Nebraska Healthcare Collaborative
powered by CyncHealth

Project Proposal Guidelines Manual

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Section I. Introduction

Background on the Collaborative

Vision: To transform the health of our population.

Mission: To facilitate cross-sector collaborations of diverse stakeholders optimizing health care delivery through teams that study and propose solutions to improve population health.

Values:

- **Collaboration is our core** – Address complex problems and societal issues requires collaboration across sectors and industries. No one can do it alone, and we engage our collaborators to tackle challenges and develop solutions related to population health.
- **Diverse perspectives solve complex problems** – Complex problems have many potential solutions and we value diverse expertise to generate questions and solutions that drive us toward clarity and enhancements.
- **Data drives decisions** – Data exists in many forms and from many sources in today's healthcare landscape. Addressing current challenges requires turning disparate data into actionable information. We design and implement projects using data from comprehensive and reliable data sources that inform our decisions in population health.
- **Learning and teaching focused** – The current and future workforce needs assistance managing the multiple complexities of health data to improve cost, quality and experience of patients and providers. We support collaborations that promote learning and teaching across sectors both for teams and individuals to transform health care education and delivery.

Tagline: Cultivating collaborative, informed, and innovative solutions for health

Aims of Projects

The aims of projects are to align with the strategic vision of the organization.
The intent is to support a threefold approach:

- Develop an informed workforce with an understanding of data science and population health.
- Engage in projects that improve population health.
- Support innovation to improve health care delivery for our partners.

Intent of Manual

The intent of this manual is to provide guidance for individuals submitting a project proposal to the Nebraska Healthcare Collaborative (NHC). Proposals must align with

organizational values and include the rigor associated with excellence expected for dissemination either through presentations or publications. Additionally, project requests must align with the data available within CyncHealth and congruent with the goals of our partners. Proposals will be peer reviewed and must adhere to data governance protocols along with federal, state, and institutional guidelines. Not all proposals submitted will be accepted due to proposal volume, quality of proposal, value alignment of proposal, and other potential rationales. Questions on aspects of these statements should be directed to collaborative@cynchealth.org.

Section II: Project Requirements

Project Categories

The Nebraska Healthcare Collaborative supports projects that fit into the following categories:

Research – A research project seeks to answer a defined question(s) with rigor and methods established through best practices in scientific inquiry. Research projects with CyncHealth typically use aggregate, limited data sets from CyncHealth's population health utilities, including the health information exchange (HIE), prescription drug monitoring program (PDMP) and social determinants of health (SDOH) platform.

> Example: Using data from the HIE to explore low back pain diagnoses and imaging diagnostic codes to determine if imaging was necessary.

Quality improvement - A quality improvement (QI) project focuses on an organization's current performance in a specific area using an attribution or eligibility file. QI projects intend to lead to improved health care delivery or positive impact on the health of patients or populations in that organization.
QI projects follow a process improvement lifecycle (e.g., Plan Do Study Act (PDSA)). Data may include personally identifiable information (PII) and include HIE, SDOH and/or prescription medication elements as approvable by data governance.

> Example: A hospital wants to determine if a new medication reconciliation process at discharge is effective at reducing readmissions for its hospitalized patients.

For more information on how to conduct a QI project, consult the following resources:

- How to get started in quality improvement
- Institute for Healthcare Improvement Quality Improvement Essentials Toolkit

Program evaluation – Program evaluation is a process to demonstrate the outcomes and effectiveness of a program. The format and approach of program evaluation varies based on the type of program. Data elements may include a hybrid of internally sourced and tracked data as well as data obtained from the HIE.

Example: A local county Area office on Aging wants to track the utilization, falls within 6 months, and cost savings of a fall prevention program for older adults in its catchment area.

For more information on how to conduct a program evaluation project, consult the following resources:

- Introduction to Program Evaluation for Public Health Programs: A SelfStudy Guide

Types of Datasets

CyncHealth has a variety of options for data when considering data requests. CyncHealth is home to the designated HIE in Nebraska and Iowa, which holds electronic health record data from the state; the PDMP; and a SDOH platform.

When engaging in a project, the type of data requested is an important consideration and will be weighted in the review of projects. In addition, the type of data approved will be influenced by the reported project design.

Projects approved typically use de-identified or limited data sets. Deidentified data is a data set which has identifying information removed and is often considered low risk by data governance and an institutional review board (IRB). Identifiers include any information that is specific to a person's identity including name, age, gender, racial/ethnic identity, etc.
A limited data set is a data set that is stripped of certain direct identifiers specified in the HIPAA Privacy Rule. A limited data set may be disclosed to an outside party without a patient's authorization only if the purpose of the disclosure is for research, public health, or health care operations purposes and the person or entity receiving the information signs a data use agreement (DUA) with the covered entity or its business associate.

Limited data sets may include only the following identifiers:

- Dates, such as admission, discharge, service, and date of birth (DOB)
- City, state, and zip code (not street address)
- Age
- Any other unique code or identifier that is not listed as a direct identifier.

A limited data set is private health information (PHI) that excludes the following direct identifiers of the individual (or the individual's relatives, employers or household members):

- Names
- Address information, other than city, state and zip code
- Telephone numbers
- Fax numbers
- E-mail addresses
- Social Security numbers

- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) addresses
- Biometric identifiers, including fingerprints and voiceprints
- Full-face photographs and any comparable images

A limited data set is still protected health information (PHI) under HIPAA. It is not deidentified data, as that term is defined under HIPAA, and thus, must be safeguarded and protected as required under the Privacy Rule. As part of the project proposal, the types of data sets for the project are required to determine next steps in data governance. For more about the HIPAA Privacy Rule, visit here.

Project Eligibility

All project proposals must align with the values and mission of CyncHealth. The individual or team submitting a project must be:

- A CyncHealth participating organization
- An employee and/or student of a community-based organization, academic institution and/or health system whose mission aligns with the mission of CyncHealth

Most proposed projects will be retrospective in nature, and de-identified samples are encouraged when possible and appropriate. All projects must satisfy state and federal statute, meet data governance guidelines and be compliant with other relevant CyncHealth policies. Projects involving certain data may require additional review and approval based on data privacy and security standards.

Prior to project approval, a member of the CyncHealth Support Team will conduct a scoping session based on submitted documents and prepare an estimate of labor for data extraction and preparation. Data requests or assistance that exceed the initial estimate and reasonable follow-up and consultation may result in additional fees. Due to data governance guidelines for PII/PHI, data analyses should be performed based on the research question and/or project purpose and only include members of the project team identified in the Data Use Agreement (DUA) and IRB protocols.

All projects must be reviewed and approved by the CyncHealth data governance process, including compliance with CyncHealth's small numbers policy . Projects must obtain and report to CyncHealth IRB approval prior to project implementation. CyncHealth does not host its own IRB and recommends use of the requester's IRB. All

participants in projects must demonstrate successful completion of HIPAA training prior to project approval. Participants may be asked to sign a conflict of interest form or other necessary business requirements dependent on the project type.

Projects that fail to follow all policies and data governance will be terminated immediately. Questions about project appropriateness can be vetted by contacting CyncHealth at collaborative@cynchealth.org. The NHC team is here to provide support and ensure project success.

Project Cost

NHC does not charge for health information data from any of the platforms. However, data extraction and statistical analyses has cost commensurate with the request. The NHC offers an hourly rate for services and will work with each requester to establish a cost estimate and explore funding options.

Section III: Project Process

a. Step 1: Collaborative Project Request Form

Prior to submitting a full proposal, the team must submit an initial Collaborative Project Request Form for review by the NHC to determine the project's viability. The Collaborative Project Request Form is available on the website. The Collaborative Project Request Form is a brief overview of the proposal including the following components:

1. Applicant Information
2. Project Title
3. Project Overview
    a. Project justification supported by literature/evidence
    b. Hypothesis or research question
    c. Project objectives
    d. Mission alignment
4. Project Approach/Methods
    a. Proposed data analysis
    b. Proposed sample size
    c. Proposed project timeline
    d. Data elements needed
    e. Potential risks associated with proposed project
5. Project Sustainability
    a. Funding sources
    b. Dissemination plans

You are strongly encouraged to contact the Collaborative to discuss questions about fit or scope prior to submitting a Collaborative Project Request Form. Once a Collaborative Project Request Form is submitted, a team member will review and may set up a consultation meeting to discuss the project proposal's fit and viability.

All project proposals will be reviewed per the rubric included in Appendix C and provided feedback.

b. Step 2: Data Request Form

Once NHC has identified the project as viable, the next step is to complete a Data Request Form. Section III outlines the requirements for a Data Request Form.

Section IV: Data Request Form

If a project has been approved, a Data Request Form should include the following components identified below. Forms lacking these elements will either require revision prior to approval at a forthcoming scheduled data governance meeting or be rejected due to not meeting standards. Quality and thoroughness are expected.

1. Title and Contact Info
2. Project Plan: This section should be supported with literature and evidence to support the project. Consider the following questions throughout this section to develop a quality proposal:
    - Does the project summary establish a clear understanding for the intended project?
    - Are refereed journals and primary sources appropriately used?
    - Are the references relevant to the topic areas of CyncHealth (i.e. health information exchange, population health)?
    - Are there sufficient credible sources?
    - Are the findings of the sources appropriately analyzed and appraised?
    - Is relevant information carefully selected from the various sources?
    - Is relevant information critically integrated into major topics?

    a. What is the plan for data use and analyses?
        - Is your analysis plan outlined and commensurate with the sample size and data elements requested?

    b. If research, what is the hypothesis or the research question?
        - Are the research questions based on findings gleaned from the project background?
        - Are the research questions linked to the study purpose?
        - Are the research questions answerable with CyncHealth data and partnership?
        - Are variables or constructs clearly identified in the research questions?
        - Are the hypotheses clearly stated and linked to the research questions?

c. What data elements are requested (e.g., aggregate data, Personal Health Information (PHI)/Personally Identifiable Information (PII), de- identified data)?

d. What is the sample size needed and inclusion or exclusion criteria (e.g., power analysis)?

- Standardized data elements • Who are the targeted participants?
- What is the desired sample size?
- How was the sample size determined?
- What are demographic characteristics of the sample?
- What are the inclusion and exclusion criteria?
- If applicable, identify any ICD-10 and/or CPT codes.

e. When do you need the data and how frequently do you need data refreshed (e.g., one-time or ongoing)?

f. Describe funding source(s) for this project (e.g., source, amount, duration)?

g. Who will access this data in any form (e.g., name, titles, role, level of access)?

3. Project Value: This section focuses on how the project supports and enhances population health aligning with the mission of the Collaborative, CyncHealth, or DHHS
   a. How does the project facilitate better experiences and/or health outcomes for Nebraskans?
   b. How does the project align with the business needs of Nebraska Department of Health and Human Services (DHHS), CyncHealth or the participating organizations? (e.g. For Medicaid data requests, describe direct benefits to the Medicaid program.)
4. Compliance and Risks: This section focuses on procedures to ensure project compliance, protect health information and mitigate project risk. When writing this section, consider the following questions:
   a. Are the steps for the execution of data collection clearly and succinctly described?
   b. Are there any ethical issues regarding the steps of data use? If so, how will these be addressed?
   c. Are procedures in place to ensure confidentiality of data?

d. How will any risks associated with data use be addressed?
e. How will you protect any limited data sets provided to you by CyncHealth?
f. How is the request compliant with HIPAA and other state and federal policies and regulations (e.g. combining with other datasets, completed HIPAA and/or CITI training (attach certificates)? If not, how will you remediate any concerns?
g. If requesting PII/PHI, can this project be completed with de-identified information? Why or why not? What measures are planned to ensure privacy and confidentiality?
h. Is consent required from the data owner to access this data? If yes, describe how you will obtain consent. If no consent is required, provide a rationale.
i. How long will the data be stored and how will it be destroyed after the specified retention period? (e.g., Will any data be retained for re-use in the future?)
j. What potential risks may be present for this request and what safeguards have been implemented to address these risks?
k. Have you received IRB approval? If not, do you plan to? (Attach a copy of the approval.)
l. What precedent exists for sharing similar data within Nebraska or other states? (e.g., literature review, state statutes, federal regulations)

5. Technical Feasibility: This section focuses on the technical support for the project.
   a. What is the proposed data flow to fulfill the request? (e.g. Who will receive the data and how will it be transferred?)
   b. What technology/software is needed for the project? (e.g. Will any webbased applications or interfaces be used? What type and level of data encryption will be used?)
   c. What other technology considerations are needed to manage risks?

Section V. Project Review Process

A. Collaborative Project Review

A Collaborative Project Request Form is submitted via the website and follows the guidelines. The Collaborative Project Request Form will be reviewed by the Collaborative team members for project rigor, methodology and fit. If deemed to have any concerns, the submitter will be notified promptly and asked to resubmit if appropriate. The project will be reviewed for mission alignment/fit, quality, applicability, cost, timeline, and workload using the rubric as a guide. If questions arise, the submitter(s) may be asked to meet with the Collaborative team to discuss and further review the project.
If no revisions are needed, the proposal will be submitted to the members of the Nebraska Healthcare Collaborative and Foundation Boards for review.

The review will lead to three outcomes:

1. **Endorsement** – The proposal meets all requirements, is well written and aligns with NHC mission. Once endorsed, the submitters will be asked to submit a full a Data Request Form and routed to the Project Management Officer for Data Governance.

2. **Endorsement pending revision** – The project fits NHC mission but needs modification and/or editing prior to moving forward. The proposal will be returned with suggested modifications and a timeline for re-submission. The proposal must be resubmitted with a redline and clean copy version and include a cover letter identifying changes made or include rationale for reasons not to include suggested changes. Once resubmitted, the proposal will be rereviewed. If revisions are appropriate, the project will receive endorsement and the submitters will be asked to submit a full a Data Request Form and routed to the Project Management Officer for Data Governance. If revisions are not appropriate, the proposal may be allowed further edits or may be rejected per the purview of the reviewers.

3. **Rejection** – Projects may be rejected for the following reasons. A rationale for rejection will be provided for each proposal submitted.
    a. Project does not align with organizational mission and/or priorities.
    b. Project does not meet formatting requirements and/or is of poor quality.
    c. Project does not benefit from or align to the data that CyncHealth can provide.
    d. Project is outside data governance guidelines established by CyncHealth.

(a) Data Request Form Review Process

Once the Data Request Form is received, the NHC team will send to the Project Management Officer (PMO) with letter of support by NHC as an acceptable project. The PMO will coordinate with data governance committees that include membership from healthcare entities throughout the state and the Department of Health and Human Services and state legislature. The PMO serves as a chaperone for the request and coordinates with NHC who will inform you of the status of the request or concerns. The meetings occur generally monthly as scheduled, so planning accordingly is necessary.

(b) Institutional Review Board Process

Projects are not allowed to begin, and data will not be shared with teams until CyncHealth is provided with formal organization IRB approval through CyncHealth's project portal. Upon IRB approval, and completion of all required project documentation and governance processes, the project can proceed in partnership with CyncHealth.

Section VI: Project Implementation

(c) Project Implementation Workflow

Investigators must be mindful that careful data management is essential and fundamental for reliable and valid results. While implementing data use and analysis, the project must comply with proposal guidelines approved through data governance and IRB guidelines focused on maintaining participant confidentiality; protecting any collected records and/or data; and securing approval of any change from the original IRB approved proposal/protocol. Once a project is approved, they will be sent a Project Agreement Form. In addition, before distribution of any data, a Data Use Agreement must be signed by an authorized representative. The Project Agreement Form must be completed and signed by all project team members. After receipt of the Project Agreement Form(s) and any other required documents, a CyncHealth analyst will collaborate with the proposal team for data extraction and delivery through an approved and secured mechanism. Additional requests for data that exceed the initial estimate and reasonable follow-up or consultation may result in fees. The data analysis should be performed based on the research question and/or project purpose and include only members of the project team disclosed to CyncHealth in the DUA.

For all projects, CyncHealth maintains data rights. During a project, all team members are responsible to ensure proper data protection and storage procedures as outlined in the approved DUA. Failure to comply with any of these guidelines will lead to project termination and other appropriate consequences.

For research integrity, it is the responsibility of the project team to review the IRB policies of your institution. Also, it is your responsibility to protect participants' rights and

confidentiality. More importantly, it is your responsibility to follow the ethical research standards that are presented and discussed in the Collaborative Institutional Training Initiative (CITI) training courses in protection of human research subjects.

(d) Project Reporting and Accountability

Project leaders are responsible for reporting to CyncHealth on the progress of projects. Project Progress Reports are expected quarterly and provide an overview of project progress along with any concerns or changes. A meeting to touch base around any changes may be required after review of the Progress Report. Within three months of project completion, an Executive Summary is required. If the team members have written a manuscript, this may suffice as the summary. All reporting forms are available on the website and due dates will be identified as part of project implementation. Projects not compliant with these requirements are subject to termination.

(e) Project Dissemination

CyncHealth encourages authors to disseminate results of projects with proper attribution and acknowledgement. CyncHealth will provide logos and support to disseminate projects successfully. Publication guidelines will be outlined in the DUA.

Additionally, all publication materials must be reviewed and approved by CyncHealth to ensure appropriate use of data and attribution prior to submission for publication. If CyncHealth team members are not included as co-authors on the project, the following acknowledgement is required:

> *This project was supported in a partnership with the CyncHealth. For more information, visit www.cynchealth.org. The views expressed herein are those of the author(s) and do not necessarily reflect the views of collaborating organizations or funders, or of the CyncHealth or any of its organizations.*

(f) Determining Authorship

The following are guidelines for authorship of an approved project. Authorship should be discussed with the entire research team including those involved at CyncHealth. The decision of authorship needs to be reviewed starting at the selection of the topic and throughout the entire project sequence. The authorship hierarchy depends on the level of contribution for the following:

(a) the conception and design, acquisition of data, or analysis and interpretation of data
(b) writing and revising the paper
(c) final approval of the final draft of the paper

Additionally:

(a) Each author takes personal and public responsibility and credit for the work

(b) Each author can present, discuss, interpret, and defend the work, analysis, and conclusions

Completing ONLY one of the following DOES NOT justify authorship: (a) identifying the title of project
(b) acquisition of funding
(c) collection of data
(d) general supervision of the research group
(e) providing consultation for statistical analysis or editing
(f) contributing to/completing isolated portions of the project/paper

Author order should be determined prior to the beginning of a manuscript and discussed collectively among the team. If heavily involved, CyncHealth staff are encouraged to act as co-authors.

Most professions agree that:
(a) the first author is principal contributor (not necessarily the principalinvestigator)
(b) subsequent authors listed in order of decreasing contribution.

Preventing authorship problems:
(a) identify and assign study tasks that are key for authorship, and those warranting only acknowledgement
(b) link authorship to quality and completion of work not to an individual's role or title
(c) renegotiate authorship and author order when new tasks emerge, responsibilities alter, or people enter or leave the collaborative group.

In addition, International Committee of Medical Journal Editors has guidelines that define the role of authors and contributors (http://www.icmje.org/recommendations/browse/roles-andresponsibilities/defining-therole-of-authors-and-contributors.html).

Glossary

Data governance - the process of oversight of the use of data focused on privacy and appropriate ethical use of data

Data science – "the application of quantitative and qualitative methods to solve relevant problems and predict outcomes" (Waller & Fawcett, 2013)

Data use agreement (DUA) - a specific type of agreement that is required under the HIPAA Privacy Rule and must be entered into before any use or disclosure of a Limited Data Set from a health care record to an outside institution or party for one of the three purposes: (1) research, (2) public health, or (3) health care operations purposes.

De-identified data set – According to HIPAA, de-identified "information does not identify an individual and with respect to which there is no reasonable basis to believe

that the information can be used to identify an individual is not individually identifiable health information" (Health and Human Services, 2012)

Electronic health record (EHR) – digitized patient record

Health information exchange (HIE) - a source of vital health information often fed from electronic health records (HealthIT.gov, 2019)

Interoperability – "ability of different information systems, devices and applications ('systems') to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally" (HIMSS, 2020)

Limited data set – A data set that is stripped of certain direct identifiers specified in the HIPAA Privacy Rule. A Limited Data Set may be disclosed to an outside party without a patient's authorization only if the purpose of the disclosure is for research, public health, or health care operations purposes and the person or entity receiving the information signs a data use agreement (DUA) with the covered entity or its business associate. A Limited
Data Set is still Protected Health Information (PHI) under HIPAA. It is not De-Identified Data, as that term is defined under HIPAA, and thus, must be safeguarded and protected as required under the Privacy Rule.

Population health – the health outcomes of a group of individuals, including the distribution of such outcomes within the group (Kindig & Stoddard, 2003)

Prescription drug monitoring program (PDMP) - electronic database that tracks prescriptions (CDC, 2017)
Program evaluation - a process to demonstrate the outcomes and effectiveness of a program

Protected health information (PHI) – any identifiable health information

Quality improvement (QI) – a project that focuses on an organization's current performance in a specific area using an attribution or eligibility profile and intended to lead to improved health care delivery or positive impact on the health of patients or populations in that organization

Research - seeks to answer a defined question with rigor and methods established through best practices in scientific inquiry

Small numbers policy – Set of guidelines that defines small numbers as less than a minimum numerator or denominator and provides strategies to enable credible and confidential reporting of rates and proportions from aggregated data. A copy of the CyncHealth small numbers policy is available upon request.

Social determinants of health (SDOH) - Social determinants of health include factors like socioeconomic status, education, neighborhood and physical environment, employment, and social support networks, as well as access to health care. Addressing social determinants of health is important for improving health and reducing longstanding disparities in health and health care. (Reference: Artiga, S. & Hinton, E. (2018). “Beyond health care: The role of social determinants in promoting health and health equity.” Issue Brief. Retrieved from: https://www.kff.org/racial-equity-andhealthpolicy/issue-brief/beyond-health-care-the-role-of-social-determinants-inpromotinghealth-and-health-equity/)

APPENDIX A

Letter of Agreement

_____
DATE

Dear Members of the IRB:

We are familiar with [NAME OF PI]'s research project entitled [XXXXX]. I understand [Agency or Organization's name]'s involvement to be [specific and detailed description of the ROLE OF THE AGENCY or ORGANIZATION]. (List all data collection activities and groups)

We understand that this research will be carried out following sound ethical principles and analytical strategies, that participant involvement in this research study is strictly voluntary, and that confidentiality of participants' research data is ensured, as described in the protocol.

Therefore, as a representative of [Agency or Organization], I agree that [NAME OF PI]'s research project may be conducted in partnership with our agency/organization.

Sincerely,

_____
Signature

_____
Typed Name
Title

APPENDIX B

Collaborative Project Request Form

Request Date:	
Organization	
Name, Title, Credentials	
Contact Information Project	

Title:

Project Overview:

1. Why is this project necessary and what literature supports the investigation?

2. What is the hypothesis or the research question?

3. What are the objectives for the project?

4. How does the project align with the mission of the Nebraska Healthcare Collaborative?

Project Approach/Methods:

1. What is the project methodology and analyses?

2. What is the sample size needed and inclusion or exclusion criteria *(e.g., power analysis)*?

3. What is the timeline for the project and how frequently do you need any data refreshed (one-time or ongoing)?

4. Who will access this data in any form *(i.e., name, titles, role, level of access)*?

5. What potential risks may be present for this request and what safeguards have been implemented to address these risks? *(e.g. Has your institution completed the CMS Security Assessment and Authorization process?)*

Project Sustainability:

6. Describe funding source(s) for this project *(e.g., source, amount, duration)*?

7. How will you share results and how do you plan to acknowledge CyncHealth? *(e.g. publications, presentations, sharing with organizations)*

APPENDIX C

Nebraska Healthcare Collaborative Project Request Form Review Rubric

Title of Project:_____

Reviewer Name:_____

Date of Review:_____

Proposal Review Checklist	Yes	No	N/A	Comments
Applicant Information				
1. Identifiers included: organization; name, title, credentials; contact information				
2. Title is reflective of the project planned				
Project Overview				
3. Project overview gives clear summary of project				
4. Project overview includes citations from reliable sources				
5. Importance and relevance of project is clear				
6. Research question is clear and executable				
7. Research question aligns with project background				
8. Research question aligns with study purpose				
9. Research question is possible with CyncHealth				
10. Hypothesis is well written and clear				
11. Hypothesis links to research question				
12. Project objectives are clear and relevant				
13. Project aligns with the mission of the Nebraska Healthcare Collaborative				
Approach/Methods				

14. Project methods and analyses are appropriate for proposed project				
15. Project design has clear rationale included				
16. The specific number of participants to be included in the study is identified along with rationale for sample size				
17. Demographic criteria for sample are explicit and clear				
18. Both the inclusion and exclusion criteria are identified				
19. Project timeline is clear				
20. Individuals accessing data are clearly identified				
21. Any possible risk or discomfort that may be experienced as a result of participation is described				
Project Sustainability				
22. Funding sources included and described				
23. Dissemination plans included and described				

I recommend this project be
_____ Endorsed (i.e. ready to move to Data Request Form)
_____ Endorsed pending revisions (Please provide a rationale for edits)
_____ Rejected (Please provide a rationale for rejection)

Provide any additional comments or thoughts below you want the project submitters to know.

APPENDIX D

Project Memo

Memorandum

Nebraska Healthcare Collaborative
To: Submitter
From: Reviewer

CC: Team members on proposal
Date:
Re: Nebraska Healthcare Collaborative Proposal Review Feedback

Thank you for submitting your project for review. The purpose of this review is to determine that the proposal

1. uses procedures consistent with sound research and or project design,
2. uses procedures which minimize risk to participants, and
3. Advances the scientific knowledge in areas consistent with the vision of the NHC

The NHC has reviewed your research proposal as required prior to IRB submission. The **Proposal Review checklist** used to review your proposal is attached. Please read carefully. The outcome of the review was:

_____ **Endorsed**. Your project is approved to move to the next phase. You will be sent the Data Request Form and your project will be scoped by an analyst for any applicable cost estimates.

_____ **Endorsed pending revisions**. Please review the required revisions needed to move to the next phase. Return a redline copy and clean copy and include a cover letter outlining changes made within four weeks of receiving this notice. Once revisions are received, the proposal will be re-reviewed and a recommendation for next steps will be made.

_____ **Rejection**. Your proposal has been rejected for the following reasons:

APPENDIX E
Data Request Form

Please complete this form to the best of your ability.

Request Date	
Requestor Organization Requestor Name, Title, Credentials Contact Information (email, phone)	

Title:

PROJECT PLAN

8. What is the plan for data use and analyses?

9. If research, what is the hypothesis or the research question?

10. What data elements are requested? *(e.g., raw data, aggregate data, Personal Health Information (PHI)/Personally Identifiable Information (PII), de-identified data)?*

Data request	**Data elements**
e.g. diagnosis	*e.g. ICD-10 codes*
e.g. age	*e.g. age or date of birth*

11. What is the sample size needed and inclusion or exclusion criteria *(e.g. power analysis)?*

12. When do you need the data and how frequently do you need data refreshed (*e.g. one-time or ongoing)?*

13. Describe funding source(s) for this project (*i.e., source, amount, duration)* ?

14. Who will access this data in any form (*i.e., name, titles, role, level of access)*?

VALUE

15. How does the project facilitate better experiences and/or health outcomes for Nebraskans?

16. How does the project align with the business needs of Nebraska Department of Health and Human Services (DHHS), CyncHealth or the participating organizations? *(e.g. For Medicaid data requests, describe direct benefits to the Medicaid program)*

COMPLIANCE & RISKS

17. How is the request compliant with HIPAA and other state and federal policies and regulations? *(e.g. combining with other datasets, completed HIPAA and/or CITI training (attach certificates))?* If not, how will you remediate any concerns?

18. If requesting identifiable information, can this project be completed with de-identified information? Why or why not? What measures are planned to ensure privacy and confidentiality?

19. Is consent required from the data owner to access this data? If yes, describe how you will obtain consent. If no consent is required, provide a rationale.

20. How long will the data be stored and how will it be destroyed after the specified retention period? (*i.e. Will any data be retained for re-use in the future?)*

21. What potential risks may be present for this request and what safeguards have been implemented to address these risks?

22. Have you received IRB approval? If not, do you plan to? *(Attach copy of approval.)*

23. What precedence exists for sharing similar data within Nebraska or other states? *(e.g., literature review, state statutes, federal regulations)*

TECHNICAL FEASIBILITY

24. What is the proposed data flow to fulfill the request? *(e.g. Who will receive the data and how will it be transferred?)*

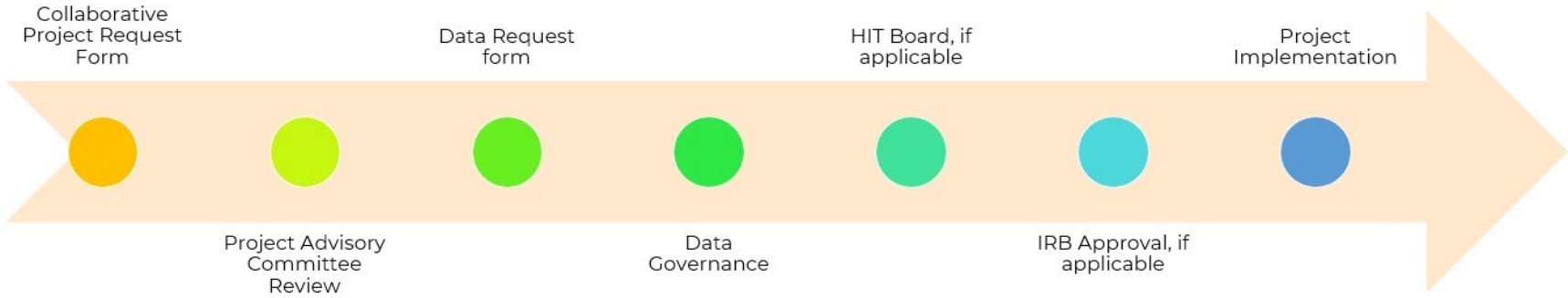
25. What technology/software is needed for the project? *(i.e. Will any webbased applications or interfaces be used? What type and level of data encryption will be used?)*

26. What other technology considerations are needed to manage risks?

APPENDIX F

Overview of Project Phases

Please note, CyncHealth has an obligation to ensure responsible stewardship of health information. This process from project ideation to implementation takes times. Please note some of these committees only meet monthly or quarterly. Contact the Collaborative for more details on the timeline.



APPENDIX G

Project Agreement Form

Congratulations! Your project has been approved to move into implementation. A CyncHealth staff member will be assigned to support your project.

As you implement your project, you will need to agree to the following requirements of CyncHealth. If you do not meet these requirements, your project is subject to termination. Complete this agreement and return to move forward with your project.

I understand and commit to:

☐Follow all guidelines laid out in the data use agreement and by the institutional review board.

☐Review, approve, and execute the "CyncHealth Data Request" form.

☐Provide a copy of the IRB approval, if a research project.

☐Submit Quarterly Progress Reports.

☐Submit an Executive Summary upon one month of project completion.

☐If disseminating any project results, I agree to recognize CyncHealth in an acknowledgement or include a CyncHealth team member as a co-author, as agreed upon per data use agreement.

☐Provide CyncHealth a copy of all reports, manuscripts, briefs, and/or presentations that may come from the project and data.

Name:_____

Date:_____

Signature:_____

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