Mobile Contingency Management for Concurrent Abstinence From Alcohol and Smoking

NCT02995915

Informed Consent Forms

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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
Mobile Contingency Management for Concurrent Abstinence from Alcohol and Smoking (Stage 2)

CONCISE SUMMARY

The purpose of this study is to learn more about ways to help people quit smoking and drinking alcohol. This study is looking specifically at the use of monetary rewards and a smart phone application for smoking and alcohol cessation.

If you are eligible to participate in the study, we will randomly assign you to one of two groups using a process like drawing a number out of a hat. No matter which group you are assigned to, you will receive counseling sessions, medications to help you quit smoking, and mobile technology to monitor your drinking and smoking. If you are assigned to the mobile contingency management group, you will receive additional incentives to quit smoking and drinking alcohol. In this group, you are paid if your home monitoring suggests that you have been abstinent from smoking and/or drinking.

If you participate in the study, there may be a direct benefit to you. You may benefit from stopping smoking and drinking alcohol, but this benefit is not guaranteed. Risks of the study include smoking withdrawal symptoms and alcohol withdrawal symptoms. There are also some risks involved in taking the study medications, including risk of nausea and skin irritation with nicotine patch use. The most common side effects of bupropion include dry mouth, trouble sleeping, and nausea.

Your active participation in the study will last about eight weeks. You will have a follow-up session six months after your smoking and alcohol quit date. Altogether, your participation will last about 7 ½ months.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you smoke and drink alcoholic beverages and wish to quit. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her 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. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Dedert's and his research team's salaries will be paid by this grant.

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WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Drs. Scott Moore and Eric Dedert will be your doctors for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn more about ways to help people quit smoking and drinking alcohol. This study is looking specifically at the use of monetary rewards and a smart phone application, or app, for smoking and alcohol cessation.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 70 people will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?

This table summarizes the study procedures, and they are also described in detail in the text.

Table 1. Study Procedures

Session #	Location of Visit	Procedures	Payment
1	Lab	Consent; psychiatric interview; questionnaires; urine drug screen and pregnancy test; carbon monoxide and breath alcohol readings	$50
1-3 weeks			
2	Phone	Counseling session 1 of 4	n/a
1 week			
3	Phone	Counseling session 2 of 4; begin practice mCM monitoring, begin bupropion if eligible	Up to $34 for monitoring
1 week			
4	Phone	QUIT DATE; counseling session 3 of 4; begin active mCM monitoring OR active mobile monitoring; begin nicotine replacement therapy (NRT)	n/a
2 weeks			
5	Phone	Counseling session 4 of 4; continue active mCM monitoring OR active mobile monitoring	n/a
1 week			

6	Phone	End active monitoring; begin wash-out monitoring in mCM group; questionnaires	Up to $702 (mCM) OR $132 (MM) for active monitoring; $50 for assessment
2 weeks			
7	Lab	End monitoring; return equipment; questionnaires; end NRT and bupropion; saliva sample; interview about treatment	Up to $400 (mCM) OR $88 (MM) for continuing monitoring; $35 for equipment return; $50 for assessment; $50 for saliva sample
6 months after Session 4			
8	Lab	Questionnaires; saliva sample; blood spot collection	$50 for assessment, $50 for saliva sample, $50 for blood spot test
TOTAL COMPENSATION POSSIBLE:		**mCM Group Mobile Monitoring**	**$1521* $639***

*because compensation depends partly on the number of alcohol breathalyzer prompts that are randomly generated, it is possible that the total maximum compensation will vary slightly.

Session 1: If you agree to be in this study, you will be asked to sign and date this consent form. We will ask you to do the following tests and procedures to make sure that you are eligible:

- provide a breath sample by blowing into a device that measures the amount of carbon monoxide (CO, a gas found in your breath) in your breath, which will indicate how much you are smoking;
- participate in an interview about your current mental health; and
- provide a urine sample so that we can test for substances such as cocaine, heroin, and amphetamines. If you are a woman of child-bearing age and/or potential, we will also use this urine to perform a pregnancy test. If the urine pregnancy test is positive, you will not be allowed to continue study participation.

We will ask you to fill out some questionnaires about yourself. These will include questions about your substance use, mood, any self-injurious behaviors, beliefs, and your smoking history.

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If the screening session results in your being enrolled in the study, you will be randomly assigned to one of two treatment groups using a process like drawing a number out of a hat. If you are assigned to the first group, you will receive the "Mobile Monitoring" treatment to help you stop drinking alcohol and smoking cigarettes. This treatment includes counseling sessions, medications, and a mobile technology for you to use in monitoring your alcohol drinking and cigarette smoking behaviors. If you are assigned to the "Mobile Contingency Management" group, you will receive the same treatment, except that the amount of money you receive as compensation for providing video of tests of your alcohol drinking and cigarette smoking behaviors using the mobile health technology will depend on providing test values indicating that you have abstained from alcohol and cigarettes. You have a 2 out of 3 chance of being assigned to the "Mobile Contingency Management" group.

If you are enrolled, you will be given a CO monitor, breathalyzer, and mobile telephone to take home for several weeks. You will use this equipment to monitor yourself taking CO readings twice per day at least 8 hours apart. You will also use the equipment to monitor yourself taking breathalyzer readings when prompted by alarms from the mobile telephone, and upload them to the study team. The mobile telephone has a small video camera. You will be trained how to use the CO monitor and breathalyzer, and how to use the telephone to record yourself using the monitors. You will also be trained how to upload the video to this study's website using a mobile application (mCM) that will be on the phone you're given. You will begin practicing monitoring after this appointment. Between session 1 and session 3 (up to four weeks), you will practice monitoring to make sure you have learned how to complete monitoring procedures, but you will not be paid for monitoring.

At the end of the study, we will ask you to return the study equipment to the study staff. If you misplace the study equipment, or it is stolen while you have it, we ask you to tell a study staff member immediately. The telephone has tracking software on it, and we may be able to use the software to locate the phone, shut it down, and get all of the data you have stored on it. We will only use the tracking software if you report the telephone as lost or stolen, or you fail to return it to us at the end of the study. If your telephone or other equipment has been misplaced or stolen, and you still need the equipment to continue in the study, we will provide you with a replacement at no cost.

All together, this visit will take about 5 ½ hours to complete. We will pay you $50 for completing this session.

Session 2: No matter which treatment group you get as your assigned group, session 2 occurs sometime in the first three weeks after Session 1, depending on how long it takes to arrange medications to help with your quit attempt. In this phone session, you will participate in the first of four counseling sessions designed to prepare you for quitting smoking and drinking alcohol. Each of your phone counseling sessions will be audio recorded using an iPad or iPhone. About one in five of your sessions will be reviewed by a study staff member to ensure that the phone counseling treatment is being done correctly. The recording will be moved from the recording device to a Duke secured server. You will not be paid for Session 2.

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Session 3: Session 3 occurs about one week after Session 2. If you are medically eligible, we will give you a medication to begin taking one week before your smoking quit date. The medication is bupropion SR, an antidepressant medication that is FDA approved for treating depression and for helping smokers to stop smoking. Before we give you this medication, though, we will make sure you are medically eligible to take it. To do that, we may attempt to contact your primary care doctor and/or other treating doctor in order to consult with him/her prior to your beginning the medication. If you indicate that you have any contraindications to taking the study medication, we will definitely try to contact your physician so that he/she can make an informed decision. If you have ever had seizures or currently have seizures, please tell the study coordinator. You should not take bupropion if you have uncontrolled diabetes, kidney impairment, current or past hepatitis, or current or past cirrhosis. You will still be allowed to participate in the rest of the study if your doctor or the study doctor determines you shouldn't take bupropion. You will take 150 mg each day for 7 days and then 300 mg each day and continue taking the medication for seven weeks. If you would like to continue using bupropion after this eight week period, you will need to speak with your personal doctor about a prescription. You will also be given two forms of nicotine replacement therapy, or NRT. This includes nicotine patches and a "rescue method," like nicotine gum or lozenges. We'll ask you what you prefer. You will be asked to begin using these medications on your quit date.

No matter which treatment group you get as your assigned group, starting at Session 3 and lasting until Session 7, you will be asked to record and upload your breath alcohol readings each time you hear an alarm on your phone. The study phone will send text messages to your personal cell phone each time that the alarm sounds. You can opt out of receiving text messages on your personal phone at any time. This will happen on average about ten times per week. You will be asked to upload your CO readings twice per day with at least eight hours between the readings. You can do the CO readings at whatever time you choose. The study's website will include a personalized study area for you. The study area will allow you to see how many readings have been uploaded, and will provide information about monetary rewards for your readings. For the first week of monitoring (between session 3 and 4), you will be paid $1.00 for each CO reading that you upload regardless of how high or low your CO reading is. You will be paid another $2.00 for each breath alcohol reading you upload. In sum, for this practice week of monitoring you can earn up to $34 for uploading your readings.

Session 4: This session will occur on your quit date. You will participate in the third counseling session. You will be asked to start using nicotine patches and your preferred rescue method. Also, you'll be asked to continue home monitoring. If you are assigned to the Mobile Monitoring group, you will continue to be paid regardless of how high or low your alcohol and smoking test readings are. This means you will be paid $1.00 for uploading each CO reading video, and $3.00 for uploading each breathalyzer reading video within the one hour time period after an alarm.

However, if you are assigned to the Mobile Contingency Management group, starting at this session, you will only receive payments for uploading videos that indicate you haven't been smoking and/or drinking. For example, if you upload a video that indicates that you are still smoking, you won't get paid

for the smoking video. Abstinent readings are breathalyzer readings that are < 0.02 BrAC and CO readings that are based on reductions from your baseline value for the first week, and are < 6 parts per million after the first week of the quit attempt. Your beginning payment for uploading an alcohol breathalyzer video that shows you haven't been drinking is $3.00. Your beginning payment for uploading a CO reading video that shows you haven't been smoking is $1.00. If you upload videos that suggest that you are abstinent from both alcohol and smoking, you will be paid a bonus payment. On Sundays through Wednesdays, that bonus will be $5.00. On Thursdays through Saturdays, that bonus will be $10.00. The amount that you earn for uploading "clean" readings will increase each time, as long as you continue to remain abstinent. If you upload a "dirty" reading (i.e., the number on the monitor indicates that you have been using that substance) or do not respond to the alarm, the amount of payment will be reset back to the original amounts ($3 and $1). However, after you've had three "clean" readings, we will reset your payment to the higher amount you were making before. The payment schedule for monitoring is complicated, but the study coordinator will provide you with a manual that explains it in detail. Actual payment for monitoring will be provided after session 7.

Session 5: Session 5 will occur about two weeks after session 4. In this session, you will have your final counseling session, where your counselor will talk to you about strategies for remaining smoke-free. You will be asked to continue at-home monitoring. You are not paid for Session 5, but you may be paid for "clean" monitoring readings if you are in the Mobile Contingency Management group. You may be paid for any monitoring readings if you are in the Mobile Monitoring group.

Session 6: This session will occur about one week after session 5. In this session, the study coordinator will ask you some questions about your symptoms and about the treatment, and you will complete some questionnaires. You will be paid $50 for completing this session over the phone.

If you are in the Mobile Management group, you will continue to upload videos and payment will remain the same. If you are in the Mobile Contingency Management Group, will be asked to continue monitoring, but the payment scheme for monitoring will change. Between sessions 6 and 7 (two weeks), you are paid $200 at the end of each week if you upload at least 90% of all possible videos for the week with clean readings. If you are abstinent from only one substance but have uploaded at least 90% of videos for that week, you will earn $50.

Session 7: This session will occur about two weeks after session 6. You will be asked to return the CO monitor, the breath alcohol monitor, and the telephone, and to stop doing at home-monitoring. You will be asked to complete some questionnaires about the treatment you received and about smoking and alcohol use. The study coordinator will also interview you about your experiences with the treatment you received. This interview will be audio-recorded using an iPad or iPhone. You will be asked to stop using bupropion and NRT. However, if you're still smoking and would like to try to make another quit attempt, you may be allowed to continue using NRT. We will ask you to provide a saliva (spit) sample. You can choose to do session 7 in the lab or by telephone. If you choose to do session 7 by phone, we will provide you with a safe and cost-free way to mail in your equipment and your saliva sample. You

will be paid $50 for participating in the assessments in session 7, and $50 for providing a saliva sample. You will be paid $35 for returning the study equipment.

Session 8: This session occurs 6 months after your quit date (session 4). In this session, you will complete some questionnaires about your smoking and alcohol use. We will ask you to provide a saliva (spit) sample. We will pay you $50 for participating in this session, $50 for providing the saliva sample, and $50 for providing a blood sample by finger prick for a dried blood spot test.

The investigational parts of this study are the questionnaires that we ask you to complete, the home monitoring and uploading of videos, and the payments for not smoking and/or not drinking alcohol. If you were to go to a doctor for help in stopping smoking, you might not be asked to do those parts.

HOW LONG WILL I BE IN THIS STUDY?
Your active participation in this study will last about eight weeks. You will have a follow-up session six months after your quit date. Altogether, your participation will last about 7 ½ months. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

Clinically relevant results of this research will be communicated with you.

WHAT ARE THE RISKS OF THE STUDY?
As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

Stopping smoking causes withdrawal symptoms. Symptoms can last for a few days to several weeks. These may include: headaches, dizziness, nausea, anxious or depressed mood, feelings of frustration and anger, trouble sleeping, bad dreams, trouble concentrating, restlessness, tiredness, increased appetite, weight gain, and craving for cigarettes.

Stopping alcohol use may cause withdrawal symptoms. Symptoms of alcohol withdrawal may include headache, insomnia, sweating, shakiness, and rarely, seizures or hallucinations.

There are no known risks associated with completing paper and pencil measures or electronic diary entries. There is a possible risk of temporary anxiety associated with discussing psychiatric symptoms. There is a potential risk for loss of confidentiality associated with using the mobile application(s).

Using nicotine in the form of patches, gum, inhaler, or lozenge may cause some, all, or none of the side effects listed below.

More likely

- acid or sour stomach
- belching

- coughing
- heartburn
- indigestion
- mouth and throat irritation
- stomach discomfort, upset, or pain
- stuffy nose

Less likely:

- anxiety
- back pain
- change in taste
- diarrhea
- dizziness
- feeling of burning, numbness, tightness, tingling, warmth, or heat
- flu-like symptoms
- general pain
- hiccups
- mental depression
- pain in the jaw and neck
- pain in the muscles
- passing of gas
- problems with teeth
- trouble with sleeping
- unusual tiredness or weakness
- fast or irregular heartbeat
- fever with or without chills
- headache
- nausea with or without vomiting
- runny nose
- shortness of breath
- tightness in the chest, trouble with breathing, or wheezing
- skin rash, itching, or hives
- tearing of the eyes

Nicotine patches may cause skin irritation, increased heart rate, nightmares, and increased blood pressure. Nicotine gum and lozenges may cause a tingling or burning sensation in the mouth. Nicotine inhaler doesn't have any additional risks.

Bupropion may cause some, all or none of the side-effects listed below.

More likely

- dry mouth
- trouble sleeping
- nausea
- constipation
- headache
- shakiness or jitteriness
- skin rash
- sweating
- change in appetite
- weight loss
- dizziness
- tremor
- hot flashes
- ringing in the ears

Less Likely

- unusual fatigue
- diarrhea or abdominal pain
- muscle or joint aches that last days
- yellowing of your skin
- seizures
- thinking abnormally

The Food and Drug Administration (FDA) has recommended that individuals taking certain medications including bupropion SR should watch out for worsening depression, or suicidal thoughts and behavior. You should also watch for sudden and severe changes in feelings such as: anxiety, agitation, feelings of panic, irritability, hostility, aggressiveness, impulsivity, severe restlessness, feeling overly excited or hyperactive, or not being able to sleep. In addition, you should tell family members or caregivers to watch out for these symptoms while you are taking the medicine. If you, your family members, or your caregivers notice any of these symptoms, you should notify the study doctor as soon as possible. If you are having suicidal thoughts or behaviors, you should go the nearest hospital emergency room.

You should avoid driving a car or operating heavy machinery until you know how the medications affect you.

If you are a female: Being a part of this study while pregnant may expose the unborn child to significant risks, some of which may be currently unforeseeable. Therefore, pregnant women will be excluded from the study. If you are a woman of childbearing potential, a urine pregnancy test will be done, and it must be negative before you can continue in this study. If sexually active, you must agree to use appropriate contraceptive measures for the duration of the study. Medically acceptable contraceptives include: (1) surgical sterilization (such as a tubal ligation or hysterectomy), (2) approved

hormonal contraceptives (such as birth control pills (if you are under 35 years of age), patches, implants or injections), (3) barrier methods (such as a condom or diaphragm) used with a spermicide, or (4) an intrauterine device (IUD). Contraceptive measures such as Plan B (TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use. If you do become pregnant during this study or if you have unprotected sex, you must inform your study physician immediately.

Drug and Food Interactions: For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study. Bupropion may increase the risk of likelihood of seizures, especially if you are drinking while taking it. **If you begin drinking more frequently than you reported in your first session, please notify the study coordinator.** It is important for us to know this so that we can help protect you from the health risks of drinking and taking the medications. If at any point we believe that your alcohol use might be a health risk because of the medications, we will withdraw you from the study or ask you to quit taking the medication(s) that can cause this health risk.

Blood Spot Collection: At the 6-month follow-up, you will be asked to provide a blood sample to assess drinking status. Blood will be taken from your index, middle, or ring finger with a very simple prick to your finger, collecting about 3mL of blood. The risks of having a blood puncture includes temporary pain for the needle stick, bruising, and rarely, infection. Some people may experience dizziness, possibly lightheadedness, or rarely, fainting. Should any of these symptoms occur, the collection process will stop and the collector will follow health and safety protocols as required.

There may be risks, discomforts, drug interactions, or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct medical benefit to you. You may benefit from stopping smoking and drinking alcohol. However, we cannot guarantee that you will stop smoking or drinking during this study. We hope that in the future the information learned from this study will benefit other people who are trying to stop smoking and/or drinking.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
Instead of being in this study, you could enroll in another smoking and/or drinking cessation treatment program. There may be other treatment programs available to you in the community. Please talk to your doctor about these and perhaps other options.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum

necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Duke University Health System Institutional Review Board, National Institutes of Health, the Office for Human Research Protections, and/or the Food and Drug Administration, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

The mCM mobile application will upload the videos you take to InMotion Hosting, Inc. The data may be permanently kept by this group and/or their contracting partners. The mobile application was developed by a study staff member who is our partner at the Durham, NC Department of Veterans Affairs Medical Center.

If you are loaned a Duke phone for use during this study and you use it for non-study related reasons, this could add your personal information onto the device and potentially result in it being sent to unauthorized persons. The device will be preset with security settings. Please do not alter these during the course of the study. We will limit some of the phone functions, like internet searching and emailing. You should not attempt to re-install those functions. You should not use the phone for personal use, for example, personal phone calls or taking pictures during the study. If you do so, this could add your personal information onto the phone and potentially result in it being sent to unauthorized persons. You are encouraged to limit personal identifiers you enter into mobile applications (particularly your name, date of birth, address, place of employment, and other details that could allow someone to identify you) only to those that you wish to voluntarily share with others. When you return the device at the end of the study, the device will be cleaned to remove any of your personal information. If the device is lost or stolen during the course of the study, please contact the study team immediately.

We are not asking you to make any health decisions based on the use of these mobile apps. You should discuss health decisions directly with your healthcare provider.

As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

All of the urine and saliva, and blood sample studies are being done only because you are in this study. The study results will not be given to you to send OR sent to your physician to include in your medical record.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative,

legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

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WHAT ARE THE COSTS TO YOU?
You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Dedert**.** At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

Duke University Medical Center will provide the bupropion, NRT and equipment free of charge for your use in this study. At the conclusion of the study, or if you decide to withdraw from the study, you must return all unused medications to the study coordinator. Dr. Dedert may request that you return for a checkup before you stop your medications if he thinks that stopping them suddenly may harm you. He may also ask you to complete the tests that would ordinarily occur when a person completes the study.

WHAT ABOUT COMPENSATION?
You will be reimbursed up to $250 for your expenses related to your participation (parking, gas, and time). You will be compensated $50 for a saliva sample at Session 7.

If you are assigned to the Mobile Contingency Management group, you will also be compensated up to $1,136 for at-home monitoring and abstinence from drinking and smoking. Most people do not earn this much money for at-home monitoring. This compensation is offered as an incentive for you to stop drinking alcohol and stop smoking cigarettes. In total, you will be compensated up to $1471 for participation, depending on how many prompts you receive to complete Breathalyzer readings and how well you do in completing readings and stopping your substance use.. If you are assigned to the Mobile Monitoring group, you will also be compensated up to approximately $589 for at-home monitoring regardless of whether you stop drinking alcohol and smoking cigarettes. These numbers may vary slightly due to variations in the possible number of alcohol alarms. If you do not complete the study, you will be given partial compensation for those parts you have completed.

Payment will be given to you in several installments. Payment will be requested for session 1 just after you have completed it. Payments during monitoring will be requested as frequently as weekly and payment for session 8 will be requested just after you have completed it. After we request payment, it may take up to four to six weeks for you to receive payment.

Payment received as compensation for participation in research is considered taxable income to the research subject. If payment to an individual exceeds $600 in any one calendar year, Duke University is

required to report this information to the Internal Revenue Service (IRS). Research subject payments to a non-employee of Duke University exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Dedert at 919-384-8582, ext. 4055 during regular business hours and at 919-286-0411 and ask the operator to contact Dr. Dedert at home after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Dedert in writing and let him know that you are withdrawing from the study. His mailing address is Eric Dedert, Ph.D., Duke University Medical Center, Box 2969, Durham, NC 27705. You will be asked to return any study equipment you have been loaned.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. Reasons why this might occur include failure to follow the instructions of the study staff, inability to complete the study requirements, or inability to attend study visits as scheduled. If this occurs, you will be notified and your study doctor will discuss other options with you.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
Mobile Contingency Management for Concurrent Abstinence from Alcohol and Smoking (Stage 2)

A description of this clinical trial will be available on https://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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Dedert at 919-684-9022 or 919-384-8582 x4055 during regular business hours, or toll free at 1-888-878-6890 and ask the operator to contact Dr. Dedert at home after hours and on weekends and holidays. You may also contact Dr. Scott Moore at 919-286-0411, ext. 7695, or toll free at 1-888-878-6890 and ask the operator to contact Dr. Moore at home after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time