Preface

Remove before finalizing and distributing the protocol.

This is a suggested template to be used for Network protocols.

Template Instructions:

- Instructions: Instructions or explanations appear in comment boxes
- Sample text: appears in regular font and can be modified as needed or deleted
- <insert here> or highlights: angular brackets or highlighting indicate text to be customized as needed
- Required text: change to black font prior to finalizing

Version Control

With each revision, update the version number and date at the bottom of the page.

- V.0.X denotes the draft versions
- V.X.0 is the final version
- Use the international date format (day month year, with month in text)

Assumptions

- Pediatric chronic disease learning system
- Registry: hosted at CCHMC
- Registry: limited dataset for research purposes
- Consent: Consent and Assent (11-17) is included on 1 form

<STUDY TITLE>

Protocol Identifying Number:

Network Principal Investigator:

Local Principal Investigator:

Funded by:

Version Number: V.<x.x>

<Day Month Year>

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LIST OF ABBREVIATIONS

Insert or remove abbreviations as needed

ABP	American Board of Pediatrics
BMI	Biomedical Informatics
CCHMC	Cincinnati Children's Hospital Medical Center
CE	Comparative Effectiveness
CFR	Code of Federal Regulations
CRF	Case Report Form
EHR	Electronic Health Record
FDA	Food and Drug Administration
HIPAA	Health Insurance Portability and Accountability Act
IOM	Institute of Medicine
IRB	Institutional Review Board
MRN	Medical Record Number
NIH	National Institute of Health
ORCRA	Office of Research Compliance and Regulatory Affairs
PHI	Personal Health Information
QI	Quality Improvement

Protocol Summary

Use wording from the protocol

Title:	
Overview:	
Objectives:	
Endpoint:	
Population:	
Duration:	
Number of Participating Sites:	
Keywords:	

1 Introduction: Background Information and Scientific Rationale

1.1 Background Information

Description of learning health network. References for the sample wording are located at the end of the template.

New biomedical discoveries, advances in information technology, and implementation research offer the potential for immediate, continuous, and transformative improvement in health care, but not within our current health care system. As envisioned by the Institute of Medicine (IOM), a learning health care system comprises a community of front-line clinicians, patients, and scientists who view each clinical encounter as an opportunity to learn and apply learning to improve care, and ultimately patient outcomes [1]. They rely on large registries and open-science networks that foster collaborative improvement, research, data sharing, and innovation. In its most advanced state, such a system for clinical care, improvement and research will use clinical registries, as well as incorporating the efforts of patients, families, clinicians, and scientists to apply quality improvement methods and conduct research to improve patient outcomes.

1.1.1 Sub-Specialty Research and Improvement Networks: "Laboratories" for Quality Improvement, Health Services, Outcomes and Comparative Effectiveness Research

Create subsections for the background section as needed

Most pediatric chronic conditions meet the NIH definition of a rare disease (fewer than 200,000 affected individuals in the US), and no single care center has a sufficient number of patients to produce generalizable knowledge, a barrier that, unless addressed by networks, will slow the pace of knowledge acquisition and outcomes improvement. The American Board of Pediatrics (ABP) has supported the establishment of sub-specialty improvement and research networks in all 13 pediatric sub-specialties. The common themes drawn from collaborative pediatric research networks that have demonstrated marked improvement in the outcomes of children with chronic disease are an unrelenting commitment to collecting high quality data, continuously evaluating and proving their value to clinicians making in-the-trenches decisions, and the long-term engagement of the participants and their institutions to sustaining the network [2,3,4,5,6,7].

Sub-specialty research and improvement networks offer advantages that are foundational for research "laboratories" that can support a pediatric chronic disease learning system. Creating total population registries at each care center provides large and diverse study samples. By standardizing practice, variations in outcomes due to care delivery are reduced, thereby increasing statistical power. By linking research to care delivery and engaging clinicians directly, networks provide a forum for user-led comparative effectiveness research (CER). Not only are the end-users of CER--clinicians--in a unique position to identify critical health care knowledge gaps, they along with their patients are the final common pathways for change at the point-of-care.

1.1.2 <Network Name>: A Practice-Based Research and Improvement Network

Customize the description of the specific Network here; include: network background, name, focus area, # centers, # patients, # physicians, location of centers (US/International). The sample text is from ImproveCareNow. Text should be modified or deleted and replaced as needed.

Pediatric gastroenterologists formed ImproveCareNow as a sub-specialty research and improvement network to study and improve the care of children with inflammatory bowel disease. The ImproveCareNow network (prior name – PIBDNet) was the pilot for the American Board of Pediatrics sub-specialty network initiative, which now involves networks in 8 of the 13 pediatric sub-specialties, including ImproveCareNow as the focus of effort for pediatric gastroenterology. ImproveCareNow's practice-based

improvement activities enable pediatric gastroenterologists to meet new competency requirements in systems thinking and performance in practice. As of January 2013, ImproveCareNow has grown to over 50 care centers located at universities, children's hospitals, multi-specialty clinics and private practices, and includes both rural and urban settings. With the addition of a care center in London, England, ImproveCareNow is now an international collaborative. The aim of ImproveCareNow is increase the number of participating centers to over 100 by 2018. Care centers receive formal quality improvement training, develop and share evidence-based changes to support good chronic illness care, including; pre-visit assessment, creating a chronic care registry, population management review, a growth and nutrition algorithm, "model" care guidelines, and a guideline to standardize physician disease severity assessment. Communication is multi-modal and involves transparent sharing of performance data.

In a recent evaluation of the ImproveCareNow registry, a data quality metric that measures the proportion of visits with all critical data elements recorded resulted in a score was 89%. That is, 89% of all visits in the registry had complete data for all of the following data elements: height, weight, physician global assessment, the data elements required to compute appropriate disease activity indices (i.e., short PCDAI, PUCAI), and all data elements related to medication data. For the purpose of this metric, data elements marked as not done or unknown were counted as incomplete. This suggests that the network has achieved a good level of data quality, although opportunity exists for improvement and efforts are ongoing to improve the quality of data. All performance data are shared transparently, enabling care centers to identify those centers that are achieving unusually good performance so they can learn from one another. The project described in this protocol will continue and extend these successful efforts by expanding the ImproveCareNow network to enable deeper, more continuous engagement of physicians, increase opportunities for patient engagement in designing and testing new tools to improve self-management, and to make the rich source of data available more expeditiously to researchers inside and outside the network.

1.1.3 Electronic Health Records, Registries, Comparative Effectiveness and Quality Improvement Research

Description of interplay between EHRs, Registries, Research, and QI

Through its Electronic Health Record (EHR) Innovation Collaborative, the IOM has stimulated the development of several learning health care systems. Core concepts of the IOM vision include: a focus on continuously improving outcomes; learning as a partnership enterprise among patients, clinicians, and researchers; the point-of-care serves as the knowledge engine; advancing clinical data as a public utility; building CE research into practice; and, a governance model that promotes diverse leadership.

1.2 Rationale

State the problem or question, limitations, and hypothesis

We intend to achieve this vision of a learning health care system by building a registry, "the <Name of Network> Learning Health System Registry (LHS Registry)" for <target population> with <chronic disease>, by collecting data directly in the EHR, facilitating greater collaboration among clinicians, patients and researchers, and by promoting the use of data for multiple purposes including one-on-one clinical care, population management, quality improvement and research.

1.3 Potential Risks and Benefits

Review Risks and Benefits for the specific LHS and make adjustments as needed

1.3.1 Potential Risks

There are no direct risks of physical harm from entry into the registry. The greatest risk would be from an inappropriate distribution of participant information to other parties. The use of appropriate authentication (username & password combination) will help to ameliorate this risk while also providing an audit trail.

To monitor the conduct of the registry, we will immediately report any patient contact related to research that lies outside the parameters set within this IRB application and informed consent. In the event inappropriate distribution of participant information occurs at any study care center, the event will immediately be reported to the Central and Local IRB per institutional policy. Further, participants will be notified of the breach by the study staff via phone or mail, if deemed appropriate. Any adverse events resulting from the use of this registry will be reported to the Central and Local IRBs per institutional policy.

1.3.2 Potential Benefits

The knowledge gained from the information collected may quickly improve the outcomes for patients in the registry as well as benefit patients with <chronic disease> from around the world. This project will build capacity to accelerate the uptake of evidence-based findings and tools for <chronic disease> care, and make continuous improvement a key part of the fabric of pediatric <chronic disease> centers.

2 Objectives and Purpose

Describe the primary and secondary reasons for performing the study in terms of the scientific question to be answered. Include the global aim.

Transforming health care and outcomes for children and adolescents with chronic health conditions is difficult within the current health care system. There is great variation in care delivery, inadequate and slow application of existing evidence, and ineffective use of available data to generate new knowledge. In order to redesign the system, changes must take place at multiple levels, including the patient, clinician, practice and the network.

The purpose of this project is to design, develop, and test further refinements to an improvement and research network focused on <chronic disease>, to use a registry to simultaneously improve clinical care, redesign care delivery systems and to conduct quality improvement, health services, outcomes, and comparative effectiveness research.

The project will take advantage of recent advances in information technology, implementation research and collaborative networks to develop new models and methods to enable patients, families, clinicians, and scientists to work together to simultaneously improve care, create innovations in care delivery, and generate new knowledge.

3 Study Design and Endpoints

3.1 Study Design: <Network name> Registry

Description of the registry; Adjust the bullets below as needed for the specific LHS

The <Network name> registry database will be a full population registry that aims to ultimately encourage every eligible patient (described below) seen at participating centers (i.e., observational cohort design) to participate. The registry will be used to support better clinical care, conduct quality improvement and assess changes in the clinical outcomes of patients over time.

Research conducted with data from the registry may include:

- Evaluating the effects of quality improvement and system redesign efforts using an interrupted time series design
- Observational cohort designs to address comparison of treatment strategies
- Cross-sectional studies to assess the diagnostic accuracy of screening instruments
- Randomized trials of therapies are also likely

3.1.1 Data Collection

Description of how the data will be collected: to include the data source(s), where the data is housed, who can see the data, forms and support documents, who will upload the data. Include note about other data sources that may be included at a later date. The sample text below identifies the EHR as a data source, with mobile as a future source. Adjust the text to describe sources for your specific LHS. Also include entities where CCHMC may receive data from.

A key design goal of this proposal is to apply the principles of quality and systems improvement to create an LHS registry where data are collected at the point of care during routine clinical workflows in a center's EHR. Data collection in the LHS registry, called <Network Registry name>, will occur in one of two different ways, depending on the sophistication of the care center's EHR.

In the first approach, centers will access the registry through a common web front-end. When trained users at a center log into the system, they can see and modify the data from their own center. Using data collection forms, data will be abstracted from the clinical chart and manually entered into the registry. In the second method of data collection, the majority of registry data elements will be captured directly in the EHR at the point-of-care and transferred electronically to <Network Registry name>. To ensure that the data are collected properly and that the same definitions are used, each center will be given an EHR template that contains all the fields needed to collect the <Network name> registry data elements in the health record.

Each center will be given a set of sample database reports that contain the logic necessary to pull the data elements out of the EHR. Both the EHR template and the reports are customizable to satisfy center conditions. Each center will create a set of Excel or text-based reports (EHR extracts), which will then be uploaded into the <Network Registry name> registry by study personnel.

Data from other external sources, such as external data systems used by Centers for similar data elements or patient reported outcomes systems (PROs), may ultimately be collected via the web or mobile handheld devices as part of the clinical care process and transferred to the registry. If PROs are collected under separate studies, IRB amendments will be submitted before these additional data are incorporated to the registry.

3.1.2 <Network Registry name> Databases: Research and Reporting

Description of the databases within the registry, highlighting how the identifiers are in a separate database, allowing the research database to be a limited dataset. Includes description of how the registry is set up, the reporting structure, how center data is aggregated, how PHI is stored and replaced with study identifiers

Each center's data will be segmented from other center data within the Network. The patient-level data from each center will be used to generate a series of quality improvement and analytical reports.

The EHR extracts will contain personal health information, like patient and visit identifiers, which are needed for data linking (see below), quality assurance improvement purposes, and to allow the <Network name> clinicians to re-identify their patients so they can provide more targeted clinical care to their patients. These identifiers will be encrypted and stored in a segregated data store. Study specific patient identifiers will be created allowing for a limited data set for quality improvement and either a de-identified or limited data set for research.

The registry data will be used routinely for quality improvement performance measurement and clinical purposes, like patient and population management and pre-visit planning (see diagram). Reports will be available on demand and can be generated by each of the centers. A center will have access to all of its patients' data, but will see only aggregate performance data from other centers.

3.1.2.1 Linking Patients and Visits to Study ID

Detailed description of how/why PHI is used and how/why the data are linked and stored. Insert visuals as available.

Data extracted from the medical record include patient and visit identifiers. This information is needed to link visit data that may change over time or be entered after the initial upload and to provide <Network name> clinicians with a way to re-identify patients in order to take clinical action. Patient and visit identifiers will be encrypted and stored in a separate data store from the limited dataset registry data for each Center..

3.1.3 Data Elements

List of the variables collected. This section will be specific to the LHS.

The <Network name> registry will include data about patient characteristics, disease characteristics, the clinical care provided during each encounter (e.g., medication use), and patient reported outcomes. The registry elements include demographics, medication orders, laboratory results and clinical observations. Data are also collected about the characteristics of the care centers and their teams.

Patient identifiers include medical record number (MRN), name and date of birth. Patient identifiers are stored in the Linkage database described above.

3.1.4 Analysis

Description of CE research, QI, comparisons across centers, reporting and measures. Note: measures are specific to the LHS and should be adjusted as needed.

Both research and quality improvement will be made possible using data stored in the registry database. Informatics applications will be used to analyze and present these data to facilitate performance management at the centers. Outcomes will be continuously monitored to identify gaps in care. These processes form an iterative cycle: data collected at the point of care using EHRs; new knowledge generated and evaluated (i.e., learning using CE research methods); standardized management practices with minimal variation across centers and providers; standardization and high reliability enhancing signal detection in research studies (an often-overlooked link between CE research and quality improvement).

Research analyses will make comparisons across centers (e.g., to determine if changes to the system of delivery have been successfully implemented at individual centers as well as across all centers), and across

patients (e.g., to compare the effects of different treatment strategies on outcomes), depending on the study question being addressed. Research involving human subjects (as defined by applicable federal regulations) that involves the use of data collected under this protocol will be conducted under this registry protocol in accordance with the terms of the consent/parental permission obtained for this protocol. Research involving human subjects (as defined by applicable federal regulations) that either involves the collection of additional data, not covered by this protocol, or direct interaction with human subjects will only be conducted with additional project specific IRB review and approval.

3.1.5 Data Quality

Explanation of data quality reports

We will apply principles of quality and systems improvement to increase the quality of data collected during routine clinical care. Reports will be created so that each center can assess the quality of the data being uploaded into the registry from the EHR. These reports will include a list of exceptions (i.e., data discrepancies) that centers can resolve or use as a learning experience to avoid making similar mistakes in the future.

3.2 Study Endpoints

Indefinite population registry

The registry will exist for an indefinite amount of time and data collection and analysis will be on going in order to identify areas that may impact the care of patients with <chronic disease>, as well as additional potential research studies.

4 Study Enrollment and Withdrawal

4.1 Participant Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

- <insert criteria here>

4.2 Participant Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

- <insert criteria here>

4.3 Strategies for Recruitment and Retention

Patient recruitment and enrollment will be conducted by the centers listed in the Data Coordinating Center IRB [<insert Protocol/IRB #>]. Center physicians or trained staff included on the center IRB protocol will be responsible for identifying and recruiting potential patient participants.

Number of Centers: <#> as of <date>

Location: Centers are located in <both the US and international>

Maximum Target Enrollment: None – this is intended to be a population registry.

Vulnerable Populations: Patients who meet the qualifying criteria, regardless of age, gender, or race, will be recruited by the <Network name>-affiliated physician or an approved member of the team to participate in registry.

Duration: Enrollment will continue indefinitely, as will maintenance of data in the registry database.

Compensation and Cost: Participants will not incur any costs associated with the registry and will not be paid for participation as the registry activities are part of their clinical care. For future research studies, participants may receive reimbursement, which will be addressed in future protocols.

Advertisements: Any advertisement for participation in the research portion of the Network will be submitted to the IRB of record for approval prior to use.

4.4 Participant Withdrawal

Explanation of how participants can withdraw and what will happen to their data, noting how the data will continue to be collected for QI purposes.

Patient subjects may withdraw their consent for the use and disclosure of their PHI for research studies at any time. To do so, they must request to withdraw in writing or calling the <Network name> center Principal Investigator, as directed on the informed consent form. If a patient decides to withdraw consent to use their data for research, their data will still be collected and retained for clinical, quality improvement and other activities that do not meet the regulatory definition of human subjects research. They will no longer be included in the registry for human subjects research purposes. No attempt will be made to retrieve data that has already been distributed for research purposes.

5.0 Ethics/Protection of Human Subjects

5.1 Institutional Review Board

General description of IRB procedures and explanation of the single IRB model

The protocol, informed consent form(s), and materials for recruitment to use data for research will be submitted to the IRB of record for review and approval. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

This type of research requires participation and cooperation among all members of the network. Therefore, we propose that <Network name> centers adopt a single IRB approach to all aspects of IRB implementation to support standardization across participating centers. Approval of both the protocol and the consent form from the IRB of record and approval of IRB reliance and/or center IRB approval must be obtained before participants may be enrolled.

5.2 Clinical Care and Quality Improvement

Address collection of data for purposes outside of research and how this information will be governed

All eligible patients at each center will be included in the registry for clinical care, quality improvement and other activities that do not meet the regulatory requirements of human subjects research. Use of data for these purposes is not considered to be a human subjects research activity[1] and will be covered under a <insert description of legal documents – DUA and BAA>.

[1] If data collection is for performance improvement it is considered part of health care operations (45 CFR 164.501) and patient consent is not required. Health care operations includes conducting quality assessment and improvement activities, population-based activities relating to improving health or reducing health care costs, and case management and care coordination; reviewing the competence or qualifications of health care professionals, evaluating provider and health plan performance, training health care and non-health care professionals, accreditation, certification, licensing, or credentialing activities. However, if the purpose of the data collection is for research, it is not considered as part of health care operations and consent is needed.

5.3 Human Subjects Research

Clarify when data will be used for research purposes

This protocol is also focused on the use of the patient data for human subjects research purposes. Although the <Network name> database will contain patient data on all patients at participating centers (per the terms of the <legal agreements> referenced above), NO data from any patient will be used for human subjects research (as defined by federal regulations) unless an informed consent for research has been obtained or this requirement has been waived by an IRB.

5.4 Informed Consent/Assent Process

Describe consenting/assenting process, including the consenting instructions, how to address both adult consent and minor assent, and how/where the consent status is stored. Sample text below outlines multiple methods using 1 consent form for both assent and consent. Also include what the consent is and is not used for (QI vs Research). This section should be modified based on the specific needs of the LHS. Text can be retained, modified, or deleted as needed.

Patients may consent to this study using one of several methods: 1) in-person traditional paper consent, or 2) remote consent. Centers will be responsible for tracking this information within the registry and keeping it up-to-date.

If a patient declines to participate, centers will note that decision in the registry and that patient's data will not be used for human subjects research (as defined by applicable federal regulations). Similarly, if a patient elects to withdraw consent at a later date, their records will be marked and their data will be excluded from all future human subjects research activities.

If a patient chooses not to consent for research, their data will still be included for clinical, quality improvement and other activities that do not meet the regulatory requirements of human subjects research purposes. This separation allows all eligible patients at participating centers to receive the benefits that result from any improvements in care achieved using the registry while still giving them the ability to choose whether they also want to be included in human subjects research.

5.4.1 Description of the assent process for participants ages 11-17 years:

In-Person Paper method:

Parents and patients will review the consent form and be given a chance to ask questions. Patients will be given an opportunity to ask questions without their parents present. Once parent(s) and patient are comfortable that they understand the study, they will be asked to sign on the appropriate lines (parental permission line for parents and assent line for patients) of the consent form.

Remote Consent:

We anticipate the need to consent participants when they are not physically present and able to go through the traditional consent process. Parents will receive information about the study. Included in the application will be an option for parents or patients to e-mail study staff if they have questions. Parents or patients can also provide a phone number if they wish to be called to discuss their questions over the phone. If parents or patients have questions, they will be asked to come back to the application after those questions have been resolved.

Once the participant/LAR signs and dates the consent form, they will transfer a copy of the signed and dated document to the research team electronically (via fax or email) or by mail. Some participants do

not have access to the necessary technology to fax or email the consent back and we do not want to exclude a participant for this reason. With the mail-back option, the person who consented the participant/LAR will sign and date the consent upon receipt, therefore the participant and witness' dates of signature will be different.

5.4.2 Description of the consent process for adult participants:

Address age of majority, grace period (including rationale), and differences in the consent procedures from above.

It is important to note that some states have different ages that denote the age of majority. As with other state and local laws, the process for consenting as an adult will occur on the age of majority as designated by the center's state.

For patients who turn the age of majority, but are lost to follow-up before turning the age of majority, we are requesting a waiver of consent to continue to use previously-collected data for human subjects research. In the event that the patient has future contact with the participating <Network name> center they will be prompted to obtain an adult consent.

For patients who turn the age of majority and are still seen by a physician in <Network name>, we propose a 12-month period to obtain the adult consent. This proposal is made to allow sufficient time to obtain a meaningful consent in conjunction with the patient's regular clinical visit schedule. Patients are typically seen by their care provider on average 3 times per year, but may not be seen for 6 to 12 months. Study staff will be able to generate a report from the registry that provides a list of their patients who are turning the age of majority. All attempts will be made to gain a patient's consent as soon as possible after they turn the age of majority.

If, after the 12-month period, the patient's consent has not been obtained (but has not been refused), their consent status will revert to "expired" in the database. The "expired" designation indicates that consent is neither valid nor refused and efforts may continue to secure the patient's consent as an adult. Data collected before the age of majority will continue to be included in research datasets.

5.4.3 Description about the expectation of each center to incorporate their institution's HIPAA language into their consent process and document.

Each center will have the opportunity to either incorporate HIPAA language into the approved consent form or a separate form that will become part of the consent process. These revised forms will be presented during the clinic visit. They may also be loaded into the e-consent application where they will be presented to the patients of that particular center.

5.4.4 Waiver of Authorization

Include rationale for a waiver of authorization, if requested.

This protocol includes a partial waiver of authorization for recruitment purposes. The purpose of this waiver is to allow the ongoing review of PHI locally at the centers for the purpose of identifying patients who need to be approached to obtain consent/authorization for the research use of their clinical data as part of the <Network name> project. This review will include all patients who are currently having their clinical data shared with <Network name> as part of the clinical and quality improvement (i.e. non-human subjects research) activities of the consortium. For each of these patients, we will use the following

information to identify the patient within the database: first name, last name, MRN, and date of birth. All four points of information are be used to ensure that we are identifying the correct person in order to minimize the potential for mislabeling records and/or contacting the incorrect person.

5.5 Participant and Data Confidentiality

Address confidentiality and how the data is protected and monitored

The data in the registry will be hosted by Biomedical Informatics in the CCHMC data center, which is located in Cincinnati, OH. In the future, the registry may be hosted in a different location chosen by CCHMC or <Network name>. Centers will access the registry via a web-browser. The connection is encrypted using SSL and is limited to authorized users, who have a unique username and password. The data from each center will be stored in a network-specific database which will be queried when creating reports (population management, pre-visit planning, data quality, monthly outcome reports, etc.).

5.5.1 Data Safety & Monitoring

There are no known risks or discomforts resulting from participating in this study. The project team will perform quarterly reviews to address unanticipated problems to the subjects or others. Results will be generated in a report and distributed to the relevant IRB committee, <name of the Prime Entity for the LHS grant>, as well as the other performance centers in the network.

5.5.2 Use of data

Description of how the data and the PHI will and will not be used. Address whether the data will be retrospective, prospective or both. Address legacy restrictions around the data (from stakeholders, contracts, etc.)

Data will be collected during the course of clinical care and entered into the medical record. Data collected prior to and post IRB approval will be incorporated into the registry. The data will be used for clinical care, quality improvement and other activities that do not meet the regulatory definition of human subjects research.

5.5.3 Retention and Future Use

Describe how the data and identifiers are retained

We will store values for first and last name, visit number(s), MRN, date of birth, and visit dates. Other identifiers that may be needed in the future will also be stored. Identifiers will be retained indefinitely.

Data without identifiers will be maintained for additional analyses that continue to advance the purpose of the study/study questions that were initially communicated to participants.

5.5.4 Data Sharing

Describe the governance and data sharing procedures; who CCHMC will share the data with, procedures for an investigator interested in accessing the data for research studies, to include committee approvals, additional IRB approvals, data sharing agreements, etc. Text should be adjusted to reflect the procedures specified to the specific LHS.

To expand the possibilities for conducting outcomes research beyond the network investigators, data will be shared, following an internal review process, with qualified investigators external to the network who are employed at, or affiliated with, institutions that are interested in conducting health services or comparative effectiveness research.

Following the procedures listed in the Data Use Request (attached), they will submit a proposal to the Research Committee, which will review it for scientific merit as well as make an objective assessment of the outside researcher's qualifications to conduct the proposed research. Once approved, the outside investigator will be asked to sign a data sharing expectations document (developed and approved by the <Network name>, also attached) that specifies the conditions under which the data can be used and published (i.e., must take appropriate steps to maintain data security; not transfer, distribute or sell the data; make no attempt to re-identify any individual patient in the data; cannot use the data in harmful ways, including discrimination; or make unavailable the knowledge created). Once signed, a de-identified or limited data set will be sent to the investigator following the workflow documented in the data sharing procedure (attached).

Investigators within the network can request a de-identified or limited dataset using a similar workflow. The only difference is that they are required to sign the data sharing expectations document upon joining the network.

In all cases the Research Committee will ensure that any requests that constitute research involving human subjects have received appropriate IRB review and approval prior to releasing data.

6.0 Publication

Description of the manuscript process, authorship policy and/or procedures, and access

Manuscripts and abstracts developed from analyzing these data will be submitted for publication and presentation at national and international conferences. They will be made available to all network members and patients (if they are interested in obtaining a copy). A repository will be created to house all manuscripts and other documents so they can be easily shared and accessed by those interested in improving outcomes for <insert population>.

Investigators using data from the <Network name> registry will follow the Authorship Policy, as created by the <Network name> Research Committee.

7.0 Literature References

Include references. Sample text includes references from the sample text throughout the document.

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