

COVID-19 Information Sheet about participation in a research study

Information About This Form

You may be eligible to take part in a research study. This form gives you important information about participation in the study during the COVID-19 pandemic.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign a consent form. Before you sign the consent form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

Study Site Details

The study site visit will be conducted at the Wicha Lab for Brain, Language and Cognition at the University of Texas at San Antonio and will involve face-to-face (F2F) interaction between the researcher(s) and study participants.

COVID-19 Study Site Precautions

The following COVID-19 specific precautions will be followed to ensure the health and safety of research personnel and study participants.

Personal Protective Equipment

All study investigators, coordinators, visitors and staff in our research areas are required to wearing mask and practice hygiene at all times. Additionally, lab coats, masks, gloves and face shields will be worn by all researchers when interacting with study participants.

Study participants will be provided with a sterile surgical grade facemask, even if they are wearing their own face covering, and will be asked to wear this properly covering both their nose and mouth at all times during the F2F session. They will also be asked to wash their hands, following CDC guidelines, immediately upon entering the Wicha Lab. Hand sanitizer will also be available.

Facility

UTSA Facilities Office has confirmed that BSE 2.206 (Wicha Lab) is treated as a wet lab, which means that outside air is pumped in and actively removed at a minimum of 6 times per hour. This significantly improves air quality by removing potentially accumulated viral particles from any room. Study participants will sit in the EEG recording chamber with the chamber door open whenever possible to increase air circulation. After an extended period of having the chamber door closed with a participant inside, the chamber door will be left open for at least 10 minutes to ensure at least one full exchange of air before the researcher enters the chamber.

Equipment

Equipment used by study participants, such as behavioral response devices, will be cleaned after each use with disinfectant wipes. If possible, these devices will be enclosed in a zip-lock bag or plastic wrap to make cleaning easier.

Hard-surface areas, such as desks and door handles, should be wiped down after use with a 60% or higher concentration ethanol solution (provided by UTSA safety).

A new pen or pencil will be provided for each participant when completing hard copy forms (e.g. consent forms, etc).

Health Screening for Study Participants

All study participants will complete a COVID-19 screening questionnaire once 24 hours prior to the scheduled visit and once upon arrival at the Wicha lab. The responses from the questionnaire will be logged and will determine if the study participant has a temperature of 100 degrees or higher, has come in contact with individuals with COVID-19 or is experiencing symptoms related to COVID-19. Should the answer be yes to any of these, the F2F appointment will be cancelled. In person screening will occur in the UTSA BSE building, second floor atrium seating area prior to entering the lab. Participants will be asked to rest in this area for 5 minutes prior to taking their body temperature.

Health Screening for Researchers

Research personnel are expected to measure their temperature (following operating procedures for the thermometer) and respond to the COVID-19 Questionnaire on days that they will be in the Wicha Lab. Researchers that answer yes to any of the questions related to COVID-19 exposure or symptomatology are expected to refrain from all in person lab activities and report the principle investigator (PI) immediately.

Study Participant Scheduling and Visit Log

Only one participant will be scheduled at a given time. All study participants will provide their name and best contact information should contact tracing become necessary. Research personnel will log this information along with the date and time of participation. The log will be maintained separate from any data or medical records. The log will be destroyed at the completion of F2F data acquisition, or after 3 weeks, whichever takes longer.

Other Protective Measures

Cell phones

Study participants will be asked to place their cell phones in a container upon entering the lab to avoid researchers touching the phone; cell phones are not permitted in the recording chambers and are highly touched surfaces.

Social Distancing

When possible, all personal interactions will adhere to the minimum 6-foot distance social distancing guideline, recommended by the CDC.

Research Personnel Calendar/Log

To maintain proper social distancing measures, the number of researchers in the Wicha Lab at any given time will be kept to a necessary minimum – usually no more than 2 lab personnel. Research personnel will enter their schedule for being in the Wicha Lab on a shared virtual calendar.

While in the lab, research personnel will maintain a minimum 6-foot distance from other lab personnel whenever possible, will limit their use of lab equipment (e.g., computers, etc.) to one area of the lab whenever possible, should not share any lab equipment with other lab members or study participants (e.g. computer keyboards or writing instruments), and will avoid being in smaller enclosed areas (e.g., testing rooms) within the lab with another lab member or minimize these interactions when necessary to less than 10 minutes while maintaining a 6-foot distance.

COVID-19 Specific Risks

Despite all of these precautions, it is still possible that someone might show no symptoms and still spread the virus. If a member of our team reports having symptoms after interacting with you, we will contact you to report possible COVID-19 exposure. We also ask that you contact our team if you develop COVID-19 related symptoms after your F2F study visit.

A weak or compromised immune system (including, but not limited to, conditions like diabetes, asthma, COPD, cancer treatment radiation, chemotherapy and any prior or current disease or medical condition), can put you at greater risk for contracting COVID-19. Please disclose to us any condition that compromises your immune system and understand that we may ask you to consider rescheduling the study visit after discussing any such conditions with us.

If you consent to participation in the study, you are willingly and knowingly consenting to participating during the COVID-19 Pandemic.

Contact Information

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

Primary Contact:

Dr. Rocio Norman (210) 450-8352 Email: normanr@uthsca.edu

Secondary Contact:

Dr. Nicole Wicha (210) 450-7013 Email: Nicole.Wicha@utsa.edu

The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830,7703 Floyd Curl Drive, San Antonio, TX 78229-3900.