Biomonitoring California Laboratory Studies

Request for Information 2011-2012

A. Introduction

Biomonitoring is a tool to help assess human exposure to environmental contaminants. Measuring potentially toxic chemicals in blood, urine, or other biological specimens can offer important public health information not provided by traditional air, water, and soil monitoring. The California Environmental Contaminant Biomonitoring Program (CECBP, also known as Biomonitoring California or the Program) is a collaborative effort of the California Department of Public Health (CDPH), the Office of Environmental Health Hazard Assessment (OEHHA), and the Department of Toxic Substances Control (DTSC). Biomonitoring California is the first legislatively mandated state biomonitoring program in the country. The Program focuses on the analysis of priority chemicals recommended by an external Scientific Guidance Panel, but also can choose from a broader pool of designated chemicals.

Biomonitoring California's goals include determination of baseline levels of environmental chemicals in a representative sample of California residents, establishing trends in these chemical levels over time, and helping to assess the effectiveness of environmental regulatory programs. The Program's enabling legislation also provides for community studies; thus, Biomonitoring California has also partnered with several organizations on focused biomonitoring efforts involving various subpopulations.

In collaboration with academic and other researchers, Biomonitoring California actively collects human biospecimens from California residents. In addition, the Program's laboratories analyze archived California-specific biological samples obtained by others in the course of research studies. In 2008, Biomonitoring California issued a Request for Information (RFI) to researchers throughout the United States to identify those who had recently collected blood or urine specimens from California residents. Based on a set of screening criteria, the Program selected and analyzed blood and urine samples from several research studies.

In this second RFI for collaborative biomonitoring, the Program is again seeking to work with researchers who have collected urine or blood specimens from California residents. The objectives of this RFI are to support ongoing epidemiological or exposure assessment studies and to provide Biomonitoring California with additional data supporting its goals.

B. Laboratory Capabilities and Capacity

The Program's laboratories have extensive experience analyzing biological specimens for chemical contaminants. Assays currently conducted in Biomonitoring California laboratories are summarized in Table 1. To maximize the information obtained in collaborative studies, Biomonitoring California may choose to analyze additional chemical classes beyond those initially requested by investigators. All analyses will be conducted with the knowledge and consent of collaborating investigators, and will be based on mutual agreements signed by representatives of Biomonitoring California and collaborating institutions.

C. Application Process

Researchers interested in collaborating with Biomonitoring California must submit an RFI Project Application (see format in Attachment A) by February 15, 2012.

As part of the application process you will be asked to provide the following information:

1. Names of Investigators/Co-Investigators/Institution(s)
2. Project title
3. Study abstract
4. Research question(s) and study design
5. Demographic information of the study population (e.g., age distribution, gender, race/ethnicity,) and from whom and when samples were collected
6. Availability of demographic information related to the samples
7. Specimen use information (e.g., Institutional Review Board (IRB) approval, stipulations contained in informed consent)
8. Sample collection and storage protocols
9. The types of chemical analyses planned or already conducted
10. Availability of funding to support the Program's laboratory analyses.

D. Criteria for Selecting Collaborators

The following criteria will be used to evaluate and select prospective partners:

Samples

1. Specimens have been collected in 2005 or later, and preferably in 2008 or later. Consideration may be given to historical archives of longitudinal specimens (10+ years).
2. Sample volumes are adequate to undertake the requested analyses using Biomonitoring California laboratory methods.
3. Sample collection and storage protocols have been well documented and minimize risks of contamination, breakdown, and loss of the chemicals of interest.

Population

1. Study populations are of sufficient size to provide useful exposure information for the targeted population.
2. The study population consists exclusively of California residents.
3. Populations at higher risk for exposures or health effects, such as children, pregnant women or workers are of particular interest.

Other

1. Chemical analyses will add substantial value to the original study.
2. The potential partner(s) can contribute resources toward the collaboration.
3. Potential partner(s) are planning to or will consider returning individual results to participants who request them.
4. Community involvement in study implementation is a plus.

E. Selected Collaborators will be asked to provide the following.

If selected, collaborating organizations will be asked to provide the following:

1. The biological specimens to be analyzed, along with field blanks, if available
2. Collection and storage container blanks, if available; other sample processing materials as relevant
3. A blank copy of informed consent form(s)
4. Patient information (e.g., name, date of birth, address, contact information) for any samples to be analyzed for lead, as these results will require notification under state law.

As part of the Materials Transfer Agreement, Biomonitoring California will work with selected collaborators to negotiate an agreement on:

1. Shared authorship of publications resulting from sample analyses and
2. Support provided to Biomonitoring California.

F. Deadline for Submission

The RFI Project Description Form is due no later than 5:00 pm PST on February 15, 2012. Completed forms should be submitted electronically to Mr. Danny Kwon at Danny.Kwon@cdph.ca.gov. Inquiries about the RFI may also be directed to Mr. Kwon. We anticipate that researchers selected for collaboration will be notified within two months of the submission deadline.

Following such notification, Biomonitoring California and each collaborating institution will negotiate and execute a Materials Transfer Agreement(s) prior to submission of samples to the Biomonitoring California laboratories. Timelines for results return to study researchers will depend on the specific assays conducted. The approximate timeline is given below. All times following the submission deadline are tentative and subject to change.

Depending on the scope of the projects, we anticipate up to three investigator collaborations will be selected.

Approximate Timeline

December 1, 2011	Request for Information and Project Description Forms distributed
February 15, 2012	Submission deadline for Project Description Forms
April 15, 2012	Researchers selected for collaboration are notified
June 15, 2012	Materials Transfer Agreement(s) negotiated and executed
July 15, 2012	Samples submitted to Biomonitoring California laboratories
Jan 2013 – July 2014	Laboratory reports produced and returned to researchers (timeline will depend on biological medium and analyte(s))

For more information please contact Mr. Danny Kwon at Danny.Kwon@cdph.ca.gov.

TABLE 1

Capability of Biomonitoring California Laboratories

Analytes	Matrix
Metals – Lead (Pb), Mercury (Hg), Cadmium (Cd), Manganese (Mn)	**Whole blood**
Metals – Pb, Hg, Cd, Mn, Arsenic (As) (total and speciated); several other metals may be available upon request	**Urine**
Pyrethroid pesticide metabolite – 3-Phenoxybenzoic acid (3-PBA)	
Organophosphate pesticide metabolites – chlorpyrifos metabolite, 3,5,6-trichloro-2-pyridinol (TCPy), and nonspecific dialkyl phosphate (DAP) metabolites	
Perchlorate*	
Phenols – Bisphenol A (BPA), Triclosan, 4-tert-octylphenol, benzophenone-3	
Phthalate metabolites – monobutyl phthalate, monoethyl phthalate, monobenzyl phthalate, and mono-(2-ethyl-5-carboxypentyl) phthalate	
Mono-hydroxy Polycyclic Aromatic Hydrocarbons (PAHs)	
Persistent organochlorine pesticides -DDT, DDE, oxychlordane, trans-nonachlor, hexachlorobenzene, beta-hexachlorocyclohexane	**Serum**
Polychlorinated Biphenyls (PCBs), hydroxylated PCBs	
Polybrominated Diphenyl Ethers (PBDEs), hydroxylated PBDEs	
Perfluorinated chemicals, including, but not limited to perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA)	
Phenols - BPA, tetrabromobisphenol A (TBBPA), 2,4-dibromophenol (2,4-DBP), 2,4,6-tribromophenol (2.4.6-TBP)	

*Analysis method expected to be available in August 2012

ATTACHMENT A

Biomonitoring California

RFI Project Application 2012

Directions:
Use the expandable text boxes to answer the questions below. If you have any questions about this form, please send your inquiry to danny.kwon@cdph.ca.gov

Contact Name and Title	
Contact Phone #:	
Contact E-mail:	
Contact Address:	

1. Investigators/Co-Investigators/Institution(s):

2. Project Title:

3. Please provide an abstract of the study for which you collected biospecimens.

Please provide the following information for the study in which you collected biospecimens:

4. Research questions and study design

a. Research question(s) that you hope to answer

b. Study design

5. Study population

a. Describe the racial/ethnic, age, and gender makeup of the study population (e.g., 50 Mexican American women, ages 25-40 years old)

b. Describe the geographic distribution of the study population at the time of sample collection.

c. Describe other important characteristics of the study population (e.g., pregnant women, occupational cohort)

6. Check the following boxes for demographic information related to the samples that can be provided to Biomonitoring California (if other, list below).

☐ Age

☐ Gender

☐ Address

☐ Ethnicity

☐ Other (please list below)

7. Use of specimens

a. Which Institutional Review Board(s) approved the collection and/or use of specimens?

b. Is the original informed consent broad enough to allow for analyses of biological specimens by Biomonitoring California without re-consenting the subjects? Yes ☐ No ☐
Provide additional comments (as needed).

c. If your project is selected by Biomonitoring California, is the informed consent broad enough to allow additional analyses of leftover samples not specified in your original proposal without re-consenting the subjects? Yes ☐ No ☐
Provide additional comments (as needed).

d. Does the informed consent allow for return of results to participants? Yes ☐ No ☐
If yes, provide additional comments (as needed).

8. Sample collection, storage, and analysis

   Please fill out the following table, indicating responses to the following questions:
   The items below correspond to the columns in the table. If you have collected biological samples that are not listed in the table, please describe in the designated area in Question 9.

   a. Total number of each type of sample.

   b. When were the specimens collected (e.g., 2005-2010)? If specimen collection is still in progress, please indicate when it will be completed.

   c. Approximate volume (ml) of each type of sample that is available for the Biomonitoring California analysis.

   d. What types of tubes or containers were used for the drawing or initial collection? (e.g., red top, lavender top, etc.)

   e. What types of tubes or containers are used for specimen storage? Describe the materials of the storage tube/container, cap and any lining (e.g., glass tube with Teflon®-lined plastic screw cap).

   f. At what temperature(s) are the specimens stored?

   g. Have these tubes or containers of specimen already been handled for other analyses? Have they been refrozen after having been thawed? If so, how many times? Or were they aliquoted before freezing? Please describe.

   h. Please list any preservatives that have been added to the samples.

SAMPLE COLLECTION, STORAGE, AND ANALYSIS TABLE

Biological specimen	a. Total number of samples	b. Collection dates	c. Volume of sample (ml)	d. Collection container	e. Storage container / material	f. Storage temp.	g. Handled for other analyses? If yes, describe	h. Added preservatives
Whole Blood								
Plasma								
Serum								
Urine								
RBC Clot								
Other*								

*Please describe type of biological specimen in Question 9 below.

9. Describe any additional relevant information about the specimens not included in the table in Question 8.

10. What chemicals have already been, or are planned to be, analyzed in your samples?

11. What additional chemicals, from the list in Table I, would you like Biomonitoring California laboratories to analyze?

12. How will your overall study benefit from analysis of specimens by the Biomonitoring California laboratories?

13. Results Communication

a. Will individual biomonitoring results from the Program's analyses be communicated to participants? Yes ☐ No ☐

If "Yes", how? Please explain below.

b. If the results may have recognized clinical implications, how will participants be informed?

c. If the results may have recognized clinical implications, what mechanisms are in place for referral to medical or follow-up services?

d. If results are communicated to participants, will language- and literacy-appropriate materials and resources also be offered? Yes ☐ No ☐

If "Yes", please describe below.

14. Community participation

Does the study incorporate community participation and input into study implementation?

Yes ☐ No ☐ If "Yes", how?

15. Funding

a. What are the sources and levels of funding for the overall study? Please also include in-kind support.

b. Please describe the type and amount of resources that you can provide to support Biomonitoring California's laboratory analyses.

16. Please add any additional information that you would like us to consider about the study not described above.