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

View xForm - Unanticipated Problem or Adverse Event Form v2

Use this form to report unanticipated problems (including breach of data security) or adverse events involving risks to human subjects while the research is being conducted.

Data Entry
- Submitted 10/14/2025 2:14 PM ET by Kerry Padgett, Ph.D.

UP or AE Questions

Submitter

December 2025 cycle.

10/14/2025 • Sussan Atifeh • Internal

Connie Chung, MPH

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Project number

12-10-0804

Principal Investigator

Kerry Padgett, Ph.D.

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

Study 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

Study personnel

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
Kerry Padgett, Ph.D.	Principal Investigator

Monitoring Entity

Principal Investigator

Report Type

Protocol deviation or violation that was harmful (caused harm to participants or others, or placed them at risk of harm - including physical, psychological, economic, or social harm)

Provide a brief description of event or information for your selection above

On September 28, 2025, a 3-month old patient at a California hospital had blood mistakenly drawn to obtain serum for IBTPP research purposes. Per the protocol, verbal consent was obtained on September 25, 2025 from the family for IBTPP to obtain residual serum from blood draws that had already been done. That same day, a call was made to the California hospital lab to see if there was any residual serum available for the patient and it was communicated that there was no residual serum available. On Friday, October 10, 2025, a serum sample was received at IBTPP for the patient. IBTPP followed up with the California hospital laboratory and learned that the serum was ordered specifically for our research request on September 28, 2025 at 09:54. The patient was diagnosed with infant botulism type A and discharged home from the California hospital on October 9, 2025. As of the last clinical update received by the IBTPP on October 6, 2025, the patient was improving and breathing on room air with plans to discharge with a nasogastric feeding tube in place. The IBTPP first learned of this event on Friday October 10, 2025 when the serum specimen arrived at the CDPH-Botulism Reference Unit (BRU). CDPH-BRU promptly notified the research team and the IBTPP team immediately began an investigation to gather relevant facts. Study team member epidemiologist Connie Chung and IBTPP epidemiological staff obtained information from the hospital laboratory. The apparent cause of this Adverse Event was human error that resulted from misunderstanding the verbal request for residual serum. The human error resulted in the patient being given an unnecessary blood draw on September 28, 2025.
The research team will await the committee's decision on final disposition of the research specimen.

Date of event
09/28/2025

Date PI learned of event
10/10/2025

Enrolled in OSHPD research (OSHPD campus including Foothills facilities)?
No

Are there proposed changes to the protocol?

No

Attach any relevant documents to the report

No answer provided.

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

Signed Tuesday, October 14, 2025 2:14:02 PM ET by Kerry Padgett, Ph.D.

Notify IRB for Pre-Screening

IRB pre-screening

Is the AE report ready to be reviewed by the Chair/designee?

No answer provided.