

STANFORD UNIVERSITY Research Consent Form		IRB USE ONLY Approval Date: January 31, 2022 Expiration Date: <u>January 31, 2023</u>
Protocol Director: Dr. Anthony D. Wagner	ep 10944	
Protocol Title: Studies of Language and Memory		

Protocol Director: Dr. Anthony D Wagner. Department of Psychology and Neurosciences, Stanford University, Stanford, CA 94305-2130. Phone 650-723-4048.

DESCRIPTION: You are invited to participate in a research study that aims to assess how the brain supports language and memory in younger and older healthy adults. We hope to learn more about the brain and cognitive mechanisms that support these cognitive abilities. As a healthy volunteer, you have been asked to participate in this study because our objective is to understand the cognitive functions supported by the healthy human brain.

If you decide to participate, the procedure will be described to you in the written task instructions. You will be asked to either passively attend to or actively respond in one or more of the following experimental conditions:

1. Passive watching or listening to stimulus information (e.g., visually presented patterns, visually or auditorily presented words or numbers);
2. Watching or listening to stimuli and making a response (e.g., a finger response) about the type of stimuli seen or heard;

Some of the stimuli used in the experiment may have an affective component (i.e., pleasant or unpleasant words), while others will be affectively neutral.

Instructions may be given through Stanford approved online video conferencing systems.

As your participation in the experiment is voluntary, you are free to discontinue the experiment at any point.

At the discretion of the protocol director subjects may be taken out of this study due to unanticipated circumstances. Some possible reasons for withdrawal are:

- failure to follow instructions
- the investigator decides that continuation would be harmful to you
- the study is canceled
- not meeting inclusion criteria
- other administrative reasons

If you are apprehensive about one aspect of the procedure, or if you desire to have more information about the procedure, you should ask the investigator any questions you have about the procedure and request that they respond satisfactorily to your questions.

TIME INVOLVEMENT: Your participation in this experiment will take between 10 and 180 minutes. Some studies may require participants to come back for multiple sessions over consecutive or non-consecutive days. The investigator should have already informed you of the time requirements of the particular study you are enrolling in today. Please ask the investigator for clarification prior to beginning the tasks.

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RISKS AND BENEFITS: There are no known significant risks or benefits associated with participation in this study. We cannot and do not guarantee or promise that you will receive any benefits from this study.

If you are asked to perform tasks involving virtual environments, you may experience symptoms of motion sickness. We do not anticipate that these symptoms will be more extreme than those experienced through routine activities such as playing video games or riding in a car. If you experience any symptoms of motion sickness, let the experimenter know.

PAYMENTS: As compensation for your participation, you will be paid \$15/hour or one SONA credit per hour, based on expected task completion time after your responses are screened. Some studies may also pay an additional performance-based bonus.

If you do not complete the task, or we feel that you completed it to an unsatisfactory standard (i.e. you do not follow the instructions), you will not be compensated. This policy is in line with payment standards for online studies. There is no cost to you for this study.

SUBJECT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty. You have the right to refuse to answer particular questions. Your individual privacy will be maintained in all published and written data resulting from the study.

CONFIDENTIALITY:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number in a de-identified, individual-level format. Information about the code will be kept in a secure location and access limited to research study personnel.

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The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be revealed. De-identified, individual-level data will be deposited to the National Institute of Mental Health Data Archive (NDA), such as the Research Domain Criteria Database and/or the National Database for Clinical Trials Related to Mental Illness, for research purposes. De-identified, individual-level data may also be deposited to other open data sharing platforms, such as Open fMRI and/or Open Science, for research purposes. For archiving, the de-identified, individual-level data will include descriptive and/or analyzed files.

RESIDENTS OF THE EUROPEAN UNION:

As described elsewhere in this informed consent form, during the study, data pertaining to your participation in the study will be generated and recorded. In addition, we will collect from you your personal data and sensitive personal data, including health-related data. We refer to all such data as “Your Study Data,” which will be specifically regulated in the EU/EEA under the General Data Protection Regulation (the “GDPR”). Your Study Data may be processed or used for the following purposes, which we refer to, collectively, as “Data Processing”:

- to carry out the study;
- to confirm the accuracy of the study;
- to monitor that the study complies with applicable laws as well as best practices developed by the research community;
- to make required reports to domestic and foreign regulatory agencies and government officials who have a duty to monitor and oversee studies like this one; and,
- to comply with legal and regulatory requirements, including requirements that data from this study, without information that could directly identify you, be made available to other researchers not affiliated with the study sponsor or with the study team. It is possible, for example, that as part of efforts to make research data more widely available to researchers, regulatory authorities in some countries may require that Your Study Data, without information that could directly identify you, be made publicly available on the internet or in other ways.

The following entities and organizations may engage in Data Processing of Your Study Data:

- the study team, including other people who, and organizations that, assist the study team:
 - o Dr. Anthony Wagner
 - o The Stanford University Administrative Panel on Human Subjects and any other unit of Stanford University as necessary
 - o Research Staff
- the study sponsor: National Institutes of Health and Lund University
- the ethics committee or institutional review board that approved this study; and
- domestic and foreign regulatory agencies and government officials who have a duty to monitor or oversee studies like this one.

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We may conduct the study in the United States or in other countries where the laws do not protect your privacy to the same extent as the laws in your country of residence. In addition, we may disclose Your Study Data for Data Processing to entities and individuals located in the United States or in other countries where the laws do not protect your privacy to the same extent as the laws in your country of residence. However, all reasonable steps will be taken to protect your privacy in accordance with the applicable data protection laws.

The GDPR gives you certain rights with regard to Your Study Data. You have the right to request access to, rectification of, or erasure of, Your Study Data. You also have the right to object to or restrict our Data Processing of Your Study Data. Finally, you have a right to request that we move, copy or transfer Your Study Data to another organization. In order to make any such requests, please contact the lab coordinator at 650-723-8999 or Dr. Anthony D. Wagner at 650-723-4048.

There is no limit on the length of time we will keep Your Study Data for this research because it may be analyzed for many years. We will also retain your Study Data to comply with our legal and regulatory requirements. We will keep it as long as it is useful, unless you decide you no longer want to take part. You are allowing access to this information indefinitely as long as you do not withdraw your consent.

You may withdraw your consent at any time. If you withdraw your consent, this will not affect the lawfulness or our collecting, use and sharing of Your Study Data up to the point in time that you withdraw your consent. Even if you withdraw your consent, we may still use Your Study Data that has been anonymized so that the data no longer identifies you. In addition, we may use and share Your Study Data that has been pseudonymized (by removal of your name and certain other identifiers so that the data does not directly identify you) as permitted by applicable law for purposes of: (a) public health (e.g., ensuring high standards quality and safety of health care and/or of medicinal products or medical devices), (b) scientific or historical research or statistical analysis as permitted by applicable European Union or European Union Member State laws and (c) archiving in the public interest. Further, we will maintain Your Study Data in fully identifiable form if required by law.

You consent to the collection, use and transfer of Your Study Data, which includes health and other sensitive personal data, for the purpose of carrying out the research study and know that you can withdraw your consent at any time, and we will stop processing your personal data, except as described above.

CONTACT INFORMATION:

Questions: If you have any questions, concerns or complaints about this research study, its procedures, risk and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Anthony D. Wagner. You may contact him now or later at 650-723-4048.

If you feel you have been hurt by being part of this study, or need immediate assistance, please contact the lab coordinator at 650-723-8999 or Dr. Anthony D. Wagner at 650-723-4048.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a

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participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650) 723-2480 or toll free at 1-866-680-2906, or email at irbnonmed@stanford.edu. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Please print a copy of this page for your records.

If you agree to participate in this research, please proceed to the next page and complete the surveys and tasks.