September 07, 2022

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SCHOOL OF MEDICINE/DEANS OFFICE

RE: UCI IRB #20043786 Epidemiology and Natural History of Hepatitis B, Hepatitis C and Hepatocellular Carcinoma

The above-referenced human-subjects research project has been approved by the University of California, Irvine Institutional Review Board (UCI IRB). In addition, an amendment has been approved. Specific changes approved by the IRB are noted below.

This approval is limited to the activities described in the approved protocol and extends to the performance of these activities at each respective site identified. In accordance with this approval, the specific conditions for the conduct of this research are listed below, and informed consent from subjects must be obtained unless otherwise indicated below. Additional conditions for the general conduct of human-subjects research are detailed on the attached sheet. If the approved amendment(s) includes changes to the informed consent document, the approved stamped consent form is enclosed. Please discontinue use of any previous versions of the informed consent document and use only the most updated version for enrollment of all new subjects.

NOTE: Approval by the Institutional Review Board does not, in and of itself, constitute approval for the implementation of this research. Other institutional clearances and approvals may be required. Research undertaken in conjunction with outside entities, such as drug or device companies, are typically contractual in nature and require an agreement between the University and the entity. Such agreements must be executed by an institutional official in Sponsored Projects, a division in the UCI Office of Research. The University is not obligated to legally defend or indemnify an employee who individually enters into these agreements and investigators are personally liable for contracts they sign. **Accordingly, the project should not begin until all required approvals have been obtained.**

Below is a summary of the approved changes requested:
Request: Administrative Change
Rationale: Transitioned to the 2018 Common Rule as part of the transition to the Kuali Research Protocol system

AMENDMENT NOTES: The IRB may not have approved all changes proposed in the amendment application. Review the above summary of approved changes and any revised documents provided with this letter. If a requested change does not appear in the summary or in the revised documents, the IRB did not approve that change. Please consult with Human Research Protections (HRP) Staff for further information. Unless emergent and / or necessary to protect human subjects, changes to approved protocols may not be made without prior approval by the IRB.

Questions concerning the approval of this research project may be directed to the Office of Research, 160 Aldrich Hall, Irvine, CA 92697-7600; 949-824-6068, 949-824-2125, or 949-824-0665 (biomedical committee) or 949-824-6662 (social-behavioral committee).

Important Reminder: UCI is in Research Phase 4 as of June 22, 2021. UCI's research activities will increase over time in parallel with the stages in California's Pandemic Roadmap and other public health and higher education guidance. Refer to the Office of Research webpage on Research Continuity for more details.

Minimal Risk (Expedited) Review Category(ies): 5

Melissa Camarena, MLFP
Alternate Member, Institutional Review Board

Approval Issued: September 07, 2022
Expiration Date: September 06, 2025
UCI (FWA) 00004071, Approved: January 31, 2003

IRB Determinations as Conditions of Approval:

Study Status:

1. Retrospective Review of Records from 07-01-2001 through to 12-31-2010

Informed Consent Determinations:

2. Waiver of Informed Consent Granted
3. Waiver of UC HIPAA Research Authorization Granted

APPROVAL CONDITIONS FOR ALL UCI HUMAN RESEARCH PROTOCOLS

POST-APPROVAL INVESTIGATOR RESPONSIBILITIES (PAIR):
In accordance with Federal regulations and HRP policies, there are Investigator responsibilities during the conduct, as well as after completion, of your research. Use the PAIR Worksheet to ensure adherence with your post-approval regulatory responsibilities.

UCI RESEARCH POLICIES:
All individuals engaged in human-subjects research are responsible for compliance with all applicable UCI Research Policies. The Lead Researcher (and Faculty Sponsor, if applicable) of the study is ultimately responsible for assuring all study team members adhere to applicable policies for the conduct of human-subjects research.

LEAD RESEARCHER (LR) RECORDKEEPING RESPONSIBILITIES:
LRs are responsible for the retention of protocol–related records. For more information about the LR's recordkeeping responsibilities for the preparation and maintenance of research files, visit: Post-Review Responsibilities.

APPROVED VERSIONS OF CONSENT DOCUMENTS, INCLUDING STUDY INFORMATION SHEETS:
Unless a waiver of informed consent is granted by the IRB, the consent documents (consent form; study information sheet) with the UCI IRB approval stamp must be used for consenting all human subjects enrolled in this study. Only the current approved version of the consent documents may be used to consent subjects. **Approved consent documents are not to be used beyond the expiration date provided on the IRB approval letter.** IRB approved materials can be found in Kuali Research Protocols (KRP) in the attachments section.

PROTOCOL EXPIRATION:
The UCI IRB approval letter references the protocol expiration date under the IRB Chair's signature authorization. A courtesy email will be sent prior to expiration reminding the Lead Researcher to apply for renewal**. It is the LR's responsibility to apply for renewal to ensure continuous approval throughout the conduct of the study.** Lapses in approval must be avoided to protect the safety and welfare of enrolled subjects.

AMENDMENTS:
The UCI HRP does not require the submission of minor changes to exempt research. For those studies in which a lead researcher (and faculty sponsor (FS), if applicable) has submitted to and received UCI IRB confirmation of exemption, minor changes may be made without notifying the UCI IRB. For more information about this including what constitutes a minor change versus a change that must be prospectively submitted for review and approval by the UCI IRB via a formal amendment, visit: Post-Review Responsibilities.

CHANGES IN FINANCIAL INTEREST:
Any changes in the financial relationship between the study sponsor and any of the investigators on the study and/or any new potential conflicts of interest must be reported immediately to the UCI Conflict of Interest Oversight Committee (COIOC). If these changes affect the conduct of the study or result in a change in the text of the approved informed consent document, these changes must also be reported to the UCI IRB via an amendment.

GRANT CONGRUENCE REVIEWS:
If this human subject research is funded or supported by a Federal Agency, it is the LR's responsibility to submit amendments, as necessary, to assure that the IRB protocol continues to be identical in principle and congruent with the scope of work outlined in the proposal application.

REPORTING A PROBLEM:

In accordance with Federal regulations and HRP policies, only internal (where UCI serves as the IRB of record), Unanticipated Problems must be reported to the UCI IRB. Unanticipated Problems should also be reported to the UCI IRB when UCI is relying on an external IRB, and the incident occurred at UCI or the incident occurred at an offsite location on a study conducted by a UCI LR. Unanticipated Problems must be submitted to the IRB within 5 business days upon the LR's knowledge of the event. For more information, visit: Post-Review Responsibilities.

POSTING OF THE INFORMED CONSENT DOCUMENT:
Clinical trials initially approved by the IRB on or after January 21, 2019, must post one (1) IRB-approved clinical trial consent form at a publicly available federal website. The consent form must be posted after recruitment closes, and no later than 60 days after the last study visit. For additional guidance, refer to the OHRP FAQs on Informed Consent.

CLOSING REPORT:
A closing report should be filed with the UCI IRB when the research concludes. For more information, visit: Post-Review Responsibilities.