UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

June 19, 2019

Re: Common Information Requested by Sponsors

Dear UCSD and/or RCHSD Principal Investigator:

This information is being provided in response to common requests from sponsors. Please forward this letter to sponsors as needed.

Federalwide Assurances (FWA) and Institutional Review Board (IRB) Registration:

The University of California, San Diego (UCSD) holds FWA number 00004495. The UCSD FWA also covers UC San Diego Health. Rady Children's Hospital and Health Center (RCHHC) holds FWA number 00000021. The RCHHC FWA includes two components, Rady Children's Hospital San Diego (RCHSD) and Rady Children's Institute for Genomics Medicine (RCIGM). These FWAs remain in effect unless the institutions are otherwise notified.

With these FWAs, UCSD and RCHHC assure that they will meet all requirements of Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) for all human subjects research supported by the federal government.

UCSD, which by written agreement also provides IRB review services to the RCHSD component, is in compliance with both Department of Health and Human Services (DHHS) regulations at 45 CFR 46 Subpart E and Food and Drug Administration (FDA) regulations at 21 CFR 56.106 requiring IRB registration with DHHS. Sponsors may verify the current status of the UCSD and RCHHC FWAs and the UCSD IRB registrations (IORG0000210) online.

IRB Membership:

UCSD IRBs meet membership requirements of both DHHS (45 CFR 46.107) and FDA (21 CFR 56.107) regulations. UCSD does not currently make member rosters available, but roster information is properly filed with DHHS.

Furthermore, the UCSD IRBs comply with paragraphs 107(d) and 107(e) of the respective regulations, which states that "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest except to provide information requested by the IRB." Members with a conflicting interest are asked to leave the room during deliberations and voting, although they may be invited to provide information to the IRB before its deliberations or vote.

Compliance with FDA Regulations and International Conference on Harmonization (ICH) Guidelines:

All clinical investigations are reviewed in accordance with FDA regulations at 21 CFR 50 and 56 and with any IRB-related provisions of the investigational product regulations (such as 21 CFR 312 and 812). UCSD IRBs follow ICH Guideline E6 only to the extent it comports with FDA regulations.

The most recent FDA inspection of the UCSD IRBs occurred March 4-7, 2019. The inspection did not result in any significant findings and the inspector did not issue a Form 483.

Confidentiality of Medical Records:

Due to the complexities of the federal Health Insurance Portability and Accountability Act (HIPAA), the state Confidentiality of Medical Information Act (CMIA), RCHSD's status as a covered entity, and the University of California's (UC) status as a hybrid covered entity, university as well as RCHSD policy requires the use of a standard, stand-alone, UC system-wide authorization form. This form governs access to, use of and disclosure from RCHSD- and/or UC-held medical records for research purposes. A version of the UC form has been formatted for use by RCHSD.

As these standard forms may not be altered, the UCSD IRBs do not review or approve the forms on a study-by-study basis and do not stamp the forms. Principal Investigators are responsible for recording appropriate information in the blank areas (for example, the IRB number and title) before the form is discussed with and signed by research participants. RCHSD and UCSD reserve the right to request amendment to the form if it is not filled in correctly before the study may begin enrolling patients.

Standard Injury Language in Consent Forms:

UCSD and RCHSD use standard consent language to describe treatment and compensation for research injuries. This language is designed to dovetail with regulatory requirements and with institutional contracting parameters and injury policies while conveying basic and necessary information to participants. This approach allows the IRB to focus on its responsibility without time-consuming study-by-study verification of contract terms.

Sponsors often request changes to specify the conditions and process under which the sponsor will reimburse UCSD or RCHSD for costs incurred in meeting obligations to participants. The clinical trial agreement is the proper venue for addressing these issues. The standard consent language is designed to account for a number of situations and neither alters contractual provisions nor creates new obligations for sponsors. **Contractual details do not belong in the consent form.**

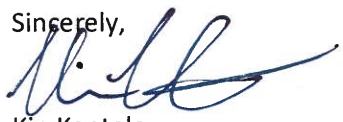
The following are the only changes to this language within the IRB's authority to accept. Please note that even if accepted by the IRB, changes to the consent do not change contractual terms:

- References to the sponsor may be deleted from this section (and only this section).
- A brief paragraph of no more than two sentences may be added describing only what the sponsor *will* cover and must correspond with clinical trials agreement terms (verification of this may delay IRB approval). The IRB cannot accept a paragraph that describes what the sponsor will not cover or that refers to third party carriers, government programs or lost wages.

The IRB does not have the authority to negotiate any other changes to this language or to accept injury language elsewhere in the consent form. Requests for changes will result in delays to IRB approval.

I hope the above information will answer your study sponsor's questions. If there are other questions, please refer your sponsor to me at 858-822-1870 or kkantelo@ucsd.edu.

Sincerely,



Kip Kantelo
Director