

## **MARQUETTE GENERAL HOSPITAL DATA PRIVACY STATEMENT FOR RESEARCH STUDY**

A federal government rule has been issued to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule is designed to protect the confidentiality of your personal health information. Your personal health information is information about you that could be used to find out who you are. For this research study, this includes information in your existing medical records needed for this study and new information created or collected during the study.

This Data Privacy Statement explains how your personal health information will be used and who it will be given to ("disclosed") for this research study. It also describes your privacy rights, including your right to see our personal health information.

By signing this document, you will give permission ("authorization") for the uses and disclosures of your personal health information that are described in this Data Privacy Statement. Even if you are only considering participation in a research study, by signing this Data Privacy Statement, you are allowing access to your health records to determine eligibility. If you do not want to allow these uses, you should not participate in this study, or sign this document.

If you agree to participate in the research study, your personal health information will be used and disclosed in the following ways:

- The study doctor and staff will use your medical records and information created or collected during the study to conduct the study.
- The study doctor and staff will send your study-related health information ("study data") to the sponsor of the study and its representatives ("sponsor"). Because the sponsor conducts business related to clinical research in many countries around the world, this may involve sending your study data outside of the United States. Other countries may have privacy laws that do not provide the same protections as the laws in this country. However, the sponsor will respect the terms of this Data Privacy Statement in all countries.
- The study sponsor may be provided some of your personal health information or other information that directly identifies you (e.g. name, address, social security number, and date of birth) by the research staff when registering you to the study. After you have been registered, the sponsor will assign a code number and may use your initials on any data that is submitted. If you have questions about the specific health information that will be sent to the sponsor, you should ask the study doctor.
- The sponsor will use the study data for research purposes to support the scientific objectives described in the consent document and the process of getting regulatory approvals for its drugs.
- The sponsor may add your study data and data from other studies in research databases so that it can study better measures of safety and effectiveness, study other therapies for patients, develop a better understanding of diseases, or improve the design of future clinical trials.
- Your study data, either alone or combined with data from other studies, may be shared with regulatory authorities in the United States and other countries, doctors at other institutions participating in the study, and the ethical review board overseeing this study.
- Study data that does not directly identify you may be published in medical journals or shared with others as part of scientific discussions.
- Your original medical records, which may contain information that directly identifies you, may be reviewed by the sponsor, the ethical review board overseeing this study, and regulatory authorities in the United States and other countries. The purpose of these reviews is to assure the quality of the study conduct and the study data, or for other uses authorized by law.
- The sponsor may work with business partners in drug development. The sponsor may share your study data with these business partners, but only if the business partners need the information as a part of this work with the sponsor, and only if the business partners signs a contract that requires it to protect your study data in the same was as the sponsor.

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- The sponsor will not disclose personal health information to insurance companies unless required to do so by law, or unless you provide separate written consent to do so.
- Your medical records and study data may be held and processed on computers.

Your personal health information may no longer be protected under the HIPAA privacy rule once it is disclosed by your study doctor to these other parties.

You have the right to see and copy your personal health information related to the research study for as long as this information is held by the study doctor or research institution. However, to ensure the scientific integrity of the study, you will not be able to review some of the study information until after the study has been completed.

You may cancel your authorization at any time by providing written notice to the study doctor. If you cancel your authorization, the study doctor and staff will no longer use or disclose your personal health information in connection with this study, unless the study doctor or staff needs to use or disclose some of your personal health information to preserve the scientific integrity of the study. The sponsor will still use study data that was collected before you cancelled your authorization. If you cancel your authorization, you will no longer be able to participate in the study. However, If you decide to cancel your authorization and withdraw from the study, you will not be penalized or lose any benefits to which you are otherwise entitled.

Your authorization for the uses and disclosures described in this Data Privacy Statement does not have an expiration date.

\_\_\_\_\_  
Signature (Subject/Patient)

\_\_\_\_\_  
Date  
Subject/Pt must personally date

\_\_\_\_\_  
Subject/Patient Name (Print or Type)

\_\_\_\_\_  
Initials

Complete this section if authorization is provided by a legal representative of the Subject or Patient.

\_\_\_\_\_  
Signature of Legal Representative

\_\_\_\_\_  
Date  
Representative must personally date

\_\_\_\_\_  
Legal Representative Name (Print or Type)

\_\_\_\_\_  
Legal Representative relationship to  
Patient or other basis for legal authority

Initial IRB Approval Date: 04/09/03  
Revised/IRB Approval Date: 05/14/03  
Revision Date: 09/16/03 Approved by MGH Privacy Officer