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MISSION

Through worldwide collaboration, CROES seeks to assess, using evidence based scientific methodology, the various aspects of clinical endourology.

VISION

By applying rigorous scientific evaluation to the field of clinical endourology, CROES will enable all urologic surgeons to bring to their patients the most effective and efficient care possible.

PROJECTS

- Global PCNL study
- Global URS study
- Global Greenlight Laser study
- Global Renal Mass study
- Global NBI study

CONTACT

For more information please contact Sonja van Rees Vellinga (info@croesoffice.org).

DATA TRANSFER AGREEMENT FORM FOR CROES RESEARCH PROJECTS

Jean de la Rosette and Stavros Gravas

The Clinical Research Office of the Endourological Society (CROES) aims to promote and support high quality international patient-centered research in a transparent way. At present, 5 studies are in progress; CROES recognizes the importance of the communications derived from the different studies and has therefore prepared guidelines for publications.[1] In addition, CROES has taken several other initiatives to further enhance the quality of the research projects.[2]

Data sharing is essential for expedited translation of research results into knowledge, products and procedures to improve human health. CROES is aware that data sharing may be complicated in some cases by institutional policies, local Institutional Review Board rules, and national laws and regulations. In addition, complete, accurate and transparent reporting is an integral part of responsible research conduct.

In light of all these considerations, a data transfer agreement has been developed. This agreement defines the obligations and rights of each involved party regarding the use of data. Due to limited space, the present manuscript will highlight the main terms of this agreement. The full version of the data transfer agreement is available at the official CROES webpage *www.croesoffice.org*.

The Data Transfer Agreement is made between the "Researcher" and the Endourological Society ("Recipient"). The parties hereby agree as follows:

1. Data. The data to be furnished by Researcher to Recipient consists of the items defined in and set forth in an Appendix 1 (attached "Study").

2. Permitted uses. Recipient will only use Data for the purpose(s) and project(s) specifically set forth in the Appendix (the "Study"). However, it is acknowledged that the Data may be a resource for other scientific projects or uses. As such, the parties agree that the Recipient has the right to use and further distribute and/or transfer the Data to any third-party, provided that such use or transfer is made for a scientifically approved project or use as determined by Recipient, and is done in accordance with applicable laws, rules and regulations regarding the use, handling and transfer of the Data.

3. Researcher's compliance with patient privacy obligations. Researcher represents, warrants and covenants that its transfer of Data to Recipient is compliant with all applicable rules, regulations and policies of any and all applicable Institutional Review Boards, the Health Insurance Portability and Accountability Act of 1996, as amended from time to time ("HIPAA"), patient informed consent documents, as well as all applicable federal, state and local laws, statutes, ordinances, rules and regulations regarding patient privacy and/or the transfer of the Data.

4. Recipient obligations.

- **a. Collaboration Requirement.** Recipient agrees to work closely with the Researcher familiar with the Data provided hereunder.
- **b. Informed Consents.** Recipient agrees to comply fully with study participants' informed consent documents as provided by Researcher.

c. **Confidential Information.** Recipient agrees that the Data shall be held in confidence by the Recipient.

5. Term and right to terminate. This Agreement shall be effective from the Effective Date until the completion of the Study unless otherwise extended or amended by agreement of the parties, or as earlier terminated pursuant to this Section. Either party to this Agreement may terminate this Agreement at any time for any reason or no reason, upon five (5) days prior written notice to the other party.

6. Data and intellectual property ownership. Recipient shall have the sole and absolute right to create, control, own, have title in, disclose and use any Intellectual Property that relates to the subject matter of, or arises out of, the Study, the Data or the services performed by Researcher under this Agreement. Intellectual Property shall include but not be limited to any trademarks, service marks, copyrights, patents, inventions, products, equipment, processes, technology, computer programs, works of authorship, improvements, discoveries, developments, designs, data, know-how, ideas made or conceived or reduced to practice, in whole or in part.

7. Costs. The Researcher and Recipient agree to cover their own costs and expenses incurred in the performance of this Agreement.

8. No warranties. The institute in which the researcher conducted the study is not responsible for warranties, either express or implied, with respect to the data or other results arising from the study or with respect to any confidential information it may disclose to Recipient.

9. Publication. Nothing contained in this Agreement shall infringe or otherwise adversely impact Recipient's sole, exclusive and unfettered right to publish any and all results of the Study, including the Data and any information relating to or derived from the Study or Data. Recipient shall provide appropriate acknowledgment of the Researcher in all publications arising from the Study, if possible.

10. Liability. Each party hereto agrees to be responsible and assume liability for its/his/her acts or omissions, and for the acts and omissions of those for whom it/he/she is in law responsible, arising out of or as a result of, or in connection with the conduct of the Agreement to the full extent required by law, and agrees to hold the other party harmless from any such liability, limitation, reasonable legal fees and cost, and each party agrees to maintain reasonable and customary insurance coverage for the activities contemplated under this Agreement.

11. General.

a. **Relationship of Parties.** Nothing in this Agreement shall be construed so as to create a legal relationship of partnership, agency, joint venture, or employment among or between the parties.

b. **Governing Law.** This Agreement shall be governed by the laws of the State of New York, United States of America, without reference to any choice of law rules that would result in the application of the substantive law of any other jurisdiction.

c. **Entire Agreement.** This Agreement represents the entire understanding of the parties with respect to the subject matter hereof. This Agreement supersedes any and all prior agreement or understandings, whether oral or written, among the parties.

d. **Inspection.** Researcher represents, warrants and covenants that the Data is accurate, objective and verifiable. The Researcher agrees and acknowledges that Recipient (or any other third-party as designated by Recipient), upon reasonable advanced notice to Researcher, shall have the right to audit, inspect, verify and/or validate the accuracy and objectivity of the Data, including the methodology and/or processes used in obtaining the Data.

Since CROES projects need long-term cooperation from participants, it is essential to arrive at a mutual robust commitment that will secure the ethical and scientific integrity of clinical research globally, resulting in the absolute best, least invasive, quality of care for all patients. CROES clearly states its policy regarding use of data in order to prevent premature agreements and avoid participation refusals arising from misconceptions. "The time is now—with CROES, the ability is yours"[3].

References

1. de la Rosette J, Gravas S. Guidelines for CROES publications. J Endourol 2010;24:167–169.
2. de la Rosette J, Gravas S. Quality and transparency in CROES research projects. J Endourol 2010;24:317–319.
3. de la Rosette J. A platform for global endourological research. J Endourol 2009;23:1551–1553.

- The Global PCNL observational study was closed on December 31, 2009.
- Ongoing projects are: the Global Greenlight Laser observational study, the Global Ureteroscopy study, and the Global Renal Mass study. At present a randomized study on Narrow Band Imaging versus White Light Imaging is in preparation.
- For further information please visit: www.croesoffice.org or contact the Office Manager of CROES, Mrs. Sonja van Rees Vellinga (info@croesoffice.org).

This article has been cited by:

1. 2010. Clinical Research Office of the Endourological SocietyClinical Research Office of the Endourological Society. *Journal of Endourology* **24**:6, 881-883. [Citation] [Full Text] [PDF] [PDF Plus]