



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: National Healthcare Safety Network Occupational Surveillance (Occupational Health Safety Network)

Project Officer(s): Ahmed Gomaa

Proposed Project Dates: Start:

End:

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

NIOSH IRB No. 16-DSHEFS-NR01

NAME: Angela M. Morley, JD, MPH

SIGNATURE: 

DATE 11/26/16

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

Comments/Rationale for Determination (attach additional comments):

The activity described is a surveillance system that is designed to identify and control a health problem. The long term objective is to improve the working conditions of healthcare workers by helping healthcare facilities collect and use data to establish and evaluate prevention activities for common occupational health problems among their personnel. The activity is non-research.

Morley, Angela (CDC/NIOSH/OD)

From: Gomaa, Ahmed (CDC/NIOSH/DSHEFS)
Sent: Tuesday, January 26, 2016 8:44 AM
To: Morley, Angela (CDC/NIOSH/OD)
Cc: Trout, Douglas (CDC/NIOSH/DSHEFS); Sweeney, Marie (CDC/NIOSH/DSHEFS); McConnell, Gail (CDC/NIOSH/OMSHR); Masterson, Kathy J. (CDC/NIOSH/OD); Morris, Diane C. (CDC/NIOSH/OD); NIOSH HSRB Office (CDC)
Subject: RE: Request for Confirmation Determination: Additional Information Required

Angela, Below is the description of the current OHSN:

The broad, long term objective of this Occupational Health Safety Network (OHSN) is to improve the working conditions of healthcare workers by helping healthcare facilities collect and use data to establish and evaluate prevention activities for common occupational health problems among their personnel. This project is ongoing surveillance to provide hospitals and the nation with data needed to identify problem areas and work practices, evaluate the effectiveness of prevention efforts, and ultimately minimize or eliminate occupational injury among healthcare personnel working in hospitals or other healthcare facilities belonging to hospitals in the United States.

The intended uses of the data are: estimation of the magnitude of occupational injury among healthcare personnel working in hospitals and other hospital-affiliated healthcare facilities; monitoring trends in occupational injury among healthcare personnel working in hospitals; Facilitation of intra-facility and inter-facility comparisons that can be used for benchmarking and prevention activities; objectively measure progress of prevention efforts; and facilitate compliance with regulatory and administrative requirements for recording and reporting occupational injuries.

Occupational health professionals within healthcare facilities (e.g., hospitals) already collect data on occupational injuries and illnesses among their personnel to meet OSHA requirements, Joint Commission recommendations, and internal needs. The majority of health care facilities use software (either programs developed in-house or commercial products) to track these outcomes, but that there is a need for a standard protocol to collect, aggregate, and analyze these data. To enable comparison of injury data within and among different participating hospitals and healthcare systems, NIOSH, in partnership with healthcare partners, created the NIOSH Standard Occupational Data Architecture (SODA) establishing defined standard data elements or variables (OHSN format.)

The standard data for OHSN are all collected electronically via a secure internet application. NIOSH receives monthly data files from the occupational health professionals at participating healthcare facilities. Individual healthcare workers will be represented by unique ID numbers, the data files will not include names or other personally identifiable information, and NIOSH staff will not interact with the individual healthcare workers. Thus, for the first time, the extensive existing facility-level injury data currently locked in disparate systems will be available for aggregation and benchmarking by individual hospital and NIOSH.

Participating healthcare facilities are able to access their own data any time and analyze them through the internet portal. Preplanned analyses such as injury counts, rates, tables, and graphs were designed in collaboration with participating healthcare facilities and can be customized to their needs. Reports containing aggregated data will be produced annually and posted on OHSN website, which is <http://www.cdc.gov/niosh/topics/ohsn/>. Other in-depth analysis of data from OHSN will be published in peer-reviewed journals, and presented at scientific and professional meetings.

The data are collected by occupational health professionals at the healthcare facility level and submitted monthly to OHSN. The data collected by OHSN are used by the facility and NIOSH to:

- Enhance healthcare facilities' ability to make use of existing federally mandated data to evaluate injury trends, identify risk factors associated with the injuries and track success of prevention programs while complying with OSHA requirements for recording and reporting occupational injuries using the OSHA 300.
- Estimate the magnitude of work-related injuries among healthcare personnel working in hospitals.

- Identify what, where, to whom, and how injuries are occurring most frequently each month and over time.
- Monitor work-related injury trends among healthcare personnel working in hospitals and other hospital-affiliated health care facilities.
- Facilitate intra-facility and inter-facility comparisons and data analysis that can be used for benchmarking and prevention activities.
- Provide timely and customized reports and information needed to meet OSHA regulatory and Joint Commission accreditation requirements.
- Apply up-to-date web-based surveillance information for prevention.
- Produce output reports that visually show facilities' progress in addressing its most prominent workplace safety and health concerns.

From: Morley, Angela (CDC/NIOSH/OD)

Sent: Monday, January 25, 2016 4:31 PM

To: Gomaa, Ahmed (CDC/NIOSH/DSHEFS) <ayg0@cdc.gov>

Cc: Trout, Douglas (CDC/NIOSH/DSHEFS) <dyt1@cdc.gov>; Sweeney, Marie (CDC/NIOSH/DSHEFS) <mhs2@cdc.gov>; McConnell, Gail (CDC/NIOSH/OMSHR) <gfm7@cdc.gov>; Masterson, Kathy J. (CDC/NIOSH/OD) <kjm3@cdc.gov>; Morris, Diane C. (CDC/NIOSH/OD) <awu6@cdc.gov>; NIOSH HSRB Office (CDC) <cin-hsrb@cdc.gov>

Subject: Request for Confirmation Determination: Additional Information Required

Good afternoon Ahmed,

Thank you for requesting a confirmation determination from the NIOSH IRB that the OHSN is not research involving human subjects.

In order for me to provide a confirmation determination, I ask that you please email me a description of the current OHSN activity. The prior IRB Chair made his determination based on your description of the OHSN as a proposed, future activity. I will need a similar description for the current, established OHSN.

As you prepare your activity description, please refer to the attached CDC Policy for Distinguishing Public Health Research and Public Health Non-Research, specifically the discussion on pages 4-5 regarding when surveillance systems are likely to be research or non-research. I will apply the Policy to make my determination, and it will be very helpful to me if you state specifically the purpose of your activity and highlight any non-research attributes of your project in your description.

Please let me know if you have any questions. I will look forward to hearing from you.

Kind regards,

Angela

Angela M. Morley, JD, MPH

Human Research Regulatory Administrator

CDC/NIOSH IRB Human Research Protection Program

Associate Director for Science Office

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NIOSH HRPP Office Email: niosh-hsrb@cdc.gov

CDC/NIOSH HRPP Intranet: <http://inside.niosh.cdc.gov/hsrb/default.htm>

CDC/NIOSH HRPP Internet: <http://www.cdc.gov/niosh/pgms/HSRB>

From: Trout, Douglas (CDC/NIOSH/DSHEFS)
Sent: Thursday, January 21, 2016 9:46 AM
To: Masterson, Kathy J. (CDC/NIOSH/OD) <kjm3@cdc.gov>; NIOSH HSRB Office (CDC) <cin-hsrb@cdc.gov>; Gomaa, Ahmed (CDC/NIOSH/DSHEFS) <ayg0@cdc.gov>
Cc: Sweeney, Marie (CDC/NIOSH/DSHEFS) <mhs2@cdc.gov>; Morley, Angela (CDC/NIOSH/OD) <kto0@cdc.gov>; McConnell, Gail (CDC/NIOSH/OMSHR) <gfm7@cdc.gov>; Morris, Diane C. (CDC/NIOSH/OD) <awu6@cdc.gov>
Subject: RE: NIOSH Web-Portal -- Occupational Health Safety Network (OHSN) - Request for updated determination from your office; D.Trout confirm

Hi Kathy – yes, DSHEFS would like to request this R/NR determination for Ahmed’s project in DSHEFS/Surveillance Branch - "National Healthcare Safety Network Occupational Surveillance" – we refer to this commonly as the ‘Occupational Health Safety Network’ (OHSN). thanks

Doug
(513) 841-4558

From: Masterson, Kathy J. (CDC/NIOSH/OD)
Sent: Thursday, January 21, 2016 9:33 AM
To: Gomaa, Ahmed (CDC/NIOSH/DSHEFS) <ayg0@cdc.gov>; Trout, Douglas (CDC/NIOSH/DSHEFS) <dvt1@cdc.gov>
Cc: Sweeney, Marie (CDC/NIOSH/DSHEFS) <mhs2@cdc.gov>; Morley, Angela (CDC/NIOSH/OD) <kto0@cdc.gov>; McConnell, Gail (CDC/NIOSH/OMSHR) <gfm7@cdc.gov>; Morris, Diane C. (CDC/NIOSH/OD) <awu6@cdc.gov>; NIOSH HSRB Office (CDC) <cin-hsrb@cdc.gov>
Subject: FW: NIOSH Web-Portal -- Occupational Health Safety Network (OHSN) - Request for updated determination from your office; D.Trout confirm

Thank you, Ahmed, for following up with the NIOSH IRB regarding your prior IRB 2010 non-research determination.

Since 2011, we have a procedure in place for requesting a formal IRB research/non-research determination, in that the request needs to come from DLO leadership (Director, Deputy Director, or ADS). I’ve included Doug Trout to reply to agree/confirm your request for a formal IRB determination.

Doug, do you confirm this formal IRB R/NR determination request regarding the described activity (attached)?

Thank you, both.
Kathy.

Kathy Masterson, CIP
Administrator, CDC/NIOSH IRB (HSRB) Office
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CDC/NIOSH HSRB inTRANet link: <http://inside.niosh.cdc.gov/hsrb/default.htm>
CDC/NIOSH HSRB Internet link: <http://www.cdc.gov/niosh/pgms/HSRB/>

From: Gomaa, Ahmed (CDC/NIOSH/DSHEFS)
Sent: Thursday, January 21, 2016 7:58 AM
To: Masterson, Kathy J. (CDC/NIOSH/OD) <kjm3@cdc.gov>
Subject: NIOSH Web-Portal -- Occupational Health Safety Network (OHSN) - Request for updated determination from your office

Kathy,
Back in 2010, I received the attached email from your office. At that time, Our team got a waiver from OMB clearance and was not required. However, we have now been told that we have to submit an OMB package. Therefore, I need an updated determination from your office since the attached email is outdated (from 12/3/2010). My research activity has not change since 2010, the 12/3/2010 Non-Research Determination still holds; however, Tamela Sawyer and Tamekia Foley wanted an updated determination from your office since the attached email is outdated (from 2010). Effective 12/3/2010, our non-research activity described below has been given # HSRB 10-DSHEFS-NR03 re "National Healthcare Safety Network Occupational Surveillance.". Please let me know what we can do to get the updated statement from your office to submit to Tamela and Tamekia. Our topic page is located at <http://www.cdc.gov/niosh/topics/ohsn/> . Please contact me directly if you have any question.

Ahmed Goma, MD, ScD, MSPH
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