



October 22, 2024

Zachary Smith
QKS4@cdc.gov

RE: Approval of Exempt Research Protocol 7513, "RANDS 11"

Dear Zachary Smith:

On October 21, 2024, the CDC Human Research Protections Office (HRPO) and the CDC Institutional Review Board (limited review) reviewed your submission of research study, "RANDS 11," and have determined that it meets the criteria for exemption under 45 C.F.R. 46.104(d)(2)(iii). Therefore, HRPO approved your research study for exemption, and assigned it CDC Protocol Number 7513.

The Program has selected to apply the Assurance of Confidentiality (AOC) to this research study.

If the research is not complete within one year, you must submit [Form 1259](#), Study Progress Report form, by October 20, 2025, for continuing review 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", written in a cursive style.

Robert Chirila, Lead
Human Research Protections Office

cc: Amanda Titus
Kathy O'Connor