

On October 13, 2016 at 2:36:13 PM, Gabriella Foe, (gabriella.foe@mssm.edu) wrote:



DETERMINATION REGARDING ENGAGEMENT IN HUMAN RESEARCH

Date: 10/13/2016

To: **Venkatesh Mani, PhD** (venkatesh.mani@mssm.edu)

On 10/13/2016 the IRB determined that the following proposed activity is human research as defined by DHHS and FDA regulations and that Mount Sinai is not engaged in the human research.

Project Title:	Evaluation of safety and thrombolytic effect of ascending doses of DS9231(TS23) in patients with acute intermediate-risk (sub-massive) pulmonary embolism (PE)
Investigator:	Venkatesh Mani, PhD (Dept: R - Radiology)
Project Information:	HS#: 16-01201 GCO#1: 16-1941(0001) Daiichi Sankyo Inc
Sites:	Mount Sinai
IND or IDE (if any):	IND# 118619; No IDEs;
Submission Details (if any):	IRB-16-00773

IRB review and approval by Mount Sinai is not required. This determination applies only to the activities described in the submission made to the PPHS, and does not apply should any changes be made. If changes are made and there are questions about whether these activities change the engagement status, please submit a new request to the PPHS for a determination.

Sincerely,
The Program for Protection of Human Subjects

cc: Study Contact(s): Juan Gilberto Aguinaldo (gilbert.aguinaldo@mssm.edu)

Gabriella Foe, MS

IRB Analyst I

Program for the Protection of Human Subjects (PPHS)

Icahn School of Medicine at Mount Sinai
One Gustave L. Levy Place, Box 1081
New York, NY 10029-6574

Phone: (212) 824-8218



This message and any attachments are intended only for the use of the addressee and may contain information that is privileged and confidential. If the reader of the message is not the intended recipient or an authorized representative of the intended recipient, you are hereby notified that any dissemination of this communication is strictly prohibited. If you have received this communication in error, notify the sender immediately by return email and delete the message and any attachments from your system.

 Mount Sinai	<p>Icahn School of Medicine at Mount Sinai Mount Sinai Beth Israel Mount Sinai Brooklyn The Mount Sinai Hospital Mount Sinai Queens New York Eye and Ear Infirmary of Mount Sinai Mount Sinai St. Luke's Mount Sinai West</p>	<p>Program for the Protection of Human Subjects <i>Institutional Review Boards</i> Mount Sinai Health System One Gustave L. Levy Place, Box 1081 New York, NY 10029-6574 T 212-824-8200 F 212-876-6789 irb@mssm.edu icahn.mssm.edu/pphs</p>
---	---	--

image001.jpg



image002.jpg