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 03/21/2025 11:56 PM ET by Megan Mahoney, MD MBA

UP or AE Questions

Submitter

Megan Mahoney, MD MBA

Email: megan.mahoney@ucsf.edu **Business:** (628) 278-2524

Project number

13-02-1077

Principal Investigator

Jennifer Rienks, Ph.D.

Email: jennifer.rienks@ucsf.edu **Business:** (415) 476-5288

Study title

Longitudinal Study of Hospital Outcomes for California's Children

Study personnel

Name	Role
Jennifer Rienks, Ph.D.	Co-Principal Investigator
Jennifer Rienks, Ph.D.	Principal Investigator
Kevin Grumbach, MD	Responsible Official
Linda Remy, MSW PhD	Co-Principal Investigator
Megan Mahoney, MD MBA	Responsible Official

Monitoring Entity

Other

Report Type

Protocol deviation or violation that was possibly serious or continuous noncompliance

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

We are submitting an Adverse Event Report to the Committee for the Protection of Human Subjects through IRBManager to report a deviation from the approved study protocol. The two Principal Investigators (PIs) have left UCSF, and yet no amendments had been submitted to the CPHS documenting these changes and the above-named researchers retained possession of state data related to Project #13-02-1077. To mitigate this risk we are requesting that all project data will be relocated and securely stored in a University of California, San Francisco (UCSF) secure storage facility as soon as possible.

To mitigate any potential risks to human subjects, we have ensured that data security and confidentiality measures remain in place during this transition. All data will be stored in compliance with UCSF policies and regulatory requirements for research data retention.

Date of event
01/03/2025

Date PI learned of event
03/19/2025

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.

PI Signature for Coordination Submission
- Submitted 03/24/2025 11:08 AM ET by Agnieszka Rykaczewska, PhD

PI Signature

Is this form ready to be reviewed by the IRB? If not, choose no to have the application sent back to the coordinator for revisions.

Yes

To sign this form, enter your IRBManager password. By signing this form, you are indicating that the information within this formis accurate and reflects the proposed research.

Signed Monday, March 24, 2025 11:08:46 AM ET by Agnieszka Rykaczewska, PhD

IRB pre-screening

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

Yes

Reportable Event Status

Review required

Please provide a rationale for your decision above.
Adverse Event for project 13-02-1077

Assign Presenter

Laura Lund, MA

Select the chair or designee who will review this UP/AE.
Catherine Hess, PhD

If necessary, choose the second reviewer who needs to review this AE/UP.
Larry Dickey, MD, MPH, MSW

Chair Review & Full Board Set-Up
- Submitted 03/26/2025 1:00 PM ET by Sussan Atifeh

Full Board Meeting Setup

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

Does the chair agree that this event needs to be reviewed?

Yes

Enter the date for the meeting at which this event will be reviewed.

04/04/2025

Full Board Review and Office Processing

Post Full Board Review Processing

CPHS IRB Administration will complete the questions on this page after the full board meeting has occurred and the minutes complete.

Board determination

No answer provided.