PaTH NETWORK AGREEMENT

This Agreement is entered into as of this 24th date of August, 2017 ("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, collectively The Pennsylvania State University and The Milton S. Hershey Medical Center, Temple University – Of the Commonwealth System of Higher Education, University of Utah, and University of Pittsburgh Medical Center (each individually a "PaTH Site").

WHEREAS, Pitt has been awarded from the Patient Centered Outcomes Research Institute a contract to develop the PaTH Network (PaTH; http://www.pathnetwork.org) as part of PCORnet and in an effort to accelerate a national learning health system;

WHEREAS, PaTH Sites are each subrecipients of the Pitt PCORI contract CDRN-1306-04912 ("Contract"), 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 three PaTH principal investigators named in PCORI Contract CDRN-1306-04912 ("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 PaTH SOP for User Registration.

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.

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

1.5. **"SHRINE"** shall mean the open source framework for research funded through the Clinical Translational Sciences Award (CTSA). This software was designed to connect i2b2 instances into a research network. The software only permits exchange of aggregate counts from the source i2b2 systems. Further details are available at: https://open.med.harvard.edu/project/shrine/.'

1.6. **"SHRINE +"** shall mean the custom software package developed at the University of Pittsburgh that augments the functionality in SHRINE. SHRINE+ was developed as part of PaTH phase 1 to extract, de-identify, and build patient-level datasets from PaTH Site i2b2 data.

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

1.8. **"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/.

1.9. **"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.

1.10. **"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.

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

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

1.13. **"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.

1.14. **"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 **Software.** PaTH Site agrees that it shall install i2b2, SHRINE, and SHRINE + for purposes of accessing data for PaTH use; including timely installation of all updates. PaTH Site shall adhere to the Security Standards in its operation and participation in PaTH. PaTH Site shall be bound by the licensing terms applicable to i2b2, SHRINE, and SHRINE + software; nothing in this Agreement or the Exhibits hereto is intended to modify the license terms.

3.3 **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.

(ii) 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 Committee for review and possible action.

(iii) 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 i2b2 and SHRINE + software;

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

d. Each PaTH Site shall perform regular updates from the site EHR to the site i2b2 and PCORnet 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.

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,.

4.6. 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. 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 thatPaTH 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 i2b2 and PCORnet CDM data at least every six 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 Working Group) 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
Attn: Clinical/Corporate Research
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 Utah:

University of Utah
Office of Sponsored Projects
75 South 2000 East
Salt Lake City, UT 84112
Telephone: (801) 585-3344

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.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their respective duly authorized representatives as of the date first above written.

UNIVERSITY OF PITTSBURGH – OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION

By: C. McClure
Name: Christine McClure
Title: Associate Director, Office of Research
Date: 10.11.17

DocuSigned by:
By: Kathleen McTigue
8B032A5BD53A488...
Name: Kathleen McTigue, MD, MSc
Title: PaTH Principal Investigator
Date: 10-03-2017 | 4:55 PM EDT

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 PI; 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., CITI 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 PARTICIPANT]

_____

By:
Title:

ACCEPTED BY FOUNDING PARTICIPANTS:

_____

By:
Title:

_____

By:
Title:

_____

By:
Title:

_____

By:
Title:

PaTH Network

PaTH STANDARD OPERATING PROCEDURE	
TITLE: **Governance**	**NUMBER: SOP- Version: 0.2**
PREPARED BY: **Rachel Hess**	**APPROVED BY:**
DATE WRITTEN: **08-02-2015**	**DATE APPROVED:**

REVISION HISTORY

Date	Rev. No.	Modification
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

ABSTRACT

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 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.

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 work-groups as needed for specific tasks and for the creation of work products (e.g., the cohort work groups, Institutional Review Board work group, and Patient-reported Outcomes work group). 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.

PI Group: The Principal Investigator(s) listed on the PCORI contract –Phase 2: Kathleen McTigue and Michael Becich (University of Pittsburgh) and Rachel Hess (University of Utah). The PI Group will review any policies and issues to be managed within the PaTH Executive Committee.

Receiving Site: A PaTH Network Site (usually the HSRDC) that is one of the recipients of a query made from an Originating PaTH Site.

Health Services Research Data Center (HSRDC): The central data hub for PaTH at the University of Pittsburgh's Network Operating Center.

2. Background

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. The PaTH network was created to foster stake-holder engaged, 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 expands its presence in the Mid-Atlantic region with the addition of Geisinger Health System (GHS) and in the Mountain West, a region not well covered by PCORnet to date, with the addition of University of Utah and University of Utah Health Care (UofU). 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 18-month infrastructure-building phase and aims to achieve sustainability as an independent, contributing member of PCORnet over the next 3 years.

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 develop 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, and regulatory expertise 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.

During the Phase 2 PaTH infrastructure funding award, the Executive Committee will be chaired by the lead PI of the infrastructure contract. After that time, the committee will be chaired by a PI member, who will serve a 1-year term. If an individual is unable to serve, a new member will be appointed by the PI group.

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

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 work-groups as needed for specific tasks and for the creation of work products (e.g., the cohort work groups, Institutional Review Board work group, and Patient-reported Outcomes 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.

Each sub-committee and Work Group is required to provide timely minutes, circulated to the PaTH team and stored in the appropriate folder of the PaTH *box*.

When a subcommittee or the PaTH Executive Committee charges a workgroup with a specific task, the charge will include a plan for reporting to the Executive Committee (quarterly, or in 2 months, etc.). A designee of the workgroup will provide oral updates to the Executive Committee according to this schedule. Upon task completion, a formal report will be submitted to the charging committee within 1 month, for review and possible revision request.

PaTH Network Protocol Review Committee (PNPRC): The PaTH Network Protocol Review Committee (PNPRC) is charged by the PaTH Executive Committee to review all investigational protocols that will use the PaTH network prior to submission to the overseeing IRB.

The PNPRC will review research study applications, prior to formal IRB submission, in order to provide a forum for more comprehensive input from patient partners, identify concerns an IRB committee might have, and attempt to create consistency about how IRBs would address the concerns. The PNPRC provides feedback to investigators regarding the investigational protocol and provides recommendations to the PaTH IRB of record. The overseeing IRB shall have ultimate authority to review and approve protocols.

The PNPRC is comprised of one IRB professional and one patient or community stakeholder from each PaTH network site. The PaTH Network Site PI will nominate representatives to participate in the PNPRC. These representatives will possess appropriate experience, authority, and knowledge to assist in growing PaTH. The PNPRC is chaired by one of the network site IRB professionals. The chair is designated by the Executive Committee and can vary based on the lead IRB site for a particular protocol.

Project Management: Each PaTH site has a project manager, and a lead project manager resides at the PaTH lead site, Pitt. The Project Management team will:

- Provide a single point of contact for information, while managing and facilitating all communication and reporting across the PaTH program.
- Deploy a consistent set of tools and processes to assist the individual site implementations.
- Encourage collaboration, best practices, and information sharing across the sites.

7. Voting

Quorum will require that at least one PaTH network PI, one representative of each PaTH Site, and one patient representative is present. If the PaTH Site-PI is not able to attend, he or she may designate another individual (either on the executive committee or from his or her site) to attend in his or her stead.

Once quorum is achieved, all votes will require a two-thirds majority of those present. If an individual represents more than one interest (e.g., network PI and site PI) he or she will only have one vote (unless serving as a proxy for another executive committee member). A voting member may vote in absentia (e.g. email) as needed.

8. Communications - Guidelines are provided for external communications to stakeholders and internal communication – between sites, workgroups, subcommittees and executive committee, and external communication to stakeholders.

- **External Communications**
    - PCORI
        - Communications with PCORI are facilitated by the contact PI or designee.
        - Communications with PCORI are both informal and formal. These communications will also be shared with the PaTH Sites in order to foster understanding, trust, and confidence.

        - Status updates to PCORI from PaTH will be provided in a timely manner as per the contract (e.g., deliverables, progress reports). The sub-committee or workgroup lead, or their designee, will provide a draft to the PaTH Executive Committee that is then reviewed, revised if needed, and sent to PCORI.
        - Meetings with PCORI leaders, to discuss project progress, may include invited speakers from the project and from sites, as recommended by PCORI and the PaTH Executive Committee. Presentations should be shared with the entire PaTH team.
        - Information from meetings should be communicated back to the entire PaTH team and archived in the designated area, currently the PaTH *box.*
    - Potential Sites - Project status and information regarding participation in the network should be provided to potential sites by the PaTH Executive Committee, as prepared by its Work Groups. Material should be made available online, as well as document format (PDF) for emailing as attachment. The following are principles governing communications with potential sites:
        - Transparent communications are critical.
        - Inquiries from potential sites must be managed by the Executive Committee.
    - The Public - PaTH will maintain a document management site, providing the following forms, documents and checklists:
        - Governance documents
        - Requirements for participating in PaTH
        - Policies and procedures for using PaTH
        - Standard Operating Procedures for PaTH
        - Progress Reports
        - PaTH work products such as data harmonization.
    - Media - All inquiries from the media should be referred to the PaTH executive committee or its designee.
- **Internal Communications**
    - Principles
        - The work of parts of the team must be visible to the entire team.
        - Promote transparency and open communications. That is, the work of each team member must be visible to the entire team.
        - Promote continuity. Sub-committee and Work Group communications must facilitate network-focused communications, help the sites participate in the network, and serve the needs of the network as a whole.
    - Characteristics
        - Dissemination of decisions, status updates
        - Key project information such as schedules, budget, risks, modifications
        - Transparency of meeting schedules
        - Freedom for ad hoc meetings/calls as Work Groups require
        - Site-specific information including numbers of records in the CDMs, years covered, date of last refresh, etc.
- **Contact List** – PaTH will maintain an up-to-date contact list for all active PaTH team members. This is currently housed in the PaTH *box.* Each site project manager is responsible for ensuring that this information is maintained for their site.
    - Contact information for each person should include:
        - Name
        - Institution/Site
        - Email address
        - Office Phone
        - Mobile Phone

        - Committee/Work Group(s) and role (e.g., Governance Work Group, Communications subcommittee lead)
- Standard communication language for participants: PaTH Sites will agree to use (or base their own communications) on standard language that can be used with participants regarding such issues as disclosure, transparency, security, protection of data, etc.

9. PaTH Site Policies

- All institutions desiring to participate in the PaTH Network must agree to and officially sign the PaTH Network Agreement that incorporates the following principles of participation: PaTH Sites will secure IRB review and approval for their i2b2, PCORnet CDM, and Shrine + participation in the PaTH Network.
- The PaTH Sites will implement the Terms of Query Access and Standard Operating Procedures that will permit approved users access to the SHRINE + federated query tool, as well as access to the PCORnet CDM SQL tool, with adherence to the all PaTH SOPs.
- Insuring Integrity of Data Use:
    - All PaTH network users must obtain approval from the Future Research Topics sub-committee, and complete and sign the PaTH Terms of Query Access before making a data request; this module will contain the following elements:
        - Acknowledgement of principles regarding ethical considerations in using shared clinical data;
        - Statement prohibiting any attempt to identify any individual patient;
        - Appropriate language regarding protection of intellectual property;
        - Publication policy (regarding citation of PaTH contract, use of participating PaTH Network Site names, etc.)
        - Statement of penalty for violating agreement.
    - 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 Working Group) with obtaining this feedback.

10. Terms of Query Access for PaTH

The Terms of Query Access is designed to permit approved users access to the PaTH federated network SHRINE + federated query tool and issue SQL queries including to the PCORnet CDM for the purpose of requesting and receiving data from participating PaTH Network Sites through the HSRDC. Each Organization individually contributes and allows access to clinical data for research purposes including observational studies, clinical trials, or feasibility of clinical trials. This section provides a framework intended to ensure that research collaborations among the PaTH Network investigators are realized in an ethical, respectful and transformative fashion.

Access to Data

- **PaTH Qualified User: a** PaTH Qualified Faculty User a faculty appointee 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 PI; or 4) User not affiliated with a PaTH network site who is approved by the

Future Research Topics sub-committee and Executive committee and entered into an appropriate network data use agreement. All PaTH Sites are required to certify that PaTH Qualified Users at their sites have appropriate IRB certification (e.g., CITI 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.
- 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 order to facilitate the use of de-identified data, PaTH Site shall obtain the prospective review of the PaTH Site Institutional Review Board ("IRB") 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.
- 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 Committee for review and possible action.
- 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(s) from which the identifiable or limited data set will be obtained.
- All appropriate institutional, state and federal policies, laws and regulations governing specially protected information will apply.

PaTH Network

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** .

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., HSRDC)
        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 PaTH SHRINE + queries and PaTH SQL 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 Network

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 including the use of the SHRINE + query tool and Hashing algorithm

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)

POLICY: The PaTH network will use a federated data query tool, SHRINE + for data aggregation or Structured Query Language (SQL). SHRINE + retrieves data from individual PaTH institution i2b2 instances and aggregate those data to single analytic data sets. 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 secure FTP to the receiving site, such as the University of Pittsburgh Health Services Research Data Center (HSRDC). In addition, PaTH will employ a hashing algorithm to reduce duplication of records within the PaTH datasets. Individual sites will make the final determination as to whether a hashing method is sufficient for that site to consider the data to be de-identified

DEFINITIONS:

RESPONSIBILITIES:

PROCEDURES:
The SHRINE + data query or SQL data query will:

1. 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
3. Providers are identified only by a 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 SHRINE+ or CDM SQL queries are included in an accompanying appendix.

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

Identification of Duplicate Patients: PaTH will use the Distributed Common Identify for the Integration of Regional Health Data (DCIFIRHD) software developed by the CAPriCORN CDRN.

1. The following identifiers will be encrypted using the DCIFIRHD algorithm to allow exchange and matching, but not re-identification, or "hashed":
    1) first name
    2) last name
    3) date of birth
    4) gender
    5) zip code
2. In the event a match is found, investigators will simultaneously review the chart at applicable sites and will verify by telephone whether there is truly a match.
3. If a match is found, the EHR data will be merged in the de-identified PaTH database stored at the University of Pittsburgh HSRDC.
4. The investigators will determine which site will be the primary site of enrollment and communicate this information to the participant.

Example: Since Mr. D has been seen at both Penn State and Temple for IPF-related health care, he will be identified by the IPF computable phenotype algorithm at both institutions. Thus, Mr. D will be included in

the “hash” files from both Penn State and Temple. The “hash” files from all 4 PaTH sites are delivered to the University of Pittsburgh HSRDC, where the DCIFIRHD algorithm is applied and it is determined that Mr. D has patient records at both Penn State and Temple.

Data File	Contents	PHI	How is file shared?	Purpose
Research File	Survey data, EHR data, biospecimen data (including gender, date-shifted date of birth, and 3 digit zip code).	No (PHI will be retained locally, but will be removed when made available HSRDC)	4 sites share research file with HSRDC	Data analysis
Hash File	Hashed versions of 1) first name 2) last name 3) date of birth 4) gender 5) zip code 6) Social Security # if available	No	4 sites deliver hash file to HSRDC	Automated identification of duplicate patients without PHI

APPENDICIES:

Protection of Patient Privacy in SHRINE+ and CDM SQL queries

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. The obfuscation algorithm is based on what has been published by researchers at Partners HealthCare in "A Security Architecture for Query Tools used to Access Large Biomedical Databases" (Murphy, SN and Chueh, HC, Proc AMIA Symp. 2002:552-6).
- 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: