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!

Basic Request Information

Full Name	Xing
Email address	xsm7f@health.missouri.edu
Employee of a GPC Institution?	⊗ Yes ◯ No
Institution	◯ Allina ◯ Children's Mercy Hospital, Kansas City, MO ◯ Indiana University ◯ Intermountain ◯ Marshfield Clinic ◯ Medical College of Wisconsin ◯ University of California, Los Angeles (UCLA) ◯ University of California, Davis ◯ University of Kansas Medical Center (KUMC) ◯ University of Iowa Healthcare ◯ University of Minnesota ⊗ University of Missouri ◯ University of Nebraska Medical Center ◯ University of Texas Health Sciences Center at Houston ◯ University of Texas Health Sciences Center at San Antonio ◯ University of Texas Southwestern Medical Center ◯ University of Wisconsin - Madison ◯ University of Utah ◯ Washington University in St. Louis
Title of the Research:	Personalized Stroke Risk Stratification in Atrial Fibrillation
Request Type:	◯ GPC i2b2 Access ◯ Feasibility Query (Distributed) ◯ Feasibility Query via GROUSE (run by GPC Central) ◯ Line-item Data Query (Distributed) ⊗ GROUSE Access
Would you like claims data only, site data only, or claims data + site i2b2/CDM data?	⊗ Site CDM Data Only ◯ Claims Data + Site CDM Data ◯ Claims Data Only

Purpose of Request	◯ Support of proposal development ◯ Data for paper, poster, or presentation ⊗ Other
Define Other Purpose	For supporting a funded R01 project: https://reporter.nih.gov/search/bhKf69xGSEWTrxXZCi0aIQ/project-details/11025957
Is there funding for this request?	⊗ Yes ◯ No
What is the funding allocation for each site?	A total of $9,235 has been budgeted to participation sites

Description of Requested Data

Data Request Description	This project aims to develop and validate a novel stroke risk prediction model for patients with atrial fibrillation (AF). We are requesting claims data and site Common Data Model (CDM) data to identify clinical and social risk factors for stroke, link with Acxiom social determinants of health data, and build explainable machine learning models. The data will be used to assess model performance, compare it against the CHA_2DS_2-VASc score, and evaluate fairness across demographic and socioeconomic groups. We request to re-use a subset of the GROUSE EHR data (Afib cohort) and link it with Acxiom data to support this project. Acxiom data linkage can be achieved using one of the following approaches: 1. MU-as-Linkage-Broker: Centralized Linkage Sites will submit a Finder File (including names, addresses, and PATID) to the Coordinating Center at MU for centralized linkage in a secure environment. 2. Site-as-Linkage-Broker: Local Linkage For sites that are unable to participate in centralized linkage, a local linkage option will be supported. Sites will receive scripts to complete linkage on their end and submit a fully linked, de-identified dataset. In reciprocal, we offer to release the linked Acxiom data back to sites.
Please list your detailed Inclusion Criteria	Adults aged 18 years or older with at least one atrial arrhythmia diagnosis by ICD code (427.3*, I48.*)
Please list your detailed Exclusion Criteria	N/A

IRB Information

Do you have a Letter of Non-Human Subjects Determination from IRB?	◯ Yes ⊗ No

Choose which institutions to query for data.	☒ All ☐ Allina ☐ Children's Mercy Hospital, Kansas City, MO ☐ Indiana University ☐ Intermountain ☐ Marshfield Clinic ☐ Medical College of Wisconsin ☐ University of California, Los Angeles (UCLA) ☐ University of Kansas Medical Center (KUMC) ☐ University of Iowa Healthcare ☐ University of Minnesota ☐ University of Missouri ☐ University of Nebraska Medical Center ☐ University of Texas Health Sciences Center at Houston ☐ University of Texas Health Sciences Center at San Antonio ☐ University of Texas Southwestern Medical Center ☐ University of Wisconsin - Madison ☐ University of Utah ☐ Washington University in St. Louis

Constructor for SAA institution checkboxes in the SAA documentation.
 	
Update as institutions_gpc2 is updated.
 	
Guide:
 	
- Replace ### with the number choice of the institution from institutions_gpc2
- Replace XXX with the institution associated with the number.
- Copy from if to the last comma
- Add a new line after the last comma in the Action tags
- Paste
if([institutions_gpc2(###)],'✓ ',
if(Checked,'✓ ','☐')),
'XXX
',
	✓ 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

Details for Sites to Run the Request

Upload a list of your search criteria

Supporting Materials

Attach Supplemental documentation (optional)	[FILE: UT_IRB_00190712.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: UT_IRB_Approval.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: R01 AF PBC SAs.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: Participating_Site_SOW.docx] (* 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: GPCResearchOpportunityAssess...5_1810.pdf] (* if you already have prepared documentation on your research and protocol which may assist the DROC in understanding your request, attach it here.)
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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: GPCPMO-L@PO.MISSOURI.EDU

With copies to: System Privacy Officer, at: privacyofficer@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 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:

Submission Confirmation

Please provide the name of the individual filling out the submission:	Xing Song
Please provide your Email Address	xsm7f@health.missouri.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	06-24-2025