

THE LONG-TERM CARE DATA COOPERATIVE

CATEGORIES OF RESEARCH CATALOGUE

MISSION

The mission of the Long-Term Care (LTC) Data Cooperative is to improve the quality of care within skilled nursing facilities by compiling the most comprehensive data on nursing home residents nationwide – and to translate these data into accessible and actionable information designed to help clinicians, managers and policy makers improve care.

GOAL

The LTC Data Cooperative is a cooperative led by the American Health Care Association (AHCA) in collaboration with skilled nursing facilities, certain vendors of electronic medical records (EMRs), Exponent, Inc., and Brown University to construct and maintain a national data system comprised of nursing home electronic health records (EMR data), compiled from EMR vendors and any future data partners.

The vision of the LTC Data Cooperative is to build a near-real time EMR system for thousands of skilled nursing facilities, assisted living facilities, and other long term and post-acute care providers—in order to:

- Support improved healthcare operations, including care coordination;
- Develop shared public health surveillance & reporting mechanisms that align with the mission of the LTC Data Cooperative;
- Support research funded through NIH Funded academic partners; and
- Support research funded by commercial entities.

Healthcare operations, such as care coordination, is the purview of the core collaborators in the LTC DATA COOPERATIVE. However, under the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) the cooperative may support third-party research, as long as researchers meet all necessary requirements for data use.

I. OBJECTIVE

The objective of this guide is to provide researchers with an overview of the four categories of research supported by the LTC Data Cooperative and outline the necessary components related to the use of electronic health records (EMR) data for research purposes for each category of research.

II. APPLICATION PROCESS

All researchers are required to submit an application to access data from the LTC Data Cooperative. Funding must be available to support research services provided by AHCA Solutions/Exponent. Preliminary applications should be submitted if applications for funding proposed to use the Data Cooperative, but final approval will be granted upon proof of funding.

All LTC Data Cooperative participants will be provided a summary of each funded researcher application for an open comment period. This preliminary approval process from enrolled providers on research proposals, and also reviewing reports and publications prior to release, will assure they are consistent with the DUA permissions. This will help maintain trust with providers, which is critical to their continued participation and ability to continue to enroll additional providers. Provider assessed applications will be reviewed by the Leadership Committee and approved by the LTC Data Cooperative Review Committee (*specifications outlined in Section IV below*).

III. RESEARCH CATEGORY TYPES

- Four categories of research are supported by the LTC Data Cooperative. Each category has specific requirements that must be met to comply with HIPAA for use of clinical EMR data. The following categories are described further below. **An example is provided for each category in Appendix I.**

- 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 is required

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

- i. Data views, which qualify as de-identified under the HIPAA Privacy Rule, as amended, include Safe Harbor views and Statistically De-Identified views. Statistical de-identification will be certified by an expert third party.
- ii. Applicants requesting use of this data format must provide:

- i. Completed Application
 - ii. Listing of key personnel and affiliations
 - iii. Report of funding source (or type)
 - iv. Signed data use agreement (DUA), and
 - v. All applicable costs for use.
- iii. Researchers will have direct access to these data sets through a managed desktop application, which most often will allow them to do their own analyses. This would be a simple summary data set with selected facility aggregates to help investigators with such activities as identifying facilities to be recruited for subsequent research studies of different types, and a simple set of tables, such as NCI has for SEER data that makes it possible to generate preliminary data and describe the data set in research grant proposals.

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

- i. This category, defined by the HIPAA Privacy Rule, allows for the use of data that do not meet standards of de-identification or the limited use of protected health information (PHI) as permitted under a Business Associate Agreement (BAA), if a Waiver of Consent is granted by an appropriate IRB/Privacy Board (PB).
- ii. This category includes identifiable data categories such as: gender, race, age bands, activities of daily living (ADL), diseases, approximate dates of service(s), and admitting and discharging facility. These files resemble the Centers for Medicare and Medicaid Limited Data Sets (LDS).
- iii. Applicants must provide:
 - i. Completed application
 - ii. Listing of key personnel and affiliations
 - iii. Report of funding source (or type)
 - iv. A record of the IRB/PB approvals, and
 - Applicants MUST provide IRB certification that is the research has a waiver of informed consent;
 - v. Signed DUA, and
 - vi. All applicable costs.

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

- i. LTC Data Cooperative will support research where facilities have given consent to participate.

- ***Note: This category is solely for the permission to use identifiable data as a link to any primary data collected as part of the trial if all facilities have agreed to be part of the study.***
- ii. IRB and other applicable approvals (e.g., FDA) will need to be provided to the Review Committee.
- iii. Applicants must provide:
 - i. Complete application
 - ii. listing of key personnel and affiliations,
 - iii. report of funding source (or type),
 - iv. a record of the IRB/PB approvals,
 - v. consent materials,
 - included a rationale for facility level consent
 - vi. Signed DUA,
 - vii. all applicable costs.

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

- i. All projects seeking individual consent must first seek facility consent to approach individuals.
- ii. IRB and other applicable approvals (e.g., FDA) will need to be provided to the Review Committee.
- iii. Applicants must provide:
 - i. Completed application,
 - ii. listing of key personnel and affiliations,
 - iii. report of funding source (or type),
 - iv. a record of the IRB/PB approvals,
 - v. all consent materials,
 - vi. a rationale of individual level consent,
 - vii. Signed DUA, and
 - viii. all applicable fees.
- iv. Once all of these approvals have been obtained and the trial is underway in the facilities that have agreed to participate and among patients who have consented, data from the LTC Data Cooperative pertaining to consented patients may be downloaded for purposes of merging with primary data collected as part of the trial.

IV. REVIEW COMMITTEE

- A. The review committee reviews each application to assure it is consistent with the mission of the Data Cooperative and is comprised mostly by providers, but also representatives from the research community and Data Cooperative team to assure the requests can be met by the data cooperative.
- B. The membership of the committee includes:

- Long-Term Care Data Cooperative Leadership Committee:
 - A representative from AHCA Solutions Staff
 - A representative from Exponent
 - A representative from Brown and/or NIA
- One Long-Term Care Data Cooperative Advisory Committee Member
- Six Long-Term Care Data Cooperative Participants to ensure provider representation

- Advisory Committee & Participant representatives will serve a maximum of a two-year term up to three terms.
- Each member should have a named alternate in the event the Committee member is unavailable.

- C. The Review Committee & Leadership Committee will assess whether the research proposed in an application:
 - Fits within the mission of the LTC Data Cooperative
 - Merits scientific priority within the LTC Data Cooperative
 - Utilizes data elements that are sufficient in quality and completeness to address the research objectives
 - Is sufficiently detailed to determine the feasibility of the data to address the research objectives, and
 - Does not place an unusually heavy burden on data processing staff to generate the necessary requested files
 - Project personnel/investigative team are well-qualified to execute the study as proposed
 - Meets the requirements of allowed data use and IRB/PB approvals

- D. The Review Committee must confer recommendations via Virtual Conference, or if a conference is not available, all recommendations and rationales must be sent via SurveyMonkey. Timelines for recommendations, and receipt of rationales will be provided on an ad hoc basis.

TABLE 1. SUMMARY OF THE REQUIRED COMPONENTS FOR EACH TYPE OF DATA USE

<u>Required information</u>	<u>Type 1</u>	<u>Type 2</u>	<u>Type 3</u>	<u>Type 4</u>
<u>Completed Application</u>	<u>YES</u>	<u>YES</u>	<u>YES</u>	<u>YES</u>
<u>Listing of key personnel and all of their affiliations</u>	<u>YES</u>	<u>YES</u>	<u>YES</u>	<u>YES</u>
<u>Report funding source</u>	<u>YES</u>	<u>YES</u>	<u>YES</u>	<u>YES</u>
<u>Record/Copy of IRB/PB approval</u>	<u>NA</u>	<u>YES</u>	<u>YES</u>	<u>YES</u>
<u>IRB waiver of consent</u>	<u>NA</u>	<u>NA</u>	<u>YES</u>	<u>YES</u>
<u>Consent materials</u>	<u>NA</u>	<u>NA</u>	<u>YES</u>	<u>YES</u>
<u>Rationale for facility consent</u>	<u>NA</u>	<u>NA</u>	<u>YES</u>	<u>YES</u>
<u>Facility consent</u>	<u>NA</u>	<u>NA</u>	<u>DEPENDS</u>	<u>YES</u>
<u>All costs</u>	<u>YES</u>	<u>YES</u>	<u>YES</u>	<u>YES</u>

APPENDIX I. EXAMPLES OF TYPES OF PROTOCOLS

Type 1 Example:

Research activities under this category fall into two broad types. First are investigations in preparation for another category of research. This includes investigators querying the data to ascertain the feasibility of conducting a study on a given topic that might be determined by the prevalence of patients with a certain diagnosis or receiving a given treatment. For example, prior to preparing a detailed grant proposal, the investigator might want to determine the number of admissions to nursing home directly from home that have a diagnosis of dementia. If there are not “enough” or they are distributed in an unbalanced way across the country or across other patient characteristics, a study of this population might not be viable. Similarly, those interested in exploring the feasibility of conducting a clinical trial in a reasonable number of facilities might want to select those facilities with a minimum number of residents with a particular characteristic or receiving a particular treatment. If there aren’t enough such facilities, the proposed study might not be viable.

The second type of research done under this category is largely descriptive and doesn’t need to have identifiable information about the residents to find a topic of interest to some audience that would be interested in learning about the percentage of individuals residing in nursing homes with a particular characteristic and/or how they are distributed across facilities. This is not unlike investigators working with the aggregated information that is available on LTCFocus.org or the Dartmouth Atlas.

Type 2 Example:

This category of research includes most types of observational studies that require linking records from the data base to the same individual patient so that they can be followed over time, including in transitions from one nursing home to another. There are numerous examples of studies in this category, ranging from policy evaluations to epidemiological studies of disease prevalence and incidence to more classic pharmaco-epidemiologic studies of drug effectiveness. One type of observational study that is frequently done includes long term care policy analyses that might try to estimate the impact of, for example, a new Medicare payment policy or a new approach to infection control education and regulation, on the outcomes of nursing home residents in the form of the rates of physical therapy use on the one hand or the risk of acquiring a diagnosis of infection with *CDifficile*. Another type of study in this category would include observational studies of the rate of adverse events experienced following the introduction of a new treatment, be it a new vaccine or a new pharmaceutical agent where the impact might be measured in terms of the risk of acquiring selected diagnoses or of being hospitalized.

Type 3 Example:

This would be a non-inferiority trial using comparative effectiveness procedures. Nursing homes in the Cooperative would be recruited for an Influenza season. Each participating facility would be paid a certain amount, BUT only an estimated 1/3 which experience influenza outbreaks would have to do anything and they would be paid extra. Our CRO, Insight Therapeutics would deliver packages with product (randomly assigned and possibly blind), rapid test kits to all facilities which would be used if an outbreak occurs. Some share of test results would be split and sent to a study lab for sequencing. Outcome data would be derived from the data base to track ADLs, illness, bed days and hospital transfers as well as drug and treatments. Since the data would be accessible quickly and facilities would have given permission, it would be possible to monitor Tamiflu administration in the absence of a documented Influenza case, etc. Preliminary sample size is about 500 facilities per arm. This would be waiver of consent since it is really access to data without individual consent and the facility might need to inform staff, patients and families in an announcement that rather than using Tamiflu they might be using an FDA approved alternative.

This will be an investigator-initiated grant from Pharma. Facilities would be paid directly for their participation and more if they have to do and report testing in the event of an outbreak. The grant would be to Brown with sub-contracts to Insight Therapeutics (or the other way around) and payment to the Cooperative for data access. Brown investigators would need access to the data ONLY of those facilities that had agreed to join. All analyses would be done on the AWS system. The grant might ALSO include a separate DUA to use the EMR/Medicare match data base to differentiate between Inpatient admissions, ED visits and possibly to do cost effectiveness analyses and to track people discharged to other facilities.

Type 4 Example:

This category of study involves recruiting facilities willing to host a study that requires some degree of new primary data collection directly from residents and/or their family care partners, and, as such, necessarily requires obtaining individual consent. Two types of research can be highlighted here, although there are certainly additional types. First, there may be many studies where it is desirable to better characterize clinical changes in nursing home residents or post-acute care patients. For example, doing a study of what the potential value might be of continuous glucose monitoring might be of residents with diabetes requiring insulin or not requiring insulin. In this instance, an investigator might want to first identify facilities in the Cooperative with a minimum number of residents with diabetes (that might be located in a particular area or region to facilitate primary data collection) that are taking selected medications for diabetes control. Then the investigator would reach out to recruit those facilities and then, among those willing to participate the investigators' staff would approach patients and/or their proxy to obtain consent to have them wear a non-invasive monitor for

some period of time. The monitor reading data would then be merged with the consented residents' EMR data.

The other type of study requiring patient or proxy consent would be some form of individual random assignment trial of a specialized program such as weight training for physical therapy or an experimental pharmaceutical agent that hasn't been approved by the FDA for general use. Investigators interested in conducting such studies would first identify facilities with adequate numbers of potentially eligible patients and then recruit them as to their willingness to host such a study and then, if they'd agreed, would set about the process of recruiting and gaining consent from individual patients and/or their proxy respondents. Any detailed new data collected would have to be integrated with the consented residents' EMR data.