

GPC DROC Oversight Request

Submit this form if you are a researcher seeking patient counts, de-identified data or limited data.

Limited data is a limited set of identifiable patient information that includes ages, geographical details such as zip code, and dates such as date of birth, admission, and discharge. It will not include MRN or patient contact information. http://www.hopkinsmedicine.org/institutional_review_board/hipaa_research/limited_data_set.html

Getting started with data requests from MU or other GPC institutions

Please complete the survey below.

Thank you!

Response was added on 11/21/2022 10:51am.

Basic Request Information

PI Full Name	Xing Song
Email address	xsm7f@health.missourk.edu
Employee of a GPC Institution?	<input checked="" type="radio"/> Yes <input type="radio"/> No
Institution	<input type="radio"/> Allina <input type="radio"/> Children's Mercy Hospital, Kansas City, MO <input type="radio"/> Indiana University <input type="radio"/> Intermountain <input type="radio"/> Marshfield Clinic <input type="radio"/> Medical College of Wisconsin <input type="radio"/> University of Kansas Medical Center (KUMC) <input type="radio"/> University of Iowa Healthcare <input type="radio"/> University of Minnesota <input checked="" type="radio"/> University of Missouri <input type="radio"/> University of Nebraska Medical Center <input type="radio"/> University of Texas Health Sciences Center at Houston <input type="radio"/> University of Texas Health Sciences Center at San Antonio <input type="radio"/> University of Texas Southwestern Medical Center <input type="radio"/> University of Wisconsin - Madison <input type="radio"/> University of Utah <input type="radio"/> Washington University
Title of the Research:	GPC-DaVINCI Linkage Pilot
Requested Data Type:	<input type="radio"/> GPC's Datamart Feasibility Query (counts only) <input type="radio"/> GPC's Datamart Data Use (line-item data) <input type="radio"/> GROUSE Claims Environment Feasibility Queries via Ruffed GROUSE (cell size >10) <input checked="" type="radio"/> Use/Reuse GROUSE Environment for Analysis

What kind of data set are you requesting from the Greater Plains Collaborative?	<input checked="" type="radio"/> De-identified Data about Human Subjects <input type="radio"/> Limited Data Set <input type="radio"/> Personally Identifiable Information - Common Rule Only <input type="radio"/> Personally Identifiable Information - HIPAA <input type="radio"/> Personally Identifiable Information - FERPA
Purpose of Request	<input type="radio"/> Support of proposal development <input type="radio"/> Data for paper, poster, or presentation <input checked="" type="radio"/> Other
Define Other Purpose	Fulfill one of the contractual millstones for PCORnet phase 3 on advancing Datavant tokenization and linkage with DaVINCI database
Date of expiration	(Leave blank if there is no date of expiration.)

Description of Requested Data

Data Request Description	<p>As one of the contractual milestones for PCORnet Phase 3, GPC will advance Datavant tokenization of the Veterans Administration (VA) and Department of Defense (DoD) electronic health records to support linkage across PCORnet and the corresponding Governance processes. Leveraging existing inter-network resources and in support of the brain injury data sharing (BIDS) project, we propose a demonstration linkage project between GPC EHR data and DoD/VA EHR data to advance the understanding of treatment, progression and long-term outcomes of traumatic brain injury (TBI) for Servicemembers and Veterans.</p> <p>Participating sites will need to maintain Datavant® software for generating GPC-specific hash token used for linking with VA health data in support of the proposed overlapping analysis and federate modeling. Sites are expected to submit hash token tables to GPC CC following the established process of submitting their CDM datamarts onto GROUSE.</p> <p>All documents and information are maintained and updated on: https://github.com/gpcnetwork/gpc-va-linkage </p>
Please list your detailed Inclusion Criteria	All EHR patients with required data elements for tokenization.
Please list your detailed Exclusion Criteria	N/A

Linkage with Other Datasets

Will the requested data be linked with other datasets, either before or after the investigator receives the data? (e.g. a finder file, BC Survey Data, Obesity Survey Data, RUCA Codes, etc)

☒ Yes
☐ No

Please explain the details of the data being linked:

We will leverage Datavant PPRL technology to link GPC data with DaVINCI population, and perform overlap analysis.

Is there an IRB protocol covering this data linkage?

☐ Yes
☒ No

Please explain why IRB approval is not needed:

Given that no PHI information will need to be shared for this study, it has been determined by IRBs of both leading site (university of utah) and coordinating site (university of missouri) as non-human-subject research (NHS).

Details for Sites to Run the Request

Upload a list of your search criteria

Supporting Materials

Attach Supplemental documentation (optional)

[FILE: Final BIDS DaVINCI GPC Linka...02) FE.pdf]
 (* if you already have prepared documentation on your research and protocol which may assist the DROC in understanding your request, attach it here.)

Attach Supplemental documentation (optional)

[FILE: NHS-Kean-UU.pdf]
 (* if you already have prepared documentation on your research and protocol which may assist the DROC in understanding your request, attach it here.)

Attach Supplemental documentation (optional)

[FILE: NHS-Song-MU.pdf]
 (* if you already have prepared documentation on your research and protocol which may assist the DROC in understanding your request, attach it here.)

Data Transfer and Use Agreement

EXHIBIT B GPC DATA TRANSFER AND USE AGREEMENT

Recipient desires to perform a Project (as defined in Attachment 1) through the Greater Plains Collaborative, a collaboration of the academic medical centers and other research institutions listed herein ("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 above-named "GPC Coordinator". Recipient hereby agrees and acknowledges that as a condition of performing the Project and receiving resulting data from the GPC System, Recipient must comply with the terms and conditions of this GPC Data Transfer and Use Agreement (the "DTUA"). Recipient acknowledges that violation of this DTUA 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.

Terms and Conditions

1. Accepting GPC Providers, as defined herein, via the GPC Coordinator shall provide the data set described in Attachment 1 (the "Data") to Recipient for the research purpose set forth in Attachment 1 (the "Project"). The Project may be either retrospective or prospective, and the Data derived from the GPD System and provided for or resulting from (as applicable) the Project may, depending on the design of the Project, be either de-identified data, a limited data set, or include individually identifiable health information, as such terms are defined in the Health Insurance Portability and Accountability Act of 1996 and regulations promulgated thereafter, as may be amended from time to time ("HIPAA").
2. The Data will only include data from the following GPC institutions which have agreed to participate in the Project (each selected institution an "Accepting GPC Provider") as designated below:

☐Allina Health System ☐Trustees of Indiana University ☐IHC Health Services, Inc. ☐Marshfield Clinic Research Institute ☐The Medical College of Wisconsin, Inc. ☐University of Kansas, on behalf of its University of Kansas Medical Center ☐University of Iowa ☐The Curators of the University of Missouri, on behalf of The University of Missouri - Columbia School of Medicine ☐Board of Regents of the University of Nebraska d/b/a the University of Nebraska Medical Center ☐University of Texas Health Sciences Center at San Antonio ☐University of Texas Southwestern Medical Center ☐University of Utah ☐University of Texas Health Sciences Center at Houston ☐The Washington University
3. Accepting GPC Providers shall retain ownership of any rights it may have in the Data, and Recipient does not obtain any rights in the Data other than as set forth
4. If applicable, reimbursement of any costs associated with the preparation, compilation, and transfer of the Data to the Recipient will be addressed in Attachment
5. Recipient shall not use the Data except as authorized under this DTUA. The Data will be used solely to conduct the Project and solely by Recipient Scientist and Recipient's faculty, employees, fellows, students, and agents ("Recipient Personnel") and Collaborator Personnel (as defined in Attachment 3) that have a need to use, or provide a service in respect of, the Data in connection with the Project and whose obligations of use are consistent with the terms of this DTUA (collectively, "Authorized Persons"). Recipient must designate Authorized Persons permitted to use or receive Data, other than solely de-identified data, in Attachment 3.
6. Except as authorized under this DTUA or otherwise required by law, governmental regulation, or any governmental entity with jurisdiction, Recipient agrees to retain control over the Data and shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data to any third party, except Authorized Persons, without the prior written consent of each Accepting GPC Provider. Notwithstanding, Recipient agrees not to disclose the Data on the basis that such disclosure is required by law, governmental regulation, or any governmental entity with jurisdiction without notifying the GPC Data Request Oversight Committee ("DROC") and the GPC Coordinator and the Accepting GPC Provider(s) will have the opportunity to object to the disclosure and to seek appropriate relief. Recipient further agrees to cooperate fully with all reasonable efforts by GPC Coordinator or an Accepting GPC Provider to challenge the validity of such a request.
7. Recipient agrees to establish and use appropriate administrative, technical, and physical safeguards, including but not limited to encryption, to prevent unauthorized use of or access to the Data and comply with any other special requirements relating to safeguarding of the Data as may be set forth in Attachment 2.
8. Recipient agrees to use the Data only for bona fide research purposes and not to use the Data for competitive institutional or individual advantage. Recipient agrees to retain control over the Data and to limit use and disclosure of the Data to only Authorized Persons for the research purpose described in Attachment 1.
9. Recipient agrees not to collaborate or allow collaboration with a for-profit entity by providing access to or use of the Data, except with the prior written consent of the Accepting GPC Provider(s).
10. Recipient agrees not to use the Data or other information obtained from GPC to make clinical or medical decisions

11. Recipient agrees not to share or allow someone else to use his/her GPC user ID or password. Recipient will not disclose the Data to any person or entity except the Authorized Persons listed on Attachment 3 with a need to know, except with the prior written consent of the GPC DROC.

12. Recipient agrees to complete all human subjects research training, and/or receive appropriate Institutional Review Board approval, as may be necessary to use or receive the Data pursuant to this DTUA.

13. Recipient agrees to require Authorized Persons who use or receive Data, unless solely de-identified data, to agree to (a) the terms of this DTUA evidenced by each Authorized Person signing Attachment 3, and (b) GPC policies available on the GPC website. Recipient acknowledges his/her responsibility for ensuring appropriate use and disclosure of the Data by Recipient and Authorized Persons.

14. Recipient agrees to immediately return or destroy any Data that comes into Recipient's possession that Recipient is not authorized to possess pursuant to the terms of this DTUA. Recipient agrees to return or destroy the Data when the Data is no longer needed for research purposes for the Project.

15. Recipient agrees to use the Data in compliance with all applicable laws, rules, and regulations, as well as all professional standards applicable to such research. Specifically, Recipient agrees to fully comply with the requirements of HIPAA, including without limitation, 45 C.F.R. 164.514. Recipient will not (and will ensure that any Authorized Person does not) use or disclose the Data in any manner that would violate the requirements of HIPAA if Recipient or such Authorized Person were a Covered Entity.

16. Recipient agrees to notify GPC Coordinator in writing of any 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 Data within five (5) business days of Recipient's Recipient further agrees to comply with any additional notice requirements as may be set forth in Attachment 2.

17. Notices required under this DTUA and Attachment 2 shall be made to the following:

To DROC: [INSERT NOTICE INFO]

To GPC Coordinator: Russ Waitman, PhD, at: russ.waitman@health.missouri.edu

With copies to: Nicole Epstein, System Privacy Officer, at: epsteinn@health.missouri.edu;

University of Missouri Sponsored Programs Office, at grantsdc@missouri.edu.

18. Recipient agrees that research publications arising from the use of the Data will contain only aggregate data that does not specifically identify any Individual (as defined under HIPAA) whose data or information is accessed pursuant to this DTUA unless a specific authorization is obtained from the Individual. With the exception of the acknowledgement required in section 18 below, Recipient further agrees not to publish any Data derived from the GPC System (including any data on an institutional level basis) in a form that identifies the institution that supplied the Data, unless prior written permission of the Accepting GPC Provider that supplied the data has been obtained. Such Data includes, without limitation, patient volume, source of reimbursement data, any of the Accepting GPC Provider's practice patterns, and their respective quality and outcome measures.

19. Recipient is encouraged to make publicly available the results of the Project. Recipient agrees to acknowledge the GPC in all oral and written presentations, disclosures, and publications resulting from any analyses of the Data. 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 People-Centered Research Foundation and Patient Centered Outcomes Research Institute and institutional funding from its member organizations."

20. Recipient agrees to recognize the contribution of each Accepting GPC Provider as the source of the Data in all written, visual, or oral public disclosures concerning Recipient's research using the Data, as appropriate in accordance with scholarly standards and any specific format that has been indicated in Attachment 1.

21. From time to time upon reasonable notice, or upon reasonable determination by the GPC DROC or the GPC Coordinator that Recipient has breached this DTUA, at mutually agreeable times, one or more representatives of the GPC and/or other Accepting GPC Providers may inspect the facilities, systems, books and records of Recipient to monitor compliance with this DTUA during regular business hours and upon advance written notice.

22. Unless terminated earlier in accordance with this section, this DTUA shall expire as of the End Date set forth above. The GPC Coordinator, on behalf of the GPC DROC, may unilaterally terminate this DTUA at any time in the event that Recipient or any Authorized Person breaches or violates a material term of this DTUA as determined by the DROC in its sole discretion. Either party may terminate this DTUA with thirty (30) days written notice to the other party's Authorized Official as set forth below. Upon expiration or early termination of this DTUA, Recipient shall return or destroy any Data accessed pursuant to this DTUA. If the Data cannot be returned or destroyed then the protections set forth in this DTUA shall be extended to such Data so long as Recipient holds such Notwithstanding, Recipient may retain one (1) copy of the Data to the extent necessary to comply with the records retention requirements under any law, and for the purposes of research integrity and verification. This section will survive

termination of this DTUA.

23. Except as provided below or prohibited by law, any Data delivered pursuant to this DTUA is understood to be provided "AS IS." GPC COORDINATOR AND ACCEPTING GPC PROVIDERS MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Notwithstanding, GPC Coordinator and Accepting GPC Providers, to the best of their knowledge and belief, have the right and authority to provide the Data to Recipient for use in the Project.
24. Except to the extent prohibited by law, the Recipient assumes all liability for damages that may arise from its use, storage, disclosure, or disposal of the Data. The GPC Coordinator and Accepting GPC Provider will not be liable to the Recipient for any loss, claim, or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Data by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the respective GPC Coordinator or Accepting GPC Provider. No indemnification for any loss, claim, damage, or liability is intended or provided by either party under this DTUA
25. None of the parties shall use another party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may disclose factual information regarding the existence and purpose of the relationship that is the subject of this DTUA for other purposes without written permission from the other party provided that any such statement shall accurately and appropriately describe the relationship of the parties and shall not in any manner imply endorsement by the other party whose name is being used.
26. Unless otherwise specified, this DTUA and the below listed Attachments embody the entire understanding between the GPC Coordinator, Accepting GPC Providers and Recipient regarding the transfer of the Data to Recipient for the Project:
- a. Attachment 1: Project Specific Information
 - b. Attachment 2: Data-specific Terms and Conditions
 - c. Attachment 3: Identification of Authorized Persons
27. Each Accepting GPC Provider is a third-party beneficiary of this DTUA and is entitled to enforce any obligation or responsibility of the Recipient pursuant to this DTUA.
28. No modification or waiver of this DTUA shall be valid unless in writing and executed by duly authorized representatives of both the GPC Coordinator and Recipient.
29. The undersigned Authorized Officials of GPC Coordinator and Recipient expressly represent and affirm that the contents of any statements made herein are truthful and accurate and that they are duly authorized to sign this DTUA on behalf of their institution. Any electronic signatures below constitute acceptance and agreement to the terms of this DTUA with the same validity and meaning as handwritten signatures that will be considered "in writing" and "wet signed". Recipient will not, at a later date, repudiate the meaning of any electronic signature or claim that electronic signature is not legally binding.

Attachment 1

ATTACHMENT 1
GPC DATA TRANSFER AND USE AGREEMENT Project Specific Information

Please refer to the submitted GPC Data Request

ATTACHMENT 2
Data-specific Terms and Conditions: De-identified Data about Human Subjects

ATTACHMENT 2
GPC DATA TRANSFER AND USE AGREEMENT
Data-specific Terms and Conditions: De-identified Data about Human Subjects

Additional Terms and Conditions:

1. The Data will not include personally identifiable information as defined in NIST Special Publication 800-122. If the Data being provided is coded, the GPC Coordinator on behalf of the GPC Accepting Provider(s) will not release, and the Recipient will not request, the key to the code.
2. If GPC Accepting Provider(s) is a Covered Entity, the Data will be de-identified data, as defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").
3. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to identify or contact individuals who are or may be the sources of Data without specific written approval from GPC Accepting Provider(s) and appropriate Institutional Review Board (IRB) approval, if required pursuant to 45 CFR 46. Should Recipient inadvertently receive identifiable information or otherwise identify a subject, Recipient shall promptly notify GPC Coordinator and GPC Accepting Provider(s) and follow GPC Coordinator's and GPC Accepting Provider(s)'s reasonable written instructions, which may include return or destruction of the identifiable information.
4. By signing this DTUA, Recipient provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB or ethics review or approval that may be required.
5. Recipient shall promptly report to the GPC Coordinator and GPC Accepting Provider(s) any use or disclosure of the Data not provided for by this DTUA of which it becomes aware.

ATTACHMENT 2
Data-specific Terms and Conditions: Other

Select Other Terms

Are there any additional terms and conditions that may be required by law, regulation, or an agreement with a third party data provider.

(If no such requirements exist, None should be checked.)

- ☒ None. No additional terms and conditions are required.
☐ The additional terms and conditions are as set forth below and agreed upon between the Parties:

ATTACHMENT 2
Data-specific Terms and Conditions: Other

ATTACHMENT 2 GPC DATA TRANSFER AND USE AGREEMENT

Data-specific Terms and Conditions: Other:

Additional Terms and Conditions:

- ☒ None. No additional terms and conditions are required. OR
☐ The additional terms and conditions are as set forth below and agreed upon between the Parties:

ATTACHMENT3**Identification of Authorized Persons****ATTACHMENT 3 TESTING GPC DATA TRANSFER AND USE AGREEMENT Identification of Authorized Persons**

The following individuals (referred to as Authorized Persons, including Recipient Personnel and Collaborator Personnel who use or receive Data pursuant to the GPC Data Transfer and Use Agreement) are authorized to receive and use the Data as provided therein and for the purposes described therein.

For all purposes of this DTUA, the definition of "Collaborator Personnel" checked below will pertain:

faculty, employees, fellows, or students of an academic institution, which institution (i) has agreed to collaborate in the Project, (ii) has faculty, employees, fellows, or students who have a need to use or provide a service in respect of the Data in connection with its collaboration in the Project, and (iii) has been made aware of the terms of this DTUA and agreed to comply, and to cause its personnel to comply, with such terms.

ASSURANCE OF COMPLIANCE WITH

GPC DATA TRANSFER AND USE AGREEMENT By signing below, we acknowledge and agree to abide by the restrictions on our use and disclosure of the Data in accordance with the GPC Data Transfer and Use Agreement, as a Recipient and as an Authorized Person defined therein.

Agree and accepted by:

Xing Song
(Enter first and last name)

Submission Confirmation

Please provide the name of the individual filling out the submission: Xing Song

Please provide your Email Address xsm7f@umsystem.edu

By clicking yes, I agree that all of the information provided above is correct and I agree to comply with the terms of the data use agreement listed above. ☒ Yes

Date of Submission 11-21-2022