

PEDIATRIC **R**HEUMATOLOGY

INTERNATIONAL **T**RIALS

ORGANISATION

(PRINTO)

BYLAWS

TABLE OF CONTENTS

- **ARTICLE I** (Purpose)..... pag. 2
- **ARTICLE II** (Membership)..... pag. 2
- **ARTICLE III** (Governing body - The Advisory Council) pag. 2
- **ARTICLE IV** (Organisation)..... pag. 3
- **ARTICLE V** (Activation of the PRINTO membership for purpose
of conducting a study) pag. 4
- **ARTICLE VI** (Authorship of journal articles and other publications
using PRINTO generated data) pag. 4
- **ARTICLE VII** (Liaison to other organisation and groups) pag. 5
- **ARTICLE VIII** (Disciplinary actions) pag. 5
- **ARTICLE IX** (Amendments) pag. 5
- **ARTICLE X** (Transition rules)..... pag. 6
- **ARTICLE XI** (List of founders) pag. 6
- **PRINTO ORGANISATION CHART** pag. 7

**BYLAWS OF THE
PEDIATRIC RHEUMATOLOGY
INTERNATIONAL TRIALS ORGANIZATION
Genova, October 1, 2003**

ARTICLE I

PURPOSE

The purpose of the Paediatric Rheumatology International Trials Organisation (PRINTO) is to foster, facilitate, and conduct high quality research in the field of paediatric rheumatology.

ARTICLE II

MEMBERSHIP

Centres: The PRINTO is composed of clinical centres that actively engage in the diagnosis and management of children with rheumatic diseases. New centres who wish to become members apply by letter to *the Chairman* of the PRINTO group. If approved by majority vote of the *Advisory Council* (4/6), the applicant centre is considered probationary until successful performance is evidenced in at least one PRINTO study. Following this, the centre is considered to be in good standing.

Physicians: Each centre must have a designated *Centre Director* who is a physician with documented experience in paediatric rheumatology. Centres also may have additional paediatric rheumatologists who participate actively in PRINTO studies, with the approval and supervision of the *Centre Director*.

ARTICLE III

GOVERNING BODY- THE ADVISORY COUNCIL

Functions: The governing body of the PRINTO is the *Advisory Council* (AC). The chief functions of the AC are to provide leadership and guidance for the PRINTO in the following areas: identification and facilitation of research areas most likely to be successful and clinically or scientifically useful; seeking of funded support for the groups research efforts; management and quality assurance of the PRINTO's membership, its scientific studies, statistical analyses, databases generation, and publications.

Authority: The AC has the authority to: decide membership of the PRINTO, approve grant proposals and study protocols which call for the utilisation of the PRINTO's patient resources, approve the use of PRINTO databases by members of the group and non-members who have use for such data and discipline PRINTO members. The AC also has authority to appoint sub-committees to study certain issues when the need arises.

Members of the AC: The AC has six voting officers. Five *Counsellors* (one of whom act as *Chairman*), and the *Senior Scientist*. All the voting officers must be paediatric rheumatologists and, except for the position of *the Senior Scientist*, must come from different states.

Election to the AC: The election process will occur prior to July 1 of the terms in office, with the newly elected (or re-elected) member's term commencing the following January 1. The officers of the AC are elected in the following manner:

1. *Counsellors*: solicited and elected by majority vote by the National Co-ordinating Centres (one country one vote).
2. *Senior Scientist*: appointed by the Counsellors.
3. *Chairman*: the AC will elect by majority vote (4/6) one of the five *Counsellors* to the position of Chairman.

Terms in Office: The officers of the AC have the following terms in office (beginning January 1 after election). For the seek of continuity there should not be a complete change of the AC at any point in time.

1. *Counsellors*: five years.
2. *Senior Scientist*: appointed for a 10 years term to ensure continuity in the activity of the group;
3. *Chairman*: five years

(Article III amended on October 1st, 2003 by the AC)

Meetings of the AC: The AC will have at least one meeting per year, and may have more if the AC decides that the extra meetings are necessary. Minutes of each meeting will be kept by *the Senior Scientist* and distributed to the general membership following approval by the AC.

ARTICLE IV

ORGANISATION

International Co-ordinating Centre (ICC): The ICC has the function to: facilitate the logistic and scientific details necessary to design, launch and manage a multi-centred, multi-national, collaborative clinical trial. The ICC could assist the Principal Investigator (PI) in the design of the protocol, statistical analysis and generation of the final report and of the manuscript. Access to the electronic database: each member has direct access to the data of his own centre, and NCC can have direct access to the data of his own country. The complete database will be provided to members and non-members after proper request by letter to the Chairman, and approval by the AC.

National Co-ordinating Centres (NCC): The function of each NCC is to: facilitate the participation of the greatest number of individual PRINTO members, disseminate the information about on-going trials in the local national setting, provide the translation of all the forms to be completed by the parents/patients, or the physician if not familiar with the English language (official language used by the PRINTO group).

ARTICLE V

ACTIVATION OF THE PRINTO MEMBERSHIP FOR PURPOSES OF CONDUCTING A STUDY

Any member of the PRINTO in good standing may submit a protocol to the AC for approval. Protocols may be submitted in either one of two forms: a complete protocol, or an idea protocol.

Complete Protocol. If a member of the PRINTO has written a complete protocol for the conduction of a study (either clinical or basic science studies), and needs assistance in recruiting patients or could benefit from the other resources of the PRINTO such as computational assistance, the protocol is submitted to the *Chairman* for approval to the AC. If approved, the investigator submitting the protocol will serve as PI for that study. The AC can decide to assist the PI in obtaining funding for the study if not already secured.

Idea Protocol. If a member of the group has an idea for a study, but lacks the time or expertise to develop a full protocol, an idea protocol can be submitted by the member to the *Chairman* for approval to the AC. If approved, the Chairman and the *Senior Scientist* and other appropriate resources within the group will assist the member in the development of the full protocol. In this case, the AC will designate one person to serve as PI and the member who proposed the idea as co-PI.

ARTICLE VI

AUTHORSHIP OF JOURNAL ARTICLES AND OTHER PUBLICATIONS USING PRINTO GENERATED DATA

Primary Results of a PRINTO Study: In most cases, the lead authorship of a journal article that reports the primary results of a PRINTO study will be the PI of that study. Additionally, several other individuals who played key roles in the study's development, conduction, or analysis may be included as co-authors. Following the named authors, the statement "for the Paediatric Rheumatology International Trials Organisation" will be included. The cover page of the paper will list the names of all members of the PRINTO who participated actively in the study being reported.

The AC will determine prior to beginning a study a minimum number of patients that must be enrolled in each centre. If the minimum number of qualified patients is enrolled at one centre, then a single investigator will be included from that centre as an author on the subsequent publication reporting the primary results of the study. A centre that enrolls patients, but does not meet the minimum number as set forth by the AC, will be recognised in the cover page of the paper.

Secondary Results of a PRINTO Study: Articles reporting results of studies that use data from any PRINTO database will have as the lead author the person most responsible for the design, analysis and reporting of the results. This person may or may not have been the PI of the original study. Other authors will be included as deemed appropriate by the lead author. Following the named Authors the statement "for the Paediatric Rheumatology International Trials Organisation" should be included.

ARTICLE VII

LIAISON TO OTHER ORGANISATIONS AND GROUPS.

The AC can appoint official liaisons to other groups as deemed appropriate.

ARTICLE VIII

DISCIPLINARY ACTIONS

The AC has the authority to discipline PRINTO members whose conduct during a study has compromised the study's results or successful completion, or endangered a patients well-being.

International and national co-ordinating centres: The ICC and the NCCs may have their role revoked and be placed on probation by majority vote (4/6) of the AC. Adequate causes for a change in status of the ICC or the NCCs include inadequate performance during a study such that the integrity or success of the study is threatened. Good status may be reinstated following correction of the deficiency and majority vote (4/6) of the AC.

Individual centres: Individual centres may have their good standing status revoked and be placed on probation by majority vote (4/6) of the AC. Sufficient causes for a change in status of a centre include the departure of the Centre Director without replacement by a paediatric rheumatologist, or other changes that would compromise the centre's ability to carry on high quality clinical research. Good status rating may be reinstated following correction of the deficiency and majority vote of the AC (4/6).

Individual physicians. Individual physicians may be placed on probation by majority vote (4/6) of the AC. Adequate reason for placing a physician on probation include inadequate performance during a study such that the integrity or success of the study is threatened. A physician on probation may reapply for full membership if desired.

Officer of the AC: Any officer of the AC may be removed from office or AC membership by majority vote (4/6) of the AC.

ARTICLE IX **AMENDMENTS**

These bylaws may be amended by a majority vote (4/6) of the AC according to the suggestion of the NCCs.

ARTICLE X
TRANSITION RULES

For the first three years of existence (starting on January 1, 1998) of the PRINTO, the Officers will be the Founders of the Organisation:

ARTICLE XI
LIST OF FOUNDERS

ADVISORY COUNCIL

Chairman:

<i>Alberto Martini, MD</i>	Genova	Italy
----------------------------	--------	-------

Counsellors

<i>Boel Andersson Gäre, MD, PhD</i>	Jönköping	Sweden
<i>Wietse Kuis, MD</i>	Utrecht	The Netherlands
<i>Anne Marie Prieur, MD</i>	Paris	France
<i>Patricia Woo, MD</i>	London	United Kingdom

Senior Scientist

<i>Nicolino Ruperto, MD, MPH</i>	Genova	Italy
----------------------------------	--------	-------

NATIONAL CO-ORDINATING CENTRE DIRECTORS

<i>Boel Andersson Gäre, MD, PhD</i>	Jönköping	Sweden
<i>Zsolt Balogh, MD</i>	Budapest	Hungary
<i>Jaime De Inocencio, MD</i>	Madrid	Spain
<i>Øystein Førre, MD</i>	Oslo	Norway
<i>Hans-Iko Huppertz, MD</i>	Wüerzburg	Germany
<i>Wietse Kuis, MD</i>	Utrecht	The Netherlands
<i>Alberto Martini, MD</i>	Genova	Italy
<i>Jose' A. Melo-Gomes, MD</i>	Lisboa	Portugal
<i>Freddy Karup Pedersen, MD</i>	Copenhagen	Denmark
<i>Pirkko Pelkonen, MD</i>	Helsinki	Finland
<i>Anne Marie Prieur, MD</i>	Paris	France
<i>Alexander Shaikov, MD</i>	Moscow	Russia
<i>Eric Veys, MD</i>	Gent	Belgium
<i>Patricia Woo, MD</i>	London	United Kingdom

Liaison with the Paediatric Rheumatology Collaborative Study Group (PRCSG) in North America

The AC of the PRINTO will request that the AC of the PRCSG elect one of their members to act as non-voting observer. Additionally, the PRINTO will request that one of our members act in a similar capacity to the PRCSG.

Italy, June 15, 1997

PRINTO ORGANISATION CHART

ADVISORY COUNCIL

Voting Officers:

Chairman:

Alberto Martini, MD, Genova, Italy

Centre Directors:

Boel Andersson Gäre, MD, PhD Jönköping, Sweden

Wietse Kuis, MD, Utrecht, The Netherlands

Anne Marie Prieur, MD, Paris, France

Patricia Woo, MD, London, United Kingdom

Senior Scientist

Nicolino Ruperto, MD, MPH Genova, Italy

One Observer from the PRCSG



INTERNATIONAL COORDINATING CENTRE

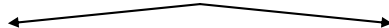
International Trials Co-ordinator

Nicolino Ruperto, MD, MPH Genova, Italy



NATIONAL COORDINATING CENTRE

Centre Director



INDIVIDUAL CENTRE

Centre Director

INDIVIDUAL CENTRE

Centre Director

NATIONAL COORDINATING CENTRE

Centre Director



INDIVIDUAL CENTRE

Centre Director

INDIVIDUAL CENTRE

Centre Director

