

Appendix F

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

Project Title: **A Survey of Fire and Life Safety Education Activities Among Pennsylvania Fire Departments**

Science Officer(s): Shane Diekman Division: DUIP Telephone: 770-488-4901
Ethics verification number: 13435

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Proposed Project Dates: Start: 09/01/2007 Ending: 09/01/2009

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.
- 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.

-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...* **or...**
- C.** Activity is research using *unlinked anonymous data or specimens*: **All** (1-4) of the following are required:
 - 1. No contact with human subjects is involved for the proposed activity...**and**.
 - 2. Data or specimens are/were collected for another purpose...**and**,
 - 3. No extra data/specimens are/were collected for **this** purpose...**and**,
 - 4. Identifying information either was not obtained **or** has been removed so that data cannot be linked or re-linked with identifiable human subjects anywhere in the world. (Note: under certain conditions, research *may* qualify as non-human subjects when identifiers are removed by local staff; contact NCIPC ADS office for details.)
- D.** **Public health practice** activity; data are used for administrative or program development purposes (e.g., *developing research agendas or strategic plans*)

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

-OR-

X 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.

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

The Division of Unintentional Injury Prevention contracted Johns Hopkins University to carry out the survey. CDC will not be engaged in either obtaining the data or interacting with participants. In addition, CDC will not have access to identifiable data.

Attached is a summary of the project.

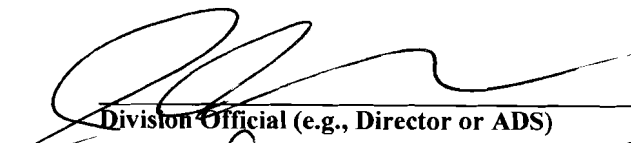
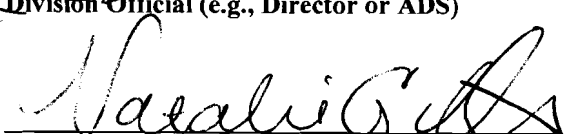
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Attach project description in enough detail to clarify “non-human subjects”, “non-research” or “not-engaged” nature of the product.

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:

 _____	11/12/2007 _____
Division Official (e.g., Director or ADS)	Date
 _____	11/19/2007 _____
National Center Human Subjects Contact	Date

Project Title: A Survey of Fire and Life Safety Education Activities Among Pennsylvania Fire Departments

Goals and Objectives: The United States Fire Administration (USFA) annually awards millions of dollars to local fire departments for fire prevention activities. The USFA is collaborating with the Centers for Disease Control (CDC) to determine whether these fire prevention programs are effective. Johns Hopkins is working with the CDC on this initiative to determine the scope of fire prevention activities and to describe elements of effective fire prevention programs. **Setting and participants:** The state of Pennsylvania was selected for the current project because of its focus on fire prevention and because it has the largest number of fire departments in the nation. Contact information for the fire departments in Pennsylvania will be obtained through the 2007 National Directory of Fire Chiefs and EMS Administrators. **Design and methods:** A statewide survey of Fire and Life Safety Education (FLSE) will be undertaken to determine the scope of fire prevention activities in the state. The 35-item survey, which will be mailed to all 2,199 fire departments in Pennsylvania, has three sections. Section I collects information about the fire chief and general aspects related to fire prevention activities. Section II asks about the types, number, focus, target population and partners of prevention activities offered by each fire department. Section III collects information about the barriers and facilitators for fire prevention activities. As a follow-up, a reminder postcard will be mailed to all non-responding fire departments two months after the initial survey mailing. Four months after the initial mailing, phone calls will be made to all non-responding fire chiefs to again solicit their participation. **Other data sources:** To inform the larger goals of the study, several key informant interviews will be conducted with fire department officials at the state and local level. **IRB Review:** This study poses minimal risk to participants. All data collected will be confidential and stored in locked filing cabinets. Participants will also be provided with a letter that explains the purpose of the survey, the voluntary nature of the research, the procedures used for confidentiality, and provides contact information for questions or concerns. Human subjects approval from the Johns Hopkins School of Public Health IRB will be obtained before any participants are contacted.