

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

Depending on the evaluation and data collection requirements of the particular funding opportunity for which you are applying or the evaluation design you propose in your application, you may have to comply with the Protection of Human Subjects Regulations (45 CFR part 46). The NOFA will indicate whether all applicants for a particular funding opportunity must comply with the Protection of Human Subject Regulations.

Applicants must be aware that even if the Protection of Human Subjects Regulations do not apply to all projects funded under a given funding opportunity, the specific evaluation design proposed by the applicant may require compliance with these regulations.

Applicants whose projects must comply with the Protection of Human Subjects Regulations 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, these applicants 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 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) 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 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 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 4, "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—Funding 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 Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0428).]

Appendix A—Checklist for Application Formatting Requirements

Your application must adhere to these formatting requirements. Failure to do so will result in your application being screened out and returned to you without review. In addition to these formatting requirements, there may be programmatic requirements specified in the NOFA. Please check the NOFA before preparing your application.

- Use the PHS 5161-1 application.
- The 10 application components required for SAMHSA applications must be included (*i.e.*, Face Page, Abstract, Table of Contents, Budget Form, Project Narrative and Supporting Documentation, Appendices, Assurances, Certifications, Disclosure of Lobbying Activities, and Checklist.)
 - Text must be legible.
 - Paper must be white paper and 8.5" by 11.0" in size.