

ImproveCareNow Data Authorship and Acknowledgement Policy

A primary goal of ImproveCareNow (ICN) is to create a community of patients, families, clinicians, and researchers working together to improve the health and lives for children with Inflammatory Bowel Disease (IBD). Patients make a major contribution towards this vision by agreeing to invest their data in the ICN registry and participate in research studies. The ICN physicians and Centers also make a significant contribution by taking time to recruit their patients to participate, by entering patient data into the registry, and by sharing data about their performance and describing changes they are making to improve care delivery. Researchers contribute when they use the rich repository of data to discover new insights into treating and curing IBD.

ICN is a learning health system, and research is a core component of this system, as are quality improvement, patient engagement, and creation and expansion of the learning community. In other words, without the integration of activities across the ICN Centers, research and learning among patients and clinicians in the network could not occur.

This document details the ICN policies related to publications that are based on ICN related studies. Investigators for each study agree to follow this policy where ICN is a partner. Sponsor publication policies/requirements take precedence as long as they are not in direct conflict with existing ICN policies. ICN data may not be submitted to study sponsors or journals without prospective approval from the network.

I. Roles & Responsibilities within ICN Network and Writing Team

A. ICN Research Committee

The ICN Research Committee provides guidance to the research functions of the ImproveCareNow Network. The Committee is charged with approving and monitoring all research that occurs within ICN. The Committee members may include a combination of physicians, researchers, quality improvement experts, administrative staff, and parents of and patients with IBD.

B. ICN Center

This is a provider organization that participates in ICN. An ICN Center includes the participating pediatric gastroenterology practice and its affiliated physicians, nurses, and scientists within the provider organization.

C. ICN Physician Leader

The Physician Leader is designated by the Network Director to serve as a liaison with ICN and to participate in the administration of network-wide activities, such as the production of the ICN database.

D. Study Principal Investigator (PI)

The PI is responsible for ensuring that the primary results of the study are disseminated in the form of a scientific paper. The PI will work with the study investigators to identify a Core Writing

Group and a Primary Author for each paper developed. The results of all ICN studies are expected to be submitted for publication within **one year** of the completion of primary data collection or within **6 months** of data extraction (secondary data).

E. Primary Author

The Primary Author is responsible for the main writing task and is the corresponding author for the paper. The primary author is the final decision maker within the writing team in matters of style, organization and interpretation of findings. For main effects papers, the Primary Author is typically the Study Principal Investigator. Primary investigators are required to notify the ICN Research Committee of any manuscripts accepted for publication within **15 days** of acceptance. The final citation and the PubMed link to the article should be provided to the ICN Research Committee within **15 days** of publication.

F. Core Writing Group

This group (typically about 4 persons including the Primary Author) is responsible for the content of the paper, including the main outcomes and results reported. The Core Writing Group determines the target journal and is responsible for responding to peer reviews and revising the manuscript as required in a timely manner. The core writing group will develop publication procedures for identifying manuscript topics and approval processes, and offering authorship to the appropriate data contributors/individuals. The Core Writing Group is responsible for broad dissemination of the study findings; and where applicable, sharing the results with study participants.

G. Group Authors

Group authors includes other members of the Study Team, i.e., all individuals that contribute to the conduct of the overall research study in a substantive way. Group authors meet ALL of the following International Committee of Medical Journal Editors (ICMJE) criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work;
- Drafting the work or revising it critically for important intellectual content;
- Final approval of the version to be published; and
- 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.

II. Types of Manuscripts

The ICN Research Committee will be responsible for the assignment of research proposals and manuscripts into “Core” or “Ancillary” categories. The Committee will make every effort to provide this definition at the time of approval of the research proposal, although final classification will be made at the time of the approval of the draft manuscript by the Research Committee.

A. Core Manuscripts

Core manuscripts are those manuscripts generated from proposals to answer research hypotheses related to the Mission Statement of the ICN Network. These studies are likely to involve interventional, observational or randomized studies that require new effort by center clinicians. Examples include network results of quality improvement efforts, studies of stakeholder engagement, comparative effectiveness studies, and clinical trials. They are more likely to be supported by grants. Such core studies should involve more extensive participation. Each ICN Center will be invited to designate a single author to be a member of the authorship team. This invitation can be accepted or declined, according to the Authorship Acceptance Flow Diagram. Each author must meet authorship guidelines as defined by the International Committee of Medical Journal Editors (see Part V).

B. Ancillary Manuscripts

Ancillary manuscripts are those manuscripts that are generated from hypotheses of individual researchers. They will more likely use existing data. These ancillary manuscripts may have a more limited authorship team, which can be initially defined by the principal investigator and submitted for review by the ICN Research Committee. Again, each author must meet authorship guidelines as defined by the International Committee of Medical Journal Editors.

III. Review and Approval Process for ICN Manuscripts

After an investigator has gained approval for research using data from the ICN registry, each Study Team will develop publication procedures which will minimally address the following:

- Development and selection of paper concepts;
- Identification of authors; and
- Approval of final manuscript/s.

Publication procedures will be submitted to the ICN Research Committee within three months of the study start date.

Upon producing a draft manuscript from the research conducted using that data, that investigator must submit that draft manuscript to the ICN Research Committee for review. The ICN Research Committee will review the manuscript and determine approval for submission for publication. If approval is not granted, the ICN Research Committee Chair will communicate the committee's concerns to the lead author.

A. Format for Byline, Authorship Appendix, and Acknowledgements in Manuscripts

i. Byline

All publications using data provided by ICN will include a list of authors and either, for Core Studies, the phrase **“and the ImproveCareNow Pediatric IBD Learning Health System.”** or, for Ancillary Studies, **“for the ImproveCareNow Pediatric IBD Learning Health System.”**

ii. Authorship Appendix

The authorship appendix will consist of the complete list of authors in cases where a journal may limit the number of authors in the byline.

iii. Acknowledgements

The acknowledgements will be comprised of two parts: [1] a website address for the ICN Network where a list of all current ICN Centers can be found and [2] a list of researchers who do not qualify as primary or secondary authors but contributed to the research. Authors should follow the International Committee of Medical Journal Editors' guidelines for acknowledgments:

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chairperson who provided only general support.

B. Manuscript Text

It must be made clear in the manuscript text that the ICN dataset was used for analysis, for example: "This research has made use of data provided by the ImproveCareNow Network and collected by Centers participating in the ImproveCareNow Network." The manuscript should include a description and limitations of the ICN dataset.

In addition, all publications should include:

- A statement that acknowledges the study sponsor and lists the appropriate grant number/s;
- A statement that the ICN endorsed study was approved/reviewed by institutional review board(s) for protection of human research participants;
- A statement that acknowledges the contribution of ICN data contributors to the ICN endorsed study. This contribution can be acknowledged by listing the names of ICN institutions in the Acknowledgement section, unless the journal prohibits an acknowledgement of this type. All acknowledgements will follow the Uniform Requirements for the Acknowledgement section. (ICMJE Acknowledgements)
- Key Words - Most journals ask authors to submit keywords that relate to the content of the article. Authors must include keywords that describe the topic of the study. All articles related to ICN studies or data are required to list "ImproveCareNow" as a keyword.

C. ICN Branding and Logo

When Study PIs or other team members present ICN data at scientific or public meetings, all presentations (oral and poster) must use the ICN logo and acknowledge the grant and data contributors using the appropriate acknowledgement statement. The ICN logo and template slides are available upon request at info@improvecarenow.org.

IV. Qualifications for Authorship or Acknowledgement

The uniform requirements for manuscripts (URM) established by the [International Committee of Medical Journal Editors \(ICMJE\)](#) recommends that authorship credit should be assigned only to those individuals who do all of the following 3 things:

- A. provide substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data
- B. participate in drafting the article or revising it critically for important intellectual content
- C. provide final approval of the version to be published

*Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.

The ICMJE URM recommends the following criteria for inclusion in the acknowledgements section:

- A. Contributors who do not meet the criteria for authorship and those who provided financial and material support should be acknowledged
- B. Contributors are the individuals who provided assistance with study design, data collection, data analysis, or manuscript preparation

V. Dispute Resolution

The Principal Investigator is ultimately responsible for the authorship of all manuscripts according to the guidelines listed within. Any disputes that arise as a result of these guidelines that cannot be adjudicated by the Principal Investigator and ICN Research Committee should be referred to ICN Research Committee Co-chairs to help resolve disputes. The specific disagreement should be described in detail by the study PI, or if involving the study PI, by another investigator in writing and submitted to the ICN Research Committee. The ICN Research Committee may request additional information from the parties involved. The ICN Research Committee will facilitate a final decision and inform the study PI in writing.