

calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows: none.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement must be less than 12 months of age.

6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or e-mail to: Robin Forbes, Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, 4770 Buford Hwy, NE., Mailstop K-62, Atlanta, GA 30341. Telephone: 770-488-4037; fax: 770-488-1662; email: cipert@cdc.gov.

Application Submission Address: Submit the original and five copies of your application by mail or express delivery service to: Technical Information Management—PA# 04062, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

V. Application Review Information

1. Criteria

You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the "Purpose" section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

The goals of CDC-supported research are to advance the understanding of biological systems, improve the control and prevention of disease, and enhance health. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals.

The scientific review group will address and consider each of the

following criteria in assigning the application's overall score, weighting them as appropriate for each application.

The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative, but is essential to move a field forward.

The criteria are as follows:

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed experiment take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

Additional Review Criteria: In addition to the above criteria, the following items will be considered in the determination of scientific merit and priority score:

- Does the applicant describe either (a) existing instruments appropriate for use with the proposed population or (b) scientifically sound plans for developing such instrument(s)?
- Does the applicant describe research methods appropriate for a study in the proposed institutional setting?
 - Are there adequate plans for data collection and data management including security of data and assurance of participant confidentiality?
 - Is there a statistical analysis plan appropriate for the study design?

- Does the applicant provide a detailed and appropriate timeline for the study?

Protection of Human Subjects from Research Risks: 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 is so inadequate as to make the entire application unacceptable.

Inclusion of Women and Minorities in Research: Does the application adequately address the CDC Policy requirements regarding the inclusion of woman, 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; and (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.

Inclusion of Children as Participants in Research Involving Human Subjects

The NIH maintains a policy that children (*i.e.*, individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at: <http://grants.nih.gov/grants/funding/children/children.htm>.

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. This announcement does not use the modular budget format.

2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) and for responsiveness for other eligibility requirements by the National Center for Injury Prevention and Control. Incomplete applications and applications that are non-responsive will not advance through the review