University of California
San Francisco

Human Research Protection Program
Institutional Review Board (IRB)

Expedited Review Approval

Principal Investigator
Victor I. Reus, MD

Co-Principal Investigator
Lewis Perdue

Type of Submission: Continuing Review Submission Form
Study Title: Clinical blood profile assays as biomarkers to directly assess potential health effects resulting from the controlled elimination of suspected dietary and environmental chemical toxins.

IRB #: 15-17703
Reference #: 265715
Committee of Record: San Francisco General Hospital Panel
Study Risk Assignment: Minimal

Approval Date: 10/27/2019 **Expiration Date:** 10/26/2020

Regulatory Determinations Pertaining to this Approval:
This research is not subject to HIPAA rules.

This submission was eligible for expedited review as:

Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture (healthy non pregnant adults 110lbs or more, no more than 550mL in 8 weeks and no collection more than 2x a week OR other adults and children not exceeding the lesser of 50 ml or 3 ml per kg in an 8 week period and no collection more than 2x a week)
Category 3: Prospective collection of biological specimens for research purposes by noninvasive means

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.

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.