



HonorHealth Research Institute

DATE: September 12, 2016

TO: Janet Reiser, MD

FROM: HonorHealth Institutional Review Board

PROJECT TITLE: [910650-1] Phase 2 Active Comparator Clinical Trial of HepAssure™ Medical Food Protocol for Subjects with Detectable Hepatic Fibrosis with Liver Stiffness Measurement (LSM) of 10 kPa to 35 kPa by FibroScan™ Diagnostic Device

SUBMISSION TYPE: New Project

ACTION: APPROVED

APPROVAL DATE: September 8, 2016

EXPIRATION DATE: August 23, 2017

REVIEW TYPE: Full Committee Review

Thank you for your submission of New Project materials for this project. The Institutional Review Board has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission. This submission has received Full Committee Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require that each participant receives a copy of the consent document.

Please note that any revision to previously approved materials must be approved by this committee prior to initiation. Please use the Modifications/Changes form for this procedure.

All UNANTICIPATED PROBLEMS involving risks to subjects or others (UPIRSOs) and SERIOUS and UNEXPECTED adverse events must be reported promptly to this office. Please use the Adverse Events form for this procedure.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this office.

Please note that all research records must be retained for a minimum of three years after the completion of the project.

If you have any questions, please contact Julie Washington at 480-323-3071 or julie.washington@honorhealth.com. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within HonorHealth Institutional Review Board's records.