

FWA #: FWA00000929  
Institution: VA Palo Alto Health Care System  
Expires: 07/18/2022

OMB No. 0990-0278  
Approved for use through August 31, 2017

## Federalwide Assurance (FWA) for the Protection of Human Subjects

### 1. Institution Filing Assurance

Legal Name: VA Palo Alto Health Care System  
City: Palo Alto State/Province: CA Country: USA

### 2. Institutional Components

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (\*) any alternate names under which the Institution operates.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below.

Name of Component or Alternate Names Used	City	State (or Country if Outside U.S.)
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### 3. Statement of Principles

This Institution assures that all of its activities related to human subjects research, regardless of the source of support, will be guided by the following statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. (indicate below)

#### ***The Belmont Report***

### 4. Applicability

(a) This Assurance applies whenever this Institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), unless the research is otherwise exempt from the requirements of the Common Rule or the department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance.

(b) Optional: This Institution elects to apply the following to all of its human subjects research regardless of the source of support, except for research that is covered by a separate assurance:

***The Common Rule (see section 3 of the Terms of the FWA for a list of U.S. federal departments and agencies that have adopted the Common Rule and the applicable citations to the Code of Federal Regulations)***

#### 5. Assurance of Compliance with the Terms of the Federalwide Assurance

(a) This Institution assures that whenever it engages in research to which this Assurance applies, it will comply with the Terms of the Federalwide Assurance (contained in a separate document on the Office for Human Research Protections (OHRP) website).

#### 6. Designation of Institutional Review Boards (IRBs)

This Institution assures that it will rely upon only IRBs registered with OHRP for review of research to which this FWA applies. This institution (a) designates the following internal IRB(s) for review of research under this Assurance; or (b) does not have an internal IRB and designates the following external IRB for review of all research to which this FWA applies or, if multiple external IRBs are relied upon, the following external IRB that reviews the largest percentage of research to which this FWA applies.

NOTE: Institutions designating internal IRBs do not need to designate any of the external IRBs upon which it relies.

HHS IRB Registration Number	Name of IRB as Registered with HHS	Is the IRB Internal or External to the Institution?
IRB00000348	Leland Stanford Junior U IRB #1	E
IRB00000350	Leland Stanford Junior U IRB #3	E
IRB00000351	Leland Stanford Junior U IRB #4	E
IRB00004593	Leland Stanford Junior U IRB #5	E
IRB00004947	Leland Stanford Junior U IRB #6	E
IRB00005136	Leland Stanford Junior U IRB #7	E
IRB00006208	Leland Stanford Junior U IRB # 8	E
IRB00006332	Veterans Hlth Administration Central Ofc IRB #1	E

7. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First Name: Kristin Middle Initial: B Last Name: Frazier  
 Degrees or Suffix: J.D. Institutional Title: Human Protections Administrator  
 Institution: Veterans Affairs Palo Alto Health Care System  
 Telephone: 650 493-5000 FAX: 650 852-3203 E-Mail: kristin.frazier@va.gov  
 Address: Veterans Affairs Palo Alto Health Care System  
 Research Administration (151A)  
 3801 Miranda Ave  
 City: Palo Alto State/Province: CA Country: USA

8. Signatory Official (i.e., Official Legally Authorized to Represent the Institution)

I have read and agree to the Terms of the Federalwide Assurance.

I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education and training about human subject protections will help ensure that the requirements of this Assurance are satisfied.

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. The IRB(s) that this institution relies upon will comply with the Terms of the Federalwide Assurance when reviewing research covered by this Assurance and possess appropriate knowledge of the local context in which this Institution's research will be conducted.

All information provided with this Assurance is up-to-date and accurate. I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.

Signature: Thomas J Fitzgerald III

Date: 07/13/2017

First Name: Thomas Middle Initial: J Last Name: Fitzgerald

Degrees or Suffix: III Institutional Title: Director

Institution: Veterans Affairs Palo Alto Health Care System

Telephone: 650 493-5000 654 FAX: 650 852-3228 E-Mail: Tony.Fitzgerald@va.gov

Address: Veterans Affairs Palo Alto Health Care System  
Office of the Director (00)  
3801 Miranda Ave

City: Palo Alto State/Province: CA Country: USA

9. FWA Approval

The Federalwide Assurance for the Protection of Human Subjects for Institutions Within the United States submitted to HHS by the above Institution is hereby approved.

Assurance Number: FWA00000929

Expiration Date: 07/18/2022

Signature of HHS Approving Official: Gail Holloway

Date: 07/18/2017

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-0278 . The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance

Department of Health and Human Services  
Federalwide Assurance of Protection for Human Subjects

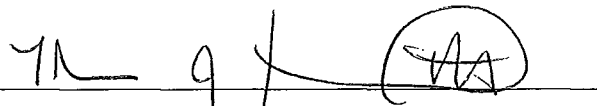
VA ADDENDUM TO FEDERALWIDE ASSURANCE FOR  
DEPARTMENT OF VETERANS AFFAIRS  
VETERANS HEALTH ADMINISTRATION FACILITIES

**VA Palo Alto Healthcare System**

assures that all of its activities related to human subject research will comply with all requirements of Department of Veterans Affairs regulations at Title 38 Code of Federal Regulations Part 16 (38 CFR 16), and all other applicable Department of Veterans Affairs policies and procedures, including policies and procedures of the Office of Research Oversight (ORO) and the Office of Research & Development (ORD), issued in Handbooks and other relevant authorized Directives.

Designation on the FWA of an IRB operated by another institution requires a Memorandum of Understanding (MOU) between the institutions. VA Institutional Official certifies on this Addendum that any MOU executed for the purpose of using an IRB operated by another institution will contain a commitment from that institution to provide complete access to all IRB records and related documents to the VA Medical Center. This commitment applies to VA-affiliated medical and dental schools or any other IRBs approved for use by VA.

**(7a.) Official Legally Authorized to Represent the Institution (VA Medical Center Director):**

Signature  Date: 7-10-17

First Name: Thomas Middle Initial: J Last Name: Fitzgerald

Degree or Suffix (e.g., MD, PhD) III Institutional Title: Director

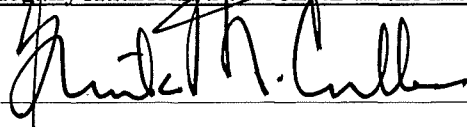
OHRP FWA Online Training Modules last taken on: 08/13/2015

Address: 3801 Miranda Avenue

City: Palo Alto State: CA Zip Code: 94304

Telephone: 650-858-3939 FAX: 650-852-3228 E-Mail: Tony.Fitzgerald@va.gov

**(7b.) Official Legally Authorized to Concur in the Institution's Approval (VHA VISN Director):**

Signature  Date: 7/12/2017

First Name: Sheila Middle Initial: M. Last Name: Cullen

Degree or Suffix (e.g., MD, PhD) Institutional Title: Director, VISN # 21

OHRP FWA Online Training Modules last taken on: 08/25/2015

Address: 201 Walnut Avenue

City: Mare Island State: CA Zip Code: 94592

Telephone: 707-562-8350 FAX: 707-562-8369 E-Mail: Sheila.cullen@va.gov

**Department of Health and Human Services  
Federalwide Assurance of Protection for Human Subjects**

**VA ADDENDUM TO FEDERALWIDE ASSURANCE FOR  
DEPARTMENT OF VETERANS AFFAIRS  
VETERANS HEALTH ADMINISTRATION FACILITIES**

**(7c.) Department of Veterans Affairs Approval**

*Section below to be completed by the Office of Research Oversight*

This Federalwide Assurance of Protection for Human Subjects is hereby approved for submission to the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP).

Signature of VA Approving Official:

Signature \_\_\_\_\_ Date: \_\_\_\_\_

\_\_\_\_\_, Health Science Specialist, Federalwide Assurances  
Office of Research Oversight (10R)  
810 Vermont Avenue, NW  
Washington, DC 20420

Phone:  
Cell:  
E-mail:

Any Additional Comments: