University of California
San Francisco

Human Research Protection Program
Institutional Review Board (IRB)

Expedited Review Approval

Principal Investigator
J Easton

Co-Principal Investigator
Ahmad M Ahmad, Anh T Nguyen, Elizabeth A Cahill, Jesse C Hemphill, Kathryn A Kvam, Natalie T Cheng, MD, Neel S Singhal, MD PHD, Nirav H Shah, Qingyang Yuan, Shahed Toossi, Wade S Smith, MDPhD

Type of Submission: Submission Correction for Modification Form
Study Title: Platelet-Oriented Inhibition in New TIA and minor ischemic stroke (POINT)

IRB #: 11-06356
Reference #: 161202

Committee of Record: San Francisco General Hospital Panel

Study Risk Assignment: Greater than minimal

Approval Date: 03/30/2016 **Expiration Date:** 06/24/2016

All changes to a study must receive UCSF IRB approval before they are implemented. Follow the modification request instructions. The only exception to the requirement for prior UCSF IRB review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103.b.4, 21 CFR 56.108.a). In such cases, report the actions taken by following these instructions.

Expiration Notice: The iRIS system will generate an email notification eight weeks prior to the expiration of this study's approval. However, it is your responsibility to ensure that an application for continuing review approval has been submitted by the required time. In addition, you are required to submit a study closeout report at the completion of the project.

Documents Reviewed and Approved with this Submission (includes all versions – final approved versions are labeled 'Approved' in the Outcome column):

Other Study Documents

Study Document			
Title	Version #	Version Date	Outcome
Clopidogrel Package Insert	Version 5.1	01/01/2015	Approved
POINT Protocol v6.0 Log of Changes 19MAR2016	Version 4.4	03/19/2016	Approved
POINT Protocol v6.0 29FEB2016	Version 4.4	02/29/2016	Approved

POINT Drug Label	Version 1.0	03/16/2016	Approved

For a list of all currently approved documents, follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

San Francisco Veterans Affairs Medical Center (SFVAMC): If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to UCSF IRB approval and follow all applicable VA and other federal requirements. The UCSF IRB website has more information.