Research Informed Consent
Title of Study: Charcot-Marie-Tooth North American Database

“You” refers to you, your child or your ward.

You are being asked to be in a research study of individuals with Charcot-Marie-Tooth disease at Wayne State University and Indiana University. Please read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by Michael Shy MD, Neurology. The funding for this study is being provided by the Charcot-Marie-Tooth Association and the Muscular Dystrophy Association.

DATABASE PURPOSE

The purpose of the study is to gather information about individuals with different genetic mutations through a variety of medical and family history questionnaires. The database aims to help researchers access large amounts of information about people with CMT. By using this database, researchers may better understand the progression of CMT and in this way find more helpful therapies. The expected number of study participants to be enrolled at Wayne State University is about 3000.

PROCEDURE FOR ADDING YOUR INFORMATION TO THE DATABASE

If you take part in the study, you will be asked to complete a Family History Questionnaire and a Questionnaire for Affected Individuals. Your physician will be asked to fill out questionnaires on your neurological and physical examinations. You will sign a separate consent form to release medical records pertaining to CMT.

You may be contacted by the database staff at Indiana University (see below) and invited to participate in additional research studies that will be explained at that time. This participation is not needed in order to be eligible for the database and will require a separate statement of consent. Identifying information will not be released without your written consent.

BENEFITS FROM PARTICIPATION IN THIS DATABASE

There will be no direct benefits for you; however, your participation may provide additional information regarding the understanding of CMT, which may lead to better ways to diagnose and treat people with this condition.

POSSIBLE RISKS

The risks from participating in this study are minimal. Medical and family history information that you provide on the patient questionnaires, as well as medical information your physician provides, will be entered into a database at Indiana University Department of Medicine and Molecular Genetics. There is a slight risk that someone could breach the security of this computer system, and access information about your history of CMT. Extensive safeguards are in place to minimize this risk. The risks for additional research studies, should you choose to participate in them, will be explained to you at the time of your consent to them.
**ALTERNATIVES**

The only other option is not to participate in this study.

**COMPENSATION**

You will not be financially compensated for participation in this database and there should be no cost for your participation. In the unlikely event of harm resulting from your participation in this research study, there will be no compensation, reimbursement or other services provided by Wayne State University or Indiana University.

**PRIVACY/CONFIDENTIALITY**

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. By signing this document, you give permission to use information about you for medical and scientific purposes, including teaching, research, and/or publication. Information that identifies you personally will not be released without your written permission. However, the study sponsor, the Human Investigation Committee (HIC) at Wayne State University or federal agencies with appropriate regulatory oversight, may review your records.

Personal Health Information (PHI) used and disclosed for the purposes of this study is protected under the federal regulation known as HIPAA (Health Insurance Portability and Accountability Act). Your study investigator will discuss with you your rights under this federal regulation and obtain your authorization to allow the research team to access your PHI.

**RIGHT TO REFUSE OR WITHDRAW**

Enrollment in this database is totally voluntary. You may at any time decide to discontinue your participation in this database and request that any information about you be removed from the database. You are under no obligation to participate in this study and your medical care will in no way be affected by your choice to participate or not to participate.

**WHO TO CONTACT WITH QUESTIONS**

If you have any questions now or in the future, you may contact Dr. Michael Shy or one of his research team members at Wayne State University at (313) 577-5273, Monday through Friday, 9:00 am – 5:00 pm EST. If you have questions or concerns about your rights as a research participant, the Chair of the Human Investigation Committee can be contacted at (313) 577-1628.
CONSENT TO PARTICIPATE IN THE DATABASE

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study, you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered.

Signature of Participant / Legally Authorized Representative

Printed Name of Participant / Authorized Representative

Signature of Witness (When applicable)

Printed Name of Witness

Signature of Person Obtaining Consent

Printed Name of Person Obtaining Consent

** Use when participant has had consent form read to them (i.e., illiterate, legally blind, translated into foreign language).