Attachment F: IRB Letter of Approval

NOTIFICATION - NO HUMAN SUBJECTS

From: Carolyn Tschopik

To: Tom LaTourrette - PI

Cc: Tom LaTourrette - Primary Contact
Tom LaTourrette - Study Team

ID: 2015-0840

Title: Assessment of the Market for Electronic Technology for Underground Coal Mining Safety and Health Applications

Description: The HSPC has determined that this project does not involve human subjects as defined by the regulations at 45 CFR 46.102(f) and therefore is not subject to further review.

Planned activity is advisory or analysis role with no individual data being obtained. If additional tasks or design elements are added please contact the HSPC to obtain a revised determination.

Please contact the HSPC immediately if the project changes in any ways that may affect human subjects involvement.

Action Required: No action is required of you at this time. If you wish to view the status of your application, please login to RHINO, then click on the study ID above to navigate to the project workspace.

Date of Determination: 12/8/2016

CURRENT STUDY REVIEW STATUS

Project Number: There are no items to display

Funding Source: NIOSH

Prime Recipient: RAND

RAND Unit(s): Justice, Infrastructure, and Environment *

Human Subjects: No

Type of Review: Expedited

Component Approvals:

	Procedure	Approved	Motion	Category
Mining technology suppliers and users	Part 1 (funded): Design agenda and select sample for delphi workshop to be submitted as part of OMB application. Part 2 (unfunded): Conduct workshop after OMB approval.	Thu Dec 8 00:00:00 PST 2016	No Human Subjects	
	Part 1 (funded): Design protocol and select sample for structured interviews to be submitted as part of OMB application. Part 2 (unfunded): Conduct interviews after OMB approval.	Thu Dec 8 00:00:00 PST 2016	No Human Subjects	

Assurance number: FWA00003425

IRB number: IRB00000051

Administrator: Carolyn Tschopik

The HSPC is RAND's Institutional Review Board to review research involving human subjects, as required by federal regulations. RAND's "Federalwide Assurance for the Protection of Human Subjects" (FWA00003425, effective through July 1, 2018, at http://intranet.rand.org/groups/hspc/fwa.pdf) serves as our assurance of compliance with the regulations of 16 federal departments and agencies. According to this assurance, the Committee is responsible for review regardless of source of funding.

NIOSH Research/Non-Research Determination Form

This form can be used by the Division, Laboratory, or Office leadership (Director, Deputy Director, and Associate Director for Science) or the NIOSH IRB Office. Conduct of Human subjects research requires IRB review as defined in HHS 45-CFR-46. Conduct of Human Subjects Non-Research does not require IRB review.
Include with this form a description or protocol and, if necessary, a brief justification for the proposed categories.

Project Title: Assessment of the Market for Electronic Technology for Underground Coal Mining Safety and Health Applications

Project Officer(s): David Snyder

Proposed Project Dates: Start: 1/1/2017 **End:** 12/31/2019 **Activity NEW:** ☒ **OR Existing:** ☐

Signatory Should Check Appropriate Categories (D/L/O or NIOSH IRB)

☐ **I Activity is RESEARCH if both the following apply:**
- ☐ **A** Activity is a systematic investigation, including systematic collection of data, and
- ☐ **B** Activity is designed to develop or contribute to generalizable knowledge.

☒ **II. Activity is NON-RESEARCH that does not contribute to generalizable knowledge because the primary intent is either:**
- ☐ **A** Emergency Response to identify, characterize, and solve an imminent health issue; or
- ☐ **B** Surveillance that is a routine ongoing collection of data for disease or injury control; or policy purposes; or
- ☒ **C** Public Health Program that serves to educate, monitor, support, market, register, demonstrate, manage; or
- ☐ **D** Program Evaluation for measuring or monitoring the efficacy, implementation, or utility of an established activity; or
- ☐ **E** Laboratory proficiency testing.

☐ **III. Activity INVOLVES HUMAN SUBJECTS if information collected about a living individual is either:**
- ☐ **A** Identifiable private information; or
- ☐ **B** Is collected through intervention or interaction with the individual.

☐ **IV. Activity DOES NOT INVOLVE HUMAN SUBJECTS if activity is either:**
- ☐ **A** Collection or analysis of data about groups or organizations, not about persons; or
- ☐ **B** Data or specimens from deceased (only) persons; or
- ☐ **C** Anonymous (no links) data or specimens collected for another purpose; nothing collected for present purpose; or
- ☐ **D** Data collected for another purpose is not anonymous but personal identifiable information is protected through a data use agreement (CDC 0.1375B) prohibiting the release of the key to CDC investigators under any circumstances.

☐ **V. Activity is Human Subjects Research but CDC/NIOSH is not ENGAGED (not requiring IRB review) if all the following apply:**
- ☐ **A** NIOSH/CDC employees (FTE/Contractor) will not have contact (interact or intervene) with human subjects; and
- ☐ **B** NIOSH/CDC employees will not obtain or access personal identifiable information (no links or CDC 0.1375B); and
- ☐ **C** NIOSH/CDC employee involvement is limited to technical assistance or manuscript writing and no current CDC funding.
- ☐ **D** Collaborative Institutions must have IRB Review documentation and a valid Federalwide Assurance (FWA); Institution name , FWA#

RECOMMENDATION/DETERMINATION:
☐ Activity **DOES require** IRB Review. **OR** ☒ Activity **DOES NOT require** IRB Review.

APPROVING OFFICIAL TITLE: Chair, NIOSH Institutional Review Board **NAME:** Angela M. Morley **SIGNATURE:** Angela Morley -S Digitally signed by Angela Morley -S Date: 2016.12.16 15:24:37 -05'00' **DATE** 12.16.16	**NIOSH IRB No.** 16-OD-NR08

If IRB (HSRB) Review is required, suggested review is: ☐ Full Board Review ☐ Expedited Review ☐ Exempt Review

Comments/Rationale for Determination (attach additional comments):

The MINER Act was designed to improve the safety of mines and miners. Pursuant to the Act, this project will identify and prioritize barriers to commerical development and adoption of protective technology. The information collected will enable NIOSH to improve the efficacy of the contract and grant awards that NIOSH administers under the Act. The information collected is limited to that needed to achieve the objective. The

knowledge to be gained is not expected to be generalizable beyond the respondents and their organizations.

Materials Reviewed: Statement of Work, Supporting Statement Part A, RAND IRB Determination, Information Collection Instruments