WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

Office of Research

INSTITUTIONAL REVIEW BOARD.

MEMORANDUM

To: Andrew DeLemos
Atrium/Carolinas Healthcare System

From: Jeannie Sekits, Senior Protocol Analyst,
Institutional Review Board

Date: 7/6/2022

Subject: Human Protocol: IRB00082128
Hepatocellular carcinoma (HCC) in Patients with Underlying Nonalcoholic Fatty Liver Disease (NAFLD)

Study Documents:
«phoneScriptsName»

This is to confirm for your record that the Institutional Review Board reviewed your progress report and consent form, containing compounded HIPAA authorization language, if applicable, for the above-named protocol. IRB approval was activated on 7/6/2022 and will expire on 7/5/2023. If the protocol is to remain active longer, a written request for renewal, together with a summary progress report, and a copy of the current consent form, if applicable, should be submitted to the Board at least one month prior to expiration.

Please provide a final report to the Board when the project is completed and Board approval can be terminated.

The Wake Forest School of Medicine IRB is duly constituted, has written procedures for initial and continuing review of clinical trials; prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with requirements of FDA regulations 21 CFR Parts 50 and 56, HHS regulations 45 CFR 46, and International Conference on Harmonisation (ICH) E6, Good Clinical Practice (GCP), as applicable. WFSM IRB is registered with OHRP/FDA; our IRB registration numbers are IRB00000212, IRB00002432, IRB00002433, IRB00002434, IRB00008492, IRB00008493, IRB00008494, and IRB00008495.
WFSM IRB has been continually fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2011.

Medical Center Boulevard, Winston-Salem, NC 27157-1023 (336) 716-4542 / fax (336) 716-4480