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

## Application & Review Process

**Step One: Upload a 1-page Specific Aims page here.**

- 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 the mission of the LTC Data Cooperative.
- Feedback will be given to researchers within two weeks.

**Step Two: Submit Application.**

- If the Specific Aims page is approved, researchers will be directed to submit an application here.

**Step Three: Initial Review**.

- *If a letter of support is requested:* The LTC Data Cooperative Research Review Committee will perform an initial review and provide a preliminary approval decision.
    - Researcher is notified within two weeks of the preliminary approval decision and if approved, a letter of support is sent.
    - Once the researcher is ready to move forward in the application process (either once funding is received or if the researcher wishes to move forward without funding), the researcher will contact LTCDataCooperative@AHCA.org to progress to the next step, the provider community comment period.
- *If a letter of support is not requested:* The application will move onto the provider community comment period.

**Step Four: Provider Community Comment Period**

- The plain language abstract is sent out to providers enrolled in the LTC Data Cooperative during an open public comment period to solicit their feedback about the value of the proposal.

**Step Five: Application Review.**

- The LTC Data Cooperative Research Review Committee will review the application and comments from providers and make a recommendation.

**Step Six: Decision & Notification.** Final decision will be shared with the researcher within 4-6 weeks from date of application submission.

- *If application is recommended:*
    - Researchers will be directed to complete and sign a Data Use Agreement (DUA) with the LTC Data Cooperative.
    - Once a DUA is executed, researchers will be provided with an onboarding packet and instructions for accessing the EHR data workspace.
    - Please note: If the study is requesting access to the CMS-EHR linked data, the researcher will also be directed to completed and sign a DUA with NIA LINKAGE.
- *If application is NOT recommended or more information is required:* The researcher will be notified of the decision, along with a rationale, and offered an opportunity to discuss the feedback and potential next steps.


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Section I: General Information

* **Which of the following four categories does your project fall under?**

- ◯ 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** | |


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

## 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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## Funding Source

**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.

## 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."*
- **The EHR data elements you are requesting 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

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

Choose File Choose File No file chosen


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

## Section IV: IRB Documentation

*** Under which category of research does your project fall?**

- ◯ De-identified Data, Exempt from IRB approval
- ◯ Research Conducted under a Waiver of Patient Consent for Use of Protected Health Information
- ◯ Research Requiring Facility Consent Only (e.g., cluster randomized trial with waiver of patient consent)
- ◯ Research Requiring Patient/Proxy Consent – and, therefore, facility consent

**Please upload here the IRB letter of approval (or waiver of consent) and the approved IRB protocol. Also upload proof of privacy board approval here, 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** (if applicable)

*Please combine all documents into a single PDF file.*

Choose File Choose File No file chosen

**Patient Consent Documents** (if applicable)

*Please combine all documents into a single PDF file.*

Choose File Choose File No file chosen

Long-Term Care
DATA COOPERATIVE

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

### Section V: 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 NIA Data LINKAGE 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):