HUMAN SUBJECT PROTECTION AGREEMENT
BETWEEN
U.S. DEPT. OF VETERANS AFFAIRS PALO ALTO HEALTH CARE SYSTEM, PALO ALTO INSTITUTE FOR RESEARCH AND EDUCATION, INC. AND THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY

Introduction/Preamble

This agreement outlines the details of the relationship between Veterans Affairs Palo Alto Health Care System ("VAPAHCS"), Palo Alto Institute for Research and Education, Inc. ("PAIRE"), and The Board of Trustees of the Leland Stanford Junior University ("Stanford") in assuring the protection of human subjects in VAPAHCS research, including the responsibilities of each. In addition it delineates the terms and conditions under which VAPAHCS and PAIRE may utilize Stanford's Institutional Review Boards ("IRBs").

This agreement is entered into by and between the U.S. Department of Veterans Affairs Palo Alto Health Care System, which includes, as legally inseparable entities, Palo Alto Division, Menlo Park Division, Livermore Division, Monterey Outpatient Clinic, Capitola Outpatient Clinic, Stockton Outpatient Clinic, Modesto Outpatient Clinic, San Jose Outpatient Clinic, Sonora Outpatient Clinic, Fremont Outpatient Clinic, and its officials and employees, with its principal office and place of business at 3801 Miranda Avenue, Palo Alto, CA; Palo Alto Institute for Research and Education, which includes as legally inseparable its officials and employees with its principal office and place of business at 3801 Miranda Avenue, Palo Alto, CA; and Stanford, which includes as legally inseparable entities its officials and employees with its principal office and place of business at Stanford, CA, 94305.

WHEREAS, VAPAHCS and PAIRE wish to retain, pursuant to the terms and conditions of this agreement, the services of Stanford through its Vice Provost and Dean of Research and its IRBs, i.e., Medical Administrative Panels on Human Subjects in Research to perform research review functions as required by statute and regulations of DHHS and DVA; and

WHEREAS, Stanford is interested in facilitating participation in VA Research by faculty members with dual appointments (Stanford and VAPAHCS), recognizes the administrative preference of hosting review of VA Research, and wishes to avoid the inefficiencies of duplication of efforts in human subject use review; and

WHEREAS, all parties to this agreement agree that the Veterans Health Administration (VHA) Central Office operates a VA Central Institutional Review Board and that the VA CIRB will be solely responsible for the initial and continuing review as well as review of amendments, monitoring, reporting, and other relevant requirements, for select Veterans Administration Office of Research and Development funded multi-site research projects involving human subjects as set forth in the Memorandum of Understanding between Veterans Health Administration (VHA) Central Office and VA Palo Alto health Care System.

WHEREAS, all parties to this agreement understand that the ethical conduct of research is a shared responsibility requiring cooperation, collaboration, and trust among institutions, investigators and their research staff, the subjects who enroll in research, and the Institutional Review Boards' members and staff; and

WHEREAS, PAIRE is a nonprofit corporation authorized under Title 38, subchapter IV to provide a flexible funding mechanism for the conduct of approved research at VAPAHCS and as such, has no authority to approve the conduct of VA Research; and

WHEREAS, Stanford's IRBs possess valuable skills, knowledge, expertise, and resources in the area of human subject protection in research; and

WHEREAS, Stanford, VAPAHCS and PAIRE recognize the presence of common professional and community standards; familiarity with each other's operational policies, constraints, procedures, and commitments; and geographic proximity of the institutions; and

WHEREAS, all parties to this agreement agree that terms used in this agreement shall have the same meaning as those terms in 45 CFR 160.103 and 164.501, Title 38, Part 16 of the Code of Federal Regulations, Title 45, Part 46 of the Code of Federal Regulations, and Title 21, parts 50 and 56 of the code of Federal Regulations.

Therefore, in consideration of the promises and undertakings set forth herein, VAPAHCS, PAIRE, and Stanford agree as follows:

A. Applicability

1. Except for human subjects research subject to review by the VA Central IRB, this agreement applies to all research involving human subjects, and all other activities which even in part involve such research, regardless of whether the research is otherwise subject to VA regulation, if:

    a. the research is sponsored by the VA, or
    b. the research is conducted by or under the direction of any employee or agent of VAPAHCS (full-time, part-time, intermittent, consultant, without compensation (WOC), on-station fee-basis, on-station contract, or on-station sharing agreement basis) in connection with her/his VAPAHCS responsibilities, or
    c. the research is conducted using any property or facility of VAPAHCS, or
    d. the research recruits veteran subjects on VA property, or
    e. the research involves the use of the VA's nonpublic information to identify or contact human research subjects or prospective subjects or to use such data for research purposes.

2. Research meeting these criteria will be referred to as "VA Research" throughout this agreement.

B. Institutional Responsibilities

1. Stanford, VAPAHCS, and PAIRE agree that all three are collectively responsible for attempting to identify research proposals prior to their initiation that meet the definition of VA Research, in order that such research may be processed and reviewed in accordance with this MOU.

2. Stanford, VAPAHCS and PAIRE will maintain their respective Federalwide Assurances ("FWAs") with the Department of Health and Human Services' Office of Human Research Protections and agree to abide by the terms of these FWAs.

3. Stanford authorizes the designation of the Stanford Health and Human Services registered IRBs for review of research under the VAPAHCS FWA 00000929 and PAIRE FWA 00000937.

4. Each institution will support and maintain open channels of communication across institutional boundaries between IRB members and staff, investigators and research staff, facility management, research administrators and institution officials regarding human subject protections.

5. Stanford, VAPAHCS and PAIRE will comply fully with the requirements set forth at Title 38, Part 16 of the Code of Federal Regulations (38 CFR 16, Department of Veterans Affairs and the Common Rule) as well as at Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46, Department of Health and Human Services), Title 21, parts 50 and 56 of the code of Federal Regulations (where applicable) and VHA Handbook 1200.05 for all VA Research.

6. Except for human subjects research subject to review by the VA Central IRB, VAPAHCS, its Research and Development (R&D) Committee, and PAIRE designate Stanford's Institutional Review Boards (IRBs) to be responsible for the initial and continuing review of all VA human subject research. Research reviewed by the VA CIRB will not be subject to review by Stanford's IRBs. This designation gives these IRBs statutory authority to take any action necessary to protect the rights and welfare of human subjects in VA Research. These IRBs have the authority to approve, require modifications in, or disapprove human subject use in VA Research.

7. VAPAHCS shall ensure that VA human subject research will be conducted in full accordance with the determinations of the Stanford IRB.

8. VAPAHCS agrees to cooperate with Stanford IRBs and take all necessary action to allow the IRBs to review the research submitted to them for purposes of carrying out the requirements of human subject use review and applicable laws and regulations. Actions include, but are not limited to:

    a. Responding to questions and requests for information;
    b. Allowing access to pertinent records consistent with routine VA IRB uses of veteran, patient, employee, volunteer and R&D project records;
    c. Allowing access to pertinent financial records;
    d. Allowing access to facilities where research is performed;
    e. Providing access to monitor ongoing research, including witnessing the informed consent process and the implementation of the entire research protocol.

9. Stanford and PAIRE acknowledge that the VAPAHCS R&D Committee represents a required second level of review for all VA Research. No VA Research may be undertaken without VA R&D Committee review and approval. When funding for VA Research will be administered by Stanford or PAIRE, Stanford and PAIRE will notify the protocol director that authorization by the VAPAHCS R&D Committee is necessary prior to expenditure of funds or accrual of subjects in VA Research.

10. VAPAHCS and its R&D Committee cannot approve research that has been disapproved by a Stanford IRB. If, in the course of its review, the R&D Committee requires changes to the protocol that relate to the determination of the protection of human subjects, the R&D Committee must refer those changes to the IRB for its approval before the R&D Committee can give final approval.

11. VAPAHCS remains ultimately responsible for the maintenance of its overall institutional system to protect human subjects.

12. VAPAHCS will periodically assess Stanford IRB performance as to VA Research in the following essential components of the VAPAHCS Human Research Protection Program:

    a. Content and accuracy of informed consent forms;
    b. IRB analysis of risks and benefits including designation of minimal risk;
    c. Special considerations and protections for vulnerable or potentially vulnerable populations;
    d. Privacy and confidentiality protections;
    e. Continuing review of approved research;
    f. Ongoing review of previously approved research ,e.g., review of amendments and adverse events;
    g. Use of expedited review or other procedures requiring review of less than the full IRB;
    h. Granting exemption from Federal requirements for IRB review;
    i. Granting waivers for documentation of informed consent;
    j. Granting waivers of any elements of informed consent;
    k. Managing conflict of interest of IRB members

    This will be accomplished via:

    a. Regular review of IRB documents pertaining to VA Research by the VAPAHCS R&D Committee;
    b. Annual review of IRB composition by VAPAHCS for regulatory compliance, appropriateness as related to the research being reviewed, and inclusion of representatives with an interest in or experience with vulnerable populations;
    c. Annual review of documented IRB policies and procedures for compliance with applicable regulations;
    d. Periodic attendance by a VAPAHCS representative at IRB meetings as a non-voting member.

13. As part of VAPAHCS annual review of HRPP resources and resource requirements, Stanford will provide an annual report to the VA R&D Committee. This report will summarize the functioning of the IRBs with respect to VA Research and delineate any problems, realized or potential, therewith. An analysis of the volume of research considered by the IRBs will be included in the report. This report will be discussed at an R&D Committee meeting where a representative of Stanford's Research Compliance Office and a VA representative to the IRB are invited to attend.

14. VAPAHCS will ensure via written communication with Stanford's Research Compliance Office that the IRBs are informed of all VA requirements relating to the protection of human subjects in research.

15. Stanford and its IRBs will incorporate in or attach to their IRB Standard Operating Procedures any policies and procedures specific to VA Research.

16. VAPAHCS, Stanford and PAIRE will collaborate to maintain a system of protections applicable to all human subject research covered by this agreement.

17. Each institution remains responsible for safeguarding the rights and welfare of human subjects within its local context.

18. Each institution will require disclosure of conflict of interest by individuals conducting research, i.e. individuals designing research, directing research, serving as principal investigator, enrolling subjects, making decisions regarding subject eligibility to participate in research, analyzing or reporting research data, or submitting manuscripts concerning the research for publication. All disclosed conflicts will be managed, mitigated, or eliminated by Stanford, VAPAHCS, and/or PAIRE, as appropriate.

19. Each institution is responsible for educating the members of its research community in order to maintain a culture of compliance with Federal regulations and institutional policies relevant to the protection of human subjects. Training may be conducted jointly.

20. VAPAHCS and PAIRE are responsible for implementation, within their local research context, of appropriate oversight mechanisms to ensure compliance with the determinations of the reviewing IRB.

21. VAPAHCS and Stanford acknowledge the understanding that each party shall be responsible and liable for the negligent conduct of its own research and any and all resulting damages or injury to human subjects.

22. Stanford acknowledges that the privacy provisions of the federal law – the Health Insurance Portability and Accountability Act of 1996 (HIPAA) – apply to health information created or maintained by health care providers who engage in certain electronic transactions, that the Department of Health and Human Services has issued the regulation entitled "Standards for Privacy of Individually Identifiable Health Information" applicable to entities covered by HIPAA, and that the services provided under this Agreement may involve the

receipt and use of Protected Health Information (PHI) as defined in 45 CFR 164.501. Furthermore,

(a) Stanford may use PHI for the proper management and administration of the Stanford IRBs or to carry out the legal responsibilities of Stanford and to perform functions, activities, or services for, or on behalf of, VAPAHCS as specified throughout this Agreement, provided that such use would not violate the Privacy Act, Title 5 U.S.C. 552a, if done by VAPAHCS.

(b) Stanford agrees to not use or further disclose PHI other than as permitted or required by the Agreement or as required by law.

(c) Stanford agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement.

(d) Stanford agrees to report to VAPAHCS any use or disclosure of the Protected Health Information not provided for by this Agreement.

(e) Stanford agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from VAPAHCS, or created or received by Stanford on behalf of VAPAHCS, agrees to the same restrictions and conditions that apply through this Agreement to Stanford with respect to such information.

(f) Stanford agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for a covered entity to respond to a request by an individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits VAPAHCS to comply with the Privacy Act.

23. Stanford shall serve as the research Privacy Board for VAPAHCS and PAIRE, and will be responsible for approval/disapproval of Waivers of Authorization for VA Research. The Stanford IRB shall report to VAPAHCS and PAIRE when any incident of unauthorized use, loss, or disclosure of individually-identifiable VAPAHCS study subject information occurs. Stanford IRB is responsible for implementing policies and procedures that comply with the data security reporting policies of VAPAHCS. Specifically the Stanford IRB agrees to notify VAPAHCS Privacy Officer within one hour of becoming aware of any incident involving the unauthorized use, loss or disclosure of individually-identifiable VAPAHCS study subject information.

24. All parties agree that this agreement is not intended, and shall not be construed, to bestow any benefits on any individual or entity that is not a party to this agreement, including any individual participating in human subject research covered by this agreement.

25. If required to do so by law or VAPAHCS policy, VA shall inform the appropriate Federal agency (e.g., OHRP, FDA, NIH, etc.) of:
    (a) any unanticipated injuries or problems involving risks to subjects or others in VA Research;
    (b) any serious or continuing noncompliance with the provisions of this agreement or the determinations of the IRB; and
    (c) any suspension or termination of IRB approval for VA Research protocols.

    Unless immediate reporting is required or warranted, to avoid duplicate reporting, VA shall send these letters after the IRB's determination and copy Stanford's Research Compliance Director, currently Kathy McClelland, and Stanford's Vice Provost and Dean of Research, currently Ann Arvin, on all letters to Federal agencies provided under this Section. If the VA reports on behalf of Stanford, then Stanford has no obligation to submit reports that are otherwise submitted by VAPAHCS.

26. VAPAHCS monitoring reviews of research protocols are considered to be part of the HRPP monitoring activities. Consequently, Stanford may rely on VAPAHCS monitoring reviews for purposes of satisfying its monitoring requirements.

C. Institutional Review Board Responsibilities

1. Stanford IRBs assume responsibility for initial and continuing review and approval of all protocols submitted to them as VA Research.

2. In reviewing these protocols, the IRBs will comply fully with the requirements of all applicable Federal policies and guidelines.

3. The IRBs will have the authority to approve, require modification in, or disapprove all VA Research involving human subjects.

4. IRB reviews of activities identified as VA Research will take into account the required criteria for approval, the facilities and capabilities of VAPAHCS, the measures taken by VAPAHCS to ensure compliance with their determinations, as well as the VAPAHCS community attitudes.

5. The membership of each IRB will include at least two voting members who are VAPAHCS representatives. VAPAHCS shall assist the IRBs in recruiting VAPAHCS representatives for IRB membership.

6. The IRBs will have the authority to suspend or terminate approval of VA human subject research.

7. The IRBs will have the authority to observe and/or monitor VA Research to whatever extent necessary to protect human subjects.

8. The IRBs will maintain processes to identify the financial conflict of interest of individuals conducting research as it relates to human subject protection.

9. The IRBs may require that the proposed research is reviewed and approved by VAPAHCS or Stanford committees on Radiation Safety, Bio-Safety, or other relevant VA or Stanford committees prior to granting their own approval.

10. The membership of each IRB will include at least one member who does not have any association with Stanford, VAPAHCS or PAIRE and is not part of the immediate family of a person who is affiliated with these organizations.

11. The IRBs will prepare and maintain adequate documentation of its activities in accordance with applicable regulations.

12. The IRBs shall maintain records to document the current IRB approval status of the VA's current research. Such records will be made accessible to authorized VAPAHCS personnel and others with legitimate rights of access.

13. IRB records will be maintained and/or stored as required to protect the privacy and confidentiality of subjects.

14. The IRBs will retain records for a minimum of three years following completion of the study.

15. The IRBs will inform the VAPAHCS R&D Committee in writing of all identified VA Research that was reviewed and the outcomes of each of these reviews after each IRB meeting.

16. The IRBs will make records related to VA Research accessible for inspection and copying by authorized representatives of VA, including accreditors and appropriate Federal departments or agencies, at reasonable times and in a reasonable manner.

17. The IRBs will report promptly to Stanford, PAIRE, and VAPAHCS officials, as well as to any applicable regulatory authority:

    a. any unanticipated injuries or problems involving risks to subjects or others in VA Research;
    b. any serious or continuing noncompliance with the provisions of this agreement or the determinations of the IRB; and
    c. any suspension or termination of IRB approval for VA Research protocols.

18. The IRBs will provide the VA R&D Committee copies of any reports or correspondence related to VA Research to or from regulatory and compliance enforcement agencies or offices, including PHS, NIH, OHRP, and FDA, upon their receipt or dispatch.

19. Stanford's IRBs may be called into an interim review session by the Chairperson at the request of any IRB member or appropriate Stanford or VAPAHCS official to consider any matter concerned with the rights and welfare of any subject involved in VA Research.

D. Principal Investigator Responsibilities

1. Stanford, VAPAHCS, and PAIRE acknowledge that Principal Investigators are responsible for ensuring the following:

    a. except for human subjects research subject to review by the VA Central IRB, all VA human subject research has received initial prospective review and approval by a Stanford IRB;
    b. continuing review and approval of the research has been accomplished within the time frame stipulated by the IRB;
    c. the research is conducted at all times in compliance with all applicable regulatory requirements and the determinations of the designated IRB;
    d. VA R&D Committee approval has been received prior to any VA Research activity commencing;
    e. no changes in approved research protocols or consent forms are initiated without prior IRB approval, except where necessary to eliminate apparent immediate hazards to subjects;
    f. no research may be continued beyond the IRB-designated approval period;
    g. any serious adverse events or unanticipated problems involving risks to subjects or others are promptly reported to the IRB and VA Research Administration;
    h. any serious or continuing non-compliance with applicable regulatory requirements or determinations of the designated IRB of which investigators become aware are promptly reported to the IRB and VA Research Administration;
    i. copies of any reports or correspondence to or from any regulatory or compliance enforcement agency, such as OHRP, FDA, etc, that exercises oversight for the protection of human subjects in research are provided to the IRB.

E. Performance Period

1. This agreement shall be effective upon May 30, 2014 and shall remain in effect for a period of three years.

F. Financial Remuneration

1. Sponsored VA research administered by PAIRE is subject to initial and continuing review IRB review fees. Request for payment of these fees will be directed to PAIRE.

2. PAIRE agrees to pay appropriate charges within 30 days of receipt of invoice referencing specific protocols for which review has been completed.

G. Termination

1. Either party may terminate this agreement if the other party breaches any of its obligations or provisions, provided however, that the defaulting party shall be given not less than ninety (90) days prior written notice of such intent to terminate and the opportunity to cure the default during such period.

2. Either party may terminate this Agreement for cause or convenience upon one hundred and eighty (180) days written notice.

3. VAPAHCS and PAIRE agree that if this agreement should be terminated they shall immediately amend their FWAs to remove Stanford as designated IRB. If reasonably possible, the effective date of the amendments of the FWAs shall be the effective date of the termination.

H. Notices/Modifications

Any changes or modifications should be mailed to:

Stanford

Contact Title:	Research Compliance Director
Name:	Kathy McClelland
Address:	Research Compliance Office Stanford University, Stanford, CA 94305

VAPAHCS

Contact Title:	ACOS/Research and Development
Name:	Philip Tsao, Ph.D Ph.D.
Address:	VA Palo Alto Health Care System 3801 Miranda Avenue (151), Palo Alto, CA, 94304-1290

PAIRE

Contact Title:	Chief Executive Officer
Name:	Kerstin Lynam
Address:	P.O. Box V-38 Palo Alto, CA, 94304-0038

I. Applicable Law

1. This Agreement shall be construed, interpreted and enforced under federal law and, when not inconsistent, the laws of the State of California.

J. Signature Page

IN WITNESS WHEREOF, the parties hereto have executed this agreement as of the date set forth above.

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY:
By: Ann M. Arvin, M.D.

Signature: _____
Title: Vice Provost and Dean of Research

VETERANS AFFAIRS PALO ALTO HEALTH CARE SYSTEM:
By: Elizabeth J. Freeman

Signature: _____
Title: Director

PALO ALTO INSTITUTE FOR RESEARCH AND EDUCATION, INC.:
By: Kerstin Lynam

Signature: Kerstin Lynam
Title: Chief Executive Officer

Date: 05/27/2014

Approved: Ann M. James Senior University Counsel

AGREEMENT CONCERNING
RESEARCH INVOLVING HUMAN SUBJECTS
BETWEEN STANFORD HOSPITAL AND CLINICS
AND STANFORD UNIVERSITY

THIS AGREEMENT ("Agreement") concerning research involving human subjects is effective as of September 1, 2005 between THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY ("SU") and STANFORD HOSPITAL AND CLINICS ("SHC").

Recitals

Whereas, the US Department of Health and Human Services ("DHHS") requires that institutions performing research involving human subjects that is supported by a federal department or agency supply an assurance to it that the research will be conducted in accordance to its regulations (Part 46 of Title 45 of the Code of Federal Regulations);

Whereas, the Federal Drug Administration ("FDA") has similar regulations for other types of research involving human subjects (Part 50 of Title 21of the Code of Federal Regulations) as do other federal agencies;

Whereas, SU and SHC together and separately perform research involving human subjects;

Whereas, SHC has filed an assurance as required by DHHS and as attached ("Assurance") that designates SU's institutional review board to review the research involving human subjects performed by SU and SHC together and separately;

Whereas, SU has established a human research protection program (HRPP) that addresses the principles and standards of the Association for the Accreditation of Human Research Protection Programs, requires compliance with applicable laws such as the Common Rules (45 CRR Part 46) and FDA regulations relating to human subjects (21 CFR Parts 50 and 56), and incorporate ethical standards such as the Belmont report;

Whereas, SHC wishes to continue to retain SU in order to be covered by the HRPP and have it perform the research review functions required by that Assurance and the federal laws administered by DHHS, the FDA, and other federal agencies;

Now, the parties agree as follows:

1. Through this Agreement, SHC retains SU to incorporate it into the HRPP and carry out the primary activities of the HRPP on its behalf as specified in the HRPP, including the research review functions ("Research Review") for research involving human subjects as required by DHHS and the FDA through the federal statute and regulations relating to such research in Part 46 of Title 45 and Part 50 of Title 21of the Code of Federal Regulations or any successor regulations as well as that required by any other federal agency that has adopted the Common Rule.

2. SU agrees to file an assurance as required by DHHS and provide the Research Review to SHC in accordance with the terms of this Agreement through its Vice Provost

and Dean of Research and Graduate Policy and its institutional review board currently known as the "Administrative Panel on Human Subjects In Medical Research" ("IRB").

3. SHC and SU agree to:

a) Communicate, coordinate and cooperate as necessary to establish and maintain the HRPP;

b) Maintain the assurances required by DHHS during the term of this Agreement;

c) Abide by the provisions of their respective assurances in carrying out research involving human subjects that is covered by their assurances (e.g., at or by SU and SHC); and

d) Abide by all laws applicable to research involving human subjects at or by SHC or SU.

4. The duties of SU pursuant to Section 2 to provide the Research Review shall include but not be limited to:

a) Establishing, maintaining, and overseeing the HRPP;

b) Assisting SHC in drafting and seeking approval from DHHS for the Assurance and any amendments to the Assurance;

c) Establishing, staffing, and administering its IRB;

d) Reviewing research involving human subjects through its IRB that is covered by the Assurance or is otherwise by or at SHC;

e) Communicating with DHHS regarding the Assurance and compliance with the Assurance; and

f) Communicating with the FDA (and any other federal agency that has adopted the Common Rule) regarding research involving human subjects falling under its jurisdiction and compliance with laws it administers relating to human subjects research conducted at or by SHC; and

g) Investigating any complaints of human subjects, unanticipated problems under the research protocol, or any potential non-compliance with the research protocol or of the law related to research involving human subjects at or by SHC or otherwise covered by the Assurance and HRPP.

5. SHC agrees to cooperate with SU and take all reasonable, necessary action to allow SU to carry out the HRPP, including but not limited to:

a) Responding to questions and requests for information related to the Research Review;

b) Allowing access to records, as allowed by law, which are relevant to the Research Review;

c) Allowing access to facilities where the research is to be performed, including access for monitoring the ongoing research and witnessing the informed consent process and the implementation of the entire research protocol;

d) Maintaining the confidentiality of human subjects information as required by law or as promised in an informed consent form to a human subject;

e) Participating as necessary in reviews relating to human subjects and concerning possible non-compliance with the research protocol or laws, or unanticipated problems under the research protocol.

6. This Agreement shall continue in effect so long as the Assurance is in effect. The parties agree to meet and confer in order to enter into a similar agreement for any new assurance covering human subject research by or at SHC prior to the expiration of the Assurance.

Therefore, the parties have executed this Agreement in duplicate.

STANFORD HOSPITAL CLINICS

By: Michael Peterson

Michael Peterson
Chief Operating Officer

Date: 8/10/05

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY

By: A. Bienenstock

Arthur Bienenstock, Ph.D.
Vice Provost and Dean of Research
and Graduate Policy

Date: 8/17/05

RJ

AGREEMENT CONCERNING
RESEARCH INVOLVING HUMAN SUBJECTS
BETWEEN STANFORD UNIVERSITY AND
LUCILE SALTER PACKARD CHILDREN'S HOSPITAL AT STANFORD

THIS AGREEMENT ("Agreement") concerning research involving human subjects is effective as of September 1, 2005 between THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY ("SU") and LUCILE SALTER PACKARD CHILDREN'S HOSPITAL AT STANFORD ("LPCH@S").

Recitals

Whereas, the US Department of Health and Human Services ("DHHS") requires that institutions performing research involving human subjects which is supported by a federal department or agency supply an assurance to it that the research will be conducted in accordance to its regulations (Part 46 of Title 45 of the Code of Federal Regulations);

Whereas, the Federal Drug Administration ("FDA") has similar regulations for other types of research involving human subjects (Part 50 of Title 21of the Code of Federal Regulations) as do other federal agencies;

Whereas, SU and LPCH@S together and separately perform research involving human subjects;

Whereas, LPCH@S has filed an assurance as required by DHHS and as attached ("Assurance") that designates SU's institutional review board to review the research involving human subjects perform by SU and LPCH@S together and separately;

Whereas, SU has established a human research protection program (HRPP) that addresses the principles and standards of the Association for the Accreditation of Human Research Protection Programs, requires compliance with applicable laws such as the Common Rules (45 CRR Part 46) and FDA regulations relating to human subjects (21 CFR Parts 50 and 56), and incorporate ethical standards such as the Belmont report;

Whereas, LPCH@S wishes to continue to retain SU in order to be covered by the HRPP and have it perform the research review functions required by that Assurance and the federal laws administered by DHHS, the FDA, and other federal agencies;

Now, the parties agree as follows:

1. Through this Agreement, LPCH@S retains SU to incorporate it into the HRPP and carry out the primary activities of the HRPP on its behalf as specified in the HRPP, including the research review functions ("Research Review") for research involving human subjects as required by DHHS and the FDA through the federal statute and regulations relating to such research in Part 46 of Title 45 and Part 50 of Title 21of the Code of Federal Regulations or any successor regulations as well as that required by any other federal agency that has adopted the Common Rule.

2. SU agrees to file an assurance as required by DHHS and provide the Research Review to LPCH@S in accordance with the terms of this Agreement through its Vice Provost and Dean of Research and Graduate Policy and its institutional review board

currently known as the "Administrative Panel on Human Subjects In Medical Research" ("IRB").

3. LPCH@S and SU agree to:

a) Communicate, coordinate and cooperate as necessary to establish and maintain the HRPP;

b) Maintain the assurance required by DHHS during the term of this Agreement;

c) Abide by the provisions of their assurances in carrying out research involving human subjects which is covered by their assurances (e.g., at or by SU or LPCH@S); and

d) Abide by all laws applicable to research involving human subjects at or by LPCH@S or SU.

4. The duties of SU pursuant to Section 2 to provide the Research Review shall include but not be limited to:

a) Establishing, maintaining, and overseeing the HRPP;

b) Assisting LPCH@S in drafting and seeking approval from DHHS for the Assurance and any amendments to the Assurance;

c) Establishing, staffing, and administering its IRB;

d) Reviewing research involving human subjects through its IRB that is covered by the Current Assurance or is otherwise by or at LPCH@S;

e) Communicating with DHHS regarding the Assurance and compliance with the Assurance; and

f) Communicating with the FDA (and any other federal agency that has adopted the Common Rule) regarding research involving human subjects falling under its jurisdiction and compliance with laws it administers relating to human subjects research conducted at or by LPCH@S; and

g) Investigating any complaints of human subjects, unanticipated problems under the research protocol, or any potential non-compliance with the research protocol or of the law related to research involving human subjects at or by LPCH@S or otherwise covered by the Assurance and HRPP.

5. LPCH@S agrees to cooperate with SU and take all reasonable, necessary action to allow SU to carry out the HRPP, including but not limited to:

a) Responding to questions and requests for information related to the Research Review;

b) Allowing access to records, as allowed by law, which are relevant to the Research Review;

c) Allowing access to facilities where the research is to be performed, including access for monitoring the ongoing research and witnessing the informed consent process and the implementation of the entire research protocol;

d) Maintaining the confidentiality of human subjects information as required by law or as promised in an informed consent form to a human subject;

e) Participating as necessary in reviews relating to human subjects and concerning possible non-compliance with the research protocol or laws, or unanticipated problems under the research protocol.

6. This Agreement shall continue in effect so long as the Assurance is in effect. The parties agree to meet and confer in order to enter into a similar agreement for any new assurance covering human subjects research by or at LPCH@S prior to the expiration of the Assurance.

Therefore, the parties have executed this Agreement in duplicate.

LUCILE SALTER PACKARD
CHILDREN'S HOSPITAL
AT STANFORD

By: _____
Cynthia Haines
Senior Vice President
Business Development
& Strategic Planning

THE BOARD OF TRUSTEES OF
LELAND STANFORD JUNIOR
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