PCORnet COORDINATING CENTER DATA SHARING AGREEMENT v5.0

This PCORnet Coordinating Center Data Sharing Agreement v5.0 (the "**Agreement**") is entered into by and between Duke University, a tax-exempt research and educational institution, acting for and on behalf of its Duke Clinical Research Institute ("**DUKE**"), The Children's Hospital of Philadelphia, a non-profit corporation ("**CHOP**"), and The University of Iowa, a state-owned institution of higher education ("**IOWA**"), on one hand and on the other hand, _____ ("**Network Participant**"). DUKE, CHOP, IOWA, and Network Participant are each referred to herein as a "**Party**" and, collectively, as the "**Parties**."

WHEREAS, PCORnet®, the National Patient-Centered Outcomes Research Network, is a distributed research network 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;

WHEREAS, DUKE has received an award from the Patient-Centered Outcomes Research Institute "**PCORI**") to manage and coordinate the PCORnet Coordinating Center;

WHEREAS, DUKE, together with IOWA and CHOP, its subcontractors, are serving as a coordinating center to support PCORnet infrastructure (DUKE, CHOP, and IOWA together referred to hereinafter as "the **Coordinating Center**" and the "**CC**", as further defined in Section I.e);

WHEREAS, as part of managing and coordinating PCORnet, the Coordinating Center will issue queries for, and collect data from, participants in the network to assure proper functioning of PCORnet and to facilitate the conduct of research in accordance with PCORnet Policies;

WHEREAS, Network Participant may, from time to time and at its discretion, respond to queries as part of its participation in PCORnet and send data via the Coordinating Center's data hosting service provider for retrieval by the Coordinating Center and subsequent transfer to a data Requestor (as defined below);

WHEREAS, the Parties seek to enter into this Agreement in order to clarify their responsibilities with respect to the sharing of data by Network Participant as part of PCORnet.

NOW, THEREFORE, the Parties agree to the following.

I. Definitions

Except as otherwise expressly provided herein, terms used in this Agreement shall be defined as follows:

a. **Affiliate(s)**: Any company or business entity controlled by, controlling, or under common control with a Party. For this purpose, "control" means direct or indirect beneficial ownership of at least fifty percent (50%) interest in the voting stock (or the equivalent) of such company or business entity or possessing, directly or indirectly, the

power to direct or cause the direction of the management or policies of any such company or business entity (whether through ownership of securities or partnership or other ownership interests, by contract, or otherwise).

b. **Aggregate Data**: Aggregated, De-identified, non-Individual Level Data across specified strata of individuals. For example, counts of patients within a stratum that includes a particular age group, gender and diagnosis.

c. **Authorized Users**: Individuals associated with and selected by Network Participant who have been granted access to the Secure File Transfer Method in accordance with minimum standards developed by the Coordinating Center.

d. **Breach**: The acquisition, access, use or disclosure of PHI (as defined herein) in a manner not permitted by the HIPAA Privacy Rule that compromises the security or privacy of PHI, and subject to the exceptions set forth in 45 CFR 164.402.

e. **Clinical Research Network ("CRN")**: A clinical research network that participates in PCORnet.

f. **Coordinating Center ("CC")**: DUKE, CHOP, and/or IOWA serving in their respective roles managing, coordinating and leading PCORnet activities including, but not limited to, issuing the various PCORnet Queries outlined in Section II (Responsibilities of the Coordinating Center) of this Agreement.

g. **De-identified Data**: This term has the meaning ascribed to it in the HIPAA Privacy Rule at 45 CFR Section 164.514(a). Processes for de-identifying data are set forth in 45 CFR Section 164.514(b) of the HIPAA Privacy Rule.

h. **De-Identified Individual Level Data**: Health information that (i) is not aggregated, (ii) is derived from a specific individual, (iii) does not identify the individual, and (iv) does not have a reasonable basis for belief that the information can be used to identify the individual.

i. **HIPAA**: The Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, and all implementing regulations, as may be amended from time to time.

j. **HIPAA Privacy Rule**: The HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164), as may be amended from time to time.

k. **HIPAA Security Rule**: The HIPAA Security Rule (45 CFR Part 160 and Subparts A and C of Part 164), as may be amended from time to time.

l. **Individual Level Data**: Data that are not Aggregate Data. Individual Level Data contain information that is specific to individual patients. Individual Level Data may or may not be De-Identified Data.

m. **Limited Data Set**: This term has the meaning ascribed to it in the HIPAA Privacy Rule at 45 CFR Section 164.514 (e).

n. **Minimum Necessary**: This term has the meaning ascribed to it in the HIPAA Privacy Rule at 45 CFR Section 164.514(d).

o. **Network Participant Data ("Data")**: Data generated, collected, processed, maintained, held or stored by Network Participant locally in connection with its participation in PCORnet, which may be transferred to the Coordinating Center in response to a PCORnet Query.

p. **PCORnet Policies**: Policies adopted by PCORnet leadership and made available to Network Participants regarding the operation and governance of PCORnet, which may be amended from time to time.

q. **PCORnet Query ("Query")**: A query of Network Participant Data sent from the Coordinating Center using a Secure File Transfer Method.

r. **Protected Health Information ("PHI")**: This term has the meaning ascribed to it in the HIPAA Privacy Rule at 45 CFR Section 160.103.

s. **Requestor**: An individual who may or may not be affiliated with Network Participant, who submits a request for a PCORnet Query and receives the results.

t. **Secure File Transfer Method**: A method to securely transfer (i) PCORnet Queries from the Coordinating Center to the Network Participant, and/or (ii) Network Participant Data from the Network Participant to the CC in response to a Query. This method will be specified for each Query and Data transfer by the CC, subject to Network Participant's approval, and may include PopMedNet, Duke Box, sFTP or another secure file transfer method.

u. **Tokens**: Encrypted character strings representing De-identified Individual Level Data incapable of being reverse-engineered to reveal the original information that are generated from a one-way hash process using various combinations of elements of individual patients' personally identifiable information. De-identification of Tokens is accomplished through the expert determination method.

v. **Unsecured PHI**: PHI that is not rendered unusable, unreadable or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary in the guidance issued under section 13402(h)(2) of Public Law 111-5, as the term is defined in 45 CFR 164.402.

II. Responsibilities of the Coordinating Center

a. Data Completeness and Data Characterization Activities. From time to time, the Coordinating Center shall issue queries in support of PCORnet infrastructure activities, as outlined below.

i. Administrative Queries. From time to time, the Coordinating Center shall issue queries of Network Participant Data seeking return of Aggregate Data. DUKE has received blanket approval from DUKE's Institutional Review Board (an "**IRB**")

for all Administrative Queries initiated by DUKE. CHOP and IOWA will each obtain approval from an appropriate IRB for all Administrative Queries initiated respectively by CHOP and IOWA. The purpose of such Queries shall be to inform the CC of Data availability and Data quality (a "**Data Curation Query**"), to enable the CC to share Aggregate Data with Requestors, and to present Aggregate Data in venues such as public-facing websites or interfaces (e.g., PCORnet.org) or in manuscripts consistent with the guidelines of the International Committee of Medical Journal Editors ("**ICMJE**") and/or for use in PCORnet marketing materials ("a **PCORnet Front Door Query**"). The data requested, level of aggregation (e.g., PCORnet, CRN or Network Participant (a "**DataMart**") and planned use(s) will accompany each request and be specified per PCORnet Policy. Such Queries shall be referred to herein as "Administrative Queries," and relevant Data shall flow as outlined in the "Data Flow Documentation" attached hereto as Exhibit A and hereby incorporated into the Agreement, recognizing that in some scenarios, the CC also acts as Requestor. Pursuant to Section III.a.i (Participation in a Query), participation in Administrative Queries is at the discretion of each Network Participant.

ii. Matching Assessment Queries. From time to time, the Coordinating Center may issue Queries of Network Participant Data, seeking return of Tokens produced from Network Participant's use of privacy-preserving record linkage software, to allow the CC to assess the performance of the privacy-preserving record linkage algorithm(s) utilized by PCORnet and ensure they are functioning properly. These Queries are administrative in nature, but unlike the Queries defined above in Section II.a.i (Administrative Queries), the results of these Queries will not be published on any websites or used in publications. They will simply be used to monitor matching performance and troubleshoot any potential anomalies. Such Queries shall be referred to herein as "Matching Assessment Queries", and relevant Data shall flow as outlined in the "Data Flow Documentation" attached hereto as Exhibit A, recognizing that in this instance, the CC also acts as Requestor. Pursuant to Section III.a.i (Participation in a Query), participation in Matching Assessment Queries is at the discretion of each Network Participant.

iii. Token Queries to Identify Overlap with External Partners. From time to time, the Coordinating Center shall issue Queries seeking return of Tokens produced from Network Participant's use of privacy-preserving record linkage software and potentially limited demographic variables in order to allow the CC to identify the overlap between Network Participant's data and data from external data holders. Network Participant's response to this Query will indicate Network Participant's approval for the CC to transfer said Tokens and limited demographic variables, if applicable, to a privacy-preserving record linkage vendor to determine the percentage of PCORnet participants who have records that exist in the data sources held by external data partners. The privacy-preserving record linkage vendor has certified that inclusion of limited demographic variables will not render the De-Identified Individual Level Data returned by Network Participant identifiable in the expert determination available at https://pcornet.imeetcentral.com/p/ZgAAAAAA8HaT

iv. Minimum Necessary. For Administrative Queries, Matching Assessment Queries, and Token Queries to Identify Overlap with External Partners, the Coordinating Center shall request the Minimum Necessary Network Participant Data to fulfill the purpose of the Query.

v. Use Limitation. The Coordinating Center shall use Network Participant Data returned from an Administrative Query, Matching Assessment Query, or Token Query to Identify Overlap with External Partners solely for the purposes set forth in Section II.a.i (Administrative Queries), Section II.a.ii (Matching Assessment Queries) or Section II.a.iii (Token Queries to Identify Overlap with External Partners), respectively, of this Agreement.

vi. Retention. The Coordinating Center shall retain Network Participant Data returned from an Administrative Query, a Matching Assessment Query, or a Token Query to Identify Overlap with External Partners, only for as long as necessary to fulfill the purpose of the Query, and in any event no longer than five (5) years from the date of the last use of the Data (the "**Retention Period**"). The CC shall not store the Data during the Retention Period other than as provided herein, and no Data shall be maintained outside of the U.S. ("**Offshore Storage**"), either by the CC itself, or at any data service provider facility outside of the U.S., without first providing thirty-five (35) days advance written notice to Network Participant. In the event that Network Participant objects to Offshore Storage of its Data by the CC, Network Participant shall provide written notice to the CC of its objection with an indication of its option to: (a) withdraw its participation in the Query and have its Data removed from the combined PCORnet Data set resulting from the Query, (b) withdraw its participation in PCORnet by terminating this Agreement immediately in accordance with the terms set forth in Section IV.b.i (Termination by Network Participant), or (c) have its Data immediately destroyed by the CC rather than allowing the CC to retain the Data for the full five (5) year Retention Period. If the full Retention Period remains in effect either because Network Participant has no objection to Offshore Storage or the Data remains and is maintained in the U.S. only, then at the end of the Retention Period, the CC shall destroy the Data in accordance with HIPAA's requirements.

b. Analytic Queries. From time to time, the Coordinating Center shall issue queries of Network Participant Data seeking return of certain Data in order to prepare for research (each, a "**Pre-Research Query**") or for research purposes (each, a "**PCORnet Query**" and, together with "**Pre-Research Query**", the "**Analytic Queries**"). Each Analytic Query will specify the Data requested, a summary of the objective of the Query and the proposed schedule for return of the Data to the CC. Only the Minimum Necessary amount of Data will be requested by an Analytic Query. When applicable, the CC shall confirm necessary approvals (including approved IRB waivers of the individual authorization requirement and data use agreements, as applicable) are in place prior to transfer of Data received by the CC from Network Participant to Requestor. Each of Network Participant, the CC and/or the Requestor may rely on the receipt of another's IRB approval, but is not required to do so. IRB approval for the transfer of Data may be obtained by the Parties and/or the Requestor separately. Relevant Data shall flow as outlined in the "Data Flow Description Documentation" attached hereto as Exhibit

A. Pursuant to Section III.a.i (Participation in a Query), participation in Analytic Queries is at the discretion of Network Participant.

i. Analytic Queries Seeking Return of Aggregate Data. In most cases, 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). At the election of Network Participant, Aggregate Data may be transferred from Network Participant to the Coordinating Center with or without the prior execution of a data use agreement between the Requestor and the CC. In the event a data use agreement is executed, it will be in substantially the same form as the Data Use and Transfer Agreement attached hereto as Exhibit B, and notice of the same will be provided by the CC to Network Participant. Network Participant shall provide prompt notice to the CC as to whether it will require execution of a separate data transfer agreement to ensure the CC's compliance with the requirements of this Section. Aggregate Data is, by definition, De-Identified Data.

ii. Analytic Queries Seeking Return of De-Identified Individual Level Data. From time to time, the Coordinating Center shall issue Queries seeking return of De-Identified Individual Level Data. At the election of Network Participant, De-Identified Individual Level Data will be transferred from Network Participant to the CC with or without the prior execution of a data use agreement between the Requestor and the CC. In the event a data use agreement is executed, it will be in substantially the same form as Exhibit B and notice of the same will be provided by the CC to Network Participant. Network Participant shall provide prompt notice to the CC as to whether it will require execution of a separate data transfer agreement to ensure the CC's compliance with the requirements of this Section.

iii. Analytic Queries Seeking Return of a Limited Data Set. From time to time, the Coordinating Center shall issue Queries of Network Participant Data seeking return of a Limited Data Set as part of a PCORnet Query for an approved study. Pursuant to Section III.a.iii (Rights to Share Network Participant Data) of this Agreement, Network Participant will ensure appropriate permissions and approvals are in place prior to the transmission of any Limited Data Set containing Protected Health Information, and Data will be transferred from Network Participant to the CC only after the CC has notified Network Participant that it has executed a data use agreement with Requestor in substantially the same form as Exhibit B.

iv. Analytic Queries Seeking Return of Protected Health Information Other than in a Limited Data Set. Some PCORnet Queries may seek the return of identifiable Individual Level Data. Depending on the source, this may or may not be Protected Health Information, as defined in HIPAA. Pursuant to Section III.a.iii (Rights to Share Network Participant Data) of this Agreement, Network Participant will ensure appropriate permissions and approvals are in place prior to the transmission of any Protected Health Information, and Data will be transferred from Network Participant to the CC only after the CC has notified Network Participant that it has executed a data use agreement with Requestor in substantially the same form as Exhibit B.

v. Use Limitation. The Coordinating Center shall use Network Participant Data returned from a Query only (a) in accordance with the Data use specifications and information required in the Query request, (b) as allowed by the informed consent provided by patients, if applicable, and (c) in accordance with the terms of this Agreement. The CC may only disclose Data to Requestor in accordance with the appropriate IRB's approval as necessary to comply with applicable law and regulation. The CC will not use or further disclose such Data, except as permitted hereunder or as otherwise required by applicable law. The CC agrees to enter into agreements with Requestors in substantially the same form as contained in Exhibit B, to ensure that Requestor's use or disclosure of the Data provided in response to a Query is only for the purpose(s) of the Data use specifications information required in the Query request and only in compliance with the terms contained in this Agreement and the requirements set forth in Exhibit B.

vi. Retention. The Coordinating Center shall retain Network Participant Data returned from an Analytic Query only for as long as necessary to fulfill the purpose of the Query and in any event, no longer than the five (5) year Retention Period (as defined above in Section II.a.vi (Retention)) to allow re-use of the Data consistent with the justification in the study protocol and/or the Query. During the Retention Period, the CC shall not store the Data other than as provided herein, and no Data shall be maintained by Offshore Storage, either by the CC itself, or at any off-shore data service provider facility, without first providing thirty-five (35) days advance written notice to Network Participant. In the event that Network Participant objects to Offshore Storage of its Data by the CC, Network Participant shall provide written notice to the CC of its objection with an indication of its option to: (a) withdraw its participation in the Query and have its Data removed from the combined PCORnet Data set resulting from the Query, (b) withdraw its participation in PCORnet by terminating this Agreement immediately in accordance with the terms set forth in Section IV.b.i (Termination by Network Participant), or (c) have its Data immediately destroyed by the CC rather than allowing the CC to retain the Data for the full five (5) year Retention Period. If the full Retention Period remains in effect either because Network Participant has no objection to Offshore Storage or the Data remains and is maintained in the U.S. only, then at the end of the Retention Period, the CC shall destroy the Data in accordance with HIPAA's requirements. The CC shall require Requestors to comply with substantially similar retention terms as those contained herein.

c. Test Queries. From time to time, the Coordinating Center may issue test Queries (each a "**Test Query**") of Network Participant Data in advance of an Administrative or Analytic Query seeking return of either Aggregate Data, De-identified Individual Level Data, a Limited Data Set or Protected Health Information other than in a Limited Data Set for the purpose of beta testing the operability of software programs used in connection with PCORnet and other PCORnet Query enhancements. Depending on the type of Data requested for return, each Test Query shall be subject to the same requirements as set forth above for Administrative Queries, Matching Assessment Queries or Analytic Queries, as applicable. With approval from the CC, Network Participant may elect to return Data containing only simulated Protected Health Information ("**Dummy Data**") in response to a Test Query. In such a case, the Dummy Data shall not be subject to the requirements set forth in this Agreement or HIPAA.

Pursuant to Section III.a.i (Participation in a Query), participation in Test Queries is at the discretion of Network Participant. Results returned from Test Queries will not be combined with Results from any other Query, or shared with any individual, organization or other entity not a Party to this Agreement, except as agreed with Network Participant for specific Queries.

i. Retention Period. In the event that Network Participant returns Network Participant Data in a form other than Dummy Data in response to a Test Query, the Coordinating Center shall retain such Data only for as long as necessary to fulfill the purpose of the Test Query, and in any event, no longer than the Retention Period. During the Retention Period, the CC shall not store the Data other than as provided herein, and no Data shall be maintained by Offshore Storage, either by the CC itself, or at any off-shore data service provider facility, without first providing thirty-five (35) days advance written notice to Network Participant. In the event that Network Participant objects to Offshore Storage of its Data by the CC, Network Participant shall provide written notice to the CC of its objection with an indication of its option to (a) withdraw its participation in the Query and have its Data removed from the combined PCORnet Data set resulting from the Query, (b) withdraw its participation in PCORnet by terminating this Agreement immediately in accordance with the terms set forth in Section IV.b.i (Termination by Network Participant), or (c) have its Data immediately destroyed by the CC rather than allowing the CC to retain the Data for the full five (5) year Retention Period. If the full Retention Period remains in effect either because Network Participant has no objection to Offshore Storage or the Data remains and is maintained in the U.S. only, then at the end of the Retention Period, the CC shall destroy the Data in accordance with HIPAA's requirements. The CC shall require Requestors to comply with substantially similar retention terms as those contained herein.

d. Secure File Transfer Method. The Coordinating Center must submit all Queries covered by this Agreement to Network Participant through a Secure File Transfer Method.

e. Security of Network Participant Data.

i. Compliance with the HIPAA Security Rule. The Coordinating Center agrees to adopt and use physical, administrative and technical safeguards consistent with the HIPAA Security Rule to protect any Network Participant Data received from Network Participant pursuant to this Agreement, and to use all reasonable measures, including encryption, to prevent any use or disclosure of Data other than as provided by this Agreement.

ii. Breach. In the event of a known or suspected Breach of Unsecured PHI by the Coordinating Center that would trigger notification to individuals or regulators if the CC were a HIPAA covered entity or business associate (as those terms are defined in HIPAA), or in the event of any use or disclosure of Network Participant Data other than as permitted by this Agreement, the CC shall notify Network Participant, Network Participant's Authorized User(s) and the other CCs in writing (e.g., email or letter) as soon as possible (and in no event no later than 10 days) after discovery of the known or suspected Breach or any other use or disclosure of

Data other than as permitted by this Agreement. A known or suspected Breach or any other use or disclosure of Data other than as permitted by this Agreement shall be treated as discovered by the CC as of the first business day on which such known or suspected Breach or other impermissible use or disclosure of Data is known to the CC or, by exercising reasonable diligence, would have been known to the CC. The CC shall provide reasonable assistance to Network Participant and cooperate with Network Participant's implementation of HIPAA's risk assessment process outlined in the HIPAA Breach Notification Rule at 45 CFR §§ 164.400-414. The CC agrees to take reasonably appropriate steps to prevent further unauthorized disclosure, to investigate and mitigate the Breach or other use or disclosure not permitted by this Agreement, and to reasonably cooperate with Network Participant as it develops any notifications to individuals, regulators or the media that are either required by applicable law or Network Participant policy.

iii. Authorized User(s). The Coordinating Center shall provide log-in credentials to Network Participant's Authorized User(s) for the Secure File Transfer Method and shall monitor and maintain a record of access of Network Participant's Authorized User(s). In the event Network Participant changes its Authorized User(s), Network Participant must provide written notice to the CC, and the CC shall invalidate the previous Authorized Users' credentials and issue new, distinct credentials to the new Authorized User(s).

f. Network Participant Data Integrity. Once the Coordinating Center receives Network Participant Data from Network Participant, the CC is responsible for assuring that the Data have not been altered or destroyed in an unauthorized manner ("**Integrity**," as such term is defined in HIPAA).

g. Network Participant Identification. Each Query will specify how and/or if Network Participant will be identified to the Requestor, in accordance with PCORnet Policies. Network Participant may also request additional restrictions aimed at preserving confidentiality pursuant to Section III.h (Network Participant Data Confidentiality) below, and the Coordinating Center shall comply with such requests where feasible. The Coordinating Center will notify Network Participant if the CC believes compliance with a requested restriction is not feasible. The Parties will then use good faith efforts to resolve the issue. For clarity and avoidance of doubt, nothing in this Section prohibits Network Participant from withdrawing its participation in a PCORnet Query if the issue is not resolved.

h. No Re-Identification. Except with the express, written permission of Network Participant and IRB approval, the Coordinating Center agrees not to re-identify or attempt to re-identify individuals whose information is contained in any dataset returned to the CC in response to a Query. In its role as a CC, the CC shall not attempt to contact any patient whose information is provided hereunder unless required to do so by applicable law or government regulation, or as permitted under a documented IRB partial waiver of the HIPAA authorization requirement for recruitment purposes only consistent with an IRB-approved protocol. In any event, the CC will provide written notice to Network Participant and the IRB prior to such contact.

i. Employees and Representatives. The Coordinating Center shall ensure that its employees and representatives comply with the terms and conditions of this Agreement and ensure that its agents and subcontractors to whom the CC provides Network Participant Data agree in writing to comply with the same restrictions and conditions that apply to the CC hereunder.

III. Responsibilities of Network Participant

a. Local Obligation and Authority.

i. Participation in a Query. Network Participant retains discretion over whether it will participate in any Query from the Coordinating Center. Where Network Participant is a CRN, such Network Participant is obligated to ensure that its participation in any Query from the CC is consistent with its own policies.

ii. Network Participant Data Security and Integrity. Network Participant is solely responsible, up to the point when Network Participant initiates transmission in response to a Query by the Coordinating Center, for the privacy and security and Data Integrity (as such term is defined in HIPAA) of Network Participant Data. Network Participant shall appoint Authorized User(s) and shall be solely responsible for said Authorized Users' conduct with respect to PCORnet and performing activities related to this Agreement.

iii. Rights to Share Network Participant Data. Network Participant is solely responsible for ensuring that it has all necessary rights, approvals and consents, where applicable, to disclose Network Participant Data through the Secured File Transfer Method.

iv. Withdrawal of Response. Once Network Participant Data are transmitted to the Coordinating Center, such Data may only be removed from a report via a written request by the Network Participant before a report of findings is submitted back to the Requestor.

b. Administrative Query Response. For Administrative Queries in which Network Participant chooses to participate, Network Participant shall return Aggregate Data in accordance with the specifications of the Query.

c. Matching Assessment Query Response. For Matching Assessment Queries in which Network Participant chooses to participate, Network Participant shall return De-Identified Individual Level Data in accordance with the specifications of the Query.

d. Analytic Query Response. For Analytic Queries in which Network Participant chooses to participate, Network Participant shall return Network Participant Data in accordance with the specifications of the Query.

e. Test Query Response. For Test Queries in which Network Participant chooses to participate, Network Participant shall return Network Participant Data or, with prior approval from the Coordinating Center, may elect to return Dummy Data in accordance with the specifications of the Query.

f. Review of Results; Low Cell Counts. For PCORnet Queries in which Network Participant chooses to participate Network Participant shall return low cell counts of Network Participant Data so that accurate counts of the availability of PCORnet's total results can be obtained. Low cell counts will be suppressed and changed so that only cell counts less than 11 will be returned to the Requestor.

g. Use of PCORnet's Secure File Transfer Method. For PCORnet Queries in which Network Participant chooses to participate, Network Participant must respond to such PCORnet Queries using the specified Secure File Transfer Method. Network Participant assumes no responsibility or liability for the availability, operation or maintenance of the specified Secure File Transfer Method.

h. Network Participant Data Confidentiality. Network Participant, in preparing a response to Query, may require that reports, descriptions or other materials created by the CC or a Requestor from its Network Participant Data not describe institution-level results if Network Participant believes it would be possible to identify its organization through specific characteristics of the populations or practice patterns. However, Network Participant acknowledges that any such requirements may preclude Network Participant's participation in a particular Query.

i. Use of Standalone Data Use and Transfer Agreement. A template Standalone Data Use and Transfer Agreement is attached to this Agreement as Exhibit C (the "Standalone DUTA"), and is intended as an option for use between, and at the sole discretion of, Network Participants without the use of, or reliance on, either the Coordinating Center or PCORnet. The use of the Standalone DUTA does not rely on or invoke any of the terms and conditions of this Agreement. The Standalone DUTA (i) is provided for convenience of use only and (ii) will be negotiated by the individual parties who seek to utilize it. Neither PCORI nor any Party to this Agreement takes responsibility for any negotiations or the terms and conditions agreed to between parties utilizing the Standalone DUTA.

IV. Term and Termination

a. Term. This Agreement shall become effective on the date of the last signature below (the "**Effective Date**"), shall continue until December 31, 2025 (the "**Initial Period**") unless terminated earlier in accordance with the terms herein, and shall renew automatically for additional one-year periods on the first day of each subsequent calendar year thereafter beginning on January 1, 2026 (each a "**Renewal Period**"), provided that each renewing Party receives continued funding for ongoing participation in PCORnet.

b. Termination.

i. Termination by Network Participant. This Agreement shall automatically terminate immediately (i) upon Network Participant's written notice to the Coordinating Center of its intent to end its participation in PCORnet, or (ii) at the end of the Initial Period or any Renewal Period, if Network Participant is no longer receiving continued funding for ongoing participation in PCORnet. In the case of

termination due to discontinued funding, the Network Participant ***must*** provide written notice to the Coordinating Center not later than thirty (30) days prior to the end of the Initial Period or the Renewal Period.

ii. Termination by a Coordinating Center. DUKE, CHOP, or IOWA may withdraw as a Party from this Agreement if that Party ceases to serve as a coordinating center in PCORnet by providing written notice to Network Participant and the other non-terminating Parties. Such withdrawal shall become effective as of the date of the terminating Party's notice, and the Agreement shall remain in full force and effect as it relates to Network Participant and the other non-terminating Parties.

iii. Termination by Any Party. Network Participant or the Coordinating Center may terminate this Agreement with or without cause upon thirty (30) days prior written notice to the other Parties.

iv. Data Disposition. Upon termination or expiration of this Agreement for any reason, the Coordinating Center will return or, at Network Participant's direction, ensure destruction of all of Network Participant's Data in the control of the CC in any form or in any medium. The CC will ensure completion of the return or destruction of such Data as soon as reasonably practical, but not later than ninety (90) days after the effective date of the termination of this Agreement. To the extent that the destruction of Network Participant's Data is infeasible, the preceding sentence shall not apply and the CC may retain such Data until such time as the CC's record retention policies provide for destruction. Until such destruction, Network Participant Data shall be protected and maintained as confidential pursuant to the terms of this Agreement.

c. Survival. The obligations of the Parties set forth in the following sections shall survive termination of this Agreement: within Section II (Responsibilities of the Coordinating Center), subsections a.iv (Use Limitation), a.v (Retention), b.v (Use Limitation), b.vi (Retention), e.i (Compliance with the HIPAA Security Rule), e.ii (Breach), f (Network Participant Data Integrity), and h (No Re-Identification); within Section III (Responsibilities of Network Participant), subsection a.iv (Withdraw of Response); within Section IV (Term and Termination), subsection c (Survival); and within Section VI (Miscellaneous), subsections a (Indemnification; Limitation of Liability; and Insurance OR Liability; Limitation of Liability; and Insurance) and, as applicable, b (Network Participant Institutional/State Requirements).

V. Amendment.

a. Changes in PCORnet. From time to time, any Party may need to amend this Agreement to respond to changes in applicable law, PCORnet Policies, or other operations of PCORnet. Any such amendments shall take effect upon the sooner of the effective date of the change precipitating the amendment or thirty (30) days after notice by one Party to the others of the need for the amendment, and unless otherwise required by such change, shall only apply to PCORnet Queries and transfers of Network Participant Data made after the time the change becomes effective. In the event that Network Participant disagrees with any such amendment, it may terminate this Agreement upon written notice to the other Parties in accordance with Section IV.b (Termination).

b. Other Amendments. Except as provided in Section V.a, (Changes in PCORnet) the Parties may amend this Agreement only by a written agreement signed by all Parties.

VI. Miscellaneous

[Alternate language option: Each Network Participant must choose one of the following two bracketed Options to appear as Section VI.a. in their DSA]

[Option 1. If this is chosen, please delete Option 2 below.]

a. Indemnification; Limitation of Liability; and Insurance.

i. To the extent permitted under applicable law, each Party (the "**Indemnifying Party**") will indemnify, defend and hold harmless the other Parties and any of their Affiliates, and their respective trustees, officers, directors, employees and agents ("**Indemnitees**") from and against any third-party claim, cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorney's fees and court costs) arising out of or resulting from negligence, willful misconduct or breach of this Agreement on the part of the Indemnifying Party or any employee, subcontractor, agent or person under the control of the Indemnifying Party. Notwithstanding the foregoing, the Indemnifying Party shall have no obligation to the extent of the other Parties' negligence, willful misconduct or breach of this Agreement. Notwithstanding any other terms or conditions of this Agreement, no state agency or corporation deemed to be a 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. The Parties hereby acknowledge that IOWA is a public institution and a nonprofit state agency. Accordingly, to the extent permitted by Article VII, §1 of the Iowa Constitution, as interpreted by the Iowa Attorney General, and subject to the rights and protections afforded IOWA under the Iowa Tort Claims Act (Iowa Code Chapter 669), IOWA's obligation to indemnify, defend and hold harmless shall be limited to the extent of IOWA's sovereign immunity under applicable federal, state, or local laws. In such cases where IOWA's obligation to indemnify may be limited due to the requirements of applicable federal, state, or local laws, IOWA shall be responsible for the negligent acts and omissions of IOWA's agents, officers, directors and employees acting within the scope of their employment causing harm to persons not a party to this Agreement.

ii. 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 any indirect, incidental, special or consequential damages of any kind, including lost profits (whether or not the Parties have been advised of such loss or damage) arising in any way in connection with this Agreement.

iii. Each Party shall maintain in force at its sole cost and expense with reputable insurance companies, insurance of a type and in an amount reasonably sufficient to protect against liability hereunder. In addition to such insurance and/or in the alternative, a Party may maintain a program of self-insurance to protect against the

same. Each Party shall have the right to request evidence of such insurance and/or self-insurance from the other Parties for the purpose of ascertaining the sufficiency of such coverage. Notwithstanding any other terms or conditions of this Agreement, no state/federal public institution that is an instrumentality of a state/federal government shall be required to comply with the insurance requirements of this Section so long as such institution relies on the applicable law of its state/federal jurisdiction to protect and limit its liability as an instrumentality of such state/federal government.

[End of Option 1.]

OR

[Option 2. If this is chosen, please delete Option 1 above.]

a. Liability; Limitation of Liability; and Insurance.

i. Each Party shall be responsible for its own negligent acts and omissions under this Agreement and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by applicable law.

ii. Under no circumstances will any Party be liable to another Party for any indirect or consequential damages of any kind, including lost profits (whether or not the Parties have been advised of such loss or damage) arising in any way in connection with this Agreement.

iii. Each Party shall maintain in force at its sole cost and expense with reputable insurance companies, insurance of a type and in an amount reasonably sufficient to protect against liability hereunder. In addition to such insurance and/or in the alternative, a Party may maintain a program of self-insurance to protect against the same. Each Party shall have the right to request the appropriate certificates of insurance from the other Parties for the purpose of ascertaining the sufficiency of such coverage. Notwithstanding any other terms or conditions of this Agreement, no state/federal public institution that is an instrumentality of a state/federal government shall be required to comply with the insurance requirements of this Section so long as such institution relies on the applicable law of its state/federal jurisdiction to protect and limit its liability as an instrumentality of such state/federal government.

[End of Option 2.]

b. Network Participant Institutional/State Requirements. The Parties acknowledge and agree that Network Participant and this Agreement may be subject to certain institutional and/or state law requirements which must be included herein. Accordingly, the Parties agree as follows:

i. ***[Insert title of requirement (underlined) with requested language OR mark "Reserved". Do not delete this section.]*.**

c. Use of a Party's Name. Neither Party will use the name, trademark, logo, symbol, or other image of the other Party, a Network Participant from whom the Data originated or that Party's or Network Participant's employee or agent in marketing, advertising, publicity or public relation purposes without the prior written consent of the affected Party or Network Participant.

d. No Warranties. All Network Participant Data sent to the Coordinating Center pursuant to this Agreement by Network Participant is provided "AS-IS." Network Participant expressly disclaims any and all warranties regarding such Data pursuant to this Agreement, including, without limitation, warranties of accuracy, completeness, fitness for a particular use or any other express or implied warranties.

e. Relationship of the Parties. Nothing contained in this Agreement shall constitute, or be construed to create, a partnership, joint venture, agency or other relationship between the Parties other than that of independent contractors to the Agreement. The Parties acknowledge that the Coordinating Center is not a business associate, as that term is defined in the HIPAA regulations, of Network Participant.

f. Assignability. In no event shall any Party assign any of its rights, powers, duties or obligations under the Agreement without the written consent of the other Parties, which shall not be unreasonably withheld, and any attempt to do so shall be void.

g. Severability. Any provision of this Agreement that proves to be invalid, void or illegal ("**Invalid**") shall in no way affect, impair or invalidate any other provision of the Agreement and such other provisions shall remain in full force and effect, unless the declaration of invalidity materially (i) impairs the ability of a Party to perform its obligations, (ii) impairs the benefits received by a Party, or (iii) adversely affects a primary purpose of the Agreement (collectively, "**Impairment**"). If an Invalid provision causes Impairment, the Parties agree to cooperate in making a good faith effort to replace such provision with one that is valid and that will achieve the original intent of the Parties. If the Parties are unable to agree upon a replacement provision when an Impairment results from an Invalid provision, then a Party may terminate its participation in the Agreement upon written notice to the other Parties in accordance with Section IV.b (Termination).

h. Enforceability. The Agreement shall be enforceable only by the Parties hereto, and their successors pursuant to a valid assignment pursuant to this Agreement. In all other respects, this Agreement is not intended, nor shall it be construed, to create any third party beneficiary rights.

i. Notices. Any notices (except those required under Section II.e.ii (Breach) to individuals) shall be deemed effectively given when personally received by the intended recipient, and shall be sent by (a) email transmission with non-automatic acknowledgment from the recipient indicating receipt; (b) express or overnight courier with proof of delivery; or (c) United States Postal Service, certified or registered mail with signed return receipt, addressed to the person or persons identified herein.

For DUKE:	**With a copy to**:
Duke University	Contracts Management

Office of Research Contracts
2200 W. Main Street
Suite 900, Erwin Square
Durham, NC 27705
Phone: 919-684-6278
contracts.management@mc.duke.edu.

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

For CHOP:
The Children's Hospital of Philadelphia
Roberts Center for Pediatric Research, 15th Floor
2716 South Street
Philadelphia, PA 19146
Attn: Director, Office of Collaborative and Corporate Research Contracts
researchcontracts@chop.edu

With a copy to:
Office of General Counsel
Roberts Center for Pediatric Research, 20th Floor
2716 South Street
Philadelphia, PA 19146
legal@chop.edu

For IOWA:
Division of Sponsored Programs
2 Gilmore Hall
Iowa City, IA 52242
dsp-contracts@uiowa.edu

For Network Participant:
_____
_____
_____
_____

j. Signing Authority. Each person signing the Agreement hereby represents that he or she is authorized to enter into the Agreement on behalf of the Party for which he or she is signing.

k. Counterparts and Electronic Signature. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same Agreement. Delivery of an executed signature page to the Agreement by facsimile transmission, when receipt of such transmission is acknowledged by the receiving Party, or by PDF will be as effective as delivery of a manually signed counterpart.

l. Entire Agreement. This Agreement constitutes the full and complete understanding of the Parties hereto with respect to the subject matter hereof and supersedes all prior understandings and agreements with respect to such subject matter including, as applicable, the PCORnet Coordinating Center Data Sharing Agreement previously

executed by the Parties, which is hereby terminated as of the date of full execution of this Agreement. Any handwritten modifications to this Agreement shall be null and void unless such modifications are initialed by all Parties.

[NEXT PAGE IS SIGNATURE PAGE]

IN WITNESS WHEREOF, DUKE, CHOP, IOWA, and Network Participant have entered into this Agreement as of the Effective Date.

DUKE UNIVERSITY

By:_____

Name: Susan Hayden, JD

Title: Director, Research Program Collaborations
Office of Research Contracts

Date: _____

CHILDREN'S HOSPITAL OF PHILADELPHIA

By:_____

Name: Charles T. Bartunek, JD

Title: Director, Office of Collaborative and
Corporate Research Contracts

Date: _____

THE UNIVERSITY OF IOWA

By:_____

Name: Wendy Beaver

Title: Executive Director, Division of Sponsored Programs

Date: _____

Network Participant:

[NAME]

By:_____

Name: _____

Title: _____

Date: _____

[Optional IRB signature block added if necessary and required by Network Participant. Otherwise, please delete.]

Read and Acknowledged by Network Participant's Institutional Review Board:

[IRB NAME]

By:_____

Name: _____

Title: _____

Date: _____

Exhibit A

Data Flow Documentation

This Data Flow Documentation ("**Documentation**") describes and illustrates how data flows through the PCORnet data network in response to a question (a PCORnet Query) from the time a Query is sent from the PCORnet Coordinating Center to Network Participants, until the time data resulting from the Query is released by Network Participants and delivered to Requestor by the Coordinating Center. Only the physical aspects of the movement of data through the network are addressed in this Documentation, but not the legal, administrative or regulatory requirements for data transfer or use of the data by the Requestor.

Please note that unless otherwise specified, all capitalized terms used in this Documentation have the same meaning assigned to them as in the PCORnet Data Sharing Agreement to which it is attached.

I. DESCRIPTION.

A. PCORnet Data Network Architecture. The PCORnet data network uses a distributed architecture in which there is no central data repository. Instead, networks (CRNs) must standardize locally-held electronic health data in accordance with the PCORnet "Common Data Model". Queries are programmed by the Coordinating Center, and distributed to networks using a Secure File Transfer Method.

B. PCORnet Common Data Model. In the PCORnet Common Data Model, which is based on the FDA Sentinel Initiative Common Data Model (www.sentinelsystem.org), each partner network securely collects and stores data behind its own firewall, and maps it to the same consistent format (i.e., with the same variable name, attributes, and other metadata). It leverages standard terminologies and coding systems for healthcare (including ICD, SNOMED, CPT, HCPSC, and LOINC) to enable interoperability with, and responsiveness to, evolving data standards. The PCORnet Common Data Model (www.pcornet.org/pcornet-common-data-model) is maintained and managed by the Coordinating Center in collaboration with the network.

C. Issuing a PCORnet Query. The Coordinating Center will issue any PCORnet Query and send these to the network through a Secure File Transfer Method after its review and approval of a Requestor's request.

D. Response to a PCORnet Query. A PCORnet Network Participant receives all PCORnet Queries through a Secure File Transfer Method. A Network Participant may respond to queries by returning their data through the Secure File Transfer Method, but can choose not to respond to any Query. Data is not sent directly to a Requestor from a Network Participant in response to a Query, but is first retrieved by the Coordinating Center from the Secure File Transfer Method.

E. Transfer of Data and Delivery to Requestor. After the Coordinating Center retrieves all Network Participant Data, the data is then transferred to the Requestor following execution of a HIPAA-compliant data use agreement, as applicable.

II. ILLUSTRATION. The diagram below illustrates the data flow and transfer process.

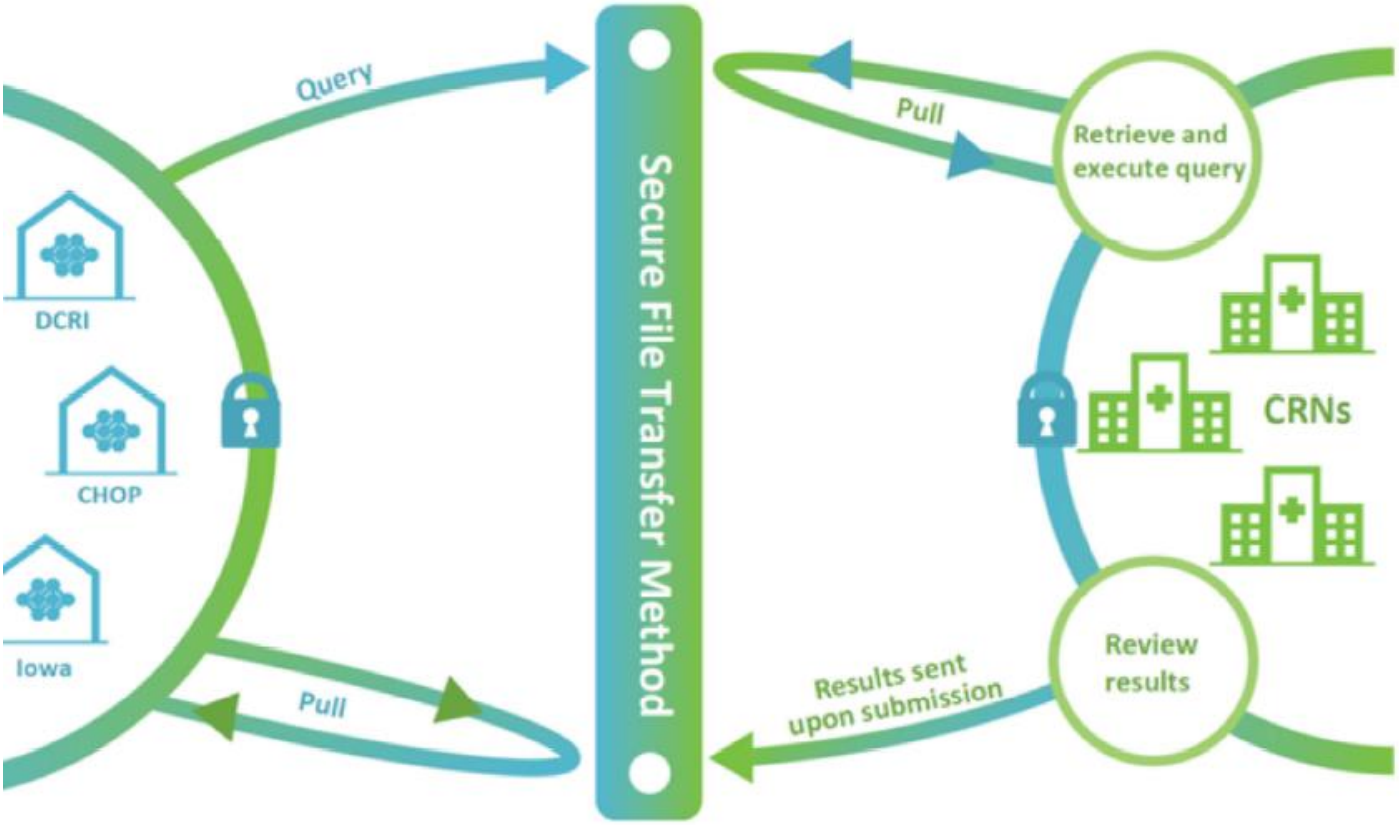

EXHIBIT B

DATA USE AND TRANSFER AGREEMENT

This Data Use and Transfer Agreement ("**Agreement**") is entered into as of the date of the last signature below ("**Effective Date**") by and between:

☐ Duke University ("**DUKE**"), a tax-exempt research and educational institution, acting for and on behalf of its Duke Clinical Research Institute; or

☐ The Children's Hospital of Philadelphia ("**CHOP**"), a non-profit corporation; or

☐ The University of Iowa ("**IOWA**"), a state-owned institution of higher education; or

(DUKE, CHOP, or IOWA referred to herein as the "**Coordinating Center**" or the "**CC**")

and

_____[Name of contracting party]____ ("**RECIPIENT**")

(the Coordinating Center and RECIPIENT together referred to herein as the "**Parties**").

WHEREAS, PCORnet®, the national Patient-Centered Outcomes Research Network, is 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;

WHEREAS, in its role as the Coordinating Center, the CC is in possession of certain Network Participant Data (as defined below) received from Network Participant(s) (as defined below) who have agreed to share their patient health information in response to a PCORnet Query pursuant to the terms of a five-party Data Sharing Agreement ("**DSA**") entered into by and among DUKE, CHOP, IOWA, and Network Participants;

WHEREAS, RECIPIENT has, where required by law or institutional policy, requested and received approval from its Institutional Review Board ("**IRB**") for receipt of patient health information for the following purpose (the "**Purpose**"):

Research Project Name: _____ (the "**Project**")

Protocol #: _____

IRB #: _____ *Approval Date:* _____

Principal Investigator: _____

Purpose (description of data requested, use and research justification): _____

_____

_____

Project Team Members: _____

WHEREAS, the Coordinating Center shall disclose Network Participant Data (as defined below) to RECIPIENT, subject to the terms and condition contained in this Agreement, in a form identified below (all forms referred to hereinafter as "**the Data**"):

☐ a De-identified Data set containing no individual patient identifiers constituting Protected Health Information ("**PHI**") (as further defined below), which is not subject to the requirements of HIPAA (as defined below); or

☐ a Limited Data Set of PHI, so that RECIPIENT is a "Limited Data Set Recipient" as defined in HIPAA, and is therefore subject to the requirements of HIPAA; or

☐ a Data set containing more PHI than permitted in a Limited Data Set under HIPAA, and is therefore subject to the requirements of HIPAA.

NOW, THEREFORE, the Parties agree to the provisions of this Agreement in order to address the requirements of HIPAA, to protect the interest of both Parties, and to comply with the terms of the DSA and PCORnet Policies.

1. **DEFINITIONS**. Except as otherwise defined herein, any and all capitalized terms in this Agreement shall have the definitions set forth in HIPAA. In the event of any inconsistency between the provisions of this Agreement and mandatory provisions of HIPAA, as amended, the HIPAA provisions shall control. Where provisions of this Agreement are different from those provided in HIPAA, but are permitted by HIPAA, the provisions of this Agreement shall control. The following terms shall have the meaning ascribed to them below and in the DSA:

    a. **Breach**: The acquisition, access, use or disclosure of PHI (as defined herein) in a manner not permitted by the HIPAA Privacy Rule that compromises the security or privacy of the PHI, and subject to the exceptions set forth, in 45 CFR 164.402.

    b. **HIPAA**: The Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act (HITECH), and all implementing regulations, as may be amended from time to time.

    c. **HIPAA Privacy Rule**: The HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164), as may be amended from time to time.

    d. **HIPAA Security Rule**: The HIPAA Security Rule (45 CFR Part 160 and Subparts A and C of Part 164), as may be amended from time to time.

    e. **Network Participant**: An individual site or organization that is a party to a four-party DSA by and amongst DUKE, CHOP, and IOWA which contributes Network Participant Data to PCORnet at its discretion in response to a query by the Coordinating Center for permitted use by a Requestor.

    f. **Network Participant Data ("Data")**: Data generated, collected, processed, maintained, held or stored by Network Participant locally in connection with its participation in PCORnet, which may be transferred to the Coordinating Center in response to a PCORnet Query.

g. **PCORnet Policies**: Policies adopted by the PCORnet Leadership regarding the operation and governance of PCORnet, as may be amended from time to time.

h. **PCORnet Query**: A query of Network Participant Data that uses a Secure File Transfer Method.

i. **Project Team Members**: Individuals serving under the direction of RECIPIENT's Principal Investigator or lead investigator as team members for the Project who have permitted access to the Data disclosed to RECIPIENT by the CC. Project Team Members may include RECIPIENT's employees and/or its authorized agents and subcontractors.

j. **Protected Health Information ("PHI")**: Individually identifiable health information as more fully defined in the HIPAA Privacy Rule at 45 CFR Section 160.103.

k. **Requestor**: An individual who may or may not be affiliated with Network Participant or another participant in PCORnet, but who is authorized by a Network Participant or another participant in PCORnet to develop and submit a request for a PCORnet Query and receive the results.

l. **Unsecured PHI**: PHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary in the guidance issued under section 13402(h)(2) of Public Law 111-5, as the term is defined in 45 CFR 164.402.

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

3. **APPROVAL CERTIFICATION**. As applicable, and to the extent required by law and the institutional policy of the Network Participant(s) from whom the Data originated, each Party certifies that it has obtained IRB approval for RECIPIENT's right to use and disclose the Data provided to RECIPIENT by the Coordinating Center for the Purpose described herein, and/or that such IRB approval is based on valid individual subjects' authorization or a waiver of the authorization requirement. RECIPIENT and the CC acknowledge that the CC's disclosure of the Data under this Agreement is permitted pursuant to (a) the Network Participant(s)' from whom the Data originated receipt of valid individual subjects' authorization, as certified in the DSA executed, or (b) the IRB's waiver of the authorization requirement. In the event of RECIPIENT's receipt of an IRB waiver, RECIPIENT shall provide a copy of the same to the CC upon request. RECIPIENT accepts responsibility and liability for any unauthorized use or disclosure of the Data following RECPIENT's receipt of such Data pursuant to this Agreement.

4. **PERMITTED USE**. The Coordinating Center will provide the Data to RECIPIENT in the form identified herein, as either a De-identified Data Set, a Limited Data Set, or a Data set containing more PHI than permitted in a Limited Data Set, as indicated above. RECIPIENT agrees that it shall treat the Data in confidence and shall avoid disclosure of the Data to any other person, firm or corporation unless necessary to complete the Purpose. RECIPIENT shall have the right to use the Data only for its analysis related to the Project and not for any other purpose, including commercial use or otherwise. The Data may be shared with RECIPIENT's Project Team Members,

which may include its employees, and/or its authorized agents and subcontractors only on a need-to-know basis, and shall not be shared with any other third-party without the express written prior consent of the CC, provided that the CC first obtains the express written consent of the Network Participant from whom the Data originated prior to sharing such Data with any other third-party. In the event RECIPIENT discloses the Data to its authorized agents or subcontractors who have a need to use and access the Data to enable RECIPIENT to fulfill the Purpose, RECIPIENT will ensure that such agents or subcontractors enter into an agreement with no less restrictive terms than those contained herein including, but not limited to, those addressing data privacy, security, and breach notification.

5. **RESTRICTIONS ON USE**. RECIPIENT agrees that the Data it receives will not be used in any manner not allowed by the informed consent and/or authorization provided by individual subjects, if applicable, or in any manner inconsistent with the Purpose, or with the terms of RECIPIENT's IRB's approval of RECIPIENT's use and receipt of the Data. RECIPIENT further agrees that it, any Project Team Members identified herein, and any other authorized third-party to whom it discloses the Data, will not use or further disclose the Data other than as permitted by this Agreement, or as otherwise required by law or regulation. RECIPIENT shall not, or attempt to, re-identify the individuals to whom the Data pertains, or attempt to contact such individuals. RECIPIENT also shall not attempt to identify the Network Participant(s) from whom the Data originated. No license or additional rights are provided to RECIPIENT in connection with the Data under any patent applications, copyrights, trade secrets or other proprietary rights of PCORnet, the Coordinating Center or the Network Participants.

6. **DATA SECURITY**. Regardless of whether the Data contains PHI, all Data disclosed by the Coordinating Center shall be maintained by RECIPIENT under appropriate administrative, physical and technical safeguards, including encryption while in transit, to protect the confidentiality and integrity of the Data, and its electronic and physical security from misuse or inappropriate disclosure. RECIPIENT shall use all reasonable measures to prevent any use or disclosure of the Data other than as provided in this Agreement, and shall protect the Data in strict confidence in the same manner as it would protect its own confidential information.

7. **COMPLIANCE WITH LAWS**. RECIPIENT will ensure that the Project for which the Data is received is conducted in accordance with all federal, state, and local laws and regulations applicable to the Project, and RECIPIENT will comply with the same.

8. **REPORTING**. RECIPIENT shall promptly report to the Coordinating Center, but in no event later than (five) 5 business days after discovery, any use or disclosure of the Data not provided for in this Agreement of which RECIPIENT becomes aware, regardless of whether the Data contains PHI. The CC shall promptly inform the Network Participant(s) from which such Data originated of such unauthorized use or disclosure. RECIPIENT will take reasonable steps to limit any further such use or disclosure.

9. **BREACH NOTIFICATION**. Following the discovery of a Breach of Unsecured PHI contained in the Data received from the Coordinating Center, RECIPIENT shall notify the CC of such known or suspected Breach pursuant to the terms of 45 CFR § 164.410 and cooperate in the CC's and, if applicable, the Network Participant(s)' from whom the data originated, Breach analysis procedures, including risk assessment, if requested, and any mitigation processes. RECIPIENT may conduct its own risk assessment and mitigation processes, provided however, that such action

doesn't conflict with or affect those of the CC or of the Network Participant(s). RECIPIENT understands and agrees that the Network Participant(s) from whom the Data containing PHI originated may, at its/their discretion, participate in the CC's Breach analysis procedures and risk assessment. A Breach shall be treated as discovered by RECIPIENT as of the first day on which such Breach is known to RECIPIENT or, by exercising reasonable diligence, would have been known to RECIPIENT. RECIPIENT will provide such notification to the CC and if required, RECIPIENT's IRB, without unreasonable delay and in no event later than Five (5) business days after discovery of the Breach in order for the CC to provide notice to the Network Participant(s) of the known or suspected breach, and to comply with its contractual obligations under the DSAs with the Network Participant(s). Such notification will contain the elements required in 45 CFR § 164.410. The CC, in consultation with the Network Participant(s) from whom the Data originated, shall determine any required actions with respect to any such Breach. RECIPIENT shall cooperate and comply with such actions required by the CC and Network Participant(s) including, but not limited to, the development of any notifications to individuals, regulators or the media that are either required by law or Network Participant(s)' policy(ies).

10. **ACCESS AND INSPECTION**. From time to time upon reasonable advance notice, at mutually agreeable times and during standard business hours, or upon a reasonable determination by the Coordinating Center that RECIPIENT has breached this Agreement, the CC may inspect the facilities, systems, books and records of RECIPIENT where and in which the Data is maintained, at mutually agreeable times, to monitor compliance with this Agreement. The fact that the CC inspects, or fails to inspect, or has the right to inspect, RECIPIENT's facilities, systems and procedures does not relieve RECIPIENT of its responsibility to comply with this Agreement, nor does the CC's (a) failure to detect or (b) detection of, but failure to notify RECIPIENT or to require RECIPIENT's remediation of, any unsatisfactory practices constitute acceptance of such practice or a waiver of the CC's enforcement or termination rights under this Agreement. The Parties' respective rights and obligations under this Section 10 shall survive termination of the Agreement for as long as the Data is maintained in RECIPIENT's possession until returned to the CC or destroyed in accordance with Section 11 (Retention).

11. **RETENTION**. RECIPIENT shall retain the Data only for as long as necessary to fulfill the Purpose, and in any event no longer than five (5) years or the time required by the Coordinating Center that is consistent with the research justification in the Protocol (the "**Retention Period**"). RECIPIENT shall not store the Data during the Retention Period other than as provided herein, and shall not be maintained outside of the U.S. either by RECIPIENT itself, or at any data service provider facility outside of the U.S. At the end of the Retention Period, RECIPIENT shall destroy the Data in accordance with HIPAA's requirements. If return or destruction is not feasible, RECIPIENT shall inform the CC of the reason it is not feasible and shall continue to extend the protections of this Agreement to such Data and limit further use and disclosure of such Data to those purposes that make the return or destruction of such Data infeasible.

12. **TERM AND TERMINATION.** This Agreement shall become effective on the Effective Date, and shall continue during the Retention Period, unless otherwise terminated by applicable law or regulation. This Agreement shall terminate upon completion of the Project. Should RECIPIENT receive Data containing PHI and commit a material breach of this Agreement, which is not cured within thirty (30) business days after RECIPIENT receives notice of such breach from the Coordinating Center, then the CC will discontinue disclosure of the Data containing PHI and will report the breach to the Network Participant(s) from whom the Data originated and to the Secretary, United States Department of Health and Human Services.

13. **USE OF A PARTY's NAME**. Neither Party will use the name, trademark, logo, symbol, or other image of the other Party, a Network Participant from whom the Data originated or that Party's or Network Participant's employee or agent in advertising, publicity, or otherwise without the prior written consent of the other Party or Network Participant.

14. **NOTICE**. Any notices (except those required under Section 9 to individuals) shall be deemed effectively given when personally received by the intended recipient, and shall be sent by (a) email transmission with non-automatic acknowledgment from the recipient indicating receipt; (b) express or overnight courier with proof of delivery; or (c) United States Postal Service, certified or registered mail with signed return receipt, addressed to the person or persons identified herein.

As to the Coordinating Center:

If to DUKE
Office of Research Contracts
2200 W. Main Street, Suite 900
Durham, NC 27705
Attention: Director

With copy to:
Duke Clinical Research Institute
300 West Morgan Street, Suite 800
Durham, NC 27701
Attention: Contracts Management

For CHOP:
The Children's Hospital of Philadelphia
Roberts Center for Pediatric Research, 15th Floor
2716 South Street
Philadelphia, PA 19146
Attn: Director, Office of Collaborative and Corporate Research Contracts
researchcontracts@chop.edu

With a copy to:
Office of General Counsel
Roberts Center for Pediatric Research, 20th Floor
2716 South Street
Philadelphia, PA 19146
legal@chop.edu

For IOWA:
DSP Contracts
2 Gilmore Hall
Iowa City, IA 52242
dsp-contracts@uiowa.edu

As to RECIPIENT:
_____
_____
_____
_____

15. **MODIFICATION.** Any alteration, modification, or amendment to this Agreement must be in writing and signed by both Parties.

16. **ASSIGNMENT.** This Agreement may not be assigned by either Party without the prior written consent of the other.

[NEXT PAGE IS SIGNATURE PAGE]

IN WITNESS WHEREOF, the Coordinating Center entering this Agreement and RECIPIENT have signed or caused this Agreement to be signed as of the dates indicated below.

Coordinating Center	**Recipient**
DUKE UNIVERSITY	**[NAME]**
By: _____	By:_____
Name: Susan Hayden, JD	Name: _____
Title: Director, Research Program Collaborations Director – Office of Research Contracts	Title: _____
Date: _____	Date:_____

CHILDREN'S HOSPITAL OF PHILADELPHIA

By:_____

Name: Charles T. Bartunek, JD

Title: Director, Office of Collaborative and Corporate Research Contracts

Date: _____

THE UNIVERSITY OF IOWA

By:_____

Name: Wendy Beaver

Title: Executive Director, Division of Sponsored Programs

Date: _____

EXHIBIT C
STANDALONE DATA USE AND TRANSFER AGREEMENT

This Standalone Data Use and Transfer Agreement ("**Agreement**") is entered into as of the date of the last signature below ("**Effective Date**") by and between:

_____[Name of contracting party]____ ("**DISCLOSER**")

and

_____[Name of contracting party]____ ("**RECIPIENT**")

(the DISCLOSER and RECIPIENT together referred to herein as the "**Parties**").

WHEREAS, PCORnet®, the national Patient-Centered Outcomes Research Network, is 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;

WHEREAS, DISCLOSER is in possession of certain Data (as defined below) and desires to share such Data with Recipient for the Purpose (defined below), and;

WHEREAS, RECIPIENT has, where required by law or institutional policy, requested and received approval from its Institutional Review Board ("**IRB**") for receipt of patient health information for the following purpose (the "**Purpose**"):

Research Project Name: _____ (the "**Project**")

Protocol #: _____

IRB #: _____ *Approval Date:* _____

Principal Investigator: _____

Purpose (description of data requested, use and research justification): _____

_____

_____

Project Team Members: _____

WHEREAS, DISCLOSER shall disclose the Data (as defined below) to RECIPIENT, subject to the terms and conditions contained in this Agreement, in a form identified below (all forms referred to hereinafter as "**the Data**"):

☐ a De-identified Data set containing no individual patient identifiers constituting Protected Health Information ("**PHI**") (as further defined below), which is not subject to the requirements of HIPAA (as defined below); or

☐ a Limited Data Set of PHI, so that RECIPIENT is a "Limited Data Set Recipient" as defined in HIPAA, and is therefore subject to the requirements of HIPAA; or

☐ a Data set containing more PHI than permitted in a Limited Data Set under HIPAA, and is therefore subject to the requirements of HIPAA.

NOW, THEREFORE, the Parties agree to the provisions of this Agreement in order to address the requirements of HIPAA, to protect the interests of both Parties.

1. **DEFINITIONS**. Except as otherwise defined herein, any and all capitalized terms in this Agreement shall have the definitions set forth in HIPAA. In the event of any inconsistency between the provisions of this Agreement and mandatory provisions of HIPAA, as amended, the HIPAA provisions shall control. Where provisions of this Agreement are different from those provided in HIPAA, but are permitted by HIPAA, the provisions of this Agreement shall control. The following terms shall have the meaning ascribed to them below:

    a. **Breach**: The acquisition, access, use or disclosure of PHI (as defined herein) in a manner not permitted by the HIPAA Privacy Rule that compromises the security or privacy of the PHI, and subject to the exceptions set forth, in 45 CFR 164.402.

    b. **Data**: Data generated, collected, processed, maintained, held or stored by DISCLOSER.

    c. **HIPAA**: The Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act (HITECH), and all implementing regulations, as may be amended from time to time.

    d. **HIPAA Privacy Rule**: The HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164), as may be amended from time to time.

    e. **HIPAA Security Rule**: The HIPAA Security Rule (45 CFR Part 160 and Subparts A and C of Part 164), as may be amended from time to time.

    f. **Project Team Members**: Individuals serving under the direction of RECIPIENT's Principal Investigator or lead investigator as team members for the Project who have permitted access to the Data disclosed to RECIPIENT by DISCLOSER. Project Team Members may include RECIPIENT's employees and/or its authorized agents and subcontractors.

    g. **Protected Health Information ("PHI")**: Individually identifiable health information as more fully defined in the HIPAA Privacy Rule at 45 CFR Section 160.103.

    h. **Unsecured PHI**: PHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary in the guidance issued under section 13402(h)(2) of Public Law 111-5, as the term is defined in 45 CFR 164.402.

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

3. **APPROVAL CERTIFICATION**. As applicable, and to the extent required by law and the institutional policy of DISCLOSER from whom the Data originated, each Party certifies that it has obtained IRB approval for RECIPIENT's right to use and disclose the Data provided to RECIPIENT by DISCLOSER for the Purpose described herein, and/or that such IRB approval is based on valid individual subjects' authorization or a waiver of the authorization requirement. RECIPIENT and DISCLOSER acknowledge that DISCLOSER's disclosure of the Data under this Agreement is permitted pursuant to DISCLOSER's receipt of valid individual subjects' authorization, as certified in the DSA executed, or (b) the IRB's waiver of the authorization requirement. In the event of RECIPIENT's receipt of an IRB waiver, RECIPIENT shall provide a copy of the same to DISCLOSER upon request. RECIPIENT accepts responsibility and liability for any unauthorized use or disclosure of the Data following RECIPIENT's receipt of such Data pursuant to this Agreement.

4. **PERMITTED USE**. DISCLOSER will provide the Data to RECIPIENT in the form identified herein, as either a De-identified Data Set, a Limited Data Set, or a Data set containing more PHI than permitted in a Limited Data Set, as indicated above. RECIPIENT agrees that it shall treat the Data in confidence and shall avoid disclosure of the Data to any other person, firm or corporation unless necessary to complete the Purpose. RECIPIENT shall have the right to use the Data only for its analysis related to the Project and not for any other purpose, including commercial use or otherwise. The Data may be shared with RECIPIENT's Project Team Members, which may include its employees, and/or its authorized agents and subcontractors only on a need-to-know basis, and shall not be shared with any other third-party without the express written prior consent of DISCLOSER. In the event RECIPIENT discloses the Data to its authorized agents or subcontractors who have a need to use and access the Data to enable RECIPIENT to fulfill the Purpose, RECIPIENT will ensure that such agents or subcontractors enter into an agreement with no less restrictive terms than those contained herein including, but not limited to, those addressing data privacy, security, and breach notification.

5. **RESTRICTIONS ON USE**. RECIPIENT agrees that the Data it receives will not be used in any manner not allowed by the informed consent and/or authorization provided by individual subjects, if applicable, or in any manner inconsistent with the Purpose, or with the terms of RECIPIENT's IRB's approval of RECIPIENT's use and receipt of the Data. RECIPIENT further agrees that it, any Project Team Members identified herein, and any other authorized third-party to whom it discloses the Data, will not use or further disclose the Data other than as permitted by this Agreement, or as otherwise required by law or regulation. RECIPIENT shall not, or attempt to, re-identify the individuals to whom the Data pertains, or attempt to contact such individuals. No license or additional rights are provided to RECIPIENT in connection with the Data under any patent applications, copyrights, trade secrets or other proprietary rights of DISCLOSER.

6. **DATA SECURITY**. Regardless of whether the Data contains PHI, all Data disclosed by DISCLOSER shall be maintained by RECIPIENT under appropriate administrative, physical and technical safeguards, including encryption while in transit, to protect the confidentiality and integrity of the Data, and its electronic and physical security from misuse or inappropriate disclosure. RECIPIENT shall use all reasonable measures to prevent any use or disclosure of the Data other than as provided in this Agreement, and shall protect the Data in strict confidence in the same manner as it would protect its own confidential information.

7. **COMPLIANCE WITH LAWS**. RECIPIENT will ensure that the Project for which the Data is received is conducted in accordance with all federal, state, and local laws and regulations applicable to the Project, and RECIPIENT will comply with the same.

8. **REPORTING**. RECIPIENT shall promptly report to DISCLOSER, but in no event later than (five) 5 business days after discovery, any use or disclosure of the Data not provided for in this Agreement of which RECIPIENT becomes aware, regardless of whether the Data contains PHI. RECIPIENT will take reasonable steps to limit any further such use or disclosure.

9. **BREACH NOTIFICATION**. Following the discovery of a Breach of Unsecured PHI contained in the Data received from DISCLOSER, RECIPIENT shall notify DISCLOSER of such known or suspected Breach pursuant to the terms of 45 CFR § 164.410 and cooperate in DISCLOSER's Breach analysis procedures, including risk assessment, if requested, and any mitigation processes. RECIPIENT may conduct its own risk assessment and mitigation processes, provided however, that such action doesn't conflict with or affect those of DISCLOSER. A Breach shall be treated as discovered by RECIPIENT as of the first day on which such Breach is known to RECIPIENT or, by exercising reasonable diligence, would have been known to RECIPIENT. RECIPIENT will provide such notification to DISCLOSER and if required, RECIPIENT's IRB, without unreasonable delay and in no event later than Five (5) business days after discovery of the Breach. Such notification will contain the elements required in 45 CFR § 164.410. DISCLOSER shall determine any required actions with respect to any such Breach. RECIPIENT shall cooperate and comply with such actions required by DISCLOSER including, but not limited to, the development of any notifications to individuals, regulators or the media that are either required by applicable law or DISCLOSER's policies.

10. **ACCESS AND INSPECTION**. From time to time upon reasonable notice, or upon a reasonable determination by DISCLOSER that RECIPIENT has breached this Agreement, DISCLOSER may inspect the facilities, systems, books and records of RECIPIENT where and in which the Data is maintained, at mutually agreeable times, to monitor compliance with this Agreement. The fact that DISCLOSER inspects, or fails to inspect, or has the right to inspect, RECIPIENT's facilities, systems and procedures does not relieve RECIPIENT of its responsibility to comply with this Agreement, nor does DISCLOSER's (a) failure to detect or (b) detection of, but failure to notify RECIPIENT or to require RECIPIENT's remediation of, any unsatisfactory practices constitute acceptance of such practice or a waiver of DISCLOSER's enforcement or termination rights under this Agreement. The Parties' respective rights and obligations under this Section 10 shall survive termination of the Agreement for as long as the Data is maintained in RECIPIENT's possession until returned to DISCLOSER or destroyed in accordance with Section 11 (Retention).

11. **RETENTION**. RECIPIENT shall retain the Data only for as long as necessary to fulfill the Purpose, and in any event no longer than five (5) years or the time required by DISCLOSER that is consistent with the research justification in the Protocol (the "**Retention Period**"). RECIPIENT shall not store the Data during the Retention Period other than as provided herein, and shall not be maintained outside of the U.S. either by RECIPIENT itself, or at any data service provider facility outside of the U.S. At the end of the Retention Period, RECIPIENT shall destroy the Data in accordance with HIPAA's requirements. If return or destruction is not feasible, RECIPIENT shall inform DISCLOSER of the reason it is not feasible and shall continue to extend the protections of this Agreement to such Data and limit further use and disclosure of such Data to those purposes that make the return or destruction of such Data infeasible.

12. **TERM AND TERMINATION.** This Agreement shall become effective on the Effective Date, and shall continue during the Retention Period, unless otherwise terminated by applicable law or regulation. This Agreement shall terminate upon completion of the Project. Should RECIPIENT receive Data containing PHI and commit a material breach of this Agreement, which is not cured within thirty (30) business days after RECIPIENT receives notice of such breach from DISCLOSER, then DISCLOSER will discontinue disclosure of the Data containing PHI and will report the breach to the Secretary, United States Department of Health and Human Services.

13. **USE OF A PARTY's NAME**. Neither Party will use the name, trademark, logo, symbol, or other image of the other Party in advertising, publicity, or otherwise without the prior written consent of the other Party.

14. **NOTICE**. Any notices (except those required under Section 9 to individuals) shall be deemed effectively given when personally received by the intended recipient, and shall be sent by (a) email transmission with non-automatic acknowledgment from the recipient indicating receipt; (b) express or overnight courier with proof of delivery; or (c) United States Postal Service, certified or registered mail with signed return receipt, addressed to the person or persons identified herein.

    As to DISCLOSER:

    _____
    _____
    _____
    _____

    As to RECIPIENT:

    _____
    _____
    _____
    _____

15. **MODIFICATION.** Any alteration, modification, or amendment to this Agreement must be in writing and signed by both Parties.

16. **ASSIGNMENT.** This Agreement may not be assigned by either Party without the prior written consent of the other.

[NEXT PAGE IS SIGNATURE PAGE]

IN WITNESS WHEREOF, DISCLOSER and RECIPIENT have signed or caused this Agreement to be signed as of the dates indicated below.

Discloser	**Recipient**
[NAME]	**[NAME]**
By: _____	By:_____
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date:_____