NEBRASKA'S HEALTH SCIENCE CENTER

Office of Regulatory Affairs (ORA)
Institutional Review Board (IRB)

June 13, 2019

Yazen Alnouti, Ph.D
COP Pharmaceutical Science
UNMC - 6025

IRB # 487-10-EP

TITLE OF PROPOSAL: SULFATION OF BILE ACIDS AS A BIOMARKER FOR HEPATOBILIARY DISEASES

DATE OF EXPEDITED REVIEW: 06/13/2019

VALID UNTIL: 06/13/2020

EXPEDITED CATEGORY OF REVIEW: 45 CFR 46.110; 21 CFR 56.110, Category 2,3,5

SUBPART B CATEGORY OF REVIEW: 45 CFR 46.204

The UNMC IRB has completed its review of the Application for Continuing Review for the above titled research project including the complete protocol file and has expressed it as their opinion that you have provided adequate safeguards for the rights and welfare of the subjects involved in this study and are in compliance with HHS regulations (45 CFR 46) and FDA regulations (21 CFR 50.56) as applicable.

This letter constitutes official notification of the re-approval of your research project (Application V.9 & Adult CF V.6) by the IRB for the IRB approval period indicated above. You are therefore authorized to continue this study. **All copies of the outdated consent form must be discarded immediately.** The original IRB stamped form may be archived.

We wish to remind you that, under the provisions of the Federal Wide Assurance (FWA 00002939) from the Institution to HHS, the Principal Investigator is directly responsible for keeping the IRB informed of any proposed changes involved in the procedures or methodology in the protocol and for promptly reporting to the Board any unanticipated problems involving risks to the subjects or others.

In accordance with HRPP policies, this project is subject to periodic review and monitoring by the IRB and, as part of their monitoring, the IRB may request periodic reports of progress and results. For projects which continue, it is also the responsibility of the Principal Investigator to initiate a request to the IRB for Continuing Review of the research project in consideration of the IRB approval period.

On Behalf of the IRB,

Signed on: 2019-06-13 12:34:00.000

Bobbi Chapman, MS
IRB Administrator/Continuing Review Coordinator
Office of Regulatory Affairs