

## Pediatric Trials Network Publication Policy

### Version 3.0

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

#### Revision History

<b>Version #/Issue Date</b>	<b>Changes/Comments</b>
September 5, 2011	First version
January 7, 2016	Version 2/ Modified to include public data usage and publication rights
October 1, 2019	Version 3/ Restructured the contents; added NIH public access policy compliance. Also added Appendixes*

\*changes or updates in Appendixes will not require revision of the policy or re-signatures

## SCOPE

The Pediatric Trials Network (PTN) and Data Coordinating Center (DCC) work collaboratively under the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Best Pharmaceuticals for Children Act (BPCA) Clinical Program to conduct of activities and projects for improving knowledge gaps in pediatric drug labeling and therapeutics.

This policy applies to all abstracts, manuscripts, slides, and texts of oral or other presentations, as well as texts of transmission through any electronic media outlet (“Public Presentations”) that are intended to represent PTN, are supported by PTN, or have used data provided by PTN.

All PTN publications must be submitted (before submission to a scientific journal, conference, organization, or other publishing body, or before being posted in a public domain) to the PTN Publication Committee; this committee has the right to review publications before submission.

### 1. 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 Publication Committee will also ensure that any confidential or proprietary information is protected, and that all appropriate statistical analyses have been included.

The Publication Committee is comprised of thought leaders and representatives of the Network Cores, DCC, and PTN. Members include:

- PTN Principal Investigator
- DCC Principal Investigator
- NICHD Contract Officer Representative (COR)
- Publications Committee Chairperson
- PTN Program Manager
- Two members of the PTN Steering Committee

### 2. PTN Publication Committee Review Process

The Publication Committee will act as an independent body of scientific and medical experts with the following responsibilities:

- The Chairperson is responsible for coordinating review of publications that report scientific findings based on data generated by or derived from research performed by the PTN.

- The PTN Program Manager will be the primary contact for the Committee Chair, with responsibility for receiving and disseminating contact information and documents.
- The Publication Committee will read and constructively critique all qualifying publications for presentation or publication. The Publication Committee will consider each publication with due regard for scientific merit, with the goal of promoting timely dissemination of scientific and medical knowledge.
- The PTN Program Manager or designee will track drafts and published products.

### 3. Submission and Timeline

- All submissions are to be made through the PTN Program Manager. Manuscripts and abstracts will be submitted via email ([PTN-Program-Manager@dm.duke.edu](mailto:PTN-Program-Manager@dm.duke.edu)) in an editable electronic format, such as Microsoft Word.
- The PTN Program Manager or designee will notify the Publication Committee Chairperson to request review.
- Upon receiving request, the Publication Committee Chairperson will assign at least two reviewers for each manuscript and at least one reviewer for each abstract. Each assigned reviewer has the right to delegate review to a designee with an appropriate level of expertise, but the assigned reviewers are still responsible for the review's quality and timeliness.

The Publication Committee will be given 30 days written notice for written publications, 1 week written notice prior to submission for abstracts, and 15 days written notice for oral presentations /posters to permit time for review.

If the Publication Committee does not endorse a proposed manuscript or presentation, then the author still maintains the right to present locally collected, generated, or analyzed data; however, the author may not include aggregate PTN study results without Publication Committee approval and must include the following disclaimer: *“This [publication type] is not endorsed by the PTN Publication Committee.”*

**Note that the applicable project team /leading author is responsible to ensure that:**

- All publications must conform to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (International Committee of Medical Journal Editors [ICMJE]) with regard to authorship, disclosure, scientific integrity, and other requirements. All public presentations need to be consistent with usual academic standards.
- All applicable clinical trials must be registered in ClinicalTrials.gov prior to

enrollment of the first subject.

#### 4. Authorship

All authors listed on a publication should have contributed significantly to the protocol design and development, statistical design or analysis, laboratory methodology, or any other significant operational or scientific aspect of the study. Authors may include the following:

- Principal Investigator
- Lead statistician 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.

All PTN publications will include “**on behalf of the Best Pharmaceuticals for Children Act – Pediatric Trials Network Steering Committee**” at the end of the masthead.

(Note that personal names of the committee members will be provided to the publisher for inclusion as **collaborator names**, if applicable, in the article. Otherwise, the members will be included in the Acknowledgement section.)

The Steering Committee is managed by the PTN Program Manager. [Refer to Appendix B for the list of current Steering Committee Members.](#)

#### 5. Funding Source Acknowledgment

The following funding statement must be on every PTN publication ([see notes below](#)):

“This work was funded under National Institute of Child Health and Human Development (NICHD) contract HHSN275201000003I ([or HHSN275201800003I](#)) for the Pediatric Trials Network (PI Danny Benjamin) and HHSN275201700002C for BPCA DCC (PI Ravinder 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 PTN contract number ends as letter I not number 1. PTN2.0 projects are funded under [HHSN275201800003I](#). For publications coming out of studies supported by BPCA DCC (i.e. Emmes), include DCC contract information as well. Please customize accordingly)

For publications arising from affiliated studies, the acknowledgement should be modified to state the following:

“This work was supported in part by the National Institute of Child Health and Human Development (NICHD) contract HHSN275201000003I [[or 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. PTN2.0 projects are funded under HHSN275201800003I. Please customize accordingly.)

## 6. Acknowledgment

All PTN publications should acknowledge the following groups – see more details in Appendix C:

- PTN Steering Committee Members (if the publisher is unable to include/list individual names as collaborator names)
- PTN Publication Committee Chair and Reviewers
- Study Site Investigators and Coordinators or other Designees
- Study Operational Teams

## 7. Data Sharing Statement

When needed or requested by journal/publisher, state the statement below:

To help expand the knowledge base for pediatric medicine, the Pediatric Trials Network is pleased to share data from its completed and published studies with interested investigators. For requests, please contact: [PTN-Program-Manager@dm.duke.edu](mailto:PTN-Program-Manager@dm.duke.edu).

In addition, de-identified dataset and redacted study documents from the Best Pharmaceuticals for Children Act (BPCA)-sponsored clinical trials are also placed on the NICHD Data and Specimen Hub (DASH) website as well.

## 8. 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 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, please visit [http://publicaccess.nih.gov/submit\\_process\\_journals.htm](http://publicaccess.nih.gov/submit_process_journals.htm).)

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

- **Copyright compliance** - PTN authors must ensure that agreements with publishers permit the submission of the author’s manuscript to NIH. Upon submitting your manuscript to the journal, please 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, the publication will receive a NIH Manuscript Submission ID number. Once a manuscript is available in PubMed Central, it will be assigned a PubMed Central ID number. Effective May 25, 2008, authors must cite PubMed Central ID or NIH Manuscript Submission ID numbers for any articles cited in progress reports, new applications, and renewals.

## Appendix A: PTN Publication Review Workflow

### **Project Team /Author**

- Draft manuscript/abstract per the applicable target journal format
- Collect coauthors review
- Submit via email [PTN-Program-Manager@dm.duke.edu](mailto:PTN-Program-Manager@dm.duke.edu)



### **PTN Program Manager**

- Notify Publication Committee Chair to request review
- Cc DCRI Communication Specialist on above notifications
- Send Publication Committee's reviews to project team/author

## Appendix C: Acknowledgement

- **Study Site Investigators and Coordinators/Other Designees**  
(include study sites here, eg. based on # participant enrolled /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;

- **Study Operational Teams**  
(include applicable DCRI and BPCA-DCC operational team members), example:

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 Emmes Company (BPCA-Data Coordinating Center), Rockville, MD: xxx (Project Manager), xxx (Clinical Trial Manager), xxx (Data Specialist), xxx (Monitor), xxx (Statistician)