Reset Form

NIOSH IRB Determination Form

This form can be used by the NIOSH Division Official and the Human Research Protection Program (HRPP) to document IRB determinations.

☑ **New Request** ☐ **Amendment**

Project Title:		Project Location/Country(ies):
Raising skin cancer awareness among Spanish-speaking outdoor workers		Cincinnati, OH, USA
NIOSH Principal Investigator: Michael Flynn & Brenda Jacklitsch	Division: Division of Science Integration	Telephone/email: 513-533-8568/mflynn@cdc.gov
NIOSH Primary Contact: Michael Flynn	Division: Division of Science Integration	Telephone/email: 513-533-8568/mflynn@cdc.gov
Proposed Start Date (mm/dd/yyyy): 09/01/2019	Proposed End Date (mm/dd/yyyy): 09/30/2020	

Funding Type, if applicable

CoAg, Grant or contract #:	75D30118P01625
Title of CoAg, Grant, or Contract	Raising skin cancer awareness among Spanish-speaking outdoor workers

Please check the appropriate category and subcategory. Definitions are available at the end of this document for italicized terms.

Research or Nonresearch Determination

☐ **I. The activity is research if it is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (Continue to III.)**

☑ **II. The activity is NOT research*. The purpose of the activity is to prevent or control disease or injury and improve health, or to improve a public health program or service. (Check one and stop.)** 🛑

- ☐ **A.** Epidemic or endemic disease control activity
- ☐ **B.** Routine surveillance activity*
- ☐ **C.** Program evaluation activity
- ☑ **D.** Public health program activity**
- ☐ **E.** Laboratory proficiency testing
- ☐ **F.** Other

*See CDC Policy on Distinguishing Public Health Research and Public Health Nonresearch. Surveillance can be research or nonresearch, per CDC Policy.
**E.g., service delivery; health education programs; social marketing campaigns; program monitoring; electronic database construction and/or support; development of patient registries; needs assessments; and demonstration projects intended to assess organizational needs, management, and human resource requirements for implementation.

Human Subjects Determination

☐ **III. The activity involves human subjects because the investigator conducting research: (Continue to V.)**

- ☐ **A.** *Obtains* data about living individual(s) through *intervention* or *interaction* with the individual(s) or
- ☐ **B.** *Obtains identifiable private information** about living individual(s).

*See attached guidance on human subjects and coded private information.

☐ **IV. The activity does NOT involve human subjects because: (Check appropriate boxes and stop.)** 🛑

- ☐ **A.** The activity is research involving collection or analysis of data about health facilities or other organizations or units (NOT persons).
- ☐ **B.** The activity is research involving data or specimens from only deceased persons.
- ☐ **C.** The activity is research involving unlinked or anonymous data or specimens collected for another purpose.
- ☐ **D.** Other

NIOSH Engagement Determination

☐ **V. NIOSH is engaged in the research involving human subjects because its employees or agents*, for the purposes of the research project:**

- ☐ **A.** Obtain data about the subjects of the research through intervention or interaction with them, or
- ☐ **B.** Obtain identifiable private information about the subjects of the research, or
- ☐ **C.** Obtain the informed consent of human subjects for the research.

*See attached guidance on engagement and NIOSH contractors.

➡ ***If NIOSH is engaged, please submit the study for IRB review or request an exemption determination.***

☐ **VI. NIOSH is NOT engaged in the research involving human subjects. IRB review and approval is not required.**
However, non-CDC collaborators engaged in the research involving human subjects must have a valid Federalwide Assurance and IRB approval.

Non-CDC Collaborator:	FWA #:	IRB Approval Attached: Y/N
Non-CDC Collaborator:	FWA #:	IRB Approval Attached: Y/N

Suggested Review (HRPP Only)

The activity is research involving human subjects that requires submission to the NIOSH Human Research Protection Program. The following is recommended:

- ☐ A. Full Board Review (Use forms 0.1250, 0.1370-research partners)
- ☐ B. Expedited Review (Use same forms as A above)
- ☐ C. Exemption Determination (Use forms 0.1250X, 0.1370-research partners)
- ☐ D. Reliance
  - ☐ 1. Allow CDC to rely on a non-CDC IRB (Use same forms as A above, plus 0.1371)
  - ☐ 2. Allow outside institution to rely on CDC IRB (Use same forms as A above, plus 0.1372)

Comments/Rationale for Determinations:

The purpose of this public health activity is to inform and improve the informational resources of the Occupational Health Equities program for a specific group of workers, Spanish-speaking outdoor workers. Focus groups will be conducted to inform researchers about the information needs of this specific group of workers regarding the prevention of skin cancer and how to most effectively address those needs. The information collected will primarily benefit the focus group participants and is not generalizable, it is not research. This information will improve the service of this public health program. No personally identifiable information will be collected.

If this activity changes it will be reassessed.

Approvals/Signatures:	**Date:**	**Remarks:**
Kathleen L. Macmahon -S Digitally signed by Kathleen L. Macmahon -S Date: 2019.08.30 13:34:58 -04'00' Division Official	8/30/2019	This activity will be reassessed in one year, September 2020, or before then if the activity changes.
NIOSH Institutional Review Board Chair or Co-Chair		

Note: Although IRB review is not required for certain projects under this determination, CDC investigators and project officers are expected to adhere to the highest ethical standards of conduct and to respect and protect to the extent possible the privacy, confidentiality, and autonomy of participants. All applicable country, state, and federal laws must be followed. Informed consent may be appropriate and should address all applicable elements of informed consent. NIOSH investigators should incorporate diverse perspectives that respect the values, beliefs, and cultures of the people in the country, state, and community in which they work.

Definitions, Guidance and Additional Resources

Definitions

Agent – A nonemployee of CDC who conducts research under CDC's FWA. This generally includes all persons cleared for access to CDC networks and who use CDC networks or physical facilities for human research activities.

Epidemic disease control (aka, emergency response) – A public health activity undertaken in an urgent or emergency situation, usually because of an identified or suspected imminent health threat to the population, but sometimes because the public and/or government authorities perceive an imminent threat that demands immediate action. The primary purpose of the activity is to document the existence and magnitude of a public health problem in the community and to implement appropriate measures to address the problem (Langmuir, Public Health Reports 1980; 95:470-7).

Identifiable private information

Private information – Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Private information must be **individually identifiable** (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

Interaction – Communication or interpersonal contact between the investigator and the subject.

Intervention – Physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Obtains – Using, studying or analyzing for research purposes identifiable private information or identifiable specimens that have been provided to investigators by any source or were already in the possession of the investigator.

Program evaluation – The systematic collection of information about the activities, characteristics, and outcomes of programs to make judgments about the program, improve program effectiveness, and/or inform decisions about future program development. Program evaluation should not be confused with treatment efficacy which measures how well a treatment achieves its goals which can be considered as research.

Surveillance – The ongoing systematic collection, analysis and interpretation of health data, essential to the planning, implementation and evaluation of public health practice, closely integrated to the dissemination of these data to those who need to know and linked to prevention and control.

Guidance

Human Subjects and Coded Private Information or Specimens: Research involving only coded private information or specimens does not involve human subjects if: (1) the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and (2) the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example: a "data use agreement" or institutional policy prohibits release of the code key to investigators. (NIOSH is not engaged when NIOSH is prohibited from receiving the identifying key to coded private information (see CDC Form 0.1375B TITLE)).

Human Subjects, Non-CDC Collaborators and Coded Private Information: Suppose a collaborator has the key to coded private information collected for a different purpose. Assume the collaborator plans to provide the coded private information to NIOSH and be involved in: (1) the study, interpretation or analysis of the data resulting from the coded specimens or (2) authorship of presentations or manuscripts related to the research. The collaborator is an investigator because the collaborator is involved in conducting the research. The project involves human subjects because the investigator has obtained identifiable private information.

Requirements for Engaged Institutions: Institutions that are engaged in non-exempt human subjects research are required to: (1) hold or obtain an applicable OHRP-approved Federalwide Assurance (FWA); and (2) certify to the HHS agency conducting or supporting the research that the research has been reviewed and approved by an IRB designated in the FWA, and will be subject to continuing review by an IRB.

Engagement and NIOSH Contractors: Suppose a NIOSH contractor has applied for and been awarded HHS funds for an activity. The Statement of Work indicates that the activity includes research involving human subjects. The contractor is engaged in human subjects research because the contractor is either: (1) obtaining data about the subjects of the research through intervention or interaction with them; (2) obtaining identifiable private information about the subjects of the research; or (3) obtaining the informed consent of human subjects for

the research. As an engaged institution, the contractor must hold or obtain an OHRP-approved FWA and certify to NIOSH that the human subjects research will be/has been approved by an IRB designated in the FWA and will be subject to continuing review by an IRB – and the Statement of Work states these responsibilities. Generally, NIOSH does not become engaged in non-exempt human subjects research solely because a contractor is engaged in non-exempt human subjects research. If the contractor is on-site (physically at NIOSH, has an SEV # and user-ID), the IRB Chair or ADS must determine if the contractor is acting on behalf of NIOSH. If the contractor is acting on behalf of NIOSH, then NIOSH is engaged (usually, if the contractor is onsite and acting on NIOSH's behalf, there is also an FTE working with the contractor who will serve as the PI on the activity). If the contractor is not acting on behalf of NIOSH but on behalf of the contractor, then NIOSH is not engaged.

Newborn Dried Blood Spots
If the activity involves any newborn dried blood spots collected after March 17, 2015, please note the Newborn Screening Saves Lives Reauthorization Act of 2014 applies the following provisions until HHS updates the Common Rule: (1) requires federally funded research on newborn dried blood spots to be considered research on human subjects, and (2) eliminates the ability of an Institutional Review Board to waive informed consent.

Table: Distinguishing Public Health Research from Nonresearch±

	Research	**Practice (nonresearch)**
Definition	"...systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." (ref. 45 CFR 46) The purpose of the activity is to develop or contribute to generalizable knowledge to improve public health practice; intended benefits of the project can include study participants, but always extend beyond the study participants, usually to society; and data collected exceed requirements for care of the study participants or extend beyond the scope of the activity.	The purpose of the activity is to identify and control a health problem or improve a public health program or service; intended benefits of the project are primarily or exclusively for the participants (or clients) or the participants' community; data collected are needed to assess or improve the program or service, the health of the participants or the participants' community; knowledge that is generated does not extend beyond the scope of the activity; and project activities are not experimental. May use scientific methods to identify and control a health problem with benefits for the study participants or their communities.
Primary Purpose	To generate new or generalizable knowledge (information that can be applied in other settings)	To benefit study participants or the communities from which they come
Methodology	Scientific principles and methods used Hypothesis testing/generating Knowledge is generalizable	Scientific principles and methods may be used. Hypothesis testing/generating Knowledge may be generalizable
Examples		
Surveillance Projects	Requested data are broad in scope (and may involve as yet unproven risk factors) Comparison of different surveillance approaches Hypothesis testing Subsequent studies planned using cases identified	Regular, ongoing collection and analyses to measure occurrence of health problem Scope of data is health condition or disease, demographics, and known risk factors Invokes public health mechanisms to prevent or control disease or injury
Emergency Response	Samples stored for future use Additional analyses performed beyond immediate problem Investigational drugs tested	Solves an immediate health problem No testing of methods or interventions
Program Evaluation	Test an untried intervention Systematic comparison of standard and nonstandard interventions, in any combination	Assess success of established intervention Evaluation information used for feedback into program (management)

± Adapted by CDC's Human Research Protection Office from the 2010 CDC Policy on "Distinguishing Public Health Research and Public Health Nonresearch"

Additional Resources

- CDC Human Research Protections Policy (2010): http://aops-mas-iis.cdc.gov/Policy/Doc/policy556.pdf
- CDC Policy on Distinguishing Public Health Research and Public Health Nonresearch (2010): http://aops-mas-is.cdc.gov/policy/Doc/policy557.pdf
- CDC Scientific Ethics Verification # database (intranet): http://scientificethics.cdc.gov/reprint/reprintmenu.asp
- HHS Title 45 Code of Federal Regulations Part 46, Protection of Human Subjects (Revised 2009):
- http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
- OHRP Guidance on Engagement of Institutions in Human Subjects Research: http://www.hhs.gov/ohrp/policy/engage08.html
- OHRP Guidance on Research Involving Coded Private Information or Biological Specimens: http://www.hhs.gov/ohrp/policy/cdebiol.html
- OHRP FederalWide Assurance number database: http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc