

Name of journal: World Journal of Hepatology

ESPS Manuscript NO: 16069

Columns: Retrospective study

2/27/2015

Dear Editor,

You will find below the Institutional Review Board letter from our institution the Cleveland Clinic. It indicates the approval of waiver of Informed Consent and waiver of HIPAA authorization for our retrospective study.

Sincerely,

A handwritten signature in cursive script that reads "Clara Antoury".

Clara Antoury, MD

Department of Internal Medicine,

Cleveland Clinic Foundation

9500 Euclid Avenue, Cleveland, OH, 44195

Tel: 440-3543714

Email: antourc@ccf.org



Institutional Review Board
AAHRPP Accredited

December 3, 2013

Naim Alkhouri, M.D.

RE: IRB # 13-1471: Medical Records: Hepatocellular Carcinoma in Alpha-1 Antitrypsin deficiency

Dear Dr. Alkhouri:

Your new study application received on 12/3/2013 was processed under expedited review and **approved for the period 12/3/2013 through 12/2/2014** with use of Medical Records Application 12/3/2013; Protocol 12/3/2013 and Data Collection Sheet 12/3/2013.

This is a minimal risk study using data collected for routine clinical practice.

A waiver of Informed Consent and waiver of HIPAA authorization is approved. Sharing or releasing identifiable data to anyone other than the study team is not permitted without additional IRB approval.

Any changes or amendments require IRB review and approval prior to implementation. Unanticipated problems including adverse events and deviations are to be reported in accordance with IRB Policy 60: Adverse Events and IRB Policy 70: Unanticipated Problems.

This study may not continue beyond the approved expiration date. Submit a renewal application up to 30 days prior to expiration to allow sufficient time for IRB review or a completion report for closure.

Sincerely,

A handwritten signature in black ink that reads "Daniel Beyer". The signature is fluid and cursive, with a long horizontal stroke at the end.

Daniel Beyer, MS, MHA, CIP
Executive Director, IRB and Human Research Protections

DB/rf

Expiration Date: 12/2/2014