Department of Veterans Affairs	INFORMED CONSENT FORM
Subject Name:	Date:
Title of Study: A pharmaco-imaging approach to predicting social functioning and clinical responses to oxytocin administration in schizophrenia	
Principal Investigator: Joshua Woolley, M.D., Ph.D.	San Francisco VAMC

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

This is a research study designed to examine how the naturally occurring compound called oxytocin affects the behavior of people with schizophrenia. The study researchers, Joshua Woolley M.D., Ph.D. Ellen Bradley M.D. from the University of California at San Francisco (UCSF) Department of Psychiatry and San Francisco Veterans Affairs Medical Center (SFVAMC), or one of their research assistants will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by Joshua Woolley M.D., Ph.D., and Ellen Bradley M.D., at UCSF.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Purpose of the study: The purpose of this trial is to study how a nasal spray with oxytocin may improve the abilities of people with schizophrenia to engage socially with other people. Oxytocin is approved by the U.S. Food and Drug Administration for use during childbirth and breastfeeding. It is not currently approved for use in schizophrenia; its use in this study is considered experimental. Oxytocin has been used in research studies to test its effects on trust and other elements of social behavior.

You are being asked to participate because you are a Veteran and have been diagnosed with schizophrenia or a related disorder. Taking part in this study is your choice.

Study Procedures:
Before today, you expressed interest in participating in this study. You were contacted by phone to determine if you could participate in the study. During this conversation, you were asked questions about your mental and physical health and your background.

If you choose to be in this study, you will be interviewed to confirm your eligibility. If you are eligible, you may then take part in four testing days split into two parts.

In the first part of the study, you will come to the lab for two testing days. During the first of these testing days, you will be

asked questions about your mental health and symptoms. During each testing day, you will receive a spray inside your nose of either oxytocin or a salt solution which looks like study drug, but has no active drug in it. You will then complete computer tasks while in a magnetic resonance imaging (MRI) scanner. The MRI works as a large magnet that takes pictures of your brain. While in the MRI, you will be reading sentences and pressing buttons on a box in response to questions. These first two testing days will be separated by at least one week.

The second part of the study includes two more testing days. On the first testing day for the second part of the study, you will have one blood draw. During these testing days, we will ask you questions about your symptoms, show you videos, and ask you to complete computer tasks. The second part of the study also includes approximately three weeks of giving yourself a nasal spray of oxytocin or placebo outside of the lab setting, completing surveys, and participating in secure video calls with study staff every time you give yourself the nasal spray.

On weekends, the study team will not perform video calls, but you will still be asked to give yourself the nasal spray and complete surveys. If you are able to become pregnant, all testing days also include a pregnancy test (up to 4 total).

In total, the study lasts approximately 15 hours across all five testing days. Some test days will take place at the SFVAMC and one will occur remotely using UCSF Zoom. There are risks to participating in this study. Some risks are very serious, and there might be side effects that we do not know about yet. We will tell you more about these risks and other risks of taking part in the study later in this consent form.

There will be no direct benefit to you from participating in this study. However, the researchers hope that information gained from this study will help us understand and treat schizophrenia and related disorders.

The following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to look at in the future.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Research studies include only people who choose to take part. Please take your time to make your decision about participating and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you are a Veteran and have been diagnosed with schizophrenia or a related disorder.

Why is this study being done?

The purpose of this study is to study how oxytocin may help people with schizophrenia or related disorders.

What is oxytocin and what is the dose in this study?

Oxytocin is a hormone found naturally in both female and male bodies. Oxytocin is approved by the U.S. Food and Drug Administration for use during childbirth and breastfeeding. It is not currently approved for use in schizophrenia; its use in this study is considered experimental. Oxytocin has been used in various research studies to test its effects on trust and other elements of social behavior.
The synthetic version (Syntocinon) has been given intranasally in many different research studies. The dose that you will receive (20 or 40 International Units (IU)) has also been used in many different research studies. [Syntocinon, Novartis]. You will receive a single dose of either 20IU or 40IU of intranasal oxytocin and a single dose of placebo during the initial part of

this study in a random order. Following the initial part of the study, you will be randomly assigned to receive either oxytocin or placebo, at the same dose that you received in the first phase. You will give yourself this spray twice daily for approximately three weeks.

Who pays for this study?

The Department of Veterans Affairs funds this research.

How many people will take part in this study?

Approximately 188 people will take part in this study.

What will happen if I take part in this research study?

If you agree, the following procedures will occur:

Baseline Visit:

Interviews will be conducted during your first appointment to make sure that you are eligible for this study. This visit may occur remotely through UCSF Zoom. These interviews may ask questions about your quality of life, your social behavior, and symptoms. These interviews are meant to assess your psychiatric history and will take approximately 2-3 hours. Interviews will video and audio recorded. If you're eligible, you will continue to testing days.
You will not receive study drug during this visit.

Testing Days (Part 1):

You will be asked to take part in two testing days during the first part of the study. These will include pregnancy testing if you can become pregnant, a spray inside your nose of either oxytocin or a saline solution, and computer tasks (see below) completed while in an MRI scanner. These testing days should take approximately 1 - 3 hours each and will be separated by at least 1 week. Below is a more detailed breakdown of the procedures that you will be completing during these days.

- Pregnancy Test: If you are able to become pregnant, you will be asked to take a urine pregnancy test on each day that you will receive oxytocin or placebo. You should not become pregnant while in this study, because oxytocin may induce labor. If you are able to have children, we ask that you use a form of birth control for the duration of your participation. Acceptable methods include condom AND spermicide, diaphragm AND spermicide, or abstinence. Hormonal forms of birth control are not allowed because of possible interactions with oxytocin. Pregnancy tests will be done regularly throughout the study to make sure that you are not pregnant. If you are found to be pregnant during the study, you will not be eligible for our study and will not be paid for your time. If you become pregnant during the study, study treatment will stop. If you are practicing abstinence, you must agree to continue abstinence or use an acceptable method of birth control if you become sexually active. A medically licensed doctor will also be available throughout the study to answer any questions you may have.
- Picture and/or voice recording: We will be videotaping you during any interviews and computer tasks. The footage will be kept private and confidential and used by researchers to study your behavior, including facial expressions and what you talk about. Videos will also be used for training purposes. Picture and/or voice recordings will be kept indefinitely for purposes of data analysis related to this study. Picture and/or voice recordings may be disclosed to the study staff, the UCSF Institutional Review Board, the FDA, and the SFVA (4150 Clement Street, San Francisco, CA 94121). Identifiable recordings may also be shared with academic researchers or commercial entities to help with data analysis. For example, this may include collaborators at other academic institutions and HIPAA-compliant, speech-to-text transcription services. Any data transferred outside of UCSF or the SFVA will involve a legally

binding, signed agreement to ensure that collaborators adhere to appropriate procedures regarding participant confidentiality. We will not share your name or additional personal information. When possible, we will only share de-identified data sets. Shared data sets will be destroyed when analysis is complete.

- Reading Test: You must pass a reading test to be eligible for this study. The reading test will be used to confirm that you are able to read at the level required to complete computer tasks. If you are unable to pass the reading test, then you will not be eligible for our study and will not be paid for your time.
- Nasal passage check: Before the oxytocin/placebo spray, we will also ask you questions about your nasal passages. If you have any nasal complications (such as cold, congestion), you will not be eligible for our study and will not be paid for your time.
- Oxytocin/Placebo Administration: Oxytocin or a placebo (a salt solution) will be given to you as a nasal spray. After receiving this spray, you will wait for approximately 30 to 60 minutes before computer testing.
- Computer Tasks: You will be reading short stories and answering questions using a keyboard and/or control box in your hands. These computer tasks will measure the ways you interpret different social situations.
- Questionnaires: In this part of the study, a trained study staff member will ask you questions about your current symptoms. You may be asked questions about how you experience relationships and how often you experience certain feelings. You may be asked to complete surveys about your social life and may be asked about the history of certain behaviors. These questionnaires may be completed as password protected online questionnaires.
- MRI: The MRI will take a picture of your brain using a magnet. It will also take pictures of your brain while you are doing tasks. You cannot have any metal on your body, and you will be asked to remove your shoes. You will be asked to lie down on a bed that can be slid into the middle of a large magnet. A plastic MRI imaging headpiece called a coil will surround your head. Foam pads will be placed around your head to limit head movement during the experiment. We will then slide you into the magnet and take pictures of your brain. During this part, it is important that you lie still.

Testing Days(Part 2):

The last two testing days will include interviews similar to the baseline visit, computer tasks, and questionnaires. You will also be having your blood drawn on the first of these testing days. You will be asked to practice taking a survey and answering video calls, and you will learn how to give yourself a nasal spray. Each testing day should take about 3 to 4 hours, and testing days will be separated by approximately three weeks. In between these two testing days, you will be given a supply of oxytocin or placebo intranasal spray to take outside of the lab every day, twice a day, for approximately three weeks. During each spray of oxytocin or placebo during those weeks, you will video call with study staff and complete a survey. These calls may be recorded. During these video calls, you will give yourself the spray. On weekends, the study team will not perform video calls, but you will still be asked to give yourself the nasal spray and complete surveys. For video calls, we may supply you with an iPad that must be returned to us after you complete the study, or you may use your own device. Here are the procedures that you will complete in more detail:

- Pregnancy Test: If you are able to become pregnant, you will be asked to take a urine pregnancy test on each day that you will receive oxytocin or placebo. You should not become pregnant while in this study, because oxytocin may induce labor. If you are fertile, we ask that you use a form of birth control for the duration of your participation. Acceptable methods include condom AND spermicide, diaphragm AND spermicide, or abstinence. Hormonal forms of birth control are not allowed because of possible interactions with oxytocin. Pregnancy tests will be done regularly throughout the study to make sure that you are not pregnant. If you are found to be pregnant during the study, you will not be eligible for our study and will not be paid for your time. If you become pregnant during the study, study treatment will be discontinued. If you are practicing abstinence, you must agree to continue abstinence or use an acceptable method of contraception if you become sexually active. A medically licensed doctor will also be available throughout the study to answer any questions you may have
- Blood Draw: 10 mL of blood will be taken from a vein in your arm. This blood will be drawn at the SFVAMC. Samples may be sent to an outside lab for analysis of hormone levels and other blood components in your body.

Samples not used for analysis may be stored in a repository indefinitely and used for future research.

- Picture and/or voice recording: We will be videotaping you during any interviews, computer tasks, and video calls. Video calls may be recorded using the video calling software or a third party application, Ilumivu. Ilumivu is secure, encrypted, and HIPAA-compliant. The footage will be kept private and confidential and used by researchers to study your behavior, including facial expressions and what you talk about. Videos will also be used for training purposes. Picture and/or voice recordings will be kept indefinitely for purposes of data analysis related to this study. Picture and/or voice recordings may be disclosed to the study staff, the UCSF Institutional Review Board, the FDA, and the SFVA (4150 Clement Street, San Francisco, CA 94121). Identifiable recordings may also be shared with academic researchers or commercial entities to help with data analysis. For example, this may include collaborators at other academic institutions and HIPAA-compliant, speech-to-text transcription services. Any data transferred outside of UCSF or the SFVA will involve a legally binding, signed agreement to ensure that collaborators adhere to appropriate procedures regarding participant confidentiality. We will not share your name or additional personal information. When possible, we will only share de-identified data sets. Shared data sets will be destroyed when analysis is complete.
- Nasal passage check: Before giving you a three-week supply of oxytocin or placebo to take home, we ask you questions about your nasal passages. If you have any nasal complications (e.g. cold, congestion), you will not be eligible for our study and will not be paid for your time.
- Weight: During each in-person visit and before nasal spray administration, we will record your weight.
- Oxytocin/placebo self-administration: In between the two testing days, you will need to self-administer oxytocin or placebo as a nasal spray, twice a day, every day, for approximately three weeks. On weekdays, you will have a video call with study staff each time you administer a dose of oxytocin or placebo. This will also give you an opportunity to let us know if you are having any difficulties or problems with the nasal spray.
- Survey: During each oxytocin or placebo dose, you will also be asked to complete a brief survey about your social life in the recent past.
- Video call: You may be given an iPad, to be returned upon the completion of the study, for video calls prior to each oxytocin or placebo dose. You may also use your own device. These calls will help make sure that you are giving yourself oxytocin or placebo using proper technique.
- Questionnaires: In this part of the study, a trained study staff member will ask you questions about your current symptoms. You may also be asked about how you experience relationships and how often you experience certain feelings. You may also be asked about the history of certain behaviors. These questionnaires may be completed as interviews or as password protected online questionnaires.
- Computer tasks: During these testing days, you will complete computer tasks. You will watch videos of two people in social situations and make selections on a keyboard/answer questions about their behavior by providing verbal responses.

Additional Information:

- If you have participated in the study, "Randomized clinical trial of intensive computer-based cognitive remediation in recent-onset schizophrenia" IRB #10-01125 or "Clinical and Neurocognitive Assessment of Adolescents and Young Adults at Risk For Serious Psychiatric Disorders" IRB #10-00610 or other previous studies, information collected about you in those studies may be used in this study.
- Information regarding your treatment for schizophrenia or related disorders will be collected from your health care provider if necessary. With your permission, we may contact your primary physician in case of emergency or if we need additional information about your symptoms and medications that you cannot provide.
- Your specimens will be stored indefinitely by the study team, and may be re-examined if new ideas emerge and can be tested using specimens collected for this study. Specimens will consist of blood samples taken on the third testing day.
- If at any point in this study, you report having current thoughts of hurting yourself or others, you will consult with one of the study psychiatrists. If necessary, a staff member will take you to the emergency department for further

evaluation. Your health care provider may also be contacted in this emergency event.

- If at any time you would like to take a break during the study, you can let the researcher know, and you will be given a break and provided with snacks upon request. You must tell the researcher of any food allergies prior to consumption of the snack.

Study location:

Most testing will be conducted at the SFVAMC. Some study visits will occur using UCSF Zoom. You will give yourself oxytocin or placebo in your home, or any other location you prefer.

How long will I be in the study?

Participation in the study will take a total of approximately 15 hours across all five visits. In addition, you will complete surveys during secure video calls with study staff twice a day, every weekday, for approximately three weeks. This will take up to 20 minutes per day, and up to 7 hours in total over the three-week period. On weekends, the study team will not perform video calls, but you will still be asked to give yourself the nasal spray and complete surveys.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

- Pregnancy test: There is a possibility that your urine pregnancy test may come back falsely positive. A positive pregnancy test will make you ineligible to participate in our study. An appointment may be scheduled for a later day to confirm your results. The results of the pregnancy screen will be permanently kept in our records, including false positive pregnancy tests.
- Intranasal Spray of Oxytocin/Placebo: Potential side effects of the nasal spray include a runny, stuffy, or irritated nose. A medically licensed doctor will be available by pager throughout the study.
- MRI: There are no known health risks associated with MRI techniques. These procedures do not involve injections or radiation exposure. While there are no significant risks, your participation may mean some added discomfort. You may be uncomfortable lying in the enclosed space of the MRI scanners. Due to the physical weight limitations of the scanner, individuals over 300 pounds or those unable to fit comfortably within the scanner may not be included. Additionally, the MRI machines function like a large magnet, so we ask that you remove any jewelry, including body piercing. You cannot participate in this study if you have a pacemaker, extensive dental work, or metal implants in your body such as an aneurysm clip, ear implant, nerve stimulator, etc. You also cannot have ever worked with metal. We are doing the MRI in this study to answer research questions, not to give you medical care. The information created by this study will usually not become part of your hospital record.
    - This MRI is not the same as one that your own doctor would order. It may or may not show problems that would be found on a standard MRI. If we do see something that looks like a medical problem, we will ask a radiologist (a doctor who reviews x- rays and imaging studies) to review the results. If the radiologist thinks there might be a problem, we will tell you and refer you to follow- up care. If the radiologist thinks that you might have a medical problem, but it turns out after more tests that you don't, we may have caused you to worry needlessly about your health.
- Blood Collection and Storage: Risks of venipuncture for blood draw are extremely small but may include bleeding, bruising, feelings of lightheadedness, fainting, or infection. The blood draws will be performed by trained specialists

but may be more difficult to obtain in some individuals and may require several attempts. The greatest risk of allowing us to store blood is the possible loss of privacy. Specimens will be coded with a study ID number. This study ID number will be linked with your name in a separate document available only to study investigators. Specimens will be stored in locked freezers, accessible only by trained personnel. Your specimens will be stored indefinitely by the study team and may be re-examined if new ideas emerge over time.

- Computer Tasks: There are no known risks associated with performing the computer tests administered in this study. However, we will ask that you look at the computer screen for a period of up to an hour and a half without significant rest. You may find the tasks challenging or frustrating at times. The tests are designed to be challenging, and no one is likely to get all the answers correct. All we ask is that you simply do the best that you can. If needed, you may take some breaks during the testing.
- Personal Health History: Participation in the study presents a risk of loss of privacy and confidentiality, particularly with respect to potentially embarrassing or harmful personal health information. This includes detailed and sensitive information regarding alcohol and drug use, and psychiatric symptoms. Potential release of such information could have serious ramifications for employment and insurability. To protect against this, data are coded, stored in a locked file cabinet, and retained in a locked office in which the data key is kept separately and securely. Electronic data are password-protected and stored on either the secure VA network or the VA-approved Research Electronic Data Capture (REDCap) system, a secure, HIPAA-compliant, encrypted storage system with password protection for managing research.
- Clinical Interviews and Assessments: You may experience anxiety and/or distress during the assessments due to the nature of personal questions regarding mental health, substance use, and life experiences. We will be monitoring nonverbal signs of distress and inquire about how you are feeling during the assessment at regular intervals to minimize any strain you may be experiencing. You may decline to answer any questions or to stop the interviews at any time.
- Picture and/or voice recording: Video and audio recording during the study increases the risk that your confidentiality and privacy may be compromised given the identifiable nature of video. Such recordings will be saved on password protected computers that are within the VA network, on a secure, encrypted, and password protected hard drive. Audio and video recordings will be stored indefinitely for purposes of data analysis for this study. Recordings will be coded with unique participant IDs and stored without any identifying information. Recordings will be viewed by researchers involved in the study to ensure interviews are being conducted in a standardized manner. Identifiable recordings may also be shared with academic researchers or commercial entities to help with data analysis. For example, this may include collaborators at other academic institutions and HIPAA-compliant, speech-to-text translation services. Shared data poses an additional risk. However, we will take all possible measures to minimize this risk, including requesting that collaborators and commercial entities sign a legally binding document, agreeing to adhere to appropriate procedures regarding participant confidentiality. De-identified data will be shared whenever possible, and datasets will be destroyed when analysis is complete.
- Video Call: Confidentiality during Internet communication procedures cannot be guaranteed, and it is possible that information beyond that collected for research purposes may be captured and used by others not associated with the study. However, we will take every precaution to safeguard your information. We will not collect any additional information from the device (e.g. location, name, etc.) during these calls.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, the investigator hopes that the information gained from this study will help us understand and treat schizophrenia and related disorders.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually

do.

How will my information be used?

Researchers will use your information to conduct this study. Once the study is done using your information, we may share it with other researchers, so they can use it for other studies in the future. We will not ask you for additional permission to share this de- identified information.

Picture/audio recording: Your video and audio recordings will be stored indefinitely. Recordings will be coded with unique participant IDs. Recordings will be stored on password protected computers within the VA network and on secure, encrypted, and password protected hard drives, separate from any identifying information. After the study ends, we may continue to use identifiable video and/or audio recordings for purposes of data analysis for this study. We may also share identifiable video and/or audio recordings with outside academic collaborators and commercial entities for purposes of data analysis for this study. We will not include your name or additional personal information. Any data transferred outside of UCSF or the SFVA will involve a legally binding, signed agreement to ensure that collaborators maintain patient confidentiality and perform appropriate analyses. When possible, we will only share de-identified data sets. Shared data sets will be destroyed when analysis is complete.

Contact information and blood specimens: With your consent, your contact information and blood samples will be stored indefinitely in a specimen repository to be used for future research. Blood samples will be coded with unique participant IDs and stored separate from any identifying information. This is optional. You may indicate your consent or opt out of these procedures on page 11. If you consent, you will not be contacted again for your permission to use this data.

Research results: There may be times when researchers using your information may learn new information. The researchers may or may not share these results with you, depending on several factors.

How will information about me 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 privacy. Some information from your medical records will be collected and used for this study. If you do not have a SFVAMC medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your SFVAMC medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Identifiers may be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the Department of Veterans Affairs
- Representatives of the University of California
- Representatives of the Food and Drug Administration (FDA)

Additionally, if you demonstrate that you are a risk to yourself, have intentions of committing suicide or harming someone

else, the researchers are obligated to report you under State and Federal law.

Are there any costs to me for taking part in this study?

No. The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.

Will I be paid for taking part in this study?

Baseline Visit:
You will be paid $20/hour with a maximum of $50 for this visit. If the interviews disqualify you from participating in this study, you will still be paid $10 for your time.

Testing Days (Part 1):
You will be paid $20/hour. The first of these testing days has a maximum of $70 and the second of these testing days had a maximum of $40. You will only be paid for time required to complete the tasks, and not for any time spent during unscheduled breaks.

Testing Days (Part 2):
You will be paid $20/hour with a maximum of $80 for each testing day. You will only be paid for time required to complete the tasks, and not for any time spent during unscheduled breaks.

You will also be paid $2 for each video call, survey, and self-administered a dose of oxytocin or placebo during the at-home period. Because there are 2 administrations per day ($4 total/day), and approximately 21 days in this part of the study, you may earn up to a maximum of $84 for the surveys and video calls. If you are unable to complete the at-home period in 21 days (for example: your schedule prevents you from returning to the lab for your final study visit on day 22), you will be asked to continue administering the nasal spray until you are able to return to the lab for your last study visit. After the 21 day mark, you will not be paid for self-administration, and you will not be required to continue participation in video calls or surveys. You will only receive your payment after returning the iPad, if provided, at the completion of the study.

In addition, at the end of each video call with the study staff you will have the opportunity to participate in a Behavioral Economic Intervention. In this, you will pick one number from 0-to-99, and the study staff will roll two die (each die has ten sides and will be numbered 0-to-9. If one of your numbers matches one of the dice, you will win $5 (you will have a 1-in-5 chance or 20% chance of winning $5 each time you play). If both numbers match both dice, you will win $100 (you will have a 1-in-100 chance or 1% chance of winning $100 each time you play). Because there will be up to 42 phone calls, you will have 42 chances to win.

You may be paid in cash or using direct deposit to your bank account or a VA Direct Express account. If you do not have a VA Direct Express account and would like one, the study team will assist you with setting one up.
You will be paid at the end of each testing day, including payment for the twice daily surveys and video calls. You will be reimbursed for travel to the San Francisco VA Medical Center, up to $15 for each visit. You may also receive meal vouchers to the VA canteen for completion of the study. If you withdraw from the study for any reason and return the device, you will be compensated for the procedures that have been completed. Your social security number and home address are required for you to receive payment.

In total you can make up to $404 for completing all portions of the study, plus any earnings from the behavioral economic intervention.

Payments for being a part of this research study will count as income and may affect your income taxes.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Joshua Woolley, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at 415-221-4810 x2-4117. For further information about this, call the VA Regional Counsel at (415) 750-2288 or the office of the UCSF Institutional Review Board at (415) 476-1814.

If you are experiencing a medical emergency, please call 9-1-1. If you incur an injury or illness as a result of being in this study, the Department of Veterans Affairs (VA) will ensure that treatment is made available at a VA medical facility or non- VA facility, as appropriate. If you were following study instructions, the costs of such treatment will be covered by the VA or the study sponsor (if applicable). If you were NOT following study instructions, the costs of such treatment may be covered by the VA or the study sponsor (if applicable), or may be billed to you or your insurer just like any other medical costs, depending on a number of factors. The VA and a study sponsor do not normally provide any other form of compensation for injury or illness. For further information about this, call the study team at the number(s) provided.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty against you, and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution. We will inform you of new information or changes to the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Your study doctor, Joshua Woolley, at (415) 221-4810 x2-4117.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at (415) 476-1814.

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.

Please read each sentence below and think about your choice. After reading each sentence, put your initials in the "Yes" or "No" box.

If you have any questions, please talk to your doctor or nurse, or call our research review board at IRB's phone number. No matter what you decide to do, it will not affect your care.

(1) Someone may contact me in the future to ask me to take part in more research.

YES	NO

(2) I am interested in finding out which day I received oxytocin or placebo. Someone may contact me in the future to give me this information.

YES	NO

(3) I agree to allow my videotapes to be used publicly in scientific presentations.

YES	NO

(4) I agree to allow my specimen(s) to be stored for an indefinite amount of time and/or used for future research.

YES	NO

Informed Consent Questionnaire

The following questionnaire is designed to assess your understanding of the major aspects of the study. We are asking these questions to make sure you understand the nature of the study, its risks, and your rights as a research participant. This must be completed and reviewed prior to your signing the informed consent form. Please read each statement about the research study described in the consent form and indicate whether you think it is true or false.

1) Potential side effects of oxytocin include a runny, stuffy, or irritated nose. (T) or F

2) My participation in this study is voluntary and I may withdraw at any time. (T) or F

3) I will be asked questions about my medical and psychiatric history as part of this study. (T) or F

4) I will receive payment for completing the study or for any parts of the study in which I participate. (T) or F

5) The data collected from me during this study is confidential—I will not be identified by name in any reports of the data I contribute to the study. (T) or F

6) I can drop out of the study at any time. (T) or F

Nam_____ Date_____

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date_____ Participant's Signature for Consent_____

Date_____ Person Obtaining Consent_____

UCSF
University of California
San Francisco

IRB NUMBER: 19-27265
IRB APPROVAL DATE: 04/05/2022
IRB EXPIRATION DATE: 04/04/2023

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
EXPERIMENTAL SUBJECT'S
BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1) To be told what the study is trying to find out,
2) To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,
3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes,
4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be,
5) To be told of the other choices I have and how they may be better or worse than being in the study,
6) To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,
7) To be told what sort of medical treatment is available if any complications arise,
8) To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study,
9) To receive a copy of the signed and dated consent form,
10) To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions I should ask the researcher or the research assistant. In addition, I may contact the Institutional Review Board, which is concerned with protection of volunteers in research projects. I may reach the committee office by calling: (415) 476-1814 from 8:00 AM to 5:00 PM, Monday to Friday, or by writing to the UCSF Human Research Protection Program, Box 0962, 3333 California St., Ste. 315, San Francisco, CA 94143.

Call 476-1814 for information on translations.

Department of Veterans Affairs
Veterans Health Administration
NOTICE OF PRIVACY PRACTICES
Effective Date September 23, 2013

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED OR DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION.

PLEASE REVIEW IT CAREFULLY.

The Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) is required by law to maintain the privacy of your protected health information and to provide you with notice of its legal duties and privacy practices. VHA is also required to abide by the terms of this Notice and its privacy policies.

How VHA May Use or Disclose Your Health Information without Your Authorization (See below for more information about these categories)

- Treatment (e.g., giving information to VHA and other doctors and nurses caring for you)
- Payment (e.g., giving information to non-VHA facilities that provide care or services
- Health Care Operations (e.g., giving information to individuals conducting Quality of Care reviews)
- Eligibility and Enrollment for VA Benefits (e.g., giving information to officials who decide benefits)
- Abuse Reporting (e.g., giving information about suspected abuse of elders or children to government agencies)
- Health or Safety Activities
- Public Health Activities (e.g., giving information about certain diseases to government agencies)
- Judicial or Administrative Proceedings (e.g., responding to court orders)
- Law Enforcement
- Health Care Oversight (e.g., giving information to the Office of Inspector General or a Congressional Committee)
- Cadaveric Organ, Eye, or Tissue Donation
- Coroner or Funeral Activities
- Services (e.g., giving information to contractors or business associates performing services for VHA)
- National Security Matters
- Workers' Compensation Cases (e.g., giving information to officials who decide payments for workplace injuries Payment (e.g., giving information to non-VHA facilities that provide care or services)
- Correctional Facilities and/or Parole Officers
- When Required by Law
- Activities Related to Research (e.g., certain activities with only minimal or limited privacy or confidentiality risks)
- Planning VA research projects (e.g., investigator accesses, but does not disclose or record, individual health information to determine feasibility of opening a study)
- Military Activities (e.g., giving information to the Department of Defense (DoD)
- Academic Affiliates (e.g., giving information to assist in training medical students)
- State Prescription Drug Monitoring Program (SPDMP) reporting and query
- General Information Disclosures (e.g., giving out general information about you to your family and friends)
- Verbal disclosures to others while you are present
- Verbal Disclosures when you are not present (e.g., assisting Family Members or Designated Individuals Involved in your Care)

Other Uses and Disclosures with Your Authorization. We may use or disclose your health information for any purpose based on a signed, written authorization you provide us. Your signed written authorization is always required to disclose your psychotherapy notes if they exist. If we were to use or disclose your health information for marketing purposes we would require your signed written authorization. In all other cases, we will not use or make a disclosure of your health information without your signed, written authorization, unless the use or disclosure falls under one of the exceptions described in this Notice. When we receive your signed written authorization we will review the authorization to determine if it is valid, and then disclose your health information as requested by you in the authorization.

Revocation of Authorization. If you provide us a written authorization or permission to use or disclose your health information, you may revoke that permission, in writing, at any time. If you revoke your authorization, we will no longer use or disclose your health information except to the extent that VHA has relied on your written authorization. Please understand that we are unable to take back any uses or disclosures we have already made based on your authorization.

Your Privacy Rights

Right to Request Restriction.
You may request that we not use or disclose all or part of your health information to carry out treatment, payment or health care operations, or that we not use or disclose all or part of your health information with individuals such as your relatives or friends involved in your care, including use or disclosure for a particular purpose or to a particular person.

Please be aware, we are not required to agree to such restriction, except in the case of a disclosure restricted under 45 CFR § 164.522(a)(1)(vi). This provision applies only if the disclosure of your health information is to a health plan for the purpose of payment or health care operations and your health information pertains solely to a health care service or visit which you paid in full. However, VHA is not legally able to accept an out of pocket payment from a Veteran for the full cost of a health care service or visit. We are only able to accept payment from a Veteran for co-payments. Therefore, this provision does not apply to VHA and VHA is not required or able to agree to a restriction on the disclosure of your health information to a health plan for the purpose of receiving payment for health care services provided to you.

To request a restriction, you must submit a written request that identifies the information you want restricted, when you want it to be restricted, and the extent of the restrictions. All requests to restrict use or disclosure should be submitted to the facility Privacy Officer at the VHA health care facility that provided or paid for your care. If we agree to your request, we will honor the restriction until you no longer make the restriction request valid or you revoke it.

NOTE: *We are not able to honor requests to remove all or part of your health information from the electronic database of health information that is shared between VHA and DoD, or to restrict access to your health information by DoD providers with whom you have a treatment relationship.*

Right to Review and Obtain a Copy of Health Information. You have the right to review and obtain a copy of your health information in our records. You must submit a written request to the facility Privacy Officer at the VHA health care facility that provided or paid for your care.

NOTE: *Please send a written request, to your VHA health care facility Privacy Officer. The VHA Privacy Office at Central Office in Washington, D.C. does not maintain VHA health records, nor past military service health records. For a copy of your military service health records, please contact the National Personnel Records Center at (314)801-0800. The Web site is http://www.archives.gov/veterans/military-service-records/medical-records.html.*

Right to Request Amendment of Health Information. You have the right to request an amendment (correction) to your health information in our records if you believe it is incomplete, inaccurate, untimely, or unrelated to your care. You must submit your request in writing, specify the information that you want corrected, and provide a reason to support your request for amendment. All amendment requests should be submitted to the facility Privacy Officer at the VHA health care facility that maintains your information.

If your request for amendment is denied, you will be notified of this decision in writing and provided appeal rights. In response, you may do any of the following:

- File an appeal
- File a "Statement of Disagreement"
- Ask that your initial request for amendment accompany all future disclosures of the disputed health information

Right to Request Receipt of Communications in a Confidential Manner. You have the right to request that we provide your health information to you by alternative means or at an alternative location. We will accommodate

easonable requests, as determined by VA/VHA policy, from you to receive communications containing your health information:

- At a mailing address (e.g., confidential communications address) other than your permanent address
- In person, under certain circumstances

Right to Receive an Accounting of Disclosures. You have the right to know and request a copy of what disclosures of your health information have been made to you and to other individuals outside of VHA. To exercise this right, you must submit a written request to the facility Privacy Officer at the VHA health care facility that provides your care.

Right to a Printed Copy of the Privacy Notice. You have the right to obtain an additional paper copy of this Notice from your VHA health care facility. You can obtain this Notice from the facility Privacy Officer at your local VHA health care facility. You may also obtain a copy of this Notice at the following website, http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=1089

Notification of a Breach of your Health Information. If a breach of any of your protected health information occurs, we will notify you and provide instruction for further actions you should take, if any.

Complaints. If you are concerned that your privacy rights have been violated, you may file a complaint with:

- The VHA health care facility's Privacy Officer, where you are receiving care. Visit this Web site for VHA facilities and telephone numbers http://www1.va.gov/directory/guide/division_flsh.asp?dnum=1.
- VA via the Internet through "Contact the VA" at http://www.va.gov; by dialing 1-800-983-0936 or by writing the VHA Privacy Office (10P2C1) at 810 Vermont Avenue NW, Washington, DC 20420.
- The U.S. Department of Health and Human Services, Office for Civil Rights at http://www.hhs.gov/ocr/privacy/hipaa/complaints/index.html
- The Office of the Inspector General. http://www.va.gov/oig/contact/default.asp
- Complaints do not have to be in writing, though it is recommended.
- An individual filing a complaint will not face retaliation by any VA/VHA organization or VA/VHA employee.

Changes. We reserve the right to change this Notice. The revised privacy practices will pertain to all existing health information, as well as health information we receive in the future. Should there be any changes we will make available to you a copy of the revised Notice within 60 days of any change.

When We May Use or Disclose Your Health Information Without Your Authorization

Treatment. We may use and disclose your health information for treatment or to provide health care services. Treatment may include:

- Emergency and routine health care or services, including but not limited to labs and x-rays; clinic visits; inpatient admissions
- Contacting you to provide appointment reminders or information about treatment alternatives
- Prescriptions for medications, supplies, and equipment
- Coordination of care, including care from non-VHA providers
- Coordination of care with DoD, including electronic information exchange

NOTE: *If you are an active duty service member, Reservist or National Guard member, your health information is available to DoD providers with whom you have a treatment relationship. Your protected health information is on an electronic database that is shared between VHA and DoD. VHA does not have the ability to restrict DoD's access to your information in this database, even if you ask us to do so.*

Examples:

1) A Veteran sees a VHA doctor who prescribes medication based on the Veteran's health information. The VHA pharmacy uses this information to fill the prescription.

2) A Veteran is taken to a community hospital emergency room. Upon request from the emergency room, VHA discloses health information to the non-VHA hospital that needs the information to treat this Veteran.
3) A National Guard member seeks mental health care from VHA. VHA discloses this information to DoD by entering the information into a database that may be accessed by DoD providers at some future date.

Payment. We may use and disclose your health information for payment purposes or to receive reimbursement for care provided, including:

- Determining eligibility for health care services
- Paying for non-VHA care and services, including but not limited to, CHAMPVA and fee basis
- Coordinating benefits with other insurance payers
- Finding or verifying coverage under a health insurance plan or policy
- Allowing you to pay for your health care out of pocket so that your insurance is not billed
- Pre-certifying benefits
- Billing and collecting for health care services provided
- Providing personal information to consumer reporting agencies regarding delinquent debt owed to VHA

Examples:
1) A Veteran is seeking care at a VHA health care facility. VA uses the Veteran's health information to determine eligibility for health care services.
2) The VHA health care facility discloses a Veteran's health information to a private health insurance company to seek and receive payment for the care and services provided to the Veteran.

Health Care Operations. We may use or disclose your health information without your authorization to support the activities related to health care, including:

- Improving quality of care or services
- Conducting Veteran and beneficiary satisfaction surveys
- Reviewing competence or qualifications of health care professionals
- Providing information about treatment alternatives or other health-related benefits and services
- Conducting health care training programs
- Managing, budgeting and planning activities and reports
- Improving health care processes, reducing health care costs and assessing organizational performance
- Developing, maintaining and supporting computer systems
- Legal services
- Conducting accreditation activities
- Certifying, licensing, or credentialing of health care professionals
- Conducting audits and compliance programs, including fraud, waste and abuse investigations

Examples:
1) Medical Service, within a VHA health care facility, uses the health information of diabetic Veterans as part of a quality of care review process to determine if the care was provided in accordance with the established best clinical practices.
2) A VHA health care facility discloses a Veteran's health information to the Department of Justice (DOJ) attorneys assigned to VA for defense of VHA in litigation.

Eligibility and Enrollment for Federal Benefits. We may use or disclose your health information to other programs within VA or other Federal agencies, such as the Veterans Benefits Administration, Internal Revenue Service or Social Security Administration, to determine your eligibility for Federal benefits.

Abuse Reporting. We may use or disclose your health information without your authorization to report suspected child abuse, including child pornography; elder abuse or neglect; or domestic violence to appropriate Federal, State, local, or tribal authorities. This reporting is for the health and safety of the suspected victim.

Health and Safety Activities. We may use or disclose your health information without your authorization when necessary to prevent or lessen a serious threat to the health and safety of the public, yourself, or another person. Any disclosure would only be to someone able to help prevent or lessen the harm, such as a law enforcement agency or the person threatened. You will be notified in writing if any such disclosure has been made by a VHA health care facility.

Public Health Activities. We may disclose your health information without your authorization to public health and regulatory authorities, including the Food and Drug Administration (FDA) and Centers for Disease Control (CDC), for public health activities. Public health activities may include:

- Controlling and preventing disease, injury, or disability
- Reporting vital events such as births and deaths
- Reporting communicable diseases such as hepatitis, tuberculosis, sexually transmitted diseases & HIV
- Tracking FDA-regulated products
- Reporting adverse events and product defects or problems
- Enabling product recalls, repairs or replacements

Judicial or Administrative Proceedings. We may disclose your health information without your authorization for judicial or administrative proceedings, including:

- We receive an order of a court, such as a subpoena signed by a judge, or administrative tribunal, requiring the disclosure
- To defend VA in judicial and administrative proceedings

Law Enforcement. We may disclose your health information to law enforcement agencies for law enforcement purposes when applicable legal requirements are met. These law enforcement purposes may include:

- Responding to a court order
- Responding to a specific request when in pursuit of a focused civil or criminal law enforcement investigation
- Reporting crimes occurring at a VHA site
- Identifying or apprehending an individual who has admitted to participating in a violent crime
- Reporting a death where there is a suspicion that death has occurred as a result of a crime
- Reporting Fugitive Felons
- Routine reporting to law enforcement agencies, such as gunshot wounds
- Providing certain information to identify or locate a suspect, fugitive, material witness, or missing person

Health Care Oversight. We may disclose your health information to a governmental health care oversight agency (e.g., Inspector General; House Veterans Affairs Committee) for activities authorized by law, such as audits, investigations, and inspections. Health care oversight agencies include government agencies that oversee the health care system, government benefit programs, other government regulatory programs, and agencies that enforce civil rights laws.

Cadaveric Organ, Eye, or Tissue Donation. When you are an organ donor and death is imminent, we may use or disclose your relevant health information to an Organ Procurement Organization (OPO), or other entity designated by the OPO, for the purpose of determining suitability of your organs or tissues for organ donation. If you have not specified your donation preferences and can no longer do so, your family may make the determination regarding organ donation on your behalf.

Coroner or Funeral Services. Upon your death, we may disclose your health information to a funeral director for burial purposes, as authorized by law. We may also disclose your health information to a coroner or medical examiner for identification purposes, determining cause of death, or performing other duties authorized by law.

Services. We may provide your health information to individuals, companies and others who need to see your information to perform a function or service for or on behalf of VHA. An appropriately executed contract and business associate agreement must be in place securing your information.

National Security Matters. We may use and disclose your health information without your authorization to authorized Federal officials for the purpose of conducting national security and intelligence activities. These activities may include protective services for the President and others.

Workers' Compensation. We may use or disclose your health information without your authorization to comply with workers' compensation laws and other similar programs.

Correctional Facilities. We may disclose your health information without your authorization to a correctional facility if you are an inmate and disclosure is necessary to provide you with health care; to protect the health and safety of you or others; or for the safety of the facility.

Required by Law. We may use or disclose your health information for other purposes to the extent required or mandated by Federal law (e.g., to comply with the Americans with Disabilities Act; to comply with the Freedom of Information Act (FOIA); to comply with a Health Insurance Portability and Accountability Act (HIPAA) privacy or security rule complaint investigation or review by the Department of Health and Human Services).

Activities Related to Research. Before we may use health information for research, all research projects must go through a special VHA approval process. This process requires an Institutional Review Board (IRB) to evaluate the project and its use of health information based on, among other things, the level of risk to you and to your privacy. For many research projects, including any in which you are physically examined or provided care as part of the research, you will be asked to sign a consent form to participate in the project and a separate authorization form for use and possibly disclosure of your information. However, there are times when we may use your health information without an authorization, such as, when:

- A researcher is preparing a plan for a research project. For example, a researcher needs to examine patient medical records to identify patients with specific medical needs. The researcher must agree to use this information only to prepare a plan for a research study; the researcher may not use it to contact you or actually conduct the study. The researcher also must agree not to remove that information from the VHA health care facility. These activities are considered preparatory to research.
- The IRB approves a waiver of informed consent and a waiver of authorization to use or disclose health information for the research because privacy and confidentiality risks are minimal and other regulatory criteria are satisfied.
- A Limited Data Set containing only *indirectly* identifiable health information (such as dates, unique characteristics, unique numbers or zip codes) is used or disclosed, with a data use agreement (DUA) in place.

Military Activities. We may use or disclose your health information without your authorization if you are a member of the Armed Forces, for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, when applicable legal requirements are met. Members of the Armed Forces include Active Duty Service members and in some cases Reservist and National Guard members. An example of a military activity includes the disclosure of your health information to determine fitness for duty or deployment to your Base Commander.

Academic Affiliates. We may use or disclose your health information, without your authorization, to support our education and training program for students and residents to enhance the quality of care provided to you.

State Prescription Drug Reporting Program (SPDMP). We may use or disclose your health information, without your authorization, to a SPDMP in an effort to promote the sharing of prescription information to ensure appropriate medical care.

General Information Disclosures. We may disclose general information about you to your family and friends. These disclosures will be made only as necessary and on a need-to-know basis consistent with good medical and ethical practices, unless otherwise directed by you or your personal representative. General information is limited to:

- Verification of identity
- Your condition described in general terms (e.g., critical, stable, good, prognosis poor)
- Your location in a VHA health care facility (e.g., building, floor, or room number)

Verbal Disclosures to Others While You Are Present. When you are present, or otherwise available, we may disclose your health information to your next-of-kin, family or to other individuals that you identify. For example, your doctor may talk to your spouse about your condition while at your bedside. Before we make such a disclosure, we will ask you if you object. We will not make the disclosure if you object.

Verbal Disclosures to Others When You Are Not Present. When you are not present, or are unavailable, VHA health care providers may discuss your health care or payment for your health care with your next-of-kin, family, or others with a significant relationship to you without your authorization. This will only be done if it is determined that it is in your best interests. We will limit the disclosure to information that is directly relevant to the other person's involvement with your health care or payment for your health care.

Examples of this type of disclosure may include questions or discussions concerning your in-patient medical care, home-based care, medical supplies such as a wheelchair, and filled prescriptions.

IMPORTANT NOTE: *A copy of your medical records can be provided to family, next-of-kin, or other individuals involved in your care* ***only*** *if we have your signed, written authorization* ***or*** *if the individual is your authorized surrogate (the individual who is authorized to make health care decisions on your behalf if you can no longer do so) and the practitioner determines that the information is needed for the individual to make an informed decision regarding your treatment.*

When We Offer You the Opportunity to Decline to the Use or Disclosure of Your Health Information

Patient Directories. Unless you opt-out of the VHA medical center patient directory when being admitted to a VHA health care facility, we may list your general condition, religious affiliation and the location where you are receiving care. This information may be disclosed to people who ask for you by name. Your religious affiliation will only be disclosed to members of the clergy who ask for you by name. **If you do object to being listed in the Patient Directory, no information will be given out about you unless there is other legal authority. This means your family and friends will not be able to find what room you are in while you are in the hospital. It also means you will not be able to receive flowers or mail, including Federal benefits checks, while you are an inpatient in the hospital or nursing home. All flowers and mail will be returned to the sender.**

When We Will Not Use or Disclose Your Health Information

Sale of Health Information. We will not sell your health information. Receipt of a fee expressly permitted by law, such as Privacy Act copying fees or FOIA fees is not a sale of health information.

Genetic Information Nondiscrimination Act (GINA). We will not use genetic information to discriminate against you either through employment or to determine your eligibility for VA benefits.

Contact Information.

You may contact your VHA health care facility's Privacy Officer if you have questions regarding the privacy of your health information or if you would like further explanation of this Notice. The VHA Privacy Office may be reached by mail at VHA Privacy Office, Office of Informatics and Analytics (10P2C1), 810 Vermont Avenue NW, Washington, DC 20420 or by telephone at 1-877-461-5038.

NOTE: *A large print version of this Notice is available upon request from the facility where you are receiving care.*

VA | U.S. Department of Veterans Affairs

Acknowledgement of the Notice of Privacy Practices

Acknowledgement of Department of Veterans Affairs, Veterans Health Administration (VHA) Notice of Privacy Practices

The signature below only acknowledges receipt of the VHA Notice of Privacy Practices, effective date 23 September 2013.

Signature of Patient/Patient Representative	Date
Name of Patient/Representative	Relationship to patient (if applicable)
Last four SSN	

VA FORM JUL 2015 **10-0483**

Adobe Forms Designer

Department of Veterans Affairs

Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

VA Facility (Name and Address):
San Francisco VA Health Care System
4150 Clement Street
San Francisco, CA 94121

VA Principal Investigator (PI):	**PI Contact Information:**
Dr. Joshua Woolley, M.D., Ph.D.	(415) 221-4810 x2-4117

Study Title:
19-27265: A pharmaco-imaging approach to predicting social functioning and clinical responses to oxytocin administration in schizophrenia

Purpose of Study:
The purpose of this study is to examine if exogenous oxytocin is a novel treatment for the difficult-to-treat social cognitive deficits in patients with schizophrenia.

USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI):

Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care.

Signing this authorization is completely voluntary. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign this authorization.

Your individually identifiable health information used for this VA study includes the information marked below:

☒ Information from your VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings

☒ Specific information concerning:

☒ alcohol abuse ☒ drug abuse ☐ sickle cell anemia ☐ HIV

☒ Demographic Information such as name, age, race

☐ Billing or Financial Records

☒ Photographs, Digital Images, Video, or Audio Recordings

☒ Questionnaire, Survey, and/or Subject Diary

☒ Other as described: blood samples, health care provider

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

USE OF YOUR DATA OR SPECIMENS FOR OTHER RESEARCH: (Instruction: When banking or further analysis is an **optional** research activity, complete page 5 and leave this section blank. If banking is a required research activity to store "Data" and/or "Specimen" for future use or if "Not Applicable" is selected, remove page 5 in its entirety.)

☐ Not Applicable - No Data or Specimen Banking for Other Research

An important part of this research is to save your

☐ Data

☐ Specimen

in a secure repository/bank for other research studies in the future. If you do not agree to allow this use of your data and/or specimen for future studies approved by the required committees, such as the Institutional Review Board, you will not be able to participate in this study.

DISCLOSURE: The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

☒ Non-VA Institutional Review Board (IRB) at the University of California, San Francisco (UCSF)
who will monitor the study

☒ Study Sponsor/Funding Source: Department of Veterans Affairs
VA or non-VA person or entity who takes responsibility for; initiates, or funds this study

☒ Academic Affiliate (institution/name/employee/department): the University of California, San Francisco (UCSF)
A relationship with VA in the performance of this study

☒ Compliance and Safety Monitors: VA Regulatory Personnel
Advises the Sponsor or PI regarding the continuing safety of this study

☒ Other Federal agencies required to monitor or oversee research (such as FDA, OHRP, GAO):
FDA, OHRP

☐ A Non-Profit Corporation (name and specific purpose):

☒ Other (e.g. name of contractor and specific purpose):
UCSF's MyResearch; REDCap
Research collaborators at UCSF and SFVAMC.
Research collaborators at other academic institutions for the purpose of analyses and interpretation of data, including video recordings.
External companies/commercial entities for purposes of transcription of audio recordings.

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

Note: *Offices within VA/VHA that are responsible for oversight of VA research such as the Office of Research Oversight (ORO), the Office of Research and Development (ORD), the VA Office of Inspector General, the VA Office of General Counsel, the VA IRB and Research and Development Committee may also have access to your information in the performance of their VA/VHA job duties.*

Access to your Individually Identifiable Health Information created or obtained in the course of this research:
While this study is being conducted, you

☐ will have access to your research related health records

☒ will not have access to your research related health records

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

REVOCATION: If you sign this authorization you may change your mind and revoke or take back your permission at any time. You must do this in writing and must send your written request to the Principal Investigator for this study at the following address:

Dr. Joshua Woolley M.D., Ph.D.
San Francisco VA Medical Center, 4150 Clement Street 116C
San Francisco, CA 94121

If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator.

EXPIRATION: Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will:

☐ Expire at the end of this research study

☒ Data use and collection will expire at the end of this research study. Any study information that has been placed into a repository to be used for future research will not expire.

☐ Expire on the following date or event:

☐ Not expire

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research		
Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

TO BE FILLED OUT BY THE SUBJECT

Research Subject Signature. This permission (authorization) has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint.

I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this form. I will be given a signed copy of this form for my records.

Signature of Research Subject Date

Signature of Legal Representative (if applicable) Date

To Sign for Research Subject (Attach authority to sign: Health Care Power of Attorney, Legal Guardian appointment, or Next of Kin if authorized by State Law)

Name of Legal Representative (please print)

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

VA Facility (Name and Address):
San Francisco VA Health Care System
4150 Clement Street
San Francisco, CA 94121

VA Principal Investigator (PI):	**PI Contact Information:**
Dr. Joshua Woolley, M.D., Ph.D.	(415) 221-4810 x2-4117

Study Title:
19-27265: A pharmaco-imaging approach to predicting social functioning and clinical responses to oxytocin administration in schizophrenia

Optional Authorization Supplement for Placing My Data or My Biological Specimens in a Repository or for Conducting Optional Analysis of My Specimens for Future Use in Research

Purpose. This supplement to the authorization is for either banking of data and/or biological specimens (for example blood, urine, tissue) collected during the study for future research or for conducting optional analysis for this study . You are not required to provide this permission and not providing this permission will have no impact on your participation in this study, i.e., granting this permission is not a condition of participating in this study.

Research Subject Signature. This additional permission (authorization) has been explained to me and I have been given the opportunity to ask questions about this activity. By signing below, I am giving my permission for VHA to:

☒ Store my health information in a research data repository at
Bonding and Attunement in Neuropsychiatric Disorders (BAND) Lab
and sponsored/run by Dr. Joshua Woolley, MD/PhD, Building 16

☐ Store my biological specimens (blood, tissue, urine, etc.) in a research biological specimen/tissue repository at _____

and sponsored/run by _____

☐ Further optional analysis of my specimens for the current study occurring below:

Future research of data maintained within a research data repository will only occur after further Institutional Review Board and/or other applicable approvals of the new research to ensure the protection of your individual privacy. Future use of my biological specimens will only occur after the new research has been approved by all required committees.

Signature of Research Subject _____ Date _____

Signature of Legal Representative (if applicable) _____ Date _____

To Sign for Research Subject (Attach authority to sign: Health Care Power of Attorney, Legal Guardian appointment, or Next of Kin if authorized by State law)

Name of Legal Representative (please print) _____

OMB Number: 2900-0250
Estimated Burden: 2 minutes

Department of Veterans Affairs

REQUEST FOR AND AUTHORIZATION TO RELEASE MEDICAL RECORDS OR HEALTH INFORMATION

Privacy Act and Paperwork Reduction Act Information: The execution of this form does not authorize the release of information other than that specifically described below. The information requested on this form is solicited under Title 38, U.S.C. The form authorizes release of information in accordance with the Health Insurance Portability and Accountability Act, 45 CFR Parts 160 and 164, 5 U.S.C. 552a, and 38 U.S.C. 5701 and 7332 that you specify. Your disclosure of the information requested on this form is voluntary. However, if the information, including Social Security Number (SSN) (the SSN will be used to locate records for release) is not furnished completely and accurately, Department of Veterans Affairs will be unable to comply with the request. The Veterans Health Administration may not condition treatment, payment, enrollment or eligibility on signing the authorization. VA may disclose the information that you put on the form as permitted by law. VA may make a "routine use" disclosure of the information as outlined in the Privacy Act systems of records notices identified as 24VA19 "Patient Medical Record - VA" and in accordance with the VHA Notice of Privacy Practices. You do not have to provide the information to VA, but if you don't, VA will be unable to process your request and serve your medical needs. Failure to furnish the information will not have any affect on any other benefits to which you may be entitled. If you provide VA your Social Security Number, VA will use it to administer your VA benefits. VA may also use this information to identify veterans and persons claiming or receiving VA benefits and their records, and for other purposes authorized or required by law. The Paperwork Reduction Act of 1995 requires us to notify you that this information collection is in accordance with the clearance requirements of section 3507 of the Paperwork Reduction Act of 1995. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a valid OMB number. We anticipate that the time expended by all individuals who must complete this form will average 2 minutes. This includes the time it will take to read instructions, gather the necessary facts and fill out the form.

ENTER BELOW THE PATIENT'S NAME AND SOCIAL SECURITY NUMBER IF THE PATIENT DATA CARD IMPRINT IS NOT USED.

TO: DEPARTMENT OF VETERANS AFFAIRS (Print or type name and address of health care facility)	PATIENT NAME (Last, First, Middle Initial) SOCIAL SECURITY NUMBER

NAME AND ADDRESS OF ORGANIZATION, INDIVIDUAL OR TITLE OF INDIVIDUAL TO WHOM INFORMATION IS TO BE RELEASED

San Francisco VA Medical Center, 4150 Clement Street, San Francisco, CA 94121 and UCSF Langley Porter Psychiatric Institute, 401 Parnassus Ave, San Francisco, CA 94143.

VETERAN'S REQUEST: I request and authorize Department of Veterans Affairs to release the information specified below to the organization, or individual named on this request. I understand that the information to be released includes information regarding the following condition(s):

☒ DRUG ABUSE ☒ ALCOHOLISM OR ALCOHOL ABUSE ☐ TESTING FOR OR INFECTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV) ☐ SICKLE CELL ANEMIA

INFORMATION REQUESTED (Check applicable box(es) and state the extent or nature of the information to be disclosed, giving the dates or approximate dates covered by each)

☒ COPY OF HOSPITAL SUMMARY ☒ COPY OF OUTPATIENT TREATMENT NOTE(S) ☒ OTHER (Specify)

Drug and alcohol abuse history and mental health information.

PURPOSE(S) OR NEED FOR WHICH THE INFORMATION IS TO BE USED BY INDIVIDUAL TO WHOM INFORMATION IS TO BE RELEASED

The recipient may use the information authorized on this form for research purposes as part of research studies at the University of California, San Francisco, and the San Francisco VA Medical Center.

NOTE: ADDITIONAL ITEMS OF INFORMATION DESIRED MAY BE LISTED ON THE BACK OF THIS FORM

AUTHORIZATION: I certify that this request has been made freely, voluntarily and without coercion and that the information given above is accurate and complete to the best of my knowledge. I understand that I will receive a copy of this form after I sign it. I may revoke this authorization, in writing, at any time except to the extent that action has already been taken to comply with it. Written revocation is effective upon receipt by the Release of Information Unit at the facility housing the records. Redisclosure of my medical records by those receiving the above authorized information may be accomplished without my further written authorization and may no longer be protected. Without my express revocation, the authorization will automatically expire: (1) upon satisfaction of the need for disclosure; (2) on _____ (date supplied by patient); (3) under the following condition(s):

1 year after the end of study closure.

I understand that the VA health care practitioner's opinions and statements are not official VA decisions regarding whether I will receive other VA benefits or, if I receive VA benefits, their amount. They may, however, be considered with other evidence when these decisions are made at a VA Regional Office that specializes in benefit decisions.

DATE	SIGNATURE OF PATIENT OR PERSON AUTHORIZED TO SIGN FOR PATIENT (Attach authority to sign, e.g., POA)

FOR VA USE ONLY

IMPRINT PATIENT DATA CARD (or enter Name, Address, Social Security Number)	TYPE AND EXTENT OF MATERIAL RELEASED	
	DATE RELEASED	RELEASED BY

VA FORM MAY 2005 **10-5345**

USE EXISTING STOCK OF VA FORM 10-5345, DATED NOV 2004.