

SAMPLE: Confidentiality and Use and Disclosure of Health Information for Research Purposes

**Approved for Public Distribution
March 6, 2003**

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Study records that identify you will be kept confidential as required by law. You agree to allow ***[Name of the Principal Investigator at the Site]*** and his/her staff {Researchers} conducting the research study to use and disclose health information about you to the Institutional Review Board ***[or IEC]*** of ***[institution]***, the sponsor, ***[name of sponsor]***, representatives of the sponsor assisting with the research (such as the contract research organization, the study monitors, auditor, and project manager), central laboratory, and government agencies where permitted or required by law (such as the Food and Drug Administration (FDA) and the United States Department of Health and Human Services) {Receivers}.

Health information includes all information about you which is collected during the research study for research purposes and the health information about you in medical records that is related to the research study. For example, this information would include laboratory tests such as your blood counts and tests to measure the function of your liver and kidneys, x-rays or scans and the following health information and tests: ***[provide specific details, but to a reasonable extent]***

Health information about you will be used and disclosed for medical, statistical, and regulatory purposes related to the research. Representatives of the sponsor and representatives of government agencies, such as the FDA may also use your health information to verify the research. If your health information is reviewed by one of these people, then they may need your entire medical record. The people listed above may further disclose this health information about you. If disclosed by them, the information may no longer be covered by the federal or state privacy regulations

The health information about you may be used to create information that does not identify you. The de-identified data may be used and released by Researchers for this study, including use for other research purposes. However, you will not be identified by name in any resulting publication or presentation that utilizes the health information about you.

Authorization for Use of Health Information for Research Purposes

By signing this consent form, you authorize the use of the health information about you as described above. This Authorization will not have an expiration date. However, you have the right to revoke this Authorization, in writing, at any time by sending written notification to ***[Name of the Principal Investigator at the Site OR Name of the Researchers' Privacy Contact (identify this person as the privacy contact)]*** at ***[mailing address of site. May also include email address]***.

If you revoke your Authorization for Use and Disclosure of Health Information for Research Purposes, you will be discontinued from the research. If you revoke this Authorization, the Researchers may still use and disclose the health information that has already been obtained to maintain the reliability of the research. You cannot be denied medical treatment because you do not give this Authorization. However, you will not be allowed to participate in this research study. You will not have access to the information about you in the research study records until the end of the study.

Right to Withdraw

Your participation in this research study is voluntary. You may decide not to begin or to stop this study at any time without any penalty or loss of benefits to which you may otherwise be entitled. Your care and relationship with health care providers at ***[institution]*** will not be affected in any way. ***[Name of the Principal Investigator at the Site]*** may stop the study if the research is not helping you, if you do not follow the research directions, or if you have a serious side effect to the research drug. The sponsor, FDA, or the IRB/EC may

