University of California
OTT
OFFICE OF TECHNOLOGY TRANSFER
Office of the President

MEMO
Operating Guidance
No. 08-02
March 10, 2008

INTELLECTUAL PROPERTY DIRECTORS
CONTRACT AND GRANT DIRECTORS
VICE CHANCELLORS - RESEARCH/ADMINISTRATION

Subject: Second Amendment to Cooperative Technology Administration Agreement with U.S. Department of Veterans Affairs

In late November 2007, after consulting with the five campuses with VA affiliations, the University and the U.S. Department of Veterans Affairs (VA) executed a Second Amendment to the Cooperative Technology Administration Agreement (CTAA), whereby the VA may, under certain conditions, take the lead in managing and licensing inventions in which the University has an interest. The Second Amendment specifies the circumstances and procedure that the VA and the VA Non-Profit Research Corporations (NPCs) associated with VA facilities must follow before executing a Clinical Trial Cooperative Research and Development Agreement (CRADA) with a third-party Clinical Trial sponsor that commits license rights to future inventions made by Dual Appointment Personnel (DAP). A copy of the Second Amendment and associated appendices detailing this procedure are attached to this document.

CTAA Background
The initial CTAA, executed in May 2000, allows the University to manage the licensing and revenue distribution for any Subject Invention in which both the VA and the University have an interest, that is made by a DAP or at least one inventor from each entity, and that is not a Disclaimed Invention. A side letter agreement signed on January 30, 2001, allows the University to enter into interinstitutional agreements that allow a third-party co-inventing institutions to take the lead on filing and prosecuting patent applications and marketing, negotiating, executing and administering license agreements.
In October 2001, the University and the VA executed the First Amendment to the CTAA, which clarified that Subject Inventions would include those made by Without Compensation (WOC) employees involving significant participation in the making of the inventions or involving significant use of VA facilities/resources. It also clarified a few technical and drafting issues remaining from the initial agreement.

Second Amendment Provisions
To more efficiently execute clinical trial agreements that are conducted at the VA and involve DAP investigators, the VA requested the ability to take the lead in managing certain inventions so that it is able to promise certain future license rights to its clinical trial sponsors. This Second Amendment contains two key components: first, it establishes the conditions under which the VA may take the lead in managing inventions involving a DAP; and second, it specifies a procedure to ensure that revenue distributions are aligned as closely as possible with the CTAA.

Through this Second Amendment, the University has agreed that when the VA enters into a Phase II, III or IV Clinical Trial Cooperative Research and Development Agreement (CRADA) that involves a DAP and is solely conducted within VA facilities with VA resources only, the VA may choose to file patent applications and license resulting subject inventions. In order to minimize the chances of conflicting legal obligations, OTT and the VA developed an Expedited Review Process (ERP) checklist of questions to determine if the set of circumstances allows the VA to move forward expeditiously. If the VA successfully completes the checklist, it may proceed with executing its clinical trial agreement without consulting with the affiliated University technology transfer office, as the risk of conflicting obligations is minimal. If the VA/NPC cannot successfully complete the ERP, then it must obtain approval from the affiliated University technology transfer office to allow the opportunity to identify potential conflicting legal obligations.

Clinical Trial Review Checklist
The ERP involves a Clinical Trial Review Checklist (and accompanying instruction sheet) with a series of questions intended to filter out CRADAs that could lead to conflicting obligations to subject inventions (Appendix A). Specifically, the VA would be required to consult with the affiliated University technology transfer offices prior to entering into a CRADA if any one of the following conditions exists:

- Subjects are University patients.
- The research is pre-clinical, Phase I, or involves animals.
- University employee(s) or DAP provided input or wrote part of the protocol (including serving as a consultant).
- The scope of the VA clinical trial overlaps with research work or clinical trials currently done by the DAP at the University.
- The clinical trial will be performed at both VA and the University.
- The DAP is aware of other research at UC using the Collaborator Study Drug or Device that is the subject of the proposed clinical trial.
- Background inventions of the University or DAP are needed for the proposed clinical trial.
- The DAP also has an appointment with a University affiliate, e.g., HHMI, Gladstone Institute, Burnham Institute, etc.

Revenue Distribution
So that the revenue distribution remains as close as possible to existing procedures in the CTAA, the University would distribute revenues for these subject inventions. The Second Amendment specifies a licensing revenue distribution procedure whereby the VA remits all gross revenues, minus its unreimbursed patent expenses, to UC for further distribution, following the schedule outlined in the CTAA. This provision ensures that all inventors receive essentially the same inventor shares as they would have if the University managed the invention under the CTAA. Appendix B to the Second Amendment presents an example CTAA revenue flow chart, illustrating the allocation of revenues among the VA, the inventors and the University.

Finally, the Second Amendment reasserts UC's right to practice any subject inventions managed by the VA for non-profit purposes, including sponsored research and collaborations, and to permit other non-profit research institutions to do the same.

If you have any questions concerning the Second Amendment to the CTAA, please contact:

Charles Drucker
(510) 587-6011
charles.drucker@ucop.edu

Sincerely,

Wendy D. Streitz
Director
Policy, Analysis and Campus Services

Enclosures: A: Second Amendment to CTAA with U.S. Department of Veterans Affairs
B. Appendix A to Second Amendment (ERP Checklist and Contact List)
C. Appendix B to Second Amendment (Example Revenue Flow)

cc: Executive Director Tucker
University Counsel Simpson
Assistant Director Tom
UCRAO-L listserv
CLIN-L listserv
LICENSE-L listserv

SECOND AMENDMENT TO

COOPERATIVE TECHNOLOGY ADMINISTRATION AGREEMENT

BETWEEN

U.S. DEPARTMENT OF VETERANS AFFAIRS

AND

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

THIS SECOND AMENDMENT ("Second Amendment") is effective this 19th day of November 2007 by and between the U. S. Department of Veterans Affairs ("VA"), having its principal place of business at Office of Research and Development, 810 Vermont Ave. NW, Washington, D.C. 20420 and The Regents of the University of California, as represented by the Office of Technology Transfer, having an address at 1111 Franklin Street, 5th Floor, Oakland, California 94607-5200 ("University").

RECITALS

Whereas, the parties to this amendment are also parties to a certain Cooperative Technology Administration Agreement dated May 19, 2000 ("Agreement") as amended on October 2, 2001; and

Whereas, the parties desire to modify the Agreement as amended by allowing the VA, under certain circumstances, to take the lead in managing and licensing certain Subject Inventions that are made under certain collaborator-initiated, late-stage clinical trials being conducted in VA facilities; and

Whereas the parties recognize that if the VA is to take the lead in managing and licensing such inventions, the circumstances surrounding each project will need to be reviewed prior to project commencement under a mutually developed procedure to ensure there are no conflicting obligations to other sponsors or overlap with University research; and

Whereas the parties further recognize that when the VA does take the lead in licensing such inventions, the revenue distribution procedures will need to be modified to remain consistent with the intent of the Agreement as amended;

NOW THEREFOR, for and in consideration of the covenants, conditions and undertakings hereinafter set forth, it is agreed by and between the parties, that the following amendments be made:

1. A new paragraph 2.8 will be added to Section 2, Patent Prosecution and Protection, as follows:

2.8 - Where the VA enters into a phase II, III, or IV Clinical Trial Cooperative Research and Development Agreement (CRADA) or VA Cooperative Studies Program CRADA for a phase II, III, or IV clinical trial under the Federal Technology Transfer Act (FTTA) that involves a Dual Appointment Personnel, then the VA shall have the right to file patent applications and/or market and license such Subject Inventions made in the performance of such CRADA, provided that prior to execution of the CRADA, the VA has successfully completed an agreed-upon Expedited Review Process for that CRADA (an example of which is provided as Appendix A to this Second Amendment) or, if it is determined the Expedited Review Process cannot be used, has obtained case-specific approval from the affiliated University technology transfer office. University agrees to review such requests for approval in a timely fashion. In the event that such a CRADA is conducted at VA, the distribution of revenues received by the VA for the licensing of any Subject Inventions shall conform to the following procedure:

a. The VA may recover its unreimbursed patent expenses from Gross Revenues received from licensee(s);
b. The VA shall remit Gross Revenues minus its unreimbursed patent expenses to University for further distribution;
c. University shall further distribute such remaining revenues according to the schedule outlined in the CTAA, except that an administrative fee (calculated as 15% of the amount remaining after deduction of Inventors Shares and Research Shares) shall be returned to the VA rather than retained by University;
d. When the VA is managing a Subject Invention, Net Revenues will be distributed on a case-by-case basis, exempt from the definition of Pooled Amount and section 4.3 of the Agreement as amended, and at the same time as the distribution of other revenues under the Agreement as amended.

An example of the above revenue distribution process, illustrating percentages and amounts in the case of a single inventor who is a DAP, is provided as Appendix B to this Second Amendment. This example is intended to be illustrative rather than definitive, and in all cases University shall operate in good faith to maintain the intent of the Agreement as amended with respect to allocation of revenues from such Subject Inventions.

The VA Technology Transfer Program shall notify University in writing promptly if it determines that a Subject Invention has been made under such a CRADA and in any event shall notify University before filing a patent application, marketing or licensing any such Subject Invention.

2. A new paragraph 3.5.5 will be added to Section 3.5 as follows:

3.5.5 "**University Retained Rights.**" University retains the right, on behalf of itself and all other non-profit research institutions, to practice Subject Inventions for any non-profit purpose, including sponsored research and collaborations. VA agrees that, notwithstanding any other provision of this Agreement as amended, neither it nor any licensee of Subject Inventions shall have any right to enforce Patent Rights against University or any such institution. University and any such other institution have the rights to publish any information in Patent Rights.

The remaining provisions of the Cooperative Technology Administration Agreement and the First Amendment to that Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the parties have caused this Second Amendment to be executed in duplicate by their duly authorized representatives as follows:

U.S. Department of Veterans Affairs

By: _____
(Signature)

Name: Joel Kupersmith, M.D.
Title: Chief Research and Development Officer

Date: 11-30-07

The Regents of the University of California

By: _____
(Signature)

Name: William T. Tucker
Title: Executive Director
Research administration and Technology Transfer

Date: November 19 2007

Approved as to legal form: P. Martin Simpson, Jr. 11/7/2007
P. Martin Simpson, Jr.
University Counsel
Office of General Counsel

Appendix A

EXPEDITED REVIEW PROCESS

For VA Commitment of Licensing Rights to Company Collaborators
Under Phase II, III, and IV Collaborator-Initiated Clinical Trial CRADAs

Purpose: The purpose of the Expedited Review Process is to facilitate prompt execution of VA CRADAs without compromising potential UC interests and rights in inventions. To accomplish this, it is necessary to conduct an assessment of each proposed study to determine whether the VA may take the lead on licensing inventions made by a Dual Appointment Personnel (DAP) under a clinical trial CRADA involving the VA, or the VA and the VA-affiliated non-profit corporation (NPC), without prior consultation with the UC affiliate. If the assessment results in a positive conclusion, the Expedited Review Process may be used (i.e., no UC review is required). If the Expedited Review Process cannot be used, case-specific approval should be obtained by contacting the affiliated UC technology transfer office (see attached contact list) which can evaluate the particular circumstances.

The Expedited Review Process **MAY** be used if **ALL** of the following conditions exist:

- The UC employee involved in the clinical trial is a DAP.
- The clinical trial is a Phase II, III, or IV clinical trial.
- The Company Collaborator initiated the clinical trial, VA or NPC has verified that the Study Drug or Device or other material(s) to be used in the study are free from conflicting obligations, and the protocol was written by the Collaborator or a non-UC, non-DAP VA or NPC employee.
- All work is to be conducted within VA facilities (or "the VA facility") using only VA and/or NPC resources.
- All funding is provided by the Company Collaborator, VA, the NPC, or a combination thereof, in a VA Cooperative Studies Program study.
- Sole UC employees, UC funds (including funds transferred to or from the NPC) and UC resources (which include, but are not limited to, the Study Drug or Device) will NOT be used for performance of the clinical trial.
- There is no known overlap with specific research being conducted at UC.

The Expedited Review Process may **NOT** be used if **ANY** one of the following conditions exists:

- Subjects are University patients.
- The research is pre-clinical, Phase I, or involves animals.
- UC employee(s) or DAP provided input or wrote part of the protocol (including serving as a consultant).
- The scope of the VA clinical trial overlaps with research work or clinical trials currently done by the DAP at UC.
- The clinical trial will be performed at both VA and UC.
- The DAP is aware of other research at UC using the Collaborator Study Drug or Device that is the subject of the proposed clinical trial.
- Background inventions of UC or DAP are needed for the proposed clinical trial.
- The DAP also has an appointment with a UC affiliate, e.g., HHMI, Gladstone Institute, Burnham Institute, etc.

If a sole UC employee is involved or expected to be involved in the clinical trial, then case-specific approval must be acquired from the affiliated UC technology transfer office. However, completion of the Checklist prior to contacting the UC office would expedite the process of seeking case-specific approval.

Completion of Checklist: The VA or NPC signing the Clinical Trial CRADA should coordinate with the DAP, Company Collaborator and others to complete the Clinical Trial Review Procedure Checklist.

- If the Checklist responses allow use of the Expedited Review Process, the VA or the VA and NPC are allowed to proceed expeditiously to signing the Clinical Trial CRADA without UC consultation.
- If any Checklist answer prevents use of the Expedited Review Process, then the VA or NPC should contact the local UC technology transfer office for case-specific approval. Forward to the UC office a copy of the completed Checklist to start the UC review process. VA and UC will work together in a timely manner to find a mutually acceptable way to proceed with the trial.

If more than one DAP is involved in the clinical trial, complete a separate Checklist form for each DAP.

RECORDS: THE ORIGINAL CHECKLIST SHOULD BE RETAINED IN VAMC OR NPC RECORDS PERTAINING TO THE STUDY. UPON REQUEST, THE VAMC ASSOCIATE CHIEF OF STAFF FOR RESEARCH AND DEVELOPMENT (SEE ATTACHED CONTACT LIST), OR A DESIGNATED NPC STAFF, WILL PROMPTLY PROVIDE TO THE UNIVERSITY A COPY OF THE COMPLETED CHECKLIST AND EXECUTED CLINICAL TRIAL CRADA (OMITTING PROPRIETARY PROTOCOLS AND BUDGETS UNLESS THE COLLABORATOR HAS APPROVED RELEASE OF SUCH INFORMATION). IN ADDITION, THE ACOS R&D WILL COOPERATE IN REVIEWING AND ASSESSING THE STATUS OF ANY AFFECTED SUBJECT INVENTION.

Appendix A

CLINICAL TRIAL REVIEW PROCEDURE

Checklist for VA Commitment of Licensing Rights to Company Collaborators

This Checklist shall be used in accordance with the Expedited Review Process by any VA entity/facility or VA non-profit corporation (NPC) that is signing a Phase II, III or IV Sponsor-Initiated Clinical Trial CRADA with a Company Collaborator and that involves either a sole UC employee or a UC/VA Dual Appointment Personnel (DAP) as defined in the Cooperative Technology Administration Agreement (CTAA) signed by the two parties. If it is determined that the Expedited Review Process can NOT be used, then approval for the VA to commit licensing rights to a Phase II, III, or IV clinical trial Company Collaborator needs to be secured directly from the affiliated University technology transfer office. When the Expedited Review Process is not available, this Checklist may also be used to gather information for case-specific approval sought from the affiliated UC campus to allow the VA to commit licensing rights to clinical trial Company Collaborators.

1. Title of Clinical Trial: _____
2. Protocol Number: _____
3. Name of Proprietary Compound: _____
4. Company Collaborator receiving licensing rights: _____
5. Principal Investigator: _____ DAP? ☐ Yes ☐ No
6. Name of DAPs involved in the Clinical Trial (if different from PI above): _____
_____

(A separate Clinical Trial Review Procedure form should be completed for each DAP.)

7. This is a ☐ Phase II, ☐ Phase III, or ☐ Phase IV Clinical Trial CRADA to be signed by: _____
_____

(Insert name of VA entity signing the CRADA. If not a Phase II, III, or IV Clinical Trial, the Expedited Review Process may NOT be used.)

8. What is the source of funding for this clinical trial? (list all sources) _____
_____

☐ Yes ☐ No 9. Is any portion of the Study Drug or Device being provided through UC?

☐ Yes ☐ No 10. Will any portion of the clinical trial be conducted using UC Funds (including funds transferred to or from the NPC), at facilities affiliated with UC OR with university based patients? If yes, please explain (do not include other non-UC sites in a multi-site trial). _____
_____

☐ Yes ☐ No 11. Will <u>any</u> of the work be done at the UC campus, including data analysis? If yes, where? _____
_____

☐ Yes ☐ No 12. Did the DAP or any UC employee write or provide input to the protocol? If yes, in what way? _____
_____

☐ Yes ☐ No 13. Are any sole UC employees involved in the clinical trial? If yes, who? _____

☐ Yes ☐ No 14. Does the scope of this clinical trial overlap with research being done by the DAP at either the VA (but not including VA merit awards) or UC? If yes, which research projects? _____
_____

☐ Yes ☐ No 15. Are you aware of any other research or clinical trial conducted at UC that uses the company's Study Drug or Device involved in this clinical trial? If yes, which? _____
_____

☐ Yes ☐ No 16. Are there any Background Inventions of UC or the DAP being used under this clinical trial CRADA? If yes, which? _____

☐ Yes ☐ No 17. Does the DAP also have an appointment with a UC affiliate, e.g., HHMI, Gladstone Institute, Burnham Institute, etc.? If yes, which? _____

*** * *If any of the above answers is "yes," the Expedited Review Process may NOT be used.* * ***

The below individuals have diligently checked and confirm the above information.

_____ _____

Dual Appointment Personnel Date

VA Title: _____

UC Title: _____

_____

Authorized VA Official Date

Title: _____

Cc: Executive Director of VA affiliated NPC

November, 2007

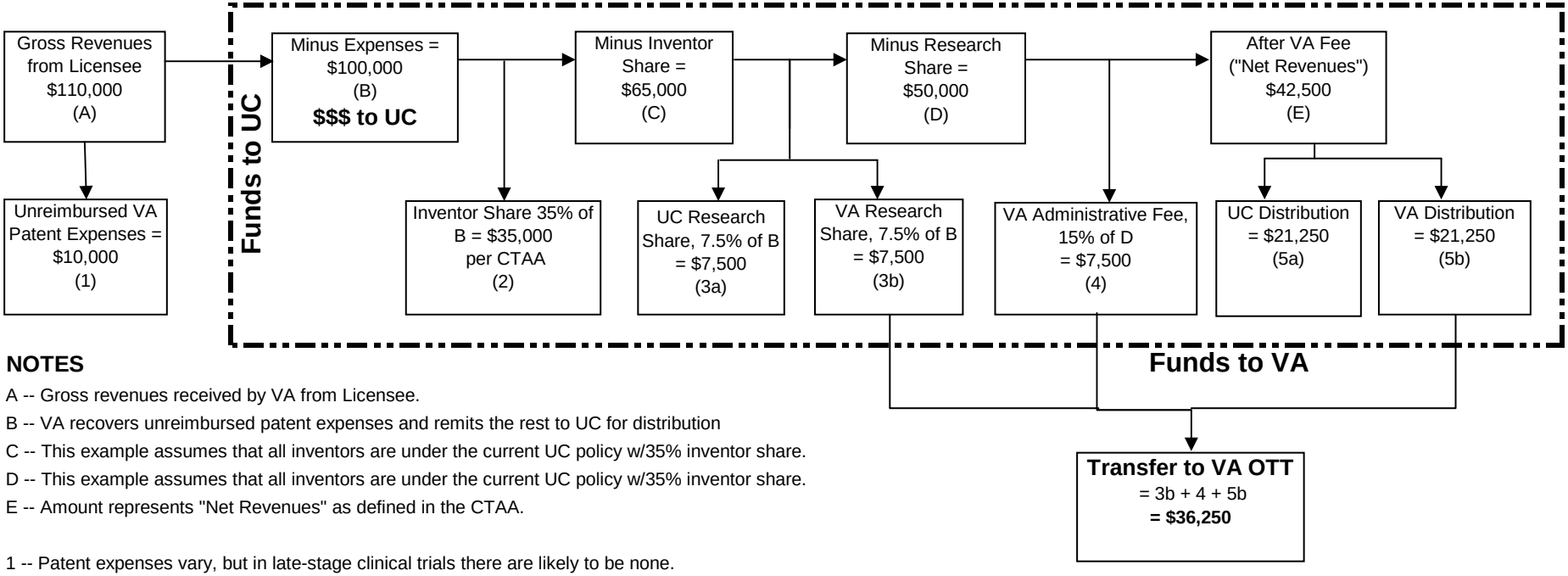
Appendix A NOTE: AN UPDATED LIST MAY BE ACCESSED HERE

UC Campus	UC Contact	VA Contact	VA Non-Profit Executive Director
UC Davis	Luanna Putney UC Davis Office of Research 1850 Research Park Dr. Davis, CA 95618 Phone: (530) 757-3166 Fax: (530) 747-3904 lkputney@ucdavis.edu	Karen Sigvardt, Ph.D. Deputy ACOS VA Northern CA HCS 150 Muir Road Martinez, CA 94553 (925) 372-2003 Fax:(925) 228-5738	Ms. Theresa Azevedo President East Bay Institute for Research and Education, Inc. P.O. Box 2339 Martinez, CA 94553 (925) 372-2343 Fax: (925) 372-2561 tazevedo@ebire.org
UC Irvine	Kevin Kennan UC Irvine Office of Technology Alliances 380 University Tower University of California Irvine, CA 92697-7700 Phone: (949) 824-4608 Fax: (949) 824-2899 kkennan@uci.edu	Chris Reist ACOS/R&D (151) VA Long Beach HCS 5901 East 7th.Street Long Beach, CA 90822 (562) 826-8000x4941 Fax: (562) 826-5675 chris.reist@med.va.gov	Ms. S. Lea Lowe Executive Director Southern California Institute for Research & Education 5901 East 7th Street (151) Long Beach, CA (562) 826-5747 Fax: (562) 826-8138 lea.lowe@va.gov
UC Los Angeles	Kathryn Atchison, DDS, MPH UCLA Office of Intellectual Property Administration 10920 Wilshire Blvd., Suite 1200, Mail Code 140648 Los Angeles, CA 90024-1406 Phone: (310) 794-0558 Fax: (310) 794-0638 KAtchison@resadmin.ucla.edu	Dean Yamaguchi, M.D., Ph.D. ACOS/R&D (151) VA Greater Los Angeles HCS 11301 Wilshire Blvd Research Service (151) Los Angeles, CA 90037 (310) 268-4437 Fax: (310) 268-4856 Dean.yamaguchi@med.va.gov	Bonita L. Krall Executive Director Sepulveda Research Corporation 16111 Plummer St. Sepulveda, CA 91343 (818) 895-5881; Fax: (818) 895-9383 bonita.krall@med.va.gov Kenneth G. Hickman, Ph.D. Executive Director Brentwood Biomedical Research Institute PO Box 25027 Los Angeles, CA 90025-0027 (310) 312-1554, ext, 218; c: (818) 731-6963 Fax: (310) 478-4538 Hickman@brentwoodResearch.org
UC San Diego	Alexa Falkenstein UC San Diego Technology Transfer and Intellectual Property Services 9500 Gilman Drive La Jolla, CA 92093-0910 Phone: (858) 822-45428 Fax: (858) 534-7345 afalkenstein@smtp.ucsd.edu	Stephen M. Baird, M.D. ACOS/R&D (151) VA San Diego HCS 3350 La Jolla Village Drive San Diego, CA 92161 (858) 552-8585,x3657 Fax: (858)552-7436 Stephen.Baird@med.va.gov	Ms. Kerstin Lynam Executive Director Veterans Medical Research Foundation of San Diego 3350 La Jolla Village Drive (V151A) San Diego, CA 92161 (858) 642-3070 direct;(858) 552-8585 x3070 or x3080 office, press 4 Fax: (858) 642-3081 klynam@vapop.ucsd.edu
UC San Francisco	Joel Kirschbaum UCSF Office of Technology Management 185 Berry Street, Suite 4603 San Francisco, CA 94107 Phone: (415) 353-4462 Fax: (415) 348-1579 joel.kirschbaum@ucsf.edu	Lynn Pulliam, M.S., Ph.D. ACOS/R&D (151) VA Medical Center 4150 Clement Street San Franciso, CA 94121 (415) 221-4810x2490 Fax: (415) 750-6906 Lynn.pulliam@med.va.gov	Mr. Robert Obana Executive Director Northern California Institute for Research and Education, Inc. 4150 Clement Street San Francisco, CA 94121 (415)750-6954; (415) 750-2295 direct; Fax: (415) 750-9358 robert.obana@ncire.org

Appendix B

Example CTAA Royalty Flow, With VA Lead & UC Distribution of Inventor and Research Shares

Example: One Dual Appointment Personnel (DAP)



NOTES

A -- Gross revenues received by VA from Licensee.

B -- VA recovers unreimbursed patent expenses and remits the rest to UC for distribution

C -- This example assumes that all inventors are under the current UC policy w/35% inventor share.

D -- This example assumes that all inventors are under the current UC policy w/35% inventor share.

E -- Amount represents "Net Revenues" as defined in the CTAA.

1 -- Patent expenses vary, but in late-stage clinical trials there are likely to be none.

2 -- Current UC Policy sets inventor share at 35% of revenues after deducting unreimbursed expenses. Some inventors, however, operate under a pre-1997 Policy with a 42.5% share.

3 -- UC policy and CTAA sets the Research Share at 15% of revenues after deducting unreimbursed expenses.
This amount is divided between UC and the VA according to the affiliations of the inventors; in this example, 50-50.

4 -- VA Administrative fee of 15% is taken after Inventor Share and Research Share are deducted so that Research Share is not less than under present CTAA distribution arrangement.

5 -- The parties have agreed that when the VA is managing the invention, the Net Revenues will be distributed equally without cumulative pooling.

Example Distribution Summary

$10,000	VA Unreimbursed Patent Expenses
$35,000	Inventor Share
$15,000	Research Share (in this example, divided evenly between UC and VA)
$7,500	VA Administrative Fee
$21,250	UC Distribution
$21,250	VA Distribution