UNIVERSITY OF CALIFORNIA, DAVIS

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March 6, 2018

David Shatz, MD
Department: Med - Surgery
Phone: 916-734-5535
Email: dvshatz@UCDAVIS.EDU

Dear Dr. Shatz:

On March 6, 2018 the UC Davis IRB reviewed the following protocol:

Type of Review:	Amendment/Modification
Title:	Immunologic Response to Pneumococcal Polysaccharide Vaccine in Splenic Injury Patients
Investigator:	Shatz, David, MD
IRB ID:	1036320-6
Funding:	Merck
Grant ID and Title:	NA
IND, IDE or HDE:	NA
Documents Submitted:	• Amendment/Modification - HRP-213-FORM-Modification.docx • Consent Form - Combined spleen Consent_TC .docx • Consent Form - Combined spleen Consent .docx • Protocol - HRP-503-Protocol_tc.docx • Protocol - HRP-503-Protocol.docx • UC Davis - Initial Review Application

The IRB approved protocol from March 6, 2018 to June 20, 2018 inclusive.

Risk Determination:	Minimal Risk
Category:	Expedited

As indicated in Section 46.107(e) of Title 45 of the Code of Federal Regulations and per the practice of this Institutional Review Board (IRB), no IRB member will participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. No IRB member with a conflicting interest participated in this determination.

This Assurance, on file with the Department of Health and Human Services, covers this activity:

FWA No: 00004557
Expiration Date: March 8, 2022
IORG: 0000251

Before May 6, 2018 or within 25 business days of study closure, whichever is earlier, you are to submit a completed “FORM: Continuing Review (HRP-212)” and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of June 20, 2018 approval of this protocol expires on that date.

You must use the most currently approved consent document(s).

If your research involves recombinant DNA molecules, human gene transfer, infectious agents, or biohazardous materials, please contact the Institutional Biosafety Committee to determine if a Biological Use Authorization is required.

Studies involving laboratory testing or sample retrieval (including tissue specimens) through UCDMC must coordinate services with the Department of Pathology and Laboratory Medicine. Call (916) 734-2112, or email hs-pathresearch@ucdavis.edu to coordinate the services as soon as possible to avoid delays or complications.

In conducting this protocol, you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103). Refer to the letter, HRP-510-Approval of Protocol, published following initial review to find the remaining requirements.