INSTITUTIONAL REVIEW BOARD STATEMENT

Name of Journal: *World Journal of Hepatology*
ESPS Manuscript NO: 27502
Manuscript Type: Original Article
Observational Study

Factors associated with success of telaprevir- and boceprevir-based triple therapy for hepatitis C virus infection

Kian Bichoupan, Neeta Tandon, Valerie Martel-Laferriere, Neal M Patel, David Sachs, Michel Ng, Emily A Schonfeld, Alexis Pappas, James Crismale, Alicia Stivala, Viktoriya Khaitova, Donald Gardenier, Michael Linderman, William Olson, Ponni V Perumalswami, Thomas D Schiano, Joseph A Odin, Lawrence U Liu, Douglas T Dieterich, Andrea D Branch

Below you will find the approval for the Icahn School of Medicine Institutional Review Board for the project submitted.

Icahn School of Medicine at Mount Sinai

Institutional Review Board
Program for the Protection of Human Subjects

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APPROVAL OF RESEARCH

Date: 6/3/2015

To: **Andrea D. Branch, PhD (andrea.branch@mssm.edu)**

On **5/29/2015**, an Institutional Review Board of the Mount Sinai School of Medicine, in accordance with Mount Sinai's Federal Wide Assurances (FWA#00005656, FWA#00005651) to the Department of Health and Human Services approved the following human subject research from **5/29/2015** until **5/19/2016** inclusive:

Type of Review:	**Continuing Request for Approval**
Project Title:	**Outcomes in Liver Disease Patients with and without HIV Co-Infection**
Investigator:	**Andrea D. Branch, PhD (Dept: ME - Medicine) (Div: ID - Infectious Diseases)**
Project Information:	**HS#: 11-01334** **GCO#1: 10-0032(0001) Icahn School of Medicine at Mount Sinai** **GCO#2: 10-0032(0003) Janssen**

Sites:	**Beth Israel, Mount Sinai, Roosevelt Hospital, St. Luke Hospital**
IND or IDE (if any):	**No INDs;No IDEs;**
Submission Details (if any):	**Personnel Changes:** **Lawrence Ku, Jillian Nickerson, Badr Aljarallah, Sanders Chang, Bevin Hearn, Rachana Yalamanchilli have been removed from the study.** **Adiba Azad, Sweta Chekuir, Deepika Devuni, Alisse Doherty Hannaford, M. Isabel Fiel, Naveen Ganjoo, Joshua Hartman, Yujin Hoshida, Mark Miller, Ankur Panchal, Neal Patel, Chiara Rocha are being added to the study.**

Between **4/4/2016** and **4/7/2016**, or within 30 days prior to study close, whichever is earlier, you are to submit a completed FORM HRP-212: Continuing/Final Review Progress Report and required attachments, in order to request continuing IRB approval or study closure. If IRB continuing review approval is not granted before the expiration date of **5/19/2016**, IRB approval of this research expires on that date.

- The IRB has determined that this research involves no greater than MINIMAL RISK. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45CFR.46.102; 21CFR50.3k).
- The IRB approved this research under **expedited review procedure category(ies) 5**

The MSSM IRB approved the request for Waiver of Authorization for use and disclosure of PHI for this project on 1/25/2012. This request was reviewed and approved by expedited review procedures. The IRB determined that the waiver of authorization satisfies the following criteria:

1. The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of:
    i. an adequate plan to protect the identifiers from improper use and disclosure;
    ii. an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
    iii. the PI has provided adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study or for other research for which the use or disclosure of PHI would be permitted by the Privacy Regulations.
2. The research could not practicably be conducted without the waiver;
3. The research could not practicably be conducted without access to and use of the PHI.

The PHI for which access has been determined to be necessary for this project [which are the minimum necessary] include the following: date of birth, name, medical record number and health information on patients infected with Hepatitis B and/or Hepatitis C, with and without HIV, which therapies were used and the length of time patients undenwent treatment for Hepatitis B and/or Hepatitis C or patients with sicle cell disease and patients with the other blood diseases that require transfusion. HIV-related infonmation (CD4 cell count, HiV viral load and antiretroviral therapies) will be extracted, clinical and lab values (at basetine and later on during and after treatment) related to chronic hepatitis infection and metabolic syndrome:

gender, ethnicity, weight, BMI, blood pressure, social habits, medications, CBC, AST, ALT, GGT, lipid panei, fasting glucose, fasting total insulin, hemoglobin Aic, liver biopsy results, HCV viral load, HBV viral load, HBV-related antigens and antibodies.

- The request for access to decedent PHI was approved on 1/25/2012
- The request for waiver of informed consent was approved on 5/29/2015. This waiver is granted for all research procedures.
- IRB re-approval was not obtained prior to the expiration date. It must be noted that if any subjects were entered or research procedures conducted between 5/19/2015 and the final approval date of this renewal, the research was unauthorized by the IRB.

In conducting this research you are required to follow the requirements listed in the **Investigator Manual**. If stamped approved consent forms are attached, use copies of these forms to document consent. IRB approval does not constitute or imply institutional support for the conduct of this research. Additionally, all required local committee approvals at each **research affiliate** site must be obtained prior to initiation.

Thank you,

Nadia Andrianov, MS, CIP
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