CLINICAL COMMUNITY DATA INITIATIVE OF NORTH CAROLINA MASTER CONSORTIUM AGREEMENT

This **Clinical and Community Data Initiative of North Carolina Master Consortium Agreement** ("**CODI-NC Master Consortium Agreement**" and "**Agreement**"), effective as of the date of the last signature below (the "**Effective Date**"), is entered into by and among Duke University ("**DUKE**"), a tax-exempt, research and educational institution located in Durham, North Carolina, acting for and on behalf of its Duke Clinical Research Institute, the Collaborative Studies Coordinating Center ("**UNC-CSCC**"), a non-profit public health organization located at The University of North Carolina, Gillings School of Global Public Health in Chapel Hill, North Carolina, and _____[SITE NAME]_____ located at _____[SITE ADDRESS]____ ("**DATA OWNER**") (DUKE, UNC-CSCC and DATA OWNER referred to individually as "**a Party**," and collectively hereinafter as "**the Parties**").

Recitals

WHEREAS, the Clinical and Community Data Initiative of North Carolina ("**CODI-NC**"), led by the Centers for Disease Control and Prevention ("**CDC**") is the expansion of a health-focused consortium composed of a distributed health data network using common data models, and a partnership of member health care, community and municipal organizations in North Carolina (each a "**Data Owner**") that agree to share Data (as defined below), technology and knowledge to conduct research, surveillance, quality improvement and evaluation for the improvement of public health;

WHEREAS, the Parties acknowledge that the Data Owners identified in **Exhibit A** attached to this Agreement have executed, or will execute, a CODI-NC Master Consortium Agreement under substantially the same terms and conditions contained in this Agreement;

WHEREAS, DUKE, the Data Coordinating Center (the "**DCC**") for CODI-NC, is responsible for its implementation in North Carolina and to provide Request administration, Data Curation, Query development and execution, Data reconciliation and Data aggregation activities in support of CODI-NC (as the forgoing capitalized terms are defined below);

WHEREAS, as part of its participation in CODI-NC, DATA OWNER may, from time-to-time at its discretion, respond to Queries from the DCC by providing certain Data, as described in the "CODI Research Data Model Descriptions" document attached hereto as **Exhibit B**, which Data will be transferred either directly to the DCC through a secure distributed network, or to UNC-CSCC, the CODI-NC data hosting partner, for subsequent transfer by UNC-CSCC to the DCC through a secure distributed network;

WHEREAS, upon the DCC's receipt of DATA OWNER's Data from UNC-CSCC, the DCC will combine the Data with Data from other Data Owners for CODI-NC-approved projects for subsequent disclosure to a Data requestor (as "**Requestor**" is defined below) subject to the terms and conditions set forth herein; and

WHEREAS, the Parties seeks to enter into this Agreement to establish and specify their individual rights and responsibilities with respect to the sharing of DATA OWNER's Data with the DCC, other Data Owners and Data Users (as defined below) for the purposes set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual promises contained herein, and of the mutual benefit to be derived hereunder, the Parties 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**. De-identified Data for individuals that are compiled or grouped into data summaries or summary reports. Aggregate Data for small geographic areas, those with sparse or vulnerable populations, and/or those that include unique characteristics should be carefully evaluated to ensure that individuals are not identifiable. Aggregate Data does not include Individual-Level Data and is not considered Confidential Information.

    b. **Applicable Law**. All applicable Federal, state and local statutes, regulations, standards, guidelines and policy requirements including, without limitation, HIPAA Regulations, applicable provisions of the Special Supplemental Nutrition Program for Women, Infants and Children ("**WIC**") regulations published at 7 CFR Part 246, and all requirements imposed by legally constituted IRBs.

    c. **CODI-NC Datamart**. A database created by, or for, a Data Owner containing Individual-Level Data without Personally Identifiable Information in accordance with the CODI Research Data Model, as defined in Exhibit B.

    d. **Confidential Information**. Any information about an individual subject, regardless of how obtained, that identifies directly or can be used to indirectly identify an individual subject. Confidential Information includes all Data (except Aggregate Data and De-identified Data), PII, PHI, Individual Identifiers, Individual-Level Data that has not been de-identified, and any unique ID, identifier or code related to or derived from an existing Individual Identifier that can be used to re-identify an individual subject.

    e. **Data**. Data collected by a Data Owner and stored in a CODI-NC Datamart consistent with the definition in Exhibit B. This information may include, but is not limited to, Protected Health Information (PHI), De-identified Data (as defined in the HIPAA Regulations at 45 CFR § 164.514(a)), Individual-Level Data, pseudonymized Data, metadata, digital credentials and schema. All Data, except Aggregate Data and De-identified Data, is considered Confidential Information.

f. **Data Curation**. The process undertaken by the DCC to examine Data quality of the CODI-NC Datamarts for each Data Owner. Data Curation happens at least twice (2xs) per year when the CODI-NC Datamarts are refreshed.

g. **Data User**. Any individual or institution receiving a CODI-NC-approved Project Dataset from the DCC.

h. **Deduplication**. 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).

i. **De-identified Data**. Individual subject Data stripped of personal and indirect identifiers so that individuals cannot be identified, either directly from the data or when data are linked or combined with other information as defined by the HIPAA Privacy Rule at 45 CFR. § 164.514(a). Processes for de-identifying Data are set forth in 45 CFR § 164.514(b) of the HIPAA Privacy Rule. De-identified Data is not considered Confidential Information.

j. **Encryption Key**. A randomly generated value provided as an extra input to the hashing function.

k. **Hash**. The product of the hashing function which is a cryptographic function that transforms sensitive information into a sequence of bits that can be used for matching without revealing any sensitive information.

l. **Health Care Provider**. The meaning set forth at 45 CFR § 160.103 of the HIPAA Regulations.

m. **HIPAA Regulations**. The Standards for Privacy of Individually Identifiable Health Information and the Security Standards for the Protection of Electronic Protected Health Information (45 CFR 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 Effective Date of this Agreement and as may be amended, modified or renumbered.

n. **HOUSEHOLD_ID**. An arbitrary, network-wide unique identifier generated from the Record Linkage process that can be used to link households across Data Owners. The HOUSEHOLD_ID is not PHI and is not considered Confidential Information.

o. **Individual Identifier**. A locally-generated unique identifier for each individual in a given CODI-NC Datamart such as a medical record number or member ID. Different CODI-NC Datamarts will have different Individual Identifiers for the same individual. All Individual Identifiers are considered Confidential Information.

p. **Individual-Level Data**. Contains information that is specific to individuals. Individual-Level Data may or may not be De-identified Data. Individual-Level Data that is not de-identified is considered Confidential Information. Individual-Level Data that is de-identified is not considered Confidential Information.

q. **Key Escrow**. The organization generating the Encryption Key and providing the key to Data Owners using a secure channel.

r. **Limited Dataset**. Data from any source that excludes direct identifiers of an individual subject, but may include indirect identifiers connected or related to an individual subject such as geographic or temporal information (e.g., ages, dates and/or any elements of postal address including state, county, city, zip code, or census tract). As it relates to the HIPAA Privacy Rule at 45 CFR § 164.514(e), a limited data set is Protected Health Information of an individual subject that may be disclosed with a data use agreement for purposes of public health, research or health care operations. A Limited Dataset is considered Confidential Information.

s. **LINK_ID**. An arbitrary, network-wide unique identifier that links Individual-Level Data across Data Owners. The LINK_ID is not PHI and is not considered Confidential Information.

t. **Minimum Necessary**. Shall have the meaning ascribed to it in the HIPAA Privacy Rule at 45 CFR § 164.514(d).

u. **Notice or Notification**. A written communication, unless otherwise specified in this Agreement, sent to the appropriate Data Owner's representative at the address specified in Section 12 (Notices) of the Clinical and Community Data Initiative Master Consortium Agreement between that Data Owner and the DCC.

v. **Operational Warehouse**. A database that contains the PII and PHI used to populate a CODI-NC Datamart.

w. **Personally Identifiable Information (PII)**. Information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information, that is linked or linkable to a specific individual as defined by OMB A-1301. All PII is considered Confidential Information.

x. **Prep-to-Research**. The use of aggregated counts, which are de-identified, to assess the feasibility of research or apply for a grant or other funding source.

y. **Privacy Protect Record Linkage (PPRL)**. The process of matching individuals and households based on de-identified information, as more fully described in **Exhibit C**.

z. Project Dataset. A CODI-NC-approved project dataset produced by the DCC, resulting from aggregation, merging and/or reconciliation of Query Results from multiple Data Owners.

aa. **PROJECT_HOUSEHOLD_ID**. An arbitrary, project-specific, site-agnostic, unique identifier that identifies a unique household in a CODI-NC-approved project dataset. A PROJECT_HOUSEHOLD_ID is not considered Confidential Information.

bb. PROJECT_ID. An arbitrary, project-specific, site-agnostic, unique identifier that identifies an individual in a CODI-NC-approved project dataset. A PROJECT_ID is not considered Confidential Information, unless unrelated to or derived from any existing identifier and can be used to re-identify an individual subject.

cc. **Protected Health Information (PHI)**. Any information in the medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service such as diagnosis or treatment as defined by the HIPAA Privacy Rule. All PHI is considered Confidential Information.

dd. Query. A query of Data, as set forth in Section 4 and **Exhibit D** of this Agreement.

ee. Query Results. The Aggregate Data or Individual-Level Data resulting from a Query requested by a Data Owner or UNC-CSCC on behalf of a Data Owner as set forth in Section 4 and Exhibit D of this Agreement.

ff. Record Linkage. Combining information from a variety of Data sources for the same individual.

gg. Request. A submission to the CODI Front Door, as set forth in **Exhibit F**, requiring aggregate or individual-level results.

hh. Requestor. The individual submitting a Request for Data from CODI-NC. A Requestor may or may not be a Data User.

ii. **Use and Disclosure**. These terms shall have the meaning ascribed to it under the HIPAA Regulations at 45 CFR § 160.103.

jj. **Data Product**. A product for a CODI-NC-approved project produced by the DCC, resulting from de-identification, aggregation, merging and/or reconciliation of Query Results from a Data Owner or multiple Data Owners (i.e. analytic findings, summaries, reports, maps, graphs). For the avoidance of doubt, Data Products shall not include Individual-Level Data, PII or PH and are not considered Confidential Information.

2. **Incorporation of Recitals**. The Recitals set forth above 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.

3. **DATA OWNER Requirements**. As participants in the CODI-NC Network, DATA OWNER agree to fulfil the following requirements:

   a. Identify a governance representative to participate in CODI-NC governance activities as set forth in Exhibit F of this Agreement or waive governance participation.

   b. Participate in Privacy Protect Record Linkage ("**PPRL**") activities, as needed (e.g., extract data, generate Hashes, install software), and identify individuals and resources to support the PPRL process as set forth in Exhibit C. DATA OWNER will enter into a separate agreement with the National Association of Community Health Centers (NACHC), the CODI-NC-approved privacy preserving record linkage agent to complete the PPRL activities.

   c. Build a CODI-NC Datamart in the requisite format as set forth in Exhibit B, and populate their CODI-NC Datamart with Individual-Level Data from their organization.

   d. Review and approve or decline requests for project participation as set forth in Exhibit F.

   e. For Requests in which DATA OWNER participates, DATA OWNER will identify a co-investigator or waive co-investigator participation, as set forth in Exhibit F.

   f. DATA OWNER will perform activities needed to receive and respond to Queries (e.g., install software) and delegate authority to at least two (2) representatives to respond to Queries.

   g. DATA OWNER will respond to Queries by providing Query Results either (1) directly to the DCC, or (2) to UNC-CSCC, the CODI-NC data hosting partner, to define the parameters of the collaborative Query response and to facilitate DATA OWNER's sharing of a Limited Dataset with the DCC in the requisite format, as set forth in Exhibit D and **Exhibit E**.

4. **UNC-CSCC Requirements**. As the CODI-NC data hosting partner, UNC-CSCC will, at DATA OWNER's election, provide:

   Hardware, systems, software and the infrastructure required to store and manage access to DATA OWNER's Data, including any disaster recovery or business continuity related processes,

   Geocoding services,

   Assistance to the DATA OWNER to participate in the PPRL process,

Data mapping and hosting services to DATA OWNER to define the parameters of the collaborative Query response,

Assistance to the DATA OWNER to participate in Data quality and curation activities as directed by the DCC, and

Assistance to DATA OWNER facilitating the response to Queries and sharing of a Query Results with the DCC.

5. **UNC-CSCC Use Parameters and Limitations**. As the CODI-NC data hosting partner, UNC-CSCC's assistance to DATA OWNER will be based on and include the following parameters and limitations.

   a. UNC-CSCC will store DATA OWNER's Data securely in compliance with Section 7 (Security) of this Agreement.

   b. UNC-CSCC may use DATA OWNER's Data solely for the "Permitted Purpose(s)," as the same is/are defined in the materials submitted through the CODI-NC Front Door Request process outlined in Exhibit E, the IRB Protocol and this Agreement. UNC-CSCC shall not Use or Disclose Query Results other than as permitted hereunder or as otherwise required by Applicable Law.

   c. UNC-CSCC will only share the results of its data hosting activities with DATA OWNER, but not with other Data Owners, the DCC or any other third party.

   d. UNC-CSCC shall not Use the LINK_ID and HOUSEHOLD_ID to reidentify or contact an individual or household in any Query Results or Project Datasets. UNC-CSCC is prohibited from including the LINK_ID or the HOUSEHOLD_ID in any Query Results shared with the DCC.

   e. UNC-CSCC will retain DATA OWNER's Data only for as long as necessary to the conduct data hosting services required under this Agreement on behalf of DATA OWNER, or for the period specified by DATA OWNER. Upon completion of UNC-CSCC's use of DATA OWNER's Data, the same will be returned or destroyed in accordance with the requirements set forth in Section 8(d) (Return or Destruction of Data).

6. **DCC Requirements and Data Sharing Parameters**. The DCC may share DATA OWNER's Data with Data Users based on the following parameters.

   a. The DCC will manage and coordinate Data sharing with all Data Users within defined projects that begin with the submission of a Request and results in the sharing of a Project Dataset with a Data User. No Data from CODI-NC may be shared with a Data User without affiliation with a CODI-NC-approved project. Each CODI-NC-approved project shall:

1. Adhere to CODI Network and Data Use Policies, a copy of which is attached hereto as Exhibit F;

2. Comply with the requirements of this Agreement, and Applicable Law;

3. Be supported by evidence of the Requestor's and/or Data User's receipt of the appropriate Institutional Review Board ("**IRB**") approvals or designations; and

4. Be subject to and supported by an appropriate fully executed Data Use Agreement ("**DUA**") between the DCC, DATA OWNER, other applicable Data Owners and the Requestor and/or Data User.

b. Requests for Data by External Data Users. Upon the DCC's receipt of a Data Request approved through the CODI-NC Front Door Request process from a Requestor, and subject to the DCC's requirements and data sharing parameters set forth above in Section 6a, the DCC may share a Project Dataset with a Data User external to the CODI-NC distributed health network following full execution of a project-specific DUA by and between the DCC, DATA OWNER, other applicable Data Owners and the Data User in substantially the same form as the sample DUA template attached hereto as Exhibit H. The following types of Data may be returned in response to Analytic Queries, which are more fully described in Exhibit E:

1. Analytic Queries Seeking Return of a De-Identified Project Dataset that includes only the type of Data defined in Exhibit B of this Agreement; or

2. Analytic Queries Seeking Return of a Limited Dataset that includes only the type of Data defined in Exhibit B of this Agreement.

c. Requests for Data by DATA OWNER acting as a Data User. Upon the DCC's receipt of a Data Request approved through the CODI-NC Front Door Request process from a Requestor, and subject to the DCC's requirements and data sharing parameters set forth above in Section 6a, the DCC may share a Project Dataset with DATA OWNER or another Data Owner pursuant to the terms of each party's separate CODI-NC Master Consortium Agreement executed by and between the DCC, UNC-CSCC and DATA OWNER (or the relevant Data Owner) when DATA OWNER (or other Data Owner) is acting in the capacity of a Data User. DATA OWNER's Agreement (or that of the other Data Owner) will serve as and includes the requirements of a DUA for the following types of Data returned in response to Analytic Queries, which are more fully described in Exhibit E:

1. Analytic Queries Seeking Return of a De-Identified Project Dataset that includes only the type of Data defined in Exhibit B of this Agreement; or

2. Analytic Queries Seeking Return of a Limited Dataset that includes only the type Data defined in Exhibit B of this Agreement.

d. Request for a Data Product. Upon the DCC's receipt of a Request for a Data Product approved through the CODI-NC Front Door Request process from a Requestor, and subject to the DCC's requirements and data sharing parameters set forth above in Section 6a, subsections 1, 2 and 3, the DCC will, in consultation with DATA OWNER (and applicable Data Owners), evaluate the need for a project-specific DUA by and between the DCC, DATA OWNER, other applicable Data Owners and the Data User on a case-by-case basis.

e. DCC Use Limitations.

1. The DCC shall not Use the LINK_ID and HOUSEHOLD_ID to re-identify or contact an individual or household in any Query Results or Project Datasets. The DCC and UNC-CSCC are prohibited from including the LINK_ID or the HOUSEHOLD_ID in any Project Dataset.

2. The DCC may Use, and will ensure that Data Users Use, Data Products and Project Datasets solely for "Permitted Purpose(s)," as the same is/are defined in the materials submitted through the CODI-NC Front Door Request process outlined in Exhibit E, and in the IRB Protocol, this Agreement, and/or the project-specific DUA, as applicable. Neither the DCC nor a Data User may Use or Disclose a Data Product or Project Dataset other than as permitted hereunder or as otherwise required by Applicable Law.

3. The DCC will ensure that any DUA executed between the DCC, DATA OWNER, other applicable Data Owners and a Data User contains language that the Data User may not Use any elements in the Project Dataset to re-identify or contact an individual or household in any Query Results or Project Datasets, unless permission to do so is otherwise obtained in accordance with Applicable Law and approved by DATA OWNER's IRB and, as the case may be, the multiple Data Owners' IRB from where the Data originated.

f. Retention. The purpose of retention of Query Results and Project Datasets by the DCC is to preserve data provenance and reproducibility for the duration of Project Dataset use. The DCC shall retain Query Results returned for as long as necessary to fulfill the purpose of the Query, and in any event no longer than five (5) years (the "**Retention Period**"). At the end of the Retention Period, DCC shall return or destroy the Query Results and Project Dataset in accordance with the HIPAA Security Rule and the requirements set forth in Section 8d (Return or Destruction of Data) of this Agreement. The DCC will ensure that Data Users agree to retain Query Results and Project Datasets for the retention period pursuant to the policies and procedures of the IRB of record.

7. **Security**. The Parties agree to the following security requirements.

a. General. The DCC, UNC-CSCC and DATA OWNER shall each be responsible for maintaining a secure environment for Data, Query Results and Project Datasets while the same are in their possession in accordance with Applicable Law. The DCC, UNC-CSCC and DATA OWNER shall use appropriate safeguards to prevent Use or Disclosure of Query Results and Project Datasets other than as permitted by this Agreement, including reasonable and appropriate administrative, physical and technical safeguards that protect data confidentiality, integrity and availability in accordance with the HIPAA Security Rule, 45 CFR Part 160 and Part 164, Subparts A and C ("**Security Rule**"). If an "addressable" implementation specification identified in the Security Rule is not reasonable and appropriate for a Party, then that Party must document why it would not be reasonable and appropriate to implement the implementation specification. In such a case, the Party unable to meet the addressable implementation specifications shall implement an equivalent alternative measure if reasonable and appropriate, and if that Party is UNC-CSCC or DATA OWNER, then UNC-CSCC or DATA OWNER shall obtain written consent from the DCC regarding such alternative measure insofar as the use of such alternative measure would affect the Data, Query Results and Project Datasets. The DCC, UNC-CSCC and DATA OWNER shall, as appropriate under either the HIPAA Regulations, or under Applicable Law, have written privacy and security policies in place. The DCC and UNC-CSCC shall promptly report to DATA OWNER and to the other Party any Use or Disclosure of the Data, that is not a Permitted Purpose hereunder of which it becomes aware. The DCC will ensure Data Users' Data Use Agreement complies with the requirements of this section, and ensure that each Data User promptly reports to the DCC and DATA OWNER any Use or Disclosure of Query Results or a Project Dataset that is not a Permitted Purpose hereunder or under the DUA executed by the DCC, DATA OWNER and the Data User of which the Data User becomes aware.

b. Malicious Software. The DCC, UNC-CSCC and DATA OWNER shall ensure that they employ security controls that meet applicable industry or Federal standards so that the Data, Query Results and Project 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-NC or any part thereof or any hardware or software used by CODI-NC 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-NC or any part thereof or any hardware, software or data used by CODI-NC in connection therewith, to be improperly accessed, destroyed, damaged, or otherwise made inoperable.

c. Monitoring and Audits. The DCC and UNC-CSCC represent that, through their respective agents, employees and independent contractors, and as applicable, they shall have the ability to monitor and audit all access to and Use of the Data, Query Results and Project Datasets received from DATA OWNER and other Data Owners related to this Agreement, for system administration and security. The DCC and UNC-CSCC shall ensure that any agents to whom DATA OWNER's Data, the Query Results or a Project Dataset is provided agree to the same restrictions and conditions that apply to the DCC and UNC-CSCC's Use and Disclosure of DATA OWNER's Data, Query Results and a

Project Dataset hereunder. The DCC shall ensure Data Users' Data Use Agreement complies with the requirements of this Subsection.

d. Breach by the DCC or UNC-CSCC. In the event of a breach of the requirements for Use or Disclosure of DATA OWNER's Data, Query Results or a Project Dataset by the DCC or UNC-CSCC that would trigger notification to individuals or regulators if the DCC or UNC-CSCC were a HIPAA covered entity or business associate (as those terms are defined in HIPAA), the DCC or UNC-CSCC, whichever the case may be, shall notify DATA OWNER in writing if DATA OWNER's Data are suspected to be involved in the breach as soon as reasonably possible (and no later than ten (10) business days) after the DCC or UNC-CSCC becomes aware of the known or suspected breach. The DCC and UNC-CSCC agree to take reasonably appropriate steps to investigate and mitigate the known or suspected breach and to reasonably cooperate with DATA OWNER to develop any notifications to individuals, regulators or the media that are either required by Applicable Law or DATA OWNER's written institutional policy.

e. Breach by Data User. In the event of a breach of the requirements for Use or Disclosure of Query Results or a Project Dataset by a Data User that would trigger notification to individuals or regulators if said Data User were a HIPAA covered entity or business associate (as those terms are defined in HIPAA), the DCC will ensure that the Data User notifies the DCC and DATA OWNER in writing if the Query Results or Project Dataset are suspected to be involved in the breach as soon as reasonably possible (and no later than ten (10) days) after the Data User becomes aware of the known or suspected breach. The DCC shall ensure Data Users' Data Use Agreement requires Data User to take reasonably appropriate steps to investigate and mitigate the known or suspected breach and to reasonably cooperate with DATA OWNER and the DCC to develop any notifications to individuals, regulators or the media that are either required by Applicable Law or DATA OWNER's written institutional policy.

8. **Term and Termination.**

a. Term. The term of this Agreement shall commence upon full execution (the date of the last signature by a Party) ("**Effective Date**"), and continue for a period of five (5) years from the Effective Date, unless terminated earlier in accordance with the terms of this Section 6 or upon the earlier conclusion of the CODI-NC initiative. This Agreement may be renewed for an agreed-upon period(s) through written amendment to this Agreement signed by each Party.

b. Termination by a Party. Any Party may terminate this Agreement at any time for any reason, or for no reason, by giving ninety (90) days written notice to the other Parties and to the other Data Owners.

c. Termination by DATA OWNER. DATA OWNER may terminate this Agreement immediately upon written notice to the DCC, the DCC's Office of Research Contracts, and to UNC-CSCC at the addresses listed below in Section 12 (Notices) in the event (i) that DATA OWNER becomes aware of any Use or Disclosure of Data in breach of this

Agreement, (ii) of a material breach of this Agreement by the DCC or UNC-CSCC that is not cured within thirty (30) days of the occurrence of such breach, or (iii) of the addition of a new Data Owner not approved by DATA OWNER in accordance with Section 11 (Addition of New Data Owners).

d. Return or Destruction of Data. Upon termination of this Agreement by a Party or as a result of the conclusion of CODI-NC, the DCC will, at DATA OWNER's direction, if feasible and in accordance with HIPAA Regulations, return or destroy all of DATA OWNER'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 OWNER's Data. The DCC will require Data Users in receipt of DATA OWNER's Data to do the same in the separate DUA executed between the DCC, DATA OWNER and Data Users. The DCC, and DATA OWNER will require any subcontractor or agent, to which the DCC and/or Data Users have disclosed a Project Dataset to, if feasible, return to or destroy the Project Dataset in whatever form or medium received from the 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 Project Dataset, and certify to DATA OWNER that all such information has been returned or destroyed. The DCC will complete these obligations as promptly as possible, but not later than forty-five (45) days following the effective date of the termination or other conclusion of the Agreement, and will require Data Users' compliance with the forgoing requirements.

e. Infeasibility. Upon termination of this Agreement for any reason, the DCC will identify, and the DCC will ensure that Data Users identify, any Data and Query Results from DATA OWNER, including any that the DCC and/or Data User(s) have disclosed to subcontractors or agents, that cannot feasibly be returned to DATA OWNER or destroyed and the DCC will explain, and the DCC will require Data User(s) to explain, why return or destruction is infeasible. Where DATA OWNER agrees that such return or destruction is infeasible, the DCC will limit and ensure that Data User(s) limit, their further Use or Disclosure of such information to those purposes that make return or destruction of such information infeasible (such as an ongoing research project). The DCC will not include DATA OWNER's Data in any further research initiatives, and the DCC shall prohibit Data Users from doing the same. The DCC will, by its written contracts with any subcontractor or agent to which the DCC discloses DATA OWNER's Data, require such subcontractor or agent to limit its further use or disclosure of DATA OWNER's Data that such subcontractor or agent cannot feasibly return or destroy to those purposes that make the return or destruction of such information infeasible. The DCC will complete these obligations as promptly as possible, but not later than forty-five (45) days following the effective date of the termination or other conclusion of the Agreement. The DCC will ensure Data Users' compliance with the obligations of this Subsection 6.e.

f. Continuing Privacy and Security Obligation. The Parties' obligation to protect the privacy and safeguard the security of DATA OWNER's Data will be continuous and survive termination or other conclusion 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, the DCC, UNC-CSCC or DATA OWNER may amend this Agreement in such manner as the Party requesting the amendment determines is necessary to comply with such law or regulation. If a Party is unable to agree on an amendment within thirty (30) days thereafter, the Party requesting the amendment may immediately terminate this Agreement on written notice to the other Parties and other Data Owners.

8. **Sensitive Data**. The Parties hereby acknowledge that (a) all Parties and all other CODI-NC Data Owners who provide healthcare services may house PHI or other Confidential Information that is subject to HIPAA Regulations or other Applicable Law, (b) all Parties and all other Data Owners house Data that may be considered sensitive, (c) all Parties and all other Data Owners have an obligation under each of their separate CODI-NC Master Consortium Agreements to maintain the security and confidentiality of PHI and other Confidential Information that may be contained in the Data. Each Party agrees to comply with Applicable Law related to the confidentiality of Confidential Information, including, as applicable, the HIPAA Regulations. In addition, DATA OWNER acknowledges that DATA OWNER is solely responsible for obtaining any permissions necessary for DATA OWNER to Disclose PHI, PII and other Confidential Information to the DCC and UNC-CSCC under this Agreement.

9. **Compliance with IRB Requirements**. The Parties agree that the conditions for Requests and Use of Query Results are subject to the following:

    a. The DCC infrastructure and support activities provided by DUKE has been reviewed and approved by the CODI-NC IRB of Record (Exhibit F) in accordance with the Department of Health and Human Services regulations at 45 C.F.R. Part 46; and

    b. Each project requires IRB review and approval or exemption as non-human subjects research; and

    c. Approved Use of a Project Dataset as defined in the CODI-NC Front Door Request submission and project-specific IRB protocol and Data Use Agreement 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

    d. Changes to a project or Project Dataset require additional IRB review and approval and an amendment to project-specific Data Use Agreement between the DCC and the Data User.

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

11. **Addition of New Data Owners**. The Parties acknowledge and agree that new Data Owners may be added to the CODI-NC network by execution of a CODI-NC Master Consortium Agreement. Accordingly, an updated Exhibit A with new Data Owners may be updated from time-to-time, as necessary, and will be provided by the DCC to all current Data Owners.

12. **Notices.** Any notice required to be given the Parties hereunder 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:

As to the DCC (ORC physical address):
Duke University
Office of Research Contracts
Duke University – Erwin Square Plaza
2200 W. Main Street, Suite 1000
Durham, NC 27705
contracts.management@mc.duke.edu

With a copy:
Contracts Management
Duke Clinical Research Institute
300 W. Morgan Street, Suite 800
Durham, NC 27701
Phone: 919-668-8081

And to (ORC Campus Mailing Address:
Office of Research Contracts
Box Number 104025
Durham, NC 27710
Phone: (919) 681-0846
Fax: (919) 684-4595

As to UNC-CSCC:
Collaborative Studies Coordinating Center
The University of North Carolina
Gillings School of Global Public Health
123 W. Franklin Street, Suite 450, CB #8030
Chapel Hill, NC 27516
Phone: (919) 962-6971
Fax: (919) 962-3265
E-mail: csccmail@unc.edu

As to Data Owner:
[DATA OWNER NAME]
[ADDRESS]
[ADDRESS]
Phone: [INSERT]
Email: [INSERT]

13. **Applicable Law.** Each Party shall comply with Applicable Law as defined above in Section 1 (Definitions).

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 any Party may terminate this Agreement upon thirty (30) days' written notice to the other Parties and to the other Data Owners.

15. **Waiver**. The failure by a Party to enforce, at any time, any of the provisions of this Agreement, or to require at any time performance by another Party 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 Party or any other Party thereafter to enforce each and every provision in accordance with the terms of this Agreement or their separate and respective CODI-NC Master Consortium Agreements.

17. **Liability**. Each Party shall be responsible for its own negligent acts and omissions, including those of their respective officers, directors, employees and agents while performing their professional duties as set forth in this Agreement, as determined by a court of competent jurisdiction. Under no circumstances will any Party be liable to another Party for any indirect or consequential damages of any kind, including lost profits (whether or not a Party has been advised of such loss or damage) arising in any way in connection with this Agreement.

18. **Insurance**. Each Party shall maintain in force at its sole cost and expense with reputable insurance companies, insurance of a type and in an amount reasonably sufficient to protect against liability hereunder. In addition to such insurance and/or in the alternative, a Party may maintain a program of self-insurance to protect against the same. Each Party shall have the right to request the appropriate certificates of insurance from the other Parties for the purpose of ascertaining the sufficiency of such coverage.

18. **Relationship of the Parties and Data Owners**. The Parties acknowledge that all Parties to this Agreement are independent entities. Nothing in this Agreement shall be construed to create a partnership, agency relationship, or joint venture between and/or among the DCC, UNC-CSCC, DATA OWNER and/or the other Data Owners other than independent contractors. No Party shall have any authority to bind or make commitments on behalf of another Party or a Data Owner for any purpose, nor shall any Party hold itself out as having such authority. The Parties further acknowledge that neither the DCC nor UNC-CSCC is a business associate, as that term is defined in the HIPAA Regulations, of DATA OWNER.

19. **Use of Name**. No Party shall, without the prior written consent of the other Parties, use the name, trade name, trade mark, logo, symbol or other image of any other Party or of any Data Owner in any publicity release, policy recommendation, advertising, publications, abstracts or any commercial communication without the prior written authorization of the affected Party or other Data Owner. Notwithstanding anything herein to the contrary, the DCC shall have the right to use the CODI-NC initiative name, and to post individual CODI-NC project names for which DUKE is participating in the research, on DUKE's publically accessible lists of research conducted at DUKE and as may be required in submissions to funding agencies.

20. **Remedies**. Each Party acknowledges and agrees that money damages might not be a sufficient remedy for any breach of this Agreement by another Party. Therefore, in addition to all other remedies available at law (which no Party waives by the exercise of any rights hereunder), the non-breaching Parties 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 any Party without the prior written consent of the other Parties, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that DATA OWNER may assign its rights or delegate its obligations, without such consent, to (a) one or more of its affiliates ("**Affiliates**," as defined below), or (b) an entity other than a competitor of DATA OWNER that acquires all or substantially all of the business or assets of such DATA OWNER to which this Agreement pertains, whether by merger, reorganization, acquisition, sale, or otherwise by providing notice to the DCC and UNC-CSCC at the address set forth above in Section 12 (Notice) and to all Data Owners included in Exhibit A at the address posted on each of their respective publicly facing websites.

    a. As used in this Section 22, "Affiliate(s)" shall mean any entity that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with another entity. "Control" and, with correlative meanings, the terms "controlled by" and "under common control with" shall mean (i) the power to direct the management and or policies of an entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, resolution, regulation or otherwise, or (ii) to own fifty percent (50%) or more of the outstanding voting securities or other ownership interest of an entity.

[Separate Signature Page to Immediately Follow.]

IN WITNESS WHEREOF, the Parties hereto have entered into this Agreement as of the Effective Date.

DUKE UNIVERSITY	**[DATA OWNER's NAME]**
By:_____	By:_____
Name: Susan Hayden, JD	Name: _____
Title: Director, Research Program Collaborations Office of Research Contracts	Title: _____ _____
Date: _____	Date: _____

COLLABORATIVE STUDIES COORDINATING CENTER

By:_____

Name: _____

Title: _____

Date: _____

EXHIBIT A

Data Owners

Data Owner	**Institutional Lead and Primary Contact Person**	**Technical Lead**
Duke University Health System	Janis Curtis	Curtis Kieler
University of North Carolina, Chapel Hill	Suzanne Kennedy	Anna Jojic
YMCA of the Triangle	Gary Autrey	Mark Julian
Town of Chapel Hill	Monica Rainey	Scott Clark
City of Durham	Jason Jones	Rich Hahn
Durham County Health Department	Marissa Mortiboy	John Paul Zitta
North Carolina Coalition to End Homelessness	Brian Alexander	Andrea Carey
North Carolina Department of Health and Human Services, Division of Public Health, Women and Children's Health Section, Nutrition Services Branch, Special Supplemental Nutrition Program for Women, Infants and Children (WIC)	Mary Anne Burghardt	Jim Finley

EXHIBIT B

CODI Research Data Model Definitions

CODI Research Data Model

The CODI Research Data Model leverages existing tables from the PCORnet CDM; Observation Medical Outcomes Partnership ("**OMOP**") CDM; and adds ancillary tables to accommodate conceptual themes that do not exist in PCORnet CDM, or OMOP CDM.

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 an individual's reported address, at the geographic granularity that is permitted in an 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.
- **CONDITION (O):** This table includes information about reported conditions (e.g., code, code type, and source) as well as links to the encounter and provider, when available, that generated each CONDITION report. If any of an individual's conditions indicate a social determinant of health (e.g., food insecurity, housing insecurity) then it is highly recommended for inclusion in CODI.
- **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.
- **ENROLLMENT (R):** This table contains an individual's program enrollment, its date, and optionally, the program completion date, or description of circumstances under which an individual ended their program participation.
- **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.
- **IMMUNIZATION (O):** This table contains records of vaccinations that have been delivered within the health system as well as reports of those administered elsewhere.

- **LINKAGE (R):** This table includes the LINK_ID, which is an individual pseudo-identifier for use in cross-site individual matching and longitudinal record assembly, as described in Exhibit C.
- **PREGNANCY (O):** This table contains one record for each time an individual is pregnant. It stores information about the pregnant person and the circumstances of the pregnancy, such as the individual's BMI, use of tobacco, use of alcohol. This table consolidates pregnancy information that is otherwise found in multiple clinical and assessment records.
- **PREGNANCY OUTCOME (O):** This table contains one record for each infant resulting from a given pregnancy. It stores information about the individual(s) resulting from the pregnancy. It consolidates information about the child's height and weight at birth, breastfeeding, and exposure to tobacco.
- **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.
- **PRO_CM (R):** This table is used to store responses to patient-reported outcome measures (PROs) or questionnaires. This table can be used to store item-level responses as well as the overall score for each measure. This table is for storing individual-level SDOH screenings.
- **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 about health interventions specific to controlling or preventing chronic disease 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.
- **SDOH_EVIDENCE_INDICATOR (R):** This table contains information on whether evidence exists on an individual regarding social conditions that may determine that individual's health risks. The indicator also provides the location of that evidence in the CODI data model.
- **SESSION (R):** The SESSION table has two purposes. First, it captures details about an individual's visits to community health intervention programs (e.g., a physical activity intervention like a community-based exercise program or a housing intervention). 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, an individual'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.

CODI Record Linkage Data Model

CODI uses privacy preserving record linkage to protect anonymity so that CODI users can construct a longitudinal record of an individual's health and intervention activity from the information supplied by multiple data partners. CODI uses the individual-to-household linking to enable analysts to explore health and behavior correlations among household members.

The Record Linkage Data Model (RLDM) defines the data tables and data elements needed to perform the record linkage process. It includes two tables from the PCORnet CDM that contain unencrypted PII. Data owners temporarily populate those two tables in a secure repository and then apply a cryptographic hash function to generate deidentified hash bundles of the PII. This process is described in Exhibit C and in the CODI Privacy Preserving Record Linkage Implementation Guide.

The following is a list of the conceptual components of the RLDM:

- **PRIVATE_DEMOGRAPHIC (R):** This table includes the name, sex, and birthdate of an individual which is protected while the data owner uses it to generate an anonymous id for linking data from multiple owners.
- **PRIVATE_ADDRESS_HISTORY (R):** This table includes the best-known physical address for an individual which is protected while the data owner uses it to generate an anonymous household identifier and a corresponding Census areal unit (e.g., Census tract)
- **LINK (R):** This table includes the anonymous identifier used to link an individual's health and intervention information from across multiple data providers.
- **HOUSEHOLD_LINK (R):** This table includes the anonymous identifier used to link individuals to a common household.

Data Model Documentation

Detailed specifications for the CODI Research and Record Linkage Data Models are available in the Data Model Implementation Guide accessible here or by contacting the Data Coordinating Center. The Data Model Implementation Guide may be updated periodically.

Parameters of Data Contribution

Data shall be contributed from each Data Owner according to the following parameters:

- Historical Data beginning January 1, 2017 for individuals of all ages, or when first available to Data Owner
- 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 Owner
- Ongoing Data submissions at biannual intervals

EXHIBIT C

Record Linkage Process

In CODI, Privacy Preserving Record Linkage (PPRL) is the Record Linkage method used to link individual-level and household information across organizations. By using PPRL, CODI can perform this linkage without sharing personally identifiable information (PII) outside institutional boundaries. Once individual records are linked, information from the various records can be reconciled into a longitudinal record. This exhibit summarizes the PPRL process. Detailed descriptions of the PPRL process are available in the PPRL Implementation Guide: https://raw.githubusercontent.com/mitre/codi/main/CODI%20PPRL%20Implementation%20Guide.pdf.

Process Summary

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

1. A linkage agent shares configuration information with the data owners. The Key Escrow provides a secret "salt" value to the data owners. The salt value will be the same for all data owners.

2. Each data owner creates a de-identified data set of individuals by:
   - Extracting PII from its operational database.
   - Passing the PII and salt value through a hashing process that will garble the information.
   - Sharing the garbled data with the linkage agent.

3. The linkage agent develops individual LINKIDs by:
   - Determining which de-identified values correspond to the same individual.
   - Establishing a unique LINKID for each individual.

4. The linkage agent shares the LINKIDs with each data owner and deletes the individual Hash values following a quality assurance process.

5. Steps 2-4 are repeated for households, generating HOUSEHOLDIDs

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 Owners have

information about John Doe, they will Hash John Doe to the same value. The linkage agent 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 Owners have information about John Doe. To protect against this attack, a “salt”, or encryption secret, is added to the inputs before Hashing.

Step 1: Configuration Provided to Data Owners

For record linkage to be successful, every Data Owner needs to process PII in an identical manner. Thus, the first step in PPRL is for the linkage agent to communicate to the Data Owners the steps they will follow, including the set of attributes that will serve as inputs to Hashing, and the steps needed to normalize those attributes.

The salt is a randomly generated value provided as an extra input to the Hashing function to make the Hash deidentified. The salt must be transmitted securely by the Key Escrow to all Data Owners.

Step 2: Data Owners Generates Hash Values

Next, each Data Owner extracts PII from its operational data. The Data Owners 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 Record Linkage Data Model as represented in Exhibit B.

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

Finally, each Data Owner sends its collection of Hash values to the linkage agent.

Step 3: Linkage Agent Performs Matching

By comparing the Hash values across Data Owners, the linkage agent is able to determine which Hashes correspond to the same individual, and creates a new (arbitrary and unique) LINK_ID for each unique individual.

Step 4: LINK IDs Shared with Data Owners

Then, the linkage agent sends these results back to each Data Owner. This transmission maps each Data Owner's individual identifier to the globally unique LINK_ID. Each Data Owner stores its individuals' LINK_IDs in its local CODI-NC Datamart for use in future queries.

Step 5: Household Linkage

Finally, steps 2 through 4 are repeated for households, producing HOUSEHOLD IDs. This step is run separately from individual linkage as an additional means to reduce the risk of identifying the individuals being linked.

EXHIBIT D

Query Architecture, Longitudinal Record Assembly, and Data Reconciliation and Delivery

Query Architecture

The CODI architecture is a distributed data network where the DCC queries data across multiple Data Owners as if all data were stored in the same data warehouse. The distributed data network operates by gathering relevant data from the Data Owners using Queries and combining Query Results at the DCC for each Request.

Once a Query has been tested and agreed upon by the DCC, and necessary Data Use Agreements and IRB approvals are in place, the DCC distributes Queries using secure file transfer tools to the Data Owners. Data Owners, or the UNC-CSCC on behalf of some Data Owners, execute the query and approve results before returning results to the DCC, also through secure file transfer tools.

Query Results returned to the DCC may contain Personal Health Information (PHI) but not Personally Identifiable Information (PII). The types of queries permitted in CODI and the associated workflows are described in greater detail in Exhibit E. The DCC may distribute more than one Query to Data Owners before completion of a given project. The DCC will seek to minimize the number of Queries distributed for a given project while also minimizing the amount of PHI shared with the DCC.

Query Testing

Administrative, Prep, and Analytic Queries are tested using Test Queries (Exhibit E) prior to distribution to ensure accuracy and performance.

Project Dataset

The DCC combines Query Results from Data Owners into a Project Dataset in accordance with the applicable protocol and returns the Project Dataset to the Data User.

Unique Identifiers

The LINK_ID and HOUSEHOLD_ID assigned by the Linkage Agent are included with each individual record in the Query Results. The DCC uses the LINK_ID and HOUSEHOLD_IDs to merge Query Results across Data Owners. After merging Query Result, the DCC prevents disclosure of the LINK_ID or the HOUSEHOLD_ID to the Data User by replacing the LINK_ID with a project-specific PROJECT_ID and replacing the HOUSEHOLD_ID with a project-specific PROJECT_HOUSHOLD_ID.

Data Reconciliation

CODI facilitates the creation of individual longitudinal records for Data Users by gathering Data from multiple Data Owners. Data Users are responsible for transforming multiple records for an individual into a single unified view. The methods used to reconcile Data between records may

vary based on the question being answered. CODI recognizes that as a result of Record Linkage, the same individual may have conflicting birth dates, genders, or racial/ethnic groups which are time-invariant and recommends that Data Users deconflict these attributes in their Project Dataset prior to use.

De-identified Data and Data Products

For Requests where the Data User seeks to receive De-identified Data from a Request, the DCC can de-identify Individual-Level Data or create an aggregate Data Product that is de-identified. A description of desired De-identified Data or of an aggregate Data Product that is de-identified must be defined within the Request process. In the event of a Request for a Data Product, the DCC will, in consultation with applicable Data Owners, evaluate the need for a project-specific Data Use Agreement on a case-by-case basis.

Use Limitation

DCC shall Use Query Results solely for the purposes set forth in this Agreement. Data Users shall only use Project Datasets for the purposes set forth in the submitted Request, the project-specific DUA, and the IRB protocol.

Retention

Retention of Query Results and Project Datasets by the DCC and Data Users shall be as set forth in Section 6f (Retention) of the Agreement to which this Exhibit D is attached.

Minimum Necessary

For all Queries described here, DCC shall request the Minimum Necessary Data to fulfil the purpose of the Query and provide the Minimum Necessary Data to the Data User to fulfil the Request.

EXHIBIT E

Query Descriptions

The Queries issued by the DCC and referenced throughout this Agreement have the following definitions and associated requirements. Queries may only solicit Data as defined in Exhibit B of this Agreement. Queries are exclusively distributed through the Query Architecture described in Exhibit D.

1. **Administrative Queries:** Such Administrative Queries will seek return of Aggregate Query Results (for example, counts of individuals by age or counts of individuals receiving health care or services over time). The purpose of such Queries shall be administrative including but not limited to Data Curation to examine data quality and to inform the DCC of Data availability and fitness for use in response to CODI Requests. Administrative Queries include recurring Data Curation. Administrative Queries are unrelated to a Request and the results of Administrative Queries are not disclosed by the DCC to any external parties.

2. **Test Queries:** Such Test Queries are created by the DCC for approved CODI Requests and are tested for accuracy or performance at one or multiple Data Owners before being distributed. Test queries are also used to identify potential data quality issues that could impact the query structure and project. Test Queries may require the return of Aggregate Data or Individual-Level Data and may be shared back with that originating Data Owner for validation or data quality purposes. The Aggregate or Individual-Level Data created from Test Queries will not be shared with other Data Owners or Data Users.

3. **Prep Queries:** Such Prep Queries are created for approved CODI Requests which are categorized as Prep-to-Research or for project specific data curation, and require the return of Aggregate Query Results (for example, counts of individuals with a specific diagnosis or receiving a specific service). Prep Query Results are evaluated by the DCC may be shared with the Requestor. No small cells will be shared with the Requestor, as defined by Exhibit F. Because Prep Queries are a tool to evaluate the feasibility of a future project, no DUA or IRB approval is required and no identified or individual level data are shared with the Requestor.

4. **Analytic Queries:** Such Analytic Queries, which are created for approved CODI Requests, require the return of three types of Query Results:

    a. **Analytic Queries Requiring Return of a Limited Dataset:** These Analytic Queries include Queries Requiring Return of an Aggregate or Individual-Level Limited Dataset, as defined by HIPAA and this Agreement. Limited Datasets are permitted to contain limited PHI including encounter dates, birth dates, ages >90 years, five-digit zip codes, and census tracts.

    b. **Analytic Queries Requiring Return of De-Identified Individual-Level Data:** Queries seeking return of De-Identified Aggregate or Individual-Level Query Results, as defined by HIPAA in this Agreement.

    Query Results from Analytic Queries are aggregated across Data Owners and assembled as Project Datasets by the DCC and shared with the Data User.

EXHIBIT F

CODI Network and Data Use Policies

Decision-making Authority

The CODI-NC Governance Council ("GC"), which meets regularly and represents all Data Owners and the DCC, is the decision-making body for the CODI-NC. The DCC reports summary information about requests for CODI-NC data to the GC based on the policies for data use stipulated below.

CODI Data and Data Contribution

CODI Data

The data available for query through CODI-NC are data that can be housed within the CODI Research Data Model that is defined in Exhibit B of this Agreement. Data Owners populate the CODI Research Data Model based on availability and feasibility; thus, the completeness of Data within the CODI Research Data Model varies across Data Owners.

Approaches to Data Contribution

Data Owners include health care providers, social service organizations, health departments, municipalities, and community organizations who make their data available upon request through a query fulfilment process managed by the DCC. Data Owners maintain and host their own CODI-NC Datamart and data are extracted from the organization's source information system(s) to the CODI-NC Datamart and delivered to the DCC through secure file transport protocol.

UNC-CSCC may support Data Owners' CODI-NC participation by hosting their CODI-NC Datamart and responding to queries on their behalf. When using UNC-CSCC, the CODI-NC data partner, decisions regarding project participation will be made by the Data Owner, but the technical work of executing queries and transferring results will be conducted by UNC-CSCC. Data Owners will also be responsible for reviewing and approving results before UNC-CSCC releases them to the DCC. The Data Owners and UNC-CSCC will enter into a data sharing agreement which stipulates the parameters of data exchange and expectations around data management, data security, project-participation and communication.

Either approach to CODI-NC participation and Data contribution is permitted.

Requesting Data

Front Door

The CODI-NC Front Door is a publicly available website (www.CODINetworkNC.org) that is the primary point of access for interested parties to learn about the CODI-NC network and/or

initiate a Request for CODI-NC Data. To inform Requests, the Front Door contains information about the CODI-NC Data Models and the participating Data Owners.

Request Processing

Upon submission, the DCC acknowledges receipt of the Request within one business day via email. Requests are first evaluated by the DCC for feasibility, meaning if the request can be fulfilled by information available through the CODI-NC data model and for alignment with the CODI-NC goals and mission. During this evaluation, the DCC may hold a consultation with the Requestor to gather additional Request-related information. The DCC then categorizes the Request as a Prep Request or an Analytic Request based on the description in Exhibit E. Prep Requests are fulfilled by Prep Queries and Analytic Requests are fulfilled by Analytic Queries.

If the evaluation finds that a Request is not feasible or aligned with CODI-NC's mission, the Request is rejected by the DCC and the Requestor is notified immediately via email. If the Request is both feasible and aligned with the CODI mission, the Request proceeds towards Project status.

Next, a summary of the Request is circulated by the DCC to the CODI-NC network Data Owners for review and participation consideration. Data Owners are asked to respond with their intention to participate within a specific time period. Data Owners may request an extension to determine their intent to participate or more information from the DCC or Requestor about the Request. The request-specific time period is determined by the DCC based upon level of complexity, requirements of participating Data Owners, and end use of the data.

Data Owners then notify the DCC of their intent to participate in the Request via email and for those participating, identify an organizational lead. If >1 Data Owner agrees to participate, the Request proceeds. If only one Data Owner chooses to participate, the Request is deemed to have insufficient participation to move forward and the DCC connects the single interested Data Owner with the Requestor, and closes the Front Door request.

At this point in the process, the procedure advances based on request type.

Costs

Requesting data from CODI-NC can incur costs for the Requestor. This Exhibit D describes the process for requesting data but does not address the cost of fulfilling a data request or how funds are collected, allocated, or distributed.

Analytic Requests and Queries

The purpose of Analytic Queries is to retrieve all necessary data elements and records to address a research, evaluation, or surveillance question.

For Analytic Requests, the following actions occur. Upon receipt of >1 Data Owner participation responses, the Request transitions into a CODI-NC Project. The DCC notifies the Requestor about which Data Owners have agreed to participate in and that the Request will proceed into a

CODI-NC Project. The DCC then works with the Requestor to document specifications about the project, execute data use agreements, submit an IRB application, and develop a query to retrieve data from participating CODI NC network partners.

Prep Requests and Queries

The purpose of Prep Queries is to assess the feasibility of conducting a project and confirm that adequate data exists among participating Data Owners for the project to be completed. Prep queries return only aggregate de-identified counts, do not require a data use agreement under HIPAA, and do not require an IRB protocol, although individual institutions may require other forms of review.

Data Owners must choose to opt in to Prep request; only participating Data Owners will receive a Prep Query. If a Data Owner's local institution requires a different process for Prep Queries, the Requestor must work with that Data Owner and the DCC or to ensure that the site's requirements are satisfied before the Prep Query is fulfilled.

Prep Queries are initiated through the aforementioned Front Door, and if sufficient interest is expressed by Data Owners, the DCC works with the Requestor to understand and operationalize specifications about site-level stratification. Site level stratification may be permitted for aggregate results only with written approval by all participating Data Owners.

Prep Queries are sent only to Data Owners who have agreed to participate. Upon receipt of all Query Results, the DCC compiles and delivers aggregate results to the Requestor that provide an indication of the feasibility of their intended project, with interpretation and advice from the DCC regarding how to proceed. As aggregate results from Prep Queries are de-identified, they are permitted to be delivered via email.

Prep Queries do not include Record Linkage as individual level data is required and Prep Queries cannot return individual-level results. Thus, aggregate counts are non-deduplicated. The Requestor must work with the DCC to design a Prep Request that is reasonable in scope and not overly burdensome on the DCC or participating sites.

Results from Prep Queries must adhere to the small cell suppression policy defined below and are not permitted to be published in abstracts, reports, or publications but may be used in proposals.

Agreements and Regulations

Data Use Agreements

Data Use Agreements are required for all CODI-NC projects except Prep requests, regardless of the format or contents of the resulting Project Dataset. The purpose of the Data Use Agreement is to describe the nature of the partnership between CODI-NC and the Data User, define the parameters of data sharing, what data will be shared with the Data User, and how the Project Dataset may be used. Data Users may only use the Project Dataset obtained from CODI-NC for purposes identified in the Data Use Agreement.

CODI-NC implemented a reciprocal master consortium agreement which allows the CODI-NC master consortium agreement to serve as the Data Use Agreement when the Requestor is a CODI-NC Data Owner. Thus, CODI-NC Data Use Agreement requirements differ, dependent upon the Data User:

a) For a project when the Data User is not a Data Owner, a project-specific Data Use Agreement is required.

b) For a project when the Data User is a Data Owner, a project-specific Data Use Agreement is not required.

IRB

CODI-NC will use the Duke University Health System IRB (DUHS IRB) for most IRB governed activities. All CODI-NC projects require IRB review and approval or designation as non-human subjects research, granted by either the DUHS IRB of Record or an accredited IRB of the Data User's choice. Unless a Data User has an IRB of record, Duke School of Medicine will serve as the IRB of record.

The DCC has received approval for the CODI-NC technical infrastructure which should be referenced by researchers in project-specific protocols. Content from the DCC protocol and the approval letter are available upon request.

Small Cell Suppression

Small cell suppression is a method of protect individual privacy that is implemented on aggregate counts to reduce the risk of reidentification.

Though small cell counts are not considered PHI under HIPAA, small cell counts are sensitive and can pose a risk of reidentification.

CODI-NC defines small cells as any cell <11, excluding zero in accordance with the Centers for Medicaid and Medicare Services (CMS) small cell suppression policy. For cells where the value is zero, a zero may appear but for cells where the value is 1-10, a placeholder value such as '-' or '<11' should replace the cell's true value.

In CODI-NC, the small cell policy applies as follows:

1. When the DCC is sharing Results of a Prep Query with a Requestor, the DCC will suppress small cells prior to sharing Results with the Requestor.
2. When the DCC is sharing an individual-level Project Dataset with a Data User, Data Users must suppress small cells when creating data products or reporting exclusions. Data Users are legally bound to adhere to this small cell suppression policy as it is included in the CODI-NC Data Use Agreement template (Exhibit H) and may not be removed.
3. When the DCC is sharing an aggregate Project Dataset or resulting data product (e.g., map or summary report) with a Data User, Data Users must apply the small cell suppression policy when creating data products. Data Users are legally bound to adhere

to this small cell suppression policy as it is included in the CODI-NC Data Use Agreement template (Exhibit H) and may not be removed.

This small cell suppression policy is applicable to small cells representing individuals and households.

Data User Expectations

Identification and Engagement of Organizational Leads by Data User

Data Owners may appoint an organizational lead for each Analytic Request it participates in, for the purpose of ensuring accurate representation of contributed data. When an appropriate lead is unavailable or deemed unnecessary, Data Owners are permitted to waive their right to appoint a lead.

The Data User may engage organizational leads in the following project activities: informational review of data analytical findings, interpretation, presentations, reports, abstracts, and manuscripts.

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 and co-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 CODI Governance Council has the final say on who meets authorship criteria and what order authors appear. When approval of presentations, reports, abstracts, or publications is needed from coauthors, the Data User will allow at least ten business days for a response; if none is received within this timeframe, the Data User may proceed without approval.

Corporate Authorship

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.

Data Products and Reporting

DCC Reporting Requirements

The DCC will maintain a report that inventories all Front Door activity, including both approved and denied requests and ongoing and completed projects. The Front Door activity report will be shared with the GC on a routine basis, coinciding with GC meetings, and to CODI-NC Data Owners upon request. At the initiation of every project, Data Requestors assist the DCC in creating a plain language summary of the request. Each Request is labelled as planned, ongoing, or completed. At the completion of the project, key findings and conclusions are added to the project description and dissemination activities such as publications and presentations will be communicated by the Data User to the Data Coordinating Center for documentation, as noted in Data User Requirements below.

Data User Requirements

In accordance with protections of intellectual property, summary analytic findings and data products must be reported to the DCC and shared with the GC and participating Data Owners. Data Users are required to notify the DCC of any manuscripts accepted for publication and abstracts or papers accepted for presentation within 15 days of acceptance.

Data Analyses Results

Identification of Data Owners in Data Analyses Results

Data Users are not required to identify participating Data Owners in project publications and presentations. Identification can occur in various sections of a publication or presentation: an acknowledgement, description of methods or project population, presentation of results (e.g., tables and figures), or discussion of findings. For each project and when necessary, Data Users are required to work with the DCC to request and secure permission from participating Data Owners in writing, to name in publication or presentation sections.

Acknowledgements in Publications and Presentations

Data Users are required to formally acknowledge the CODI-NC network in all publications and presentations resulting from the analyses of Project Datasets. The following acknowledgement language is recommended:

"*The authors acknowledge the contribution of the CODI-NC network and participation of CODI-NC data owners: [name all participating health systems] in this project. This network is supported in part by XXXXXXXX"*

TEMPLATE v1.0

EXHIBIT G

CODI-NC Data Use Agreement (DUA) Template

This CODI-NC Data Use Agreement ("**Agreement**") is entered into as of the date of the last signature below ("**Effective Date**") by and between Duke University, a tax-exempt, research and educational institution located in Durham, North Carolina, acting for an on behalf of its Duke Clinical Research Institute ("**DUKE**"),
_____[INSERT DATA OWNER NAME]____ located at ___[INSERT CITY and STATE]__,
_____[INSERT DATA OWNER NAME]____ located at ___[INSERT CITY and STATE]__,
_____[INSERT DATA OWNER NAME]____ located at ___[INSERT CITY and STATE]__,
_____[INSERT DATA OWNER NAME]____ located at ___[INSERT CITY and STATE]__,
_____[INSERT DATA OWNER NAME]____ located at ___[INSERT CITY and STATE]__,
_____[INSERT DATA OWNER NAME]____ located at ___[INSERT CITY and STATE]__
("**DATA OWNER(s)**") and ____[INSERT NAME]___ ("**Data User**" and "**RECIPIENT**") located at ___[INSERT CITY and STATE]___herein). DUKE, DATA OWNER(s) and RECIPIENT are referred to hereinafter individually as the "**Party**" and together as the "**Parties**."

WHEREAS, DUKE, in its role as the Data Coordinating Center ("**DCC**") for the Clinical and Community Data Initiative of North Carolina ("**CODI-NC**"), is in possession of certain human subject research data received from DATA OWNER(s), CODI-NC member health care, community or municipal organizations, who have agreed to share their patient health information in response to a CODI-NC query pursuant to the terms of a 3-party CODI-NC Master Consortium Agreement ("**CODI-NC MCA**") entered into separately by and between DUKE, the Collaborative Studies Coordinating Center ("**UNC-CSCC**") and each Data Owner;

WHEREAS, RECIPIENT has requested and received, where required by law or institutional policy, approval from an Institutional Review Board ("**IRB**") for receipt of such patient health information for the purpose described in the "CODI-NC Data Request Form" attached hereto as Schedule 1 (the "**Purpose**"):

WHEREAS, under the direction of DATA OWNER(s), DUKE is providing a CODI-NC dataset produced by DUKE in its capacity as the CODI-NC Data Coordinating Center, resulting from aggregation, merging and/or reconciliation of query results from DATA OWNER(s) (a "**Project Dataset**") to RECIPIENT in the form of:

- ❑ a De-identified Dataset or Data Product containing no individual patient identifiers, which is not subject to the requirements of HIPAA (as defined below); or

- ❑ a Limited Dataset of Protected Health Information ("**PHI**") (as defined in HIPAA), so that RECIPIENT is a "Limited Dataset Recipient" as defined in HIPAA, and is therefore subject to the requirements of HIPAA;

for the Purpose(s) identified in paragraphs 4 and 5 of the "CODI-NC Project Data Request Form" attached hereto as **Schedule 1**, in accordance with the requirements set forth in "Definition of Data (CODI Research Data Model)" attached hereto as **Schedule 2**, and as specified in the "Data Extraction Description and Variable List attached hereto as **Schedule 3**.

NOW THEREFORE, the Parties agree to the provisions of this Agreement in order to address the requirements of HIPAA, as applicable, to protect the interest of both Parties, and to comply with the terms of the CODI-NC MCA and CODI-NC Policies.:

1. **DEFINITIONS**. Except as otherwise defined herein, any and all capitalized term used in this Agreement and not otherwise defined, shall have the meaning set forth in the Health Insurance Portability and Accountability Act of 1996, as amended ("**HIPAA**"). In the event of any inconsistency between the provisions of this Agreement and mandatory provisions of HIPAA, the HIPAA provisions shall control. Where provisions of this Agreement are different from those provided in HIPAA, but are permitted by HIPAA, the provisions of this Agreement shall control.

    a. "Applicable Law" means all applicable Federal, state and local statutes, regulations, standards, guidelines and policy requirements including, without limitation, HIPAA Regulations, applicable provisions of the Special Supplemental Nutrition Program for Women, Infants and Children ("**WIC**") regulations published at 7 CFR Part 246, and all requirements imposed by legally constituted IRBs.

    b. "Confidential Information" means any information about an individual subject, regardless of how obtained, that identifies directly or can be used to indirectly identify an individual subject. Confidential Information includes all DATA OWNER(s)' data (except aggregate data and data de-identified in accordance with HIPAA requirements), personally identifiable information ("**PII**"), Protected Health Information ("**PHI**," as the same is defined in HIPAA) individual subject identifiers, individual-level data that has not been de-identified, and any unique ID, identifier or code related to or derived from an existing Individual Identifier that can be used to re-identify an individual subject.

2. **HIPAA APPLICABILITY**. The Parties acknowledge and agree that if the Project Dataset contains no PHI, then its use and disclosure is not subject to the requirements of HIPAA. The Parties further acknowledge and agree that if the Project Dataset contains PHI, then its use and disclosure is subject to the applicable requirements of HIPAA.

3. **USE OR DISCLOSURE**. RECIPIENT shall have the right to use and disclose all PHI and other Confidential Information provided to it by DUKE and DATA OWNER(s) for the CODI-NC-approved Purpose(s) outlined in Schedule 1, and in the format specified in the Data Definition (CODI Research Data Model) attached hereto as Schedule 2.

4. **OWNERSHIP**. DATA OWNER(s) retain all rights, title, and interest in their respective (a) operational data included as part of the Project Dataset disclosed by DUKE and DATA OWNER(s) to RECIPIENT, (b) as applicable, the CODI-NC Datamart, which is the database created by, or for, a Data Owner containing individual-level data without Personally Identifiable Information in accordance with the CODI Research Data Model, and (c) CODI-NC query results submitted by DATA OWNER(s) to the DCC. DUKE, as the DCC, retains all right, title, and interest in the CODI-NC-approved Project Dataset(s) sent by the DUKE to RECIPIENT to the extent they contain any results, data, or analyses generated from DUKE's management of CODI-NC query results. The Parties hereto acknowledge that DATA OWNER(s) and the other Data Owners have granted DUKE a royalty-free, limited license to use DARA OWNER(s)' and other Data Owners' query results in connection with

the management of query results and CODI-NC-approved Project Datasets consistent with the purposes of this Agreement.

5. **COMPLIANCE**. RECIPIENT shall comply with all applicable federal, state and local laws, rules and regulations relating to the maintenance of the Project Dataset, the safeguarding of the confidentiality of PHI, all other Confidential Information contained in a Project Dataset, and the Use and Disclosure of the Project Dataset.

6. **RESTRICTIONS ON USE**. RECIPIENT agrees that it, and any employees, agents, subcontractors and all Project Team Members identified in Schedule 1 to whom it discloses the Project Dataset and any PHI or other Confidential Information contained therein, shall Use and Disclose the Project Dataset, PHI and other Confidential Information only for the Purpose(s) identified in Schedule 1, as otherwise required by law, and for no other purpose. RECIPIENT will ensure that its employees and representatives comply with the terms and conditions of this Agreement, and ensure that its agents, Business Associates and subcontractors to whom RECIPIENT provides the Project Dataset agree to comply with the same restrictions and conditions that apply to RECIPIENT hereunder. RECIPIENT shall not provide the Project Dataset to any third party.

7. **NO RE-IDENTIFICATION**. RECIPIENT shall not attempt to re-identify the individuals or households contained in the Project Dataset, nor contact any of the individuals whose information is contained in the Project Dataset. RECIPIENT shall not identify or attempt to identify the other Data Owners from whom the Project Dataset originated, unless identification of a Data Owner has been agreed to by that Data Owner in writing.

8. **LIABILITY**. RECIPIENT shall be responsible for the negligent acts and omissions of its Project Team Members, employees and agents, to the extent allowed by law.

9. **DATA SECURITY**. RECIPIENT shall employ appropriate safeguards to prevent the Use and Disclosure of the Project Dataset, PHI other Confidential Information, other than for a Use or Disclosure expressly permitted by this Agreement. Regardless of whether the Project Dataset contains PHI, all data disclosed by DUKE shall be maintained by RECIPIENT under appropriate administrative, physical and technical safeguards, including encryption while in transit, to protect the confidentiality and integrity of the Project Dataset, and its electronic and physical security from misuse or inappropriate disclosure. RECIPIENT shall use all reasonable measures to prevent any Use or Disclosure of the Project Dataset other than as provided in this Agreement, and shall protect the Project Dataset in strict confidence in the same manner as it would protect its own confidential information.

10. **TRANSMISSION OF PROJECT DATASET**. Transmission of the Project Dataset shall be through the Duke virtual private network ("**VPN**"), encrypted email or Duke Box. Any RECIPIENT access to DUKE's network may only be made using DUKE-approved secure remote access. RECIPIENT agrees to only access the DUKE network using DUKE-provided solutions. All RECIPIENT activities during remote access may be monitored by DUKE.

11. **TERM**. This Agreement shall commence on the Effective Date and continue in effect for as long as RECIPIENT retains the Project Dataset or until otherwise terminated in accordance

with Section 12 below, or as required by law or regulation. RECIPIENT shall not retain the Project Dataset beyond the "Expected Project End Date" set forth in Schedule 1, without first executing a written amendment to extend the term with all parties to this Agreement.

12. **TERMINATION**. DUKE or DATA OWNER(s) may terminate this Agreement and any disclosures of PHI or Confidential Information pursuant hereto, upon ten (10) days' notice to RECIPIENT, if RECIPIENT violates or breaches any material term or condition of this Agreement. DUKE or DATA OWNER(s) may terminate this Agreement without cause upon thirty (30) days' written notice RECIPIENT. Upon termination, RECIPIENT shall promptly return or dispose of the Project Dataset received from DUKE in connection with the Purpose identified on Schedule 1. If return or disposal of the Project Dataset is not feasible, RECIPIENT shall continue the protections required under this Agreement for the Project Dataset consistent with the requirements of this Agreement, HIPAA privacy standards and Applicable Law. If RECIPIENT ceases to do business or otherwise terminates its relationship with DUKE and/or DATA OWNER(s), RECIPIENT agrees to promptly return or dispose of all information contained in the Project Dataset received from DUKE and DATA OWNER in a timely manner.

13. **REPORTING**. RECIPIENT shall promptly report to DUKE and DATA OWNER(s) any Use or Disclosure of the Project Dataset not provided for in this Agreement of which RECIPIENT becomes aware, regardless of whether the Project Dataset contains PHI. RECIPIENT will take reasonable steps to limit any further such Use or Disclosure. Should RECIPIENT commit a material breach of this Agreement, which is not cured within thirty (30) days after RECIPIENT receives notice of such breach from DUKE or DATA OWNER(s), then DUKE and/or DATA OWNER(s) will discontinue disclosure of PHI and DUKE may report the breach to the Secretary, Department of Health and Human Services.

14. **GOVERNING LAW AND VENUE**. This Agreement shall be governed by the laws of the State of North Carolina. Venue for any claim, action or suit, whether state or federal, between RECIPIENT, DUKE and DATA OWNER(s) shall be Durham County, North Carolina.

15. **RETENTION**. Unless the Project Dataset is returned or destroyed earlier pursuant to Section 12 (Termination), RECIPIENT agrees to retain Project Datasets for the duration of the period set forth in the policies and procedures of the Institutional Review Board of record (the "**Retention Period**"), or for five (5) years from the Effective Date of this Agreement. At the end of the Retention Period, RECIPEINT shall dispose of the Project Dataset in accordance with the HIPAA Security Rule and provide written verification of its disposal to DUKE, DATA OWNER(s) or, at the specific written request of DUKE or DATA OWNER(s), return the Project Dataset.

[NEXT PAGE IS SIGNATURE PAGE]

IN WITNESS WHEREOF, the Parties hereto have entered into this Agreement as of the Effective Date.

DUKE UNIVERSITY

By:_____

Name: Susan Hayden, JD

Title: Director, Research Program Collaborations
Office of Research Contracts

Date: _____

[RECIPIENT's NAME]

By:_____

Name: _____

Title: _____
_____

Date: _____

[DATA OWNER's NAME]

By:_____

Name: _____

Title: _____

Date: _____

[DATA OWNER's NAME]

By:_____

Name: _____

Title: _____

Date: _____

[DATA OWNER's NAME]

By:_____

Name: _____

Title: _____

Date: _____

[DATA OWNER's NAME]

By:_____

Name: _____

Title: _____

Date: _____

[DATA OWNER's NAME]

By:_____

Name: _____

Title: _____

Date: _____

[DATA OWNER's NAME]

By:_____

Name: _____

Title: _____

Date: _____

SCHEDULE 1

CODI-NC Project Data Request Form

1. **Date of Full Execution (Effective Date)**: _____
2. **Expected Project End Date**: _____

2. **Name of DUKE Individual/Dept. Releasing Project Dataset:** _____

3. **Name of RECIPIENT Individual Receiving Dataset:** _____

4. **Purpose of Project Dataset Disclosure**: _____

_____

_

_____

_

5. **Project Request Title**: _____

_____

_

6. **Principal Investigator**: _____
7. **Request Type**:
   - o Research
   - o Public Health Surveillance
   - o Evaluation
   - o Other
8. **IRB #:** _____
9. **Individuals at the Recipient organization ("Project Team Members") who will have access to the Dataset include:** _____

_____
_
_____
_
_____
_
_____
_

Schedule 2

Definition of Data (CODI Research Data Model)

The CODI Research Data Model leverages existing tables from the PCORnet CDM; Observation Medical Outcomes Partnership ("OMOP") CDM; and adds ancillary tables to accommodate conceptual themes that do not exist in PCORnet CDM, or OMOP CDM.

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 individual's reported address, at the geographic granularity that is permitted in an 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.
- **CONDITION (O):** This table includes information about reported conditions (e.g., code, code type, and source) as well as links to the encounter and provider, when available, that generated each CONDITION report. If any of an individual's conditions indicate a social determinant of health (e.g., food insecurity, housing insecurity) then it is highly recommended for inclusion in CODI.
- **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.
- **ENROLLMENT (R):** This table contains an individual's program enrollment, its date, and optionally, the program completion date, or description of circumstances under which an individual ended their program participation.
- **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.
- **IMMUNIZATION (O):** This table contains records of vaccinations that have been delivered within the health system as well as reports of those administered elsewhere.
- **LINKAGE (R):** This table includes the LINK_ID, which is an individual pseudo-identifier for use in cross-site individual matching and longitudinal record assembly, as described in "Exhibit C".
- **PREGNANCY (O):** This table contains one record for each time an individual is pregnant. It stores information about the pregnant person and the circumstances of the pregnancy, such as the individual's BMI, use of tobacco, use of alcohol. This table consolidates pregnancy information that is otherwise found in multiple clinical and assessment records.
- **PREGNANCY OUTCOME (O):** This table contains one record for each infant resulting from a given pregnancy. It stores information about the individual(s) resulting from the pregnancy. It consolidates information about the child's height and weight at birth, breastfeeding, and exposure to tobacco.
- **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.
- **PRO_CM (R):** This table is used to store responses to patient-reported outcome measures (PROs) or questionnaires. This table can be used to store item-level responses as well as the overall score for each measure. This table is for storing individual-level SDOH screenings.
- **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 about health interventions specific to controlling or preventing chronic disease 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.
- **SDOH_EVIDENCE_INDICATOR (R):** This table contains information on whether evidence exists on an individual regarding social conditions that may determine that individual's health risks. The indicator also provides the location of that evidence in the CODI data model.

- **SESSION (R):** The SESSION table has two purposes. First, it captures details about an individual'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, an individual'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.

2. Detailed specifications for the CODI Research Data Model are available in the Data Model Implementation Guide accessible here or by contacting the Data Coordinating Center. The Data Model Implementation Guide may be updated periodically.

3. Data shall be contributed according to the following parameters:

- Historical Data beginning January 1, 2017 for individuals of all ages, or when first available to Data Owner
- 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 Owner
- Ongoing Data submissions at biannual intervals

SCHEDULE 3

Data Extraction Description and Variable List
For [INSERT REQUEST TITLE]

Description of Data Extraction Process and Criteria

Table 1. CODI Data Model Data Elements requested By Table

TABLE	VARIABLES REQUESTED
ALERT	
ASSET DELIVERY	
CENSUS_LOCATION	
CENSUS_DEMOG	
COST	
DEMOGRAPHIC	
DIAGNOSIS	[Specify diagnosis types, codes, and codesets including sources]
ENCOUNTER	
ENROLLMENT	
FAMILY_HISTORY	
IMMUNIZATION	
LAB_RESULT	[Specify lab types]
PREGNANCY	
PREGNANCY_OUTCOME	
PRESCRIBING	[Specify medication types, codes, and codesets including sources]
PROCEDURES	[Specify procedure types]
PRO_CM	
PROGRAM	
SDOH_EVIDENCE_INDICATOR	
SESSION	
SESSION_ALERT	
VITAL	[Description of any calculated variables needed]

Schedule 4

Analysis Plan for Request Entitled, “REQUEST NAME”

[Must include specific research questions and planned analysis methods for each question]

Schedule 5 Responsible Use of CODI Data

The Responsible Use of CODI Data Agreement defines the expectations of a Data User, as a recipient of a CODI Project dataset from DCC, and the limitations on the Use of that Project 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 project 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. As a recipient of the dataset from CODI, the Recipient understands that they are responsible for using the dataset appropriately, and for ensuring that all individuals with access to the dataset 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 Dataset are detailed in Schedule 1 of this Agreement.

All individuals with access to the CODI dataset agree to the following:

- I have accurately and thoroughly described the project and the intended use of the project data in the CODI Request and IRB protocol.
- I acknowledge that DCRI is the Data Coordinating Center (DCC) for CODI and will direct any notifications and requests for approvals to DCRI on behalf of CODI.
- I have read and agree to comply with all of the terms and conditions in this Data Use Agreement.
- I will only use the dataset for the approved project described in the Project Description section of in the approved CODI Project Intake form, the approved IRB protocol, and appropriate agreement for my project.
- If I wish to use the dataset for further analyses or studies, I will obtain written agreement from the DCRI, on behalf of CODI for these additional uses.
- I will not disclose the dataset to anyone who is not specified as a permitted individual (listed in Schedule 1), including, but not limited to, peer reviewers, data archiving sites, or similar scientific groups, without prior permission from DCRI on behalf of CODI unless required to by law.

- I will not attempt to re-identify or contact any individual through use of the dataset, or by combining it with any other data, except as provided for in the CODI approved project protocol.
- I will store the 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 dataset, I will notify DCRI within 24 hours and will cooperate with DCRI to limit the harm done.
- I will acknowledge in data products that rely on the dataset the contribution made by CODI and its Data Owners.
- I will provide to the DCC a copy of summary analysis results and all data products including but not limited to publications, abstracts, and report so CODI can meet its archiving obligations to its sponsors and Data Owners.