

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

August 13, 2024

Brianna Eiter viy3@cdc.gov

RE: Approval of Exempt Research Protocol 7507, "Developing a Framework to Identify and

Address Hazards Unique to Women Mine Workers"

Dear Brianna Eiter:

On August 13, 2024, the CDC Human Research Protections Office (HRPO) reviewed your submission of research study, "Developing a Framework to Identify and Address Hazards Unique to Women Mine Workers," 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 7507.

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. This protocol may be tracked using <u>OSIRIS</u>.

If the research is not complete within one year, you must submit <u>Form 1259</u>, <u>Study Progress Report Form</u>, by August 12, 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 I via email at uno4@cdc.gov, or telephone at 404-639-8379.

Sincerely,

Robert Chirila, Lead

Human Research Protections Office

cc: NIOSH HSRB Office <u>cin-hsrb@cdc.gov</u>