***Confidentiality and SAMHSA Participant Protection***

The proposed project is an evaluation project and is not a research project. Since the design of this project is an evaluation of a service program, this project is exempt from IRB approval.

**1. Protect Participants and Staff from Potential Risks**

*Physical, medical, psychological, social, legal risks or potential adverse effects for clients*:The current literature does not identify any side effects in association with the assessments or treatment procedures used in this project. However, as with many assessments and clinical interventions, some people may experience mild fatigue, momentary concern about their ability to do well, temporary upset, or a short-lived increase in symptoms. The following section outlines the potential adverse effects clients may experience as a result of participation in the program.

*Procedures to minimize or protect against risks, including confidentiality risks.*

*Client Initial Contact and Assessment*: The clients may experience temporary emotional upset during the initial contact or during the assessment process while discussing personal matters. In order to minimize the potential risks and harm to the clients, all staff will receive training in interviewing skills and in discussing potentially sensitive information. The training also will emphasize skills in handling and discussing sensitive information in a supportive, non-threatening, non-judgmental manner. The staff also will receive training in confidentiality and ethical behavior. The client always is provided with the option to refuse to answer questions about or discuss information that makes them too uncomfortable. A trained staff member will conduct all assessments. As with the clinical staff, the staff member will receive training on interviewing skills, ethical behavior, and confidentiality. If a client becomes distressed, the client will be assessed to determine the extent of the effect and additional counseling will be provided and/or appropriate referrals will be made.

It is possible that a client may become upset, have a worsening of symptoms, or experience a crisis situation following a session as a result of discussing sensitive or traumatic information. In this event, program staff will provide clients with program contact numbers and instruct the client to call. Trained staff will conduct an on-phone screening and determine the need for additional counseling and/or referrals. In the event that the client becomes excessively upset, experiences feelings of violence, has suicidal/homicidal ideations, or experiences psychotic-like symptoms, program staff will instruct them to call a crisis hotline immediately. Staff will provide this information and crisis hotline numbers to the clients during the initial intake and consenting session. Risks are minimized because issues generally occur in the context of treatment and recovery support service delivery, where the appropriate resources are readily available to mitigate any distress incurred during the interview.

Participants will be informed from the beginning that all information disclosed during program

activities will remain confidential unless it is determined that they are a danger to themselves or others. If such information comes to the attention of project staff, appropriate action will be taken in accordance with legal requirements and the appropriate agencies will be contacted. Project staff will respond to any incident by identifying and responding to the participant’s needs in a safe, confidential setting. Every effort will be made to ensure that all personal and sensitive information disclosed is kept confidential.

*Staff:* Funded agencies will employ established internal policies and procedures to mitigate potential risks to staff, including but not limited to comprehensive training and education that includes strategies for managing stressful and emergent situations, crisis management protocols that address both client-related crises and staff well-being, promotion and prioritization of self-care activities, and regular supervision and consultation with senior staff and/or supervisors to help manage complex situations and problem solve. For Peer Support Specialists, supervision is contractual, mandatory, and ongoing to ensure a safe and supportive environment that helps maintain personal recovery and avoid adverse effects such as return to use.

*Plans and Guidance to Assist Participant with Adverse Events*: Staff will use several strategies to assist and guide clients if and when an adverse event occurs. The strategies include:

• Providing the clients with crisis hotline numbers at the time of the initial intake and consenting process

• Providing the clients with program contact numbers

• Conducting screening and assessment when there is suspicion that an adverse event took place

• Assisting the client in obtaining additional services not provided by the program

• Assisting the client in obtaining crisis intervention services

• Providing additional counseling and intervention services as needed

• Discussing information and recommendations with the clients prior to disclosing information

• Obtaining necessary disclosure forms

• Advising the clients of the legal obligation to report certain situations (e.g., child neglect or abuse) prior to the actual report

*Physical, medical, psychological, social, legal risks or potential adverse effects for staff.* Risks to staff are minimal but include possible adverse effects, such as secondary traumatic stress, experienced as a result of hearing clients recount traumatic events related to addiction, trauma, family conflict, or medical issues. In particular, Peer Support Specialists or other staff with lived experience may encounter some discomfort, over-identification, or vicarious trauma while working with persons in active addiction or recovery.

*Plans and Guidance to Assist Staff*: Risks to staff are defined as minimal and include possible adverse effects that arise from working with individuals in which addiction, trauma, family conflict, and medical issues are discussed. There is also potential that staff who have lived experience in one or more of those areas may experience some discomfort while working with persons in active addiction or recovery. Supervision is mandatory and ongoing for all staff to ensure a safe environment.

**2. Fair Selection of Participants**

The target population served under the treatment portion of this grant is female and males aged 16 and higher of all racial/ethnic backgrounds who have a diagnosis of opioid use disorder and/or stimulant use disorder or are at risk of developing one, are at or below 300 percent of the poverty line, are uninsured or underinsured. This includes males, females, and members of the LGBTQ populations, all racial/ethnic backgrounds, socioeconomic groups, pregnant women, the homeless, and veterans. Participants will be recruited and selected at the local level by agency staff that are contracted to provide services under the grant and have experience serving the identified populations. Trained staff at the organizations will conduct an intake process to assess the eligibility of potential participants. Potential participants could be excluded if they do not meet the qualifications for the program. No exclusions will be made based on cultural background, age, ability, socioeconomic status, or gender specific needs.

**3. Absence of Coercion**

*Participation*: Participation in this project will be voluntarily and the program will not coerce the clients into participation. Participants will not receive renumeration. Contingency management programs will not be used.

*Explanation of Study Involvement*: After identifying an individual, trained staff will explain the purpose of the project to the client. Program staff will explain that services are not in any way contingent upon participation in data collection activities and, as such, participation is entirely voluntary. The informed consent will explain the scope of services and provide a rationale for the project and explain the follow-up phase of the program in a culturally competent manner. The client also will be aware of the voluntary nature of participation in the project. The client also will be aware that he/she may withdraw from participating at any time for any reason or may choose not to participate at all. There will not be any adverse consequences to the client in neither instance.

**4. Data Collection**

Data will be collected from consenting participants who are receiving treatment and/or recovery support services. Data collection and reporting will be comprised of the Government Performance and Results Act (GPRA) as federally mandated. Data collected are used to monitor the progress of the Substance Abuse and Mental Health Services Administration (SAMSHA) discretionary grants, serve as a decision-making tool on funding, and improve the quality of service provided through the program. Client level data are collected including demographics, ICD10 diagnostic categories, substance use and abuse, mental health and physical health functioning, and other variables. A link to the GPRA is provided in Attachment 2. No blood or urine samples will be collected.

Trained treatment and recovery support staff will administer treatment intake, 6-month follow-up, and treatment discharge interviews at their respective agencies. Staff will be responsible for entering data through a secure and HIPAA-compliant, web-based Web Infrastructure for Treatment (WITS) platform housed at and maintained by FEI, Inc. De-identified, client-level data will be batched to SAMHSA’s SPARS portal regularly. Administration will occur during face-to-face interviews. The staff member also shall verify the identity of the client, in accord with HIPAA standards.

Other data collection efforts will include quarterly collection of de-identified demographic information on all clients served by all harm reduction, treatment, and recovery support programs. Demographics include age, gender, race, ethnicity, pregnancy status, and MOUD services received. Demographics will be analyzed at the program and project levels to monitor reach, equity in service access, delivery of MOUD, and program-specific outcomes (e.g., treatment linkage rates). In addition, quarterly narrative reports will collect qualitative data on program implementation status, reach, and barriers. Demographics and narrative reports will inform mid and end-year grant reports to SAMHSA.

Data collection efforts will be monitored to ensure that information is collected in a way that protects the privacy and rights of participants. Access to the database will be restricted to project staff who have undergone confidentiality training and limited to when access is necessary to fulfill primary job functions. The Data Coordinator will report aggregate data to the applicant agency to satisfy federal reporting requirements and to support decision making about future replication efforts.

**5. Privacy and Confidentiality**

Client information is maintained in a confidential manner in accordance with the regulations governing confidentiality of alcohol and drug abuse client records (42 CFR, Part II, Subpart B) and Health Insurance Portability Accountability Act (HIPAA). A centrally managed database will be used to coordinate information. Access will be restricted to selected individuals. The community-based organizations and specifically the program data coordinator strictly control access to the data and file systems. Passwords and pins are used to restrict entry into the databases. Project personnel will have access to the confidential information only as far as it is required for the performance of specified duties. Participant’s personally identifiable information is not used by program evaluators, rather a unique number identifier is assigned to the participant.

The following clarifies the policies and procedures for the handling of client information with regard to computerized information: (a) only authorized personnel may input and retrieve information from the computer, (b) computer printouts containing client identifying information must be filed appropriately after use; or if needed, must be destroyed using the paper shredder, (c) personnel who have access to the computer are responsible for ensuring that unauthorized personnel do not gain access to any client information.

FEI is compliant with requirements that include the Federal Information Security Management Act (FISMA), Health Information Portability and Accountability Act (HIPAA)/ Health Information Technology for Economic and Clinical Health Act (HITECH) for securing personal health information, and general best practices for the protection of sensitive corporate data. All services provided by FEI are conducted in accordance with their defined Encryption Standard, which stipulates when such data protection measures are required and what methods are to be used accordingly. For information in transit, data are either encrypted directly or transmission is restricted to protected tunnels. For data at rest (endpoints), FEI personnel are formally trained in security and privacy measures for the associated handling of sensitive data. Team members take corresponding precautions to protect data and do not store sensitive information on their desktops, workstations, laptops, or mobile devices. Nevertheless, for 100% of FEI portable endpoints (i.e., laptops and notebooks), they apply whole disk encryption to protect information at rest. For data at rest (serves/SAN), FEI leverages Nimble Storage platforms, which are capable of encrypting of data at rest. The platforms use FIPS 140-2 validated cryptographic modules. Encryption is via AES-256 in XTS cipher mode, specifically for storage. Encryption keys are stored locally in a table encrypted using a master key, which is in turn encrypted by a passphrase that the user creates when initializing encryption for the first time. WITS collects PII to facilitate completion of follow-up and discharge GPRAs. PII are sequestered within the WITS system and are only accessible to approved agency staff who submit accurate password and pin codes to enter the system.

**6. Adequate Consent Procedures**

After identifying a client, a trained staff member explains the purpose of the project. The informed consent will explain the initial assessment; delivery of treatment; provide a rationale for the project; and explain the follow-up phase of the project. The client also will be aware of the voluntary nature of participation. The client will be aware that he/she may withdraw from participation for any reason at any time or may choose not to participate at all. There will be no adverse consequences to the client in either case. In addition, the clients will understand that the data will assist in determining the effectiveness of the services. Furthermore, the client will understand that the program will only present data in aggregated format and will not under any circumstance, reveal individual data or names. A trained staff member will explain confidentiality to the clients and will inform the client that any specific information regarding their case is available only to appropriate personnel. A trained staff member will read consent forms to clients who have inadequate English reading skills or who are illiterate. After explanation of the consent forms, the clients will answer specific questions to ascertain adequate understanding of the project. The client will receive additional information and clarification if necessary. If a client does not consent to inclusion in the project, refuses inclusion following initial consent, or refuses to participate in any aspect of the evaluation process, he/she may receive program services but will not be included in the evaluation data.

Individuals under the age of 18 are eligible to receive services through this project. North Carolina state law for youth participant informed consent is governed by G.S. 90-21.10B(a) and (b) prohibit a health care practitioner or health care facility from providing, soliciting, or arranging treatment for a minor child without first obtaining written or documented consent from the child’s parent, “[e]xcept as otherwise provided in this Article [1A] or by a court order. Agency staff will request permission from the legal guardian for a minor to participate in the program. The program will be fully explained to the legal guardian and participant, including the data collection time points, what assessments will be used, risks, protection of confidentiality, and that participation is entirely voluntary. Care will be taken so that the consent forms do not imply that the participant waives or appears to waive any legal rights. A copy of the consent form will be given to the legal guardian and the participant for review. If the legal guardian gives consent, they will sign the form giving their consent as the legal guardian. Participants will have access to copies of what they sign.

**7. Risk/Benefit Discussion**

The risks to the clients are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that reasonable is expected from this program. The clients are likely to benefit from the clinical and recovery services offered by the program. These benefits likely are to include the prevention of substance use/misuse relapse, prevention of criminal recidivism, and improved educational, vocational, and/or employment situations. Clients also may benefit from being able to receive appropriate referrals, linkages to care, and services to address their needs.