

## **PaTH NETWORK AGREEMENT**

This Agreement is entered into as of this 1<sup>st</sup> date of March, 2022 ("Effective Date") by and between the University Of Pittsburgh - Of the Commonwealth System of Higher Education ("Pitt"); Boston Medical Center, Geisinger Clinic, Johns Hopkins University School of Medicine, The Ohio State University, collectively The Pennsylvania State University and The Milton S. Eisenhower Medical Center, Rush University 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 RI-PITT-01-PS1 ("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 RI-PITT-01-PS1 ("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](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/](http://www.pcornet.org/pcornet-common-data-model/).

**I.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.

**I.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.

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

**II.1. "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 Committee for 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 site 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, 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  
Telephone: (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 Rush University Medical Center:

Chief Research Administrator  
Rush University Medical Center  
Office of Research Affairs  
1653 West Congress Parkway  
Jelke Building, Suite 601  
Chicago, Illinois 60612

With a copy to:

General Counsel  
Rush University Medical Center  
Office of Legal Affairs  
1700 West Van Buren, Suite 301  
Chicago, Illinois 60612



In the case of Boston Medical Center:

Boston Medical Center  
One Boston Medical Center Place  
Boston, MA 02118  
Telephone: (617) 638-8000

In the case of UPMC:

UPMC  
Office of Sponsored Programs and Research Support  
US Steel Tower, 58<sup>th</sup> 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) 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 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, RI-PITT-01-PS1 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)

\_\_\_\_\_  
Name:  
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

---



<b>PaTH STANDARD OPERATING PROCEDURE</b>	
<b>TITLE:</b>  <b>Governance</b>	<b>NUMBER: SOP- Version: 0.2</b>

### **DRAFTING AND REVISION HISTORY**

<b>Date</b>	<b>Rev. No.</b>	<b>Modification</b>
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

## Table of Contents

- Terms and Definitions .....3
- Background.....4
- Governance Document .....4
- Governance Principles .....4
- Governance Scope .....4
- Governance Structure .....5
- Voting.....6
- Communications .....6
- PaTH Network Responsibilities .....7
- PaTH Site Policies.....8
- PaTH Terms of Query Access .....8

## 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 Committee 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 aspects 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.

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 OneDrive.

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 and other Funders
    - Communications with network infrastructure funders are facilitated by the contact PI or designee.
    - Communications with network infrastructure funders 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 network infrastructure funders 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 network infrastructure funders leaders, to discuss project progress, may include invited speakers from the project and from sites, as recommended by the network infrastructure funder 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 OneDrive.
- 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 OneDrive. 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 data repository and data sharing processes for 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 federated query tool, as well as direct site access to query the local PCORnet CDM. , 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 Sub-Committee) with obtaining this feedback.

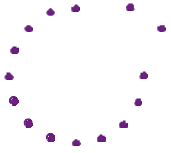
## 10. Terms of Query Access for PaTH

The Terms of Query Access is designed to permit approved users access to the PaTH federated network's 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 PaTH Network Secure Enclave. 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 STANDARD OPERATING PROCEDURE	
<b>TITLE:</b> Data Aggregation	<b>NUMBER: SOP- Version: 0.1</b>
<b>PREPARED BY:</b> Rachel Hess	<b>APPROVED BY:</b>
<b>DATE WRITTEN:</b> 08-02-2015	<b>DATE APPROVED:</b>

**PURPOSE:** To define the methods for data aggregation in PaTH

**REVISION HISTORY:**

<b>Date</b>	<b>Rev No.</b>	<b>Modification</b>
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:**

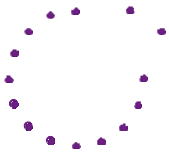
##### **Protection of Patient Privacy with the PaTH Data Query and Sharing Tool**

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

- o Each user of the system needs to be authenticated at their individual institution to verify employment and faculty status.
- o All communications are encrypted using standards approved by the W3C Consortium.
- o 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.
- o 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.
- o If any count returned is less than 10, the result states '<=10' which addresses small cell counts.
- o No personally identifiable patient information ever leaves an individual institution.
- o Institution-specific user log-in credentials never leave an individual institution.
- o 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	
<b>TITLE:</b> Monitoring and Auditing	<b>NUMBER: SOP- Version: 2</b>
<b>PREPARED BY:</b> Rachel Hess	<b>APPROVED BY:</b>
<b>DATE WRITTEN:</b> 08-02-2015	<b>DATE APPROVED:</b>

**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.

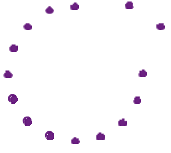
#### **RESPONSIBILITIES:**

**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	
<b>TITLE:</b> Terms of Query Access	<b>NUMBER:</b>

**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]