

Centers for Disease Control and Prevention (CDC) Atlanta GA 30329-4027

November 29, 2023

Meghan Holst ows6@cdc.gov

RE: Approval of Exempt Research Protocol 7479, "Outbreak Prevention and Response

Study"

Dear Meghan Holst:

On November 29, 2023, the CDC Human Research Protections Office (HRPO) reviewed your submission of research study, "Outbreak Prevention and Response Study," and has determined that it meets the criteria for exemption under 45 C.F.R. 46.104(d)(2)(i). Therefore, HRPO approved your research study for exemption, and assigned it CDC Protocol Number 7479.

Please note that a Certificate of Confidentiality (COC) applies to this study, and the recommended COC language has been added to the study's protocol, and will be included in the verbal informed consent.

If the research is not complete within one year, you must submit a Progress Report Form to maintain exempt status for the research. Any changes to this protocol may not be implemented until they are reviewed by HRPO and determined to be consistent with the exemption categories.

Please note that investigators remain responsible for the ethical conduct of this research and for ensuring appropriate human research protections even for research that is exempt from the regulations governing the protection of human subjects in research.

If you have any questions, please contact your Associate Director for Science, your National Center Human Subjects Contact, or me via email at uno4@cdc.gov, or telephone at 404-639-8379.

Sincerely,

Robert Chirila, Lead

Human Research Protections Office

cc: Alfonsina De Leon Salazar

Shirley Ding