

Attachment D: Human Subjects Research Determination

Date received by Human Subjects Contact Office:

NCHS Request for Review of Changes to a Previously Reviewed Human Subject Research Determination Submission

1 Protocol Identifiers

Research Determination Protocol ID: RD 17-02
Protocol Title: National Survey of Long-Term Care Providers (NSLTCP) Frame Development
Amendment Number:
Amendment Title:

2 Key NCHS Personnel

	Name and degrees (First name Last name, Degrees)	User ID	SEV#	Telephone#	NCHS Division/Branch
Primary Contact	Christine Caffrey, PhD	GW09	15238	301-458-4137	DHCS/LTCSB
Principal Investigator	Lauren Harris-Kojetin	FT13	12682	303-458-4369	DHCS/LTCSB

3 NCHS' Role in the Project

Has NCHS' role in this project changed? Yes No

Check yes or no for each of the following, even if there has been no change in NCHS's role.

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.

4 Summary of Proposed Changes

What type of revision is being requested? Check all that apply and provide a justification for each selected item. Also, please include both a marked copy of the previously submitted materials noting the proposed changes and a clean copy with the changes incorporated.

Change to the protocol

- Describe the change.

The purpose of this project is twofold: (1) to develop an up-to-date, state-based sampling frame of residential care facilities like has been done for the previous three waves of the National Study of Long-Term Care Providers (NSLTCP) ("conventional" residential care facilities) and (2) for the first time, include and flag in the frame residential care communities licensed to exclusively serve the intellectually disabled/developmentally disabled populations. The conventional residential care facility sampling frame will be used to draw a nationally representative sample for the next wave of the National Study of Long-Term Care Providers (NSLTCP), currently planned for 2018. The frame of residential care facilities licensed to exclusively serve the intellectually disabled/developmentally disabled, although not used for the next NSLTCP wave, will be used to identify the prevalence and distribution of these facilities, to

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inform inclusion and sampling design decisions for future NSLTCP waves. All data collection procedures will remain the same. 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.

Attached is a revised protocol summary and attachments with proposed changes in track changes. Please note that we are providing all attachments because we made recent changes to the confidentiality language.

- Provide a justification for why this change does not affect this project's current human subjects research determination of not meeting the definition of human subjects research.

Since the new proposed activity still consists of a systematic investigation designed to develop generalizable knowledge, the investigators have concluded that this revised protocol continues to meet the definition of research as stated by 45 CFR 46.102. It is also not believed that the research meets the criteria of involving human subjects. All collected information will still be at the state or residential care community level. The project will not collect information about the actual state officials or community 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.

Change to the non-protocol materials

- Describe the change. _____

- Provide a justification for why this change does not affect this project's current human subjects research determination of not meeting the definition of human subjects research.

Other Change

- Describe the change. _____

- provide a justification for why this change does not affect this project's current human subjects research determination of not meeting the definition of human subjects research.

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

Date: 4/14/13 Signature: [Signature]

Remarks: Good for Donna Miller, Confid
off on

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

Date: _____ Signature: _____

Remarks: _____
