UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

Date: December 2, 2008

To: Richard Garfein Mailcode: 0622

Re: Project #080900
Study to Assess Hepatitis C Risk (STAHR) among Young Adult Injection Drug Users

Dear Dr. Garfein:

Your November 21, 2008 request to amend project 080900 has been reviewed and approved. The following changes have been approved:

1. The number of vacutainer tubes used during blood draws has increased from 2 tubes to 3 tubes. The additional tube is required by the testing lab because the blood must be drawn directly into a separate PPT tube without aliquoting. This change will not affect the amount of blood drawn from each participant.
2. The name of the clinic you will be referring HCV positive participants to has changed to Family Health Centers of San Diego or County of San Diego Health Services. It is noted that you recently learned that the UCSD Liver Clinic no longer received patients without insurance or prior clinical diagnostic history for HCV infection. Given that the study is for research purposes only, your results don't meet the clinics criteria, therefore, a change was warranted.
3. Participants will be given written documentation of their test results upon request.

A copy of your revised, approved consent form is enclosed.

Please note that the amendment approval date does not alter the study expiration date. A modification is given approval only to the expiration date that was received at the most recent initial or continuing review. Also, please check your most recent initial or continuing review approval letter and ensure that continuing review materials are submitted approximately 45 days prior to that expiration. Thank you for keeping us informed.

On behalf of the UCSD Institutional Review Board,

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Michael Caligiuri, Ph.D.
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