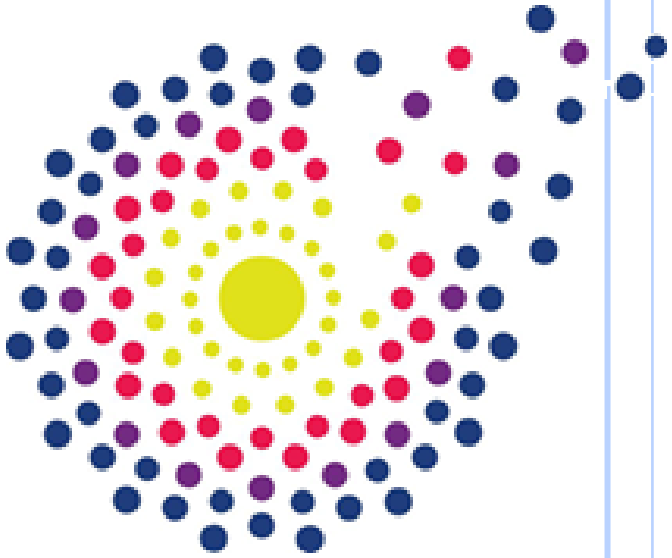
PaTH Publication Guide

A Guide for Authors, Co-Authors, and Collaborators



Future Research Topics Workgroup

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TABLE OF CONTENTS

Publication Policy

Purpose of the PaTH Publication Proposal Policy

PCORI requires the PaTH Network to report the status of all publications (i.e., in preparation to be submitted, submitted, accepted, in-press, and published) arising from this Clinical Data Research Network (CDRN).

PUBLICATIONS INCLUDE:

- Abstracts – require PaTH approval
- Articles (Lay Press)
- Invited Talks / Best Practice Sessions
- Manuscripts – require PaTH

The PaTH Publication proposal policy allows the PaTH Publications Committee to approve and monitor the progress of all PaTH-related publications and to ensure compliance with PaTH's and PCORI's requirements.

Existing condition-specific PaTH CDRN cohorts (i.e., idiopathic pulmonary fibrosis, atrial fibrillation, healthy lifestyles cohort) are **REQUIRED** to submit publication proposals via the online publication tracking system.

Studies that have received funding outside of the PaTH CDRN (e.g. WISE, TARGET, NEXT-D, etc.), and use the PaTH infrastructure (PaTH Network Protocol Review Committee (PNPRC), Future Research Topics Group (FRT), PaTH Cost Model, etc.) are **STRONGLY** encouraged to submit publication proposals via the online publication tracking system.

THE PaTH PUBLICATION PROPOSAL POLICY ACCOMPLISHES THE FOLLOWING:

- Allows the publication committee to review publication proposals for scientific and methodologic validity
- Establishes authorship groups with clear roles and expectations for authors as per the International Committee of Medical Journal Editors (ICMJE).
- Gives authorship teams access to PaTH data as needed for analysis.
    - data can only be used for the agreed upon research questions
- Allows investigators to browse approved proposals and request to join an authorship team, if appropriate
- Ensures that:
    - **New** publication proposals have not previously been addressed in PaTH
    - **Draft** and **Accepted** manuscripts are reviewed by PaTH; this is a requirement
    - **Draft** abstracts are reviewed by PaTH prior to submission

Submitting Proposals

Establishing Priority for Submitting a Publication Proposal

For existing condition-specific PaTH CDRN cohorts (i.e., idiopathic pulmonary fibrosis, atrial fibrillation, weight cohort), the PaTH cohort investigators will have priority for submitting publication proposals. Investigators should only submit proposals for publications they plan on working on in the next **three-months**. Subsequently, non-cohort investigators can submit publication proposals that use the condition-specific PaTH cohort data, with the expectation that a cohort investigator will be identified as a senior PaTH author.

All proposed publications requesting secondary use of study data must be done in accordance with existing contracts, IRB reviews and PCORnet policies and procedures. If you have questions, please contact your local PaTH project manager or e-mail path@hmc.psu.edu.

Submitting a Publication Proposal

For existing condition-specific PaTH CDRN cohorts (i.e., idiopathic pulmonary fibrosis, atrial fibrillation, weight cohort), PCORI requires PaTH to report the status of all abstracts and manuscripts (in preparation to be submitted, submitted, accepted, in-press, and published). It is **required** that Publication proposals be submitted via the online tracking system.

Studies that have received funding outside of the PaTH CDRN and use the PaTH infrastructure (PNPRC, FRT, PaTH Cost Model, etc.) are **expected** to submit publication proposals via the online publication tracking system.

Publication reports and analytics are available upon request. If you have questions, please contact your local PaTH project manager or e-mail path@hmc.psu.edu.

Abstracts

Responsibilities of Authorship

The PaTH CDRN strictly adheres to the recommendations of the International Committee of Medical Journal Editors (ICMJE).

AUTHORSHIP IS BASED ON THE FOLLOWING FOUR CRITERIA:

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

Those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be designated as authors. Those who do not meet all four criteria should be acknowledged. More details about the ICMJE recommendations can be found at www.icmje.org. Authorship conflicts will be resolved by the Publications Committee.

Obtaining Approval to Work on a NEW Abstract

PaTH **requires** that Publication proposals be submitted via the online tracking system for existing condition-specific PaTH CDRN cohorts.

After the proposal is submitted, the PaTH FRT workgroup will review the submission using the following criteria:

FRT WORKGROUP REVIEW CRITERIA

- ☑ No overlap with previously approved abstract
- ☑ Scientific and methodologic validity— the FRT may request the proposal be reviewed by another PaTH workgroup, such as the Patient-Reported Outcomes (PRO), Methodology, or a cohort workgroup, as appropriate

Note: At least two representatives in the relevant fields need to be present for the review and at least one representative from each site involved in the project needs to be present.

Obtaining PaTH Approval on a COMPLETED Abstract

It is expected that abstracts are submitted to the PaTH FRT workgroup at least **three business days** before the submission deadline. The workgroup will review the abstract to ensure compliance with PaTH standards and policies.

Abstracts not reviewed prior to submission, will be reviewed by the workgroup after submission. The workgroup may request changes to the abstract if it is accepted for presentation or request withdrawal of the submission if the information presented is inappropriate or inaccurate.

FRT ABSTRACT APPROVAL CHECKLIST:

- ☑ PaTH appropriately represented
- ☑ PCORI funding statement and disclosure included on final presentation materials (i.e., poster, slides)
- ☑ Science and methodology approved by at least two representatives in the relevant fields
- ☑ Current PaTH investigator is a senior co-author

Notification of Public Acceptance - Abstracts

PCORI requires PaTH to report the status of all abstracts **within 30 days of acceptance**, as per PCORI contract requirements.

A project manager will follow-up with you regularly until information has been obtained:

- ✓ Status of abstract
  - Submitted
  - Accepted
  - Rejected

Abstract reports and analytics are available upon request. If you have questions, please contact your local PaTH project manager or e-mail path@hmc.psu.edu.

Manuscripts

Responsibilities of Authorship

The PaTH CDRN strictly adheres to the recommendations of the International Committee of Medical Journal Editors (ICMJE).

AUTHORSHIP IS BASED ON THE FOLLOWING FOUR CRITERIA:

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

Those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be designated as authors. Those who do not meet all four criteria should be acknowledged. More details about the ICMJE recommendations can be found at www.icmje.org. Authorship conflicts will be resolved by the Publications Committee.

Obtaining Approval to Work on a NEW Manuscript

PaTH **requires** that Publication proposals be submitted via the online tracking system for existing condition-specific PaTH CDRN cohorts.

After the proposal is submitted, the PaTH FRT workgroup will review the submission using the following criteria:

FRT WORKGROUP REVIEW CRITERIA

- ☑ PaTH investigator on writing group as senior co-author
- ☑ No overlap with previously approved manuscript
- ☑ Scientific and methodologic validity— the FRT may request the proposal be reviewed by another PaTH workgroup, such as the Patient-Reported Outcomes (PRO), Methodology, or a cohort workgroup, as appropriate

Note: At least two representatives in the relevant fields need to be present for the review and at least one representative from each site involved in the project needs to be present.

The FRT workgroup will notify the author of the proposal status usually within **two-weeks.**

The lead author will be asked to provide a progress **update every three-months**. If the author(s) have not made adequate progress on an approved request, the FRT workgroup can set deadlines for the writing group or rescind approval.

UPDATING PROGRESS:

If you have questions, or need your REDCap return code resent (to update progress), please contact your local PaTH project manager or e-mail path@hmc.psu.edu.

A project manager will follow-up with you regularly until all information has been obtained.

Obtaining Approval(s) for a COMPLETED Manuscript

All completed manuscripts must be submitted to the PaTH FRT workgroup **prior to journal submission.**

The PaTH FRT workgroup will review the completed manuscript to ensure compliance with PaTH standards and policies (*see Describing PaTH in Publications*).

FRT MANUSCRIPT APPROVAL CHECKLIST:

- ☑ PaTH appropriately represented
- ☑ PCORI funding statement and disclosure included
- ☑ Science and methodology approved by at least two representatives in the relevant fields
- ☑ Current PaTH investigator is a senior co-author

The FRT workgroup will notify the author of the proposal status usually within **two-weeks.**

A project manager will follow-up with the author(s) until all information has been obtained:

- ✓ Date manuscript was submitted
- ✓ Status of manuscript
  - In Preparation to be submitted
  - Submitted
  - Accepted
  - In-Press
  - Published
  - Rejected
- ✓ Manuscript link and Citation

Notification of Public Acceptance – Manuscripts

PCORI requires PaTH to report the status of all Manuscripts **within 30 days of acceptance**, as per PCORI contract requirements.

Manuscript reports and analytics are available upon request. If you have questions, please contact your local PaTH project manager or e-mail path@hmc.psu.edu.

Other Activities

Submitting Other Activities

PaTH Publications Committee requests that articles (lay press) and invited talks/best practice sessions also be reported using PaTH's online system. These activities do not require PaTH or PCORI review.

UPDATING PROGRESS:

If you have questions, or need your REDCap return code resent (to update progress), please contact your local PaTH project manager or e-mail path@hmc.psu.edu.

A project manager will follow-up with you until all information has been obtained.

Obtaining PaTH Approval on a Completed Publication – externally funded projects that use PaTH Infrastructure

Studies that have received funding outside of the PaTH CDRN and use the PaTH infrastructure (PNPRC, FRT, PaTH Cost Model, etc.) are **expected** to submit publication proposals via the online publication tracking system.

The review will assess for appropriate PaTH representation. The FRT workgroup will notify the author if the proposal is approved, usually within **two-weeks.**

FRT MANUSCRIPT APPROVAL CHECKLIST:

- ☑ PaTH appropriately represented
- ☑ PCORI Acknowledgement/Disclaimer Statement

DESCRIBING PATH IN PUBLICATIONS

When describing PaTH in publications, it is recommended that authors draw upon the descriptions below of the PaTH mission, goals, funding source, and participating institutions, in order to ensure accurate representation.

The PaTH Network (full-length):

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 is one of 13 clinical data research networks (CDRN) funded by the Patient-Centered Outcomes Research Institute (PCORI), a nonprofit created through the Patient Protection and Affordable Care Act.

The PaTH Network is a collaboration between the University of Pittsburgh, UPMC, Penn State Milton S. Hershey Medical Center, Penn State College of Medicine, Lewis Katz School of Medicine at Temple University, Temple Health, Johns Hopkins Medicine and Johns Hopkins Health System, University of Utah Healthcare, and Geisinger Health System. Our goal is to conduct research that matters most to our patients.
PaTH provides an infrastructure for pragmatic observational studies and pragmatic clinical trials that need populations beyond a single health system to answer important clinical questions. This infrastructure includes institutional relationships with data use agreements, a streamlined and centralized IRB review process, site champions to assist in identifying investigators, and data intra-operability between the electronic health records (EHRs).

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

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

The PaTH Network (abbreviated):

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 is one of 13 clinical data research networks funded by the Patient-Centered Outcomes Research Institute (PCORI), a nonprofit created through the Patient Protection and Affordable Care Act.

The PaTH Network is a collaboration between the University of Pittsburgh, UPMC, Penn State Milton S. Hershey Medical Center, Penn State College of Medicine, Lewis Katz School of Medicine at Temple University, Temple Health, Johns Hopkins Medicine and Johns Hopkins Health System, University of Utah Healthcare, and Geisinger Health System. Our goal is to conduct research that matters most to our patients.

PaTH Network 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.

PCORI Acknowledgement/Disclaimer Statement:

PCORnet Phase I/II Awardees (CDRNs) must acknowledge PCORI funding in scientific publications (e.g., peer-reviewed journal articles), scientific posters, and slide presentations.

Publications that relate to PCORI's infrastructure funding of CDRNs for development of PCORnet by including the following acknowledgement statement and disclaimer statement (as applicable).

Acknowledgement and Disclaimer Statements for Infrastructure Funding:
"This [work, publication, article, presentation, etc.] was funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (PCORI CDRN #1306-04912) for development of the National Patient-Centered Clinical Research Network, known as PCORnet."

In addition, for any substantive works that present findings, conclusions or other editorial content, awardees are directed to include the following disclaimer statement which may also be appropriate in this case depending on the content of the video:

"The [views, statements, opinions] presented in this [work, publication, article, etc.] are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee or other participants in PCORnet."

Any discussion of PCORI beyond the statements above must be limited to the following factual reference.

The Patient-Centered Outcomes Research Institute (PCORI) is an independent, nonprofit organization authorized by Congress in 2010. Its mission is to fund research that will provide patients, their caregivers, and clinicians with the evidence-based information needed to make better-informed healthcare decisions. PCORI is committed to continually seeking input from a broad range of stakeholders to guide its work.

PCORnet, the National Patient-Centered Clinical Research Network, is an innovative initiative of the Patient-Centered Outcomes Research Institute (PCORI). The goal of PCORnet is to improve the nation's capacity to conduct comparative effectiveness research efficiently by creating a large, highly representative network for conducting clinical outcomes research.

Acknowledgment of Research Reviewed by the PNPRC:

This study underwent review by the PaTH Network Protocol Review Committee (PNPRC.) The PNPRC was established to ensure input from each institution prior to review by the central IRB at Johns Hopkins University. The PNPRC has representation from at least one local IRB official and one patient representative from each PaTH institution.

Acknowledgement of Multi-Lateral Institutional Review Board Authorization Agreement:

[Insert institution name] serves as the IRB of record for the **[insert study name]** study. An IRB of Record or Multi-Lateral Institutional Review Board (IRB) Authorization Agreement is a special agreement between two or more institutions who are engaged in human subject's research.

This research was reviewed by the IRB of Record **[insert protocol number]** and logged locally **[insert protocol number].**

Publications Based On Research Using REDCap Data:

Study data were collected and managed using REDCap electronic data capture tools hosted at **[Insert institution name]**.1 REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

1Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81