OUHSC Consent Form Instructions Page

Consent Form to Participate in a Research Study
University of Oklahoma Health Sciences Center (OUHSC)

Study Title: Cigarette Smoking in Young Adults

Sponsor: National Institute on Drug Abuse/Food and Drug Administration Center for Tobacco Products (CTP)

Principal Investigator: Amy M. Cohn, PhD
Phone Number: 405-271-1903

KEY INFORMATION ABOUT THE RESEARCH STUDY

You are being asked to participate in a research study. Research studies are voluntary and include only people who choose to take part. This consent form begins with a ‘Key Information’ section to provide important information to help you decide whether or not to participate in this study. More detailed information is provided after the key information. Please take your time, discuss this with family and friends, and ask the investigator and study team any questions you may have.

WHY HAVE I BEEN ASKED TO PARTICIPATE IN THIS STUDY?
You are being asked to participate in this research study because you are a current smoker and meet study eligibility criteria. This study is not going to ask you to quit smoking. This study is being conducted by the University of Oklahoma Health Sciences Center and is funded by the National Institutes of Health (NIH) and the FDA Center for Tobacco Products. Joining the study is voluntary. You do not have to answer any questions that make you feel uncomfortable. You can stop participating or answering questions at any time.

WHY IS THIS STUDY BEING DONE AND HOW LONG WILL IT LAST?
The purpose of this study is to understand how people will smoke very low nicotine cigarettes (VLNCs). We are interested in how smoking these cigarettes affects your smoking, how you feel, and attitudes about different types of VLNCs. We think that you will be in the study for about 2 months.

WHAT WILL I BE ASKED TO DO IN THIS STUDY?
To prioritize the participants’ and the study team’s health, the sequence of study requirements may vary due to COVID-19, rules and guidelines set by authorities at the National, Local, or University level. This may mean that the in-person study visits may become virtual (e.g. online video calls) visits.

If you agree to participate and are found eligible, you will be asked to do the following:

- Attend 1 pre-screen/baseline assessment visit in our laboratory (or virtually) which may last up to 1 hour. During this visit you will complete medical history questionnaires and complete a series of web-based surveys on your health and smoking behaviors to determine your eligibility in the study.
- Attend 3 experimental visits in our laboratory (or virtually), which may last up to 2 hours each, where you will smoke a cigarette.
- You will be asked to refrain from cigarette smoking or using other nicotine products for at least 12 hours before each smoking visit. We will also ask you not to drink any coffee, soda, or energy drinks for an hour before each visit.
701A Consent | OUHSC IRB Version Date: 9/10/2019

If you are eligible, you will be asked to smoke your usual brand of cigarettes at home for 7-days and then once in the laboratory.

You will also be asked to smoke menthol flavored and traditional tobacco flavored research cigarettes in your environment for 7 days each, and then once in the laboratory. These research cigarettes contain less nicotine than a normal cigarette. The order in which we ask you to use the menthol or non-menthol (tobacco flavored) research cigarettes will be determined randomly.

You will provide breath samples at the beginning of each smoking visit (or virtual session) to measure when you last smoked.

We will also ask you to sign a document confirming you have not smoked for the last 12 hours and haven’t had any caffeine in the last hour before each smoking session. If you complete your sessions remotely, we will confirm this with you verbally over the phone.

For each of the 7-day “take home” smoking period, you will complete daily surveys about your mood and smoking behavior on a phone, two random times a day.

If you prefer not to use your personal phone or if your personal phone is not compatible with the application that we use for the daily cell phone surveys (Android compatible), we will give you a study phone. You will have to return this phone at the end of the study in order to receive the full amount of compensation you have earned. We will provide only 1 replacement phone per participant, at no cost to you. If you lose or misplace your phone more than 1 time, you may be withdrawn from the study.

When you smoke in the laboratory (or remotely), you will smoke one cigarette through a machine that measures smoking. You will complete questionnaires about your behavior and mood, both before and after smoking. We will also measure your heart rate and blood pressure before and after smoking and take another breath sample. (We will not be able to measure blood pressure for virtual/remote visits).

In the final experimental session, you will complete a computerized task. This task will ask you how much you are willing to pay and use different amounts of cigarettes and other tobacco products. This visit will may take up to 1 hour to complete. You will have the option to purchase no tobacco products at all in this computerized task.

Finally, 30-days after your final study visit, you will complete a brief survey (on the telephone or in-person) about your tobacco use and behavior and one more brief computer task about your tobacco purchasing preferences.

We will provide all the research cigarettes at no cost to you.

If you take your sessions remotely, we will also give you a mouthpiece you can use to provide the breath samples of recent smoking (exhaled Carbon Monoxide), as well as a machine to measure your puff behavior. The mouthpiece can connect directly to the study smartphone and works with an app.

If any instructions are not followed, or if your breath sample shows that you have been smoking recently, the session will be cancelled and rescheduled for another time. If you reschedule your visit more than 3 times for any reason, you may be withdrawn from the study.

For a complete description of the study procedures, refer to the Detailed Information section of the consent form.

WHY MIGHT I WANT TO PARTICIPATE IN THIS STUDY?

If you agree to take part in this study, you may benefit directly through increased understanding of factors underlying your use of cigarettes. We also hope that the information learned from this study will benefit other people in the future.
WHY MIGHT I NOT WANT TO PARTICIPATE IN THIS STUDY?
This study has minimal risk however there are known complications that arise from smoking cigarettes that may affect the individual or an embryo, fetus, or infant. The researchers do not know all of the side effects that could happen. For a complete description of known risks, refer to the Detailed Information section of the consent form.

WHAT OTHER OPTIONS ARE THERE?
You may choose not to participate in this study. If at any point during the in-person study visits you decide to stop smoking, you will be reimbursed for your time up to that point and will be able to complete the remainder of the study assessments. We will not ask you to smoke cigarettes if you decide you want to stop smoking. You may choose to decline using the study cigarettes and still be retained in the study and complete all study assessments. We will also provide you with a list of places where you may choose to seek treatment to stop smoking. If you decide to stop smoking at any point you will still be able to continue in the study unless you tell us you want to drop-out of the study.

HOW WILL PARTICIPATING IN THE STUDY AFFECT ME FINANCIALLY?
You will be paid for your time and effort. Below describes the compensation for attending each visit. Below is a table outlining the schedule of what you might get paid.

In addition to attending 5 sessions in the laboratory, and completing brief surveys about your smoking on a phone, you can be eligible to receive an incentive for returning unused research cigarettes ($0.25 per cigarette), for up to $20 per participant. For returning used cigarettes (e.g., cigarette butts) at Visits 3 and 4 of the study, you will be compensated as follows: $7 for 75-100% returned; $5 for 50%-74% returned, $2.50 for 25%-49% returned; and $0.00 for 0-24% returned.

The total possible compensation (including a one-time referral) is $551. Full payment for the 30-day follow-up and completion bonus will be provided if you complete those portions of the study and when you return the study provided phone and smoking behavior machine (if you use one). You can choose to be reimbursed through Amazon Gift Card code, which is emailed, or a reimbursable gift card which can be given to you directly either via mail or at your first in-person visit. If your first study visit is taken remotely, we can only provide Amazon gift card code as the payment for this session. You may choose reloadable gift card after that session, if you are eligible to continue in the study.

Reimbursable gift cards are provided through Greenphire who is a company working with the researchers and the university. In order to set up and process payments your first and last name, home address, and birth date will be required. When a visit or task is completed, funds will be approved and loaded onto your card. Greenphire will not have access to your research data, only the information required to set up the card. Greenphire will not have access to your research data, only the information required to set up the card.

Note: If during the study your ClinCard is lost or stolen, we will replace it one time, at no charge to you. The new card will be linked to your existing account and the old card will be deactivated. If you lose your ClinCard after your one free replacement you may contact Greenphire, the card issuer, for a replacement for a $7 fee at your expense.

You will be asked to provide you social security number, your residency status (a copy of your green card must be provided if applicable), and whether you are a University of Oklahoma employee for tax reporting.
purposes. If you are unwilling or unable to provide your social security number, residency status (and
green card if applicable), or University of Oklahoma employment status you will not be eligible to
participate in the research study.

For additional information about possible costs, please refer to the Detailed Information section of the
consent form and ask the study team about any expected additional costs or insurance problems.

DETAILED INFORMATION ABOUT THE RESEARCH STUDY

The following pages of the consent form will provide you with more information about this study. Please
take your time in reviewing this information and ask the investigator and study team any questions you
may have.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
About 172 people will take part in this study. All of these individuals will participate at this location.

WHAT IS THE STATUS OF THE DRUGS/DEVICES/PROCEDURES USED IN THIS STUDY?
You will smoke your own or usual cigarette brand and very low nicotine research cigarettes in this study.
We are calling these research cigarettes. The U.S. Food and Drug Administration regulates cigarettes
and the use of very low nicotine research cigarettes (0.4 mg nicotine/g tobacco) in this study is
investigational. The word “investigational” means that these cigarettes are not approved for marketing or
use as a treatment by the U.S. Food and Drug Administration (FDA). The FDA has allowed research
studies in which a person have volunteered to use these cigarettes for testing purposes. The FDA is
aware that these cigarettes will be used in this research study. These cigarettes are provided by the
National Institute on Drug Abuse Drug Supply Program.

WHAT IS INVOLVED IN THE STUDY?
If you are eligible, this study will require 1 pre-screen/baseline assessment to determine your eligibility,
and 5 in-person (or remote) visits to our lab: The baseline assessment will last about 1 hour. If you are
eligible and agree to participate, your next 4 visits will be scheduled and will last between 1 and 2 hours,
depending on the session. We will ask that you refrain from cigarette smoking and using other nicotine
products for at least 12 hours before each experimental visit (in person or remote). You will also be asked
not use caffeine (soda, energy drinks, or coffee) for an hour before each experimental session. You will
be asked to smoke your usual brand cigarette, and two different types of research cigarettes, each in
your home environment for 7 days and then in the laboratory (or remotely). When you are using the
research cigarettes for each 7-day period, we ask you that refrain from smoking your usual brand
cigarette, and use the research cigarettes instead. One of these research cigarettes will be flavored to
taste like mint/menthol and the other will taste like traditional tobacco. These will be very low nicotine
research cigarettes that are available from the National Institute on Drug Abuse Drug Supply Program
(DSP). The order in which you are assigned to smoke the two types of study cigarettes will be randomly
chosen.

If you are female, we will ask you to take a pregnancy test at each experimental study visit. We expect
that if you are a female of child bearing age who is able to conceive, you will use reliable contraception
and not be planning pregnancy or breastfeeding during the study. Participants with a positive pregnancy
test will be notified and will not be able to continue participation in study. If you become pregnant, please
let staff know as soon as possible.
Visit 1 (Pre-screen/baseline): We will review eligibility criteria similar to what you answered over the phone. If you are eligible and you agree to participate, we will ask you to provide some additional information about yourself and your use of cigarettes, other tobacco products, and behaviors related to tobacco use.

In Between Visit 1 and Visit 2 (Take Home Smoking): Following Visit 1, you will smoke your usual brand of cigarettes for 7 days, as you normally would. During this 7-day period, you will record your cigarette smoking, mood, and attitudes about smoking twice a day with a smartphone app.

Visit 2 (Smoking Usual Brand Cigarette): You will smoke one of your own cigarettes that you have with you. Before you smoke, we will test your breath to see when you last smoked, and check your heart rate and blood pressure, called your vitals. **For females: We will confirm you are not pregnant with a pregnancy test prior to beginning the session. You will smoke your cigarette through a mouthpiece that allows us to measure the puffs you take. After you finish smoking, we will conduct another breath test, and check your vitals (heart rate and blood pressure). Both before and after smoking we will have you answer some questionnaires about how you are feeling. *If you are taking your visits remotely, we may not be able to take your blood pressure.

At the end of this visit, we will dispense your first set of research cigarettes. We will give you enough research cigarettes to last you for 7-days. This amount will be based on how many cigarettes you typically smoke of your usual brand during a 7-day period. You are not allowed to share research cigarettes or keep them beyond the 7-day period. **If your session is remote, we will arrange a time and day for you to pick-up the research cigarettes, either at our research lab or at a public location (mall, restaurant, library, etc).

In Between Visits 2 and 3 (Take Home Smoking): After Visit 2, you will smoke the first set of research cigarettes in your home environment, for 7-days, and will record your cigarette smoking, mood, and attitudes about smoking and other tobacco use with a smartphone app. We ask that you not smoke your usual brand of cigarettes during this 7-day period. We will ask you to keep track of your used and unused cigarettes, as you return these cigarettes at your next study visit so we can review how many you did and did not use. You are not allowed to share research cigarettes or keep them.

Visit 3 (Smoking Research Cigarette): After using the first research cigarette in your home environment for 7 days, you will return to the laboratory on the 7th day, and smoke that research cigarette, as you wish, through a machine. This smoking session will be identical to the first smoking session. **This visit may occur remotely, if you are unable to return to the lab due to COVID-19. We will also ask you to return used (e.g., butts) and unused research cigarettes. If your session is remote, we will count your used and unused cigarettes during the remote session and then have you return them at your next curbside pick-up/drop-off. You will be compensated for returning used and unused research cigarettes so that we can be sure you have not shared them with anyone.

In Between Visits 3 and 4 (Return to smoking as usual): After Visit 3, you may return to smoking your usual brand of cigarettes, as normal, for 7-days. You do not need to do anything different than you normally would during this week. This is called a "wash-out" period. At the end of the 7-day "wash out" period, you will pick up your second set of research cigarettes. **You will return your used and unused cigarettes at this time and be compensated for used/unused cigarettes. This will take 10 -15 minutes. You will then smoke the second set of research cigarettes in your home environment, for 7 days, and will record your cigarette smoking, mood, and attitudes about smoking twice a day with your phone. We will give you enough research cigarettes to last you for 7-days. You are not allowed to share research cigarettes or keep them beyond the 7-day period.
Visit 4: Visit 4 will be identical to Visit 3. After 7-days of using the second type of research cigarette in your home environment, you will return to the laboratory on the 7th day, and smoke that second research cigarette, as you wish, through a machine. We will also ask you to return unused research cigarettes, as well as used research cigarettes (e.g., cigarette butts). If your session is remote, we will count your used and unused cigarettes during the remote session and then have you return them at your next curbside pick-up/drop-off. You will be compensated for returning used and unused cigarettes so that we can make sure you have not shared them with anyone else.

Visit 5: For your final visit, you will be asked to complete a computer task in which you can use money to hypothetically pay for and use different amounts of research cigarettes or other tobacco products, or no products at all. This visit will take about an hour. The tobacco products you can buy will be those that are currently available at a local store, as well as the research cigarettes you used over the course of the study. The amount of money that you will have to spend on these products will be based on the typical amount of money you spend on tobacco products each week.

30-Day Follow-up Assessment: Finally, 30-days after Visit 5, we will do a short survey with you, preferably in our lab, but if you cannot make it, we can do it remotely. This survey will ask about your smoking and tobacco use and tobacco-related behaviors. You will also be asked to complete another brief computer task in which you can use money to hypothetically pay for and use different amounts of research cigarettes or other tobacco products, or no products at all.

CAN I WITHDRAW FROM THE STUDY?
You can stop participating in this study at any time. However, if you decide to stop participating in the study, we encourage you to talk to let the research team know. Refusal to participate or withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you withdraw, you will be compensated for your time up to that point. Your data up to that point may be used for study purposes unless you request otherwise. You can also stop using the research cigarettes at any time without penalty. If you do not want to use the research cigarettes, you may still be able to remain in the study and complete the rest of the study assessments. If you decide you no longer wish to receive the study cigarettes, please let us know as soon as possible.

There may be circumstances under which your participation may be terminated by the investigator without your consent. These include:
- If we believe being in the study may put you at significant risk or feel that it is in your medical best interest
- If you are unable or unwilling to follow study procedures, such as keeping your visit appointments or unwilling or unable to abstain from nicotine or tobacco products and any other combustible product (e.g., marijuana)
- If you are pregnant or breastfeeding, or become pregnant
- The study is stopped by the Sponsor

WHAT ARE THE RISKS OF THE STUDY?
Discomfort from withdrawal: You may experience nicotine withdrawal symptoms during this study. These symptoms can include anger, irritability, frustration, anxiousness, depressed mood, craving for a cigarette, difficulty concentrating, increased appetite, weight gain, sleep problems, restlessness, impatience, constipation, dizziness, coughing, nightmares, nausea and sore throat. These feelings can be uncomfortable, but they are normal, temporary, and are usually mild.
Risks related to smoking: The cigarettes you smoke during this study will be your own brand and the research cigarettes that we provide to you. The research cigarettes contain tobacco and nicotine. All cigarettes, including the research cigarettes, are bad for a person’s health and can lead to heart disease, lung diseases, cancer, and death. Acute side effects of nicotine include headache, nausea/vomiting, increased heart rate, increased blood pressure, runny/stuffy nose, change in taste, heartburn, hiccups, sweating, or diarrhea. Although smoking is associated with disease, we do not expect the disease risk to be significantly greater or lower when smoking the research cigarettes versus the cigarettes you typically smoke. At the end of the study, or if you request, you will be offered resources to help you stop smoking. Quitting smoking can greatly reduce risks to your health.

Discomfort from interview procedures: Some questions may make you feel uncomfortable. You may refuse to answer any questions. However, if you refuse to answer questions that are required to determine your eligibility for the study, you will not be able to continue in the study. There is a potential risk for an unanticipated breach of confidentiality. Below we describe the methods we will follow to ensure your confidentiality is maintained.

The procedures may involve risks that are currently unforeseeable. For more information about risks and side effects, contact the PI Amy Cohn, PhD or the study coordinator Michael Smith at (405) 271-7759, 24 hours a day. We are available Monday through Friday during regular business hours (9-5pm) to return phone calls.

REPRODUCTIVE RISKS FOR WOMEN: If you are a female, you must not be and should not become pregnant nor breast-feed an infant while this study. Smoking cigarettes while you are pregnant or breastfeeding may involve risks to an embryo, fetus, or infant, including birth defects which are currently unforeseeable. In order to reduce your risk of pregnancy, you or your partner should use one or more of the acceptable methods of birth control listed below, regularly and consistently, while you are in this study.

Acceptable methods of birth control (continuing throughout the study) include:

- An approved oral contraceptive (birth control pill)
- Intra-uterine device (IUD)
- Hormone implants
- Contraceptive injection (Depo-Provera)
- Barrier methods (diaphragm with spermicidal gel or condoms)
- Transdermal contraceptives (birth control patch)
- Vaginal contraception ring (birth control ring)
- Sterilization (tubal ligation, hysterectomy or vasectomy)

Certain drugs may interact with contraceptive agents and reduce their effectiveness; therefore, you should inform the study staff of all medications (prescription and over-the-counter) that you are currently taking or begin taking during the study.

IN CASE OF PREGNANCY: If you become pregnant or suspect that you are pregnant, you should immediately inform the study personnel. We will perform a pregnancy test at each in-person visit or remote study session. If pregnancy is confirmed, you will be withdrawn from the study. Payment for all aspects of obstetrical, child, or related care will be your responsibility. The study doctor and the Sponsor will follow the progress of your pregnancy and will request access to your and/or your infant's medical records for least eight
weeks after delivery. Payment for all aspects of obstetrical, child, or related care will be your responsibility.

TO WHAT EXTENT WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Efforts will be made to keep your personal information confidential. You will not be identifiable by name or description in any reports or publications about this study. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. You will be asked to sign a separate authorization form for use or sharing of your protected health information.

There are organizations outside the OUHSC that may inspect and/or copy your research records for quality assurance and data analysis. These organizations may include the US Food & Drug Administration and other regulatory agencies, and the National Institutes of Health. The OUHSC Human Research Participant Program office, the OUHSC Institutional Review Board, OUHSC Office of Compliance, and other University administrative offices may also inspect and/or copy your research records for these purposes.

We work with an internal vendor at our university who supplies the mobile application for the automated daily cell phone surveys. The company will take appropriate steps to protect your privacy. Your information is stored securely and separately from your survey responses. Your personal information will not be sold or given to any other people or companies for any purpose. We also work with an internal vendor (Greenphire ClinCard) who supplies the gift cards you may choose for compensation. This company will not have access to your research data. We do provide this company your name, address, and birth date in order to setup the automatic study payments.

Posting Study on ClinicalTrials.gov:

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

Certificate of Confidentiality:

To help protect your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. This Certificate means that the researchers cannot be forced (for example by court subpoena) to share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the U.S. government that is used for checking or evaluating federally-funded projects or for information that must be disclosed in order to meet the requirements of the US Food and Drug Administration.

The protection offered by the Certificate of Confidentiality does not prevent us from being required by applicable state law to report information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject’s threats of violence to self or others. If any member of the research team is given such information, he or she will be required to make a report to the appropriate authorities.

The Certificate, however, does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. This means that you and your family should actively protect your own privacy.
Identifiable Private Information:

- Your information may be used for future studies without your additional consent. We will remove direct identifiers from your information/specimen and assign a code. The key to this code will be kept separately and only the researcher and approved study personnel for this study will have access to the code. If your information is shared with another investigator for research purposes, they will not be able to re-identify you.

WHAT ARE THE COSTS?
You may have some travel costs for your study visits and you will be using your own cigarettes for part of the study. If you use your personal phone to complete the daily automated phone calls, we will reimburse you $40 for the month that you have it, or you may have a study phone provided to you if your phone does not have the Android operating system. There are no other costs to you.

WHAT IF I AM INJURED OR BECOME ILL WHILE PARTICIPATING IN THIS STUDY?
You will be watched throughout the study for Adverse Events. All Adverse Events will be recorded and will be followed until they are resolved or stabilized. Formal policies are in place for emergency procedures. In the case of injury or illness results from this study, emergency medical treatment is available. Any expenses will be your responsibility. You or your insurance may be charged for this treatment. Complications arising as a result of the natural progression of an underlying or pre-existing condition will be billed to you or your insurance. Please check with the investigator or with your insurance company if you have questions.

No other funds have been set aside by the University of Oklahoma Health Sciences Center, to compensate you in the event of injury, illness, or for other damages related to your event of injury or illness.

WHAT ARE MY RIGHTS AS A PARTICIPANT?
Taking part in this study is voluntary. You may choose not to participate. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

If you agree to participate and then decide against it, you can withdraw for any reason and leave the study at any time.

We will provide you with any significant new findings developed during the course of the research that may affect your health, welfare, or willingness to continue your participation in this study.

You have the right to access the medical information that has been collected about you as a part of this research study. However, you may not have access to this medical information until the entire research study has completely finished. You consent to this temporary restriction.

DO I HAVE ANY OTHER RIGHTS OVER MY DATA?
Depending on where the sponsor for your study is located and other factors, you may have additional rights over your personal data collected in this study. For example, the European Union General Data Protection Regulation (GDPR) and some state privacy laws might apply. If the GDPR applies, generally you may have the following rights:

1. The right to request the information collected to be corrected.
2. The right to withdraw your consent for the use of your personal information at any time.
3. The right, in some circumstances, to receive your personal information in a structured, commonly used and machine-readable format and the right to provide your information to a third party.

4. The right to strict confidentiality of your personal data when it is used/shared.

5. The right to limit the use/sharing of your personal information in certain circumstances.

6. The right under some circumstances to request the erasure of your personal data.

7. The right to file a complaint with a privacy protection regulator if you believe any of the rights above have been violated.

You can receive more information regarding these rights in the Privacy Notice for Research Participants, located on the OUHSC Office of Human Research Participant Protection (HRPP) website at https://compliance.ouhsc.edu/HRPP/Participant/Privacy-Notice.

If you have any questions and requests, please contact the HRPP Office at 405-271-2045.

WHOM DO I CALL IF I HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

If you have questions, concerns, or complaints about the study or have a research-related injury, contact Amy M. Cohn, PhD or the study coordinator Michael Smith at 405-271-7759 or at Enhance@ouhsc.edu.

If you cannot reach the Investigator or wish to speak to someone other than the investigator and for questions about your rights as a research participant, contact the OUHSC Director, Office of Human Research Participant Protection, at 405-271-2045.

SIGNATURE:

By signing this form, you are agreeing to participate in this research study under the conditions described. You have not given up any of your legal rights or released any individual or entity from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

I agree to participate in this study:

______________________________________ ____________________________      __________
PARTICIPANT SIGNATURE (age ≥18)  Printed Name         Date

______________________________________ ____________________________     ___________
SIGNATURE OF PERSON     Printed Name                    Date
OBTAINING CONSENT