CHLA Human Subjects Protection Program
General Office: (323) 361-2265
IRB Reliance Email: irbreliance@chla.usc.edu

CHLA Institution Profile Information Sheet

Version: June 1, 2022

This information sheet may be provided to a Reviewing IRB for details about CHLA's institutional profile and local context requirements.

IRB Reliance Contacts:
Shannen Nelson, RN, MSN, CCRP, CCRC
Executive Director, Clinical Research Operations
Office: (323)-361-8685
Email: shnelson@chla.usc.edu

Institutional Official:
Jodi Ogden Rivera, MBA, CRA
Vice President, Research Operations
Office: (323)-361-4661
Email: jogden@chla.usc.edu

Federal Wide Assurance #: FWA00001914
Accreditation Status: Full AAHRPP Accreditation
Most Recent Reaccreditation: September 15, 2020

CHLA Institutional Policies

- Short form consent may be used to enroll non-English speaking subjects
- CA Research Bill of Rights must be provided to subjects when studies include "medical experiments"
- Separate CHLA HIPAA Research Authorization is required when written HIPAA authorization is required
- Consent documents for use at CHLA will include required language before a study is cleared by CHLA for review by the Reviewing IRB
- Any additional CHLA department/division and ancillary reviews will be obtained before a study is cleared by CHLA for review by the Reviewing IRB
- All CHLA investigators and research staff involved with the conduct of this research have taken CHLA Collaborative IRB Training Initiative (CITI) Training

CHLA Study Population, Age of Majority, Assent from Children

CHLA Study Population: CHLA's patient population includes parents, minors (children) and adults that require a legally authorized representative

California Age of Majority: 18 years of age or older

Assent from Children: CHLA requires assent to be obtained (not necessarily documented) from children 7 years of age or older, per CA law. Assent is not required from children who do not have the capacity to assent. For children who are able to assent:

Children ages 7 to 13: CHLA requires an assent information sheet to guide the assent discussion.

- If there Is not a template assent form available from the reviewing IRB, create an assent form using the CHLA simplified assent template.

Children ages 14 to 17: CHLA requires adolescents sign the parental consent form. A separate assent form is not required.

- Adolescents should sign the parental consent form.

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. The study team must describe the re-consenting process that will be followed to Reviewing IRB. If the adult subject is incapable of providing consent, surrogate consent must be obtained per CA Law.

California Laws that Pertain to Human Research

CA Family Code

- **Minor Consent** (Sections 6920-6929): Describes when minors (children) may consent for themselves.
- **Emancipated Minors** (Sections 7000-7002; 7050-7052; 7120-7123): Defines an emancipated minor and rights of emancipated minors

CA Health and Safety Code

- **Protection of Human Subjects in Medical Experimentation Act** (Sections 24170-24179.5): Describes the informed consent process and requires that the "experimental subject's bill of rights" be provided to all research subjects in medical experiments
- **Experimental Use of Drugs and Consent for Minors Provision** (Sections 111515-111545): Minor consent is required prior to administering an experimental drug. Parental or legal guardian consent (permission) is required and minor consent (assent) is required for children 7 years of age or older.
- **Surrogate Decision Maker** (Section 24178): With respect to medical experiments that relate to the cognitive impairment, lack of capacity or serious or life-threatening diseases and conditions of research participants, investigators may obtain surrogate informed consent following a specific hierarchy for nonemergency and emergency room environments.

CA Education Code

- **Parental Consent for Children to Participate in Research** (Section 51513): For K-12 students – tests, questionnaires, surveys, or examinations containing any questions about the pupil's or the pupil's family's personal beliefs or practices in sex, family life, morality, and religion require written parental consent (permission).