THE MIND RESEARCH NETWORK

**MIND RESEARCH NETWORK**
**CONSENT TO PARTICIPATE IN RESEARCH**

**Lorcaserin effects on smoking behaviors**

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision about whether or not to participate. This form will explain the study to you, including the possible risks as well as the possible benefits of participating, so you can make an informed choice about whether or not to participate in this study. Please read this consent form carefully. Ask the investigators or study staff to explain any words or information that you do not clearly understand.

| **Key Information for You to Consider** |
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| • You are being asked to participate in a research study about how the medication *lorcaserin* affects smoking-related behaviors (such as cigarette craving and decisions about smoking) and behavioral factors related to smoking (such as impulsive responding). Participation is voluntary and it is up to you whether or not you choose to participate.<br>• Your participation is expected to last about 18 hours over 5 weeks. This will include up to 5 study visits, with an additional 30-60 min. over the phone.<br>• During the study you will answer questions in interview and computerized format, perform computerized tasks, take the study medication and placebo pills, and complete two sessions in which you will have the opportunity to smoke cigarettes.<br>• You will also complete some medical tests such as collection of blood samples, collection of urine, and breath alcohol (to detect recent alcohol use) and breath carbon monoxide (to detect recent cigarette use) tests<br>• The primary potential risks of this study include boredom, discomfort and fatigue from study procedures, and potential side effects from the medication.<br>• You are not expected to receive any specific benefits from participating.<br>• This is not a treatment study.<br>• Taking part in this study is voluntary so you can choose not to participate. |

## Purpose and General Information

You are being asked to participate in a research study that is being done by Eric Claus, Ph.D., and Christian Hendershot, Ph.D. who are the Principal Investigators (PIs). This research is being done to evaluate how the medication *lorcaserin* affects cigarette smoking and related responses (e.g., craving). Lorcaserin is approved by the Federal Drug Administration (FDA) for the purpose of weight management. The medication is typically prescribed to help people who have a body mass index (BMI) over 30 lose weight. Research in

animal studies has also shown this medication may influence responses to nicotine and decision-making tasks. This study also will try to identify, using questionnaires and computerized tasks, whether lorcaserin influences responses to nicotine in certain groups of people. *This study is not a treatment study.*

You are being asked to participate in this research study because you report smoking cigarettes at a level that meets criteria for "dependence," you express interest in eventually quitting, and you report that you are not actively planning to quit in the next several weeks. Up to 100 people will be enrolled into the study to obtain a final sample of approximately 40-50 people; this study will take place at the Mind Research Network. This study is funded through the National Institute on Drug Abuse (a division of the National Institutes of Health).

## What will happen if I participate?

If you agree to be in this study, you will be asked to read and sign this consent form. You can discuss any questions you may have about this form with the study staff. After you sign the consent form, the following things will happen:

You will answer a series of questions about your alcohol use, cigarette use, and medical history, as well as other questions to make sure that you're eligible for the study. You will also meet with a member of the study staff to complete a medical history interview, as well as some brief assessments (e.g., breath carbon monoxide, blood pressure, etc.), height/weight measurement, and heart function (described below).

If you are eligible for the study, you will be asked to take the active medication for approximately one week, and placebo pills for approximately one week (a placebo is a pill that looks like the active medication, but has no active medication in it). The order in which you take the pills will be randomized, meaning that some people will take the active medication the first week and the placebo during the second week, and some people will take the placebo the first week and the active medication the second week. Randomization means you will be assigned to a group based on chance, like a flip of a coin. Neither you nor any member of the research team chooses your assigned group or will know what group you are assigned to, however, in an emergency (e.g., if you are hospitalized or in an accident and knowing the drug would be important for your treatment), the study doctor can get this information.

Participation will occur over the course of roughly 5 weeks, and will include a total of approximately 5 visits to MRN (approximately 16-18 hours total), including 1 hour over the phone (roughly 4, 15-minute calls). The study visit schedule is as follows:

- One **screening visit** (today) to complete the consent process, eligibility interviews, and medical assessment (2-3 hours). (Note: the medical assessment may be conducted on a separate day to accommodate scheduling.)
- If you are eligible after the screening visit, you will then complete a **baseline visit** (2-3 hours). At this visit you will complete additional questionnaires and computerized tasks, and receive the first set of study pills (active medication or placebo).
- **Follow-up visit 1** (up to 5 hours). After taking the first set of study pills for roughly one week, you will complete a follow-up visit that includes a repeat medical assessment, a blood draw, as well as follow-up questionnaires and computerized tasks. This visit will take place after you have taken the study pills for roughly one week. This visit will also include a cigarette smoking session (described in more detail below).
- Next, you will have a **medication break** (no pills or study visits) for at least 7 days.

- **Medication refill visit** (1 hour). This appointment will take place about 1-2 weeks after follow-up visit 1. At this appointment you will be asked to complete some follow-up questionnaires and medical assessments (e.g., weight, blood pressure), and will receive the next set of study pills (active medication or placebo).
- **Follow-up visit 2** (up to 5 hours). This visit will take place after you've taken the second set of study pills for roughly one week. The study visit procedures will be identical to follow-up visit 1.
- **Telephone check-ins** (5-15 minutes each, total of 4 check-ins): During weeks when you are taking the study pills, a member of the study staff will call you on the phone to ask about potential side effects, as well as alcohol and nicotine use.

If you are unable to commit to the timeframe of the study (6 weeks) or if you plan to travel out of town, you should let us know, as this will make you ineligible for participation.

We have organized the different parts of the study into three categories (*Screening visit, Baseline visit*, *Medication weeks*, and *Follow-up visits*), described in more detail below.

I. Screening Visit

As part of screening to see if you qualify for the study, we will ask you about your current and previous smoking history, and conduct a structured interview asking you about your other substance use and medical history. You will meet with a member of our medical staff, and we will ask you to complete some brief assessments, including expired carbon monoxide (CO), heart rate/blood pressure, body weight/height, a blood sample (approximately 4 teaspoons), and an electrocardiogram (ECG) to measure heart function. You will be asked to provide a urine sample to test for the presence of several drugs, including cocaine, heroin, methamphetamine, and marijuana. You will be able to collect the sample in a bathroom without anyone watching you. For females, this urine test will also be used to complete a pregnancy test (as a safety precaution). If your pregnancy test shows a positive result at any point during the study, we will tell you this result in a private room. If you test positive for drugs (other than marijuana) or pregnancy, you will not be eligible for the study. These tests are mostly used to make sure it is safe for you to take the study medication. The blood sample will be checked for kidney function, electrolytes, liver function, nicotine metabolites, and blood cell counts. Your urine sample will also be saved and analyzed to measure levels of nicotine and nicotine metabolites. If the tests on your blood sample are abnormal or if your ECG or vital signs seem abnormal, the study's medical staff will notify you of the findings; you will not be notified about any genetic results.

*Saliva Collection.* Finally, we will ask you for a saliva sample to collect genetic material (genes or DNA). We will provide you with a small cup and ask you to fill it with saliva up to a certain line (less than half a teaspoon). The purpose of collecting saliva for DNA in this study is to examine whether medication effects might be different according to certain genetic factors. Your saliva will be labeled only with a special number (code), which will remain linked to your identity. We will store this sample until we are ready to analyze it. If you agree, we may keep your saliva for a very long time (indefinitely) for future research. Please see optional procedures at the end of this consent form.

The screening procedures are expected to take up to 3 hours. Depending on scheduling, you may be asked to return to complete the medical assessment at a separate visit (resulting in two 1.5 hour visits).

II. Baseline Visit

If you are eligible after the screening visit and wish to participate, you will be asked to return for a baseline visit. During this visit you'll be asked to complete a number of computerized questionnaires (about smoking history, substance use, personality, etc.), and do some computerized tasks (to measure things such as impulsive responding and reward-based responding). Women will complete a urine pregnancy test again before receiving any medication. You will be asked to provide a saliva sample for DNA analysis (see genetic analysis section below). You will also receive your first set of study pills along with instructions on how to take them. This visit is expected to take around 2-3 hours.

III. Medication Weeks

You will be asked to take each type of study pill (active medication or placebo) for 7 days each, with a break of at least 7 days in between. At the end of this 7-day break, you will complete a brief visit to MRN to pick up the second set of study pills. During each of the medication weeks, you will be asked to take the study medication (consisting of 2 pills daily), and to complete a daily log to record the number of pills taken, potential side effects, cigarette use, other drug use, cravings, and questions related to eating/hunger. Additionally, a member of the study team will contact you at two scheduled times (e.g., 2 and 4 days after starting the medication) to review your medication-taking and any side effects by telephone. These calls are expected to last 5-15 minutes each.

IV. Follow-up Visits

Each of the medication weeks will end with a follow-up visit to MRN (i.e., Follow-up Visits 1 and 2). These sessions will require that you spend most of the day in the lab (up to 5 hours). Additionally, these visits will require *overnight abstinence from smoking*. We will ask you refrain from smoking starting at midnight the night before the visits. When you arrive at the lab, you will take a CO test by blowing into a machine to confirm overnight abstinence. *If the CO test does not show recent abstinence, your visit may be rescheduled.* If the test shows abstinence, you will receive a monetary bonus (see compensation section).

You also must agree not to consume alcohol or use recreational drugs within 24 hours of these visits, and not to eat for 4 hours before arriving at MRN. After arriving, you will be asked to provide a urine sample for a urine drug test and a breath alcohol reading to confirm recent abstinence from alcohol and drugs. For females, the urine sample may also be used for a pregnancy test. If you test positive for recent use of recreational drugs (with the exception of marijuana) you may be rescheduled or withdrawn from the study. The urine will also be tested to determine whether you have been taking the medication. The medication includes a small amount of riboflavin, a substance that can be detected in urine. If you have not taken the medication for the prior week, you may be rescheduled or withdrawn from the study. We will also collect a blood sample (approximately 4 teaspoons at each follow-up visit) that will be used to detect whether you took the medication for the week.

At these visits you will complete brief follow-up interviews with the study staff and a member of the medical team, about your smoking behaviors, craving, and eating habits. You will be asked to complete follow-up computerized questionnaires and tasks, similar to the baseline session. You will also be asked to repeat the brief medical assessments from the baseline session (weight, heart rate/BP) and will be asked about any side effects you have experienced. In the event that the study medical staff members have any reason to believe that continuing to participate in the study would not be safe for you, you may be removed from the study.

*Smoking session*. Each of the two follow-up visits will include a smoking session. For these sessions we will ask that you bring one unopened package of your preferred brand of cigarettes. First, you will be asked to light a cigarette without smoking it, and to complete questionnaires about your mood and craving. Next, you will have the opportunity to smoke cigarettes or to delay smoking. Finally, you will have the opportunity to smoke additional cigarettes if you wish. The smoking session will last 1-2 hours. You do not have to smoke during this session, but the session will last the same amount of time whether you choose to smoke or not.

## What are the possible risks or discomforts of being in this study?

**Medication.** There are certain risks/side effects of the study medication. In studies where lorcaserin was taken for a longer period of time (at least one year), the most commonly reported side effects (i.e., greater than 5% of participants and more common than placebo) included:

- headache
- dizziness
- fatigue
- nausea
- dry mouth
- constipation
- nasopharyngitis (nasal/throat irritation, similar to a common cold)

Additionally, the less common side effects (reported by 2% or more of patients) included:

- diarrhea
- vomiting
- upper respiratory tract infection
- urinary tract infection
- back pain
- musculoskeletal pain
- cough
- oropharyngeal pain (e.g., sore throat)
- sinus congestion
- rash

*A full summary of safety information and potential side effects is included in the medication brochure that you have received today.* We encourage you to pay attention to any potential side effects you might experience. We will check for side effects at every visit and the study medical staff (physician or nurse practitioner) may choose to discontinue the medication if you are showing signs of serious side effects. You will also receive a phone number to contact medical staff on the study with any questions. If you visit a physician or are prescribed any medications while enrolled in this study, you should inform your physician that you will be taking lorcaserin while participating.

**Blood Draw.** Drawing blood may cause temporary pain and discomfort from the needle stick, occasional bruising, sweating, feeling faint or lightheaded, and in rare cases, infection or nerve pain.

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**Smoking Session.** It is possible that smoking cigarettes can lead to temporary symptoms such as dizziness, or nausea. You do not have to smoke at the follow up visits. It is also possible that you might experience temporary discomfort or withdrawal symptoms while abstaining from smoking overnight.

**Interview and Questionnaire Responses.** It is possible you could experience emotional stress, inconvenience or an invasion of privacy when answering questions in this study. However, you may refuse to answer any questions or perform any test that you do not wish to answer or do.
Every effort will be made to protect the information you give us. However, there is a small risk of loss of confidentiality that may result in stigmatization. Additionally, there may also be side effects or risks to study participation that are unexpected and not known at this time. Procedures we will use to protect the information you give us are described below.

**Genetic Analyses.** DNA samples will be labeled with a number only (not your name) and analyzed at an outside laboratory. The main aim of this analysis will be to examine the *CYP2A6* gene, which is related to nicotine metabolism. These analyses may also focus on genetic factors potentially associated with drug use or related behaviors. The risks associated with genetic (DNA) tests are unknown. Genes may be shown at some point in the future to be related to mental illnesses or tendency to addiction. Since in some cases the results of these genetic tests may allow us to predict the risk of getting an illness, we will keep the results confidential (only scientists working on this research project will know the results). There may also be unexpected risks connected with this type of testing. At some point in the future, your genetic information could be used to identify you; however, we have put precautions in place to help reduce this risk. We will not complete whole genome sequencing on your DNA sample. We will take every measure to protect you from the risks of other people finding out about the results of your genetic tests, which include people like insurance companies or future employers.

There are risks of loss of privacy, getting insured, being employed, and stigmatization (treated badly due to your genetic testing results). There are some protections afforded by the Genetic Information Nondiscrimination Act (GINA). For a detailed list of protections, please read the GINA information sheet on our website at http://www.mrn.org/about/policies/ or ask the research team for a copy.

**Unforeseeable risks.** The particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant becomes pregnant) that are currently unforeseeable.

## How will my information be kept confidential?

We will take measures to protect your privacy and the security of all your personal information. Your name and other identifying information will be maintained in locked files and/or restricted databases, available only to authorized members of the research team for the duration of the study. All of the information we collect about you will be coded with a unique research subject identifier (URSI) or other subject code and will be kept on password protected computers, and stored securely in restricted and protected databases according to MRN information security policies. The record linking your name to your study ID number will be kept indefinitely (forever) at the MRN in a confidential manner so that you may continue to have access to your information. De-identified data (meaning data that cannot be traced back to you) from this study may also be presented at meetings, published in journals/books, used in classrooms for training/teaching purposes, and may be used and shared with other researchers for future research purposes, which includes scientists at other universities and institutions. However, your name and other identifying information will never be used in any published reports about this study.

The urine and blood samples will be labeled with your URSI number and date of study visit and stored in a secure freezer at MRN. These samples will be stored indefinitely until we are able to send all samples for analysis. The blood and urine samples collected at the screening visit will be sent to an outside laboratory for analysis.

Your DNA sample will be stored with an URSI to protect your identity. Your name and other identifiable information will be linked to the URSI but will not be present on stored samples. If you agree, your sample may be used for future undetermined research. It will be stored at the Mind Research Network or another secure storage facility indefinitely or until it has been completely used. You may request that your DNA sample be destroyed by providing a written request or phone call to the research team listed on this consent form. It is possible we will not be able to destroy your sample if the link to your identity has already been removed because your personal information is no longer associated with your sample.

To help us protect your information, this research study has a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, the research team cannot be forced to provide your name or any identifiable research data or specimens to people who are not connected with this study, including Federal, state or local authorities, even under a subpoena. The protection offered by the certificate does not stop us from reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or that you plan to harm yourself or someone else. If any member of the research team is given such information, we will make a report to the appropriate authorities.
Information from your participation in this study may be reviewed by MRN, federal and state regulatory agencies, the Food and Drug Administration (FDA), and by the University of New Mexico Institutional Review Board (IRB) which provides regulatory and ethical oversight of human research. Also, because this research it sponsored by NIDA, staff from that and other DHHS agencies may review records that identify you only for audit or program evaluation.

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

## What are the benefits to being in this study?

There are no expected direct benefits for participating in this study. However, knowledge gained through this study may aid the development of more effective treatments for smoking.

## What other choices do I have if I don't participate?

Taking part in this study is voluntary so you can choose not to participate. If you would like to receive a list of referral options for alcohol or smoking cessation treatments, we will provide one to you.

## New information that may impact your decision to participate

You will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating. If any new information related to the medication used in the study becomes available, study staff will inform you of the new information and you will be able to discuss this information with the PI or study physician to determine whether it changes your decision to participate.

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**Are there any costs to me for participating?**
You will not be charged for any of the experimental study procedures. You will be asked to bring a package of your cigarettes to the follow up visits, and to use your own cigarettes during the smoking session. This is only to ensure that you will be smoking your preferred brand of cigarettes.

**Will I be paid for taking part in this study?**
In return for your time when participating in this study, you will be paid up to $500 total in cash for participation. The payments are as follows: $50 for completing the screening visit, $60 for the baseline visit; $100 for completing follow-up visit 1 (plus an extra $30 bonus for showing overnight abstinence); $150 for completing the medication refill visit and follow-up visit 2 (plus an extra $30 bonus for showing overnight abstinence). Between follow-up visits 1 and 2, you will need to come to MRN to pick up your medication refill. You will also receive a $30 bonus for completing at least 75% of scheduled phone-check-ins, and a final bonus of $50 for completing all of the study visits (to be paid at the final visit). In the event you are not able to pick up your final cash payment in person, we can also send the final payment via electronic gift card to your email address.

Compensation for participation in research is considered taxable income and should be reported on your income tax return. If you earn $600 or more participating in MRN research studies, you will be sent a W-9 form to collect your tax information which will be reported to the Internal Revenue Service (IRS) as required by law. The information provided to the IRS will not disclose your participation in a research study; instead the income will be listed as "nonemployee compensation."

If MRN and/or the investigators develop intellectual property and/or commercialize products or services, directly or indirectly, based on the results of the research done with your data, there are no plans to provide you with any financial compensation.

**Can I stop being in the study once I begin?**
Yes. You can withdraw from this study at any time without affecting your access to care, education, or other services to which you are entitled. If you decide you would like to stop the study medication during the study, please let the medical staff/team know as soon as possible and we will help you discontinue it.

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, if you do not follow study procedures, (e.g., you do not abstain from alcohol prior to the follow-up visits or test positive for recreational drugs at the follow-up visits), or if it is in your best interest or the study's best interest to stop your participation. NIDA may stop the study at any time.

**What will happen if I am injured or become sick because I took part in this study?**
If you are injured or become sick as a result of this study, any emergency treatment will be at your cost. No commitment is made by the MRN or UNM to provide free medical care or money for injuries to participants in this study.

It is important for you to tell the Principal Investigator or study physician immediately if you believe you have been injured or become sick because of taking part in this study.

**Refusal to Sign**

If you choose not to sign this consent form, you will not be allowed to take part in the research study.

**What if I have questions or complaints about this study?**
If you have any questions, concerns or complaints at any time about the research study, Eric Claus, Ph.D., or his associates will be glad to answer them at 505-272-5028. If you would like to speak with someone other than the research team to obtain information or offer input, or if you have questions regarding your rights as a research participant, please contact the IRB. The IRB is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving people: UNM Office of the IRB, (505) 277-2644, irbmaincampus@unm.edu. Website: http://irb.unm.edu/

**Consent**
You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you). By signing this consent form, you are not waiving any of your legal rights as a research participant.

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**OPTIONAL:**
We would also like to request your permission to store all of the data that was collected in this study in The Mind Research Network Data Sharing Repository for other, future research. The stored data will include information such as your age and gender, as well as assessment data that were collected about you during the course of this study. It is possible that this information may remain linked to your name. It will be handled with the same care and confidentially as it is for the current study. Research done with information from the data repository could lead to improved diagnostic and treatment interventions for illnesses and brain disorders. If published, results will be presented in summary form only and will not include your name or other identifying information. If MRN develops intellectual property and/or commercialize products or services, directly or indirectly, based on the results of the research done with your data, there are no plans to provide you with any financial compensation.

You have my permission to store my data in the MRN Data Sharing Repository for future research. Please initial next to your choice below.
YES _____ Initials
NO _____ Initials

We would like to request your permission to contact you for participation in future studies at the Mind Research Network. If you agree, your contact information may be shared with other scientists at MRN.

You have my permission to contact me about participation in future research studies. Please initial next to your choice below.
YES _____ Initials
NO _____ Initials

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this consent form, I agree to participate in this study. A copy of this consent form will be provided to me.

_____ _____/_____
Name of Adult Participant (print) Signature of Adult Participant Date

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information in this consent form and freely agrees to participate.

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| _____ | _____/ _____ |
| Name of Research Team Member | Signature of Research Team Member/Date |