

Research Assent Form

Brigham and Women's Hospital
Dana-Farber Cancer Institute
Massachusetts General Hospital

Version III.a August 1998
Pi_dist9.doc

Imprint Patient ID Number

Protocol Title: Neuroimaging Characteristics in Fabry Disease: Quantitation of Central Nervous System White Matter Lesions

Principal/Overall Investigator: Katherine Sims, MD

Site-Responsible Investigator(s)/Institution: _____

Description of Subject Population: Males and females with Fabry disease who have available digitized MRI images

We are doctors from Massachusetts General Hospital. We would like to learn more about children who have a medical condition called Fabry disease.

To do this, we are asking you and other children with Fabry disease to take part in a research study. The results of the study will help us understand how pictures of children's brains look when they have Fabry disease.

If you agree, you will let us look at pictures that have been already taken of your brain when you had test called an MRI.

We will ask you some questions about your health. This should take about 20 minutes. You might get bored or tired when the doctor is asking you questions. You may not know the answers to some of the questions. We will ask your parents to help answer these questions.

The information collected about you during this study will be kept safely locked up, and nobody will know who you are except the people doing the research. If we write an article about what we learn from the study, we will not use your name.

Before you decide to take part in this study, we will answer any questions you have. You can also talk to your mom or dad, or your doctor. You do not have to be in this study, it is okay to say no. If you decide to be in this study, you can change your mind and stop being part of it at any time.

You will be given a copy of this form to keep for yourself.

If you decide to be in the study, please sign your name below.

Subject Population: Males and Females with Fabry disease who have available digitized MRI images (Assent form)

IRB Protocol No.: 2009P002777

Sponsor Protocol No.: N/A

Consent Form Valid Date: 12/15/2011

IRB Amendment No.: N/A

Sponsor Amendment No.: N/A

IRB Expiration Date: 12/15/2012

IRB Amendment Approval Date: N/A

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Imprint Patient ID Number

Subject's Signature

Date

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Consent Form Valid Date: <u>12/15/2011</u>	IRB Amendment No.: <u>N/A</u>	Sponsor Amendment No.: <u>N/A</u>
IRB Expiration Date: <u>12/15/2012</u>	IRB Amendment Approval Date: <u>N/A</u>	