Long-Term Care
DATA COOPERATIVE

Research Application to the Long-Term Care (LTC) Data Cooperative

Application Process

1. **Step One**: Upload a 1-page Specific Aims page here.
   a) A representative from the LTC Data Cooperative team will review the Specific Aims page and conduct a brief review to ensure that the proposed study aligns with approved research categories. Feedback will be given to researchers within two weeks.
2. **Step Two:** If the Specific Aims page is approved, researchers will be directed to submit an application.
   a) Once received, applications will be reviewed administratively to ensure that all required materials have been submitted and that all necessary components were provided.
3. **Step Three:** If the project is not yet funded, the LTC Data Cooperative Review Committee will perform an initial review and provide a preliminary approval decision.
   a) Once funded, researchers must submit proof of funding and any additional required documents (IRB or privacy board approval, consent documents if applicable) to LTCDataCooperative@AHCA.org.
   b) If the project has already received funding (or once proof of funding is sent to the LTC Data Cooperative), the application will move onto the application review process.
4. **Step Four**: Application Review Process
   a) A review will be conducted by providers enrolled in the LTC Data Cooperative through an open "public comment period". They will review the "plain-language" structured abstract from each funded researcher application to provide feedback about the value of the proposal and assure it is consistent with the mission of the cooperative (*further information and instructions on this abstract are found on page 5 of this application*). This will help maintain trust with providers, which is critical to their continued participation.
   b) The LTC Data Cooperative Review Committee will review the application and comments from members and make a recommendation. The review committee is comprised of ten members: seven long-term care providers and three research experts.

Final decision will be shared with the Principal Investigator (PI) within 4-6 weeks from date of submission.

If application is recommended:

- The LTC Data Cooperative Review Committee will notify PI of recommendation, listing any outstanding materials and onboarding information, within 4-6 weeks from date of submission.
- PIs will be directed to complete and sign a Data Use Agreement (DUA).

If application is NOT recommended or more information is required:

- The LTC Data Cooperative Review Committee will notify PI of recommendation and provide a feedback report and rationale within 4-6 weeks from date of submission.

If applicant is requesting access to CMS-EHR linked data:

- If application has been approved, the PI will receive an approval letter and information on how to apply to MedRIC to use the CMS-EHR linked data.

* Have you submitted a Specific Aims page and received approval to apply?

- ◯ Yes
- ◯ No

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Section I: General Information

* **Please select research category type** (a catalogue of research categories and examples can be found here for reference):

- ◯ 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

* **Which of the following best describes this project?**

- ◯ Health care operations and population health analytics
- ◯ Public health surveillance
- ◯ Observational, comparative effectiveness research
- ◯ Clinical research studies, including provider and patient recruitment into Phase 3 and Phase 4 randomized trials

* Project Title

Contact Information for Principal Investigator

NOTE: Graduate students may not be listed as the PI.

* Principal Investigator's Information

Name	
Organization	
Address	
Address 2	
City/Town	
State/Province	-- select state --
ZIP/Postal Code	
Country	
Email Address	
Phone Number	

Contact Information for Alternate

(e.g., project analyst; faculty supervisor/mentor of postdoctoral fellow)

Alternate's Information

Name	
Organization	
Address	
Address 2	
City/Town	
State/Province	-- select state --
ZIP/Postal Code	
Country	
Email Address	
Phone Number	

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Section II: Funding Source

Note: Funding must be available to support research services provided by the LTC Data Cooperative.

*** Does this project currently have funding?**

- ◯ Yes
- ◯ No, I will email LTCDataCooperative@AHCA.org with notice of funding once received.

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Does this request require a letter of support to the funding entity?

- ◯ Yes
- ◯ No

Please describe funding source below. Specify the role of the funder, if any, in the study design, collection, management, analysis, interpretation and reporting of findings. Include whether they will have ultimate authority over any of these activities.

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

- ◯ Yes
- ◯ No

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

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Section III: Project Description

Plain-Language Abstract

All applications must include a plain language structured abstract (750 words max). The audience for this abstract is nursing home providers who have expertise in the long-term care policy and practice environment, and are not formally trained in research. They will review the abstract and provide feedback to the LTC Data Cooperative Review Committee during the public comment period of the application review process. If either the nursing home providers or the Review Committee do not believe an application aligns with the mission or approved data uses of the LTC Data Cooperative, it may be rejected.

The abstract should clearly and succinctly describe, in **plain language**:

- **Objective(s) and importance.** What are you trying to demonstrate and how will it help providers improve resident care?
- **Study design**, stated briefly in plain language
- **Study population**. If you only need data on a subset of nursing homes and/or residents, state that here.
- **Intervention, if applicable**
- **Key measures and outcomes**
  Example: *"We will compare the rates of antibiotic prescriptions and urinalyses between nursing homes that did vs. did not receive antibiotic stewardship training."*
- **Data requested and why**
  Example: *"We will use medication administration records (MAR), vital signs, and diagnoses that are linked to MDS data and Medicare claims to look at antibiotic prescribing and hospitalizations for residents with dementia."*
- **Provider engagement**. If and how you have engaged, or will engage, nursing home providers in your study. For intervention studies, specify whether you have already recruited nursing homes for participation.
- **Implications for providers**, such as: Potential impact on practice and/or policy; Alignment with nursing home provider priorities; Acceptability, i.e. how likely are providers to adopt the intervention and/or findings?; Feasibility, i.e. how practical is the intervention and/or findings under current conditions? and; Any costs, burden, or risks for providers, residents, or other key stakeholders.

Abstracts with overly-technical academic language or failing to include the above elements will be returned for revisions.

Choose File Choose File No file chosen

* **Research Objectives (i.e. Specific Aims)**

* **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.*

* **Outcome Measures**

Describe all primary and secondary outcomes that will be ascertained from EHR data. *Note: if you need to validate a measure in the data as a preliminary phase of your research, you must describe how that validation process fits into your longer-term research plan.*

Intervention Protocol: If this study involves an intervention, please upload a copy of the intervention protocol.

Choose File Choose File No file chosen

Copy of IRB and Privacy Board Approval (if applicable)

If this project has yet to receive IRB approval, please email LTCDataCooperative@AHCA.org once received.

Choose File Choose File No file chosen

Facility Consent Documents: only applicable for Type 3 (Research Requiring Facility Consent) and Type 4 (Research Requiring Patient/Proxy Consent) studies

Please combine all documents into a single PDF file.

Choose File Choose File No file chosen

Patient Consent Documents: only applicable for Type 4 (Research Requiring Patient/Proxy Consent) studies

Please combine all documents into a single PDF file.

Choose File Choose File No file chosen

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Section IV: Data

* **What domains of EHR data will you need access to as part of your research?** Please check all that apply.

- [ ] **Patient**: Basic demographic information for patients/residents, including location, sex, age, race, and ethnicity.
- [ ] **Facility**: Facility information, including location, key characteristics, and CMS quality metrics from Nursing Home Compare (Name and identifiers may be available on request).
- [ ] **Provider**: Basic demographic and professional information regarding service providers, including physicians, nurses, and clinical and non-clinical staff who render services to patients/residents in a care setting (Name and identifiers may be available on request).
- [ ] **Episode**: Information about admissions from and discharges to the facility, along with admission and discharge timing and circumstances, where available.
- [ ] **Stay**: Information about the presence of the resident within and outside the facility, including dates of arrival and departure, room location, and reasons for status changes, allowing day-to-day census calculations.
- [ ] **Assessment**: Standard assessments, instruments, surveys, and other question-response style information, such as the MDS-3 (reported by EMRs), Activities of Daily Living (ADL), PHQ-9 and PHQ-9-OV, BIMS, and other physical, behavioral, and cognitive assessments.
- [ ] **Condition**: Information about the medical state of the patient, including diagnoses, as assessed by a provider or clinician, the date/time of the diagnosis, diagnosis code, and circumstances of assessment.
- [ ] **Observations – Vitals**: Vitals readings made by providers in the facility, including blood pressure, pulse rate, temperature, height, weight, respirations, blood oximetry, pain levels, and O2 saturation.
- [ ] **Observations – Labs:** Lab results and measurements relating to the state of the patient, including the type of order or panel, the type of result, and available metadata about the result.
- [ ] **Medication**: Orders for and administration of medications by facility staff or providers, including prescription medications as well as over-the-counter medications and treatments.
- [ ] **Vaccination**: Information about vaccines administered to patients, records of historical vaccinations reported by patients, providers, and their representatives, and records of vaccination declinations as reported by patients or their representatives.

Other EHR data element(s) not listed (please specify):

*** Are you requesting access to CMS-EHR linked data?**

- ◯ No
- ◯ Yes *(Note: If application has been approved, PI will receive an approval letter and information on how to apply to MedRIC to use the CMS-EHR linked data)*

What analytic software are you requesting access to for this project?

- ☐ R
- ☐ Python
- ☐ Other open-source software (please specify):

  [ ]