Subject: FW: Approval of Continuing Review of Research Project GCO#10-0032
Date: Thursday, July 27, 2017 at 6:14:19 PM Eastern Daylight Time
From: Crismale, James
To: Crismale, James
Attachments: APPROVAL OF RESEARCH GCO#1: 03-0425(0002) .eml, APPROVAL OF RESEARCH for GCO 10-0679.eml, image001.jpg

From: King, Keith
Sent: Tuesday, June 13, 2017 10:28 AM
To: Branch, Andrea
Cc: King, Keith
Subject: Approval of Continuing Review of Research Project GCO#10-0032

Mount Sinai

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Mount Sinai Brooklyn
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APPROVAL OF RESEARCH

Date: 6/13/2017

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

On **6/13/2017**, 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 **6/13/2017** until **5/19/2018** 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, Mount Sinai West, St. Luke Hospital**
IND or IDE (if any):	**No INDs;No IDEs;**

Submission Details (if any):	**1) Modification to the protocol by indicating that the study group will range in size up to 80,000 (rather than 70,000 in the previously-approved version). This change is requested because the population of patients with liver disease receiving care at Mount Sinai has increased.** **2) Delete the following investigators from the study team: Sweta Chekun, Noah Cohen, Alisse Doherty-Hannaford, Nicolas Goossens, Joshua Hartman, Arielle Klepper, Donald Kotler, Jasnit Makkar, Michel Ng, Alicia Stivala Brill, Alyssa Trochtenberg, and Daniel Waintraub.** **3) Add the following investigators to the study team: Sherley Abraham, Deeva Berera, Danielle Carter, Michael Crane, Claudia Henschke, Artit Jirapatnakul, Li Li, Suresh Misra, Brian Rice, Adam Winters, and Brooke Wyatt.**

Between **4/3/2018** and **4/7/2018**, 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 **5/19/2018**, 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 underwent treatment for Hepatitis B and/or Hepatitis C or patients with sickle cell disease and patients with the other blood diseases that require transfusion. HIV-related information (CD4 cell count, HIV viral load and antiretroviral therapies) will be extracted, clinical and lab values (at baseline 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 panel, fasting glucose, fasting total insulin, hemoglobin A1c, liver biopsy results, HCV viral load, HBV viral load, HBV-related antigens and antibodies, liver volume.

- The request for access to decedent PHI was approved on 1/25/2012
- The request for waiver of informed consent was approved on 6/13/2017. This waiver is grante 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 5/19/2017 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 **Investigato 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.

Keith J. King, CIP
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