

RESEARCH COLLABORATION AGREEMENT

This Research Collaboration Agreement (the "Agreement") between Cincinnati Children's Hospital Medical Center, located at 3333 Burnet Ave, Cincinnati, OH, 45229 ("CCHMC") and Istituto G. Gaslini (IGG), Università di Genova, Pediatria II, Reumatologia EULAR Centre of Excellence in Rheumatology 2008-2013 Largo Gaslini, 5 16147 Genova Italy ("IGG") is entered into this 31st day of January, 2011.

WHEREAS, CCHMC is the project Coordinating Center responsible for planning, supporting, and implementing the Pediatric Rheumatology Collaborative Study Group ("PRSCG"); and

WHEREAS, IGG is the project Coordinating Center responsible for planning, supporting, and implementing the Pediatric Rheumatology International Trials Organisation ("PRINTO"); and

WHEREAS, the primary mission of the PRSCG and PRINTO networks (collectively, the "Networks") is to perform high-quality clinical research aimed at improving the quality of life and overall outcome of children with rheumatic diseases primarily done through the design and conduct of clinical trials developed collaboratively by both Networks; and

WHEREAS, the Networks interact with pharmaceutical companies in the pursuance of the above mentioned goals, and also support investigator-initiated clinical research; and

WHEREAS, The Parties would like to formalize their relationship and interactions and their roles and responsibilities as they relate to the Networks;

NOW, THEREFORE, in consideration of the mutual promises and covenants herein contained, the parties agree as follows:

1. PRINTO and the PRCSG will be mutually supportive and facilitate each other's research.
2. The PRCSG will focus on childhood rheumatic disease research conduction in the United States (U.S.), associated U.S. territories and Canada; PRINTO will focus on childhood rheumatic disease research conduction in all other countries and continents.
3. Both PRINTO and PRCSG will work together to maximize the impact of childhood rheumatic disease research.
4. The PRCSG and PRINTO will support each other's interests in interactions with organizations and sponsors.
5. PRINTO and the PRCSG will collaborate in the development of globally accepted disease status, measures of outcome and response criteria for childhood rheumatic diseases.
6. The PRCSG and PRINTO will synergize their efforts in the training and certification of childhood rheumatology health-professionals for the purpose of clinical research.

This includes but is not limited to joint assessor certification and good clinical practice.

7. Pre-study negotiations with sponsors and officers of the PRCSG/PRINTO will include discussions of the future use of data generated from the studies by members and non-members of the Networks. In all cases, publications resulting from subsequent analyses of PRCSG/PRINTO generated data will state that the authors' utilized data derived from the efforts of the Networks. Anyone seeking the endorsement of PRCSG and/or PRINTO for subsequent analyses of data, must submit a written description of the proposed study prior to initiation of the analyses for their study and also a copy of the manuscript describing the results of the analyses at the end of the study to the Directors of the PRCSG and the PRINTO. The study proposal and manuscript will be reviewed by the PRCSG Advisory Council and PRINTO Advisory Council and each committee will decide independently to endorse or not endorse. For the purposes of collaborative studies with pharmaceutical companies it will be the responsibility of the PRINTO and PRCSG coordinating centres to select the final of co-authors and to maintain relationship with their respective members for paper drafting and submission; this list will then be discussed with the sponsor.
8. PRINTO and PRCSG will collaborate with data management of international studies. This includes, but is not limited to development and maintenance of study databases and data security such as data disaster recovery plans.
9. PRCSG and PRINTO will co-develop and are co-owners of software used for the conduct of pediatric rheumatology.
10. The Parties will perform all obligations under this Agreement in compliance with applicable laws and regulations, including but not limited to, applicable laws and government regulations relating to privacy, professional confidentiality and security. Each Party will be responsible for compliance with applicable laws and regulations related to their Networks' third party collaborations.
11. Parties agree that they will not use, make reference to, or otherwise designate the other party's trademarks, service marks, or trade names without the express written consent of the owning party, which shall not be unreasonably withheld.
12. Each party (as a "Receiving Party") shall keep confidential all aspects of this agreement, and shall not appropriate for its own use, reveal, or disclose to anyone, except as necessary to fulfill a party's obligations hereunder, any confidential information of the other (as a "Disclosing Party") which may become known to it prior to or during the term of this Agreement. Each party agrees to take necessary and prudent steps to protect and maintain the confidentiality of any such confidential or proprietary information of the other. "Confidential or proprietary information" shall mean any information maintained as confidential by the other which is not publicly known and not lawfully available without restriction from a third party. The foregoing restrictions will not apply to any such Confidential Information that is (i) required to be disclosed by the court order or decree or in compliance with applicable law, (ii) in the public domain or enters the public domain other than through a breach hereof by the Receiving Party, (iii) known to the Receiving party prior to its receipt from the Disclosing Party hereunder and not subject to a confidentiality obligation, (iv) independently developed by the Receiving Party, or (v) received by the Receiving Party from a third party and not subject to a confidentiality obligation.

13. The sole relationship between the parties shall be that of independent contractor. Nothing contained in this Agreement, nor any action taken by any party to this Agreement, shall be deemed to constitute either party (or any of such party's employees, agents, or representatives) an employee, agent, or legal representative of the other party, nor to create any partnership, joint venture, association, or syndicate among or between the parties, nor to confer on either party any express or implied right, power or authority to enter into any agreement or commitment on behalf or (nor to impose any obligation upon) the other party.
14. This Agreement is effective on the effective date and will continue until terminated by either party for any reason by providing written notice to the other party. The termination shall be effective thirty (30) days after notice of termination is provided to the other party.
15. This Agreement represents the entire agreement and understanding between the parties with respect to the subject matter hereof, and may not be amended except by the written agreement of both parties. Exceptions to and modifications of this agreement may be made when and if deemed appropriate by the elected officials of the two organizations.

IN WITNESS WHEREOF, the parties set their hands to this Agreement as of the day and year written below.

**Cincinnati Children's Hospital
Medical Center**

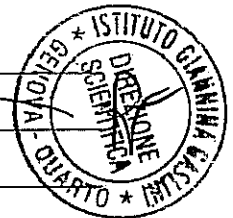
Istituto G. Gaslini

For Institution:

By: [Signature]
Name: John Maybury
Title: Vice President, CHRF
Date: 8/16/11

By: [Signature]
Name: Prof. Vincenzo Lorenzelli
Title: Presidente
Date: _____

By: [Signature]
Name: Prof. Lorenzo Moretta
Title: Direttore Scientifico
Date: _____



FOR PRCSG:

By: [Signature]
Name: Daniel J. Lovell, MD, MPH
Title: Chairman, PRCSG
Date: Aug. 15, 2011

FOR PRINTO

By: [Signature]
Name: Prof. Alberto Martini, MD
Title: Chairman, PRINTO
Date: 01/08/2011

By: [Signature]
Name: Hermine Brunner, MD, MSc
Title: Scientific Director, PRCSG
Date: Aug 15, 2011

By: [Signature]
Name: Dr Nicolino Ruperto, MD, MPH
Title: PRINTO Senior Scientist
Date: 01/08/2011