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: Petition for the Addition of a New WTC-Related Health Condition for Coverage under the WTC Health Program

Project Officer(s): Rachel Weiss

Proposed Project Dates: Start: 5/1/2015 **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 <u>about</u> 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 **<u>DOES</u> require** IRB Review. **<u>OR</u>** ☒ Activity **<u>DOES NOT</u> require** IRB Review.

APPROVING OFFICIAL TITLE: NIOSH IRB (HSRB) Chair **NAME: Gail McConnell, V.M.D., M.P.H., NIOSH IRB Chair (Acting)** **SIGNATURE:** Gail M McConnell **DATE** 01/08/15	**NIOSH IRB No.** HSRB 15-OD-NR01

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

Comments/Rationale for Determination (attach additional comments)**:**

Activity involves a process for adding health conditions to a federal health monitoring program for individuals directly impacted and adversely affected by terrorist attacks of September 11, 2001 and is not research as defined by HHS.

NOTE: IF THIS ACTIVITY IS DETERMINED THAT CDC NIOSH IRB (HSRB) IS NOT REQUIRED.

Although CDC IRB review is not required for projects approved 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 privacy laws must be followed.

Although this project may not constitute "research" involving human subjects, informed consent may be appropriate. Information conveyed in an informed consent process should address all applicable required elements of informed consent.

ADDITIONAL INFORMATION:

1. Activities may be research or non-research depending on the circumstances. Please see "CDC Guidelines for Distinguishing Public Health Research and Public Health Non-Research" http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf.

2. Laboratory proficiency testing; Information gathering activity involving human subjects that does not meet the HHS definition of research (which is a systematic investigation designed to develop or contribute to generalizable knowledge). Information gathered must not be about persons; risks must be minimal; informed consent and supervisory approval are required.

3. DHHS regulations allow for "expedited" review of certain types of research which involves minimal risk and meets certain criteria. See: http://inside.niosh.cdc.gov/hsrb/ExpeditedReview.html

4. Research seeking "exempted" status requires submission of appropriate forms and protocol for review by NIOSH IRB and CDC HRPO. See: http://inside.niosh.cdc.gov/hsrb/ExemptReview.html

Definitions/Links

HHS OHRP defines ***research*** as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research, whether or not these activities are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102(e)

OHRP defines a ***human subject*** as a **living** individual **about whom** an investigator (whether professional or student) conducting research obtains:
(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information.

Intervention includes both 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. Interaction includes communication or interpersonal contact between investigator and subject. ***Private information*** includes 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) in order for obtaining the information to constitute research involving human subjects. HHS OHRP human subjects regulations link: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

HHS OHRP considers that an institution becomes ***"engaged"*** in human subjects research when its employees or agents intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes. An institution is **automatically** considered to be "engaged" in human subjects research whenever it receives a direct HHS award to support such research. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award. http://www.hhs.gov/ohrp/policy/engage08.html. ***Agents*** include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility, e.g., contractors.

CDC defines ***surveillance*** as "the ongoing, systematic collection, analysis, and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know. The final link of the surveillance chain is the application of these data to prevention and control. A surveillance system includes a functional capacity for data collection, analysis, and dissemination linked to public health programs." (CDC 1986)

Program evaluation is 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. CDC guidance on **research/non-research: http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf**