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

Project Title Evaluation of the Field Triage Decision Scheme Educational Initiative

Science Officer(s): Vikas Kapil, DO, MPH, FACOEM Division: NCIPC/DIR
Telephone: 770-488-3816
Ethics verification number:

Project Officer(s) Kelly Sarmiento, MPH Division: NCIPC/DIR Telephone: 770-488-1384
Ethics verification number: 9256

Proposed Project Dates: Start: 05 /15/2009 Ending: 05/01/2010

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:

_X_ **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)
- X C. **Program evaluation** activity; data are used primarily for assessing, monitoring or improving a program in a specific population/setting.

Justification: Data collected from participants will be used to improve the educational materials developed as part of the Field Triage Decision Scheme Educational Initiative. Please attach for 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*.

Justification:

-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:

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:

11/20/08
Division Official (e.g., Director or ADS) **Date**

11/20/08
National Center Human Subjects Contact **Date**