

EAST CAROLINA UNIVERSITY University & Medical Center Institutional Review Board 4N-64 Brody Medical Sciences Building· Mail Stop 682 600 Moye Boulevard · Greenville, NC 27834 Office 252-744-2914 · Fax 252-744-2284 · rede.ecu.edu/umcirb/

Notification of Amendment Approval

From:Social/Behavioral IRBTo:Mostafa NamianCC:Mostafa NamianDate:2/13/2023Re:Ame2_UMCIRB 22-001818

<u>UMCIRB 22-001818</u> Fatigue among construction workers

Your Amendment has been reviewed and approved using expedited review on 2/13/2023. It was the determination of the UMCIRB Chairperson (or designee) that this revision does not impact the overall risk/benefit ratio of the study and is appropriate for the population and procedures proposed.

Please note that any further changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must adhere to all reporting requirements for this study.

If applicable, approved consent documents with the IRB approval date stamped on the document should be used to consent participants (consent documents with the IRB approval date stamp are found under the Documents tab in the study workspace).

The approval includes the following items:

Document Benign Behavioral Interventions consent template_1.21.19 - Spanish.docx(0.01) Spanish survey - V1.pdf(0.01) Description Consent Forms Surveys and Questionnaires

For research studies where a waiver or alteration of HIPAA Authorization has been approved, the IRB states that each of the waiver criteria in 45 CFR 164.512(i)(1)(i)(A) and (2)(i) through (v) have been met. Additionally, the

elements of PHI to be collected as described in items 1 and 2 of the Application for Waiver of Authorization have been determined to be the minimal necessary for the specified research.

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

IRB00000705 East Carolina U IRB #1 (Biomedical) IORG0000418 IRB00003781 East Carolina U IRB #2 (Behavioral/SS) IORG0000418