Appendix I – IRB approval letter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention (CDC)

Memorandum

Date June 28, 2021

From Suzanne E. Tomasi, DVM, MPH, DACVPM
IRB Reviewer, NIOSH Institutional Review Board

Subject IRB Approval of New NIOSH Protocol 20-NIOSH-26, "Seat belt use among workers who drive as part of their job: what's not "clicking?" (Expedited)

To Rosa L. Rodríguez-Acosta, PhD
Project Officer, NIOSH/DSR

The NIOSH IRB reviewed the new protocol 20-NIOSH-26, "Seat belt use among workers who drive as part of their job: what's not "clicking?" The IRB determined the study poses minimal risk to subjects. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), category (7). Continued review is not required for this protocol since it is eligible for expedited review.

Please note that your protocol currently contains procedures that include in-person interaction. At this time all in-person interactions with human subjects are currently and indefinitely paused due to risks of harm to subjects, staff and others from COVID-19 exposure and infection. The only study activities approved at this time by the IRB are those that do not involve in-person interactions. Until further notice, if you want to resume or initiate in-person interactions with human subjects you must obtain advanced written approval from the IRB and NIOSH DLO Director. If your research happens on-site at NIOSH facilities, you must obtain written approval from NIOSH OD Facilities. Contact your Associate Director for Science for all COVID-19 requirements.

The request for waiver of documentation of informed consent is granted per 45 C.F.R. 46.117 (c)(1).

Due to the funding and collection of identifiable, sensitive information the project is determined to be covered by a Certificate of Confidentiality under section 301(d) of the Public Health Service Act.

If other institutions involved in this protocol are being awarded NIOSH funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

Investigators are required to report incidents to the HRPP in accordance with CDC/NIOSH policy and procedure. Any proposed changes to the protocol should be submitted as an amendment to the protocol for NIOSH IRB approval before they are implemented.

If you have any questions, please contact the NIOSH Human Research Protection Program (513) 533-8591 or e-mail: NIOSH IRB Mailbox.