Fondazione PRINTO Bylaws

ARTICLE I

PURPOSE

The purpose of Fondazione Paediatric Rheumatology INternational Trials Organisation ETS (hereinafter referred to as "Fondazione PRINTO") is to foster, facilitate, and conduct high quality research in the field of paediatric rheumatology.

ARTICLE II

MEMBERSHIP

For Centres

Fondazione 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 need to apply via Fondazione PRINTO website to the Chairman of Fondazione PRINTO. The applicant centre is considered probationary until successful performance is evidenced in at least one Fondazione PRINTO study. Following this, the centre is considered to be in good standing.

For 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 Fondazione PRINTO studies, with the approval and supervision of the Centre Director.

ARTICLE III

THE ADVISORY COUNCIL

President, Vice-President and Scientific Director

As founder of Fondazione PRINTO and to ensure continuity in the activities, Prof. Alberto Martini, MD and Prof. Nicolino Ruperto, MD, MPH are respectively the President and the Vice-President and Scientific Director of Fondazione PRINTO.

The scientific body of Fondazione PRINTO is the Advisory Council (AC). The chief functions of the AC are to provide scientific guidance for Fondazione 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 President, the Vice-President/Scientific Director and six elected Counsellors. All the voting officers must be paediatric rheumatologists.

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).

The six Counsellors of the AC are elected for a five-year 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 their own centre, and NCC can have direct access to the data of their 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 Fondazione PRINTO members, disseminate the information about ongoing 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 Fondazione PRINTO group). The NCCs, with proven active role in collaborative Fondazione PRINTO studies, are chosen within the border of each countries by the centres belonging to Fondazione PRINTO. Every 5 years the previous NCC should obtain confirmation of their position by Fondazione PRINTO members of the country.

ARTICLE V

STUDY ACTIVATION

Any member of Fondazione 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 Fondazione 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 Fondazione 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 Fondazione PRINTO Study

In most cases, the lead authorship of a journal article that reports the primary results of a Fondazione 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 Fondazione PRINTO who participated actively in the study being reported.

The Fondazione 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 Fondazione PRINTO Study

Articles reporting results of studies that use data from any Fondazione 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 Fondazione 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 June 2025.

ARTICLE X

LIST OF FOUNDERS

ADVISORY COUNCIL

President:
Alberto Martini, MD

Scientific Director and Vice- President:

Nicolino Ruperto, MD, MPH

NATIONAL CO-ORDINATING CENTRE DIRECTORS

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

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

Italy, June 15, 1997

Last revision Italy, June, 2025