Study Title: Blood Pressure Control in Hypertensive Smokers

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INFORMED CONSENT DOCUMENT

Project Title: **Blood Pressure Control in Hypertensive Smokers**

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This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are an adult who wishes to stop smoking cigarettes, and has elevated blood pressure.
The purpose of this research study is to:

- Provide smokers with hypertension (high blood pressure) or pre-hypertension (elevated blood pressure that does not yet meet the criteria for hypertension) assistance in stopping smoking
- Evaluate the effectiveness of three programs designed to help manage weight gain and control blood pressure after quitting smoking

The treatment that you will receive during this study is not intended to replace the care you may be receiving for high blood pressure from your primary care provider. Please continue your ongoing care from your personal physician throughout the duration of the study.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 912 people will take part in this study conducted by investigators at the University of Iowa. A total of approximately 2320 people will take part in this study at 3 study centers across the United States.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 14 months.

- There are 8-25 visits, depending upon which group you are assigned to
- Visits will range from ½ hour to 3 hours each
- Visits will range from days, weeks, and up to 6 months apart
- The last (follow up) visit is approximately 12 months after you quit smoking

WHAT WILL HAPPEN DURING THIS STUDY?

Study Visits

Study visits will be conducted at the Preventive Intervention Center at the University of Iowa Hospitals and Clinics (UIHC) in Iowa City. Some visits are conducted over the phone rather than in person. There is an initial screening visit to determine eligibility, and the study itself is a two part study. In the first part, every participant will complete four sessions with a health educator to address smoking cessation. If you are able to successfully quit smoking, you will then be randomly assigned to one of three treatment groups. This means that whichever study treatment group you are placed in will be determined purely by chance, like flipping a coin. You will have a 1 out of 3 chance of receiving any one of the study treatments. The 3 groups include interventions to help with weight management, to assist with blood pressure control, or self-help materials to manage weight and blood pressure on your own. The first two groups (weight management and blood pressure control) will be led by a health educator. The last group (self-help materials) will be self guided with no meetings. Finally, you will be brought back in for two follow up visits.

Screening Visit

The first visit will take about 2-3 hours to complete. During the first visit, the following procedures will be performed, and information will be obtained to determine if you are eligible to continue in this research study:

- Complete medical/surgical history–questions about past and current illnesses; it is very important that you tell your study doctor or nurse about all medical problems you have now or have had in the past, medications you have been taking, or allergic reactions you have had to medications, foods, or other allergies you have.
- Smoking history–questions regarding how much and for how long you have been a smoker and what you have done to try to quit in the past
- Urine pregnancy test (for female subjects)
- You will be asked about medications you are taking presently and over the prior three months
- Physical Examination (unless the study staff determines that you have been seen recently by a primary care provider and that you have given the study doctor permission to access your medical records) and measurements of your weight, height, heart rate, blood pressure, waist, and percent body fat. Percent body fat will be measured by a monitor the looks like a bathroom scale. The monitor has two foot sensor pads containing electrodes that send a low, safe, and painless current throughout your body. The scale can estimate body fat by the length of time it takes the signal to pass through your body.
- CO (carbon monoxide) monitoring where you will exhale into a handheld device that will measure the amount of carbon monoxide in your lungs (carbon monoxide is a gas that is found in higher levels in the breath of cigarette smokers)
- You will be asked to complete the following questionnaires: (1) a questionnaire that asks about your smoking patterns and history; (2) a short questionnaire that asks about your level of confidence in your ability to quit smoking; (3) a questionnaire asking about what you think the

advantages and disadvantages are of quitting smoking; (4) two brief interviews about health-related barriers to engaging in physical activity and how your body reacts to exercise; (5) a brief questionnaire about your level of motivation to quit smoking, and (6) a brief questionnaire about how you tend to respond to disagreements with people and discourtesies. . You may skip any question(s) that you prefer not to answer.

With your permission, we may collect information on your blood pressure from your primary care physician if you recall a recent blood pressure reading. Blood pressure readings can be quite variable. Because of this, we may have you come back to the research visit area on one or more days to have your blood pressure measured to be sure that you have blood pressure readings in the range needed for this study. We will need at least 2 documented blood pressure readings within the target range. The target range is blood pressure that is considered pre-hypertensive or hypertensive.

Smoking Cessation Visits

If you are eligible to continue in the study, you will have four sessions with a health educator to address smoking cessation, some sessions will be in person, and some may be done over the phone. Each session is about 1 hour long. You will receive an individualized program to help you prepare to quit, assist you through the quitting process, and to help prevent starting smoking again. You may also receive six weeks of the nicotine patch at no cost to you. The dosage of the nicotine patch that you receive will depend upon the number of cigarettes you smoke each day. If you smoke 20 or more cigarettes per day, you will start on the 21 mg patch. After two weeks of the 21 mg patch, the dosage will be reduced to 14 mg for two weeks. The dosage will be further reduced to 7 mg for the final two weeks that you use the patch. If you smoke 10-19 cigarettes each day, you will initially be placed on the 14 mg patch. After two weeks, the dosage will be reduced to 7 mg for the remaining four weeks that you will use the patch. If you smoke 5-9 cigarettes each day, you will receive the 7 mg patch for a period of six weeks.

Current Smoking Status: Number of cigarettes	Strength of Patch for weeks 1 and 2	Strength of Patch for weeks 3 and 4	Strength of Patch for weeks 5 and 6
20 or more cigarettes per day	21 mg	14 mg	7 mg
10-19 cigarettes per day	14 mg	7 mg	7 mg
5-9 cigarettes per day	7 mg	7 mg	7 mg

The side effects of the patch will be discussed with you, and your use of the patch will be monitored to ensure your safety. We ask that you do not use any over-the-counter smoking cessation aides (e.g. nicotine patch, lozenges, or gum) or prescription smoking cessation aides (e.g., nicotine inhaler, nicotine nasal spray, Bupropion (Wellbutrin/Zyban) or
Chantix) while you are taking the study medication.

At each session you will be asked to report any medications you are taking, any adverse events (side effects you have been feeling) and your current smoking activity, followed by a carbon monoxide (CO) assessment. On the forth cessation visit you may be asked to give a salivary cotinine test or a thiocyanate test if the CO assessment does not give a confirming result. In a salivary cotinine test, a small amount of saliva is collected to check for cotinine, a chemical that the body makes while breaking

down the nicotine you get by smoking cigarettes. In a thiocyanate test, we will have to draw approximately 1 teaspoon of blood from your arm in order to measure levels of thiocyanate in your body. The amount of thiocyanate in a person's blood provides information about their level of exposure to cigarette smoke. Blood draws to test for thiocyanate will only be done when carbon monoxide and cotinine tests may not be accurate for verifying smoking status.

Next, there will be four follow-up phone calls to encourage you to keep from smoking, help remind you of the information from the sessions with the health educator, and to offer support. These phone calls will be made in the first few months surrounding your quit date and will take about 10-15 minutes each. Finally, you will receive six mailings with information to help you keep from smoking, information about stress management, secondhand smoke, and other health related topics at 1 week, 4 weeks, 9 weeks, 7 months, 9 months, and 11 months after you quit smoking.

If you are unsuccessful in your initial attempts to quit smoking, you may be given the option of receiving the smoking cessation intervention a second time if you so choose. You will be provided with 6 additional weeks of nicotine patches (at no cost to you) during the second time. You will still be a part of the study if you go through the cessation program a second time. If you are unsuccessful in your attempt to quit smoking the second time, you will not be allowed to go through the smoking cessation program a third time and you will not be able to proceed to the weight or blood pressure intervention portion of the study. You may be contacted by phone six and 12-months later and asked to complete a questionnaire asking you about your current health and lifestyle patterns.

If you do quit smoking in your first or second round of the smoking cessation program, you will be asked to continue in the study. We may also provide you with Nicotine Gum to help you stay quit. We can provide the gum to you if you do not have conditions that would be harmful in combination, such as having dentures, TMJ (TemporoMandibular Joint) Disorder, or active Peptic Ulcer disease.

We will also provide you with some handouts about remaining smoke free, to help with staying quit.

Group Assignment Visit

If you quit smoking and are eligible to continue in the study, you will come back for a visit about seven weeks after your screening visit. This visit will take about two hours to complete. At this visit you will repeat some of the procedures from earlier visits:

- Provide current smoking status
- CO (carbon monoxide) monitoring
- Saliva cotinine tests
- Some participants may be asked to undergo a blood draw of approximately 1 teaspoon of blood from a vein in their arm in order to measure levels of thiocyanate in their blood
- Update of medical history
- Your height, weight and blood pressure will be taken and your waist circumference and percentage of body fat will also be measured
- Adverse events and use of medications will be reviewed
- Any female participant who has the potential to be pregnant will be given a urine pregnancy test.
- You will be asked to complete several questionnaires about your beliefs about your smoking.

You may skip any question(s) that you prefer not to answer

You may also be asked to undergo these additional procedures:

- An ECG or electrocardiogram (measurement of your heart activity). If the results of the test are inconclusive, you will be advised to consult with your primary care provider and will not be able to participate in the study unless you undergo an exercise stress test under the supervision of your primary care provider. In order to participate, your primary care provider and the study physician must determine that it is appropriate for you to enroll in the study based on the results of the exercise stress test and your medical history.
- There are some additional questionnaires that ask you about some of the foods you eat and your physical activity. You may skip any question(s) that you prefer not to answer.
- You will be asked to collect several small urine samples at home to test for the amount of chloride in your urine. We will provide you with the collection cups. This will be done to estimate the amount of salt in your diet. You will be asked to collect urine samples at given times, put a tester stick into the urine samples, mark the levels from the tester sticks on the record form, and mail back the record forms in the stamped, addressed envelope provided.

If you are not able to quit smoking, and therefore not assigned to one of the three treatment groups, you may be contacted by phone six and 12-months later and asked to complete a questionnaire asking you about your current health and lifestyle patterns.

Interventions

If you are able to successfully quit smoking, you will then be assigned, by chance, to one of three treatment groups:

- A seventeen session program to help with weight management (guided by health educator)
- A seventeen session program to assist with blood pressure control (guided by health educator)
- Self-help materials that were designed to help you manage your body weight and blood pressure on your own (self-guided)

Those assigned to the blood pressure control program or the weight management program will attend 5 individual and 12 group meetings, led by a health educator. Each meeting is about ½ - 1 hour long. If you have to miss a session it may be possible to make up the session over the phone. Depending on which group you are assigned to, the visits may require you to perform some of the previous procedures again. Regardless of your group assignment, you will also return for follow-up visits at six months and 12 months. Here is a list of the procedures that you will be asked to perform during one or more of the individual or group meetings:

- Provide current smoking status
- Serious adverse events and use of medications will be reviewed
- CO (carbon monoxide) monitoring
- Your height, weight and blood pressure will be taken

Follow Up Visits

If you quit smoking and were eligible to continue in the study, we ask you to come back in for visits at six and 12 months after you quit smoking so we can follow up with you. At those visits, you will repeat some of the procedures performed earlier in the study:

- Provide current smoking status
- CO (carbon monoxide) monitoring
- Saliva cotinine test
- Your height, weight and blood pressure will be taken and your waist circumference and percentage of body fat will also be measured
- Serious adverse events and use of medications will be reviewed
- You will be asked to complete several questionnaires. You may skip any question(s) that you prefer not to answer.
- You will be asked to collect several small urine samples at home to test for the amount of chloride in your urine. We will provide you with the collection cups.

You will also be asked to complete a brief questionnaire asking about your health and lifestyle patterns. Each visit should take about 2 hours to complete. As mentioned before in the Smoking Cessation program description, if you do not quit smoking during the smoking cessation portion of the study (therefore are not eligible to continue in the study) we will still ask you to participate in a brief phone interview at six and 12-months. The phone interview will include the questions about health and lifestyle patterns, and should take about 15 minutes.

Safety Monitoring

During the study, the study staff will be periodically taking your blood pressure and watching for other signs of medical problems. If your blood pressure increases to an unsafe level or you do have other signs of a problem with your blood pressure, you will be advised to contact your primary care provider for evaluation and treatment as necessary. If you do not have a primary care provider, you will receive the phone numbers to several local clinics that provide medical care. If your blood pressure rises to a dangerous level and/or you have other signs of an urgent medical problem, you will be evaluated by a study physician who will determine the appropriate course of action, which may include directing you to the emergency room. We may also contact your primary care provider.

<u>Audio Recording</u>

One aspect of this study involves making audio recordings of some of your individual smoking cessation sessions as well as the group and individual weight management or the blood pressure control sessions. The session will be recorded so we can evaluate the group leader, to make sure they are delivering the session correctly. It will not be reviewed for anything you say or do. Anything you say in the sessions will not be discussed with anyone outside of the research team. Not all sessions will be recorded. The recordings will only be assessable to the main researchers. They will be kept in the main researcher's office in a locked filing cabinet. The recordings will be destroyed at the end of this study. You can still be in the study without being audio recorded.

[ ] Yes [ ] No I give you permission to make audio recordings of me during this study.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study. Other drugs may be given to make side effects less serious and uncomfortable.

Likely / Common (more than 35%)

Life Threatening

none

Serious

none

Mild

- nicotine withdrawal symptoms resulting from quitting smoking including one or more of the following: depressed mood, difficulty sleeping, irritability, anxiety, difficulty concentrating, restlessness, and increased appetite or weight gain
- slight bruising at the site of the blood draw to measure level of thiocyanate in your blood

Less Likely / Less Common (10% - 35%)

Life Threatening

none

Serious

none

Mild

- skin irritation at the site of the patch
- sleep disturbance due to the patch
- upset stomach, hiccups, heartburn, or flatulence due to nicotine gum
- mouth or jaw soreness, cough, or headache due to the nicotine gum

Rare (less than 10%)

Life Threatening

- Angina (chest pain) or myocardial infarction (heart attack) resulting from physical activity. This is potentially life-threatening and requires prompt medical attention.

Serious

- infection at the site of the venipuncture (blood draw)

Mild

- nicotine overdose, which could include one or more of the following symptoms: headache, dizziness, upset stomach or vomiting, diarrhea, cold sweats, blurred vision, difficulty with hearing, weakness, and/or drooling
- respiratory symptoms

Women Capable of Becoming Pregnant

There is not enough medical information to know what the risks might be to a breast-fed infant or to an

unborn child carried by a woman who takes part in this study. If you are a woman who is capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. For the pregnancy test, you will give a urine sample and will be told the results of the pregnancy test. If the pregnancy test is positive, you will not be able to take part in this study. You must use effective birth control methods and try not to become pregnant while participating in this study. The following birth control measures are acceptable: oral contraceptives, approved hormonal implants, intrauterine devices, diaphragm with spermicide, and condom with spermicide. Breast-feeding mothers must stop breast-feeding to take part in this study. If you become pregnant, there may be unknown risks to your fetus, or risks to your fetus that we did not anticipate, associated with being in the study. There may be long term effects of the treatment being studied that could increase the risk of harm to an unborn child. If you believe or know you have become pregnant while participating in this research study, please contact **the Preventive Intervention Center RN at 319-384-5050** as soon as possible.

Physical Activity
You may be assigned to one of the groups that include a recommendation for mild to moderate physical activity. Increasing one's physical activity slightly increases the risk of a cardiac event such as angina or a myocardial infarction (heart attack). Steps will be taken, however, to minimize this risk, including a detailed medical history and measure of your heart activity (electrocardiogram) to ensure that increasing physical activity is appropriate for you. In addition, you will be asked to exercise at a low to moderate level of intensity, and will not be asked to take part in any vigorous exercise. You are encouraged to contact study staff (319-384-5050) if you have any concerns about your activity level.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study. However, counseling to aid in stopping cigarette smoking and nicotine replacement therapy (the patch) can help some people quit smoking. Therefore, it is possible that you will be able to stop cigarette smoking for some time during this study. It also is possible that your weight and/or blood pressure control may improve.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, the study staff will discuss the other options that are available to you. Other treatments for smokers include other forms of nicotine replacement therapy such as nicotine gum, nicotine nasal spray, nicotine lozenge, and nicotine inhaler; or medications such as Zyban® and Chantix and/or counseling. Other options for treatment of blood pressure include medication and lifestyle modification programs to help you change your diet and physical activity level. You should talk to the researcher and your regular physician about each of your choices before you decide if you will take part in this study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs specifically for being in this research study.
You will not need to pay for any tests and procedures which are done for this research study. These tests and procedures include: the nicotine patches for six weeks (12 weeks if you need to go through the smoking cessation program twice); possibly a brief physical examination; urine testing; saliva test to measure cotinine or blood test to measure thiocyanate; urine pregnancy tests; and an electrocardiogram.

You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses. In the event that that the results of your electrocardiogram are abnormal or inconclusive and you subsequently elect to undergo further evaluation (an exercise stress test) under the supervision of your primary care provider, you will be responsible for the expenses associated with that procedure.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may also need to provide your address if a check will be mailed to you.

If you finish the study you will receive up to $100. This money is for the time you spend in this study. If you start the study but stop before finishing the study, you will receive part of this money based on which visits you have completed. Partial payment will be made as follows:
1 Completion of Screening Visit = $25
2 Completion of Screening and Group Assignment Visit = $25, ($50 total)
3 Completion of Screening, Group Assignment, and 6 Month Follow Up Visits = $25 ($75 total)
4 Completion of Screening, Group Assignment, 6 Month, and 12 Month Follow Up Visits = $25 ($100 total)
Please note: Participants who do not quit smoking during the smoking cessation portion of the study are not eligible to continue in the study (to the group assignment visit, interventions, or follow up visits). However, we ask that they complete a short phone interview at the 6 and 12 month time points. For those phone visits you would be compensated $10 (compared to $25 for the in-clinic follow up visit).

WHO IS FUNDING THIS STUDY?

US Department of Health & Human Services, National Institutes of Health (NIH) is funding this research study. This means that the University of Iowa is receiving payments from the NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics
- No compensation for treatment of research-related illness or injury is available from the University of Iowa unless it is proven to be the direct result of negligence by a University employee
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these

records could contain information that personally identifies you.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will only allow members of the study team to access your information. We will store paper records in locked file cabinets. We will assign an ID code to use instead of your name, to ensure that we do not use your name when it is not needed. The research coordinator will keep the ID coding system in a secure place so it can not be decoded. We will use a secure network to enter data. The computer system will be password protected, meaning no unauthorized users will be able to access the electronic data. The audio recordings of sessions will be destroyed. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires your health care provider to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study and for your treatment. Once your health care provider has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies and the University of Iowa Institutional Review Boards and support staff.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes your health care provider to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Dr. Mark Vander Weg at VA Iowa City Medical Center, 601 Highway 6 West, 3E-23; Iowa City, Iowa, 52246. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen if it is in your best interest, if you do not follow the study rules, or if the study is stopped.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Mark Vander Weg; 319-338-0581 x 7717; or Coordinator Mollie Kilburg; 319-688-3508. If you experience a research-related injury, please contact: Preventive Intervention Clinic RN; 319-384-5050. If a problem or a question arises at after hours or on weekends or holidays, you can call the hospital paging service at (319) 356-1616 and ask for the Internal Medicine resident on call.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 340 College of Medicine Administration Building, The University of Iowa, Iowa City, Iowa, 52242, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://research.uiowa.edu/hso. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after EXPIRATION DATE: 11/02/10.

_____ _____

(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)