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

The following document aims at describing the policy of the F-PRINTO and PRCSG networks concerning authorship and publication of manuscripts and abstracts arising from collaborative multicenter research. This policy is published on the networks of the Fondazione Paediatric Rheumatology International Trials Organization (F-PRINTO) 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)[1].

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. "***[2]

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 PRCSG/F-PRINTO Authorship and Manuscript Publication Policy for authorship necessitates active (as opposed to passive) participation in all three critical conditions 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 PRCSG/F-PRINTO 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.prcsg.org).

## PRCSG-F-PRINTO AUTHORSHIP AND PUBLICATION POLICY SPECIFICS

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

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 F-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".

[1] ICMJE | Recommendations | Defining the Role of Authors and Contributors
[2] Verbatim from ICMJE statement

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 PRCSG Scientific Director and the F-PRINTO Senior Scientist, in collaboration with other relevant parties (pharmaceutical industry or other relevant Sponsors) are responsible for selecting the eligible authors based on the number of enrolled patients **AND** the requirements listed under Section 1.

**3.** The F-PRINTO and the PRCSG Scientific Directors, in collaboration with other relevant parties (pharmaceutical industry or other relevant Sponsors) will 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 PRCSG Scientific Director and the F-PRINTO Senior Scientist 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.** PRCSG Scientific Directors and the F-PRINTO (or their representatives) will be the principal points of contact for their respective memberships, e.g. managing, on behalf of the first author of a manuscript, requests for review of manuscript drafts or revisions, disclosures forms and requests for final approval to ALL of the co-authors that are part of the Networks. These documents are regularly shared with Sponsor representatives. This requirement and the following apply to **ALL** manuscripts resulting from a study program. A similar, possibly simplified, procedure will be followed for abstract submissions, as needed. Agreements will be reached with the sponsor for all practical aspects such es electronic submission systems.

***PRCSG & F-PRINTO will be responsible for:***

- Preparing the first draft and subsequent draft of the paper/abstract, in collaboration with the Sponsor or Sponsor representatives such as professional medical writing consultants.
- Distributing all manuscript versions to authors who are members of the F-PRINTO/PRCSG networks;
- Collecting and coordinating comments from authors who are members of the F-PRINTO/PRCSG networks;
- Submitting the comments from the F-PRINTO/PRCSG-member Authors via email to the pharmaceutical companies/medical writing consultants/editor;
- Ensuring that all listed F-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 F-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 F-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, if desired by the first Author, the PRCCG/F-PRINTO 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 Fondazione Paediatric Rheumatology International Trials Organization (F-PRINTO) and the Pediatric Rheumatology Collaborative Study Group (PRCSG)" if the lead author is from F-PRINTO and if the lead author is from PRCSG then "for the Pediatric Rheumatology Collaborative Study Group (PRCSG) and the Fondazione Paediatric Rheumatology International Trials Organization (F-PRINTO)".
9. The protocol should mention that publication will follow the ICMJE and F-PRINTO/PRCSG policy.

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Prof. Nicolino Ruperto, MD MPH
F-PRINTO Scientific Director

Prof. Hermine Brunner, MD MSc MBA
PRCSG Chair & PRCSG Scientific Director

Alberto Martini, MD, MPH
Prof. F-PRINTO President

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