Form Version Date 05.12.08

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

Project Title____Cost and Follow Up of Fall Prevention Programs

Science Officer(s)__Judy Stevens, PhD____ Division: __DUIP_____Telephone: 770-488-4649__
Ethics verification number:_____

Project Officer(s)_same as above_____ Division: _____ Telephone: _____
Ethics verification number:_____

Proposed Project Dates: Start: _9___/_30____/_2009___ Ending: __9___/_30____/_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*.

**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:

| | |
|---|---|
| [signature] | 9/30/2009 |
| **Division Official (e.g., Director or ADS)** | **Date** |
| [signature] | 1/30/2009 |
| **National Center Human Subjects Contact** | **Date** |

# Justification

CDC/NCIPC is working with the Administration on Aging (AoA) and the National Council on Aging (NCOA) to learn more about three AoA-funded fall prevention programs.

NCIPC will1) estimate the cost of implementing each of the three AoA-funded fall prevention programs for older adults (Stepping On, Moving for Better Balance and Matter of Balance) and 2) assess fall prevention behaviors among Matter of Balance program participants six months after they have completed the program.

To assess fall prevention behaviors, CDC's contractor, Booz Allen Hamilton, will conduct telephone interviews of a random sample of 300 Matter of Balance program participants from five states (California, Colorado, Maine, Ohio and South Carolina) who completed the program six months earlier. Participants will be asked to complete a 45-minute telephone survey that will assess their knowledge and self-efficacy related to falls as taught in the course, their activity and exercise levels, and their reported falls both before and after the program. The results will establish the extent to which preventive behaviors learned during the Matter of Balance program are maintained and can continue to reduce fall risk.

The cost assessment will calculate the lifecycle cost of the Stepping On, Moving for Better Balance, and Matter of Balance programs. For each state, program coordinators for the local sites will collect the cost data using lifecycle cost spreadsheets. These will be collected by the state program coordinator and returned to Booz Allen Hamilton for analysis. The analysis will include calculating the investment costs required to implement each program as well as each program's ongoing operational costs. These costs will be allocated over a defined time period, depending on the average or standard amount of time these programs continue to operate (standard lifecycle analysis ranges from five to 10 years). These data will allow CDC to compare program costs and to identify specific cost drivers, cost risks, and unique financial attributes of each program.

To sustain programs after AoA funding ends, states will require data on impact and cost. The results of these studies will provide this information; will support the replication and dissemination of these programs; and will enable states to reach more older adults.

No information deemed sensitive by participants will be collected for either the follow-up assessment of AoA-funded Matter of Balance programs or the cost assessment of AoA-funded fall prevention programs. Personally identifiable information will be collected by the Booz Allen Hamilton contractors in order to contact the potential participants. Personal information will be kept secure by Booz Allen Hamilton. CDC will receive materials that are aggregated and de-identified. There is no formal informed consent procedure for this information collection because it is not classified as research but as an evaluation. An evaluation that is not generalizable to the public but merely evaluates the impacts of a program does not require IRB approval or informed consent.