

a. Provide technical assistance, guidance, and training in biomonitoring, including information about analytical methods and instrumentation used by CDC for biomonitoring.

b. Provide information about sources for reagents, supplies, standards, quality assurance materials, equipment, etc. These sources may include commercial vendors, other Federal, State, or international agencies, professional societies or standard-setting bodies, contractors to CDC, and CDC laboratories, as appropriate.

c. Provide analytical support as requested for biomonitoring studies initiated by the recipient (subject to availability and competing national priorities).

d. Assist in the development of a research protocol for projects in which CDC provides a staff member to serve as principal investigator or co-investigator or when CDC conducts sample analysis. IRB approval will be required from all institutions participating in the research. CDC IRB must review and approve the protocol initially and at least on an annual basis until the research project is completed. For those research projects that do not have a CDC staff member serving as the principal investigator or co-investigator, technical assistance in the form of advice, recommendations, and expert opinions will be provided.

F. Content

Letter of Intent (LOI)

A LOI is optional for this program. The Program Announcement title and number must appear in the LOI. The narrative should be no more than one page, single-spaced, printed on one side, with one-inch margins, and unrounded 12-point font. The LOI will be used for CDC planning purposes. The LOI must indicate whether the applicant plans to apply as an individual state applicant or as the lead member of a consortium and should identify the states that are anticipated to be consortium partners.

Applications

The Program Announcement title and number must appear in the application. Use the information in the Program Requirements, Content, Other Requirements, and Evaluation Criteria sections to develop the application content. The application will be evaluated on the criteria listed, so it is important to follow them in laying out the program plan. The narrative should be no more than 25 pages, double-spaced, printed on one side, with one-inch margins, and unrounded 12-point font.

The narrative should consist of, at a minimum, a Workplan, Objectives, Methods, Personnel, Evaluation Scheme, and Budget. A two- to three-page executive summary of the applicant's plan developed under PA 01072 shall be included preceding the narrative. The application must also include, as an attachment, a full copy of the plan from the planning grant. The page limitation is exclusive of the attached copy of the plan.

The application must also:

1. Discuss how the recipient will develop, implement, and apply biomonitoring laboratory capacity by following the biomonitoring plan that was developed with funding under PA 01072.

2. Outline how biomonitoring will be applied within the community served by the applicant and distinguish between those needs that are single issue and those that exist on an on-going basis. Describe how collaboration with other public health partners, including public health physicians and epidemiologists in making this needs assessment will be accomplished. Special consideration should be given to evaluating exposures in under-served population groups that may be at increased risk from exposure.

3. Discuss how the program will use biomonitoring laboratory data to answer the important public health questions as listed in items 1. through 6. of Attachment 2 as posted on the CDC Web site. The application should not include complete study protocols, as they will be developed after award of a cooperative agreement and prior to commencing the study.

4. Tell how requirements for local IRB or Human Subjects review will be met and how approval for any such projects which constitute research as defined in 45 CFR part 46 will be obtained. (See <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.102>.)

5. Provide an inventory of existing biomonitoring methods in use by the applicant, and for each method specify: Toxic substance(s) measured; method of measurement (e.g., GC-MS, atomic absorption); current instrumentation used; the limit of detection for each analyte (and how the limit of detection was determined); known interferences; description of method's quality control; any external proficiency testing program in which the laboratory currently participates for the method; an approximate sample throughput per day; and the approximate number of human specimens analyzed in the past 12 months. Emphasize in this section how the existing biomonitoring capacity

will be used to address needs identified in the paragraphs above. As part of this explanation, specify the collaborations with public health partners (State and local health officials, schools of public health, academic centers, community groups, etc.) who will work with the laboratory to use biomonitoring data to help address these public health needs. Include documentation from each public health partner of its willingness to collaborate. Acceptable documentation may be letters of support or formal agreements among partners.

6. For each new biomonitoring method needed, describe additional requirements for personnel, instrumentation, and facilities modification or expansion. Provide cost estimates for facilities modification or expansion, if applicable.

7. Describe specimen management and security protocols that are in place or that are to be implemented to support the biomonitoring program.

8. Describe the data management and communications resources and plans available or needed to support the biomonitoring program. The relationship (or lack thereof) with other public health data management and communications initiatives (e.g., National Electronic Disease Surveillance System, Health Alert Network, etc.) should be discussed.

9. Discuss requirements for compliance with the Clinical Laboratory Amendments of 1988 (CLIA).

10. Develop an evaluation plan to provide periodic and on-going assessment of progress in expanding the laboratory's biomonitoring capacity and to assess the impact of biomonitoring measurements on addressing the identified public health needs within the State(s) or community.

11. Applications from consortia must provide documentation from each member of the consortium of their willingness to collaborate, to share resources, and/or to perform work within the consortium under reciprocal arrangements, to pool data from each site in their proposed consortium as appropriate to the goals of the consortium, and to participate in periodic meetings (or conferences via electronic media) among consortium laboratories for the purpose of planning, conduct of consortium business, training, and technology transfer. Acceptable documentation may be letters of support or formal agreements among the consortium members.

12. Discuss anticipated problems with the implementation of the biomonitoring plan and outline proposed solutions. Potential problems might include state restrictions on