



October 30, 2024

John Donovan

ILJ1@cdc.gov

RE: Approval of Exempt Research Protocol 7519, “Effectively empowering and equipping primary care providers in addressing the burden of hepatitis C among under- and uninsured patients”

Dear John Donovan:

On October 30, 2024, the CDC Human Research Protections Office (HRPO) reviewed your submission of research study, “Effectively empowering and equipping primary care providers in addressing the burden of hepatitis C among under- and uninsured patients,” and 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 7519.

As CDC will not receive any identifiable information, including coded information, a Certificate of Confidentiality does not apply to this research study.

Please note that Karina Rapposelli is restricted from involvement with this research study until such time that she completes the required CITI human subjects research training as outlined [here](#) and confirms training completion with HRPO at huma@cdc.gov. If the research is not complete within one year, you must submit [Form 1259](#), Study Progress Report form, by October 29, 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: nchhstphumansubjects@cdc.gov