



# **BYLAWS**

## **OF THE PEDIATRIC RHEUMATOLOGY COLLABORATIVE STUDY GROUP**

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### **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 and other health professionals located in academic and clinical Centers that 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, Nurse Practitioners, Physician Assistants, Research Nurses, Pediatric Rheumatology Researchers; Definition of Clinical Centers**

There are two levels of membership, Full Membership and Associate Membership. Associate Members receive all PRCSG general communications; have access to all parts of the PRCSG website; will be invited to PRCSG general membership meetings; and will be invited to participate in all young investigator training activities performed by the PRCSG. Full Members have all the rights of Associate Members plus will be informed about participation in upcoming studies and serve as site investigators on PRCSG studies. Both Full and Associate Members have full voting rights in elections.

## Full Members

**Paragraph 1:** To be eligible for full 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 by either the American Board of Pediatrics or the Royal College of Physicians and Surgeons of Canada.
  - 1.2 If an applicant has completed an approved pediatric rheumatology fellowship program satisfactorily so that board-certification requirements in either the US or Canada 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 If an applicant is board certified in Internal Medicine and Adult Rheumatology in either the US or Canada and spends at least 50% of their clinic time caring for children with rheumatic diseases in a pediatric department in an academic institution (applicant will be asked to provide a letter of support from a pediatric rheumatologist).
  - 1.4 If an applicant has completed an approved adult rheumatology fellowship program satisfactorily so that board-certification requirements in either the US or Canada are fulfilled but is not yet board-certified in adult rheumatology and spends at least 50% of their clinical time caring for children with rheumatic diseases in a pediatric department in an academic institution, then membership can be granted for up to 4 years with the expectation that proof of board-certification in adult rheumatology is provided by the end of the 4-year period (applicant will be asked to provide a letter of support from a pediatric rheumatologist).
  - 1.5 Individuals who trained in pediatric rheumatology outside North America or who currently practice pediatric rheumatology outside North America and who wish to become members must meet **all** the following requirements:
    - 1.5.1 Completion of at least two years of fellowship training in pediatric rheumatology;
    - 1.5.2 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.
    - 1.5.3 Meaningful accomplishment in research as documented by one of the following: first or co-author of a published original 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 eligible for full membership in the PRCSG, a nurse practitioner or physician assistant must fulfill the following criteria:

1. Completion of required degree program and/or license/certification by the appropriate agency to practice as a nurse practitioner or physician assistant.
2. Adequate training in the field of pediatric rheumatology as documented by at least 2 years of experience in pediatric rheumatology and a letter of support from a PRCSG member physician working in the same location as the nurse practitioners /physician assistants.
3. Work under a standard care arrangement document (or other document as per state laws) with one or more PRCSG physician members in a PRCSG Clinical Center.
4. 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.
5. Active involvement in clinical practice or clinical research that has an element related to pediatric rheumatology documented in a letter of support from a Full PRCSG member.

### **Associate Members**

**Paragraph 3.** To be eligible for associate membership in the PRCSG, Research Nurse must fulfill the following criteria:

1. Adequate experience in the field of pediatric rheumatology as documented by at least 2 years of work in pediatric rheumatology and a letter of support from a PRCSG member physician working in the same location.
2. 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 research that has an element related to pediatric rheumatology documented in a letter of support from a Full PRCSG member.

**Paragraph 4.** To be eligible for associate membership in the PRCSG, a Research Professional must fulfill the following criteria:

1. Research Professionals must have obtained a relevant master's degree or higher in a research related field (e.g. MPH, MSc, DrPH, PharmD, DrPT, DrOT, etc.).
2. 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 research that has an element related to pediatric rheumatology documented in a letter of support from a Full PRCSG member.

**Paragraph 5.** Individuals in North America who are currently in a pediatric rheumatology fellowship can join the PRCSG as an *Associate Members*. At the end of the fellowship, an application for Full membership should be submitted. To be eligible the applicant must fulfill the following criteria:

1. Currently be in a pediatric rheumatology fellowship or be a medicine pediatrics resident in a combined adult and pediatric rheumatology fellowship as documented by a letter of support from fellowship program director.
2. 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.

**Paragraph 6.** Any member of the PRCSG AC or general membership can be removed from membership for disciplinary reasons by a unanimous vote of the AC.

**Paragraph 7.** To be considered a *PRCSG Clinical Center*, a Center must have at least one physician who is a Full PRCSG member. In some instances, and at the discretion of the Full PRCSG member, physicians in locations outside of the primary center can participate in studies done by the Clinical Center.

## **Section C. Application and Election to the PRCSG**

**Paragraph 1:** Any person 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, which must include the reasons for wanting to become a member of the PRCSG.
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
5. Letter of recommendation (if applicable)

**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 participation by the PRCSG's members and their patients or utilization of other resources
3. Discipline PRCSG members whose conduct during a study has seriously compromised the study's results, validity, successful completion or submission of the resulting manuscript to a journal for publication
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 Chair, and
  - 1.2 A Scientific Director, who also serves as Secretary.
  - 1.3 Either the Chair or the Scientific Director must be a board-certified pediatric rheumatologist.
  - 1.4 The AC may have additional non-voting Ex-Officio Officers:
    - 1.4.1 The Immediate Past-Chair and Immediate Past-Scientific Director who are Non-Voting Members (Section C6. below).

1.4.2 A Chair-Elect and Scientific Director-Elect.

2. Clinical Investigators. Besides the PRCSG Officers, the AC is composed of a minimum of five PRCSG Clinical Investigators with Voting Rights; up to two of these Clinical Investigators should be Early Career Investigators. All Clinical Investigators must be Full Members of the PRCSG.

2.1 The Early Career Investigators 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. Pediatric Rheumatology fellow/s. The AC will have up to 2 pediatric rheumatology fellows who are Associate Members of the PRCSG Advisory Council. This will be a one-year term with the potential for reappointment for 1 additional year, as long as the person will still be a fellow at the end of the second year. Fellows will be nominated by a PRCSG Full member and will be elected by majority vote of the AC. This is a non-voting position.
4. There will be at least 1 representative on the AC that represents relevant allied health professionals who is an Associate Member of the PRCSG.
5. 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 Professionals
  - Rheumatology Nurses Society
  - FDA
  - NIH
  - National Office of the Arthritis Foundation
  - Childhood Arthritis and Rheumatology Research Alliance
  - American College of Rheumatology
  - Lupus Foundation of America
6. 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 actual 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 whom 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. Election of Clinical Investigators, Early Career Investigators and the Associate Member. Among the nominees with completed application materials the general membership will then elect these representatives by majority vote.

4. Election of Chair Elect and Scientific Director Elect. Among the nominees with complete application materials the voting members of the AC will then elect these individuals by majority vote.
5. If possible, the election of a new Chair and new Scientific Director should be separated by a period of at least 2 years.
6. Participation of the immediate Past Chair and immediate Past Scientific Director on the AC as non-voting members requires approval by the majority of the AC voting members.
7. 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.
8. Election of fellow representatives to the AC requires approval by the majority of the AC voting members.
9. 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. Chair and Scientific Director: 4-year terms, with no restriction on the number of terms that may be served.
  - 2.1 The Chair 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 Chair and/or Scientific Director receive/s a vote-of-no-confidence, or if the Chair or Scientific Director wishes to step down, then an election will be held according to the process described above.
  - 2.3 If the outgoing Chair or Scientific Director step down, he/she may serve as a non-voting member of the AC as the Immediate Past Chair or Immediate Past Scientific Director for a period not to exceed 4 years.
  - 2.4 The Chair-Elect and the Scientific Director-Elect will serve a maximum of 2 terms of 2 years per term. At the end of this 2 or 4-year period, the Chair-Elect or Scientific Director-Elect must be elected by unanimous vote of the AC membership.
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 for a second 4-year term. 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. Exceptions are the Early Career Investigator who can serve only 1 term and the Fellow member who can serve up to two years.

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, Representatives of Organizations or Advisors 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 is detailed in Paragraph 2. However, an election will be held immediately to replace the removed AC member; 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 should have at least one face-to-face meeting approximately every 2 years and more often if the AC decides that additional face-to-face 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 Chair 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.
4. PRCSG members are not restricted from participating in investigator-initiated research studies that are not endorsed by the PRCSG AC.



## **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. PRCSG members 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.** The authorship policy of all PRCSG articles will be consistent with the requirements of the International Committee of Medical Journal Editors. All publication practices are in compliance with the PRCSG Publication Policy (separate document).

## **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.