, we will ask you to make 2 study visits to Ferkauf Graduate School of Psychology.

What will happen if I participate in the study?

The Screening Visit (Study Appointment 1) will take about 1 hour to complete. During this visit, we will ask some questions and go through some procedures to see if you are eligible to take part in this research study. The study staff or PI will review the results of these tests and procedures. If you are not eligible, the study staff will tell you why. If you are eligible, you will be asked to:

- Provide demographic information (such as gender and age).
- Fill out some questionnaires about your general health and well-being, smoking, self-control, personality, and mood.
- Give a breath sample as a measure of current smoking.
- Go through a procedure that involves squeezing a hand-grip as long as you can twice.

At the end of the study visit, you will be scheduled to come back for the second study appointment one week later. During the week you will be asked to practice a task at home. You will be randomly assigned (like a coin toss) to a task. For example, you might be asked to delay smoking or to try to pay attention to your posture and sit or stand as straight as possible. You will also be asked to complete some questions each night about how much you practiced the task, how difficult the task was, and how many cigarettes you smoked that day.

Visit 2 (Study Appointment 2) will take approximately 30 minutes to complete. At this visit we will ask you to:

- Fill out some questionnaires about your general health and well-being, smoking, self-control, personality, and mood.
- Give a breath sample as a measure of current smoking.
- Go through a procedure that involves squeezing a hand-grip as long as you can twice.

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

This study will not involve genetic research or genetic testing.

Will I be paid for being in this research study?

You will receive $20 for completing the entire first study appointment and $30 for completing the entire second study appointment. This means you can receive a total of $50 for completing both of the 2 study visits. If you choose to withdraw from the study before all visits are completed, you will be paid only for the visits that you completed.

Will it cost me anything to participate in this study?

There will be no cost to you to participate in the study.

What will happen if I am injured because I took part in this study?

If you are injured as a result of this research, only immediate, essential, short-term medical treatment, as determined by the participating hospital, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document.
- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems, or injuries that you experience during the course of your participation in the study to Dr. Weinberger at (718) 430-3946.

What else do I have to do?

- You may carry out all your normal daily activities.

Are there any risks to me?

Confidentiality
We will keep your information confidential, however, a risk of taking part in this study is that your confidential information might be shared accidentally with someone who is not on the study team and is not supposed to see or know about your information. This is very unlikely, because the study team takes confidentiality of your information seriously. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password-protected. Your study information will be kept as long as it is useful for this research.

The only people who can see your research records are:
- the research team and staff who work with them.
- the organization that funded the research.
- groups that review research (the Einstein IRB and the Office for Human Research Protections).

These people who receive your health information may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

Are there any times you would not keep my data confidential?
If you give us information that suggests that your child or any other child is being abused, we are required by law to report that information to the Administration for Children's Services (ACS). Reporting this information may put you, your family, or others who are involved at risk of questioning and legal action by the authorities.

If you give us information that suggests that you may hurt yourself or someone else, or if you report abuse of a child, elderly person, or person with a developmental disability, then members of the research team will make a report to the appropriate authorities.

Questionnaire
You may feel uncomfortable answering questions about your smoking behavior or your current mood. You can choose not to answer questions that make you feel uncomfortable.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Are there possible benefits to me?

You will not experience any direct benefit personally from participating in this study. We hope that you will participate because the study will generate important information about learning more about your smoking behavior. You will receive information about your smoking level from the breath sample and about your strength from the hand-grip test.

What choices do I have other than participating in this study?

You can refuse to participate in the study.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part in the study, you are free to stop participating at any time without giving a reason. However, some of the information may have already been entered into the study and that will not be removed.

Can the study end my participation early?

We will not let you participate in the study anymore if you report that you are planning to hurt yourself or someone else. In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date	Time
Printed name of the person conducting the consent process	Signature	Date	Time