Pædiatric **R**heumatology **I**nter**N**ational
Trials **O**rganisation

BYLAWS OF THE

PEDIATRIC RHEUMATOLOGY

INTERNATIONAL TRIALS

ORGANIZATION

(PRINTO)

TABLE OF CONTENTS

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 via the PRINTO website to *the Chairman* of the PRINTO group. 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 or health professionals (co-workers) who participate actively in PRINTO studies, with the approval and supervision of the *Centre Director*.

ARTICLE III

THE ADVISORY COUNCIL

Chairman and Senior Scientist: As founder of PRINTO and to ensure continuity in the activities, Prof. Alberto Martini, MD and Dr Nicolino Ruperto, MD, MPH are respectively the Chairman and the Senior Scientist of PRINTO.

Functions: The scientific body of the PRINTO is the *Advisory Council* (AC). The chief functions of the AC are to provide scientific 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 its scientific studies, statistical analyses, databases generation, and publications.

Members of the AC: The AC has eight voting officers: the Chairman, the Senior Scientist and six elected *Counsellors*. All the voting officers must be paediatric rheumatologists.

Election to the AC: The election process for six *Counsellors* will occur every 5 years, with the newly elected (or re-elected) member's term commencing the following January 1. The six *Counsellors* of the AC are proposed by the previous AC and/or solicited and elected by majority vote by the National Co-ordinating Centres (one country one vote).

Terms in Office: The six *Counsellors* of the AC are elected for a five years term.

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). The NCCs, with proven active role in collaborative PRINTO studies, are chosen within the border of each countries by the centres belonging to PRINTO. Every 5 years the previous NCC should obtain confirmation of his/her position by the PRINTO members of the country.

ARTICLE V

STUDY ACTIVATION

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

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 or the contributor's list of the paper, will list the names of all members of the PRINTO who participated actively in the study being reported.

The PRINTO Senior Scientist 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 enrols patients, but does not meet the minimum number as set forth by the Senior Scientist, will be recognised in the cover page of the paper. Centres not listed in the primary publications will be listed in secondary publications that might arise from the same project.

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 PRINTO Senior Scientist. Following the named Authors the statement "for the Paediatric Rheumatology International Trials Organisation" should be included.

ARTICLE VII

LIAISON TO OTHER ORGANISATIONS.

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

ARTICLE VIII
AMENDMENTS

These bylaws may be amended by a majority vote (5/8) of the AC.
The current version of the bylaws have been amended by the AC on November 2011**.**

ARTICLE IX
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 X
LIST OF FOUNDERS

ADVISORY COUNCIL

Chairman:

Alberto Martini, MD	Genova	Italy

Counsellors

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

NATIONAL CO-ORDINATING CENTRE DIRECTORS

Boel Andersson Gäre, MD, PhD	Jönköping	Sweden
Zsolt Balogh, MD	Budapest	Hungary
Jaime De Inocencio, MD	Madrid	Spain
Øystein Førre, MD	Oslo	Norway
Hans-Iko Huppertz, MD	Wüerzburg	Germany
Wietse Kuis, MD	Utrecht	The Netherlands
Alberto Martini, MD	Genova	Italy
Josè A. Melo-Gomes, MD	Lisboa	Portugal
Freddy Karup Pedersen, MD	Copenhagen	Denmark
Pirkko Pelkonen, MD	Helsinki	Finland
Anne Marie Prieur, MD	Paris	France
Alexander Shaikov, MD	Moscow	Russia
Eric Veys, MD	Gent	Belgium
Patricia Woo, MD	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
Last revision Italy, November 21, 2011

ORGANISATIONAL CHART