

PROTOCOL TITLE:

Modifying (Phase I) and Evaluating (Phase II) Virtual Reality Job Interview Training for Youth in Transition

NCT03514134

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*****Phase I data is completing collection at Northwestern University where the PI is adjunct faculty until 07/31/2018.**

*****The UM research team will be responsible for analyzing the Phase I data and executing the Phase II Randomized Controlled Trial.**

1.0 Purpose of the Study:

The prevalence of autism spectrum disorders (ASD) in the U.S. is estimated at 1%¹, with 50,000 youth with ASD turning 18 annually². These youth as well as others with developmental disabilities have a high unemployment rate (50-75%)³⁻⁵ which could be explained by the limited availability of services to support their transition to employment^{6, 7}. Age of transition ranges from 16 years old through the early adult years (e.g., age 21) after high school may have been completed. The high unemployment rate demonstrates a clear need to develop evidence-based services to support transition-age youth with ASD to prepare for employment before they face additional barriers to employment in adulthood⁸. We propose to modify and test the acceptability and effectiveness of an existing virtual reality training program to improve job interview skills for these youth with ASD. Current services for these youth minimally focus on practicing interview skills, which were identified as a potential mechanism to increase the likelihood to obtain work in recent studies of adults with neuropsychiatric disorders^{9, 10}, including adults with ASD¹¹ and by community stakeholders (i.e., individuals with ASD, parents, educators, employers)¹².

The social communication symptoms of ASD and other developmental disabilities make it difficult to socially interact and relate to the experiences of others¹³⁻¹⁵. These symptoms present a major barrier for youth with ASD to develop effective job interview skills, which are critical for obtaining employment^{12, 16-18}. Current interventions for individuals with ASD largely focus on sustaining active employment¹⁹⁻²⁵ and provide minimal job interview training^{3, 6}. Thus, developing a novel intervention to target interview skills among youth with ASD in the safe learning environment of their high school could be a highly effective approach to their vocational outcomes. The successful deployment of such an intervention could help fill a critical gap in services for this population.

A long-term goal of our research program is to increase employment for individuals with ASD and other educational disabilities. Our collaborative team received two NIMH SBIR grants to develop and evaluate “**Virtual Reality Job Interview Training**” (VR), which improved interview skills and vocational outcomes for adults with severe mental illness (SMI)^{9, 26-29}. Although the learning objectives that guide VR were adopted to support adults with SMI, the objectives were not well-aligned with “best practices” for youth with ASD. However, we pilot tested VR in young adults with ASD, which demonstrated efficacy at improving interview skills and vocational outcomes^{11, 28}. Thus, we will build significantly on this work to invite students, parents, employers and vocational teachers to use VR and provide constructive feedback to guide the development of a modified VR (VR-M) system that targets students with educationally-defined disabilities

Phase I: To create VR-M to focus on virtual reality job interview training for transition-age youth with ASD receiving vocational services. We will solicit feedback on the training tool using mixed-method semi-structured feedback forms with high school (HS) youth with ASD (n=20) or other educationally defined disabilities (n=10) as well as employed adults with ASD or other prior educational disability as well as parents, employers, and vocational counselors that support youth with ASD, educational disability, or adjudication (n=30) to systematically evaluate the core components of VR (e.g., interview content, virtual character, VR interface, and didactic content). Qualitative interview data will be analyzed for themes regarding technical content-based limitations of VR. SIMmersion will then integrate the qualitative results to create a tailored learning system.

Phase II: To evaluate the feasibility and preliminary effectiveness of VR-M in a randomized pilot trial comparing vocational-services-as-usual with VR-M added on (VSU+VR-M) to VSU only. Transition-age youth with ASD (n=90) will be enrolled in a 6-month trial to test all study protocol

aspects including VR-M training effectiveness, recruitment procedures, and assessment tools. VR-M will be administered at educational programs supporting rural, suburban, and urban youth to capture greater variation in programming and students. We will monitor VR-M treatment fidelity, acceptability, usability, feasibility, and tolerability.

Phase IIa: To assess whether VR-M is associated with enhanced job interview skills (primary target) and interviewing self-confidence, and reduced interviewing anxiety. Compared to VSU, the VSU+VR-M group will improve interview skills (**Hyp 1**), increase self-confidence (**Hyp 2**), increase motivation (**Hyp 3**) and reduce anxiety (**Hyp 4**).

Phase IIb: To assess whether VR-M is associated with higher employment rates and attaining employment sooner at 6-month follow-up. Compared to VSU, the VSU+VR-M group will: a) have a greater likelihood of attaining employment (**Hyp 5**) and b) attain employment sooner at 6-month follow-up (**Hyp 6**).

Exploratory Aim 1: To develop hypotheses for future trials, we will explore mechanisms for improving interview skills and employment outcomes (mediators) or differential response to VR-M (moderators) as well as conduct a preliminary evaluation of VR-M delivery within a school setting. Mediators will include interview skills (for evaluating outcomes), self-confidence, and anxiety. Moderators will include VR-M performance scores and ASD heterogeneity variables (i.e., ASD-symptoms (e.g., social communication), depressive symptoms, and cognition). We will also explore ASD heterogeneity as a mechanism for differential response to VR-M, and collect exploratory implementation data.

Pilot Implementation Aim: To conduct a preliminary implementation evaluation of delivering the new VR-M to students in educational programming. We will ask teachers (n= 30) to complete Installation Cost Capture forms, Delivery Cost Capture forms, Teacher Context Form and a brief survey regarding their use of evidence based practice and whether they observed any factors that became barriers to delivering VR-M or factors that helped facilitate the delivery and feasibility of VR-M. Teachers may also be asked to participate in an audio recorded semi-structured interview. We will provide up to \$45.00 in gift cards for participation in total.

2.0 Background / Literature Review / Rationale for the study:

The rate of employment among individuals with ASD is 25-50%^{2, 4, 30} and is much lower (6-12%) among recent high school (HS) graduates^{5, 30}. Transition-age youth with ASD and without an intellectual disability (ASD-ID) were more likely to be competitively employed than those with an ID (ASD+ID) (11.8% vs. 4.1%, respectively). However, these rates were similar between these groups when enrolled in SE (11.8 vs. 12.2%, respectively)³⁰. More than 50% of these youth with ASD attempt to pursue work or education immediately after HS^{2, 31, 32}, while others delay their engagement in these activities for two years after HS graduation². In part, the struggle to find a job could be explained by inadequate transition planning during HS, and gaps between vocational needs and available services^{6, 7}. The ASD-ID group has limited access to transition planning and SE services^{3, 8} and a much lower rate for attaining any type of job than the ASD+ID group (who has greater access to services) (18% vs. 86%, respectively)³⁰. Thus, novel interventions are needed to enhance the vocational services for this population^{4, 30}.

Evidence suggests the job interview is a major barrier to employment for individuals with ASD^{33, 34}. Moreover, *Autism Speaks* hosted a roundtable discussion with community stakeholders that concluded interviewing is a barrier to employment for the 500,000 teens and young adults with ASD who will begin looking for work over the next decade¹². Specifically, the social communication deficits that characterize ASD are both verbal (e.g., difficulty with small talk) and nonverbal (e.g., poor eye contact) and interfere with the reciprocity and flow of conversation during an interview³⁵. Moreover, individuals with ASD have deficits in adaptive social skills even in the presence of typical intellectual ability³⁶. These characteristics suggest that youth with ASD may struggle with using and interpreting nonverbal communication, conveying their qualifications for a job, and engaging in small talk during an interview. Adults with ASD from a small study reported that they feel uncomfortable and lack confidence at making a good first impression during a job interview²⁸. As such, these individuals may have difficulty successfully navigating the job interview. The interview process is also a barrier to employment for adults with severe mental illness (SMI)²⁶ whose social deficits converge with those observed in ASD³⁷. A promising new intervention developed by our group suggests that using virtual reality to train interview skills increases the likelihood for both adults with SMI⁹ or ASD¹¹ to obtain work. Although youth with ASD typically access jobs via vocational counselors, family referrals, or community resources, enhancing their interview skills will open up additional opportunities as they pursue competitive employment in the community.

Schools are critical settings in which educational professionals can address the vocational needs of students with ASD who will be transitioning to the workforce. Students with ASD often view their adult educators as reliable, helpful, and supportive³⁹, which helps facilitate learning sustainable behavior^{40, 41}. Also, the school is an important setting to develop novel services as it provides a unique opportunity for researchers to access a large number of students and stakeholders whose involvement will help drive the development of evidence-based interventions. Overall, school-based learning is an ideal mechanism for delivering VR to students with ASD as many of them will need to develop these skills to prepare for their transition into post-secondary school career development.

3.0 Inclusion and exclusion criteria:

Phase II: To evaluate the feasibility and preliminary effectiveness of VR-M in a randomized controlled trial (RCT) comparing vocational-services-as-usual with VR-M added on (VSU+VR-M) to VSU only

All study procedures for students will take place at educational programs where students receive services.

The **inclusion criteria for students** are as follows:

1. 16-26 years old and enrolled in high school or post-high school transition programming;
2. Educational Diagnosis of autism spectrum disorder using the Social Responsivity Scale 2nd Edition²⁸, or a diagnosis of cognitive impairment, emotional disability, educational impairment or other health impairment according to the students Individualized Education Plan (IEP). They may have diagnosis of autism spectrum disorder as indicated in their IEP/school plan, or as indicated by a parent;
3. Fluency in English with at least a 3rd grade reading level (confirmed with the Wide Range Achievement Test);

4. Currently receiving transitional services as specified in IEP or other;
5. Willing to be video-recorded; and
6. Willing and able to provide informed consent.

The exclusion criteria for students are as follows:

1. Has an uncorrected hearing or visual problem that prevents him or her from using the training.
2. Has a medical illness that compromises their cognition (for example, moderate to severe traumatic brain injury)

Inclusion and exclusion criteria is subject to PI discretion. Some students may still be enrolled after discussion with the teacher if it is determined that they still might be able to participate despite matching exclusion criteria, or not meeting all of the inclusion criteria. These cases will be documented in REDCap. We will also report to IRB as ORIO.

The ***inclusion criteria for teachers/educational professionals*** are as follows:

1. 18 years or older;
2. Provides transitional services to students at the participating educational partners: Ann Arbor Academy, Beaumont Hospital, Troy Project Search Program, Southfield Public Schools, and Lincoln Park Avenues Mixer Institute for Transition.

4.0 Procedures Involved:

A. Study Settings

This study will collect human subject data from students in these primary locations: Ann Arbor Academy (1153 Oak Valley Dr., Ann Arbor, MI 48108) Beaumont Hospital, Troy Project Search (44201 Dequindre Rd, Troy, MI 48085), Southfield Public Schools (16299 Mt Vernon St, Southfield, MI 48075), Mixer Institute of Transition (2201 Electric, Lincoln Park, MI 48146), and Autism Model School (3020 Tremainsville Rd, Toledo, OH 43613). Other locations to be identified at a later point. Personal information about schools or districts that participate will not be shared without their expressed consent. Each study site is the location of an educational partner where high school students or transition-age youth with autism or other ED receive vocational services or a community program serving transition age youth with ED. Each location has classrooms where program evaluation will take place. All students will provide written informed consent (if 18-26) or written assent (if 16-17 years old; with parental permission). Students who are 18-26 and whose parents have educational rights will require the parent to sign.

B. Study Design

We will conduct a single-blind randomized controlled trial to evaluate the effectiveness of VR-M by comparing a vocational services-as-usual group to a group actively using the intervention. We will then conduct a 6 month follow up interview with the participants to evaluate their community outcomes.

C. Study Intervention

SIMmersion, LLC designed VR to enhance job interview skills for adults with SMI. The new tool to be used in Phase II was designed for transition-age youth based on feedback from Phase I. The job-related interview learning goals are:

1. Are You someone people want to work with?
 - a. Confident
 - b. Positive
 - c. Professional
 - d. Interested
2. Are You a Good Worker?
 - a. Honest
 - b. Dependable
 - c. Teamwork
3. Are You Good for the Job?
 - a. Strength and skills
 - b. Past experiences
 - c. Overcoming limitations

SIMersion designed VR-M with the following components to help learning:

C.1.a. Electronic Learning (e-learning): Interactive e-learning screens display critical information needed to prepare for a job interview such as creating a resume, researching a position, types of questions to ask, advice on how to disclose a disability, and an emphasis on effective skills for interacting with the interviewer (e.g., dealing with emotionally provocative questions).

C.1.b. VR-M Interface and “Travis/Rita”: After using the e-learning module, trainees will navigate the program to begin the simulated interviews with either Mr. Travis Bishop or Ms. Rita Muniz, virtual human resource staff members at a department store named “Wondersmart”. Travis/Rita start of seated in an office where the trainee has joined them for an interview. When Travis/Rita speaks, the program enters Full Screen mode so that they are speaking directly to the trainee without any distractions on screen. When they finish asking a question, the program returns to the interface where trainees speak a prescript response of their choosing.

There are three difficulty levels: easy (e.g. friendly), medium (e.g. direct), and hard (e.g. stern or asks illegal questions). VR-M uses “memory” and the interviewer behavior is driven by an advanced “emotional model”. For example, if a trainee responses inappropriately to several questions, “Travis/Rita” may become dismissive and end the interview, but if the trainee continually answers appropriately, they may become more friendly and encouraging. Based on the trainee’s statement, the software must then choose a reply for Travis/Rita. Selection is based on three factors: 1) difficulty, 2) the history of the conversation, and 3) Travis/Rita’s evolving relationship with the trainee, driven by trainee responses. Each factor will be used to computer conditional probabilities associated with each possible reply and one is selected. Travis/Rita stay true to his or her character and the emotional state created during the play, and therefore may behave differently each time the system is used.

Buttons at the top of the screen control the interface. The text displays various statements that can be spoken to respond to the interviewer’s questions. The interview transcript can be accessed through a tab in the middle of the screen. The trainee may change the topic during the conversation using buttons to the left of the yellow text. An on-screen coach appears in the bottom right of the interface. The trainees can take notes and review prior questions (white and gray boxes)..

C.1.c. Video Clips: Professional actors/actresses portrayed Rita/Travis during the video-recorded sessions. The videos were separated into >1,000 question and response clips that are played during the simulated interview. Trainees talk with Travis/Rita using a microphone and voice recognition

software. This method exposes trainees to an interactive environment and helps them learn to react to an interviewer's social cues.

C.1.d Pre-scripted Statements and Voice Recognition: A panel of vocational experts supervised hundreds of responses to standard interview questions written by professional scriptwriters during the initial SBIR grant award. The scriptwriters worked with the scientific team to compose realistic dialogue that provides trainees with opportunities to practice the skills identified in the learning objectives. Trainee statements included a wide variety of natural choices with 5-15 potential responses that vary in appropriateness of their content. This method allows trainees to choose and learn from their responses. VR-M uses voice recognition technology so trainees can practice speaking the pre-scripted responses to difficult questions in a stress-free environment. Then, trainees can use the rehearsed answers in real interviews.

C.1.e Non-branching Logic: SIMmersion's PeopleSIM™ technology uses non-branching logic; which allows trainees to behave and speak freely within the confines of a safe simulation. Most social simulations, in contrast, use branching logic where trainees select a response from a list of options, which terminate when all options are exhausted. This approach minimizes repeated use to a few trials. SIMmersion's technology integrates the video clips and non-branching logic to enable Travis/Rita to vary his/her memory, emotion, and personality. This variation supports hours of unique repeated practice and naturalistic conversations with VR-M.

C.1.f Job Coach and Help Buttons: Trainees receive in-the-moment feedback from an on-screen coach named Kendra who provides nonverbal cues regarding the trainee's choice of questions and statements. If further clarification is needed, the trainee can click "help" buttons that provide additional detail to clarify the interview question or the trainee's response statement. For example, the coach gives the trainee a "thumbs down" sign if an inappropriate response is selected. If the trainee is unclear about the negative feedback, he or she can click the help button to get a more detailed written and verbal explanation about why the statement was inappropriate (e.g., "This statement focuses on a negative character trait; try focusing on your strengths").

C.1.g Individualized Customization: Prior to starting VR interviews, trainees complete an online job application, which includes questions about employment history and work skills. Trainees will specify one of fourteen different jobs (auto repair, cashier, child care, clerical, customer service, food service, greeter, inventory, janitorial, maintenance/grounds, security, stock clerk, tech support, web developer). This "on-line" application procedure is based on applications currently in use by employers such as Target and Home Depot. This practice prepares trainees to accurately complete online applications. Additionally, the application data will populate the list of questions from which VR-M will draw. For example, a trainee may apply for a customer service position on the application, yet identify previous experience in inventory; Travis/Rita may ask, "I see from your resume that you have experience in inventory and are applying for a customer service position. Why are you looking to make that change?" This innovative feature allows trainees to customize their interview experiences to better prepare themselves for future interviews.

C.1.h VR Transcripts: During or after the interview, trainees can view a transcript that replays individual exchanges or the entire conversation. If trainees are using the speech recognition feature, the transcript will also replay his or her recorded voice. This feature lets the trainee hear (and reflect upon) the tone of voice used to ask questions and make statements. The transcripts are color coded to reflect helpful, unhelpful, and neutral responses. Participants can click on the response to receive detailed information

about why a response was helpful for hurtful to their job interview and learn how Travis/Rita understood their responses.

C.1.i. Scoring and Summary Feedback: After each virtual interview, trainees receive scores in categories based on the learning goals. The scores are scaled from 0-100 and are computed via an algorithm, which accounts for the types of responses provided by the trainee throughout the course of the interview. Participants view this scoring feedback and if they score 80 or higher they are informed if they got the job or not. Trainees also receive feedback summaries of what they did well and where they need improvement. This feedback helps trainees understand the subtleties of their interview skills.

D. Study Visit Procedures

The research team will evaluate the initial effectiveness of the training by conducting a randomized controlled trial (RCT) at Ann Arbor Academy and Troy Beaumont Hospital Project Search.

For Phase II, school vocational teachers will review school records to screen which of their students meet eligibility criteria in terms of age, diagnosis, and reading level. Teachers will keep this list internally and will not share with the study team. Once students are identified, the teachers will send a prepared email to the parents of the study with a copy of the consent form, and invite them sign the form and return it to study team via email or fax if they wish to participate and allow their child to participate. If a family does not have access to email/fax, the parents can return the signed copy of the permission form to the student's teacher at school. They will also be provided contact information to the study team so they can ask them any questions. This is not a recruitment email and the teachers will be acting in their paid capacity as a teacher and not a researcher. All parents have given consent to be emailed or called by the teacher for matters related to events at the school. They may also be invited to attend an information meeting hosted by the PI and/or study team. During the informational meeting, the research team will provide a power point presentation to educate parents about the interview training and the study. After the meeting, parents will be invited to take home a parental permission form. They will be asked to sign and return this form to the research team via a scanned copy through email or fax. If a family does not have access to email/fax, the parents can return the signed copy of the permission form to the student's teacher at school. The teacher will place this form in a folder (kept in a locked cabinet in a locked office) and will give the hard copy to the research team. We will emphasize that we want parent permission forms returned and not student consent/assents, as those will be obtained during the study visit.

The PI and or study team will be available to answer any questions the parents may have while reviewing the permission form. After the parents return the form, students under 18 years of age will be approached at school during Study Visit 1 to provide assent. Parents and students will be informed that choosing not to participate will not affect their or the student's relationship with the school or teachers. For students 18 years or older, the research team will send an informational letter home informing the parents of the study and then the research team will approach the students 18-26 years old in order to obtain written informed consent.

Also, teachers from all schools/programs will be recruited to participate in this study as part of an initial implementation. The teachers will be recruited beforehand during a phone call, or through the same educational meeting hosted at the school to inform parents and recruit students.

D.1. Pre-Study Visit:

Parents and teachers will be asked to complete surveys prior to Study Visit 1. Surveys will be administered electronically, or by pen and paper. Completers will receive \$15 (parents and/or teachers).

Parents will be asked to complete:

1. Student Background Form and Contact Info Form (age, gender, race, ethnicity, etc.)
2. Behavior Checklist (ABCL or CBCL) (Achenbrock & Edelbrock, 2001). These surveys assess behavioral problems and social competencies as reported by parents and/or teachers. They are standardized in the field and have a long history of validity and reliability. If parents do not complete this form, then we will ask the teachers to do so (ABCL/CBCL/TRF).
3. Social Responsiveness Scale 2nd Edition (SRS-2) (Constantine & Gruber, 2005), which is a teacher/parent based rating scale that measures the severity of autism spectrum symptoms

Teachers will be asked to complete:

1. Teacher Demographic Form
2. Social Responsiveness Scale 2nd Edition (SRS-2) (Constantine & Gruber, 2005), which is a teacher/parent based rating scale that measures the severity of autism spectrum symptoms
3. Behavior Checklist (ABCL/CBCL/TRF) if parents do not complete the form
4. Student Background Form and Contact Info if parents do not complete the form

D.2. Study Visit 1 & 2:

These visits should last approximately 60 minutes each. Students will receive a \$25 gift card for each visit. The consent and reading test will always be first, but the following activities may be done in a different order depending on the student availability. We aim to work best within the school and their availability. Study staff will complete the following tasks with student:

- Assent/Consent
- Reading Level: Wide Range Achievement Test (4th Edition) to assess current reading level. (If students do not pass a 3rd grade reading level, participation will end and they will be compensated \$10).
- Cognitive Assessments on an iPad using the National Institute of Health Tool Box Application
- Baseline Employment Survey
- Mood Survey
- Job practice interview Role-Play (audio and video recorded)
- Self-Report Surveys about:
 - a. Anxiety
 - b. Motivation
 - c. Self-confidence

D.4. Randomization:

Students will be randomized into the VR-M group or the control group. This will be done at a ratio of 2:1 (VR-M:control). Family and teachers will be informed by research team if student is active in the Intervention group or the Control group. The Control group will continue their educational services as usual and skip “visits” 3-16. They will return for the last in person Study Visit 17. Block randomization

tables will be created prior to the study based on computer generated blocks of four. Blocks of four will ensure nearly equal groups. Envelopes or paper containing the randomization by sequential subject entry number will be created and stored, and then opened when a participant has completed pre-randomization procedures.

D.5. Study Visit 3:

Students randomized to the VR-M group will receive a 45-60 minute orientation to use the Virtual Interview Training program.

D.6. Study Visit 4:

Students will train with the educational content. Study staff will be on site to help troubleshoot and answer questions if needed.

D.7. Study Visit 5:

Students will use one class period for orientation to learn to navigate and participant in the virtual interview.

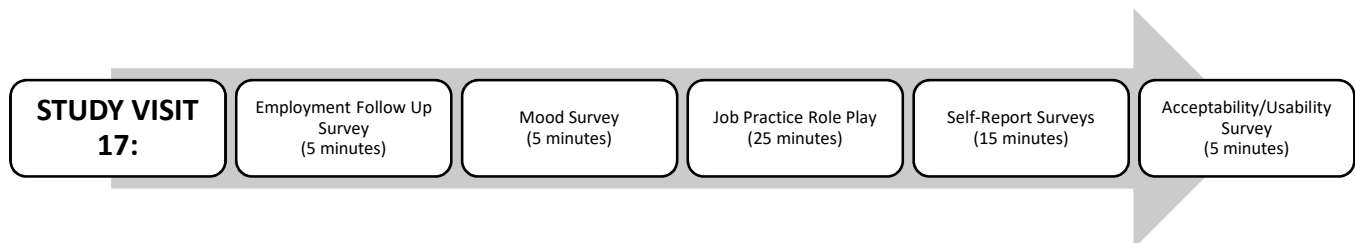
D.8. Study Visit 6-16:

Students will complete up to 3 virtual job interviews per class period. Teachers will help implement this in their classrooms and may decide to utilize homework for the students where they are assigned to use the tool at home as well as in the school.

D.9. Study Visit 17:

This visit should last approximately 60 minutes. Students will receive a \$25 gift card for this visit. If the student does not complete this study visit on the scheduled dates, the study team will continue to follow up with the student via phone or email five to six times during the follow up phase. If the student has not responded after three months, the study team will consider the student lost to follow up. If it is more convenient for the student, the study team will make arrangements to complete the study visit at the University of Michigan School of Social Work. Study staff will complete the following tasks with student:

1. Employment Follow Up Survey
2. Mood Survey
3. Job practice interview Role-Play (audio and video recorded)
4. Self-Report Surveys about:
 - a. Anxiety
 - b. Motivation
 - c. Self-confidence
5. Acceptability/Usability of VR-M



D.10. 6 Month Follow Up:

All students will complete a follow-up survey by phone or over email. We will send a letter reminding them of their 6-month follow up and asking them to give us a call. In this letter it will specify that the survey can be completed by students, parents, or students and parents together. We will also follow up with them by phone or email after the letter is sent by using an IRB approved script. This script will be similar to the IRB approved letter. Survey will include follow up questions about their employment. Students will receive \$10 gift cards for this survey.

D11. 9 Month Follow Up: (For COVID-impacted Autism Model School students only)

Students and/or parents of students who participated from Autism Model School will be asked to complete a 9 month follow up survey by phone or email. The call will be optional and students/parents are allowed to opt out if they choose. We will read a consent/assent addendum script at the 9-month follow up call. We are adding the 9 month follow up to account for COVID-related issues in finding employment during the pandemic.

E. Study Procedures for Phase II Pilot Implementation Evaluation and Teacher Involvement

Approximately n=30 teachers will be involved in the delivery of VR-M and will be asked to complete a series of online surveys about VR-M including: Installation, Delivery, and Implementation and Feasibility regarding the potential barriers, and costs of delivery of the intervention to their students. These surveys will require approximately 30 minutes to complete electronically and include:

1. Installation (5 minutes)
2. Delivery (5 minutes)
3. Adaptation (5 minutes)
4. Cost Capture (5 minutes)
5. Implementation (10 minutes)

Teachers will receive a \$25 gift card at the end of the study with the completion of these surveys.

Teachers may also be asked to participate in an audio recorded semi-structured interview at the end of Implementation and will be compensated \$20 gift card if they participate.

Teacher involvement throughout the study will include reviewing records so they may inform families with students 16 years and older (via email or phone) that the school is partnering with the University of Michigan to evaluate the job interview tool. The teachers will share the research team's contact information with the families so they may contact the research team directly if they are interested in participating in the study. Teachers may also complete surveys on students who have consented or assented to participate. Parents will be asked to complete the following surveys first, and the teachers will serve as a backup to complete teacher-report versions if the parents do not participate. These surveys may include, for example, the ABCL/CBCL/TRF surveys, and the SRS survey, which are surveys that contain questions on student demographic information as well as behavioral information. They may also be asked to complete the Student Background survey if parents do not complete them. If teachers are unsure or do not know the answers to some of the questions regarding a student's background, they will leave that question blank and will allow research staff to follow up with the students if needed.

Also, the University of Michigan research team will train teachers how to teach students to use the job interview tool to the students who are randomly assigned to receive the virtual interview training. As transition teachers, the teachers are already providing vocational training to the students and so this type of training fits within the normal scope of their teaching efforts. The teachers are showing students

how to log into the website, then the teachers do a demonstration of how students can use the tool via point and click within the interface. Then the teacher does a brief interview with the virtual hiring manager so that the students can see/learn how to interact with the virtual character (pointing and clicking as well as speaking to the virtual hiring manager). Then the students are expected to use the tool on their own in an independent fashion. That is the extent that we are training teachers to 'teach' the tool. Where the naturalistic setting comes into play is that part of our study is an implementation evaluation....beyond what we are training teachers to do.....what happens during the natural course of delivery in the school setting. How do the students respond to the tool? Do the students find it usable and acceptable? Does the delivery go as planned or do teachers need to adapt the strategy for delivery? For example, we recommend students engage with the tool for 3 hours per week; however, some programs may only have 2 hours per week to give....or teachers planned to deliver the tool within the school's computer lab but perhaps that didn't work as well as they thought and they are now delivering the tool with chromebooks in the classroom. Any questions about technology-related glitches and such are covered by the research team who are onsite.

F. Participant Timelines

Phase II: Students enrolled in the Phase II randomized controlled trial will complete study visits 1 -16 within approximately 5 weeks of enrolling in the study. Their participation will be complete after completing the 6 month follow-up. Educational professionals and leadership enrolled in the Phase II pilot implementation will complete surveys for pilot implementation related to installation costs; delivery costs; delivery feasibility; barriers and facilitators to delivery; and a semi-structured interview around potential adaptations to delivery.

G. Site Specific Regulations

Ann Arbor Academy, Beaumont Hospital Troy Project Search, Southfield Public Schools, Lincoln Park Avenues Mixer Institute of Transition, and Autism Model School will not have any local scientific or ethical review structure that is required to approve the study and will use the University of Michigan's IRB as the IRB of record.

H. Vulnerable Population Safeguards

Minors will participate in this study. A legal guardian will be required to provide parental consent and if the child participates in the study, they will be assented using the most appropriate form for their language and cognitive level. Pregnant women will not be excluded from the study. Their participation will not differ from participants who are not pregnant.

5.0 Multiple Sites:

This is a multi-site project funded by the National Institute of Mental Health and discretionary funding where the Principal Investigator is Dr. Matthew Smith located at the University of Michigan. He has previously worked directly with teachers at each site where the teachers provided information to families and then directed them to Dr. Smith so that he can facilitate the recruitment of students and families into the study to complete the feedback forms, and train local school staff at each study site to administer the intervention.

- A. University of Michigan School of Social Work is the coordinating site where all data will be entered, cleaned, stored, and analyzed

- B. Ann Arbor Academy is research site #1. Ann Arbor Academy has students from grade 4-12 with a variety of learning issues including students with autism spectrum disorder as well as other educational/ learning impairments. Their college prep program prepares students for higher education and the workplace. At this site, we will recruit research participants (both minors and adults) to participate in this research study. Although data will be collected at this site, research staff will transfer the collected data in a locked box to the UM research site for processing.
- C. Troy Beaumont Project Search is research site #2. Troy Beaumont Project Search is a business-led program for post high school age students with intellectual and developmental impairments between the ages of 18 and 26. The program is conducted entirely at the workplace where students receive instruction and training in a workplace setting. Although data will be collected at this site, research staff will transfer the collected data in a locked box to the UM research site for processing.
- D. Southfield Public School is research site #4. Data collection will primarily take place at the Kennedy Learning Center. Their goal is to provide their student population with a supportive and caring environment as well as to teach them skills to achieve their best potential. They work with a variety of students with disabilities. Although data will be collected at this site, research staff will transfer the collected data in a locked box to the UM research site for processing.
- E. Lincoln Park Avenues Mixter Institute of Transition is research site #5. Data collection will primarily take place at Mixter Institute of Transition. Their goal is to help students with autism improve their abilities to learn, function independently, and socialize so that they may realize their full potential to pursue post-secondary education goals such as joining the workforce and/or participating in their communities. Although data will be collected at this site, research staff will transfer the collected data in a locked box to the UM research site for processing.
- F. Autism Model School is research site #6. Data collection will primarily take place at Autism Model School. The school is a nonprofit community school that serves over 100 students ages 5 to 22 years old with the goal to provide a nurturing environment and assist with developing the full potential of differently-abled students who have Autism Spectrum Disorder.
- G. When new research sites become available, the IRB will be notified and appropriate IRB documentation will be submitted.
- H. The school will disseminate an approval letter for the research team to conduct the study once the UM IRB has approved the protocols for the study and submitted the approval letter and a copy of the study protocol to each school for their records.
- I. The research coordinator will provide the PI with an electronic copy of the approved protocol and consent forms. The PI and research coordinator will be responsible to provide the Principals and lead educational staff/teachers at each study site with an updated version of the protocol and consent forms as well as a summary of changes that change the study procedures or change the potential risk of study participation (and any other related documentation) after receiving the IRB approval letter from the research coordinator.

- J. There are no local site investigators for this study. Based on the preliminary nature of this investigation, UM research personnel will supervise teachers facilitating the program evaluation completed by the students. UM research personnel will train on-site teachers to orient students on how to navigate the intervention as it is web-based.

6.0 Incomplete Disclosure or Deception:

This study will not be using deception.

7.0 Recruitment:

Phase I data collection is being completed at Northwestern University and will be sent to UM for analysis. Thus, there will be no Phase I data collection.

For Phase II, school vocational teachers will review school records to screen which of their students meet eligibility criteria in terms of age, diagnosis, and reading level. Teachers will keep this list internally and will not share with the study team. Once students are identified, the teachers will send a prepared email to the parents of the study with a copy of the consent form, and invite them sign the form and return it to study team via email or fax if they wish to participate and allow their child to participate. If a family does not have access to email/fax, the parents can return the signed copy of the permission form to the student's teacher at school. They will also be provided contact information to the study team so they can ask them any questions. This is not a recruitment email and the teachers will be acting in their paid capacity as a teacher and not a researcher. All parents have given consent to be emailed or called by the teacher for matters related to events at the school. They may also be invited to attend an information meeting hosted by the PI and/or study team. During the informational meeting, the research team will provide a power point presentation to educate parents about the interview training and the study. After the meeting, parents will be invited to take home a parental permission form. They will be asked to sign and return this form to the research team via a scanned copy through email or fax. If a family does not have access to email/fax, the parents can return the signed copy of the permission form to the student's teacher at school. The teacher will place this form in a folder (kept in a locked cabinet in a locked office) and will give the hard copy to the research team. We will emphasize that we want parent permission forms returned and not student consent/assents, as those will be obtained during the study visit.

The PI and or study team will be available to answer any questions the parents may have while reviewing the permission form. After the parents return the form, students under 18 years of age will be approached at school during Study Visit 1 to provide assent. Parents and students will be informed that choosing not to participate will not affect their or the student's relationship with the school or teachers. For students 18 years or older, the research team will send an informational letter home informing the parents of the study and then the research team will approach the students 18-26 years old in order to obtain written informed consent.

Also, teachers from all schools/programs will be recruited to participate in this study as part of an initial implementation. The teachers will be recruited beforehand during a phone call, or through the same educational meeting hosted at the school to inform parents and recruit students.

8.0 Consent Process:

- A. Consent/Assent Procedures: Parents will receive an email from teachers with information about the study and a copy of the parent consent form, along with contact information for study team staff. They are allowed to sign and email the consent form back to the study team and give permission for their child to participate. They may also return the signed form to the school, where study staff will pick it up. Alternatively, the research team will provide a permission form to all parents who attend an informational meeting, and provide a consent form to the teachers to hand out to any parents that may have been missing. These forms can be reviewed at home, signed, and returned to the PI via email or as a hard copy.

After receiving permission from parents, the research team will obtain written assent/consent form students. This will be done during Study Visit 1. The teacher will escort the student to the private study visit room for the research staff to complete the assent/consent procedures. These procedures will take place in a private office or room to maintain student privacy and confidentiality. Students will then have an opportunity to review the form with the research staff prior to signing their consent/assent.

- B. Consent Team: The consent process will be conducted by the study team staff who have up to date PEERS training for the protection of human subject research.
- C. Consent Timeline: The assent/consent process will require approximately 10 minutes to read and up to 5-10 minutes to discuss to make sure that the participants fully understand the extent of their involvement in the study.
- D. Consent Process: Informed consent will be obtained in full accordance with the University of Michigan IRB guidelines.
- E. Re-consenting: Re-consenting will occur only if the study protocol involves changes in the data collection process, if there is a change in risk level for participation, or other changes the participant should be aware of.

It is necessary that one parent or legal guardian give permission for the participation of a minor that is under his/her care. Written assent will be obtained from all participating minors under 18 years of age. Adult students will provide informed consent while meeting with the research team in a private room onsite at the school. All participants will be given the opportunity to ask questions regarding the study and their consent/assent prior to providing consent/assent. Participants will be informed of their right to withdraw from the research at any time without consequence. Informed consent is then documented as “obtained” in the study’s database. Adults have an option to email or provide a hard copy of the signed consent over to the research team.

It is possible that students will turn 18 during the research. We will request a waiver of informed consent as these students provided their assent to participate based upon the same information that was provided in the adult consent form. There would be no change in protocol or in the follow up survey due to their change in age, and the consent form is the same as the assent form.

9.0 Risks to Participants:

This study involves students completing a battery of clinical, cognitive, and role-play assessments.

There is no risk associated with participation in this study for students (both minor and adult) beyond potential boredom from navigating and using the computer program. All students will complete the studying within their high school setting.

Teacher participants face even fewer risks as they will provide their feedback in the context of an internet-based survey.

Confidentiality and safety procedures will be in full compliance with the Institutional Review Board of University of Michigan.

When obtaining consent, participants are notified that they may stop participating at any time without repercussion. If consent is revoked in writing, the consent specifies the right to use or share information previously obtained as needed for the purpose of the study.

10.0 Potential Benefits to Participants:

Participants completing the intervention could possibly learn some new strategies to be more successful at Job Interviewing.

Results from this study may lead to a better understanding of helping improve job interview skills for youth with disabilities. It is therefore possible that results of this study may aid in intervention strategies for youth with disabilities.

11.0 Financial Compensation:

Students will be paid up to \$85 in gift cards for completion of assessments, self-report measures, role-play interviews, and a 6-month follow up. Parents can receive \$15 in gift cards for completion of surveys. Teachers can receive up to \$45, with an optional \$15 if parents do not complete pre-visit surveys.

A. Students:

- | | |
|---|----------------|
| a. Study Visit 1: | \$25 gift card |
| b. If ineligible after WRAT (Study Visit 1) | \$10 gift card |
| c. Study Visit 2: | \$25 gift card |
| d. Study Visit 17: | \$25 gift card |
| e. 6 Month Follow Up: | \$10 gift card |

B. Parents:

- | | |
|---------------------------------------|----------------|
| a. If they complete pre-visit surveys | \$15 gift card |
|---------------------------------------|----------------|

C. Teachers:

- | | |
|---|----------------|
| a. If parents do not complete pre-visit surveys | \$15 gift card |
|---|----------------|

- | | |
|--|----------------|
| b. Teacher implementation/evaluation surveys | \$25 gift card |
| c. Semi-structured Interview | \$20 gift card |

12.0 Provisions to Protect the Privacy Interests of Participants:

To minimize stress and fatigue during testing, participants will be assessed in an encouraging and accepting atmosphere. They can take breaks during the assessment process and may discontinue the assessment if they do not wish to continue. The research team have been trained in the administration of the research measures and have undergone training procedures to help minimize the stress this may cause.

The research assessments and intervention use will be conducted in a private or semi-private computer lab or educational room setting for the students. For teachers, the feedback form will be conducted in a setting of the participant's choosing. All methods of correspondence will be secure, including telephone, voicemails, text messages, or email. Participants will provide informed consent with respect to their preferred method of communication. In addition, we will use a personal identification number (PIN) to protect participant privacy by labeling all study documents with the PIN rather than any identifying information. The use of the PIN will help keep participant enrollment confidential.

Access to protected information will be limited to the PI and research team members. There will be a document located on the UM servers (password protected behind firewalls) that links PINs to study participant names. The PI and research team will have access to this file in order to coordinate study visits and track participant progress to complete the study. REDCap, a HIPAA compliant and encrypted database may also be used to host protected participant information.

While testing participants at the schools, we will record data on either secure electronic equipment (i.e., laptop or tablet) or paper forms. The information linking the identifiable information with the testing forms will never be stored on the portable equipment. Data will be uploaded to the server and removed from the device as soon as possible. All precautions will be taken to protect the electronic devices from theft or loss. If a device is lost, this will not pose any risk to the participant since no data can be linked to their identifiable information.

All forms and materials will be kept in a locked file in a locked room accessible only to research personnel. Confidentiality procedures will be in full compliance with the Institutional Review Board of University of Michigan. Any confidential data obtained at the study site will be transferred back to the School of Social Work via a lock box to be secured into a locked file and in a locked room.

13.0 Confidentiality and Data Management:

Description of Security measure to Protect Data Sources: If REDCap is not being used, paper research records will be created at the schools and labeled with the PIN, where participants may provide consent

and complete study measures. All study data will be stored in a locked cabinet within a locked office at the school. These records will serve as the source for electronic data entry. Once per week, the research records will be transferred via a locked box to the UM research team where the data will be cleaned, re-entered into the electronic database, and stored in a locked drawer in a locked room. All records will be de-identified after study completion. All paper research data will be stored on password protected servers for a period of 7 years.

All participant documents at UM will be labeled with the participant's PIN. Each page of each document will be labeled with the PIN. Documents will be organized into a study binder that is also labeled with the participant PIN. All Binders and Study Documents will be stored in locked file drawers within a locked room.

Quality Assurance Measures: All participants will be recruited using strategies, documents, and text approved by the University of Michigan Institutional Review Board (IRB). The research team will regularly hold meetings to discuss the effectiveness of approved recruitment strategies and if new strategies should be reviewed by the IRB and then implemented. The study coordinator will screen participants for eligibility using formal study forms. The PI will regularly audit accrual to ensure that participants meet eligibility criteria and that the study enrollment is consistent with the projected enrollment targets agreed upon with NIMH. In addition, the study coordinator will audit all study files to ensure that all required study data is completed on each form, and that there is no missing data. Data will be double entered on electronic REDCap data entry forms to maintain the validity and integrity of the collected data. The REDCap system is accessible via a virtual private network that is password protected and behind firewalls. The data will be transported from the schools to UM in a locked storage box. To protect confidentiality, all data will be numerically coded using a personal identification number (PIN), and information linking the PIN to the subject's name will be kept in a secured file cabinet and office. All video files will be encrypted prior to being stored electronically. In addition, computer data files will be stored on password-protected computers and communication among the staff will use PINs, not names. No information concerning data will be presented with participant names. The biostatistician and project coordinator will also perform all necessary checks and controls to ensure the reliability and validity of the data, including monitoring data collection and collection procedures, data storage, data management, and data analysis.

Data Sharing: This study involves modifying an intervention to help adolescents with autism spectrum disorder. We will share de-identified data with a neuropsychologist in order to have reports written up and provided to participants and/or participant parents. This is stated in the consent form, and participants have the option to share the information with educational staff or to not share with educational staff. If younger than 18, both parent and student must agree to share data in order for it to be shared; if one person says no, then the reports will not be shared with educational staff or schools. Also, a data sharing plan is currently in place with NIH to provide all clinical data collected in our autism-related research to the National Database for Autism Research (NDAR). This includes submission of de-identified descriptive data from the samples proposed for collection on a semi-annual basis (January 15th and July 15th) and submission of all other experimental data upon completion of the three year award period. The goal of this data sharing policy is to facilitate autism spectrum disorder research by giving the autism research community access to publicly made data. Existing mechanisms and protocols for data submission already established by NDAR will be employed in the dissemination of our data, to include a computerized database with de-identified data, and strict quality control, described as follows:

- A. Computerized database – With assistance from the study's biostatistician, we will develop an enrollment strategy to obtain the information necessary to generate a Global Unique Identifier (GUID) for each participant and an electronic database in REDCap to manage this information

and all data derived from this project. The data entered on each subject will include results from diagnostic evaluations for autism on all subjects (using SRS-2), neuropsychological data from the NIH Toolbox, role-play scores, 6-month employment data, and vocational training data. All data in this project will be verified and provided for release in .csv (comma separated values) submission files to NDAR.

- B. Quality control - We currently have in place a variety of measures to ensure and check the quality of clinical data. All interviewers participate in a formal training course and all clinical data are verified through evaluations by an editor and diagnostician. Data collectors also receive extensive training in the administration of all measures and assessments.
- C. Human Subjects Issues - We will use consent language that will clearly stipulate: (1) disclosure that clinical research data will be deposited to this NIH autism database; (2) assurance that such data will be provided without personal identifiers; (3) disclosure that analyses of these data will be conducted by other scientists not included within the current research team; and (4) disclosure that there is no plan to provide subjects with any financial benefits from commercial products derived from the data. All consent materials will be in full accordance with IRBs of participating institutions.

14.0 Data Analysis:

Phase I Data Analysis. The qualitative interview data will be analyzed inductively and iteratively using thematic analysis and the constant comparative approach^{43, 44} to identify emergent themes regarding potential modifications to VR. The research team will analyze a subset of transcripts from the qualitative data to iteratively develop codes until a final codebook is agreed upon by the team and intercoder reliability is achieved; codes will then be applied to transcripts^{45, 46}.

Phase II Data Analysis. For Phase II, between-group differences in the characteristics of the VSU+VR-M and VSU groups will be examined using Chi-Square analysis (categorical variables) or an analysis of variance (ANOVA) (scaled variables). Variables with significant between-group differences will be examined as covariates in all subsequent analyses. Measures of dispersion (mean, standard deviation, variance, range) and distribution (kurtosis, skewness) will be computed. Scatterplots will be generated to review bivariate relationships.

Phase II emphasizes the evaluation of VR-M training on interviewing skills and attaining employment. We recognize that the heterogeneity of ASD may affect these outcomes. We will assess the effect of VR-M on changes in job interview skills, self-confidence, motivation, and anxiety between pretest and posttest. We will determine the likelihood of attaining a job for the two conditions by 6 months, a “real-world” outcome and the issue of greatest concern. The mean number of interviews per week and time-to-employment for the two groups at 6-month follow-up will be examined. Additional analyses will evaluate the mechanisms of VR-M that lead to improved interview performance and positive employment outcomes via mediators (improved self-confidence, improved motivation, reduced anxiety) and moderators (e.g., ASD-related symptoms, depressive symptoms, and neurocognitive function) that might affect responsiveness to VR-M. This data will inform our understanding of how interventions like VR-M affect outcomes. We will use repeated-measures ANCOVAs with ASD-related symptoms, depressive symptoms, neurocognitive function, and social cognitive function (now listed as heterogeneity variables) as covariates. We will also use ANCOVA to evaluate the change over time, with posttest scores as the dependent variables while covarying for pretest variables. Cohen’s d effect sizes will characterize the observed differences. We will use a log-rank test comparing time-to-position

in the two groups to determine a hazard ratio to test if time-to-position differs between groups. The effects of covariates, including blocking factors, on time to employment will be assessed using Cox proportional hazards regression⁴⁷.

Exploratory Data

We will explore potential mechanisms for VR-M effectiveness (i.e., improved interview skills, attain a job), by first analyzing mediators (i.e., interview skills, self-confidence, and anxiety) and moderators (e.g., ASD heterogeneity variables) using boot strapping (for mediators)⁴⁸ and linear regression (for moderators)⁴⁹. Second, we will explore potential mechanisms for a lack of improvement in interview skills and failure to attain a job) by examining group differences and associations with ASD heterogeneity between groups who did or did not have poor outcomes. Third, we will collect exploratory implementation data by interviewing vocational counselors and school administrators (n=10) about: 1) potential barriers and facilitators for VR-M implementation and scalability; and 2) how VR-M might reduce staff time required to deliver services. We will analyze this exploratory implementation data iteratively using thematic analysis and the constant comparative approach^{43, 44} to identify emergent themes regarding the barriers and facilitators of implementing VR-M.

14.0 Data Monitoring Plan to Ensure the Safety of Participants:

This is a clinical trial and will have a data safety and monitoring plan. It will be strictly monitored by the PI who regularly reviews testing and data management procedures to ensure protection of human subjects. We follow IRB guidelines to minimize risk and report problems. We plan to establish a Data Safety and Monitoring Board to meet annually during the active phase of the RCT. The DSMB will review the research protocol and plans for data safety and monitoring, adverse events, risk management policies, and preliminary data analysis. We plan to invite University of Michigan faculty members: Joseph Himle, Addie Weaver, University of Wisconsin: Lauren Bishop-Fitzpatrick, and community partner: Joselyn Reese. We are required by our funding agency to report results annually.

All data reported is de-identified prior to entry and analysis. We initiate protocol revisions with the IRB when necessary. All electronic data is stored on a secure server managed by University of Michigan School of Social Work, and access to the server requires a password and netID, and is fire walled, requiring VPN connection if off campus (per IT security protocols). REDCap will be another storage site. An additional password is needed to access identifiable data stored on this secure server and on REDCap. Further, all data collected in the field is stored on encrypted drives and also identified only by ID number. All paper data is stored in locked filing cabinets in our lab at UM. Data analysis is completed by approved project personnel.

15.0 Qualifications to Conduct Research and Resources Available:

Overview and anticipated contribution to success of the proposed work: The University of Michigan (UM) is one of the most resource intensive universities in the world, with state-of-the-art computing, statistical, library, and research consultation resources readily available to faculty researchers. The facilities and resources necessary for the proposed work are all currently available to Dr. Smith and his team. Below, the key units and facilities are described in detail to provide information about the specific contribution of each.

University of Michigan

Office: The facilities and resources necessary for the proposed work are all currently available to Dr. Smith and his team. Dr. Smith and the study staff have offices at the School of Social Work. The study staff and Dr. Smith have meeting and office space within the Curtis Research Center where Dr. Smith is the contributing faculty.

Computer: The P.I. and the research staff have computer resources for data analysis and word processing for manuscript preparation.

Scientific Environment:

- A. School of Social Work: The UM is a leader in social work education and research and is ranked first in the *U.S. News and World Report* rankings of social work programs. The interdisciplinary *Joint Doctoral Program in Social Work and Social Science* stands alone in the nation. This distinctive program trains academics, researchers, and practitioners to meet the challenges of society by utilizing theories and research from anthropology, economics, political science, psychology and sociology. There are approximately 600 MSW and approximately 75 Ph.D. students enrolled each term in the School of Social Work programs. For this project, Dr. Smith will regularly involve graduate students as work-study research assistants and they will facilitate data cleaning and double data entry in addition to other project supports.
- B. The Vivian A. and James L. Curtis Research and Training Center: Through the generous contribution of the Curtis family, *The Vivian A. and James L. Curtis Research and Training Center* is funded to foster interdisciplinary externally funded research and UM-community evaluation research partnerships to advance knowledge in the areas of mental health, substance abuse, and health. The Curtis Center's research agenda focuses in studying health and mental health disparities and on the conduct of translational research to ameliorate these disparities. Center support includes study design consultation, advanced statistical consultation, grant and manuscript writing assistance, research space, and several other services. Expert consultation is provided by a multidisciplinary group of experienced, federally funded researchers. For this project, the Curtis Center will serve as the hub for the project staff and Dr. Smith. We will utilize its research consultation and research support resources to increase chances of success in completing the proposed project.
- C. CTSA – (Clinical Translational Science Awards) and Michigan Institute for Clinical and Health Research (MICHR): The University of Michigan is the recipient of an NIH CTSA award, which has its home in MICHR (<http://www.michr.umich.edu>). MICHR provides a comprehensive institutional source of support and infrastructure for clinical and translational researchers at the University of Michigan. It is designed to serve any investigator, in any school of the University, performing clinical or translational research. It serves to connect and integrate education, career development, infrastructure, and to catalyze research that spans the laboratory, the clinic, and the community. MICHR is organized in fourteen unique resource programs, focusing on the following domains: novel methods, technical core, Clinical Research Unit (MCRU), education/career development, biomedical informatics, regulatory support, pilot grants, biostatistics, research ethics, pediatric research, community engagement, clinical translation sciences, and health disparities research. Research Support Services include research development, data management and project management and monitoring (PMM) of federally funded, multi-center trials. MICHR offers all investigators expert consultation, budgeting and

administrative support for project development, funding for pilot studies, the *Engage* participant recruitment portal, and support for clinical research management system, among other research development services. For this project, MICHR will provide assistance in data management, based on the REDCap platforms. REDCap is an electronic data capture (EDC) system that is secure, HIPAA compliant, and web-based. This easy-to-use, no-cost tool for the University of Michigan Clinical Researchers is intended to replace Microsoft Excel and Access. Using REDCap's stream-lined process for rapidly developing databases, an investigator may create, design, and manage clinical research data online. Further, REDCap provides automated export procedures for seamless data downloads to common statistical packages (SPSS, SAS, Stata, R), as well as a built-in scheduling calendar, ad hoc reporting tools, and advanced electronic data capture form features, such as branching logic, file uploading, and calculated fields.

- D. Center for Statistical Consultation and Research (CSCAR): CSCAR is a service and research unit under the administrative oversight of the VPR that provides integrated, comprehensive statistical consulting services covering all aspects of research design and analysis from initial study design through presentation of research findings. CSCAR provides free statistical support to UM faculty and research staff and is located approximately three blocks from the School of Social Work. Among the CSCAR services provided are those related to proposal presentation and study design (e.g., power and sample size calculations), dataset consulting (e.g., database design, transferring datasets across platforms and different software packages), choice of statistical methods, use of statistical software (e.g., SAS, SPSS, SYSTAT, S-Plus, BMDP, JMP, LISREL, and AMOS on Windows, UNIX, and Macintosh platforms), interpretation of and presentation of results, collaborative research, workshops, remote consultation using “whiteboard” software, and geographic information systems consultation. With regard to computing resources, CSCAR provides PCs and Mac computers with the latest versions of a large number of software programs such as STATA, MPLUS, AMOS, MATLAB, R, SAS, SPSS, ArcGIS, and ArcView GIS, among others. The CSCAR Library PC also has a variety of statistical software packages available for use including a sample size and power analysis package. For this project, CSCAR will provide any statistical consultation needed to increase the chances of success of this project.

Dr. Smith's Autism Research Recruitment Pipeline

Dr. Smith developed a recruitment network across the State of Illinois while he was a faculty member at Northwestern University. These programs consist of vocational service providers that include: Alexian Brothers Autism Spectrum & Developmental Disorders Resource Center, Anixter Center, Aspiritech, Chicagoland Autism Connection, Easter Seals Metropolitan Chicago, Have Dreams, New Connections Academy & South Campus, and No Boundaries. In addition, the Illinois Department of Human Services, Division of Rehabilitation Services (DRS) oversees 70+ standardized vocational training program across the State of Illinois.

As part of the proposed project, we will continue our collaborative work with our community partners in order to disseminate research findings to families and the broader autism community. We have several methods to share research findings with the autism community and general public (e.g., presentations at community meetings and family conferences; television interviews). For instance, in addition to presenting at conferences for research professionals, we will share findings with stakeholders by giving presentations at the Autism Society of Illinois, Chicagoland Autism Connection, and during quarterly

calls for the Illinois DRS. Additionally, family reports will be distributed to all study participants and made publicly available on our partner's and UM websites.

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