Efficacy of Two Novel Behavioral Post-cessation Weight Gain Interventions

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THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER

Main Consent Form

TITLE: Efficacy of Two Novel Behavioral Post-Cessation Weight Gain Interventions

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1. INTRODUCTION:

You are being given the opportunity to participate in this research study. The purpose of this consent form is to help you decide if you want to be in the research study. This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. Please tell the study staff if you are taking part in another research study.

This research study is being conducted at the University of Tennessee Health Science Center (UTHSC) and is sponsored by the National Institute of Diabetes and Digestive and Kidney Disease. The purpose of this study is to determine whether three promising methods of reducing post cessation weight gain, a weight stability intervention versus a weight loss intervention versus a self-guided intervention, followed by a smoking cessation intervention, are effective for reducing post cessation weight gain.

Up to 1500 subjects will be enrolled, in order to have up to 400 subjects complete the study. Subjects will participate in groups of about 40 at a time (a study wave) that will be divided into smaller groups of about 8-20 people.

The study will take place at 66 N. Pauline St., Suite 501, Memphis TN 38105.

Your participation in this study will last for about 13 months. The entire study will last for 5 years.

2. PROCEDURES TO BE FOLLOWED:

There are a total of 7 remote (i.e. phone-based) visits. The remote visits will be done with phone and mail or email, as needed. Some visits will require the completion of documents via mail or email and at other visits, you will have the option to complete some of the questionnaires by either phone, mail, or online.

Screening Visit (60 minutes)

You will complete a remote screening visit which will last about 60 minutes. If you complete a remote screening visit with phone and mail, this visit will be divided into two parts each 30 minutes long (the informed consent and other questionnaires). During this visit the following materials will be collected from you:

- Informed Consent
- Demographics Questionnaire
- Smoking History Questionnaire

- Why Do You Smoke Questionnaire
- Self-Efficacy Questionnaire
- Treatment Preference Questionnaire
- Weight Concern Questionnaire
- Return to Smoking Questionnaire
- Importance of Weight and Smoking Cessation Questionnaire
- Smoking Behaviors Questionnaire
- Difficulty of Weight Program and Perceived Effectiveness Questionnaire
- Weight Efficacy Lifestyle Questionnaire
- Perceived Stress Scale
- Healthy Days Core Module
- International Physical Activity Questionnaire
- Depression Questionnaire
- Suicide Severity Questionnaire
- Self-reported Weight and Height
- Following the visit, a Urine Pregnancy Test (if appropriate) will be mailed to you for you to administer at home, and staff will follow-up with you via phone to obtain your self-reported result, or you may send a photo of the test result to the study email if you choose.

After all assessments are complete, you will be assigned three tasks to complete prior to your next visit, including completing 3 days of a diet and exercise journal, liking the study on Facebook (this task is optional, and you may need to create a Facebook account online if you do not already have one), and obtaining physician clearance to participate in the study.

Baseline Visit (15 to 30 minutes)

You will complete a remote baseline visit which will last a minimum of 15 minutes and maximum of 30 minutes. During this visit staff will confirm the receipt of the following materials:

- A completed daily diet and exercise journal (3 days)
- Confirmation that you have liked the study on Facebook (optional)
- A signed medical clearance letter

Following the visit, an electronic scale will be sent to you, and you will be asked to weigh yourself (with no shoes on and in light clothing). Staff will follow-up with you via phone to verify this.

Randomization Visit (15 to 30 minutes)

When the study wave has been filled, you will be invited to a remote study visit to find out your randomization assignment. You will be randomly assigned (like the flip of a coin) to one of the following groups: a weight stability intervention (Group 1), a weight loss intervention (Group 2), or a self-guided intervention condition (Group 3). Prior to this visit, you will receive your group-specific weight intervention materials in the mail and be asked to send in a headshot photo of yourself by mail or email (encouraged, but not required). If you prefer to send the photo by mail an addressed and stamped return envelope will be sent to you. At the visit, you will meet your interventionist and go over the materials. You have a 2 to 2 to 1 ratio chance of being randomized to Group 1, Group 2, or Group 3. However, if the wave is less than 40 participants, then you will have a more even chance of being randomized to each group.

Your photo will be used in your intervention sessions along with a brief biography about yourself, to help your group members become familiar with you. You may choose not to have your photo taken or not

have it shared with the other members in your randomized group assignment, along with not participating in the brief biography.

Put your initials on the line below if you are willing to provide a photo.

_____ I am willing to provide a photo.

All three groups receive a smoking cessation program and 6 months of varenicline (Chantix™). Participants randomized to the Group 1 and 2 will receive monthly booster weight management sessions, after completing the smoking cessation intervention. Study measures will be obtained at baseline, randomization, 2 month, 4 month, 8 month, and 12 month follow-ups and will include weight, smoking status, and weight concern. Process measures (e.g., session attendance, varenicline utilization) will be collected throughout the trial.

Below is a summary of what each group will do at each phase of the study.

Weight Management Phase (this phase will last 8 weeks for all participants).

Group 1:

- Those assigned to be in Group 1 will receive a Small Change Intervention.
- Participants will be asked to maintain their current weight for the initial eight weeks of the study and if they gain any weight, they will be asked to make additional small changes in the following days.
- Participants in Group 1 will also be asked to reach a goal of increasing their number of steps per day by 2000-3000 steps over what they are doing when they start the program, depending on whether they are staying weight stable. Participants will be provided with Fit Bit activity trackers to self-monitor their steps.
- Over the course of the initial eight weeks of the study, they will receive weekly sessions (8 total) to help them keep their weight stable. These sessions will occur in a phone-based group setting, and will last one hour. The phone sessions will be recorded for quality control purposes.
- In addition to the weekly intervention sessions, they will be asked to engage in daily weight self-monitoring as well as monitoring the small changes that they make. In order to achieve this, a Body Trace e-scale will be given to the participant during their Randomization Visit. Each time they weigh on the BodyTrace e-scale, the e-scale will upload the weight automatically to a secure database. Both the participant and the study team will be able to view these weights. To report on the small changes, participants will receive a daily questionnaire sent by email to complete.
- If you are randomized to Group 1, you will receive via mail a small reward valued less than two dollars, each week during the weight and smoking cessation sessions, then monthly during the booster sessions, if you maintain your baseline weight or maintain a weight that is less than 1.4 kilograms above your baseline weight.

Group 2:

- Those assigned to be in Group 2 will receive a Weight Loss Intervention.
- Participants will be asked to lose at least 5% of their baseline weight by week 8.
- Over the course of the initial eight weeks of the study, they will receive weekly sessions (8 total) to help them achieve a 5% weight loss. These sessions will occur in a phone-based group setting, and will last one hour. The phone sessions will be recorded for quality control purposes.

- In addition to the weekly weight loss sessions, they will be asked to engage in daily weight self-monitoring. In order to achieve this, a Body Trace e-scale will be given to the participant during their Randomization Visit. Each time they weigh on the BodyTrace e-scale, the e-scale will upload the weight automatically to a secure database. Both the participant and the study team will be able to view these weights.
- In addition to weighing, they will be asked to engage in daily dietary intake and physical activity self-monitoring using the My Fitness Pal website and/or application.
- Participants in Group 2 will be provided with 8 weeks worth of meal replacements in order to achieve the study's calorie and fat goals and as a strategy to control portions. Participants will be encouraged to replace 2 meals (typically breakfast and lunch) with a meal replacement and will be advised to consume a third meal of conventional foods as well as additional fruits and vegetables until they reach their daily caloric goals.
- Participants in Group 2 will also be asked to reach a goal of at least 175 minutes of moderate intensity exercise *(e.g., brisk walking),* over the course of a week. Participants will be provided with Fit Bit activity trackers to self-monitor their steps.

Group 3:

- Those assigned to be in Group 3 will receive the Eating Well Diet book that will provide a self-directed program for weight management and then in 8 weeks, initiate the same smoking cessation intervention as the other two groups.
- A Body Trace e-scale will be given to the participant during their Randomization Visit. Each time they weigh on the Body Trace e-scale, the e-scale will upload the weight automatically to a secure database. Both the participant and the study team will be able to view these weights.

For all groups, your study participation will not be discontinued if you fail to meet the study-specific weight management goals. In this case, you be encouraged to continue participating in the study.

2-month Follow-up Visit (60 minutes)

At 2 months, you will have a remote follow-up visit which will last about 60 minutes. During this 2-month follow-up visit the following materials will be collected from you.

- Weight Concern Questionnaire
- Return to Smoking Questionnaire
- Importance of Weight and Smoking Cessation Questionnaire
- Smoking Behaviors Questionnaire
- Difficulty of Weight Program and Perceived Effectiveness Questionnaire
- Weight Efficacy Lifestyle Questionnaire
- Weight Management Behaviors Questionnaire
- Perceived Stress Scale
- Healthy Days Core Module
- International Physical Activity Questionnaire
- Depression Questionnaire
- Suicide Severity Questionnaire
- Program Satisfaction Questionnaire
- You will be asked to weigh yourself on your BodyTrace e-scale.

- If you have self-reported abstinence, following the visit, a Salivary Nicotine Test will be mailed to you for you to administer at home, and for you to send a photo of the test result to the study email or text a photo to the study phone number.

Week 9-14: Smoking Cessation Intervention + Varenicline Phase:

The Smoking Cessation Intervention + varenicline Phase will last for 6 weeks for all participants no matter what group they have been randomly assigned to. Each group session will last one hour and will be weekly.

- You will get a 6 session phone- and group-based smoking cessation intervention, and one individual session. You will receive the smoking cessation intervention with the same group with whom you received the weight management intervention (or in the case of Group 3, a group will be formed at this point). The phone sessions will be recorded for quality control purposes. Participants will report daily on smoking behavior through a questionnaire sent by email.
- In addition to the smoking cessation intervention, all participants in all groups will receive varenicline (i.e., Chantix™).
  - You will receive varenicline 0.5 mg once daily for 3 days, increasing to 0.5 mg twice daily for days 4 to 7, and then to the maintenance dose of 1 mg twice daily for a total of 6 months of treatment.
  - You will receive a medication phone call two weeks after your first dose and then a monthly medication phone call to assess varenicline utilization, adverse events and suicidal ideation.
  - After the completion of the monthly medication call or remote visit (in the case of the 2 month and 4 month visit), varenicline will be distributed by mail monthly. After the 2 month visit, staff will conduct an additional brief call with you to go over the medication before mailing the first box.

4-month Follow-up Visit (45 minutes)

At 4 months, you will have a remote follow-up visit which will last about 45 minutes. During this 4-month follow-up visit the following materials will be collected from you.

- Smoking Behaviors Questionnaire
- Difficulty of Smoking Cessation Program
- Weight Efficacy Lifestyle Questionnaire
- Weight Management Behaviors Questionnaire
- Perceived Stress Scale
- Healthy Days Core Module
- International Physical Activity Questionnaire
- Depression Questionnaire
- Suicide Severity Questionnaire
- Program Satisfaction Questionnaire
- If you have self-reported abstinence, following the visit, a Salivary Nicotine Test will be mailed to you for you to administer at home, and for you to send a photo of the test result to the study email or text a photo to the study phone number.
- You will be asked to weigh yourself on your BodyTrace e-scale.

Weight Booster Sessions (if in Groups 1 & 2) + Varenicline Phase:

- **Groups 1 & 2:** Participants assigned to be in Groups 1 & 2 will receive monthly booster weight management phone sessions, after completing the 6-week behavioral smoking cessation intervention.

  - There will be 5 booster sessions over the course of 5 months, one each month (week 16, 20, 24, 28, and 32) that will focus on problem solving related to weight management. Each session will last one hour. Participants will receive the booster sessions with the same group with whom they received the initial weight management phase and smoking cessation interventions. The phone sessions will be recorded for treatment fidelity.
- **All Participants**: All participants who complete the monthly medication call will continue to receive varenicline during this phase.

8-month Follow-up Visit (45 minutes)

At 8 months, you will have a remote follow-up visit lasting about 45 minutes. During this follow-up visit the following materials will be collected from you.

- Smoking Behaviors Questionnaire
- Difficulty of Smoking Cessation Program
- Weight Efficacy Lifestyle Questionnaire
- Weight Management Behaviors Questionnaire
- Perceived Stress Scale
- Healthy Days Core Module
- International Physical Activity Questionnaire
- Depression Questionnaire
- Suicide Severity Questionnaire
- Program Satisfaction Questionnaire
- If you have self-reported abstinence, following the visit, a Salivary Nicotine Test will be mailed to you for you to administer at home, and for you to send a photo of the test result to the study email or text a photo to the study phone number.
- You will be asked to weigh yourself on your BodyTrace e-scale.

12-month Follow-up Visit (45 minutes)

At 12 months, you will have a remote follow-up visit lasting about 45 minutes. During this follow-up visit the following materials will be collected from you.

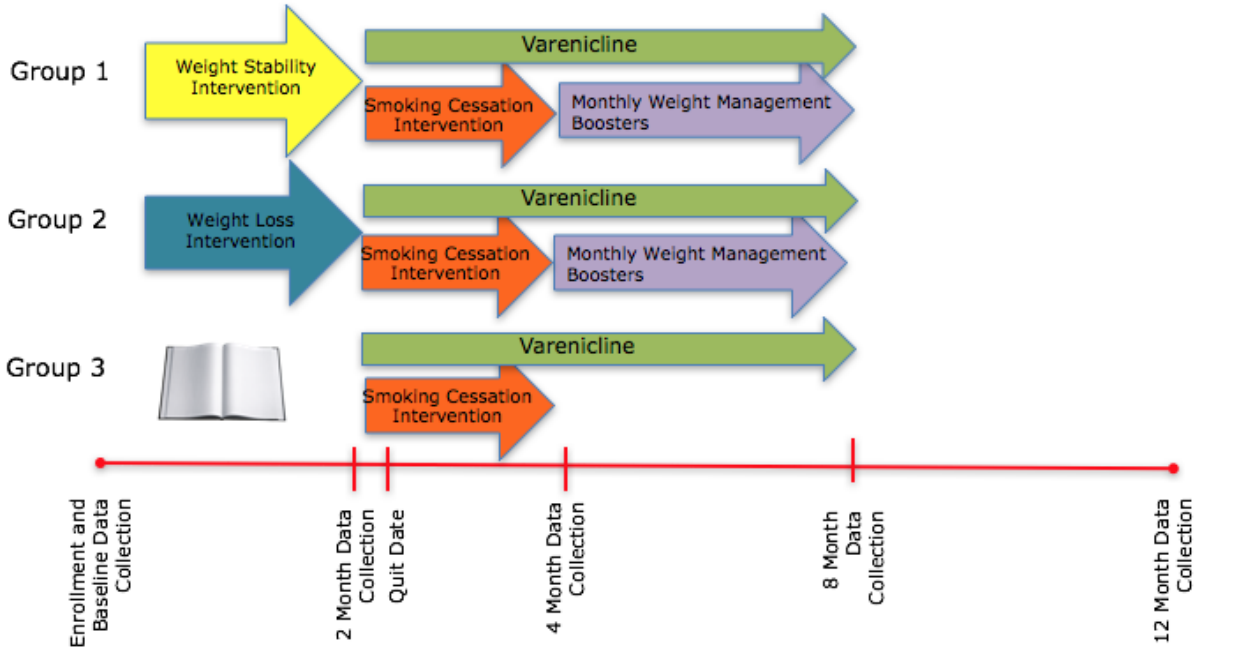
- Smoking Behaviors Questionnaire
- Weight Efficacy Lifestyle Questionnaire
- Weight Management Behaviors Questionnaire
- Perceived Stress Scale
- Healthy Days Core Module
- International Physical Activity Questionnaire
- Depression Questionnaire
- Suicide Severity Questionnaire
- Program Satisfaction Questionnaire
- If you have self-reported abstinence, following the visit, a Salivary Nicotine Test will be mailed to you for you to administer at home, and for you to send a photo of the test result to the study email or text a photo to the study phone number.
- You will be asked to weigh yourself on your BodyTrace e-scale.

All of the procedures listed in this section are for research purposes.

If at any time you report emotional distress during a data collection visit, the staff member will assess whether or not your depression and risk of harm warrant additional attention. In the event that we determine you are experiencing extreme depression and a high risk of self-harm, we will refer you to emergency services.

For a visual overview of the procedures, please refer to Figure 1 below.

Figure 1. Study Design



3. RISKS ASSOCIATED WITH PARTICIPATION:
Potential research risks with this study include those associated with: 1) study medication (varenicline); 2) nicotine withdrawal; 3) failure to lose weight or weight gain; and 4) inconvenience of study visits and questionnaires.

All drugs can have side effects. Although not all or none of these side effects may occur, if they do occur, they may need medical attention. You must notify your study doctor about all symptoms, side effects, complaints, illnesses, or injuries which you experience during the course of the study regardless of whether or not you think these are related to the study drug. You should discuss these with your study doctor as well as your regular health care provider, if you choose.

Varenicline:

Side Effects:

- Common (21-50%)
  - Nausea
- Occasional (6-20%)
  - Insomnia
  - Abnormal Dreams
  - Headache
  - Constipation

i. **Abuse Potential:** The manufacturer's data, available in the package insert, suggests that varenicline is not likely to be abused. The FDA did not classify varenicline as a controlled substance.

ii. **Drug Interactions:** Varenicline is not known to interact with any medications and has no contraindications.

iii. **Drug Warnings*:*** The FDA has previously required a "black" box warning on the varenicline label to alert physicians and patients to risks possibly associated with the use of this medication. Although rare, the labeling warned of the risk of behavioral changes, depression, hostility, aggression, suicidal thoughts, suicide, and vehicular crashes. However, based on the latest research, the black box warning was removed in 2016.

Only you should take the study drug. It must be kept out of reach of children or anyone else who may not be able to read or understand the label.

Tobacco Withdrawal
Symptoms:

- Very Common (51-100%)
  - Irritability
- Common (21-50%)
  - Depressed mood
  - Difficulty Sleeping
  - Difficulty Concentrating
  - Restlessness
  - Increased Appetite
  - Weight Gain
- Occasional (6-20%)
  - Anxiety

Potential Failure to Lose Weight or Gain Weight
The behavioral weight management interventions in all of the conditions recommend that individuals make changes to dietary intake and physical activity to keep weight stable or to lose weight; all of these dietary and physical activity changes are consistent with medical guidelines. The most common risk associated with participation in the physical activity aspects of these interventions is soreness, although this occurs infrequently. Precautions will be taken to further minimize risk by making recommendations for graded increases that slowly increase activity duration and recommendations for exercise safety.

Although it is expected that all of the weight management interventions will be either beneficial or neutral (with no effect at all), it is possible that the intervention that a participant is assigned to, may later be shown to be less effective than other interventions. As smoking cessation is associated with weight gain, it is possible that some participants will gain weight after quitting smoking.

Study Visits
You may be inconvenienced by the completion of study visits and questionnaires. We have carefully balanced the minimization of the study visits with the need to ensure participant safety. We have flexibility in the scheduling of appointments and will make every attempt to work around participant schedules. We have also carefully planned the study visits in order to minimize the amount of time spent on study questionnaires during any individual visit.

Questionnaires
Completion of the questionnaires may make you feel uncomfortable or cause troublesome feelings or emotions. You may refuse to answer any of the questions, and you may take a break at any time during the study.

Photography/Audio Recordings
Having your photograph taken and your voice recorded may make you feel uncomfortable. You may take a break during any time of the study. There is also a potential risk of loss of confidentiality that someone who listens to your audio recording or views your photo might identify you.

Pregnancy Risks for Females
Females who are pregnant or nursing a child may not take part in this study. If you are a female and are able to become pregnant, you will be sent a urine test to make sure that you are not pregnant before you receive treatment in this study and will be asked to report the results of the test. If you are planning to become pregnant during your participation in the study, please let study staff know immediately.

If you are a female and are able to become pregnant and you choose to take part in this study, you must use birth control such as:

- sexual abstinence;
- birth control pills, birth control shots, IUD, birth control implants (placed under the skin by a health care provider), or patches (placed on the skin);
- sexual activity with a male partner who has had a vasectomy (surgery to become sterile); OR
- the combination of 2 forms of other types of birth control, such as condom/diaphragm AND spermicidal foam or gel

You must use this birth control for the duration of the study. If your participation in the study is discontinued for any reason, you must also use this birth control for at least 5 days after your last dose of any study medication.

Study Risks
There is a risk that your private identifiable information may be seen by people not involved in the research (such as if a researcher's computer is stolen or an electronic database is hacked). However, we will use very careful security measures (such as locks on file cabinets, computer passwords, etc.) to minimize the chance that any unauthorized persons might see your confidential information.

The research may involve risks to you which are currently unforeseeable. You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

4. BENEFITS ASSOCIATED WITH PARTICIPATION:
Your health may improve while you are in this study; however, this cannot be promised. It is possible that you will be able to stop smoking for some time with the help of this research study. Participants in all groups may increase their knowledge about healthy eating and physical activity. Participants in the Group 1 will learn how to keep their weight stable, and participants in Group 2 and 3 will learn how to lose weight.

There is no guarantee or promise of any direct benefit for you by participating in this study. This research study will contribute to the existing literature by assisting with recommendations on how to manage weight among those people who are trying to quit smoking.

5. ALTERNATIVES TO PARTICIPATION:
You may receive varenicline or weight management without participating in this study through your primary care provider. If you decide not to enter this study, there are other choices available. Alternatives for smoking cessation include nicotine replacement therapy in the form of patch, gum, nasal spray, lozenge, or inhaler. Ask the study staff to discuss these alternatives with you. You do not need to be in this study to receive treatment.

6. CONFIDENTIALITY:
Research Records
All your paper research records will be stored in locked file cabinets and will be accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

All your electronic research records will be computer password protected and accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

Medical Records
Information about your participation in this study or the results of procedures performed in this study will not be placed in your medical record.

Presentations/Publications
While individual details about your case might be provided in publications or presentations about this research, they will not be discussed in a way that would allow you to be individually identified as a participant.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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.

Authorization to Use and Disclose Information for Research Purposes
Under federal privacy regulations, you have the right to decide who can review and copy your personal health information (called "protected health information" or PHI). PHI collected in this study may include information such as:

- Past and present medical records
- Records about your study visits
- Records about phone calls made as part of this research
- Research records

By signing this consent form, you are authorizing the researchers to have access to the PHI collected in this study; we will not have access to your medical records.
Your PHI may be shared with other persons involved in the conduct or oversight of this research. For example:

- The Institutional Review Board (IRB) at the University of Tennessee Health Science Center

- The National Institute of Diabetes and Digestive and Kidney Diseases, which sponsors and provides funds for this study
- A Data and Safety Monitoring Board
- The US Food and Drug Administration (FDA)
- MyFitnessPal and/or FitBit will have temporary access to an email address of your choosing.
- Facebook will have access to your name when you set up your account. Facebook will not have access to any study data. In addition, liking the study on Facebook does not disclose a person's Facebook identity. However, if you like or comment on a post on the Fit & Quit Facebook page, this would make your Facebook identity public. To keep your identity private, we recommend that you private message the study on Facebook. As an additional precaution, we will monitor the Facebook page regularly and take down posts to ensure that all who have queries or comments about the study do not risk confidentiality.
- BodyTrace will have temporary access to your address in order to mail you an e-scale.
- Amazon may have temporary access to your address in order to mail you study supplies.

However, some of these organizations or institutions above do not have the same obligations to protect your PHI.

Your PHI will only be used and/or given to others:

- To do the research
- To study the results
- To see if the research was done correctly

Your PHI will be used for as long as the sponsor reports study information to the FDA.

You may withdraw or take away your permission to use and disclose your PHI at any time. You do this by sending written notice to the Principal Investigator listed on the first page of this document. If you withdraw your permission, you may not be able to stay in the study.

When you withdraw your permission, no new PHI will be gathered after that date. However, information that has already been gathered may still be used and given to others. The federal regulations allow you to review or copy your PHI that is used in this study.

However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. Once the study is over, your right to review and copy your PHI will be reinstated.

7. COMPENSATION AND TREATMENT FOR INJURY:

You are not waiving any legal rights or releasing the University of Tennessee or Regional One Health, or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and Regional One Health do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and Regional One Health do not provide treatment or reimbursement for such injuries.

If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide acute medical treatment, and will provide you with a subsequent referral to

appropriate health care facilities. You and/or your insurance will be billed for the costs associated with this medical treatment.

No compensation will be available to you for any extra expenses that you may have as the result of research related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc. No compensation will be available to you for any non-physical injuries that you may have as a result of research participation, such as legal problems, problems with your finances or job, or damage to your reputation.

8. QUESTIONS:
Contact the Study Coordinator at 901-448-1083 (office number) or Dr. Rebecca Krukowski at 901-448-2426 (office number) if you have questions about your participation in this study, or if you have questions, concerns, or complaints about the research.

If you feel you have had a research-related injury or a reaction to the study drug, contact Dr. Catherine Womack at 901-448-8405. This phone number will be forwarded to an answering service for after-hour calls.

You may contact Cameron Barclay, MSA, UTHSC IRB Director, at 901-448-4824, or visit the IRB website at http://www.uthsc.edu/research/compliance/irb/ if you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research.

9. PAYMENT FOR PARTICIPATION:
You will receive an Amazon gift card at the completion of the 4- ($30), 8- ($35) and 12-month ($35) follow-up visits. If all three visits are complete, you will receive a total of $100 for participating in the study. In addition, you will receive a $50 Amazon gift card for every participant that you refer who becomes randomized, if you are also randomized. You may refer up to two participants, for a total of $100.

At month 11, you will receive a small gift valued at less than $10.

10. COSTS OF PARTICIPATION:
There are no costs to you for participating in this study.

11. VOLUNTARY PARTICIPATION AND WITHDRAWAL:
Your participation in this research study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

If you are a student of University of Tennessee participating or not participating in this study will in no way influence your grade in any course. If you are an employee of University of Tennessee, participating or not participating in this study will not affect your employment status.

If you decide to stop being part of the study, you should tell your study doctor, and any information that you have already provided will be kept in a confidential manner.

Your participation in this research study may be discontinued for any of the following reasons:

- If you do not show up for visits

- If you do not follow the study doctor's instructions
- If you withdraw consent
- If you become pregnant

12. FUTURE CONTACT:

If we lose contact with you during the study for any reason (your phone number changes; your physical or email address changes; you are not responding to our attempts to contact you about your continued participation; etc.), we will attempt to find you or make contact with you in the following ways.

Put your initials on the lines below if we CAN attempt to find/contact you in the following ways:

_____ The phone number(s) you provided to us will be called or texted, but if you are not the person who answers, we will not say the title of the study or the fact that you are/were participating in a study.

_____ A letter will be sent to the address(es) you provided to us, but neither the return address nor any markings on the envelope will identify the title of the study or the fact that you are/were participating in a study.

_____ A message will be sent on Facebook

_____ Public records searches

If we MAY NOT attempt to find/contact you in the above ways, put your initials on the line below:

_____We MAY NOT attempt to find/contact you in the above ways.

Main Consent Form

13. CONSENT OF SUBJECT:

You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

_____	_____	_____ am/pm
Signature of Research Subject (18 years +)	**Date**	**Time**

_____
Printed Name of Adult Research Subject

_____	_____	_____ am/pm
Signature of Person Obtaining Consent	**Date**	**Time**

_____
Printed Name of Person Obtaining Consent

In my judgment, the subject has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____	_____	_____ am/pm
Signature of Investigator	**Date**	**Time**