

INSTITUTIONAL REVIEW BOARD APPROVAL FORM

Principal Investigator Notification:**From:** Mayo Clinic IRB**To:** Lewis Roberts**CC:** Priscilla Flynn

Nasra Giama

Keith Knutson

Teresa Mettler

Gloria Petersen

Lewis Roberts

Abdirashid Shire

Re: IRB Application # [09-001670](#)

Study Title: Hepatitis B and Hepatitis C as Risk Factors for Hepatocellular Carcinoma in Somali Immigrants: Role of Viral Genetics and the Immune Response

Please note that all correspondence (modifications, continuing reviews, reportable events) related to this application must be submitted electronically in the IRBe system.

The following is an excerpt from the minutes of the Mayo Clinic Institutional Review Boards (IRB-C) meeting dated 7/2/2010:

DECISION: The Committee reviewed and approved the above referenced application and noted that all requirements for approval of research (45CFR46.111) were met. This approval is valid for one year unless during that time the IRB determines that it is appropriate to halt or suspend the study earlier. IRB approval will expire on July 01, 2011. The Committee approved the accrual of 180 male and female adult subjects. The Committee approved the following sites to conduct this study: Mayo Clinic in Rochester.

REVIEW: The Committee noted receipt of the protocol dated May 28, 2010. The Committee noted that the Data Safety Monitoring Plan was appropriate for the study. Funding for the study is provided by KL2 Mentored Career Development Award. The Committee approved remuneration up to \$20.00.

CONTACT MATERIALS: The Committee approved the questionnaires and telephone script as written and the recruitment letter with minor edits.

CONSENT: The Committee approved the consent form (00) with minor edits. The final approved consent form will be provided under the Documents tab of the main study workspace in IRBe.

REMINDERS: The Committee:

- Reminds the investigator that, per HIPAA regulations, protected health information collected during the screening of prospective subjects who do not subsequently sign the consent form and/or HIPAA authorization form must be discarded or de-identified.
- Refers this study to the expedited review procedures for continuing review.

Clarke, Bart L. M.D., Chair
Tamyra Dull , Correspondent
Mayo Clinic Institutional Review Boards

IRB-C