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 nursing homes 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 led by the American Health Care Association (AHCA) in collaboration with nursing homes, electronic medical records (EMR) vendors, Exponent, Inc., and Brown University to construct and maintain a national data system comprised of nursing home electronic health records (EHR data).

The vision of the LTC Data Cooperative is to build a near-real time EHR database for thousands of nursing homes 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

Healthcare operations, such as care coordination, is the purview of the core collaborators in the LTC Data Cooperative. Under the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA), the LTC Data Cooperative also supports academic 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 needed to apply for each category of research.

II. APPLICATION PROCESS

The steps to apply are as follows:

1. Upload a 1-page Specific Aims page at www.ltcdatacooperative.org/Pages/Researchers.
2. 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.
3. If the Specific Aims page is approved, researchers will be directed to submit an application.
4. Once received, applications will be reviewed administratively to ensure that all required materials have been submitted and that all necessary components were provided.
5. If the project is not yet funded, the LTC Data Cooperative Review Committee will perform an initial review and provide a preliminary approval decision. 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.
6. If the project has already received funding (or once proof of funding is sent to the LTC Data Cooperative), the application will move onto an open public comment period.
7. A review will be conducted by providers enrolled in the LTC Data Cooperative through an open public comment period. They will review the 1-page "plain-language" synopsis from 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.
8. 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.
9. Final decision will be shared with the Principal Investigator (PI) within <u>4-6 weeks</u> 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.

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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.

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. Notice of funding,

        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.

    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. Notice of funding,

        iv. A record of the IRB/Privacy Board approvals, and

          – Applicants MUST provide IRB certification that the project has a waiver of informed consent;

        v. Signed DUA, and

        vi. All applicable costs.

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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.   List of key personnel and affiliations,
      iii.   Notice of funding,
      iv.   Record of the IRB/Privacy Board approvals,
      v.   Consent materials,
- included a rationale for facility level consent

      vi.   Signed DUA, and
      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.   notice of funding,
      iv.   a record of the IRB/Privacy Board 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/Privacy Board 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

Required information	Type 1	Type 2	Type 3	Type 4
Specific Aims Page	YES	YES	YES	YES
Completed Application	YES	YES	YES	YES
Listing of key personnel and affiliations	YES	YES	YES	YES
Notice of funding	YES	YES	YES	YES
Copy of IRB/Privacy Board approval	NA	YES	YES	YES
IRB waiver of consent	NA	YES	YES	YES
Consent materials	NA	NA	YES	YES
Rationale for facility consent	NA	NA	YES	YES
Facility consent	NA	NA	DEPENDS	YES
All costs	YES	YES	YES	YES

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:

An example 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 randomly assigned to receive one of two alternative influenza vaccines that are already FDA approved. Participating facilities would receive their allocation of vaccine for all residents. (If it is the policy of the facility that residents can opt out and not be vaccinated or select a preferred type of vaccine, that can happen since the brand of vaccine is recorded in the EMR.). Any primary data collected as part of the vaccine administration process can be merged into the EMR data that is already being captured and this is the data base on which the analyses of comparative effectiveness would be based.

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.

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