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VII. Agency Contacts

The NOFAs provide contact information for questions about program issues.

For questions on grants management issues, contact: Stephen Hudak, Office of Program Services, Division of Grants Management, Substance Abuse and Mental Health Services Administration/OPS, 5600 Fishers Lane, Rockwall II 6th Floor, Rockville, MD 20857, (301) 443-9666, shudak@samhsa.gov.

VIII. Other Information

A. SAMHSA Confidentiality and Participant Protection Requirements and Protection of Human Subjects Regulations

You must describe your procedures relating to Confidentiality, Participant Protection and the Protection of Human Subjects Regulations in Section H of your application, using the guidelines provided below. Problems with confidentiality, participant protection, and protection of human subjects identified during peer review of your application may result in the delay of funding.

Confidentiality and Participant Protection: All applicants must address each of the following elements relating to confidentiality and participant protection. You must document how you will address these requirements or why they do not apply.

1. Protect Clients and Staff from Potential Risks

- Identify and describe any foreseeable physical, medical, psychological, social, legal, or other risks or adverse affects.
- Discuss risks that are due either to participation in the project itself or to the evaluation activities.
- Describe the procedures you will follow to minimize or protect participants against potential risks, including risks to confidentiality.
- Identify plans to provide help if there are adverse effects to participants.
- Where appropriate, describe alternative treatments and procedures that may be beneficial to the

participants. If you choose not to use these other beneficial treatments, provide the reasons for not using them.

2. Fair Selection of Participants

- Describe the target population(s) for the proposed project. Include age, gender, and racial/ethnic background and note if the population includes homeless youth, foster children, children of substance abusers, pregnant women, or other groups.
- Explain the reasons for including groups of pregnant women, children, people with mental disabilities, people in institutions, prisoners, or others who are likely to be vulnerable to HIV/AIDS.
- Explain the reasons for *including or excluding* participants.
- Explain how you will recruit and select participants. Identify who will select participants.

3. Absence of Coercion

- Explain if participation in the project is voluntary or required. Identify possible reasons why it is required, for example, court orders requiring people to participate in a program.
- If you plan to pay participants, state how participants will be awarded money or gifts.
- State how volunteer participants will be told that they may receive services even if they do not participate in the project.

4. Data Collection

- Identify from whom you will collect data (e.g., from participants themselves, 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). Where data are to be collected through observational techniques, questionnaires, interviews, or other direct means, describe the data collection setting.
- Identify what type of specimens (e.g., urine, blood) will be used, if any. State if the material will be used just for evaluation or if other use(s) will be made. Also, if needed, describe how the material will be monitored to ensure the safety of participants.
- Provide in Appendix 2, "Data Collection Instruments/Interview Protocols," copies of *all* available data collection instruments and interview protocols that you plan to use.

5. Privacy and Confidentiality

- Explain how you will ensure privacy and confidentiality. Include who will collect data and how it will be collected.

- Describe:
- How you will use data collection instruments.
- Where data will be stored.
- Who will or will not have access to information.
- How the identity of participants will be kept private, for example, through the use of a coding system on data records, limiting access to records, or storing identifiers separately from data.

Note: If applicable, grantees must agree to maintain the confidentiality of alcohol and drug abuse client records according to the provisions of Title 42 of the Code of Federal Regulations, Part II.

6. Adequate Consent Procedures

- List what information will be given to people who participate in the project. Include the type and purpose of their participation. Identify the data that will be collected, how the data will be used and how you will keep the data private.
- State:
- Whether or not their participation is voluntary.
- Their right to leave the project at any time without problems.
- Possible risks from participation in the project.
- Plans to protect clients from these risks.
- Explain how you will get consent for youth, the elderly, people with limited reading skills, and people who do not use English as their first language.

Note: If the project poses potential physical, medical, psychological, legal, social or other risks, you must get *written* informed consent.

- Indicate if you will get informed consent from participants or from their parents or legal guardians. 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?
- Include sample consent forms in your Appendix 3, "Sample Consent Forms." If needed, give English translations.

Note: Never imply that the participant waives or appears to waive any legal rights, may not end involvement with the project, or releases your project or its agents from liability for negligence.

- Describe if separate consents will be obtained for different stages or parts of the project. For example, will they be needed for both participant protection in treatment intervention and for the collection and use of data.
- Additionally, if other consents (e.g., consents to release information to others