

Childhood Obesity Data Initiative Master Data Sharing and Use Agreement

This Childhood Obesity Data Initiative (“CODI”) Master Data Sharing and Use Agreement (the “Agreement”), effective as of the Date of Full Execution, is entered into by and among the **[DATA COORDINATING CENTER (CENTER) PARENT ORGANIZATION]**, as Data Coordinating Center of the Childhood Obesity Data Initiative (“CODI”) **[SITE]** and the entities listed in “Exhibit A” (each a “Data Partner” and collectively the “Data Partners”).

Recitals

WHEREAS, the Centers for Disease Control and Prevention (“CDC”) is a health-focused United States government agency that operates as the nation's health protection agency responsible for saving lives and protecting people from health threats by conducting critical science and providing health information that protects our nation against expensive and dangerous health threats, and responds when these arise; and

WHEREAS, the Patient Centered Outcomes Research Trust Fund (“PCOR Trust Fund”) is an independent non-profit research organization created to help patients, clinicians and others to make better informed health decisions by advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders and other health conditions; and

WHEREAS, the Assistant Secretary for Planning and Evaluation (“ASPE”) is the principal advisor to the Secretary of the U.S. Department of Health and Human Services on policy development, and is responsible for major activities in policy coordination, legislation development, strategic planning, policy research, evaluation, and economic analysis including the coordination of a portfolio of intradepartmental projects that build data capacity for conducting patient-centered outcomes research (“PCOR”); and

WHEREAS, the Public Health Informatics Institute (“PHII”) is a program of the Task Force for Global Health, a 501(c)(3) nonprofit organization affiliated with Emory University created to support public health organizations in using data and information effectively; and

WHEREAS, the PCOR Trust Fund dollars allocated to building data capacity for patient-centered outcomes research are administered by ASPE; and

WHEREAS, CDC conceptualized and submitted a proposal to ASPE for PCOR Trust Fund dollars to support the Childhood Obesity Data Initiative (“CODI”) with the intention of building data capacity to assess strategies to prevent and treat childhood obesity; and

WHEREAS, CDC is the recipient of PCOR Trust Fund dollars to establish CODI; and

WHEREAS, it is contemplated that CODI will be an infrastructure composed of a data network and a partnership of member healthcare organizations and community organizations that agree to share data, technology, and knowledge to conduct research, surveillance, quality improvement, and evaluation; and

WHEREAS, the **[CODI DEMONSTRATION SITE]** is the identified pilot site for implementation of CODI; and

WHEREAS, [NETWORK] is a network of healthcare organizations in the [SITE] area that provides electronic health record (EHR) data to Data Users; and

WHEREAS, [SITE's] CODI implementation is a demonstration project of [NETWORK] and is dependent upon the [NETWORK] infrastructure and decision-making processes as described in "Exhibit F"; and

WHEREAS, [CENTER] is the identified Data Coordinating Center ("DCC") for the CODI [SITE] implementation and provides research engagement, identity management, query architecture, data reconciliation and data aggregation services; and

WHEREAS, the Data Partners seek to enter into this Agreement in order to describe and clarify their responsibilities with respect to the sharing of data by each Data Partner with DCC and Data Users for the purposes set forth in this Agreement; and

WHEREAS, the Data Partners will provide certain data described in "Exhibit B" across a secure distributed network with DCC where data will be combined across sites for Projects subject to the terms and conditions set forth herein; and

WHEREAS, DCC agrees to restrict sharing of a Research Dataset to a Data User where a study-specific Data Use and Transfer Agreement has been executed unless otherwise set forth herein; and

WHEREAS, DCC agrees to limit its use of Query Results in accordance with the terms of this Agreement and the HIPAA Regulations.

WHEREAS, Data-Partner Data Users agree to limit their use of Research Datasets in accordance with the data use terms of this Agreement and the HIPAA Regulations.

NOW, THEREFORE, in consideration of the mutual promises contained herein, and of the mutual benefit to be derived hereunder, the Data Partners hereto agree as follows:

1. **Definitions.** For the purposes of this Agreement, the following terms shall have the meaning ascribed to them below. All defined terms are capitalized throughout this Agreement.
 - a. **Aggregate Data** shall mean aggregated, De-identified Data across specified strata of individuals. For example, counts of patients within a stratum that includes a particular age group, gender, and diagnosis. Aggregate Data does not include Individual-Level Data.
 - b. **Applicable Law** shall mean all applicable state and Federal statutes, regulations, standards and policy requirements.
 - c. **Authorized Users** shall mean DCC staff, representatives, agents and/or contractors who have been granted access to Query Results or Research Datasets by DCC in accordance with Applicable Law and the minimum standards set forth in this Agreement.
 - d. **CODI Warehouse** shall mean a Data Partner-maintained database containing the Data.
 - e. **Data** shall mean the definition in "Exhibit B"
 - f. **Data Coordinating Center** shall mean an organization providing research engagement, identity management, query architecture, data reconciliation, and data aggregation services for the CODI project.
 - g. **Data Partner** shall mean an organization contributing Data to a CODI Warehouse in order to share

Research Datasets with Data Users.

- h. **Data Query** shall mean a query of Data as set forth in both Section 4 (Data Sharing Parameters) and “Exhibit E” of this Agreement.
- i. **Data User** shall mean any individual receiving a Research Dataset from the DCC, including two types:
 - a. **Data-Partner Data User** affiliated with a Data Partner
 - b. **Non-Data-Partner Data User** not affiliated with a Data Partner
- j. **De-identified Data** shall have the meaning ascribed to de-identified health information in the HIPAA Privacy Rule at 45 C.F.R. Section 164.514(a). In this Agreement, De-identified Data can but does not necessarily refer to Data collected by a Health Care Provider. Processes for de-identifying data are set forth in 45 C.F.R. Section 164.514(b) of the HIPAA Privacy Rule.
- k. **Deduplication** shall mean consolidating information across records to create a clean copy of the record that does not have duplicates (original records, with duplicate, may be preserved separately).
- l. **Encryption Key** shall mean a randomly generated value provided as an extra input to the Hashing function.
- m. **Hash** shall mean the product of the Hashing function.
- n. **Hashing** shall mean a cryptographic Hash function that transforms sensitive information into a sequence of bits that can be used for matching without revealing any sensitive information.
- o. **Health Care Provider** shall have the meaning set forth at 45 C.F.R. § 160.103 of the HIPAA Regulations.
- p. **Health Plan** shall have the meaning set forth at 45 C.F.R. § 160.103 of the HIPAA Regulations.
- q. **HIPAA Regulations** shall mean the Standards for Privacy of Individually Identifiable Health Information and the Security Standards for the Protection of Electronic Protected Health Information (45 C.F.R. Parts 160 and 164) promulgated by the U.S. Department of Health and Human Services under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, as in effect on the Date of Full Execution of this Agreement and as may be amended, modified, or renumbered.
- r. **Individual-level De-identified Data** includes De-identified Data that is specific to a given individual and that is not Aggregate Data.
- s. **Key Escrow** shall mean the organization generating the Encryption Key and providing the key to Data Partners using a secure channel.
- t. **Limited Dataset** shall have the meaning ascribed to it in the HIPAA Privacy Rule at 45 C.F.R. Section 164.514 (e).
- u. **LINK_ID** shall mean an arbitrary, network-wide unique identifier that links patient-level data across Data Partners. The LINK_ID is not PHI.
- v. **Minimum Necessary** shall have the meaning ascribed to it in the HIPAA Privacy Rule at 45 C.F.R. Section 164.514(d).
- w. **Notice or Notification** shall mean a written communication, unless otherwise specified in this Agreement, sent to the appropriate Data Partner’s representative at the address listed in Section 11 herein.
- x. **Operational Data** shall mean electronic data used for a Data Partner’s operations, including PII and, for Health Care Providers, PHI; used to populate the CODI Warehouse (per Exhibit B) and the CODI Identity Management Data Model (per Exhibit C).
- y. **Patient Identifier** shall mean an arbitrary, locally unique identifier for each patient in a given CODI Warehouse. Different CODI Warehouses will have different Patient Identifiers for the same patient.
- z. **Personally Identifiable Information (PII)** shall mean information that can be used to

distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual, as defined in Office of Management and Budget Memorandum M-07-1616. Management and use of PII for CODI is described in Exhibit C.

- aa. **Permitted Purposes** shall mean: Projects approved by the sharing Data Partner in accordance with this Agreement.
- bb. **PopMedNet** shall mean the software used by DCC to distribute a query and receive Query Results.
- cc. **Prep-to-research (PTR)** shall mean the use of aggregated counts, which are de-identified, to assess the feasibility of research or apply for a grant or other funding source.
- dd. **Project** shall mean any activity requiring the creation of one or more Research Datasets and/or a signed Responsible Use of Data agreement, as defined in "Exhibit I."
- ee. **Query Results** shall mean the site-specific Limited or De-identified Datasets produced from Data Queries and shared with DCC.
- ff. **Record Linkage** shall mean combining information from a variety of data sources for the same individual. This process occurs after record matching.
- gg. **Record Matching** shall mean comparing data from multiple sources to identify records that represent the same individual.
- hh. **Research Dataset** shall mean a dataset produced by the DCC, resulting from aggregation, merging and/or reconciliation of Query Results from multiple Data Partners
- ii. **STUDY_ID** shall mean an arbitrary, study-specific, site-agnostic, unique identifier that identifies a patient in a Project dataset.

2. **Incorporation of Recitals and Exhibits.** The Recitals set forth above and the Exhibits listed after the body of this Agreement are hereby incorporated into this Agreement in their entirety and shall be given full force and effect as if set forth in the body of this Agreement. A list of Exhibits is included below for reference:

- a. Exhibit A: Data Partners
- b. Exhibit B: Definition of Data (CODI Research Data Model)
- c. Exhibit C: Record Linkage Process
- d. Exhibit D: Query Architecture, Longitudinal Record Assembly, and Data Reconciliation and Delivery
- e. Exhibit E: Data Query Descriptions
- f. Exhibit F: CODI Research Participation Policy
- g. Exhibit G: Joinder
- h. Exhibit H: Study-Specific Data Use and Transfer Agreement Template
- i. Exhibit I: Responsible Use of CODI Data Agreement
- j. Exhibit J: **[NETWORK]** Governance Plan

3. **Data Partner Requirements.**

- a. Data Partner shall provide Query Results to **[DCC]** and its Authorized Users in the requisite format as set forth in Exhibit B, subject to Data Partners' ability, in accordance with the HIPAA Regulations. DCC may use Query Results solely for Permitted Purposes, and shall not Use or Disclose Query Results or a Research Dataset other than as permitted hereunder or as otherwise required by Applicable Law.
- b. Data Partner will generate the Hashes necessary to assign a study specific LINK_ID and assemble a longitudinal record as set forth in Exhibit C.

- c. Data Partner will respond to study participation requests and will identify a co-investigator or waive co-investigator participation.
- d. Data Partner will perform activities needed to receive and respond to research Data Queries (e.g., install software) and delegate authority to at least two representatives to respond to Data Queries.
- e. Data Partner will respond to Data Query(ies).

4. Data Sharing Parameters.

- a. Each study, which may include a PTR query, pursuant to which the DCC administers the Data Query(ies) and shares a Research Dataset with a Data User, shall:
 - i. Be in accordance with the [NETWORK] Governance Plan, which is summarized in “Exhibit F” and available, in full, in “Exhibit J.”. The [NETWORK] Governance Plan may be updated from time to time, upon approval by the [NETWORK] Governance Committee through a majority vote; and
 - ii. Be in accordance with CODI Research Policies, which are attached as “Exhibit F” of this Agreement; and
 - iii. Be in accordance with this Agreement, and Applicable Law; and
 - iv. Be supported by Institutional Review Board (IRB) approvals or determination, as appropriate and
 - v. Be supported by a signed Responsible Use of CODI Data agreement in accordance with “Exhibit I.” The DCC will distribute a copy of the signed agreement to Data Partners who provided data, and retain the signed agreement for the life of the study.
- b. DCC is prohibited from including the LINK_ID in any Research Dataset.
- c. DCC and Data-Partner Data Users may use Research Datasets and, in the case of DCC Query Results, solely for Permitted Purposes defined in the [NETWORK] Governance Plan, IRB Protocol, and/or this Agreement as applicable and shall not Use or Disclose Data other than as permitted hereunder or as otherwise required by Applicable Law.
- d. DCC and Data-Partner Data User agree to retain Research Datasets and, in the case of DCC Query Results, for the duration pursuant to the policies and procedures of the Institutional Review Board of record (the “Retention Period”), as applicable. At the end of the Retention Period, Data-Partner Data User shall dispose of the Research Dataset in accordance with the HIPAA Security Rule and provide written verification of its disposal to DCC or, at the specific written request of DCC, return it to DCC. At the end of the Retention Period, DCC shall dispose of the Research Dataset and Query Results in accordance with the HIPAA Security Rule (45 C.F.R. Section 164.310(d)(2)) and provide written verification of their disposal to study-participating Data Partners.
- e. The DCC may issue one or more test queries (each a “Test Query”) of Data as described in “Exhibit E.” Query Results from each Test Query shall be subject to the same requirements as set forth in this Agreement.
- f. Additional Data Sharing Parameters depend on the type of Data Query, as defined in “Exhibit E,” as well as the type of Data User. Pursuant to this Agreement, executed by DCC with Data Partners, the DCC may share Research Datasets as follows:
 - i. DCC may share a Research Dataset generated from any type of Data Query with

- Data-Partner Data Users. This Agreement permits the DCC to share a Limited Dataset with a Data-Partner Data User, upon execution of Exhibit I.
- ii. DCC may share PTR results or a Research Dataset of Aggregate Data, with a Non-Data-Partner Data User. No additional agreement is required.
 - iii. DCC may share a Research Dataset that either meets the definition of a Limited Dataset or the definition of Individual-Level De-identified Data, with a Non-Data-Partner Data User only after a study-specific Data Use and Transfer Agreement is executed. The study-specific agreement shall be based on a template, attached in "Exhibit H." The DCC will sign the Study-specific agreement on behalf of participating Data Partners. Non-Data-Partner Data User must also sign Exhibit I.

5. Security.

- a. **General.** DCC and Data-Partner Data User shall be responsible for maintaining a secure environment in accordance with Applicable Law. DCC and each Data-Partner Data User shall use appropriate safeguards to prevent Use or Disclosure of Query Results and Research Datasets, as applicable, other than as permitted by this Agreement, including appropriate administrative, physical, and technical safeguards that protect data confidentiality, integrity, and availability. Appropriate safeguards shall be those identified in the HIPAA Security Rule, 45 C.F.R. Part 160 and Part 164, Subparts A and C, as safeguards, standards, "required" implementation specifications, and "addressable" implementation specifications to the extent that the "addressable" implementation specifications are reasonable and appropriate. If an "addressable" implementation specification is not reasonable and appropriate for a Data Partner, then such Data Partner must document why it would not be reasonable and appropriate to implement the implementation specification and implement an equivalent alternative measure if reasonable and appropriate, and obtain written consent from DCC to such alternative measure insofar as the use of such alternative measure would affect Data. DCC and each Data Partner shall, as appropriate under either the HIPAA Regulations, or under Applicable Law, have written privacy and security policies in place. DCC shall promptly report to Data Partner any Use or Disclosure of the Data that is not a Permitted Purpose hereunder of which it becomes aware. Each Data User shall promptly report to DCC any Use or Disclosure of Data that is not a Permitted Purpose hereunder of which it becomes aware.
- b. **Malicious Software.** DCC shall ensure that they employ security controls that meet applicable industry or Federal standards so that the information, Query Results and Research Datasets will not introduce any viruses, worms, unauthorized cookies, trojans, malicious software, "malware," or other program, routine, subroutine, or data designed to disrupt the proper operation of CODI or any part thereof or any hardware or software used by CODI in connection therewith, or which, upon the occurrence of a certain event, the passage of time, or the taking of or failure to take any action, will cause CODI or any part thereof or any hardware, software or data used by CODI in connection therewith, to be improperly accessed, destroyed, damaged, or otherwise made inoperable.
- c. DCC and Data-Partner Data User represents that, through its agents, employees, and independent contractors, it shall have the ability to monitor and audit all access to and use of the Data received related to this Agreement, for system administration and security. DCC and Data-Partner Data User shall ensure that any agents to whom it provides a Research Dataset, and in the case of DCC Query Results, agree to the same restrictions and conditions that apply

to DCC and Data User's Use and Disclosure of Research Datasets and Query Results hereunder.

- d. **Breach by DCC.** In the event of a breach of Query Results or Research Dataset by DCC that would trigger notification to individuals or regulators if DCC were a HIPAA covered entity or business associate (as those terms are defined in HIPAA), DCC shall notify Data Partner in writing if Data Partner's Data are suspected to be involved in the breach as soon as possible (and no later than 10 business days) after incident date. DCC agrees to take reasonably appropriate steps to investigate and mitigate the breach and to reasonably cooperate with Data Partner to develop any notifications to individuals, regulators or the media that are either required by Applicable Law or Data Partner policy.
- e. **Breach by Data-Partner Data User.** In the event of a breach of a Research Dataset by Data-Partner Data User that would trigger notification to individuals or regulators if Data User were a HIPAA covered entity or business associate (as those terms are defined in HIPAA), Data User shall notify DCC and Data Partner in writing if Research Dataset are suspected to be involved in the breach as soon as possible (and no later than 10 days) after incident date. Data User agrees to take reasonably appropriate steps to investigate and mitigate the breach and to reasonably cooperate with Data Partner as it develops any notifications to individuals, regulators or the media that are either required by Applicable Law or Data Partner policy.
- f. **Conflicts with ISA.** If applicable, in the event of a conflict between the provisions of this Section 5. and the provisions of a separate information security agreement ("ISA") between DCC and a Data Partner, the provisions of the ISA shall prevail with respect to such Data Partner.

6. Term and Termination.

- a. The term of this Agreement shall commence upon the Date of Full Execution and continue for a period of five (5) years from the Date of Full Execution. This Agreement may be renewed for an agreed-upon period(s) through written amendment to this Agreement.
- b. DCC or Data Partner may terminate this Agreement at any time for any reason or for no reason by giving ninety (90) days written notice to the DCC and other Data Partners.
- c. Data Partner may terminate this Agreement immediately upon written notice to DCC and **[NETWORK]** Governance Committee in the event (i) that it becomes aware of any Use or Disclosure of Data in breach of this Agreement, (ii) of a material breach of this Agreement that is not cured within thirty (30) days of the occurrence of such breach, or (iii) of the addition of a new Data Partner not approved by Data Partner in accordance with Section 11.
- d. **Procedure When Return or Disposal of Data Is Feasible.** Upon Data Partner's termination of their participation in this Agreement, the DCC's termination of their participation in this Agreement, or the Termination of this Agreement due to the conclusion of CODI's existence, DCC and Data Users, will, if feasible, return to Data Partner or dispose of all of Data Partner's Data in whatever form or medium, including all copies thereof and all data, compilations, and other works derived therefrom that are deidentified or allow identification of any individual who is a subject of Data Partner's Data. DCC and Data Partners will require any subcontractor or agent, to which DCC and Data Users have Disclosed a Research

Dataset to, if feasible, return to or dispose of the Research Dataset in whatever form or medium received from DCC, including all copies thereof and all compilations, and other works derived therefrom that allow identification of any individual who is a subject of the Research Dataset, and certify to Data Partner that all such information has been returned or disposed of. DCC and Data User will complete these obligations as promptly as possible, but not later than 45 days following the effective date of the termination or other conclusion of the Agreement.

- e. **Procedure When Return or Disposal Is Not Feasible.** Upon Data Partner's termination of their participation in this Agreement or the Termination of this Agreement due to the conclusion of CODI's existence or [NETWORK]'s existence, DCC and Data Users will identify any of Data Partner's Data, including any that DCC and Data Users have Disclosed to subcontractors or agents, that cannot feasibly be returned to Data Partner or disposed of and explain why return or disposal is infeasible. Where Data Partner agrees that such return or disposal is infeasible, DCC and Data Users will limit their further Use or Disclosure of such information to those purposes that make return or disposal of such information infeasible (such as an ongoing research study). DCC and Data Users will not include Data Partner's Data in any further research initiatives. DCC and Data Users will, by their written contracts with any subcontractor or agent to which DCC and Data Users Discloses Data Partner's Data, require such subcontractor or agent to limit its further use or disclosure of Data Partner's Data that such subcontractor or agent cannot feasibly return or disposed of to those purposes that make the return or disposal of such information infeasible. DCC and Data Users will complete these obligations as promptly as possible, but not later than 45 days following the effective date of the termination or other conclusion of the Agreement.
- f. **Continuing Privacy and Security Obligation.** DCC's and Data Users' obligation to protect the privacy and safeguard the security of Data Partner's Data will be continuous and survive termination or other conclusion of services and this Agreement.

- 7. **Change in Law.** Upon the enactment of any law or regulation affecting the Use or Disclosure of data, or the publication of any decision of a court of the United States or of a court of the state in which this Agreement is performed relating to any such law, the publication of any interpretive policy or opinion of any governmental agency charged with the enforcement of any such law or regulation, or the opinion of counsel, DCC or a Data Partner may amend this Agreement in such manner as DCC or Data Partner determine necessary to comply with such law or regulation. If the Data Partners are unable to agree on an amendment within thirty (30) days thereafter, any one of them may immediately terminate this Agreement on written notice to the other Data Partners.
- 8. **Sensitive Data.** The Data Partners acknowledge their respective obligations under this Agreement to maintain the security and confidentiality of the Protected Health Information and PII contained in the Data. The Data Partners agree to comply with Applicable Law related to the confidentiality of patient information, including, as applicable, the HIPAA Regulations. In addition, Data Partner acknowledges that Data Partner is solely responsible for obtaining any permissions necessary for Data Partner to Disclose Protected Health Information and PII to DCC under this Agreement.
- 9. **Compliance with IRB Requirements.**

The Data Partners and Data Users agree that the conditions for Use of Query Results and Research Datasets are subject to the following:

- a. As applicable, Use of the Data and related infrastructure as defined in “Exhibit B”, “Exhibit C”, and “Exhibit D” has been approved by the Institutional Review Board(s) (IRB(s)) and by [NETWORK] Governance Committee in accordance with the Department of Health and Human Services regulations at 45 C.F.R. Part 46; and/or
- b. For each study, approved Use of the Research Dataset as defined in the [NETWORK] Project Intake Form, approved by the [NETWORK] Governance Committee, and IRB protocol, approved by the Institutional Review Board(s) (IRB(s)) of Participating Data Partners, in accordance with this Agreement, and in accordance with the Department of Health and Human Services regulations at 45 C.F.R. Part 46; and/or
- c. Any changes a study or analysis require additional IRB review and approval; and/or
- d. Sharing of the De-identified Data is not subject to IRB review, but is subject to this Agreement and all Participating Data Partner policies. Use of De-identified Data may be subject to Data Partner organizational policies.

10. Amendments. The terms of this Agreement and the Exhibits attached hereto and incorporated herein by this reference may not be waived, altered, modified, or amended except by a written agreement executed by all the Data Partners.

11. Addition of New Data Partners. New Data Partners will be added to this Agreement, upon approval by a majority vote of the [NETWORK] Governance Committee. Each new Data Partner must complete and execute the Joinder in Exhibit G. Following execution of the Joinder, an updated Exhibit A with the new Data Partner will be provided to all current Data Partners.

12. Notices. Any notice to be given to Data Partners shall be given in writing and delivered to the following addresses by certified or registered mail, return receipt requested, or in person with proof of delivery. Such notice shall have been deemed received upon the date of mailing if by certified or registered mail or electronic mail and upon the date of delivery if by private courier or hand delivery:

DCC: Chief Executive Officer
[DCC]
add address here

Data Partner: To the address and contact listed in Exhibit A.

13. Governing Law. INTENTIONALLY LEFT BLANK.

14. Severability. If one or more of the provisions in this Agreement are declared by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect (“Invalid”), the enforceability of the remaining provisions shall not be impaired unless the declaration of invalidity materially (i) impairs the ability of a party to perform its obligations, (ii) impairs the benefits received by a party, or (iii) adversely affects a primary purpose of this Agreement (“Impairment”). If an Invalid provision causes Impairment the parties agree to make a good faith effort to replace such provision with one that is valid and that will achieve the original intention of the parties. If the parties are unable to agree upon a replacement provision when there is Impairment then either party may terminate this Agreement upon thirty (30) days’ written notice.

15. Waiver. The failure by any Data Partner to enforce, at any time, any of the provisions of this

Agreement or to require at any time performance by another Data Partner of any of the provisions hereof shall in no way be construed to be a waiver of such provisions, to affect either the validity of this Agreement, or any part hereof, or the right of any Data Partner thereafter to enforce each and every provision in accordance with the terms of this Agreement.

16. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which shall together constitute one agreement. The Data Partners agree that electronic signatures and signatures delivered by facsimile, PDF or other electronic means shall be valid, binding and enforceable.
17. Liability. Each Data Partner shall be responsible for its own acts or omissions or those of its officers, employees, or Agents while performing their professional duties as set forth in this Agreement, as determined by a court of competent jurisdiction. The data provided by Data Partner is provided on an “as-is”, “where-is” basis, with no express or implied warranties of any kind. Data Partner specifically disclaims any implied warranty of merchantability, non-infringement or fitness for a particular purpose. Specifically acknowledges and accepts that the data provided by Data Partner may contain errors, incorrect information and/or missing information, and DCC and Data User agree that Data Partner is under no duty of any nature to prepare, “scrub,” or otherwise review such information for accuracy or completeness prior to submission to DCC.
18. Relationship of the Data Partners. The Data Partners are independent contracting entities. Nothing in this Agreement shall be construed to create a partnership, agency relationship, or joint venture among the Data Partners. No Data Partner shall have any authority to bind or make commitments on behalf of another Data Partner for any purpose, nor shall any such Data Partner hold itself out as having such authority. No Data Partner shall be held liable for the acts or omissions of another Data Partner.
19. Use of Name. No Data Partner shall use the name, trade name or trade mark of any other Data Partner in any publicity release, policy recommendation, advertising, publications, abstracts or any commercial communication without the prior written authorization of such Data Partner.
20. Order of Priority. In the event of a conflict between the CODI Research Participation Policy which is attached as “Exhibit F” of this Agreement and the [NETWORK] Governance Plan, the terms of this Agreement shall control.
21. Remedies. Each Data Partner acknowledges and agrees that money damages might not be a sufficient remedy for any breach of this Agreement by such Data Partner. Therefore, in addition to all other remedies available at law (which neither Data Partner waives by the exercise of any rights hereunder), the non-breaching Data Partner shall be entitled to seek injunctive and other equitable relief as a remedy for any such breach.
22. Assignment. This Agreement may not be assigned by a Data Partner without the prior written consent of the other Data Partners, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that a Data Partner may assign its rights or delegate its obligations, without such consent, to (a) one or more of its affiliates, or (b) an entity other than a competitor of a Data Partner that acquires all or substantially all of the business or assets of such party to which this Agreement pertains, whether by merger, reorganization, acquisition, sale, or otherwise by providing notice to all Data Partners as set forth in Section 12 of this Agreement.
23. Ownership. Data Partner retains all right, title, and interest in its Operational Data and its CODI

Warehouse, as well as Query Results submitted by it to the Data Coordinating Center. Data Coordinating Center retains all right, title, and interest in the Research Datasets sent by the Data Coordinating Center to a Data User to the extent they contain any results, data, or analyses generated from the Data Coordinating Center's management of Query Results.

Data Partner grants to the Data Coordinating Center a royalty-free, limited license to use Data Partner's Query Results in connection with the management of Query Results and Research Datasets consistent with the purposes of this Agreement.

[Separate Signature Page to Immediately Follow.]

IN WITNESS WHEREOF, the Data Partners have entered into this Agreement as of the Date of Full Execution.

ADD SIGNATURE LINES FOR Data Partner**S**

“Exhibit A” – Data Partners

Data Partner	Institutional Lead and Primary Contact Person	Address

“Exhibit B” - Definition of Data (CODI Research Data Model)

“Data” shall mean Operational Data collected by a Data Partner and stored in a CODI Warehouse in accordance with the CODI Research Data Model. Elements stored in a CODI Warehouse include both De-identified and Limited Dataset elements. All CODI Research Data Model elements are contained in the tables described below. Each element is eligible to be submitted to DCC in Query Results and combined with other Query Results into Research Datasets.

The CODI Research Data Model leverages existing tables from the PCORnet CDM; Observation Medical Outcomes Partnership (“OMOP”) CDM; CHORDS VDW; and ancillary tables to accommodate conceptual themes that do not exist in PCORnet CDM, OMOP CDM, or CHORDS VDW data models currently.

The CODI Research Data Model tables (required [R]; optional [O]) comprise:

- **ALERT and SESSION_ALERT (O):** The ALERT table includes a description of each alert and its trigger conditions. Alerts are components of a clinical decision support system. Only obesity- or weight-related alerts are captured for CODI. The SESSION ALERT table captures each time the alert is triggered.
- **ASSET_DELIVERY (O):** This table is populated with information about the asset(s) (e.g., the food or monetary resources) received, including details about the purpose of the asset and the frequency and duration over which the asset is provided.
- **CENSUS_LOCATION (R):** This table includes geocoded location information, based on a patients reported address, at the geographic granularity that is permitted in a LDS (e.g., census tract). Valid date ranges for that location information as well as geocoding meta data are also included.
- **CENSUS_DEMOG (R):** This table is a static reference table that contains community level attributes for each census tract or county.
- **COST (O):** This table includes information about the charges resulting from any medical event recorded or service provided in the CODI Research Data Model tables.
- **DEMOGRAPHIC (R):** This table includes date of birth, gender, race, ethnicity, and preferred language.
- **DIAGNOSIS (R):** This table includes information about diagnoses (e.g., code, code type, and source) as well as links to the encounter and provider, when available, that generated each diagnosis.
- **ENCOUNTER (R):** This table includes encounter admission and discharge date, encounter type, payer information, provider, and other general encounter information.
- **FAMILY_HISTORY (O):** This table includes information about any family medical history that may be indicators of risk factors for obesity or comorbidities of interest.
- **LINKAGE (R):** This table includes the LINK_ID, which is an individual pseudo-identifier for use in cross-site patient matching and longitudinal record assembly, as described in “Exhibit C”.
- **PRESCRIBING (R):** This table includes information about medication orders (e.g., RXNORM, order date, start and end date, dose, unit, source and quantity) as well as the prescribing provider.

- **PROCEDURES (R):** This table includes information about procedures (e.g., code and code type) as well as links to the encounter and provider that generated each procedure.
 - **PROGRAM (R):** This table is populated with information specific to the pediatric weight-related program(s) and should be updated when program specifics change. A free-text description of the program is included as well as information about the program aims and intended frequency and duration to support estimates on intended (i.e., prescribed) dosing for participants.
 - **SESSION (R):** The SESSION table has two purposes. First, it captures details about children's visits to community health intervention programs. These non-clinical encounters cannot be captured in the ENCOUNTER table. Second, the SESSION table includes data concepts about interventions offered during a clinical encounter. In some multidisciplinary weight management clinics, for example, a child's clinical encounter might encompass a session with a dietician for a behavioral intervention on nutrition, a session with an exercise physiologist for a physical activity intervention, and a session with a physician for a medical intervention to manage comorbidities. Each one of these sessions within the clinical encounter would be captured as a unique SESSION record.
 - **VITAL (R):** This table includes height, weight, blood pressure, body mass index, and measure data and time information.
 - **REFERRAL (O):** This table captures information about incoming and outgoing referrals to clinical and community health programs and services.
1. Detailed specifications for the CODI Research Data Model are available by contacting the [NETWORK] research project manager.
 2. Data shall be contributed according to the following parameters:
 - a. All historical Data beginning May 1, 2016 for individuals aged 2 to 19 years of age (based on the date of the healthcare event), or when first available to Data Partner
 - b. As some CODI Research Data Model tables are required and some are optional, Data will be populated for all required tables (R) and may be populated for optional tables (O) at the discretion and feasibility of Data Partner
 - c. Ongoing Data submissions at quarterly intervals

“Exhibit C” – Record Linkage Process

In CODI, Privacy Preserving Record Linkage (PPRL) is used to link individual-level information across Query Results. By using PPRL, CODI can perform this linkage without sharing Personally Identifiable Information (PII), as defined above and in the HIPAA Privacy Rule 45 C.F.R. 164.514 (b), outside institutional boundaries. Once patient records are linked, information from the various records is reconciled into a longitudinal record. This exhibit summarizes the PPRL and Data reconciliation processes.

Process Summary

In this section we provide a summary of the process by which globally unique LINK_IDs are established for each individual, without revealing any PII. The details of each step appear in the following sections.

1. The DCC shares configuration information with each Data Partner.
2. A Key Escrow shares the Encryption Key with each Data Partner.
3. Each Data Partner creates a Hashed Dataset; to do this:
 1. Each Data Partner extracts PII from its Operational Data.
 2. Each Data Partner Hashes the PII.
 3. Each Data Partner shares the Hashed Data with the DCC.
4. The DCC develops LINK_IDs; to do this:
 1. The DCC determines which Hash values correspond to the same individual.
 2. The DCC establishes a unique LINK_ID for each individual.
 3. The DCC shares the LINK_IDs with each Data Partner.
5. Each Data Partner stores the LINK_IDs for future research queries.

Hashing Description

Hashing is a mathematical function with two key properties. First, the same inputs always produce the same Hashed output. Second, given the output, it is nearly impossible to determine which inputs were used.

Hashing is an integral component of PPRL because if two Hash values are identical, then the inputs that produced those Hash values must also be identical. Thus, if two Data Partners have information about John Doe, they will Hash John Doe to the same value. The DCC can therefore establish a globally unique LINK_ID for John Doe without receiving any PII for John Doe.

One weakness of Hashing is that an adversary can independently create Hash values for an individual. For example, by Hashing every person in the phone book (including John Doe), the adversary can learn which Data Partners have information about John Doe. To protect against this attack, an Encryption Key is added to the inputs before Hashing. An Encryption Key is a randomly generated value provided as an extra input to the Hashing function. As long as the Encryption Key is kept secret, Hashing is safe from this kind of attack.

Step 1: Data Coordinating Center Provides Hash Instructions to Data Partners

For record linkage to be successful, every Data Partner needs to process PII in an identical manner. Thus, the first step in PPRL is for the DCC to communicate to the Data Partners the steps they will follow.

The necessary information is consolidated into a configuration record. This record contains the following:

- The steps that Data Partners need to take to normalize PII before Hashing. Normalization describes how to standardize names and dates, how to deal with missing values, etc. After normalizing PII, each Data Partner should have a consistent representation of PII.
- The sets of attributes that will serve as inputs to Hashing.

Step 2: Key Escrow Generates and Securely Distributes Encryption Key Value to Data Partners

The Encryption Key is a randomly generated value provided as an extra input to the Hashing function to make the Hash deidentified. The Encryption Key must be transmitted securely. The Encryption Key provider conducts the following tasks:

- Generates the Encryption Key
- Distributes the Encryption Key using a secure data exchange method to all Data Partners

Step 3: Data Partners Generates Hash Values

Next, each Data Partner extracts PII from its Operational Data. The Data Partners put these PII into a temporary database that persists until the Hashing process is complete. The specific PII used by CODI appear in the CODI Identity Management Data Model, which is distinct from the CODI Research Data Model referenced in “Exhibit B.” The CODI Identity Management Data Model may be maintained separately from the CODI Research Data Model and includes such attributes as people's names, addresses, and phone numbers stored in the following two tables:

- **IDENTIFIER:** The IDENTIFIER table captures those Data concepts that will support record linkage. The IDENTIFIER table contains PII and includes name, address, phone number, insurance number, email, and parent name. Which Data from the IDENTIFIER table are used in CODI’s PPRL may vary based on record linkage algorithm.
- **IDENTITY_HASH_BUNDLE:** The PPRL approach works by combining Data concepts from the IDENTIFIER table, such as GIVEN NAME, INSURANCE NUMBER, and ADDRESS ZIP, and Hashing the resulting value. For a given individual, different combinations of Data concepts will be combined resulting in a collection of Hash values. A Hash bundle is the collection of those Hashed identifiers that the CODI record linkage tool will use to match records across organizations. This table does not contain PII.

Based on the configuration file sent by the DCC, the Data Partner computes the specified Hash values. These Hash values are derived from PII, but because of the properties of Hash algorithms and the presence of an Encryption Key value, the Hash values cannot be used to identify any individuals.

Finally, each Data Partner sends its collection of Hash values to the DCC. Because a given individual corresponds to multiple Hash values, the Data Partner also includes a HASHEDID, which is the Hash of that site’s arbitrary patient identifier from the CODI warehouse. These Data are not PII; no special precautions are needed for this Data transmission.

Step 4: Data Coordinating Center

The DCC receives the collections of Hashed values from each Data Partner. The DCC builds a Hash index from these values to identify any matches. Whenever a match occurs, two Data Partners share information about an individual.

By combining the Hash values with the Data Partners' Hashed patient identifiers, the DCC is able to determine all of the Hashes that correspond to the same individual. The DCC creates a new (arbitrary and unique) LINK_ID for each unique individual.

Then, the DCC sends these results back to each Data Partner. This transmission maps each Data Partner's Hashed patient identifier to the globally unique LINK_ID. Each Data Partner stores its patients' LINK_IDs in its local CODI warehouse for use in future research queries.

Hashing Example

PPRL techniques generate multiple Hash values for a given record. These Hash values are created by combining different Data elements from the patient's record and Hashing the resulting values. Consider the following synthetic record:

Data Element	Value
First Name	John
Last Name	Doe
Date of Birth	7/4/2005
State	MA
Insurance Number	23-0009876

Different Data elements will be combined to generate multiple Hashes for the individual. The exact combination of Data elements and number of Hashes has yet to be determined for CODI. As an example, three Hashes are generated for this record:

Data Elements	Value	Hashed Value
First Name + State + Insurance Number	JohnMA23-0009876	1bf6e725d482e28d774a987688c59e4faca0213f
Last Name + Date of Birth + State	Doe7/4/2005MA	ccc20f4d42210c781e1be805ce6162a8c718059c
First Name + Last Name + Date of Birth	JohnDoe7/4/2005	0a49bf0326dbdfd3e29ec18a50bc71701c8c42d2

As described in the Hashing section, these Hash values could be calculated by an attacker with knowledge of PII. As a result, an Encryption Key value is added as an input to the Hashing function to prevent this type of attack. For this example, a random set of characters can be generated for use with the above data:

Encryption Key	tm0eoRWdkW
----------------	------------

Revisiting the previously generated Hashes would now yield the following results:

Data Elements	Value	Hashed Value
First Name + State + Insurance Number + Encryption Key	JohnMA23-0009876tm0eoRWdkW	99f04beb9494b66ba0530b1c6c4eae91c8ac45dc
Last Name + Date of Birth + State + Encryption Key	Doe7/4/2005MAtm0eoRWdkW	6759019832dbdfbe300fc257f0d0dbbc57378d5b

First Name + Last Name + Date of Birth + Encryption Key	JohnDoe7/4/2005tm0eoRWdkW	9b4d8ebae857caef82949a6fd 87f4522afcb496b
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Use of the Encryption Key changes the Hash values. This prevents an attacker from gathering information on whether a patient has a record at a given facility based on generating their own Hash values based on known PII.

The resulting Hash values will be shared with the DCC, which can compare this set of Hash values against Hash values generated by other organizations, to find matches. There does not need to be a complete overlap between Hash values for two records to be considered a match. Variation in Data, such as a typo in the insurance number, would result in a different Hash value for records. While this would alter the first Hash value, the second two would still be the same, assuming that the other information is unaltered.

Comparing Hash Values

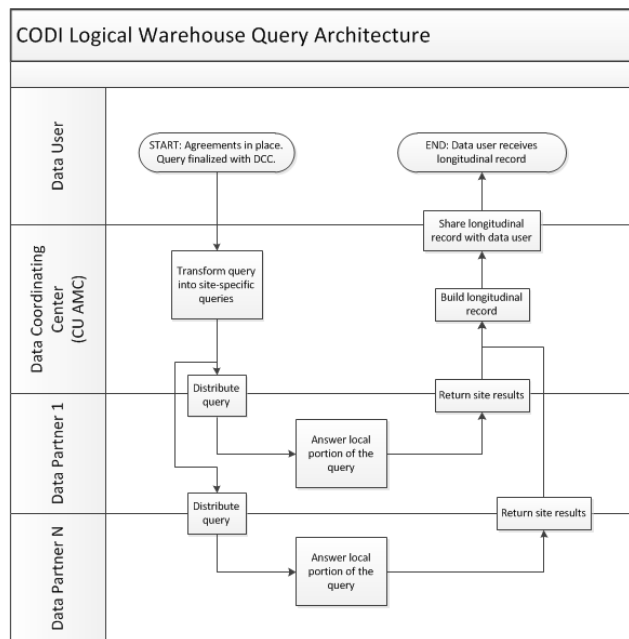
An algorithm will be used to compare Hash values among CODI patients and identify matches. Depending on Project needs, the threshold and settings used to determine a match pair of patient records can be customized to meet the researcher needs. The same algorithm may be used for all CODI record linkage activities or modified to fit the study.

Detailed technical information about the exact algorithm used for record linkage in a specific study is available to Data Partners and Data Users upon request by contacting the [NETWORK] research project manager.

“Exhibit D” – Query Architecture, Longitudinal Record Assembly, and Data Reconciliation and Delivery

Query Architecture

The query architecture for CODI is a logical query architecture (see image at right). In a logical query architecture, researchers query data across multiple sites as if all data were stored in the same data warehouse. A logical query architecture operates by gathering relevant information from the Data Partners and combining Data at the DCC for each query. Once an executable research query is agreed upon by the researcher and the DCC, and necessary agreements are in place, the DCC distributes queries through PopMedNet to Data Partners. Data Partners execute the agreed-upon query and review site-specific results before returning results to the DCC. The DCC combines site-specific results to build a longitudinal record in accordance with the applicable protocol and returns the Research Dataset to the researcher.



Query Results returned to the DCC may contain Personal Health Information (PHI). Several types of queries are described in greater detail in Exhibit E. The DCC may create site-specific queries tailored to each Data Partner. The DCC may distribute more than one query to Data Partners before completion of a given research study. The DCC will seek to minimize the number of queries distributed for a given study while also minimizing the amount of PHI shared with the DCC.

Longitudinal Record Assembly

Data Partners respond to queries by compiling individual-level records stored in the Data model. The LINK_ID assigned by the DCC is included with each individual record in the site-specific results. The DCC uses the LINK_ID to merge Data from multiple sites. After merging records across sites, the DCC prevents disclosure of the LINK_ID to the Data User by replacing the LINK_ID with a study-specific STUDY_ID, unique to the query. Data from multiple sites are reconciled using a process described below.

Data Reconciliation

CODI creates a longitudinal record for researchers by gathering Data from multiple Data owners. The process of transforming multiple records for an individual into a single unified view is complex. The methods used to reconcile Data between records may vary based on the research question being answered. To provide the greatest utility to researchers, CODI has adopted a Data element specific reconciliation strategy.

The CODI project divides Data reconciliation strategies into two groups:

- **Time-invariant Data:** These Data concepts capture characteristics of an individual that do not change over time. An example of this is date of birth.

- Time-varying Data: These Data concepts include characteristics expected to change over time. An example of time-varying data is an individual's weight.

In the CODI project, time-invariant Data will be deconflicted by the DCC. Consider the following example, which shows a portion of the CODI Research Data Model DEMOGRAPHIC table from three sites followed by the view given to the researcher:

Column	Site A	Site B	Site C	Researcher View
LINK_ID	1234	1234	1234	Replaced by STUDY_ID
SEX	M	M	M	M
BIRTH_DATE	7/4/2005	4/7/2005	7/4/2005	7/4/2005

In the example, at Site B, the month and day of the patient's birth date are transposed. In the CODI project, the DCC will examine the conflicting birth dates and resolve this for the researcher. Additionally, researchers may request to see the underlying Data and resolve the conflict themselves.

Finally, by default, researchers will receive all time-varying Data available in the CODI Research Data Model that are relevant for a given query. This may include conditions, encounters, procedures, etc. The CODI project will provide tools that researchers can include in their queries to reconcile information. Examples of this include evaluating all recorded conditions to provide a single problem list or examining labs to eliminate duplicate values. These tools will not be a part of research queries by default and researchers will be able to modify the CODI reconciliation tools or provide their own.

“Exhibit E” - Data Query Descriptions

For all Data Queries referenced throughout this Agreement, the DCC shall request the Minimum Necessary Data to fulfill the purpose of the query.

Data Queries have the following definitions and associated requirements:

1. **Administrative Queries:** Related to Data Queries generated for CODI Projects, from time to time, DCC shall issue queries of Data Partners seeking return of Aggregate Data Query Results. The purpose of such queries shall be to inform the DCC of Data availability and fitness for use in response to CODI Projects.
2. **Data Queries Requiring Return of Aggregate Data:** Such Data Queries will seek return of Aggregate Data Query Results (for example, counts of individuals meeting certain criteria, or counts of exposures, outcomes or exposure/outcome pairs) and combined into Aggregate Data across sites. These Data Queries could be associated with PTR queries or retrospective studies.
3. **Data Queries Requiring Return of Individual-level De-identified Individual-Level Data:** Queries seeking return of Individual-level De-identified Data, as defined in this Agreement.
4. **Data Queries Requiring Return of a Limited Dataset:** These Data Queries include Queries Requiring Return of a Limited Dataset that includes the Data covered in “Exhibit B” of this agreement.
5. **Test Queries Requiring Return of a Limited Dataset, Aggregate Data, or Individual-level De-identified Data:** These queries including queries created by the DCC for future study or PTR purposes that are assessing query performance, testing the interoperability of software programs, and/or identifying potential data quality issues at one or multiple CODI Data Partners. The Limited Datasets, Aggregate Data, or Individual-level De-identified Data created from Test Queries may be shared back with that originating Data Partner for validation or data quality purposes. The Limited Datasets, Aggregate Data, or Individual-level De-identified Data created from Test Queries will not be shared with Data Users.

“Exhibit F” – CODI Research Participation Policy

CODI is a demonstration project of the [NETWORK] network and operates within the [NETWORK] governance framework. The [NETWORK] Governance Committee, which meets regularly and represents all [NETWORK] participants, is the decision-making body for both the CODI project and the [NETWORK] network. The [NETWORK] Research Council, which meets monthly and reports to the Governance Committee, will review all CODI Data requests and make recommendations to the [NETWORK] Governance Committee. [NETWORK] has created and maintains a governance plan, which stipulates [NETWORK] policies and procedures. The [NETWORK] governance plan policies and procedures apply to requests by any Data User to conduct research using CODI’s infrastructure.

The [NETWORK] governance plan includes principles, policies, and procedures related to initiating a CODI study, reviewing and approving study, conflicts of interest and scientific misconduct, enforcement and dispute resolution, regulatory requirements (e.g., DUA and IRB expectations), study participation of Data Partners related to Data contribution and co-primary investigator engagement, general network

governance, Data quality, Data access, security, privacy and confidentiality, and publication and presentation guidelines.

CODI Data Partners include existing members of the [NETWORK] network and two community partner organizations, who are not current members of the [NETWORK] network. For the CODI project, community partners are considered affiliates of the [NETWORK] network, the Governance Committee, and the Research Council. Affiliates will not become full [NETWORK] Data Partners, but will participate in Governance Committee and Research Council discussions specific to the CODI project, for the life of the CODI project. The [NETWORK] Research Project Manager (“RPM”), who convenes the Research Council, will act as the liaison between CODI Project needs and [NETWORK] Governance Committee.

For CODI-specific issues incompletely addressed in the [NETWORK] governance plan, CODI-specific policies and procedures are described below. Each section below begins with an explanation of the [NETWORK] processes and procedures, followed by a description of how CODI differs from the [NETWORK] process or procedure.

Data Model

The CODI Data Model, pursuant to “Exhibit B” of this Agreement, relies heavily on the [NETWORK] data model but is not identical to the [NETWORK] data model. CODI includes ancillary Data tables specific to obesity-specific interventions; the CODI ancillary tables are not part of the [NETWORK] data model. [NETWORK] data quality activities do not include monitoring Data quality in CODI-specific Data Model elements.

CODI Data Partners populate the CODI Data model based on availability and feasibility; thus the completeness of Data within the CODI Data model varies across Data Partners.

Approaches to Study Participation and Data Contribution

[NETWORK] Data Partners include healthcare and mental health providers that establish connections between a [COMMON DATE MODEL WAREHOUSE] and the [NETWORK] network using PopMedNet to participate in [NETWORK] request. [NETWORK] Data Partners participating in CODI maintain their own CODI Data warehouse and connection to PopMedNet. CODI Data Partners who do not participate in [NETWORK] may use a hybrid approach where they partner with a technical partner, usually a HIPAA-covered entity, to support the Data Partner’s CODI participation by hosting their CODI Data warehouse. When using a hybrid approach, the hosted-Data Partner will consent to participate in a Project but the technical partner will receive Project queries and collaborate with the hosted-Data Partner regarding approving queries to run and reviewing results before release. The hosted-Data Partner and technical partner will enter into a legal agreement which stipulates the parameters of Data exchange and expectations around Project-participation and communication. Either approach to CODI participation and Data contribution is permitted.

All Data Partners are permitted to review and approve all CODI Query Results prior to returning Query Results to the DCC. A hosted-Data Partner collaborates with the technical partner to review and approve CODI Query Results. A hosted-Data Partner may transfer authority for review and approval to the technical partner; a transfer of authority must be documented in writing and be retained by the technical partner. Further expectations surrounding review and approval may be specified in agreements between the hosted-Data Partner and technical partner.

Data Use and Transfer Agreements

CODI implemented a reciprocal master sharing and use agreement which codifies a strategy to Data Use Agreements for CODI studies. The master sharing and use agreement permits the DCC to sign Data Use and Transfer Agreements on behalf of Data Partners (“Exhibit H”).

CODI Data Use and Transfer Agreement requirements pertaining to receipt of a Limited Dataset or Individual-Level De-Identified Dataset differ, dependent upon the Data User:

- a) For a study led by a Non-Data-Partner Data User, a study-specific Data Use and Transfer Agreement is required.
- b) For a study led by a Data-Partner Data User, a study-specific Data Use and Transfer Agreement is not required.

Responsible Use of CODI Data Agreements

All CODI Data Users are required to sign a Responsible Use of CODI Data Agreement (“Exhibit I”) and return the signed agreement to the DCC. The Responsible Use of CODI Data Agreement defines the expectations of a Data User, as a recipient of a CODI Research Dataset from DCC, and the limitations on the Use of that Research Dataset. When a Data User receives a Research Dataset containing Individual-level data from the DCC, the Responsible Use of CODI Data Agreement functions in concert with the specific terms detailed in the Data Use and Transfer Agreement.

The agreement is signed by a Responsible Official at the Data User’s institution, which may be the study PI or an organizational signatory. When a signatory signs, it is the responsibility of the PI to communicate the Responsible Use of CODI Data Agreement expectations to the analytic team and collaborators.

Regulations and IRB

All CODI studies require IRB approval or designation as non-human subjects research. CODI received approval for the CODI technical infrastructure which should be referenced by researchers in study-specific protocols. For community partners, [DESIGNATED IRB] will serve as the IRB of record.

Prep-to-Research (PTR)

For CODI studies vetted by the RPM and approved by the [NETWORK], Data Users may request PTR aggregate count Data from participating sites through the DCC, including specifications about site-level stratification. Site level stratification may be permitted for PTR aggregate results upon written approval by all participating Data Partners.

PTR queries are sent only to Data Partners who have agreed to participate in the study. Upon receipt of all sites’ Query Results, the DCC conducts Data quality checks in partnership with all participating Data Partners to verify the accuracy of site-level and overall PTR aggregate results. When Data quality issues arise the DCC may revise and resubmit the PTR query or Data Partners may decline study participation and have their results excluded from PTR aggregate results.

Data Users receive PTR aggregate results following the completion of Data quality activities and approval of all participating Data Partners. No individual-level PTR Data requests are permitted. CODI PTR requests do not include Records Linkage and counts are non-deduplicated. The Data User must work with the RPM to design a PTR request that is reasonable in scope and not overly burdensome on the DCC or participating sites.

PTR results are not permitted to be published in abstracts, reports, or publications but may be used in proposals.

Data Users interested in executing a PTR query for a study may contact the [NETWORK] RPM.

Co-Investigator Engagement by Data User

Data Partners are permitted to appoint a co-investigator to any study where that site's Query Results were contributed. When an appropriate co-investigator is unavailable, Data Partners are permitted to waive their right to appoint a co-investigator. The Data User must engage all co-investigators in the following study activities: Data interpretation, review of analytic findings, and development of presentations, reports, abstracts, and manuscripts.

Co-Authorship

All Data Partners participating in the study are permitted to include the co-investigator and other study contributors as co-authors in presentations, reports, abstracts or publications, assuming co-authors meet authorship criteria. The Data User is responsible for soliciting co-authorship information from Data Partners. If no co-authors are provided by a Data Partner, the Data User must secure institutional approval of presentations, reports, abstracts or publications materials from the Data Partner's CODI institutional lead listed in "Exhibit A". When approval of presentations, reports, abstracts or publications is needed, Data User will allow at least 5 business days for response. If Data Partner is not responsive within the allotted review time period, the Data User is permitted to proceed without approval.

Criteria for Authorship

Authorship assigns responsibility and provides appropriate credit for the development of intellectual work. Assigning authorship should reflect the honest contributions made to both the development and finalization of the finished product.

The International Committee of Medical Journal Editors (ICMJE) recommends that authorship is based on the following four criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All those designated as authors shall meet all four ICMJE criteria for authorship, and all who meet the four criteria shall be identified as authors. Those who meet some but not all four criteria shall be acknowledged as contributors, typically in the acknowledgements section in the manuscript. Permission from individuals is required before acknowledgement in a publication. It is suggested that written documentation is attached to the final manuscript record that outlines how each author meets the four ICMJE criteria. If disagreements arise, the [NETWORK] Governance Committee has the final say on who meets authorship criteria and what order authors appear.

Corporate authorship is encouraged when appropriate. A corporate author may include a commission, a committee, a government agency, or a group that does not identify individual members on the title page.

Corresponding Author

The role of corresponding author should be determined prior to outset of the manuscript. The corresponding author is responsible for managing the submission and revision process, along with other administrative tasks.

Order of Authorship

Designation of authorship order varies across geographies, disciplines, and research entities. It is therefore difficult to suggest a universal standard for authorship order. Instead, the following should be used as a guide for determining order:

- Authorship order should be decided and agreed upon prior to manuscript development (with the understanding that order might evolve as roles/obligations/contributions change).
- Authors should follow guidelines of the publication for specifying contributions that each author made.
- Primary author should document authorship order and contributions. This should remain with the manuscript records.

Study-specific Reporting Requirements

Unless otherwise specified, participating Data Partners are not identified in study publications and presentations. Identification can occur in various sections of a publication or presentation: an acknowledgement, description of methods or study population, presentation of results (e.g., tables and figures), or discussion of findings. For each study and when necessary, Data Users are required to work with [NETWORK] RPM to request and secure permission from participating Data Partners in writing, to name in publication or presentation sections.

Data Users are required to formally acknowledge CODI in all publications and presentations of research conducted using the network. In addition to an acknowledgement of CODI, the following standardized acknowledgement of the CODI partnership will be used for ALL publications, presentations, and other dissemination-related activities, regardless of the authors listed: “*The authors acknowledge the participation of CODI partners: [name all participating Data Partners] in this project.*” It is also recommended that the [NETWORK] network is acknowledged in the Acknowledgements Section of the manuscript or report using language stipulated in the [NETWORK] Governance Plan.

“Exhibit G” – Joinder

**JOINDER
TO
CODI MASTER DATA SHARING AND USE AGREEMENT**

The undersigned, a duly authorized representative of _____, (“Data Partner”) hereby represents that he or she has read the CODI Master Data Sharing and Use Agreement (“Master DSUA”), effective [insert date], and that Data Partner agrees to hereafter abide by and be governed by the terms of the Master DSUA. This Joinder shall be effective upon approval by a majority vote of the [NETWORK] Governance Committee. This Joinder shall be attached to said Master DSUA and deemed to be a part thereof for all purposes.

(Entity name)

Signature: _____

Printed Name: _____

Title: _____

Date: _____

Address: _____

“Exhibit H” – Study-Specific Data Use and Transfer Agreement Template

[INSERT TEMPLATE AGREEMENT FROM YOUR NETWORK HERE]

“Exhibit I” – Responsible Use of CODI Data Agreement

As a recipient of the Research Dataset from CODI, I understand that I am responsible for using the Data appropriately, and for ensuring that my team and collaborators do so as well. This includes using the Data for valid scientific purposes and respecting the privacy of the individuals who have contributed information to CODI. The specific terms for Use of the Data are detailed in the Data Use and Transfer Agreement for the Research Dataset.

I understand that the appropriate agreement(s) has been signed by a Responsible Official at my institution, and my Use of the CODI Data is bound by those terms. Consistent with the Data Use and Transfer Agreement or the CODI Master Data Sharing and Use Agreement and with applicable laws, including applicable privacy laws, and regulations, I agree to the following on behalf of my team and collaborators:

_____ I have accurately and thoroughly described the study and the intended use of the study data in the CODI Project Intake form and IRB protocol.

_____ I acknowledge that [DATA COORDINATING CENTER (CENTER) PARENT ORGANIZATION] is the Data Coordinating Center (DCC) for CODI and will direct any notifications and requests for approvals to [DCC] on behalf of CODI.

_____ I have read and agree to comply with all of the terms and conditions in the Data Use and Transfer Agreement for my study.

_____ I will only use the Research Dataset for the approved study described in the Project Description section of in the approved CODI Project Intake form, the approved IRB protocol, and appropriate agreement for my study.

_____ If I wish to use the Research Dataset for further analyses or studies, I will obtain written agreement from the [DCC], on behalf of CODI for these additional uses.

_____ I will not disclose any CODI Data to anyone who is not specified as a permitted Data User (listed in the Data Use and Transfer Agreement for my study), including, but not limited to, peer reviewers, data archiving sites, or similar scientific groups, without prior permission from [DCC] on behalf of CODI unless required to by law.

_____ I will not attempt to re-identify or contact any individual through use of the Research Dataset, or by combining it with any other data, except as provided for in the CODI approved study protocol.

_____ I will store the Research Dataset securely, using appropriate administrative, technical, and physical safeguards, such as encryption and restricted-access computers.

_____ If I lose or accidentally allow unapproved access to the Research Dataset, I will notify [DCC] within 24 hours and will cooperate with [DCC] to limit the harm done.

_____ I will acknowledge in publications that rely on the Research Dataset the contribution made by CODI.

_____ I will provide to the DCC a copy of summary analysis results and publications, so CODI can meet its archiving obligations to its sponsors and Data Partners.

_____ I will ensure that any agent, including a subcontractor, to whom I provide the Research Dataset, agrees to the same restrictions and conditions that apply through this Agreement to the Data User with respect to such information.

Investigator: _____

Date: _____

Institutional Signatory: _____

Date: _____

DCC Signatory: _____

Date: _____

“Exhibit J” – [NETWORK] Governance Plan

The current [NETWORK] Governance Plan can be found by accessing this link:

[LINK]