

## View xForm - Amendment Form for Projects Approved in Calprotects v3.0

**Use this form to submit an amendment to the CPHS IRB for a project approved within Calprotects (or for a project that did not involve submitting an initial application or determination of exempt/not research IRBManager xform). If your study was reviewed and approved in IRBManager, do not complete this form.**

### Data Entry

**- Submitted 09/03/2026 8:08 PM ET by Nerissa Wu, PhD**

### Amendment Header

#### Submitter

Nerissa Wu, PhD

**Email:** nerissa.wu@cdph.ca.gov **Business:** (510) 620-3666

#### Project number

16-11-2767

#### Project title

Sample Collection for Biomonitoring Method Development and Refinement

#### Current Approval

6/5/2026 for 12 months - Expiration: 6/4/2027

#### PI output

Nerissa Wu, PhD

**Email:** nerissa.wu@cdph.ca.gov **Expirations:**

#### PI institution:

California Department of Public Health

#### PI City Output

Richmond

#### PI Location State Output

CA

### Current contacts on project

| Name              | Role                      |
|-------------------|---------------------------|
| Dina Dobraca, MPH | Research Team             |
| Duyen Kauffman    | Administrative contact    |
| Edgar Vidrio, MS  | Responsible Official      |
| jianwen She, PhD  | Co-Principal Investigator |
| Kiera Melton, MPH | Research Team             |

**Click 'next' and to proceed in this form**

### Requested Changes

#### Choose the project types for this amended study

Common rule/Human subjects

**Choose all that apply:**

Minimal Risk

Non-English translation required

Consent form

#### Select all that apply

Other (examples such as, but not limited to: budget changes, project site)

**Clearly summarize and justify your proposed changes to the protocol in layman's terms for all selections made above.**

This project enables the program to enroll a convenience sample of participants and collect biological samples for use in developing new methods to measure chemicals of concern. In the last round of sample collection, we evaluated novel micro-sampling devices, collecting blood using two types of micro-samplers and via traditional phlebotomy for comparison. Collected blood samples were analyzed for heavy metals, some of which have clinical reference values.

Biomonitoring California has an established protocol for participant follow-up for analytes with program-defined "Levels of Concern" (LOCs). This protocol has been incorporated into multiple studies, all of which have been submitted to and approved by CPHS. Because we have not measured heavy metals in prior rounds of this study, the LOC protocol has not previously been added to the study protocol.

In this current amendment, the LOC protocol has been added (see attached Tracked and Clean versions of updated study protocols). We will also add information on the LOC protocol to the informed consent for subsequent rounds of sample collection. However, the samples that were recently analyzed for heavy metals were collected under the existing consent form, which does not include a description of the LOC protocol.

Under the LOC protocol, laboratory results will be reviewed by program staff to identify participants with any blood result that meets or exceeds an LOC. Participants with elevated levels of lead, cadmium, or mercury will be sent a letter notifying them of the result. In order to return health-relevant information back to participants as quickly as possible, LOC notification letters may be sent to participants before full result packets are sent out.

LOC notification letters include the following:

- Participant result for blood lead, cadmium, or mercury
- Level of concern
- Direct contact information for a Biomonitoring California health educator
- Advisory that program staff will be reaching out by telephone to offer optional individual follow-up. This will include conducting a survey to identify potential exposure sources and exposure reduction advice. Participants can decline this offer.
- In the case of lead exceedances, as described in the consent form, notification that lead results, along with participant name, contact information, gender, and date of birth will be reported to the Occupational Lead Poisoning Prevention Program (OLPPP) in CDPH as mandated by law (California Health and Safety Code Sections 124125-124165). OLPPP has established follow-up protocols, including possible investigation, based on the participant's blood lead level.

A flow chart of the protocol, including an example of the LOC Notification Letter, is included as Attachment AA.

- Flow chart
- Results letter
- Metals factsheets
- Mercury survey

All other results will be provided to participants following the Program's usual results return protocol. Results materials for this round of results, including cover letter, results template, chemical factsheets, and frequently asked questions, are included as Attachment AB.

### Indicate the Level of Risk involved with the changes proposed.

Level of Risk has not changed

### For protocol revisions, upload two copies; one with track changes and one final copy. For form revisions see below.

|                                                                  |          |
|------------------------------------------------------------------|----------|
| WU 16-11-2767 - Amended protocol - CLEAN - September 2026.docx   | Protocol |
| WU 16-11-2767 - Amended protocol - Tracked - September 2026.docx | Protocol |

### Upload any documents that require revisions due to this amendment (i.e. consent form, recruitment materials, proposals)

|                                                                                                     |            |
|-----------------------------------------------------------------------------------------------------|------------|
| Attachment AA - LOC Notification - Flow Chart - Letter - Factsheets - Survey - September 3 2026.pdf | Misc/Other |
| Attachment AB - Results return materials - metals - September 2026.pdf                              | Misc/Other |

## PI Signature

**To sign this form, enter your IRBManager password. By signing this form, you are indicating that the information within this application is accurate and reflects the proposed research and that you attest to the conflict of interest disclosures for all study team members.**

Signed Thursday, September 3, 2026 8:08:44 PM ET by Nerissa Wu, PhD

## Notify IRB for Pre-Screening

- Submitted 09/21/2026 2:07 PM ET by Sussan Atifeh

### Internal IRB Screening

**CPHS Office:** The questions on this page will appear every time the project is resubmitted to the CPHS IRB (even after review). Once the project has been reviewed by a committee member, unless researcher has changed questions on the form that impact the level of review, you do not need to update the questions here. If the changes made are not clear and require additional clarification change the 'ready for review' to 'no' and require changes. When you change the answer back to yes, it will remember your previous answers.

**Note that this version of the amendment form uses the new reviewer functionality for expedited reviews and approved deferrals by the full board**

**Is this study ready to be reviewed by the CPHS panel?**

Yes

**Is this amendment for addition/removal of personnel only?**

No

CPHS

**Level of review determination**

Full Board Minimal Risk

**Please provide a rationale for your level of review preliminary determination**

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**Choose the CPHS Chair**  
Catherine Hess, PhD

**Select the vice chair of the committee**  
Larry Dickey, MD, MPH, MSW

**Assigner for Reviews**  
Sussan Atifeh

**Review Cycle Month (question added on October 25, 2017; will be blank if form submitted prior)**

October

**Review cycle year**  
2026



**Chair Review and Full Board Set-Up**  
**- Submitted 09/21/2026 2:09 PM ET by Sussan Atifeh**

**Full Board Meeting Setup**

**The office will complete the questions on this page and submit the form after the teleconference with the chairs regarding this project is completed.**

**Confirmation of level of review**

Full Board Minimal Risk

**Provide the rationale for the level of review determination**

Primary Reviewer Determination: Although all of the subjects have consented to receive results, not all have been consented to receive proactive counseling and source investigation for increased level. This is an expansion of project activities that needs to be addressed in the protocol and the consent and will need full committee approval.

**Assign the appropriate reviewer/SME**

Larry Dickey, MD, MPH, MSW

**Enter the meeting date for this project**

10/02/2026

## SME Review

### SME Review

**After reviewing the application, complete the question(s) below. If you wish to make comments on the application for the researcher, use the 'add note' feature on each question (be certain to unmark the internal only box and do not mark changes required). To navigate the application, you can either use the 'previous' button at the bottom of the page or from the drop down at the top of this page choose 'view previous stages'. Once you have completed the questions that appear on this page (different questions will appear depending on your answer to the first question), you will need to click 'next' (from either the top of the bottom of the screen) and then click 'submit'.**

**If you are requiring revisions before the full committee review, the form will be returned to the researcher for revisions and returned to you upon re-submission.**

**Does the researcher need to provide additional information/revisions before the committee meeting? If there is insufficient time for the researcher to make changes prior to the committee meeting, choose 'no' in order to route the form correctly.**

*No answer provided.*

**In order to either return this application to the researcher or to move forward for the full meeting review, click 'next' and 'submit' on the next screen.**

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