June 7th, 2022

LETTER TO STUDY SPONSORS

From: CHLA HSPP Director Nelson, Shannen Digitally signed by Nelson, Shannen
DN: dc=ORG, dc=CHLA, dc=AD, dc=LA, ou=CHLA, ou=Users, ou=MC, ou=NPT, ou=Finance, cn=Nelson, Shannen, email=shnelson@chla.usc.edu
Date: 2022.06.07 16:18:04 -07'00'

Re: CHLA Institutional Review Board

This letter is in response to common requests from study sponsors for information about the CHLA Institutional Review Board (IRB).

The CHLA IRB is organized and operates in compliance with the Department of Health and Human Services (DHHS) regulations, as described in 45 CFR 46, for federally funded research and Food and Drug Administration (FDA) regulations, as described in 21 CFR Parts 50 and 56, International Conference on Harmonization (ICH) E6, and Good Clinical Practice (GCP), as applicable for FDA regulated research. In addition, the IRB operates in compliance with portions of the HIPAA Privacy Rule that apply to research, as described in 45 CFR Parts 160 and 164.

CHLA holds a Federal Wide Assurance (FWA0001914). The CHLA IRB complies with the registration requirements for both OHRP and the FDA.

The membership of the CHLA IRB complies with all federal regulatory requirements. The CHLA IRB includes voting members, including a chair and vice chairs, in addition to a variable number of alternate members. Members are selected for their willingness to serve, expertise, and familiarity with research design and procedures. Members include faculty from a wide variety of clinical disciplines and specialties to ensure adequate expertise. The IRB also includes nurses, pharmacists and others to provide needed expertise, and community members and non-scientists to represent the viewpoint of the general community and lay audience. Representatives unaffiliated with CHLA also serve on the IRB. The IRB also has a number of consultants to supplement existing expertise on the IRB. By maintaining a diverse membership, the CHLA IRB is able to review a wide variety of research studies conducted at CHLA. A copy of the CHLA IRB Member roster is available on the CHLA HSPP website: https://www.chla.org/research/hspp.

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All IRB members are required to recuse themselves from the discussion and vote of any research review where they have a conflicting interest. A member involved in research review is automatically considered to have a conflicting interest when the individual or the individual's spouse, domestic partner, children, and dependents have any of the following interests in the sponsor, product, or service being tested, or competitor of the sponsor held by the individual of the individual's immediate family:

- Involvement in the design, conduct, or reporting of the research
- Ownership interest, stock options, or other ownership interest of any value exclusive of interests in publicly-traded, diversified mutual funds.
- Compensation of any amount in the past year or of any amount expected in the next year, excluding compensation for costs directly related to conducting research.
- Proprietary interest including, but not limited to, a patent, trademark, copyright or licensing agreement.
- Board or executive relationship, regardless of compensation.
- Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center.
- Any other reason for which the individual believes that he or she cannot be independent.

While FDA regulations require study investigators to report promptly to the sponsor any adverse effect that may be reasonably regarded as caused by, or probably cause by, the drug or device under study, not all events need to be reported to the CHLA IRB. It is the policy of the CHLA IRB that study investigators report new information (reportable events) if it falls into one or more of the categories below. Reportable new information must be submitted to the CHLA IRB within 5 business days. Information that does not fall under any of these categories does not require reporting to the CHLA IRB.

1. Information that indicates a new or increased risk, or a new safety issue.
2. Harm experienced by a subject or other individual, which in the opinion of the investigator is unexpected and probably or possibly related to the research procedures.
3. Non-compliance with the federal regulations governing human research, or with the requirements or determinations of the IRB, or an allegation of such noncompliance.

More information about New Information that Requires Prompt Reporting is available on the CHLA HSPP website: https://www.chla.org/research/hspp. If you have other questions about the CHLA IRB reporting policy, please contact the HSPP Director at (323) 361-8685.