NCIPC Determination of Applicability of Human Subjects Regulations, Request to Classify Project as Not Involving Human Subjects or Research

Project Title National Violent Death Reporting System

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Proposed Project Dates: Start: 10 / 26 / 2010 Ending: 10 / 25 / 2015

Categories of data collection that do not constitute human subjects research **OR** do involve human subjects but CDC not engaged are listed below. Please check appropriate category:

___ **I. Activity is not research.** Primary intent is public health practice: disease/injury control, surveillance, improvement of programs or services. Objectives focused on a specific population.

- ___ **A.** Epidemic/endemic **disease/injury control** activity; collected data directly relate to *immediate* disease control needs.
- _X_ **B.** Routine **disease/injury surveillance** activity; data used for disease control program or policy purposes for a specific health condition/disease in a specific population and setting. (Includes disease reporting)
- ___ **C. Program evaluation** activity; data are used primarily for assessing, monitoring or improving a program in a specific population/setting.

Justification: Please attach project goals/aims, objectives, design, setting and participants, methods, and data sources.

The goal of NVDRS is to provide communities with a clearer understanding of violent deaths so they can be prevented. NVDRS provides data to decision makers and program planners about the magnitude, trends, and characteristics of violent deaths to inform targeted prevention efforts and may also be used to evaluate state-based prevention programs and strategies. To accomplish this goal, NVDRS has four main objectives:

- *to link records on violent deaths that occurred in the same incident to help identify risk factors for multiple homicides or homicides-suicides;*
- *to provide timely preliminary information on violent deaths (e.g., basic counts of murders and suicides) through faster data retrieval. Currently, vital statistics data are not available until two years after a death;*
- *to describe in detail the circumstances that may have contributed to a violent death; and to better characterize perpetrators, including their relationships to victim(s).*

NVDRS collects data on violent deaths from a variety of sources, including death certificates, law enforcement investigations, medical examiner and coroner reports, crime laboratories, and FBI Supplemental Homicide Reports. The surveillance system employs a distributed software system that allows efficient, standardized data entry in each state health department. Data entry is accomplished in health department offices or in the field in

the offices of medical examiners and police departments. States have the option of manually inputting or electronically importing death certificate, medical examiner/coroner and law enforcement data into the system.

-OR-

___**II. Activity is research but does NOT involve identifiable human subjects.** Primary intent is to develop or contribute to generalizable knowledge.

___**A.** Activity is research involving collection/analysis of data about health facilities or other organizations or units, which are *not individual persons*.... **or**...

___**B.** Activity is research involving data and/or specimens from *deceased persons*.

Justification: Please attach project goals/aims, objectives, design, setting and participants, methods, and data sources.

-OR-

___**III. Activity is research involving human subjects but CDC – including employees, visiting scientists, fellows, and on-site contractors (but not off-site contractors or other collaborators) - will NOT obtain data by intervening or interacting with participants and will NOT have access to identifiable (including coded) private data or biological specimens.**

Justification: Please provide a summary of CDC's role and explain that CDC will not be "engaged" in either obtaining data by intervening or interacting with participants or have access to identifiable data. Staff can have access to data that have been stripped of the codes that link information to individuals and still be considered to not be "engaged" in human subjects research. Also, please attach a summary of project goals/aims, objectives, design, setting and participants, methods, other data sources and plans for local IRB review.

Data is maintained securely throughout the data collection and data processing phases. Data is stored at the state level in secured computers that reside within state health department firewalls. Before any data is sent to the CDC, all identifiers that could potentially lead to identification of an individual, such as names, address, SSN, death certificate number, date of birth, etc., are stripped at the state level. De-identified data is sent to the CDC encrypted with secure-socket-layer technology for additional security. NVDRS follows NCHS guidelines on suppression of small sample sizes in data tabulations to prevent the inadvertent identification of an individual through the combination of various demographic characteristics

Once local IRB approval has been obtained please forward a copy (electronic preferred) to the Human Subjects Contact (Jahlani Akil) for records keeping purposes.

Attach project description in enough detail to clarify "non-human subjects", "non-research" or "not-engaged" nature of the product.

Comments/Rationale:
Although CDC Human Subjects (IRB) review is not required in this instance, investigators/project officers are expected

to adhere to ethical principles and standards by respecting and protecting to the maximum extent possible the privacy, confidentiality and autonomy of participants. All applicable State and Federal privacy laws must be followed.

Additional Comments:

Required Signatures:

10/20/10

Division Official (e.g., Director or ADS) **Date**

11/1/2010

National Center Human Subjects Contact **Date**