



Dr. Zaigham Ababs
Liver Stomach Clinic
3rd Zamzama Commercial Lane
DHA, Karachi

Date: 11th January 2012

Subject: Allied Med Ethics IRB Approval for Study Protocol Number ML25746

Dear Dr. Zaigham,

With reference to your application dated 05th January 2012 for above noted subject. We would like to inform you that Allied Med Ethics Independent Review Board upon reviewing the study document noted below has approved to conduct the clinical study entitled **"To evaluate the efficacy of pegylated interferon alpha -2 with entecavir in the treatment of patients with chronic hepatitis D infection"**. This study is being conducted at Liver Stomach Clinic, 03rd Zamzama Commercial Lane, DHA, Karachi, Pakistan.

Documents Reviewed and Approved:

- Protocol Number (ML25746) Synopsis templates version 1.2, (effective 11 November 2010)
- Informed Consent Forms, English Version, (Co-treatment with Pegylated interferon alfa 2A and Entecavir in Chronic Hepatitis D (COPE-D))
- Informed Consent Forms, Urdu Version (Co-treatment with Pegylated interferon alfa 2A and Entecavir in Chronic Hepatitis D (COPE-D))
- Principal Investigator CV

The Allied Med Ethics Review Board approves this study from an ethical point of view. Please note that approval given by Allied Med Ethics is valid for a period of one year only. You must inform Allied Med Ethics when the study has been completed. If you are unable to complete your study within one year validation period, you will be required to write to Allied Med Ethics to request an extension or you will need to re-apply to get an IRB approval.

The Allied Med Ethics Independent Review Board abides by ICH GCP, P-GCP and local regulatory requirements. As per the same guidelines, you are requested to keep us informed about the progress of the study and about any serious adverse events or significant change which occurs in connection with this study and / or which may alter its ethical consideration must be reported immediately to Allied Med Ethics. Any study progress and safety updates, amendments or interim reports need to be forwarded to Allied Med Ethics upon availability.

Best Regards

Dr. Faisal Afzal (MBBS, MCPS)
Chairman, Allied Med Ethics
Shan Hospital
ST-19, Block-5,
Gulshan-e-Iqbal, Rashid Minhas Road

APPROVED
11 JAN 2012
Sign:
ALLIED MEETHICS
Independent Ethics Review Board

cc: List of members attached