CENTER FOR DATA INSIGHTS AND INNOVATION
CALIFORNIA HEALTH & HUMAN SERVICES AGENCY

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

Choose the IRB committee to review this study (this defaults to CPHS)

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

Load into IRBManager
- Submitted 09/21/2026 2:08 PM ET by The System

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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