Principal Investigator Notification:

From: Mayo Clinic IRB

To: Lewis Roberts

CC: Nasra Giama
Lewis Roberts
Nicha Wongjarupong

Re: **IRB Application #:** 17-001912

Title: BALAD and BALAD-2 score as predictors of mortality and cancer recurrence in post-transplant and post-hepatectomy hepatocellular carcinoma patients

IRBe Protocol Version: 0.04
IRBe Version Date: 3/16/2017 4:48 PM
IRB Approval Date: 3/30/2017
IRB Expiration Date: 3/29/2020

The above referenced application is approved by expedited review procedures (45 CFR 46.110, item 5). This approval is valid for a period of 3 years. The Reviewer conducted a risk-benefit analysis, and determined the study constitutes minimal risk research. The Reviewer determined that this research satisfies the requirements of 45 CFR 46.111.

The Reviewer approved waiver of the requirement to obtain informed consent in accordance with 45 CFR 46.116 as justified by the Investigator, and waiver of HIPAA authorization in accordance with applicable HIPAA regulations.

The Reviewer approved the accrual of 400 subjects and to review data that exist between January 1, 2000 and December 31, 2016.

AS THE PRINCIPAL INVESTIGATOR OF THIS PROJECT, YOU ARE RESPONSIBLE FOR THE FOLLOWING RELATING TO THIS STUDY:
1) When applicable, use only IRB approved materials which are located under the documents tab of the IRBe workspace. Materials include consent forms, HIPAA, questionnaires, contact letters, advertisements, etc.
2) Submission to the IRB of any modifications to approved research along with any supporting documents for review and approval prior to initiation of the changes.
3) Submission to the IRB of all Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO).
4) Compliance with Mayo Clinic Institutional Policies.

Mayo Clinic Institutional Reviewer