



Memorandum

Date January 21, 2020 Revised: Site restriction lifted

From Jerrell Little
IRB-Committee Administrator
Human Research Protection Office

Subject CDC IRB Approval of New Protocol 7242.0, "Aerosols from cyanobacterial blooms: exposures and health effects in a highly exposed population." (Expedited)

To Lorraine Backer, PhD, MPH
NCEH/DEHSP

CDC's IRB-Committee 2 has reviewed the request for approval of new protocol 7242.0, "Aerosols from cyanobacterial blooms: exposures and health effects in a highly exposed population." The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories 2a, 2b, 3, 4, and 7. You are required to close out expedited protocols as soon as CDC staff are no longer engaged in the research activity. The Human Research Protection Office (HRPO) may follow up with you periodically to check the status of CDC's engagement in this research activity.

This approval confirms that CDC's IRB-Committee 2 has determined that a Certificate of Confidentiality applies to this study and protects the privacy of individuals who are subjects of this research, pursuant to subsection 301(d) of the Public Health Service Act.

The IRB determined that the study poses minimal risk to subjects. The IRB approves the inclusion of pregnant women (45 CFR 46.204). The IRB has approved a waiver of documentation of informed consent for adults under 45 CFR §46.117(c).

If other institutions involved in this protocol are being awarded CDC funds through the CDC Office Financial Resources (OFR), you are required to send a copy of this IRB approval to the CDC OFR award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided OFR with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for 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 at (404) 639-7570 or email at huma@cdc.gov.

cc: NCEH/ATSDR HS mailbox