

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 06/03/2026 6:35 PM ET by Kimberly Berger, MPH, PhD

UP or AE Questions

Submitter

Kimberly Berger, MPH, PhD

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Project number

2025-133

Principal Investigator

Kimberly Berger, MPH, PhD

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Study title

Evaluating the Effectiveness of Air Quality Monitoring and Health Education on Reducing Indoor Pollution Exposure in Low-Income Housing Communities

Study personnel

Name	Role
Charlene Sacramento	Research Team
Daniella Rodrigues, AA, AS	Research Team
Hannah Wohl Sanchez, BS	Research Team
Jeff W Sanchez, B.A.	Responsible Official
Kazukiyo Kumagai, Ph.D	Research Team
Kimberly Berger, MPH, PhD	Principal Investigator
Ping Wang, PhD	Research Team
Rosemary Castorina, PhD MPH	Co-Principal Investigator
Zhong-Min Wang, Ph.D.	Research Team

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 Saturday, May 30 a participant emailed cphs@otsi.ca.gov with me cc'd with the following message:

"I need to be paid for my time. The Air Smart Study personnel barraged me with phone calls, texts and emails and questioned me about incidents that that they were informed about themselves as they were copied on emails. I had NOT given permission (nor was I even asked for permission) to text me yet my data plan was compromised by the Air Smart company's texts. The angst, time and expense alone requires a payment of \$50.00 sent to me ASAP from Air Smart as an additional 20 minutes of my time was taken from me this morning. NO ONE should be subjected to this barrage of phone calls, texts and emails and then denied promised payment. California Committee for the Protection of Human Subjects, please see that I am compensated for my time and suffering, otherwise please shut the study down so no other unfortunate subjects are harmed. Thank you, "

Below is a summary of our interactions with this participant.

The participant booked a phone appointment for May 26 to go over our informed consent form. After she booked the appointment she emailed us to ask for the phone number we would be calling from, which I responded to with our study phone number. I called her on the 26th but she didn't answer, so the next day I texted her and sent an email asking if she wanted to reschedule. Turns out she had rescheduled for May 29 and I hadn't seen it. She responded to my text with STOP, so I did not text her again. At the time I texted her, she had not consented to receiving text messages.

Hannah called the participant for her appointment on May 29. I received a call shortly after they hung up with Hannah in tears. Hannah reported that the participant had been aggressively rude, impatient, and accusatory on the call. She repeatedly cut Hannah off, called her a liar, and was aggressive in her words and tone. After speaking with Hannah I decided to withdraw the participant from the study because I was not comfortable sending my staff into her home, which would have been the next step in the study. I sent the participant a respectful email informing her that we were withdrawing her, cancelling the study visit that she and Hannah had scheduled on their call, and deleting her information from our systems. That is the last interaction we had. I was on vacation that day so I did not get a chance to delete her information before she emailed CPHS the next day. I will hold off for now until this is resolved.

Here is the content of both the text and email I sent her on May 28: "Hi. This is Kim from the Air Smart Research study. We tried to call you yesterday for our appointment but didn't get an answer. Would you like to reschedule?"

And here is the email I sent her on May 29:
"Hello,

I am writing to inform you that I have decided to withdraw you from the Air

Smart Research study. Respectful communication with study staff is required for participation, and the conduct during your recent phone call with our team does not meet that expectation.

We will remove your information from our study systems and cancel the appointment we scheduled earlier today.

Thank you,
Kim"

In total, we called her twice (one missed call from me, one answered call from Hannah), texted her once, and emailed her three times (once as a confirmation of the phone appointment she booked, once in response to her email asking for the phone number we would be calling from, and once to tell her we were withdrawing her). Our eligibility survey and informed consent form (which she did sign) is very clear that the first payment comes after the first study visit is complete. This participant did not complete the study visit.

After this incident, I went back through my phone records and found three other participants who I texted before they opted in to receiving text messages. I have discontinued texting all participants, except for the few who explicitly requested to receive text message reminders. To correct this deviation, we will: 1) amend our informed consent form to include a checkbox to opt in to receiving text messages for study activity reminders, 2) use that consent form going forward, and 3) re-consent the participants who explicitly requested to receive text messages with the new informed consent form.

Following study protocol is a top priority and I apologize for and regret this deviation. I will follow any guidance from you on communications or decisions regarding the participant above; my current intent is to not pay her compensation because she did not complete the study visit. I also do not intend on initiating further communication with her.

Thank you,
Kimberly Berger

Date of event

05/30/2026

Date PI learned of event

05/30/2026

Enrolled in OSHPD research (OSHPD campus including Foothills facilities)?

No

Are there proposed changes to the protocol?

Yes

As you indicated that there are proposed changes to the protocol, you will need to submit an amendment to your project. In order to do so, you will need to go into your study in IRBManager and click on the 'initial submission event'. Once inside the event, go to the xform list and click the 'copy for amend' icon next to your application name.

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 Wednesday, June 3, 2026 6:10:08 PM ET by Kimberly Berger, MPH,
PhD

Notify IRB for Pre-Screening

IRB pre-screening

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

No answer provided.

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