CHLA CHECKLIST FOR REQUIRED CONSENT LANGUAGE WHEN RELYING ON AN EXTERNAL IRB

This checklist provides general instructions about how to customize the approved Reviewing/External IRB's consent form template(s) to be compliant with CHLA required language.

Do NOT use this checklist for studies reviewed by CHLA IRB, WCG IRB, NCI CIRB or NMDP IRB.

For CHLA IRB, NCI CIRB and NMDP IRB consent instructions refer to the HSPP website.

This form identifies CHLA-consent language **that is required** for ***all*** CHLA main study consent forms, parental/guardian permission forms and pregnant partner/subject consent forms.

You must be familiar with the study to efficiently edit the consent form(s). If you are unsure about what language applies in certain sections of the consent form, please discuss with your PI and/or study team.

IMPORTANT!

- ✓ **Do not use** this checklist to edit consents for studies to be reviewed by CHLA IRB, WCG IRB, NMDP IRB or NCI CIRB, as there are different procedures in place for these IRBs.
- ✓ **Do not** submit this checklist with your ceded application in iSTAR**.**

Version 1.2, 10OCT24

Background:

When CHLA agrees to rely on the review of an external IRB (aka Reviewing IRB, IRB of Record, Central IRB, Commercial IRB, sIRB), the Reviewing IRB is responsible for the review and approval of the research protocol and the consent document(s). CHLA IRB does not review or provide oversight of the research. Therefore, study teams must ensure the Reviewing IRB approves a consent document(s) that includes the information identified below, per CA state law and/or CHLA institutional requirements. Typically, this requires study teams to make changes to the Reviewing IRB's approved consent form template(s).

CHLA study teams are to use this checklist when editing their **initial** study consent forms only. Study Teams must take into consideration whether these requirements also are applicable to assent forms and information sheets; the applicable language must be incorporated into those documents.

Additionally, some language may not be applicable to your study. Please consult with your PI/study team if needed, to confirm which language is most appropriate.

As part of the CHLA HSPP Office initial ceded clearance process, IRB Reliance Administrators will review the consent and assent form(s) prior to the study team's submission to the Reviewing IRB, to ensure that the consents are compliant with CHLA required language. The initial clearance process takes place by submitting an initial ceded study application in iSTAR. Once CHLA clearance to cede is granted, the draft consent forms may be submitted for review and approval to the Reviewing IRB.

INSTRUCTIONS

✓Use the checkboxes to assist you when revising the Reviewing IRB approved consent form templates.

☐ Obtain the IRB stamped and approved consent and assent form template(s).

☐ Have the IRB approved protocol available to refer to.

☐ Always enable **tracked (redline) changes**.
To enable tracked changes: Click on Review Tab ⇨ click 'Track Changes' and make changes ⇨ save.

☐ Formatting should be in 12pt font, unless a larger font is appropriate to the study.

☐ Starting from the top of this checklist, work your way down to insert the required language into the most appropriate sections of the consent.

☐ If additional reference or language is needed, you may refer to the CHLA Consent Form Standards and Sample Language document located on the HSPP website, if the IRB of Record or Sponsor do not have set language. *Please check with Sponsor or the Reviewing IRB first.*

NOTES

The checklist below is organized beginning with a:
- section heading/section name,
- instructions for that heading/section, and
- suggested, example or required language for that heading/section.

Please note that the IRB approved consent form template(s) may contain headings that vary in name slightly from this checklist. For example, "Key Information Summary" may be "Key Information Details". If that is the case, renaming headings is not necessary.

Additionally, the IRB approved consent form template(s) may contain similar section language to that outlined in this checklist. Minor deviations in language are acceptable, given the overall meaning of the statement does not change.

The terms "Reviewing IRB" and "IRB of Record" are used interchangeably.

KEY

Highlighted Text should be customized to the study and document, as appropriate.

• Bullets under each header are guidance to aid in completing the section.

Text in blue are instructions to the editor.

Language in [red text and brackets] are prompts that may have additional guidance for the editor, to help determine what language to insert.

Instructions for the TITLE	EXAMPLE
Required on all main consents, parental/legal guardian permission forms, and assent forms. ☐ Add "Children's Hospital Los Angeles" ☐ Customize the title for the appropriate study population. Examples: - Use "Consent" when the study includes adult subjects. - Use "Permission" when the study includes children as subjects and permission of their parent/guardian is required. - Use "Assent" when the study includes children as subjects. ○ Optional: age range can be added after 'Assent'. Ex.: *Assent 14-17* - To help with consent burden on subjects, the main consent form, parental/guardian permission, and youth assent may be combined into one document. ☐ For Pregnant Partner/Subject consent forms, please add in "Children's Hospital Los Angeles" only.	**CHILDREN'S HOSPITAL LOS ANGELES** **INFORMED CONSENT/PARENTAL PERMISSION/ASSENT TO PARTICIPATE IN A RESEARCH STUDY**
Instructions for the SUBJECT IDENTIFIER BOX	**Subject Identifier box**
Required on all main consents, parental/guardian permission forms and assent forms. ☐ Add in the CHLA Subject Identifier box.	**Subject's Name:** _____ **Birth Date:** _____ **CHLA MRN#** _____ [remove MRN line if N/A]

Instructions for KEY INFORMATION SUMMARY and Corresponding Language combined below for readability

KEY INFORMATION SUMMARY

- Required on main consent form and parental/guardian permission form greater than 4 pages long, not including the signature page.
- Key Information Section **must** come after the Study and PI information on page 1 and should be a concise summary of information that is relevant to why someone may or may not want to take part in the research.
- The entirety of this section should fit on approximately one page.
- Do not add to Assents or Pregnant Partner/Subject consent forms.
- If the approved consent template already includes a key information section that touches on every header listed, even if the language is not verbatim, then this language does not need to be inserted.

☐ Add in the following language, edit where appropriate:

You are being asked to participate in a research study. This section describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details of the research.

A person who takes part in a research study is called a research subject or research participant. If you are reading this consent form as a [parent/legal guardian and/or legally authorized representative, as applicable] "you" also refers to ["your child" (the research participant) and/or the research participant, as applicable].

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't want to take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask the research team questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

Participation will last up to ____. [indicate max time of participation, if a subject completes all procedures]

Why is this research being done?

This research is being done to find out ____. [keep to a single sentence, such as "… the best way to treat people with Cystic Fibrosis." or "…how teens think about drug use in their social group."]

What happens to me if I agree to take part in this research?
Study procedures for this research are:
[Briefly in simple layman's terms list/describe the procedures that are **key** to the research and are most likely to affect someone's decision about joining. A bulleted list is acceptable. Examples:]

- Take a study drug every week by injection under your skin,
- CT scan(s). If you are not able to lie still during the scan, you will get some medicine to help you sleep.
- Complete questionnaires about your view on drug use in teens and young adults.
- Have blood drawn by inserting a needle into a vein or by using your port.
- Complete a diary every day to record your medication use and any side effects you experience,
- Let the research team record information from your medical record related to your condition and the treatment you receive.

Could being in the research hurt me?
The most important risks or discomforts that you may expect from taking part in the research are: [Briefly list up to 5 main study risks in lay-terms most likely to affect someone's decision about joining the study – pick only the most common risks. A bulleted list is acceptable. Examples:]

- Trouble breathing,
- Feeling uncomfortable answering personal questions about yourself,
- Chemo side effects, such as feeling tired, losing hair, and nausea,
- Allergic reactions,
- Irregular heartbeat.

Please see the RISKS AND DISCOMFORTS section below for a complete list of expected risks.

Will being in this research benefit me?
The most important benefits that you may expect from taking part in this research are:
[Briefly list the reasonably expected benefits to the subject most likely to affect someone's decision about whether to join the study. Keep it to one sentence if possible. If there are no benefits, state: "It is not expected that you will personally benefit from this research."]

What other choices do I have besides taking part in this research?
Instead of being in this study, your choices may include:
[List the major approved alternative options that are available that may be advantageous to the subject. If this is a study in which there is no disease or condition being treated, ***you can eliminate*** this section from the summary. If there are no alternatives to participation, this section can be ***omitted***. Briefly list the alternatives: 2 maximum]

- Continue routine care or treatment for your condition.

- Join another clinical research study.

What else should I know about this research?
Other information that may be important for you to consider so you can decide whether to take part in this research is:
[Describe any additional information that may be important to know for this study, such as study requirements that may burden participants, example: an extensive study visit schedule, time away from home/work/school, overnight stays, etc. ***[If this does not apply, this section can be omitted.]***

Instructions for the CONFLICT-OF-INTEREST section	Corresponding COI Language
Required on main consent forms, parental/guardian permission forms, and pregnancy consent forms. • Do not add to Assent forms. • Placement of this section can be ahead of the Procedures section. • Are there any NEW conflicts to add to DisCLose? If yes, iSTAR **must** be updated and a new CMP will need to be generated. ☐ If there is no Conflict-of-Interest section in the approved template, add in the header and language as appropriate to this study.	[If there ***is*** a conflict of interest identified by CHLA COIRC, include the required language as outlined in the Conflict Management Plan.] *** [If there is ***no*** conflict of interest to disclose, include the following line:] There are no investigator conflict of interest to disclose to subjects.
Instructions for the PROCEDURES section	**Corresponding Language**
Per California state law, the following information regarding Pregnancy and HIV/STI testing is to be included, *as applicable to the study*. • Insert the applicable language into the Main Consents, and Parental/Guardian Permission forms. • Insert the applicable language into all Assent forms. *** • **Pregnancy testing:** The appropriate statement(s) should be added if the study includes pregnancy testing of children. *** • **HIV/STI testing:** The appropriate statement(s) should be added if the study includes HIV/STI testing of children.	**Pregnancy Testing** ☐ **Add to the Main Consent Form(s) and Parental Permission, when applicable:** Your child's pregnancy test results will not be shared with you. ☐ **Add to the Assent Form(s), when applicable:** Your pregnancy test results will not be shared with your parent(s). *** **HIV/STI Testing** ☐ **Add to the Main Consent Form(s) and Parental Permission, when applicable:** If your child's HIV/Sexually Transmitted Infection (STI) test is positive and they are at least 12 years of age, we will not share the results with you unless your child tells us we can. If your child's HIV/Sexually Transmitted Infection (STI) test is positive and they are under the age of 12, the results will be shared with you.

	☐ **Add to the Assent Form(s):** If your HIV/Sexually Transmitted Infection (STI) test is positive and you are at least 12 years of age, we will not share the results with your parent(s) unless you tell us we can. If your HIV/Sexually Transmitted Infection (STI) test is positive and you are under the age of 12, the results will be shared with your parent(s).
Instructions for the COSTS section	**Corresponding COSTS Language**
Required on main consent, parent/guardian permission form when/as applicable to the study. • CHLA ***prefers*** the use of the following language in place of Sponsor's. ☐ Insert the following language and edit as it applies to the research. ○ If Sponsor or the IRB requests a deviation in the language, please reach out to your Regulatory Specialist, who can review and approve minor changes to the required language that do not necessarily conflict with federal regulations, state laws, and institutional policies. ○ Regulatory specialists may escalate to Reliance Administrators to involve in language negotiations when necessary. ○ If needed, Reliance team will escalate further.	Taking part in this research study might lead to added costs to you or your insurance company. The [name(s) of drug(s)/device(s)] will be provided to you at no cost while you take part in the study. [The next sentences should be included as applicable: You and your health plan/insurance company will need to cover the cost of the infusion/injection of the study drug. It is possible that [name of drug] may not continue to be supplied while you are on the study. If this occurs, the research doctor will talk to you about your options.] Most of the [tests, procedures, and/or drugs] provided to you as part of this study are routinely used to treat your [illness/condition]. You would receive these [tests, procedures, and/or drugs] even if you were not participating in this study. You or your health plan/insurance company will need to pay for this routine care. You will also be responsible for any co-payments or deductibles required by your health plan/insurance company. Some health plans/insurance companies will not pay the costs associated with these [tests, procedures, and/or drugs] because you are in a research study. If your health plan/insurance company will not pay these costs, you will have additional expenses from being in this study, such as the costs associated with treating side effects. If you have questions about your insurance coverage, or the items you might be required to pay for, please discuss them with the study team.

	Include the following for <u>all</u> cancer clinical trials: The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below or can be provided by the study team: www.cancer.gov or 1-800-4-CANCER (1-800-422-6237).
Instructions for the INJURY section	**Corresponding RESEARCH SUBJECT INJURY Language**
Required on main consent forms and parental/guardian permission forms for studies that are <u>more than</u> minimal risk. • Do not add to assents or pregnant partner/subject consent forms. • CHLA ***prefers*** to use this language for describing treatment and compensation for research injury. • The CHLA HSPP Office will not approve language that: o Attempts to define a research-related injury (ex.: by specifically excluding pre-existing conditions and underlying disease) o Attempts to impose standards of behavior on participants (ex.: "Sponsor will pay your costs if you followed the study team directions") o Attempts to limit the amount of coverage that will be provided (ex.: "Sponsor will pay your reasonable medical costs only," or "Sponsor will not pay for lost wages") o Includes legal or not lay-friendly terminology (ex.: "Sponsor will not pay if the investigator was negligent or engaged in willful misconduct") o Discusses the Sponsor's obligations versus the institution's (ex.: "Sponsor will not pay if the study team did not follow the protocol") o Appears contractual or is potentially exculpatory (ex.: "You agree that Sponsor is not responsible")	**Use this language for non-industry sponsored or unfunded studies:** If you think you have been hurt by taking part in this study, tell the doctor in charge of this research study as soon as possible. The study doctor's name and phone number are listed on the first page of this consent form. CHLA will offer you the care needed to treat injuries directly resulting from taking part in this research. This care will be billed to you or your insurance company. You will be responsible for deductible and co-payments, or any costs not paid by your insurer. **Use this language for industry sponsored studies:** If you think you have been hurt by taking part in this study, tell the doctor in charge of this research study as soon as possible. The study doctor's name and phone number are listed on the first page of this consent form. CHLA will offer you the care needed to treat injuries directly resulting from taking part in this research. The sponsor will pay your costs for reasonable and necessary care if you have been injured because of taking part in this research study. If you receive Medicare/Medicaid and the sponsor pays for medical treatment for injury relating to your participation in this research, the sponsor will need to collect certain personal information about you, such as your name, date of birth, gender, social security number or Medicare/Medicaid identification number and information related to this research study. By signing and dating this informed consent form, you are giving permission to the sponsor to collect your personal and treatment related information and report it to the Centers for Medicare & Medicaid Services (CMS), while

☐ Insert the standard subject injury language statement as appropriate to the research. ○ If Sponsor or the IRB requests a deviation in the language, please reach out to your Regulatory Specialist, who can review and approve minor changes to the required language that do not necessarily conflict with federal regulations, state laws, and institutional policies. ○ Regulatory specialists may escalate to Reliance Administrators to involve in language negotiations when necessary. ○ If needed, Reliance team will escalate further.	participating in the study and for as long as the sponsor is required by the government to report this information. The sponsor will not use this information for any other purpose. **Must be included *regardless* of which language from above is used:** CHLA and the sponsor have no plans to pay you or give you other compensation for injury. You do not give up your legal right to pursue a claim through the legal system by signing this form.
Instructions for HIPAA LANGUAGE	**Corresponding HIPAA Language**
Required on main consent forms, parental/guardian permission forms, and pregnant partner/subject consent forms. • Do not add to assent forms. • For reasons of State law, **remove any HIPAA language** that is embedded in the main consent, parental/guardian, assent, addendum, or pregnant partner/subject consent form(s). • The separate CHLA HIPAA Research Authorization Form must be used to access, use, create or disclose PHI from CHLA medical records. Please be sure the Reviewing IRB understands this is a CHLA requirement. • The corresponding language can be added to or combined with the Confidentiality section (next section). ☐ If the template consent form includes embedded HIPAA language, delete it and replace it with the following:	You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.
Instructions Regarding CONFIDENTIALITY Language	**Corresponding CONFIDENTIALITY Language**
Required for main consent forms, parent/guardian permission and pregnant partner/subject consent forms. • Do not add to assent forms. • The confidentiality language in the consent form must include language that allows the **CHLA Institutional Review Board**	***Suggested language:***

(IRB) and CHLA authorized individuals to review study data and records to monitor the study. • Please keep in mind that template consents may have Confidentiality language combined within the embedded HIPAA language. • Often Sponsor, or the Reviewing IRB, will have templated or study specific Confidentiality language. Please check with the IRB of Record **first** if Confidentiality language is missing/needed. ☐ If the form **does** have a dedicated Confidentiality section: Insert: 'CHLA Institutional Review Board (IRB) and CHLA authorized individuals' into the list of individuals/entities that may review the study data. ☐ If the form does **not** have a dedicated Confidentiality section after removing HIPAA: ○ Reach out to Sponsor or the IRB of Record to request study specific language.	The research study team, **CHLA Institutional Review Board (IRB) and CHLA authorized individuals**, the study sponsor, and regulatory agencies such as the Food and Drug Administration (FDA), may have access to study data and records to monitor the study.
Instructions Regarding CA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS (ESBOR)	**Corresponding CA ESBOR Language**
Required for main consent forms, and parental/guardian permission forms if the study is a "medical experiment". • A "medical experiment" is defined as: "The severance or penetration or damaging of tissues of a human subject, or the use of a drug or device as defined in section 26009 of 26010 (of the Health and Safety Code), electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of such subject or otherwise directly benefitting such subject." • The CHLA IRB has interpreted this definition to include almost all interventional studies involving biomedical procedures, placebo controls, innovative therapy and/or normal volunteer subjects.	You will be given a copy of this consent form and the Research Participant's Bill of Rights to sign and keep.

• This statement can be combined with the HIPAA statement above, if both apply. ☐ Insert the following language to inform subjects that they will be given a copy of the California ESBOR to sign and keep, if applicable.	
Instructions Regarding CHLA INVESTIGATOR'S CONTACT INFORMATION	**Corresponding Language**

Required for main consent forms, parent/guardian permission forms, and pregnant partner/subject consent forms.
• You can use the Reviewing IRB's template language to convey this information, but it must include these required elements:
  ○ How to contact the CHLA investigator with any questions, concerns or complaints about the research,
  ○ How to contact the CHLA investigator in event of a research-related injury
• Assents should list how to reach the study team; however, language can vary.
 	
☐ Insert the applicable language if the reviewing IRB's template does not convey the required information.
	Language for research involving more than minimal risk:
	If you have questions, concerns, or complaints about the study, or think this research has hurt you or made you sick, talk to the CHLA research team at (XXX)-XXX-XXXX.
	
	Language for research that is minimal risk:
	If you have questions, concerns, or complaints about the study, or think this research has harmed you, talk to the CHLA research team at (XXX)-XXX-XXXX.

Instructions Regarding CHLA HSPP OFFICE CONTACT INFORMATION	**Corresponding Language**
Required for main consent forms, parent/guardian permission forms, and pregnant partner/subject consent forms. • The Reviewing IRB's template language can be used to convey this information, but the CHLA HSPP office information must **also** be listed for questions about the research or subject rights and include these required elements: ○ Questions, concerns or complaints about the research, and	**Language to be listed *after* the Reviewing IRB's contact information:** You may also call Children's Hospital Los Angeles, Human Subjects Protection Program office at (323) 361-2265.

○ Questions about their rights as a research subject ☐ Insert the applicable language if the reviewing IRB's template does not convey the required information.	
Instructions the OPTIONAL PROCEDURES SECTION	**Corresponding OPTIONAL PROCEDURES Language**
Required in the main consents, and parental/guardian permission forms when subjects must agree to optional procedures. • If there are optional procedures included in the research, subjects should provide their initials, not check marks, beside their decision. ☐ Add to all main consent, and parental/guardian permission forms, when applicable.	Subjects should provide their initials, not check marks, beside their decision _____Yes _____No [Subject] [Add if minors 14 years and older are included] _____Yes _____No [Parent/Legal Guardian/Legally Authorized Representative (for children or adults unable to consent)]

See next page for signature block instructions/guidance

Instructions for SIGNATURE BLOCKS and Corresponding Language (combined below for readability)	
Signatures Please keep in mind the following information: • Do not include signature blocks that are not applicable to the study. • Can use the Reviewing IRB's signature blocks, however, you must ensure that the appropriate signatures are captured. • If any print lines, signature lines/blocks are missing, please add. • Please keep in mind that although used interchangeably, Legally Authorized Representative (LAR) is not always the same as a Legal Guardian. If unsure, please discuss with the Reviewing IRB. • **Children who Become Adults:** Children who reach the age of majority (per CA Law, i.e., age 18, married, joined the armed forces, legal emancipation) during study participation must be re-consented as adults. If the adult subject is incapable of providing consent, surrogate consent must be obtained per CA law.	
☐ Add the following signature section for documentation of consent from adults who are capable of providing consent, and/or documentation of assent from children ages 14 to 17 years old. Age ranges for readability are determined by the IRB of Record (i.e. Simplified Assent: 7-11, 7-12, 7-13. Adolescent Assent: 12-17, 13-17, 14-17).	**Adult Subject Consent/Assent** **SIGNATURE OF RESEARCH SUBJECT** (*For adults who are capable of providing consent 18+; and children ages 14 to 17 years old who are capable of providing assent*) Your signature below indicates: • You have read this document and understand its meaning; • You have had a chance to ask questions and have had these questions answered to your satisfaction; • You consent/assent to your participation in this research study; and • You will be given a signed copy of this form. _____ Print Name of Subject _____ Signature of Subject _____ Date

☐ Add the following signature section for documentation of parental/guardian permission from the parent(s) or legal guardian(s) of children. • The number of signatures needed will vary based on the Reviewing IRB's determination. • Add in a second set of Print, Signature and Date lines if permission from two (2) parents/legal guardians are needed. • If only one parent permission is required, delete any extra signature lines.	**Parent / Legal Guardian consent** **SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S)** (*For Parent(s)/Legal Guardian(s) of subjects under the age of 18*) Your signature(s) below indicates: • You have read this document and understand its meaning; • You have had a chance to ask questions and have had these questions answered to your satisfaction; • You agree to your child's participation in this research study; • [Include the following statement if the parent completes any questionnaires or participates in other research activities related to the child:] You agree to your own participation in this research study; and • You will be given a signed copy of this form. _____ Print Name(s) of Parent(s)/Legal Guardian(s) _____ Signature of Parent/Legal Guardian _____ Date
☐ Add the following signature section for documentation of consent from a legally authorized representative for adults lacking the capacity to consent.	**Legally Authorized Representative (LAR):** **SIGNATURE OF LEGALLY AUTHORIZED REPRESENTATIVE** (*For adult subjects who are not capable of providing consent*)

	Your signature below indicates: • You have read this document and understand its meaning; • You have had a chance to ask questions and have had these questions answered to your satisfaction; • You consent to allow the subject to participate in this research study; and • You will be given a signed copy of this form. _____ Print Name(s) of Legally Authorized Representative _____ Signature of Legally Authorized Representative _____ Date
INDIVIDUAL OBTAINING/CONDUCTING THE CONSENT OR ASSENT PROCESS **Required for main consents, parental/guardian permission forms, pregnant partner/subject consent forms.** ☐ Add the following signature section for documentation of obtaining consent/permission/ assent. **** ☐ Add the Assent Instructions to the main consent form or parent/guardian permission when children and/or adults lacking the	**SIGNATURE OF INDIVIDUAL OBTAINING CONSENT/PERMISSION/ASSENT** I have explained the research to the subject and/or the subject's parent(s)/legal guardian(s)/[legally authorized representative, as applicable] and have answered all of their questions. I believe that they understand all of the information described in this document and freely give consent/permission/assent to participate. **** **Assent Instructions:** All subjects unable to consent are required to assent, unless the investigator determines that the

capacity to consent are subjects. Age ranges can vary based on the IRB of Record's determination.	capability of the subject is so limited that the subject cannot reasonably be consulted. Subjects ages 7 to 13: If assent is obtained, subjects must be given a simplified assent form. Subjects ages 14 to 17: If assent is obtained, have the subject sign this consent form, unless the investigator determines that the subject is not capable of signing. Adults subjects who are not capable of providing consent: If assent is obtained, subjects must be given a simplified assent form, or the subject can sign this consent form. **** ☐ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study. OR ☐ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted. _____ Print Name of Individual Obtaining Consent/Assent _____ Signature of Individual Obtaining Consent/Assent _____ Date

☐ Add the following section for documentation of a witness signature for every consent form, unless rationale is provided by the IRB and/or PI for omitting this section.	**SIGNATURE OF WITNESS (if applicable)** Your signature below indicates: • You were present for the entire consent conference; • The information in the consent document and any other written information was accurately explained to the subject and/or the subject's parent(s)/legal guardian(s)/[legally authorized representative, as applicable]; • The subject and/or the subject's parent(s)/legal guardian(s)/[legally authorized representative, as applicable] had an opportunity to ask questions and those questions were answered; and • The subject and/or the subject's parent(s)/legal guardian(s)/[legally authorized representative, as applicable] voluntarily signed the consent/permission/assent form in your presence. _____ Print Name of Witness _____ _____ Signature of Witness Date

Information on Documentation of Assent

Please keep in mind the following information:

- **Assent from Children/Cognitively Impaired Adults**: All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.
- **Per CA law, assent** must be obtained (not necessarily documented by the child subject) from children 7 years of age or older. Assent is not required from children who do not have the capacity to assent.
- Signatures by subjects on the appropriate forms ***may be collected***, if the subject is physically able to sign. If the subject is not physically able to sign, the assent process can be documented by the study team member conducting assent in the subject's medical record, on the main study consent form, or parent/guardian permission form, as indicated in the Assent Instructions above.

- Age ranges for readability are determined by the IRB of Record (i.e. Simplified Assent: 7-11, 7-12, 7-13. Adolescent Assent: 12-17, 13-17, 14-17).
- To ease the consent burden, Adolescents may sign on the Main consent, or the Parent/Guardian Permission form.

Children ages 7 to ~13: If assent is obtained, subjects must be given the CHLA Simplified Assent Form when the sponsor-template for the simplified assent form (7-13) is not available.

Children ages ~14 to 17: If assent is obtained, subjects may sign the subject line on the main consent or parental/guardian permission form, unless the investigator determines that the subject is not capable of signing.