

Notice of Privacy Practices

A federal regulation, known as the “Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule”, requires that we provide detailed notice in writing of our privacy practices. This Notice of Privacy Practices describes how we may use and disclose health information about our research participants. It also describes your rights to access and control your protected health information. The HIPAA Privacy Rule requires that we protect the privacy of health information that identifies you, or where there is a reasonable basis to believe the information can be used to identify you.

For purposes of a research study, the study doctor and the study center will use medical information (Protected Health Information or “PHI”) collected or created as part of the study. PHI includes, but is not limited to: age; address; e-mail address; telephone and fax numbers; social security numbers; and your medical records, which may include mental health records and test results.

Our Responsibilities

We are required by law to:

Maintain the privacy of protected health information about you. Give you this notice of our legal duties and privacy practices with respect to protected health information; and Comply with the terms of our Notice of Privacy Practices that is currently in effect.

How We May Use and Disclose Your Protected Health Information

When you sign consent to participate in a research study, you agree to allow the study doctor and the study center to obtain and use any of your records that they request for study purposes from your regular doctor and/or your other health care providers. The study doctor and study center will also gather information regarding your past and present medical history and medication usage to determine if you qualify to participate in the study. Tests and ECGs may also be performed as part of your participation in a study. Additionally, the study doctor and study center will compile data regarding your response to the treatment under investigation. The study doctor and the study center may use and share this information with the parties described below.

Unless required by law, the study doctor and the study center will share your records only with;

The study staff and other professionals involved with the study

The study sponsor and people who work for or with them

The U.S. Food and Drug Administration (FDA) and governmental agencies in the U.S. and in other countries where the study drug may be considered for approval

An Institutional Review Board

The purpose for using and sharing your records with these parties is to perform the study, to make sure the study data is correct, to check participant safety, and for other uses allowed by law.

There are national and state laws that require the study doctor to protect the privacy of your records. Although efforts will be made to protect the privacy of your records, absolute privacy cannot be guaranteed because of the need to share information as described above. Your records may be shared with parties who are not required to protect the privacy of your records.

Information about your participation in this study may be used in books, magazines, journals, or meetings. If this happens, your name or other information that could be used to personally identify you will not be used.

If you get hurt or sick possibly because of being in the study, and you seek medical treatment:

The study doctor and sponsor may obtain study-related records from your other health care providers to learn more about the effects of the study and your condition. >Information about this study might be given to your health care payer for the purpose of resolving your claim.

The sponsor might give information that identifies you to its insurance carrier or other third parties for the purpose of resolving your insurance claim.

We may use and/or disclose your PHI to contact you to remind you that you have an appointment with us. We may also use and/or disclose PHI to provide you with information about treatment alternatives or health-related benefits and services that may be of interest to you. For example, you name and address may be used to send you information from our office regarding the services we offer or about other research studies. These may be sent to you through the USPS with our practice information on the envelope /postcard. You name will also be placed in our confidential database to be searched for future studies.

Your Rights

During the study, you may not see your study records. You will be allowed to see your records once the study is over.

You have the right to cancel your permission to use and share your records at any time by giving written notice to the study doctor. If you cancel your permission, the study doctor and the study center will no longer use or share your records, unless it is necessary to do so to preserve the scientific integrity of the study. Canceling your permission will not affect the use and sharing of your records that occurred before you cancelled your permission.

Unless you give your permission to use and share your records, or if you cancel your permission later, you will not be able to participate in the study, and you will not receive any treatment provided as part of the study. Unless and until you cancel your permission to use and share your records, your consent to share your information will remain valid as specified in the consent form.

This privacy policy is provided as an overview of our Standards of Practice in regard to the "HIPAA Privacy Rule". Research participants must sign a consent form prior to being evaluated for every study which will discuss the privacy rule as it relates to that study.