Research Action for Health Network (REACHnet) Master Data Sharing and Use Agreement

This Research Action for Health Network (REACHnet) Master Data Sharing and Use Agreement (the "Agreement"), effective as of the 1st day of April, 2018 (the "Effective Date"), is entered into by and among the Louisiana Public Health Institute ("LPHI"), as administrator of the Research Action for Health Network ("REACHnet") and the entities listed in Exhibit A (each a "Participant" and collectively the "Participants"), individually referred to as "Party" and together referred to as the "Parties".

Recitals

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

WHEREAS, PCORI created a large, highly representative, national network for conducting clinical outcomes research, known as the National Patient-Centered Clinical Research Network ("PCORnet"), which is made up of Clinical Data Research Networks ("CDRNs"), which are research networks based on healthcare delivery systems, and Patient Powered Research Networks ("PPRNs"), which are groups of patients that form a research network and participate in research, designed to transform clinical research by engaging patients, care providers and health systems in collaborative partnerships that leverage health data to advance medical knowledge and improve health care by creating a "network of networks" that harnesses the power of large amounts of health information and unique partnerships among patients, clinicians, health systems and others; and

WHEREAS, LPHI is the recipient of PCORI funding to establish REACHnet; and

WHEREAS, LPHI is responsible for operation of REACHnet and thus serves as the REACHnet Coordinating Center; and

WHEREAS, LPHI has previously executed the PCORnet Coordinating Center Data Sharing Agreement in order to clarify its responsibilities with respect to the sharing of data by LPHI on behalf of Participants as part of PCORnet; and

WHEREAS, the PCORnet Coordinating Center Data Sharing Agreement reflects that PCORI has contracted with Duke Clinical Research Institute ("Duke") to manage and coordinate PCORnet as a coordinating center, and Duke has subcontracted with Harvard Pilgrim Health Care Institute, LLC ("HPHCI") to serve as a co-coordinating center with Duke (Duke and HPHCI are together referred to as the "PCORnet Coordinating Center"); and

WHEREAS, the Parties seek to enter into this Agreement in order to describe and clarify their responsibilities with respect to the sharing of data by each Participant with LPHI, other Participants, and Research Partners for the purposes set forth in this Agreement; and

WHEREAS, Participant will provide certain data to LPHI as described herein (collectively the "Data"), across a secure network to be shared among Participants and with Research Partners, for research subject to the terms and conditions set forth herein; and

WHEREAS, LPHI and the Participants agree to limit their use of the Data in accordance with the terms of this Agreement and the HIPAA Regulations.

NOW, THEREFORE, in consideration of the mutual promises contained herein, and of the mutual benefit to be derived hereunder, the 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** shall mean aggregated, De-identified Data across specified strata of individuals. For example, counts of patients within a stratum that includes a particular age group, gender, and diagnosis. Aggregate Data does not include Individual Level Data.
    b. **Applicable Law** shall mean all applicable state and Federal statutes, regulations, standards and policy requirements.
    c. **Authorized Users** shall mean LPHI staff, representatives, agents and/or contractors who have been granted access to Participant Data by LPHI in accordance with Applicable Law and the minimum standards set forth in this Agreement.
    d. **Data** shall have the definition in Exhibit B, subject to Participants' ability to provide data elements outside of the PCORnet Common Data Model, as may be amended from time to time to include additional Limited Data Sets or identifiable Individual Level Data as required for specific research studies, upon approval of Participants through an amendment to this Agreement and based on Participants' ability to provide the additional data elements. This information includes, but is not limited to, Protected Health Information (PHI), De-identified Data (as defined in the HIPAA Regulations at 45 C.F.R. § 164.514), Individual Level Data, pseudonymized data, metadata, digital credentials, and schema.
    e. **Data Query** shall mean a query of Participant Data as set forth in Section 4 and Exhibit D of this Agreement.
    f. **De-identified Data** shall have the meaning ascribed to it in the HIPAA Privacy Rule at 45 C.F.R. Section 164.514(a). Processes for de-identifying data are set forth in 45 C.F.R. Section 164.514(b) of the HIPAA Privacy Rule.
    g. **Health Care Provider** shall have the meaning set forth at 45 C.F.R. § 160.103 of the HIPAA Regulations.
    h. **Health Plan** shall have the meaning set forth at 45 C.F.R. § 160.103 of the HIPAA Regulations.
    i. **HIPAA Regulations** shall mean the Standards for Privacy of Individually Identifiable Health Information and the Security Standards for the Protection of Electronic Protected Health Information (45 C.F.R. Parts 160 and 164) promulgated by the U.S. Department of Health and Human Services under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, as in effect on the Effective Date of this Agreement and as may be amended, modified, or renumbered.
    j. **Individual Level Data** shall mean Data that are not Aggregate Data. Individual Level Data contains information that is specific to individual patients. Individual Level Data may or may not be De-Identified Data.
    k. **Limited Data Set** shall have the meaning ascribed to it in the HIPAA Privacy Rule at 45 C.F.R. Section 164.514 (e).
    l. **Minimum Necessary** shall have the meaning ascribed to it in the HIPAA Privacy Rule at 45 C.F.R. Section 164.514(d).
    m. **Notice or Notification** shall mean a written communication, unless otherwise specified in this

Agreement, sent to the appropriate Party's representative at the address listed in Section 11 herein.

n. **Participant Data Recipient**: Participant that receives other Participant Data pursuant to Section 4 of this Agreement.

o. **PCORnet Common Data Mode**l shall mean the data standardization model implemented by PCORnet and required for all Clinical Data Research Networks, as further described in Exhibit B, and amended from time to time.

p. **Permitted Purposes** shall mean:

   i. Research, only as approved by the sharing Participant in accordance with Section 4.

   ii. LPHI administrative usage, including but not limited to system upgrades, system development, system optimization, system testing, quality, auditing, Data integration, Data processing, Data optimization, Data storage (including back-ups for redundancy), Data quality assurance, Data validation, Data characterization, and Data standardization, if and to the extent, and only to the extent, that such administrative usage is for the purpose of "research" as that term is used in 45 C.F.R. § 164.514(e)(3).

   iii. Data sharing pursuant to Section 4 below, if and to the extent, and only to the extent, that such parameters are for the purpose of "research" as that term is used in 45 C.F.R. § 164.514(e)(3).

q. **Research Partners** shall mean institutions involved in the conduct of research as defined at 45 C.F.R. § 64.10 of the HIPAA Regulations, including but not limited to PCORI, the PCORnet Coordinating Center, PCORnet Clinical Data Research Networks, PCORnet Patient Powered Research Networks, and health plans.

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. Participant Data Contribution Requirements.

   a. Participant shall provide Data to LPHI and its Authorized Users in the requisite format as set forth in Exhibit B, subject to Participants' ability to provide data elements outside of the PCORnet Common Data Model, in accordance with the HIPAA Regulations. LPHI may use Data solely for Permitted Purposes, and shall not use or disclose the Data other than as permitted hereunder or as otherwise required by Applicable Law.

   b. Participant will generate the hash bundles necessary for the Global Patient ID generation and patient deduplication process as set forth in Exhibit C or utilizing a comparable method as approved by the REACHnet Coordinating Center.

4. Data Sharing Parameters.

   a. Each new data query pursuant to which LPHI, as administrator of REACHnet, shares Participant's Data with other Participants and/or Research Partners shall

      i. Be in accordance with the REACHnet Research Participation Policy, which is attached as Exhibit E of this Agreement and may be updated from time to time, upon approval by the REACHnet Governance Board (Co-Principal Investigator Group) through a majority vote; Depending on the type of study, require Participant Co-Principal Investigator or designee participation approval and/or the express written

consent of the sharing Participant for data release, which may be provided via email by the Participant Co-Principal Investigator or designee, unless such express written consent is waived as set forth in the REACHnet Research Participation Policy and summarized in this section

1) Prospective studies, for which Co-Principal Investigator or designee approval must be provided for study participation and for which written consent is waived for data release
2) Retrospective studies, for which Co-Principal Investigator or designee approval must be provided for study participation and for which written consent is waived for data release.
3) Prep to analysis (PTA) queries, for which Co-Principal Investigator or designee approval for participation must be provided and for which written consent for data release is required.
4) Pre-prep to research (pPTR) queries for which Co-Principal Investigator or designee approval for participation is not required and for which written consent is waived for data release.
5) Prep to research (PTR) queries, for which Co-Principal Investigator or designee participation approval is not required and a response by the Participant Co-Principal Investigator or designee regarding data release is only necessary if Participant is opting out of sharing data for the query.

ii. Be in accordance with Participant's express written consent, as applicable, this Agreement, and Applicable Law, and be supported by the appropriate Institutional Review Board (IRB) approvals, if applicable.

b. LPHI may share Participant's Data with other Participants without requiring an additional Data Query-specific data sharing and use agreement for the following types of Data Queries, as further defined in Exhibit D.
   i. Analytic Queries Requiring Return of Aggregate Data
   ii. Analytic Queries Requiring Return of De-Identified Individual Level Data
   iii. Analytic Queries Requiring Return of a Limited Data Set that includes only the Data covered in Exhibit B of this agreement

c. LPHI may share Participant's Data with other Participants, pursuant to a Data Query-specific data sharing and use agreement executed by LPHI, applicable Participant(s) and applicable Participant Data Recipient(s), for the following types of Data Queries, as further defined in Exhibit D.
   i. Analytic Queries Requiring Return of a Limited Data Set that includes data elements outside of the Data covered in Exhibit B of this Agreement
   ii. Analytic Queries Requiring Return of Identifiable Individual Level Data

d. LPHI may share Participant's Data with the PCORnet Coordinating Center (Duke Clinical Research Institute and Harvard Pilgrim Health Care Institute, LLC), pursuant to the PCORnet Coordinating Center Data Sharing Agreement, executed by LPHI on behalf of Participants, without requiring an additional Data Query-specific data sharing and use agreement for the following types of Data Queries, as further defined in Exhibit D:
   i. Administrative Queries
   ii. Analytic Queries Requiring Return of De-Identified Aggregate Data
   iii. Analytic Queries Requiring Return of De-Identified Individual Level Data

e. LPHI may share Participant's Data with the PCORnet Coordinating Center (Duke Clinical Research Institute and Harvard Pilgrim Health Care Institute, LLC), pursuant to the PCORnet Coordinating Center Data Sharing Agreement, executed by LPHI on behalf of Participants, and pursuant to LPHI's and PCORnet Coordinating Center's execution of a Data Query-specific data sharing and use agreement based on a template, attached as a sample in Exhibit G, for the following types of Data Queries, as further defined in Exhibit D:
    i. Analytic Queries Requiring Return of a Limited Data Set that includes the Data covered in Exhibit B of this agreement

f. LPHI may share Participant's Data with the PCORnet Coordinating Center (Duke Clinical Research Institute and Harvard Pilgrm Health Care Institute, LLC), pursuant to the PCORnet Coordinating Center Data Sharing Agreement, executed by LPHI on behalf of Participants, and pursuant to LPHI's execution of a Data Query-specific data use agreement with the PCORnet Coordinating Center and Participant(s), for the following types of Data Queries, as further defined in Exhibit D:
    i. Analytic Queries Requiring Return of a Limited Data Set that includes data elements outside of the Data covered in Exhibit B of this agreement
    ii. Analytic Queries Requiring Return of Identifiable Individual Level Data

g. LPHI may share Participant's Data with Research Partners, pursuant to LPHI's and applicable Research Partners' execution of a Data Query-specific data sharing and use agreement based on a template, attached as a sample in Exhibit G, for the following types of Data Queries, as further defined in Exhibit D.
    i. Analytic Queries Requiring Return of De-Identified Aggregate Data
    ii. Analytic Queries Requiring Return of De-Identified Individual Level Data
    iii. Analytic Queries Requiring Return of a Limited Data Set that includes only the Data covered in Exhibit B of this agreement

h. LPHI may share Participant's Data with Research Partners, pursuant to LPHI's execution of a Data Query-specific data use agreement with the applicable Research Partner(s) and Participant(s), for the following types of Data Queries, as further defined in Exhibit D.
    i. Analytic Queries Requiring Return of a Limited Data Set that includes data elements outside of the Data covered in Exhibit B of this agreement
    ii. Analytic Queries Requiring Return of Identifiable Individual Level Data

i. **Test Queries**: From time to time, LPHI may issue test queries (each a "Test Query") of Participant Data in advance of an Administrative or Analytic Query seeking return of either Aggregate Data, a Limited Data Set, or Protected Health Information other than in a Limited Data Set for the purpose of beta testing the interoperability of software programs used in connection with REACHnet enhancements. Depending on the type of Data requested for return, each Test Query shall be subject to the same requirements as set forth in this Agreement for Administrative Queries.

j. **Global Patient ID and Patient Deduplication Management** in accordance with Exhibit C of this Agreement or utilizing a comparable method as approved by the REACHnet Coordinating Center.

k. LPHI and Participant Data Recipients may use Data solely for Permitted Purposes, and shall not use or disclose the Data other than as permitted hereunder or as otherwise required by

Applicable Law.

l. LPHI and Participant Data Recipients agree not to identify the information contained in any Limited Data Set received pursuant to this Agreement or contact the individual unless permission to do so is otherwise obtained in accordance with Applicable Law and approved by the sharing Participant's Institutional Review Board.

5. Security.

a. **General**. LPHI and each Participant shall be responsible for maintaining a secure environment in accordance with Applicable Law. LPHI and each Participant shall use appropriate safeguards to prevent use or disclosure of Data other than as permitted by this Agreement, including appropriate administrative, physical, and technical safeguards that protect the confidentiality, integrity, and availability of that Data. Appropriate safeguards shall be those identified in the HIPAA Security Rule, 45 C.F.R. Part 160 and Part 164, Subparts A and C, as safeguards, standards, "required" implementation specifications, and "addressable" implementation specifications to the extent that the "addressable" implementation specifications are reasonable and appropriate. If an "addressable" implementation specification is not reasonable and appropriate for a Participant, then such Participant must document why it would not be reasonable and appropriate to implement the implementation specification and implement an equivalent alternative measure if reasonable and appropriate, and obtain written consent from LPHI to such alternative measure insofar as the use of such alternative measure would affect Data. LPHI and each Participant shall, as appropriate under either the HIPAA Regulations, or under Applicable Law, have written privacy and security policies in place. LPHI shall promptly report to Participant any use or disclosure of the Data that is not a Permitted Purpose hereunder of which it becomes aware. Each Participant Data Recipient shall promptly report to LPHI any use or disclosure of Data that is not a Permitted Purpose hereunder of which it becomes aware.

b. **Malicious Software**. LPHI and each Participant shall ensure that they employ security controls that meet applicable industry or Federal standards so that the information and Data 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 REACHnet or any part thereof or any hardware or software used by REACHnet 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 REACHnet or any part thereof or any hardware, software or data used by REACHnet in connection therewith, to be improperly accessed, destroyed, damaged, or otherwise made inoperable.

c. LPHI and each Participant Data Recipient represents that, through its agents, employees, and independent contractors, it shall have the ability to monitor and audit all access to and use of the Data received related to this Agreement, for system administration and security. LPHI and each Participant Data Recipient shall ensure that any agents to whom it provides the Data agree to the same restrictions and conditions that apply to LPHI's or Participant Data Recipient's use and disclosure of the Data hereunder.

d. **Breach by LPHI.** In the event of a breach of Participant Data by LPHI that would trigger notification to individuals or regulators if LPHI were a HIPAA covered entity or business associate (as those terms are defined in HIPAA), LPHI shall notify Participant in writing if

Participant's Data are suspected to be involved in the breach as soon as possible (and no later than 10 days) after discovery. LPHI agrees to take reasonably appropriate steps to investigate and mitigate the breach and to reasonably cooperate with Participant as it develops any notifications to individuals, regulators or the media that are either required by Applicable Law or Participant policy.

e. **Breach by Participant Data Recipient.** In the event of a breach of Participant Data by Participant Data Recipient that would trigger notification to individuals or regulators if Participant Data Recipient were a HIPAA covered entity or business associate (as those terms are defined in HIPAA), Participant Data Recipient shall notify LPHI and Participant in writing if Participant's Data are suspected to be involved in the breach as soon as possible (and no later than 10 days) after discovery. Participant Data Recipient agrees to take reasonably appropriate steps to investigate and mitigate the breach and to reasonably cooperate with Participant as it develops any notifications to individuals, regulators or the media that are either required by Applicable Law or Participant policy.

f. **Conflicts with ISA.** If applicable, in the event of a conflict between the provisions of this Section 5. and the provisions of a separate information security agreement between LPHI and a Participant ("ISA"), the provisions of the ISA shall prevail with respect to such Participant.

6. Term and Termination**.**

a. The term of this Agreement shall commence upon the Effective Date of April 1, 2018 and continue for a period of five (5) years ending March 31, 2023. This Agreement may be renewed for an agreed-upon period(s) through written amendment to this Agreement.

b. LPHI or Participant 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.

c. Participant may terminate this Agreement immediately upon written notice to LPHI in the event (i) that it becomes aware of any use or disclosure of Data in breach of this Agreement, (ii) of a material breach of this Agreement that is not cured within thirty (30) days of the occurrence of such breach, or (iii) of the addition of a new Participant not approved by Participant in accordance with Section 11.

d. Procedure When Return or Destruction of Data Is Feasible. Upon Participant's termination of their participation in this Agreement or the Termination of this Agreement due to the conclusion of REACHnet's existence, LPHI and Participant Data Recipients, will, if feasible, return to Participant or destroy all of Participant's Data in whatever form or medium, including all copies thereof and all data, compilations, and other works derived therefrom that allow identification of any individual who is a subject of Participant's Data. LPHI and Participant Data Recipients will require any subcontractor or agent, to which LPHI and Participant Data Recipients have disclosed Participant's Data to, if feasible, return to or destroy all of Participant's Data in whatever form or medium received from LPHI and Participant Data Recipients, including all copies thereof and all data, compilations, and other works derived therefrom that allow identification of any individual who is a subject of Participant's Data, and certify to Participant that all such information has been returned or destroyed. LPHI and Participant Data Recipients will complete these obligations as promptly as possible, but not later than 45 days following the effective date of the termination or other

conclusion of the Agreement.

e. Procedure When Return or Destruction Is Not Feasible. Upon Participant's termination of their participation in this Agreement or the Termination of this Agreement due to the conclusion of REACHnet's existence, LPHI and Participant Data Recipients will identify any of Participant's Data, including any that LPHI and Participant Data Recipients have disclosed to subcontractors or agents, that cannot feasibly be returned to Participant or destroyed and explain why return or destruction is infeasible. Where Participant agrees that such return or destruction is infeasible, LPHI and Participant Data Recipients will 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 study). LPHI and Participant Data Recipients will not include Participant's Data in any further research initiatives. LPHI and Participant Data Recipients will, by their written contracts with any subcontractor or agent to which LPHI and Participant Data Recipients discloses Participant's Data, require such subcontractor or agent to limit its further use or disclosure of Participant'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. LPHI and Participant Data Recipients will complete these obligations as promptly as possible, but not later than 45 days following the effective date of the termination or other conclusion of the Agreement.

f. Continuing Privacy and Security Obligation. LPHI's and Participant Data Recipients' obligation to protect the privacy and safeguard the security of Participant's Data will be continuous and survive termination or other conclusion of services and this Agreement.

7. Change in Law. Upon the enactment of any law or regulation affecting the use or disclosure of Data, or the publication of any decision of a court of the United States or of a court of the state in which this Agreement is performed relating to any such law, the publication of any interpretive policy or opinion of any governmental agency charged with the enforcement of any such law or regulation, or the opinion of counsel, LPHI or a Participant may amend this Agreement in such manner as LPHI or Participant determine necessary to comply with such law or regulation. If the Parties are unable to agree on an amendment within thirty (30) days thereafter, any one of them may immediately terminate this Agreement on written notice to the other Parties.

8. Sensitive Data. The Parties acknowledge their respective obligations under this Agreement to maintain the security and confidentiality of the Protected Health Information contained in the Data. The Parties agree to comply with Applicable Law related to the confidentiality of patient information, including, as applicable, the HIPAA Regulations. In addition, Participant acknowledges that Participant is solely responsible for obtaining any permissions necessary for Participant to disclose Sensitive Data to LPHI under this Agreement

9. Compliance with IRB Requirements.

The Parties agree that the conditions for use of Data are subject to the following:

a. As applicable, use of the Data as defined in Exhibit B has been approved by the Institutional Review Board(s) (IRB(s)) selected by REACHnet governance in accordance with the Department of Health and Human Services regulations at 45 C.F.R. Part 46; and/or
b. Amendment of this Agreement to include additional Limited Data Sets or identifiable Individual Level Data as required for specific research studies will require additional IRB

approval; and/or

c. Use of the Data for completely de-identified data analysis is not subject to IRB review, unless Participant policy requires IRB review.

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

11. Addition of New Participants. New Participants will be added to this Agreement, upon approval by a majority vote of the REACHnet Governance Board (Co-Principal Investigator Group). Each new Participant must complete and execute the Joinder in Exhibit F. Following execution of the Joinder, an updated Exhibit A with the new Participant will be provided to all current Participants.

12. Notices. Any notice to be given to Parties 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:

LPHI: Chief Executive Officer
Louisiana Public Health Institute
1515 Poydras St., Suite 1200
New Orleans, LA 70112

Participant: To the address and contact listed in Exhibit A.

13. Governing Law. INTENTIONALLY LEFT BLANK.

14. Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be void, invalid or unenforceable, the same shall in no way affect any other provision of this Agreement, and application of any such provision in any other circumstances, or the validity or enforceability of this Agreement and this Agreement shall be construed as if such void, invalid or unenforceable provision had been stricken from this Agreement as of its effective date.

15. Waiver. The failure by any 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 any Party thereafter to enforce each and every provision in accordance with the terms of this Agreement.

16. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which shall together constitute one agreement. The Parties agree that electronic signatures and signatures delivered by facsimile, PDF or other electronic means shall be valid, binding and enforceable.

17. Indemnification.

a. Each Party (the "Indemnifying Party") will indemnify and hold harmless the other Parties, including such Parties' affiliates, officers, directors, employees or agents, from

and against any third party claim, cause of action, liability, damage, cost or expense, including reasonable and actual attorneys' fees and court or proceeding costs, arising out of or in connection with the Indemnifying Party's non-permitted use or disclosure of Data or other material breach of this Agreement.

b. Notwithstanding the foregoing, the Indemnifying Party shall have no obligation to the extent of the other Parties' gross negligence, willful misconduct or material breach of this Agreement. Notwithstanding any other terms or conditions of this Agreement, no state agency or corporation deemed to be nonprofit under the laws of its jurisdiction shall be deemed to waive any privileges or immunities that might be available to it under Applicable Law.
c. Except for any such damages arising from breach of a Party's indemnification obligations under this Section, under no circumstances will any Party be liable to another Party for such other Party's indirect or consequential damages of any kind, including lost profits (whether or not the Parties have been advised or notified of the possibility or likelihood of such loss or damage) arising in any way in connection with this Agreement.
d. LPHI will indemnify and hold harmless the other Parties, including such Parties' affiliates, officers, directors, employees or agents, from and against any claim, cause of action, liability, damage, cost or expense, including attorneys' fees and court or proceeding costs, arising out of or in connection with LPHI's administration and operation of REACHnet.

18. Relationship of the Parties. The Parties are independent contracting entities. Nothing in this Agreement shall be construed to create a partnership, agency relationship, or joint venture among the Parties. No Party shall have any authority to bind or make commitments on behalf of another Party for any purpose, nor shall any such Party hold itself out as having such authority. No Party shall be held liable for the acts or omissions of another Party.

19. Use of Name. No Party shall use the name, trade name or trade mark of any other Party in any publicity release, policy recommendation, advertising, publications, abstracts or any commercial communication without the prior written authorization of such Party.

20. Order of Priority. In the event of a conflict between this Agreement and the then current REACHnet Research Participation Policy which is attached as Exhibit E hereto, the terms of this Agreement shall control.

21. Remedies. Each Party acknowledges and agrees that money damages might not be a sufficient remedy for any breach of this Agreement by such Party. Therefore, in addition to all other remedies available at law (which neither Party waives by the exercise of any rights hereunder), the non-breaching Party shall be entitled to seek injunctive and other equitable relief as a remedy for any such breach.

22. Assignment. This Agreement may not be assigned by a Party without the prior written consent of the other Parties, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that a Party may assign its rights or delegate its obligations, without such consent, to (a) one or more of its affiliates, or (b) an entity other than a competitor of a Party that acquires all or substantially all of the business or assets of such party to which this Agreement pertains, whether by merger, reorganization, acquisition, sale, or otherwise by providing notice to all Parties as set forth in Section 12 of this Agreement.

[Separate Signature Page to Immediately Follow.]

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

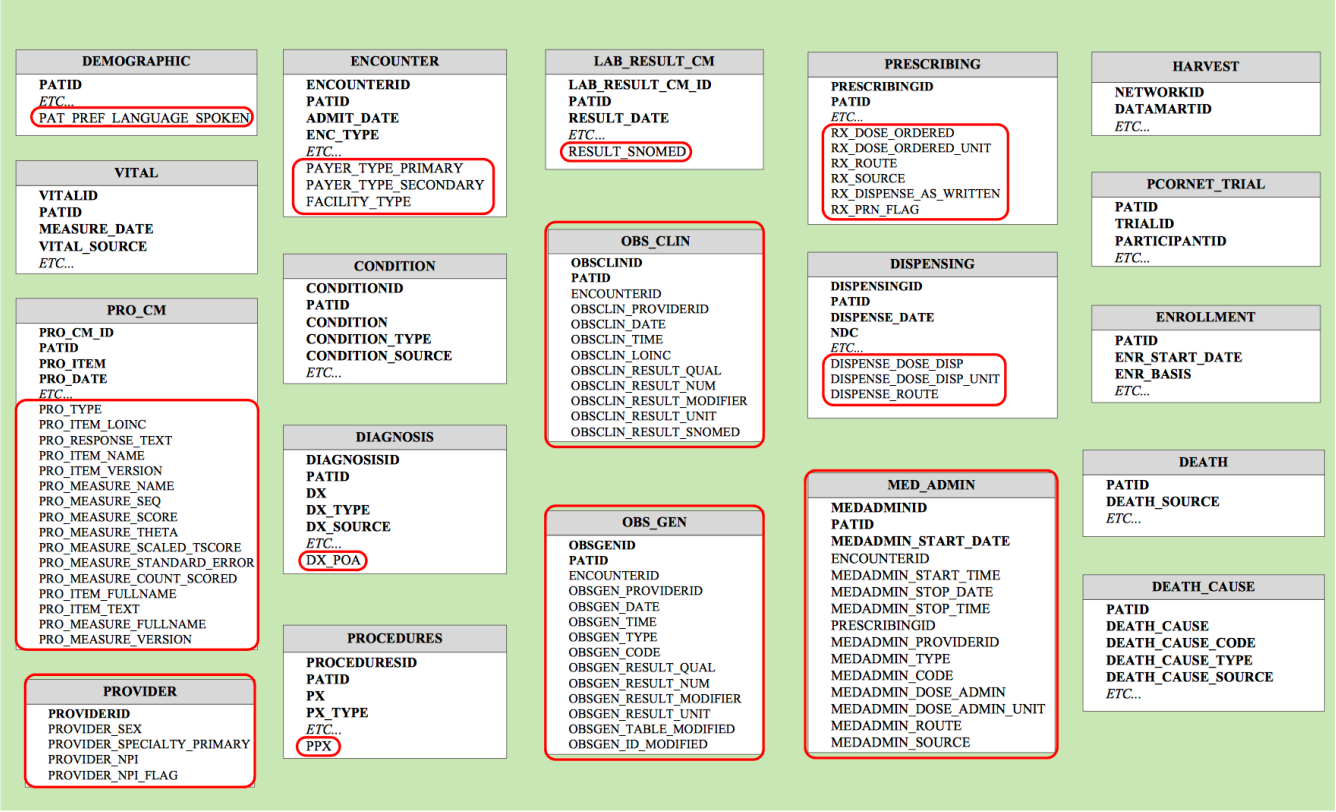
ADD SIGNATURE LINES FOR PARTIES

Exhibit "A" – Participants

Participant	**Contact Person**	**Address**

Exhibit "B" - Definition of Data (REACHnet Common Data Model)

1. Data shall include the PCORnet Common Data Model v4.1 LDS elements listed below (as well as additional LDS elements in future versions of the PCORnet Common Data Model), submitted according to the data validity, quality, and characterization standards established by PCORI (as set forth at http://www.pcornet.org/pcornet-common-data-model/) and the REACHnet governance structure. Data shall be contributed according to the following parameters:
    a. All historical data beginning in 2010, or when first available to Participant
    b. Ongoing data submissions at regular intervals



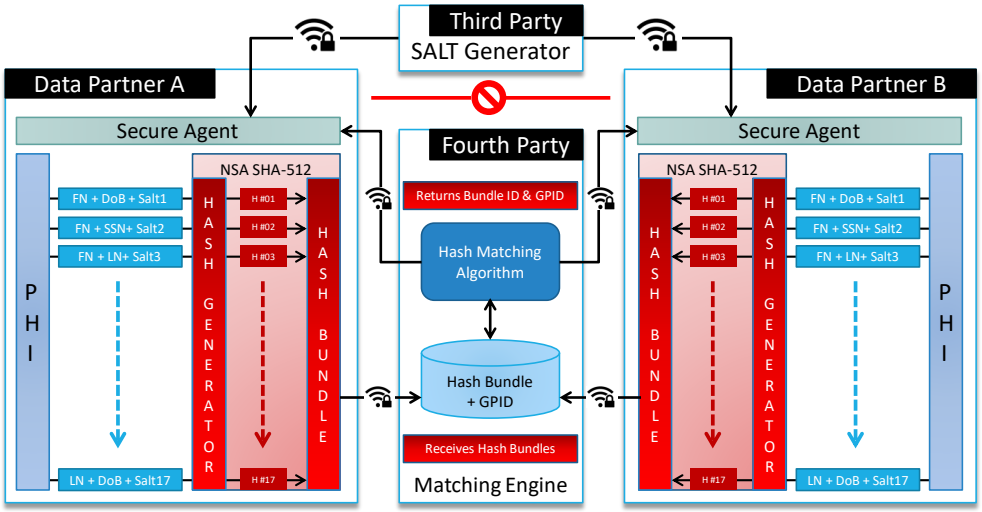
2. Data may include the following additional LDS data elements that are outside of the PCORnet Common Data model:
    a. Financial class associated with each encounter, mapped to the following predefined value set:

• CP = Commercial/private • MC = Medicare • MD = Medicaid • OG = Other Government • WC = Workman's Compensation	• UI = Uninsured • SP = Self-pay • OT = Other • NI = No Information

    b. Geospatial data elements, including:
        - Census tract, geocoded within Participant environment
        - Zip code + four
    c. Provider taxonomy code

Exhibit "C" – Patient Deduplication and Global Patient ID Generation Process and Participant Requirements

1. Participant maintains a data table of HashID/PatID (pseudo non-derived ID, not PHI) and MRN (or other data contributor-specific patient identifier).
2. A third party (Health DataLink), with no connection to REACHnet, has pre-existing SALT values created specifically for REACHnet. SALT value is random letters and numbers added to a PHI element. The SALT is used to defend against dictionary attacks and pre-computed rainbow table attacks.
3. SALT combined with PHI elements create a hash combination. A hash function is any function that can be used to map digital data of an arbitrary size to digital data of a fixed size. Each hash produced is unique but always repeatable and the function is unidirectional. This creates a completely random set of characters that alone cannot be linked back to the original PHI elements.
4. Up to 10 PHI elements (DOB, SSN, gender, first name, last name, middle name, phone no, email add, zip code, address) are combined with the REACHnet-specific SALT value to create multiple unique hash combinations.
5. The set of hash combinations, along with corresponding HashID/PatID, are sent to the REACHnet data warehouse as the hash bundle.
6. The REACHnet data warehouse utilizes a matching engine (hosted or API) to process all data contributors hash bundles and HashIDs/PatIDs. The deterministic algorithm in the Matching engine will find duplicates utilizing hash bundles delivered to REACHnet by data contributors. The algorithm can match hash bundles from multiple institutions. Once a match is identified, the matching engine allocates/or assigns the corresponding GPID for the patient.
7. REACHnet maintains a table of GPIDs and HashIDs/PatIDs for future matching and re-identification.



Example:

1. **Step 1:** Suppose we have a patient in a partner's EMR with the following PHI:
   First Name: John, Middle Name: Jr., **Last Name**: Dow, **Date of Birth**: 01/01/1901, **SSN**: 555-55-555, **Gender**: Male, **Phone No:** 123-456-7890, **Email:** johndow@gmail.com, **Zip Code:** 10111,

2. **Step 2:** The secure agent will generate multiple pairs of PHI for this patient.
   Examples: **Pair 1**: John, Dow, 555-55-555, **Pair 2**: John, Dow, 01/01/1901, **Pair 3**: Dow, John, 555-55-555… **Pair 18**: Joh, Dow,555, .

3. **Step 3:** Hash Generator adds a SALT to each pair combination of PHI for this patient. The SALT is generated by the Third Party and securely accessed by the data partners secure agents. Suppose SALT is combination of: s0mRIdlKvI and 875420 Then the PHI pair + SALT combinations would: **Combination 1**: s0mR42 John, 555-55-555, 8750IdlKvI; **Combination 2**: s0mR42 John, 01/01/1901, 8750IdlKvI; **Combination 3**: s0mR42 Dow, 555-55-555, 8750IdlKvI…

4. **Step 4**: The Hash Generator converts combinations of PHI pairs and Salts into a secure hash using NSA's SHA-512 Hash Implementation. The hashes with the above values would look like:
   Combination 1 hash:
   2ef500a825b068a962c972b705a96a8607daa375146ad609622b37b053caf2392e384efcc093ead5711
   8159bb9abeaf82f79b0e25b9d71d151ac24ffb271004a
   Combination 2 hash:
   01d99f9bca874e8079a9c6699cb8815a67da19c1acf1c63482ca33d21dc4d8f3a36fffa5cb16cf0bcb03fc
   fc93b4b1e3703bda4d780b88dbc5dcf8eb67a4a715
   Combination 3 hash:
   07f149336ce43aacf80bc383b1f6766957da1af426242d65bdaeafa9a476f2cf4cc2eb3b1bcc5a8501039
   d13bb7a0c7ed3d18e23c32f500d6f2b4f1ebb31228a

5. **Step 5:** All the hashes generated for a patient are combined in a hash bundle and sent to the REACHnet hash Matching Engine. These are used to find duplicate patients and generate GPIDs. The hash bundle for 3 combinations above would look like:
   Hash Bundle:
   2ef500a825b068a962c972b705a96a8607daa375146ad609622b37b053caf2392e384efcc093ead5711
   8159bb9abeaf82f79b0e25b9d71d151ac24ffb271004a01d99f9bca874e8079a9c6699cb8815a67da19c
   1acf1c63482ca33d21dc4d8f3a36fffa5cb16cf0bcb03fcfc93b4b1e3703bda4d780b88dbc5dcf8eb67a4a
   71507f149336ce43aacf80bc383b1f6766957da1af426242d65bdaeafa9a476f2cf4cc2eb3b1bcc5a8501
   039d13bb7a0c7ed3d18e23c32f500d6f2b4f1ebb31228a

"Exhibit D" - Data Query Definitions

The Data Queries referenced throughout this Agreement have the following definitions and associated requirements:

1. **Administrative Queries:** Related to Data Queries generated by the PCORnet Coordinating Center, from time to time, Duke shall issue queries of Participant Data seeking return of Aggregate Data, for which Duke has received blanket approval, including waiver of the HIPAA patient authorization requirement, from Duke's Institutional Review Board (the "Duke IRB"). The purpose of such queries shall be to inform the PCORnet Coordinating Center of data availability and fitness for use in response to PCORnet Queries, as defined in the PCORnet Coordinating Center Data Sharing Agreement.
    a. Minimum necessary: For Administrative Queries, Duke and HPHCI shall request the Minimum Necessary Participant Data to fulfill the purpose of the Query.
    b. Use Limitation: Duke and HPHCI shall use Data returned from an Administrative Query solely for the purposes set forth in this Agreement.
    c. Retention: Duke and HPHCI shall retain Data returned from an Administrative Query only 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, Duke and HPHCI shall destroy the data in accordance with the HIPAA Security Rule and provide written verification of its destruction to Participant or, at the specific written request of Participant, return it to Participant.

2. **Analytic Queries Requiring Return of Aggregate Data:** Such Analytic Queries will seek return of Aggregate Data (for example, counts of individuals meeting certain criteria, or counts of exposures, outcomes or exposure/outcome pairs). Aggregate Data is, by definition, De-Identified Data. These Analytic Queries could be associated with prep to analysis (PTA) queries, pre-prep to research (pPTR) queries, formal prep to research (PTR) queries, retrospective studies, or prospective studies. For prep to analysis (PTA) queries, Participant is identified after Co-PI approves release of system-specific results. For formal prep to research (PTR) queries, Participant is identified after Co-PI approves release of results (approval by not indicating intent to opt out within 72 hours). For retrospective and prospective studies, Participant is identified when data is released after Co-PI approves participation in the study. For pre-prep to research (pPTR) queries, Participant is NOT identified as results are pooled for all REACHnet partner health systems.

3. **Analytic Queries Requiring Return of De-Identified Individual Level Data:** Queries seeking return of De-Identified Individual Level Data, as defined in this Agreement. These Analytic Queries could be associated with retrospective studies or prospective studies.

4. **Analytic Queries Requiring Return of a Limited Data Set:** These Analytic Queries include the following distinct query types and could be associated with retrospective studies or prospective studies:
    a. Analytic Queries Requiring Return of a Limited Data Set that includes the Data covered in Exhibit B of this agreement.
    b. Analytic Queries Requiring Return of a Limited Data Set that includes data elements outside of the Data covered in Exhibit B of this agreement.

5. **Analytic Queries Requiring Return of Identifiable Individual Level Data:** Depending on the source, this may or may not be Protected Health Information. These Analytic Queries could be associated with retrospective or prospective studies.

Research Participation & Data Governance Policy

Contents

I. Overview

A. Purpose: The purpose of this policy is to:

a. Inform investigators how to collaborate with the Research Action for Health Network (REACHnet) in the following capacities:
   - Requesting REACHnet resources and services for their own research initiatives;
   - Representing their health system as the site Investigator in another investigator's research initiatives; and/or
   - Representing the network as the local (i.e., REACHnet) Principal Investigator in a PCORnet study

b. Govern REACHnet's process for determining network and site participation in research projects

c. Govern approvals of data sharing pursuant to the terms of the REACHnet Master Data Sharing and Use Agreement, other applicable Data Sharing and Use Agreements, and IRB requirements

B. Scope: This policy applies to requests by the National Patient-Centered Clinical Research Network (PCORnet) and non-PCORnet Research Partners (institutions involved in the conduct of research as defined at 45 C.F.R. § 64.10 of the HIPAA Regulations and health plans, including REACHnet-affiliated and non-REACHnet-affiliated partners) to conduct research using REACHnet's infrastructure for:

1. Obtaining any data;
2. Conducting observational or interventional studies;
3. Collecting patient-reported/generated data; and/or
4. Accessing stakeholder engagement resources and services.

As set forth below, the research review process for PCORnet requests does not involve all of the steps required for non-PCORnet studies.

C. Decision-making: The REACHnet Coordinating Center facilitates the network's decision-making regarding research participation and the release of clinical and/or research data by working closely with a defined group of health system leaders who represent each of REACHnet's participating health systems, including: Ochsner Health System; Baylor Scott & White Health; Pennington Biomedical Research Center; Tulane University Schools of Medicine and Public Health/Tulane Medical Center [HCA]; LSU Health Sciences Center/University Medical Center New Orleans (LCMC Health); Lallie Kemp Regional Medical Center; and Partnership for Achieving Total Health (PATH) community-based clinics and hospitals). Hereafter, this decision-making body is referred to as "*Partner Health System Leadership*". Members of REACHnet's Partner Health System Leadership are listed in **Appendix A**.

The REACHnet Coordinating Center and Partner Health System Leadership govern the network's research participation and data sharing as follows:

1. First, the REACHnet Coordinating Center performs an administrative review of a given research request, data request, or service request to assess feasibility. Using guidelines approved by Partner Health System Leadership, the REACHnet Coordinating Center conducts this preliminary assessment to determine if the request for services and/or collaboration should be shared with leaders.

2. The REACHnet Coordinating Center communicates about research participation and data sharing opportunities with Partner Health System Leadership on a rolling basis. As research opportunities are shared, each leader acts as a liaison between REACHnet and their partner health system to determine system-level interest in participation and, if applicable, recruit system-level investigators and sites.

Decision-making for research participation is further discussed in the *Requesting Research Services* sections of this policy (sections II and III). Decision-making for the release of data is discussed in the *Data Governance* section of this policy (section V).

II. Requesting Research Services – Process for Investigators

A. Submission Procedures

Investigators who are interested in leveraging REACHnet resources and/or services are invited to submit the appropriate REACHnet Service Request Form(s) via REACHnet's online submission portal, Eco (https://eco.reachnet.org). Using Eco, investigators are able to organize all request-related forms in one project space and track the status of requests. REACHnet may also correspond with investigators via phone or email to discuss content of an application form before the form(s) is formally reviewed.

Investigators can find submission forms and information about REACHnet services on REACHnet's website (http://www.reachnet.org/resources/forms/). Forms applicable to the research participation process include:

- *Prospective Research Request Form* (see Sections II.B. and V.A.)
- *Data Request Form* (i.e., for retrospective research; see Sections II.C. and V.B.)
- *Prep-to-research Query Request Form* (see Section V.C.)
- *Request for Engagement Services* (see Section VI)

Details for completing each form are described below.

B. Prospective Research Requests

Investigators who wish to access REACHnet services are invited to submit an application addressing the following components of their proposed research project:

1. Specific Aims / Research Questions
2. Target population
3. Description of intervention(s) and comparison groups or study cohort
4. Data needs, including clinical and patient-reported data collected by REACHnet
5. Proposed research sites (health systems), if applicable
6. Research team (by name and institution)
7. Funding details, if applicable
8. Use of REACHnet resources/services (note: services will require appropriate budget allotments)
9. Engagement Plan detailing how patients, clinicians, and other stakeholders (as applicable) will be engaged in the protocol development and project execution
10. Use of other CDRN or PPRN resources/services
    - Investigators who are interested in engaging other PCORnet Patient Powered Research Networks (PPRNs) or Clinical Data Research Networks (CDRNs) to

collaborate on a study are encouraged to communicate with the REACHnet Coordinating Center about their research ideas and potential PCORnet collaboration
- If deemed feasible, the REACHnet Coordinating Center will advise investigators through the additional application procedures through the PCORnet Front Door
- The use of other CDRN or PPRNs for research purposes will require additional regulatory documentation beyond that required for REACHnet

The *REACHnet Prospective Research Request Form* reflects the above requirements. The request must be submitted, reviewed, and approved prior to receiving a letter of support from REACHnet for a funding application**. Please allow at least 30 days for the review process.**

C. Retrospective Research Requests (i.e., data-only requests)

Investigators who wish to obtain a single flat file of REACHnet partner data are invited to submit a *Data Request Form* addressing the following components of their proposed research project:

1. Specific Aims / Research Questions
2. Description of population of interest, including query parameters for inclusion/exclusion criteria
3. Engagement Plan detailing how patients, clinicians, and other stakeholders (as applicable) have been or will be engaged in generating the project idea or interpreting the results
4. Data needs, including specific clinical and patient-reported data elements collected by REACHnet
5. Funding details, if applicable
6. Use of other CDRN or PPRN resources/services
    - Investigators who are interested in engaging other PCORnet Patient Powered Research Networks (PPRNs) or Clinical Data Research Networks (CDRNs) to collaborate on a study are encouraged to communicate with the REACHnet Coordinating Center about their research ideas and potential PCORnet collaboration
    - If deemed feasible, the REACHnet Coordinating Center will advise investigators through the additional application procedures that are outlined in the PCORnet Front Door Policy
    - The use of other CDRN or PPRNs for research purposes will require additional regulatory documentation beyond that required for REACHnet

D. Review Process, Partner Health System Participation, and Communication of Decision

1. The investigator will receive an email notification through Eco that the status of their project is "under review" or "needs action" within 10 working days of submission. The REACHnet Coordinating Center may communicate with the investigator during this time to clarify data needs and requested services. If necessary, the investigator will be responsible for revising the request form during this time.
2. The REACHnet Coordinating Center will review the submitted form and determine whether fulfilling the request is feasible.
3. If deemed feasible, the REACHnet Coordinating Center will present the opportunity to REACHnet Partner Health System Leadership, and leaders will determine whether their respective health system is interested in participating. Leaders will identify co-investigators and sites from their respective health systems for interventional studies or

determine if their respective health system will contribute requested data in response to data-only requests or prospective observational studies (for which co-investigators may also be recruited).

4. In response to both prospective and data-only research opportunities, the REACHnet Coordinating Center must receive express written consent to participate via email from Partner Health System Leadership.
5. The REACHnet Coordinating Center will communicate a final decision about collaboraton through Eco within 30 working days after the Eco project was changed to "under review". If the research request is approved, REACHnet will inform the investigator of the decision by changing the status of the Eco project to "approved". If collaboration is deemed unfeasible during the formal review process, the Eco project status will be changed to "rejected". Investigators are invited to resubmit requests or contact the REACHnet Coordinating Center directly with questions about this decision.

III. Requesting Research Services – Process for PCORnet Research Opportunities

A. Opportunities to participate in studies initiated through PCORnet will be managed by the REACHnet Coordinating Center.
B. The REACHnet Coordinating Center will determine whether the research opportunity is feasible.
C. If deemed feasible, the REACHnet Coordinating Center will present the opportunity to the Partner Health System Leadership, and leaders will determine whether their respective health system is interested in participating. Leaders will identify co-investigators and sites from their respective health systems for interventional studies or determine if their respective health system will contribute requested data in response to data-only requests or prospective observational studies (for which co-investigators may also be recruited).
D. In response to both prospective and data-only research opportunities, the REACHnet Coordinating Center must receive express written consent to participate via email from Partner Health System Leaders.
E. The REACHnet Coordinating Center will communicate with PCORnet about whether the network (i.e., some combination of component health systems, but not necessarily all) will participate in a proposed study, based on the systems' willingness to participate.

IV. Regulatory Requirements

All approved research requests are subject to:

A. Applicable IRB approval requirements based on the type of study (see Table 2 for more information);
B. The terms of the REACHnet Master Data Sharing and Use Agreement, which sets forth any additional Data Sharing and Use Agreements that must be executed before data is shared; and
C. Partner Health System Leader approval for data sharing as set forth in the *Data Governance* section below.

V. Data Governance

REACHnet partner data is available to investigators to support prospective and data-only research projects. In addition, REACHnet partner data can support research preparation projects through prep-to-research queries and administrative queries geared toward ensuring data quality and

readiness. Data governance differs based on the type of data requested. Data type definitions are aligned with those specified in the REACHnet Master Data Sharing and Use Agreement and PCORnet Data Sharing Agreement (DSA). They include:

1. Type 1: Administrative Queries (e.g., PCORnet Data Characterization)
2. Type 2: Analytic queries requiring return of de-identified aggregate data
3. Type 3: Analytic queries requiring return of de-identified individual level data
4. Type 4: Analytic queries requiring return of a limited data set (CDM[1] or CDM+[2])
5. Type 5: Analytic queries requiring return of identifiable individual level data

REACHnet references these five data types throughout the *Data Governance* section of this policy. The sections below describe regulatory and administrative approval requirements for sharing the data types listed above. Table 1 provides an overview of these requirements.

A. <u>Data to support prospective research</u>

Data to support prospective research will take the form of data types 2-5. To receive data for prospective research projects, the researcher must complete the steps described in the *Requesting Research Services* and *Regulatory Requirements* sections of this policy.

1. No data, regardless of type, will be released without Partner Health System Leader participation approval, as set forth in the *Requesting Research Services* sections (II and III) above and fulfillment of applicable regulatory requirements as summarized in the *Regulatory Requirements* section (IV) above.
2. Once Partner Health System Leadership approves participation and applicable regulatory requirements are met, data types 2-5 can be released without additional review and/or approval from participating Partner Health Systems Leadership.
3. Ongoing releases of data types 2-5 can occur without additional approval from participating Partner Health System Leadership.
4. Additional data requests beyond those expressely defined in the applicable IRB, REACHnet Master Data Sharing and Use Agreement, and additional Data Sharing and Use Agreements, if applicable, will need to be assessed and regulatory requirements implemented before data sharing can occur.
5. All data transfer will occur in a secure capacity.

B. <u>Data to support retrospective research</u>

Data to support retrospective research typically take the form of data types 3 and 4 (but could also include types 2 and 5). To receive data for retrospective research projects, the researcher must complete the steps described in the *Requesting Research Services* and *Regulatory Requirements* sections of this policy.

1. No data, regardless of type, will be released without Partner Health System Leader participation approval, as set forth in the *Requesting Research Services* sections (II and

[1] The PCORnet Common Data Model (CDM) is a way of organizing clinical health data into a standard structure. Each PCORnet partner network maps data to the same consistent format (i.e., with the same variable name, attributes, and other metadata). For more information, visit http://www.pcornet.org/pcornet-common-data-model/.

[2] REACHnet has the capacity to assist investigators in acquiring data outside of the CDM from REACHnet partner health systems for research purposes.

III) above and fulfillment of applicable regulatory requirements as summarized in the *Regulatory Requirements* section IV above.
2. Once Partner Health System Leadership approves participation and applicable regulatory requirements are met, data types 2-5 can be released without additional review and/or approval from participating Partner Health System Leadership.
3. Additional data requests beyond those expressely defined in the applicable IRB, REACHnet Master Data Sharing and Use Agreement, and additional Data Sharing and Use Agreements, if applicable, will need to be assessed and regulatory requirements implemented before data sharing can occur.
4. All data transfer will occur in a secure capacity.

C. Data to inform future research

Data to inform future research takes the form of a prep-to-research (PTR) or prep-to-analysis (PTA) query. Prep-to-research/analysis queries are data type 2. Prep-to-research queries assess the number of eligible patients meeting defined inclusion/exclusion criteria, while prep-to-analysis queries assess the frequency of outcomes among defined patient groups. Query requests are received locally via Eco as *Query Request Forms*. REACHnet also receives prep-to-research queries through the PCORnet Distributed Research Network.

1. Approval from Partner Health System Leadership is not required prior to running a prep-to-research query, but pre-approval from Partner Health System Leadership is required prior to running a prep-to-analysis query.
2. No data, regardless of type, will be released without fulfillment of applicable regulatory requirements as summarized in the *Regulatory Requirements* section IV above.
3. Once prep-to-research/analysis queries are complete, results are sent to respective Partner Health System Leadership via email or through the REACHnet Query Tracking System. For prep-to-research queries, the Partner Health System Leadership is allowed 72 hours (3 business days) to review their health system specific results from each prep-to-research query and respond if they wish to opt out of sharing results with the requester. Active approval is not required to share results with the requester. For prep-to-analysis queries, approval from Partner Health System Leadership obtained with written consent via email or within the Query Tracking System is required to release results to the requester.
4. Prep-to-analysis query results cannot be released to requesting investigators without the approval of the Partner Health System Leadership.

To protect patient privacy, REACHnet does not release query results where the cell count is between 1-10. If query results are between this range, they are marked as "LE 11" or "below threshold (BT)."

D. Data to inform *potential* future research

Data to inform potential future research takes the form of a pre-prep-to-research query. Pre-prep-to-research queries are a data type 2; however, pre-prep-to-research queries only release aggregate results for all of REACHnet and do not provide system-specific results.

1. No data, regardless of type, will be released without fulfillment of applicable regulatory requirements as summarized in the *Regulatory Requirements* section IV above.
2. Approval from Partner Health Systems Leadership is not required prior to running a pre-prep-to-research query or releasing the results to the requester.

To protect patient privacy, REACHnet does not release query results where the cell count is between 1-10. If query results are between this range, they are marked as "LE 11" or "below threshold (BT)."

E. Data for administrative purposes

Data for administrative purposes are defined as data type 1.

1. No data, regardless of type, will be released without fulfillment of applicable regulatory requirements as summarized in the Regulatory Requirements section IV above.
2. Approval from participating health systems is not required prior to running data type 1 queries.
3. Once results of administrative queries are ready, they are sent to respective Partner Health System Leadership via email or through the REACHnet Query Tracking System. The Partner Health System Leadership is required to review and approve their health system-specific results from each administrative query. Approval is obtained with written consent via email or by indicating their approval within the Query Tracking System.
4. Administrative or data type 1 results cannot be released to PCORnet without the approval of the participating health system.

Table 1: Partner Health System Leadership Approval Requirements for Data Types

CATEGORY	REACHnet & PCORnet DSA data types	APPROVAL REQUIREMENT (for partner health system participation)	APPROVAL REQUIREMENT (before data release)
Prospective studies (e.g.,ongoing study with multiple data deliverables)	Types 2-5	Approval to participate must be sent to REACHnet Coordinating Center via email	No approval necessary before data release
Retrospective studies (e.g., data-only request associated with one single data deliverable)	Types 2-5	Approval to participate must be sent to REACHnet Coordinating Center via email	No approval necessary before data release
PTR queries (e.g., not yet associated with an active or proposed study)	Type 2	Approval is NOT required prior to query run	Approval is NOT required prior to releasing results (72 hours/3 business days allowed for review and opt-out)
PTA queries (e.g., not yet associated with an active or proposed study)	Type 2	Approval required prior to query run	Approval is required prior to releasing results
Pre-PTR queries	Type 2	Approval is NOT required prior to query run	Approval is NOT required prior to releasing results
Administrative queries	Type 1	Approval is NOT required prior to query run	Approval is required prior to releasing results

VI. Engagement Services

Engaging patients, clinicians, and community stakeholders during this initial stage of proposal development follows PCORI's suggested steps for engaging stakeholders throughout the entire research process. (More information about stakeholder engagement can be found in PCORI's Engagement Rubric.)

To help support investigators with project-specific engagement needs, REACHnet has developed an engagement infrastructure that includes services such as consultation on engagement plan development and resources such as access to REACHnet's *Health in Our Hands* patient network. Investigators who are interested in collaborating with REACHnet to fulfill their engagement needs are encouraged to submit a *Request for Engagement Services* form.

NOTE: Investigators who are requesting engagement services *in addition to other REACHnet services* as a component of prospective research do not need to complete a separate *Request for Engagement Services* form. Instead, this request should be detailed in the section entitled "Stakeholder Engagement Services" of the *Prospective Research Request* form.

Given that many funding opportunities now require that proposals outline plans for engagement of patients and other stakeholders, (e.g. caretakers, community members, clinicians, etc.), it is strongly recommended that investigators complete this form *several months prior* to preparing their proposal.

A. Requirements for Engagement Services Requests

Investigators who wish to access REACHnet engagement services are invited to submit a request addressing the following components of their proposed research project:

1. Purpose of engagement within the project
2. Description of condition or community of interest
3. Description of project's engagement needs and goals
4. Description of research team's current resources and level of experience with engagement in research
5. Selection of specific REACHnet engagement services/resources
6. Engagement requirements set forth by funder, if applicable

B. Review Process & Communication of Decision

Requests for Engagement Services will be reviewed by the REACHnet Coordinating Center's engagement personnel. Within 5 working days after the request is submitted via Eco, the investigator will receive an email notification that their project is "under review". If the engagement request is deemed feasible by the REACHnet Coordinating Center, the investigator will receive an email notification that their project is "approved". At this time, REACHnet engagement personnel will communicate directly with the investigator via Eco, phone, or email to more thoroughly discuss the investigator's request and collaborate on the development of next steps.

VII. IRB Requirements

REACHnet-initiated projects are required to follow REACHnet's streamlined IRB review process, which entails a shared or ceded review model among REACHnet partners. REACHnet partner health system IRBs are members of two national platforms that facilitate shared and ceded reviews: (1) IRBchoice (https://www.irbchoice.org/p/) and (2) SMART IRB (https://smartirb.org/).

Prior to IRB submission, investigators are encouraged to contact REACHnet personnel for guidance on IRB procedures using one of the two shared review platforms. PCORnet-designated and NIH-funded studies are required to use SMART IRB. All other studies may use SMART IRB (if applicable) or IRBchoice.

The IRB processes for various research scenarios are summarized in Table 2.

Table 2: IRB Process Guidance by Research Scenario

Research Design	Partnership Framework	IRB Framework
Deidentified data Observational No individual patient consent	Co-investigators at each data contributing institution	Lead IRB identified; ceded or shared review by all data contributing institutions using IRB choice or SMART IRB
	Some data contributing institutions do not have an investigator engaged in the research	Lead IRB identified; ceded or shared review by data contributing institutions with investigators engaged using IRB choice or SMART IRB; *IRBs for data contributing institutions without investigators engaged in the research do not require review*
Limited dataset Observational No individual patient consent	Co-investigators at each data contributing institution	Lead IRB identified; ceded or shared review by all data contributing institutions using IRB choice or SMART IRB
	Some data contributing institutions do not have an investigator engaged in the research	Lead IRB identified; ceded or shared review by data contributing institutions with investigators engaged using IRB choice or SMART IRB; IRBs for data contributing institutions without investigators engaged in the research will be asked for a determination on whether or not the study constitutes human subjects research and requires review
Health in Our Hands and/or survey data collection Prospective Patient recruitment/consent	Co-investigators at each participating institution	Lead IRB identified; ceded or shared review by all participating institutions using IRB choice or SMART IRB
Interventional trial Prospective Patient recruitment/consent	Co-investigators at each participating institution	Lead IRB identified; ceded or shared review by all participating institutions using IRB choice or SMART IRB

VIII. Reporting Requirements

At the conclusion of the study, research findings must be reported to REACHnet. It is recommended that investigators assist in the summary and dissemination of results in a patient-friendly format, including through the Health in Our Hands patient network and on the REACHnet website.

Investigators are required to notify REACHnet of any manuscripts accepted for publication and abstracts or papers accepted for presentation within 15 days of acceptance. Authors/presenters are required to formally acknowledge REACHnet in all publications and presentations of research conducted using the network.

Please refer to REACHnet's Dissemination Policy for all manuscripts and conference presentations derived from research conducted via REACHnet.

1. **Acknowledgments section of manuscript or report:**
    a. It is recommended that the following language be included in the Acknowledgements Section of the manuscript or report to properly acknowledging collaboration with REACHnet: "*Supported in part by CDRN 1306-04864 from the Patient Centered Outcomes Research Institute. The content is solely the responsibility of the authors and does not necessarily represent the official views of the Research Action for Health Network (REACHnet), Patient Centered Outcomes Research Network (PCORnet), or Patient Centered Outcomes Research Institute (PCORI).*"
    b. In addition to a funding acknowledgement, the following standardized acknowledgement of the REACHnet partnership will be used for ALL publications, presentations, and other dissemination-related activities, regardless of the authors listed: "*The authors acknowledge the participation of REACHnet partner health systems: [name all participating health systems] in this project.*

2. **Citing a prep-to-research query or analysis using data from REACHnet's CDM Data Warehouse:** Investigators are required to cite all results acquired from REACHnet partner data that are presented in any format. The following language is recommended for citing prep-to-research or analysis results using data from REACHnet's CDM Data Warehouse: Research Action for Health Network, Louisiana Public Health Institute. Date dataset was created or updated. *Title or brief description of dataset, including time period, target patient population and health system(s) covered in the data if applicable* [Data file/Prep-to-research query]. New Orleans, Louisiana: Louisiana Public Health Institute.

Appendix A: REACHnet Partner Health System Leadership

As mentioned throughout this policy, REACHnet's decision-making is primarily governed by a group of health systems leaders from REACHnet's partner health systems (i.e., data contributors) and institutions. The appointees' decision-making responsibilities vary by health system/institution depending on the extent of the system's data contribution. The table below lists the representatives from each partner health system/institution who are responsible for system or clinic-level decision-making for REACHnet.

REACHnet Decision-Making: Partner Health System Leadership	
Ochsner Health System	**Eboni Price-Haywood, MD, MPH, FACP** *Director, Center for Applied Health Service Research* Ochsner Health System
Baylor, Scott & White Health	**Andrew Masica, MD, MSCI** *Vice President, Chief Clinical Effectiveness Officer* Baylor Scott & White Health
Pennington Biomedical Research Center (PBRC) NOTE: PBRC does not house clinical data and is therefore only responsible for sharing research opportunities with institutional investigators.	**Peter Katzmarzyk, PhD, FACSM, FAHA** *Associate Executive Director for Population and Public Health Sciences, Marie Edana Corcoran Endowed Chair in Pediatric Obesity and Diabetes* Pennington Biomedical Research Center
Tulane University Schools of Medicine and Public Health/Tulane Medical Center (HCA)	**Vivian Fonseca, MD, FRCP** *Tullis-Tulane Alumni Chair in Diabetes, Professor of Medicine, Chief – Section of Endocrinology* Tulane University School of Medicine
Partnership for Achieving Total Health (PATH)/Greater New Orleans Health Information Exchange (GNOHIE) NOTE: Approval for release of query results is given by the Executive Director, whereas approval to participate in prospective research is solicited at the clinic level.	**Clayton Williams, MBA** *Director of Clinical Transformation, Executive Director of PATH* Louisiana Public Health Institute
LSU Health Sciences Center/University Medical Center New Orleans (LCMC Health)	**Jyotsna Fuloria, MD** *Vice President of Clinical Research* University Medical Center New Orleans

Exhibit "F" – Joinder

JOINDER
TO
REACHnet MASTER DATA SHARING AND USE AGREEMENT

The undersigned, a duly authorized representative of _____, ("Participant") hereby represents that he or she has read the REACHnet Master Data Sharing and Use Agreement ("Master DSUA"), effective [insert date], and that Participant agrees to hereafter abide by and be governed by the terms of the Master DSUA. This Joinder shall be effective upon approval by a majority vote of the REACHnet Governance Board (Co-Principal Investigator Group). This Joinder shall be attached to said Master DSUA and deemed to be a part thereof for all purposes.

_____
(Entity name)

Signature:_____

Printed Name:_____

Title:_____

Date:_____

Address:_____

_____

_____

Exhibit "G" – Use Case-Specific Data Sharing and Use Agreement Template

Research Action for Health Network Data Sharing and Use Agreement

This Data Sharing and Use Agreement (the "Agreement") is made effective as of the ___ day of _____ (the "Effective Date"), by and between [*Investigator Entity*] ("Research Partner"), a [State] [Type of Entity], and The Louisiana Public Health Institute, a Louisiana 501(c)(3) non-profit corporation ("LPHI"), (collectively referred to as the "Parties" and singularly referred to as "Party").

Recitals

WHEREAS, Louisiana Public Health Institute ("LPHI") is the recipient of Patient Centered Outcomes Research Institute ("PCORI") funding and established the Research Action for Health Network ("REACHnet");

WHEREAS, LPHI is responsible for operation of REACHnet and thus serves as the REACHnet coordinating center;

WHEREAS, pursuant to the REACHnet Master Data Sharing and Use Agreement ("REACHnet MDSUA"), REACHnet participating health systems have contributed a Limited Data Set to LPHI for various purposes including research;

WHEREAS, Research Partner will perform a research study entitled [*Study Title*] [*Study Shorthand Reference*] in accordance with in accordance with the Analysis Plan set forth in Exhibit "C" and desires to access certain Data, as defined below, for purposes of the [*Study Shorthand Reference*]; and

WHEREAS, the following REACHnet participating health systems have approved participation in the [*Study Shorthand Reference*]: [*list of applicable REACHnet participating health systems*] ("Participants").

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** shall mean aggregated, De-identified Data across specified strata of individuals. For example, counts of patients within a stratum that includes a particular age group, gender, and diagnosis. Aggregate Data does not include Individual Level Data.
    b. **Applicable Law** shall mean all applicable state statutes and regulations as well as all applicable Federal statutes, regulations, standards and policy requirements.
    c. **De-identified Data** shall have the meaning ascribed to it in the HIPAA Privacy Rule at 45 C.F.R. Section 164.514(a). Processes for de-identifying data are set forth in 45 C.F.R. Section 164.514(b) of the HIPAA Privacy Rule.
    d. **Data** shall have the definition in Exhibit "A", as amended. This information includes De-Identified Data and/or Protected Health Information (PHI) in the form of a LDS (as defined in the HIPAA Regulations at 45 C.F.R. § 164.514).
    e. **Health Care Provider** shall have the meaning set forth at 45 C.F.R. § 160.103 of the HIPAA Regulations.

f. **HIPAA Regulations** shall mean the Standards for Privacy of Individually Identifiable Health Information and the Security Standards for the Protection of Electronic Protected Health Information (45 C.F.R. Parts 160 and 164) promulgated by the U.S. Department of Health and Human Services under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, as in effect on the Effective Date of this Agreement and as may be amended, modified, or renumbered.
g. **Individual Level Data** shall mean information that is specific to individual patients. Individual Level Data may or may not be De-Identified Data; provided, however, that any Individual Level Data that are not De-Identified Data shall be in the form of a Limited Data Set.
h. **Limited Data Set ("LDS")** shall have the meaning ascribed to it in the HIPAA Privacy Rule at 45 CFR Section 164.514 (e).
i. **Notice or Notification** shall mean a written communication, unless otherwise specified in this Agreement, sent to the appropriate Participant's representative at the address listed herein.
j. **Permitted Purpose** shall mean Study Data Set analyses by [*Researcher and Affiliations*], for the research as set forth fully in the Analysis Plan of the [*Study Shorthand Reference*], attached as Exhibit "C".
k. **Study Data Set** shall mean Aggregate Data or Individual Level Data, as defined above, and further described in Exhibit "B".

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 Sharing Requirements.

a. Participants are Health Care Providers and, pursuant to the REACHnet MDSUA, have provided Data to LPHI, in the requisite format as set forth in Exhibit "A" ("Common Data Model") in accordance with HIPAA Regulations.
b. On behalf of Participants, LPHI will provide the Study Data Set, to Research Partner in a secure manner in accordance with the terms of this Agreement.
c. Minimum Necessary Data Fields in the LDS. In preparing the LDS, LPHI shall include the data fields specified in writing by authorized representatives of the Parties from time to time, which are the minimum necessary to accomplish the Permitted Purpose of this Agreement.

4. Research Partner Functions and Responsibilities.
Research Partner will:
a. Utilize the Study Data Set for the Permitted Purpose only or as required by law;
b. Use appropriate safeguards to prevent use or disclosure of the Study Data Set other than as permitted by this Agreement or as required by law;
c. Report to LPHI and Participant(s), within three (3) business days of discovery, any use or disclosure of the Study Data Set of which it becomes aware that is not permitted by this Agreement or required by law, including the presence of any of the following prohibited identifiers: name; telephone and fax numbers; email addresses; URLs and IP addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate and license numbers; vehicle identification numbers; device identifiers and serial numbers; biometric identifiers (such as voiceprints and fingerprints); and full face photographs or comparable images;
d. Require any of its subcontractors or agents that receive or have access to the Study Data Set to agree to the same restrictions and conditions on the use and/or disclosure of the Study Data Set

that apply to Research Partner under this Agreement;

e. Not use the information in the Study Data Set, alone or in combination with any other information, to identify or contact the individuals who are subjects; and
f. If Research Partner desires to publish or present [*Study Shorthand Reference*] results, Research Partner shall comply with the REACHnet Dissemination Policy set forth in Exhibit "D".

5. Ownership of Data. Each Participant holds all right, title and interest in and to any and all portion(s) of their Data and/or Study Data Set, and neither Research Partner nor LPHI shall acquire, by virtue of this Agreement, any right, title or interest in or to such Data, Study Data Set, or any portion thereof.

6. Term and Termination.
   a. The term of this Agreement shall commence upon the Effective Date and continue until the completion of the [*Study Shorthand Reference*].
   b. Termination by Research Partner. Research Partner may terminate this Agreement at any time by providing written notice of immediate termination to LPHI.
   c. Termination by LPHI. LPHI may terminate this Agreement at any time by providing thirty (30) days prior written notice to Research Partner. Notwithstanding the foregoing, LPHI may terminate this Agreement immediately upon written notice to Research Partner in the event that LPHI becomes aware of any use or disclosure of data in breach of this Agreement.
   d. Upon termination of the Agreement, Research Partner must return or destroy Study Data Set within thirty (30) days following the termination date and submit a certification statement to LPHI that such return or destruction is complete; provided, however, that the return or destruction of the Study Data Set is subject to Applicable Law, regulation, document retention requirements, or compliance policies. If, for reasons related to the foregoing, return or destruction of the Study Data Set is not feasible, Research Partner shall inform LPHI of the reason it is not feasible and shall continue to extend the protections of this Agreement to the Study Data Set and limit further use and disclosure of such Study Data Set to those purposes that make the return or destruction of such Study Data Set infeasible.

7. Change in Law. Upon the enactment of any law or regulation affecting the use or disclosure of Data and/or Study Data Set, or the publication of any decision of a court of the United States or applicable state 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 Parties may, amend this Agreement in such manner as the Parties determine necessary to comply with such law or regulation. If the Parties are unable to agree on an amendment within thirty (30) days thereafter, one of them may terminate this Agreement on written notice to the other.

8. Amendments. The terms of this Agreement may not be waived, altered, modified, or amended except by a written agreement executed by all the Parties.

9. Notices. Any notice to be given to a Party 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:

Research Partner:

_____
_____
_____
_____
Attn: _____

With copy to: _____
_____
_____
_____
Attn: _____

LPHI: Attention: Thomas W. Carton, MS, PhD, REACHnet Principal Investigator
Louisiana Public Health Institute
1515 Poydras St., Suite 1200
New Orleans, LA 70112
tcarton@lphi.org

10. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Louisiana, without regard to its conflict of laws provisions.[-or- **[Intentionally Left Blank]]**

11. Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be void, invalid or unenforceable, the same shall in no way affect any other provision of this Agreement, and application of any such provision in any other circumstances, or the validity or enforceability of this Agreement and this Agreement shall be construed as if such void, invalid or unenforceable provision had been stricken from this Agreement as of its effective date.

12. Waiver. The failure by any 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 any Party thereafter to enforce each and every provision in accordance with the terms of this Agreement.

13. INTENTIONALLY LEFT BLANK

14. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which shall together constitute one agreement. The Parties agree that electronic signatures and signatures delivered by facsimile, PDF or other electronic means shall be valid, binding and enforceable.

15. Indemnification.
    a. Research Partner agrees, to the extent authorized by law, to defend, indemnify and hold harmless each Participant and LPHI from and against any claims or causes of action that might be brought against Participant, or LPHI, and/or Participant's or LPHI's board of supervisors, directors, officers, employees, physicians, nurses, and/ or agents as a result of any negligence, breach of contract or other tortious conduct arising out of or in connection with any unauthorized or prohibited use or disclosure of the Study Data Set or any other breach of this

Agreement on the part of Research Partner, and/or Research Partner's board of supervisors, directors, officers, employees, physicians, nurses, students and/or agents.

b. LPHI agrees, to the extent authorized by law, to defend, indemnify, and hold harmless Research Partner from and against any claims or causes of action that might be brought against, Research Partner, or Research Partner's board of supervisors, directors, officers, employees, physicians, nurses, students, and/or agents, by third parties as a result of any negligence, breach of contract or other tortious conduct arising out of or in connection with any unauthorized or prohibited use or disclosure of the Study Data Set or any other breach of this Agreement on the part of LPHI, or LPHI's board of supervisors, directors, officers, employees, physicians, nurses, students and/or agents.

16. Relationship of the Parties. The Parties are independent contracting entities. Nothing in this Agreement shall be construed to create a partnership, agency relationship, or joint venture among the Parties. No Party shall have any authority to bind or make commitments on behalf of another Party for any purpose, nor shall any such Party hold itself out as having such authority. No Party shall be held liable for the acts or omissions of another Party.

17. Use of Name. No Party shall use the name, trade name or trade mark of any other Party in any publicity release, policy recommendation, advertising, publication, abstract or any commercial communication without the prior written authorization of such Party.

[SIGNATURE PAGE FOLLOWS – REMAINDER INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the Parties have executed this Agreement by its duly authorized representatives on the dates listed below to be effective as of the Effective Date.

Research Partner

_____

Signature

Name: _____

Title: _____

Date: _____

Louisiana Public Health Institute

_____

Signature

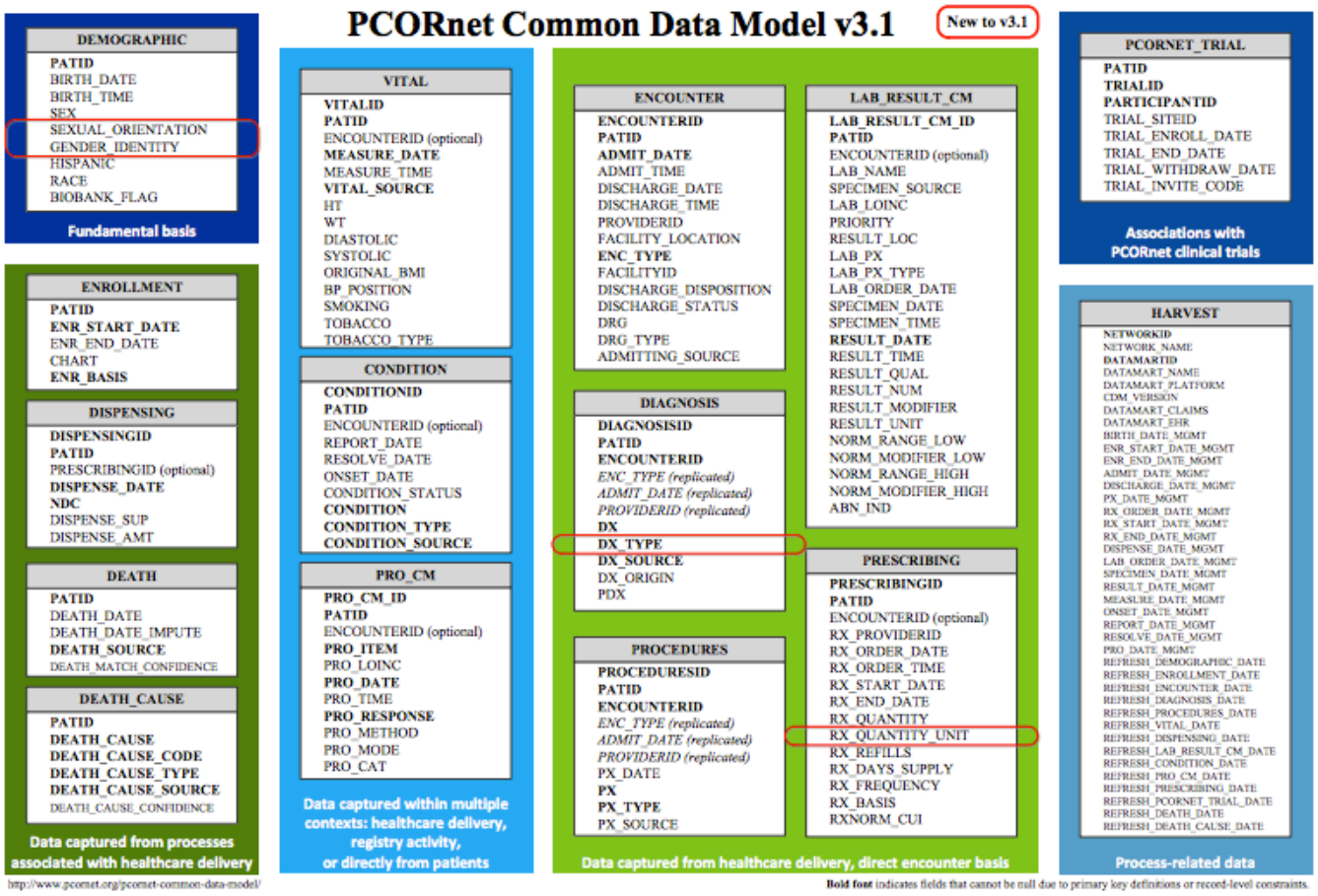
Name: Joseph D. Kimbrell, MA, MSW

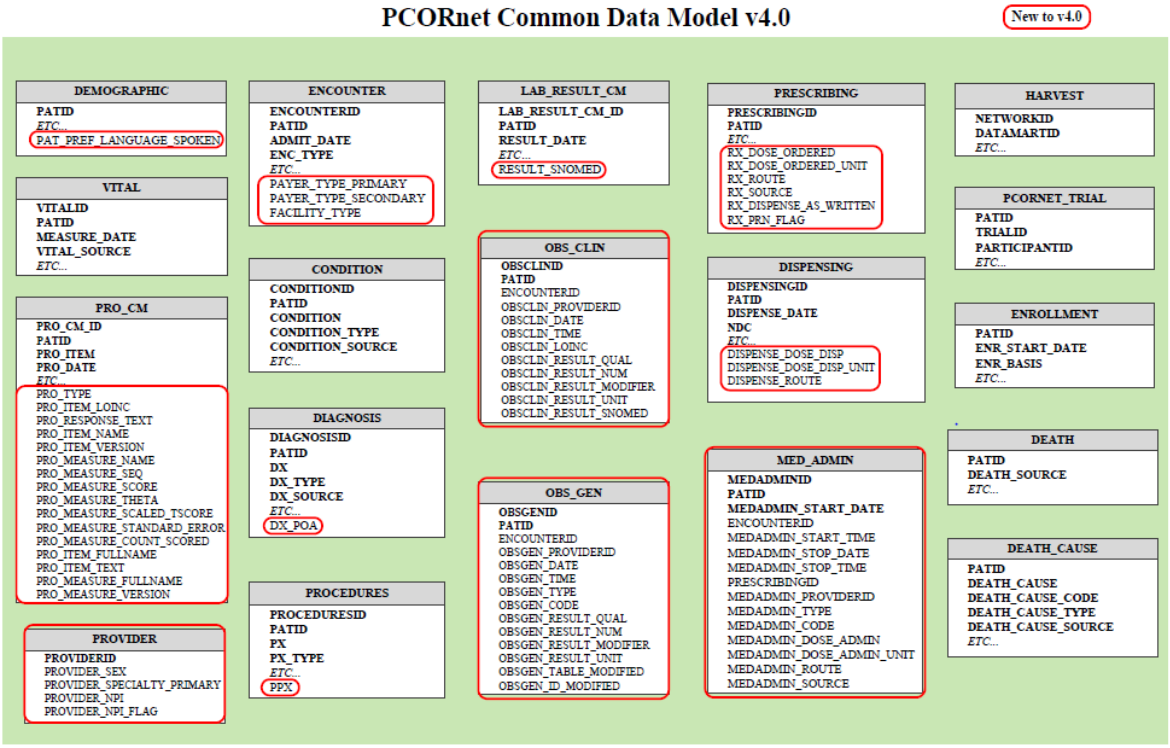
Title: Chief Executive Officer

Date: _____

Exhibit "A" – Definition of Data (REACHnet Common Data Model)

1. Data contributed to LPHI by Participant includes the PCORnet Common Data Model v3.1 and v4.0 (v4.0 to be implemented by Participants in April-June 2018) LDS elements listed below (as well as additional LDS elements in future versions of the Common Data Model),submitted according to the data validity, quality, and characterization standards established by PCORI (as set forth at http://www.pcornet.org/pcornet-common-data-model/) and the REACHnet governance structure. Data is contributed according to the following parameters:
    a. Up to a 5 year backfill of historical data (with the 5 year or other applicable time period to be calculated back from the effective date of this Agreement)
    b. Ongoing data submissions at regular intervals





2. Data contributed to LPHI by Participant may also include the following additional LDS elements that are outside of the PCORnet Common Data model:
    a. Financial class associated with each encounter, mapped to the following predefined value set:

• CP = Commercial/private • MC = Medicare • MD = Medicaid • OG = Other Government • WC = Workman's Compensation	• UI = Uninsured • SP = Self-pay • OT = Other • NI = No Information

    b. Geospatial data elements, including:
        - Census tract, geocoded within Participant environment
        - Zip code + four
    c. Provider taxonomy code

Exhibit "B" – Common Data Model Variable List for Study Entitled, [Study Title]

[Extraction Criteria]

Table 1. Common Data Model data elements requested

Common Data Model Table	**[Variables Requested]**
Demographic	
Enrollment	
Death	
Death cause	
Vital	
Procedures [Specify procedure types]	
Condition	
Encounter	
Diagnosis [Specify diagnosis types]	
Lab Result [Specify lab types]	
Prescribing [Specify medication types]	
Pro_CM	
PCORnet_Trial	
Harvest	
Medication Administration [Specify medication types]	
Provider	
Clinical Observations [Specify clinical observations]	
General Observations [Specify general observations]	
Other (financial class, geospatial data elements, provider taxonomy code)	

Exhibit "C" – Analysis Plan for Study Entitled,
"[STUDY NAME]"

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

Exhibit "D" - Dissemination Policy

Research Dissemination Policy

Guidance for Dissemination-Related Activities

Modified on January 3, 2018

This document sets forth guidelines for the dissemination of outputs which rely on REACHnet resources, including peer-reviewed manuscripts, conference presentations, and other opportunities for formal dissemination of project activities and results.

Criteria for Authorship

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

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

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

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

Corresponding Author

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

Order of Authorship

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

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

Conference Presentations

Conference abstracts or papers should be submitted to REACHnet[3] with as much advanced notice as possible, but a minimum of one week prior to submission. REACHnet will review to ensure that the network is accurately and appropriately described. Allow a minimum of 5 business days to obtain approval from REACHnet. Investigators are required to notify REACHnet of abstracts or papers accepted for presentation within 15 days of acceptance. Conference posters or presentations should be submitted to REACHnet with as much advanced notice as possible, but a minimum of one week prior to final submission. REACHnet will review to ensure that the network is accurately and appropriately described in all dissemination materials. Allow a minimum of 5 business days to obtain approval from REACHnet.

All REACHnet partner health systems who contributed data to the study must either: a) have a co-author on the presentation, or b) provide prior institutional approval of the presentation from the health system's REACHnet Co-PI. When Co-PI approval is needed, REACHnet will request it during the 5-day review period.

Publications

Manuscripts should be submitted to REACHnet[4] with as much advanced notice as possible, but a minimum of two weeks prior to submission to a journal. REACHnet will review to ensure that the network is accurately and appropriately described. Allow a minimum of 10 business days to obtain approval from REACHnet. Investigators are required to notify REACHnet of manuscripts accepted for publication within 15 days of acceptance.

All REACHnet partner health systems who contributed data to the study must either: a) have a co-author on the manuscript, or b) provide prior institutional approval of the presentation from the health system's REACHnet Co-PI. When Co-PI approval is needed, REACHnet will request it during the 10-day review period.

Acknowledgement of REACHnet Support

Investigators are required to acknowledge REACHnet support and cite results acquired from health system data obtained through REACHnet appropriately in all funding applications, presentations, and publications in accordance with the following guidelines:

1. Investigators are required to notify REACHnet of any manuscripts accepted for publication and abstracts or papers accepted for presentation within 15 days of acceptance.

[3] Submit conference abstracts, papers, posters, and/or presentations to the REACHnet co-author(s), if applicable, or to bnauman@lphi.org and/or mcanterberry@lphi.org

[4] Submit manuscripts to the REACHnet co-author(s), if applicable, or to bnauman@lphi.org and/or mcanterberry@lphi.org

2. Investigators are required to formally acknowledge REACHnet in all publications and presentations of research conducted using the network. It is recommended that the following language be included in the Acknowledgements Section of the manuscript or presentation to properly acknowledge collaboration with REACHnet:

   "*Supported in part by CDRN 1306-04864 from the Patient Centered Outcomes Research Institute. The content is solely the responsibility of the authors and does not necessarily represent the official views of the Research Action for Health Network (REACHnet), its partner health systems, National Patient Centered Clinical Research Network (PCORnet), or Patient Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee."*

   In addition to the funding acknowledgement, the following standardized acknowledgement of the REACHnet partnerships will be used for ALL publications, presentations, and other dissemination-related activities, regardless of the authors listed.

   "*The authors acknowledge the participation of REACHnet partner health systems: [name all participating health systems, if permission is given to list*] in this project.*

   **Participating data contributor names may be listed, if approval from the respective health system's REACHnet Co-PI is obtained. If the participating health systems wish to remain anonymous, their name(s) will not be listed here.*
3. Investigators are required to cite all results acquired from REACHnet partner data that are presented in any format. The following language is recommended for properly citing prep-to-research or analysis results using data from REACHnet:

   Research Action for Health Network, Louisiana Public Health Institute. [Date dataset was created or updated.] *Title or brief description of dataset, including time period, target patient population and health system(s) covered in the data if applicable* [Data file/Prep-to-research query]. New Orleans, Louisiana: Louisiana Public Health Institute.

Please contact the REACHnet Coordinating Center with any questions about citing data obtained from REACHnet.