

UNIVERSITY AT BUFFALO  
HUMAN RESEARCH PROTECTIONS PROGRAM  
**Authorization Template for the Use and Disclosure of  
Identifiable Health Information for Research Purposes**

You have been asked to be part of a research study under the direction of Dr. Georgirene Vladutiu, the Principal Investigator, and her research team. The study is called **Genetic Susceptibility to Lipid-Lowering Drug-Induced Myopathies**. The purpose of the study is to determine if individuals who are treated with cholesterol-lowering drugs are at increased risk for developing muscle disease symptoms when they are found to have underlying genetic factors that are known to contribute to the development of muscle disease.

This authorization form describes information about you and about your health that will be obtained by the researchers when you participate in the research study. Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

**1. What protected health information will be collected about you as part of this research study?**

Data will be collected during the study include your name, address, telephone number, and date of birth. From your health records, you will be asked to provide current medications and dosages and any symptoms you may have pertaining to problems with muscle function. If you do not know the names and dosages of your present medications, you may authorize the Principal Investigator in writing to obtain this information from your physician.

**2. Who is authorized to provide or collect his information?**

- √ Other: Your Physician
- √ Principal Investigator or designee

**3. With whom may your protected health information be shared?**

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

- √ Clinical staff at your physician's office not involved in this research study, but who may become involved in your care if it is potentially relevant to your treatment.
- √ The sponsor of this research study, list specific sponsor, cooperative group, etc., or its agents.

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Your information may also be shared with individuals responsible for general oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

#### **4. How long will this information be kept by the Principal Investigator?**

√ This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

#### **5. What are your rights after signing this authorization?**

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual:

Georgirene D. Vladutiu, PhD  
Robert Guthrie Biochemical Genetics Laboratory  
Buffalo General Hospital  
100 High Street, A762  
Buffalo, NY 14203

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

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**6. What will happen if you decide not to sign this authorization?**

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

**Name (please print)** \_\_\_\_\_

**Signature** \_\_\_\_\_

**Date:** \_\_\_\_\_

**After signing, you will be provided with a signed copy of this authorization form.**

**Section for Personal Representatives (i.e. parent, legal guardian):**

**Name (please print)** \_\_\_\_\_

**Signature** \_\_\_\_\_

**Date:** \_\_\_\_\_

**You must provide a description of the personal representative's authority to act for the individual:**

11/08/07

**HSIRB Approved Date** 12-18-07 *M/G*