

**PAEDIATRIC RHEUMATOLOGY INTERNATIONAL TRIALS
ORGANIZATION (PRINTO) AND PEDIATRIC RHEUMATOLOGY
COLLABORATIVE STUDY GROUP (PRCSG)
AUTHORSHIP AND PUBLICATION POLICY**

The following document aims at describing the policy of the PRINTO and PRCSG networks concerning authorship and publication of manuscripts and abstracts arising from collaborative multicenter research. This policy is published on the networks' websites of the Paediatric Rheumatology International Trials Organization (PRINTO, www.printo.it) and of the Pediatric Rheumatology Collaborative Study Group (PRCSG, www.prcsg.org).

BACKGROUND

The networks' authorship and publication policy is in line with that of the International Committee of Medical Journal Editors (ICMJE).

As per the ICMJE “*authorship credit should be based on three conditions: **condition 1**) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; **condition 2**) drafting the article or revising it critically for important intellectual content; and **condition 3**) approval of the final version to be published and **condition 4**) Each author is aware of and accountable for the work of other coauthors* The ICMJE requires that authors meet conditions 1, 2, 3 and 4.”¹

Specifics of the process of acquiring eligibility for authorship are described below and closely aligned with the spirit of the aforementioned ICMJE policy- i.e. authors *earning* the right to authorship by *actively* performing certain study related activities. Hence, the PRINTO/PRCSG Authorship and Manuscript Publication Policy for authorship necessitates active (as opposed to passive) participation in all three critical aspects of the authorship requisites listed above. Of note, this policy does not ascribe or support an arbitrary number of authors; rather it ascribes the inclusion only of those authors who satisfy all three of the ICMJE authorship conditions.

The PRINTO/PRCSG Authorship and Manuscript Publication Policy detailed below has been acceptable to multicenter, multi-authors publication of pharmaceutical Sponsors' initiated and/or supported trials to the following medical journals: The New England Journal of Medicine, Lancet, The Annals of Rheumatic Diseases, and Arthritis & Rheumatism (complete list of publications at www.printo.it or www.prcsg.org).

PRINTO-PRCSG AUTHORSHIP AND PUBLICATION POLICY SPECIFICS

Herein, the authorship and publication policy prerequisites of the PRINTO and PRCSG networks are described. Details of this policy are provided on the websites of the Paediatric Rheumatology International Trials Organization (PRINTO, www.printo.it) and of the Pediatric Rheumatology Collaborative Study Group (PRCSG, www.prcsg.org), respectively.

¹ Verbatim from JEMC statement

1. Active participation in relevant study-related activities as per the ICMJE is present if Investigators fulfill requirements A and B plus C detailed below:

A. If Investigators of a site/hospital/research organization are members of either the PRINTO or PRCSG networks and participate in an academic study or industry-sponsored study, then the Investigators meet condition #1 of being "directly and substantially involved in acquisition of data".

B. Investigators meet condition #2, i.e. "reviewed the draft of the outline and also the draft of the manuscript" as follows. To be eligible for authorship, investigators are required to either provide written revisions OR certify in writing (email, letter, fax) the review of the outline/manuscript draft in full but have no revisions. Failure to provide written feedback indicates that these Investigators do not meet condition #2;

C. Investigators meet condition #3 in the same way as detailed for condition #2 above- i.e. written approval (email, letter, fax) of the manuscript draft content without further edits OR edits to the manuscript draft prior to submission;

2. The PRINTO Senior Scientist and the PRCSG Scientific Director together with other relevant parties (pharmaceutical industry or other relevant Sponsors) are responsible for selecting the eligible authors on the basis of the number of enrolled patients AND the requirements listed under Section 1.

3. The PRINTO Senior Scientist and the, PRCSG Scientific Director together with other relevant parties (pharmaceutical industry or other relevant Sponsors) determine the leading three Authors and the Co-senior and Senior Authors. Generally, the leading Authors, the Co-Senior Author and Senior Author will be members of the networks who were actively involved in the study design, conduct or analysis. All remaining Authors from the networks will follow as per the number of patients contributed to the study and in alphabetical order.

If a study results in more than one publication, then the PRINTO Senior Scientist and the PRCSG Scientific Director will make every effort to offer Authorship to at least 1 publication for each PRINTO or PRCSG Investigator who enrolled at least 1 patient; Investigators who contributed a high number of patients to a given study can be expected to be listed in multiple publications.

4. The PRINTO Senior Scientist and PRCSG Scientific Director will send on the behalf of the first author of a manuscript requests for revision and disclosures forms to ALL of the co-authors. These documents are regularly shared with Sponsor representatives. This provision and the following apply to ALL manuscripts. A similar, possibly simplified procedure will be followed for abstract submissions, as needed.

PRINTO and PRCSG will be responsible for:

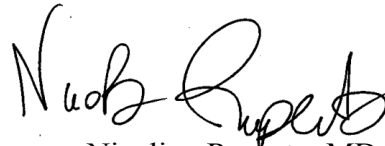
- Preparing the first draft and subsequent draft of the paper/abstract. In this setting Sponsor representatives may be professional medical writing consultants.
- Distributing all versions to authors who are members of the PRINTO/PRCSG networks;

- Collecting and coordinating comments from the PRINTO/PRCSG-member Authors;
 - Submitting the comments from the PRINTO/PRCSG-member Authors via email to the pharmaceutical companies/medical writer/editor;
 - Ensuring that all listed PRINTO/PRCSG-member Authors fulfill requirements for Authorship detailed in Section 1;
 - Collecting and submitting written documentation (i.e. fax, email or written letter) from each individual PRINTO/PRCSG-member Authors regarding approval of the final manuscript.
5. The final decision of the list of Authors that will appear in publication is a shared decision between PRINTO, PRCSG and the pharmaceutical Sponsor.
 6. After approval of the final version of the manuscript has been obtained from all Authors, it is the responsibility of the first Author (or alternatively the PRINTO/PRCSG international coordinating centers) to submit or resubmit to the manuscript for peer-review to the selected target journal.
 7. In each manuscript, all site Investigators not listed as a named Author will be listed in the Acknowledgments section or, alternatively if allowed by the journal, as authors list group on the cover page of the manuscript.
 8. Each manuscript will report after the byline of Authors “for the Paediatric Rheumatology International Trials Organization (PRINTO) and the Pediatric Rheumatology Collaborative Study Group (PRCSG)” if the lead author is from PRINTO and if the lead author is from PRCSG then “for the Pediatric Rheumatology Collaborative Study Group (PRCSG) and the Paediatric Rheumatology International Trials Organization (PRINTO)”.
 9. The protocol should mention that publication will follow the ICMJE and PRINTO/PRCSG policy.

October 22nd, 2013



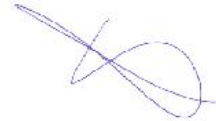
Alberto Martini, MD
PRINTO Chairman



Nicolino Ruperto, MD, MPH
PRINTO Senior Scientist



Daniel Lovell, MD, MPH
PRCSG Chairman



Hermine Brunner, MD MSc MBA
PRCSG Scientific Director