Attachment C: HSRB Determination

Revised 06/21/2012

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: A Pilot Project to Evaluate the Use of Exposure Control Plans for Bloodborne Pathogens in Private Dental Practices

Project Officer(s): James Boiano

Proposed Project Dates: Start: 3/21/2013 **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: NIOSH IRB (HSRB) Chair

NAME: Mark A. Toraason, Ph.D., NIOSH IRB Chair

SIGNATURE: Mark Toraason **DATE** 03/21/2013

NIOSH IRB No. HSRB 12-DRDS-NR01C

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

Comments/Rationale for Determination (attach additional comments):

Protocol modified from initial R/N-R determination (01/18/2012) by increasing number of questionsfrom 11- 26. Intent remains about dental practice and not about persons. Protocol modified (03/21/2012) by changing title and PI.

CDC/NIOSH IRB Registration #: 00000186 **CDC FWA#:** 00001413 1