

April 10, 2013

Steven Herrine, M.D.
Medicine/Gastroenterology-Hepatology

Dear Dr. Herrine:

The Institutional Review Board (IRB) has reviewed the involvement of humans as research subjects in your study entitled:

“Retrospective Analysis of Clinical, Laboratory, Radiographic, and Pathology Features of Patients with Hepatocellular Carcinoma Predicting Carcinoma Predicting Post-Transplant Clinical Outcome” (Departmental) 45 CFR 46.110 (5-retrospective record/chart/database/film review; IDs required) Control #13D.153

In accordance with Federal-Wide Assurance #00002109 to the U.S. Department of Health and Human Services, this study was administratively approved for one year on 04.10.13 Board #153 will be notified at the 04.11.13 meeting.

EXPEDITED/NEW (X)

REVIEW

PURSUANT TO TITLE 45 CODE OF FEDERAL REGULATIONS PART 46.116 (d), THE IRB HAS GRANTED A WAIVER OF INFORMED CONSENT.

This approval expires 04.09.14 one year from the original approval date of the study, unless suspended or terminated earlier by action of the IRB. Prior to the expiration date, a report (Form OHR-9) must be submitted to the IRB summarizing progress on the study during that period.

Any injury and/or unanticipated problem involving risks to the human research subjects not included in the written consent form must be reported promptly to the IRB using via the electronic Serious Adverse Events reporting system or by using Form OHR-10 OFF-SITE for adverse events occurring off-site. This report should describe the event, evaluate its probable relationship to the experimental treatment received by the subject, and summarize the resulting outcome of the event.

Any proposed change in the protocol or in the written consent form must be submitted to the IRB for review and approval using Form OHR-12 before the proposed change can be implemented.

This approval verifies that the IRB operates in accordance with applicable federal, local and institutional regulations that govern IRB operations.

Sincerely yours,



Kyle Conner, M.A., CIP
Associate Director
Division of Human Subjects Protection

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