PaTH NETWORK AGREEMENT

This Agreement is entered into as of this 1st date of March, 2022 ("Effective Date") by and between the University Of Pittsburgh - Of the Commonwealth System of Higher Education ("Pitt"); Geisinger Clinic, Johns Hopkins University School of Medicine, Ohio State University, collectively The Pennsylvania State University and The Milton 5. Hershey Medical Center, Temple University - Of the Commonwealth System of Higher Education, University of Michigan and University of Pittsburgh Medical Center (each individually a "PaTH Site").

WHEREAS, Pitt has been awarded from the Patient-Centered Outcomes Research Institute (PCORI) a contract to further develop and deploy the PaTH Network (PaTH; http://www.pathnetwork.org) as part of a national network to support people-centered research (e.g., PCORNet) and in an effort to accelerate a national learning health system;

WHEREAS, PaTH Sites are each subrecipients of the Pitt PCORI contract XXXX ("Contract") or other network funding, and PaTH Sites shall participate in constructing and accessing PaTH as part of their performance under that subaward between the parties;

WHEREAS, parties desire to enter into this Network Agreement to describe the governance framework for the PaTH Network, and to allow PaTH Sites access to PaTH and the data contained therein;

WHEREAS, PaTH Sites have agreed to abide by all relevant Standard Operating Procedures ("SOPs") approved by the PaTH Executive Committee governing the PaTH Network;

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, and intending to be legally bound hereby, the parties agree as follows:

ARTICLE I
DEFINITIONS

1.1. **"PaTH Executive Committee"** shall mean the committee comprised of the PaTH principal investigators named in PCORI Contract XXXX ("PaTH PIs"), PaTH Site principal investigators ("Site PIs"); two patient partner representatives nominated by the PaTH PIs; the technology lead representative (who is currently one of the PaTH PIs) and methodology lead representative, as named in the Contract. Additional non-voting members may be added as set forth in the PaTH Governance SOP.

1.2. **"PaTH User"** shall mean individuals who have (i) received approval from authorized representatives of PaTH Site; and (ii) have been qualified in accordance with the language regarding PaTH Qualified Users in the PaTH Governance SOP.

1.3. **"PaTH Data"** shall mean all de-identified data sets or cohort query responses, obtained by a PaTH User through use of the PaTH Network.

:IA **Data Query and Sharing Software"** shall mean the software system or techniques used by the PaTH network to securely query and return data from the PCORnet CDM data repositories in-network. Data queries and transfers of the following types are allowed:

a. Query and return a single count of aggregated data to Pitt without any approvals.
b. Return case level data based on a query defining an aggregated count of patients with explicit approval from individual sites.
c. Return tables of data defined by custom queries.

LS. **"PCORnet"** shall mean the National Patient-Centered Outcomes Research Network, created by PCORI and including PaTH as a Clinical Research Network member. Further details regarding PCORnet are available at http://www.pcornet.org.

"PCORnet CDM" shall mean the data structure used by the National Patient-Centered Clinical Research Network (PCORnet). More details regarding the PCORnet CDM are available at http://www.pcornet.org/pcornet-common-data-model/.

l.7. **"Terms of Data Access"** shall mean the terms for the use of the project specific, data accessed by PaTH Site's PaTH User, as set forth in Section 3.3 and in Exhibit A.

l.8. **"Instrument of Adherence"** means an instrument of adherence in the form of Exhibit B annexed hereto, pursuant to which an entity agrees to become a PaTH Site in accordance with the terms of this Agreement.

1.9. **"PaTH SOP for User Registration"** shall mean the procedure for processing requests for data access as set by the PaTH Executive Committee.

l.10. **"PaTH Site Representative"** shall mean the representative who has been appointed by PaTH Site to participate in PaTH governance matters.

II1. **"PaTH SOPs"** shall mean the Standard Operating Procedures ("SOPs") adopted by the PaTH Executive Committee as amended from time to time. The currently approved PaTH SOPs are posted on the PaTH website at: http://www.pathnetwork.org. Reference to any SOP not otherwise defined herein shall mean the current PaTH SOP with that title, posted on the PaTH website.

1.12 **"PaTH Governance SOP"** shall mean the document attached hereto as amended from time to time in accordance with its terms.

ARTICLE II

GOVERNANCE AND ADMINISTRATION

2.1 Creation of the PaTH Network. The parties hereby reaffirm their participation as a PaTH Site of the PaTH Network. The purpose of PaTH is laid out in our mission statement: PaTH is Patient Empowered Research. Our mission is to address questions and concerns that matter most to the communities we serve in order to make more informed health decisions. PaTH conducts research across multiple diseases that provide information to patients and health care providers about options for treatment and expected outcomes related to these treatment approaches so that stakeholders can make informed decisions.

2.2 PaTH Executive Committee. The PaTH Executive Committee operates in accordance with the PaTH Governance SOP, approves SOPs for the PaTH Network, approves the addition of new PaTH Sites, assures the proper operation of the PaTH Network, and promotes the use of the PaTH. The PaTH Executive Committee shall meet regularly, but not less than quarterly, and such meetings may be by telephone or other electronic means.

2.3 PaTH Policies and Processes Subcommittee. The PaTH Policies and Processes Subcommittee is responsible for drafting policies, procedures and recommendations to be considered by the PaTH Executive Committee. The committee will meet not less than quarterly. The membership of this Subcommittee is as outlined in the PaTH Governance SOP.

2.4 PaTH Information Technology Subcommittee. The Information Technology Subcommittee provides a forum for trans-network communication on matters such as de-identification quality, security and privacy safeguards, and regulatory compliance. The subcommittee meets no less than monthly and includes a representative from each PaTH Site. Members are primarily responsible for providing access to data for local investigators. The Information Technology Subcommittee reports to the PaTH Executive Committee on any matters that may require changes in PaTH Network SOPs.

2.5 PaTH Future Research Topics Subcommittee. The Future Research Topics Subcommittee interfaces with investigators wishing to use the PaTH Network. The membership of this Subcommittee is outlined in the PaTH Governance SOP.

2.6 PaTH Network Protocol Review Committee. The PaTH Network Protocol Review Committee (PNPRC) is composed of one community representative and one IRB professional from each PaTH Site. The PNPRC provides a review of all PaTH Studies prior to submission to the overseeing IRB. The overseeing IRB shall have ultimate authority to review and approve protocols.

2.7 PaTH Network Administration and Communication. Given its responsibilities as the prime recipient, Pitt will serve as the central PaTH Network administrative site. The Pitt

PI will provide leadership and coordinate communications among the PaTH Sites as needed.

2.8 Addition of New PaTH Sites. New PaTH Sites may be added to PaTH upon the consent of the PaTH Executive Committee, compliance with all PaTH SOPs, and the execution of an Instrument of Adherence.

2.9 Termination of PaTH Sites. The PaTH Executive Committee shall have the authority to determine that a PaTH Site is in material noncompliance with the terms of this Agreement, including determining that PaTH Users at PaTH Site are misusing the PaTH Network, or misusing data obtained from the PaTH Network. The PaTH Executive Committee may, based upon such determination, terminate a PaTH Site's participation in the PaTH Network in accordance with the provisions of Section 4.2 of this Agreement.

ARTICLE III
OPERATION OF PaTH NETWORK

3.1 Access to PaTH. PaTH Site may request access to the PaTH Network for PaTH Users during the Term. For each PaTH User, PaTH Site shall ensure that the PaTH Terms of Data Access as set forth in Exhibit A are met for such PaTH User and shall monitor the use of the PaTH Network by such PaTH User as set forth in Section 3.3 of this Agreement.

3.2 Data Use.

(i) PaTH Sites may use PaTH for work preparatory to research, such as cohort exploration and cohort counts, or they may use PaTH to access de-identified data, in accordance with the terms of the PaTH SOPs and this Agreement.

In order to facilitate the use of de-identified data, each PaTH Site shall obtain the prospective review of the PaTH Site Institutional Review Board ("IRB") protocol for its participation in the PaTH Network and shall provide a copy of the IRB approval letter, or determination of "no human subjects," to Pitt as part of the request for PaTH access. PaTH Site shall use appropriate safeguards, consistent with PaTH Network SOPs to prevent use or disclosure of the data accessed through the PaTH Network other than as permitted by these terms.

Each PaTH Site is responsible for monitoring queries to the PaTH Network from its site in order to determine if they conform to the terms of this Agreement and the PaTH Network SOPs, in accordance with the PaTH Auditing SOP. Any queries that do not conform will be reported to the PaTH Executive Committeefor review and possible action.

(m) All requests to access identifiable or limited data sets will require that the requesting PaTH Site provide a protocol, appropriate IRB approvals, and enter

into a direct data use agreement with the PaTH Site from which the identifiable or limited data set will be obtained.

(iv) Requests for data access from researchers not at a PaTH Site must be approved by the Future Research Topics sub-committee and PaTH Executive Committee. All such researchers must also enter into an appropriate data use agreement in a format approved by the PaTH Sites from which the data is extracted.

ARTICLE IV
PATH SITE RESPONSIBILITIES

4.1 PaTH Sites hereby agree to the following obligations as a condition of remaining a PaTH Site:

a. Each PaTH Site must demonstrate that it has the support and commitment from institutional leadership to achieve the goals of the PaTH project;

b. Each PaTH Site shall install the current PCORnet Common Data Model (CDM),query tool, and other tools as required by PCORnet;

c. Each PaTH Site shall respond to data queries as required in the PaTH Data Aggregation SOP.

d. Each PaTH Site shall perform regular updates from the site EHR to the sitePCORnet CDM;

e. Each PaTH Site shall maintain a dedicated informatics staff to support software and informatics systems and upgrades; and

f. Each PaTH Site shall demonstrate that it has a patient population that will contribute to diversity across the network.

4.2 The PaTH Site PI will nominate representatives to participate in working groups and serve on sub-committees, workgroups, and the PNPRC. These representatives will possess appropriate experience, authority, and knowledge to assist in growing PaTH.

4.3. PaTH Sites will participate in PaTH and PCORnet research as appropriate. It is expected that each PaTH Site will participate to the fullest extent possible, including supporting the development or co-development of potential PCORnet Studies.

4.4. PaTH Sites will participate in preparatory to research queries for PCORnet studies and those studies approved by the PaTH Future Research Topics sub-committee to the fullest extent possible.

4.5. PaTH Sites agree to adhere to PaTH policies regarding data harmonization, data privacy, communications and dissemination of results, and attribution.

PaTH Sites shall be responsible for ensuring integrity of data use, by taking at least the following actions:

a. PaTH Site shall ensure that all data queries from PaTH Site will be archived and can be included in reports to PCORI.

b. PaTH Site shall appoint a Local Data Steward who will periodically (no less than four times per quarter) audit individual data queries for compliance with the original intent of the query and participate in PaTH network data quality initiatives. The Local Data Steward will report to the PaTH Executive Committee any audit results that indicate that a PaTH User is not utilizing the PaTH Network in accordance with the terms of this Agreement.

4.7 Technical Obligations of PaTH Sites.

a. PaTH Site agrees to ensure that PaTH Network uptime will be maintained in the following manner:

i. The Hub Operations Coordinator at the PaTH Site (HOC) will run routine tests of the network that will check for operational issues.

ii. Each PaTH Site will designate a member of their staff as the Site Operations Coordinator (SOC) who is responsible for local technical operations.

iii. The SOC will be the main point of contact for local users (users at that PaTH Site) regarding possible operational and technical access issues.

iv. Scheduled PaTH Site technology downtime will occur during nights (between 12pm EST and 8am EST) and/or weekends.

v. Scheduled downtime will be communicated by the SOC to all other network SOCs and the HOC at least 24 hours prior to the event.

vi. Each PaTH Site's SOC will be responsive to other PaTH Site SOCs and the HOC regarding possible operational issues at their site (respond within 2 hours).

vii. If an operational error is identified at a PaTH Site, the SOC for that PaTH Site will coordinate resolution of that error and the process of bringing their site back online. That SOC will notify all other SOCs and the HOC that the issue is recognized and is being addressed within four hours of initial report.

b. PaTH Sites are expected to ensure network participation by adhering to these uptime agreements and the following site maintenance criteria:

i. Each PaTH Site is expected to refresh their PCORnet COM data at least every three months, or as designated by PCORnet.

ii. Utilization Reporting - each PaTH Site will provide reporting to the PaTH Executive Committee on numbers of users and queries on a regular basis.

iii. Feedback from users - the Executive Committee will encourage feedback regarding the use of PaTH from users. The Executive Committee may charge a sub-committee or working group (e.g., the Future Research Topics Sub-Committee) with obtaining this feedback.

ARTICLE V
MISCELLANEOUS

5.1 Notice. Any notice or communication pursuant to this Agreement shall be sufficiently made or given if sent by certified or registered mail, postage prepaid, or by overnight courier, with proof of delivery by receipt, addressed to the address below or as either party shall designate by written notice to the other party.

In the case of PITT:

Office of Research
University of Pittsburgh
123 University Place -Lower Lobby
Pittsburgh, PA 15213
Telephone: (412) 624-7400

In the case of the Geisinger Clinic:

Geisinger Clinic
100 North Academy Avenue
Danville, PA 17822
Telephone: (570} 214-7021

In the case of Johns Hopkins University School of Medicine:

Johns Hopkins University School of Medicine
733 N. Broadway, Suite 117
Baltimore, MD 21205
Telephone: (443} 287-0982

In the case of The Pennsylvania State University:

The Pennsylvania State University

500 University Drive
Hershey, PA 17033
Telephone: (717) 531-7644

In the case of Temple University of The Commonwealth System of Higher Education

Temple University of the Commonwealth
System of Higher Education
3440 North Broad Street
Philadelphia, PA 19140
Telephone: (215) 707-7379

In the case of the University of Michigan:

Office of Sponsored Research Projects
University of Michigan
3003 S State Street
Ann Arbor, MI 48109 Attn: Patrick Woods

In the case of the Ohio State University:

OSU Biomedical Informatics 250 Lincoln Tower
1800 Cannon Drive Columbus, OH - 43210 Tel 614-292-4778
Fax 614-688-6600

With a copy to:

OSUWMC Office of Legal Affairs Attn: Associate General
Counsel 1590 N High St Ste 500
Columbus OH 43201

In the case of UPMC:

UPMC
Office of Sponsored Programs and Research Support
US Steel Tower, 58th Floor Mail Stop: UST 01-58-01
600 Grant Street
Pittsburgh, PA 15219

5.2 **Termination.** This Agreement may be terminated as to any PaTH site prior to the expiration of the Term should any one or more of the following events occur: any party provides the others with sixty (60) days advance written notice; or a PaTH Site(s) materially breaches this Agreement, and one or more non-breaching PaTH Site(s) the provides the breaching party with thirty (30) days advance written notice of termination and such breach is not remedied within such thirty (30) day period. All PaTH Sites agree that, should this Agreement terminate for any reason, PaTH Site shall cease use of all data accessed under this Agreement.

5.3 **Entire Agreement.** This Agreement, together with the subaward, the PaTH SOPs and all attachments and exhibits, constitutes the entire agreement and understanding between the parties and supersedes any prior or contemporaneous negotiations, agreements, understandings, or arrangements of any nature or kind with respect to the subject matter herein.

5.4 **Waiver.** None of the parties waives its right to enforce any and all provisions of the Agreement at any time during the Term. Any party's failure to enforce any provision shall not prejudice such party from later enforcing or exercising the same or any other provision of the Agreement.

5.5 **Modifications.** This Agreement may not be changed, altered, modified, amended, rescinded, canceled or waived except by a writing executed by authorized representatives the parties.

5.6 **Binding Agreement on Successors.** This Agreement shall be binding upon each party's successors and assigns.

5.7 **Audit.** Pitt, shall have the rights, as the prime on the Contract, to monitor and audit PaTH Sites' performance under the Contract, including their compliance with the terms of this Agreement.

5.8 **Term.** The parties shall perform their respective obligations for the project commencing with the Effective Date of this Agreement and terminating upon the termination of the Contract, including any period of no-cost extension of the Contract.

5.9 Each party hereto shall be responsible for complying with all applicable federal, state or local laws governing the data accessed by the PaTH Network and the party's respective performance hereunder.

5.10 **Counterparts.** This Agreement may be executed in counterparts, and by all parties on separate counterpart, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

5.11 No Party shall use the name, trademarks or logos of another Party or any of its staff in connection with any products, promotion, or advertising without the prior written approval of such other Party. Notwithstanding, no party shall be prevented from disclosing the existence of this Agreement, the identity of the parties, or the basic nature and scope of the purpose of this Agreement.

EXHIBIT A
PaTH NETWORK TERMS OF DATA ACCESS

PaTH Site shall limit access to the PaTH Network to PaTH Qualified User PaTH Qualified Faculty Users are a faculty appointees of an PaTH Network Site that fits the following criteria: 1) Faculty at or above Instructor level, 2) Clinical and Research Fellows, residents or doctoral students if approved by and actively supervised by the Fellow's or student's designated faculty mentor, 3) Operational staff employed by the PaTH Site and working under the direct supervision of approved by the PaTH Site Pl; or 4) User not affiliated with a PaTH network site who is approved by the Future Research Topics sub-committee and Executive committee and has entered into an appropriate data use agreement. All PaTH Sites are required to certify that PaTH Qualified Users at their sites have appropriate regulatory certification (e.g., CITl training).

All requests for access to PaTH Network data shall be approved by the PaTH Executive Committee based on recommendations from the Future Research Topics Subcommittee.

All data accessed through PaTH is solely for research purposes. Each PaTH Site agrees that data accessed through the PaTH Network may not be disclosed to any other third party, or used for any purpose other than the approved research.

Any breach of the terms of Data Access by a PaTH User will result in the immediate termination of that PaTH User account by the PaTH Site.

EXHIBIT B

INSTRUMENT OF ADHERENCE

Reference is made to PaTH Network Agreement dated as of_____ _, 2016 among the University of Pittsburgh, XXXX and such other parties as have executed an Instrument of Adherence thereto {the "PaTH Network Agreement"). Capitalized terms used herein and not otherwise defined have the respective meanings assigned in the PaTH Network Agreement.

The undersigned hereby agrees to the terms and conditions of the PaTH Network Agreement and to the designation of the undersigned as PaTH Site thereunder as of the Adherence Effective Date specified below.

Annex I attached hereto specifies the undersigned's (a) point of contact for administrative matters, for purposes of Section 4.1 of the PaTH Network Agreement; {b) approval rules, for purposes of approving PaTH Users for the undersigned.

(NAME OF ADDITIONAL PARTICIPANTI

_____

]h_;_

Title:

ACCEPTED BY FOUNDING PARTICIPANTS:

_____

_____

_____

_____

PaTH Network Agreement Instrument of Adherence
Annex!

Grant Subaward Number:_____
PaTH Network Site Representative:_____

Notice Address:

Administrative Contact:

Approval Rules

PaTH STANDARD OPERATING PROCEDURE	
TITLE: **Governance**	**NUMBER: SOP- Version: 0.2**

DRAFTING AND REVISION HISTORY

Date	Rev. No.	Modification
8/2/2015	0	Drafting of the document
11/18/2015	1	Transfer of "Network Responsibilities" to Network Agreement; Updating of PaTH User definition; removal of language about the use of the PaTH name
02/02/2016	2	Adjustment of "qualified user" definition; removal of sections on use of PaTH name and citations (governed by PCORI contract); shift of PaTH Site Responsibilities to network agreement; shift of Site Technical Service Level Agreements to network Agreements
3.17.2016	3	Table of content updates; name update for CERC-DC (now HSRDC); addition of Steering Committee; addition of approved users not affiliated with PaTH network to the PaTH Qualified User description
4.11.2016	4	Addition of language about Executive Committee chair during the timeframe of PaTH infrastructure awards.
1.8.17	5	Addition of (a) the PCORnet CDM as a necessary component of IRB approvals needed for PaTH; (b) the need for the Terms of Query Access and SOPs to permit approved users access to PCORnet CDM SQL tools
9.5.2018	6	Updates to reflect shift in infrastructure funder to PCRF and addition of new sites. Adjustment of language to reflect move away from i2b2 as the network query tool.
2.16.2022	7	Updated the cloud storage platform from Box to OneDrive, consistent with the shift in University of Pittsburgh preferred solution; Update the term "Health System Research Data Center" with the more general "Secure Enclave"; Updated the examples of work group names to be consistent with current work groups; substituted in "patient-centered" instead of "stakeholder engagement" as the field appears to be shifting away from the term "stakeholder" as something that may be viewed as offensive by members of certain cultural groups.

ABSTRACT

PaTH supports Patient Empowered Research. Our mission is to address questions and concerns that matter most to the communities we serve in order to make more informed health decisions. PaTH accomplishes this goal through a federated network of health systems who partner with patient, clinician, and researcher stakeholders to leverage the widespread implementation of the electronic health record (EHR) and the well-established extensive informatics and regulatory expertise at our sites and across PCORnet

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1. Terms and Definitions

PaTH Data Steward: Designee(s) of an PaTH Site with auditing and monitoring responsibility of the local PaTH Site – including data quality and conformance to Terms of Query Access Policy.

PaTH Executive Committee: Formed by the PaTH PI(s), PaTH Site PI; 2 patient representatives nominated by the PaTH PIs; and the technology lead representative and the methodology lead representative as named in the contract. Additional non-voting members may be added as set forth in the PaTH Governance SOP. This committee decides on the priorities and deliverables for each PaTH sub-committee and can charge new sub-committees and work groups.

PaTH Steering Committee: This committee is co-chaired by the PaTH PIs and includes the informatics lead from each site, the network's methodology lead and two patient partners. The Steering Committee oversees the operation of the PaTH subcommittees, committees and work groups, as well as progress towards network goals.

PaTH Site: An institutional member of the PaTH network; one who has signed the PaTH Network Site Agreement.

PaTH Network Site Agreement: Agreement signed by each institutional member of the PaTH Network. Includes policies and procedures the site must follow to participate in the PaTH Network.

PaTH Network User: A person with authority to query the PaTH network per the PaTH Network Site Agreement and the Terms of Query Access.

PaTH Qualified User: PaTH Qualified Users are defined in Exhibit A (PaTH Network Terms of Data Access) of the PaTH Network Agreement.

PaTH Terms of Data Use: The terminology that defines the processes and policies surrounding potential study participant data used for the purpose of recruiting participants into the nation's highest priority clinical trials.x

PaTH Work Groups, subcommittees, and committees: There are three standing subcommittees: Policies and Processes, Information Technology, and Future Research Topics; and one committee: The PaTH Network Protocol Review Committee. Each subcommittee has a lead authorized to create workgroups as needed for specific tasks and for the creation of work products (e.g., the Legacy PaTH Cohort work groups, Stakeholder Work Group, Sustainability). Sub-committees may be added or removed by the executive committee.

EHR: Electronic Health Record. Used in lieu of Electronic Medical Record (EMR) as well.

Originating Site: The PaTH Site from which a user makes a query to the PaTH Network.

Network infrastructure funder: An organization providing funding specifically to support the infrastructure of the PaTH network (as distinct from support of specific studies; e.g., PCORI, PCRF).

PI Group: The Principal Investigator(s) listed on the PCRF contract -- Kathleen McTigue and Michael Becich (University of Pittsburgh). The PI Group will review any policies and issues to be managed within the PaTH Executive Committee.

Receiving Site: A PaTH Network Site (currently the HSRDC) that is one of the recipients of a query made from an Originating PaTH Site. The PaTH Network is planning to transition to a cloud-based secure enclave to provide a central data hub and analytic environment for researchers.

Health Services Research Data Center (HSRDC): The central data hub for PaTH maintained and overseen by the University of Pittsburgh's Network Operating Center. Restrictions prevent data from being removed from HSRDC "desktops." Analysis can be removed, but transactions are regularly audited to ensure that files being removed contain no protected health information (PHI).

Cloud-Based Secure Enclave

In the interest of providing researchers with a more scalable and cost-effective environment for data storage and analysis, the PaTH network will be transitioning from HSRDC to a cloud-based secure enclave solution. Oversight, including the development and maintenance of policies for data access and permissions will be the responsibility of Dr. Jonathan Silverstein, Chief Research Informatics Officer of the University of Pittsburgh's Department of Biomedical Informatics.

The PaTH Steering Committee will be required to approve all PaTH Network Secure Enclave policies and procedures prior to implementation. In the event the Steering Committing deems the Secure Enclave does not adequately meet its data security and oversight standards, the network reserves the option to continue using the existing HSRDC environment until such time that the issues and concerns regarding the Secure Enclave are resolved.

2. Background

PaTH supports Patient Empowered Research. Our mission is to address questions and concerns that matter most to the communities we serve in order to make more informed health decisions. The PaTH network was created to foster patient-centered, efficient observational and interventional research that leverages electronic health records and contributes to a learning health system. The University of Pittsburgh and UPMC (Pitt), Penn State College of Medicine and Hershey Medical Center (PSCoM), Temple University Health System (TUHS), and Johns Hopkins University Health System (JHUHS) came together as PaTH in Phase 1 of the PCORnet Clinical Data Research Networks (CDRNs). In Phase 2, PaTH expanded its presence in the Mid-Atlantic region with the addition of Geisinger Health System (GHS) and the University of Utah and University of Utah Health Care (UofU). In the transition to PCRF leadership, PaTH was joined by the University of Michigan and Ohio State University, while UoU has left the network. PaTH organizations include many community-based hospitals, outpatient practices, rehabilitation hospitals, dialysis centers, fitness and wellness centers, psychiatric hospitals, ambulatory surgery centers, and home healthcare agencies, as well as traditional academic-affiliated hospitals.

PaTH, independently and with its PCORnet partners, provides a national resource for the more efficient conduct of patient-centered research. The purpose of this document is to outline the governance principles and procedures to be used by PaTH in its administrative functions.

PaTH has completed its initial infrastructure-development phase and aims to achieve sustainability as an independent, contributing member of PCORnet.

3. Governance Document

This document is designed to allow for future amendments in order to include additional stakeholders, sponsors, and other items described herein. Each PaTH Site will collaborate with other institutions within the PaTH Network and across PCORnet to develop the stakeholder engagement, informatics tools, and regulatory infrastructure that are required to conduct patient-centered research that leverages the EHR, and embeds clinical trials within the usual clinical workflow. Each PaTH Site will lend its expertise in the utilization of their EHR, informatics infrastructure and regulatory expertise to navigate their institutional policies and procedures to solidify the PaTH Network and conduct observational studies and randomized controlled trials both with PCORnet and other academic, federal, and private collaborators.

4. Governance Principles

Governance includes the processes we define and use to make key decisions on how PaTH will operate, accomplish strategic goals, and optimally deploy resources. The purpose of governance is to support PaTH as it works to achieve its goals and aims. Organizationally, and particularly in Academic Health Center settings, there is often a strong desire for comprehensive and highly formal governance, but this can also undermine organizational agility. PaTH governance attempts to strike a balance between ensuring an equitable decision making process that facilitates consensus seeking while minimizing unnecessary bureaucracy. Our governing principles are as follows:

- Strive for a balanced governance that encourages open discussion and transparency
- Implement a structured, thoughtful and comprehensive governance while minimizing bureaucracy
- Ensure equitable representation that encourages consensus-seeking

5. Governance Scope

Governance is an essential component of decision-making in a consortium and enabling progress towards goals and objectives. Important aspect of governance include:

- WHAT types of decisions are covered by the governance entity or entities
- WHO will be involved
- HOW will decisions be made
- WHEN and WHERE decisions will be made
- FINANCIAL CLARITY regarding allocations, authority, and accountability

The scope of PaTH requires each *site* to collaborate with other institutions within PaTH and PCORnet to implement the informatics tools and regulatory infrastructure required to conduct observational studies and randomized controlled trials that are stakeholder driven and leverage the PaTH and PCORnet common data models (CDMs). Each *site* will lend its expertise in the use of their EHR, informatics infrastructure, stakeholder engagement, regulatory expertise, observational research and pragmatic trials to navigate their institutional policies and procedures to contribute to the success of PaTH and PCORnet. By participating, the member Institutions of PaTH concede oversight and management of the PaTH program to the PaTH Executive Committee.

6. Governance Structure

The governance structure developed for PaTH includes required reporting to PCORI through the PaTH Executive Committee, an entity providing executive oversight for the project.

PaTH Governance Elements

1. PI Group
2. PaTH Executive Committee
3. PaTH Sub-committees, PNPRC, and work groups

PI Group: Formed by the PaTH PIs, this group is ultimately responsible for the overall performance and strategy for PaTH. As such, the PI group has the authority to adjudicate decisions and issues.

PaTH Executive Committee: Formed by the PaTH PI(s), PaTH Site PIs; 2 patient representatives approved by the PaTH PIs; and the technology lead representative and the methodology lead representative as named in the contract. Additional non-voting members may be added as set forth in the PaTH Governance SOP. This committee decides on the priorities and deliverables for each PaTH sub-committee and can charge new sub-committees and work groups. The goal of this committee is to make most or all decisions by consensus and/or voting for PaTH. It decides on the priorities and deliverables for each PaTH sub-committee and directly chartered working groups. One of the PaTH principal investigators will be appointed to serve as the committee chair.

The Executive Committee will be chaired by the contact PI of the infrastructure contract.

The executive committee will record and circulate minutes in a timely manner and place them in the appropriate location in the PaTH OneDrive.

PaTH sub-committees and Work Groups**:** There are three standing subcommittees: Policies and Processes, Information Technology, and Future Research Topic. Each subcommittee has a lead authorized to create workgroups as needed for specific tasks and for the creation of work products (e.g., the PaTH Legacy Cohort work groups, Institutional Review Board work group, Sustainability Work Group and Stakeholder work group). Sub-committees may be added or removed by the executive committee.

Each sub-committee, and executive committee-chartered work group, reports to the Executive Committee; sub-committee chartered work groups report to that sub-committee. The Executive Committee can sunset sub-committees and work groups and create new sub-committees and work groups to support the project as PaTH evolves.

Governance is an essential component of decision-making in a consortium and enabling progress towards goals and objectives. Important aspect of governance include:

- WHAT types of decisions are covered by the governance entity or entities
- WHO will be involved
- HOW will decisions be made
- WHEN and WHERE decisions will be made
- FINANCIAL CLARITY regarding allocations, authority, and accountability

The scope of PaTH requires each *site* to collaborate with other institutions within PaTH and PCORnet to implement the informatics tools and regulatory infrastructure required to conduct observational studies and randomized controlled trials that are stakeholder driven and leverage the PaTH and PCORnet common data models (CDMs). Each *site* will lend its expertise in the use of their EHR, informatics infrastructure, stakeholder engagement, regulatory expertise, observational research and pragmatic trials to navigate their institutional policies and procedures to contribute to the success of PaTH and PCORnet. By participating, the member Institutions of PaTH concede oversight and management of the PaTH program to the PaTH Executive Committee.

7. Governance Structure

The governance structure developed for PaTH includes required reporting to PCORI through the PaTH Executive Committee, an entity providing executive oversight for the project.

PaTH Governance Elements

4. PI Group
5. PaTH Executive Committee
6. PaTH Sub-committees, PNPRC, and work groups

PI Group: Formed by the PaTH PIs, this group is ultimately responsible for the overall performance and strategy for PaTH. As such, the PI group has the authority to adjudicate decisions and issues.

PaTH Executive Committee: Formed by the PaTH PI(s), PaTH Site PIs; 2 patient representatives approved by the PaTH PIs; and the technology lead representative and the methodology lead representative as named in the contract. Additional non-voting members may be added as set forth in the PaTH Governance SOP. This committee decides on the priorities and deliverables for each PaTH sub-committee and can charge new sub-committees and work groups. The goal of this committee is to make most or all decisions by consensus and/or voting for PaTH. It decides on the priorities and deliverables for each PaTH sub-committee and directly chartered working groups. One of the PaTH principal investigators will be appointed to serve as the committee chair.

The Executive Committee will be chaired by the contact PI of the infrastructure contract.

The executive committee will record and circulate minutes in a timely manner and place them in the appropriate location in the PaTH OneDrive.

PaTH sub-committees and Work Groups**:** There are three standing subcommittees: Policies and Processes, Information Technology, and Future Research Topic. Each subcommittee has a lead authorized to create workgroups as needed for specific tasks and for the creation of work products (e.g., the PaTH Legacy Cohort work groups, Institutional Review Board work group, Sustainability Work Group and Stakeholder work group). Sub-committees may be added or removed by the executive committee.

Each sub-committee, and executive committee chartered work group, reports to the Executive Committee; sub-committee chartered work groups report to that sub-committee. The Executive Committee can sunset sub-committees and work groups and create new sub-committees and work groups to support the project as PaTH evolves.

PaTH STANDARD OPERATING PROCEDURE	
TITLE: **Data Aggregation**	**NUMBER: SOP- Version: 0.1**
PREPARED BY: **Rachel Hess**	**APPROVED BY:**
DATE WRITTEN: **08-02-2015**	**DATE APPROVED:**

PURPOSE: To define the methods for data aggregation in PaTH

REVISION HISTORY:

Date	Rev. No.	Modification
1/27/17	1	Addition of SQL queries as an approach for querying the Common Data Model; update the name of the Health Services Research Data Center (HSRDC)
9/7/2017	2	Removed references to i2b2/SHRINE; added the PaTH Data Query and Sharing Tool; omitted commitment to a specific hashing algorithm
1/24/2022	3	Removed references to HSRDC and replaced with references to PaTH Network Secure Enclave; removed references to Daquery

POLICY: The PaTH network will use Structure Query Language (SQL) for data aggregation. SQL queries retrieve data from individual PaTH institutional PCORnet CDM instances. When using SQL queries directly to the PCORnet CDM, the querying site will distribute SQL to each PaTH institution and each institution receiving the SQL query will retrieve their data from their site CDM instance and return it via a secure, encrypted method to receiving site.

DEFINITIONS:

RESPONSIBILITIES:

PROCEDURES:

The PaTH Data Query and Sharing tool will:

1. Maintain the capability to shift dates by 1 day – 2 years. Individual records will be randomly assigned an offset, which will not be stored. All dates in each record will contain the same off-set.
2. Zip codes will be limited to first 3 digits unless otherwise approved by the IRB
3. Providers are identified only by a study-specific pseudo-identifier
4. To ensure that site technical personnel can perform quality assurance checks on the data, all records are assigned a pseudo-identifier at the site level. The linkage to this pseudo-identifier is accessible only to site personnel and is not accessible to personal from any other site or the Pittsburgh core (except in the instance of Pittsburgh data, which are accessible to the Pittsburgh core).

The procedures are congruent with our PaTH data use agreement, which allow the sharing of de-identified data. Additional details regarding de-identification using the Path Data Query and Sharing tool are included in an accompanying appendix below.

This method will either (1) not query identifiable information or (2) be used with appropriate institutional review board and data sharing oversight.

The PaTH approach to identification of duplicate patients is not yet determined.

APPENDICIES:

Protection of Patient Privacy with the PaTH Data Query and Sharing Tool

The system architecture is configured with the following protections in place:

- Each user of the system needs to be authenticated at their individual institution to verify employment and faculty status.
- All communications are encrypted using standards approved by the W3C Consortium.
- Initial queries return only aggregate counts. If additional data are required for an approved study, the coordinating site will request those data and each site will run, review, and approve data submission to the coordinating site, and then send the data as appropriate.
- Aggregate numbers are blurred (or obfuscated), so that the counts returned are an estimate of the number of patients meeting the queried upon criteria at each institution.
- If any count returned is less than 10, the result states '<=10' which addresses small cell counts.
- No personally identifiable patient information ever leaves an individual institution.
- Institution-specific user log-in credentials never leave an individual institution.
- Users must register the topics they would like to query with the network Data Steward. The network Data Steward manually reviews all query requests to make sure they are in compliance. Actual

query histories are logged and audited on a regular basis to ensure that there have been no violations of the Terms and Conditions.

REFERENCES:

PaTH STANDARD OPERATING PROCEDURE	
TITLE: **Monitoring and Auditing**	**NUMBER: SOP- Version: 2**
PREPARED BY: **Rachel Hess**	**APPROVED BY:**
DATE WRITTEN: **08-02-2015**	**DATE APPROVED:**

PURPOSE: In order to determine if the PaTH Network is achieving its goals, that sites are participating in accordance with the network agreement and that users are not engaging in abuse of the network it is necessary to establish a Monitoring and Auditing function. This requires that information about the functioning of the network be archived in accordance with the PaTH Governance SOP and that reporting mechanisms are created to analyze and summarize this information.

REVISION HISTORY: 10-18-2015

Date	Rev. No.	Modification
1.9.17	**1**	**Addition of PCORnet CDM queries to quarterly reporting requirements; update name change from CERC-DC to HSRDC** .
1.24.22	**2**	Removed references to HSRDC and replaced with references to PaTH Network Secure Enclave

POLICY: In order to track functioning of this network a central archive of high-level network transactions is needed. At the same time, it is also important to protect the confidentiality of researcher queries by limiting the information in this archive to only those characteristics of the transactions or queries that are relevant to monitoring and auditing. We aim to ensure that protected health information (PHI) is not transmitted without intent; when PHI is transmitted, appropriate authorization [e.g., institutional review board (IRB)] is secured; data transmitted is as approved by oversight authorities (e.g., IRB, PaTH executive committee); aggregated data is stored in a secure manner; and data are not transmitted to unapproved third parties.

RESPONSIBILITIES:

PROCEDURES: The following defines the process of collecting this information including the metadata that will assist in the monitoring and reporting process. For purposes of this SOP, the originating site is the PaTH site where the query is initially constructed and that initiates distributing of that query to other network sites. The receiving site is any site that receives the query, executes that query with respect to their local data and returns the results to the originating site.

1) PaTH will establish and maintain a central query metadata archive for the purpose of monitoring, auditing and reporting PaTH network activity.
2) All queries and their associated metadata may also be archived at both the originating and responding sites.
3) The query metadata to be collected will be:
    a) From the Originating Site
        i) PaTH unique site identifier
        ii) Site unique faculty identifier(s)
        iii) Site unique query identifier
        iv) Date-time stamp of the query transmission
        v) Query Intent
    b) From the Receiving Site (e.g., PaTH Network Secure Enclave)
        i) Items i – iv above
        ii) Receiving Site unique query identifier
        iii) Query receipt date-time
        iv) Query execution date-time
        v) Receiving site identifier
        vi) Results transmission date-time
        vii) Time to execute query
4) All query archives should be considered protected information and only accessible to authorized individuals for a set of agreed upon purposes.
    a) Monitoring and reporting on system activity
    b) Detecting and reporting abuse of the system
5) The local Data Steward is responsible for monitoring queries in order to determine if they conform to the Terms of Query access. Any queries that do not conform will be reported to the PaTH Executive Committee for review and possible action. The action will be taken at the PaTH Network Site that is the origin of the reported query.
6) A report of all approved and PCORnet CDM queries and associated system use will be provided by the Data Stewards to the PaTH Executive Committee and to each participating PaTH Network Site on a quarterly basis.

APPENDICIES:

REFERENCES:

PaTH STANDARD OPERATING PROCEDURE	
TITLE: **Terms of Query Access**	**NUMBER:**

PURPOSE: The PaTH Steering Committee has identified a set of principles that investigators should adhere to in order to use PaTH data. We anticipate that these principles may evolve over time as the network gains more experience with the needs of investigators and partnering institutions.

REVISION HISTORY:

Date	Rev. No.	Modification
9/1/18		Simplification of language of the PaTH Data Attestation Form; removal of language redundant with the network agreement; Modification of language regarding intellectual property.

POLICY and PROCEDURES:

1. **Need for Attestation:** Before a principal investigator is given access to PaTH data, s/he is required to review **the PaTH Network Agreement and SOPs**, and attest to this using the PaTH Data Attestation Form, updated by the FRT team with a copy of the approved study aims.

2. **Principles and Purposes of Data Use**

   Data released for through PaTH are only to be used for the purposes outlined in the study's specific aims as approved by the PaTH Future Research Topics Sub-Committee (see Appendix), which is incorporated herein.

   Query data from PaTH will be accessed, used, and stored in a manner that:
   - Is consistent with the information provided to PaTH
   - Balances the value of data sharing with the need to minimize harm and promote fairness, reciprocity and trust
   - Is in compliance with the IRB approved research project including any applicable Data Use Agreement
   - Is in accordance with all PaTH policies related to the access, acquisition, and storage of electronic protected health information for research purposes
   - Abides by all local, state, and federal guidelines related to the security of electronic protected health information, including all HIPAA regulations.

   No attempts will be made to identify any individual de-identified patient.

   All aspects of PaTH SOPs must be followed, including that the data must be stored on the PaTH Network Secure Enclave at all times unless PaTH has agreed to alternate arrangements and appropriate data sharing agreements are in place. Data should not be transferred through e-mail.

3. **Publication and Intellectual Property**

   - Any investigator that has reason to believe that the confidentiality of the data have been compromised must contact PaTH within 72 hours.
   - Researchers who analyze data from PaTH queries must notify PaTH of all uses of these data (posters, presentations, abstracts, papers, etc.) in advance of publication and follow the PaTH Publication Guidelines for reporting planned dissemination of data.
   - If there are possibilities of intellectual property generation through use of PaTH query data, all investigators involved (including any relevant members of the PaTH team) shall notify their respective institutions immediately before any work is commenced. In the instance of multiple institutions, a multi-site intellectual property arrangement shall be agreed to.
   - All analyses will be statistically adjusted for site (i.e., the partnering PaTH institutions), blinding the readers to site unless specified by the study design.
   - In all publications, presentations, and other public release of study findings, no findings will be identifiable by site without the express written permission of the PaTH Executive Committee.
   - Each site that contributes data to a PaTH-specific analysis should have the opportunity to participate in all writing groups related to that data. That is, a potential author should be provided with the opportunity to meet ICMJE authorship criteria (and would need to meet them all in order to be listed as a publication author).

4. Consequences of SOP violation

If the PaTH terms of query access are violated, the PaTH team will report the research team to the appropriate authorities at participating institutions and access to PaTH data will be revoked. A PaTH committee will be formed to determine appropriate steps.

Appendix: Study Specific Aims

[FRT PM, please insert the Specific Aims for the approved research study]

PaTH Network

PaTH STANDARD OPERATING PROCEDURE	
TITLE: **PaTH Publication Policy**	**NUMBER: SOP- Version:**
PREPARED BY: **Kathleen McTigue**	**APPROVED BY:**
DATE WRITTEN: **08-16-24**	**DATE APPROVED:**

PURPOSE: The PaTH publication policy allows PaTH to approve and monitor the progress of all PaTH-related publications and to ensure compliance with PaTH and PCORI® requirements. This policy pertains to studies that use the PaTH infrastructure and to publications developed by the PaTH infrastructure team.

PCORI requires the PaTH Network to report the status of all presentations at national conferences and manuscripts submitted for peer review from this Clinical Research Network (CRN) to help demonstrate the value of PaTH and PCORI to the public who ultimately fund our work. The twice-annual *Investigator Survey*, sent by PaTH central administration to PaTH study teams, provides an avenue to ensure that publications are captured in a timely manner.

For publications developed by the PaTH infrastructure award team and directly related to PCORnet® work to PCORI, the PaTH team is required to track and report publications during development. This is in concordance with the requirement that PCORI shall be provided with the opportunity to review and comment on draft articles or manuscripts prior to its submission for publication or distribution.

The PaTH Publication Policy Allows PaTH's Publication Committee to:

- Review manuscripts and high-profile presentations to ensure that the PaTH infrastructure is appropriately described, and the funding adequately acknowledged.
- Track progress of manuscripts
- Report this information to PCORI at regular intervals
- Help disseminate the scientific products of PaTH supported studies

REVISION HISTORY:

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1. Responsibilities of Authorship

The PaTH CRN strictly adheres to the recommendations of the International Committee of Medical Journal Editors (ICMJE) under which authorship is based on the following criteria:

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

Those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be designated as authors. Those who do not meet all four criteria should be acknowledged. The ICMJE states that "in addition to being accountable for the parts of the work done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors." More details about the ICMJE recommendations can be found at www.icmje.org. Authorship conflicts will be resolved by the Publications Committee.

2. Describing the PaTH CRN in Publications

When describing the PaTH Network in publications, PCORI's Guidelines for the Use of the PCORnet Name and Logos must be strictly followed: https://www.pcori.org/sites/default/files/PCORI-Guidelines-For-Use-Of-PCORnet-Names-Logos.pdf

For most articles, the text below is appropriate:

- PaTH is a Network Partner in PCORnet® which has been developed with funding from the Patient-Centered Outcomes Research Institute® (PCORI®). PaTH's participation in PCORnet is funded through PCORI Award RI-PITT-01-PS1.

For investigators who would like to supplement the PCORnet Branding Guidelines with additional information, the text below may be of use:

> The PaTH Clinical Research Network is a collaboration between the University of Pittsburgh/UPMC, Boston Medical Center, Geisinger Health System, Johns Hopkins University/Johns Hopkins Health System, Penn State College of Medicine/Penn State Milton S. Hershey Medical Center, the Lewis Katz School of Medicine at Temple University/Temple Health System, RUSH University/RUSH University Medical Center, The Ohio State University, The Ohio State University/Wexner Medical Center, University of Michigan/Michigan Medicine.
>
> PaTH provides an infrastructure for real world evidence observational studies and pragmatic clinical trials that need populations beyond a single health system to answer important clinical questions. This infrastructure includes institutional relationships with data use agreements, a streamlined and centralized IRB review process, site champions to assist in identifying investigators, and data intra-operability between the electronic health records (EHRs).

The PaTH infrastructure allows researchers to conduct secondary data analysis on clinical data, use EHR data to identify research-eligible patients more easily, efficiently recruit patients, and rapidly implement interventions. PCORnet has specified a Common Data Model (CDM), which is a set of individual-level data variables defined and organized in a standardized manner to which all CRN's are required to comply. The PCORnet® CDM and PaTH-specific common data elements provide predictors, covariates, and outcomes to clinical researchers, facilitating the collection of relevant data for study participants while minimizing burden for both patient research participants and researchers.

PaTH also enables staffing efficiencies, for example, enabling a study to hire skilled project and data managers with experience working with the PaTH multi-site EHR dataset on a part-time basis, and sharing code between programmers at PaTH sites.

3. Describing Specific Health System Findings in Publications

PaTH site names must be de-identified when describing site-specific findings in publications except with written permission from the named site's PaTH Principal investigator.

4. Documenting PaTH-affiliated Publications & Ensuring Appropriate Communications about PaTH

Each study PI for PaTH-affiliated studies must acknowledge receipt and review of the PaTH publication policy and PCORnet publication guidance, and agreement to adhere to the processes laid out in these documents before starting their research.

Prior to publication, all manuscripts and high-profile presentations leveraging PaTH data or other PaTH resources and/or evaluate PaTH processes must be submitted to the PaTH Publications Committee to ensure that the PaTH infrastructure is appropriately described, and the funding adequately acknowledged.

- Abstracts must be submitted at least 48 hours prior to submission and will be reviewed by one PaTH Network or Site Principal Investigator; if no feedback is forthcoming within the next 36 hours, the authors may proceed with submission.
- Manuscripts from studies leveraging PaTH resources should be submitted at least 2 weeks prior to journal submission or resubmission to allow sufficient time for review and feedback.
- Manuscripts specifically focused on PaTH infrastructure (e.g., describing or evaluating an infrastructure component) should be submitted at least 3 weeks prior to journal submission to allow for PCORI review.

If language related to PaTH or PCORnet is adjusted after PaTH approval (e.g., for a manuscript resubmission), the manuscript should be resubmitted to the PaTH Publications Work Group for re-review.

A brief bi-annual online survey is distributed by the PaTH Coordinating team to ensure that all published papers and abstracts from studies leveraging PCORnet resources are reported to PCORI, the PCORnet funder. In 2024, it will be extended to PaTH sites to ensure complete documentation of PaTH-infrastructure-related publications.

The PaTH Coordinating team will highlight publications on PaTH Newsletter and social media venues.