

Attachment A

NCHS Human Subject Research Determination Request Form

Protocol Identifiers

Protocol Title: Subject Matter Expert Interviews to Identify Gaps in Coverage of Long-Term Care Services Providers and Service Users in the National Study of Long-Term Care Providers (NSLTCP)

NCHS Primary Contact

	Name and degrees (First name Last name, Degrees)	User ID	Telephone#	NCHS Division/Branch
Primary Contact	Lauren Harris-Kojetin, Ph.D.	FTI3	301-458-4369	DHCS/LTCSB

NCHS' Role in the Project

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

Yes 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.)

This project entails conducting telephone interviews with 18 subject matter experts (see attached project summary). These individuals will include researchers, state officials (e.g., Medicaid agencies and state regulatory offices), and staff at disability advocacy organizations and long-term care services provider associations. Subject matter experts will be asked for their feedback and insights on what gaps exist in the current coverage of paid, regulated long-term care services providers and service users in NCHS' National Study of Long-Term Care Providers (NSLTCP), and ways to address those gaps in future waves of the biennial NSLTCP.

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)]?

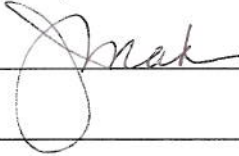
This project is an evaluation of the gaps that remain in NSLTCP's coverage of paid, regulated long-term care service providers and users in the United States, with the results used to improve NSLTCP by identifying gaps and ways to most effectively fill those gaps. The proposed activity does not consist of a systematic investigation designed to develop generalizable knowledge, and although there will be interaction with individuals through semi-structured interviews, this project will not collect or release private information about the subject matter experts (researchers, state officials, association staff). Instead, it will collect information on the subject matter experts' professional insights about NSLTCP, its gaps in coverage, and how to address those gaps. This project is being done as an evaluation of the current NSLTCP data collection strategy with the results used to inform future improvements to the NSLTCP design. 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.

Human Subject Contact Office Use Only

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

Date: 3-21-16

Signature: _____



Remarks: _____

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

Date: _____

Signature: _____

Remarks: _____
