

D. Funding

Availability of Funds

Approximately \$5,000,000 is available in FY 2003 to fund approximately ten awards. Funding will range from \$200,000, up to \$3,000,000 per award. Funding estimates may change. It is expected that the awards will begin on or about September 15, 2003, and will be made for an initial 9-month budget period, which will end on June 30, 2004. Future budget periods will be 12 months in duration for a total project period of up to four years and nine months.

Continuation awards within an approved project period will be made on the basis of the availability of funds and satisfactory progress as evidenced by required reports.

Funding will be awarded in two categories:

Individual States: Maximum award of up to \$1,000,000 for individual States.

Consortia: Maximum award of up to \$3,000,000 based upon the number of States within the consortium. A range of \$200,000–\$600,000 per State consortium member is anticipated.

Applications exceeding the foregoing maxima will be returned without review. Eligible applicants are only allowed to apply for one of the two categories described above.

Use of Funds

Funds may be used to develop and implement a biomonitoring program, conduct demonstration projects, purchase equipment and supplies, hire and train personnel, conduct appropriate and relevant travel, hire consultants, pay for services, and renovate or modify existing laboratory areas. Funds provided by CDC under this cooperative agreement may not be used for construction of new laboratory space. Funds may not be used to support activities otherwise funded, or eligible to be funded, through the Superfund Program or the Agency for Toxic Substances and Disease Registry. However, because toxicants from Superfund sites may contribute to the total exposures of a given population, funds may be used to assess the exposure status of populations not already addressed under Superfund.

Funding Preferences

Preference for awards will be given to ensure geographic diversity, distribution, and balance among laboratories which serve people living in various settings such as urban, rural, agricultural, and industrial communities; among laboratories that have various levels of expertise,

experience, capacity, and need for biomonitoring. Preference will be given to applications with the greatest need for biomonitoring expansion or implementation based on documented or suspected environmental toxicant exposures among persons living within the applicant's area of responsibility.

Recipient Financial Participation

Matching funds are not required for this program.

E. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities listed under 1. Recipient Activities, and CDC will be responsible for the activities listed under 2. CDC Activities.

1. Recipient Activities:

a. Implement and apply biomonitoring laboratory capacity by following, as closely as possible, the biomonitoring plan(s) that the recipient developed with funding under PA 01072, Public Health Laboratory Biomonitoring Planning Grant.

b. Address the needs for, and proposed application of, biomonitoring 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. Collaborate with other public health partners, including public health physicians and epidemiologists, in making this needs assessment. Special consideration should be given to evaluating exposures in under-served population groups that may be at increased risk from exposure. (E.g. minorities, the very young, and the elderly may have a greater risk of exposure or harmful effects.)

c. Incorporate the application of laboratory data to respond to important public health issues as listed in items 1. through 6. of Attachment 2, "Biomonitoring and Complementary Programs." Please see all attachments referenced in this announcement as posted with the full announcement on the CDC Web site: <http://www.cdc.gov/od/pgo/funding/grantmain.htm>. Uses may include population based or targeted health exposure surveys, health effects studies, sentinel monitoring of at-risk populations, case-control studies, studies involving analyses of stored specimens, or other recognized epidemiologic tools. The applicant must develop complete study protocols after award of a cooperative agreement and prior to commencing the study.

d. Meet requirements for local Institutional Review Board (IRB) or Human Subjects review and obtain approval for any such projects which constitute research as defined in 45 CFR

part 46. (See <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.102>)

e. Biomonitoring research projects that the applicant plans to undertake without substantial CDC involvement do not require CDC IRB approval. However, the applicant will be required to submit a copy of their proposed protocol and a copy of their IRB approval letter (and all subsequent approval renewals) to CDC. Research projects that applicants wish to undertake with substantial CDC involvement will require joint development of detailed protocols with CDC and approval from both CDC IRB and the applicant's local IRB. **Note:** CDC IRB may defer to the local IRB or the local IRB may defer to CDC IRB. Because funds currently available to support the biomonitoring implementation program under this cooperative agreement are limited and are primarily intended for biomonitoring capacity building, applicants are discouraged from relying on this agreement to fund complex and costly epidemiologic studies. Rather, activities should be limited to demonstration projects, pilot surveys, and preliminary investigations. More detailed and costly epidemiologic studies employing biomonitoring should be developed jointly and in detail among the interested laboratories, their epidemiology partners, and others with funding sought from other sources as stand-alone projects.

f. Implement the plan for developing (or expanding) and applying biomonitoring capacity in the public health laboratory. This implementation must follow the specific, measurable, and time-framed goals and objectives presented in the plan.

g. Develop an evaluation plan by which the recipient may conduct periodic and on-going assessments 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.

h. Participate in external proficiency testing and quality control programs, perform biomonitoring pilot and demonstration studies (including performance of biomonitoring analyses on previously collected samples), participate in the prospective planning and conduct of biomonitoring research projects or population exposure surveys, and perform other activities that enhance the recipient's ability to implement a biomonitoring program.

2. CDC Activities: