

Informed Consent Form(s) or Document(s)

Name of Journal: World Journal of Radiology

Manuscript Type: Observational Study

Segmentation of carotid arterial walls using neural networks

Daniel D. Samber, Sarayu Ramachandran, Anoop Sahota, Sonum Naidu, Alison Pruzan,
Zahi A. Fayad, Venkatesh Mani

Informed consent statement: Waiver of institutional review board (IRB) approval was obtained from the IRB as only deidentified data was used in this study. The images analyzed for this study were anonymized and devoid of any Protected Health Information.

Data for this study was obtained as part of the following protocol. "A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, EVENT DRIVEN TRIAL OF QUARTERLY SUBCUTANEOUS CANAKINUMAB IN THE PREVENTION OF RECURRENT CARDIOVASCULAR EVENTS AMONG STABLE POSTMYOCARDIAL INFARCTION PATIENTS WITH ELEVATED HSCRIP: AN IMAGING SUBSTUDY EVALUATING THE EFFECT OF CANAKINUMAB ON CAROTID ATHEROSCLEROSIS" PI: Zahi Fayad.

Please see IRB determination indicating that Mount Sinai is not engaged in human research for this project and that IRB review /approval is not required.

If you have any further questions, please feel free to contact me.

Sincerely,



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



Program for the Protection of Human Subjects

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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 HSCR: 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