GREATER PLAINS COLLABORATIVE
COOPERATIVE MEDICAL INFORMATICS DATA SHARING AND NETWORK INFRASTRUCTURE AGREEMENT

This Greater Plains Collaborative Cooperative Medical Informatics Data Sharing and Network Infrastructure Agreement (the "Agreement"), effective as of the ___ day of _____, _____ (the "Effective Date"), is entered into by and among the following entities (each a "Party" and collectively the "Parties"):

i. _____

ii. _____

iii. _____

WHEREAS, The Parties desire to lead the way in biomedical informatics data sharing and network infrastructure through the formation of the Greater Plains Collaborative and the sharing of biomedical data with appropriate privacy and security protections, in order to facilitate information sharing, strengthen outreach and research capabilities, facilitate translational research and enable the deployment of increasingly sophisticated techniques to optimize care;

NOW, THEREFORE, in consideration of the mutual representations, warranties and covenants herein contained, and on the terms and subject to the conditions herein set forth, the Parties hereby covenant and agree as follows:

ARTICLE I.
DEFINITIONS AND KEY TERMS

In addition to the defined terms that appear throughout the Agreement, the following terms, when capitalized, have the following meanings:

1.01 Accept. The term "Accept," and all other tenses of the word, used alone or as a modifier to another defined term (e.g., 'Accepting Participant'), indicates a Participant's agreement to provide its Information (in the form of either De-Identified Information or a Limited Data Set) for a Feasibility Query or Research Project pursuant to a Request for such Participant's involvement. A Participant may only Accept a Feasibility Query or Research Project in accordance with Section 4.02(d)(ii) or 4.02(g)(ii), as applicable.

1.02 Affiliate Investigator: The term "Affiliate Investigator" means a researcher who is not Qualified Faculty, but who is (i) an employee, student, resident or fellow of a Participant and is supervised by Participant's Qualified Faculty, or (ii) another individual providing services to Participant under contract.

1.03 Aggregate Response. The term "Aggregate Response" means the compiled Information (in the form of either De-Identified Information or a Limited Data Set) of all Accepting Participants which is disclosed to the Data Requestor of an Approved Feasibility Query or Approved Research Project.

1.04 Agreement. The term "Agreement" means this Greater Plains Cooperative Medical Informatics Data Sharing and Network Infrastructure Agreement, as amended from time to time.

1.05 Approve. The term "Approve," and all other tenses of the word, used alone or as a modifier to another defined term (e.g., "Approved Research Project") indicates the approval of a Patient Count Query, a Feasibility Query, or Research Project by the requisite GPC Committee(s).

1.06 Babel. The term "Babel" means the GPC terminology alignment service managed by the GPC Infrastructure and Software Development Core to facilitate creation of interoperable Information and to inform Qualified Faculty and Affiliate Investigators of a Participant's data domains available for Proposed Feasibility Queries and Proposed Research Projects.

1.07 Data Contributor. The term "Data Contributor" means an organization or individual other than a Participant who provides information to a Research Repository managed by a Participant. Data Contributors may include but are not limited to: health care providers, government agencies, payors, research databases, or any organization that collects health data and has contracted with a Participant to administer a data repository for a non-commercial purpose.

1.08 Data Request Oversight Committee (DROC). The term "Data Request Oversight Committee" or "DROC" means the GPC Committee charged with reviewing and approving Proposed Feasibility Queries and Proposed Research Projects.

1.09 Data Requestor. The term "Data Requestor" means the person submitting a Patient Count Query, Feasibility Query, or Research Project. Such researcher shall only be a Qualified Faculty or Affiliate Investigator.

1.10 De-identified Information. The term "De-identified Information" means Information that has been de-identified in accordance with the requirements for de-identification of Protected Health Information under 45 CFR §164.514(b).

1.11 Extract Transfer Load or ETL. The term "Extract Transfer Load" or "ETL" means to extract Information from a Participant's local electronic medical records system, transform Information to align with GPC standards, and load Information to a Research Repository.

1.12 Feasibility Query. The term "Feasibility Query" means a query, submitted to the DROC pursuant to Section 4.02(d) below, for preliminary De-identified Information from one or more Participants which is necessary for a Qualified Faculty or Affiliate Investigator to generate a hypothesis and/or determine if a Research Project is feasible within the GPC, which may include not only patient counts but also other descriptive statistics, lab results, etc.

1.13 GPC. The term "GPC" means the Greater Plains Collaborative as further defined in ARTICLE II below.

1.14 GPC Committee. The term "GPC Committee" means a committee described in this Agreement or the PCORI Subcontract, or otherwise approved by the GPC Governing Council, to carry out the activities of the GPC.

1.15 GPC Infrastructure and Software Development Core. The term "GPC Infrastructure and Software Development Core" means the team of representatives from each Participant responsible for establishing the technical infrastructure (such as GPC Hosted Services defined in Section 1.17), development processes, harmonizing the site i2b2 instances and developing methods and infrastructure for patient-reported outcome measures and comparative effectiveness research trials in conjunction with Participant informatics/electronic medical record teams.

1.16 GPC Governing Council. The term "GPC Governing Council" means the Greater Plains Collaborative leadership body as further described in Section 2.03 below.

1.17 GPC Hosted Services. The term "GPC Hosted Services" means the suite of software services to be managed by the GPC Infrastructure and Software Development Core as described in Section 3.04a and additional software services that may be required over time to participate in PCORNet or other data sharing activities as approved by the GPC Governing Council.

1.18 Participant Honest Broker. The term "Honest Broker" means an individual identified and authorized by a Participant to conduct queries on behalf of Participant for Approved Feasibility Queries and Approved Research Projects, and to extract Information (in the form of either De-Identified Information or a Limited Data Set) from such Participant's Research Repository.

1.19 GPC Honest Broker. The term GPC Honest Broker means an individual identified and authorized by the GPC Governing Council to create the Aggregate Response for use in accordance with the System Access Agreement.

1.20 i2b2. The term "i2b2" means the Informatics for Integrating Biology and the Bedside open-source software framework for research, created by a project sponsored by the National Institutes of Health, which supports the management of an integrated clinical data repository and features a web-based query interface. Further details regarding i2b2 are available at https://www.i2b2.org.

1.21 Information. The term "Information" means written or electronic patient information or data, in any form, of the type identified in Section 3.02 of this Agreement.

1.22 Individual. The term "Individual" has the same meaning as the term "individual" in 45 CFR § 160.103 and includes a person who qualifies as a personal representative in accordance with 45 CFR § 164.502(g).

1.23 IRB. The term "IRB" means the leading Institutional Review Board as determined by the GPC's Institutional Review Board (IRB) Authorization Agreement attached hereto as Exhibit D, as amended from time to time.

1.24 Limited Data Set. The term "Limited Data Set" or "LDS" has the same meaning as the term "limited data set" in 45 CFR §164.514(e).

1.25 Participant. The term "Participant" means each Party to this Agreement, in its role as a maintainer of a Research Repository for, and a provider of Information (in the form of either De-Identified Information or a Limited Data Set) to, the GPC.

1.26 Patient Count Query. The term "Patient Count Query" means a direct query of the Research Repositories of one or more Requested Participants for De-identified Information in the form of patient counts necessary for a Data Requestor to generate a hypothesis and/or determine if a Research Project is feasible within the GPC.

1.27 PCORI. The term "PCORI" means the Patient Centered Outcomes Research Institute, a District of Columbia non-profit organization whose principal office is at 1828 L Street, NW, Suite 900, Washington, DC 20036 and which is an independent, non-Federal, non-profit research organization created pursuant to the Patient Protection and Affordable Care Act, 42 U.S.C. § 118001.

1.28 PCORI Prime Contract. The term "PCORI Prime Contract" means the Contract for Funded Clinical Data Research Network Project CER-1306-02496 by and among PCORI, _____, and _____RI effective March 6, 2014. The Participants are held to the Applicable Terms of the PCORI Prime Contract, Attachment F to the PCORI Subcontract.

1.29 PCORI Subcontracts. The term "PCORI Subcontracts" means the several subcontracts to the PCORI Prime Contract, executed by _____ and _____RI with each other Party to this Agreement individually, effective on or after March 6, 2014.

1.30 Privacy Rule. The term "Privacy Rule" means the Standards for Privacy of Individually Identifiable Information at 45 CFR Part 160 and Part 164, Subparts A and E, as amended from time to time.

1.31 Propose. The term "Propose," and all other tenses of the word, used alone or as a modifier to another defined term (e.g., 'Proposed Research Project') indicates submission to the required GPC Committee(s), for review and Approval.

1.32 Protected Health Information (PHI). The term "Protected Health Information" or "PHI" has the same meaning as the term "protected health information" in 45 CFR § 160.103.

1.33 Quorum. The term "Quorum" means the presence of or vote by representatives of at least sixty percent (60%) of Parties. All votes require a Quorum. .

1.34 Qualified Faculty. The term "Qualified Faculty" means a Participant's employed faculty who is appointed at or above the instructor level. Qualified Faculty shall not include students, residents or non-employed faculty of Participant.

1.35 Request. The term "Request," and all other tenses of the word, used alone or as a modifier to another defined term (e.g., 'Requested Participant') indicates the request by a Data Requestor in his or her Proposal to the GPC that a particular Participant provide its Information (in the form of either De-Identified Information or a Limited Data Set) for a Patient Count Query, Feasibility Query, or Research Project.

1.36 Research Project. The term "Research Project" means a research protocol which contemplates the use of an Aggregate Response.

1.37 Research Repository. The term "Research Repository" means a database containing Information maintained by each Participant that utilizes and supports the i2b2 software and schemas and whose data is mapped to GPC data terminology standards.

1.38 Security Rule. The term "Security Rule" means the Standards for Security of Individually Identifiable Information at 45 CFR Parts 160, 162 and 164.

ARTICLE II.
GOVERNANCE AND ADMINISTRATION

2.01 Creation of GPC. The Parties hereby reaffirm their participation as a member of the Greater Plains Consortium (GPC). The purpose of the GPC is the formation of a clinical data research network, as envisioned by PCORI, dedicated to improving the health of residents of the Greater Plains and beyond by improving information sharing, strengthening outreach and research capabilities, facilitating translational research and enabling the deployment of increasingly sophisticated techniques to optimize care.

2.02 Scope of Agreement. The following Research Projects and/or Information are beyond the scope of this Agreement:

(a) Any Request requesting the use or disclosure of Information which does not constitute either a fully de-identified data set as defined by 164.514(b), or a limited data set as defined by 45 CFR 164.514(e). Any such requests must be directly proposed to, and approved and contracted for by, the Requested Participant individually and must be approved by such Participant's institutional review board in accordance with its usual policies and procedures.

(b) Any Proposal requesting the use or disclosure of Information which consists of alcohol and drug abuse patient records, or data derived from such records, that are maintained in connection with the performance of any federally assisted alcohol and drug abuse program which are protected from disclosure by 42 C.F.R. Part 2, psychotherapy notes as defined by 45 C.F.R. § 164.501, or where otherwise protected by state or Federal law.

2.03 GPC Governing Council. The GPC will have a GPC Governing Council which shall initially be comprised of the principal investigator, the subinvestigator(s) named in each Party's PCORI Subcontract, and each Party's chief medical informatics officer or individual designated by such Party. The GPC Governing Council will oversee the Infrastructure and Software Development Core and various GPC Committees. When a majority vote is required to rule on an issue, if a tie vote occurs, no action will be taken on the issue. The tie will be managed by tabling the issue, engaging in negotiations regarding the issue, and recalling the issue for a re-vote at a later time. Notwithstanding the foregoing, the Parties agree that the terms of the PCORI Subcontract shall be determinative and govern as to the issues addressed therein, and shall remain binding upon the Parties as written. In the event of expiration or termination of the PCORI Subcontract, the GPC Governing Council shall consist of two representatives from each Party, who shall be appointed by the chief executive officer of each Party.

2.04 GPC Working Group. A GPC Working Group will be created, initially to be led by _____, of _____, and _____, of _____. The GPC Working Group will consist of these two individuals, three (3) additional subinvestigators and three (3) additional chief medical informatics officers from the GPC Governing Council, elected by a majority vote of the GPC Governing Council. The GPC Working Group will oversee day-to-day operations and drive project management, with the guidance of the Infrastructure and Software Development Core and various GPC Committees.

2.05 Administration and Communication Coordination.

(a) Given its responsibilities as the prime recipient, _____ will initially serve as the central GPC administrative site (the "GPC Administrative Site"). _____ will appoint a part time Administrative Director for the GPC (the "Director"). The Director will provide leadership and oversight of GPC operations throughout the region, including development and facilitation of research collaborations throughout the network, strategic planning, and facilitation of adoption of standard operating procedures, and coordination of GPC meetings and other communications. The Director will serve as a liaison to the PCORI National Coordinating Center, and work with the GPC members to evaluate sustainability. The Director will be responsible for leading the development of standard operating procedures ("SOPs") for the GPC and implementation of this Agreement. The SOP's will be implemented by the Parties after review and written approval of the GPC Governance Council and the authorized representative of each Party.

ARTICLE III.
MANAGEMENT OF DATA REPOSITORIES

3.01 Databases. Each Participant will create and maintain locally a Research Repository to incorporate Information from its own records and those of its Data Contributors, if any, that complies with https://informatics.gpcnetwork.org/trac/Project/wiki/DataRespositoryManagement as updated from time to time, and subsequent requirements to participate in PCORNet.

3.02 Included Information. Each of the Participants will include in its Research Repository for participation in GPC, at a minimum, the following data (collectively "Information") from the sources identified below:

(a) Encounter data for each emergency department visit, outpatient clinic visit or hospital visit, including: patient demographic information, reason for visit, treating health care provider(s), date of visit, place of visit, diagnoses, and procedures; and

(b) Electronic medical record data such as vital signs, pathology results, radiology results, discharge summaries, operative notes, medications, laboratory test results, cardiology studies, orders, allergies, history and physicals, nursing observations and assessments, outpatient prescriptions, and other diagnostic tests; and

(c) Patient registries such as hospital tumor registries in standard formats (eg. North American Association of Central Cancer Registries), patient reported outcomes, and biospecimen sample characteristics.

(d) Codes related to billing activity (e.g., DRGs, HCPCS, ICD-9, ICD-010, CPT, and dental codes) but not costs or charges.

(e) Solely at Participant's option, financial data related to payment of patients' claims whether governmental, commercial or self-pay. The Parties understand and agree a Participant may withhold any such data in its discretion, including without limitation any financial information such as hospital charges, third party pricing, and costs from data provided under this Agreement and fee information unless such information is specifically approved in writing by an authorized representative of the Accepting Participants.

Unless otherwise mutually agreed by the Participants, the Participants will not provide such data stored on other systems or in paper format. No Participant will be required to include in its Research Repository any information it is holding pursuant to a contractual or legal obligation requiring confidentiality or prohibiting its use for this purpose.

Except as otherwise agreed to herein, Participants may include data in addition to the minimum set of Information required by this Section 3.02 and are encouraged to include any and all information that may be relevant to the clinical care or health status of a patient. Notwithstanding the foregoing, Participants will not include alcohol and drug abuse patient records, or data derived from such records, that are maintained in connection with the performance of any federally assisted alcohol and drug abuse program which are protected from disclosure by 42 C.F.R. Part 2, psychotherapy notes as defined by 45 C.F.R. § 164.501, or where otherwise protected by state or Federal law.

3.03 <u>Storage, Transfer, and Maintenance of Information</u>.

(a) The Information included in the Research Repository by each Participant, including Information from a Participant's Data Contributor, will be stored locally by each Participant in its locally approved formats.

(b) Assisted by software methods developed and shared by the GPC members, each Participant's informatics team will create a Research Repository.

(c) For each Patient Count Query, and each Approved Feasibility Query or Approved Research Project which Participant has Accepted, Participant will ETL those requested items of its Information into its Research Repository.

(d) The GPC Infrastructure and Software Development Core will provide technical assistance to the Participant regarding ETL and data standardization processes required by this Agreement.

(e) The Participant will refresh the Information within its Research Repository in a manner responsive to the needs of both (i) the Data Requestor and (ii) PCORNet as determined by the GPC Governing Council. During network development, the refresh frequency may vary,

but by completion of phase 1 of the PCORI Subcontract, each Participant will refresh its Research Repository at least quarterly. The Participant, in accordance with Section 4.06(b), will also update the software versions used for its Research Repository to be complaint with GPC and PCORNet requirements as determined by the GPC Governing Council.

3.04 After each refresh, the Participant will provide to the GPC Infrastructure and Software Development Core lead the i2b2 concept paths contained in its Research Repository and summary statistics to Babel, a GPC Hosted Service that describes the GPC's research capacity to potential investigators.

(a) The GPC Infrastructure and Software Development Core will maintain the GPC Hosted Services. Any information transmitted (data in motion) and will be secured in accordance with the Security Rule by the Participant sending the data in motion. Any information stored (data at rest) will be secured in accordance with the Security Rule by the Party receiving and storing the data at rest. Participants will provide information regarding implementation as reasonably requested by the GPC Governing Council. Support for additional services and processes will be determined and approved by the GPC Governing Council.

(i) Babel will host Participants' Research Repository i2b2 concept paths (with no underlying Information) on a shared i2b2 instance so that Qualified Faculty and Affiliate Investigators may identify Participants appropriate for their research. Access will require the Data Requestor to submit a valid user name and password to gain access to Babel and will be logged for review by the DROC.

(ii) Access to Babel and explanatory materials will be incorporated into the GPC website to facilitate collaboration within the GPC and with PCORNet national collaborators.

(iii) The GPC Infrastructure and Software Development Core will also maintain GPC Hosted Services to facilitate review, approval and auditing of the DROC and Honest Broker activities described in Article IV.

(iv) The Parties acknowledge an interest in identifying opportunities to make the GPC self-sustaining, including exploring the feasibility of assisting PCORI-funded Approved Research Projects, on a fee for service basis, with meeting PCORI's data sharing obligations by maintaining databases and software systems for aggregating and archiving the De-identified Information resulting from such Approved Research Projects. The Parties agree to actively consider such opportunities, and negotiate in good faith any additional agreements which may be required to implement them. No Parties shall be obligated to provide any funding for this purpose until definitive written agreements are executed by their authorized representatives.

(b) Each Participant will implement the GPC-compliant software and organizational processes needed to be responsive to Patient Count Queries, and Approved Feasibility Queries, and to extract and securely transmit De-identified Information and Limited Data Sets to the GPC Hosted Services to support Approved Research Projects, whether they be observational studies, prospective trials, or distributed analyses. Any information transmitted (data in motion) will be secured in accordance with the Security Rule by the Participant sending

the data. Any information stored (data at rest) will be secured in accordance with the Security Rule by the Party receiving and storing the data. Participants will provide information regarding implementation of the software processes and security as reasonably requested by the GPC Governing Council.

ARTICLE IV.
HANDLING REQUESTS FOR INFORMATION

4.01 DROC and Honest Broker. Each Participant will appoint one (1) representative and two (2) alternate members to the DROC. If a Participant's representative or alternate member resigns from the DROC, the Participant will appoint new representative or alternate within seven (7) business days. The Chairs of the GPC Governing Council and GPC Aligning Health Systems Quality Improvement for CER Committee (AHSQIC) will be ex-officio nonvoting members. Each member of the DROC will have the responsibility and authority to review, Approve, disapprove or defer Proposed Feasibility Queries and Research Projects. A majority vote by a Quorum of DROC representatives will be required to Approve or defer any Proposal, and any Proposal which is not Approved or deferred by such a majority vote of a Quorum of DROC representatives will be considered disapproved. In addition to such DROC representatives, each Participant will at all times have a Participant Honest Broker authorized to query the Participant's Research Repository upon its Acceptance of a Feasibility Query or Research Project and access Information from it, as set forth in Section 4.02(d)(iii) or Section 4.02(g)(v), as applicable, below. The Participant Honest Broker will be an employee of Participant and will meet the requirements set forth by the GPC Governing Counsel.

4.02 Requests for Information. Requests for access to Participant Information (in the form of either De-Identified Information or a Limited Data Set) will occur as follows:

(a) Authorization and Oversight of Investigators. The Parties will agree upon one or more request forms and/or agreements outlining the responsibilities of Data Requestors. Data Requestors will be required to sign an agreed upon request form/agreement, obtain the prior approval of an authorized representative, and submit the required form/agreements to the GPC Administrative Site.

(b) Other Preliminary Considerations. Only Qualified Faculty and authorized Affiliate Investigators may submit Patient Count Queries, Proposed Feasibility Queries, and Proposed Research Projects to the GPC. The Participant responsible for the Data Requestor will verify that such Data Requestor is a Qualified Faculty or authorized Affiliate Investigator, and has completed any and all human subjects research training, and/or received IRB approval, as may be necessary for the Patient Count Query, Proposed Feasibility Query or Proposed Research Project. Participants shall provide, or shall require the Data Requestor to provide, proof of such qualification, training and IRB approval to the GPC, and the Proposed projects will be archived in accordance with, processes to be outlined in the SOPs and approved by the GPC Governing Council.

(c) External Affiliate Investigators. The Participants, the GPC Governing Council, and DROC will finalize an external institution collaborator agreement ("Collaborator Agreement"). Organizations who are not Participants or individuals who are not Qualified Faculty or Affiliate Investigators (each an "External Affiliate Investigator") that want to submit Patient Count Queries, Proposed Feasibility Queries, or Proposed Research Projects to the GPC must execute a Collaborator Agreement. External Affiliate Investigators must sign, Exhibit A, GPC System Access Agreement and/or Exhibit B, GPC Data Use Agreement which holds the External Affiliate Investigator to the same requirements and standards as Participants in this Agreement.

(d) Feasibility Queries.

(i) The Data Requestor will submit to the GPC Administrative Site a fully-executed GPC System Access Agreement, which will prohibit the downloading, printing, or retaining of the Aggregate Response obtained as a result of the Feasibility Query, prohibit use of the Aggregate Response for any purpose other than determining the feasibility of a potential Research Project, and require the conduct of the cohort identification in a responsible manner and in compliance with applicable laws. A copy of the GPC System Access Agreement is set forth as Exhibit A.

(ii) Upon the GPC Administrative Site's receipt and processing of the GPC System Access Agreement, the Data Requestor may submit a Proposed Feasibility Query, via a request management system to be determined and configured by the GPC Administrative Site, to the DROC for review in accordance with Section 4.01. The Proposed Feasibility Query will include a list of Requested Participants. DROC representatives will first review in good faith the Proposed Feasibility Query for alignment with the goals of, and suitability for, the GPC generally. If the Feasibility Query is Approved by a majority vote of a Quorum of DROC representatives, then each Participant (following its own internal approval process) will determine if the Participant wishes to Accept it. Participants may not Accept any Feasibility Query which is not Approved. Any Participant may refuse to Accept any Feasibility Query in which it does not want to participate.

(iii) Upon completion of the review process described in the previous paragraph, the Participant Honest Broker for each Accepting Participant will query its Research Repository as directed by the Approved Feasibility Query and submit the requested Information (in the form of De-Identified Information) to the designated GPC Honest Broker. The GPC Honest Broker will create the Aggregate Response for use in accordance with the System Access Agreement. The Aggregate Response will be stored on GPC Hosted Services, and will be available on a REDCap data base with attached files for retrieval by the Data Requestor.

(iv) The Data Requestor will submit a valid user name and password to gain access to the GPC Hosted Services hosting the Aggregate Response. Each session will be logged by the GPC Hosted Services for review by the DROC as desired.

(v) To prevent inadvertent identification of patients, Information for sample sizes of fewer than ten (10) patients will not be provided to the Data Requestor.

(e) Patient Count Queries. The Parties will work together to develop a process, to include the development of appropriate agreement(s) and procedures regarding system and data access, whereby a Participant may allow Data Requestors to directly perform Patient Count Queries using open-source software of a type to be determined (e.g., SHRINE) and configured by _____, which will be linked to the Participant's Research Repository. Each Participant may decide whether or not to authorize such automated Patient Count Queries.

(f) Feasibility Queries In addition to the process described in Section 4.02(d) above, the Parties will work together to develop a process, to include the development of appropriate agreement(s) and procedures regarding system and data access, whereby a Participant may allow Data Requestor to directly perform Feasibility Queries using open-source software of a type to be determined (e.g., SHRINE) and configured by _____, which will be linked to the Participant's Research Repository. Each Participant may decide whether or not to authorize such automated Feasibility Queries.

(g) Research Projects.

(i) The Data Requestor may submit a Proposed Research Project via a request management system to be determined and configured by GPC Administrative Site to the DROC for review in accordance with Section 4.01. The Proposed Research Project will include, at a minimum: a list of Requested Participants; a detailed protocol; documentation of IRB approval and waiver, if necessary, if the protocol design so requires (IRB approval will not be required for Research Projects requesting only De-identified Information); and the identity of any other entities supporting the Research Project, whether by funding, study drug support, or otherwise and the amount of such support.

(ii) The DROC will first review the Proposed Research Project for alignment with the goals of, and suitability for, the GPC generally. DROC representatives may request additional information from the Data Requestor, at any time to aid in its review. If the Research Project is Approved by a majority vote of a Quorum of DROC representatives, a DROC representative from each Requested Participant will then review it pursuant to that Participant's own internal approval process, to determine if such Participant wishes to Accept it. Participants may not Accept any Research Project which is not Approved by the DROC. Any Participant may refuse to Accept any Research Project in which it does not want to participate.

(iii) The GPC Administrative Site will notify the Data Requestor upon Approval of the Research Project and provide a list of Accepting Participants. If the Data Requestor wishes to proceed, regardless of whether the Information requested is De-identified or a Limited Data Set, the Data Requestor will be required to submit to the GPC Administrative Site an executed GPC Data Use Agreement naming _____and all Accepting Participants as parties prior to being permitted to access the Aggregate Response. A copy of the GPC Data Use Agreement is set forth as Exhibit B.

(iv) The Participants acknowledge that some Approved Research Projects may require additional agreements, such as clinical trial agreements, depending on factors such as the protocol design and the conditions of any supporting entities. Each Participant acknowledges that by its Acceptance of an Approved Research Project, it agrees to provide the

administrative resources necessary to negotiate such agreements. Each Participant further agrees that it will not release any Information (in the form of either De-Identified Information or a Limited Data Set) for an Approved Research Project to the GPC or Data Requestor unless and until all necessary agreements are fully executed.

(v) Upon completion of the review and contracting processes described in the preceding paragraphs, and the collection of prospective data if applicable, the Participant Honest Broker for each Accepting Participant will query its Research Repository as directed by the Approved Research Project and submit the Information in the agreed upon format to the GPC Honest Broker.

(vi) The GPC Honest Broker will create the Aggregate Response for use in accordance with the Data Use Agreement and any other agreements which may apply to the Approved Research Project. The Aggregate Response will be stored on the GPC Hosted Services, and will be available on a REDCap data base with attached files for retrieval by the Data Requestor.

(vii) The Data Requestor of the Approved Research Project will submit a valid user name and password to gain access to the GPC Hosted Services hosting the Aggregate Response. Each session will be logged by the GPC Hosted Services for review by the DROC as desired.

(h) To prevent inadvertent identification of patients, De-Identified Information for sample sizes of fewer than ten (10) patients will not be provided to the Data Requestor..

(i) Access by Individuals. Information will not be kept in a designated record set as defined by HIPAA. Requests, if any, from Individuals for access or amendment to their PHI in a designated record set as defined under HIPAA will be referred to the relevant Participant so that the Participant can prepare a timely response to the Individual.

(j) Access Reporting. Through reporting tools provided by GPC Hosted Services and managed by the GPC Honest Broker, Participants will be able to access a report of all Approved Feasibility Queries and Approved Research Projects, and their associated system use, on a quarterly basis including, without limitation, expiration or termination of an ongoing Approved Research Project.

4.03 DROC Review and Approval.

(a) The DROC will make good faith efforts to take no more than seven (7) business days from the date of submission to complete its review of a Proposed Feasibility Query or Proposed Research Project, unless extended dialogue is warranted, in which case the DROC will notify the Data Requestor within seven (7) business days from the date of submission that additional time is needed to evaluate the Proposed Feasibility Query or Proposed Research Project and the time at which the evaluation will be completed.

(b) In reviewing Proposed Feasibility Queries and Proposed Research Projects, the DROC will verify the identity of the Data Requestor and the authority of that individual to receive the Aggregate Response or system access from GPC.

(c) The DROC, with the assistance of the Director, will audit at least quarterly the use of the Aggregate Response by Data Requestors for compliance with the Data Use Agreement. Procedures for such auditing will be determined by the GPC Governing Council.

4.04 Data Use Agreement for Research Projects

(a) Each Party agrees to use of the Data Use Agreement set forth in Exhibit B for each Approved Research Project for which it is an Accepting Participant. If a Data Requestor requests substantive revisions, the Administrative Site will provide an editable Word version of such revisions to the designated representative of each Accepting Participant for their review and comment. Any Data Use Agreement with such substantive revisions, once finalized by all parties to it, will be signed by an authorized signatory for each Accepting Participant.

(b) The Data Use Agreement set forth at Exhibit B will require research publications arising from the use of the Aggregate Response to contain only aggregate data that does not specifically identify any patient. In addition, other than use of an acknowledgement statement approved by the GPC Governing Council, the Data Use Agreement will prohibit the publication of Information (including aggregate data on a Participant-level basis) in a form that identifies the Accepting Participant(s), unless the Data Requestor has obtained the prior written permission of all identified Accepting Participant(s).

(c) The Data Use Agreement prohibits any third party access to or use of the Aggregate Response not disclosed during the initial submission to the GPC, unless the Data Requestor has obtained the prior written permission of the GPC members and all Accepting Participants.

4.05 Data Use Agreement Among the Parties.

(a) Confidentiality; Use and Disclosure. The GPC Administrative Site agrees that any Information obtained by the GPC Administrative Site from any Participant for the purposes described herein, including but not limited to for purposes of creation and release of Aggregate Responses in accordance with Section 4.02, will be kept confidential by the GPC Administrative Site, its employees and agents, pursuant to the Privacy Rule and all other applicable laws. Such Information shall be used and disclosed by the GPC Administrative Site, its employees and agents receiving such Information only for the limited research purposes described herein, and only as authorized by this Agreement. The GPC Administrative Site agrees not to use or disclose the Information for any other purpose, except as required by law. The GPC Administrative Site agree not to ascertain the identity of, and agree not to contact the subjects of any Information, unless required to do so by law, regulation, or government order. The GPC Administrative Site agrees to educate its employees and agents with a need to know, about these confidentiality requirements and obligations. This Section 4.05(a) will not apply to a Participant's receipt of Aggregate Responses which will be governed solely by the Data Use Agreement in Exhibit B.

(b) Compliance with Applicable Laws. In performance of this Agreement, each Party shall comply with all applicable laws, rules and regulations, including the Privacy Rule and Security Rule. Each Party agrees to use appropriate physical, technical, and administrative safeguards to prevent use or disclosure of the Information other than as provided for by this Agreement.

(c) Reporting; Breach. Each Party agrees to report, within five (5) days of discovery, any use or disclosure of Information not provided for by this Agreement, of which it becomes aware, to the Privacy Officer of the Administrative Site and the Privacy Officer of the Participants that supplied the Information. The Parties agree to cooperate in the handling and mitigation of any unauthorized use, disclosure or breach of Information in accordance with the requirements of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their implementing regulations, and any other applicable laws.

(d) Agents; Subcontractors. The Parties agree to ensure that any agent or subcontractor, to whom the Party provides the Information, agrees to the same restrictions and conditions that apply through this Agreement, with respect to such Information.

4.06 GPC Network Administration.

(a) Participant Role. Each Participant is responsible for technical administration of its Research Repository. Such technical administration will employ security measures which comply with the Security Rule (45 CFR Parts 160, 162 and 164) issued pursuant to the Health Insurance Portability and Accountability Act of 1996 to provide for the security of the Information.

(b) Provision of System Equipment and Software. Participants will use their own computers, video terminals, printers and supplies (e.g., printer paper, ink cartridges, toner, etc.) to maintain and access their Research Repositories. Each Participant will provide, at its own cost or using funds provided pursuant to its PCORI Subcontract, the computer software and hardware necessary to allow Participants to store and access Participant Information in its Research Repository and will arrange for the installation of, and bear the cost of, the necessary communication lines and/or encryption devices to allow the secure transfer of the Information (in the form of either De-Identified Information or a Limited Data Set) by the Participants. Participants will provide personnel to assist with the mapping of clinical information such as test results and physician codes into a standard form as agreed upon by GPC.

(c) Ownership of System Equipment. Any equipment, supplies and communication lines supplied by a Participant will remain the sole property of such Participant. From time to time, grants and contracts in which the Participants agree to participate may provide for purchase of equipment related to GPC. The ownership of any such equipment will be governed by the relevant grant or contract.

(d) Network Operating Expenses. All expenses for GPC Hosted Services, such as software engineering, system/security/database administration, and other network expenses related to operating the network; are anticipated to be sufficiently covered by the PCORI Subcontracts or through existing informatics personnel and equipment at the Participant sites during the term of such contracts. The GPC will evaluate ongoing network sustainability as required by the PCORI Subcontract milestone 7.3. In coordination with milestone 7.3 and evaluation of anticipated Phase 2 PCORI CDRN funding opportunities, sustainable funding of network operating expenses will be determined and agreed upon by the GPC Governing Council.

ARTICLE V.
RECORDS AND AUDITS

5.01 Audit Logs. Each Participant will maintain a system for its Research Repository to maintain an audit log process whereby access to the system is logged and recorded in accordance with the requirements of the Security Rule. The Audit Log process will be subject to approval of the GPC Governing Council. The GPC through its GPC Infrastructure and Software Development Core will maintain corresponding Audit Log processes for GPC Hosted Services.

5.02 Participant Audit Rights. Each year, the GPC through its GPC Governing Council and GPC Infrastructure and Software Development Core will carry out a review of the GPC Hosted Services' security controls and security-related activities consistent with the requirements of the Security Rule and NIST Special Publication 800-53. The results of the review will be made available to the GPC Governing Council and the Parties.

ARTICLE VI.
TERM AND TERMINATION

6.01 Term. This Agreement will commence on the Effective Date and will expire on January 1, 2016. Thereafter, this Agreement will automatically renew for successive three (3) year terms (each a "Renewal Term"). The withdrawal or termination of less than all of the Parties will not be considered a termination of this Agreement and the remaining Parties will continue to operate under the terms of the Agreement, as amended. The "Term" of this Agreement includes the Initial Term and all Renewal Terms.

6.02 Withdrawal.

(a) Without Cause Withdrawal. Any Party may withdraw from this Agreement without cause upon one hundred eighty (180) days prior written notice to the other Parties.

(b) With Cause Withdrawal. Any Party may withdraw from this Agreement with cause, as follows:

(i) A material breach of one or more other Party's duties under Article II, III, or IV of this Agreement, or a significant breach of the GPC Governing Council's or the DROC's duties under this Agreement, with regard to the any Party's Information, provided that the withdrawing Party has allowed at least thirty (30) days written notice to the breaching Parties, the GPC Governing Council or the DROC to cure its breach.

(ii) The failure of the GPC to remedy a material deficiency in the GPC Hosted Services identified as a result of the review conducted pursuant to Section 5.02 within fourteen (14) business days of discovery of the material deficiency.

6.03 Termination by _____. _____ may terminate a Party to this Agreement for cause. The following constitutes adequate cause for _____ to terminate a Party from this Agreement:

(a) Termination of the Party's PCORI Subcontract by _____ or the Party. The Party's termination as a Party to this Agreement will be effective upon written notice by _____.

(b) A Party's failure to appoint an authorized representative to the DROC by January 1, 2015, failure to fill a DROC vacancy for thirty (30) days, failure to appoint a Participant Honest Broker within thirty (30) days of execution of this Agreement, or failure to replace a vacancy of the Participant Honest Broker for thirty (30) days. Such Party's termination as a Party to this Agreement will be effective upon written notice by _____.

(c) Such Party's failure to Accept at least thirty-three percent (33%) of the Approved Feasibility Queries and Approved Research Projects submitted by Data Requestors external to the Party for which the Party was a Requested Participant, as calculated over a two (2) year period of time where the number of Requests to the Party exceeds ten (10) during the evaluated period. Such Party's termination as a Party to this Agreement will be effective upon written notice by _____. A Party's failure to Accept requests for data under Section 3.02(d) of this Agreement shall not be taken into account in determining whether the thirty-three percent (33%) criterion set forth in this Section 6.03(c) has been satisfied.

6.04 Effect of Termination or Withdrawal Termination of this Agreement or withdrawal of a Party will result in termination of the PCORI Subcontract for the affected Party. The Party and its Qualified Faculty and Affiliate Investigators will continue to be bound by the terms of any agreement(s) governing any ongoing Research Project(s) or possession of Aggregate Response(s) from a completed Patient Count Query, Feasibility Query, or Research Project.

6.05 Use and Disclosure of Information after Withdrawal or Termination. Upon a Party's withdrawal from or termination of this Agreement, the GPC Administrative Site will return to the withdrawing or terminating Party, or if such return is not feasible destroy, all of each withdrawing or terminating Party's Information residing in its electronic files other than Aggregate Responses which have already been created for Data Requestors and archived prior to the date of withdrawal or termination, which may continue to be used and disclosed in accordance with the terms of this Agreement, solely for purposes of ongoing Research Projects initiated prior to the effective date of the Party's withdrawal or termination and for purposes of any regulatory or oversight requirements pertaining to such Research Projects.

A Party's obligation to respond to new Requests for Information (in the form of either De-Identified Information or a Limited Data Set) in accordance with this Agreement ends upon that Party's withdrawal from or termination of, this Agreement.

Destruction of Information as described above will be done with the use of technology or methodology that renders PHI unusable, unreadable, or undecipherable to unauthorized individuals as specified by the U.S. Department of Health and Human Services ("HHS"). If the GPC Administrative Site believes that the return or destruction of Information as described above is not feasible, it will provide written notification to the relevant Participants of the conditions that make return or destruction infeasible. The GPC Administrative Site will cause the protections of this Section 6.05 of the Agreement to be extended to Information received from the other

Participants, and will limit further uses and disclosures of such Information, for so long as the GPC Administrative Site maintains the Information.

ARTICLE VII.
MISCELLANEOUS

7.01 Intellectual Property Rights of Participants. Ownership and control of all intellectual property rights associated with the activities of the GPC and Participants under this Agreement will be governed by Section V.C of the PCORI Subcontracts. If this Agreement remains in effect after the termination or expiration of all PCORI Subcontracts, the Parties will negotiate in good faith an amendment to this Agreement to specify appropriate intellectual property terms.

7.02 Additional Participants. The Parties acknowledge that additional entities may desire to participate in GPC in the future. Additional participating entities will be added only upon the unanimous approval of GPC Governing Council and execution by all of the Parties of a mutually acceptable amendment to this Agreement, or a new agreement as deemed appropriate by all of the Parties.

7.03 Disclaimer of Liability. The Parties make no warranties, expressed or implied, as to any matter whatsoever, including, without limitation, the Information, condition of the research or any invention(s) or product(s), whether tangible or intangible, conceived, described or developed under this Agreement, or the ownership, merchantability, or fitness for a particular purpose of the Information, research or any such invention or product. In no event will any Party be liable for any indirect, special, consequential, incidental, punitive or non-contractual damages or lost profit or income arising out of or related to this Agreement, even if a Party has been advised of the possibility thereof. Each Party will be solely responsible for obtaining, and hereby represents that it has obtained, any necessary approvals and authorizations from Individuals and Data Contributors, regarding the inclusion of Information in the Data Repository managed by the Party. Each Party agrees to be responsible for the negligence, of any of its Affiliate Investigators, and for assuring the Affiliate Investigator's compliance with the agreement(s) governing the Affiliate Investigator's receipt of Information from the GPC. No Party will be responsible for claims, expenses, damages or liabilities arising out of the negligence or wrongful act or omission of another Party or that other Party's agents, servants or employees in connection with this Agreement. Liability for Parties that are state institutions is limited to the extent of liability incurred under the Party's applicable state tort claims act.

7.04 Restrictions on Use. No Party will use any Information of any other Party, regardless of the context or format in which the Information is received, for its competitive institutional or individual advantage, including but not limited to patient recruitment or marketing purposes. No Party will, under any circumstance, sell or permit the sale of any Information obtained from another Party for any purpose.

7.05 Binding Effect. This Agreement will inure to the benefit of, and will be binding upon, the Parties hereto and their respective successors and assigns.

7.06 No Third-Party Beneficiaries. This Agreement will not confer any benefit or rights upon any person other than the Parties hereto and no other third party (including, without limitation, Qualified Faculty acting in their individual capacity and not as representatives of one of the parties) will be entitled to enforce any obligation, responsibility or claim of any party to this Agreement.

7.07 Non-Assignment. This Agreement may not be assigned, nor any duty or obligation delegated, by any Party hereto without the express written consent of all the other Parties.

7.08 Modification and Amendment. Except for the definition of Information, which may be modified unilaterally by the GPC Governing Council as described in Section 3.02 above, this Agreement may be modified or amended only by a writing mutually authorized and executed by the Parties. Any amendment purporting to allow transmission of PHI other than in the form of a Limited Data Set (accompanied by a valid Data Use Agreement) shall be null and void.

7.09 Severability. If any provision of this Agreement is, or is adjudged as, unlawful or contrary to public policy, then that provision will be deemed null and void and severable from the remaining provisions of this Agreement, and in no way will affect the validity of this Agreement.

7.10 Change in Law/Adverse Determination. In the event of any legislative or regulatory change or judicial or regulatory determination, whether state or federal, which would result in sanctions against any Party hereto in connection with the performance of this Agreement or substantially alter any material obligation or duty under this Agreement, or in the event that performance by any Party of any term, covenant, condition or provision of this Agreement should for any reason be in violation of any statute, regulation or otherwise be deemed illegal, the affected Party or Parties will have the right to require that the other Parties renegotiate the terms of this Agreement such that performance of this Agreement by all Parties complies with all applicable laws, regulations and determinations. The Parties will have the affirmative duty to negotiate in good faith replacement terms that comply with applicable laws, rules, and regulations and that reflect, to the maximum extent possible, the purpose and spirit of this Agreement. Such renegotiated terms become effective when unanimously agreed to in writing by all the Parties. If the Parties fail to reach an agreement satisfactory to all Parties within thirty (30) days of the request for renegotiation, any Party may immediately terminate this Agreement upon written notice to the other Parties hereto.

7.11 Entire Agreement. This Agreement, in conjunction with the PCORI Prime Contract, PCORI Subcontracts, and GPC Institutional Review Board (IRB) Authorization Agreement, constitute the entire understanding among the Parties hereto regarding the subject matter of this Agreement. Any prior agreements, promises, negotiations, oral or written, not expressly set forth herein which relate to the subject matter of this Agreement are of no force or effect.

7.12 Confidentiality. Except as otherwise permitted herein, no Party hereto will disclose any privileged or confidential information obtained or learned from any other Party as a result of this Agreement, except as may be required by applicable law, regulation or order of a court with jurisdiction or as set forth below.

7.13 Subpoenas and Other Compelled Disclosure. If any Party or any of its agents are required in any legal or governmental proceeding, or otherwise required by law, to disclose any confidential information or Information, such Party will: (i) immediately notify the other Parties in writing of the existence, terms and circumstances surrounding such event, and (ii) consult and cooperate with the other Parties so that the other Parties may seek an appropriate protective order and/or waive compliance with the confidentiality provisions of this Agreement. If, in the absence of a protective order or the receipt of a waiver hereunder, such Party or any of its agents are nonetheless legally required to disclose the information or else stand liable for contempt or suffer other censure or penalty, such Party or its agents, as the case may be, may disclose the information to the minimum extent so required without liability hereunder;

7.14 Notices. Unless otherwise provided in this Agreement, all notices, certificates, or other communications will be sent in writing, will be deemed given at the time received, and may be sent by personal delivery, overnight express, next-day delivery service, courier, or registered or certified mail, postage prepaid, return receipt requested, addressed as outlined in Exhibit C attached hereto and incorporated herein. Any Party may, by notice as provided in this Section 7.14, designate any further or different addresses to which subsequent notices, certificates or other communications will be sent.

7.15 Counterparts. This Agreement may be executed in any number of counterparts, each of which will be treated as an original, but all of which collectively constitutes a single agreement; facsimile and/or portable document format (PDF) to be accepted as original and legally binding.

7.16 Adoption of Agreement. Each Party to this Agreement represents to the other parties to this Agreement that the person signing for such Party has full authority to bind the party he/she represents and to sign on behalf of such Party.

7.17 Waiver of Breach. No waiver of a breach of any provision of this Agreement will be construed to be a waiver of any breach of any other provision of this Agreement or of any succeeding breach of the same provision. No delay in acting with regard to any breach of any provision of this Agreement will be construed to be a waiver of such breach.

IN WITNESS WHEREOF, the parties have executed this Agreement through their duly authorized representatives.

EXHIBIT A

GPC SYSTEM ACCESS AGREEMENT
(PREPARATORY TO RESEARCH)

_____ ("Data Requestor"), desires to perform a Feasibility Query (as such term is defined in Section 1 below) of the Greater Plains Collaborative, a collaboration of the academic medical centers and other research institutions listed in Section 2 below ("GPC") which have implemented certain technologies and procedures to make their research repositories interoperable (such network of interoperable repositories, the "GPC System"), which is coordinated by the _____ ("_____"). Data Requestor acknowledges that as a condition of performing such Feasibility Query, Data Requestor must comply with the terms and conditions of this GPC System Access Agreement ("Agreement").

Data Requestor acknowledges that violation of this Agreement may subject him/her to sanctions including but not limited to loss of the privilege to perform any type of research using the GPC System in the future and/or institutional disciplinary action.

1. SYSTEM ACCESS SCOPE AND PURPOSE

Data Requestor understands that the access to the GPC System authorized by this Agreement is limited to the conduct of a query to view de-identified data sets, solely for purposes of generating a hypothesis and/or determining if a research project is feasible within the GPC, including but not limited to patient counts, descriptive statistics, and lab results ("Feasibility Query" and the deliverable resulting from such Feasibility Query, the "Output"). Data Requestor understands that such access may be terminated by GPC at any time. For purposes of this Agreement, the term "de-identified" is defined in 45 C.F.R. §164.514(b).

_____, as well as each Accepting GPC Participant (as such term is defined in Section 2 below), disclaims all warranties as to the accuracy of the data in the Output, or the fitness of the Output for any particular purpose. Data Requestor accepts the Output AS IS WITH ALL FAULTS.

2. REQUESTED GPC PARTICIPANTS

Data Requestor desires to perform a Feasibility Query of the following components of the GPC System (each selected institution a "Requested GPC Participant"):

- _____
- _____
- _____

Data Requestor understands that, upon execution of this Agreement and submission of the Feasibility Query to the GPC, both the GPC's Data Request Oversight Committee ("DROC") and a representative of each Requested GPC Participant will review and approve or reject the Feasibility Query. Data Requestor understands that the DROC may reject the Feasibility Query, or

if the DROC approves, fewer than all, or none of the Requested GPC Participants may agree to provide data for the Output (those Requested GPC Participants which do provide data for the Output, the "Accepting GPC Participants").

3. DATA REQUESTOR DUTIES:

Data Requestor hereby agrees:

A. To comply with all local, state, and federal confidentiality laws, including but not limited to, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and its implementing regulations, as amended from time to time, as well as the privacy rules and policies of Data Requestor's employing institution, and any GPC's system policies and procedures posted on the GPC's website as of the date of execution of this Agreement.

B. That only Data Requestor will be permitted to use Data Requestor's GPC user ID and password to submit the Feasibility Query to the GPC System and access the resulting Output. Data Requestor is prohibited from sharing or disclosing his/her GPC user ID and password and the Output with other individuals or entities, except as required by law.

C. That the Output will only be viewed by Data Requestor within the GPC system/environment. No Output will be extracted from the GPC System via printing, downloading, screenshots, saving webpages or other methods.

D. To restrict Feasibility Queries to bona fide research issues preparatory to research as described above. Data Requestor agrees not to formulate Feasibility Queries that could be used for the institutional or individual competitive advantage of any party.

E. That the Data Requestor has sufficient scientific knowledge, skill, and experience in the subject matter of the Feasibility Query.

F. Not to identify, or attempt to identify, data contained in the Output by any means, including using any Accepting GPC Participant's electronic medical records system (e.g., Cattails, Cerner, Epic) or other information together with the Output (e.g., voter registration records), or to contact any Individual (as such term is defined by HIPAA) whose identity is discovered by way of the Output.

G. To report in writing to _____'s Privacy Official _____ or such other contact information as _____ may provide to Data Requestor from time to time) and _____ staff coordinating the GPC (_____ or _____, or such other contact information as _____ may provide to Data Requestor from time to time) any: (i) existence, use or disclosure of protected health information (as defined by HIPAA in 45 C.F.R. 160.103) that was inadvertently included in the Output or otherwise becomes known to Data Requestor; and (ii) use or disclosure of the Output not provided for by this Agreement. These reports will be made within twenty-four (24) hours of Data Requestor's discovery.

H. To immediately destroy or return any data which comes into Data Requestor's possession which Data Requestor is not authorized to possess pursuant to the terms of this Agreement.

I. To not use the Output or other information obtained from GPC Systems to make clinical or medical decisions.

J. To not, under any circumstance, sell the Output.

4. _____ and each Accepting GPC Participant are third-party beneficiaries of this Agreement and are entitled to enforce any obligation responsibility of the Data Requestor pursuant to this Agreement.

5. This Agreement may be terminated at any time, with or without cause, by a majority vote of all Accepting Participants.

6. By signing this document electronically, Data Requestor agrees that:

A. He/she is authorized by his/her employing institution to execute this Agreement;

B. The electronic signatures below constitute acceptance and agreement to the terms of this Agreement with the same validity and meaning as handwritten signatures which will be considered "in writing" and "wet signed;

C. Data Requestor will not, at a later date, repudiate the meaning of the electronic signature or claim that electronic signatures are not legally binding; and

D. A printed copy of this electronically signed Agreement will be deemed an original.

AGREED TO AND ACCEPTED BY:

Data Requestor:

_____

Name: _____
Title: _____
Date: _____

(Original or Electronic Version to be filed with the GPC)
(Data Requestor to retain copy for research file)

EXHIBIT B

GPC DATA USE AGREEMENT

_____ ("Data Requestor") desires to perform a Research Project (as such term is defined in the Section below) through the Greater Plains Collaborative, a collaboration of the academic medical centers and other research institutions listed in the Section below ("GPC") which have implemented certain technologies and procedures to make their research repositories interoperable (such network of interoperable repositories, the "GPC System"), which is coordinated by the _____ ("_____"). Data Requestor hereby agrees and acknowledges that as a condition of performing the Research Project and receiving resulting data from the GPC System, Data Requestor must comply with the terms and conditions of this GPC Data Use Agreement (the "Agreement"). Data Requestor acknowledges that violation of this Agreement may subject him/her to sanctions including but not limited to loss of the privilege to perform any type of research using the GPC System in the future and/or institutional disciplinary action.

1. RESEARCH PROJECT SCOPE AND PURPOSE

A. This Agreement governs the disclosure of GPC System data to Data Requestor for the research project entitled [enter Research Project Title and a brief description or attach a supplemental research protocol] (the "Research Project"). The Research Project may be either retrospective or prospective, and the deliverable GPC System data provided for or resulting from (as applicable) the Research Project (the "Aggregate Response") may, depending on the design of the Research Project, be either a limited data set or de-identified data, as such terms are defined in the Health Insurance Portability and Accountability Act of 1996 and regulations promulgated thereunder, as may be amended from time to time ("HIPAA"). The Data Requestor understands and agrees that this Agreement applies in full to the Aggregate Response regardless of its classification under HIPAA. Recipient agrees to use or disclose the Aggregate Response only for the limited purpose of the Research Project. Data Requestor certifies that the Data Requestor has sufficient scientific knowledge, skill, and experience in the subject matter of the Research Project, and that, if the Research Project is retrospective, the data requested is limited in scope to the minimum information necessary to conduct the Research Project.

B. The individuals, or classes of individuals who are permitted by Data Requestor to use or receive the Limited Data Set for purposes of the Research Project are limited to:

[Does not apply to External Collaborators] The individuals not employed by Data Requestor's institution who are permitted by Data Requestor to use or receive the Limited Data Set for purposes of the Research Project are limited to:

The individuals identified in Section 1 above are referred to hereinafter as Data Requestor's "Research Team Members."

2. ACCEPTING GPC PARTICIPANTS

The Aggregate Response will only include data from the following GPC institutions which have agreed to participate in the Research Project (each selected institution an "Accepting GPC Participant") as designated below:

- _____
- _____
- _____

3. DATA REQUESTOR DUTIES

Data Requestor hereby agrees:

A. To fully comply with the requirements of HIPAA and its associated regulations, including without limitation, 45 C.F.R. 164.514, throughout the term of this Agreement. Data Requestor will not (and will ensure that any Research Team Member does not) use or disclose the Aggregate Response in any manner that would violate the requirements of HIPAA if Data Requestor or Research Team Member were a Covered Entity.

B. Not to use or disclose the Aggregate Response except as permitted under this Agreement. Without limiting the foregoing, Data Requestor agrees to use the Aggregate Response only for bona fide research purposes and to not use the Aggregate Response for competitive institutional or individual advantage. Data Requestor agrees to retain control over the resulting Aggregate Response, to limit use and disclosure of the Aggregate Response to the Research Team Members for the research purpose described above, and to use appropriate administrative, physical and technical safeguards, sufficient to comply with HIPAA and prevent any use or disclosure other than as provided for by this Agreement. Data Requestor agrees to return or destroy the Aggregate Response when the Aggregate Response is no longer needed for research purposes.

C. Not to share or allow someone else to use of his/her GPC user ID or password. Data Requestor will not disclose the Aggregate Response to any person or entity except the Research Team Members listed above on a need to know basis, except with the prior written consent of the GPC's Data Request Oversight Committee ("DROC").

D. To require his/her Research Team Members and/or any agents who use or receive a Limited Data Set to agree to (i) the terms of this Agreement evidenced by each Research Team Member and/or any agents who use or receive a Limited Data Set to signing the Assurance of Compliance attached to this Agreement and (ii) GPC policies available on the GPC website. Data Requestor acknowledges his/her responsibility for ensuring appropriate use and disclosure of the Aggregate Response by Data Requestor and the Research Team Members/agents.

E. Use appropriate safeguards, including encryption, to prevent the use or disclosure of information other than as provided by this Agreement.

F. Not to collaborate or allow collaboration with a for profit entity by providing access to or use of the Aggregate Response, except with the prior written consent of the Accepting GPC Participant(s).

G. To report in writing to _____'s Privacy Official (_____ or such other contact information as _____ may provide to Data Requestor from time to time) and _____ staff coordinating the GPC (_____ or _____, or such other contact information as _____ may provide to Data Requestor from time to time) any (i) existence, use or disclosure of direct identifiers (as defined by HIPAA in 45 C.F.R. 164.514(e)(2) that were inadvertently included in the Aggregate Response, and (ii) use or disclosure of the Aggregate Response not provided for by this Agreement. These reports will be made within twenty-four (24) hours of Data Requestor's discovery.

H. Not to disclose the Aggregate Response on the basis that such disclosure is required by law without notifying the DROC, the _____ Office of General Counsel (_____) and the _____ Privacy Official (email: _____),so that _____ and the Accepting GPC Participant(s) will have the opportunity to object to the disclosure and to seek appropriate relief. Data Requestor will cooperate fully with all reasonable efforts by _____ or an Accepting GPC Participant to challenge the validity of such a request.

I. To acknowledge the GPC in all oral and written presentations, disclosures, and publications resulting from any analyses of the Aggregate Response. A sample statement to be used in acknowledgements is "The dataset(s) used for the analyses described were obtained from the Greater Plains Collaborative, which is supported by the Patient Centered Outcomes Research Institute and institutional funding from its member organizations."

J. Not to identify the Individuals (as such term is defined under HIPAA) contained in the Aggregate Response by any means, including using any Accepting GPC Participant's electronic medical records system (e.g., Cattails, Cerner, Epic) or other information (e.g., Voter Registration records) together with the Aggregate Response, or to contact any Individual whose information is contained in the Aggregate Response.

K. To immediately destroy or return any data which comes into Data Requestor's possession which Data Requestor is not authorized to possess pursuant to the terms of this Agreement.

L. To not use the Aggregate Response or other information obtained from the GPC to make clinical or medical decisions.

M. To not, under any circumstance, sell the Aggregate Response or any data obtained from the GPC.

N. Data Requestor will indemnify and hold harmless Accepting GPC Participants from liability and claims arising out of a breach of this Agreement including but not limited to an unauthorized use or disclosure of the Aggregate Response. If Data Requestor is covered under a

federal or state tort claims act then liability will be limited to the applicable federal or state tort claims act.

4. TERM; TERMINATION

A. Term. This Agreement is effective as of the date last signed below and will continue until _____ or until the Agreement is terminated in accordance with the provisions for termination below.

B. Termination. This Agreement may be unilaterally amended or terminated at any time, by the GPOC Data Request Oversight Committee in the event that Data Requestor breaches or violates a material term of this Agreement.

C. Disposition of Records. Upon expiration or termination of this Agreement, Data Requestor will return or destroy any data accessed pursuant to this Agreement. If the Aggregate Response cannot be returned or destroyed then the protections set forth in this Agreement shall be extended to such information so long as Data Requestor holds such information. This section will survive termination of this Agreement.

5. MISCELLANEOUS TERMS

A. Publication. Data Requestor agrees that research publications arising from the use of the Aggregate Response will contain only aggregate data that does not specifically identify any Individual whose data or information is received pursuant to this Agreement unless a specific authorization is obtained from the Individual. With the exception of the acknowledgement required in section 3.I. Data Requestor further agrees not to publish any data derived from the GPC System (including data from the Aggregate Response on an institutional level basis) in a form that identifies the institution that supplied the data, unless prior written permission of the Accepting GPC Participant that supplied the data has been obtained. Such data includes, without limitation, patient volume, source of reimbursement data, any of the Accepting GPC Participant's practice patterns, and their respective quality and outcome measures.

B. GPC and _____ Right of Access and Inspection. From time to time upon reasonable notice, or upon reasonable determination by _____ or the GPC that Data Requestor has breached this Agreement, one or more representatives of _____ and/or other Accepting GPC Participants may inspect the facilities, systems, books and records of Data Requestor to monitor compliance with this Agreement during regular business hours and upon advance written notice.

C. Data Disclaimer. _____, as well as each Accepting GPC Participant, disclaims all warranties as to the accuracy of the data in the Aggregate Response, or the fitness of the Aggregate Response for any particular purpose. Data Requestor accepts the Aggregate Response AS IS WITH ALL FAULTS.

D. Third Party Beneficiaries. _____ and each Accepting GPC Participant are third-party beneficiaries of this Agreement and are entitled to enforce any obligation responsibility of the Data Requestor pursuant to this Agreement.

E. The electronic signatures below constitute acceptance and agreement to the terms of this Agreement with the same validity and meaning as handwritten signatures which will be considered "in writing" and "wet signed. Data Requestor will not, at a later date, repudiate the meaning of the electronic signature or claim that electronic signatures are not legally binding. A printed copy of this electronically signed Agreement will be deemed an original.

AGREED TO AND ACCEPTED BY:

Data Requestor:

_____

Name: _____
Title: _____
Date: _____

(Original to be filed with the GPC)
(PI to retain copy for research file)

ASSURANCE OF COMPLIANCE WITH
DATA USE AGREEMENT

The following individuals (referred to as Research Team Members and/or any agents who use or receive a Limited Data Set in the attached Data Use Agreement) are authorized to receive and use the Aggregate Response described in the attached Data Use Agreement for the purposes described therein.

By signing below, we acknowledge and agree to abide by the restrictions on our use and disclosure of the Limited Data Set in accordance with the Data Use Agreement, as Data Requestors as defined therein.

Name:_____

Signature: _____

Date:_____

Name:_____

Signature: _____

Date:_____

Name:_____

Signature: _____

Date:_____

Name:_____

Signature: _____

Date:_____

Name:_____

Signature: _____

Date:_____

Name:_____

Signature: _____

Date:_____

EXHIBIT C

NOTICES

1. _____
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2. _____
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3. _____
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