Attachment C: Human Subjects Research Determination

Date received by Human Subject Contact Office:

NCHS Human Subject Research Determination Request Form

Protocol Identifiers

Protocol Title: National Survey of Long-Term Care Providers (NSLTCP) Frame Development

NCHS Primary Contact

	Name and degrees (First name Last name, Degrees)	User ID	Telephone#	NCHS Division/Branch
Primary Contact	Christine Caffrey, Ph.D.	GWO9	301-458-4137	DHCS/LTC

NCHS' Role in the Project

[X] Yes [ ] No NCHS Employees or agents will obtain data by intervening or interacting with participants.

[ ] Yes [X] No NCHS Employees or agents will obtain or use identifiable (including coded) private data or biological specimens.

Protocol Description (Please attach copies of any relevant protocol materials.)

The purpose of this project is to develop an up-to-date sampling frame of residential facilities (see attached project summary). The sampling frame will be used to draw a nationally representative sample for a planned new survey, the National Survey of Long-Term Care Providers (NSLTCP). The frame-related data will be collected from officials in state regulatory agencies in the 50 states and the District of Columbia primarily via telephone calls, e-mails, and in a few cases, via formal written requests. The data to be collected from these regulatory agency officials will confirm that we have identified the appropriate licensure categories of residential care facilities within each state that meet the NSLTCP definition. For each relevant licensure category, we will request an electronic file (preferably in Excel format) of the licensed residential care facilities for which the agency is responsible, if such files with the needed variables are not downloadable from the state's website.

The requested information will include the name, address, phone number, and website (if available) of the residential care facility; name, phone number, and email address (if available) of facility director; licensure category; chain affiliation; ownership type; and bed size.

Assessment of Requirements for IRB Review

Please provide details as to how the protocol relates to Title 45 Code of Federal Regulations (CFR), Part 46 requirements for IRB review. (Go to http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html to access 45 CFR part 46.) Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge [45 CFR 46.102(d)]? Does the research involve a living individual about whom the investigator conducting the research obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private information [45 CFR 46.102(f)]?

Since the proposed activity does consist of a systematic investigation designed to develop generalizable knowledge, the investigators have concluded that this protocol meets the definition of research as stated by 45 CFR 46.102. However, it is not believed that the research meets the criteria of involving human subjects. All collected information will be at the state or facility level. The project will not collect information about the actual state officials or facility directors. According to 45 CFR 46.102(f), a human subject is a living individual about whom an investigator conducting research obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private information. In turn, the investigative team respectfully submits this human research determination request suggesting that this project does not meet the definition of human subject research and therefore would not be subject to IRB (NCHS ERB) review.

Attachment 01

Date received by Human Subject Contact Office:

Human Subject Contact Office Use Only

☑ Does not meet the definition of Human Subjects Research: Does not require IRB (NCHS ERB) Review

Date: 8/11/11 Signature:

Remarks:

☐ Does meet the definition of Human Subjects Research: Requires IRB (NCHS ERB) Review

Date:_____ Signature:

Remarks: