FW: APPROVAL OF RESEARCH HS#: 15-00368

Aronson, Anne

Tue 5/15/2018 4:43 PM

To: Rustgi, Sheila <sheila.rustgi@mssm.edu>;

Hi Sheila,

Just wanted to let you know that the renewal of your SEER study has been approved. Let me know if you need anything else.

Best,
Anne Aronson
Senior Clinical Research Coordinator
Division of Gastroenterology
Icahn School of Medicine at Mount Sinai
One Gustave L. Levy Place, Box 1069
New York, NY 10029-6574
Phone: 212-241-7269

From: Deluca, Selina
Sent: Tuesday, May 15, 2018 1:50 PM
To: Lucas, Aimee <aimee.lucas@mssm.edu>
Cc: Aronson, Anne <anne.aronson@mssm.edu>
Subject: APPROVAL OF RESEARCH HS#: 15-00368

Mount Sinai

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Mount Sinai Brooklyn
The Mount Sinai Hospital
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New York Eye and Ear Infirmary
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APPROVAL OF RESEARCH

Date: 5/15/2018

To: **Aimee Lucas, MD, MS (aimee.lucas@mssm.edu)**

On **5/15/2018**, 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 **6/15/2018** until **6/14/2019** inclusive:

Type of Review:	**Continuing Request for Approval**
Project Title:	**Gastroenterology Tools in Diagnosis and Treatment of Pancreatic Cancer**
Investigator:	**Aimee Lucas, MD, MS (Dept: ME - Medicine) (Div: GA - Gastroenterology)**

Project Information:	**HS#: 15-00368** **GCO#1: 15-0776(0001) Icahn School of Medicine at Mount Sinai**
Sites:	**Mount Sinai**
IND or IDE (if any):	**No INDs;No IDEs;**
Submission Details (if any):	**None**

Between **4/30/2019** and **5/3/2019**, 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 **6/14/2019**, 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 request for waiver of informed consent was approved on 5/15/2018. This waiver is granted for the retrospective component of the research .

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): Anne Aronson (Anne.aronson@mssm.edu)

Thank you,

Selina Deluca, MS, CIP
Senior IRB Analyst
Direct line: (212) 824-8207
Feel free to chat me using Lync: Deluca, Selina