

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Oxytocin: Relationships with Autism and Social Functioning

This is a research study. The study doctors Elliott H. Sherr, M.D., Ph.D. and H. Terry Hutchison, M.D., Ph.D. from the Department of Neurology and/or a research coordinator will explain this study to you.

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

You or your child are being asked to take part in this study because your/your child's doctor thinks you/your child should have a lumbar puncture (LP) as part of your/your child's medical care. An LP is a medical test that involves taking a small sample of cerebrospinal fluid (CSF) for examination. CSF is a clear, colorless liquid that transports nutrients and "cushions" the brain and spinal cord.

Why is this study being done?

This research study is being done in order to learn more about the role of oxytocin in autism and social functioning. Through this study we hope to learn about the relationship between oxytocin in the fluid around the brain (cerebrospinal fluid [CSF]) and blood oxytocin levels, and to determine if individuals with autism/social deficits have lower oxytocin levels in CSF and/or blood than individuals without autism/social deficits.

How many people will take part in this study?

About 150 people will give CSF and blood samples for this research at one of three collaborating institutions: Stanford University, Sutter Medical Center (Sacramento), UCSF, and UCSF Fresno. Approximately 75 people will participate through UCSF and UCSF Fresno.

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

If you or your child agrees to be in this study, the following will happen:

- The researchers will gather information about you/your child from your/your child's medical record using a medical diagnostic history report form.
- You will be asked to complete a few questionnaires: the Social Responsiveness Scale (SRS), the Social Communication Questionnaire (SCQ), the Child Behavioral Checklist (CBCL), the Spence Children's Anxiety Scale (SCAS), the Repetitive Behavior Scale – Revised (RBS-R), the Short Sensory Profile Questionnaire (Short SPQ), and the Wing Subgroups Questionnaire.
- A small amount of CSF (approximately one tablespoon) will be drawn with a needle from your/your child's back by your/your child's doctor for your/your child's medical care, and we will ask the doctor to collect a little extra CSF for our research study. The CSF

drawn for the purposes of our research will only be obtained after enough CSF is collected for your/your child's medical evaluation and care. CSF samples will be obtained only during the LP procedure ordered by your/your child's doctor. If extra CSF is not collected during the clinical LP, then you/your child will not continue in the study.

- A small amount of blood (approximately one tablespoon) will be drawn with a needle when blood is being collected for medical purposes or from your/your child's IV line as it is inserted or after it is established. There is a possibility that blood will not be taken as part of your/your child's medical evaluation and/or treatment. In this case, you/your child will be asked to undergo a voluntary blood draw. You/your child may decide not to undergo additional blood sampling should blood not be obtained as part of your/your child's medical evaluation and/or treatment.
- You/your child may be asked to participate in up to three follow-up appointments that will take place either at Stanford University, your home, or over the phone. During the appointment(s), Dr. Antonio Hardan, a child and adolescent psychiatrist, and/or his staff, will evaluate your/your child's social and communication skills and ask you additional questions about your/your child's health. This may take up to 8 hours over the span of 1-3 appointments. You/your child may decide not to participate in this portion of the research study.
- **Multi-site Collaboration:** Drs. Elliott Sherr and H. Terry Hutchison are collaborating with Stanford University (Drs. Joshua Elias, Antonio Hardan, Karen Parker, and Sonia Partap), and Dr. Michael G. Chez at Sutter Medical Center (Sacramento). At the end of this form, you may choose to have your/your child's personal health information shared amongst the specified collaborating institutions.

How long will I/my child be in the study?

The LP, blood sampling, completion of the medical diagnostic history form, and administration of the SRS and CBCL is expected take 1- 2 visits, requiring up to 2 hours. The additional cognitive and behavioral assessments administered by Dr. Hardan and/or his staff from Stanford University may take up to 8 hours over the span of one to three appointments. Overall the research study may take up to five visits within an average period of 6 months (total study visit time: up to 10 hours per participant).

Can I/my child stop being in the study?

If you/your child first agree to participate and then change your mind, you/your child are free to withdraw and discontinue participating at any time. If you/your child choose to tell the researchers why you are leaving the study, your/your child's reasons for leaving may be kept as part of the study record. Your/your child's decision will not affect your/your child's ability to receive medical care and you/your child will not lose any benefits to which you/your child would otherwise be entitled. Also, the investigators or other member of the research team may stop you/your child from taking part in this study at any time if he or she believes it is in your/your child's best interest, if you/your child do not follow the study rules, or if the study is stopped.

What risks can I/my child expect from being in the study?

- Any risks associated with the lumbar puncture procedure will be thoroughly explained to you by your clinician. However, there is a slight increased risk of headache associated with having extra CSF drawn.
- Drawing blood may cause temporary discomfort from the needle stick. Other risks associated with having blood draw are slight but may include fainting or feeling light-headed, bruising, and infection.
- If you/your child decide to donate blood for research purposes, you/your child might feel distressed or nervous about having blood drawn (venipuncture).
- You/your child may feel a bit of anxiety while participating in the cognitive and behavioral assessments conducted by researchers at Stanford University. However, these assessments are optional, and even if you/your child first agree to participate, you/your child can always change your mind by letting one of the researchers know.
- You/your child might feel worried about the possibility of your/your child's personal information and/or participation in this study not being kept confidential. The risk of unwanted sharing of health information will be minimized by ensuring that all study records that identify you/your child will be kept completely confidential. A unique study subject number will be used on sample tubes as well as databases containing your/your child's follow-up testing and questionnaire information. Only select members of the primary research team will have access to the original data. The information you/your child provide will be stored in a locked file cabinet in a locked office.
- There may be risks that are unforeseen and no one knows about yet. The researchers will let you know if they learn anything that might make you/your child change your mind about participating in the study.
- For more information about risks, ask one of the investigators or research coordinators.

Will my/my child's medical information be kept private?

We will do our best to make sure that the personal information in your/your child's medical record is kept private. Your/your child's information will be handled as confidentially as possible to minimize any risk to your/your child's privacy. However, we cannot guarantee total privacy. If information from this study is published or presented at scientific meetings, your/your child's name and other personal information will not be used. If you choose to allow the sharing of your/your child's personal health information with the collaborating institutions mentioned previously in this form, it may involve a loss of privacy. It is possible that researchers will need additional information from you/your child in the future. If this occurs, only the researchers at UCSF will re-contact you for follow-up information or to ask if you/your child are willing to participate in additional studies. You/your child have the right to decline these requests. Your/your child's personal information may be given out if required by law. Organizations that may look at and/or copy your/your child's medical records for research, quality assurance, and data analysis include:

- UCSF's Committee on Human Research
- Government agencies involved in keeping research safe for people, such as the Food and Drug Administration (FDA).

Sensitive research information: Participation in research may involve a loss of privacy, but information about you/your child will be handled as confidentially as possible. There is a risk that information about taking part in a study about autism and social deficits may influence insurance companies and/or employers regarding your/your child's health. However, no information obtained in this study will be placed in your/your child's medical records nor will it be provided to any insurance entity or place of employment, except in the situation described as follows: your/your child's participation in this study may be noted in your/your child's medical record since the medical staff at UCSF or UCSF Fresno may have to record the reason for drawing extra CSF or blood during your/your child's medical procedure. Therefore, your/your child's other doctors may become aware of your/your child's participation. However, hospital regulations require that all health care providers treat information in medical records confidentially, and the results of this research study, including the cognitive and behavioral assessments, will not be added to your/your child's medical record.

Are there benefits to taking part in the study?

There will be no direct benefit to you/your child from participating in this study. However, the information that you/your child provide may help health professionals better understand social deficits observed in autism spectrum disorders and/or other neurologic, psychiatric, or behavioral disorders and may support the development of novel therapeutic strategies.

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

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

What are the costs of taking part in this study?

There will be no cost to you for any of the study procedures.

Will I/my child be paid for taking part in this study?

You/your child may opt to donate a sample of CSF without completing any other study activities, in which case, you/your child will not be paid. You/your child will receive 25 dollars in cash upon completion of the CSF and blood sampling, medical diagnostic history form, SRS, and CBCL. You/your child will receive an additional 50 dollars in cash for completing all of the study procedures, including the optional behavioral and cognitive assessments. Therefore, you/your child will receive a total of 75 dollars in cash for completing all research activities for this study. The Accounting Department at UCSF may require additional information from you/your child in order to pay you/your child for taking part in this study.

What happens if I am/my child is injured because I/they took part in this study?

It is important that you tell Dr. Sherr if you feel that you/your child have been injured because of taking part in this study. You can tell the doctor in person or call him at (415) 502-8039.

Treatment and Compensation for Injury: If you/your child are injured as a result of being in this study, treatment will be available. The costs of the treatment may be covered by the University of California or the study sponsor, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at 415- 476-1814.

What are my/my child’s rights if I/they take part in this study?

Taking part in this study is your/your child’s choice. You/your child may choose either to take part or not to take part in the study. If you/your child decide to take part in this study, you/your child may leave the study at any time. No matter what decision you/your child make, there will be no penalty to you/your child and you/your child will not lose any of your/their regular benefits. Leaving the study will not affect your/your child’s medical care. You/your child can still get your/their medical care from our institution. We will tell you about new information or changes in the study that may affect your/your child’s willingness to continue in the study. In the case of injury resulting from this study, you/your child will not lose any of your/their legal rights to seek payment by signing this form.

Who can answer my/my child’s questions about the study?

You can talk to the researchers about any questions, concerns, or complaints you have about this study by calling the research staff or Dr. Sherr at (415) 502-8039.

If you wish to ask questions about the study or your/your child’s 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 Committee on Human Research at 415-476-1814.

Use of Tissue for Research

About Using Tissue for Research

Your/your child’s doctor has requested that you/your child have a lumbar puncture as part of your/their medical evaluation and care. Your/your child’s doctor will remove some body tissue to do some tests. The results of these tests will be given to you by your/your child’s doctor and will be used to plan your/your child’s care.

We would like to keep some of the tissue that is leftover for future research. If you agree, the tissue specimen(s) will be kept in storage in what is called a “tissue bank.” Two tissue banks, one at UCSF and one at Stanford University, will house tissue specimens collected for the purposes of this research study. We do not know for sure if your/your child’s tissue specimen(s) or information will be used, but they might be used in research about neurological, psychiatric and behavioral disorders. Your/your child’s specimen(s) and any information about you/your child will be kept until it is used up or destroyed. If you decide later that you do not want your/your child’s tissue specimen(s) and information to be used for future research, you can notify the investigator and/or a member of the research team by calling (415) 502-8039 and/or in writing,

and any remaining identifiable tissue specimen(s) and information will be destroyed if they are no longer needed for your/your child's care. All written requests should be directed to Elliott Sherr, M.D., Ph.D. at 675 Nelson Rising Lane, Box 3206, San Francisco, CA 94158. However, if any research has already been done using portions of your/your child's tissue specimen(s), the data will be kept and analyzed as part of those research studies. Reports about research done with your/your child's tissue will not be given to you or your/your child's doctor. These reports will not be put in your/your child's health record. The research will not have an effect on your/your child's care.

Things to Think About

- The choice to let us keep the leftover tissue specimen(s) for future research is up to you. No matter what you decide to do, it will not affect your/your child's care.
- If you decide now that your/your child's tissue specimen(s) can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your/your child's tissue. Then any tissue that remains will no longer be used for research.
- Sometimes tissue specimens are used for genetic research (about diseases that are passed on in families). Even if we use your/your child's tissue for genetic research, we will not put the results in your/your child's medical record.
- We may give your/your child's tissue specimen(s) and certain medical information about you/your child (for example, diagnosis, age, developmental history, etc.) to other scientists or companies not at UCSF, including a government health research database, but we will not give them your/your child's name, address, phone number, or any other information that would identify you/your child. Reports about any research will not be given to you or your/your child's doctor.
- You will not be charged for donating your/your child's tissue specimen(s). If any new products, tests or discoveries that result from this research have potential commercial value, you/your child will not share in any financial benefits.
- Your/your child's personal health information cannot and will not be used for additional research without additional approval from either you or a review committee.

Benefits

There is no direct benefit to you/your child for donating your/your child's tissue specimen(s) and agreeing to have your/your child's tissue specimen(s) stored and potentially used for research. However, the benefits of research using tissue include learning more about what causes neurological, psychiatric and behavioral disorders and other diseases, how to prevent them, and how to treat them.

Risks

The greatest risk to you/your child is the release of information from your/your child's health records. We will do our best to make sure that your/your child's personal information will be kept private. The chance that this information will be given to someone else, beyond those collaborating on this study, is very small.

Making Your Choice

Please read each sentence below and think about your choice. **After reading each sentence, put your initials in either 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. My/my child's tissue may be kept for use in research to learn about, prevent, or treat neurological, psychiatric and/or behavioral disorders.

YES	NO
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2. My/my child's tissue may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).

YES	NO
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3. Someone may contact me in the future to ask me/my child to take part in more research.

YES	NO
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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/your child.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You/your child 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/your child are otherwise entitled.

Multi-Site Collaboration

By initialing below, you give your permission to Drs. Elliott Sherr and H. Terry Hutchison to share your/your child's personal health information with their collaborators at Stanford University (Drs. Joshua Elias, Antonio Hardan, Karen Parker, and Sonia Partap), and Sutter Medical Center (Dr. Michael G. Chez) for the purposes of this research study.

Initials

Blood donation for research purposes

There is the possibility that blood will not be taken as part of your/your child's clinical LP, in this case we will ask you/your child to undergo voluntary venipuncture to obtain a blood sample for research purposes. You/your child may decide not to undergo additional blood sampling should blood not be obtained during your/your child's clinical LP. Please indicate your/your child's choice below by writing your initials next to the appropriate line:

_____ I consent to provide my/my child's blood should blood not be collected during my/my child's clinical LP

_____ I do not consent to provide my/my child's blood should blood not be collected during my/my child's clinical LP

Follow-up Cognitive and Behavioral Assessments

You/your child have the option to participate in up to three follow-up appointments at which cognitive and behavioral testing will be done, and questionnaires will be completed. Please indicate your/your child's choice below by writing your initials next to the appropriate line:

_____ I consent to participate/have my child participate in cognitive and behavioral testing

_____ I do not consent to participate/ have my child participate in cognitive and behavioral testing

Study Participation

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

_____ _____ _____
Date Participant's Signature for Consent Print Name

The person being considered for this study is unable to consent for himself/herself because he/she is a minor. By signing below, you are giving your permission for your child to be included in this study.

Date Parent/Legal Guardian's Signature Print Name

Relationship to Minor Name of Minor Subject

If your child is able to read and understand the procedures, risks, and benefits of the study, please have them indicate their willingness to participate by signing below, in addition to your signature above.

Date Signature of Minor Print Name

Date Person Obtaining Consent Print Name