Long-Term Care Data Cooperative Application Process

Standard Application for Researchers with Funding

Principal investigator will submit all materials to LTCDataCooperative@ahca.org:

- √ 1-Page Synopsis written in plain-language that summarizes the goals, and data analysis processes.
- √ Completed Application using Standard Application Form for Prospective Researchers.
- √ Institutional Review Board (IRB) and Privacy Board (PB) approval/determination.
- √ Proof of Funding
- √ Other necessary components for the type of research category requested.

Steps for review:

1. Application will be reviewed administratively to ensure that all required application materials have been submitted and that all necessary components within the application were provided.

   NOTE: All applications must include a 1-page synopsis written in plain-language that summarizes project objectives and analytic plans. This synopsis will reviewed by providers participating in the Long-Term Care (LTC) Data Cooperative and the review committee. It is imperative that the synopsis be written for members of the long-term care community and not in formal academic language. Summaries will be returned if not readable.

2. An initial review will be conducted by the LTC Data Cooperative participants through an open public comment period. All LTC Data Cooperative participants will be provided a summary of each funded researcher application to assure proposals are consistent with the Data Use Agreement (DUA) permissions, and mission of the cooperative. This will help maintain trust with providers, which is critical to their continued participation.

3. The LTC Data Cooperative Review Committee will make a recommendation based on the participant comment period responses to determine the final recommendation. The review committee is comprised of 6 long-term care industry experts including AHCA/NCAL Board Members, and the LTC Data Cooperative leadership committee. Further information on the application process can be found here.

4. **Final decision will be shared with Project Investigator within 4-6 weeks from date of submission.**

If Application is recommended:

- AHCA Solutions will notify Principal Investigator of recommendation, listing any outstanding materials and onboarding information, within 4-6 weeks from date of submission.

*If Application is **NOT** recommended **or** more information is required:*

- AHCA Solutions will notify Principal Investigator of recommendation, providing a feedback report and rationale within 4-6 weeks from date of submission.

Long-Term Care Data Cooperative Data for Research

Standard Application for Researchers with funding

Type of Application for data use (check the appropriate research category)

☐ Type 1: De-identified Data, Exempt from IRB approval

☐ Type 2: Research Conducted under a Waiver of Patient Consent for Use of Protected Health Information

☐ Type 3: Research Requiring Facility Consent Only (e.g., cluster randomized trial with waiver of patient consent)

☐ Type 4: Research Requiring Patient/Proxy Consent – and, therefore, facility consent

PROJECT TITLE	
SECTION I: Contact information for Principal Investigator	
NAME:	
ORGANIZATION:	
ADDRESS:	
CITY, STATE, ZIP:	
EMAIL:	
PHONE:	
NOTE: Graduate students may not be listed as the Principal Investigator.	
SECTION II: Contact information for an Alternate (e.g., project analyst; faculty supervisor/mentor of postdoctoral fellow)	
NAME:	
ORGANIZATION:	
CITY, STATE, ZIP:	

EMAIL:	
PHONE:	

SECTION III. Funding Source:
Note: Funding must be available to support research services provided by AHCA Solutions/Exponent.

Does this protocol currently have funding? Please Describe Funding Source Below.

☐ No
☐ Yes

STOP: If No, please utilize "Preliminary Approval Application located" here.

Please specify the sponsor or funder and the role of the funder, if any, in the study design, collection, management, analysis, interpretation and reporting of findings. Please specify whether they will have ultimate authority over any of these activities.

Does this protocol or any part of this study require approval by a regulator, or do you plan to submit the results of this study to a regulatory agency?

☐ No
☐ Yes

If Yes, please indicate below any relevant timeline or other relevant information that should be taken into consideration.

SECTION IV. Project Description:

A grant application may be submitted in lieu of Sections B-E below. Please indicate if a grant application is being submitted:

☐ Completed Sections B-E below
☐ Attached a grant application & specified appropriate sections below.

A. Executive Summary or AIMS Statement (**1-page plain language synopsis, must be included for all applications**)

☐ 1-page Synopsis Attached

B. Plain-Language Brief Overview (3-4 sentences):

☐ In attached Grant Application: Page Number_____ Section_____

(Insert text if grant application has not been attached)

C. Research Objectives

☐ In attached Grant Application: Page Number_____ Section_____

(Insert text if grant application has not been attached)

D. Study Population: Describe your cohort selection criteria including the sampling frame and time period. (For example, “residents with a diagnosis of dementia between 1/1/2021 and 1/2/2022” or “residents 85 years or older in facilities in Texas during 2021.) **Note: Please do not specify variables or codes of interest.**

☐ In attached Grant Application: Page Number_____ Section_____

(Insert text if grant application has not been attached)

E. Outcome Measures: Describe all primary and secondary outcomes that will be ascertained from EHR data

☐ In attached Grant Application: Page Number_____ Section_____

(Insert text if grant application has not been attached)

F. Protocol synopsis:

☐ In attached Grant Application: Page Number_____ Sections_____

If not, in attached grant application, please send 4-5 pages including all sections below:

a. Research question(s) and hypothesis
b. Description of how key study components will be identified/constructed using available data elements, including a) exposure(s), b) primary and secondary outcomes, and c) covariates.
c. Analytic plan
d. Timeline of tasks and completion
e. References, if relevant (no more than 10)

G. Project Personnel:

a. Please attach a list of all key personnel, their qualifications, and all relevant affiliations (not just the primary affiliation).
b. Please specify who will have direct access to the LTC Data Cooperative data.

H. Copy of IRB and Privacy Board (PB) approval

☐ Not applicable
☐ Attached IRB/PB approval

I. Are you requesting linkage to data sources outside of this data cooperative including CMS data?

☐ No
☐ Yes **(Note: If application has been approved,** Project Investigator will receive an approval letter to be utilized for MedRIC application process.)

J. Facility Consent [only applicable for Type 3 and Type 4 studies]

☐ Not applicable

☐ Attached

K. Patient Consent Documents [only applicable for Type 4 studies]

☐ Not applicable

☐ Attached