

- 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 4: Sample Consent Forms. If consent forms are in languages other than English, provide 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 for Service-to-Science grants must comply with the Protection of Human Subjects Regulations (45 CFR part 46).

Applicants must describe the process for obtaining Institutional Review Board (IRB) approval fully in their applications. 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 that IRB approval has been received prior to enrolling any participants 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) 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 under control no. 0920-0428; see burden statement below) is intended to keep State and local health officials informed of proposed health services grant applications submitted by

community-based, non-governmental organizations within their jurisdictions. State and local governments and Indian tribal government applicants are not subject to the following Public Health System Reporting Requirements.

Community-based, non-governmental service providers who are not transmitting their applications through the State must submit a PHSIS to the head(s) of the appropriate State and local health agencies in the area(s) to be affected no later than the pertinent receipt date for applications. This PHSIS consists of the following information:

- A copy of the face page of the application (SF 424); and
- A summary of the project, no longer than one page in length, that provides: (1) A description of the population to be served, (2) a summary of the services to be provided, and (3) a description of the coordination planned with appropriate State or local health agencies.

For SAMHSA grants, the appropriate State agencies are the Single State Agencies (SSAs) for substance abuse and mental health. A listing of the SSAs can be found on SAMHSA's Web site at <http://www.samhsa.gov>. If the proposed project falls within the jurisdiction of more than one State, you should notify all representative SSAs.

Applicants who are not the SSA *must* include a copy of a letter transmitting the PHSIS to the SSA in Appendix 5: Letter to the SSA. The letter must notify the State that, if it wishes to comment on the proposal, its comments should be sent not later than 60 days after the application deadline to: Substance Abuse and Mental Health Services Administration, Office of Program Services, Review Branch, 5600 Fishers Lane, Room 17-89, Rockville, Maryland, 20857, ATTN: SSA—Announcement No. [fill in pertinent funding opportunity number from NOFA].

In addition:

- Applicants may request that the SSA send them a copy of any State comments.

- The applicant must notify the SSA within 30 days of receipt of an award.

[Public reporting burden for the Public Health System Reporting Requirement is estimated to average 10 minutes per response, including the time for copying the face page of SF 424 and the abstract and preparing the letter for mailing. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0920-0428. Send comments regarding this burden to CDC Clearance