

Submission#: 18258

Name: Direccion de Salud IV Lima Este

OMB No. 0990-0278

Approved for use through June 30, 2014

**Federalwide Assurance (FWA)
for the Protection of Human Subjects
New Filing**

1. Institution Filing Assurance

Legal Name: Direccion de Salud IV Lima Este

City: Lima

State/Province:

Country: PERU

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 and/or Country
C.S. MADRE TERESA CALCUTA	Lima	PERU
C.S. CATALINA HUANCA	Lima	PERU
C.S. BETHANIA	Lima	PERU
C.S. ANCIETA BAJA	Lima	PERU
C.S. PRIMAVERA	Lima	PERU
C.S. EL AGUSTINO	Lima	PERU
P.S. TUPAC AMARU II	Lima	PERU
P.S. SAGRADA FAMILIA	Lima	PERU
P.S. MARISCAL CACERES	Lima	PERU
P.S. CÉSAR VALLEJO	Lima	PERU
C.S. JAIME ZUBIETA	Lima	PERU
C.S. BAYOVAR	Lima	PERU
C.S. SANTA MARIA	Lima	PERU
P.S. PROYECTOS ESPECIALES	Lima	PERU
C.S. JOSE CARLOS MARIATEGUI	Lima	PERU
C.S. CRUZ DE MOTUPE	Lima	PERU
C.S. ENRIQUE MONTENEGRO	Lima	PERU


Dirección de Salud IV Lima Este
Centro de Etica de Investigación en Salud

C.S. 10 DE OCTUBRE	Lima	PERU
C.S. SU SANTIDAD JUAN PABLO II	Lima	PERU
P.S. JOSE CARLOS MARIATEGUI V ETAPA	Lima	PERU
P.S. SANTA FE DE TOTORITA	Lima	PERU
C.S. GANIMEDES	Lima	PERU
C.S. HUASCAR II	Lima	PERU
C.S. HUASCAR XV	Lima	PERU
P.S. MEDALLA MILAGROSA	Lima	PERU
P.S. AYACUCHO	Lima	PERU
C.S. SAN FERNANDO	Lima	PERU
C.S. SAN HILARION	Lima	PERU
C.S. LA LIBERTAD	Lima	PERU
C.S. LA HUAYRONA	Lima	PERU
P.S. 15 DE ENERO	Lima	PERU
C.S. SANTA ROSA DE LIMA	Lima	PERU
C.S. ZARATE	Lima	PERU
C.S. MANGOMARCA	Lima	PERU
C.S. CAMPOY	Lima	PERU
C.S. CAJA DE AGUA	Lima	PERU
P.S. AZCARRUZ ALTO	Lima	PERU
P.S. CAMPOY ALTO	Lima	PERU
C.S. NIEVERIA DEL PARAISO	Lima	PERU
P.S. ALTO PERU	Lima	PERU
P.S. CASA HUERTA LA CAMPIÑA	Lima	PERU
P.S. VILLA MERCEDES	Lima	PERU
CS PIEDRA LIZA	Lima	PERU
C.S. CHACARILLA DE OTERO	Lima	PERU
P.S. VILLA DEL SOL	Lima	PERU
P.S. PABLO PATRON	Lima	PERU
C.S. JICAMARCA	Lima	PERU
C.S. VILLA LETICIA DE CAJAMARQUILLA	Lima	PERU
C.S. SANTA MARIA DE HUACHIPA	Lima	PERU
C.S. VIRGEN DEL ROSARIO CARAPONGO	Lima	PERU
C.S. NICOLAS DE PIEROLA	Lima	PERU
C.S. SAN ANTONIO DE PEDREGAL	Lima	PERU
P.S. CHACRASANA	Lima	PERU
P.S. YANACOTO	Lima	PERU



P.S. MARISCAL CASTILLA	Lima	PERU
P.S. SEÑOR DE LOS MILAGROS	Lima	PERU
P.S. VILLA RICA	Lima	PERU
P.S. ALTO HUAMPANI	Lima	PERU
P.S. TRES DE OCTUBRE	Lima	PERU
P.S. PERLA DEL SOL	Lima	PERU
C.S. CHOSICA	Lima	PERU
C.S. MOYOPAMPA	Lima	PERU
C.S. MIGUEL GRAU	Lima	PERU
C.S. CHACLACAYO - LOPEZ SILVA	Lima	PERU
C.S. MORON	Lima	PERU
C.S. PROGRESO	Lima	PERU
P.S. VIRGEN DEL CARMEN - LA ERA	Lima	PERU
P.S. HUASCATA	Lima	PERU
C.S. MUSA	Lima	PERU
P.S. MATAZANGO	Lima	PERU
P.S. PORTADA DEL SOL	Lima	PERU
C.S. TAMBO VIEJO	Lima	PERU
P.S. HUAYCAN DE CIENEGUILLA	Lima	PERU
P.S. COLCA	Lima	PERU
C.S. SANTA MAGDALENA SOFIA	Lima	PERU
C.S. GUSTAVO LANATTA	Lima	PERU
C.S. SALAMANCA	Lima	PERU
C.S. 7 DE OCTUBRE	Lima	PERU
C.S. LA MOLINA	Lima	PERU
C.S. VIÑA ALTA	Lima	PERU
C.S. FORTALEZA	Lima	PERU
P.S. ATE	Lima	PERU
P.S. ALFA Y OMEGA	Lima	PERU
P.S. TUPAC AMARU	Lima	PERU
C.S. SAN FERNANDO	Lima	PERU
C.S. EL BOSQUE	Lima	PERU
P.S. AMAUTA	Lima	PERU
C.S. SAN ANTONIO	Lima	PERU
P.S. HORACIO ZEVALLOS	Lima	PERU
C.S. SEÑOR DE LOS MILAGROS	Lima	PERU
P.S. LA FRATERNIDAD	Lima	PERU



C.S. MICAELA BASTIDAS	Lima	PERU
C.S. SAN CARLOS	Lima	PERU
P.S. VIÑA SAN FRANCISCO	Lima	PERU
P.S. SANTA ROSA DE QUIVES	Lima	PERU
C.S. SANTA CLARA	Lima	PERU
C.S. EL ÉXITO	Lima	PERU
C.S. MANYLSA	Lima	PERU
C.S. SANTA ANITA	Lima	PERU
C.S. COOPERATIVA UNIVERSAL	Lima	PERU
C.S. CHANCAS DE ANDAHUAYLAS	Lima	PERU
C.S. NOCHETO	Lima	PERU
C.S. HUASCAR	Lima	PERU
P.S. METROPOLITANA	Lima	PERU

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

The Declaration of Helsinki

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) Non-U.S. institutions only: This Institution assures that whenever it engages in research to which this Assurance applies it will comply with the following procedural standards (please check one or more of the following):

The Common Rule

The U.S. Food and Drug Administration regulations at 21 CFR parts 50 and 56

The current International Conference on Harmonization E-6 Guidelines for Good Clinical Practice (ICH-GCP-E6)

The current Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects

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?**



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

First Name: Americo Middle Initial: Last Name: Sandoval
Degrees or Suffix: Institutional Title: Director of Epidemiology
Institution: Direccion de Salud IV Lima Este
Telephone: 3625553 FAX: 3627878 E-Mail: sandovalamerico@hotmail.com
Address: Av. Cesar Vallejo Cda.13 S/N, El Agustino, Lima 10
City: Lima State/Province: Country: PERU



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: **Pablo Cespedes**

Date: **10/15/2011**

First Name: **Pablo** Middle Initial: Last Name: **Cespedes**
Degrees or Suffix: Institutional Title: **General Director**
Institution: **Direccion de Salud IV Lima Este**
Telephone: **3625553** FAX: **3627878** E-Mail: **pcespedes@limaeste.gob.pe**
Address: **Av. Cesar Vallejo Cda.13 S/N, El Agustino, Lima 10**
City: **Lima** State/Province: Country: **PERU**

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:

Expiration Date:

HHS Approving Official:

Date:

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

