Date received by Human Subject Contact Office:

## NCHS Human Subject Research Determination Request Form

## **Protocol Identifiers**

Protocol Title: <u>Subject Matter Expert Interviews to Identify Gaps in Coverage of Long-Term Care Services</u>

<u>Providers and Service Users in the National Study of Long-Term Care Providers (NSLTCP)</u>

	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 t	NCHS Employees or agents will ob			cting with participants.

## 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 <a href="http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html">http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html</a> 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.

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Human Subject Contact Office	e Use Only
Does not meet the defin	nition of Human Subjects Research: Does not require IRB (NCHS ERB) Review  Signature:
Remarks:	
Does meet the definition	n of Human Subjects Research: Requires IRB (NCHS ERB) Review
Date:	Signature:
Remarks:	