

INFORMATION SHEET

Database for Future Contact – University of Rochester Batten Center

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This information sheet describes a research contact database, what you may expect if you decide to take part and important information to help you make your decision. Please read this letter carefully.

Please ask questions about anything that is not clear before you agree to participate. You may take time to think about and discuss this study with family or friends. Please call Alyssa Thatcher at (585) 276-5966 with questions.

- Being in this database is voluntary – it is your choice.
- If you join this database, you can change your mind and stop at any time.
- If you choose not to take part, your medical care will not be changed in any way.
- There are risks from participating and you should understand what these mean to you.

Introduction & Purpose

The researchers in the University of Rochester Batten Center (URBC) at the University of Rochester have created a database (a list) of individuals who are interested in taking part in future research studies about Batten disease. People included in the database will be contacted when a new study starts to see if they are interested in participating.

Description of Database

If you decide to be included in the database, your contact information, your child's diagnosis, and contact information for your child's physician will be placed in this list. Researchers may then contact you in the future about updates from the URBC and new research on Batten disease. If you are contacted, you can decide at that time whether or not you are interested in participating in the study. Being included in the database does not mean that you will be enrolled in any future studies. Rather, you are only agreeing to be contacted about future research studies.

You may change your mind and have your name, and any additional information that was collected, removed from the database at any time by contacting the study team using the information below.

Risks of Participation

Participation in research may involve some loss of confidentiality. None of your information will be used for research without your permission. Your contact information will not be shared with anyone outside the study team.

Benefits of Participation

You might not benefit from being in this research database.

Costs/Payments

There will be no cost to you to participate in this database. You will not be paid for participating in this database.

Confidentiality of Records

The University of Rochester makes every effort to keep the information collected from you confidential. In order to do so, we will store all information in a locked office and on a secure server. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators, or the study sponsor. If this does happen we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

Voluntary Participation

Taking part in this research database is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this database, the information you have already provided will be kept in a confidential manner.

Contact Persons

For more information or questions concerning this research please contact Alyssa Thatcher at (585) 276-5966. Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.