



Date September 1, 2023

From Jerrell Little
IRB Administrator
Human Research Protection Office

Subject IRB Approval of Amendment to CDC Protocol 7242, "Aerosols from cyanobacterial blooms: exposures and health effects in a highly exposed population." (Expedited)

To Lorraine C. Backer, PhD, MPH
NCEH/DEHSP

The CDC IRB has reviewed and approved your request to amend protocol 7242, "Aerosols from cyanobacterial blooms: exposures and health effects in a highly exposed population". These changes included the following:

Modification #1: Reduce sample size. Approvals for IRB, OMB, PIA, and Funding for this project began in 2018. Because of the lengthy approvals processes, we were not able to align the project with the initial funding from the division. We later received funding through APHIR, but that required us to substantially reduce our study sample size from 200 to 67.

Modification #2: Expand exposures of interest. Since the project was approved, there have been no substantial cyanobacterial blooms in the geographic study area, leading to further misalignment of approvals and funding. The current funding expires with no opportunity for extension at the end of March 2024. Instead of limiting the project to exposures from cyanobacterial toxins, we request to expand the study to include exposures to toxins from other organisms associated with adverse health effects, i.e., marine algae and seaweeds, as well as cyanobacteria. We anticipate that this change will allow us to use the available funds to conduct a study that will contribute significantly to the public health science describing the impacts of algal and seaweed blooms on communities.

Modification #3: All documents where appropriate: changed title to reflect new exposure metrics, changed "cyanobacterial" to "harmful algal blooms (HABs)", changed reference specifically to Lake Okeechobee and nearby canals to "Florida waterbodies."

Modification #4: Deleted Attachment 5 (Urine Lung function Nasal swabs) Added OMB-approved to separate collection of nasal swabs and urine specimen.

Modification #5: Changed Attachment 7 from "Instructions on how to collect a water sample" to "How to record time spent outdoors." Study staff will collect the water samples. Providing a form to record time spent outdoors will help make this part of data collection easier for participants.

Modification #6. Protocol narrative changes:

- 6a. Modified background to expand the exposure of interest to HABs (marine HABs, seaweeds, and cyanobacterial blooms).
- 6b. Deleted COVID-related narrative in consent form and protocol narrative.
- 6c. Deleted specific references to potential study participants who are occupationally exposed to HABs.
- 6d. Modified the timeframe of data collection to extend throughout the bloom season and beyond (i.e., into the winter, if needed) for data collection days. This will ensure a wide variety of exposures for our data analysis.
- 6e. Added OMB box, to data collection forms.

The action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.111(b)(2), categories 2a, 2b, and 7, minor changes to previously approved research for which approval is authorized.

This study was reviewed under the Revised Common Rule and does not have an expiration date.

Any problems of a serious nature must be brought to the immediate attention of the CDC IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for CDC IRB approval before they are implemented.

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office (404) 639-7570 or e-mail: huma@cdc.gov.