

## **Confidentiality of Records and HIPAA Authorization (Data Privacy Statement)**

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 your personal health information.

By signing the consent document for this study, you will give permission (“authorization”) for the uses and disclosures of your personal health information that are described in this Data Privacy Statement. If you do not want to allow these uses, you should not participate in this study.

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/investigator and staff will use your medical records and information created or collected during the study to conduct the study.
- The study doctor/investigator and staff will send your study-related health information (“study data”) to the sponsor (if applicable) 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 represent the terms of this Data Privacy Statement in all countries.
- The study data sent by the study doctor/investigator to the sponsor does not include your name, address, social security number, or other information that directly identifies you. Instead, the study doctor/investigator assigns a code number to the study data and may use your initials. Some study data sent to the sponsor may contain information that could be used (perhaps in combination with other information) to identify you (e.g. date of birth). If you have questions about the specific health information that will be sent to the sponsor, you should ask the study doctor/investigator.

- 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 to 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 Rochester Regional Health Clinical Investigations Committee overseeing this study at RRH.
- 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 Rochester Regional Health Clinical Investigations Committee overseeing this study at RRH, 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 works 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 way as the sponsor.
- The sponsor will not disclose personal health information to insurance companies unless required to do so by the law, or unless you provide separate written consent to do so.
- Your medical records and study data will be held and processed on computers.
- If research related procedures are performed within the Rochester Regional Health (i.e. laboratory tests, imaging studies and clinical procedures) the results will be placed in your Electronic Medical Record (EMR). Once placed in your EMR, results are accessible to appropriate RRH staff who are not part of the research team.

Your personal health information may no longer be protected by HIPAA privacy rule once it is disclosed by your study doctor/investigator 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/investigator or ViaHealth. 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/investigator. If you cancel your authorization, the study doctor/investigator and staff will no longer use or disclose your personal health information in connection with this study, unless the study doctor/investigator 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 use and disclosures described in this Data Privacy Statement does not have an expiration date.