Appendix C – Confidentiality and SAMHSA Participant Protection/Human Subjects Guidelines

CONFIDENTIALITY AND PARTICIPANT PROTECTION:

It is important to have safeguards protecting individuals from risks associated with their participation in SAMHSA projects. **As part of Attachment 7 of the application, all applicants providing direct services and/or training (including those who plan to obtain Institutional Review Board (IRB) approval) must address all of the elements below.** (Projects only involving infrastructure development, such as improving information technology systems, are not required to submit this attachment). If some elements are not applicable to the proposed project, explain why the element(s) is not applicable.

In addition to addressing these elements, you will need to determine if the section below titled "Protection of Human Subjects Regulations" applies to your project. If so, you must submit the required documentation as described below. There are no page limits for your response to the elements in this appendix.

1. Protect Participants and Staff from Potential Risks

- Identify and describe the foreseeable physical, medical, psychological, social, and legal risks or potential adverse effects **participants** may be exposed to because of the project.
- Identify and describe the foreseeable physical, medical, psychological, social, and legal risks or potential adverse effects **staff** may be exposed to as a result, of the project.
- Describe the procedures you will follow to minimize or protect participants and staff against potential risks, including risks to confidentiality.
- Identify your plan to provide guidance and assistance in the event there are adverse effects to participants and/or staff.

Responses that will be considered unacceptable or incomplete:

- *Indicating that there are **no risks** to participants. If services are being delivered as part of the project, it is **very unlikely** that there will be no foreseeable physical, medical, psychological, social, or legal risks or potential adverse effects as a result of their involvement in the project.*
- *Addressing potential risks to participants but not addressing risks to staff*
- *Neglecting to describe how the organization will provide guidance and assistance in the event there are adverse effects to participants and whether alternative treatments will be available to participants.*

2. Fair Selection of Participants

- Explain how you will recruit and select participants ensuring all populations have equitable opportunities to participate in the program.
- Identify any individuals in the geographic catchment area where services will be delivered who will be excluded from participating in the project and explain the reasons for this exclusion.

Responses that will be considered unacceptable or incomplete:

- *Not explaining reasons for including or excluding participants*
- *Not identifying how participants will be selected*

3. Absence of Coercion

- If you plan to compensate participants, state how participants will be awarded incentives (e.g., gift cards, bus passes, gifts, etc.) If you plan to implement a contingency management program, specify the evidence-based model you will use and briefly justify its use with your population(s) of focus. If you have included funding for incentives in your budget, you **must** address this item. (For specific information about incentives, see https://www.samhsa.gov/grants/grants-management/policies-regulations/additional-directives)
- Provide justification that the use of incentives is appropriate, judicious, and conservative and that incentives do not provide an "undue inducement" that removes the voluntary nature of participation.
- Describe how you will inform participants in a culturally competent manner that they may receive services even if they choose to not participate in or complete the data collection component of the project.

Responses that will be considered unacceptable or incomplete:

- *Indicating that you do not plan to compensate participants, such as through incentives, but including funding for incentives in the budget or describing the use of incentives in the Project Narrative.*
- *Not specifying how participants will be told that they may receive services even if they choose not to participate in the data collection component of the project.*

4. Data Collection

- Identify from whom you will collect data (e.g., participants, clients, family members, teachers, others).
- Describe the data collection procedures and specify the sources for obtaining data (e.g., school records, interviews, psychological assessments, questionnaires, observation, or other sources). Identify what type of specimens (e.g., urine, blood) will be used, if any. State if the specimens will be used for purposes other than evaluation.
- In **Attachment 2**, "Data Collection Instruments/Interview Protocols," you **must** provide copies of all available data collection instruments and interview protocols that you plan to use (unless you are providing the web link to the standardized instrument(s)/protocol(s). Include any culturally adapted data collection instruments and interview protocols.

Responses that will be considered unacceptable or incomplete:

- *Not clearly identifying all the entities from which data will be collected.*
- *Describing the use of drug testing in the Project Narrative but not providing the requested information about specimen collection.*
- *Not including data collection instruments/interview protocols (or links to websites for the instruments) in Attachment 2.*
- *Not including how the data collection will occur (i.e., paper surveys versus electronic survey links; at a school setting or at the organization's clinic, etc.).*

5. Privacy and Confidentiality

- Explain how you will ensure privacy and confidentiality. Describe:
  - Where data will be stored,
  - Who will have access to the data collected, and
  - How the identity of participants will be kept private, for example, using a coding system on data records, limiting access to records, or storing identifiers separately from data.
- **NOTE:** Recipients must maintain the confidentiality of substance use disorder client records according to the provisions of **Title 42 of the Code of Federal Regulations, Part II, Subpart B.**

Responses that will be considered unacceptable or incomplete:

- *Not providing detailed information about where data is stored and how the identity of participants will be kept confidential.*
- *Not clearly identifying the individuals who will have access to the data.*
- *Not specifying that you agree to maintain the confidentiality of substance use disorder client records according to the provisions of Title 42 of the Code of Federal Regulations, Part II.*

6. Adequate Consent Procedures

- Include, as appropriate, sample consent forms* that provide for:

  1. informed consent for participation in service intervention;
  2. informed consent for participation in the data collection component of the project, including information that participants are informed that they may receive services even if they choose not to participate in or complete this component of the project; and
  3. informed consent for the exchange (releasing or requesting) of confidential information.
  4. Informed consent for youth participants.

  *Consent forms should be written at no higher than 8th grade reading level.

- The sample forms must be included in **Attachment 3, "Sample Consent Forms"**, of your application. If needed, provide translated forms.
- Explain how you will obtain consent for youth, the elderly, people with limited reading skills, and people who do not use English as their first language. Describe how the consent will be documented. For example: Will you read the consent forms? Will you ask prospective participants questions to be sure they understand the forms? Will you give them copies of what they sign?

  NOTE: The consent forms should never imply that the participant waives or appears to waive any legal rights. The forms should also not imply that individuals cannot end involvement with the project or that your project or its agents will be released from liability for negligence.

Responses that will be considered unacceptable or incomplete:

- *Not providing copies of sample consent forms in Attachment 3.*
- *Not providing details on how consent/assent will be obtained for youth participants.*

- *Not providing details on how consent will be obtained for non-English speaking priority populations identified in the application.*

7. Risk/Benefit Discussion

- Discuss why the risks you have identified in **Element 1. Protect Participants and Staff from Potential Risks** are reasonable compared to the anticipated benefits to participants involved in the project.

Responses that will be considered unacceptable or incomplete:

- *Indicating there are no risks to participants in the first element and noting that this element is therefore not applicable.*
- *Not mentioning any anticipated benefits to participants involved in the project.*

PROTECTION OF HUMAN SUBJECTS REGULATIONS

SAMHSA expects that most recipients funded under this announcement will not have to comply with the Protection of Human Subjects Regulations (45 CFR 46), which requires Institutional Review Board (IRB) approval. However, in some instances, the applicant's proposed project may meet the regulation's criteria for research involving human subjects. Although IRB approval is not required at the time of award, you are required to provide the documentation below prior to enrolling participants into your project.

In addition to the elements above, applicants whose projects must comply with the Human Subjects Regulations must:

- Describe the process for obtaining IRB approval for your project.
- Provide documentation that an Assurance of Compliance is on file with the Office for Human Research Protections (OHRP).
- Provide documentation that IRB approval has been obtained for your project prior to enrolling participants.

General information about Human Subjects Regulations can be obtained through OHRP at http://www.hhs.gov/ohrp or (240) 453-6900. SAMHSA–specific questions should be directed to the program contact listed in Section VII of this announcement.