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## **Cystinuria Registry and Cystinuria Contact Registry Agreement**

Last Updated: 08/05/2010

Please read the following text carefully before joining the Cystinuria Registry and the Cystinuria Contact Registry. You may wish to print a copy of this document for your files.

### **What are the Cystinuria Registry and the Cystinuria Contact Registry?**

The Cystinuria Registry was established by the Rare Kidney Stone Consortium. Data collected from volunteers, diagnosed with cystinuria, is used for a research project that aims to deepen our understanding of the disease.

The Rare Kidney Stone Consortium is based in the Mayo Clinic in Rochester, Minnesota and comprises a group of doctors interested in several rare inherited kidney stone diseases that cause loss of kidney function. A part of the consortium, headed by Dr. David Goldfarb, is based in New York, at NYU School of Medicine, and is dedicated to research in cystinuria.

We are asking your permission to allow the collection and storage of clinical information on your history with cystinuria and kidney stones. This information will be added to a secure disease databank or registry from which we hope to learn more about the disease, including how it affects people, which treatments are effective, and which tests are useful. The data will include as many aspects of your history of cystinuria as possible. The registry will be “encrypted”, meaning that it will not be possible for unauthorized people to identify you from the registry’s data.

Dr David S Goldfarb will maintain the database with his co-workers at NYU and his fellow scientists at the Mayo Clinic. He will allow it to be used for research only as permitted by the policies of NYU’s Institutional Board Of Research Associates (IBRA) and federal regulations.

In addition, the Cystinuria Registry will maintain the Cystinuria Contact Registry. The goal of the Contact Registry is to manage patients' contact information. This information is not part of the Cystinuria Registry and will allow us to communicate with cystinuria patients. Information from the Contact Registry will not be entered into the registry and will be kept at a separate and secure location at NYU School of Medicine. If you permit, we will share some contact information with patient advocacy groups that will in turn provide you with cystinuria-related news from the cystinuria community.

### **REIMBURSEMENTS:**

Participation in this registry will be at no cost to you.

### **POTENTIAL RISKS AND DISCOMFORTS/COMPENSATION FOR INJURY:**

There are no identifiable risks to participants. Your privacy will be effectively protected by maintaining your data in an “encrypted” form, in a secure computer at the Mayo Clinic.

### **POTENTIAL BENEFITS:**

We do not expect that you will directly benefit from participating in this study. It is hoped that the knowledge gained from this study will be of benefit to you or others in the future. You will not benefit financially if discoveries are made using your health information.

### **Who can join?**

Anyone with cystinuria can join the Contact and/or Cystinuria Registry as a volunteer. A parent, legal guardian or caretaker may register someone under the age of 18 or an adult that may not be able to enter in their own information.

### **What do I have to do to join?**

If you decide to sign up for the Contact Registry, you will be asked a few questions about yourself, such as your age and contact information. The Contact Registry will not include any medical information about your cystinuria. If you decide to join the Cystinuria Registry, we will mail or email you a separate, specific Informed Consent Form. We will then have you send us copies of your medical information to us. That information will be stored securely and will be kept confidential as described below and in the Registry Privacy Statement. You can join the Contact Registry without joining the Cystinuria Registry.

### **What happens once I register?**

Once you join the Cystinuria Registry, your non-identifiable information becomes part of a pool of data stored at the Mayo Clinic. We will update your data at least annually. This database will be used for a better understanding of cystinuria and for the development of research hypotheses, which will lead to future clinical trials. Access to this data, and its use, is limited to members of the Rare Disease Consortium. All future clinical trials, based on this registry, will undergo a scientific review and approval process.

The Contact Registry will help us stay in touch with registered patients and facilitate the exchange of information between the research community and cystinuria patients. If you agree to share your contact information (NOT your medical information) with the International Cystinuria Foundation (ICF) and the Cystinuria Support Network (CSN), these patient advocacy groups will send you up-to-date Cystinuria-related information.

### **How is my information protected?**

Private identifiable information about you may be used or disclosed for the purposes of this research project. That section of the consent/authorization form describes how your information will be used and shared in the research, and the ways in which NYU School of Medicine will safeguard your privacy and confidentiality.

### **Who is involved in Contact and Disease Registry?**

The registry has been developed by Dr. David Goldfarb and colleagues in collaboration with the Rare Kidney Stone Consortium and the Mayo Clinic. We work in collaboration with the ICF and CSN.

## **Does the Cystinuria Registry provide health care services?**

No. The Cystinuria Registry does not provide any medical or healthcare products, services or advice. If you have any questions about your health care or medical condition, please see your own doctor.

## **AGREEMENT**

By signing this Volunteer Agreement, you consent to the use and disclosure of your personal identifiable information on your Contact Registry profile, as outlined here. You also agree that the Contact Registry may access, keep or share your registration information if required to do so by law or in the good faith belief that it is necessary to:

- Enforce the terms of this Volunteer Agreement or the site's Terms of Use
- Respond to your requests for customer service
- Comply with federal, state or local legal processes

By completing the registration process, you represent and warrant that you are at least nineteen years of age, and that you possess the legal right and ability to enter into this Volunteer Agreement. You agree that if you register with the Contact Registry, that you will provide accurate information about yourself. You agree that if any information you provide is inaccurate, NYUSchool of Medicine may prohibit your access to the Contact Registry. If you register someone who may not be able to register themselves (including individuals under the age of 18 or someone who is unable to register without your assistance), you assert that you are their legal guardian, parent or caretaker and agree to the terms outlined in this agreement. If you agree, your profile will be added to the Contact Registry and the Cystinuria Registry as soon as you submit this form.

## **Thank you for learning more about Cystinuria! Questions or concerns?**

For general questions, please email the Cystinuria Registry at [cystinuria@nyumc.org](mailto:cystinuria@nyumc.org) or visit the Cystinuria Registry Contact page at NYU Langone Medical Center.