HIPAA AUTHORIZATION FORM

CONFIDENTIALITY AND AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

A federal regulation called the "Health Insurance Portability and Accountability Act" (HIPAA), which went into effect on April 14th, 2003, describes how your personal health information may be used, disclosed and made accessible to you. This privacy rule is designed to protect the confidentiality of your personal health information.

This research study can be performed only by collecting and using your personal medical information. Your research records will be kept as confidential as possible under local, state and federal laws. Personnel from the following organizations may examine your study records: the Sponsor, your study doctor and personnel associated with this study, regulatory agencies, such as the Food and Drug Administration (FDA), and the Liberty Institutional Review Board (IRB), a committee that has reviewed this research study to help ensure that your rights and welfare as a research participant are protected and that the research study is carried out in an ethical manner. Because of the number of people who may see your records, absolute privacy cannot be guaranteed.

Personal information that may be shared includes information that is obtained to determine your eligibility to participate and that which is collected from the procedures that are carried out. It may identify you by name, address, telephone number, Social Security number, study number, date of birth or other identifiers. Once the information is shared, it is possible that it may be shared again, at which time it may no longer be protected by federal regulations, but may be by state laws. If the final study data are prepared for publication and other reports, your identity will not be revealed. Under these federal privacy regulations, you have the right to see and copy any of the information gathered about you, until your research records are no longer kept by the study doctor. However, your records may not be available until the research study has been completed.

You may, by written notice to the study doctor, cancel your permission to use or share your personal information at any time. If you withdraw your authorization, the information collected up to that time may still be used to keep the scientific integrity (design and quality) of the research study. By

signing this consent form, you authorize this sharing of your personal information. If you do not authorize this sharing, you will not be able to participate in the research study. This authorization does not have an expiration date.

By signing below, I give my permission for the use of my Protected Health Information as described above.

Signature of Subject	Date
Printed Name of Subject	Date