Appendix O

Original IRB Approval Letter (Boot Outsole Wear Characteristics study)

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date January 14, 2016

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

Subject IRB Approval of New Protocol 15-OMSHR-06XP, "Investigation of Boot Outsole Wear Characteristics" (Expedited)

To Jonisha P. Pollard, M.S., C.P.E.
Project Officer, Workplace Health Branch, DMRO, OMSHR

NIOSH's IRB has reviewed the request for approval of new protocol 15-OMSHR-06XP, "Investigation of Boot Outsole Wear Characteristics" and has approved the protocol for the maximum allowable period of one year. NIOSH IRB approval will expire on January 13, 2017. 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) for the boot outsole wear characteristics study ("the boot scan only study").

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

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.

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 January 13, 2017.**

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-06XP

IRB Approval Letter for the most recent extension (Boot Outsole Wear Characteristics study)

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date January 7, 2019

From Kathy Masterson, CIP
IRB Administrator, NIOSH Institutional Review Board

Subject IRB Approval of Continuation of NIOSH Protocol 15-OMSHR-06XP, "Investigation of Boot Outsole Wear Characteristics" (Expedited)

To Jonisha Pollard, MS
Project Officer, PMRD, NIOSH

The NIOSH IRB has reviewed and approved your request to continue protocol 15-OMSHR-06XP for the maximum allowable period of one year and it will expire on January 13, 2020. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), Categories (6), (7) and (4).

The IRB determined the study poses minimal risk to subjects.

A waiver of documentation of informed consent is granted per 45 CFR46.117 (c)(2).

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 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.

As a reminder, the IRB must review and approve all human subjects 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 January 13, 2020.**

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 CDC Human Research Protection Program (513) 533-8591 or e-mail: cin-hsrb@cdc.gov.