Patient Hand-Out for HIPAA

You are probably asking "What is HIPAA"? HIPAA (Health Insurance Portability and Accountability Act of 1996) is a federal law designed to protect the privacy of your medical information and related paperwork. This law sets boundaries on the use and release of health records and gives patients more control over their health information.

This notice is nothing new – we have always taken great care to guard your privacy. This HIPAA document explains your rights; we are asking you to sign it to show that you have read and understand this notice.

Worldwide Clinical Trials

Authorization to Use and/or Disclose Protected Health Information

During your participation in this research study, the study doctor and study staff will collect or create personal health information about you (for example, medical histories and results of any tests, examinations or procedures you undergo while in the study) and record it on study forms. The study doctor will keep this personal health information in your study-related records (that we will refer to as "your records"). The study doctor may also obtain, and include in your records, information about your past, present and/or future physical or mental health and/or condition, such as medical records from your primary care physician. Your records may include other personal health information (such as social security number, medical record numbers, date of birth, etc.) which could be used to identify you. Health information that could identify you is called "Protected Health Information" (which we will refer to as PHI).

Examples of Protected Health Information (PHI) include:

- Name/Initials
- Address
- Telephone Number
- Social Security Number
- Health Plan Number
- Other details about you

Under federal law (the "Privacy Rule"), your PHI that is created or obtained during this research study cannot be "used" to conduct the research or "disclosed" (given to anyone) for research purposes without your permission. This permission is called an "Authorization". Therefore, you may not participate in this study unless you give your permission to use and disclose your PHI by signing this Authorization. By signing, you are agreeing to allow the study doctor and study staff to use your PHI to conduct this study; to monitor your health status; possibly, to develop new tests, procedures and commercial products.

If you decide to be in this study, medical information that identifies you and relates to your participation will be created. This may include the following types of medical information:

- Information obtained from the procedures used to find out whether you are eligible to take part in this study. This may include physical examinations, blood and urine tests, x-rays and other procedures or tests, and other information that you may release to us, including information about your health history.

- Information obtained during the study including information about your response to any study medications you receive, information related to the study visits and phone calls, physical examinations, blood and urine tests, x-rays and other tests or procedures that may be performed, and other medical information relating to your participation in this study.

By signing this authorization you are also agreeing to allow the study doctor and/or study staff to disclose your PHI as described below:

- Your PHI may be disclosed to the sponsor of this study and any agents, representatives or consultants working on behalf of the sponsor to conduct this study (referred to as the sponsor). The sponsor will analyze and evaluate the PHI and may disclose it to the United States Food and Drug Administration (FDA) or similar regulatory agencies in the United States and/or foreign countries. The study staff will assign a code number and/or letters to your records which means that you will not ordinarily be identified in the records sent to the sponsor; however, the sponsor may look at your complete study records, which would identify you. In addition, the sponsor may visit the study site to oversee the way that the study is being conducted and may review your PHI during these visits to make sure the information is correct.
- The Institutional Review Board (IRB) may have access to your PHI in relation to its responsibilities as an institutional review board.
- Other persons, agencies, or companies to whom PHI may be disclosed are:
    - Doctors and healthcare professionals taking part in the study
    - U.S. Food and Drug Administration (FDA)
    - U.S. Department of Health and Human Services (DHHS)
    - Government agencies in other countries
    - Government agencies that must receive reports about certain diseases
    - Other study participants

These disclosures also help ensure that the information related to the research is available to all parties who may need it for research purposes.

Your identity will remain confidential and, except for the disclosures described above, will not be shared with others unless such disclosure is required by law. If your PHI is given to the parties listed above and/or to others who are not required to comply with the federal law, your PHI will no longer be protected by this law and could possibly be used or disclosed in ways other than those listed here.

Your subject number, initials, and first name will be used to identify you in the presence of the study doctor, staff and other subjects during your visits to our clinic.

You have a right to see and make copies of your PHI. You are agreeing, however, by signing this form, not to see or copy your PHI until the sponsor has completed all work related to this study. At that time, you may ask to see your records.

This Authorization will never expire unless and until you revoke (cancel or withdraw) it. You have a right to revoke it at any time. If you revoke the Authorization, your PHI will no longer be used for this study, except to the extent the parties to the research have already taken action based upon your Authorization or need the information to complete analysis and reports for this research. To revoke your Authorization, you must send a written notice to the study doctor's office, stating that you are revoking your Authorization to Use or Disclose Protected Health Information. If you revoke this Authorization, you will not be allowed to continue your participation in this study.

[Please note: If signed by a legal representative, you must include on the signature page a description of the representative's authority to act on the individual's behalf.]

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

OR

_____
Printed Name of Subject's Legally Authorized Representative

_____ _____
Signature of Subject's Legally Authorized Representative Date

_____
(Authority of Legally Authorized Representative to act of behalf of subject)

_____
Printed Name of Person Obtaining Authorization

_____ _____
Signature of Person Obtaining Authorization Date