



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

April 6, 2021

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. This FWA remains 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) regulations at *45 CFR 46 Subpart E* and Food and Drug Administration (FDA) regulations at *21 CFR 56* 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, 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. Please refer to the policy entitled [IRB Member Conflict of Interest](#) on the OHRPP website for additional information if needed.

AAHRPP Accreditation:

UCLA maintains Full Accreditation status with the [Association for the Accreditation of Human Research Protection Programs, Inc. \(AAHRPP\)](#). Full Accreditation status was first earned in June 2009 and renewed in June 2017.

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. Applications are no longer accepted in other formats.

Our web-based electronic submission system 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, the system assigns a tracking number in the format YY-NNNNNNN. This number stays with the study for the life of the study.

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.

Additionally, materials that do not directly relate to the Board's ability to assess the criteria for approval are not required as part of the submission. Examples of such documents which should not be submitted with the application are:

- Subject ID cards from sponsor
- Materials used solely by the Sponsor to directly recruit participants (website/advertising, outreach materials using recruitment databases hosted by Sponsor or others outside parties, etc...)
- Validated instruments used in clinical practice
- Case Report Forms (CRF)
- Retention Materials
- Third Party Terms of Service or Privacy Agreements
- Medication Diaries and Logs

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 (R2) to the extent it comports with the FDA regulations.

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.

Signature Line on the California Bill of Rights: Per Health and Safety Code Section 24170-24179.5 – the Protection of Human Subjects in Medical Experimentation Act, holding an HHS Federalwide Assurance exempts UCLA researchers from the requirement to obtain a signature on the

California Bill of Rights (BoR). The requirement is to provide the BoR to all research subjects in medical experiments.

GDRP and CCPA:

The University of California is not subject to the EU General Data Protection Regulation (GDPR) requirements for clinical research conducted in the US or to the California Consumer Privacy Act (CCPA). However, it is understood that sponsors and collaborators may be subject to the EU or CA provisions and requirements. Therefore, as UCLA is not subject to these regulations, discussion of sponsor's and collaborator's requirements should not be included in the consent form. Instead the inclusion of a brief statement indicating a separate document outlining the use of data as it pertains to the Sponsor's or Collaborator's responsibilities should be developed and provided to the subjects. This separate document does not require review or approval by the UCLA IRB and should not contain any reference to the University of California, UCLA Researchers, or include information that either contradicts or duplicates information pertaining to privacy and confidentiality in the consent form or UC HIPAA Authorization for Research Form.

I hope the above information will answer your study sponsor's questions. If there are other questions please refer your sponsor to me at 310-825-4804 or mmimnaugh@research.ucla.edu.

Sincerely,



Mark Mimnaugh
MIRB Assistant Director