

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)

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**Program for the Protection
of Human Subjects**

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