

Institutional Review Board Approval Form or Document

July 3, 2019

No patient information was used in our study, "Segmentation of carotid arterial walls using neural networks" and therefore Institutional Review Board Approval was not required. Please see the image below for further information:

3 ASSOCIATES, LDU RD



Program for the Protection of Human Subjects

Mount Sinai School of Medicine and Mount Sinai Hospital
One Gustave L. Levy Place, Box 1075
3 East 101st Street, First Floor
New York, NY 10029-6530
Phone: (212) 824-8200
Fax: (212) 876-6789

DETERMINATION REGARDING ENGAGEMENT IN HUMAN RESEARCH

Date: July 13, 2012

To: **Zahi Fayad, Ph.D.** (zahi.fayad@mssm.edu)

On 7/13/2012 the IRB determined that the following proposed activity is human research as defined by both DHHS and FDA> regulations and that Mount Sinai is not engaged in the research.

Project Title:	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, EVENT DRIVEN TRIAL OF QUARTERLY SUBCUTANEOUS CANAKINUMAB IN THE PREVENTION OF RECURRENT CARDIOVASCULAR EVENTS AMONG STABLE POST-MYOCARDIAL INFARCTION PATIENTS WITH ELEVATED HSCRIP: AN IMAGING SUBSTUDY EVALUATING THE EFFECT OF CANAKINUMAB ON CAROTID ATHEROSCLEROSIS
Investigator:	Zahi Fayad, Ph.D.
MSSM Project #:	HS#: 12-00594, GCO#: 12-1055(0001)(01) R
Funding Agency:	Novartis Pharmaceutical Corporation
IND or IDE (if any):	
Submission Details (if any):	

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: Gilbert Aguinaldo gilbert.aguinaldo@mssm.edu

Venkatesh Mani, Ph.D.

Associate Professor, Department of Radiology

Director, Cardiovascular Imaging Clinical Trials Unit

Translational and Molecular Imaging Institute

Icahn School of Medicine at Mount Sinai