**Medical University of South Carolina (MUSC)**
**CONSENT TO BE A RESEARCH SUBJECT**

**Contingency Management to Promote Smoking Abstinence in Cancer Patients**
**PI: Dr. Benjamin Toll**
**NCT04605458**

## SUMMARY:

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. This is a research study to examine the use of a novel smoking cessation intervention.

If you agree to participate in this study, you will be randomly assigned to receive either, 1) smoking cessation counseling and nicotine replacement therapy, or 2) smoking cessation counseling and NRT with the addition of contingency management (CM; which means payments for cigarette abstinence) over the course of your pre-surgical time period (10 days to 5 weeks). Neither you nor your doctor will decide which group you are in.

You will receive counseling and NRT, in the form of patches and lozenges, to help with smoking cessation. This study may help to engage you into smoking cessation treatment, however this cannot be guaranteed or promised. Before you decide whether you want to participate, there are some risks and inconveniences that you should know about. These include side effects from the Nicotine Replacement Medications, such as nausea, skin irritation, and indigestion. If you choose not to participate in this study, you may engage in clinical treatment with other treatments available over the counter at your local pharmacy, such as nicotine replacement therapy including the nicotine lozenges, nicotine chewing gum, or the nicotine patch. Nicotine nasal spray, the nicotine inhaler, bupropion, and varenicline are available by prescription to aid in stopping smoking.

If you are interested in learning more about this study, please continue reading below

## *A.* PURPOSE AND BACKGROUND:

You are invited to participate in a research study examining the use of a novel smoking cessation intervention. You have been selected for participation in this study because you are a cigarette smoker who would like to quit smoking and

who will be undergoing surgery for any type of cancer or suspected of cancer. Two-hundred eighty-two subjects will be enrolled in this study at 2 sites. We plan to enroll 141 participants at MUSC/Hollings Cancer Center. We will determine quit rates of study participants and markers of surgical and cancer outcomes. We will also attempt to examine the use of pain medications.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

This research is sponsored by the National Cancer Institute. The investigator in charge of this study is Benjamin Toll, PhD.

## *B.* **PROCEDURES:**

This study has three parts: (1) an intake session, (2) a treatment phase, and (3) a follow-up phase.

1. Intake Procedures: Before entering the study, you will have an interview with a member of the research team that will constitute an initial eligibility screening in person or via telehealth methods. During this interview, we will ask you about your nicotine and alcohol use and other psychological and physical problems that you or your family members may have now or in the past. You will also complete a set of questionnaires about topics such as, your motivation to quit smoking, your smoking history, your mood, and some other background information. We will also measure breath carbon monoxide (CO), which is a byproduct from cigarette smoking.

   If you are a woman of childbearing potential, you will be asked to provide urine for a pregnancy test, unless there is evidence of a negative pregnancy test result in your medical record within the last 2 weeks. If there is a possibility that you might be pregnant, research staff will meet you in person at the hospital or another agreed upon location or we will send a pregnancy test via mail and have a follow-up phone call or video call to confirm the results.

2. Treatment Phase: If, on the basis of your screening appointment, you are found to be eligible and you wish to participate, then you will be enrolled in the study. You will be randomly assigned to receive either: a) smoking cessation counseling and NRT or b) smoking cessation counseling and NRT + contingency management (payments for cigarette abstinence).

   As a part of clinical care, you will meet with a smoking cessation counselor and set a date on which you will quit smoking (your "quit date"). Usually this is set within a week of the first session. Over the 10 days to 5 weeks prior to surgery, you will receive additional counseling sessions with a minimum of 3 total sessions, or more if your pre-surgical time period is longer than 3 weeks. We expect each counseling session to last approximately 15-20 minutes. At this research visit you will receive a supply of nicotine patches and lozenges, dispensed once per week.

   You will take the 21 mg patch once per day if you smoke more than 10 cigarettes per day, and you will take the 14 mg patch once per day if you smoke 10 or fewer cigarettes per day. If you are a woman, before being given the nicotine patch you may be asked to provide urine for a pregnancy test. You will take the 4 mg nicotine lozenge if you smoke your first cigarette within 30 minutes of waking up. If you smoke your first cigarette more than 30 minutes after waking up, you will take the 2 mg lozenge. The lozenges are to be taken every 1-2 hours, or when you are experiencing cravings. You should not consume more than 20 per day. Questionnaires will be given weekly with questions about your smoking habits, mood, etc. You will also meet, in person or virtually, with a staff member 3 times per week for 10 days to 5 weeks for breath CO tests to biologically confirm smoking abstinence. There is a minimum of 6 meetings, or more if your pre-surgical time period is longer. These visits may also occur virtually with the use of an iCO personal smokerlyzer if necessary. We also collect urine samples from all patients to test for anabasine, which is a chemical broken down from cigarette smoking. It is present in urine of people who have smoked tobacco, but not those who have used nicotine replacement products. If the visit is completed via telemedicine, the research staff will meet with you in-person to collect the biological samples either at the hospital or another agreed upon location. These samples will be taken at the end of treatment (i.e., day or surgery) and 6-month follow-up. If your surgery is displaced, you will still be asked to provide a urine sample at your 15$^{th}$ monitoring session, if your surgery was rescheduled, or original day of surgery, if your surgery was cancelled.

If you are assigned to the contingency management treatment, you will have the opportunity to earn money at these appointments (described in detail below). We will do our best to make sure that these appointments are as convenient as possible for you. Our research staff will attempt to meet with you at one of your routine medical appointments or at a scheduled study visit. If this is not possible or is inconvenient, a staff member will drive to a public location that is convenient for you (e.g., a restaurant near your residence) if you indicate that you are comfortable with a public meeting. These visits may also occur virtually with the use of an iCO personal smokerlyzer if necessary. When necessary, assessments/scales may also be completed at these appointments. This may occur if you are unable to come in but we need to collect some data. Counseling will be conducted in person, if possible, or using tele-health methods.

When the treatment period is complete, you will not be provided with any additional free nicotine patches or lozenges. Nicotine patches and lozenges are available over-the-counter if you choose to continue to take them. We can help you identify locations where you could purchase these medications if you are interested. Your insurance company may cover these medications, but it would be your responsibility to pursue this option.

Follow-up phase: You will complete assessments at 3- and 6 month follow-up sessions. You will complete a breath CO test and a battery of assessments. These assessments will be completed in person, by phone, or through REDCap's automated survey feature. Surveys can automatically be sent to you at the time of your 3- and 6- month follow-up sessions. At the 6-month follow-up you will also be asked to provide a urine sample for anabasine testing.

In addition, your surgeon, a member of your medical team, and/or a research assistant will assess markers of wound infections, respiratory complications, and general complications. In order to do this, the research team will have access to your lab tests, surgical reports, and physician notes. You will also complete a set of questionnaires.

In case you move during the course of the study and follow-up, and we are unable to contact you at your current address/phone number, we will ask you to give us the names of two friends or relatives whom we can contact to obtain this information. We will contact these individuals only if we are unable to contact you directly and then only for the purpose of obtaining a forwarding address and phone number. We will inform the person that you have authorized us to

contact them, and they will be asked if they are willing to give out this information. If they decline, they will not be contacted again. You should also tell these people that you have given us their name and information so if we need to call them, they are already aware. If we are unable to obtain your phone number from these contacts or you are unreachable by phone, we will send you a follow-up questionnaire with a self-addressed, stamped envelope. If you are unable to come to the clinic but are willing to complete an interview, we can meet you at a public place to obtain your breath CO samples and questionnaire data.

*C.* **DURATION:**

Participation in the study will take about 3 visits per week (either remotely or 1 at our clinic, and 2 at a location of convenience) over a period of 10 days to 5 weeks (minimum of 6 visits, or more if your pre-surgical time period is longer). You will also complete a follow-up appointment 3 and 6 months after your surgery.

*D.* **RISKS/DISCOMFORTS:**

Before you decide whether you want to participate, there are some risks and inconveniences that you should know about. These include:

a) Nicotine patch: The nicotine patch is approved by the FDA and has been available over the counter for approximately 15 years. Nevertheless, nicotine patches may cause side effects. The most common adverse effect of nicotine transdermal delivery is topical skin irritation ranging from mild itching to a more generalized skin reaction. Rotating application sites from day to day will generally be enough to help with mild reactions but stopping the nicotine patch may be necessary for more severe conditions. Nicotine replacement was reported to be associated with increased complications in subjects with preexisting cardiovascular disease in early studies, although this association has been disputed by more recent research. Other potential side effects include high blood pressure, dizziness, insomnia, vivid dreams, and abdominal discomfort.

b) Nicotine Lozenge: The nicotine lozenge is an aid to help people to quit smoking by providing low levels of nicotine to minimize withdrawal symptoms. The nicotine lozenge is also FDA approved and has been available over the counter for the past 15 years. Nicotine lozenges may cause side effects. Some of the more common side effects are sore throat, indigestion, gas and nausea. These side effects can be minimized by not sucking on the lozenge and rotating the placement of the lozenge in the mouth.

Pregnant or nursing women will be excluded from this study since the nicotine patch may have harmful consequences to the baby. We also ask that you use a reliable form of birth control during the study. Acceptable methods of birth

control include abstinence, the birth control pill, intrauterine device, injection of Depo-Provera, Norplant, tubal ligation, and barrier methods such as condoms or the diaphragm. You must tell the principal investigator if you change from your birth control plans, or if despite your plans, you think you may be pregnant.

b) Rating Scales and Assessments: These are all noninvasive and should add no risk. The major disadvantage is the time it takes to complete these questionnaires. We have done our best to make these questionnaires brief, and our past experience with these measures indicates that they are acceptable to most study participants. Careful efforts aimed at maintaining confidentiality will be made, however loss of confidentiality is a risk.

## *E.* CERTIFICATE OF CONFIDENTIALITY:

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you are a MUSC patient you have an MUSC medical record. If you have never been a MUSC patient, a MUSC medical record will be created for the purposes of this study. Results of research tests or procedures will be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law; however, there is the possibility that your research information will be disclosed.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include child abuse and neglect, or harm to self or others

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

*F.* **BENEFITS:**

You will receive counselling and NRT to help with smoking cessation. This study may help to engage you into smoking cessation treatment, however this cannot be guaranteed or promised.

*G.* **COSTS:**

There will be no additional cost to you for procedures required in this research study. All routine clinical care that you would have undergone without participation in this study, including testing and procedures, will be billed to you/your insurance company. All study-related test and procedures will be paid for by the Sponsor.

Some insurance plans will not pay for these services for people taking part in research studies. You will be responsible for any charges that your insurance does not cover including co-payments and deductibles.

*H.* **PAYMENT TO PARTICIPANTS:**

You have the opportunity to receive up to $25 following the completion of the intake session and up to $5 per week for completion of study assessments at the counseling sessions (total payment up to $15 if you are in treatment for 3 weeks) and $25 for the completion of the study follow-up appointments for a total of $50.

If you are randomly assigned to the contingency management study group, you will be eligible to receive up to an additional $670. Payment schedules, which will vary based on your date of surgery.

An example payment schedule is below. The CM schedule (3 meetings per week) will be maintained leading up to the day of surgery; however, if your pre-surgical time period is longer than 3 weeks, earnings will be capped at the value of CM Meeting 9 for all subsequent payments (i.e., $55 for each additional confirmed abstinence meeting). Payment for abstinence will follow the escalating schedule of reinforcement below, and any breath test found to be positive for smoking would result in you not being paid ($0). If your next breath test is negative for smoking, the payment will be reset to the starting value of $15. The second negative breath test would return the value to the last payment amount before the positive test and then continue to escalate from there. Using the schedule below the total payment for breath tests is $315 for perfect abstinence through Week 3 and up to $645 if treatment lasts 5 Weeks.

| | |
|---|---|
| Week 1: | CM Mtg 1: $15 for confirmed abstinence from smoking |
| | CM Mtg 2: $20 for confirmed abstinence from smoking |
| | CM Mtg 3: $25 for confirmed abstinence from smoking |
| Week 2: | CM Mtg 4: $30 for confirmed abstinence from smoking |
| | CM Mtg 5: $35 for confirmed abstinence from smoking |
| | CM Mtg 6: $40 for confirmed abstinence from smoking |
| Week 3: | CM Mtg 7: $45 for confirmed abstinence from smoking |
| | CM Mtg 8: $50 for confirmed abstinence from smoking |
| | CM Mtg 9: $55 for confirmed abstinence from smoking |
| Week 4: | CM Mtg 10: $55 for confirmed abstinence from smoking |
| | CM Mtg 11: $55 for confirmed abstinence from smoking |
| | CM Mtg 12: $55 for confirmed abstinence from smoking |
| Week 5: | CM Mtg 13: $55 for confirmed abstinence from smoking |
| | CM Mtg 14: $55 for confirmed abstinence from smoking |
| | CM Mtg 15: $55 for confirmed abstinence from smoking |

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

Payment for study visits may be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card, and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. Details of the debit card system are explained on an additional sheet.

**ALTERNATIVES:**

If you choose not to participate in this study, the following treatments are available over the counter at your local pharmacy: nicotine replacement therapy including the nicotine lozenges, nicotine chewing gum, or the nicotine patch. Nicotine nasal spray, the nicotine inhaler, bupropion, and varenicline are available by prescription to aid in stopping smoking. If you would like to pursue an alternative treatment rather than participate in this study, please let us know and we will help you arrange these services.

## *I.* DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

## *J.* NEW INFORMATION

You will be notified if there are significant findings during the course of the study.

## *K.* DISCLOSURE OF RESULTS

You will be told the results of your smoking status, but the researchers will not share your other research results with you.

## *L.* AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators are participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or

- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

### *M.* Withdrawing from the Study

You are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with MUSC or Hollings Cancer Center or Yale. You would still be eligible to receive standard therapy at the Tobacco Treatment Program at MUSC or with a cessation counsellor at Yale.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

### *N.* EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

### *O.* Clinicaltrials.gov

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

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest

hospital and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. The data collected on you to this point remains part of the study database and may not be removed. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

**Volunteers Statement**

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Benjamin Toll at (203) 376-6113. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.
*Please sign below for paper consents or scroll to the bottom of the screen to provide an electronic signature.*

_____ _____

Signature of Person Obtaining Consent Date *Name of Participant

_____

Signature of Participant Date

Participant's Personal Representative (if applicable):

_____

Name of Personal Representative *(Please print)*

_____

Signature of Personal Representative Date

Relationship: ___ Spouse ___ Parent ___Next of Kin ___Legal Guardian*
_____ DPOA for Healthcare*

**(If you are the health care agent or guardian, please provide proof of your authority to act on behalf of the patient)*