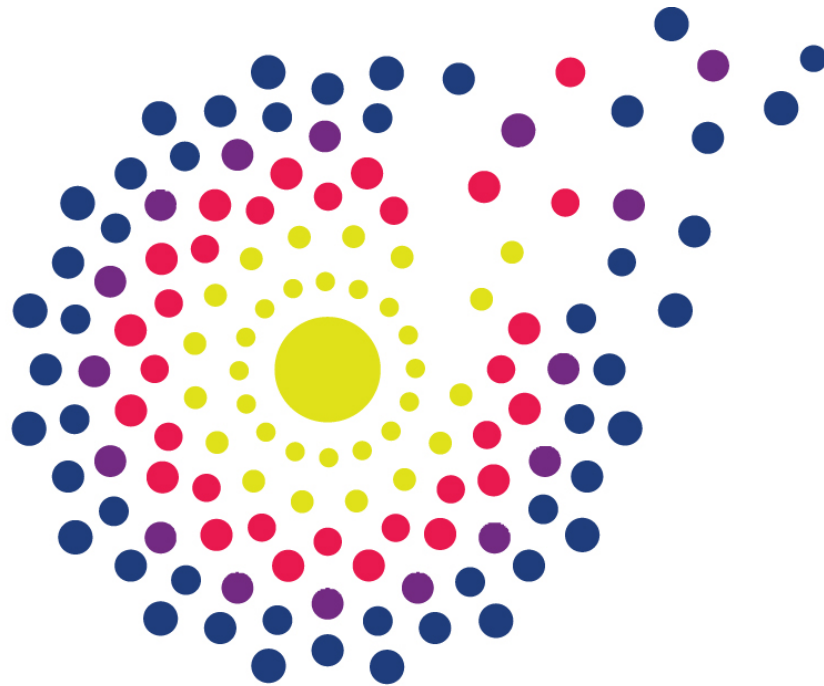# PaTH Scholars Program

Processes and Procedures

Dated May 2022

PaTH Network
patient empowered research

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PROGRAM OVERVIEW

HISTORY

The PaTH Scholars program was formally established in the PaTH Clinical Research Network in 2022 following a successful pilot implementation from 2020-2021 at the University of Pittsburgh (then called the PaTH Fellows Program). By establishing the PaTH Scholars program, PaTH Leadership demonstrates a commitment to providing opportunities for both junior and senior faculty at each of our network sites to learn about and contribute to patient-centered outcomes research activities in our network.

PURPOSE

The PaTH Scholars program aims to mentor and engage scholars through hands-on participation alongside experienced PaTH researchers, as well as improve the capacity of PaTH sites to oversee research in our network. Through this program, Scholars will:

- *Gain experience in pragmatic research*
- *Learn to design and conduct multi-site trials and electronic health record (EHR)-based observational studies*
- *Make connections with collaborators across the country*

In sum, our goal is to help researchers gain the skills and confidence needed to lead and participate in multi-site "real-world evidence" studies. Additionally, we hope that PaTH Scholar alums will serve as PCORnet Ambassadors within their home departments to help spread awareness of PaTH/PCORnet resources and stimulate new studies of national scope that leverage PCORnet resources.

DESCRIPTION

A variety of responsibilities and opportunities are available to PaTH Scholars as they represent the PaTH Network in oversight of CRN deliverables for select studies and participate in other aspects of RWE research by:

- Attending meetings of the PaTH core teams and the PaTH workgroup to gain insights into the challenges and solutions that face RWE researchers
- Representing the local PaTH team at multi-site PCORnet Study meetings, reporting on progress towards study milestones, identifying action items to share with site PaTH team, and helping to ensure those action items are implemented
- Potentially joining or leading site teams for multi-site studies and providing support of regulatory processes and study implementation. In doing so, Scholars form collaborative relationships across institutions and gain experiences with the processes of multi-site research.
- Working with investigators planning PaTH/PCORnet studies to ensure they understand the scope of available PCORnet resources
- Participating in PaTH's regional RWE Journal Club

PaTH's portfolio of active and forthcoming studies provides ample opportunities for Scholars to participate in research that is in line with their interests.

Scholars are strongly encouraged to lead the development of a scientific publication that reflects their work with PaTH. This could be an analysis of real-word data (e.g., a PaTHways Publication), qualitative analysis of My-PaTH Story Booth data, or description of a PaTH process (e.g., a data quality initiative or an innovative component of PaTH infrastructure). Scholars will work with the local PaTH leadership to identify the topic, arrange for data opportunities, and receive analytic or other support as available and as needed. The publication should include collaborators from across the PaTH sites. Scholars are also encouraged to present on their work with PaTH at a local, regional or national venue. If a Scholar is not working on a data project, they may report on the process of working with PaTH. Each site's opportunities will vary; Path Scholars should discuss possible presentations with their site PI.

ADDITIONAL OPPORTUNITIES

PaTH Scholars join a small but growing community of recent Scholar alums to mutually support career development. Such activities might include a journal club and seminars by PaTH-affiliated experts.

PaTH Scholars may also engage in optional enrichment, according to their interests and availability:
- Attending Informatics team meetings, future research topics (FRT) meetings or other committee work
- Shadowing Informatics teams to learn more about computable pheno-types and query planning
- Participating in community engagement activities, to better understand how to support and lead patient-centered research teams

ELIGIBILITY

Clinical fellows and research faculty members from PaTH-affiliated institutions who will remain at their institution for at least a year following participation in the PaTH Scholars program are welcome to apply.

FUNDING

The PaTH Scholars program provides 1-year* salary support of 10% full-time effort (FTE). A portion of the funding for the PaTH Scholars program comes from the PaTH Infrastructure contract, as laid out in the rotating schedule below.

Year 1 (2022**)	Year 2 (2023**)	Year 3 (2024**)
Pittsburgh	Johns Hopkins	U.Michigan
Penn State	Temple	TBD
Ohio State	Geisinger	TBD

*Although PaTH can only provide funding support for three Scholars per year, any site is welcome to support additional Scholars as their independent funding allows.

**Start dates are variable within the year according to the needs and opportunities at the host site. Year 1 will start July 1, 2022. Year 2 can begin as early as January 1, 2023; Year 3 on January 1, 2024.

SCHOLARS' RESPONSIBILITIES

The Scholars program is intended to strike a balance between structure and flexibility, with the understanding that Scholars will commit approximately 4 hours each week (10% FTE).

During the recruitment and selection process, the Site PI will discuss with the potential Scholar what specific research experience and interests would be well-matched with PaTH's current and forthcoming studies at that site. *It is our hope that mutual transparency at this early stage will result in an individualized and rewarding experience for the PaTH Scholar and significant benefit to the research team(s) with which they work.*

The specific responsibilities and schedule a Scholar will undertake will be negotiated with the PaTH Site PI with the goals of accommodating the Scholar's other clinical and research schedules and ensuring the Scholar is able to make substantial contributions to the PaTH research teams they join.

Optional Enrichment Activities

Scholars are welcome to participate in additional PaTH activities beyond their expected effort as a Scholar. For example, these could include more regular participation in PaTH Leadership calls, informatics work group or engagement with ongoing research teams.

SAMPLE MONTHLY PATH SCHOLAR SCHEDULE

The time allocations in the box on page 8 are meant as a sample to assist PaTH site leadership as they tailor the Scholar's activities to meet the Scholar's career goals and the expectations of the PaTH Scholar program. Actual schedules will be adjusted to be consistent with local work hours and actual meeting durations.

Represent local PaTH oversight at a PCORnet-level Study Meeting: 1 hour. When attending at a national (remote) study meeting, representing the Scholar's core PaTH team, the Scholar is expected to be prepared to report on site activities as appropriate. S/he will also gather key questions, deadlines, and action items to share with the local PaTH team.

Participate in a site team meeting for a PCORnet study: 1 hour, 1-2 times a month. In joining the local site team for a PCORnet study, the Scholar could (depending on the study design) participate in activities such as supporting project management staff in their work to complete regulatory activities and launch a study; planning and implementing "low-touch" recruitment using EHR data; participating in stakeholder engagement activities; trouble-shooting any data quality concerns that may arise; and participating in multi-site writing groups for publications.

Contribute to the local PaTH team meeting: 1 hour (may occur weekly). Attendance at local PaTH team meetings includes (a) reporting back on meetings the Scholar has attended representing PaTH oversight and helping to verify the local study team is on track to meet study goals; taking ownership of action items and ensuring they are implemented; (b) updating the team on the activities from any site teams for studies which the Scholar has joined; proposing solutions to challenges and next steps (c) learning about challenges and solutions for completion of RWE research through routine discussions of the local portfolio of PaTH/PCORnet studies.

Attend PaTH Steering Committee call: 1 hour. Scholars are expected to attend at least one PaTH leadership call per month to gain perspective on the full range of activities and decisions that are addressed by the regional team.

Work with local PaTH team to prepare a local researcher to present a PCORnet Front Door Webinar: 1 hour. The Scholar will meet with the local PaTH team and the investigator to help orient that researcher to PCORnet processes/resources, discuss data needs and stakeholder engagement, and provide feedback on a proposed presentation. In other weeks, this activity is likely to be swapped out with different tasks to help support the development of PCORnet-led studies such as presenting about PaTH & PCORnet resources at the Scholar's Division/Departmental Research Seminar or meeting individually with an Associate Professor from his/her home Division/Department who is thinking of developing a PCORnet study. In essence, Scholars are expected to serve as ambassadors for the PaTH team within their institution, and particularly within their Department/Division.

Attend a PCORnet Front Door Webinar representing local PaTH oversight: 1 hour. Front Door webinar attendance should include careful listening from the perspective of a potential site PI, considering how the study could be implemented locally and whether there are ways in which it could be more patient-centered or better leverage PCORnet resources. The Scholar is expected to ask relevant questions and take adequate notes so that s/he can subsequently frame the investigator-provided study materials for distribution to potential site PIs for the study.

Draft a deliverable document for the PCORnet Infrastructure Contract: 1 hour. The Scholar is expected to work with local PaTH leadership to help ensure that the site's PCORnet milestones are met. This could involve a variety of activities such as documenting progress in implementing a recruitment tool, engaging a local community organization, or assisting the informatics team in data quality assessment activities.

Participate in the PaTH RWE Journal Club: 1 hour. The PaTH team's nascent Real-World-Evidence (RWE) Journal club is a virtual forum where Scholars can get to know their peers, Scholar alums, and members of the PaTH site teams as we discuss the emerging evidence base focused on RWE.

Develop a manuscript for publication: variable. The manuscript could focus on qualitative or quantitative data or the processes of a distributed RWE data network.

Attend a PaTH Work Group meeting: 1-2 hours each month. The Scholar and local site PI will determine which work groups are most relevant to the scholar's career trajectory. Attendance at a PaTH Work Group is expected 1-2 times per month, with Data, Future Research Topics, and Stakeholder Work Group attendance each expected at least once during the year. The Scholar is expected to actively participate in Work Group discussions, and subsequently provide brief reflections to local PaTH leadership about ways in which site strengths could be better leveraged for that work group.

APPLICATION PROCESS

The dates for publicizing and ending the application period are at the discretion of the Site PI, based on the needs of their particular site and potential PaTH Scholars. Likewise, the Site PI may determine how and when to review applications and select a Scholar.

PROPOSED APPLICATION CONTENT

Name _____

Department Affiliation _____

Title _____

Please describe your relevant research experience and how you anticipate it will support further research activities at our institution:

What do you hope to gain from your participation in the PaTH Scholars program?

Proposed start date _____

Submit your biosketch and this application form to [the PaTH Site PI at your institution].

ORIENTATION FOR PATH SCHOLARS

GLOSSARY

There are a host of acronyms and shorthand terms you'll hear in your work with PaTH studies. We'll help you get started.

CDM: Common Data Model, a standardized format to unify selected electronic health record data from multiple systems

CER: comparative effectiveness research

CRN: clinical research network (PaTH is a CRN)

DUA: data use agreement, a contract among research institutions to allow sharing de-identified data from electronic health records and other sources. Similar terms are: data sharing agreement (DSA), data transfer agreement (DTA).

EHR: electronic health records

FRT: future research topics, a regularly-scheduled PaTH leadership meeting to review study proposals

HSRDC: Health Services Research Data Center at the University of Pittsburgh. https://www.hsrdc.pitt.edu

IRB: Institutional Review Board, the human subjects research ethics gatekeepers

NLP: Natural language processing

PaTH: This isn't actually an acronym; our network's name is a metaphor! We comprise the University of Pittsburgh (Pitt), Ohio State University (OSU), University of Michigan (UMI), Johns Hopkins University (JHU), Penn State University (PSU), Geisinger Health System, and Temple University.

PCORI: Patient-Centered Outcomes Research Institute, the funder of the PCORnet infrastructure

PCORnet®: According to their website, "PCORnet®, the National Patient-Centered Clinical Research Network, is intended to improve the nation's capacity to conduct health research, particularly comparative

effectiveness research (CER), efficiently by creating a large, highly representative network for conducting clinical outcomes research. PCORnet® has been developed with funding from the Patient-Centered Outcomes Research Institute (PCORI)."

PRO: Patient-reported outcomes

Real-world evidence: Draws upon real-world data, which is gathered in the regular course of care through electronic health records (EHRs), claims data, and patient-reported outcomes (PRO) surveys

REDCap: "REDCap is a secure, web-based application designed to optimize clinical trial data collection. It is provided at no cost for use with any IRB-approved research project."

Trello: The project-management program our network and site project managers use to track contracts, progress, and deliverables for PaTH studies.

SUMMARY OF PATH'S RESOURCES FOR RESEARCHERS

- PaTH's CDM includes >13 million people with diversity in age, geography, and race/ethnicity.
  - o Data on health system encounters, diagnoses, laboratory results, vital signs, and medications have been standardized.
  - o The large size of the PaTH CDM can facilitate the study of rare diseases.
- Five PaTH sites have obtained Medicare claims data (2011-2015) that can be linked with EHR data; in addition, three sites link with claims data from health plans affiliated with their partnering health systems.
- PaTH site teams also assist with identifying collaborators for multi-site trials, determining whether a study's processes align with local clinical workflow, recruiting eligible patients for clinical trials, obtaining preparatory-to-research data, and engaging community partners.
- PaTH supports multi-site research with query infrastructure, cost model & budgeting assistance, data sharing agreements, SMART IRB, and communication/dissemination support.

ADDITIONAL RESOURCES

PaTH website: www.pathnetwork.org

Who we are, what we do, and how we do it with thoughtful collaboration among institutions and partners in industry and our communities

PaTH Guide for Researchers [Link forthcoming on PaTH website under "Research"]

PCORnet® website: www.pcornet.org

Latest news on research on the national level and what it means to enable patient-engaged and caregiver-engaged research.

PCORnet Welcome Guide: [link forthcoming on PaTH website under "Research"]

Real-world-evidence: Brief explanation from the FDA

https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence

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[SITE-SPECIFIC INFORMATION & RESOURCES]

Local Site PIs may insert any opportunities, resources, or other information here that will be helpful to a PaTH Scholar at your institution.