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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: Voluntary Product Satisfaction and Usability Assessment

Science Officer(s)_____N/A_____ Division: _____ Telephone: _____
Ethics verification number:_____

Project Officer(s): Jennifer Middlebrooks Division: DVP Telephone: (770) 488-4223
Ethics verification number:_____8241_____

Proposed Project Dates: Start: __10__/_17____/_2009____ Ending: _10____/__17__/__2012___

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)

_X__**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-

___ **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.

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:

Division Official (e.g., Director or ADS)	**Date** 7/20/09
National Center Human Subjects Contact	**Date** 7/20/09