Attachment F: Human Subjects Determination

Date received by Human Subject Contact Office:
03/10/12

NCHS Human Subject Research Determination Request Form

Protocol Identifiers

Protocol Title: National Study of Long-Term Care Providers (NSLTCP) Data Collection

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.)

NCHS' Long-Term Care Statistics Branch in the Division of Health Care Statistics is planning primary data collection for the residential care facility (RCF) and adult day services center (ADSC) components of a planned new study, the National Study of Long-Term Care Providers (NSLTCP). The data will be collected from 9,450 RCFs and 4,601 ADSCs in the 50 states and the District of Columbia via mail and web surveys with telephone follow-up of non-responders to the mail and web surveys. In addition, data retrieval telephone calls will be used to address item non-response for critical items and resolve response inconsistencies in the mail surveys. Intended respondents are directors of ADSCs and RCFs, or their designated staff.

The data to be collected about RCF and ADSC providers include basic characteristics, services, staffing, and practices of the facilities. Information to be collected about care recipients in these facilities--demographics, physical functioning, and cognitive functioning--will be collected at the aggregate-level as distributions. All collected information will be at the facility or aggregate level. The project will not collect information about individual facility directors, staff or residents/participants (i.e., care recipients). No personal identifiers will be included.

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 facility or aggregate level. 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.

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: 2/10/2012 Signature: _____

Remarks: _____

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

Date: _____ Signature: _____

Remarks: _____