

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 - 01

Protocol Title: National Post-Acute and Long-Term Care Study (NPALS) Residential Care Facility 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	GWO9	15238	301-458-4137	DHCS/LTCSB
Principal Investigator	Lauren Harris-Kojetin	FTI3	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 to develop an up-to-date, state-based sampling frame of residential care facilities like what was done for the 2012, 2014, and 2016 waves of the National Post-Acute and Long-Term Care Study (NPALS) (formerly known as the National Study of Long-Term Care Providers or NSLTCP). This 2020 wave frame project differs from the 2018 project in that, unlike for the 2018 frame, the 2020 frame will not include facilities licensed to exclusively serve residents with intellectual or developmental disabilities. The sampling frame will be used to draw a nationally representative sample for the next wave of the NPALS, currently planned for 2020. 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

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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.

- 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. However, as with previous waves, the investigators do not believe that the research meets the criteria of involving human subjects. As with previous waves, all collected information will 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: 3/20/19

Signature: [Signature]

Donna Miller 3/20/19

Remarks: Data collected does not involve human subjects - no informed

is collected on living individuals through interviews or identifiable records
in form of data.

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

Date: _____

Signature: _____

Remarks: _____
