# NCT03046839
# Official Title: Effects of Oxytocin on Alcohol Craving and Intimate Partner Violence

# Medical University of South Carolina
# CONSENT TO BE A RESEARCH SUBJECT

**TITLE OF RESEARCH:** Effects of Oxytocin on Alcohol Craving and Intimate Partner Aggression

## A. PURPOSE OF THE RESEARCH

You are being asked to volunteer for a research study. 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 the study staff discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand.

The purpose of this study is to examine the effects of a medication called oxytocin on couples' communication skills and behaviors, as well as alcohol craving. Oxytocin is currently approved by the Food and Drug Administration (FDA) to be given intravenously to induce labor in pregnant women. However, oxytocin is considered "investigational use" in this study, meaning that the FDA has not approved it for helping improve communication skills or craving. This is a Phase II study of oxytocin, meaning that it has established use for other purposes and researchers are now testing this medication in larger populations. You are being asked to participate because you are over 18 years of age, you are in a romantic relationship, and either you or your partner drinks alcohol. The investigator in charge of the study is Dr. Julianne Flanagan of the Medical University of South Carolina (MUSC). A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Flanagan's and her research team's salaries will be paid by this grant. This study is being conducted in Charleston, SC and will involve approximately 200 participants.

## B. PROCEDURES

*If you decide to participate in the study, the following will happen:*

1. First you will be asked a few questions in order to screen you for study eligibility, which will take approximately 15-30 minutes. During that time, you will be asked to answer some questions about yourself such as your age, health, relationship status and your use of alcohol and drugs to determine if you are eligible to participate.
2. If you have recently started taking a prescription medication, you may be asked to wait 4 weeks until you participate in the study so that the effects of the medication will be stable and won't affect the study results.
3. If you meet initial eligibility criteria and you choose to participate, you and your partner will be invited to an assessment session either in person or via home based telehealth. Telehealth is a process in which you will be connected to study staff from the comfort of your home by using VA approved video technology. Before we begin, you and your partner will complete a breathalyzer or saliva alcohol test. If you are a woman, you will be asked to complete a urine pregnancy test. The urine pregnancy test must be negative in order to participate. If your

pregnancy test is negative, or if you are male, you will be asked to provide a urine sample to test for drug use if the appointment is being conducted in office. You will also be asked to provide a blood sample, if possible, to measure levels of oxytocin naturally occurring in your body. Only one blood sample may be taken during the study (about a spoonful amount). All required testing materials will be shipped to you if you complete the assessment appointment via telehealth.

4. The assessment appointment will last approximately 2-3 hours. After the breathalyzer, blood, and urine tests are completed, you and your partner will be asked to fill out some questionnaires. These questionnaires will ask you about your mental and physical health, exposure to trauma, use of alcohol and drugs, and your relationship with your partner. You do not have to answer any questions that you do not want to answer.
5. After the assessment appointment and if both partners meet eligibility criteria, we will either schedule or begin the laboratory session, which will last approximately 3-4 hours. The assessment and laboratory sessions may take up to 2 appointments. During the laboratory session we will take several measurements including your heart rate and blood pressure. You may also be asked to provide saliva samples to measure the levels of stress-related hormones. Note that you may not provide any saliva samples if the study team determines something about your health that might affect study results (including recent consumption of caffeine or food, medications that affect oxytocin (e.g., androdgel, levothyroxine, etc.) or other factors).
6. Next, you will be randomly assigned (like flipping a coin) to receive either a 40 international unit (IU) dose of oxytocin or a placebo (i.e., an inactive substance). The oxytocin or placebo will be given to you in the form of a nasal spray containing either 40 IU oxytocin or saline spray.
7. After a rest period, you will complete a 10-minute alcohol cue task during which you hold and smell glasses of water and alcohol.
8. Then, you and your partner will complete a 10-minute reaction time task on the computer.
9. If you indicate during the assessment interviews or on the questionnaires that you might harm yourself or someone else, we will ask you to sign a "safety plan". This safety plan is a promise you make to us that you will call an emergency number we give you or 911, and that you agree to refrain from hurting yourself or someone else. The numbers to call will be on the safety plan contract. We will also give you a list of local treatment referrals. If you do not agree to the safety plan, we will escort you to the Emergency Department to help ensure your safety.
10. You will be compensated for your time and given referrals for local treatment centers as needed.
11. The investigators reserve the right to discontinue study participation for any individual who is determined to be a threat to self, staff, other study participants, or who is unable to complete the study assessments or provide informed consent.

## TELEHEALTH

If there is anything that makes it difficult for you to come to the MUSC, home-based telehealth (HBT) is available for the assessment appointment portion of the study. In order to complete the session via HBT, you will need to have internet or cellular access in your

home and a computer, tablet, or smartphone capable of accessing the internet. If you complete the assessment appointment via telehealth, biological measures and specimens will not be collected. Pregnancy tests and alcohol saliva tests will be shipped to you via trackable overnight UPS shipment. Females will be required to provide verbal and photo (of dipstick) confirmation of a negative pregnancy test.

You will be asked to find a private room, away from your partner for portions of the assessment appointment. The study team can also work with you and your partner to schedule these portions individually and separately in order to maintain protection of your privacy.

If you and your partner do not live together, study supplies will be shipped to one (agreed upon) residence.

In the event you are unable to make it to the office for your assessment appointment, the study team may send you study supplies via UPS. We would like your consent to ship study supplies to the address provided on your contact information form.

Please indicate your choice below, *or scroll down to the bottom of the screen and select your choice electronically*::

____Yes, I would like study supplies shipped to my residence if I am unable to make my appointment, or in the event MUSC is closed.

____No, I would *not* like study supplies shipped to my residence if I am unable to make my appointment, or in the event MUSC is closed.

## C. DURATION

Participation in the study will take about 6 hours, which can be divided into two visits.

## D. RISKS AND DISCOMFORTS

Oxytocin: The FDA has approved oxytocin for use among women during labor. When used intravenously to induce labor, adverse effects associated with oxytocin have included seizures, mental disturbances, nausea, vomiting, irregular heartbeat, high blood pressure, and unexpected bleeding or contraction of the uterus in a small number of women. When used as a nasal spray, other side effects may include nasal irritation, runny nose, and tearing of the eyes. However, several studies have been conducted in humans with intranasal doses similar to what will be used in this study, and no adverse side effects have been reported.

Interviews and Surveys: Because this study involves answering questions about and discussing topics of a personal and sometimes sensitive nature, you may become upset. You may also experience some physical or emotional distress during the interviews, the laboratory tests, or the reaction time task on the computer. If you feel significant distress at any time, you may stop filling

out the questionnaires or decide to stop the reaction time task on the computer. You do not have to answer any questions that you do not want to answer. You may also become tired or bored while completing some of the assessments.

Risks to pregnant women: If you are a woman of childbearing potential, you will receive a pregnancy test, and if pregnant, you will not be allowed to participate in the study as oxytocin can induce labor. If you are capable of becoming pregnant, you must be using a medically approved method of birth control (such as abstinence, surgical sterilization, contraceptive pills, diaphragms, or other forms of barrier contraceptives) and you must continue to do so during the course of the study. For telehealth participants, study staff will require a verbal confirmation of the negative pregnancy test prior to continuing with the assessments.

Confidentiality: All study records will be placed in a locked, secure, limited access location. Your participation in the study and the information you provide will be treated as confidential. The information we collect will contain your initials and/or code number and not your name to protect your confidentiality. Codes linking numbers and names will be kept in a locked secure location and will not be accessible to anyone outside the research team. You should also know that if you threaten to harm yourself or others or give information about child or elder abuse, this information will be reported to appropriate clinical staff and other persons outside the research program as necessary to protect yourself and others as mandated by law.

The experimental treatment may have unknown side effects. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

## E. BENEFITS

Since this is a research study and not a treatment study, there may be no direct benefit to you from participating in this study. However, it is hoped that the information gained from this study will help us develop better treatments for couples.

## F. COSTS

There will be no cost to you as a result of participation in this study.

## G. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be compensated in the form of cash, check, or gift cards. If completing the assessment portion via telehealth, you may wait to be reimbursed during your in-person lab visit or you may be mailed a check or gift card via USPS. You and your partner will each receive $150 for completing all study requirements. If you choose not to complete the study, you will be compensated for the part(s) you have completed. Each partner will receive $25 for completing the baseline questionnaires and interviews and $125 for completing the entirety of the laboratory assessment procedures. If you arrived within 30 minutes of your first scheduled

baseline appointment, you will each receive an additional $25. Finally, if there are obstacles to participation due to transportation taxi, bus pass, or mileage compensation may be available.
You are invited to participate in the recruitment of other subjects for this study. If you choose to participate, we will provide you with cards that you may give to other people (e.g., friends, acquaintances) who you think would be eligible and interested in this study. You may choose to tell people to whom you give these cards to call the study office if they are interested in participating in the study. These individuals will not be identified unless they contact the study office themselves. If any of the cards you are given result in successful study recruitment, you will receive $10 for each referred individual who consents to participate in the study. Participation in the recruitment process is completely voluntary and if you elect not to participate, your participation in this study will not be affected in any way.
Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

## H. INVITATION TO PARTICIPATE IN FUTURE STUDIES

From time to time we have other research studies that you may be eligible to participate in. We are inviting you to allow us to contact you by phone, email or mail to see if you would be interested in participating in any future studies. By checking the "yes" box below, you are indicating that you would like us to contact you by phone, email, or mail if another study becomes available that you might qualify for. To maintain your confidentiality, we will not leave identifiable messages or any identifiable information on letters or envelopes that are mailed to you. By checking the "no" box below, you are indicating that you do not want study personnel to contact you for any future studies. You may still participate in the current study if you check "no" and you will not suffer any adverse consequences in doing so. Please indicate your choice below, *or scroll down to the bottom of the screen and select your choice electronically:*:

☐ **Yes.** I would like to be re-contacted for future studies. I give permission for study personnel to contact me by phone, email or mail to inform me of other available studies I may be eligible for.
_____initials

☐ **No**. I do not wish to be re-contacted for any future studies.
_____initials

## L. ALTERNATIVES

Whether or not you choose to participate in this study, you may receive referrals for treatment for your conditions. We will be happy to provide referrals for other treatment clinics and health care providers in the community.

## J. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

## K. STUDENT PARTICIPATION

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

## L. EMPLOYEE PARTICIPATION

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

## M. CLINICAL TRIALS.GOV

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

## N. FDA REGULATED

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

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.
Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled. The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

## O. CONSENT FOR OPTIONAL GENOMIC RESEARCH

Genomic research is the study of how your genes work. Genomic research is an increasingly important way to try to understand the role of genes in human health. We are conducting an optional sub-study to examine genomic associations with health outcomes such as substance use. As part of this optional sub-study, we would like to collect and store an additional 7 milliliters (about 2 teaspoons) of blood. You will have your blood drawn, if possible, for the main study and participating in the optional genetic sub-study will not require an extra needle stick.

There are several things you should know before you decide whether to participate in this optional sub-study:

1) Your blood sample will be stored at the MUSC Research Nexus. We will make every effort to protect your identity by giving your blood sample a numeric code. Only study personnel can link the code back to you. While we hope this will prevent any potential loss of privacy or confidentiality, we cannot make any guarantees.

2) Sometimes these samples are shared for research purposes with other investigators at other research sites. Your sample may also be sent off site for testing. If this is done, the other investigators would not know your name. Your sample will be destroyed within 6 years of study completion.

3) All genomic research will be done at an aggregate (group) level. Individual level DNA will be genotyped but it will not be interpreted or shared.

4) In addition to your name, other information about you might be connected to your sample. For instance, information about race, ethnicity, or sex might be available to investigators studying your specimen. Such information might be important for research or public health. It is possible that this information (including genetic information) might come to be associated with your racial or ethnic group.

5) You have the right to refuse to allow your blood to be studied or saved for future research studies. You may withdraw from this study at any time and remove any samples that contain identifiers from research use after the date of your withdrawal. This means that while the University might retain the identified samples (the law often requires this) they would not be used for research.

6) South Carolina law mandates that your genetic information obtained from any tests or from this research be kept confidential. Our state law prohibits any insurer using this information in a discriminatory manner against you or any of your family in issuing or renewing insurance coverage for you or your family. Our state law further prohibits our sharing your genetic information with anyone except in a few narrow circumstances, one of those being a research project of this type, approved by the Institutional Review Board and then we must take all steps

to protect your identity. You will still be responsible for paying for health care, however. The Medical University of South Carolina will not be responsible for such costs, even if care is needed for a condition revealed during research or clinical testing.

7) Genetic research raises difficult questions about informing you and other subjects of any results, or of future results. Some people feel anxious about the possibility of having a defective gene that would place them or their children at risk. Some people want to know what is found out about them; others do not. The risks of knowing include anxiety and other psychological distress. The risks of not knowing what is found include not being aware if there is treatment for the problem being studied. But these risks can change depending on whether there is a treatment or cure for a particular disease, and on how clear the results are. If there is a medical reason to seek specific information from you, your doctor will tell you this. A process called "genetic counseling" is often appropriate in such cases; you should ask your doctor about this if you have any questions. In this study, investigators will not tell you what they find out about you, nor will they contact you if a test becomes available to diagnose a condition you might have or might later develop.

8) If you are concerned about a potential genetic disorder, you and your doctor might choose to test specifically for it. This would require additional blood or tissue samples that would not be part of this research project. You should discuss this option with your doctor or genetic counselor.

9) The presence of a genetic marker does not necessarily mean that an individual will develop a disease. Informing people of all such markers independently of medical need can cause unnecessary anxiety. On the other hand, the absence of a marker does not mean that someone will not get the disease. Genetic diseases appear as a result of a complex mixture of hereditary, environmental, behavioral and other factors.

These are the best known risks and challenges of genetic research. There might be other risks we do not know about yet. It is important that you talk to your doctor if you have questions or concerns about the research study.

You have the option of refusing to submit your sample for genetic research, and still participate in the rest of the study. Please indicate your preference below, or scroll down to the bottom of the screen and select your choice electronically:

☐ Yes, I agree to have my blood saved for the duration of the study and used for genetic testing in the future.
☐ No, I do not agree to have my blood saved for the duration of the study and to be used for genetic testing in the future.

## P. CONTACT

You have the option of receiving appointment reminders and links to study surveys through text messages. Should you elect to receive text messages, normal cellular data usage and rates will apply. Please indicate your choice below, or scroll down to the bottom of the screen and select your choice electronically:

☐ Yes, I agree to be contacted via text message.
☐ No, I do not agree to be contacted via text message.

## Q. RELEASE OF MEDICAL RECORDS TO ANYONE OTHER THAN THE INVESTIGATORS

If for any reason you would like your study records released to anyone other than the investigators, you will be asked to sign an additional release of information form. You will also be asked to sign a Health Insurance Portability and Accountability Act (HIPAA) Authorization to use or disclose your protected health information for research purposes.

**Volunteers Statement**

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Julianne Flanagan (843) 792-5569. I may contact the Medical University of SC Hospital Medical Director (843) 792-9537 concerning medical treatment.

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

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below for paper consents or scroll to the bottom of the screen to provide an electronic signature.

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|---|---|---|---|
| _____ | | _____ | |
| Signature of Participant | Date | Signature of Person Obtaining Consent | Date |