Appendix N

IRB Approval Letter (Ingres/Egress Study)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date December 15, 2015

From Angela M. Morley, J.D., M.P.H.,
Chair, NIOSH IRB

Subject IRB Approval of New Protocol HSRB 15-OMSHR-04XP, "Ingress/Egress from Mobile Equipment" (Expedited)

To William L. Porter
Project Officer, OMSHR

NIOSH's IRB has reviewed the request for approval of new protocol HSRB 15-OMSHR-04XP, "Ingress/Egress from Mobile Equipment" and has approved the protocol for the maximum allowable period of one year. NIOSH IRB approval will expire on December 14, 2016. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110, categories 6 and 7. The IRB approved the requested waiver of documentation of informed consent under 45 CFR 46.117(2).

The IRB determined that the study poses minimal risk to subjects.

As a reminder, the IRB must review and approve all human subject research protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your research protocol for continuation review and approval by the IRB along with available IRB approvals from all collaborators. Please keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. **To avoid lapses in approval of your research and the possible suspension of subject enrollment and/or termination of the protocol, please submit your continuation request along with all completed supporting documentation at least six weeks before the protocol's expiration date of December 14, 2016.**

Any problems of a serious nature must be brought to the immediate attention of the NIOSH IRB, and 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 at (513) 533-8591 or by e-mail: cin-hsrb@cdc.gov.

cc:
HSRB 15-OMSHR-04XP