

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

October 1, 2024

Kristen Cibelli Pwf8@cdc.gov

RE: Approval of Exempt Research Protocol 7512, "NHIS Diabetes Study"

Dear Kristen Cibelli:

On October 1, 2024, the CDC Human Research Protections Office (HRPO) reviewed your submission of research study, "NHIS Diabetes Study," 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 7512.

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 <u>Form 1259</u>, Study Progress Report form, to HRPO by September 30, 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,

Robert Chirila, Lead

Human Research Protections Office

cc: Amanda Titus Kathy O'Connor