VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Blythe Corbett, Ph.D. **Revision Date: 1/14/2020**
Study Title: Enhancing Social Competence in Adults with ASD: A Pilot RCT
Institution/Hospital: Vanderbilt University Medical Center

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key information about this study:
You are being asked to take part in this research study because you have an autism spectrum disorder. We hope to learn about the effects of behavior therapy and theatre techniques and to determine if they are helpful in improving social and emotional behavior and reducing stress in individuals with autism.

You may be randomly assigned to either the initial study group or the waitlist comparison group for this study. If you are assigned to the waitlist comparison group, you will still complete the study procedures listed below, but not initially participate in the intervention. After the first study group completes the intervention, then you will get a form of the intervention that is comparable to the version used in the initial study. The total time commitment for this study is approximately six months.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

There are limited risks associated with the various components of the investigation. We anticipate that the participant will experience some stress or anxiety in response to his or her exposure to a new environment, new peers, and novel tasks. During testing, the participant may become anxious, frustrated, bored, or tired due to the novelty and duration of the procedures. It is possible that adult participants may become fatigued during some evaluations or may experience mild discomfort during the EEG/ERP procedure. The physical risks of the EEG procedure are minimal and comparable to every-day activities (e.g., contamination or infection).

There are no guaranteed significant immediate benefits from participation in this study. The participant will be provided with test results from their performance on standardized instruments in the form of a research letter. Previous research has shown significant gains in children and adolescents with ASD with regards to social cognition, behavior, and adaptive functioning. Thus, it is possible that adults enrolled in the treatment may experience similar benefits. It is also possible that the WLC group who will receive the treatment after all phases of testing are complete, will also experience benefits from the treatment in the form of improvement in social competence. In other words, there is potential benefit of changes in core symptoms of autism with minimal risk.

Procedures to be followed and approximate duration of the study:
The SENSE Theatre® program is a research study. In order to be in the program you must participate in the research. It will require a commitment of enrollment to attend a majority of the 10 sessions and up to two performances. Due to the considerable amount of material covered in each session, full participation is important. Thus, we request all participants to come to the majority of the sessions (i.e., 9 out of 10). Specifically, the study will include psychological assessments, Event Related Potential tasks (neuroimaging tasks using electroencephalography, or EEG), and a social interaction session conducted before and after the SENSE Theatre® program. The program includes rehearsals, therapeutic practice sessions and theatre rehearsals that will culminate in a performance of a play with music. The performances will take place over two evenings. The practice and rehearsals will involve working with a psychologist, a theatre director and fellow cast members. The practice/rehearsal sessions will involve learning about understanding and expressing emotions, speaking and

using gestures in new ways, and imitating other people's behavior. Additional cast members will participate in the rehearsals and performance of a play with music.

If you decide to volunteer, you will undergo the following procedures:

Eligibility (2-3 hours): At the first visit, you will be asked to come into the research lab for testing that will confirm your eligibility to participate in the study. A trained study clinician will evaluate you to diagnose or reconfirm the diagnosis of autism spectrum disorder. A research team member will also administer a brief intelligence test.

Pre-Intervention Assessment (1-1.5 hours): If you meet eligibility qualifications and decide to continue participation, you will be asked to complete some neuropsychological tests to see how you understand and express emotions, recognize and remember faces and use language. We will also ask you to complete some questionnaires about your stress and emotion. We will ask you to identify one parent, teacher, therapist or other professional that sees you regularly (e.g., once a week) to fill out some questionnaires.

Social Interaction Session (30 minutes): You will participate in a social interaction session. You will interact with another individual for a total of 6 minutes. You will be videotaped during the session. The videotape will be used for coding behavioral responses. This videotape will be destroyed upon completion of the study.

Event Related Potentials (ERP) Tasks Using EEG (1 hour): You will participate in an ERP session. Testing will involve recording your brain waves using soft sensors placed on your head. These sensors are arranged like a shower cap. Your head will be measured to find the right size net. Before putting on the net, it will be soaked in warm salt water. Before the EEG, you may be asked to remove any large pieces of jewelry, hair clips, or glasses to enable proper net fitting. Once the EEG net is placed, you will be able to put the glasses back on. Jewelry and hair clips may be put back on after the EEG. In this study, the EEG is collected for research purposes only. We will not be able to inform you of any diagnostic information, but if we see something unusual, you will be told, and asked to consult your doctor. Once the net is in place, you will look at pictures on a computer screen.

The Social Interaction, ERP session, and assessment will be completed in one session lasting approximately 2-3 hours. This session will occur approximately two weeks before the start of the intervention.

Intervention/Rehearsal (3.5-4 hours/week; 10 weeks): You will also participate in therapy sessions and theatre rehearsals. These sessions will include learning how to better understand and express emotions, imitate peers, practice scenes from a play, and engage in various theatre games to learn how to communicate with words, actions and singing. You will be a part of the show and will perform the play with music up to 2 times for families of participants and the public.

During various practices and during the performances, you may be videotaped while performing.

Intervention Mid-Point (**30 minutes)**: At the mid-point of the intervention, you and your caregiver or other informant will complete some of the same questionnaires from the first visit of the study.

Post-Intervention (2-3 hours): You will repeat the assessments, social interactions (with new peers), and ERP visit. We will have caregivers or other informants complete some of the same questionnaires from the beginning of the study.

Follow-Up (2-3 hours): In order to measure the longevity of changes you may make, we will ask you to repeat the assessments, social interactions (with new peers), and ERP visit approximately 3 months after the end of the SENSE Theatre® intervention.

Data from this study may be submitted to the National Database for Autism Research (NDAR). NDAR is a computer system run by the National Institutes of Health that allows researchers studying autism to collect and share information with each other. During and after the study, we will send information about your health and behavior

to NDAR. However, before we send it to NDAR, we will remove information such as name, address, and phone number, and replace that information with a code number. If you decide now or later that you do not want to share your information using NDAR, let us know, and we will tell NDAR, which can stop sharing the research information. However, NDAR cannot take back information that was shared before you changed your mind.

Expected costs:
There will be NO COST to participate in the 10-week research intervention.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:
There are minimal risks associated with your participation in this study. Everyone taking part in the study will be watched carefully for any side effects. At times the sessions may be tiresome or cause mild frustration or anxiety, but we will give you breaks whenever needed. As noted, the study is evaluating the effects of social interaction and stress. Therefore, we anticipate that you will experience some stress in response to exposure to a new environment and novel social experiences. If your anxiety becomes excessive or intolerable, the study procedures will be stopped at your request. The procedure should be no more stressful than coming to a new clinic for routine medical procedures. Therefore, although there are potential risks, the likelihood of any lasting effects from such a testing situation would be minimal.

The physical risks associated with the EEG are minimal and comparable to every-day activities. The following steps are taken to minimize such risks: (1) The EGI system used to record the brain responses is electrically isolated from the participant, eliminating the risk of any current flowing to the participant. (2) The electrodes used for this study do not require skin abrasion for proper contact and therefore minimize infection risk. Risk of infection is further reduced through specific electrode care procedures that include rinsing all electrodes with water immediately after testing and then soaking the electrode net in a cold sterilizing solution (Control III) to eliminate any contaminants that otherwise might pass from participant to participant. Following soaking, the electrodes are again rinsed and then air dried.

Unforeseeable risks:
This is a low risk study. There may be some anxiety or stress at the beginning of the intervention, similar to those experienced when meeting new people or trying new activities.

Compensation in case of study-related injury:
If it is determined by Vanderbilt and the Investigator (with input from the sponsor) that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt or the sponsor to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt or the sponsor to give you money for the injury.

Good effects that might result from this study:

a) The benefits to science and humankind that <u>might</u> result from this study.
The information we get from this study may help us to learn more about how individuals with autism understand and respond to social and emotional information. Additionally, our current and previous research emphasizes the importance of looking at both the behavioral and biological response to social stress. It is anticipated that the current study will contribute to this growing body of work and eventually help in designing treatments to reduce stress and socioemotional difficulties in individuals with autism. The efficacy of the SENSE Theatre® intervention

will be evaluated across groups of participants and the techniques will be refined based on the data collected. In the process, we hope to determine what aspects of the intervention are most beneficial to individuals with autism, what target behaviors are most improved and for whom the treatment is most efficacious.

b) The benefits you might get from being in this study.
It is possible that you will not benefit directly by participating in this study. It is also possible that you may learn from the behavioral and theatrical techniques that will result in improvement in social competence and expanded understanding and expression of emotion. You may also experience less stress and enhanced comfort in social situations as a result of this experience.

Study Results:
The results of the study will be provided to research participants upon request. Published peer-reviewed manuscripts will be shared with the autism and scientific community.

Alternative treatments available:
The study does not provide an alternative treatment. However, we will provide information on other known treatments and services that the participant or family may qualify for.

Compensation for participation:
There is no compensation for participating in this study. However, the treatment is offered at no cost.

Circumstances under which the Principal Investigator may withdraw you from study participation:
If you do not meet inclusion criteria for the study based on study measures, such as not currently having an autism spectrum disorder or if you show significant cognitive impairment, then you may be withdrawn from the study. If you respond to items on study measures indicating that you are experiencing suicidal thoughts and have a plan to harm yourself, the Principal Investigator may withdraw you from the study in order for you to seek psychiatric care. If you become uncomfortable with the study procedures or experience, the Principal Investigator may withdraw you from the study. Additionally, if you are unwilling to participate in the study or the majority of the activities you may be withdrawn from the study. If you are withdrawn from study activities, you data up to that point will be stored alongside all of the other confidential data. In published manuscripts, we will acknowledge your withdrawal, without revealing your identity in any way. We will maintain the data to be evaluated if there is any question regarding differences in individuals who completed the study and those that did not. In general, however, the data from withdrawn participants will not be included in analyses.

What happens if you choose to withdraw from study participation?
Your participation is voluntary. You may choose to withdraw from the study at any time for any reason. You can also skip any questions that you do not wish to answer. If you choose not to take part in this study, no negative consequences will occur. Your future care at Vanderbilt University will not be affected. If you are withdrawn from study activities, you data up to that point will be stored alongside all of the other confidential data. In published manuscripts, we will acknowledge your withdrawal, without revealing your identity in any way. We will maintain the data to be evaluated if there is any question regarding differences in individuals who completed the study and those that did not. In general, however, the data from withdrawn participants will not be included in analyses.

Contact Information. If you should have any questions about this research study or possibly injury, please feel free to contact the Principal Investigator, **Blythe Corbett, Ph.D.**, at **615-936-0280** or the Chair of the Department of Psychiatry, **Stephan Heckers, M.D.**, at **615-322-2665**.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

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

Confidentiality:
All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. All records associated with this study will be kept confidential. The information obtained about you will only be used by the researchers involved with this study. Dr. Corbett will treat your identity with professional standards of confidentiality. The U.S. Department of Health and Human Services has the right to inspect all of our medical records related to this research for the purpose of verifying data. The information obtained for this study may be published in medical journals but your identity will not be revealed.

All records will be kept in a locked filing cabinet. We are required by state law to immediately report any evidence of possible child abuse with identification of the alleged offender. If any information is revealed during this study concerning suicide, homicide, child abuse, or neglect, it is required by law that this be reported to the proper authorities. By signing this document you allow us to make your records available to the sponsor of the study. Any information obtained in connection with this study will be used in a manner that does not publicly disclose your identity and will be kept confidential. Absolute confidentiality cannot be guaranteed, since research documents are not protected from subpoena.

If information from the study is published or presented at scientific meetings, your name and other personal information will not be used. The Vanderbilt Institutional Review Board has the authority to review your research and medical records. This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means. It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to you or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law.

Privacy:

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Corbett and her study team may share the results of your study and/or non-study linked information as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, or the National Institutes of Health. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The sponsor and/or Vanderbilt may give or sell your health data, without identifiers, to others or use it for other research projects not listed in this form. The sponsor, Vanderbilt, Dr. Corbett and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

The study results will be kept in your research record for at least ten years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will also be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Corbett in writing and let her know that you withdraw your consent. Her mailing address is: 1500 21st Avenue South, Nashville, TN, 37212. At that time, we will stop gathering any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law.

If information from the study is published or presented at scientific meetings, your name and other personal information will not be used. The Vanderbilt Institutional Review Board has the authority to review your research and medical records.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title

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PERMISSION FOR USE OF PHOTOGRAPHS, VIDEO & SOUND

I give permission for myself, _____, to be photographed and videotaped for use in presentations or print or electronic publications about the mission and activities of the SENSE Lab and its research projects. Photos, videos and sound captured during this research may be used in presentations to the scientific community, publications in scientific journals, description of research on fliers, websites, and other media. The audience for presentations and print and electronic publications includes families affected by disability, researchers, educators, service providers, health care professionals, and the general public.

_____
Name of Participant

_____
Signature of Participant Date

_____
Address

_____
City/State/Zip Code

_____
Phone Number

Special Notes: