University Research
UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

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University of Colorado Hospital | Denver Health Medical Center | Colorado Prevention Center | Children's Hospital Colorado | Denver Health and Hospital Authority | VA Eastern Colorado Health Care System (Denver VAMC)

Certificate of Approval

20-Feb-2019

Title:	Diagnostic Accuracy of ERCP and Liver Biopsy in evaluation of elevated liver function tests in post-liver transplant patients
Subject:	COMIRB Protocol 18-0402 Continuing Review
Investigator:	Samuel Han
Sponsor(s):	None~
Effective Date:	14-Feb-2019
Expedited Category:	5

Submission ID: CRV001-1

SUBMISSION DESCRIPTION:

Study Status: Data Analysis (Closed to Enrollment of New Subjects)

This study was reviewed and approved under the “2018 Requirements” of the Federal Policy for the Protection of Human Subjects.

If continuing review is required for your research, your submission is APPROVED until the expiration date listed above. The investigator will need to submit this research for Continuing Review at least 30 days prior to the expiration date. If a study's approval expires, investigators must stop all research activities immediately (including data analysis) and contact the COMIRB office for guidance

If continuing review is not required for your research, your study has not been assigned an expiration date.

Regardless of continuing review, you are required to submit changes to your research for approval prior to implementing those changes. You are required to report unanticipated problems and serious or continuing noncompliance to COMIRB. When your research is complete you must report the study closure to COMIRB.

Your responsibilities as Principal Investigator are posted here:
http://www.ucdenver.edu/research/Research%20Administration%20Documents/Responsibilities-of-Investigators.docx

REVIEW DETAILS– Please read carefully:

The following documents have been reviewed as part of this approval:
1. PDF CR Form (CRV001)
2. Application Form v 2.17.18
3. Cover Letter v 12.27.18

4. Mentor Mentee Form 18-0402 1.2.19
5. Personnel eForm CRV v 12.27.18
6. Protocol v 2.17.18

If red-line changes were made, the tracked changes and clean versions have been uploaded into eRA (InfoEd). If the PI disagrees with these changes, submit a change form to COMIRB with the revised documents.

Click here to your submission: Submission Page

Study personnel are approved to conduct the research as described in the above documents approved by COMIRB

Information on how to submit changes (amendments) to your study, reports of unanticipated problems, and request for study closure to COMIRB can be found on the COMIRB website
http://www.ucdenver.edu/research/comirb/submissions/Pages/default.aspx

For the duration of this research the investigator must:

- Submit any change in the research design, investigator, and any new or changed study documents (including new/changed consent forms, questionnaires, advertisements, etc.) to COMIRB and receive approval before implementing the changes
- Use only a copy of the COMIRB-approved, stamped Consent and/or Assent Form. The investigator bears the responsibility for obtaining Informed Consent from all subjects as required by COMIRB prior to the start of study procedures. COMIRB REQUIRES that the subject be given a copy of the consent and/or assent form after it is signed.
- Inform COMIRB immediately of any Unanticipated Problems that are unexpected and related to the study in accordance with COMIRB Policies and Procedures.
- Remain actively engaged in the conduct of the research. The investigator must ensure that all enrolled participants are appropriate for the study prior to study procedures beginning.

As part of this review it was determined that for this research:

1. Risks to subjects are minimized.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with, and to the extent required by, §46.116.
5. Informed consent will be appropriately documented in accordance with, and to the extent required by, §46.117.
6. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. Appropriate safeguards are in place to protect potentially vulnerable populations from coercion and undue influence.

Please reply to the email containing this letter, contact the COMIRB Help Desk at COMIRB@ucdenver.edu or call 303-724-1055 if you have questions or concerns.

Sincerely,

UCD Panel C