RUTGERS
Robert Wood Johnson
Medical School

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title Of Study: Evaluating Persistence in Smokers with Schizophrenia

Principal Investigator: Marc L. Steinberg, Ph.D.

This form is part of an informed consent process for a research study and it will give information that will help you to decide whether you wish to volunteer for this research study. It will help you understand what the study is about and what will happen during the study.

If you have questions at any time during the study, you should feel free to ask. We will give you answers that you completely understand.

After all your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Who is conducting this research study?
Dr. Marc Steinberg is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the study. However, there are often other individuals who are part of the research team.

Dr. Steinberg may be reached at 732-235-4341 and/or 317 George Street, Suite 105, New Brunswick, NJ 08901.

A member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

This study is sponsored by the National Institute on Drug Abuse.
The principal investigator is being paid to conduct this study according to a budget that will cover the costs of the study, including the costs of collecting all of the information required by the study.

Why is this study being done?
We want to learn how to best help smokers with schizophrenia to quit smoking. We are examining a new counseling approach based on cognitive behavior therapy. Cognitive behavioral therapy is a commonly accepted treatment for smoking cessation.

Why have you been asked to take part in this study?
You have been asked to take part because you are an adult smoker with schizophrenia or schizoaffective disorder who is motivated to quit.

Who may take part in this study? And who may not?

You may take part in this study if you:

- Are between 18 – 64 years old.
- Are committed to quitting smoking in the next month.
- Smoked at least 5 cigarettes (including those labeled "little cigars") per day for past 6-months.
- Have a diagnosis of Schizophrenia or Schizoaffective Disorder.
- Have a working phone.
- Record greater than 5ppm on carbon monoxide monitor.
- Score less than 8 (or less than 7 for women) on the "Alcohol Use Disorders Identification Test."
- Score less than 3 on the 6-month "Drug Abuse Screening Test-10."

You may not take part in this study if you:

- Currently receive smoking cessation counseling.
- Currently take any FDA approved smoking cessation medicine daily within the past 10 days
- "Test positive" on a urine drug screen for cannabis, cocaine, or opiates. Note: Participants testing positive for opiates may participate with proof of prescription.
- Have been in the hospital for a psychiatric issue in the past 8 weeks.
- Have not been on the same dose of your psychiatric medicine for at least 8 weeks.
- Report chest pain, a heart attack, or significant irregular heartbeat in the past 90 days.
- Are pregnant, breastfeeding, or planning on becoming pregnant in the next 4-months.
- Have pending legal matters with potential to result in jail time.
- Are planning on moving outside local area in next 3-months.

How long will the study take and how many subjects will participate?
We expect 26 subjects to participate. Each subject will meet with the research team eleven (11) times over 4 months (Assessment part 1, assessment part 2, 8-weekly counseling sessions, 3-month assessment).

What will you be asked to do if you take part in this research study?
You will visit our offices 11 times. Visits 1 and 2 are "baseline" assessments. Visits 3 through 10 will be free counseling sessions. Visit 11 is a "followup" assessment.

At your "baseline" session, you will complete standard questionnaires about tobacco use and mental and physical health. Women will take a pregnancy test to rule out pregnancy. You will take a urine drug screen to rule out illegal drug use. You will also answer questions about your age, gender, race, and other demographic information. You will repeat some of these questionnaires every week. You will also complete tasks that measure something called "persistence," such as breath-holding endurance and a mirror tracing task at your first session, at session 4, at your final counseling session, and at the 3-month assessment.

In between sessions, we will ask you to record your cigarette use each day. You will be asked to provide a carbon monoxide reading at each appointment. This involves breathing into a machine that provides a digital read out of expired carbon monoxide (CO).

Questionnaires will take approximately 1.5 hours to complete at your first two appointments. You will complete questionnaires taking up to 10 minutes before your counseling sessions at counseling session 1, 2, 3, 5, 6, and 7. Questionnaires may take

approximately 45 minutes at counseling session 4 and 8 and at the final assessment appointment. The counseling sessions will occur weekly and will last for 50-minutes each. All appointments will take place in our offices at 317 George Street, New Brunswick, NJ 08901. If necessary, we may complete assessments over the phone.

We will give you free nicotine patches for 10 weeks and free weekly, individual counseling will for 8 weeks.

We will audiorecord therapy sessions to ensure that counseling is provided as intended.

What are the risks and/or discomforts you might experience if you take part in this study?
The Nicotine Transdermal Patch ("the patch") has few side effects and is sold over the counter in the United States. Potential side effects of the nicotine patch include dizziness, headache, nausea, vomiting, diarrhea, or redness or swelling at the patch site. In addition, smokers who have serious arrhythmias (a disorder of the heart rate (pulse) or heart rhythm, such as beating too fast, too slow, or irregularly) or have chest pains due to coronary artery disease should use the patch with caution.

You may experience some nicotine withdrawal when you quit smoking. If symptoms arise, they will be addressed as part of your treatment.

Also, there is a risk that your confidentiality could be violated. To reduce the risk of violating confidentiality, several steps will be taken. Only IRB approved members of the research team will have access to the data. The research staff collecting the data will bring the data to the PI within 24 hours of it being collected. Data will only be accessed when coded, entered, or audited. The PI will maintain responsibility for safe data storage. All data will be stored in locked cabinets within locked rooms. Based on these procedures, we anticipate that the risk to confidentiality is very low.

There is also a slight risk of feeling distress and frustration when completing our questionnaires and participating in counseling sessions; however, this is minimal and can be addressed by our addiction psychiatrist or clinical psychologist at any time.

Please call 911 if you have a medical emergency or Acute Psychiatric Services (APS) at 855-515-5700 if you experience a psychiatric emergency.

Are there any benefits for you if you choose to take part in this research study?
The benefits of taking part in this study includes access to high-quality, evidence-based smoking cessation treatment. If you quit smoking you will experience health benefits, however, you might receive no direct benefit from taking part in this study.

What are your alternatives if you don't want to take part in this study?
Clinical practice guidelines for smoking cessation recommend getting behavioral support plus at least one of the seven FDA approved medications for smoking cessation. If you choose not to take part in this study, we will provide you with information regarding other options that can help you receive these treatments. Examples include a free telephone QuitLine or a local smoking cessation clinic.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to go on taking part in the study. If we learn of information that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?
There is no cost to you to take part in this study other than the cost of your travel to attend our sessions.

Will you be paid to take part in this study?
You will receive reimbursement for your time for completing assessment measures of up to $100 based on the following schedule:

- $10 at the baseline assessment #1
- $30 at the baseline assessment #2
- $10 at the Quit Date assessment
- $30 at the final counseling session assessment
- $20 at the 3-month post-quit date assessment

How will information about you be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

Only IRB approved members of the research team will have access to the data. All data will be stored in locked cabinets within locked rooms.

All computer files will be kept on computers requiring login and complex passwords for entry. All files with identifying information will have the extra protection of a password to open that individual file. Your personal information will be kept separate from your study data and linked only by a study number. Your name will not be used in any publications or papers derived from this study.

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: Disclosing knowledge of child or elder abuse, or potential harm to self or others.

A description of this clinical trial will be available on 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.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?
Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of your data, but you must do this in writing to Dr. Marc L. Steinberg; Division of Addiction Psychiatry; 317 George Street; Suite 105; New Brunswick, NJ 08901

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can you call if you have any questions?
If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study principal investigator:

Marc L. Steinberg, Ph.D., Department of Psychiatry, **732-235-4341**

If you have any questions about your rights as a research subject, you can call the Institutional Review Board (IRB) Director at **(732)-235-9806** and Human Subject Protection Program at **(732)-235-8578.**

What are your rights if you decide to take part in this research study?
You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions

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PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Information about you and your health is personal and private, so this information generally cannot be used in research without your written permission. The next few paragraphs tell you about how researchers want to use and share your health information in this research study. Your information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your health information. If you sign this consent form, you agree to let the researchers use your information in the research and share it with others as described below.

What is the purpose of the research and how will my information be used?
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?
- Medical history or treatment
- Medications
- Laboratory/diagnostic tests or imaging
- Psychological testing, surveys or questionnaires

Who may use, share or receive my information?
The research team may use or share your information collected or created for this study with the following people and institutions:
- Rutgers University researchers involved in the study;
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- A data safety monitoring board (DSMB)
- National Institute on Drug Abuse (NIDA)
- Federal Drug Administration (FDA)

Those persons or organizations that receive your information may not be required by federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this research study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study).

If I say yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision: Dr. Marc Steinberg, 317 George St., Suite 105, New Brunswick, NJ 08901.

How long will my permission last?

Your permission for the use and sharing of your health information will last until the end of the research study.

Rutgers, The State University of New Jersey IRB
Audio/Videotape Addendum to Consent form

By signing below, you are agreeing to participate in a research study conducted by Marc L. Steinberg, Ph.D. We are asking for your permission to allow us to audio record your sessions as part of that research study.

The recording(s) will be used for analysis by the research team and for training clinicians.

The recording(s) will include your ID number and date of your counseling session.

Digital audio files will be stored on password protected computers and the files themselves will be password protected and encrypted using the Advanced Encryption Standard 256 method (AES-256). Files will be linked with your ID number. Files will be destroyed 6 years after the protocol is closed.

Your signature on this form grants the investigator named above permission to record you as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written permission.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legally authorized representative have been accurately answered.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____