PROTOCOL TITLE: *Promoting Optimal Wellness and Empowering Wellness through Narrative Exposure Therapy: Pilot Protocol*

INSTRUCTIONS: Complete Research Protocol (HRP-503)

- *Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, you must provide the reason why the section is not applicable for the response. For example, most behavioral studies would answer all questions in section 30 with words to the effect of "drugs and medical devices are not used in this study."*
- *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*
- *Do not remove the italics instructions or headings.*
- *If you are pasting information from other documents be sure to use the "Merge Formatting" paste option so that the formatting of the response boxes is not lost. If information is presented outside of the response boxes, it will not be accepted.*
- *If this study involves multiple participant groups who participate in different research procedures, consent processes, etc., be certain to provide information in each applicable section for each participant group and clearly label each participant group within a section or subsection.*

PROTOCOL TITLE:

Response: ***POWER-NET: Promoting Optimal Wellness and Empowering Wellness through Narrative Exposure Therapy: Pilot Protocol***

PRINCIPAL INVESTIGATOR:

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Telephone Number
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VERSION NUMBER:

Include the version number of this protocol.

Response: Version 6

DATE:

Include the date of submission or revision.

Response–*2.21.2018*

Grant Applicability:

Describe whether or not this protocol is funded by a grant or contract and if so, what portions of the grant this study covers.

Response: This protocol is covered in its entirety by funding from the *NCATS (NIH) 72401*

Table of Contents

1.0 Objectives

1.1 Describe the purpose, specific aims, or objectives.

Response:

The overall purpose of the study is twofold: 1) To increase understanding of trauma and its consequences including posttraumatic stress disorder (PTSD) in a high-risk sample of adolescents; and 2) to pilot an intervention (Narrative Exposure Therapy; NET) to treat PTSD in this sample. These two objectives will be achieved in two phases, described below.

1) **Phase I:**

   a) **Specific Aim #1:** To describe the prevalence and types of traumatic experiences associated mental health outcomes and risk behaviors among a sample of low-income, urban adolescents at risk for homelessness.

   b) **Specific Aim #2:** In this sample, to explore potential moderating and mediating factors of the relationship between trauma, posttraumatic stress, and mental health outcomes, including posttraumatic stress disorder, depression, and substance misuse (SUB).

2) **Phase II:**

   1. **Specific Aim #3**: To conduct a pilot study (N=30) to examine feasibility and preliminary treatment effects of NET on the reduction of PTSD symptoms and SUB for adolescents (ages 16-24).

1.2 State the hypotheses to be tested.

Response:

1) **Specific Aim #1:** No formal hypothesis stated.
2) ***Specific Aim #2:*** Exploratory analysis; no formal hypothesis stated.
3) **Specific Aim #3:** NET will be feasible to our target population, and will demonstrate an estimate effect size of greater than 0.

2.0 Background

2.1 Describe the relevant prior experience and gaps in current knowledge.

Response: Previous studies (including preliminary work by this PI) have established high rates of trauma, particularly among low-income, urban adolescents. The factors that contribute to the development of PTSD and other mental health outcomes including SUB and posttraumatic growth need to be explored to inform intervention development for those at greatest risk. Previous work has established the effectiveness of Narrative Exposure Therapy (NET) in treating PTSD; however, this intervention has not yet been

tested for urban adolescents in the United States. Findings will inform full-scale effectiveness and implementation trail design.

2.2 Describe any relevant preliminary data.

Response:

Preliminary Study #1: Our research team, in collaboration with colleague Dr. Ellen Volpe, has conducted studies in low-income, urban populations since doctoral research. This has included work demonstrating success in recruiting high-risk adolescent girls (ages 14-18) for cross-sectional studies in the school-based clinic setting. More specifically, our group has conducted a focus group study of community adolescents (N=28) and community health care providers (N=11). The study elicited basic information about logistical strategies to maximize NET feasibility and acceptability in the RCT. The focus groups addressed violence, cultural norms, expectations, and perspectives of engaging in psychotherapy. Other content included barriers and facilitators to therapy engagement, readability and relevance of survey measures, health care provider's experience providing care for high-risk adolescents, PTSD and depression, and SUB. Focus group data were analyzed using a socio-ecological model. Major results indicated perceived individual, relationship, community, and societal barriers and facilitators to NET participation. **The findings demonstrate that both youth and their service providers demonstrate favorable attitudes about the proposed intervention, and many youth expressed genuine interest in participating in NET.** This finding supports recruitment goals. The adolescents felt that therapist's race, gender or age mattered less than their ability to listen and understand. NET was modified to include specific skill training related to maintaining boundaries while increasing client/therapist trust (e.g. therapist personal disclosure). Furthermore, we added curriculum to discuss the intersection of race and trauma. Additionally, skill building of how to address barriers (e.g. transportation) was reviewed. Finally, measures have been adapted to respond to participant concerns (e.g. length and repetition of survey).

Preliminary Study #2 (in process): Through NIH's Clinical and Translation Science Award (CTSA) granted to UB - KL2 TR001413) Drs. Volpe and Read were able to lay the foundation of this proposal. This research team incorporated a senior investigator (Read), a junior investigator (Volpe), and two Psychology graduate students (Rodriguez, Jenzer; see Budget) who were involved in all aspects of designing, conducting and disseminating the study. Dr. Read will continue to work on this project with the two graduate students. This research team designed the study, develop an IRB application and study protocol, all, which informed protocol modifications proposed in this study. We have established the Data Safety Monitoring Board (DSMB) that has established and convened (Sept 2016). Additionally, the Community Advisory Board (CAB) has also been developed and met. Both groups will continue to meet and inform the efficacy study as proposed in this application. The research team also developed the web-based survey, REDCap. We have been working with REDCap format for data collection and exportation with good success.

The first part of this study was a baseline survey (N= 86) that explored low-income, urban adolescents' experiences of trauma, mental health (e.g. PTSD, depression), and risk behavior (SUB, delinquency). The research team members recruited at a

community site serving at risk adolescents. Data from this survey suggest that rates of trauma and PTSD symptoms are high in this sample, with an average of 10 (SD=10.6) traumatic events reported by participants. Adolescents in our sample also had high rates of PTSD, experiencing approximately 16 symptoms on average. Eighty-five percent of the sample also reported co-occurring substance use. Thus, data from this survey creates a strong case for the need for intervention in this population.

In addition to delineating the scope of the problem, our work to date has allowed us to set in place many essential elements of the trial that we now seek to conduct. Specifically, our team has developed protocols, measures, and procedures for intervention fidelity assessment. We also have developed strong relationships with community partners. This groundwork will allow our research team to effectively set up the next phase of the study without lost time for procedural set up.

Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

Response:

Urban, low-income, minority youth are at high risk for lifetime trauma; with approximately 69% reporting direct victimization (Aisenberg & Herrenkohl, 2008; Alisic et al., 2014; Gillespie et al., 2009; McDonald & Richmond, 2008). The combination of severe life stressors, developmental age, lack of resources, and coping skills increase vulnerability to trauma and posttraumatic stress disorder (PTSD; Ickovics et al., 2006). One of the most common forms of childhood trauma in this population is interpersonal trauma and can include childhood maltreatment, exposure to family or community violence, and relationship or peer violence (Gillespie et al., 2009). Often these youth are victims of multiple forms or episodes of violence creating a cumulative effect on mental health (Cloitre et al., 2009; McDonald & Richmond, 2008). Not all adolescents who experience trauma will develop PTSD. However, interpersonal trauma puts children and adolescents at the highest risk for developing complex PTSD, which can persist into adulthood (Aisenberg & Herrenkohl, 2008; Alisic et al., 2014; Stein & Kennedy, 2001).

Adolescents and young adults experiencing trauma and PTSD are also at high risk for co-occurring substance misuse (SUB) including alcohol and marijuana (Aisenberg & Herrenkohl, 2008). Heavy drinking, trauma exposure, and PTSD in adolescents has been linked to risk-taking behavior (e.g. sexual risk behavior), trauma re-exposure, psychological dysfunction, academic impairment, and increased vulnerability to violence as well as poor mental and physical health outcomes (Duncan, 2000; Fromme, Corbin, & Kruse, 2008; Messman-Moore & Brown, 2004; Read et al., 2012; Read et al., 2013).

Emerging evidence supports trauma and PTSD as important negative influences in adolescent growth and development (Kilmer et al., 2014), physical health outcomes, (e.g. cardiovascular disease and diabetes; Weiss et al., 2011), and mental health outcomes (Hovens et al., 2010). However, a greater understanding is needed of predictors of both positive and negative outcomes in those at highest risk. Therefore, the timing of PTSD treatment is critical to life trajectory. Despite the public health urgency to address adolescent PTSD and co-occurring SUB, there is a paucity of evidence-based, treatment interventions for at-risk youth most vulnerable to PTSD. Innovative, culturally-informed interventions to treat mental health have the potential to significantly contribute to adolescents' long-term health.

A particularly promising intervention to treat PTSD related to experiencing multiple traumas is Narrative Exposure Therapy (NET; Robjant & Fazel, 2010). NET

combines trauma-focused cognitive behavioral therapy and narrative therapy (Schaal, Elbert, & Neuner, 2009). NET therapists aim to facilitate the client's reconnection of trauma memories to life context to address dysfunctional thinking that triggers PTSD symptoms. It seeks to reduce PTSD by reconstructing thoughts and reactions to trauma. NET takes a relatively new treatment focus on the patients' lifetime to reduce PTSD symptoms caused by *multiple traumas,* applying it to fit the profile of urban, low-income adolescents (Schauer, Neuner, & Elbert, 2011). Individual therapy sessions allow the patient to focus on pressing traumatic and memorable events, within their life's context. The therapist assists the patient in integrating fragmented memories into a coherent, contextualized, personalized story. In international studies conducting NET in children and adolescents, NET has demonstrated 67% and 83% remission of PTSD symptoms (Catani et al., 2009; Onyut et al., 2005; Ruf et al., 2010). NET is a manualized, short treatment based on the severity and number of traumatic events (typically 8-12) (Schauer et al., 2011). NET has demonstrated effectiveness in low-income, middle-resourced countries (Cohen's d= 1.29-3.15 at follow-up, 11 RCTs), in children/adolescents (6 RCTs), and in *continued unstable* situations (Robjant & Fazel, 2010). As a relatively brief, cost-efficient intervention, NET has demonstrated effectiveness in samples in at-risk communities (Robjant & Fazel, 2010). Notably, NET was selected specifically for this population because of its cultural-sensitivity. However, this intervention has yet to be translated to adolescent populations in the United States experiencing trauma. This project aims to contribute to the evidence testing the effectiveness of NET for diverse populations experiencing multiple traumas and its effect on co-occurring SUB.

2.3 Include complete specific citations/references.

Response:

Aisenberg, E., & Herrenkohl, T. (2008). Community Violence in Context: Risk and Resilience in Children and Families. *Journal of Interpersonal Violence, 23*(3), 296-315.

Alisic, E., Zalta, A. K., Van Wesel, F., Larsen, S. E., Hafstad, G. S., Hassanpour, K., & Smid, G. E. (2014). Rates of post-traumatic stress disorder in trauma-exposed children and adolescents: meta-analysis. *British Journal of Psychiatry, 204*(5), 335-340.

Catani, C., Kohiladevy, M., Ruf, M., Schauer, E., Elbert, T., & Neuner, F. (2009). Treating children traumatized by war and Tsunami: a comparison between exposure therapy and meditation-relaxation in North-East Sri Lanka. *BMC Psychiatry, 9*, 22.

Cloitre, M., Stolbach, B. C., Herman, J. L., Kolk, B. v. d., Pynoos, R., Wang, J., & Petkova, E. (2009). A developmental approach to complex PTSD: Childhood and adult cumulative trauma as predictors of symptom complexity. *Journal of Traumatic Stress, 22*(5), 399-408.

Duncan, R. D. (2000). Childhood maltreatment and college drop-out rates - Implications for child abuse researchers. *Journal of Interpersonal Violence, 15*(9), 987-995.

Fromme, K., Corbin, W. R., & Kruse, M. I. (2008). Behavioral risks during the transition from high school to college. *Dev Psychol, 44*(5), 1497-1504.

Gillespie, C. F., Bradley, B., Mercer, K., Smith, A. K., Conneely, K., Gapen, M., . . . Ressler, K. J. (2009). Trauma exposure and stress-related disorders in inner city primary care patients. *General Hospital Psychiatry, 31*(6), 505-514.

Hovens, J. G. F. M., Wiersma, J. E., Giltay, E. J., Van Oppen, P., Spinhoven, P., Penninx, B. W. J. H., & Zitman, F. G. (2010). Childhood life events and childhood trauma in adult patients with depressive, anxiety and comorbid disorders vs. controls. *Acta Psychiatrica Scandinavica, 122*(1), 66-74.

Ickovics, J. R., Meade, C. S., Kershaw, T. S., Milan, S., Lewis, J. B., & Ethier, K. A. (2006). Urban teens: Trauma, posttraumatic growth, and emotional distress among female adolescents. *Journal of Consulting and Clinical Psychology, 74*(5), 841-850.

Kilmer, R. P., Gil-Rivas, V., Griese, B., Hardy, S. J., Hafstad, G. S., & Alisic, E. (2014). Posttraumatic Growth in Children and Youth: Clinical Implications of an Emerging Research Literature. *American Journal of Orthopsychiatry, 84*(5), 506-518.

McDonald, C. C., & Richmond, T. R. (2008). The relationship between community violence exposure and mental health symptoms in urban adolescents. *Journal of Psychiatric and Mental Health Nursing, 15*(10), 833-849.

Messman-Moore, T. L., & Brown, A. L. (2004). Child maltreatment and perceived family environment as risk factors for adult rape: is child sexual abuse the most salient experience? *Child Abuse & Neglect, 28*(10), 1019-1034.

Onyut, L. P., Neuner, F., Schauer, E., Ertl, V., Odenwald, M., Schauer, M., & Elbert, T. (2005). Narrative Exposure Therapy as a treatment for child war survivors with posttraumatic stress disorder: two case reports and a pilot study in an African refugee settlement. *BMC Psychiatry, 5*, 7.

Read, J. P., Colder, C. R., Merrill, J. E., Ouimette, P., White, J., & Swartout, A. (2012). Trauma and posttraumatic stress symptoms predict alcohol and other drug consequence trajectories in the first year of college. *J Consult Clin Psychol, 80*(3), 426-439.

Read, J. P., Wardell, J. D., Vermont, L. N., Colder, C. R., Ouimette, P., & White, J. (2013). Transition and change: prospective effects of posttraumatic stress on smoking trajectories in the first year of college. *Health Psychol, 32*(7), 757-767.

Robjant, K., & Fazel, M. (2010). The emerging evidence for Narrative Exposure Therapy: A review. *Clin Psychol Rev, 30*(8), 1030-1039.

Ruf, M., Schauer, M., Neuner, F., Catani, C., Schauer, E., & Elbert, T. (2010). Narrative exposure therapy for 7- to 16-year-olds: a randomized controlled trial with traumatized refugee children. *J Trauma Stress, 23*(4), 437-445.

Schaal, S., Elbert, T., & Neuner, F. (2009). Narrative exposure therapy versus interpersonal psychotherapy. A pilot randomized controlled trial with Rwandan genocide orphans. *Psychother Psychosom, 78*(5), 298-306.

Schauer, M., Neuner, F., & Elbert, T. (2011). *Narrative Exposure Therapy: A Short-Term Treatment for Traumatic Stress Disorders* (2n ed.). Cambridge, MA: Hogrefe.

Stein, M. B., & Kennedy, C. (2001). Major depressive and post-traumatic stress disorder comorbidity in female victims of intimate partner violence. *J Affect Disord, 66*(2–3), 133-138.

Weiss, T., Skelton, K., Phifer, J., Jovanovic, T., Gillespie, C. F., Smith, A., . . . Ressler, K. J. (2011). Posttraumatic stress disorder is a risk factor for metabolic syndrome in an impoverished urban population. *General Hospital Psychiatry, 33*(2), 135-142.

3.0 Inclusion and Exclusion Criteria

3.1 Describe the criteria that define who will be included or excluded in your final study sample.

Response:

Phase I:

Inclusion criteria: 1) Adolescents aged 16-24 receiving services at the Center for Youth (CFY), Inc., Rochester NY or Compass House, Buffalo NY.

Exclusion criteria: Not fluent in English (as determined by PI, RA, or CFY/Compass House staff). If a participant reports using alcohol or drugs on the day of the study, they will be excluded if they are unable to pass the Mini-Mental State Exam.

Phase II:

Inclusion Criteria: 1) Adolescents (ages 16-24), 2) participants reporting at least 1 Criterion B symptom, at least 1 Criterion C symptom, at least 2 Criterion D symptoms, and at least 2 Criterion E symptoms on the Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5) and 2) participants who respond "yes" to being contacted about **Phase II** (part of the **Phase I** survey) will be invited to participate.

Exclusion Criteria: 1) severe cognitive deficits (determined by inability to complete **Phase I**); or 2) active psychosis or mania (assessed by the MINI Psychiatric Interview in **Phase I**).

Describe how individuals will be screened for eligibility.

Response:

In **Phase I:** Participants will be youth receiving services at CFY or Compass House. Staff members at these locations will assist researchers in identifying youth who may be eligible. Staff members will fill out a brief screening document, which will then be given to research staff. In this document, staff members will provide the potential participant's name and contact information (phone number, email). They will also answer the following Yes/No questions: 1) is he/she between the ages of 16-24, 2) is he/she fluent in English?, 3) does he/she currently receive services at CFY or Compass House? and 4) is he/she interested in being contacted by a research staff member? If the answer is "Yes" to all of these questions, the participant is eligible to participate. Participants may also be approached

directly by research staff; in this case, eligibility with regards to these criteria will be confirmed by a staff member at these community centers.

Prior to completing the survey, participants will be asked "Have you used alcohol or drugs today?". If they respond affirmatively, they will be given the Mini-Mental State Exam, a brief (3-5 minute) interview to determine cognitive functioning. Participants who report using alcohol or drugs on the day of the survey may still participate if they pass this exam.

Phase II: Participants in **Phase I** will be screened based on a review of their responses to the **Phase I** survey: 1) positive PTSD, 2) an indication that if eligible, they would like to be contacted for more information about participating in **Phase II**, and 4) no psychosis or mania per the MINI Psychiatric Interview.

3.2 Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of these populations as subjects in your research unless you indicate this in your inclusion criteria.)

Response:

- *Adults unable to consent:* We will exclude adults (ages 18-24) who are unable to give informed consent.
- *Individuals who are not yet adults (infants, children, teenagers):* We will include individuals who are not yet adults as the focus of this study is on the unique risk factors and outcomes for adolescents ages 16-24. We will exclude individuals who are not yet adults if they are unable to give informed assent (individuals under 18 years old).
- *Pregnant women:* We will include pregnant women. Pregnancy is not a specific eligibility criterion of this study and pregnancy is unrelated to the study aims. Some female participants may be pregnant at the time that they participate in the study. NET will not adversely affect pregnant women or their fetuses. Trauma focused therapy is considered safe in pregnancy, as PTSD is a risk factor in pregnancy. There is no threat of harm to pregnant women or their fetus as a result of taking the surveys and participating in NET.
- *Prisoners:* Prisoners who are currently incarcerated will be excluded from this study, as they do not receive services from CFY or Compass House. However, we will not exclude individuals on parole or probation.

3.3 Indicate whether you will include non-English speaking individuals. Provide justification if you will exclude non-English speaking individuals.
(In order to meet one of the primary ethical principles of equitable

selection of subjects, non-English speaking individuals may not be routinely excluded from research. In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals. However, there are studies in which it would be reasonable to limit subjects to those who speak English: e.g., pilot studies, small unfunded studies with validated instruments not available in other languages, numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.)

Response: Non-English speaking adolescents will be excluded from this research in **Phase I** due to the fact that most measures included in the survey have been validated only in English and we do not have the resources to translate the measures to other languages. Non-English speaking adolescents will also be excluded from **Phase II** because an intervention delivered in a language that cannot be understood by the participant would not benefit the participant and also would not shed light on the feasibility of implementation. **Phase II** is a pilot study. In future work, we will seek to build on our findings of this preliminary work, by developing our NET intervention for individuals with broader linguistic backgrounds.

4.0 Study-Wide Number of Subjects (Multisite/Multicenter Only)

4.1 If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.

Response: Across both sites, it is expected that we will accrue 120 participants for **Phase 1**. In **Phase 2**, we will accrue 30 participants. Participants will be recruited at the Center For Youth in Rochester, New York and at the Compass House in Buffalo, New York. Based on attrition expectations, our final sample will be 100 participants in **Phase I** and 24 in **Phase II**.

5.0 Study-Wide Recruitment Methods (Multisite/Multicenter Only)

If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described later in the protocol.

5.1 Describe when, where, and how potential subjects will be recruited.

Response: For **Phase I**, participants will be recruited through fliers posted at the Center for Youth and Compass House. Additionally, participants may be recruited through referral from case managers at either site. For **Phase II**, eligible participants from **Phase I** will be contacted directly by RAs or study therapists based on the participant's preferred contact

method (phone call, email, text). Participants will be contacted up to 3 times, which will be documented in a contact log. If the participant gives no response after 3 documented attempts, the participant's case manager may be contacted in an attempt to reach the participant. If the participant cannot be reached, the participant will be considered lost to follow up.

5.2 Describe the methods that will be used to identify potential subjects.

Response: Participants will self-identify as interested in **Phase I** of the study by contacting the study PI or RAs via telephone or email. Additionally, case managers may refer participants who are interested in the study. Then the potential participant will complete the screening procedures described above to determine eligibility for **Phase I.** Participants would also self-identify as interested in **Phase II** of the study by responding "Yes" to being contacted about **Phase II** in the **Phase I** survey.

5.3 Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)

Response: Fliers will be used to recruit participants for **Phase I** (See Appendix: Recruitment Flyer).

6.0 Multi-Site Research (Multisite/Multicenter Only)

6.1 If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites, such as:

- *All sites have the most current version of the protocol, consent document, and HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data as required by local information security policies.*
- *All local site investigators conduct the study appropriately.*
- *All non-compliance with the study protocol or applicable requirements will reported in accordance with local policy.*

Response: The study PI will hold monthly meetings with all RAs in order to ensure communication of study procedures among sites. Additionally,

bi-weekly supervision meetings will be held for all study interventionists to ensure adherence to the protocol.

6.2 Describe the method for communicating to engaged participating sites

*Respon*se: Communication among sites will be conducted via telephone, email, or video conferencing. Site meetings will be held in person when possible or via telephone or video conferencing.

7.0 Study Timelines

7.1 Describe the duration of an individual subject's participation in the study.

Response: An individual participant will complete the **Phase I** survey, and the MINI Psychiatric Interview, both will be completed in one session, lasting about 60 to 90 minutes including the consent/assent process. A study staff member will be available to answer any questions about the survey. If invited for **Phase II**, participation is expected to last a total of 4-6 months (NET therapy- 4-12 weeks, follow-up survey and interview 2 weeks post-NET and 3 months post-NET). Study measures and NET sessions will last approximately 90 minutes to 2 hours. Follow-up surveys and interview are expected to take 60 to 90 minutes.

7.2 Describe the duration anticipated to enroll all study subjects.

Response: All study subjects will be enrolled in the first two years, by January 2019.

7.3 Describe the estimated date for the investigators to complete this study (complete primary analyses)

Response: The estimated date for completion of this study for primary analysis is three years, by January 2020.

8.0 Study Endpoints

8.1 Describe the primary and secondary study endpoints.

Response: The primary study endpoints are education endpoints for each of the phases of the study. In **Phase I**, we aim to understand the prevalence and types of traumatic experiences in this population. In addition, we would like to understand the moderating and mediating factors in the relationship between trauma and mental health outcomes (we will recruit 120 participants). For **Phase II**, we seek to learn about the effects of NET on PTSD symptoms and other mental health outcomes in this population (we will recruit 30 participants).

8.2 Describe any primary or secondary safety endpoints.

Response: The primary safety endpoints for both **Phase I** and **Phase II** are evidence of active suicidality or homicide risk (including active intent and the presence of a plan). Another safety endpoint for **Phase II,** although unlikely**,** will be evidence of iatrogenic effects of the NET intervention. Specifically, we will end the treatment if we have reason to believe that the study is having a negative impact on the participant (e.g. if symptoms worsen dramatically or if the participant becomes extremely distressed as treatment progresses).

9.0 Procedures Involved

9.1 Describe and explain the study design.

Response:

Phase I*:* Adolescents and young adults in low-income, urban area have high rates of experiencing or witnessing trauma. Furthermore, they are at greater risk for developing PTSD than higher-income, suburban peers who are also exposed to trauma. PTSD puts adolescents at high risk for co-occurring depression and substance misuse (SUB) including alcohol and marijuana. Heavy drinking, trauma exposure, and PTSD in adolescents have been linked to risk-taking behavior (e.g. sexual risk behavior), trauma re-exposure, psychological dysfunction, academic impairment, and increased vulnerability to violence as well as poor mental and physical health outcomes.

Emerging evidence supports trauma and PTSD as important negative influences in adolescent growth and development, physical health outcomes, (e.g. cardiovascular disease and diabetes), and mental health outcomes. However, a greater understanding is needed of predictors of both positive and negative outcomes in those at highest risk. Therefore, the ***purpose of the Phase I*** is to explore factors that are associated with the development of poor mental health outcomes (e.g. PTSD, depression, or anxiety), risk behaviors (e.g. SUB), and posttraumatic growth. Therefore, a cross-sectional survey design will allow us to *address specific aims #1 and #2.*

Phase II: Urban, low-income adolescents experience high rates of interpersonal violence among multiple experiences of trauma. These adolescents are at greater risk for PSTD and depression. However, there is a lack of evidenced-based, specific interventions to treat interpersonal trauma related PTSD and depression for adolescents. Therefore, interventions based in cognitive behavioral therapy methods, such as NET, that demonstrate promise in treating PTSD and depression resulting from multiple traumas in adolescents at high risk should be examined for potential treatment options for these adolescents in community settings. Therefore, *to address specific aim #3*, we will conduct a pilot study (N = 30 to examine feasibility and estimate NET treatment effects on the reduction of PTSD symptoms and SUB for adolescents (ages 16-24) experiencing violence-related PTSD. The methodology to achieve the

objectives of specific aim #3 is to conduct an uncontrolled, pilot intervention study in order to gather preliminary feasibility data.

For a detailed description of the full study design see Appendix: NET: PTSD Study Design.

9.2 Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.

Response: The PI will establish and meet with the community advisory board (CAB) before **Phase II**. The CAB will include Compass House agency staff (≈3), youth (≈2), and community stakeholders (≈2), to elicit study support and discuss recommendations. The CAB will inform referral resources, retention strategies, and ideas to improve collaboration.

For detailed description of full study design see Appendix: POWER-NET Study Design.

Phase I: The PI will educate community partners (CFY, Compass House) on study background and procedures through an in-service presentation. Participants (youths receiving services at CFY or Compass House) will be recruited via one of two ways: 1) adolescents who express interest in the study and agree to be contacted will be referred to study team by CFY or Compass House staff, or 2) adolescents will contact or approach the research team to learn more about the study (see Appendix: Recruitment Flyer). Interested, potential participants will receive study information, be invited to ask questions, and be consented/assented. The participant will be given a written informed consent/assent to read and sign after an opportunity to ask questions (See Appendix: Informed Consent/Assents forms). The research staff will assign each participant an identification number. Consent/assent forms will be transported in a locked box (key kept by study team) and forms kept in a separate locked file in the Dr. Read's Alcohol Research Lab (ARL) at the University at Buffalo run by PI (Dr. Jennifer Read). The consent/assent document will include all required federal and state language, all required university IRB information, including the measures to be completed and the fact that the NET sessions will be videotaped. The videotape rationale will be included which is to focus on the therapist to provide supervision and measure therapist fidelity. A separate document will be completed by the participants, providing **safe** contact numbers, emails, and text numbers for the research staff to arrange for participation in **Phase II** (See Appendix: Contact Information document). Participant contact documents will be transported in a locked box and stored in a locked cabinet in UB's ARL.

After informed consent/assent is completed, the participant will be given the baseline survey (T_0) via REDCap technology. REDCap is a secure, web-based application designed to support data capture. It is hosted by UB, School of Medicine. REDCap allows for an intuitive interface for the following: 1) validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to SPSS; and 4) procedures for importing data from external sources (See Appendix: REDCap General Security Overview for detailed description of security).

After completion of the survey and the MINI Psychiatric Interview (estimated 60-90 minutes), the participant will be compensated with $15 in cash. Primary and secondary participant contact information will be obtained for potential participation in **Phase II**. An item in the Phase I survey will indicate whether the participant has an interest in hearing about the possibility of participating in Phase II if eligible (eligibility criteria will be blinded from participants).

***Phase II*:** The research team will review the data from the **Phase I** survey to assess eligibility of participants for **Phase II**. For those that meet eligibility criteria (1. completion of **Phase I** survey [i.e., no cognitive deficits], 2. negative suicidality, 3. positive PTSD screen, and 4. negative psychosis and mania screen) and indicated interest in participating in Phase II, a member of the research team (RA, study therapist, or PI) will contact the case manager or potential participant to arrange a time to provide study information and consent/assent. A research team member (RA, study therapist, or PI) will meet with the adolescent privately to provide study information and conduct the consent process (or assent <18 years old). Before each NET session, the participant will complete study measures assessing main outcomes (e.g. symptoms of PTSD, depression, anxiety, and SUB). Then the NET session will begin. Measures and NET sessions will take approximately 90 minutes to 2 hours. Therapy sessions may be completed once or twice a week depending on the participant and therapist availability. After each session, participants will be compensated $15 in cash. Participants who complete all treatment sessions will be given an additional $25 for survey completion at the last treatment session.

After NET is completed (4-12 weeks, 4-12 sessions), the participant will be scheduled for post-intervention surveys ($T_{1\ month;}$ $T_{3\ months}$) to test for NET's effects on PTSD, depressive symptoms, anxiety symptoms, and SUB. Primary and secondary participant contact information changes will be obtained at each visit to prevent attrition. Additionally, case managers for each participant may be contacted in the event that the therapist is unable to get in contact with a participant for 2 weeks.

NET sessions will be videotaped for the purpose of therapist supervision (Dr. Read, and Dr. Carrie Hanson-Bradley, LMFT, PhD) and measuring intervention fidelity (Drs. Hanson-Bradley, Wendi Cross, and RAs). Videos of the sessions will be recorded using study video cameras. Following each session, videos will be uploaded to a secure cloud supported by the University at Buffalo, Box, Herein referred to as UBBox. Videos will not remain on video cameras once they are uploaded. One year after data collection, all videos on UBbox will be erased. Videos will focus on the therapist, though the participant will be filmed to track therapist response to participant. UBBox will offer password-protected uploading and sharing capabilities with secure password protected access. UBBox allows UB collaborators access according to user need and approval. UB collaborators include Drs. Hanson-Bradley and Cross. Dr. Hanson-Bradley, a licensed Family and Marriage Therapist (LMFT), is a NET expert and will be assisting in therapist intervention and fidelity. She is based in Lincoln, NE. She is considered one of a few

United States NET trainers. She has trained and supervised NET therapists for over 3 years. As a LMFT, Dr. Hanson-Bradley is subject to professional, HIPAA regulations.

Dr. Cross, PhD, psychologist, directs the center for Observational Research and Behavioral Technology (ORBIT) at the University of Rochester Medical Center. Dr. Cross is an expert in intervention fidelity and the study of human interactions through observational research methods that involve recording and coding real world or analogue transactions. As a clinical psychologist, she is subject to professional, HIPAA regulations.

9.3 Describe procedures performed to lessen the probability or magnitude of risks.

Response:

The following are procedures have been designed to minimize the probability or magnitude of risk:

1) The primary risk for a participant is emotional distress during survey completion or NET sessions. As noted, such distress is not common, and usually is transient, ending by the time the participant leaves the session. Still, we have several procedures in place to minimize any risk associated with such distress. The research team members and therapists have experience in collecting sensitive data regarding traumatization, mental health, and risk behavior in clinical and research settings (see preliminary studies) and have well-developed procedures in place for managing distress on the occasions that it does occur. Moreover, participants will be given an option to skip any questions that make them uncomfortable, or to withdraw from the study at any time. Indeed, during consent /assent procedures, all participants will be reminded at the point of data collection that they have the option to withdraw without penalty of services. Participants will be given extensive psychoeducation before initiating NET to provide realistic expectations of therapy intensity. Additionally, psychoeducation will be included at each NET session and will include participant self-care and safety planning. NET therapy has demonstrated low attrition rates in diverse samples. In addition, the intervention itself can serve to minimize distress, as through NET, therapists and participants will engage in problem solving to addressing barriers (including emotional distress) to completion. This has been found to be effective in NET studies.

2) Participants will be provided with resource lists and research staff will be trained to help put a participant in touch with appropriate agencies or a counselor, if necessary.

3) PI (Read) is a clinical psychologist with over 20 years of experience in the assessment of and intervention for trauma and PTSD. She will supervise the doctoral psychologist students.

4) In the case that a research staff or therapist identifies suicidal thoughts or behaviors, the interventionists will assess lethality risk consistent with procedures that we have developed in our labs and that have been used in numerous protocols over the years. This will include contacting either Dr. Read to consult on the

likelihood of imminent risk to self or others, including evaluation of participant intent, plan, and means. If the participant is deemed to be at imminent risk, Dr. Read and study staff will work with the staff at Compass House/CFY to develop an appropriate care plan, consistent with the procedures and protections of the resource center. In cases of other mental health emergencies not including suicidality, the research team or therapist will contact a local crisis services unit. If the consulting supervisor deems low risk of lethality, the research staff or therapist will document assessment and plan and file in participant study folder (transported in locked box and stored in the ARL).

5) Development of a CAB to elicit participant community members' perspectives and insight will allow us to assess risk from an emic perspective.

6) The risk of discomfort or distress will be identified and communicated to the participant and the option to refuse to answer or withdraw from the study will be presented in all survey documents.

7) To minimize distress, participants may sign a written waiver allowing their case manager to be present in the room during NET sessions.

8) Participants will be given the contact information (project phone number, e-mails for Dr. Read) in Phase I and II. Therapists will have staff contact information and emergency referrals (e.g. mobile crisis numbers) information on cards to provide to Phase II participants when needed.

9) Validated suicide, homicide risk protocols on which research staff and therapists will be trained.

10) For participants that are 16 or 17 we will obtain assent to participate in the study. A waiver of parental consent will be requested based on the youth agencies services to homeless and at-risk for homeless adolescents.

11) Digital videos will be taken with video cameras and will be uploaded to secure, password-protected cloud supported by UBBox. These videos will be deleted one year after data collection.

12) A de-identified data set will be stored on a password-protected, secure site-REDCap.

13) The PI (Read) will be available by cell phone during survey administration sessions and NET sessions are conducted for mental health emergencies.

14) NET therapists are trained clinical therapists in both the specific therapy and in general therapeutic techniques. Furthermore, they will participate in group and individual supervision by clinical experts on a bi-weekly basis for approximately two hours.

15) NET Psychoeducation is an important part of each NET session. Psychoeducation will be targeted to participants' specific concerns and needs.

16) Data confidentiality is prioritized **(See Appendix: Data Security Procedures)**

9.4 Describe all drugs and devices used in the research and the purpose of their use, and their regulatory approval status.

Response: No drugs or devices will be used in this study.

9.5 Describe the source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)

Response: **Phase I** will consist of an electronic self-report survey and two modules of the MINI psychiatric interview. Participants who report alcohol or drug use on the day of the survey will also be given the Mini-Mental State Exam. It will take approximately 60-90 minutes to complete (See Appendix: Baseline Survey Instruments). **Phase II** will include short surveys at each time point of NET to monitor symptoms throughout therapy (approximately 30 minutes; See Appendix: Pre-NET Survey Instruments), and longer surveys at completion of NET: 1) 1 month post final NET session (approximately 60-90 minutes; See Appendix: 1 Month Follow Up Survey Instruments and MINI Psychiatric Interview); and 2) 3 months post final NET session (approximately 60-90 minutes; See Appendix: 3 Month Follow Up Survey Instruments and MINI Psychiatric Interview). The measures table indicates author information, item number, psychometrics, and time point for each instrument. All study surveys will be administered on REDCap.

9.6 What data will be collected including long-term follow-up.

Response: Follow-up survey measures and interview are included in the Appendix: Measures Table.

9.7 For HUD uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

Response: Not applicable. Drugs and medical devices are not used in this study.

10.0 Data and Specimen Banking

10.1 If data or specimens will be banked for future use, describe where the data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens.

Response: Not applicable: No data or specimens will be banked for future use.

10.2 List the data to be stored or associated with each specimen.

Response: No specimens will be collected or stored.

10.3 Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who

can obtain data or specimens, and the data to be provided with specimens.

Response: Not applicable. Data or specimens are not released.

11.0 Data Management

11.1 Describe the data analysis plan, including any statistical procedures.

Response: Survey data will be collected at four time points (T_0, $T_{4\text{-}12NET}$, $T_{1\ mo}$,T_{3mo}:). Data will be exported via REDCap into a secure SPSS file, and maintained in REDCap. Data will be cleaned and evaluated for missing data. De-identified data will be shared with community sites.

Aim #1: We will examine the prevalence of trauma experiences and its relationship to mental health outcomes including PTSD, depression, anxiety, and SUB. Ordinary Least Squares (OLS) regression will be used to examine the association among trauma experiences, and mental health outcomes. Demographics and psychological symptoms will be included as covariates.

Aim #2: Moderation hypotheses will be examined to explore if relationships between PTSD and mental health outcomes are influenced by potential moderators (e.g. gender and age). Moderation analysis will be conducted using Preacher and Hayes (2014). Mediation analysis will be examined to explore if factors (e.g. intervention fidelity) explain the relationship between trauma experiences and mental health outcomes. Mediation analysis will be explored using Preacher and Hayes (2014).

Aim #3: Treatment effects will be assessed using mixed effects models to account for serial correlation within participants. Treatment effects will be determined with primary outcome of PTSD symptoms and treatment, time, and treatment time as fixed effects in site nested models. We will determine if treatment estimate PTSD symptoms and from T_0-$T_{3\ months}$ are larger or smaller than zero. Analysis will be repeated for the secondary outcome of substance and depression. This study will provide critical information regarding the implementation process (e.g. fidelity variability and effect), resources, management, and the science (treatment safety, dosage/session number, and estimation of treatment effect). Recruitment and retention rates will be determined by tracking screening, informed consent, treatment attendance, and survey completion rates. Pilot data will be used to adapt training and manual and study protocol. Data (tapes and coding) will be stored in UBBox. Fidelity codes will be de-identified and stored in UBBox and hard copies of original codes will be stored in the ARL in a locked cabinet space. Codes will be entered into SPSS and analysis regarding intervention fidelity will be merged with pilot data for analysis. Psychometrics of fidelity measures will be conducted (internal reliability, internal consistency, and relationship between adherence and competence**).** Structural equation modeling will be used to explore intervention fidelity's (adherence and competence) and its variance associations with NET's effect to evaluate for potential mediating effects.

Moderation analysis will facilitate the exploration of the direction and size effect based on the following variables (gender, age/race, pregnancy and parenting status). Mediation analysis examining fidelity variability will be explored to estimate the influence on intervention fidelity on effect. Bootstrapping will be used to accommodate a sample size, which may not meet assumptions of normal distribution

11.2 Provide a power analysis.

Response:

Phase 1: The analytic strategy for is OLS regression. Power for the OLS models was calculated with G*Power. Assuming an alpha value of 0.05, a sample size of 100, and power of at least .80, the study would be sufficiently powered to detect a medium effect size, which is supported by current literature. To account for attrition, we will recruit 120 adolescents.

Phase 2: We will recruit 30 adolescents, from CFY Inc., in Rochester, NY and Compass House in Buffalo, NY. To determine pilot study sample size, anticipated sample size for main trial was calculated using a conservative 0.4 effect size, 80% power and 5% significance level t-tests for main trail (N= 198). We calculated a pilot sample size of at least 18 using Cocks' and Torgerson (2013) approach of 9% of total sample size using 80% one-sided confidence intervals. We aim for a sample of 24 participants. We estimated a 20% attrition rate; therefore, we will recruit a sample of 30.

11.3 Describe the steps that will be taken secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.

Response:

Data will be collected using REDCap technology. REDCap is a **secure,** web-based application designed to support data capture and storage. It is hosted though UB medical school. REDCap computer services department personnel are provided access to data as needed solely for administrative purposes. All investigators, staff, and computer services staff will have certified completion of research ethics training required by the University at Buffalo, with associated certificates on file. (see Appendix: REDCap General Security Overview.)

Any paper forms (e.g., signed consent/assent forms, participant contact information sheets) will be kept in the ARL, accessible only to members of the research team. Identifying information (i.e., consent/ assent forms) will be kept separate form actual data.

Patient narratives will be written on password-protected study PCs,then uploaded on secure cloud, UBBox, and erased from hard drive. All narratives will only be identified via participant ID numbers.

Following procedures used previously by our research group, therapist video will be taken using video capabilities on study video cameras uploaded to UBBox, and erased from hard drive.

11.4 Describe any procedures that will be used for quality control of collected data.

Response: Rigorous procedures will be used to ensure the integrity of data collection, storage and sharing. The use of system-wide, web-based electronic data collection procedures in the baseline and follow-up surveys will minimize the need for data entry or scanning to process data. Further, a research assistant will be present during survey administration to address questions or concerns that the participant may have. Advanced programming will prohibit out-of-range responses as well as errors common with other techniques (e.g., illegible written responses). Data will be stored and backed-up per REDCap security protocols. NET sessions will be video-recorded on encrypted, study PCs, downloaded on a secure cloud network, UBBox.

A data safety monitoring board (DSMB) will be established to provide quality control of collected data. The following have agreed to serve on the DSMB: 1) Dr. Gerard Connors, PhD. Dr. Rina Eiden, PhD is a senior research scientist and clinical psychologist at the Research Institute of Addictions (RIA). She has been federally-funded and conducted numerous clinical trials. 2) Dr. Kim Griswold, MD, MPH, RN. Dr. Griswold is a family physician that focuses on the integration of primary care and mental health services in vulnerable populations. She conducts research in behavioral health and health care disparities. 3) Dr. Kristin Gainey, a clinical psychologist and Assistant Professor in the Department of Psychology with expertise in trauma.

The DSMB will meet once before the intervention implementation, bi-annually for an intervention safety review while the intervention and follow-up is ongoing, and once all follow-up period have been completed. The safety review will entail an adherence review for consent process, ensuring adherence in data collection protocol and monitoring of the data. Three participant cases will be randomly selected to review from recruitment to conclusion at bi-annual meeting. University at Buffalo's procedures for reporting of Serious Adverse Events (SAEs) with information specific to project will be submitted to the IRB, CFY, and Compass House. At the initial DSMB meeting, specific predetermined criteria for stopping the study at key "decision points" will be identified.

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11.5 Describe how data and specimens will be handled study-wide:

Response:

To protect participant confidentiality, only research team [(PI, RAs, fidelity consult (Cross) and supervision consultant (Hanson-Bradley)] will have access to study data with potentially identifying information. REDCap administrative staff will have access as necessary to allow for administration of study-related

computer services. None of the individual study records will be available to the CFY or Compass House, participant's family, legal, educational, or employer representatives. Study's aggregated data will be available to the community partner for the purpose of grants and program development (CFY or Compass House). All paper records will be stored in locked file cabinets kept on-site at the University at Buffalo, Alcohol Research Lab (ARL). Video-recordings of NET sessions will be uploaded via the Study PCs to UBBox and recordings will be thereafter deleted from the study PCs. Patient narratives will be written on encrypted study PCs, uploaded to UBBox, and erased from study PCs. Confidential participant information will not be stored locally on staff computers, and all electronic study data will be stored in a REDCap.

See Appendix: Data Storage Table

All consent/ assent procedures and data collection will be conducted in private interview rooms at the CFY or Compass House in small groups or individual sessions. Questionnaires via password-protected study PCs will be administered individually or in small groups (up to 3). Participants' email addresses and phone numbers will be collected as part of the baseline survey and recorded in a secure database of participant identification numbers for the purposes of Phase II invitations, NET therapy, and follow-up appointment reminders. These data will be de-identified after completion of the study.

Several additional procedures will be followed to ensure confidentiality of all research participants. Each participant will be assigned an identification code, which will be the only identifier on all written and computerized data. Consent forms will have participants' names, but will not have their identification numbers. Only the research staff will have access to a document that links participant name to their unique identifier. This listing will be part of the computerized project database, which is password protected and is located on the UB supported secure cloud, UBBox (protected behind a firewall). Baseline, Pre-NET session and follow-up survey and interview data will be collected using encrypted study PCs to access to secure REDCap. Immediately following consent/ assent process, consent/ assent forms will be stored separately in locked storage boxed to be transported to locked file cabinets in the ARL.

Videos of NET sessions will be uploaded onto a UB secure cloud server, UBBox (identifiable only with participant's unique ID number).

All research staff has been trained in the ethical issues related to participant confidentiality and have completed designated Human Subjects training courses. All presentations of the study data (e.g. conferences, manuscripts, grants, and community agency reports) will be reported only in aggregate form, no individual identifying information will be presented.

Participants will be informed of the limits of confidentiality, which include cases of suspected child abuse or neglect, and intent to harm self or others. Following requirements outlined by the funding agency, the National Institutes of Health participants are made aware that, by agreeing to be in the study, they are voluntarily providing consent to alert appropriate authorities in these specific

cases. Specifically, participants are told the following in the consent form, "I also agree that the researcher may make a report to appropriate authorities if I mention that I am an imminent threat to self or others or I reveal ongoing abuse or neglect of a child (under age 18)." Participants who do not consent to these stipulations will not be eligible to participate in the study.

11.6 What information will be included in that data or associated with the specimens?

Response: Appendix: See Data Storage and Appendix: Survey Measures

11.7 Where and how data or specimens will be stored?

11.8 Response: Participant Survey data will be stored using REDCap informatics. Participant narratives and therapist videos will be stored on UB-supported cloud, UBBox. Security of REDCap and Box will allow specific, password protected access (i.e. PI and RAs) See 11.5 and Appendix: Data Security Procedures for more detailed explanation of storage and access.

11.9 How long the data or specimens will be stored?

Response: De-identified data from the study will be submitted for archiving for a period of 7 years after the close of the study in the UB archives. In addition to de-identifying the data as part of this process, all lists that contain links between participants' ID numbers and their identifying information will be permanently deleted form the study files and databases

Videos of NET sessions will be archived at UB.

11.10 Who will have access to the data or specimens?

Response: Key personnel (PI & RAs) will have access to study data, including data that are not de-identified. Project personnel will have access to the data only for the duration of their association with the project. Any parties interested in analysis of the collected data (e.g. collaborators, CFY or Compass House) will only have access to the de-identified files. All study personnel with access to participant data will have completed CITI training. See Appendix: Data Security Procedures.

11.11Who is responsible for receipt or transmission of the data or specimens?

Response: PI Read, study therapists, and project RAs

11.12How data and specimens will be transported?

Response:

Data collected from Phase I and Phase II surveys will be simultaneously uploaded to REDCap.

Assent/Consent Forms will be collected and filed in a secure, lockbox to be transported to the ARL at the University at Buffalo, Buffalo, NY.

Videos will be uploaded from data study video cameras to UBBox.

NET Narratives will be uploaded from password-protected study PCs to UBBox.

12.0 Provisions to Monitor the Data and Ensure the Safety of Subjects

12.1 Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Response: Because of the greater than minimal risk to subjects, a Data Safety Monitoring Board (DSMB) will be convened. The DSMB will meet once before the intervention implementation, bi-annually for an intervention safety review while the intervention and follow-up is ongoing, and once all follow-up period have been completed. The safety review will entail an adherence review for consent process, ensuring adherence in data collection protocol, and monitoring of the data. Three participant cases will be randomly selected to review from recruitment to conclusion at bi-annual meeting. University at Buffalo's procedures for reporting of Serious Adverse Events (SAEs) with information specific to project will be submitted to the IRB, CFY, and Compass House. At the initial DSMB meeting, specific predetermined criteria for stopping the study at key "decision points" will be identified.

The DSMB will be made up of independent investigators without conflicts of interest in the Buffalo area: 1) Dr. Gerard Connors, PhD. Dr. Gerard Connors, PhD is a senior research scientist and clinical psychologist at the Research Institute of Addictions (RIA). He has been federally funded and conducted numerous clinical trials. 2) Dr. Kim Griswold, MD, MPH, RN, MD. Dr. Griswold is a family physician that focuses on the integration of primary care and mental health services in vulnerable populations. She conducts research in behavioral health and health care disparities. 3) Dr. Kristin Gainey, a clinical psychologist and Assistant Professor in the Department of Psychology with expertise in trauma.
. No members of this team are affiliated with the study. This team will produce a semiannual report for the UB IRB.

12.2 Describe what data are reviewed, including safety data, untoward events, and efficacy data.

Response: Participants will be continuously monitored for signs of possible distress during Phase I and II survey assessments and NET sessions by trained, research staff (PI, RAs and therapists).

Random participant survey data, NET video session and NET narrative data will be reviewed by DSMB. See above (21.1) for detailed explanation of data to be reviewed and process.

12.3 Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

Response: Safety information will be collected at each survey time point (Phase I, Phase II: before each NET session, Phase II: post NET ($T_{1\ month}$ and $T_{3\ months}$. Survey contains validating items that question intent to harm self or others.

The NET therapist will collect safety information at each NET session. Before exposure begins, the therapist will check in with the participant about how they are doing and their symptoms since the last session. Therapists are trained and supervised in addressing emotional distress and suicidality. They will also follow the suicide protocol (see section 9.3).

12.4 Describe the frequency of data collection, including when safety data collection starts.

Response: Participant survey data is collected at the following points: 1) Phase I (1 session); 2) Phase II: before each NET sessions (4-12 sessions); 3) Phase II: post NET therapy at 1 month and 3 months (2 sessions). At each data collection point, safety data is collected.

12.5 Describe who will review the data.

Response: The research staff (PI and RAs) will review the survey data, NET videotapes, and NET Narratives for safety concerns.

12.6 Describe the frequency or periodicity of review of cumulative data.

Response: Data will be monitored on an ongoing nature during the study monthly.

12.7 Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.

Response: PI will review survey data and descriptive statistics with time series analysis will be conducted at mental health outcome variables to determine if PTSD and depression scores are increasing in significant levels.

12.8 Describe any conditions that trigger an immediate suspension of the research.

Response: Suicide or homicidal attempt by any of the participants, or participant request to terminate.

13.0 Withdrawal of Subjects

13.1 Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.

Response: Subjects may be withdrawn from research without their consent if they endorse suicide or homicidal ideation with serious intent (including a plan). They will be referred to higher level of care (mobile crisis unit or psychiatric hospitalization).

13.2 Describe any procedures for orderly termination.

Response: Orderly termination will occur for the above listed reasons. If after Dr. Read determines serious lethality of suicide or homicide intent, patient will be transported to a local emergency department

13.3 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

Response: If a participant voluntarily withdraws from the NET sessions before they are completed, he or she will still be included in data collection if they agreed to continue study participation. If they withdraw from the study before data collection is complete, he and she will be compensated based on previous participation and data will be considered in the intent-to-treat analysis.

14.0 Risks to Subjects

14.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.

Response:

Phase 1: There is risk that interview and survey questions may make the subject uncomfortable.

Phase 2: NET exposure therapy is an intensive therapy that works by collaborating with the participant to process the trauma or traumas that s/he has experienced. It is expected that participants will experience some

emotional discomfort during the therapy sessions, as this is the nature of the intervention. The therapists will be trained and supervised to guide participants through these uncomfortable feelings and ensure that they leave the session in a safe place. Dr. Read will supervise therapists**. For any risk of suicidal or homicidal intent,** the research team will follow a specific protocol a lethality assessment and personal safety assessment. After the therapist has screened for suicidal ideation, plan, and intent, they will call the study supervisor (Read) to consult on lethality. If risk is determined to be high, Dr. Read may personally assess lethality. If it is determined that the participant is at imminent and high suicide or homicide risk (e.g., intent, plan, means), then Dr. Read will work with CFY or Compass House staff to formulate a safety plan. This could include transportation to a local emergency department or contact with a local crisis services team. There is an additional slight risk of loss of confidentiality to prevent any serious risk of harm to the subject or others, including child abuse and neglect. There is risk that interview and survey questions may make the subject uncomfortable. Although interview and survey questions were carefully drafted not to solicit reports of illegal activity, there is a risk that illegal activities might be disclosed during the therapy session. Coercion is a concern of the study. As with any study seeking assent or informed consent, individuals could feel coerced to participate in the study.

All therapists, researchers involved in this project and community site staff and are bound by provisions accorded in the Health Insurance Portability and Accountability Act (HIPAA) required by the Health and Human Services. Furthermore, research staff will hold current CITI certification in Social Science Research, which covers human subjects' protection, including ensuring confidentiality.

Subjects will be notified that they may end their participation in the study at any time and do not need to complete the interviews or surveys. Strict data storage measures will be taken to protect the identities of research participants. If research personnel suspect any incidences of child abuse or neglect, the PI will be immediately contacted. Potential subjects will be notified during consent that suspected child abuse and neglect will warrant a report to Child Protective Services (CPS) by the study personnel. Decision to inform subjects that confidentiality will be breached in cases of indicated harm to themselves or others will be made on a case-to-case basis based on safety risk.

Confidentiality will be protected when interacting with the CFY and Compass House staff as well as strict adherence to data storage procedures. Participants will be told that the information they provide will be kept confidential. The study personnel will clearly explain that data will only be used for research or grant acquisition purposes, and participation is voluntary and may be withdrawn at any time.

For subjects under 18. These youths are often homeless, living in a shelter, and estranged from their parents. For adolescents under age 18, we will apply for a waiver of consent because it is unreasonable to request parental permission from the adolescents

who receive services from the Center for Youth or Compass House because of their status as *"at risk for homelessness."* Prior studies have demonstrated success obtained waivers of parental consent. (F31MH082646-01A2, E. Volpe; R01 NR008194, D. Morrison-Beedy). Allowing subjects under 18 to review and sign the assent form, independent from their parents given the nature of the community-based agencies and the adolescent they serve, will minimize coercion.

Subjects will be provided with consent or assent forms written in age appropriate language explaining the study, its potential benefits, and its potential risks. All subjects may withdraw at any time and are still eligible to participate even if they are not willing to complete some/all of the NET sessions or the surveys.

14.2 If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.

Response: No risks are currently unforeseeable.

14.3 If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.

Response: No procedures, including NET therapy, will be conducted that have risks for embryo or fetus should the subject be or become pregnant during participation in the study. Treatment options that are trauma-focused are recommended for adolescents that are pregnant and experiencing PTSD.

14.4 If applicable, describe risks to others who are not subjects.

Response: There are no known risks to others who are not subjects.

15.0 Potential Benefits to Subjects

15.1 Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits.

Response:

- Adolescents participating in Phase I will be referred to NET if they endorse the minimally required PTSD symptoms and fit other eligibility criteria. Adolescent Phase II participants will receive mental health therapy services from NET-trained, supervised mental health therapists. This is therapy that they may not otherwise have received.
- Information including the prevalence of mental health issues will inform community agency grant applications.
- The participant's contribution will help increase scientific knowledge and may help raise public awareness of issues of violence and its

mental health outcomes, inform service providers about the unique needs of low-income adolescents and inform changes in the larger health system to help improve the experience of adolescents who experience violence and its correlates.

15.2 Indicate if there is no direct benefit. Do not include benefits to society or others.

Response: There is an anticipated direct benefit of receiving services for PTSD by trained therapists.

16.0 Vulnerable Populations

16.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

- *If the research involves pregnant women, review "CHECKLIST: Pregnant Women (HRP-412)" to ensure that you have provided sufficient information.*
- *If the research involves neonates of uncertain viability or non-viable neonates, review "CHECKLIST: Neonates (HRP-413)" or "HRP-414 – CHECKLIST: Neonates of Uncertain Viability (HRP-414)" to ensure that you have provided sufficient information.*
- *If the research involves prisoners, review "CHECKLIST: Prisoners (HRP-415)" to ensure that you have provided sufficient information.*
- *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children"), review the "CHECKLIST: Children (HRP-416)" to ensure that you have provided sufficient information.*
- *If the research involves cognitively impaired adults, review "CHECKLIST: Cognitively Impaired Adults (HRP-417)" to ensure that you have provided sufficient information.*
- *Consider if other specifically targeted populations such as students, employees of a specific firm or educationally/economically disadvantaged persons are vulnerable to coercion or undue influence. The checklists listed above for other populations should be used as a guide to ensure that you have provided sufficient information.*

Response: Checklist reviewed. Sufficient information provided.

17.0 Community-Based Participatory Research

17.1 Describe involvement of the community in the design and conduct of the research.

Response: The Center for Youth, Inc. has been a partner in this research endeavor for over 3 years. We have conducted pilot studies with CFY adolescents being served and CFY agency providers including prevention counselors and directors. In total, 6 CFY staff have been trained in NET. They have been supported of this research at all stages. Additionally, our partners at Compass House in Buffalo have approved the project and expressed willingness and enthusiasm about participating in the study.

Note: "Community-based Participatory Research" is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

18.0 Sharing of Results with Subjects

18.1 Describe whether or not results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared.

Response: The CFY and Compass House will receive the results of the study in aggregated, de-identified form. They will access to de-identified information upon approval from the PI (Read)

19.0 Setting

19.1 Describe the sites or locations where your research team will conduct the research.

Response: The Center for Youth, Inc. has provided services to Runaway and Homeless Youth and other youth disconnected from systems and families for four decades. CFY have provided over 7,700 youth with emergency shelter services and served 18,000 youth through street outreach. Annually, CFY provides counseling services to over 400 youth, emergency shelter to over 250 youth, and transitional living apartments/group home to over 40 youth, including parenting and pregnant teens. Last year, 86% of the youth accessing our emergency shelter identified experiencing traumatic incidences of childhood abuse, neglect and/or recent interpersonal violence. Compass House provides similar services to youth in the Buffalo area.

19.2 Identify where your research team will identify and recruit potential subjects.

Response: Center for Youth, Inc. Rochester, NY and Compass House, Buffalo, NY

19.3 Identify where research procedures will be performed.

Response: Center for Youth, Inc., and Compass House.

19.4 Describe the composition and involvement of any community advisory board.

Response: A community advisor board (CAB) will be developed to guide the study. Members from the Compass House Board of Directors will be asked to participate as well as three youth members (ages 16-25) who currently or in the past have received services from Compass House.

The CAB will meet before Phase II study initiation to advise on procedures. It will meet every 6 months after until the close of the study. At study close, the research team will present preliminary results from the study. The CAB will be asked about perspectives of next steps.

19.5 For research conducted outside of the organization and its affiliates describe:

- *Site-specific regulations or customs affecting the research for research outside the organization.*
- *Local scientific and ethical review structure outside the organization.*

Response: The Center for Youth Director of Counseling and Runaway/Homeless Youth has and the Compass House Executive Director have reviewed the research and provided approval.

20.0 Resources Available

20.1 Describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to perform their role. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research. Note- If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify people by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not usually require prior approval by the IRB, provided that person meets the qualifications described to fulfill their roles.

Response:

The assembled multidisciplinary research team represents a group of individuals with a unique expert knowledge and experience. They include a clinical

psychologist (PI Read), developmental psychologist (Eiden), bio stastician (Hutson), family and marriage counselor/NET expert (Hanson-Bradley and clinical psychologist/implementation expert (Cross). Dr. Read is a highly respected and well-funded researcher conducting numerous studies related to substance abuse and PTSD. Dr. Eiden has extensive experience in research in developmental psychology and the influence of maternal addictions on development. She has expertise in recruitment and retention of subjects that are difficult to reach. Dr. Hutson has extensive experience in the area of clinical research and statistics. Dr. Hanson-Bradley is one of the few NET trainers with extensive experience in clinical application and intervention research with diverse populations. Dr. Cross is the director of the ORBIT lab at URMC, which provides consultation and resources for those conducting fidelity research. All of the above have mentored students and junior faculty and peers with great success.

The staff will include three research assistants (psychology, mental health counseling) and six interventionists to be trained in NET. Dr. Read will select students for the NET training and oversight of study team. Each team member will complete required Human Subjects training before commencing their duties on the study, and renew those trainings when required during the course of the study.

Describe other resources available to conduct the research: For example, as appropriate:

20.2 Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

Response: The findings of the focus groups demonstrated that both youth and their service providers demonstrate favorable attitudes about the proposed intervention, and many youth expressed genuine interest in participating in NET. The CFY and Compass House provide services for adolescents at risk for homelessness and street connected youth. The majority of these adolescents have experienced trauma. Phase I will explore the amount, type and severity of trauma and the consequences of such trauma. All youth receiving services through CFY or Compass House that speak English are eligible for Phase I. It is expected that 70% of these adolescents will endorse traumatic experiences and 50% of those will exhibit symptoms of PTSD. This is adolescents are eligible for Phase II.

CFY and Compass House provide services to Runaway and Homeless Youth and other youth disconnected from systems and families for four decades. They have provided over 7,700 youth with emergency shelter services and served 18,000 youth through street outreach. Therefore, there is a sufficient population base that fit eligibility criteria.

20.3 Describe the time that you will devote to conducting and completing the research.

Response: Currently 24 months have been devoted to conducting this research. RAs and PI will be present at the Center for Youth and Compass

House for recruitment purposes 40 hours per week during recruitment and set days for conducting NET.

20.4 Describe your facilities.

Response: **Facilities and Other Resources**

This rich academic environment is unique in several ways and provides the foundation for this study to begin immediately and see its implementation to completion. *University at Buffalo (UB) Computer Resources.* Ranked as one of the most wired universities in the nation, the University at Buffalo's computer facilities is one of the top supercomputing locations in the Country. It augments individual departmental facilities and provide additional technical support. UB Information Technology (UBit) is the University's central organization that supports a diverse, technology-rich environment to meet the growing demand for larger system (timesharing) services, data network connections, telecommunication services, workstations, microcomputers and other technology concerns including student access and instructional technology support. UB provides free unlimited high-speed access to the Internet and World Wide Web, email accounts, a full suite of productivity software, and printing, including high-quality graphic printing. One division includes the UB Center for Computational Research (CCR). The CCR provides the requisite advanced computing infrastructure (hardware, software, and personnel) to support the core facilities and translational research of the Clinical and Translational Science Awards. The CCR (http://www.ccr.buffalo.edu), a leading academic supercomputing facility, maintains a high-performance computing environment, high-end visualization laboratories, and support staff of 15 with expertise in high-performance computing, software engineering, grid computing, database engineering, and advanced networking. The mission of CCR is to enable research and scholarship at UB and its affiliated institutions by providing faculty with access to advanced computing infrastructure, including personnel. CCR, which was established in 1998, is a 24x7, high-availability research computing center, having provided its users more than 720,000 CPU days of computing in 2008 alone. The CCR's extensive computing facilities, which are housed in a state-of-the-art 4000 sq ft machine room, include a Linux cluster with more than 3000 processor cores and QDR Infiniband, a subset (32) of which contain (64) NVidia Tesla M2050 "Fermi" graphics processing units (GPUs). The CCR also maintains several high-performance storage systems including Isilon-based storage (227TB) as well as a parallel storage system from Panasas (170TB). The computer visualization laboratory features a tiled display wall, and a VisDuo passive stereo system. A leading academic supercomputing facility, CCR has more than 30 Tflops of peak performance compute capacity not including GPUs. Dr. Read will be utilizing the CCR to facilitate data management and security.

Research Electronic Data Capture (REDCap). Vanderbilt University, in collaboration with a consortium of institutional partners, has developed REDCap, a software toolset and workflow methodology for electronic collection and management of research and clinical trial data. The REDCap system is a secure, web-based application that is flexible enough to be used for a variety of types of research. It provides an intuitive interface for

users to enter data and real time validation rules (with automated data type and range checks) at the time of data entry. REDCap offers easy data manipulation with audit trails and functionality for reporting, monitoring and querying patient records, as well as an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). Through the REDCap Consortium, Vanderbilt has disseminated REDCap for use around the world. Currently, over 240 academic and non-profit consortium partners on six continents with over 26,000 research end-users use REDCap (www.project-redcap.org). REDCap data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team. The iterative development and testing process results in a well-planned data collection strategy for individual studies.

REDCap servers are housed in a local data center and all web-based information transmission is encrypted. REDCap was developed in a manner consistent with HIPAA security. The team decided REDCap was the best vehicle for this grant to capture data in a timely, accurate, and efficient manner. Also this technology will be cost efficient and user friendly, lending to the exportability of this work to other venues. (See Appendix: REDCap General Security Overview.

Clinical

Distance Clinical Resources. The geographical area for clinical activities associated with this research will be in Rochester, NY and Buffalo, NY.

Library

In order to facilitate literature updates and scholarly syntheses, the eleven (with the addition of the Annex) units of the University at Buffalo Libraries offer access to a combined collection of over 3.6 million books and over 32,000 serials and periodicals (including more than 10,000 periodicals, magazines and newspapers, nearly 6000 government document serials, and more than 22,000 full-text electronic journals). BISON (Buffalo Information System Online), the UB Libraries online catalog, provides information about books, journals, audio-visual materials, government documents, and electronic resources held in or licensed by the Libraries. BISON is available from any computer with access to the World Wide Web and from public library research and cybrary workstations in all of the libraries. The Libraries' Interlibrary Loan offices have implemented the ILLiad service which allows faculty, staff, and students to submit interlibrary loan requests remotely and to monitor the status of these requests. The system greatly reduces turn-around time for article requests and delivers articles electronically in PDF format to users at their desktops. The University Libraries actively embrace service, information access, the promotion of information literacy, and support of the educational and research missions of the University. Collectively they form a major academic research library that is ranked within the top 60 research libraries in North America (source: Association of Research Libraries).

The Health Sciences Library (HSL) collects materials in the fields of medicine and biomedical sciences, dental medicine, nursing, pharmacy, public health, and the health related professions. HSL is a resource library in the National Network of Libraries of Medicine. The Library provides access to about 600 print only periodicals, 5271 health related electronic journals, including titles that are free on the Internet as well as those paid for by HSL, the UB Libraries, or consortia to which the UB Libraries belong. One such consortium is the Library Consortium of Health Institutions in Buffalo, comprised of the University and its teaching hospitals. The Consortium offers a large array of electronic resources through HUBNET (Hospital and University at Buffalo Library Resources Network). This electronic resource includes MEDLINE, CINAHL, and a large variety of full text journals, reference works, and databases. Combined book and journal holdings are in excess of 350,000, including a substantial collection of old and rare books in the History of Medicine Collection. The Digital Media Resources Center provides over 2,500 health sciences audiovisual titles and is home to the Multimedia Development Lab. A subject specialist librarian in nursing provides regularly scheduled onsite consultation hours in the School of Nursing as well as in the library.

Resources for early stage/junior tenure track investigators include monthly individual mentoring meetings with The Associate Dean of Research, Dr. Chang. The junior tenure track faculty members also meet monthly with senior investigators for ongoing support, mentorship and peer encouragement. The CNR has developed scholarship teams with shared research interests who meet on a regular basis to review and edit manuscripts and grants proposals.

20.5 Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.

Response: The Center for Youth and Compass House provide counseling services and referrals to community based mental health services as needed. The youth are linked with a case manager and prevention counselor that addresses their mental health needs and logistical planning to access these needs. The team is made up of mental health professions go to an individual's home, place of employment, school or an agency such as Center for Youth or Compass House. They offer crisis intervention/stabilization, mental health assessments, rapid linkage, interim/bridge mental health treatment, mental hygiene arrest and respite housing.

20.6 Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

Response: All persons assisting with research will be trained upon hire, including training on protocol and ethical research. Regularly scheduled meetings will be held among the PI to ensure that all persons are routinely

updated about the ongoing study. Dr. Read (PI) will conduct regularly-scheduled meetings with research staff (e.g. research assistant technicians) to ensure that all members are informed and up-to-date on protocols and procedures, as well as their duties associated with the successfully execution of these protocols and procedures.

21.0 Prior Approvals

21.1 Describe any approvals that will be obtained prior to commencing the research. (E.g., school, external site. funding agency, laboratory, radiation safety, or biosafety approval.)

Response: Approval is required by Center for Youth and Compass House before commencing the research. Approval is required by the National Center for Advancing of Translational Sciences before release of funds to conduct any human subject related research.

22.0 Recruitment Methods

22.1 Describe when, where, and how potential subjects will be recruited.

Response: Potential subjects may be referred to the study from case managers, directors, and prevention counselors at the CFY and Compass House. Potential participants will be asked of their interest in participating in a study at their intake or regular sessions/contact with CFY and Compass House staff. Potential participants may also contact research staff via IRB approved recruitment fliers posted at CFY and Compass House (See Appendix: Recruitment Flier). Finally, potential participants may approach research staff stationed at the CFY and Compass House and request information. Center for Youth has a main location and satellite locations including a school, *New Beginnings,* and transitional residential locations including Chrysalis House. Compass House has a main location, as well as a residential location.

22.2 Describe the source of subjects.

Response: Participants will be adolescents (ages 16-24) receiving services from CFY, in Rochester, NY or Compass House, in Buffalo, NY.

22.3 Describe the methods that will be used to identify potential subjects.

Response: Case managers, directors and prevention counselors at CFY in Rochester, NY or Compass House in Buffalo, NY will identify potential

participants. If interested, they will contact research staff (RAs or PI) to arrange a contact time at the CFY or Compass House. Potential participants may self-identify through recruitment material or may approach a research staff positioned at a Center for Youth or Compass House sites.

22.4 Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)

Response: Printed materials (flier) will be used to recruit subjects. They will include a brief description of the study by Phase I and Phase II, which will include the motivation to better understand their life experiences. It will include research team contact information (See Appendix: Recruitment Flyer).

22.5 Describe the amount and timing of any payments to subjects.

Response: Participants will be paid $15 cash for completing the full baseline survey. Participants who withdraw from the survey before completing it in full will be compensated for the proportion of the study questions that they completed. For NET sessions, participants will be paid up to $205 ($15 for each NET session surveys, with an additional $25 for completing surveys at the last treatment session). Participants will be paid $30 cash for completion of each of the final surveys ($T_{1\ month}$ and $T_{3\ months}$). Each payment will be given at the completion of each survey. Participant will sign a receipt. Participants who withdraw during Phase II will have received compensation for all completed surveys.

23.0 Local Number of Subjects

23.1 Indicate the total number of subjects to be accrued locally.

Response: 120 participants will be accrued locally, enrolled and screened, to participate in Phase I. We anticipate a low attrition rate since it is only 1 time point of data collection lasting approximately 90 minutes. Thirty participants will be invited to participate in Phase II, with an approximate attrition rate of 20%, 24 will complete Phase II.

23.2 If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects

needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

Response: See above.

24.0 Confidentiality

Describe the local procedures for maintenance of confidentiality.

24.1 Where and how data or specimens will be stored locally?

Response: Survey data will be stored using REDCap storage (see Appendix: REDCap Overview General Security. Participants are granted access to data collection instruments via password-protected, study PCs. Other data (e.g. Participant Narratives, video sessions) will be stored on UBBox, a secure cloud supported by University at Buffalo. REDCap has protected, password protected based on user established privileges based on research team responsibilities. (See Appendix: Data Security Procedures).

24.2 How long the data or specimens will be stored locally?

Response: A copy of the final data set will be archived at the close of the study and be maintained in the archives for 7 years at UB. Video NET sessions will be archived on the UB cloud, box. These data will remain password-encrypted and securely protected by the aforementioned procedures. Backup videos will be destroyed at that time.

24.3 Who will have access to the data or specimens locally?

Response: Only the research team will have access to data locally.

24.4 Who is responsible for receipt or transmission of the data or specimens locally?

Response: The research team and PI will be responsible for local transmission of data locally, to the ARL at UB. The PI is responsible for receipt of the data.

24.5 How data and specimens will be transported locally

Response: Written data (consent forms, paper surveys-as needed, written narratives, receipts) will be transported in locked boxes to the ARL at UB. Digital videos will be uploaded to UBBox and erased on hard drive of encrypted study PCs. Videos will be accessed by UB collaborators through access permission set up through UBBox. Survey data will be stored in REDCap secure data site.

25.0 Provisions to Protect the Privacy Interests of Subjects

25.1 Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

Response: Participants are invited to participate in the study by CFY or Compass House staff, prevention counselors, or study staff. If interested the CFY or Compass House will arrange a time for Phase I: screening, study information, consent/assent and survey completion. Participants may also contact research staff to meet for screening and study information, consent/assent and survey completion. All this will occur in a private room. After consent procedures, survey will be given on a password-protected, study PC to log into the secure REDCap.

If a participant screens eligible for Phase II and has indicated an interest in being contact for the next study phase (1-Item in Phase I survey), research team will contact the case manager or participant to schedule an appointment for Phase II information and consent process. No longer than a month will elapse between Phase I and contact for Phase II to schedule Phase II participation. This session, and all NET sessions and Phase II Surveys will be conducted in a private room at CFY or Compass House.

Study therapists will compose written narratives following each NET session on password-protected, study PCs. They will then be uploaded onto secure cloud, UBBox. The written narratives will be provided to the participants at the completion of NET.

Written materials (consent forms, written survey-forms if needed, and receipts) will be transported in locked storage box to the ARL at UB.

25.2 Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

Response: During the Phase I consent process, participants will be informed about the purpose of the study, the types of questions that they will be asked to answer in the survey, potential risks, how their privacy and confidentiality of their information will be protected, as well as their rights to refuse to answer any questions or withdraw from the study at any time. During the Phase II consent process, participants will be informed about the purpose of the study, the types of questions that they will be asked to answer in the surveys, NET sessions, potential risks, how their privacy and confidentiality of their information will be protected, as well as their rights to refuse to answer any questions or withdraw from the study at any time without interruption of their CFY or Compass House services. Research assistants will also answer any questions participants

may have about their participation, information or rights. Such disclosure should help to put participants at ease.

25.3 Indicate how the research team is permitted to access any sources of information about the subjects.

Response: All data for the study will be collected directly from participants as part of the study. These data include those from the surveys as well as personal contact information to facilitate communication and retention during the study. The current study does not involve collection of data from participant records, with or without their permission.

26.0 Compensation for Research-Related Injury

26.1 If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

Response: Not applicable. Research does not involve any invasive procedures that could cause physical injury to participants.

26.2 Provide a copy of contract language, if any, relevant to compensation for research-related injury.

Response: Not applicable. Research does not involve more than minimal risk or any invasive procedures that could cause physical injury to participants.

27.0 Economic Burden to Subjects

27.1 Describe any costs that subjects may be responsible for because of participation in the research.

Response: Subjects will not be responsible for any costs associated with participation in the study.

28.0 Consent Process

28.1 Indicate whether you will be obtaining consent

Response: Each participant (age 18-24) will be providing consent prior to participation in Phase I and Phase II. Each participant (age 16-17) will be providing unique assent prior to participant in Phase I and Phase II. A parental waiver of consent will be sought because of the adolescent's status as at-risk-for homelessness. The majority of these adolescents seek services from Center for Youth and Compass House because of chaotic home lives.

28.2 Describe where the consent process take place

Response: Consent/assent will take place at a private room at CFY or Compass House.

28.3 Describe any waiting period available between informing the prospective subject and obtaining the consent.

Response: Not applicable. No waiting time between informing the prospective subject and obtaining consent.

28.4 Describe any process to ensure ongoing consent.

Response: No process to ensure ongoing consent. Phase I and Phase II will require individual consent/assent. Participation in each NET session will imply consent or assent.

28.5 Describe whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." If not, describe:

- *The role of the individuals listed in the application as being involved in the consent process.*
- *The time that will be devoted to the consent discussion.*
- *Steps that will be taken to minimize the possibility of coercion or undue influence.*
- *Steps that will be taken to ensure the subjects' understanding.*

Response:

We will be following HRP-090 SOP procedures.

Non-English Speaking Subjects

28.6 Indicate what language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

Response: Not applicable. Eligible participants must be fluent in the English language. If participants are able to fluently comprehend English, but they cannot read up to a 6th grade level, the research staff will offer to arrange a time that they can read the survey to the participant in a private area.

28.7 If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

Response: Not applicable. Eligible participants must be fluent in the English language.

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

28.8 Review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response: Not applicable. Study does not involve a waiver or alteration of consent process besides a waiver of parental consent (see Section 28).

28.9 If the research involves a waiver the consent process for planned emergency research, please review the "CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)" to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response: Not applicable. Study does not involve emergency research.

Subjects who are not yet adults (infants, children, teenagers)

28.10 Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.) For research conducted in NY state, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."

Response: This research will include children, aged 16-17.

28.11 For research conducted outside of NY state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

Response: Not applicable. All research conducted in NY State.

28.12 Describe whether parental permission will be obtained from:

- *Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one*

parent has legal responsibility for the care and custody of the child.

- *One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.*

Response: Waiver of parental consent will be sought. This study aims to examine the effectiveness of an intervention for adolescents who have experienced multiple traumas. These adolescents seeking services from the Center for Youth or Compass House are homeless or at-risk for homeless. In the majority of these homes, the parents are not providing many of the basic necessities or actively participate in decision-making related to their child's care. Parental permission to participate would invalidate this study because the adolescents targeted would not be able to participate.

Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.

Response: Not applicable. Permission will not be obtained from individuals other than the participant.

28.13 Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.

Response: Assent will be obtained from all children aged 16 and 17.

28.14 When assent of children is obtained describe whether and how it will be documented.

Response: Assent of children aged 16 and 17 will follow the procedures of obtaining consent from the adults in the study (aged 18-24). Assent will be obtained in Phase I and Phase II at the Center for Youth and Compass House in a private area. The study will be explained. The participant will be given a copy of the consent form to read and sign. Signed copies will be transported in a locked box to the ARL.

Cognitively Impaired Adults

28.15 Describe the process to determine whether an individual is capable of consent. The IRB sometimes allows the person obtaining assent to document assent on the consent document and does not automatically require assent documents to be used.

Response: We believe it is reasonable to expect that eligible participants that we schedule to participate in the study will be capable of consent because: (1) participants are adolescents who receive services at CFY or Compass House, (2) participants are a community sample (not a clinical sample), and (3) participants participate in a screening administered by staff who will, to the best of their ability, identify only those participants whose responses to the screening questions suggest that they are capable of consenting and participating in the study. There are no formal clinical tests to determine competency, as this is beyond the scope of the proposed study and seems unwarranted given the non-clinical population of adolescents that we are targeting for recruitment

Adults Unable to Consent

When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent and, where possible, assent of the individual should also be solicited.

28.16List the individuals from whom permission will be obtained in order of priority. (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.) For research conducted in NY state, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "legally authorized representative." The list in the consent template signature section corresponds to the priority list for NYS.

Response: Not applicable. Adults unable to consent are not eligible to participate.

28.17For research conducted outside of NY state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

Response: Not applicable. All research conducted in NY State.

28.18Describe the process for assent of the subjects. Indicate whether:

- *Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.*
- *If assent will not be obtained from some or all subjects, an explanation of why not.*
- *Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.*

Response: Not applicable. Adults unable to consent are not eligible to participate.

28.19 For HUD uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.

Response: Not applicable. No drugs or devices are used in this study.

29.0 Process to Document Consent in Writing

If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.

(If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)"to create the consent document or script.)

29.1 Describe whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.

Response: We will be following SOP HRP-091 procedures for consent. Written consent/ assent for participation in Phase I of the study is obtained for interested, eligible participants. At Phase II, written consent/ assent for participation will be obtained when participant has been deemed eligible and has agreed to participate in Phase II. Consent and assent forms for Phase I and II are attached.

30.0 Drugs or Devices

30.1 If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

Response: Not applicable. No drugs or devices are used in this study.

If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

30.2 Identify the holder of the IND/IDE/Abbreviated IDE.

Response: Not applicable. No drugs or devices are used in this study.

30.3 Explain procedures followed to comply with FDA sponsor requirements for the following:

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

Response: Not applicable. Study not a clinical trial and does not use any drugs or devices; therefore, FDA regulations not applicable