PROTOCOL TITLE:
Virtual Reality Job Interview Training: An Enhancement to Supported Employment for Individuals with Severe Mental Illness

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1.0 Purpose of the Study:

Approximately 10-15% of the 9 million adults with severe mental illnesses (SMI) are employed[1-3], which is associated with reduced psychological distress[4]. However, the employment rate increases to ~30% in adults with SMI enrolled in Supported Employment (SE) (i.e., the gold standard for vocational training)[5, 6]. A recent model of SE shows that active job-seeking behavior (e.g., completing job interviews) is an essential treatment target for employment, and finding a job is moderated by self-efficacy and anxiety about interviewing[7]. Moreover, these targets are underdeveloped as adults with SMI have poor interviewing skills and want training to alleviate their fears and poor self-efficacy related to interviewing[7-14]. Currently, SE relies on role-play training led by "Employment Specialist" counselors to enhance interview skills, but SE clients reported that this method did not improve their skills[15, 16]. In response, NIMH funded the development of Virtual Reality Job Interview Training (VR) and evaluation of VR efficacy in a series of randomized controlled trials (RCTs, R44 MH080496). The results suggest that VR hit the targets by improving interview skills and self-efficacy in several cohorts with SMI[17-21] and demonstrated efficacy by increasing the likelihood of getting job offers[18, 21-23]. Of note, the integration of new technologies into SE is a top research priority for SE developers[24]. Thus, VR is an ideal intervention to evaluate as an effective enhancement to SE. Thus, there are a series of critical next steps to test if VR is effective at improving vocational outcomes for SE clients with SMI. A first step will test if replacing SE interview training with VR enhances person-level (e.g., higher employment rate) and b) system-level (e.g., staff efficiency and cost-effectiveness) SE outcomes. A second step will evaluate the initial implementation of VR within SE, while a third step will evaluate potential mechanisms for enhanced SE outcomes.

Our long-term goals are to develop, evaluate, and implement virtual reality interventions that enhance vocational recovery from SMI. The objectives of this application are to: 1) evaluate if VR enhances SE outcomes and if the benefits of VR generalize to improved social skills and reduced psychological distress; and 2) identify facilitators and barriers associated with large-scale implementation of VR. **Our central hypothesis is that VR will enhance vocational outcomes in a SE program.** This hypothesis is based on our research showing that VR performance predicted greater odds of receiving a job offer and a shorter duration until receiving a job offer[16, 19-21], and recommendations from a community advisory board of SE leaders and staff. We also recognize that VR needs research to maximize the effectiveness of VR in real-world settings.

In this application we propose to conduct a single-blinded confirmatory effectiveness RCT (and a process evaluation[25]) of VR by comparing subjects receiving SE with VR (instead of clinician role-plays) (SE+VR) to subjects receiving SE as usual (SE Only). Subjects will include adults with SMI who are newly enrolled in SE at Thresholds, the largest community mental health service provider in Chicago. We are well prepared to conduct this study because our team has extensive experience with community-based vocational and implementation research, and in leading prior studies at Thresholds. The **Specific Aims** are:

1. Evaluate if SE+VR, compared to SE Only, enhances SE outcomes for adults with SMI. At a person-level, we *hypothesize (H)* that SE+VR subjects, compared to SE Only subjects, will have higher employment rates (*H1*), greater improvement in job interview skills (*H2*), get jobs sooner (*H3*), and have reduced psychological distress (*H4*) by 6-month follow-up. At a system-level, we hypothesize that SE+VR will be more cost-effective than SE Only (*H5*). **Exploratory Subaims: 1.** Explore if VR generalizes to social skills by testing if VR training relates to enhanced social skills and longer job tenure for clients (person-level) and if SE staff spend fewer hours coaching communication at work (systems-level); **2.** Explore if SE+VR staff have increased efficiency (e.g., time spent helping clients with applications and networking with employers (system-level)).

2. Evaluate mechanisms of employment outcomes and psychological distress. Based on Corbiere's model[7], we *hypothesize* is that interview skills, measured independently during role-play, will mediate the effect of interview training on employment outcomes (*H*6). **Exploratory Subaims: 1.** Explore if post-training levels of interviewing anxiety/self-efficacy mediate the relationship between VR training and interviewing skills and if this mediation is moderated by pre-training levels of anxiety and self-efficacy (Fig 1b); **2.** Explore if employment outcomes mediate the relationship between interviewing skills and psychological distress at 6-month follow-up.

3. Conduct a multilevel, multidisciplinary, and mixed-method process evaluation of VR adoption and implementation to assess the acceptability, scalability, generalizability, and affordability of VR. We will use focus groups and interviews (with clients, staff, and leaders) to identify facilitators and barriers to implementing VR. We will use budget impact analysis to estimate the cost of implementing VR at Thresholds.

2.0 Background / Literature Review / Rationale for the study:

More than 9 million Americans have severe mental illnesses (e.g., major depression, bipolar disorder, and schizophrenia) with long periods of clinical stability when they can work[26, 27]. A primary aim for adults recovering from SMI is getting a job as 70% of this population wants to work[43, 44], and employment increases quality of life[28-31]. Thus, adults with SMI, service providers, and policy makers view a return to work as a critical milestone for recovery[32-34]. However, only 10-15% of this group is employed[1, 2] and struggling to find jobs increases their psychological distress[4, 35, 36].

The field's gold standard vocational program for adults with SMI is Supported Employment (SE)[5, 6, 37], which uses staff-based role-plays to train interview skills. However, despite their desire to improve interview skills only 30% of SE clients reported this method was helpful[16]. Also, SE clients were more likely to get a job if SE staff were present during interviews[10]. Thus, SE job interview training methods may be limited, which is a major barrier for this group to get a competitive job offer[38].

Based on the need to enhance interview skills, NIMH funded the development and evaluation of Virtual Reality Job Interview Training (VR) in a series of RCT efficacy studies (R44 MH080496). Briefly, VR overcomes the limitations of SE interview training by using behavioral learning principles[89, 90] that facilitate sustainable changes in behavior[39, 40]. VR improved interview skills in a lab setting and demonstrated efficacy (increased likelihood of attaining a job offer and getting job offers sooner) for four independent groups of adults with SMI[17-23]. Moving forward we will evaluate VR in the community at Thresholds, which is the largest SE provider in Chicago and offers a standardized version of SE called *Individual Placement and Support (IPS)*[48]. Although IPS strives for rapid job placement, it devotes much less attention to job interview training, which is a limitation to IPS given that "competitive" jobs require interviews.

Replacing typical IPS staff-led interview role-play training with VR could enhance IPS person-level and system-level employment outcomes. Moreover, VR could generalize to better person-level (e.g., social interactions, job tenure) and system-level (e.g., fewer hours spent coaching communication at work) employment outcomes, which we will explore. The improvement in these outcomes would demonstrate that VR has more than an incremental impact on employment outcomes. The effectiveness of IPS interview training has never been evaluated, and as such, this study will gain critical knowledge. We will test if VR enhances interview skills beyond the effects of IPS, and test if VR contributes to person-level and system-level employment outcomes. **IPS and SE are synonymous within this protocol.**

Lastly, prior studies evaluated the implementation of IPS[41-45]; however, the implementation of enhancements to IPS (e.g., VR) have yet to be studied. Thus, we propose to use the Consolidated Framework for Implementation Research (CFIR) to guide a process evaluation of VR[46, 47]. The CFIR organizes implementation into several domains, and we will focus on the CFIR's process domain (i.e., is an intervention being used and delivered as designed) to evaluate the 1) agency's plan to implement VR, 2) scalability of VR, and 3) client, staff, and leader views on a) barriers and facilitators to implementing VR, b) whether VR is used as designed, and c) suggested refinements. Hence, this study will gain critical knowledge by evaluating the cost effectiveness of VR and how VR fits into the system-level workflow, service structure, and billing of Thresholds to provide essential data for agencies that might consider adopting VR.

3.0 Inclusion and exclusion criteria:

We will recruit 180 IPS clients at Thresholds diagnosed with a mental disorder with or without psychotic features into the randomized controlled trial. ***Inclusion/exclusion criteria are outlined below:***

Inclusion Criteria:
1) Over 18 years old;

2a) all chronic schizophrenia spectrum disorders, including schizophrenia, schizoaffective disorder, delusional disorder, brief psychotic disorder, schizophreniform disorder, other specified schizophrenia spectrum and related disorder, and unspecified schizophrenia spectrum and related disorders;
2b) all bipolar spectrum disorders beyond bipolar type I and II to include cyclothymia, other specified bipolar and related disorder, and unspecified bipolar and related disorders;
2c) all depressive disorders, including disruptive mood dysregulation disorder, major depressive disorder, persistent depressive disorder, other specified depressive disorder, and unspecified depressive disorder;
2d) post traumatic stress disorder

3) fluency in English; 4) at least a 4th grade reading level; 5) enrolled in IPS; 6) active IPS enrollee as indicated by at least 1 contacts with his/her Employment Specialist in the past 30 days; 7) currently unemployed or underemployed; 8) Planning to go on interviews within 4 weeks of enrolling in the study; 9) willing to be video recorded; and 10) willing and able to provide informed consent. We will review each participant's medical record to confirm his/her mental health history.

Exclusion Criteria: 1) documented developmental or learning disability; 2) medical condition that may compromise cognition (e.g., Parkinson's Disease, Alzheimer's Disease, Huntington's Chorea, Moderate or Greater TBI); 3) uncorrected vision or hearing problems; 4) active suicidal ideation within the last 30 days with at least some intent to act, with or without a specific plan; this would be reflected in a score of 4 or 5 on the Suicidal Ideation section of the Columbia Suicide Severity Rating Scale (CSSRS); and 5) a past suicide attempt within the past 30 days that did not include preparatory acts or behavior, but was defined by a potentially self-injurious act committed with at least some wish to die as a result of the act.

We will not include any special populations: adults unable to consent; minors; infants; childrens; teenagers (ages 17 and younger); or prisoners.

Notably, clients will self-report their intention to go on interviews. We will over-select female clients so that they represent ~40% (n= 60) of our sample.

We will recruit 60 IPS clients from the RCT and 20 Thresholds staff, managers, and leaders into the implementation evaluation of VR. ***Inclusion/exclusion criteria are outlined below:***

Inclusion Criteria: 1) participated in RCT (IPS clients only); 2) employed by Thresholds as an Employment Specialist, Team Leader, or IPS Manager; or 3) employed by Thresholds at the level of Director or higher.

Exclusion Criteria: None.

4.0 Procedures Involved:

A. Study Settings

This study will collect human subjects data at several approved locations throughout the city of Chicago. First, subjects will be enrolled and evaluated by research team members at an approved Thresholds location (see Appendix A). Then subjects will travel to either the Northwestern University Feinberg School of Medicine (NU) campus Department of Psychiatry and Behavioral Sciences' clinical research program (680 Lake Shore Dr. Suite 1520, Chicago, IL, 60611) or an approved Thresholds site where the NU and Thresholds research teams will collect additional human subjects data. The decision on the location will be flexible due to scheduling of participant, actor, and staff availability. Subjects who are randomized to the VR training will complete the training at either NU or one of the approved Thresholds locations.

B. Study Design

This is a two arm randomized, single blinded, intent-to-treat, controlled trial (RCT) with baseline and pre-test assessments, up to 10 hours of VR training, post-test assessment, and follow-up at 6 months and at 9 months. We will evaluate both person-level and system-level outcomes associated with implementing VR at Thresholds. At the person-level, we propose to evaluate if IPS+VR, as compared to IPS Only, is associated with better employment outcomes (higher employment rate, shorter time-to-employment), job interviewing skills, and greater reductions in psychological distress. Interviewing anxiety and self-efficacy will be explored as potential mechanisms in the pathway between IPS and employment. At the system-level, we propose to conduct a cost-effectiveness analysis and budget impact analysis between IPS+VR and IPS Only as well as explore whether Employment Specialists (Thresholds Staff that work one-on-one with clients) working at Thresholds spending fewer hours leading interview training is related to spending more hours completing job applications with clients and building a network of employers. We will also explore if VR generalizes to social skills at both the person-level (via job retention measures) and the system-level (using a time log completed by Employment Specialists regarding time spent coaching communication skills at work).

C. Study Intervention

SIMmersion, LLC designed VR to enhance job interview skills for adults with SMI. The job-related interview content objectives target: 1) conveying oneself as dependable, 2) negotiating skills (e.g., asking for a day off), 3) team work, and 4) honesty (e.g., following company policy). The Interviewee performance objectives target: 1) comfort level during the interview, 2) sharing information in a positive way, 3) sounding interested in the position, 4) sounding professional, and 5) establishing a rapport with the interviewer. SIMmersion designed VR with the following components to help learning:

Figure A.

C.1.a Electronic Learning (e-learning): Interactive e-learning screens (Figure A.) 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 Interface and "Molly Porter": After using the e-learning module, trainees will navigate the program to begin the simulated interviews with a virtual human resource staff at a department store named "Molly Porter." She is sitting in her office and the trainee has joined her for an interview. When "Molly" speaks, the program enters Full Screen mode (Figure B) so that she is speaking directly to the trainee without any distractions on screen. When she finishes asking her question, the program returns to the interface in Figure C where trainees speak a prescripted response of their choosing (see C.1.d).

"Molly" has three difficulty levels: easy (e.g., friendly), medium (e.g., direct), and hard (e.g., stern or asks illegal questions). She uses "memory" and her behavior is driven by an advanced "emotional model." For example, if a trainee responds inappropriately to several questions, "Molly" may become dismissive and end the interview, but if the trainee continually answers appropriately, "Molly" may become more friendly and encouraging. Based on the trainee's statement, the software must then choose a reply for "Molly." Selection is based on three factors: 1) difficulty, 2) the history of the conversation, and 3) "Molly's" evolving relationship with the trainee, driven by trainee responses. Each factor will be used to compute conditional probabilities associated with each possible reply and one is selected. "Molly" stays true to her character and the emotional state created during the play, and thus, may behave differently each time the system is used.

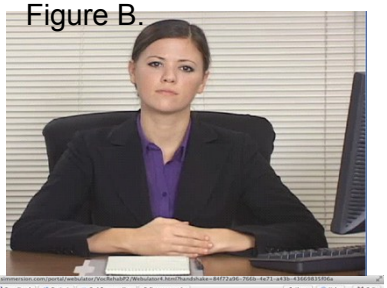
Figure B.

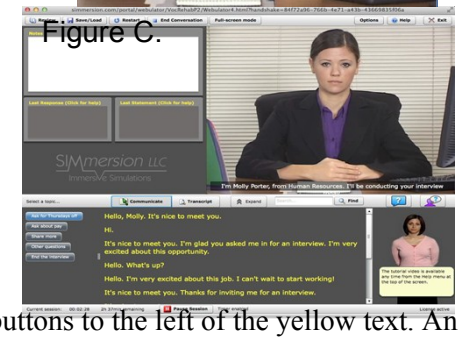

Figure C.

Figure C displays the layout of the interview interface. Buttons at the top of the screen control the interface. The yellow text displays various statements that can be spoken to respond to "Molly'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: A professional actor portrayed "Molly" 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 "Molly" 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 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 "Molly" to vary her memory, emotion, and personality. This variation supports hours of unique repeated practice and naturalistic conversations with Molly.

C.1.f Job Coach and Help Buttons: Trainees receive in-the-moment feedback from an on-screen coach (Figure D.) 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 (Figure D.). 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 eight different jobs (cashier, stock clerk, customer service, maintenance/grounds, janitorial, food service, inventory, or security). 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 "Molly" will draw. For example, a trainee may apply for a customer service position on the application, yet identify previous experience in inventory; Molly 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

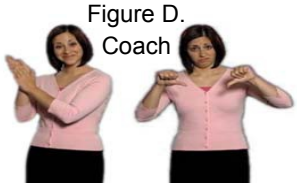
Figure D.
Coach

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 "Molly" understood their responses.

C.1.i Scoring and Summary Feedback: After each virtual interview, trainees receive scores in eight categories (based on the learning objectives). 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, "You got the job! You made a great impression on "Molly" and she decided to offer you the job. Congratulations!" (See VR Training Manual in Supporting Documents for Screen Shots). 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 Procedures for Community Effectiveness Randomized Controlled Trial

D. 1.a. Thresholds research staff will prescreen members using Electronic Health Record (EHR) information. Thresholds research staff will sit in on weekly case coordination visits with Employment Specialist (ES) to discuss members who may be a good fit for the study. If the member agrees, the ES will talk directly with the member to explain the study and see if he/she is interested. The ES may use a recruitment video at this time. Once interest is established, Thresholds research staff will reach out to the client directly via phone. The Thresholds research staff member will use the study screening form to determine the client's initial eligibility for study participation, and then schedule a baseline visit. Screening data collected from individuals who are ineligible or decline participation will be kept on file during the duration of the recruitment period in case eligibility criteria changes then this information will be destroyed after recruitment is completed.

D.1.b. The Thresholds Employment Specialist identifies members who are eligible for research participation base on member's enrollment and employment status. The Employment Specialist give members' information about the research study using the kickoff meeting recruitment script and kickoff meeting recruitment handout, and lets the member know that they may be eligible for the study. The Employment Specialist asks members if they would be interested in learning more about the study at a kickoff meeting with the research team. The kickoff meeting will be a two-hour period at a Thresholds location in which the interested member will have the option to talk to the Thresholds research team. The member will also have the option to talk to the Thresholds' research team via phone instead of attending the kickoff meeting. The Thresholds research team may use the Molly information video during the kickoff meeting. Once interest has been established in joining the study, the Thresholds research staff member will use the study screening form to determine the client's initial eligibility for the study participation, and then schedule a baseline visit. Screening data collected from the individuals who are ineligible or decline participation will be kept on file during the duration of the recruitment period in case eligibility criteria changes. Then this information will be destroyed after recruitment is complete.

D. 2. The Baseline Visit for Thresholds' Clients (completed at Thresholds) will begin with Wide Range Achievement Test (4th Edition) to assess current reading level (lasting approximately 10 minutes). If the client is found eligible based on reading level (6th grade or above), they will complete the informed consent process and provide contact information (lasting approximately 20 minutes). Thereafter, research staff will administer:

1. Structured Clinical Interview for DSM-V Axis I Disorders (SCID-5) (lasting approximately 1 hour) [48]. The SCID will provide duration of illness, number of psychiatric hospitalizations, current medication status, and educational attainment. A medication log will be used to capture the medication information.

In the SCID, if a patient endorses any items regarding suicidality (item OP8, "Suicidal ideation lifetime" [if within last 30 days], item OP9, "Suicidal ideation past week," item OP13, "Suicide attempt lifetime"

[if within last 30 days], or item OP14, "Suicide attempt past week"), research personnel will administer the **Columbia-Suicide Severity Rating Scale (C-SSRS)[49].** A total score of 4 or higher on the "Intensity of Ideation" section of this measure will indicate whether or not the participant has a level of suicidal risk that requires further consideration. Example questions from the C-SSRS are listed below),

Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note).	**Yes** □	**No** □

Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)? If yes, describe:	

The procedures outlined in section 10 (Risks to Participants) will be followed if a participant scores 4 or higher.

2. Participants will receive a 5 minute break.

3. Alcohol Use Disorders Identification Test Self Report (AUDIT-SR) (lasting approximately 5-10 minutes). The AUDIT-SR will provide self-reported alcohol use information.

4. Drug Abuse Screening Test 10 item (DAST-10) (lasting approximately 5-10 minutes). The DAST-10 will provide self-reported drug use information.

5. Job Interview Self-Efficacy is a 9-item self-report (approximately <5 minutes)

6. Personal Report of Job Interview Anxiety is a 34 item self-report to assess one's level of anxiety regarding the job interview process (approximately 2 minutes)

7. Intrinsic Motivation Inventory – Employment Research is a 30 item self-report (approximately 10 minutes)

8. Technology Comfort Level Questionnaire is a 6-item measure that assesses one's comfort level with computer technology (approximately 5 minutes).

9. Research staff will complete the inclusion / exclusion checklist. If participant is eligible to proceed, they will be scheduled to return to Thresholds for Baseline Visit 2/3.

The Baseline Visit 1 will last approximately 210 minutes or 3 hours and 30 minutes. Participants will be paid $70. This amount will be prorated on the number of assessments completed if the session ends early. For example, if a participant is excluded based on reading level, he or she will be paid $15.

D. 3. Combined Baseline Visit 2/3 for Thresholds' Clients (completed at Northwestern University or at Threshold's location) will require participants to complete:

1. Employment History Interview (EHI) The EHI will assess competitive work history data: length of time since last full-time (or any) employment, number of days employed in the past 5 years, history of prior interview training, and number of job interviews completed in the past three months. The EHI will also assess current housing status, income, and criminal justice history.

2. Brief Psychiatric Rating Scale (BPRS) (lasting approximately 30 minutes). The BPRS will assess psychiatric symptoms including somatic concern, anxiety, emotional withdrawal, conceptual disorganization, guilt feelings, tension, mannerisms and posturing, grandiosity, depressive mood, hostility, suspiciousness, hallucinatory behavior, motor retardation, uncooperativeness, unusual thought content, blunted affect, excitement, and disorientation.

3. The Beck Depression Inventory (approximately 15 minutes) is a self-report of depression symptoms.

A rating of" 2 ("I would like to kill myself," or 3 ("I would kill myself if I had the chance" on item 9 on the Beck Depression Inventory indicates presence of suicidal ideation.

When a participant meets one of the above cutoff scores, the research staff will administer the **Columbia-Suicide Severity Rating Scale (C-SSRS).** A total score of 4 or higher on the "Intensity of Ideation" section of this measure will indicate whether or not the participant has a level of suicidal risk that requires further consideration. The procedures outlined in section 10 (Risks to Participants) will be followed if a participant scores 4 or higher.

4. MATRICS Consensus Cognitive Battery (MCCB) (approximately 1 hour) [50]. The MCCB is a standardized cognitive battery for use with adults with schizophrenia and related disorders.

5. Participants will receive a break and be provided a healthy snack.

6. WHO Quality of Life-BREF (WHOQOL-BREF) (approximately 10 minutes) [51]. The WHOQOL-BREF is a brief quality of life survey.

7. The 12-item Short Form Health Survey (SF-12) (approximately 10 minutes) [53]. This assessment is a brief survey about the participant's physical health.

8. Social Skills Performance Assessment (SSPA) (approximately 15 minutes) to assess social competence. Participants will complete two video-recorded roleplays with a research assistant [54].

9. Baseline Job Interview Role-Play Assessments (approximately 90 minutes): The participant will complete a typical job application, select two fictional job openings (listed below), and participate in two job interview role-plays with two trained role-play interviewers. The interviews will be videorecorded and the videos will be scored by student raters trained to a high standard of reliability and who are blinded to condition. Participants will select two jobs from the following scenarios:

1) Scenario A: The department of Public Health at the University of Illinois at Chicago is running a nation-wide study examining the effects of a newly implemented youth exercise program in elementary schools across the country. We are hiring a team of research assistants to collect and manage our study data. We look forward to building a talented team and have position openings in the following categories: Data Entry Technician, Research Assistant, and Study Coordinator. Position to which they are applying is Data Entry Technician.

2) Scenario B: Goldberg & Jones is a new law firm opening in downtown Chicago. G&J is a promising new law firm founded by two law students who recently graduated from Kent Law School. G&J is looking for a dedicated staff to ensure the new law firm's success. Goldberg & Jones are seeking to hire individuals for the following positions: Administrative Assistants, Mail Clerks, and Paralegals. Position to which they are applying is Mail Clerk.

3) Scenario C: Lakeview Hospital has provided quality care and treatment to Chicago for the past 50 years. Lakeview Hospital is currently seeking individuals to add to their dedicated team of employees for the following positions: Medical Records Clerk and Medical Receptionist. Position to which they are applying is Medical Records Clerk.

4) Scenario D: Goldberg & Jones is a new law firm opening in downtown Chicago. G&J is a promising law firm founded by two law students who recently graduated from Kent Law School. G&J is looking for a dedicated staff to ensure the new law firm's success. Goldberg & Jones are seeking to hire individuals for the following positions: Administrative Assistants, Mail Clerks, and Paralegals. Position to which they are applying is Paralegal.

5) Scenario E: Stop & Shop is the second largest, nation-wide supermarket chain. We are opening a new store to sell food and household goods. We look forward to building a talented team and have position openings in the following categories: Customer Service, Cashier, Stock Clerk and Inventory. Position to which they are applying is Inventory Manager.

6) Scenario F: At T&C Home Goods, we are committed to quality - both in the value of our product line and in the talent employ. We offer a personalized work environment to hundreds of dedicated associates, with all the perks of a multi-million-dollar company. We offer an extensive selection of home décor and building supplies. Position to which they are applying is Sales Associate.

7) Scenario G: Stop & Shop is the second largest, nation-wide supermarket chain. We are opening a new store in Park Ridge, IL to sell food and household goods. We look forward to building a talented team and have position openings in the following categories: Customer Service, Cashier, Stock Clerk and Inventory. Position to which they are applying is Stock Clerk.

8) Scenario H: The Cook County Public Library enables researchers, students, teachers, and others to have access to the records of Illinois' past while preserving irreplaceable historical materials for future generations. The sizeable collection of books, journals, manuscripts, newspapers, maps, and prints, available to the public makes it the most frequented library in all of Illinois. Position to which they are applying is Reference Librarian.

Participants will be given an instruction card that corresponds to their selected job scenarios, which is presented below.

Instructions: [fill in company name and details] is interviewing for part-time workers, 25 to 30 hours per week. Starting pay is $15.00/hour. You are interviewing for part-time work, particularly because you need to have Thursdays off for personal reasons. You will need to negotiate for a schedule that will accommodate for Thursdays off.

10. Specific Levels of Functioning (SLOF) Assessment is a 30-item measure that assess one's functioning in the community (approximately 10 minutes) [55].

Combined Visit 2/3 (Pre-test visit) will last approximately 210 minutes or 3 hours and 30 minutes. Participants will be paid $70.

D. 4. Randomization for Thresholds' Clients. After the video-recorded pre-training role-play interviews are completed, participants will be randomized into the intervention group or the wait list control group. Block randomization tables will be created prior to the study based on computer generated blocks of six. Blocks of six will ensure nearly equal groups. Sealed envelopes 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. Visits 4-9, Virtual Reality Job Interview Training Delivery. Participants randomized to the VR training group will complete their VR training at local Thresholds location (see Appendix A), or if requested by the member (at their home). After members have completed their VR-JIT orientation and have demonstrated independence at using VR-JIT with minimal support from staff and completed at least 10 virtual interviews in lab, then study team will support the member to use VR-JIT at home **if home use is requested by the member.** To provide this support, the research team will show the member how to access the tool in the lab. Moreover, the member will be instructed to call the research team so that the research team can walk the member through accessing the tool once they are at home. In addition, the research team will provide the member with a instructional document so that they can access the tool from home.

The Thresholds Research Coordinator will schedule the study participants to complete 6 two-hour sessions of VR. When participants show up for the VR training, the visit will be run the Thresholds research staff who will provide the trainee with an initial orientation to VR and then monitor the trainee's access and performance scores during the sessions. After completing the initial 6 visits, trainees will move on to complete their post-test visit. Trainees will be invited to use VR as-needed after completing the post-test visit, which will be monitored by the Team Leaders. Those participants assigned to the SE as usual group will have the option to use the VR training in the context of their regular use of Thresholds services (i.e., they will not have access to the study resources to use VR) following the completion of their participation in the study (after their 9-month follow-up phone call). At each training session, any subject who has had to travel to use the intervention will receive $10 to reimburse them for the cost of transportation.

A note on VR delivery procedures (1/29/18): When the study initially began, Employment Specialists and Team Leaders were asked to run the VR orientation and training sessions. Due to workload expectations and coordination barriers, this responsibility was moved to the Thresholds Research Team.

D. 6. Visit 10 (Post-test Visit completed at Northwestern University, at a Threshold's Odgen location, or via a phone call or video-conference) will be a repeat of the following measures (see D.2. and D.3. for more details):

1. Brief Psychiatric Rating Scale (BPRS)
2. Beck Depression Inventory (BDI)
    a. Columbia-Suicide Severity Rating Scale (C-SSRS) if triggered by BDI scores
3. Job-Interview Role Plays
4. Social Skills Performance Assessment (SSPA)
5. Employment History Interview (follow-up version)
6. Job Interview Self-Efficacy
7. Personal Report of Job Interview Anxiety
8. Intrinsic Motivation Inventory
9. Technology Comfort Level Questionnaire is a 6-item measure that assesses one's comfort level with computer technology (approximately 5 minutes).

In addition, VR trainees will complete the 5 item Training Experience Questionnaire (TEQ; < 5 minutes). The

Posttest Visit 10 will last approximately 150 minutes or 2 hours and 30 minutes. Participants will be paid $50.

D. 7. Monthly Check-in Telephone Calls for Thresholds Clients (completed via telephone) will involve a brief (<10minutes) telephone survey asking about participants' potential interview or job-related activity in the past month. These calls will be scheduled at monthly intervals after completion of post-test until the 6-Month Follow-Up (see D. 9.), for a total of 5 calls.

D. 8. Visit 11 (6-Month Follow-Up Visit completed at Northwestern University, a Threshold's Ogden location or via a phone call or video-conference) will be a repeat of the following measures (see D.2. and D.3. for more details):

1. Brief Psychiatric Rating Scale (BPRS)
2. AUDIT-SR
3. DAST-10
4. WHOQOL-BREF
5. SF-36
6. Beck Depression Inventory
    a. Columbia-Suicide Severity Rating Scale (C-SSRS) if triggered by BDI scores
7. Employment History Interview (follow-up version)
8. Job Interview Self-Efficacy
9. Personal Report of Job Interview Anxiety
10. Intrinsic Motivation Inventory

Participants will also complete the SF-12 health questionnaire about their physical health and the Employment History Follow-up interview that will assess how many job interviews were completed, total hours worked, how many jobs were offered (and accepted), hourly wage, type of job, jobs terminated (and why).

The 6-Month Follow-Up Visit 11 will last approximately 90 minutes or 1 hour and 30 minutes. Participants will be paid $40. If the participant completed at least 3 of the 5 calls before the 6-Month Follow-Up visit, they will receive a $10 bonus.

Follow-Up Visit 10 and Visit 11 scheduling protocol.

1. Study Participants' 6-month Follow-up visit (V11) will be scheduled 2-4 weeks before their due date. Scheduling will depend on the following:
    a. If a participant is engaging in the monthly employment calls, their V11 will be scheduled at the time of their 5-month employment call.
    b. If a participant is NOT engaging in the monthly employment calls, staff will contact the participant 4 weeks before the V11 due date. The contact process will be to use the phone to call the participant up to three times per week (only one time per day). Given that this population is difficult to reach, we will follow-up this initial phone call with an email and text message (for those participants who identified on their consent form that we can contact them by phone or emai.
2. If the study participant's V11 has not been scheduled by 2 weeks before their due date, staff will reach out to the participant's employment specialist and primary clinician for support contacting the participant.
3. If the study participant's V11 has not been scheduled by the time of their due date, staff will send a letter to the participant. The letter will explain the nature of the visit, the length of time the visit will take, and the staff person they should contact to schedule.
4. If the study participant does not respond to the letter or if their V11 is not scheduled by 6 weeks past their

due-date, staff will pull any available information from the electronic health record, and the member's study participation will end.

The same process will be used for scheduling Visit 10 as well.

Our primary method to collect Visit 10 and Visit 11 study data will be to invite participants to complete the visits at their local Thresholds location or Northwestern (as is the same for all in person study visits).

Alternatively, if participants are unable to attend visit 10 and/or 11 in person, the study team will schedule a series of brief phone calls in order to collect the self-reported study data by phone. In addition, the study team will offer participants the opportunity to complete their follow-up role-play assessment by means of a videoconference through BlueJeans. The BlueJeans videoconference will then be recorded by the University of Michigan research team that is approved for this study and the recordings will be stored using the previously approved methods for storing audiovisual data.

Alternatively, if the participants do not want to complete the videoconference then the participants will be offered the opportunity to complete their follow-up role-play assessment by means of a teleconference through BlueJeans. The BlueJeans teleconference will then be recorded by the University of Michigan research team that is approved for this study and the recordings will be stored using the previously approved methods for storing audiovisual data.

D. 9. Monthly Check-in Telephone Calls for Thresholds Clients (completed via telephone) will be a repeat of procedures of the Monthly Check-in Telephone Calls for Thresholds Clients (see D. 8.). These calls will be scheduled at monthly intervals after completion of the 6-month follow-up until the 9-month follow-up (see D. 11.), for a total of 2 calls.

D. 10. The 9-Month Follow-Up for Thresholds Clients (completed via telephone) will include only the Follow-up Employment History interview that will assess how many job interviews were completed, total hours worked, how many jobs were offered (and accepted), hourly wage, type of job, jobs terminated (and why).

The 9-Month Follow-Up Telephone Call will last approximately 10 minutes. If participants complete at least one of the two check-in calls between the 6-Month and 9-Month Follow-Up calls, they will be paid $10 by Thresholds after the completion of the 9-Month Follow-Up call.

D. 11. Participation Complete. If a Thresholds client becomes employed prior to the 6-month follow-up call, they will still participate in monthly check-in phone calls and the 6-month follow-up. Their participation in the study will then be complete after completing the 6 month visit.

If the participant becomes employed between the 6- and 9-month follow-up calls, the participant will be asked additional questions on their next check-in call, which will be their last check-in.

For the Thresholds clients who do not find employment during before this time, participation is complete for this study after finishing their 9-Month Follow-Up Telephone Call.

E. Study Procedures for a Mixed-Method Multi-Level Process Evaluation.

E. 1. Level 1. The first level for the process evaluation of VR includes two pre-study implementation evaluations. The first is a 12-item Implementation Leadership Scale (<5 min) to evaluate the perspective of implementing evidence-based practice. The Thresholds Supported Employment Leadership team will complete this brief survey prior to conducting the RCT.

E. 2. Level 2. The second level for the process evaluation of VR will take place after approximately 30 VR trainees completed their work with VR and will include a series of 2-4 focus groups (consisting of 4-6 research participants per group) with existing research participants using VR. The groups will assess perceptions of initial VR implementation, with results guiding immediate modifications to VR delivery. The focus groups will be video-recorded and last approximately 60 minutes. Video-recording is required for participation in the focus groups. Each participant will be paid $20 for their time. The focus groups will be led by research staff and conducted at Thresholds. The participation in focus groups is a one-time experience. See attached list of questions guiding the focus group.

In addition, Level 2 will consist of recruiting Team Leaders and Employment Specialists to complete the 26-item Implementation Survey for Providers (<10 min).

E. 2. Level 3. The third level for the process evaluation of VR will take place after approximately 60 VR trainees completed their work with VR and will include conducting focus groups with Employment Specialists and Team Leaders involved with the study to complete 1-3 focus groups (consisting of 4-6 Thresholds Staff). The groups will target a discussion around client, service, and implementation outcomes. The focus groups will be video-recorded and last approximately 60 minutes. Video-recording is required for participation in the focus groups.. The focus groups will be led by research staff and conducted at Thresholds. The participation in focus groups is a one-time experience. See attached list of questioning guiding the focus group.

E. 3. Level 4. After 6 months after VR delivery is completed, the Thresholds Supported Employment Leadership will be invited to complete the 31-item Annual Survey of Evidence-Based Practice (<15 min). This survey will assess the likelihood that Thresholds can sustain their use of VR after the study has ended.

E. 3. Level 5. Thresholds requires Employment Specialists (staff working one on one with clients on vocational rehabilitation) and Team Leaders (staff that orient clients to use VR) to document their weekly hourly activity logs, which will be copied and provided to the research team for the duration of the Thresholds' involvement in the study. Thresholds will provide the research team with activity logs for the 8 weeks prior to the beginning of the study. This data will help us evaluate how the allocation of person hours changes as a result of using VR, and in turn, will inform the cost effectiveness of VR. The activity log is attached to the IRB application. The logs will be anonymous to the study team, but will included a personal identification number so that the logs for the 8 weeks prior to the study can be compared to the logs collected once the study begins. The research team at Thresholds and Northwestern will not have access to the personal information of the Thresholds staff connected to these logs.

F. Participant Timelines

F. 1. Thresholds Clients. Individuals receiving mental health services at Thresholds who are enrolled in the effectiveness trial will participate in the study for a period of 9 months. Over the first month, they will complete a series of study measures and if randomized to the intervention group, this participation will include up to 10 hours of virtual reality training. After the first month, the participants randomized to the training group are

welcome to use the training as-needed, which will be monitored using their ID number. Then approximately 6 months after participants complete their post-test visit, they will be invited to complete their 6-month follow-up visit. Approximately 3 months after the 6-month visit, participants will be contacted via phone for a 9-month follow-up interview. Their participation in the study will end at this time.

After 1/3 of the effective trial participants have completed their intervention training (and before the completion of the 6 month follow-up) 20 VR trainees will be recruited to participate in a series of focus groups.

5.0 Multiple sites:

This is a multi-site project funded by NIMH where the overall Principal Investigator is Dr. Matthew Smith located at University of Michigan with a subcontract to Thresholds to recruit participants, collect data, and provide the intervention, and a subcontract to NU to collect additional data as outlined in the procedures and manage all coordination activities of the study. After the study data is collected, entered, cleaned, and de-identified (except for video data) at Northwestern University, the electronic data will be shared with the overall PI on the project. Dr. Smith and his team at UM (his team is To Be Determined) will process and analyze the study data at UM.

The Northwestern PI (Dr. Jordan) will be working closely with the Thresholds Site PI who is also the Research Director at Thresholds. In order to ensure successful coordination of research activities among sites, the Northwestern PI and Thresholds' Site PI will meet weekly and as-needed during the first 6 months of the study (and monthly and as-needed) to prepare and sustain a collaborative and agreed-upon approach. In addition, the Northwestern PI and Thresholds' Site PI will receive input from a community advisory board and an expert panel to review and discuss the approach for recruitment and data collection as well as to review and approve any modifications to the study protocol regarding recruitment or data collection methods. This panel will not have access to individual participant information or data. Recommendations to modify the protocol or consent form will be reviewed by the NU IRB and approvals will be immediately communicated via email to the Northwestern PI and Thresholds' Site PI, and both the NU and Thresholds' research coordinators as well as all project staff involved in the consent and data collection processes. As a safeguard, all IRB modifications will be reviewed at the next weekly research team meeting. All non-compliance with the research protocol will be reported to the Site PI and PI who will discuss and the PI will submit any deviations to the NU IRB for review.

A signed IAA will be uploaded in the supporting documents in IRB modification #4 and before Thresholds staff engage in study activities with human subjects.

6.0 Incomplete Disclosure or Deception:

This study will not be using deception.

7.0 Recruitment:

7.1 Research staff located at Thresholds (4423 N. Ravenswood, Chicago, IL 60613) will sit in on weekly case coordination visits to educate Thresholds IPS staff about the study and discuss clients who may be a good fit for the study. The Employment Specialist will speak with the identified members to explain the study and see if they

are interested. The Employment or Research staff may also show the clients a **promotional video** about the Molly intervention to help them understand the study. If interested, the Thresholds research staff will reach out to the client directly via phone. The adults with SMI will complete a phone screener with the Thresholds Research Team to determine if they are eligibile for the study. If they are found eligible from the screener, the Research Team will schedule their first visit.

To recruit participants to evaluate the process of implementing VR within Thresholds, we will recruit the existing study participants using VR as well as Thresholds staff and leadership involved with the project. Each participant using VR, staff, and leader involved with the study will receive a study pamphlet summarizing the purpose of evaluating the implementation of VR. Individuals interested in completing this aspect of the study will be directed by the pamphlet to call the Research Coordinator at Thresholds to begin enrolling in this part of the study.

7.2 The Thresholds Employment Specialist identifies members who are eligible for research participation base on member's enrollment and employment status. The Employment Specialist give members' information about the research study using the kickoff meeting recruitment script and kickoff meeting recruitment handout, and lets the member know that they may be eligible for the study. The Employment Specialist asks members if they would be interested in learning more about the study at a kickoff meeting with the research team. The kickoff meeting will be a two-hour period at a Thresholds location in which the interested member will have the option to talk to the Thresholds research team. The member will also have the option to talk to the Thresholds' research team via phone instead of attending the kickoff meeting. The Thresholds research team may use the Molly information video during the kickoff meeting. Once interest has been established in joining the study, the Thresholds research staff member will use the study screening form to determine the client's initial eligibility for the study participation, and then schedule a baseline visit. Screening data collected from the individuals who are ineligible or decline participation will be kept on file during the duration of the recruitment period in case eligibility criteria changes. Then this information will be destroyed after recruitment is complete.

8.0 Consent Process

A. Consent Location. Participants with severe mental illness will be consented for the randomized controlled trial and their participation in the focus groups in a private research office located at the participants local Thresholds location (one of five locations: 4423 N. Ravenswood Ave, Chicago, IL 60613; 2240 W. Ogden Ave, Chicago, IL 60612; 734 W. 47th St., Chicago, IL 60609; 5000 W. Roosevelt, Chicago, IL 60644; 3638 S. Kedzie, Chicago, IL 60632). Participants with severe mental illness will be consented for their participation in the study during the initial consent process conducted at Thresholds. Thresholds staff and leadership will be consented at the above address on Ravenswood in either the research office or the staff or leader's own personal office.

B. Consent Team. The consent process taking place at Thresholds will be led by either the Study PI, Site PI, research coordinator, or research assistants who all have up-to-date CITI training.

C. Consent Timeline. The consent process will require approximately 10 minutes to read and up to 15 minutes to discuss to make sure that the participants fully understand the extent of their involvement in the study.

The details of the consent process including:

i. Steps that will be taken to minimize the possibility of coercion or undue influence.
ii. Steps that will be taken to ensure the participants' understanding.

D. Consent Addendum for Visit 10 and 11. For participants who are unable to attend Visit 10 and/or Visit 11 in person, we are providing these participants with the opportunity to complete abbreviated versions of the visit over the telephone or through videoconference (if available). In order to complete this process, the study team will call

the participants and read the consent addendum to them. When the participant provides their verbal consent (or not) then the study team will document the participant's decision and ID number on a hard copy of the addendum. Then the hard copy will be added to the participant's file. If the participant agrees to the consent addendum, then the study team will work with the participant to set up a time to complete the visit using the preferred method of communication.

9.0 Process to Document Consent:

Procedure for Consent

- The person obtaining informed consent will:
  - Introduce themselves to the potential subject
  - Provide an explanation of a) what clinical research is and why you are approaching them; b) why people generally volunteer to participate in research; c) what they can expect if they choose to participate in clinical research; d) how participating in the study will not affect their regular care or relationships with their care providers.
  - Explain that research staff will look into their medical records to confirm their past/current mental health diagnosis and that HIPPA Authorization is being obtained.
- After explaining the principles above, the person obtaining informed consent will:
  - Ask the potential subject if they want to hear the details about the particular research and answer any questions that may arise.
  - Acknowledge that the potential subject verbalized understanding of the research and research related procedures.
  - Explain to the potential subject that signing ICF is entirely voluntary.
  - Explain to the potential subject risks and benefits of participating in the particular protocol.
- The potential subject, or legally authorized representative, will;
  - be given ample time to completely read and/or listen to the consent form being read to them and ask any questions.
- The subject and the person obtaining informed consent will sign and date the last page of the consent form if they wish to participate in the study.
- A witness signature will be obtained in order to be in compliance with Illinois law pertaining to the utilization of mental health information from a HIPAA covered record.
- A copy of the fully signed consent form will be given to the subject.
- Copies will be filed in the subject's research file.
- The ICF process will be documented in the study source document by the person who is obtaining the consent.
- If during the course of the research trial, the informed consent form is revised, subjects will be re-consented using the revised IRB approved consent form, if applicable subjects will be re-consented after each IRB Continual Review with a newly IRB approved ICF even though it does not reflect any changes in the study protocol.
- Those who were consented before the study was determined to meet the definition of an NIH-funded clinical trial will be given a document at their next study visit that contains information about what this means and includes the clinicaltrials.gov identification number.

10.0 Risks to Participants:

Potential Risks and Protections in Place Against Foreseeable Risks. The potential risks of this project are minimal. The possibility exists that participants may become bored or fatigued during: 1) pre-test and post-test role-plays; 2) VR training; 3) cognitive assessments; 4) vocational history interview; or 5) mental health history

interview. In response, we will include scheduled and unscheduled breaks to protect against these risks. To minimize the risk of possible fatigue and/or boredom, breaks will be scheduled between assessments in long sessions and between role-plays, and participants will be reminded that they can request a break at any time during. Should a research staff member notice signs of fatigue and/or boredom from a participant, an unscheduled break will be taken. The research team has used these procedures for other studies, and they have been effective at reducing risks of fatigue and/or boredom for study participants.

There is a very low risk that participants could be distressed by the mental health interview or job interview role plays. If this happens, participants will be asked to take a break and be offered the chance to drop out of the study if these aspects of the study are too distressing for them. Of the more than 150 participants who completed the mental health interview and four role-plays each during the efficacy studies (600 total role-plays), no participants reported feeling distressed by the interview or role-plays.

These risks will be reviewed during the discussion regarding informed consent, and researchers will take all possible precautions to minimize these potential risks. Moreover, only personnel trained in interviewing and testing protocols with individuals 18 year and older will conduct these procedures.

Although there are no known adverse or severe adverse events that have occurred as a result of using the training, it is possible that a participant could arrive to a research visit (or escalate during a research visit) in a way that is symptomatic or suicidal during the course of the study. Per Thresholds and NU policies, both sites will have clinical staff available (including the PI, Dr. Smith) to assess the mental health and the risk of harm to self or others. If trained research staff observe a participant to be highly symptomatic or suicidal then they will follow the following policies at NU and Thresholds:

If SCID-V has been administered:

- If a participant endorses suicidal ideation and behavior within past 30 days by <u>any</u> of the following items:
    - item OP8, "Suicidal ideation lifetime" [if within last 30 days],
    - item OP9, "Suicidal ideation past week,"
    - item OP13, "Suicide attempt lifetime" [if within last 30 days], <u>OR</u>
    - item OP14, "Suicide attempt past week"),

  proceed to administer the Columbia Suicide Severity Rating Scale (C-SSRS) as instructed below.
- If participant does not meet any of the criteria above on the SCID-V, continue with study procedures per protocol.

If Beck Depression Inventory has been completed:

- For item 9 of the Beck Depression Inventory (self-report), if a participant endorses a rating a rating of 2 "I would like to kill myself," or 3 "I would kill myself if I had the chance," proceed to administer the Columbia Suicide Severity Rating Scale (C-SSRS) as instructed below.
- If participant does not meet the cutoff score on item 9 of the BDI, continue with study procedures per protocol.

If participant endorses distress during other procedures (i.e., during job-interview roleplays):

- Ask the participant if he/she would like to take a break and if the participant has any concerns about completing the [i.e., roleplay, survey].
- If participant indicates willingness to proceed, continue with study procedures per protocol.
    - Participant will be given option to reschedule remaining study procedures for another date, if preferred by participant.
- If participant indicates distress, proceed to administer Brief Psychiatric Rating Scale (BPRS) and/or

Columbia Suicide Severity Rating Scale (C-SSRS) as appropriate, as instructed below.

If suicidal ideation is detected (based on Beck Depression Inventory item 9 cut-off score of 2 or 3, OR other indication):

- Administer the Columbia Suicide Severity Rating Scale (C-SSRS). If participant scores 4 or higher on the "intensity of Ideation" section, proceed with emergency procedures.
    - If participant scores below 4, continue with study procedures per protocol and notify primary Thresholds research staff point of contact (i.e., Nikki Pashka, Karley Nelson) of C-SSRS outcome. Threshold's research staff should follow up with participant's clinical team.

Emergency procedures

- NU staff should alert the Research Manager and primary Thresholds research contact about the concern (provide with demographics and relevant medical information such as suicidal and/or homicidal ideation/intent, diagnosis, medical condition).
- Thresholds research staff should contact participant's clinical team and obtain recommended next steps (i.e. go immediately to ED, wait for clinical staff to arrive, or schedule an appointment for the participant with clinical provider).
- Pending recommendation from Thresholds clinical provider (if recommended to make appointment with provider or go immediately to Emergency Department), discuss the issue with all relevant research staff and participant.
- If recommended to make appointment with provider, ensure that appointment is secure promptly and that date, time, location, and name of provider appointment are documented before participant leaves the research premises.
- If recommended to go immediately to ED:
    - Call 911.
    - In the case of an involuntary hospitalization/ED evaluation: call Police; a research team member should go with police since "Petition" is required.
    - In the case of a voluntary hospitalization/ED evaluation: call Ambulance to escort the patient.
    - In the case of suicidal ideation/intent, a research team member must watch (i.e., must have eyes on) the participant until Police/Security/Ambulance arrives.

- ***If participant is going to ED from Northwestern Location (680 N Lake Shore Drive):***
    - Call the building security at 312-951-1844 and inform them that Police and/or Ambulance was contacted. The security officer from the building will come to NU-CRP facility, if needed. Security should arrive to facilitate within 10 minutes and help the research personnel until Police and/or Ambulance arrive.
    - A research team member must provide documentation (i.e., progress note) from the investigator to give to the police/security regarding the investigator recommendation.
    - Call ED (direct crisis line is 312.926.1878) to alert that patient is on the way and to provide with all necessary information.
    - Follow up with crisis team/on call resident to give information about the patient.
    - Email Principal Investigators and Thresholds Site PI to notify them that the emergency procedures took place.
    - Contact Thresholds research team member so that they can reach out to the participant's clinical team for follow up.
    - Coordinate with Thresholds research staff contact to follow-up with participant within 24 hours to verify they were able to access the help they needed, or follow-up with ED to verify if participant

was admitted to hospital.
- Document all activities for the study file and for correspondence with clinicians/IRB.

- ***If at Threshold's Ogden location (2240 W. Ogden Ave):***
  - Inform Nijha Maybon (773-572-5236) and/or Repsie Royster (773-572-5218) that the police and/or an ambulance are on the way. Ensure that they know where you are in the building so that they can escort emergency personnel to you when they arrive.
  - A research team member must provide documentation (i.e., progress note) from the investigator to give to the police/security regarding the investigator recommendation.
  - Document which hospital participant is being taken to then contact that hospital to provide the ED staff which all necessary information.
  - Follow up with crisis team/on call resident at hospital to give information about the participant
  - Email Principal Investigators and Thresholds Site PI to notify them that emergency procedures took place.
  - Follow up with participant's clinical team to let them know what emergency procedures took place.
  - Follow-up with participant within 24 hours to verify they were able to access the help they needed, or follow-up with ED to verify if participant was admitted to hospital.
  - Document all activities for the study file and for correspondence with clinicians/IRB.

- ***If at other Thresholds Location***
  - Inform relevant building staff/front desk staff that the police and/or an ambulance are on the way. Ensure that they know where you are in the building so that they can escort emergency personnel to you when they arrive.
  - A research team member must provide documentation (i.e., progress note) from the investigator to give to the police/emergency personnel regarding the investigator recommendation.
  - Document which hospital participant is being taken to then contact that hospital to provide the ED staff which all necessary information.
  - Follow up with crisis team/on call resident at hospital to give information about the participant
  - Email Principal Investigators and Thresholds Site PI to notify them that emergency procedures took place.
  - Follow up with participant's clinical team to let them know what emergency procedures took place.
  - Follow-up with participant within 24 hours to verify they were able to access the help they needed, or follow-up with ED to verify if participant was admitted to hospital.
  - Document all activities for the study file and for correspondence with clinicians/IRB.

<u>Withdrawal of Participants</u>

The above noted cases regarding suicidality and symptom exacerbation are the anticipated situations when the participant will be withdrawn without their consent.

Participants withdrawn from research will:
- not be called to participate in future research visits for the current study;
- have their data included in all analyses unless there is a formal, written request by the participant to have their data removed from analyses (as noted in the consent form).

11.0 Potential Benefits to Participants:

Participants randomized to the VR training group may experience an increased likelihood of receiving a job offer. This effect was observed in five efficacy studies. Across those 5 efficacy studies, approximately 50% of

VR trainees received a job offer compared to approximately 25% of study participants who received services-as-usual. Participants randomized to the control group are not likely to receive a direct benefit from participating in this study.

Participants completing the focus groups or semi-structured interviews for the implementation study are not likely to receive a direct benefit from participating in this study.

12.0 Financial Compensation:

All participants will receive compensation per visit where research assessments are collected. Potential transportation costs are included in the planned compensation payments. If a visit is not completed in full, the participant will be paid for the portions completed. These payments are approximately $70 for Baseline Visit 1 and Pretest Visit 2/3; $50 for Posttest Visit 10; and $40 for 6-Month Follow-up Visit. If a participant completes 3 out of the 5 scheduled montly calls before the 6-Month Follow-up Visit, he/she will receive an additional $10.

If the participant completes the two additional check-in calls before the 9-month follow-up telephone call, he/she will receive an additional bonus of $10 after the completion of the 9-month call, Thus, the total amount that can be received for the study is approximately $250 per participant for completing research assessments. Study participants will not be paid for completing research visits 4, 5, 6, 7, 8, and 9 because they are receiving a free intervention.

13.0 Provisions to Protect the Privacy Interests of Participants:

All methods of research data collection (interviews, self-report, role-plays) will be conducted in a private office. 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, will 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 Northwestern PI, Thresholds' Site PI, NU research team members, and the Thresholds' research team members. There will be a document located on the NU servers (password protected behind firewalls) that links PINs to study participant names. The PI, Site PI, and research teams will have access to this file in order to coordinate study visits and track participant progress to complete the study.

14.0 Confidentiality and Data Management:

Description of Security measure to Protect Data Sources. Paper research records will be created at Thresholds, and labeled with the PIN, where participants will be consented and complete baseline measures. These records will be stored in a locked cabinet within a locked office. These records will serve as the source for electronic data entry. The first entry of the data will occur at Thresholds. Upon completion of data entry at Thresholds, the paper research records will be transferred via a locked box to the NU research team where the data will be cleaned, re-entered into the electronic database, and stored in a locked drawer in a locked room. Paper research records will also be created at NU to cover role-play and research staff for the role-play and self-report data collected at NU. The NU and Thresholds records will be merged prior to long term storage. All records will be de-identified after study completion. All paper research data data will be stored on password protected servers for a period of 7 years.

Video recordings will stored for primary access on Northwestern University password protected servers behind firewalls. The video recordings will be stored using the study PIN as a filename: IDXXXX_video_a.xxx. The file name designation will also be randomized from a,b,c,d, e,f to maintain blinding as to whether the video was pre-test, post-test, or follow-up.

All participant documents at Thresholds and NU 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.

As an adjunct faculty at Northwestern University, overall PI Dr. Smith still maintains his NU netid and password. He will be able to access REDCap to download the de-identified research data in order to review the

integrity of the data. The audio/video data that is collected will be downloaded from the video camera to a NU workstation where it will be uploaded to the server. Due to his adjunct appointment at NU, Dr. Smith will still have access to the NU server and can simply move the file from the NU server to a server at UM. Both servers will be password protected with firewall protection.

Quality Assurance Measures. All participants will be recruited using strategies, documents, and text approved by the Northwestern University Feinberg School of Medicine 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. In addition, randomly selected measures will be selected for audio-taped review. Only those subjects who have given written consent to have measures audio-taped for quality control purposes will be part of the random audio-taped reviews. The study coordinator will screen participants for eligibility using formal study forms. The PI and Site 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 first entry will take place at Thresholds by subcontracted Thresholds staff (for Thresholds-based visits) or at NU by NU project staff (for NU-based visits), while the second entry will take place at NU by NU project staff (for all visits). The REDCap system is accessible via a virtual private network that is password protected and behind firewalls.The data will be transported from Threholds to NU 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 audio and video files will be stored electronically 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 Analysis Plan for Aims 1 & 2. In this intent-to-treat study, we will collect data on 160 subjects. The biostatistician will monitor the data for distribution normality and transform abnormally distributed variables if needed. **Correction for Multiple Comparisons:** To minimize spurious findings, we will adjust the 3 primary tests using a false discovery rate at 0.05[57] (see below). **Covariates:** Although randomization should protect against group differences, we will covary for any between-group differences that are observed regarding demographic, cognitive, clinical and vocational history, booster sessions, and the number of completed interviews. **Missing Data:** We will follow the intent-to-treat principle[58] and in longitudinal analyses we will use multiple imputation models to analyze the data in the presence of missing data[59-62]. Data processing and cleaning will occur during the study, including checking for missing data and inconsistencies. All videos will be stored on the project's secure server. A Data Safety and Monitoring Board will monitor for adverse events (see 15.0 below).

Hypothesis 1: IPS+VR trainees will have higher employment rates than IPS Only by T3. **To test H1**, we will use multiple logistic regression and a Wald Chi-square test of the coefficient to its standard error, to compare the adjusted employment proportions in the two conditions (attained a job=1 vs. failed to attain a job or censored with a job=0, between T1 and T3). We calculated power using simulation in R, correcting for small samples and multiple testing with false discovery rate for the 4 primary tests (our power analysis is conservative, relying on Bonferroni corrections for all tests). Accounting for 10% missing, our trial that recruits 80 subjects in each arm has 80% power for a two-sided 0.05/4=.0125 level test when the OR = 3.2, with IPS+VR effectively doubling the

rate from 25% to 53% employment. Based on our earlier study where we found an OR of 8.7, or effectively tripling the employment rate from 25% to 75%, and a power of 0.99 at this magnitude of effect, we feel confident that we will have sufficient power in this study.

Hypothesis 2: IPS+VR trainees will have greater improvement in *job interview skills* than IPS Only by T2. **To test H2**, we will conduct a repeated measures analysis of variance (RM-ANOVA) with pre and post interview scores as the repeated measures and treatment group as the fixed factor. Based on our pilot data, we expect r=.7 between T1 and T2 scores, and an effect size of d=.67 between pre and post interview role-play scores using VR. Assuming a small-to-moderate effect within IPS Only (e.g., d=.25), our best power estimate assumes a medium effect size contrasting IPS Only with IPS+VR (d=.67-.25=.42). This effect size and correlation imply an expected 6.9% reduction in within subject error for the treatment–x-time effect. Thus, 80 subjects at .0125 level will yield 82% power to detect this effect. For the ANOVA model, 160 subjects will be sufficient to detect a reduction of within subject error of 4.7% with 80% power. Assuming a full sample effect size of d=.46 (.67+.25)/2), this reduction in error corresponds to an effect size of d=.62 for the IPS+VR group and d=.30 in the IPS only group (a difference of d=.32).

Hypothesis 3: IPS+VR will get jobs sooner than IPS only by T3. **To test H3**, we will use a Cox proportional (or non-proportional) hazards regression model[63] to assess the adjusted hazard rate on time-to-employment for IPS+VR vs. IPS Only, adjusting for potential covariates (e.g., completed training trials). For a power analysis for **H3**, we assume a constant hazard rate for the distribution of time-to-employment in both groups. We also assume that a proportion of 0.20 of the subjects in the IPS Only group will find a job by T3 (that is, a hazard rate of 0.0085 for IPS Only). This analysis is estimated based on limited pilot data and log-rank power tables[64]. Thus, 160 subjects provide 80% power for a 0.0125-level test comparing time-to-employment in the two arms to detect a hazard ratio of 2.0 for IPS+VR vs. IPS Only.

Hypothesis 4: IPS+VR trainees will have greater reductions in psychological distress than IPS Only between T1 and T3. **To test H4**, groups will be contrasted on change via RM-ANOVA with time as a repeated measure and group as the main effect. Power analyses for RM-ANOVA focused on contrasts between T1 and T3. A correlation of r=.5 between T1 and T3 was assumed. Power was estimated for a range of relative effect sizes (d=.2 to d=.8; difference between IPS Only and IPS+VR) for RM-ANOVA time-by-treatment interaction effects. Assuming an overall reduction in distress of d=.5 (across both groups), all relative effect sizes were centered on this average (e.g., a relative difference in d=.8, corresponds to d=.9 for IPS+VR and d=.1 for IPS, averaging out to d=.5 overall). For ANOVA change contrasts of IPS only vs. IPS+VR between T1 and T3, 160 subjects will be sufficient to detect d=.50 (d=.75 vs .25) with 80% power for 0.0125-level test. ANCOVA will test for differences in T3 distress while covarying for T1 distress. Baseline differences (e.g., cognition) will be tested as covariates.

Hypothesis 5: IPS+VR will be more cost-effective than IPS Only. To test **H5**, we will conduct a cost-effectiveness analysis (CEA) to assess the short-term cost-effectiveness of IPS+VR relative to IPS Only using a societal perspective, which includes intervention costs and client costs provided by the IPS program director[65]. Intervention costs include variable costs (e.g., time spent by ECRs) and fixed costs (e.g., costs supporting hiring, training, and coordination). Client costs will include time using VR and travel costs. We will use standard approaches to identifying and assigning unit costs for each cost component[65]. We will use job attainment rate as our measure of effectiveness. The main step is to calculate an incremental cost-effectiveness ratio (ICER), which is defined as the difference in total costs between the IPS+VR and IPS Only groups, divided by the between-group difference in job attainment rate. Confidence intervals will be calculated around the ICER using bootstrapping and Fieller's theorem[66, 67]. We will conduct sensitivity analysis by deriving cost-effectiveness acceptability curves that display the probability of IPS+VR being cost-effective at various threshold values[68].

Exploratory (Person-Level): To study the generalizability of VR to social skills, we will evaluate if more VR training (i.e., number of trials) is associated with a longer job tenure (number of weeks) and enhanced social skills using linear regression; covariates will include demographic, cognitive, vocational, and training characteristics that differentiate groups. **Exploratory (System-Level):** We will explore if, as a result of VR, ESPs reallocate their interviewing hours towards building larger employer networks, completing more job applications with clients, and engaging in more hours of coaching work communication with clients.

Hypothesis 6: Improved interviewing skills will mediate the relationship between VR (number of completed VR trials and employment outcomes (obtaining employment). **To test H6**, we will test first for a significant IPS+VR impact on role-play scores compared to IPS alone, then check for treatment by mediator interaction[69], then on the product of the two coefficients[70] with bootstrapped confidence intervals[71]. We simulated power for this text, finding 80% power when the effect size for skills is small (effect size=0.2) and the odds for skills leading to a job is 1.8; thus we expect to have sufficient power. These older mediational models are informative but incomplete, and these will be followed by computing the *causally interpretable average natural indirect effect*[72] under assumptions i – iv therein. We plan to conduct sensitivity analyses to the assumption of "no exposure induced mediation-outcome confounding". For the exploratory moderated mediation model, we plan to use Approach 1 of Vanderweele et al.[72] to account for the combined mediated (indirect) effect of both the psychological changes in self-efficacy, anxiety, and role-play scores, as suggested in Corbiere et al.[7].

Exploratory: To test the moderated mediation (mediated effect varies as a function of a baseline variable), we will first conduct a standard model of post-intervention anxiety/self-efficacy serving as a mediator of the relationship between VR and interviewing skills using the "product of coefficients method"[73]. Mediation tests will be based on whether the confidence interval for the product of coefficients includes zero. This approach addresses the known non-normality of the test statistic[73]. To this standard mediation model we will include an interaction of baseline (pre-intervention) anxiety/self-efficacy to interact with VR training on post-intervention anxiety/self-efficacy. Similarly, we will include a baseline-by-intervention interaction on interviewing skills. The Johnson-Neyman approach will assess where mediation occurs as a function of baseline levels[74]. We will test if employment outcomes mediate the relationship between interviewing skills and psychological distress at 6-month follow-up, using the same approach outlined for **H6**.

Data Analysis Plan for Aim 3

Overview: We will recruit three levels of subjects for the VR process evaluation. ECRs will recruit IPS clients, while the PI, Site PI, and Thresholds IPS Director will recruit multidisciplinary staff (e.g., ECRs), and leaders (e.g., CEO). We will use both quantitative and qualitative methods of data collection and analysis.

Study Procedures, Measures, and Data Analysis

The mixed-method process evaluation will entail conducting focus groups and semi-structured interviews:

- Focus groups will be conducted with clients to assess: barriers (e.g., using computers) and facilitators (e.g., accessibility) to the implementation (i.e., delivery) of VR. The focus group with clients will assess perceptions of initial VR implementation, with results guiding immediate modifications to VR delivery. The focus groups with Team Leaders and Employment Specialists will assess perceptions of changes made to VR delivery and elicit new barriers/facilitators (e.g., changes in VR accessibility), with results guiding new modifications to VR delivery. We will track which subjects receive a modified delivery of VR, to be evaluated as a possible covariate. In total, 2-4 video-recorded focus groups (60 minutes, 4-6 participants each) will be conducted until reaching saturation (i.e., no new topics emerge)[75].

- Qualitative Analysis: transcribe focus group data, analyze data iteratively using thematic analysis and the constant comparative approach[76, 77] to identify emergent themes regarding the barriers and facilitators of implementing VR. Two research staff will analyze the data using The Ethnograph, a qualitative data analysis package. Staff will independently analyze a subset of transcripts to iteratively develop codes inductively as they emerge, and deductively based on initial topics (e.g., barriers, available resources). After the team agrees on a final codebook and inter-coder reliability is achieved, the codes will be applied to all transcripts[78, 79]. We will use framework analysis to compare client, staff, and leaders' perceptions of barriers and facilitators to VR implementation[80]. To facilitate comparison, a matrix of themes will be developed: subject type (x-axis) vs. barriers and facilitators (y-axis). Matrices will identify y-axis themes common to all groups, and features specific to particular subgroups[81]. For instance, the experience of implementing VR for clients may be related to organizational themes not evident among staff or leaders.

Overall, Aim 3 will optimize VR delivery and inform VR scalability, sustainability, and generalizability.

- Budget impact analysis (BIA) will assess the costs of implementing VR. BIA will yield two critical data: (1) an estimate of the cost of implementing VR at Thresholds, and (2) a spreadsheet model that other community mental health agencies can use to input site-specific parameters in order for them to estimate the costs of implementing VR. Following current best practices for BIA[82], we will use the perspective of the implementing organization and enumerate costs to Thresholds of implementing VR. Beyond the VR costs mentioned in the CEA in *H5*, we will track time spent by Team Leaders and Employment Specialists training, time spent by staff maintaining the VR hardware, and software costs. All project staff will be provided an Excel-based template to record time spent on each VR-related activity[83]. Total costs for each arm will be aggregated and compared. Sensitivity analysis will be used to vary different cost component input values (e.g., number of trials per study participant) to determine the range of estimated total costs for each arm.

15.0 Data Monitoring Plan to Ensure the Safety of Participants:

We will use a protocol-specific Data Safety Monitoring Board (DSMB). The operation of this board will adhere to the guidelines for DSMBs outlined by the NIH and the U.S. Department of Human Services. The specific aspects of the DSMB for this study are as follows:

1. The DSMB will consist of 3 members: a biostatistician (Borko Jovanovic, Ph.D., Department of Preventive Medicine), who will serve as DSMB Chair, a physician (Cindy Nowinsky, M.D., Ph.D., Department of Neurology), and a behavioral scientist (Benjamin Schalet, Ph.D., Department of Medical Social Sciences).

2. The DSMB will meet twice per year in Year 1 and annually in Years 2-5 to review study data concerning recruitment, randomization, retention, compliance, form completion, gender and minority inclusion, intervention effects, and safety. In addition, the DSMB will: 1) identify specific safety concerns for participants and communicate these to the study PI; 2) consider the need for additional data concerning participant safety; 3) consider the rationale for the continuation of the study; 4) provide a written report concerning the protocol to the IRB and to the study PI; and 5) review manuscripts reporting study results prior to submission.

3. Each meeting will consist of three parts. First, an open session will occur in which Dr. Smith and the DSMB will review the conduct of the trial (e.g., accrual, protocol compliance). Next, to maintain the

blind of the study, a closed session involving only the DSMB and the statistician will be held during which the statistician will present preliminary study data and any reported adverse events or serious adverse events. Lastly, an executive session involving only DSMB members will be held to allow the DSMB the opportunity to discuss the conduct of the trial and outcomes, including adverse events, develop recommendations, and take votes as needed.

4. The DSMB written recommendations will be provided to the NU PI and to the IRB. The DSMB will summarize AE reports for the PI and the IRB Chair, and the PI must implement any DSMB recommendations expeditiously. All DSMB recommendations will also be forwarded to the NIH and the FDA (where necessary).

16.0 Qualifications to Conduct Research and Resources Available:

Thresholds Inc.

Founded in 1959, Thresholds serves more than 6,700 people with psychiatric disabilities annually through 25 agency programs at more than 70 sites (including 60+ staffed residences) throughout Chicago and surrounding suburbs. Thresholds works with individuals experiencing most severe psychiatric disabilities, namely schizophrenia, bipolar disorder and major depression; these disabilities affect between eight to 15 million Americans annually. Individuals with psychiatric disabilities at Thresholds also comprise are a diverse population of people who enter into the system of care not only affected by mental health issues and chronic poverty, but typically with co-occurring physical health conditions and disabilities including substance abuse, diabetes, respiratory illnesses related to smoking, and other advancing health problems. Many of individuals also live with co-occurring disabilities (e.g., people who are deaf or hard of hearing), are individuals with psychiatric disabilities who are exiting inpatient psychiatric facilities, jails and prisons, or other institutional settings, experience chronic homelessness, are youth and or Wards of State, pregnant and parenting teens, and veterans. Thresholds takes pride in serving some of society's highest-need, highest-barrier populations that other service providers are ill-equipped to serve. The agency has received multiple awards, including those from the American Psychiatric Association, the Substance Abuse and Mental Health Services Administration (SAMHSA), Psychiatric Rehabilitation Association, the National Alliance on Mental Illness (NAMI), and the National Association for Business Resources, among others.

Based on the diverse and complex needs and challenges that face individuals with psychiatric disabilities, Thresholds supports comprehensive and adaptable approaches to mental and physical health recovery and wellness to ensure each individual is on a positive path towards self-sufficiency and community participation. In order to meet the needs of individuals with psychiatric disabilities, their families, and other stakeholders, Thresholds supports multi-layered, integrated systems of care, including specialized programs for individuals with other disabilities, e.g., are individuals who are deaf. Within the Research Department and Evaluation Department, Thresholds has been a partner in developing and evaluating model programs with academic centers (e.g., UIC, Northwestern University, the University of Chicago, Dartmouth College, Illinois Institute of Technology, and Boston University), among others. These programs include the implementation of recognized evidence-based practices (EBPs) in PSR, as well as other demonstration programs specifically designed, tested, and supported at the agency, such as case management, educational advancement, housing, independent living skills development, health education and assessment (including diabetes management, smoking reduction, HIV risk assessment and testing), and employment services, as part of its holistic approach to treatment. These model programs include intensive, team-based approaches that address the full spectrum of health and social service needs. To date, the agency also maintains active research and evaluation of innovative services and programs with the UIC Colleges

of Medicine and Nursing (including those related to supported employment and IPS), Dartmouth College, and Boston University, as well as other academic and community partners.

Thresholds uses the Gold Standard 'Individual Placement and Support (IPS)' version of 'Supported Employment.' Currently, more than 700 Thresholds members receive Supported Employment and they receive IPS at 4101 N. Ravenswood Ave, Chicago, IL 60613. This location is just a few miles from Dr. Jordan's office in the Department of Psychiatry and Behavioral Sciences at Northwestern University Feinberg School of Medicine.

Thresholds will allocate shared space at their main center, 4423 N. Ravenswood Ave, Chicago, IL 60613. The space will include three offices to be shared by the study with existing services provided at Thresholds. The first two rooms are already outfitted with the necessary technology to administer the intervention. Since these rooms are already being used to facilitate vocational services, the addition of the study intervention in this environment will maintain the ecological validity of an effectiveness trial. Although the rooms are shared with other vocational services, time spent on the study will be coordinated by a scheduling calendar and time spent in the rooms will be private (no one else in the room during the simulated interviews). To demonstrate the scalability and generalizability of the intervention, Thresholds will use existing computers that include a microphone and speakers so that trainees can effectively interact with the intervention.

Northwestern University Feinberg School of Medicine

Northwestern University Clinical Research Program (NU-CRP):

NU-CRP is a collaborative, interdisciplinary research program within the Department of Psychiatry and Behavioral Sciences at Northwestern University Feinberg School of Medicine that conducts translational research projects that aim to determine the disease processes that cause severe mental illness or promote its progression as well as develop treatmens. NU-CRP uses a multidisciplinary approach with PIs trained in psychiatry, radiology, chemistry, social work, epidemiology, and computer engineering.

NU-CRP Clinical Research Core. The clinical research core is located on the 15th floor at 680 North Lake Shore Drive, Chicago, IL 606011. The pretest-posttest video-recorded role-plays will be conducted at this location. The Department of Psychiatry and Behavioral Sciences has allocated dedicated clinical research space. This space is located at 680 Lake Shore Dr. Suite 1520; Chicago, IL 60611 and occupies 3776 square feet. It is in an access restricted suite that is connected to the administrative and faculty offices via a locked doorway. In addition to office and workstation space for clinic staff, the clinical research space includes 5 interview rooms that will be used for this study. There are also several other rooms available in this suite that will not be used for this study including 2 cognitive testing rooms, an eye-tracking room, a modern laboratory for processing biological specimens, a phlebotomy area with 1 station for drawing blood (including one reclining chair), and a fully equipped exam room for physical exams. The interview rooms range in size from 100 square feet to 200 square feet and four public restrooms located in the hallway outside of the suite.

Center for Prevention Implementation Methodology (Ce-PIM):

Ce-PIM is a 5-year NIDA funded P30 Center of Excellence that is housed at Northwestern University and directed by Dr. C. Hendricks Brown. Its mission is threefold: to integrate and extend systems science methods to address critical research challenges in **federally funded implementation research**, to facilitate the seamless integration of methodology into the next generation of prevention research, and to **integrate the methods into wide scale practice of implementation**. The wide-scale implementation of such programs that target large portions of the population has the potential for reducing drug, alcohol, and tobacco abuse, improving mental health, and reducing

the incidence of HIV, HPV, and other sexually transmitted diseases. We focus on *systems science* methods to advance the conduct of implementation research. The term system science refers to a transdiciplinary approach to *understanding how interactions between elementary units produce complex patterns*. The structure of Ce-PIM involves an administrative core and a Methods Core. We work closely with 12 qualified grantees and other colleagues, who are already funded to conduct research related to implementation. We have focused on innovations that address all three major stages of the implementation process, from adoption, **implementation with fidelity**, and sustainability or moving to scale. These innovative methods all emerge from a systems orientation, and they include systems engineering to characterize and advance the implementation model; social network analysis; agent based modeling; intelligent data analysis and machine learning, and design of randomized implementation trials that can be used in large systems as programs are being rolled into communities.

The Center's Administrative structure includes a committee on communication with both practitioners and scientists and partnership formation; a committee on pilot funding and mentoring of early stage investigators into the prevention implementation field. In additions, Ce-PIM is developing tools for use in both implementation research and in practice to support measurement of the implementation process and decision making by service organization and policy makers. Ce-PIM works closely with both researchers and policy makers to facilitate the development of more effective implementation strategies, to design tests and refinement procedures of these strategies, and to enhance training in implementation research methods.

The following Ce-PIM resources are fully available to assist Dr. Smith to assess the implementation of VR. First, Dr. Brown and his colleagues have experience in guiding early career investigators in the field of implementation science, and we will provide Dr. Smith access to material from their national trainings that they have conducted as well as linkages to experts around the country, a Ce-PIM expert in mixed methods who will serve as a consultant on this proposal. Secondly, Ce-PIM sponsors virtual grand rounds each week; this virtual network has a membership of over 300 researchers representing diverse areas of expertise in mental health and drug abuse. These grand rounds provide not only access to the newest research on implementation being conducted but also provide an effective way to obtain feedback from experts on this project as Dr. Smith will be asked to present his work at a point sufficiently early in the project where advice will be most beneficial. Thirdly, there will be local support from Ce-PIM that goes beyond the effort provided by Dr. Brown. Key to this project is the premise that the virtual reality based system will provide the user with practice and quality feedback around job interview skills. Fidelity monitoring and feedback is of central importance to Ce-PIM, and we have Ce-PIM experts in Dr. Smith's and Dr. Brown's department who are conducting groundbreaking research in automating such fidelity systems. The Center's mission to synergize the field will be both informed by and provide innovation to this project.

Both research locations (Thresholds and NU) are located within close proximity to mental health treatment providers. The resources in place to support participants in case of anticipated consequences are listed in 10.0 Risk to Participants

Adequate Training for Research Staff. The PI (Dr. Smith) or appropriate designate will conduct training sessions and direct research staff to run a series of mock participants in all study procedures prior to beginning the studies. All research staff will be cross-trained to administer all aspects of the research study. Prior to being authorized to provide an assessment, study personnel must observe 3 sessions of the PI or qualified research staff administering the assessment. Then the trainee must perform a series of 3 administrations with the assessment while observed by the PI or qualified research staff. After administering the assessments 3 times, the ability of the research staff will be reviewed with him or her and they will be authorized or asked to fine tune their performance until rated as acceptable.

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Appendix A: Thresholds Locations for Study Visits and Molly Delivery

12145 S. Western Ave., Blue Island IL 60406- "South Suburbs"

12151 S. Western Ave., Blue Island 60643- "New Freedom Center, South Suburbs"

4101 N. Ravenswood Ave., Chicago IL 60613- "4101"

4423 N. Ravenswood Ave., Chicago IL 60613- "Research Team Office"

5357 N. Broadway, Chicago IL 60640- "Peer Success"

734 W. 47th Street, Chicago IL 60609- "Bridge South"

4219 N. Lincoln Ave, Chicago IL 60618- "Young Adult Program"

3638 S. Kedzie Ave., Chicago IL 60632- "Bridge Southwest"

2240 W. Ogden Ave., Chicago IL 60612- "Supported Employment & Veterans Program"

5000 W. Roosevelt Rd., Chicago IL 60608- "Bridge West"

716 W. 47th Street, Chicago IL 60606- "Freedom Center, South"

2045 W. Grand Ave, Chicago IL 60612- "New Freedom Center, North"

120 S. LaSalle St., Chicago IL 60603- "HQ"

202 N. Schuyler Ave., Kankakee IL 60901- "Kankakee"

444 Frontage Rd., Northfield IL 60093- "New Foundations Center"

7400 Skokie Blvd., Skokie IL 60077- "North Suburbs"

777 Oak Lane, Westmont IL 60559- "Westmont"

109 S. Jefferson St., Woodstock IL 60098- "McHenry"