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DOE/ER/60553--T/

March 25, 1993

THIS LETTER IS THE
FINAL REPORT PER
DR. STADALNIK.RECEIVED
SEP 21 1998
OSTI

Ms. Aundra Richards
Chief, Policy Analysis Support Branch
Contract Management Division
Department of Energy
San Francisco Field Office
1333 Broadway
Oakland, CA 94612

RE: DE-FGO3-87ER60553 "Testing the Validity of a Receptor Kinetic Model Via
TcNGA Functional Imaging of Liver Transplant Recipients" -- No-cost
Extension -- Twelve (12) months to 6/30/94

Dear Ms. Richards:

I would like to request a no-cost extension for twelve months, i.e., extend the expiration date of the final budget period of the project named above to 6/30/94. This additional time is required to assure adequate completion of the original scope of work with the funds already granted.

We had accomplished the expertise for I-125-HSA plasma volume, galactose clearance for determination of hepatic plasma flow as well as finalizing the kinetic model. We have just completed modifying our microscale Scatchard assay for greater precision of receptor measurement using only 5-10 mg of liver tissue. This achievement required a great deal of work during the past project year. In addition, we determined during the past year that the most practical method and clinically reasonable measurement of liver volume was to measure the transplanted liver *in vivo* using Tc-NGA images in the anterior, posterior, and right lateral projections, using the method of Rollo and DeLand. Direct measurement of liver weight obtained during transplant operation was not reliable due to variability of fluid retention in the donor liver secondary to ischemia, preservation fluid, etc., which thereby did not reflect an accurate liver weight which is needed in our kinetic analysis comparison, i.e., V_h (hepatic plasma volume).

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K.W.
K.W.

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- 2 -

For optimal achievement of the goal of the project, that is, the simultaneous accrual of Tc-NGA studies, I-125-HSA plasma volume, galactose clearance test, determination of liver volume, followed by liver biopsy for tissue for receptor assay, needs to be adequately performed in the same patient for validation of the kinetic model. We completed 14 studies during the current project year.

We need to acquire additional patient data during our project to test the hypothesis that the parameters contained in the kinetic model are appropriate representations of the individual physiologic and biochemical processes within the human liver. A no-cost extension will enable us to acquire sufficient patient data for adequate statistical analysis. An estimate of unobligated funds remaining is \$50,000. These funds will enable us to continue support of personnel, pay the cost of obtaining patient studies at Pacific Medical Center, San Francisco, pay the costs incurred for radiopharmaceutical preparation and the analysis of blood and biopsy specimens. These costs coincide with the original budget and objectives of the project.

Sincerely,

Robert C. Stadalnik, M.D.
Professor of Radiology

RCS:jh

Doc: hr625/2

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Contracting Officer
Department of Energy
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1333 Broadway
Oakland, California 94612

APR 6 - 1993

Ms. Richards:

Extension of Grant No. DE-FG03-87ER60553
in support of project entitled
"Testing the Validity of a Receptor Kinetic Model via TcNGA
Functional Imaging of Liver Transplant Recipients"
Principal Investigator - Robert C. Stadalnik

As allowed under the provisions of the Federal Demonstration Project, an extension without additional funds has been approved by our institutional representative for the subject grant. The existing 30 June 1993 expiration date has been extended to 30 June 1994. This extension was authorized in order to assure completion of the original approved project objectives.

Thank you for your cooperation. Should there be questions, please direct them to me or my assistant Fay Yee by telephone, facsimile and electronic mail at the numbers referenced above.

Sincerely,

Louise Ivey
Sponsored Research Administrator

c. J.J. Castles
R.C. Stadalnik
G.R. Max
P. Cho, DOE

One hundred twenty-five years of service.