INSTITUTIONAL REVIEW BOARD
University of California, Davis

PROTECTION OF HUMAN SUBJECTS - DECLARATION / ASSURANCE OF IRB APPROVAL

The following research study has been determined to meet the definition of human subjects research as defined by Federal Regulations and UC Davis IRB Policy and has been reviewed by the IRB in accordance with the Common Rule and any other governing regulations:

Project Title			
[237180-2] Biomarkers of Inflammation in Diabetic and Non Diabetic Wounds			
Principal Investigator Ravi Dasu School of Medicine	**Protocol No.** 237180-2	**Approval Period** May 18, 2011 through May 17, 2012	**Risk Level** Minimal Risk
Sponsor(s) Departmental	**Status** Response/Follow-Up	**Type of Review** Expedited Review	**Category** 3, 5

As Principal Investigator for the above-referenced project, you assume certain responsibilities, including, but not limited to:

1. You will conduct the study according to the protocol approved by the IRB. As the PI you are ultimately responsible for the conduct of the research and the protection of rights and welfare of the human subjects. You will ensure, at all times, that you have the appropriate resources and facilities to conduct this study. You will ensure that all research personnel involved in the conduct of the study have been appropriately trained on the protection of human subjects, in addition to the study procedures.
2. Any unanticipated problems involving risks to participants or others will be reported within 5 days to the IRB or in accordance with IRB Standard Operating Procedures (SOPs).
3. Any changes in your research plan (including but not limited to advertisements) must be submitted to the IRB for review and approval prior to implementation of the change, except when necessary to eliminate immediate hazards to participants. Changes in approved research initiated without IRB approval to eliminate immediate hazards to the subject, are to be reported to the IRB in accordance with the SOP, "Reporting of Unanticipated Problems Involving Risks to Participants or Others."
4. Your protocol must be renewed prior to expiration of the study. Failure to submit renewal documents to the IRB Administration by the Administrative Due Date may result in a lapse in IRB approval or termination of the study by the IRB. All research involving human subjects must stop without on going IRB approval.
5. If you plan to collect protected health information, you are required to comply with HIPAA requirements.
6. Studies conducted at the CCRC must be reviewed and approved by the VA Research & Development Committee prior to initiation of the study. Contact the VA R&D Committee for submission requirements.
7. The UC Davis Health System requires that all investigational drugs be distributed through the UCDMC Pharmacy. You are required to provide a complete copy of the approved protocol to the Investigational Drug Service Pharmacy. A copy of the signed consent form must be submitted to the Pharmacy if investigational drugs are dispensed through the Outpatient Pharmacy.
8. For studies involving investigational drugs at Shriners Hospitals for Children Northern California, drugs must be distributed through Shriners Pharmacy. A copy of the signed consent form must be in the Pharmacy.

Name and Address of Institution
University of California, Davis
IRB Administration
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Sacramento, CA 95817

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This Assurance, on file with the Department of Health and Human Services, covers this activity:
FWA No: 00004557
Expiration Date: December 02, 2013
IORG: 0000251

Std. May 18, 2011