



Memorandum

Date March 29, 2023

From NIOSH Institutional Review Board

Subject NIOSH IRB Conditional Approval Report for 22-NIOSH-06, “Noise Exposures and Hearing Loss in the Oil and Gas Extraction Industry”

To Bradley King
Project Officer, WSD
Through: /Branch Official, WSD ____ ____
/Division Official, WSD ____ ____

General Comments and IRB Actions

Thank you for your responses to the NIOSH IRB Second Request for Information for 22-NIOSH-06, “Noise Exposures and Hearing Loss in the Oil and Gas Extraction Industry.” We appreciated your responses to the comments and the corresponding revisions to the protocol.

This protocol was reviewed at the March 28, 2023, convened meeting of the NIOSH IRB and granted conditional approval with satisfactory response to the issues raised in this report. The response will be reviewed by the Lead Reviewer, Sherry Xu and the NIOSH IRB Co-Chair, Brianna Eiter.

Please respond only to issues raised in this report. Any protocol changes accompanying your response must pertain to an issue raised in this report. Please advise the IRB if you wish to make any protocol changes independent of this report, as they may require separate IRB review and approval prior to implementation.

The requests below are organized according to the HHS Policy for Protection of Human Research Subjects, §46.111 Criteria for IRB approval of research and §46.116 General requirements for informed consent, in [The Revised Common Rule](#).

§46.116(a) General requirements for informed consent

The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

1. Please translate all necessary materials and informed consents into Spanish.

Other Protocol Issues

2. Please confirm/update status of researchers Snawder and Esswein in the protocol. Both are currently listed as employees of WSD but are contractors.

Please email the following documents to the [NIOSH IRB Mailbox](#) with subject heading “22-NIOSH-06 PI Response to NIOSH IRB Conditional Approval Report”:

- 1) A PDF or word document of your Response
- 2) A PDF or word document of the Clean Protocol
- 3) A PDF or word document of the Revised Tracked Protocol
- 4) The Form 0.1255

End of Report