The United States government has issued a privacy rule to protect the privacy rights of individuals enrolled in research. The Privacy Rule is designed to protect the confidentiality of an individual’s health information. This document describes your rights and explains how your health information will generally be used and disclosed for this study.

The purpose of collecting Protected Health Information (PHI) for this study is help researchers answer the questions that are being asked in this research study. The Principal Investigator or study personnel will tell you what types of PHI will be used and disclosed for this research study.

Protected Health Information may be used from your medical record or collected about you and may include laboratory results, x-ray reports, diagnosis, and clinical visit information. Your Protected Health Information will be used for study purposes. Access to your information is limited to a minimum amount of information necessary to attain study goals.

Information about you may be given out by the Principal Investigator and study personnel to representatives of regulatory agencies to ensure quality of data and study conduct as well as other entities that will be discussed with you by the Principal Investigator and study personnel. Once information about you is disclosed in accordance with this authorization, the individual or organization that receives this may redisclose it and your information may no longer be protected by Federal Privacy Regulations.

The results of this research may be published in scientific journals or presented at professional meetings, but your identity will not be disclosed.

Your PHI will be linked to your identifying information for a specific period of time. After this time, all links will be destroyed and your identity will not be able to be determined.

This authorization may expire on the date the research study ends, on an actual date of expiration, an occurrence of a particular event, or will have no expiration date.

You have the right to access your PHI that may be created during this study as it relates to your treatment or payment. Your access to research information will become available only after the study analyses are complete. Payment information may be released prior to the completion of the study for cases where your insurance will need to be billed.

If you do withdraw your authorization, any information previously disclosed cannot be withdrawn and may continue to be used. You may withdraw this authorization at any time by notifying the Principal Investigator in writing.
You may refuse to sign this authorization form. If you choose not to sign this form, you cannot participate in the research study. Refusing to sign will not affect your present or future medical care and will not cause any loss of benefits to which you are otherwise entitled.

You can obtain further information from the Principal Investigator. You may contact __________________________ at __________________________ any time you have questions about your Protected Health Information. You may contact the CHLA Human Subjects Protection Program at 323-361-2265 if you have any questions about your rights as a research subject.

_________________________________________  __________________________
Signature of Subject                        Date

_________________________________________  __________________________
Signature of Parent/Legal Guardian (if applicable)  Date

_________________________________________  __________________________
Signature of Parent/Legal Guardian (if applicable)  Date

____________________________
Printed Name of Witness

_________________________________________  __________________________
Signature of Witness*                        Date
*The witness’s signature serves to attest that he/she provided the interpreting services and assisted with conveying explanation and questions and answers in the language spoken by the subject or the subject’s parent/legal guardian.