

Pediatric Trials Network Publication Policy

Version 5.0

Sponsor: Eunice Kennedy Shriver National Institute of Child Health (NICHD)

Reviewed & Approved by	Signature/Date
Name: Ravinder Anand, PhD Title/Role: DCC Principal Investigator	<i>Ravinder Anand</i> <small>Electronically signed by: Ravinder Anand Reason: Approved Date: May 8, 2025 11:09 EDT</small>
Name: Elizabeth Payne, PhD Title/Role: DCC Co-Principal Investigator	<i>Elizabeth Payne</i> <small>Electronically signed by: Elizabeth H. Payne Reason: Approved Date: May 7, 2025 15:56 EDT</small>
Name: Daniel K. Benjamin, MD, PhD Title/Role: PTN Principal Investigator	<i>Danny Benjamin</i> <small>Electronically signed by: danny benjamin Reason: Approved Date: May 9, 2025 08:33 EDT</small>
Name: Rachel Greenberg, MD Title/Role: PTN Implementation Principal Investigator	<i>Rachel Greenberg</i> <small>Electronically signed by: Rachel Greenberg Reason: Approved Date: May 7, 2025 21:17 EDT</small>
Name: Cheryl Alderman Title/Role: PTN Program Manager	<i>Cheryl Alderman</i> <small>Electronically signed by: Cheryl Alderman Reason: Approved Date: May 7, 2025 15:04 EDT</small>
Name: Zoe Sund Title/Role: PTN Program Manager	<i>Zoe Sund</i> <small>Electronically signed by: Zoe Sund Reason: Approved Date: May 8, 2025 13:56 EDT</small>
Name: Perdita Taylor-Zapata, MD Title/Role: NICHD COR	<i>Perdita Taylor-Zapata</i> <small>Electronically signed by: Perdita Taylor-Zapata Reason: Approved Date: May 12, 2025 17:42 EDT</small>
Name: Thomas Green, MD Title/Role: PTN Publication Committee Chair	<i>Thomas Green</i> <small>Electronically signed by: Thomas Green Reason: Approved Date: May 7, 2025 14:50 CDT</small>

1. Revision History

Version #/Issue Date	Changes/Comments
Version 1/September 5, 2011	Original version
Version 2/January 7, 2016	Modified to include public data usage and publication rights.
Version 3/October 1, 2019	Restructured the contents; added NIH public access policy compliance. Also added Appendixes*
Version 4/August 28, 2023	Restructured the contents; added the requirement of inserting the National Clinical Trial number into publications; clarified terms; added requirement for author/project team to respond to reviewers' comments directly.
Version 5/May 6, 2025	Added Elizabeth Payne to list of policy approvers. Updated Author/Project Team role in PTN Publication review process. Added 'On behalf of' to PTN author byline. Added requirement to confirm PTN authorship with the PTN Implementation PI and the DCC authorship with the DCC PI. Updated PTN Steering Committee member list. Added requirement for author to confirm acknowledgments with PTN project lead, PTN program manager, and DCC PI.

*changes or updates in appendices will not require revision of the policy or re-signing by the reviewers

2. Scope

The Pediatric Trials Network (PTN) and the Data Coordinating Center (DCC) work collaboratively under the National Institute of Child Health and Human Development (NICHD) on the conduct of activities for Best Pharmaceuticals for Children Act (BPCA) projects. The PTN is housed at Duke Clinical Research Institute (DCRI), and the DCC is housed at the Emmes Company, LLC.

This PTN Publications Policy applies to information that is intended to represent PTN, is supported by PTN, or uses data provided by PTN. This information can be PTN Publications, such as abstracts, manuscripts, slide decks, and texts of oral or other presentations. Additionally, this information can be PTN Public Presentations, which are texts for social media or public-facing websites.

All PTN Publications and PTN Public Presentations must be submitted to the PTN Publication Committee before they are submitted to a scientific journal, conference, organization, or other publishing body, or before being posted in a public domain.

3. Role and Membership of the PTN Publication Committee

The PTN Publication Committee will ensure that the study results are presented by individuals who have working knowledge of PTN study design, implementation, data synthesis/analysis, and interpretation. The PTN Publication Committee will also ensure that any confidential or proprietary information is protected and that all appropriate statistical analyses have been included.

The PTN Publication Committee comprises thought leaders and representatives of the Network Cores, DCC, and PTN, including the following:

- A PTN Principal Investigator
- A DCC Principal Investigator
- A NICHD Contract Officer Representative
- A PTN Publication Committee Chairperson
- A designated PTN Program Manager
- Two members of the PTN Steering Committee

Current members are listed in [Appendix A](#).

4. PTN Publication Committee Review Process

Author/Project Team

- Drafts text for PTN Publications or PTN Public Presentations
- Collects coauthors' review
- Submits PTN Publications or PTN Public Presentations in their original file formats via email to the designated PTN Program Manager (PTN-Program-Manager@dm.duke.edu).
 - If an original file format is not compatible with email, an alternative sharing method can be determined by the designated PTN Program Manager.
 - PTN Publications must include the target journal and study abbreviation(s) (eg, POP01)



PTN Program Manager

- Sends the original file formats (and associated documents) to the PTN Publication Committee for review (including the target journal and study abbreviation(s))
 - Cc: PTN Communication Specialist



PTN Publication Committee

- Reviews and generates feedback on PTN Publications and PTN Public Presentations
- Delivers feedback/comments to the designated PTN Program Manager



PTN Program Manager

- Collates feedback from the PTN Publication Committee
- Communicates the feedback to the author/project team



Author/Project Team

- Incorporates feedback into PTN Publications or PTN Public Presentations (as applicable)
- Responds to each reviewer's comments directly, sends all responses and/or edits to: PTN-Program-Manager@dm.duke.edu. Note: at this point the author may proceed with next steps as another round of review by the PTN publications committee is not required
- Keeps the PTN Communication Specialist aware of timelines and product status (including rejection/acceptance status)
- Following submission to the journal (or other entity) and notification of request for revisions (as applicable), additional review by the PTN Publications Committee is not required



PTN Communication Specialist

- Reviews PTN Publications and PTN Public Presentations for appropriate PTN language, such as tags, numbers, statements, and acknowledgements
- May assist with medical writing, editing, and journal-specific formatting requirements
- May assist with submission to targeted journal
- Tracks statuses, such as journal acceptance

5. Timeline

The PTN Publication Committee will be given written notice for forthcoming PTN Publications and PTN Public Presentations:

- 30 days for written publications
- 1 week for abstracts
- 15 days for oral presentations/posters
- 15 days for webpages or social media

6. Renounced Submissions

If the PTN Publication Committee does not endorse a proposed PTN Publication or PTN Public Presentation, then the author maintains the right to present data that were collected, generated, or analyzed only at his/her institution. Data collected, generated, or analyzed at other institutions cannot be disseminated by the author without the PTN Publication Committee's approval. Further, any dissemination must include the following disclaimer:

“This [publication type] is not endorsed by the PTN Publication Committee.”

7. Quality Standards

The author/project team is responsible for their PTN Publication conforming to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (International Committee of Medical Journal Editors [ICMJE]) regarding authorship, disclosure, scientific integrity, and other requirements.

PTN Public Presentations must be consistent with ICMJE academic standards ([link](#)).

8. ClinicalTrials.gov Registration

All PTN clinical trials must be registered in ClinicalTrials.gov prior to enrollment of the first subject.

- ClinicalTrials.gov registration assigns a National Clinical Trial (NCT) number.
- The NCT number must be noted in relevant PTN Publications.
 - This will ensure publications are automatically linked to the ClinicalTrials.gov record.

9. Authorship

The ICMJE recommends criteria for authorship ([link](#)) relevant for PTN Publications. Briefly, all authors listed should have contributed significantly to the protocol design and development or the data acquisition, analysis, or interpretation; have drafted the work or

critically reviewed and revised the work; and approved of the final version. Authors may include the following:

- Principal Investigator
- Statistician(s) and/or PK Analyst(s) performing the analysis
- Clinical site investigators with significant contribution of samples, data, or enrolled patients
- Thought leaders with significant scientific contributions to the study protocol
- Other authors who meet the authorship criteria for peer-reviewed scientific journals

For journals that require a statement of the role/contributions of each author, the corresponding author or designee should provide the information.

The author should confirm PTN authorship with the PTN Implementation PI and the DCC authorship with the DCC PI.

All PTN Publications must include the following tag at the end of the masthead:

“On behalf of the Best Pharmaceuticals for Children Act – Pediatric Trials Network Steering Committee”

- This tag will direct readers to the members comprising the PTN Steering Committee. Their names will be provided to the publisher for inclusion as collaborators or for acknowledgements. Here is an example:

Developing lay summaries and thank you notes in paediatric pragmatic clinical trials

Kanecia O Zimmerman ^{1 2}, Brian Perry ³, Emily Hanlen-Rosado ³, Adora Nsonwu ³, Morgan D Lane ¹, Daniel K Benjamin ^{1 2}, Mara Becker ^{1 2}, Amy Corneli ^{1 3};
Best Pharmaceuticals for Children Act-Pediatric Trials Network Steering Committee

- Refer to [Appendix A](#) for the list of current members on the PTN Steering Committee.

10. Funding Source Acknowledgment

PTN Publications must add the following funding statement:

PTN1.0 publications:

“This work was funded under National Institute of Child Health and Human Development (NICHD) contract HHSN275201000003I for the Pediatric Trials Network (PI D. Benjamin). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”

PTN2.0 publications:

“This work was funded under National Institute of Child Health and Human Development (NICHD) contract HHSN275201800003I for the Pediatric Trials Network (PI D. Benjamin) and contract HHSN275201700002C for The Emmes Company (PI R. Anand). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”

Note that the contract number ends as letter I, not number 1.

PTN Publications arising from *affiliated studies* should modify the support statement:

PTN1.0 publications:

“This work was supported in part by the National Institute of Child Health and Human Development (NICHD) contract HHSN275201000003I. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”

PTN2.0 publications:

“This work was supported in part by the National Institute of Child Health and Human Development (NICHD) contract HHSN275201800003I. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”

Note that the contract number ends as letter I, not number 1.

11. Acknowledgment

All PTN Publications should acknowledge the following groups:

- PTN Steering Committee Members (if the publisher is unable to include/list individual names as collaborator names); see [Appendix A](#) for names.
- PTN Publication Committee, with designations for the Chair and Reviewers; see [Appendix A](#) for names.
- Study Site Investigators and Coordinators or other designees; see [Appendix B](#) for details.
- Study Operational Teams from the DCC and PTN; see [Appendix B](#) for details.

12. Data Sharing Statement

When a data sharing statement is requested by a journal/publisher, provide the following statement:

“To help expand the knowledge base for pediatric medicine, the PTN is pleased to share data from its completed and published studies with interested investigators. For

requests, please contact a PTN Program Manager (PTN-Program-Manager@dm.duke.edu).

13. NIH Public Access Policy Compliance

All PTN authors must follow the National Institutes of Health (NIH) Public Access Policy. For questions regarding the policy, please see the NIH Public Access Policy Frequently Asked Questions website at <http://publicaccess.nih.gov/FAQ.htm>.

The designated PTN Program Manager will ensure that all published manuscripts are submitted to PubMed Central, as required. For a list of journals that automatically submit articles to PubMed Central, visit <https://sharing.nih.gov/public-access-policy/determine-submission-methods>.

As part of the NIH policy, PTN authors are responsible for the following:

- **Copyright Compliance** - PTN authors must ensure that agreements with publishers permit the submission of the author's manuscript to NIH. Upon submitting their manuscript to the journal, they should alert the publisher to the fact that the manuscript is subject to NIH policy.
- **Citing PubMed Central ID Numbers** - When a manuscript is submitted to the NIH through the NIH Manuscript Submission (NIHMS) system, the publication will receive a NIH Manuscript Submission ID (NIHMSID) number. Once a manuscript is available in PubMed Central, it will be assigned a PubMed Central ID number (PMCID). The PMCID or NIHMSID must be cited for articles referenced in progress reports, new applications, and renewals.

Appendix A: Current Team Members

- **PTN Steering Committee Members**

Daniel K. Benjamin Jr., Kanecia Zimmerman, Phyllis Kennel, Cheryl Alderman, Zoe Sund, Kylie Opel, and Rose Beci, Duke Clinical Research Institute, Durham, NC; Chi Dang Hornik, Duke University Medical Center, Durham, NC; Gregory L. Kearns, Scottsdale, AZ; Matthew Laughon, University of North Carolina at Chapel Hill, Chapel Hill, NC; Ian M. Paul, Penn State College of Medicine, Hershey, PA; Janice Sullivan; Kelly Wade, Children's Hospital of Philadelphia, Philadelphia, PA; Leanne West, International Children's Advocacy Network; The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD);

Ravinder Anand, Elizabeth Payne, Lily Chen, Gina Simone, Jeff Mitchell, Kathleen O'Connor, Jennifer Cermak, and Lawrence Taylor, The Emmes Company, LLC (Data Coordinating Center).

- **PTN Publication Committee Members**

Thomas Green (Chair), Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, IL; Danny Benjamin; Perdita Taylor-Zapata; Kelly Wade; Greg Kearns; Ravinder Anand; Ian Paul; Julie Autmizguine; Edmund Capparelli; Kanecia Zimmerman*; Rachel Greenberg*; Cheryl Alderman*; Terren Green*

* cc for information

- **PTN Program Managers****

Cheryl Alderman and Zoe Sund

** manage the Steering Committee

- **PTN Communication Specialist**

PTN Publications: Terren Green

PTN Public Presentations: Megan Daly

Appendix B: Acknowledgement

- **Study Site Investigators and Coordinators/Other Designees**

(Include study sites here, eg, based on the number of participants enrolled and/or data contributions. The project team and/or the Protocol PI will decide which sites to be individualized here.) Example:

Site PI name, Site Coordinator, site name; site location

- The author should confirm acknowledgements with the PTN project leader or the PTN program manager

- **Study Operational Teams**

(Include applicable PTN and DCC operational team members.) Example:

Pediatric Trials Network (Duke Clinical Research Institute), Durham, NC: xxx (Project Leader), xxx (Lead Clinical Research Associate), xxx (Clinical Research Associate), xxx (Clinical Trials Specialist/Clinical Trials Assistant), xxxx (Regulatory Specialist), xxx (PK Analyst)

- The author should confirm acknowledgements with the PTN program manager

The Emmes Company (BPCA-Data Coordinating Center), Rockville, MD: xxx (Project Manager), xxx (Clinical Trial Manager), xxx (Data Manager), xxx (Clinical Research Associate), xxx (Statistician(s), Statistical Programmer(s))

- The author should confirm acknowledgements with the DCC PI












PTN pubs policy-v5.0 (2025-05-07)


Final Audit Report


2025-05-12


Created:	2025-05-07 (Eastern Daylight Time)
By:	Alan-Paul Camarena (apc44@duke.edu)
Status:	Signed
Transaction ID:	CBJCHBCAABAAPaQ_R_KfstBt7jHTes3jBtB0q4bE2qxj


"PTN pubs policy-v5.0 (2025-05-07)" History


-  Document created by Alan-Paul Camarena (apc44@duke.edu)
2025-05-07 - 2:51:21 PM EDT- IP address: 136.226.107.7
-  Document emailed to ranand@emmes.com for signature
2025-05-07 - 2:57:13 PM EDT
-  Document emailed to epayne@emmes.com for signature
2025-05-07 - 2:57:13 PM EDT
-  Document emailed to danny benjamin (danny.benjamin@duke.edu) for signature
2025-05-07 - 2:57:14 PM EDT
-  Document emailed to rachel.greenberg@duke.edu for signature
2025-05-07 - 2:57:14 PM EDT
-  Document emailed to cheryl.alderman@duke.edu for signature
2025-05-07 - 2:57:14 PM EDT
-  Document emailed to zoe.sund@duke.edu for signature
2025-05-07 - 2:57:14 PM EDT
-  Document emailed to taylorpe@mail.nih.gov for signature
2025-05-07 - 2:57:15 PM EDT
-  Document emailed to Thomas Green (tgreen@northwestern.edu) for signature
2025-05-07 - 2:57:15 PM EDT
-  Email viewed by cheryl.alderman@duke.edu
2025-05-07 - 2:57:23 PM EDT- IP address: 72.152.84.108
-  Signer cheryl.alderman@duke.edu entered name at signing as Cheryl Alderman
2025-05-07 - 3:04:05 PM EDT- IP address: 136.226.107.23


 Document e-signed by Cheryl Alderman (cheryl.alderman@duke.edu)
Signing reason: Approved
Signature Date: 2025-05-07 - 3:04:07 PM EDT - Time Source: server- IP address: 136.226.107.23


 Email viewed by Thomas Green (tgreen@northwestern.edu)
2025-05-07 - 3:49:16 PM EDT- IP address: 104.47.73.126


 Document e-signed by Thomas Green (tgreen@northwestern.edu)
Signing reason: Approved
Signature Date: 2025-05-07 - 3:50:06 PM EDT - Time Source: server- IP address: 24.13.71.152


 Email viewed by epayne@emmes.com
2025-05-07 - 3:53:08 PM EDT- IP address: 45.142.94.62


 Signer epayne@emmes.com entered name at signing as Elizabeth H. Payne
2025-05-07 - 3:56:00 PM EDT- IP address: 50.226.46.90


 Document e-signed by Elizabeth H. Payne (epayne@emmes.com)
Signing reason: Approved
Signature Date: 2025-05-07 - 3:56:02 PM EDT - Time Source: server- IP address: 50.226.46.90


 Email viewed by danny benjamin (danny.benjamin@duke.edu)
2025-05-07 - 4:52:49 PM EDT- IP address: 104.47.56.254


 Email viewed by rachel.greenberg@duke.edu
2025-05-07 - 9:16:52 PM EDT- IP address: 104.47.58.254


 Signer rachel.greenberg@duke.edu entered name at signing as Rachel Greenberg
2025-05-07 - 9:17:36 PM EDT- IP address: 136.226.53.2

 Document e-signed by Rachel Greenberg (rachel.greenberg@duke.edu)
Signing reason: Approved
Signature Date: 2025-05-07 - 9:17:38 PM EDT - Time Source: server- IP address: 136.226.53.2

 Email viewed by ranand@emmes.com
2025-05-08 - 11:06:47 AM EDT- IP address: 161.123.248.253


 Signer ranand@emmes.com entered name at signing as Ravinder Anand
2025-05-08 - 11:08:59 AM EDT- IP address: 50.226.46.90

 Document e-signed by Ravinder Anand (ranand@emmes.com)
Signing reason: Approved
Signature Date: 2025-05-08 - 11:09:01 AM EDT - Time Source: server- IP address: 50.226.46.90

 Email viewed by zoe.sund@duke.edu
2025-05-08 - 1:56:20 PM EDT- IP address: 104.47.56.254

 Signer zoe.sund@duke.edu entered name at signing as Zoe Sund

2025-05-08 - 1:56:43 PM EDT- IP address: 136.226.49.17

 Document e-signed by Zoe Sund (zoe.sund@duke.edu)

Signing reason: Approved

Signature Date: 2025-05-08 - 1:56:45 PM EDT - Time Source: server- IP address: 136.226.49.17

 Email viewed by taylorpe@mail.nih.gov

2025-05-08 - 6:12:23 PM EDT- IP address: 104.28.77.165


 Email viewed by danny benjamin (danny.benjamin@duke.edu)

2025-05-08 - 10:51:08 PM EDT- IP address: 172.226.137.8


 Document e-signed by danny benjamin (danny.benjamin@duke.edu)

Signing reason: Approved


Signature Date: 2025-05-09 - 8:33:14 AM EDT - Time Source: server- IP address: 165.225.10.223

 Email viewed by taylorpe@mail.nih.gov

2025-05-09 - 8:29:35 PM EDT- IP address: 52.244.129.126

 Email viewed by taylorpe@mail.nih.gov

2025-05-12 - 7:53:07 AM EDT- IP address: 140.248.0.1

 Signer taylorpe@mail.nih.gov entered name at signing as Perdita Taylor-Zapata

2025-05-12 - 5:42:28 PM EDT- IP address: 156.40.216.9

 Document e-signed by Perdita Taylor-Zapata (taylorpe@mail.nih.gov)

Signing reason: Approved

Signature Date: 2025-05-12 - 5:42:30 PM EDT - Time Source: server- IP address: 156.40.216.9

 Agreement completed.

2025-05-12 - 5:42:30 PM EDT