ILLINOIS
Office for the Protection of Research Subjects

Protocol Form

IRB Number: 22606

Human Subjects Research – Protocol Form

Guidelines for completing this research protocol:

- Please submit typed applications via email. Handwritten forms and hard copy forms will not be accepted.
- For items and questions that do not apply to the research, indicate as "not applicable."
- Provide information for all other items clearly and avoid using discipline specific jargon.
- Please only include text in the provided boxes. The text boxes will expand as they are typed in to accommodate large amounts of text.

Before submitting this application, ensure that the following have been completed.

- Protocol Form is complete.
- Relevant CITI modules have been completed for all members of the research team at www.citiprogram.org.
- Informed consent/assent/parental permission document(s) are provided.
- Relevant waivers and appendices are provided.
- Recruitment materials are provided.
- Research materials (e.g. surveys, interview guides, etc.) are provided.
- Any relevant letters of support are provided.

Instructions on the non-exempt review process and guidance to submitting applications, can be found on the OPRS website. You may also contact OPRS by email at irb@illinois.edu or phone at 217-333-2670.

Submit completed applications via email to: irb@illinois.edu.

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Section 1: PRINCIPAL INVESTIGATOR (PI)

The Illinois Campus Administrative Manual allows assistant, associate, and full professors to act as PI. Other individuals may serve as PI after obtaining approval from the necessary party.			
Last Name:	First Name:	Degree(s):	
Dept. or Unit: Social Work	Office Address: 2113		
Street Address:	City: Urbana	State: IL	Zip Code:
Phone:	E-mail:		
Urbana-Champaign Campus Status: Non-visiting member of (Mark One) ☒ Faculty ☐ Academic Professional/Staff (*Student Investigators cannot serve as PI*)			
Training ☒ Required CITI Training, Date of Completion (valid within the last 3 years), 2/10/2021 ☐ Additional training, Date of Completion,			

Section 2. RESEARCH TEAM

2A. Are there other investigators engaged in the research?
☒ Yes (include a Research Team Form)
☐ No

2B. If yes, are any of the researchers not affiliated with Illinois?
☒ Yes
☐ No

Section 3. PROTOCOL TITLE

COVID-19 Treatment Cascade Optimization Study (Here after referred to as COVID-19 IL Study)

Section 4. FUNDING SOURCE

4A. Is the research funded?
☐ Research is **not funded** and is **not pending** a funding decision (Proceed to Section 5).
☒ Research is **funded** (funding decision has been made).
☐ Funding decision is **pending**. Funding proposal submission date: 07/07/2021- JIT 12/13/2021

4B. Indicate the source of the funding.
☐ University of Illinois Department, College or Campus, *please specify*:
☒ Federal, *please specify*: NIH
☐ Commercial Sponsorship & Industry[1,2], *please specify*:

[1] Clarify whether or not sponsor requires specific language in the contractual agreement that impacts human subjects research
[2] Clarify whether or not the sponsor requires the protocol adhere to ICH GCP (E6) standards

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☐ State of Illinois Department or Agency, *please specify*: ☐ Other, *please specify*:
4C. Sponsor-assigned grant number, if known: 1U01AI169469 - 01
4D. A complete copy of the funding proposal or contract is attached. ☒ Attached, *please specify title*: COVID-19 Treatment Cascade Optimization Study
4E. Funding Agency Official To Be Notified of IRB Approval (if Applicable) **Name:** Program Officer TBD- Erin Khandjian, Grants Management Specialist **Agency:** NIAID/NIH **E-mail:** Erin.khandjian@nih.gov **Phone:** 301-761-6557

Section 5. CONFLICTS OF INTEREST

Please indicate below whether any investigators or members of their immediate families have any of the following. If the answer to any of the following items is yes, please submit the University of Illinois approved conflict management plan. If you have any questions about conflicts of interest, contact coi@illinois.edu.
5A. Financial interest or fiduciary relationship with the research sponsor (e.g. investigator is a consultant for the research sponsor). ☐ Yes ☒ No
5B. Financial interest or fiduciary relationship that is related to the research (e.g. investigator owns a startup company, and the intellectual property developed in this protocol may be useful to the company). ☐ Yes ☒ No
5C. Two or more members of the same family are acting as research team members on this protocol. ☐ Yes ☒ No

Section 6. SUMMARY & PURPOSE OF RESEARCH

6A. In lay language, briefly summarize the objective and significance of the research.

COVID-19 has impacted the health and social fabric of individuals and families living across the United States; and it has disproportionately affected people living in urban communities with co-morbidities, those working in high-risk settings, refusing or unable to adhere to CDC guidelines, and more. Social determinants of health (SDH), such as stigma, racial discrimination, xenophobia, incarceration, and poverty have been associated with increased exposure to COVID-19 and increased deaths. Marginalized communities, defined as low-income and racial/ethnic minority neighborhoods, where residents experience increased barriers (e.g., inadequate housing, high-risk jobs) to prevention and treatment, bear disproportionately higher rates of co-morbidities associated with more severe cases of COVID-19. While effective and potent vaccines are becoming more available, it will take time to reach herd immunity and it is unclear how long newly-developed vaccines provide protection and how effective they are against emerging variants. Therefore, prevention methods recommended by the Centers for Disease Control and Prevention (CDC) – i.e., testing, hand-washing, social distancing, contact tracing, vaccination, and quarantine -- are essential to reduce the rates of COVID-19 in marginalized

communities. Research about COVID-19 testing and vaccine uptake in these communities must occur in real time and it must account for the fast-changing landscape of the pandemic, including the impact of vaccine availability on testing uptake. Two cost-effective, evidence-based, and culturally appropriate interventions have been effective in engaging people in HIV prevention and treatment – these can be adapted and tested to help address COVID-19 prevention needs. Specifically, Navigation Services (NS) have been shown to increase HIV testing and adherence to treatment while addressing structural barriers that deter treatment engagement in high-risk communities; and Brief Counseling (BC) has been shown to increase HIV treatment engagement.

Dr. Windsor has an ongoing grant (3 R01 MD010629-04S2 – From here after referred to as COVID-19 NJ Study)) which aims to optimize an adaptive intervention to increase testing, and access to treatment and to prevention of COVID-19 infections in a medically or socially vulnerable sample of 670 people in Essex County, NJ. The COVID-19 NJ Study is under the North Jersey Community Research Initiative (NJCRI) IRB oversight, entitled *Optimization of a new adaptive intervention to increase COVID-19 testing among people at high risk in an urban community*, Protocol #: CWCOVIDSUPP-UIUC-NJCRI 102497-18274-267805 and has a reliance agreement in place with UIUC.

The new project, COVID-19 IL Study, which is being reviewed by the UIUC IRB, proposes to expand the NJ project to include a sample of 548 people in Illinois. We will use the same protocol that was used in NJ in addition to de-identified data that is currently being collected by the COVID-19 NJ Study. The final study sample will include 670 people from NJ and 548 people from IL for a total of 1,218. Data from the 670 people in NJ will be treated as secondary data and data from the 548 people in IL will be treated as primary data under the COVID-19 IL Study IRB protocol.

The COVID-19 IL Study will use Multiphase Optimization Strategy (MOST) and Community-Based Participatory Research (CBPR) principles and best practices to help facilitate recruitment and to make results readily available to the population. Illinois participants will be randomized two separate times: First, into two distinct groups to receive: (1) navigation services or (2) informational brochure. We aim to help participants to get a COVID-19 test between baseline and the first follow-up (7 days post baseline). Second, after completing the first follow-up, participants are then randomized again to continue with the original intervention or switch to a new one. We then collect data at 3; 5; 12; and 24 weeks post-baseline follow-ups.
The COVID-19 IL Study specific aims include:

Primary Aims: (1) To examine the effectiveness of an adaptive intervention to increase COVID-19 testing and adherence to CDC-recommendations of preventive behaviors – social distancing, hand-washing, mask-wearing, vaccination- on comparable but distinct samples. We will control for baseline, time, demographics and COVID risk; (2) To examine the immediate and medium-term impact of the adaptive intervention on COVID testing and adherence to recommendations by collecting follow up data at 2,5,12, and 24 weeks post baseline.

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Implementation aim: To collect intervention implementation data (context, cost, barriers, lessons learned) and develop implementation materials (facilitator training, intervention manual, treatment fidelity measure).

6B. Indicate if your research includes any of the following:

☒ Secondary data (use of data collected for purposes other than the current research project) De-identified collected data by the COVID-19 NJ Study, described in final paragraph of 6A and COVID-19 testing results collected from CBHC.

☐ Data collected internationally (include International Research Form)

☐ Translated documents (include Certificate of Translation Form and translated documents)

☐ Research activities will take place at Carle (include documentation (email or letter) from Carle stating that the review of your Research Services Request Form is complete)

6C. Letters of support from outside institutions or entities that are allowing recruitment, research, or record access at their site(s) are attached. ☒ Yes ☐ Not Applicable

Letters of support from NJCRI and CBHC are in the NIH proposal (p.129- 132 of the attached proposal PDF)

Section 7. PROCEDURES

7A. Select all research methods and/or data sources that apply.

☒ Surveys or questionnaires, *select all that apply*: ☐ Paper ☐ Telephone ☒ Online

☒ Interviews

☒ Focus groups ("Critical Dialogue" Sessions)

☐ Field work or ethnography

☐ Standardized written, oral, or visual tests

☐ Taste or smell testing

☐ Intervention or experimental manipulation

☐ Exercise and muscular strength testing

☐ Noninvasive procedures to collect biological specimens (e.g., hair and nail clippings, saliva, etc.)

☐ Noninvasive procedures to collect physiological data (e.g., physical sensors, electrocardiography, etc.)

☐ Procedures involving radiation

☒ Recording audio and/or video and/or taking photographs

☐ Recording other imaging

☒ Materials that have already been collected or already exist, *specify source of data*: De-identified data collected at another project that is led by the PI, Dr. Windsor in New Jersey at NJCRI using the same protocol will be analyzed.

☐ HIPAA-protected data

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☐ FERPA-protected data ☐ GDPR-protected data ☐ Other, *please specify*:
7B. List all testing instruments, surveys, interview guides, etc. that will be used in this research. Eligibility Screener Enrollment Baseline Survey Follow up 1 to 4 Survey Brochures **Drafts or final copies of all research materials are attached.** ☒ Yes
7C. List approximate study dates. 01/01/2022- 12/31/2023
7D. What is the duration of participants' involvement? 6 months
7E. How many times will participants engage in research activities? Participation will complete 1 baseline and 4 follow up assessments. Those randomized to Navigation Services will complete at least one phone session of up to 30 minutes on the phone. They may request as many navigation sessions as they need. Those randomized to Brief Counseling will complete one 15 minutes long phone session. Those randomized to Critical Dialogue will complete one 60 minutes long session in-person or online.
7F. Narratively describe the research procedures in the order in which they will be conducted. This study will track participants for six months in order to capture changes over time in COVID-19 testing and adherence to public health recommendations. We will use a Sequential, Multiple Assignment Randomized Trial (SMART) with a total sample of 1,218 COVID-19 medically and socially vulnerable people, 548 of which will be primary data collection and 670 will be secondary data. All participants will receive at least one intervention and no more than two interventions, depending upon randomization. After having been determined eligible through a brief phone screening process, participants will be invited to provide consent to participate and complete the baseline online. Those interested in the study will call the study phone. A research assistant or outreach worker will complete the phone screening with the participant to determine eligibility. If eligible, they will be asked to provide alternative forms of contact in case we are unable to reach them. The staff will explain that they will let the alternative contact know we are looking for the participant because it is time for them to complete their follow-up survey. Participants may choose not to provide any contacts. Those who complete the baseline will then be randomized by Redcap to either receive Navigation Services or Brochure: Navigation Services (NS): Navigation services include assessment and support with service referrals. Each participant randomized to this intervention will meet with a peer navigator in person or on Zoom Conferencing for 30 minutes to go over results from their social and health needs assessment that is retrieved from the base-line survey. The navigator shares information about COVID-19, answers questions about testing, and makes referrals to other needed services (e.g., housing, food, mental health, employment, transportation, primary care). The participant is then referred to the testing site and encouraged to get tested as soon as possible. The peer navigator calls participants who consent to follow up, find out what services they received, and what services they still need. The frequency of sessions is decided between the participant and the navigator. The peer navigator can then make new referrals and help participants address

identified barriers to services. All referrals and referral outcomes will be tracked and entered into the project database.

Brochure: This intervention includes two different electronic brochures: One with information about COVID-19 testing (including where and how to get tested), and one with information about COVID-19 prevention and treatment. The brochures will be updated in real time to reflect the most recent CDC public health recommendations. Brochures will be e-mailed to all participants automatically by Redcap upon randomization and one week after they complete the baseline.

Once randomized, all participants will receive the brochure that includes information about testing at CBHC. Navigators will speak to their clients about testing, and, if the participant is interested, they can schedule the COVID-19 test for participants. Note participants will not be pressured to test. They will simply receive the information on how to do so and we will ask them to do it prior to completing their follow-up, if they choose to get tested. Home tests will not be accepted for the purposes of the study.

One week post-baseline, participants will complete the first follow-up survey. Those who received a COVID-19 test between baseline and Follow-up 1 will be randomized to either continue to receive their original intervention (NS or Brochure) or to switch to receive Brief Counseling. Those who fail to get a COVID-19 test between baseline and first follow-up will be randomized to continue the original intervention (NS or Brochure) or switch to receive Critical Dialogue:

Brief Counseling (BC): Brief Counseling is a 15-minute post-COVID-19 test session delivered by a trained licensed clinician in person or via Zoom Conferencing. In the session, the clinician shares the test results and offers recommendations and information about COVID-19 treatment and prevention. Clinicians will be members of the research team and employed by CBHC.

Critical Dialogue (CD): Critical Dialogue includes one two-hour “focus group” session facilitated in person or online by a trained licensed facilitator. Group critical dialogue is prompted by thematic images developed by the NCCB to foster a deeper understanding of how systematic stigma, feelings of rage as victims of discrimination, and/or apathy may impact participants’ beliefs and behaviors related to COVID-19 and empower participants to make critical choices to protect their health and the health of their communities.

Participants who report not getting tested in follow-up 3 will be invited to participate in a Critical Dialogue session before completing Follow-up 4.

All participants will be asked to complete follow ups 4 and 5. We will collect screening data via phone, and in-person baseline assessment, and follow- ups at 2, 5, 12 and 24 weeks follow-ups. Participants will be encouraged to complete the surveys online, using their phones, a tablet, or computer. They can also request to meet the outreach workers at CBHC or a public place to complete the data collection using a study tablet, as long as they agree to adhere to the most current public health recommendations (e.g., social distancing).

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After each assessment, participants will be asked to provide extensive locator information, on forms used for the parent study, including formal and informal contacts who can reach the participant in a variety of contingencies. During the follow-up period, outreach workers will maintain monthly contact with participants by mail or phone and will update locator information. Randomization and data collection will be done online using Redcap. We will voice record all Critical Dialogue sessions with participants' consent and will randomly select 20% of them for analysis.

The research team will randomly select 35 participants at each site who decline to be tested for COVID-19 and invite each of them to complete an in-depth, one-on-one, qualitative interview lasting about 30 minutes. After providing written informed consent, participants will be assigned code names and asked to talk about their experiences with the intervention, barriers they faced to testing and adhering to public health guidelines, and their ideas about how to address these barriers. The interviews will be digitally voice-recorded, transcribed and entered into Atlas.ti for storage and analysis. Transcripts and Atlas.ti files will be identified only by code name.

Additionally, data from the COVID-19 NJ Study will be analyzed. These data include the exact same surveys as the data being collected in Illinois. The data is being collected under NJCRI's IRB number. UIUC deferred to the NJCRI IRB because all the NJ data is being collected there. The NJ data will be de-identified and shared electronically by the NJ research assistant using Box. The NJ data will then be merged with the Illinois data for analysis.

The figure below illustrates the study design:

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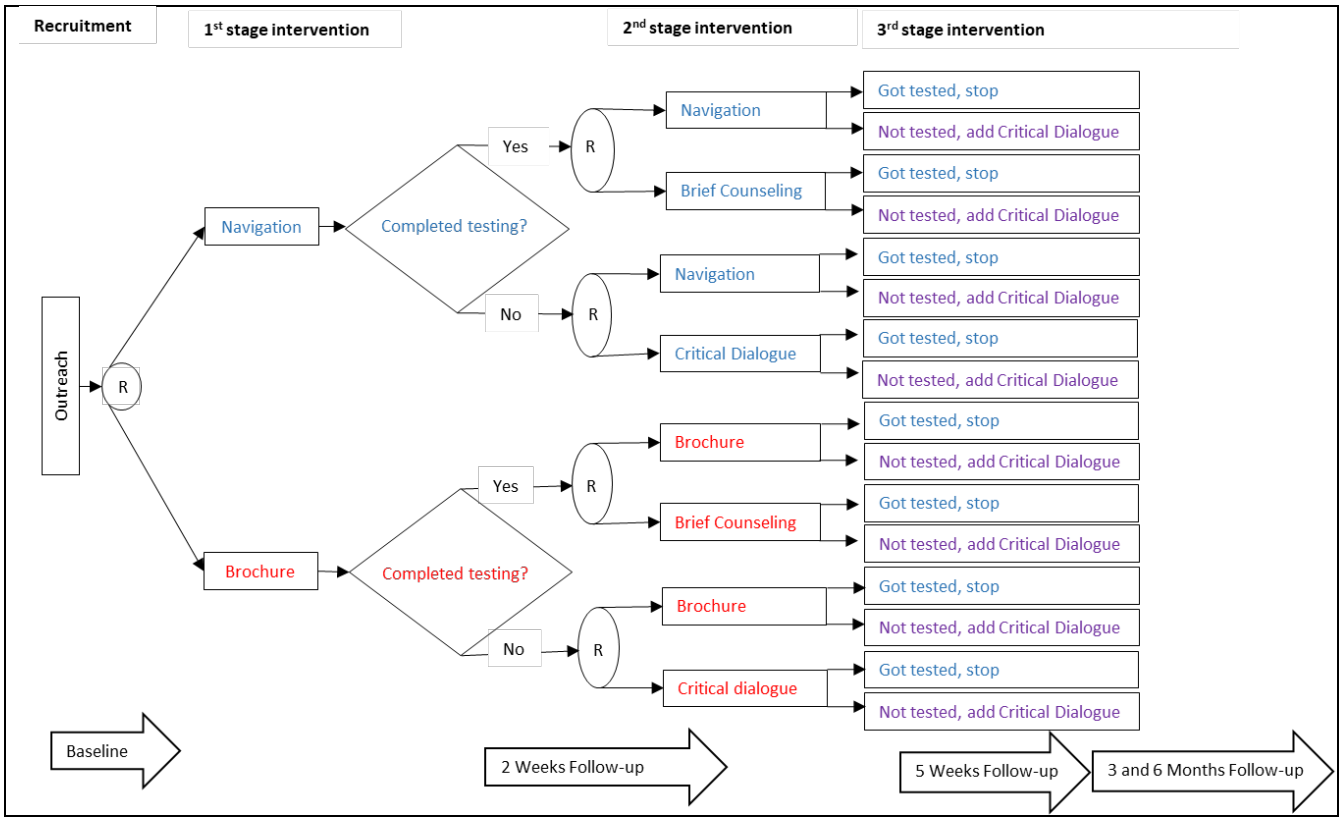

Section 8. PERFORMANCE SITES TO INCLUDE INTERNATIONAL, SCHOOL, AND COLLABORATIVE STUDIES

8A. List <u>all</u> research sites for the protocol. For non-University of Illinois at Urbana-Champaign sites, describe their status of approval and provide contact information for the site. If the site has an IRB, note whether the IRB has approved the research or plans to defer review to the University of Illinois at Urbana-Champaign.	
Performances Sites	
#1	Comprehensive Behavioral Health Center (CBHC)- East St. Louis, IL CBHC will defer to UIUC IRB
#2	North Jersey Community Research Initiative (NJCRI), Newark, NJ FWA00001870 NJCRI will defer to UIUC IRB
#3	University of Michigan (UM) FWA00004969 UM will defer to UIUC IRB
If there are additional performance sites, include them on an attachment and check here: ☐	
8B. Is this a multi-center study in which the Illinois investigator is the lead investigator, or the University of Illinois at Urbana-Champaign is the lead site? ☒ Yes ☐ No	

If yes, answer 8C and 8D. If no, proceed to Section 8E.

8C. Who is the prime recipient of funding, if funded? UIUC

8D. What is the management and communication plan for information that might be relevant to the protection of research subjects (e.g. unanticipated problems involving risks to subjects, interim results, and protocol modifications)? will be responsible for overseeing all data collection and processing. While the proposed study does not seek to test the effectiveness of drugs or a medical device delivered in multiple sites, it will test an adaptive intervention in communities with marginalized populations and there is potential for harm. Thus, we developed a Data and Safety Monitoring Plan (DSMP) and will create an independent Data Safety and Monitoring Board (DSMB) including clinical, intervention, community members, and statistical experts, to conduct periodic independent analyses of the evaluation data in the data collection phase.

Any research staff member who learns of an adverse event is responsible for reporting the event to the Principal Investigators (PI), who are in turn responsible for discussing the event to make a joint decision about whether the event is serious or non-serious. Events will be categorized as adverse or serious adverse according to NIH guidelines: "Adverse events (AEs) are defined as any untoward medical occurrence that may present itself during treatment or administration of an intervention, and which may or may not have a causal relationship with the treatment. Serious adverse events (SAEs) are defined as any medical occurrence that results in death; is life-threatening; requires inpatient hospitalization or prolongation of existing hospitalization; creates persistent or significant disability/incapacity, or a congenital anomaly/birth defects." As such, adverse events (AEs) occurring during the course of the study will be collected, documented, and reported to the PIs. Each week a study investigator will review the AE Forms from the previous week for events that were reported as new or continuing.

Any SAE will be reported to the IRB within 48 hours of the occurrence. The report of SAEs will include whether they were expected or unexpected, a rating of severity of the event, a brief narrative summary of the event, a determination of whether a causal relationship existed between the study procedures and the event, whether the informed consent should be changed as a result of the event and whether all enrolled participants should be notified of the event. Finally, as part of the annual progress report (noncompeting continuation application) to NIH, we would provide summary information on all SAEs that have occurred during that year.

Any actions taken by the IRB will be reported promptly to NIH via the Project Officer or appropriate parties.

Additionally, the PIs will closely monitor the validity and integrity of the data on an on-going basis. The DSMB with also conduct biannual monitoring of the data through spot checks and independent preliminary analysis of the data. For instance, the PIs and the project staff will meet regularly with project interviewers to review assessments and coding of incoming data. The PIs will be responsible for

ensuring that data are being coded, entered and cleaned appropriately. The full research team will meet every week for 120 minutes to review all aspects of the research study.

8E. If subjects will be recruited from Illinois public or private elementary or secondary schools, additional deadlines and procedures may apply. Criminal background clearances might be required. Special consideration must be given to the exclusion of protected populations. Please contact the School University Research Relations (researchplacements@education.illinois.edu) for more information. Select one: ☐ Illinois schools **will** be used ☒ Illinois schools **will not** be used

Section 9. SUBJECT ENROLLMENT GOAL & EQUITABLE SELECTION OF SUBJECTS

9A. For each performance site, indicate the estimated total number of participants.

Performance Site		# Male	# Female	Total
#1	CBHC	252	295	548
#2	NJCRI (oversight by NJCRI IRB)	328	341	670
#3	UM	0	0	0
TOTALS		**580**	**636**	1218

If additional performance sites are included on an attachment, check here: ☐

9B. Select all participant populations that will be recruited.

Age:
☒ Adults (18+ years old)
☐ Minors (≤17 years old)
☐ Specific age range, *please specify*:

Gender:
☒ No targeted gender (both men and women will be recruited/included)
☐ Targeted gender, *please indicate*: ☐ Men/boys ☐ Women/girls ☐ Other, *please specify*:

Race/Ethnicity:
☒ No targeted race or ethnicity (all races and ethnicities will be recruited/included)
☐ Targeted race or ethnicity, *please specify*:

College Students:
☒ No targeted college population
☐ UIUC general student body
☐ Targeted UIUC student population, *provide the instructor or course information, name of the departmental subject pool, or other specific characteristics*:
☐ Students at institution(s) other than UIUC, *please specify*:
Any research with students on UIUC's campus needs to be registered with the Office of the Dean of Students.

Other:
☐ Inpatients
☐ Outpatients
☐ People who are illiterate or educationally disadvantaged

☒ People who are low-income or economically disadvantaged
☐ People with mental or cognitive disabilities or otherwise impaired decision-making capacities
☐ Adults with legal guardians
☐ People who are non-English speaking
☐ People with physical disabilities
☐ Pregnant or lactating women, human fetuses, and/or neonates
☐ Prisoners or people with otherwise limited civil freedoms
☒ Other, *please specify*: target population faces disproportionate COVID-19 risks due to employment as essential workers, poverty, inadequate or unstable housing, and underlying medical conditions.

9C. Describe additional safeguards included in the protocol to protect the rights and welfare of the populations selected above.

To avoid possible violations of confidentiality, project staff are trained to carefully follow detailed procedures designed to assure that no information about any participant (or others they may mention) will be given to law enforcement, other government agencies, or anyone but research staff. Every member of the research team and all Newark Community Collaborative Board (NCCB) members will be required to undergo human subject protection training and provide a certificate of completion to the IRB prior to any contact with human subjects. To reflect changes resulting from expansion to the existing study, individuals from the East St. Louis area will be appointed to the NCCB as well. Standards of confidentiality include the use of code numbers and code names for participants and other individuals they may mention. The only place participants' names or other identifying information will appear is on informed consent forms and locator forms (used for follow-up interviews after the baseline). These forms will be kept electronically in REDCAP, in a folder separate from the data. Only full time, trained staff in the project including the outreach works, project coordinator, research assistant, and PIs will have access to these files. Peer navigators will not have access to data from the individuals that are randomized into their groups. They will receive a report from RedCAP highlighting any reported risk for COVID-19 exposure that they will be discussing with the participant during the navigation.

The electronic files generated through data collection will be identified by code numbers and codenames only and kept in password-protected devices/servers, separate from identifying information and available only to project staff. This helps to ensure that no identifying information will be disclosed in the unlikely event that computerized data are stolen or otherwise seen by unauthorized persons.) All identifying electronic data will be destroyed immediately after data analysis is completed. Signed consent forms will be kept for 3 years after study completion. Deidentified electronic data will be kept indefinitely. Participants may ask at any time to have recordings of their interview destroyed by calling/e-mailing one of the Principal Investigators at the numbers provided in the informed consent forms. Voice recordings will be kept indefinitely for data analysis. However, if we have reason to believe that any of these recordings contain information that can put any of our participants in danger of being harmed, we will destroy the recording.

Our interviewers are trained to watch participants carefully and will stop questioning if an individual appears uneasy. At every interview, participants will be informed that they may ask the interviewer to stop if they are feeling uncomfortable. Referrals to counselors are available if participants wish and trained clinical counselors are available at CHBC in the event that someone may need immediate assistance, whether it is during data collection or during the intervention sessions. Dr. Windsor, Dr. Benoit, and Mr. Harper will be available by phone at all times in case an emergency occurs. Clinical emergencies will be handled by treatment teams of experienced staff at CBCH under the leadership of Mr. Harper. Appropriate assessments will be conducted; treatment options will be recommended and followed through as necessary. CBHC routinely provides services to individuals with mental health and substance use disorders is fully equipped to address any potential emergencies either themselves or via referrals.

Finally, the research team and the clinical team will engage in weekly project meetings to discuss the progress of the study and identify, discuss, and address any potential issues.

Section 10. INCLUSION/EXCLUSION

10A. List specific criteria for inclusion and exclusion of subjects in the study, including treatment and control groups.

Criteria for inclusion include:

- 18 years of age or older
- having high risk to contract COVID-19 or develop related complications
- able to Speak English
- able and willing to provide informed consent

10B. Explain how the inclusion/exclusion criteria will be assessed and by whom. If special expertise is required to evaluate screening responses or data, list who will make this evaluation and describe their training and experience.

A trained outreach worker will conduct a brief phone screening using the attached brief phone screening to obtain self-reported eligibility information including risk for contracting COVID-19 and developing related complications.

10C. Drafts or final copies of all screening materials are attached. ☒ Yes ☐ Not Applicable

10D. Describe procedures to assure equitable selection of subjects. Justify the use of the groups marked in Section 9B. Selection criteria that target one sex, race, or ethnic group require a clear scientific rationale.

The proposed study does not include children because the adaptive intervention will focus on adult behaviors and it would not be appropriate to include children. The staff has been trained to work with adults and the parent grant only included individuals over the age of 18. Finally, the supplement includes several interview questions regarding social determinants of health that children would not be able to answer. Recruitment will be open to residents of both Essex County, NJ and St. Clair County, IL, but given the location of the study sites, we expect that the vast majority of participants will come from the

Newark, NJ and East St. Louis, IL areas. As such, we estimate that our sample will approximate the demographics of Newark and East St. Louis in terms of sex/gender, race and ethnicity. Because of this, we anticipate that Black participants will be overrepresented in our sample.

Section 11. RECRUITMENT

11A. Select all recruitment procedures that will be used.

- ☐ Student subject pool, *please specify*:
- ☐ Email distribution
- ☐ MTurk, Qualtrics Panel, or similar online population, *please specify*:
- ☐ US Mail
- ☒ Flyers/brochures
- ☐ Website ad, online announcement (e.g. eWeek), or other online recruitment, *please specify*:
- ☐ Newspaper ad
- ☒ Verbal announcement
- ☒ Other, *please specify*: Street outreach
- ☐ Not applicable (secondary data only)

11B. Drafts or final copies of all recruitment materials (including verbal scripts) are attached.

☒ Yes ☐ Not Applicable

11C. For each group of participants, describe the details of the recruitment process.

We will enroll a sample of 548 in St. Clair County. The NCCB and outreach staff will post fliers at bus stops, health care agencies, churches, bulletin boards, and social service agencies, giving consideration to the demographic characteristics of those agencies' clients and of neighborhoods. Individual service providers and potential participants will be asked to share the study's fliers in their neighborhoods, churches and other meeting places. Those who are interested will call the study phone number that is listed on the flyer. Street outreach will be used following social distancing protocol. All consenting CBHC clients will be screened and those eligible will be invited to participate in the study. People interested in participating will call the study's cell phone number. A trained outreach worker will conduct a brief phone screening using the same brief phone screening that is currently being used in the Essex County, NJ to obtain self-reported eligibility information including risk for contracting COVID-19 and developing related complications.

Section 12. REMUNERATION AND PLAN FOR DISTRIBUTION

Refer to the University Business and Financial Policies and Procedures for further guidance on the compensation process and reporting requirements.

12A. Will subjects receive inducements or rewards before, during, or after participation?

☒ Yes ☐ No

If yes, complete the rest of Section 12. If no, proceed to Section 13.

12B. Select all forms of remuneration that apply.

☒ Cash*, please specify amount:* $30 for baseline, $40 per follow up, and $50 for the exit interview for a maximum possible of $240 per individual

☐ Check, *please specify amount:*

☐ Gift Certificate, *please specify amount:*

☐ Lottery, *please specify amount:* *and odds:*

☐ Course Credit, *please specify amount:* *and specify equivalent alternative activity:*

☐ Other, *please specify*:

12C. Will payment be prorated before, during, or after participation?

☒ Yes, *please specify how:* Payments will be received after completion of each survey during the study.

☐ No

12D. For each group of participants, describe the details of the remuneration plan, including how, when and by whom they will be notified.

Participants will receive modest cash incentives for taking part in data collection activities. Each participant will receive $30 for completing the baseline assessment. Each participant will receive $40 per each of the four "follow up" visits. The maximum amount possible for participation is $240 per individual

12E. The information listed above is provided on the relevant consent forms.

☒ Yes

Section 13. RISKS & BENEFITS

13A. Describe all known risks to the participants for the activities proposed, such as risks to the participants' physical well-being, privacy, dignity, self-respect, psyche, emotions, reputation, employability, and criminal and legal status. Risks must be described on consent forms.

The main potential risks of this study include inadvertent violation of confidentiality and emotional distress on the part of participants. The use of code names and numbers along with other procedures described below are intended to prevent violations of confidentiality. It is important to be aware that the prospect of testing positive for COVID-19 may be a cause of substantial fear and anxiety among participants. We anticipate that more than half of our participants will be African American or Hispanic and may lack trust in medical science and practice as a legacy of medical mistreatment. Many participants will have lost loved ones to COVID-19 and all of them will be medically or socially vulnerable to poor outcomes if they become infected themselves. They live with disproportionate risk caused by any of several factors, including but not limited to employment as essential workers, poverty, inadequate or unstable housing and underlying medical conditions. CBHC has been operating as a primary provider of services in East St. Louis, IL for 50 years. It is, in general, a trusted source of care and services, but the COVID-19 pandemic is a recent, evolving development and much remains unknown about community perceptions.

It is also possible that participants who decline testing and attend Critical Dialogue sessions may be disturbed by sensitive questions raised during those sessions. Questions and discussions regarding stigma, racism, discrimination and structural inequality may cause anxiety, anger, suspicion, or other emotions. While we expect our sample to be predominantly African American, there will be some White and Latino participants as well and talking about racism in the group will elicit strong emotions. Differences among group members have the potential to harm or cause discomfort for a participant or to revive psychological dynamics that could threaten to renew old conflicts.

13B. Describe the steps that will be taken to minimize the risks listed above.

To avoid possible violations of confidentiality, project staff are trained to carefully follow detailed procedures designed to assure that no information about any participant (or others they may mention) will be given to anyone other than members of the research staff included in the IRB protocol. Every member of the research team and all NCCB members will be required to undergo human subject protection training and provide a certificate of completion to the IRB prior to any contact with human participants. Standards of confidentiality include the use of code numbers and code names for participants and other individuals they may mention. The only place participants' names or other identifying information will appear is on informed consent forms and locator forms that are password protected in RedCap, the software used in the study. This identifying information is used for follow-up interviews after the baseline, to remind participants of Critical Dialogue group sessions if they are randomized to that condition and to locate participants if we are unable to reach them. Consent forms will be stored in locked filing cabinets at CBHC, separate from any data. Mr. Harper, the Project Principal Investigator at CBHC, will retain the keys to the filing cabinets at each location. Only outreach staff, Dr. Windsor, Mr. Harper, and the group facilitators will have access to the identifying information.

The electronic files generated through data collection will be identified by code numbers only and kept in password-protected and HIPAA-compliant devices/cloud, separate from identifying information and available only to project staff. This helps to ensure that no identifying information will be disclosed in the unlikely event that computerized data are stolen or otherwise seen by unauthorized persons. All identifying electronic data will be destroyed immediately after data collection is completed. Signed consent forms and audio recordings will be kept for 3 years after study completion. De-identified electronic data will be kept indefinitely. Study participants may ask at any time to have recordings of their interview destroyed by calling/e-mailing one of the Principal Investigators at the numbers provided in the informed consent forms.

Participants will be protected by a Certificate of Confidentiality issued by the NIH. NIH issues COCs automatically upon funding approval. Under terms of the Certificate, the researchers cannot be forced to disclose information that may identify a participant, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. However, the Certificate cannot be used to resist a demand from United States Government personnel for information that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to

meet the requirements of the federal Food and Drug Administration (FDA). Researchers may also disclose the identity of participants who report intentions to harm themselves or others or if researchers have knowledge those participants are abusing children or elderly persons

Our interviewers are trained to watch participants carefully and will stop questioning if an individual appears uneasy. At every interview, participants will be informed that they may ask the interviewer to stop if they are feeling uncomfortable. Referrals to counselors are available if participants wish and trained clinical counselors are available at CBHC in the event that someone may need immediate assistance, whether it is during data collection or during the intervention sessions. The Critical Dialogue is an intervention developed by Dr. Windsor and the NCCB, to ensure that the group discussions happen in a safe way, where everyone is encouraged to challenge their own assumptions by analyzing the evidence they have that supports or challenges their positions. This starts with operational components where the intervention is clearly described so that people know what to expect, and ground rules are collaboratively created and enforced during group discussions. In preliminary research on the intervention, there were many instances where the critical questions posed led to a heated dialogue where people were able to express their conflicting views while respecting each other and considering the possibility of changing their points of view. Dr. Windsor will train a doctoral level social work research assistant to facilitate the groups. The RA has a great deal of experience facilitating groups dealing with these sensitive topics and with this marginalized population. In the unlikely event a discussion escalates to the point that it may challenge the safety of the group, there is an emergency protocol in place where trained clinical staff and security can intervene and deflect potential violence or stabilize medical emergencies. During the development and testing stages of the intervention, with close to 700 participants, no adverse events occurred as a result of critical dialogue participation.

The IRBs of the collaborating institutions, the NJCRI, CBHC, and the University of Michigan, will defer oversight to the UIUC IRB. As the applicant agency, the University of Illinois Urbana-Champaign will ensure that all institutions adhere to IRB monitoring and will keep annual certificates from each institution on file. UIUC will execute an Institutional Review Board (IRB)/Independent Ethics Committee (IEC) Authorization Agreement with all other agencies. The Officials signing this Agreement will thereby agree that their institutions may rely on the IRB of UIUC as the designated IRB for review and continuing oversight of its human subjects research described for this project.

Dr. Windsor, Dr. Benoit, Mr. Harper, and Dr. Pinto will be available by phone at all times in case an emergency occurs. Any adverse event will be reported to the IRB and funding agency within 24 hours. Through our NCCB collaboration, we have excellent relationships with the community, including community members and agencies that we can mobilize in case the need arises (e.g., access to detox and emergency services, legal support clinics).

Finally, the research team and the clinical team will engage in weekly project meetings to receive ongoing training, discuss the progress of the study and identify and address any potential issues.

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13C. Indicate the risk level.

☐ **No more than minimal risk**

(The probability and magnitude of harm or discomfort anticipated for participation in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).

☒ **More than minimal risk** (answer 13D)

13D. If you checked that the research is more than minimal risk, describe the provisions for monitoring the data to ensure the safety of subjects, such as who will monitor data and how often, what criteria will be used to stop the research, etc.

The MPIs will oversee data management, including data storage, security, random assignment and quality assurance procedures, REDCap, software and hardware, and will ensure that all staff adheres to Human Subjects guidelines. Data management activities and procedures, including data confidentiality, will employ an electronic data management system to enhance efficiency, security and integrity of study data. The NCCB will also be updated during meetings on data management and adherence to IRB protocol.

Additionally, integrity assessments will be conducted, which include: (1) a checklist completed by facilitators at the end of each intervention session to list the activities discussed in each session and participant attendance; (2) exit interview. The NCCB will review preliminary findings presented by the MPIs on a bi-monthly basis to address any potential adverse reactions that may occur and any safety concerns that may arise. If any participants are found to be unresponsive to the intervention during the course of the study, the Board will discuss the case and the participant may be terminated from the study and referred to relevant services in the community. The MPIs will meet bi-weekly with study staff to review study protocol adherence and address any potential problems. MPI Windsor will have weekly supervision meetings with intervention facilitators to review results from fidelity ratings and address any potential deviance from intervention protocols.

13E. Describe the expected benefits of the research to the subjects and/or to society.

The potential benefits to participants in this study and other members of the community are significant and may be long lasting. Significant short-term benefits include detecting and treating cases of COVID-19 and preventing further transmission of the disease. While participants are enrolled in the study, referrals to resources to address social determinants of health (e.g., housing, food insecurity) may provide immediate tangible benefits. In addition, if participants express a need for mental health assistance at any time, the project team and the NCCB are well equipped to either provide service or make appropriate referrals. After engaging in the interventions, participants may experience increased feelings of empowerment and self-esteem, both of which have been associated with improved health outcomes. If the study succeeds in reducing medical mistrust and increasing health literacy, those benefits may

belong-lasting. Both the short-term and long-term potential benefits of this study justify the potential risks involved in participation.

13F. Weigh the risks with regard to the benefits. Provide evidence that benefits outweigh risks.
Knowledge to be gained from this investigation is important for understanding and addressing COVID-19 morbidity and mortality disparities and potential barriers to testing among medically and socially vulnerable populations. The opportunity to engage residents of East St. Louis, IL in the proposed adaptive interventions is an opportunity to increase health literacy and reduce medical mistrust among a severely underserved population. This is vitally important in light of the contradictory and constantly changing information about COVID-19 being disseminated by federal and state governments and mass media. Moreover, because the knowledge generated by this study will be shared with other members of the RADx-UP consortium, it has the potential to improve access to prevention strategies, testing and treatment in vulnerable communities across the country. The value of the knowledge to be gained far outweigh the potential risks of participation described above, particularly when considering the precautions we have taken to minimize these risks. Although participants' risk of experiencing COVID-19 related distress is real, involvement in the study can also reduce fear and anxiety. As explained earlier, project staff will employ every effort to maintain confidentiality and to minimize any other potential risks; should a serious adverse event occur, it will be reported to the DSMB, Project Officer, funding agencies and the UIUC IRB within 48 hours. Adverse events will be tracked in a database and reviewed at each DSMB meeting. Our CBPR research to date indicates that community members themselves will be committed to assisting us in the successful and safe implementation of this project.

Section 14. INFORMED CONSENT PROCESS TO INCLUDE: WAIVERS, ASSENTS, ALTERATIONS, ETC.

14A. Indicate all that apply for the consent/assent/parental permission process.

☒ Written informed consent (assent) with a document signed by
  ☒ adult subjects ☐ parent(s) or guardian(s) ☐ adolescents aged 8–17 years
☐ Waiver of Documentation (signature) of Informed Consent *(include the relevant Waiver Form)*
  ☐ adult subjects ☐ parent(s) or guardian(s) ☐ adolescents aged 8–17 years
☐ Waiver of Informed Consent *(include the relevant Waiver Form)*
  ☐ adult subjects ☐ parent(s) or guardian(s) ☐ adolescents aged 8–17 years
☐ Alteration of Informed Consent *(include the relevant Alteration Form)*
  ☐ adult subjects ☐ parent(s) or guardian(s) ☐ adolescents aged 8–17 years

14B. List all researchers who will obtain consent/assent/parental permission from participants.
Researchers who may participate in obtaining consent include the PIs (Windsor & Harper), project coordinator, study outreach workers and research assistants at CBHC that will be trained and approved as members of the research team by the UIUC IRB. Note we have not yet hired the project coordinator nor the peer navigators. Staff will be added to the protocol as they are hired and complete their IRB training. Only staff that have been approved by the IRB will have contact with study participants.

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14C. Describe the method for obtaining consent/assent/parental permission. Eligible individuals will provide written informed consent before participating in the study. During the informed consent process, the study outreach worker or research assistant will explain the study design in detail, including its purpose, the source of funding, why individuals are invited to participate, what they will be asked to do, how long the study will last and how many people are expected to take part in the study. They will explain the processes of SARS antigen testing at CBHC and randomization, the interventions being tested, potential sources of risk and discomfort and measures designed to minimize both. They will answer all participant questions and will ask participants to describe in their own words what they expect to do in the study before obtaining signatures. Participants who do not comprehend the study description will not be enrolled. Participants who would like some time to think before deciding will be able to take informed consent material home with them for review and consideration. All participants who provide written consent will receive a copy of the consent document which, in addition to the study description outlined above, includes names and contact information (phone numbers and email) for the Principal Investigators and for the appropriate ethics officials at the University of Illinois Urbana-Champaign, the grantee institution.

14D. Describe when consent/assent/parental permission will be obtained. Consent will be obtained through a RedCAP survey that participants can complete online or at CBHC.

14E. Will participants receive a copy of the consent form for their records?
☒ Yes ☐ No, *if no, explain*:

14F. Indicate factors that may interfere or influence the collection of voluntary informed consent/assent/parental permission.
☒ No known factors
☐ Research will involve students enrolled in a course or program taught by a member of the research team
☐ Research will involve employees whose supervisor(s) is/are recruiting participants
☐ Participants have a close relationship to the research team
☐ Other, *specify any relationship that exists between the research team and participants*:
If applicable, describe the procedures to mitigate the above factors.

14G. Copies of the consent form(s) are attached. ☒ Yes ☐ Not applicable

14H. Will this project be registered as a clinical trial? ☒ Yes ☐ No
If yes, effective January 21, 2019, an informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit.

Section 15. DEVICES & DRUGS

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Indicate if your research includes any of the following.

☐ Equipment [Researchers collecting physiological data, not testing the device]
(*include Appendix A, the Research Equipment Form*)

☐ Devices [Researchers planning to test devices on human subjects]
(*include Appendix B, the Device Form*)

☐ Materials of Human Origin
(*include Appendix C, the Biological Materials Form*)

☐ Drugs and Biologics
(*include Appendix D, the Drug and Chemical Usage Form*)

☐ MRI AT BIC To use the Beckman Institute Biomedical Imaging Center (BIC) in human subject's research, you must obtain prior approval from the BIC (217.244.0446; ryambert@illinois.edu) and use BIC-approved screening and consent forms. Attach:
☐ BIC approval ☐ BIC screening form ☐ BIC consent form

Section 16. CONFIDENTIALITY OF DATA & PRIVACY OF PARTICIPATION

16A. How is participant data, records, or specimens identified when received or collected by researchers? Identifiers include, but are not limited to, name, date of birth, email address, street address, phone number, audio or video recordings, and SSN.

☐ No identifiers are collected
☒ Direct identifiers are collected
☒ Indirect identifiers (e.g. a code or pseudonym used to track participants);
Does the research team have access to the identity key? ☒ Yes ☐ No

16B. Select all methods used to safeguard research records during storage:

☒ Written consent, assent, or parental permission forms are stored separately from the data
☐ Data is collected or given to research team without identifiers
☐ Data is recorded by research team without identifiers
☒ Direct identifiers are removed from collected data as soon as possible
☐ Direct identifiers are deleted and no identity key exists as soon as possible
☒ Participant codes or pseudonyms are used on all data and the existing identity key is stored separately from the data
☒ Electronic data is stored in a secure, UIUC-approved location, *please specify* REDCAP
☐ Hard-copy data is stored in a secure location on UIUC's campus, *please specify*
☐ Other, *please specify*:

16C. How long will identifiable data be kept? All identifying electronic data will be destroyed immediately after data collection is completed. Signed consent forms and audio recordings will be kept for 3 years after study completion.

16D. Describe provisions to protect the privacy interests of subjects. In addition to the creation of and ongoing adherence to the DSMP and the procedures indicated earlier in this protocol, participants will be protected by a Certificate of Confidentiality issued by the NIH. Under terms of the Certificate, the researchers cannot be forced to disclose information that may identify a participant, even by a court

subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. However, the Certificate cannot be used to resist a demand from United States Government personnel for information that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). Researchers may also disclose the identity of participants who report intentions to harm themselves or others or if researchers have knowledge those participants are abusing children or elderly persons

16E. Describe the training and experience of all persons who will collect or have access to the data. All members of the research team will complete the required CITI training and will be trained on this specific study protocol by the principal investigators. Drs. Windsor, Benoit, and Pinto have extensive experience conducting similar studies and adhere to best practices in data collection and retention. Mr. Harper, as a trained social worker and executive director of CHBC, has decades of experience in service provision, client rights and privacy, and administration of federally funded programs. Once a new research team member is hired, as part of the onboarding process at CSBH, they must complete a variety of standardized trainings on confidentiality, COVID-19, and IT security. Additionally, research team members will receive training on tasks that are specific to their job expectations. Everyone will receive training on Redcap (1 hour online and homework tutorials and practices), human subjects research (CITI training), COVID-19 protocol (1 hour and ongoing training during weekly meetings), and on study protocols (includes professionalism, confidentiality, cultural humility, referral making, safety procedures). Street outreach staff will also receive training on safety while working in the field, confidentiality in the field, how to complete the study screener, and dos and don'ts when calling participants (2 hours plus homework and role plays). Peer Navigators will complete an online training on Motivational Interviewing with a professional trainer (8 hours plus homework and role plays). They will also complete a 2 hour training on Navigation Services with Dr. Pinto. They will be paired with Letitia McBride, the seasoned peer navigator from New Jersey for mentorship and extra support. They will have ongoing clinical supervision weekly meetings with Dr. Windsor to review their cases, ensure fidelity, and review study protocols. The Critical Dialogue facilitator will be trained by Dr. Windsor including a period of shadowing the facilitations, role plays, and observations, until they are approved to run the sessions on their own. Finally, during staff meetings we continually identify possible training gaps and make sure these are addressed as needed. Particularly with the changes on COVID-19 recommendations, we often use the weekly meetings to review the protocol, make sure it is up to data, and that everyone has the same understanding. All of this is tracked in minutes that are recorded and saved after each meeting. This includes a table that reflects the training and the dates in which each staff completed it.

Section 17. DISSEMINATION OF RESULTS

17A. List proposed forms of dissemination (e.g. journal articles, thesis, academic paper, conference presentation, sharing within industry, etc.).

The proposed study is purposefully planned with rapid translation, dissemination and sustainability in mind. The adaptive intervention is envisioned as an efficient and effective

model that can ultimately be replicated in the field and scaled-up with high fidelity. Beginning in the research planning stage, and iteratively throughout all phases of the study, we are ensuring that the manual, once efficacious, can be disseminated among service providers across similar settings. The Collaborative Board will design a comprehensive plan to disseminate the study findings to the community at large.

Consistent with NIH policy, the PIs in the proposed application will make the data available, on appropriate terms and conditions, to the research community in a timely manner. We will follow the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information NOT-OD-16-149. The study will be registered under the Clinical Trials Registration at ClinicalTrials.gov for public posting. The study will be registered within 21 calendar days after the enrollment of the first participant, results will be submitted no later than one year after the completion of final data collection, and all required elements will be provided. Results including participant flow, demographic and baseline characteristics, outcomes and statistical analyses, adverse events, the protocol and statistical analysis plan, and administrative information will be updated on ClinicalTrials.gov bi-annually (twice each study year).

17B. Will any identifiers be published, shared, or otherwise disseminated? ☐ Yes ☒ No
If yes, does the consent form explicitly ask consent for such dissemination, or otherwise inform participants that it is required in order to participate in the study? ☐ Yes

17C. Do you intend to put de-identified data in a data repository? ☐ Yes ☒ No
If yes, explain how data will be de-identified.

Section 18. INVESTIGATOR & DEPARTMENTAL ASSURANCES

- I certify that the information provided in this application is complete and correct.
- I certify that I will follow my IRB Approved Protocol.
- I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in this project.
- I will comply with all applicable federal, state and local laws regarding the protection of human subjects in research.
- I will ensure that the personnel performing this study are qualified and adhere to the provisions of this IRB-certified protocol.

The original signature of the PI is required before this application may be processed (electronic signatures are acceptable).

ILLINOIS
Office for the Protection
of Research Subjects

Protocol Form

2/7/2022

Principal Investigator | Date

If the PI is not eligible to serve as PI under the Campus Administrative Manual, the applicable academic dean, institute director, or campus administrative officer indicates their approval of the researcher to act as Principal Investigator. Please note that departmental assurance only needs to be provided in the initial application.

Name of Authorizing Individual

Signature of Authorizing Individual | Date