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 01/14/2026 4:06 PM ET by Kerry Padgett, Ph.D.

Amendment Header

Submitter

February 6th meeting

01/29/2026 • Nicholas Zadrozna • *Not* Internal

Kerry Padgett, Ph.D.

Email: Kerry.Padgett@cdph.ca.gov **Business:** (510) 412-3738

Project number

12-10-0804

Project title
Using Infant Feces and Serum for Polymerase Chain Reaction (PCR) and Assay with Large Immunosorbent Surface Area (ALISSA) Assay Development and Validations and for Intestinal Microbiome and Clostridium Botulinum Genomic Characterizations

Current Approval
12/5/2025 for 12 months - Expiration: 12/4/2026

PI output

Kerry Padgett, Ph.D.

Email: Kerry.Padgett@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
Connie Chung, MPH	Research Team
Connie Chung, MPH	Administrative contact
Haydee Dabritz, PhD	Research Team
Jason Barash, MT(ASCP) PHM	Co-Principal Investigator
Jessica Khouri, MD	Research Team
Katya Ledin, PhD, MPH	Responsible Official

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:
Consent form

Select all that apply

Change informed consent process/form

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

It is our intention, by revising our consent form and communications to hospital staff (in phone scripts, fax coversheets, and letterhead consent and information forms), that we made every effort to ensure we communicate clearly that no blood draws should be performed for the purposes of this project and only residual blood/sera is requested.

Indicate the Level of Risk involved with the changes proposed.

Level of Risk has decreased

Provide an detailed information about how the risks have increased or decreased for this project.
We have decreased the risk of adverse events/inadvertent blood draws by enhancing and clarifying our communication with hospital staff as detailed in the attached documents in this amendment which include a direct request to the hospital staff to include a notation in the EMR that no blood draws are to be performed for this CDPH/IBTPP request. In addition, we have revised the patient research serum consent script, the hospital request script and research serum request fax cover sheet to emphasize and reiterate that the request is for only residual/left over sera. We have also updated the verbal consent language to be used with parents to clarify that this request is for only residual sera and have included a script to notify the parents of the infant invovled in the adverse event that a blood draw occurred without their consent.

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

No answer provided.

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

Consent Script - Parents_ Revised_22Dec 25.pdf	Consent Form
Hospital Request Script_Dec25.pdf	Consent Form
Letterhead Request to hospital for Serum_Hospital_Revised_22Dec25.docx	Consent Form
Patient research serum consent script_revised_8Jan26.pdf	Consent Form
Research serum request Fax Cover_Hospital_Draft_ Revised.pdf	Consent Form

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 Wednesday, January 14, 2026 4:06:16 PM ET by Kerry Padgett, Ph.D.

Notify IRB for Pre-Screening
- Submitted 01/29/2026 3:08 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
We have decreased the risk of adverse events/inadvertent blood draws by enhancing and clarifying our communication with hospital staff as detailed in the attached documents in this amendment which include a direct request to the hospital staff to include a notation in the EMR that no blood draws are to be performed for this CDPH/IBTPP request. In addition, we have revised the patient research serum consent script, the hospital request script and research serum request fax cover sheet to emphasize and reiterate that the request is for only residual/left over sera. We have also updated the verbal consent language to be used with parents to clarify that this request is for only residual sera and have included a script to notify the parents of the infant invovled in the adverse event that a blood draw occurred without their consent.

Choose the CPHS Chair
Larry Dickey, MD, MPH, MSW

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)

February

Review cycle year
2026

Load into IRBManager
- Submitted 01/29/2026 3:08 PM ET by The System

Chair Review and Full Board Set-Up
- Submitted 01/29/2026 3:11 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
This amendment is scheduled for the February 6, 2026, full board meeting, according to a request from Dr. Dickey.

Assign the appropriate reviewer/SME

Larry Dickey, MD, MPH, MSW

Enter the meeting date for this project

02/06/2026

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.