



Human Research Protection Program
Office of Research

April 23, 2007

Committee on Human Research
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Mailing Address:
3333 California Street, Suite 315
San Francisco, CA 94118

Campus Mailing Address:
UCSF Box 0962

I-chow Hsu, MD
Radiation Oncology
Box 1708

RE:

Title of Study: Dual-Modality Prostate Imaging with PET and Transrectal Ultrasound

Reviewing Campus: UC Berkeley

Reviewing Campus Tracking Number: #2006-12-57

Reviewing Campus PI: Jennifer S. Huber

Reviewing Campus Approval Date: 4/13/2007

Reviewing Campus Expiration Date: 1/18/2008

UCSF CHR Tracking Number: 07030623

UCSF PI: I-Chow Hsu, M.D.

Dear Dr. Hsu,

This is to acknowledge that the University of California, San Francisco (UCSF), operating under Federalwide Assurance FWA00000068 has received the documentation and Institutional Review Board determination of full committee approval for the above-captioned human subjects research project and intend to rely upon the determination made by the University of California Berkeley IRB operating under Federalwide Assurance FWA00006252. The research, as described in the approved protocol, is now authorized to begin on the UCSF campus.

Any amendments to the protocol, annual renewals, and other required notifications should be submitted to the UC Berkeley IRB for approval, with copies of all submissions to the UCSF HRPP. The authorization to conduct research on the UCSF campus expires on the Reviewing Campus Expiration date, noted above.

The research must be conducted in accordance with all applicable Federal and State Laws, University of California and UCSF Policies, and with the terms of the UC MOU for IRB Review of the Multi-Campus Research.

Please feel free to contact us with any questions.

Sincerely,

Sharon K. Friend, MS
HRPP Director

cc: UCB – Reviewing Campus HRPP



OFFICE FOR THE PROTECTION OF HUMAN SUBJECTS

University of California, Berkeley
2150 Shattuck Avenue, Suite 313
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FWA#00006252

April 16, 2007

JENNIFER S. HUBER (jshuber@lbl.gov)
Medical Imaging Technology Department
1 Cyclotron Road MC# LBL/55R0121
Berkeley, CA 94720

RE: **Approval of CPHS Protocol #2006-12-57**

"Dual-Modality Prostate Imaging with PET & Transrectal Ultrasound" - DOD - Medical Imaging Technology Department - LBNL

Dear Ms. HUBER:

Thank you for submitting responsive materials relative to the above-referenced study. The Committee has reviewed these responses to the request for specific, minor revisions detailed in our letter of 1/22/07, and has found them to be in order. We have granted final approval, for one year or less, effective 4/13/2007. **This approval will expire on 1/18/2008.**

The number of this approval is **2006-12-57**. Please refer to this number in all future correspondence.

Continuation/Renewal: Approximately 8 weeks before the expiration of this approval, OPHS will send you a courtesy reminder. Applications for continuation review should be submitted no later than 6 weeks prior to the expiration date of the current approval to allow sufficient time for the renewal process. *Note: It is the responsibility of the Lead Investigator to submit for renewed approval in a timely manner.* In keeping with federal regulations, *if approval expires, all research activity (including data analysis) must cease until re-approval from CPHS has been received.* Before applying, please check current CPHS guidelines, instructions and forms available at <http://cphs.berkeley.edu>.

Amendments/Modifications: Any change in the design, conduct, or key personnel of this research must be approved by the CPHS **prior** to implementation. (For more information, see "Process for Submission & Review of Applications" and "Application Forms & Informed Consent" on CPHS website).

Adverse Events and Unanticipated Events: If any study subject experiences an adverse and/or unanticipated event involving serious risk, the CPHS must be informed within 48 hours. (For more information on definitions and reporting requirements related to adverse and/or unanticipated events, see "Adverse Events" on CPHS website).

If you have any questions about the above, please contact the Office for the Protection of Human Subjects staff at (510) 642-7461; Fax (510) 643-6272; or email ophs@berkeley.edu.

Thank you for your cooperation and your commitment to the protection of human subjects in research.

Sincerely,

A handwritten signature in dark ink, appearing to read "M Potts".

Malcolm Potts, M.B., BChir, Ph.D.
Chair, Committee for Protection of Human Subjects
Bixby Professor, School of Public Health

MP:jb

Cc: THOMAS F. BUDINGER (tfbudinger@lbl.gov)
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