ARTICLE I - MISSION

The mission of the Pediatric Rheumatology Collaborative Study Group (PRCSG) is to foster, facilitate, and conduct high quality clinical research in the field of pediatric rheumatology.

ARTICLE II - COMPOSITION OF THE PRCSG AND MEMBERSHIP QUALIFICATIONS

Section A. Composition of the PRCSG

The PRCSG is composed of pediatric rheumatologists located in academic and Clinical Centers who actively engage in the diagnosis and management of children with rheumatic and related musculoskeletal diseases. The PRCSG is governed by the Advisory Council (AC) to the PRCSG, whose composition and authorities are described in Article III. A centralized Coordinating Center facilitates and manages all administrative, financial, regulatory and scientific matters related to the PRCSG.

Section B. Membership Qualifications for Physicians and Clinical Centers

Paragraph 1: To be eligible for membership in the PRCSG, a physician must fulfill the following criteria:

1. Adequate training and qualification in the field of pediatric rheumatology; this can be documented by one the following:

1.1 Board-certification in pediatric rheumatology

1.2. If an applicant has completed an approved pediatric rheumatology fellowship program satisfactorily so that board-certification requirements are fulfilled but is not yet board-certified in pediatric rheumatology, then membership can be granted for up to 4 years
with the expectation that proof of board-certification in pediatric rheumatology is provided by the end of the 4-year period.

1.3 Individuals who trained in pediatric rheumatology outside North America and who wish to become members must meet all of the following requirements:

1.3.1 Completion of at least two years of fellowship training in pediatric rheumatology;

1.3.2 A letter of recommendation from the training program director (or equivalent) attesting to the applicant’s training program consisted of at least 50% of time in pediatric rheumatology

1.3.3 Meaningful accomplishment in research as documented by one of the following: first or co-author of a published research paper in a peer-reviewed journal; first or co-author of a research paper that is under peer-review; a Master's or PhD degree in a field of science or medicine; a thesis accepted as partial fulfillment of the requirements for a postgraduate degree in a field relevant to medical research; submission of a research grant proposal that has been approved by an extramural organization with a critical review process

2. Active proof of Human Subject Protection (HSP) and Good Clinical Practice (GCP) Training in accordance with the E6 Guideline of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) at the time of membership application.

3. Active involvement in clinical practice or clinical research that has an element related to pediatric rheumatology.

Paragraph 2: To be considered a PRCSG Clinical Center, a Center must have at least one physician who is a PRCSG member. In some instances and at the discretion of the PRCSG member, physicians in locations outside of the primary center can participate in studies done by the Clinical Center

Section C. Application and Election of Physicians to the PRCSG

Paragraph 1: Any physician who meets the eligibility requirements described in Article II, Section B may apply for membership by contacting the Coordinating Center of the PRCSG. Application is made by submission to the Coordinating Center of the following in paper form or electronically

1. Current curriculum vitae
2. Written statement; this written statement must include the reasons for wanting to become a member.
3. A description of the unit and hospital in which the applicant is primarily located, resources available for conducting clinical research, and the overall size and description of the pediatric rheumatology patient population served. Applicants who are located at an existing PRCSG Clinical Center may omit the description of the center.
4. Proof of GCP and HSP Training
Paragraph 2: Applicants are elected to membership by majority vote of the Advisory Council members during the next regulatory scheduled AC meeting.

ARTICLE III - GOVERNING BODY - THE PRCSG ADVISORY COUNCIL

Section A. Functions
The governing body of the PRCSG is the Advisory Council (AC). The chief functions of the AC are to provide leadership and guidance for the PRCSG in the following areas:
1. Identification and facilitation of research areas most likely to be successful and clinically useful
2. Seeking of funded support for the group’s research efforts
3. Management and quality assurance of the PRCSG’s membership, its scientific studies, statistical analyses, databases generated, and publications
4. Strive to increase the understanding and conduct of clinical research of its membership through the provision of appropriate educational opportunities, training, and mentorship.

Section B. Authority
The AC has the following authorities:
1. Decide on applications for PRCSG membership.
2. Approve grant proposals and study protocols that call for the utilization of the PRCSG’s patient or other resources.
3. Discipline PRCSG members whose conduct during a study has seriously compromised the study’s results, validity, or successful completion.
4. Approve the use of PRCSG databases by members of the group and non-members who have use for such data.
5. Appoint sub-committees to study certain issues when the need arises.

Section C. Membership on the AC, Election to the AC, and Terms in Office
Paragraph 1 – Membership of the AC: Besides the PRCSG Officers, the AC consists of several Voting Members and Non-Voting Members.
1. PRCSG Officers. There are regularly two PRCSG Officers who have Voting rights on the AC:
   1.1 The Chairperson, who must be a pediatric rheumatologist, and
   1.2 A Scientific Director, who also serves as Secretary.
1.3 The AC may have additional voting Ex-Officio Officers:
   1.3.1 The Immediate Past-Chairperson and Immediate Past-Scientific Director who are Non-Voting Members (Section C 4. below).
   1.3.2 A Chairperson-Elect and Scientific Director-Elect who are Non-Voting Members.
2. **Clinical Investigators.** Besides the PRCSG Officers, the AC is composed of a minimum of four PRCSG Clinical Investigators with Voting Rights; one of these Clinical Investigators should be a Junior Clinical Investigator.

2.1 The Junior Clinical Investigator must be board-certified in Pediatric Rheumatology and also have completed pediatric rheumatology training within 5 years at the time of election to the AC.

3. **Representatives of Organizations with relevance to the Mission of the PRCSG.** Other organizations may be invited by majority vote of the AC to nominate a person from their membership to serve on the AC. Unanimous approval by the sitting AC is required to elect these individuals from other organizations. Voting rights for individuals who represent such organizations is decided by unanimous vote of the AC. These organizations may include, but are not limited to the following.

- Association of Rheumatology Health Professionals,
- FDA
- NIH
- National Office of the Arthritis Foundation
- Childhood Arthritis and Rheumatology Research Alliance
- American College of Rheumatology

4. **Ad-hoc Members.** Other consultants or advisors may be invited to attend meetings of the AC as Non-Voting Members.

**Paragraph 2 - Election to the AC:** This process consists of nomination, confirmation of the interest of the nominee, the actually election process and announcement of the elected AC Member.

1. Generally, nominations will be solicited from the general membership of the PRCSG. A nomination must be supported in writing by at least two PRCSG members, one of which can be the nominee him/herself. Exceptions to this process are described in **Paragraph 2; point 5.**

2. Nominees will be contacted by the Scientific Director and, if interested, will be asked to submit a current curriculum vitae and a written statement describing the reasons for their interest in serving within a pre-specified time frame.

3. Among the nominees with completed application materials the general membership will then elect, by majority vote, the specific AC Membership position under consideration. AC positions that can be considered are:

- Chairperson-Elect
- Scientific Director Elect
- Clinical Investigators and Junior Clinical Investigator:

4. The election of a new Chairperson and new Scientific Director must be separated by a period of at least 3 years.

5. Nominations of Representatives of Organizations with relevance to the Mission of the PRCSG are solicited from the respective Organizations. Election to the AC occurs by unanimous of vote of the sitting AC.
6. In years when elections become necessary, the process will take place before the American College of Rheumatology Annual Meeting in order that the new members may be announced at the meeting.

**Paragraph 3 - Terms in Office:** There are differences in the length of the Term in Office among the AC Members and its PRCSG Officers and the number of terms of service on the AC.

1. Generally, terms in office begin on November 1 of the year in which an AC Member is elected.
2. **Chairperson and Scientific Director:** 4-year terms, with no restriction on the number of terms that may be served.
   2.1 The Chairperson and Scientific Director must receive a “vote-of-confidence” (unanimous vote by other voting members of the AC) every 4 years if they wish to remain in their positions.
   2.2 If the Chairperson and/or Scientific Director receive/s a vote-of-no-confidence, or if the Chairperson or Scientific Director wishes to step down, then an election will be held according to the process described above.
   2.3 If the outgoing Chairperson steps down, he/she may serve as a non-voting member of the AC as the Immediate Past Chairperson for a period not to exceed 4 years.
   2.4 The Chairperson-Elect and the Scientific Director-Elect will serve a 4 year term. At the end of this 4 year period, the Chairperson-Elect must be elected to be the Chairperson by unanimous vote of the AC membership.
   2.5 If the outgoing Scientific Director steps down, he/she may serve as a non-voting member of the AC as the Immediate Past Scientific Director for a period not to exceed 4 years.
   2.6 If the outgoing Chairman steps down, he/she may serve as a non-voting member of the AC as the Immediate Past Chairman for a period not to exceed 4 years.
3. **Representatives of Organizations with relevance to the Mission of the PRCSG** have no term limits. However, every 4 years, the Representatives will be asked to confirm their interest in serving on the AC. Additionally, “vote-of-confidence” (unanimous vote by other voting members of the AC) every 4 years is required to remain in their position.
4. **Clinical Investigator:** The term in office is 4 years, with a single re-election possible to a second 4-year term. The Clinical investigators will be asked to confirm their interest in serving on the AC. Additionally, a “vote-of-confidence” (unanimous vote by other voting members of the AC) is required to remain in their position for a second 4 year term. An exception is the Junior Clinical Investigator who can only serve for 1 term.
5. Individuals serving on the AC are allowed to assume other responsibilities on the AC (details see Paragraph 1), provided they are elected as detailed in Paragraph 2.

**Paragraph 4. Removal from Office or Membership.** Any AC Member, including PRCSG Officers, Clinical Investigators, Representatives of Organizations or Advisor to the AC may be removed from office or AC membership by unanimous vote of the other AC members. Removal occurs immediately after the unanimous vote-of-no-confidence. Replacement of the removed AC members are detailed in Paragraph 2. However, an election will be held immediately to replace the removed member and the term in office of the AC member who replaces the removed individual commences at the time of election.
**Section D. Meetings of the AC:** The AC will have at least one face-to-face meeting every 2 years, and more often if the AC decides that additional meetings are necessary. Minutes of each meeting will be kept by the Officers and distributed to the general membership following approval by the AC.

**ARTICLE IV - ACTIVATION OF THE PRCSG MEMBERSHIP FOR PURPOSES OF CONDUCTING A STUDY**

Both Industry-sponsored and investigator initiated protocols can be supported and conducted by the PRCSG Membership

**Section A Investigator-Initiated Protocols**

1. **Submission of Protocols.** Any member of the PRCSG in good standing may submit a protocol to the AC for approval. Protocols may be submitted in one of two forms; a complete protocol, or an idea protocol. All protocols are considered confidential.

2. **Complete Protocols.** If a member of the PRCSG has written a complete protocol for the conduction of a study, and needs assistance in recruiting patients or could benefit from the other resources of the PRCSG such as computational assistance, the protocol is submitted for approval to the AC. The protocol must be in the format prescribed by the AC (guidelines available from the Scientific Director). If approved, the investigator submitting the protocol will serve as principal investigator for that study. The AC can decide to assist the principal investigator in obtaining funding for the study if not already secured.

3. **Idea Protocols.** If a member of the PRCSG has an idea for a study, but lacks the time or expertise to develop a full protocol, an idea protocol in standard format (guidelines available from the Secretary) can be submitted by the member to the AC for approval. If approved, the Chairman and Scientific Director and other appropriate resources within the group will assist the member in the development of the full protocol. In this case, the principal investigator of the study will be decided upon by the AC after discussions with the member who proposed the idea.

**Section B Industry-Sponsored Protocols**

1. Industry-sponsored protocols require endorsement by majority vote of the PRCSG AC. Generally, a critical review is provided to the Sponsor to ensure that the research supports the mission of the PRCSG as best as possible. This may also involve contacting the PRCSG Membership to assess the feasibility of the proposed research protocol.

2. Individuals organized in the PRCSG are not restricted from participating in Industry-sponsored research studies that are not endorsed by the PRCSG AC.
ARTICLE V - AUTHORSHIP OF JOURNAL ARTICLES AND OTHER PUBLICATIONS USING PRCSG - GENERATED DATA

Section A. Lead Authorship and the Number of Authors on Articles Reporting the Primary Results of a PRCSG Study


2. In addition to the general medical journal editor guidelines, the PRCSG also has the following network publication guidelines.

   2.1 In most cases, the lead authorship of a journal article that reports the primary results of a PRCSG study will be the principal investigator of that study. Additionally, several other individuals who played essential roles in the study's development, performance, or analysis may be included as co-authors. The number of named authors must not exceed a reasonable amount. Following the named authors, the statement "for the Pediatric Rheumatology Collaborative Study Group" will be included.

   2.2 The Appendix section of the paper, which makes mention of the individuals included by name in PubMed, will list the names of all members of the PRCSG who participated actively in the study being reported, but who are not named authors. The decision about requirements for being a named author will be determined by the specific study steering committee in the absence of such a committee the leadership of the PRCSG and other networks involved in the study. The same requirements will be applied across all sites involved in the study. In general the approach will be to identify the minimum number of patients that must be enrolled by each center for a site investigator to be listed as a named author or in the Appendix.

   2.3 If the minimum number of qualified patients is enrolled by a center, then a single investigator will be included from that center as an author on the subsequent publication reporting the primary results of the study. The person to be included as an author will be decided upon by the appropriate individuals at the center.

   2.4 If a center enrolls more than the minimum number of patients, as set forth by the AC, then that center may be eligible to include more than one author on the manuscript (based on the study specific requirements for authorship). Again, the authors to be included from an individual center will be at the discretion of the center personnel.

   2.5 A center that enrolls patients, but does not meet the minimum number set will be recognized only in the Appendix section of the paper.
Section B. Other Publications Using Data Generated by the PRCSG or Using PRCSG Resources. Publications arising from approved data use of PRCSG databases by members of the group and non-members must acknowledge the PRCSG and its investigators in the resulting publications. The same is suggested for non-PRCSG studies that make use of the PRCSG Coordinating Center for the study conduct.

ARTICLE VI - LIAISON TO OTHER ORGANIZATIONS AND GROUPS
At the request of other groups, the AC can appoint official liaisons to other groups, such as the Pediatric Rheumatology International Trials Organization (PRINTO), as deemed appropriate by the PRCSG AC.

ARTICLE VII - AMENDMENTS
These Bylaws may only be amended by unanimous vote of the PRCSG AC.