Federalwide Assurance (FWA) for the Protection of Human Subjects

1. Institution Filing Assurance

Legal Name: Lucile Salter Packard Children's Hospital at Stanford
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/Province (or Country if Outside U.S.)

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.
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).

(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:

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.

<table>
<thead>
<tr>
<th>HHS IRB Registration Number</th>
<th>Name of IRB as Registered with HHS</th>
<th>Is the IRB Internal or External to the Institution?</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB00000348</td>
<td>Leland Stanford Junior U IRB #1</td>
<td>E</td>
</tr>
<tr>
<td>IRB00000349</td>
<td>Leland Stanford Junior U IRB #2</td>
<td>E</td>
</tr>
<tr>
<td>IRB00000350</td>
<td>Leland Stanford Junior U IRB #3</td>
<td>E</td>
</tr>
<tr>
<td>IRB00000351</td>
<td>Leland Stanford Junior U IRB #4</td>
<td>E</td>
</tr>
<tr>
<td>IRB00000781</td>
<td>National Cancer Inst Central IRB #1 (Adult)</td>
<td>E</td>
</tr>
<tr>
<td>IRB00004296</td>
<td>National Cancer Inst Central IRB #2 (Pediatric)</td>
<td>E</td>
</tr>
<tr>
<td>IRB00004593</td>
<td>Leland Stanford Junior U IRB #5</td>
<td>E</td>
</tr>
<tr>
<td>IRB00004947</td>
<td>Leland Stanford Junior U IRB #6</td>
<td>E</td>
</tr>
<tr>
<td>IRB00005136</td>
<td>Leland Stanford Junior U IRB #7</td>
<td>E</td>
</tr>
<tr>
<td>IRB00006208</td>
<td>Leland Stanford Junior U IRB #8</td>
<td>E</td>
</tr>
<tr>
<td>IRB00009430</td>
<td>National Cancer Institute IRB #3</td>
<td>E</td>
</tr>
</tbody>
</table>

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

First Name: Kathy                  Middle Initial: McClelland  Last Name: McClelland
Degrees or Suffix: Institutional Title: Research Compliance Director
Institution: Leland Stanford Junior University
Telephone: 650 723-4697  FAX: 650 736-2783  E-Mail: kathy.mcclelland@stanford.edu
Address: Administrative Panels Office, Stanford University
1501 S. California Avenue, Mail Code: 5579
City: Stanford  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:  Dana Haering  
Date:  12/18/2015  
First Name:  Dana  
Middle Initial:  
Last Name:  Haering  
Institutional Title:  Vice President and Chief Financial Officer  
Institution:  Lucile Salter Packard Children's Hospital - Stanford  
Telephone:  650 721-2222  
FAX:  650 725-2358  
E-Mail:  dhaering@stanfordchildrens.org  
Address:  770 Welch Road, Room 150  
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:  FWA00000933  
Expiration Date:  12/20/2020  
Signature of HHS Approving Official:  Irene Stith-Coleman  
Date:  12/20/2015