

**AUTHORIZATION TO USE AND DISCLOSE INDIVIDUALLY IDENTIFIABLE HEALTH
INFORMATION IN MEDICAL RESEARCH
HIPAA AUTHORIZATION**

Under federal privacy regulations, you have the right to determine who has access to your/your child’s personal health information (called “protected health information” or PHI). PHI collected in this study may include (modify as applicable) your/your child’s medical history, the results of physical exams, lab tests, x-ray exams, and other diagnostic and treatment procedures, as well as basic demographic information. By signing this form, you are authorizing the researchers at East Tennessee Children's Hospital to have access to your/your child’s PHI collected in this study. In addition, your/your child’s PHI may be shared with other persons involved in the conduct or oversight of this research, including the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS), the National Institutes for Health and by researchers at (modify as applicable). However, these latter organizations may not have the same obligations to protect your/your child’s PHI. The Institutional Review Board (IRB) at East Tennessee Children's Hospital may review your/your child’s PHI as part of its responsibility to protect the rights and welfare of research subjects. Your/your child’s 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 the use and disclosure of your PHI has been approved by the IRB. Your/your child’s PHI will be used only for the research purposes described in the introduction of this consent form. Your/your child’s PHI will be used indefinitely.

You may cancel this authorization in writing at any time by contacting the principal investigator. If you cancel the authorization, continued use of your/your child’s PHI is permitted if it was obtained before the cancellation and its use is necessary in completing the research. However, PHI collected after your cancellation may not be used in the study. If you refuse to provide this authorization, you/your child will not be able to participate in the research study. If you cancel the authorization, then you/your child will be withdrawn from the study. Finally, the federal regulations allow you to obtain access to your/your child’s PHI collected or used in this study. However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. When the study is completed, your right of access to this information will be reinstated.

_____/_____
Printed Name/Signature Participant or Parent

Date

_____/_____
Printed Name/Signature of Witness

Date