**From:** Richmond, Megan
**To:** Ang, Celina
**Cc:** Dharmapuri, Sirish (MSH)
**Subject:** APPROVAL OF RESEARCH GCO 18-2400
**Date:** Monday, December 17, 2018 11:28:18 AM

Mount Sinai

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Mount Sinai Beth Israel
Mount Sinai Brooklyn
The Mount Sinai Hospital
Mount Sinai Queens
New York Eye and Ear Infirmary of Mount Sinai
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**Program for the Protection of Human Subjects**
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# APPROVAL OF RESEARCH

Date: 12/17/2018

To: **Celina Ang, (celina.ang@mssm.edu)**

On **12/13/2018**, 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 **12/13/2018** until **11/27/2019** inclusive:

| | |
|---|---|
| Type of Review: | **Modification Request for Approval** |
| Project Title: | **Retrospective review of clinical outcomes of patients treated for intermediate/advanced stage hepatocellular carcinoma with Sorafenib in the second line after progression on Nivolumab at the Mount Sinai Hospital.** |
| Investigator: | **Celina Ang (Dept: ME - Medicine) (Div: HO - Hematology/Oncology)** |
| Project Information: | **HS#: 18-01171**<br>**GCO#1: 18-2400(0001) ISMMS** |
| Sites: | **Mount Sinai** |
| IND or IDE (if any): | **No INDs;No IDEs;** |
| Submission Details (if any): | **Adding MRN to the linker sheet and requesting access to patient MRNs.** |

Between **10/11/2019** and **10/16/2019**, 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 **11/27/2019**, 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 11/28/2018. 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: 1. Patient demographics: MRN, date of birth, gender, race/ethnicity
2. Hepatocellular carcinoma characteristics:
a. Date of histopathologic or radiographic diagnosis
b. BCLC stage at diagnosis – presence of macrovascular invasion, extrahepatic disease and site (including presence or absence brain metastasis).
c. BCLC stage at start of systemic therapy
d. Risk factors/etiology: Hepatitis B and Hepatitis C status, alcohol, NASH, other
e. Child Pugh score at start of first and second line therapy
f. Presence or absence of ascites and diuretic responsiveness.
g. History of Esophageal or gastric varices.
h. AFP at baseline and at start of first and second line therapy
i. Molecular data (in-house or commercial laboratory panel) where available
j. Patient home medications.
3. Therapy:
a. Locoregional therapies received and dates
b. Start and finish dates of nivolumab
c. Start and finish dates of second line systemic therapy – sorafenib, other agents
d. Treatment interruptions, adjustments, discontinuations for reasons other than disease progression
e. Best response on therapy and date
4. Outcomes
a. Date of radiographically confirmed disease progression on Nivolumab
b. Date of radiographically confirmed disease progression on sorafenib
c. Date of last follow-up
d. Vital status
i. Alive – disease status
ii. Deceased - date of death and cause (cancer vs non-cancer related)

- The request for waiver of informed consent was approved. This waiver is granted for all research procedures.

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.

cc: Study Contact(s): Sirish Dharmapuri (sirish.dharmapuri@mountsinai.org)

Thank you,

PPHS Office