TEMPLATE: HIPAA PORTION OF THE CONFIDENTIALITY SECTION OF THE CONSENT FORM

PLEASE NOTE:

The authorization language provided below should be inserted at the appropriate location in the confidentiality section of the consent form. The language in the template should be directly followed.

Study records that identify you will be kept confidential as required by law. Under federal privacy regulations, you have the right to determine who has access to your personal health information (called "PHI") which provides safeguards for privacy, security and authorized access. PHI collected in this study may include **[INSERT SPECIFIC CRITERIA AS IT RELATES TO YOUR PROTOCOL- Examples to include:** your medical history, results of physicals exams, lab tests, x-ray exams, other diagnostics and treatment procedures, as well as basic demographic information.] In addition to the investigator(s) listed on the first page of this consent form and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study. A representative of the University of Tennessee at Chattanooga Institutional Review Board may review your PHI for the purpose of monitoring the appropriate conduct of this research study. **[Remove the following sentence if not applicable to your protocol** - Reviewers may also include representatives from the Food and Drug Administration for the purpose of monitoring the accuracy of the research data, legal counsel, and your medical insurance carrier.] The University of Tennessee at Chattanooga Institutional Review Board may review your PHI as part of it's responsibility to protect the rights and welfare of research subjects. **[Remove the following two sentences if not applicable to your protocol** - PHI may also be shared with the sponsor of this study, **(INSERT SPONSOR)**, for the purpose of monitoring the accuracy and completeness of the research data and performing required scientific analyses of the research data. The investigators involved in the conduct of this research may receive funding for the sponsor to perform the research procedures and to provide the sponsor with identifiable research information related to your participation]. Your PHI will not be used or disclosed to any other person or entity, except as required by law, or for authorized oversight of this research study by other regulatory agencies, or for other research for which your PHI has been approved by the Institutional Review Board. Please be aware that once PHI is disclosed, there is the possibility that your personal health information may no longer be protected by applicable privacy laws and regulations.

The study results will be retained in your research record for a minimum of six years or until after the study is completed, whichever is longer. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results. Any research information obtained in your medical record will be kept indefinitely.

This authorization does not expire. At anytime, you may cancel this authorization in writing by contacting the principal investigator listed on the first page of the consent form. If you decline to provide this authorization, you will not be able to participate in the research study. If you cancel the authorization, then you will be withdrawn from the study. However, information gathered before the cancellation date may be used if necessary in completing the research study or any follow-up for this study. [**Remove the following sentence if protocol is a non-clinical study]** - You are permitted to obtain access to your PHI collected or used in this study. Such access will be granted at the end of the study.