

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 or gather information from others) will be used in your project, provide a description of the consents. Will individuals who do not consent to having individually identifiable data collected for evaluation purposes be allowed to participate in the project?

#### 7. Risk/Benefit Discussion

Discuss why the risks are reasonable compared to expected benefits and importance of the knowledge from the project.

##### *Protection of Human Subjects*

**Regulations:** All applicants proposing a pilot test of the best practice as part of a Phase II project must comply with the Protection of Human Subjects Regulations (45 CFR part 46).

Even if you are not proposing a Phase II pilot test of the best practice, the Protection of Human Subjects Regulations could apply depending on the evaluation you propose.

If you are a Phase II applicant proposing a pilot test or your project

otherwise falls under the Protection of Human Subjects Regulations, you must describe the process for obtaining Institutional Review Board (IRB) approval in your application. While IRB approval is not required at the time of grant award, you will be required, as a condition of award, to provide the documentation that an Assurance of Compliance is on file with the Office for Human Research Protections (OHRP) and the IRB approval has been received before enrolling clients in the proposed project.

Additional information about Protection of Human Subjects Regulations can be obtained on the web at <http://ohrp.osophs.dhhs.gov>. You may also contact OHRP by e-mail ([ohrp@osophs.dhhs.gov](mailto:ohrp@osophs.dhhs.gov)) or by phone (301-496-7005).

#### *B. Intergovernmental Review (E.O. 12372) Instructions*

Executive Order 12372, as implemented through Department of Health and Human Services (DHHS) regulation at 45 CFR part 100, sets up a system for State and local review of applications for Federal financial assistance. A current listing of State Single Points of Contact (SPOCs) is included in the application kit and can be downloaded from the Office of Management and Budget (OMB) Web site at <http://www.whitehouse.gov/omb/grants/spoc.html>.

- Check the list to determine whether your State participates in this program. You do not need to do this if you are a federally recognized Indian tribal government.

- If your State participates, contact your SPOC as early as possible to alert him/her to the prospective application(s) and to receive any necessary instructions on the State's review process.

- For proposed projects serving more than one State, you are advised to contact the SPOC of each affiliated State.

- The SPOC should send any State review process recommendations to the following address within 60 days of the application deadline: Substance Abuse and Mental Health Services Administration Office of Program Services, Review Branch 5600 Fishers Lane, Room 17-89, Rockville, Maryland, 20857, ATTN: SPOC—Funding Announcement No. [fill in pertinent funding opportunity number from the NOFA].

#### *C. Public Health System Impact Statement (PHSIS)*

The Public Health System Impact Statement or PHSIS (Approved by OMB