

c. The extent to which the applicant includes provisions for maintaining confidentiality of individual records and/or case reports, and protecting the status of reported cases.

d. The extent to which the applicant describes the adequacy of the proposed time-line and personnel for accomplishing the prevention and surveillance and monitoring activities.

e. The extent to which the application adequately addresses the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

(1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(2) The proposed justification when representation is limited or absent.

(3) A statement as to whether the design of the study is adequate to measure differences when warranted.

(4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

## 2. Quality Assurance and Program Evaluation Plan (30 points)

The extent to which the applicant describes when and how interventions, and surveillance and monitoring systems, will be evaluated. The plan should outline the methods, design and process, and impact and outcome (effectiveness and cost-effectiveness) measures to be used in determining if the objectives are being achieved.

## 3. Assessment of Need (10 points)

The extent to which the applicant understands the purpose and objectives of this project, as reflected in their statement of purpose and need for the proposed prevention interventions, and FAS surveillance and prenatal alcohol monitoring systems. A detailed description should be provided of the proposed area, region or community targeted for this project based on relevant epidemiological and demographic information. Emphasis will be placed on demonstrated access to populations considered at greater risk for high prevalence rates of FAS and risk factors associated with FAS, and to the applicant's understanding of the importance of the proposed surveillance activity in identifying cases of FAS and reducing the risk of alcohol exposed pregnancies among childbearing-age women. Measures currently being used to estimate the magnitude of FAS, prenatal alcohol exposure, and risk factors for FAS should be described in

detail and specifically related to the population(s) being targeted in the proposal.

## 4. Goals and Objectives (10 points)

The extent to which the applicant includes specific goals to be achieved by the proposed FAS prevention interventions and the proposed FAS surveillance and prenatal monitoring programs by the end of the five year project period. Each goal should be accompanied by objectives that are specific, time-phased, measurable and achievable. (See Attachment I, as posted on the CDC website.)

## 5. Organizational History and Capacity (10 points)

a. The extent to which the applicant describes past and current experience in developing and implementing effective and cost-effective FAS prevention intervention strategies, and in activities that develop and implement effective and cost-effective surveillance and prenatal alcohol exposure monitoring activities similar to the one(s) proposed in this application.

b. The extent to which the applicant describes their previous experience and accomplishments in the design, implementation, and evaluation of birth defects surveillance, prenatal alcohol exposure monitoring systems, and monitoring of population-based risk factors for FAS or other surveillance and monitoring systems.

c. The extent to which the applicant describes the training, experience, and competence of the proposed project director and staff in the design, implementation, and evaluation of surveillance and prenatal alcohol monitoring activities, and the availability of the staff to work on the proposed project. This includes staff from academic institutions that are assisting the applicant in design, implementation and evaluation of the project.

## 6. Budget Justification and Adequacy of Facilities (not scored)

The budget will be evaluated for the extent to which it is reasonable, clearly justified, and consistent with the intended use of the cooperative agreement funds. The applicant shall describe and indicate the availability of facilities and equipment necessary to carry out this project.

## 7. Human Subjects Review (not scored)

Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects? (Not scored; however, an application can be disapproved if the

research risks are sufficiently serious and protection against risks are so inadequate as to make the entire application unacceptable.)

## I. Other Requirements

### Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. An interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application and must include the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Detailed Line-Item Budget and Justification.

e. For all proposed contracts and consultants: (1) The name of contractor or consultant; (2) the method of selection; (3) the period of performance; (4) the scope of work; (5) the method of accountability; and, (6) an itemized budget with justification for each contract or consultant.

2. A financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

### Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, see Attachment II of the program announcement as posted on the CDC Web site.

AR-1 Human Subject Requirements

AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR-7 Executive Order 12372 Review

AR-8 Public Health System Reporting Requirements

AR-9 Paperwork Reduction Act Requirements

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

## J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and