The Ohio State University Consent to Participate in Research

Study Title: The Ohio State University and The Bellevue Hospital Smoking Cessation Initiative

Researcher: Joseph P. Green, Ph.D.

Sponsor: Psychology Department

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form (available upon request either in hard copy or from the study's website). You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

The Ohio State University at Lima and The Bellevue Hospital are teaming up to offer area residents a way to stop smoking. The seven-week treatment program and research study will examine how effective our program is to help you stop smoking. The program, developed by psychologists Joseph Green and Steven Lynn, is based on research and clinical observations of self-empowerment programs designed to help people stop smoking. Participants will also receive a six weeks supply of the nicotine patch. Terry Webb, a respiratory therapist at The Bellevue Hospital and an experienced *Tobacco Treatment Specialist* and smoking cessation group leader will co-facilitate the program.

We expect that the program will be effective in helping you to stop smoking. As you know, stopping smoking is not easy. Individuals are different and progress at different paces. Some people need more than one attempt before they successfully stop smoking.

Although we cannot guarantee success, we believe that our program gives you the "winning edge" that you need to achieve your goal.

The purpose of the program is two-fold. First, we wish to assist as many people as possible to stop smoking and help them enjoy a healthy, smoke-free life. Second, we hope to show that our program is effective. By collecting data throughout the program, we hope to better learn how people overcome the habit of smoking.

2. How many people will take part in this study?

We will conduct the study in small groups (typical group size may be 8-20 people). We plan to run the program multiple times over the course of several years in an effort to collect enough data (from upwards of 200 people) to find patterns in how people best learn to stop smoking.

3. What will happen if I take part in this study?

The Program:

In this program, you will learn a number of strategies designed to help you to stop smoking. These strategies are based on principles of change that have been studied by psychologists for many years. You will be given an opportunity to learn self-hypnosis to achieve your goal of becoming a non-smoker.

You will practice visualizing yourself as a non-smoking person. Social support is a key part of our program: We will run the sessions in groups and you'll be encouraged to tell family members and others about your goal to become a non-smoker. You will learn about the dangers of smoking and how to cope with urges to smoke.

Should you choose to participate, you will be asked to complete a number of questionnaires about your personality (e.g., likes and dislikes) and describe your smoking history. You will receive audio CDs, a DVD describing our program that you can watch at home, and several educational handouts and recording sheets.

Outline of Sessions:

1. Orientation and Assessment (approximately 2 hours).

During this first meeting, we will describe our program, answer any questions, distribute and collect consent forms, have you complete a number of questionnaires, and ask about your smoking history. You will also complete, in a group format, a short imagination exercise where you will be invited to imagine a number of scenes, scents, and sounds Privately (in a separate room), we will measure your height and weight and conduct a carbon monoxide breath test. This test involves you breathing into a tube connected to a hand-held sensor that can detect how much you are smoking.

2. Treatment Session One: Learning the Strategies (approximately 2 hours).

The first session features a slide presentation about the dangers of smoking, strategies to cope with smoking urges, how to learn healthy behaviors instead of smoking, why it is important to have friends and family give you support, and instructions to record how

often you smoke. Throughout the session, you will be invited to share your experiences and to discuss and react to the information presented. We will educate you about clinical hypnosis and go over common misconceptions about hypnosis. You will learn *self-hypnosis* where you hypnotize yourself and give yourself suggestions to live a healthful, smoke-free life.

The hypnosis component will be presented to the entire group. You will be given a home-practice CD (lasting approximately 12 minutes) and will be instructed to listen to it daily for one week. You will also be given a one-hour DVD copy of the educational program so that you may review it at home. We encourage you to watch the DVD with a family member or close friend. It will help you remember what you have learned in the program. You will also receive handouts and sheets to record how often you smoke. We will ask you to jot down how often you listen to the practice CD between treatment sessions 1 and 2, and how often you smoke during this time.

You will be asked to begin to cut down on the number of cigarettes you smoke between the first and second treatment sessions. *The next session is when, hopefully, you will stop smoking for good!* We will refer to this next session as your "Stop Smoking Forever! Night."

3. Treatment Session Two: Stop Smoking Forever! Night (approximately 2 hours)

As the second treatment session begins, you will turn in your recording sheets from the previous week. We will, once again, meet in a group, and you will be invited to discuss your progress up to this point. You will be invited to ceremonially discard into a trash bin a cigarette or other some other smoking-related object (e.g., an old ashtray or lighter) or a picture of such an object that we will provide to you. You'll participate in a second hypnosis-based session that is "longer and stronger" than the one from the previous week. You will be given a second CD (lasting approximately 25 minutes) to listen to daily for at least one week after this session.

You will receive a two-weeks supply of nicotine replacement therapy in the form of the nicotine patch. The patch will be provided to you free of charge, and we will discuss its proper use. You can supplement the patch with nicotine gum and/or nicotine lozenges, as needed, but you will have to purchase these products on your own.

After this treatment session - dubbed your "Stop Smoking Forever! Night" - you should plan on not smoking again.

4-5. Support Sessions (held at two and four weeks after Treatment Session Two)

We will hold group support sessions during weeks 5 and 7. These sessions will last approximately 30 minutes. During these meetings, you will be asked to discuss your progress and we will review program materials.

You will receive an additional two-weeks supply of nicotine patches at each of these sessions. In total, you will receive a six weeks supply of nicotine patches during the program.

Follow Up Assessments:

Because this is a clinical research study, we will collect information at various times during assessment, treatment, and follow up. At three-month follow up, you will be

scheduled for an individual appointment at The Bellevue Hospital to complete a second carbon monoxide breath test and a brief interview. This breath test is the same one that you completed earlier.

Short follow up assessments (by email or phone or mail) will also occur at 6, 12, and 24 months (each should take no longer than 5-10 minutes to complete).

4. How long will I be in the study?

Duration and Timeline:

- The initial assessment session and the two treatment sessions will last approximately 2 hours and will be scheduled one week apart.
- You will be asked to watch a DVD (1 hour) on your own and record your smoking during the first month of treatment.
- You will be instructed to listen to an audio CD on a daily basis for the first few weeks of treatment (CD-1 lasts approximately 12 minutes; CD-2 lasts approximately 25 minutes).
- About 1-2 weeks after the second treatment session, a member of the research team will contact you via telephone to briefly discuss your progress.
- Two group support sessions will be held during weeks 5 and 7 and should last approximately 30 minutes each.
- The 3-month follow up appointment, scheduled individually at The Bellevue Hospital, will last about 10 minutes.
- Long term follow up contacts (6, 12, and 24 months) will be brief and can be done over the phone, each lasting 5-10 minutes.

Total Time Commitment: If you participate in all of the treatment sessions, complete the follow up sessions, watch the DVD as instructed, listen to your CDs on a daily basis across three weeks of treatment, and complete the monitoring and other assignments, *we estimate that you will invest approximately 25 hours in the program over the course of the next two years.* While this may seem like a large time commitment, we encourage you to focus on the payoff – being a nonsmoker for life!

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University or The Bellevue Hospital. If you miss a session or an appointment, we may call (or email) you to determine whether you wish to continue with the program and/or reschedule.

If you wish to stop participating, please let Terry Webb know. She can be reached at 419-483-4040 Ext. 4244; or, twebb@bellevuehospital.com

6. What risks, side effects or discomforts can I expect from being in the study?

Completing the questionnaires used in this study does not pose any unique or unusual risk, beyond the time required to complete the program. Most studies using science-based hypnosis, such as those used in this study, report few, if any, negative effects. Research shows that the risks of participating in a hypnosis session are similar to those associated with sitting through a lecture, taking an exam, or completing a paper and pencil task of a similar duration. For example, after taking an exam, completing a series of questionnaires, or following a hypnosis study, a small number of individuals have reported experiencing a headache, muscle stiffness, nausea, or feeling tired. These reported "symptoms" were short lasting. It is quite likely that many of these discomforts were due to factors other than the procedures that were used in the study itself (e.g., the person might not have been feeling well before they came to the session). In summary, the risks of participating in this study are judged to be similar to those that you would likely experience by sitting through an exam or completing a series of questionnaires lasting a couple of hours.

You will be asked to use your imagination – seeing yourself in pleasant scenes and successfully resisting the urge to smoke. The strategies used in this study are designed to help you to make better decisions in your life, to better manage your time and daily routines, and to find the support of others. You are always in control of what you do during the sessions. You *can choose to respond* or *choose not to respond* to any suggestion.

As you know, some people trying to stop smoking experience nicotine withdrawal symptoms (e.g., nausea, headaches, depression, insomnia, irritability, anger/frustration, appetite and weight changes, and cravings for nicotine). It is important to note that not everyone experiences these symptoms, and that usually these withdrawal effects are temporary and manageable. You can think about these symptoms as signals that your body is healing and adjusting to living without the toxins of smoking. Our program will teach you how to deal with these symptoms should they occur.

Although most people do not experience significant problems with the use of nicotine replacement, there is a risk of negative reactions (see the next section for a list of possible side effects). We will discuss possible side effects and ways to minimize them. While nicotine replacement products have been deemed safe to use and are available over the counter, you should consult your physician or pharmacist about whether there is any reason *for you* not to use these products. If you are pregnant, have a history of heart disease, or are taking prescription medications, you should consult your physician before starting nicotine replacement therapy.

Completion of this program clearly involves an investment of time and energy on your part. You will be asked to complete a number of questionnaires, monitor and record your smoking behavior, and permit us to contact you at various times to discuss your progress.

Reported Sided Effects to Nicotine Replacement Therapy

Many people have no, or minor, side effects to nicotine replacement. Most COMMON side effects are: Abnormal dreams; headache; mild dizziness; mild redness, itching, or burning at the application site; nervousness; sweating; trouble sleeping; vivid

dreams.

Seek medical attention right away if any of these SEVERE side effects occur: Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); blurred vision; fast or irregular heartbeat; nausea; severe or persistent dizziness or headache; stomach pain or vomiting; swelling or persistent (more than 4 days) redness at the application site.

7. What benefits can I expect from being in the study?

We believe that our program can assist people who really want to stop smoking, once and for all. We will provide, without charge, a six weeks supply of the nicotine patch.

8. What other choices do I have if I do not take part in the study?

The Bellevue Hospital provides smoking cessation programs (that do not involve hypnosis) several times each year. You may check their calendar of events to find the next enrollment period.

You can also contact the American Lung Association of Ohio to learn about smoking cessation programs that might be offered in your area.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

All information that you provide to us will be treated in a confidential manner. Once we collect information from you, we will remove the cover sheet containing your name and put in a research number. Electronic data storage will *not* contain names, only research numbers. We will store consent forms and your contact form in a secure area separate from the responses that you provide to us. We will store your response forms at The Ohio State University, Lima, for a period of time required by law or by The Ohio

State University. At the conclusion of the study, all questionnaire information and contact sheets will be shredded.

You should know that we cannot guarantee confidentiality *from other group members* or prevent *other group members* from publicly stating that you are participating in our study or discussing what you say or do in our group meetings.

You should also know that online or email transmissions can be intercepted and IP (computer) addresses identified. Although every effort to protect confidentiality will be made, there is no guarantee of internet survey security. Finally, because this project is a joint venture between the The Bellevue Hospital and The Ohio State University, Lima, data will be transported between the facilities. Although highly unlikely, there is a possibility of information being lost during transport.

10. What are the costs of taking part in this study?

There is no charge to enroll in our study. Parking is free at The Bellevue Hospital. The materials that we provide to you are yours to keep. There is no charge for the nicotine patches that we will provide to you.

11. Will I be paid for taking part in this study?

For completing the study, we will provide you with a $25 gas card as an incentive to complete the study. This card will be distributed during individual follow up assessments, three months after treatment.

By law, payments to subjects are considered taxable income.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should seek immediate medical attention at your local hospital or from your physician.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may stop participating at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Joseph P. Green, Professor of Psychology at The Ohio State University, 4240 Campus Drive, Lima OH 44811; *Phone:* 419-995-8278; *email:* green.301@osu.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Joseph P. Green, Professor of Psychology at The Ohio State University, 4240 Campus Drive, Lima OH 44811; *Phone:* 419-995-8278; *email:* green.301@osu.edu.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

CONTACT INFORMATION – PLEASE PRINT NEATLY!

Please provide the following contact information so that we may call, email, or mail you information about the study or to collect information.

NAME: _____

ADDRESS: _____

_____

_____

PHONE: **Home #:** _____

Cell #: _____

BEST TIME TO CALL YOU (morning/afternoon/evening): _____

Email: _____

Please provide the name and phone number of someone else that we may contact in the event that you move, change phone numbers, or the above information is no longer valid. We will only ask this person only for your current contact information.

FRIEND/RELATIVE'S NAME: _____

THEIR PHONE: _____

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time