NEBRASKA'S HEALTH SCIENCE CENTER

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

May 20, 2017

Marco Olivera-Martinez, MD
Int Med GI
UNMC - 2000

IRB # 304-17-EP

TITLE OF PROPOSAL: Impact of pre-existing psychosocial problems and poly-substance abuse on the clinical outcomes after liver transplantation: Stratification of high-risk patient population

DATE OF EXPEDITED REVIEW: *05/05/2017*

DATE OF FINAL APPROVAL: 05/20/2017 **VALID UNTIL:** 05/05/2019

CLASSIFICATION OF RISK: Minimal

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

The UNMC IRB has completed its review of the above-titled protocol and informed consent, including any revised material submitted in response to the IRB's review. The Board has expressed it as their opinion that you are in compliance with HHS Regulations (45 CFR 46), applicable FDA Regulations (21 CFR 50, 56), and HRPP policies and you have provided adequate safeguards for protecting the rights and welfare of the subjects to be involved in this study. The IRB has, therefore, granted unconditional approval of your research project. This letter constitutes official notification of the final approval and release of your project by the UNMC IRB, and you are authorized to implement this study as of the above date of final approval.

Please be advised that the IRB accepted the justification presented in Addendum J for a waiver or alteration of consent and has therefore granted a waiver of consent under the provisions of 45 CFR 46.116(d) and HIPAA Privacy Rule (as applicable).

Finally, under the provisions of this institution's Federal Wide Assurance (FWA00002939), the Principal Investigator (PI) is directly responsible for submitting to the IRB any proposed change in the research or the consent document(s). In addition, any unanticipated adverse events or other problems related to the research which involve risk to the subject or others must be promptly reported to the IRB. This project is subject to review and monitoring by the IRB and, as part of their monitoring, the IRB may request reports of progress and results. For projects which continue beyond one year, it is the responsibility of the Principal Investigator to initiate a request to the IRB for continuing review and re-approval of the research project.

On Behalf of the IRB,

Signed on: 2017-05-20 11:16:00.000

Gail Kotulak, BS, CIP
IRB Administrator III
Office of Regulatory Affairs