The California Environmental Contaminant Biomonitoring Program (CECBP)

Laboratory Pilot Studies
Request for Information (RFI)

Due date for Responses: November 1, 2008
Please send responses and inquiries to:
Ms. Marta Lutsky at marta.lutsky@cdph.ca.gov

CECBP Laboratory Pilot Studies – Request for Information

A. Introduction

The California Environmental Contaminant Biomonitoring Program (CECBP), the first state-level biomonitoring program in the U.S., was established by legislation enacted in 2006. The CECBP is a collaborative effort between the California Department of Public Health (CDPH), the Office of Environmental Health Hazard Assessment (OEHHA), and the Department of Toxic Substances Control (DTSC). The CECBP will determine baseline levels of environmental chemicals in a representative sample of California residents, establish trends in these chemical levels over time, assess the effectiveness of environmental regulatory programs, and undertake community studies.

Analysis of human biological specimens will be conducted in CECBP laboratories located within CDPH and DTSC. These labs have a long history and experience analyzing biological specimens for chemical contaminants. CECBP laboratories have hired new staff and are acquiring new equipment in preparation for the implementation of the biomonitoring program. After the new equipment has been installed, the laboratories will conduct pilot studies with California specimens to help test sample handling logistics and laboratory readiness for sample analysis.

For these pilot studies, the CECBP is seeking to collaborate with researchers who have collected urine or blood specimens from California residents since 2003. The goals are to provide the CECBP laboratories with an opportunity to pilot the use of the new equipment, to assess the ranges of concentrations in Californians of some chemicals that may be biomonitored by the CECBP on a larger scale, and to add value to ongoing epidemiological or exposure assessment studies. Researchers interested in collaborating with the CECBP should complete and return the attached Project Description Form by November 1, 2008 (see timeline below).

B. CECBP Laboratory Capabilities and Capacity for Pilot Studies

Within the scope of the CECBP pilot studies, the laboratories will be able to analyze blood and urine samples. The laboratories will have the capacity to analyze samples from approximately 300 people in 2009, and the capability of conducting analyses for the chemical classes listed in Table I below. To maximize the information obtained from the pilot studies, the CECBP will need to analyze for as many chemical classes as possible from appropriate specimens.

Table I: Chemicals the CECBP will have the capacity to analyze in 2009

Major Polychlorinated Biphenyls (PCBs) (serum)
Major Organochlorine Pesticides (OCPs) (serum)
Major Polybrominated Diphenyl Ethers (PBDEs) (serum)
Major Hydroxy-PCBs (serum)
Major Hydroxy-PBDEs (serum)
Major Non-BDE Brominated Flame Retardants (serum)
Major Perfluorinated Compounds (PFCs: PFOS, PFOA, telomers) (serum)
Lead, Mercury, Cadmium, Arsenic (blood or urine)
Phthalate metabolites (urine)
Organophosphorous pesticide metabolites (urine)
Bisphenol A and other phenols (urine)
PAHs (urine)

C. Criteria for Selecting Collaborators

The following criteria will be used to evaluate and select prospective partners who submit the Project Description Form by COB, November 1, 2008:

Chemicals

1. The chemicals that the prospective partner(s) would like to have analyzed coincide with those that the CECBP laboratories have the capacity to analyze in 2009.

Samples (type, collection and storage)

1. Samples are whole blood, serum, plasma, and/or urine.

2. Samples are collected and archived in a manner that minimizes contamination, breakdown, or loss of the chemicals of interest.

3. Sample volumes are adequate to undertake analyses using the CECBP laboratory methods.

4. Specimens have been collected within the past five years (since 2003), and preferably within the past three years (since 2005).

5. Sample collection and storage protocols can be shared with the CECBP.

Population

1. Basic demographic data can be made available to the CECBP.

2. Study populations are of sufficient size to provide useful body burden information.

3. The study population consists of California residents, and preferably includes those at higher-risk for exposures or health effects, such as children or pregnant women.

Other

1. Chemical analyses by the CECBP laboratories will add value to the study.

2. The potential partner(s) can provide at least partial funding to support the CECBP laboratory analyses.

3. CECBP staff can share authorship of publications resulting from sample analyses conducted by CECBP laboratories.

D. Timeline

Researchers who have archived California blood and urine specimens that could be analyzed by the CECBP laboratories should submit a completed Project Description Form no later than COB, November 1, 2008. The completed form should be submitted to Ms. Marta Lutsky at marta.lutsky@cdph.ca.gov . Inquiries about this Request for Information should also be sent to Ms. Marta Lutsky, from which they will be directed to the appropriate staff to respond.

August 29, 2008 – Request for Information and Project Description Forms distributed
November 1, 2008 – Deadline for submitting Project Description Forms
January 2008 – Researchers selected for collaboration are notified
February 2009 – Materials Transfer Agreement(s) to be negotiated and executed
March 2009 – Samples to be received by the CECBP laboratories
April 2010 – Laboratory reports produced and returned to researchers

Project Description Form

Directions: Use the expandable text boxes to answer the questions. Please limit the length of your responses, excluding the table in question #8, to no more than six pages. The table in question #8 can be as long as necessary. Please submit an electronic copy of this form to: marta.lutsky@cdph.ca.gov by COB, November 1, 2008. If you have any questions about this form, please send your inquiry to marta.lutsky@cdph.ca.gov

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

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

2. Project Title:

3. Please include an abstract of your study.

4. Overall
    a. Research question(s)

    b. Study design:

5. Study population and specimens (Types and Numbers)
    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.

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

6. Can demographic information related to the samples be provided to the CECBP? If so, which data?

7. Use of Specimens
   a. What Institutional Review Board(s) approved the collection and/or use of specimens?

   b. Is the informed consent broad enough to allow for analyses of biological specimens for additional analytes without re-consenting the subjects?
   Yes ____ No ____

8. Sample Collection, Storage, and Analysis

Please fill out the following table, indicating:

a. Total number of each type of sample.
b. Approximate volume (ml) of each type of sample that is available for CECBP analysis.
c. What types of tubes or containers were used for the drawing or initial collection (e.g., red top, lavender top, etc.)?
d. When were the specimens collected? If specimen collection is still in progress, please indicate when specimen collection will be completed.
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 analysis? Please describe
h. Please list any preservatives that have been added to the samples.

	a. Total number of samples	**b. Volume (ml) of each sample**	**c. Collection container**	**d. Collection Dates (range)**	**e. Storage container**	**f. Storage Temp.**	**g. Handled for other analysis?** Yes/No	**h. Added Preservatives**
Whole Blood								
Plasma								
Serum								
Urine								

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

10. What chemicals have already been analyzed in your samples?

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

12. How will the study benefit from analysis of specimens by the CECBP laboratories?

13. Results Communication

a. Will individual results be communicated to participants? Yes __ No __
If "Yes", how?

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

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

d. If results are communicated, will language and literacy-appropriate materials and resources be offered to participants? If so, what kinds?

14. Community Participation

a. Does the study incorporate community participation and input into study implementation? Yes___ No ___

b. If “Yes”, How?

15. Funding

a. What are the sources of funding for this study? Please also include in-kind funding.

b. What amount of funding (if any) may be available to support CECBP laboratory analyses?