

# Cooperative Agreement

## BETWEEN

University of Southern California

and

Rancho Los Amigos National Rehabilitation Center /  
Los Amigos Research Education Institute

This Agreement is entered into this *21<sup>st</sup>* day of *July*, 2006 between the University of Southern California, a non-profit public benefit corporation and the Rancho Los Amigos National Rehabilitation Center/Los Amigos Research and Educational Institute.

WHEREAS, the University of Southern California ("USC") and Rancho Los Amigos National Rehabilitation Center/Los Amigos Research and Educational Institute ("RLANRCILAREI") conduct research involving human subjects at their respective institutions. Human subjects research at the institutions is subject to certain policies, procedures, guidelines and regulations (collectively "Guidelines") for the protection of human subjects, including Guidelines established by the Department of Health and Human Services ("HHS") the U.S. Food and Drug Administration ("FDA"), and the State of California ("CDH"); and

WHEREAS, pursuant to Guidelines, human subjects research at each institution is subject to oversight by an Institutional Review Board ("IRB") established by each institution, and further subject to a Federalwide Assurance with the Office of Human Research Protections (hereinafter "Assurance"), which Assurance specifically commits the respective institutions to compliance with HHS Guidelines; and

WHEREAS, USC employs faculty members who conduct research at RLANRCILAREI and in such instances the research could be subject to duplicate review and oversight by the IRBs at both institutions ("Joint Research");

WHEREAS, this Cooperative Agreement memorializes current practice between USC and RLANRCILAREI;

NOW THEREFORE, in order to facilitate Joint Research, USC and RLANRCILAREI agree to this Agreement to their respective Assurances as follows:

1. RLANRC/LAREI as Primary Reviewer. Unless a review by the relied upon IRB is denied by either of the institutions in writing, the RLANRCILAREI IRB shall be responsible for reviewing all research involving human subjects that is (a) conducted under a grant, contract or other research agreement administered by RLANRC/LAREI Research Institute; or (b) where all human subjects shall be accrued exclusively at RLANRCILAREI. **This provision shall apply even when USC employed faculty and staff members, fellows, medical students, graduate students, undergraduate students or post-doctoral students are involved in conducting the research.**

In the event that RLANRCILAREI subcontracts a portion of a sponsored research project to USC, the appropriate USC IRB shall review that portion of the research activity involving human subjects that is conducted at USC. If, however, only data analysis will take place at USC, then the RLANRCILAREI IRB will assume responsibility for reviewing the entire research protocol. Such review shall include RLANRCILAREI IRB's approval letter and protocol summary that shall include detail about the research activity occurring at USC. USC reserves the right to insist on review by its own IRB regardless of this agreement, so long as the Chair of the USC IRB indicates this preference in writing to the Chair of the RLANRCILAREI IRB in a timely manner.

2. USC IRB as Primary Reviewer. Unless a review by the relied upon IRB is denied by either of the institutions in writing, the appropriate USC IRB shall be responsible for reviewing all research involving human subjects that is (a) conducted under a grant, contract or other research agreement administered by USC; or (b) where all human subjects shall be accrued exclusively at USC.

In the event that USC subcontracts a portion of a sponsored research project to RLANRCILAREI, the IRE3 shall review that portion of the research activity involving human subjects that is conducted at RLANRCILAREI. If, however, only data analysis will take place at RLANRCILAREI, then the USC IRE3 will assume responsibility for reviewing the entire research protocol. Such review shall include the applicable USC IRB's approval letter and protocol summary that shall include detail about the research activity occurring at RLANRCILAREI. RLANRCILAREI reserves the right to insist on review by its own IRB regardless of this agreement, so long as the Chair of the IRB indicates this preference in writing to the Chair of the applicable USC IRB in a timely manner.

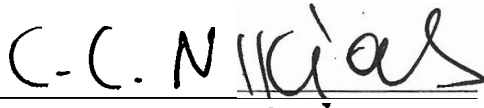
3. Notification of Action/Outcome: When the IRB from either institution acts as primary reviewer for a proposal affecting both institutions, that IRB shall notify the other IRB of the outcome of the review and significant IRB action subsequent to initial approval.
4. Representations and Warranties. Each institution represents and warrants that:
  - (a) IRB reviews shall occur with voting membership and/or consultant supplementation appropriate to any given activity. Changes in voting membership shall be reported to the Office for Human Research Protection (OHRP) as they occur;
  - (b) Each respective institution shall adequately support the IRB function, cooperate with reporting requirements and requests for additional information, and abide with IRB decisions. Non-approval may not be administratively overruled by either cooperating institution. Relevant minutes of IRB meetings shall be made available to both cooperating institutions upon request.

- (c) USC and RLANRCILAREI each specifically warrant and represent that it currently is in compliance with its respective Assurance and that it shall each use best efforts to remain in compliance with the Assurance and other applicable laws and regulations governing the protection of human subjects in research, including regulations promulgated by the Department of Health and Human Services (HHS).
5. Adherence to USC Policies. USC and RLANRCILAREI each have an obligation under their respective policies to review cases or allegations of non-compliance by their respective employees, including but not limited to issues related to scientific conduct, conflict of interest and employment discrimination, harassment or retaliation. Accordingly, RLANRCILAREI shall promptly report in writing to either the USC's Office of Compliance or the USC Vice Provost for Research Advancement any and all allegations, complaints or concerns of which it becomes aware that involve USC faculty, staff or students so that USC can ensure that its procedures are followed. USC shall promptly report in writing to the RLANRCILAREI Vice President of Research any and all allegations, complaints or concerns of which it becomes aware that involve RLANRCILAREI employees.
  6. Indemnification. Each party shall defend, indemnify and hold harmless the other party, its officers, employees, and its agents from and against any and all claims (and liabilities, judgments, penalties, losses, costs, damages, and expenses resulting therefrom, including reasonable attorneys' fees) made by third parties against the indemnified party arising out of any breach by the indemnifying party of its performance of any obligations under the terms of this Agreement.
  7. No Assignment. Neither party hereto shall have the right, directly or indirectly, to assign, transfer, convey or encumber any of its rights under this Agreement without the prior written consent of the other party hereto. Any attempted or purported assignment by a party in violation of this paragraph shall be void. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the respective successors and assigns of the parties.
  8. Governing Law. This Agreement shall be construed in accordance with and all disputes hereunder shall be governed by the laws of the State of California.
  9. Severability. If any term or provision of this Agreement is for any reason held to be invalid, such invalidity shall not affect any other term or provision, and this Agreement shall be interpreted as if such term or provision had never been contained in this Agreement.
  10. Notice. All notices to be given under this Agreement (which shall be in writing) shall be given at the respective addresses of the parties as set forth in the preamble to this Agreement, unless notification of a change of address is given in writing. Any notice required by this Agreement shall be deemed to have been properly received when delivered in person or when mailed by registered or certified first class mail, return receipt requested, or by Federal Express to the address as given herein, or such addresses as may be designated from time to time during this term of this Agreement.

11. Waiver of Breach. No party's failure to enforce any provision of this Agreement shall be deemed or in any way construed as a waiver of **any** such provision or provisions, nor prevent that party thereafter from enforcing each and every provision of this Agreement.
12. Counterparts. This agreement may be executed simultaneously in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument.
13. Entire Agreement. This Agreement fully supersedes any and all prior agreements or understandings between the parties hereto or any of their respective affiliates with respect to the subject matter hereof, and no change in, modification of or addition, agreement or supplement to this Agreement shall be valid unless set forth in writing and signed and dated by both parties hereto subsequent to the execution of this Agreement.
14. Authority of Signatories. The officials having signed below commit their respective institutions to the following binding cooperative agreement with regard to reliance upon each other's IRBs.

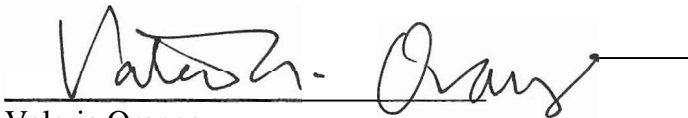
IN WITNESS WHEREOF, the parties have executed this Agreement of Affiliation as of the dates set forth below.

UNIVERSITY OF SOUTHERN CALIFORNIA



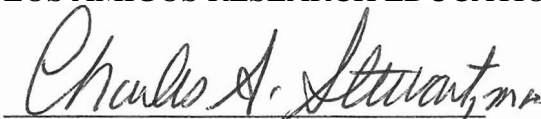
C.L. Max Nikias  
Provost and Senior Vice President for Academic Affairs

RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER



Valerie Orange  
Chief Executive Officer

LOS AMIGOS RESEARCH EDUCATION INSTITUTE



Charles A. Stewart, M.D.  
President