UNIVERSITY OF CALIFORNIA, LOS ANGELES

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OFFICE OF THE HUMAN RESEARCH PROTECTION PROGRAM
10889 WILSHIRE BLVD, SUITE 830
LOS ANGELES, CA 90095-1406

June 1, 2017

Re: Common Information Requested by Sponsors

Dear UCLA Principal Investigator:

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

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

The University of California, Los Angeles (UCLA) holds FWA number 00004642 (in effect unless the University is otherwise notified). With this FWA, UCLA assures that it 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. UCLA is in compliance with both Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations requiring IRB registration with DHHS. Sponsors may verify the UCLA FWA and IRB registrations online.

IRB Membership:

UCLA IRBs meet membership requirements of both DHHS (*45 CFR 46.107*) and FDA (*21 CFR 56.107*) regulations. Sponsors may access the current member rosters on the UCLA OHRPP website.

Furthermore, the UCLA IRBs comply with *paragraph 107(e)* of both regulations. 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. Please refer to the policy entitled *IRB Member Conflict of Interest* for additional information.

AAHRPP Accreditation:

UCLA maintains Full Accreditation status with the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) (First earned in June 2009 and renewed in June 2012).

Electronic IRB System and Documentation of IRB Approval:

All UCLA IRB review and approval activities are conducted in a web-based electronic submission and tracking system (webIRB). Applications are no longer accepted in other formats.

webIRB is a closed system designed with securities to 1) allow only appropriate individuals to execute approval activities and 2) to log the author and time for all approvals issued. The approval notices do not contain an actual signature as they are created, issued and stored electronically in compliance with FDA regulations at *21 CFR 11*.

When a PI submits a study via webIRB, the system assigns a tracking number in the format YY-NNNNNNN. This number stays with the study for the life of the study. If the study was active prior to October 1, 2010, the study would have been previously identified with a different number (in the format YY-MM-NNN-NN) until the PI transferred the study into webIRB.

IRB approval letters list those attachments approved by the IRB. Please note that letters will not indicate that the sponsor protocol or product brochure is approved. Although the IRB reviews these items in considering whether to approve the study, they often do not contain all the information that the IRB needs in order to meet its regulatory and ethical obligations, particularly with respect to locations of the study and specific details about recruitment. Furthermore, these items often contain information that is not under the purview of the IRB, such as methods of transmitting information.

Compliance with FDA Regulations and 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 drug and device regulations at *21 CFR 312 and 812*. UCLA IRBs follow International Conference on Harmonization Guideline E6 to the extent it comports with the FDA regulations.

The results of the most recent FDA inspection of the UCLA IRBs (December 4-10, 2012) indicated that "the IRB adhered to the applicable statutory requirements and FDA regulations governing the protection of human subjects."

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), and the University of California's status as a hybrid covered entity, university policy requires use of a standard UC system-wide authorization form for access to, use of and disclosure from UC-held medical records for research purposes.

As this standard form may not be altered, the UCLA IRBs do not review or approve the form on a study-by-study basis and do not stamp the form. Principal Investigators are responsible for recording the IRB number and title on the form before it is discussed and signed by research participants.

OHRPP Address Change:

As of December 19, 2016, the UCLA OHRPP office moved:

Previous Address
11000 KINROSS AVENUE, SUITE 211
LOS ANGELES, CA 90095-1694

Current Address
10889 WILSHIRE BLVD, SUITE 830
LOS ANGELES, CA 90095-1406

I hope the above information will answer your study sponsor's questions. If there are other questions please refer your sponsor to me at 310-825-5855 or kip.kantelo@research.ucla.edu.

Sincerely,

Kip Kantelo
Director