Enhancing Social Competence in Adults with Autism

PROTOCOL

NCT04349644

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ENHANCING SOCIAL COMPETENCE IN ADULTS WITH AUTISM SPECTRUM DISORDER: A PILOT RCT

PROTOCOL

(CTL+click to jump to section)

CONTENTS

RESEARCH COMPONENTS OF SENSE THEATRE®

- **Eligibility:**
  - **Consent (15-30 minutes)**
  - **Assessment Visit- research site offices (2-3 hours)**
- **Pre Intervention:**
  - **Assessment (1-2 hours)**
  - **ERP (45 minutes)**
  - **Contextual Assessment of Social Skills – research site offices (30 minutes)**
- **Intervention (10 week theatre program) or waitlist control group (equivalent theatre program offered after completion of all study visits)**
- **Intervention Midpoint (5th week of intervention):**
  - **Self-report questionnaires**
  - **Family member/Informant questionnaires**
- **Post Intervention:**
  - **Assessment (1-2 hours)**
  - **ERP (45 minutes)**
  - **Contextual Assessment of Social Skills (30 minutes)**
- **Follow-up (2.5 months after post visit)**
  - **Assessment (1-2 hours)**
  - **ERP (45 minutes)**
  - **Contextual Assessment of Social Skills (30 minutes)**

RECRUITMENT

EVENTS

- Regional autism community outreach groups (i.e. Autism Tennessee Conference)
- State Autism Speaks Walk
- Find other events, possible sources of recruitment using regional support groups and awareness programs
  Recruitment Resources
- Research Site Website: Coordinate Links and Information with PI and site information technology department

MAINTAINING RECRUITMENT

- Maintain ongoing list of interested participants and of peers/counselors.

INCLUSION/EXCLUSION CRITERIA

- Must have an autism spectrum disorder (score ≥7 on ADOS)
- An estimated scale IQ score on the WASI or WAIS of ≥70
- Baseline threshold score of ≥10 on either the Cambridge Face Memory Test or Wechsler Memory for Faces Test
- No medication restriction—although note these during the phone screen in addition to any other medical psychological diagnoses/conditions—could be exclusionary.
- Must communicate using complete sentences/have fluent speech.

- **Siblings should not be in the same cohort**
- **Aggression: During phone screen, ask if there a history of current or recent aggression**
- *If in doubt about any of these factors, consult with Dr. Blythe Corbett.

ID CONVENTION

- The ID system is STA; start with 101 for cohort 1, 201 for cohort 2, etc.
    - For example, STA 101, STA 201, etc.

SCHEDULING PARTICIPANTS

IMPORTANT POINTS TO MAKE

- Studying peer-mediated effects on social cognition, communication, and interaction through the SENSE Theatre® program. Assignment to the experimental group (SENSE Theatre®) or waitlist control (WLC) will be randomly assigned.
- Visits required: initial eligibility visit, then **pre-treatment, mid-point of treatment, post-treatment, and a 2 1/2-month follow up**.
- Autism
- Ages 18-40
- Visit breakdown
    - Eligibility: Assessment (about 2-3 hrs.)
        - Diagnostic evaluation (ADOS, ask if completed within last 2 years)
        - Estimated IQ (WASI within last year?)
    - Pre-visit:
        - Assessment (about 1 hour)—self-report forms and social perception measures
            - Cambridge Face Memory Test (CFMT)
            - Wechsler Memory for Faces (WMS-F III)
            - Computer Memory for Faces
        - CASS (about 30 Minutes)
            - Interaction in study offices
            - Two 3-minute interactions with two different adults
            - Videotaped to analyze later
        - ERP
            - 30 minutes
            - Watch a social and non-social stimuli and press button in response to stimuli.
            - Wear a mesh hair net type device with tiny sponges.
            - Hair will get slightly damp, but that is the only possible discomfort.
    - Intervention
        - 10 consecutive sessions for the SENSE Theatre® intervention.
    - Intervention Midpoint
        - Self- and family member/informant report questionnaires
    - Performance: at end of the SENSE Theatre® intervention.
    - Post and Follow-up Visits (Assessment, CASS, and ERP).
- Intervention will be free upon completion of all 4 parts (pre, midpoint, post, and follow-up)

- **Explain randomization:** You may be randomly assigned to either the initial study group or a waitlist control group. If you are assigned to the waitlist control group, you will still complete the study procedures, but will wait to participate in the intervention until after the initial experimental group.

VISIT SCHEDULING

General Notes:

- Add each component to Lab Calendar.
- Invite principal investigator and other involved lab members to all scheduled calendar components.
- Give reminder call/email several days before event.
- Testing must occur before ERP to ensure the facial stimuli in the ERP do not affect CMFT/WMS-III scores. Do not schedule ERP in between CFMT/WMS-III tasks.

Assessment (1-2 hours)

  - **Establish Days/Times** for when assessments can be scheduled.
  - **Room Schedule:** Establish a separate calendar for room reservations. If there are any organizations or individuals that site space must be shared with, ensure those individuals are informed and there are no conflicts for space/scheduling.
  - **Reserve Room:** Send email to the research space coordinators with room you are booking, Date, Times, and project for which the assessment room will be needed.
  - **Parking:** Ensure all parking has been reserved for participants upon day and time of their visit.
  - **Site Calendar:** Add Assessment to site Lab Calendar (Inclue Location, subject ID, and who is doing the assessment, in addition to any special notes : first time dx, needs ADOS, does not need ADOS, etc.)

ERP (30 minutes)

- Assessment/CASS and ERP are often scheduled on the same day for visits.
- ERP should be scheduled along the needs and requirements of the site EEG lab performing the ERP task – make sure to have a mutual calendar you can access for the purpose of scheduling appointments.
- **Immediately confirm with site EEG team of the scheduled date.**

CASS (30 minutes)

- **Before scheduling CASS** visits you must:
  - (1) Establish with any groups that share research space the times for which you will be using the facilities.
  - (2) Figure out research helper availability, so you may know which research helpers are available when.
    - Do these two things BEFORE scheduling participants!
- **Confirm Research Helpers:** After scheduling a participant, contact available research helpers to confirm their availability.
- **Confirm Research Space:** Then email any groups sharing the research to let them know the date and time you will be using the CASS. Email lab members as needed to schedule space for CASS at the beginning of each week while study is active.
- **Reserve parking** for research helpers AND subject.

- Add CASS visit to **site lab calendar**, including subject id, location, time, research helpers, and reserved parking spaces.

ELIGIBILITY VISIT

SETUP & CONSENTING

- Arrive at the assessment facilities 30 minutes prior to family arrival time.
- Gather appropriate testing materials out of cabinets (ADOS, WASI)
- When the participant arrives, take him/her into a private study room and begin consenting. (15 minutes)
    - Ensure that 2 participant consent forms and 2 family member/informant consents are signed by participant, family member/informant, and research staff (1 copy for research team & 1 for family member/informant)
    - Explain **NDAR** (National Database for Autism Research), and also explain GUID and need for **participant's city of birth** in creating unique identifier (see page 14).
- ***NOTE:** If a potential participant is legally conserved (i.e., under a legal conservatorship wherein he or she cannot sign informed consent documents on his or her own behalf), the Health Care Decision-Maker (Surrogate) authorized to make healthcare decisions on behalf of the potential participant will need to be present for the consent process. In order for the potential participant to enroll in the study, the Surrogate, a Witness, and the Person Obtaining Consent will need to provide signatures on the Surrogate Rider at the end of the ASD Adult informed consent document.
- Ask any individuals who accompanied the participant to wait in a separate room/lobby space until the assessment is over
    - Retrieve any filled surveys that will be scored later; make sure to check that all items have been answered entirely
    - **Have research helpers and peers sign consents during training; review study process and ensure copies for peer or research helper are made.**
- **Review any questionnaires to confirm they are complete**
- The Columbia-Suicide Severity Rating Scale Lifetime/Recent Version will be administered by a trained clinician during the eligibility visit. If the participant endorses suicidal ideation, Dr. Corbett or another study clinician will be contacted immediately to determine the best course of action. Options for addressing the concern may include contacting the participant's outpatient mental health care provider, prompt consultation with adult providers within the Department of Psychiatry and Behavioral Sciences, or referral for urgent psychiatric evaluation and treatment. If the threat is determined to not be imminent, the participant will be provided with local mental health resources. The clinician will also inform the participant of the importance of going to the Emergency Room should thoughts and feelings intensify. Finally, the participant will be notified that the Principal Investigator may withdraw the participant from the study due to suicidality in order for them to prioritize and receive the necessary care.

TESTING

TASKS

- **The following time frames for administration of tests are normative**
    - ADOS - 45 minutes
    - WASI Vocab - 12 minutes
    - WASI Matrix Reasoning - 8 minutes
    - WASI Similarities - 5 minutes
    - WASI Block Design - 15 minutes
    - C-SSRS Lifetime/Recent Version – 10 minutes
- **Have family members/informants complete SCQ-Lifetime at visit and, if first-time diagnosis, ASD History & Intake Form**

PRE INTERVENTION VISIT

SURVEY KIT

Send to family members/informants before the pre-intervention visit/have family members/informants complete during visit:

- Cover Letter: instructions for questionnaire packet and appointment reminder
- Directions to the site location, including where to meet
- Socioeconomic Status Questionnaire (Family member/informant report)
- ABAS Adult Form
- ASEBA ABCL
- CAARS Observer Report: Short Form
- SRS-2 Parent-Report

(Family/Informant Surveys: remind them **not** to fill in participant's name, DOB, and other identifying information)

Send to adult participant before the pre-intervention visit:

- Socioeconomic Status Questionnaire (Adult self-report)
- Medications Form (Adult self-report)
- Health History Form (Adult self-report; can be completed by family member/informant if needed)

Visit 1 (pretest) Only: Due to the unprecedented situation surrounding the global COVID-19 pandemic, we will, via email, ask families to complete the following two questionnaires, which relate to stress and coping associated with COVID-19, via REDCap online survey or, if they choose, using physical copies of the questionnaires that we would mail to them:

1) Compas Responses to Stress Questionnaire (RSQ; Compas, 2020) - COVID-19 Adult Self-Report: The RSQ can be filled out by adult participants with ASD regarding their own personal coping and involuntary stress responses in regards to how they respond to stress related to COVID-19.

2) Compas Responses to Stress Questionnaire (RSQ; Compas, 2020) - COVID-19 Parent Report on Adult Child: The RSQ can be filled out by parents of adult participants with ASD regarding their adult child's coping and involuntary stress responses in regards to how their adult child responds to stress related to COVID-19.

** Take the participant's photo (after participant has signed Video/Photo Release). Explain that picture will be used during counselor/peer matching. **

TESTING

TASKS

- **The following time frames for administration of tests are normative**
  - ABAS self-report – 10 minutes
  - ASEBA Adult Self-Report (ASR) – 10 minutes
  - Cambridge Face Memory Test – 30 minutes
  - Wechsler Memory for Faces – 30 minutes
  - Computer Memory for Faces – 30 minutes
  - BFNE – 5 minutes
  - CAARS Self-Report: Short Form – 5 minutes
  - BDI-II – 5 minutes
  - SRS-2 Self-Report – 5 minutes
  - Cohen's PSS – 5 minutes
  - Rosenberg SES – 5 minutes
  - Sensory Profile – 5 minutes
  - C-SSRS Since Last Visit Version – 10 minutes
    - Administered by a licensed clinical psychologist. See plan in "Setup and Consenting" section above for protocol if participant endorses suicidality.

PRE-ERP

- ERP should be scheduled along the needs and requirements of the site EEG lab performing the ERP task – make sure to have a mutual calendar you can access for the purpose of scheduling appointments.
- ERP visits can be scheduled for 1 hour blocks

CONTEXTUAL ASSESSMENT OF SOCIAL SKILLS (CASS)

- Protocol is based off Ratto et al. (2011).
  - Requires two opposite-sex peers to act as research helpers; one research helper and the participant are led into an observation room (site specific) and told "thank you both so much for coming in. Right now we'd like for both of you to talk to each other, then I will come back in the room."
  - Research Helper 1 will be the Interested social condition; they will act supportive and interested in the conversation.
  - Allow for 3 minutes to pass. Record on video camera the behaviors that take place during this time for future behavioral coding.
  - Once 3 minutes have passed, remove the research helper from the room. Have participant complete a conversation rating scale rating scale while the next research helper is prepared.
  - Research Helper 2 will be the Bored social condition; they will behave as bored by the conversation.
  - Once 3 minutes have passed, remove the research helper from the room.

- Following the completion of the CASS, participants will complete the **State-Trait Anxiety Inventory (STAI).** Participants will complete the **Conversation Rating Scale (CRS)** immediately after each condition (Interested and Bored). Mark the CRS forms with **"I" for interested and "B" for Bored**

MIDPOINT VISITS

MIDPOINT-ASSESSMENT

Send to family member/informant via mail:

- ABAS Adult Form
- ASEBA ABCL
- SRS-2 Parent-Report

Send to participant via mail:

- Gender Self-Report (GSR)

TESTING

TASKS

- **The following time frames for administration of tests are normative**
  - ABAS self-report – 10 minutes
  - ASEBA Adult Self-Report (ASR) – 10 minutes
  - BDI-II – 5 minutes
  - SRS-2 Self-Report – 5 minutes
  - Medications Form (Adult self-report)
  - C-SSRS Since Last Visit Version – 10 minutes
  - Gender Self-Report (GSR) – 10 minutes
- Midpoint testing will take place via Zoom; participants will be asked to fill out the above questionnaires during the testing and will be administered the C-SSRS by a licensed clinical psychologist. See plan in "Setup and Consenting" section above for protocol if participant endorses suicidality.

POST-VISIT

POST-ASSESSMENT

Send to family member/informant or have family member/informant complete at assessment:

- ABAS Adult Form
- ASEBA ABCL
- SRS-2 Parent-Report
- CAARS Observer Report: Short Form
- Socioeconomic Status Questionnaire (Family member/informant report)

Send to adult participant before the post-intervention visit:

- Medications Form (Adult self-report)
- Socioeconomic Status Questionnaire (Adult self-report)

TESTING

TASKS

- **The following time frames for administration of tests are normative**
    - ABAS self-report – 10 minutes
    - ASEBA Adult Self-Report (ASR) – 10 minutes
    - Cambridge Face Memory Test – 30 minutes
    - Wechsler Memory for Faces – 30 minutes
    - Computer Memory for Faces – 30 minutes
    - BFNE – 5 minutes
    - CAARS Self Report: Short Form – 5 minutes
    - BDI-II – 5 minutes
    - SRS-2 Self-Report – 5 minutes
    - Cohen's PSS – 5 minutes
    - Rosenberg SES – 5 minutes
    - Sensory Profile – 5 minutes
    - C-SSRS Since Last Visit Version – 10 minutes
        - Administered by a licensed clinical psychologist. See plan in "Setup and Consenting" section above for protocol if participant endorses suicidality.

POST-ERP

- Protocol for ERP does not change in post-visit.

POST-CASS

- Utilize research helpers unknown to participant (not the same research helpers as pre-CASS)
- As in pre visit, complete **CRS** after both Interested and Bored Conditions
    - Mark the CRS forms with **"I" for interested and "B" for Bored**
- As in pre-visit, complete **STAI** after CASS

FOLLOW-UP VISIT

FORMS

Send to family member/informant or have family member/informant complete at assessment:

- ABAS Adult Form
- ASEBA ABCL

- CAARS Observer Report: Short Form
- SRS-2 Parent-Report
- Socioeconomic Status Questionnaire (Family member/informant report)

Send to adult participant before the follow-up visit:

- Medications Form (Adult self-report)
- Socioeconomic Status Questionnaire (Adult self-report)

TESTING

TASKS

- ABAS self-report – 10 minutes
- ASEBA Adult Self-Report (ASR) – 10 minutes
- Cambridge Face Memory Test – 30 minutes
- Wechsler Memory for Faces – 30 minutes
- Computer Memory for Faces – 30 minutes
- BFNE – 5 minutes
- CAARS Self Report: Short Form – 5 minutes
- BDI-II – 5 minutes
- SRS-2 Self-Report – 5 minutes
- Cohen's PSS – 5 minutes
- Rosenberg SES – 5 minutes
- Sensory Profile – 5 minutes
- C-SSRS Since Last Visit Version – 10 minutes
    - Administered by a licensed clinical psychologist. See plan in "Setup and Consenting" section above for protocol if participant endorses suicidality.

FOLLOW- UP ERP

- Protocol for ERP does not change in follow-up visit.

FOLLOW- UP CASS

- Utilize research helpers unknown to participant (not the same research helpers as in the pre and post- CASS)
- As in pre visit, complete **CRS** after both Interested and Bored Conditions
    - Mark the CRS forms with **"I" for interested and "B" for Bored**
- As in pre-visit, complete **STAI** after CASS

****All forms must be completed by same rater in Pre, Post, and Follow-up (i.e. same family member/informant)! ****

SATISTACTION SURVEY

- At the conclusion of each cohort, send an email to all participants in the cohort (in both the EXP and WLC groups) who have completed the SENSE Theatre® intervention program, including the performances, requesting them to fill out a Satisfaction Survey that will be used to help improve future programs. The email will include a link to the online REDCap survey. For participants who wish to complete a paper copy of the Satisfaction Survey, mail those participants printed PDFs of the REDCap survey and ask them to complete and return.

SENSE THEATRE® INTERVENTION PREPARATION

GROUP ASSIGNMENT

- Once randomization into SENSE Theatre® or WLC is complete and participants have been assigned to groups, send letters to participants informing them to which group they have been assigned.
- Send out RedCap survey which collects information regarding Medication (see if there have been any changes), food allergies, behavioral information, t-shirt size (for SENSE Theatre®).
- Add participant and research helper contacts to a designated lab cell phone if applicable

PEERS/COUNSELORS

- **Application:** Interested peers and counselors will complete an application
- **Decisions:** Principal investigator and theatre director will narrow down who is to be interviewed for a peer and counselor position.
- **Background checks:** if required
- **Protection of Minors Training:** Make sure all counselors and peers are compliant with the site's requirements for protections of minors training. Contact site IRB for "Research Involving Minors" for more information pertinent to site requirements.
- **Consent and Video Release Forms:** sent to peers/counselors participating in intervention.
- **Intervention Information:** Send training schedule, location map, and first days schedule (via email), and an email reminder 1 week before training begins.

TRAINING

SPEAKERS

- PI will be responsible for contacting and choosing speakers.
- For SENSE Theatre® peer training, coordinate who will be presenting when, 6 weeks before intervention begins.
  - Research Assistant/Coordinator—"Introduction to Autism"
  - Confidentiality & Code of Conduct, SENSE Theatre® Manual, SENSE Lab & Theatre, Behavioral Strategies.
- Copies of past presentations can be provided to any sites by the SENSE Research Coordinator.

BINDERS

- Binder Materials (SENSE Theatre®):
    - Binder Covers (Color)
    - Binder spine labels (color)
    - Divider Tab Labels
    - Presentations (Black and White)
    - Schedule
    - Music/Lyrics (SENSE Theatre® Intervention only)
    - Name Tags
    - Pre/Post Test
    - SENSE Theatre® Manual (Black and White)
    - Script (Black and White)

The lead site investigator, theatre director, research assistant/coordinator, and nurse(s) (if applicable) should be provided a sheet that details participant contact information, allergies, and medications, along with a picture for identification purposes.

FOOD

- Create catering order 3-5 days in advance
    - A light breakfast, coffee and bagels
    - Lunch based on preference (sandwiches, pizza, salads, etc.)
- Also provide water, snacks

ROOM

- Reserve Room 2-4 weeks in advance.
- Coordinate room reservations with administration. Classrooms with projectors and whiteboard are best, conference rooms if the group is small.

INTERVENTION

Intervention Packets: before Intervention begins the following should be sent to participants 1 month before it begins.

- Letter to Participants
- Schedule with important dates
- First Day Schedule

DAILY TASKS:

- **Daily Schedule:** coordinate with principal investigator and theatre director after each day of intervention program to determine schedule for next session.
- **Daily Email**:
    - After each session, you will give a brief review of the day; give any reminders, updates, etc. Also attach schedule for next session.

- Prepare Snacks/Waters for participants/counselors/peers.
- **SENSE Theatre®:** Bring extra copies of schedule for Dry Erase Board and any participants that need a hard copy.
- Check attendance, call participants who may be running late, etc.

ONLINE VIDEOS

- Peer modeling videos will be on a password-protected website for participants to access at home—send out link after first session.

Zoom Protocol Addition

As part of our ongoing mission to safely conduct clinical research, we plan to further increase social distancing practices during the SENSE Theatre® intervention by incorporating the use of web-based, virtual learning. This will be accomplished through the Zoom platform, an online conferencing application that utilizes webcam (video and audio) technology to interact with participants. The SENSE Lab has upgraded, professional Zoom accounts that are HIPAA-compliant. SENSE Lab personnel log into Zoom using their VUMC organizational email address (@vumc.org). The intervention program will still include 10 in-person sessions, but these in-person sessions will be shorter to compensate for the addition of the Zoom sessions.

The SENSE Theatre® approach already incorporates the use of video modeling, so the addition of the use of Zoom is an extension of this. The interventional design and timeline for the program will remain the same, though some components will be further adapted for a virtual platform. Specifically, while working with typically developing peer mentors to create "character narratives" is a standard aspect of the intervention, this activity will be now be completed during Zoom sessions. Participants and their peer mentors will utilize the function of Zoom that allows for one-on-one collaboration ("break-out rooms") to work on character narratives. Additionally, participants and peer mentors will be encouraged to practice role-playing skills during Zoom sessions.

To ensure the privacy and confidentiality of research participants, entry to each Zoom meeting will be password-protected. The Meeting ID and password will be emailed to each participant in advance. Additionally, before the first Zoom meeting, participants will be reminded of confidentiality rules, to include the following:

- Screenshots of any kind are strictly prohibited during Zoom sessions.
- While participating in Zoom calls, all individuals need to be in a private space and wearing earbuds or headphones so that other people in their home environment cannot see or hear other participants.
- Recording of Zoom calls is strictly prohibited – this function will be turned off by the meeting host prior to each call.
- Confidential information discussed during Zoom calls is not to be shared with anyone outside of the program.

ORDERING

- Snacks
  - Lay's Chips, Gold Fish. Fruit Snacks, Water, Granola Bars
- SENSE Theatre® T-Shirts:
  - Principal investigator and site graphics design will coordinate on t-shirt design and ordering.
- Binders:
  - 1 ½" for peers/counselors

- 1/2” for participants in SENSE Theatre® intervention
- Dividers for peer and participant binders

- White board and markers
- Any Props/Equipment used for the production
    - Past examples include stress balls, Bradfield Lighting, etc.
    - Costumes
- Usually provided by theatre team and participants
    - Theatre director will set up a time for costumes to be coordinated
    - Prepare a document that states:
        - What participant is wearing for costume
        - What items they need to bring from home to complete costume

MAILCHIMP (PERFOMANCE INVITES)

- Vanderbilt will send this out, but create a .CSV file which follows the following format, including contact information for peers, counselors, participants, and any other new SENSE Theatre® staff.

Book1

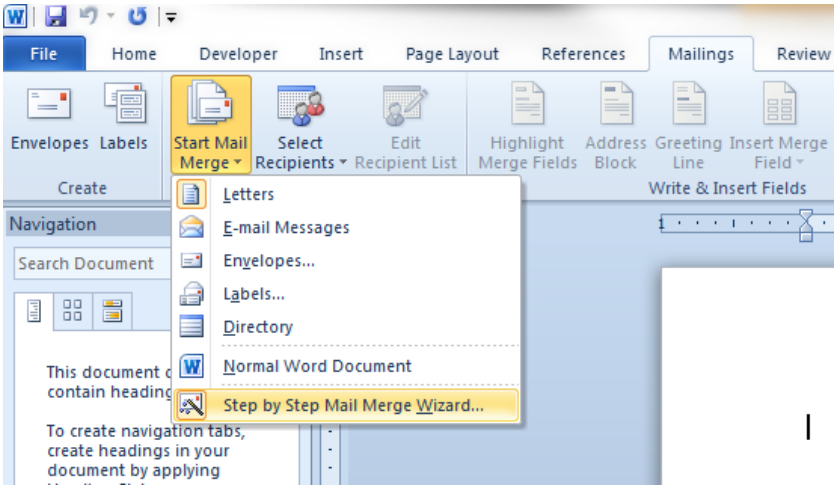
	A	B	C	D	E	F	G
1	Last Name	First Name	Email				
2	Doe	Jane					
3							
4							
5							
6							
7							

PARTICPANT, COUNSELOR, AND PEER CERTIFICATES

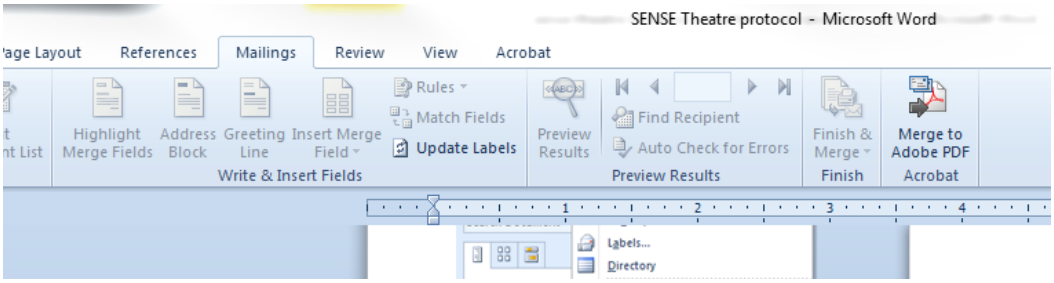
- Use Certificate of Complete and Certificate of Appreciation Template in Word
- You will be responsible for creating a Mail Merge using the template and saving it as a PDF to be printed.

Directions of Mail Merge: Adapted from this website.

1. Go to *Step by Step Mail Merge Wizard*, under the Mailings Tab in Microsoft Word.



2. Choose *Letters*
3. Use the *Current Document*
4. Use an *Existing List* (Have an already created Document with **Fields: Last Name, First Name**)
5. *Preview* your letters
6. Save Document as a PDF or select *Merge to Adobe* PDF in Mailings tab:



7. Send this Document to Graphics Design or printing service to be printed.

POST-INTERVENTION

Mail DVDs

- For individuals who cannot attend DVD screening, mail DVDs after screening to those individuals in padded envelopes.

SHARING CONTACT INFO

- Many families will want to be able to keep in touch after SENSE Theatre® is over.
- Send out an email asking families/peer/counselors if they are interested in having their contact information shared with SENSE participants/staff.
- Then you may create a list of individuals who are okay with having their contact information shared, this can be emailed then, to these families/individuals.

FIRST STEPS (VANDERBILT)

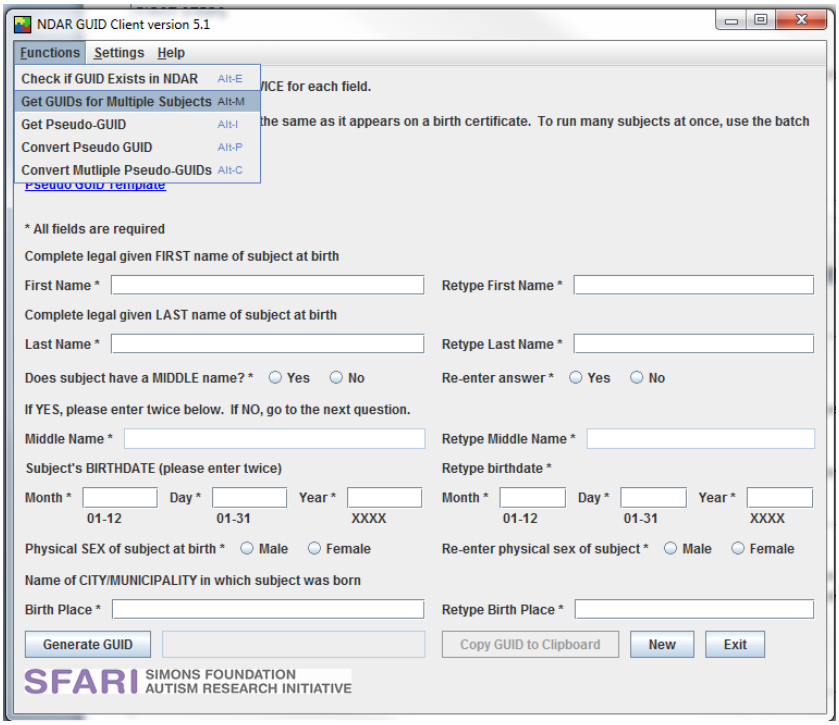
- Create an NDAR login by completing the account request form.
- Request access to the collection by emailing **NDAR help** (NDARhelp@mail.nih.gov) and including the user ID you created.
- Once you have an NDAR account/login and have access to the collection, you will be able to submit data.

NDAR DATA STRUCTURES/TEMPLATES

- Data Templates are used to enter data
- Vanderbilt will upload all data into the templates to submit to NDAR at each submission date

NDAR GUIDS

- In order to submit data to NDAR each participant you're submitting data for must have a GUID (Global Unique Identifier)
- To create a GUID, one must have subject Legal Name at Birth, Date of Birth, Sex, and City/Municipality of Birth.
- GUIDs are created by going to the **GUID Tool** which can be found on the NDAR home page under **resources**. Instead of submitting the forms for each individual separately use "Get GUIDs for Multiple Subjects" under the "Functions" tab.



- Then you will upload your GUID .csv file:

GUID_6_19

	A	B	C	D	E	F	G	H	I	J	K	L
1	ID	FIRSTNAM	MIDDLEN/	LASTNAM	MOB	DOB	YOB	COB	SEX	SUBJECTHASMIDDLENAME	USEEXISTINGGUID	
2	401	John		Doe	1	1	1999	Nashville	M	NO	YES	
3												
4												
5												

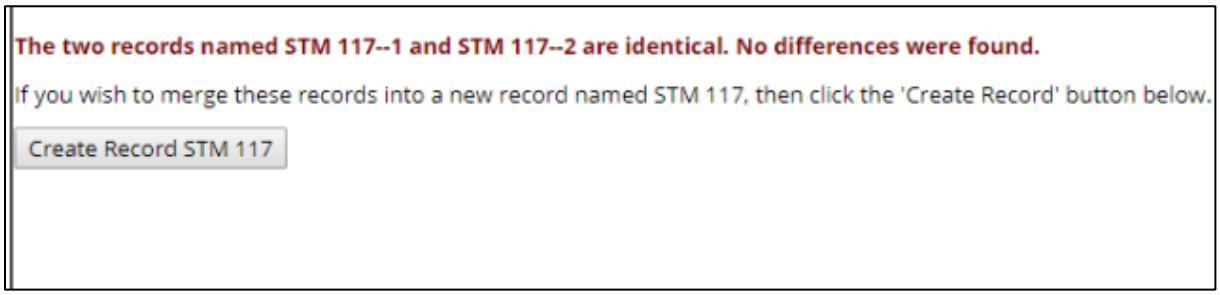
ID=Study ID, so for SENSE Theatre® it would be the numbers after STA.

Middle name is not required for a GUID, if you have subject middle name, then you would enter "YES" under the column "SUBJECTHASMIDDLENAME"

- Upload your excel .csv file, and then create GUIDs. GUIDs will automatically be saved in the folder in which you saved the GUID .CSV file. You can also **copy and paste the output into a spreadsheet.**

PREPARING DATA FOR NDAR

- To ensure the most efficient preparation for NDAR, it is best to be systematically comparing and resolving Data Entry 1 and Data Entry 2 **throughout the data entry process**
- Merging Data
    - After Data Entry 1 and 2 are compared by a reviewer, and all inconsistencies are resolved, the records can be MERGED to create **one** correct record for both future analysis and NDAR submission



NOTE: both Data Entry 1 and Data Entry 2 records are not deleted in the merging process—do **NOT delete these, as they are important backup!

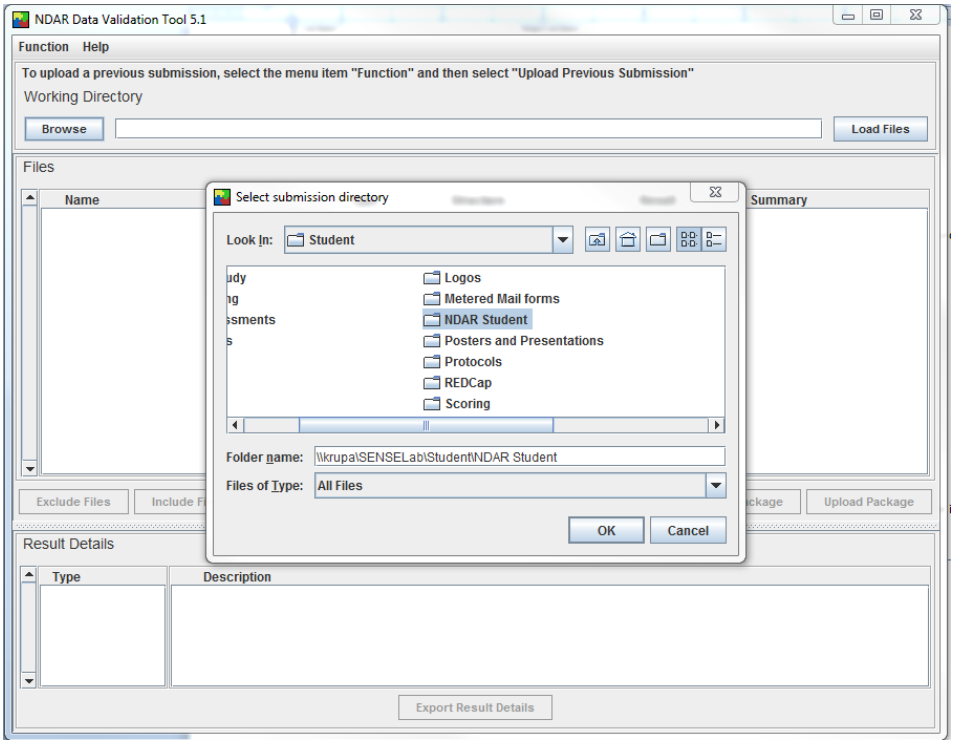
- Merge data when:
    - All 4 visits (pre, mid, post, and follow-up) are completed

AND/OR

    - In preparation for NDAR—depending on time of NDAR submission, we may only submit pre/post or pre visits. If this is the case, begin merging these incomplete records when this decision is finalized (generally 3-4 months before NDAR submission is due)
        - Since the two original records are not deleted, they can thus still be used to enter the mid/post/follow-up visits when they occur, to be merged again for future analysis or NDAR submission
- After data is merged, Vanderbilt will download, harmonize (i.e., match to NDAR's format), validate, and submit data to NDAR!

SUBMITTING DATA TO NDAR: DATA VALIDATION TOOL

- Data validation tool can be found on NDAR homepage under Resources as well.
- Choose data you wish to upload and validate.



- 1: Load files
- 2: Validate files
- 3: Check Errors/Warnings
- 4: Validate again
- 5: Repeat steps 2-4 if needed.
- Build Submission Package once all files are found to be valid.
- Upload Package
- Check NDAR site for submitted data.

NDAR CONTACTS

Name	Email	Phone
NDAR Help**	ndarhelp@mail.nih.gov	301-443-3265
Lisa Gilotty, PhD	gilottyl@mail.nih.gov	301-443-3825

IMPORTANT NOTES ABOUT NDAR

- For every NDAR submission, NDAR expects the submission to be cumulative, so submit everything you have ever submitted to NDAR for that data set each time you submit.
- Also, even if there is nothing new with your data at the submission date, still submit data.

- Sometimes you will notice during Validation, errors arise that seem to be related to the original template or data dictionary→email or call NDAR help with these issue. Sometimes corrections to templates must be made on their end.
- Private vs. Public: Be sure to check the NDAR collection page.
    - Check "Share" dates for collection.
    - Demographic-early release date
    - Dependent measures: released upon publication/completion of grant.

REDCAP

REDCAP FOR SENSE

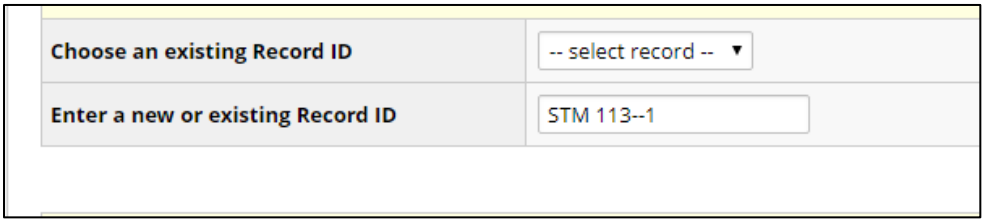
***** REDcap URL: https://redcap.vanderbilt.edu/ *****

SUBJECT ID'S

- ID's will have a 1 or 2 at the end, unlike our assigned subject numbers. This is fine—we will resolve this before final export (see "Dual Entry and Reviewing" below)

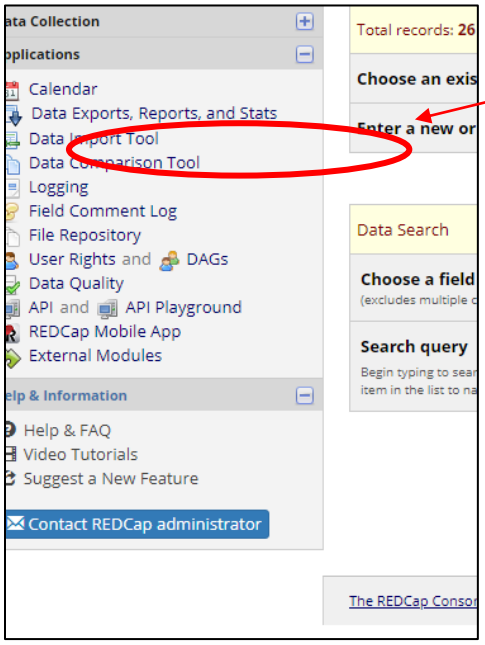
DATA ENTRY ROLES

- Enterer 1=first entry
- Enterer 2: second entry
- Reviewer(s): compare double entry for accuracy and can act as either Enterer 1 or Enterer 2
    - To act as an enterer, add --1 or –2 to the end of the Record ID when entering a new Record ID. This assigns the record to either Enterer 1 or 2, respectively

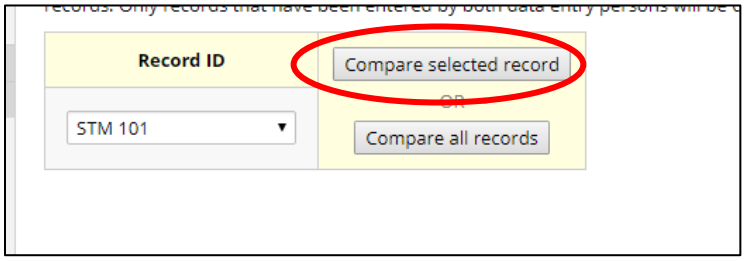


DUEL ENTRY AND REVIEWING

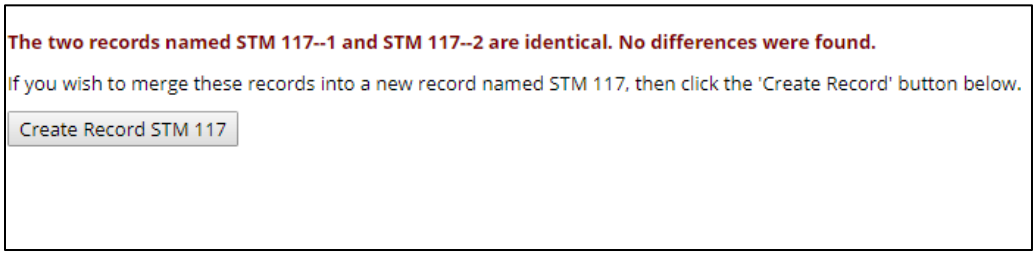
- Once a record is entered twice, a Reviewer can compare and check the records:
- Go to “Applications” (left side of the REDcap screen), and select “Data Comparison Tool”



- Choose the desired Record ID and “Compare selected record.” REDcap will then show a list of all inconsistencies.



- Resolve inconsistencies in the records — select one or the other in the list and edit. As you go through the list, inconsistencies be displayed—even after resolution— until you select “Compare selected record” again (see next step)
- After resolving all inconsistencies, again select “Compare selected record”
- If there are no more inconsistencies, REDcap will give you the option to merge the records, thus creating **one** correct record. This is an easier way to compare than exporting first, and then comparing the spreadsheets.



**However, we are NOT yet actually merging the records. We just resolve the inconsistencies, until after all 4 visits are entered (or until NDAR submission). Then we can merge for the final record more efficiently. **