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

View xForm - Continuing Review Application v6.0

Use this form to request one (1) additional year to continue your study.

Continuing Review Data Entry
- Submitted 07/24/2026 6:06 PM ET by Jessica Khouri, MD

Continuing Review Header

Use this form to request one (1) additional year to continue your project.

CPHS will not process continuing reviews submitted more than 60 days before the end of the current approval period. Continuing reviews submitted prior to this period will be returned to you.

Please note that if you need to amend your protocol, you will need to submit a separate amendment form. For instructions on how to submit an amendment, refer to the IRBManager Manual for Researchers

This is version 4.0 of this application effective October 5, 2022.

Form Creator:

Jessica Khouri, MD
Email: Jessica.Khouri@cdph.ca.gov **Business:** (510) 231-7600

This is the existing study personnel on the form. If anyone listed here is no longer on the study, you will need to submit a separate amendment to add/remove personnel. See the IRBManager Manual for Researchers for instructions on submitting an amendment.

Note that if you update the project personnel, you will need to start a new Continuing Review form to reflect those changes, once the CPHS IRB has approved the personnel changes. This form will not update the project personnel.

Principal Investigator

Jessica Khouri, MD

Email: Jessica.Khouri@cdph.ca.gov **Business:** (510) 231-7600

Administrative contact(s):

Name	Role

Study personnel list

Name	Role
Amelia Hinteregger	Research Team
Ashley Scarborough-Gonzalez, MPH	Research Team
BETHANY MOORE	Research Team
Daniel Bernal, Bachelors of Science in Biology	Research Team
Heather Lee, MSN-CNP	Research Team
Ian Baird, MD	Co-Principal Investigator
Jason Barash, MT(ASCP) PHM	Research Team
Jeff Schapiro, MD	Responsible Official
Jennifer Botte, BS, RN	Research Team
Jennifer Read, MD	Co-Principal Investigator
Jessica Khouri, MD	Principal Investigator
Nicole Cheng, B.S	Research Team

PI City Output
Richmond

PI Location State Output
California

Project information

Project Number
2023-204

Project Title
Tolerability and Immunogenicity of a Single 40-µg Dose of Recombinant Botulinum Vaccine A/B (rBV A/B) for the Production of BabyBIG® in Volunteers with Existing Botulinum Immunity

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

Project Status
Active

Project Type
Drug, Recruitment-Participant

Study Events

Does your research project involve contact or interaction with human subjects, whether in person, or by mail, phone, text message, cellphone app, online survey, etc., or by a third-party working for you?

This excludes data-only studies, in which information is obtained only from existing databases.

Yes

Study Details

Has the involvement of human subjects ended for this study?

Yes

Have any complaints (verbal or written) been received from participants in the past year?

No

When did you first begin collecting information from human subjects?

07/09/2024

How many human subjects so far are being studied?

25

How many additional human subjects will be recruited in the coming year?

0

Have there been any changes in how the study is being conducted in the past year?

Yes

Describe the changes below.
There have been no changes to how the study is being conducted in the past year. There was an administrative amendment submitted on 02 February 2026 which was approved on 03 February 2026 to change the Responsible Official for this Project to Dr. Jeff Schapiro, M.D., D(ABMM), Assistant Deputy Director, Center for Laboratory Sciences, CDPH, and to remove Dr. Katya Ledin who is no longer with CDPH.

Did CPHS approve amendments for the changes described above?
Yes

Have there been any adverse events or unanticipated problems in the past year?

*An **adverse event** is an event that occurs during the course of a research protocol that causes physical or psychological harm, increases the risk of physical or psychological harm, results in a loss of privacy and/or confidentiality to a research participant or others (such as family members), or results in a loss of privacy and/or confidentiality for data or information on research participants or others.*

*An **unanticipated problem** is any unforeseen event that increases risk to the participant or others that is related to either a research intervention or interaction, or the conduct of the study in general, including but not limited to a complaint from a research participant that indicates an unanticipated risk, or unexpected changes to the risk/benefit profile of the study.*

No

Have any breaches of data security or other new data security issues occurred in the past year?

No

What were the major activities in this project during the past year?

The major activities included finalizing validations of the data analysis, updating ClinicalTrials.gov with the study results (results were released on 21 May 2026 and subsequently posted on 18 June 2026), and preparing the final Clinical Study Report (CSR) to be submitted to FDA. Given the need to prioritize other programmatic urgencies including infant botulism outbreak responses and BabyBIG manufacturing issues, we plan to complete the submission of the CSR later this summer or early fall.

What are the major activities expected for this project in the coming year?

Submission of the Clinical Study Report to FDA.

Have there been any changes in applicable laws in the past year that could affect the research?

No

Has analysis of data ended for the study?

Yes

Explain why you are requesting continuation instead of closing the study below.
We anticipate publishing the study data.

What is the expected completion date for this project?

12/01/2029

Is this different from the previously approved completion date?
No

CPHS members are interested in the results of your research. Please attach abstracts of reports or significant interim findings.

No answer provided.

If you plan to obtain additional data in the coming year that has not been previously approved by CPHS, you must submit an amendment, for example to use a different source of data, or to obtain additional variables or additional years from a previously approved source.

PI Signature

To sign this form, enter your IRBManager password. By signing this form, you are indicating that the information within this form is accurate.

Signed Friday, July 24, 2026 6:06:21 PM ET by Jessica Khouri, MD

Notify IRB for Pre-Screening
- Submitted 07/24/2026 7:05 PM ET by Sussan Atifeh

Internal IRB Screening

This version of the continuing review form utilizes the multiple expedited reviewer functionality

Is the continuing review ready to be reviewed by the CPHS?

Yes

Does the submission require committee member review?

Continuing reviews must be reviewed by a committee member if any of the following conditions have been met:

1. Human subject involvement is ongoing.
2. Complaints have been received from participants in the past year.
3. Adverse events or unanticipated problems have occurred in the past year.
4. There have been breaches of data security or other new data security issues in the past year.
5. There have been changes in laws in the past year that could affect the research.
6. There are responses elsewhere in the application that staff think should be seen by a committee member.
7. Only administrative reviews (non-members) have been conducted in the previous 4 years.

Yes

Does vital statistics need to be copied on the approval letter?

No

Review routing

Continuing Review Required

Review cycle month
August

Review cycle year
2026

IRB committee reviewing this project (defaults to CPHS; no need to change)

CPHS

Preliminary level of review determination

Full Review

Please provide a rationale for your level of review preliminary determination

This project originally involved Greater than Minimal Risk due to human subjects' contacts components. The Human Subjects' contacts components have been ended. The decision of changing the level of risk of a project with Greater than minimal risk to "Minimal risk" should be made in a full board meeting.

Choose the CPHS Chair

Catherine Hess, PhD

Load CR/Closure into IRBManager
- Submitted 07/24/2026 7:06 PM ET by The System

Chair Review and Full Board Set-Up
- Submitted 07/24/2026 7:07 PM ET by Sussan Atifeh

Full Board Set Up

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

Confirmation of Level of Review

Full Board Greater than Minimal Risk

Provide the rationale for the level of review determination.
This project originally involved Greater than Minimal Risk due to human subjects' contacts components. The Human Subjects' contacts components have been ended. The decision of changing the level of risk of a project with Greater than minimal risk to "Minimal risk" should be made in a full board meeting.

Assign Presenter

Larry Dickey, MD, MPH, MSW

Enter the meeting date for this project.

08/07/2026

Awaiting Full Board

Awaiting Full Board Review

Instructions (Full Board Review)

The form will remain in this stage until the day of the meeting, at which point it will move to the Processing of Full Board Review stage. No action is needed form the IRB Staff at this point, and the form does not need to be submitted.