



July 16, 2024

Nancy H. Worthington
ous8@cdc.gov

RE: Approval of Exempt Research Protocol 7503, “Overdose prevention services for people experiencing homelessness”

Dear Nancy H. Worthington:

On July 16, 2024, the CDC Human Research Protections Office (HRPO) reviewed your submission of research study, “Overdose prevention services for people experiencing homelessness,” and has determined that it meets the criteria for exemption under 45 C.F.R. 46.104(d)(2)(ii). Therefore, HRPO approved your research study for exemption, and assigned it CDC Protocol Number 7503.

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 informed consent form.

If the research is not complete within one year, you must submit Form 1259, Study Progress Report form, by July 15, 2025, 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,

A handwritten signature in black ink, appearing to read "Robert Chirila".

Robert Chirila, Lead
Human Research Protections Office

cc: Karen Angel
idy6@cdc.gov