University of California
San Francisco

Human Research Protection Program
Institutional Review Board (IRB)

Full Committee 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: Continuing Review Submission Form
Study Title: Platelet-Oriented Inhibition in New TIA and minor ischemic stroke (POINT)

IRB #: 11-06356
Reference #: 166508

Reviewing Committee: San Francisco General Hospital Panel

Study Risk Assignment: Greater than minimal

Approval Date: 06/16/2016 **Expiration Date:** 06/15/2017

Regulatory Determinations Pertaining to This Approval:

Individual Research HIPAA Authorization is required of all subjects. Use the Permission to Use Personal Health Information for Research form.

A waiver of HIPAA Authorization and consent is acceptable for the recruitment procedures to identify potential subjects. The recruitment procedures involve routine review of medical or other records, do not adversely affect the rights and welfare of the individuals, and pose minimal risk to their privacy, based on, at least, the presence of the following elements: (1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, or a health or research justification for retaining the identifiers was provided or such retention is otherwise required by law; (3) adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule; (4) the research could not practicably be conducted without the waiver; and (5) the study recruitment could not practicably be conducted without access to and use of the requested information. Study participants will sign a consent form prior to participation in the study.

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):

Consent Documents

Study Consent Form			
Title	Version #	Version Date	Outcome
Platelet-Oriented Inhibition in New TIA (POINT) Informed Consent Document Hebrew	Version 4.2	05/15/2012	Approved
Platelet-Oriented Inhibition in New TIA (POINT) Informed Consent Document Chinese	Version 1.2	05/07/2014	Approved
ConsentDocument_Clean_Canadian_HC_approved_04.15.2013	Version 5.3	04/15/2013	Approved
Platelet-Oriented Inhibition in New TIA (POINT) Informed Consent Document Spanish	Version 2.5	05/15/2012	Approved
Platelet-Oriented Inhibition in New TIA (POINT) Informed Consent Document_with SFGH info_CLEAN_v5.0	Version 4.12	03/01/2013	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 IRB website has more information.